



# Acupuncture and in vitro fertilization: Critique of the evidence and application to clinical practice

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## ABSTRACT

### Keywords:

Acupuncture  
Chinese medicine  
Evidence-based medicine  
Female infertility  
In vitro fertilization

Women undergoing in vitro fertilization (IVF) commonly use adjunctive therapies to improve IVF outcomes and reduce stress, anxiety and depression. Among these acupuncture is a popular choice. Despite 40 clinical trials and 9 systematic reviews investigating the efficacy of acupuncture for improving IVF outcomes, evidence-based guidelines are difficult to devise. The methodology used in the clinical trials does not closely resemble the use of acupuncture in real world acupuncture clinics, limiting the applicability of this research. Since many women undergoing IVF are currently using acupuncture there is a pressing need for a broader understanding of the use of acupuncture for female infertility. This paper offers a critical examination of the research on acupuncture and IVF and its limitations, details the differences between these studies and real world clinical practice, and discusses Chinese medicine theory for improving fertility and its possible scientific mechanisms within the context of clinical practice.

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## 1. Introduction

Infertility is a growing problem due to the choice to have children later in life and the impact of environmental and lifestyle factors on the both the female and male reproductive systems. Many perceive in vitro fertilization (IVF) as the last remaining hope of being able to achieve a successful pregnancy. However live birth rates from IVF range from 31.9% for 35–37 year old women to 12.5% for 41–42 year olds (for fresh non-donor egg; [https://www.sartcorsonline.com/rptCSR\\_PublicMultYear.aspx?ClinicPKID=0](https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0)). Consequently most women need to undergo several IVF cycles to achieve a successful pregnancy, and many will not succeed without the use of donor eggs. Due to the significant emotional and financial stress associated with undergoing IVF many women seek out other therapies to reduce stress levels and improve their IVF success rates. Acupuncture is a common choice, partly because many randomized controlled trials (RCTs) investigating the impact of acupuncture on IVF have been undertaken. This data is accessible to patients and biomedical practitioners and can be used as an endorsement for the use of acupuncture to improve IVF success.

Close examination of the scientific evidence for the use of acupuncture to improve IVF outcomes does not however lead to simple conclusive statements. The inability to draw clear conclusions about the efficacy of acupuncture for many conditions is a pervasive problem in acupuncture research<sup>20</sup> for several reasons. Firstly, many studies have consistently shown that placebo acupuncture is not inert and does indeed have a therapeutically beneficial effect. Studies comparing verum (real) and placebo acupuncture often show that both are equally as efficacious, but more efficacious than no treatment or conventional treatment<sup>20,32</sup>. Secondly, often in acupuncture RCTs the acupuncture intervention is therapeutically suboptimal due to factors such as excluding the use of Chinese medicine diagnosis, lack of individualized treatments for subjects, and inadequate acupuncture dosage. Consequently it becomes very difficult to demonstrate a statistically significant difference between a suboptimal verum intervention and a therapeutically beneficial placebo intervention. In the RCTs investigating the impact of acupuncture on IVF outcomes this is one<sup>26</sup> of several issues that render the research data difficult to interpret and use for referral purposes and to apply to clinical practice. This paper offers a critical examination of the research on acupuncture and IVF and its limitations, details the differences between these studies and real world clinical practice, and discusses Chinese medicine theory for improving fertility and its possible scientific mechanisms within the context of clinical practice.

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## 2. The research evidence

More than 40 clinical trials investigating the impact of acupuncture on IVF outcomes have been undertaken since 1999, and nine systematic reviews have been published in an attempt to make general conclusions from the data.<sup>52</sup> From all this work the evidence is still unclear about whether a woman should have acupuncture as an adjunctive therapy for IVF.<sup>49,52</sup> The simple reasons why this evidence is inconclusive relate to issues like the heterogeneity of the studies with regard to hypotheses, subject populations, study protocols, acupuncture interventions, controls, and outcome measures. The majority of the systematic reviews did not take these factors into consideration and were not able to demonstrate significant benefits of acupuncture for IVF.<sup>9,13,14,47</sup> However, the systematic reviews that accounted for some of these issues in their statistical analysis methodology have demonstrated a clinically beneficial effect of acupuncture for IVF.<sup>8,25,29,52</sup>

## 3. Limitations of the research

Despite the many discussions about the research into acupuncture and IVF, there has been little critique of the acupuncture protocols and dosage that were used in the RCTs.<sup>4</sup> This is not uncommon in acupuncture research,<sup>18,37</sup> and reflects the possibility that acupuncture is often viewed as a standardized type of intervention, where the protocol follows linear guidelines that a trained clinician would recommend for the purposes of a clinical trial. Most of the reviewers for the journals that publish these studies and the biomedical readers are also largely unaware of how acupuncture is practiced in real world settings. Consequently there is an almost complete absence of appreciation that there are some very significant limitations in these trials related to the acupuncture protocols and dosage.

### 3.1. Problem 1: lack of diagnosis & fixed protocol bias

All of the acupuncture-IVF RCTs thus far have used the same acupuncture points (a fixed protocol) for all patients. In these studies, an obese 35 year-old with polycystic ovarian syndrome (PCOS) is given the same acupuncture protocol as a slender 42 year-old with elevated follicle stimulating hormone (FSH) levels. This is incongruent with a basic principle of Chinese medicine: that proper diagnosis is the key to successful treatment. Most people outside the field of Chinese medicine do not realize that Chinese medicine includes a complex diagnostic system, which determines acupuncture point selection. To forgo diagnosis and use a fixed acupuncture protocol is somewhat analogous to an allopathic physician treating everyone who complains of headaches with Tylenol (acetaminophen).

Chinese medicine rests on the fundamental principle of individualized treatments, whether this be acupuncture, Chinese herbs, or any of the other acupuncture associated therapies.<sup>19</sup> Patients are asked many questions about their main complaint and medical history and this information is combined with several very specific observations and palpation techniques to permit the practitioner to formulate a diagnosis. The process of diagnosing is within the context of Chinese medicine theory, which draws together many different signs and symptoms to reach a summation of the overall patient condition. Patients with the same Chinese medicine diagnosis may have many different biomedical diagnoses and clinical presentations, and be treated differently in terms of acupuncture point protocols and Chinese herbal medicine formulas. Conversely, patients with the same biomedical diagnosis (e.g., PCOS, endometriosis, low ovarian reserve etc.) may have different Chinese

medicine diagnoses and would therefore receive different treatments. It is the Chinese medicine diagnosis that determines correct treatment, not the biomedical diagnosis. It is this aspect of Chinese medicine that is least understood by other medical professionals and the lay public. As with biomedicine, expert clinicians are often revered for their capacity to accurately diagnose and select the correct treatment.

It is difficult for an RCT to accommodate this aspect of Chinese medicine. What happens in an RCT is that subjects are selected according to a biomedical diagnostic category, in this case infertility. Chinese medicine experts are asked to devise an acupuncture protocol that would be approximately appropriate for the average patient, which generally consists of the most commonly used points. Indeed, some researchers have surveyed acupuncturists to find out what are the most commonly used acupuncture protocols for infertility.<sup>10,38</sup> These average treatments are highly likely to give suboptimal clinical outcomes because they are not devised specifically for any of the subjects in the trial.<sup>20</sup>

More recently new methodology for conducting acupuncture RCTs has been developed using the Delphi approach.<sup>34</sup> In such trials a panel of experts are asked to devise a flow chart of questions that permit standardization of diagnostic methodology between different acupuncturists. Acupuncture points that must be used for each diagnostic category and additional optional acupuncture points are stipulated allowing the acupuncturist to individualize the treatment for each subject. None of the acupuncture-IVF RCTs have used this improved methodology.

### 3.2. Problem 2: acupuncture dosage

The most commonly tested protocol for acupuncture-IVF RCTs is the so called 'Paulus protocol', modeled on the protocol of Paulus et al.<sup>31</sup> who demonstrated that subjects that received acupuncture 25 min before and after embryo transfer (ET) had clinical pregnancy rates of 42.5% compared to the controls who did not receive acupuncture and had rates of 26.3%. This protocol of acupuncture 25 min before and after ET became *the* accepted protocol for acupuncture in an IVF cycle, and many women undergoing IVF request just this and/or are recommended by fertility clinics to get this treatment regime. Somehow this protocol, even though there was only one successful RCT at the time, became the gold standard. Even more surprising is the fact that many attempts to repeat this outcome have not been successful.<sup>2,12,27,39</sup>

Part of the reason for the inability to repeat this outcomes is related to the fact that later studies included a placebo control and could not demonstrate any statistical difference between the verum and placebo treatments. As discussed earlier, placebo acupuncture has been repeatedly shown to not be inert, making these comparisons problematic.<sup>20</sup> However, other important factors could account for this, including fixed protocol bias (all subjects receiving the same treatment, as discussed above) and acupuncture dosage.

Acupuncture dosage consists of two components: the number of points needed in a single treatment, and the total number of treatments that the patient receives. Although it is possible for patients to experience beneficial effects from one or two treatments and/or just the stimulation of one or two points, this is more the exception, rather than the rule. The nature and duration of the condition is a very significant determining factor as to the likelihood that just one or two treatments will be effective. Acute conditions of short duration in younger patients are most likely to respond to small dosages of acupuncture. Conversely chronic conditions of long-term duration need larger dosages of acupuncture, especially in patients with multiple health issues. Generally speaking a clinically valid dosage of acupuncture usually includes

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