

Current Status and Trends of Clinical Research on Traditional Chinese Medicine in Treating Polycystic Ovary Syndrome Infertility

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Abstract: *Polycystic ovary syndrome (PCOS) is a common endocrine and metabolic disorder in women of childbearing age. It is associated with a high incidence of infertility, complex etiologies, and significant treatment challenges. Traditional Chinese Medicine (TCM) offers unique advantages in regulating endocrine function, improving ovulatory function, and increasing pregnancy rates. This article systematically reviews the current status of clinical research on TCM treatment of PCOS infertility, including the application and efficacy evaluation of TCM, acupuncture, and integrated TCM therapies. The article also explores its mechanisms of action, including modulating hypothalamic-pituitary-ovarian axis function, improving insulin resistance, regulating sex hormone levels, and enhancing follicular development and endometrial receptivity. The article notes that current research still suffers from issues such as low-quality clinical design, inconsistent syndrome differentiation, and insufficient in-depth mechanistic research. Future research should strengthen standardization, promote high-quality clinical trials, deepen multidimensional mechanism exploration, and establish a personalized treatment system integrating TCM and Western medicine. This will enhance the scientific and standardized application of TCM in assisted reproduction and provide better solutions for women's reproductive health.*

Keywords: Traditional Chinese Medicine, Polycystic Ovary Syndrome, Infertility, Acupuncture, Traditional Chinese Medicine, Clinical Research, Mechanism of Action, Assisted Reproduction.

1. Introduction

Polycystic Ovary Syndrome (PCOS) is a common endocrine and metabolic disorder that affects the health and fertility of women of childbearing age worldwide. Its main clinical manifestations include oligomenorrhea or amenorrhea, chronic anovulation, hyperandrogenism, and polycystic ovarian changes. According to statistics, about 6%–10% of women of childbearing age suffer from PCOS, and more than 50% of patients have varying degrees of infertility problems [1].

Because the etiology of PCOS is complex and involves multi-system dysfunction, traditional Western medicine treatment can improve some symptoms, but the long-term efficacy is unstable and there is a risk of side effects. As an important part of traditional Chinese medicine, traditional Chinese medicine has unique advantages in regulating endocrine function and improving reproductive function [2]. Traditional Chinese medicine emphasizes “differentiation and treatment” and “holistic conditioning”. Through Chinese medicine, acupuncture, massage and other means, starting from the functions of the liver, spleen, kidney and other organs, it harmonizes qi and blood, removes dampness and phlegm, and soothes the liver and regulates qi, thereby improving ovulation function and increasing pregnancy rate. In recent years, with the deepening of TCM modernization research, more and more clinical and basic research has focused on the efficacy and mechanism of TCM in treating PCOS infertility, providing a theoretical and practical basis for the construction of a treatment system combining TCM and Western medicine [3].

This paper aims to systematically review the current status of clinical research on TCM in treating PCOS infertility,

summarize commonly used treatment methods and efficacy evaluation, explore its mechanism of action, and analyze the problems and future development trends in current research, in order to provide a reference for clinical practice and scientific research.

2. Understanding of the Etiology and Pathogenesis of PCOS Infertility in TCM In the TCM Theoretical System

PCOS infertility does not have a clear name, but its clinical manifestations can be classified into the categories of “irregular menstruation”, “amenorrhea”, “infertility”, “phlegm dampness”, and “blood stasis”. TCM believes that the occurrence of PCOS is closely related to kidney deficiency as the root, phlegm dampness as the symptom, and liver depression and blood stasis throughout [4].

First of all, the kidney governs reproduction and is the foundation of congenitality. Kidney deficiency leads to imbalance of Chong and Ren meridians, uterus malnutrition, irregular menstruation, ovulation disorders, and thus affects conception [5]. Secondly, phlegm and dampness are pathological products, often caused by spleen deficiency and dysfunctional transportation and transformation or improper diet. Phlegm and dampness block the uterine vessels, affecting follicular development and ovulation function, and are an important pathological basis of PCOS [6]. Thirdly, the liver governs the regulation of emotions and qi. Liver depression and qi stagnation can lead to Chong and Ren meridian disorders, blood stasis in the uterine vessels, and affect follicular excretion and endometrial receptivity [7].

According to clinical syndrome differentiation, common syndromes of PCOS infertility include kidney deficiency,

phlegm and dampness, liver depression, blood stasis, and their combined syndromes. Different syndromes correspond to different treatment strategies. For example, kidney deficiency patients should be treated with kidney tonification and essence replenishment, phlegm and dampness patients should be treated with spleen invigoration and phlegm elimination, liver depression patients should be treated with liver tonification and depression relief, and blood stasis patients should be treated with blood circulation and stasis removal. Syndrome differentiation not only helps in individualized treatment but also provides a basis for efficacy evaluation [8].

3. Current Status of Clinical Research on Traditional Chinese Medicine Treatment of PCOS Infertility

3.1 Traditional Chinese Medicine Treatment

Traditional Chinese medicine treatment is one of the core means of traditional Chinese medicine intervention for PCOS infertility. Commonly used prescriptions include Jiawei Xiaoyaosan, Liuwei Dihuang Wan, Erzhi Wan, Cangfu Daotan Wan, Bushen Huoxue Cuopao Fang, etc. [9]. These prescriptions are mostly based on regulating the liver and qi, strengthening the spleen and resolving phlegm, nourishing the kidney and replenishing essence, and promoting blood circulation and unblocking the meridians. They are added or subtracted according to different syndrome types. Clinical studies have shown that traditional Chinese medicine intervention can significantly improve patients' menstrual cycle, ovulation rate, pregnancy rate and sex hormone levels. A meta-analysis included 20 randomized controlled trials. The results showed that the ovulation rate and pregnancy rate of the traditional Chinese medicine treatment group were higher than those of the Western medicine group, and the incidence of side effects was lower [10]. In addition, traditional Chinese medicine can also improve insulin resistance, reduce weight, regulate lipid metabolism, and has a good effect on patients with PCOS and metabolic syndrome [11]. It is worth noting that some Chinese herbal compound prescriptions have been included in clinical pathway management. For example, the "Kidney-Nourishing, Blood-Activating and Ovulation-Promoting Prescription" is widely used in many Chinese medicine hospitals with stable efficacy and high safety [12]. However, there is still a lack of unified Chinese medicine treatment standards, and there are large differences in the composition and dosage of prescriptions, which affects the comparability and promotion of research results.

3.2 Acupuncture Treatment

Acupuncture, as one of the external treatment methods of traditional Chinese medicine, has unique advantages in regulating endocrine, improving mood, and promoting follicular development [13]. Commonly used acupoints include Guanyuan, Sanyinjiao, Zusanli, uterus point, Shenshu, Ganshu, etc., which are mainly used to regulate the liver and kidney, open Chongren, and calm the mind [14].

Research shows that acupuncture can improve sex hormone levels and promote follicular development and ovulation by regulating the function of the hypothalamic-pituitary-ovarian

axis (HPO axis) [15]. A clinical trial showed that acupuncture treatment of PCOS infertile patients can significantly increase ovulation rate and pregnancy rate, improve LH/FSH ratio, and reduce androgen level [16]. In addition, acupuncture can also relieve mood disorders such as anxiety and depression, and improve patient compliance with treatment [17]. The number of studies on acupuncture combined with traditional Chinese medicine or Western medicine is also increasing. Many studies have shown that combined treatment can synergistically regulate endocrine and metabolic functions, and its efficacy is better than that of single treatment methods [18]. Especially during the ovulation cycle, acupuncture can reduce the incidence of ovarian hyperstimulation syndrome (OHSS), increase the number of high-quality follicles and endometrial receptivity [19].

3.3 Comprehensive Chinese Medicine Therapy

In addition to traditional Chinese medicine and acupuncture, comprehensive Chinese medicine therapy has also shown good results in the treatment of PCOS infertility [20]. Common intervention modes include traditional Chinese medicine + acupuncture + moxibustion, traditional Chinese medicine fumigation, massage, acupoint application, etc. Through multi-method combined intervention, multi-system and multi-target regulation can be achieved to improve the overall efficacy. Some studies adopt a cyclical conditioning plan, and different treatments are given in stages according to the changes in the female menstrual cycle, such as focusing on blood circulation and blood stasis during the menstrual period, focusing on kidney tonification and ovulation promotion during the follicular period, and focusing on spleen invigoration and blood nourishment during the luteal period [21]. This type of individualized treatment model is more in line with the principle of "adapting to the times" in traditional Chinese medicine and has more significant therapeutic effects. Its clinical efficacy evaluation indicators mainly include ovulation rate, pregnancy rate, follicle size, endometrial thickness, sex hormone level, insulin resistance index, etc. Some studies also introduce auxiliary indicators such as quality of life score and mood scale to comprehensively evaluate the treatment effect [22].

4. Exploration of the Mechanism of Action of Traditional Chinese Medicine in Treating PCOS Infertility

4.1 Regulating the Function of the Hypothalamus - pituitary - ovary Axis

PCOS patients are often accompanied by HPO axis dysfunction, which manifests as increased LH, decreased FSH, ovulation disorders, etc. Chinese medicines such as Erzhi Pills and Liuwei Dihuang Pills can regulate the HPO axis, restore sex hormone balance, and promote follicle development [23]. Acupuncture stimulation of Guanyuan and uterus points can affect the activity of hypothalamic neurons, regulate GnRH secretion, and thus improve ovulation function [24].

4.2 Improving Insulin Resistance and Metabolic Disorders

Insulin resistance is one of the important pathological bases of

PCOS. Studies have found that Chinese medicines such as Cangfu Daotan Pills and Jiawei Xiaoyao Powder can reduce fasting blood sugar and insulin levels and improve insulin sensitivity [25]. Acupuncture stimulation of acupoints such as Zusanli and Sanyinjiao can also regulate the insulin signaling pathway, promote glucose metabolism, and reduce body weight and fat content [26].

4.3 Regulating Sex Hormone Levels

PCOS patients often show symptoms of sex hormone disorders, especially elevated luteinizing hormone (LH), decreased follicle-stimulating hormone (FSH), and elevated androgen (T) levels. Traditional Chinese medicine intervention can restore the normal secretion rhythm of sex hormones by regulating the function of the HPO axis [27]. Studies have found that Chinese medicines that tonify the kidneys and activate blood circulation can reduce the LH/FSH ratio and improve the environment for follicle development [28]; prescriptions that soothe the liver and relieve depression can regulate hypothalamic neurotransmitters, indirectly affecting GnRH secretion, and thus regulating gonadal hormone levels [29]. Acupuncture stimulation of acupoints such as Ganshu, Shenshu, and Sanyinjiao can also regulate pituitary hormone secretion and promote the recovery of the ovulation cycle [30].

4.4 Impact on Follicular Development and Endometrial Receptivity

Follicular development disorder and poor endometrial receptivity are important pathological bases for PCOS infertility. Traditional Chinese medicine can help follicle maturation and ovulation by improving the local microenvironment of the ovary, promoting blood circulation, and regulating local hormone levels [31]. Studies have shown that traditional Chinese medicine can increase the diameter of follicles, increase the number of dominant follicles, improve the thickness and morphology of the endometrium, and increase the embryo implantation rate [32]. Acupuncture can regulate local uterine blood flow, reduce endometrial inflammatory response, improve endometrial receptivity, and provide a good environment for embryo implantation [33].

5. Research Status and Existing Problems

5.1 The Quality of Clinical Research Needs to be Improved

Currently, most clinical studies are single-center, small-sample, short-term observational studies, lacking strict randomized controlled designs and long-term follow-up data [34]. Some studies have problems such as non-standard blind implementation, inconsistent intervention measures, and highly subjective efficacy evaluation indicators, which affect the scientific nature and reproducibility of the research results [35]. In addition, some studies have not clearly defined the criteria for syndrome differentiation and classification, resulting in a lack of targeted treatment plans and difficulty in reflecting the core advantage of TCM's "differentiation and treatment".

5.2 Imperfect Efficacy Evaluation System

Current clinical studies mostly use ovulation rate, pregnancy rate, sex hormone levels, etc. as the main efficacy indicators, lacking a comprehensive evaluation of multiple dimensions such as quality of life, emotional state, and metabolic indicators [36]. Some studies have not established a unified efficacy judgment standard, resulting in large heterogeneity in results, making it difficult to conduct horizontal comparisons and meta-analyses. In the future, a scientific, objective, and systematic efficacy evaluation system should be established, covering multiple levels such as reproduction, physiology, and psychology.

5.3 Inconsistent TCM Syndrome Differentiation and Classification Standards

TCM syndrome differentiation and classification is the basis for guiding the formulation of treatment plans, but currently, various studies have different classification standards for PCOS infertility, and there is a phenomenon of mixing "different treatments for the same disease" and "same treatment for different diseases" [37]. Some studies have not clearly defined the basis for syndrome differentiation and only use TCM intervention based on Western medicine diagnosis, which weakens the guiding role of TCM theory. Therefore, it is urgent to formulate a unified and authoritative standard for TCM syndrome differentiation to improve the standardization and comparability of research.

5.4 Insufficient Depth and Breadth of Mechanism Research

Although some studies have explored the mechanism of action of TCM from the aspects of nerves, endocrine, and immunity, they are still in the preliminary stage and lack systematicity and depth [38]. Most mechanism studies focus on animal experiments, with few clinical sample studies and relatively simple research methods. Emerging technologies such as genomics, transcriptomics, metabolomics, multi-omics analysis, systems biology, and network pharmacology have not yet been widely used in TCM mechanism research, which limits its modernization.

5.5 Safety and Compliance Issues Need Attention

Although TCM treatment of PCOS infertility is generally safe, some TCMs have potential toxic side effects, especially when taken for a long time or in combination with other drugs, monitoring should be strengthened [39]. Although acupuncture treatment is a non-drug intervention, it may have compliance issues such as fear and pain in children or emotionally sensitive patients [40]. Currently, there is still a lack of a systematic safety assessment system and adverse reaction monitoring mechanism for TCM, which requires clinical attention.

6. Future Research Trends and Outlook

6.1 Establishing a Standardized Syndrome Differentiation and Classification System

Traditional Chinese Medicine (TCM) syndrome differentiation and classification is the core of guiding individualized treatment, but currently there is a lack of

unified, authoritative classification standards. In the future, we should combine clinical big data with expert consensus to develop a scientific and operational syndrome differentiation and classification system, and integrate it with Western medical diagnostic standards to enhance the precision and standardization of TCM interventions.

6.2 Promoting High-Quality Clinical Research

Clinical research is a key step in verifying efficacy. Multicenter, large-sample, randomized controlled trials should be conducted, using standardized intervention protocols and unified efficacy evaluation indicators to enhance the scientificity and credibility of research. Furthermore, long-term follow-up should be strengthened, focusing on long-term indicators such as pregnancy outcomes, fetal development, and maternal and fetal safety, to comprehensively evaluate the clinical value of TCM treatments.

6.3 Deepening Multidimensional Exploration of Mechanisms of Action

The mechanisms of action of TCM are complex, involving multiple systems, including the nervous, endocrine, immune, and metabolic systems. Modern technologies, such as genomics, transcriptomics, proteomics, and metabolomics, should be utilized to systematically uncover the molecular mechanisms and signaling pathways underlying TCM interventions. At the same time, network pharmacology and systems biology can be combined to construct the action networks of traditional Chinese medicine compound formulas, enhancing the systematicity and depth of mechanistic research.

6.4 Exploring Integrated Traditional Chinese and Western Medicine Treatment Models

Integrating traditional Chinese and Western medicine is an important approach to improving treatment outcomes. Future research could explore comprehensive intervention models such as combining traditional Chinese medicine with Western medicine for ovulation induction, acupuncture-assisted artificial insemination, or IVF. These interventions leverage the strengths of traditional Chinese medicine in regulating physical constitution, improving endometrial receptivity, and reducing side effects, thereby establishing a diversified and personalized treatment system.

6.5 Establishing Guidelines for Traditional Chinese Medicine Interventions in Assisted Reproduction

To promote the standardized application of traditional Chinese medicine in assisted reproduction, clinical practice guidelines should be developed to clarify indications, treatment plans, operational procedures, and safety assessment standards. Furthermore, medical personnel training should be strengthened to enhance the professional expertise and service capabilities of traditional Chinese medicine in the field of reproductive medicine.

7. Conclusion

Polycystic ovary syndrome (PCOS) infertility is a complex endocrine and metabolic disease that seriously impacts women's reproductive health and quality of life. Traditional Chinese medicine, with its holistic approach and syndrome-based treatment, demonstrates unique advantages in improving ovulation function, regulating endocrine function, and increasing pregnancy rates. In recent years, clinical research on Traditional Chinese Medicine (TCM) for the treatment of PCOS infertility has continued to deepen, with efficacy gradually validated and initial results achieved in exploring its underlying mechanisms. However, current research still faces numerous challenges, including low clinical research quality, inconsistent syndrome differentiation, and insufficient depth in mechanistic research. Future efforts should strengthen standardization, promote high-quality clinical trials, deepen multidimensional mechanistic research, and explore integrated treatment models combining traditional Chinese and Western medicine to enhance the scientific and standardized nature of TCM in the field of assisted reproduction. In summary, TCM holds broad prospects for the treatment of PCOS infertility. Supported by modern medical concepts and technologies, TCM has the potential to provide infertile women with safer, more effective, and personalized treatment options, contributing to the development and advancement of reproductive health.

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