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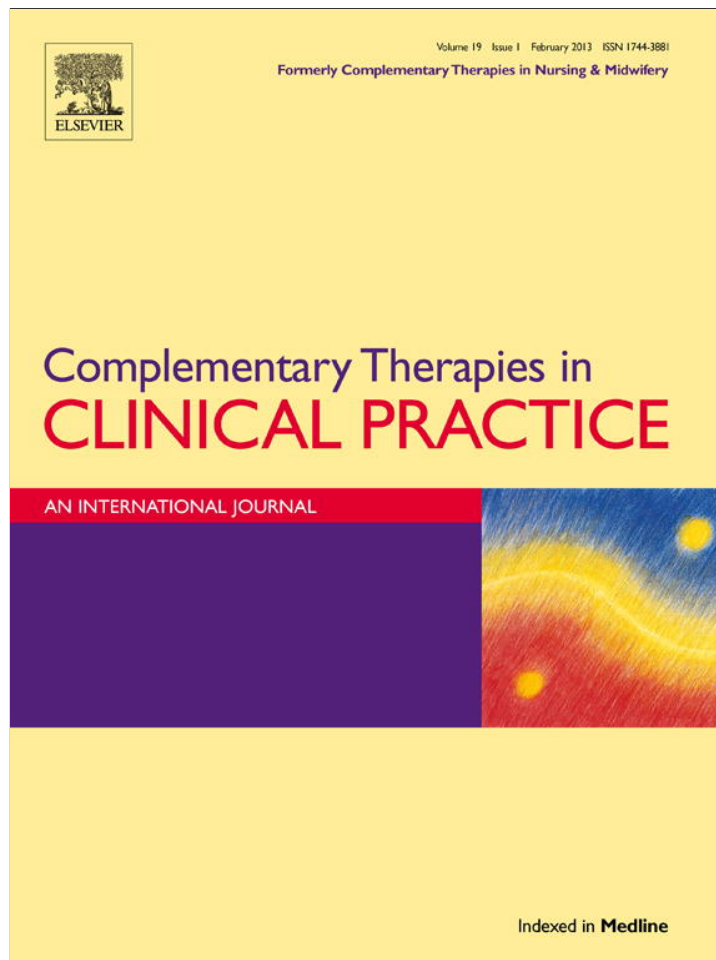
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Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

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

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A B S T R A C T

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). 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 research²⁰ 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^{20,32}. 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 one²⁶ 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.⁵² From all this work the evidence is still unclear about whether a woman should have acupuncture as an adjunctive therapy for IVF.^{49,52} 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.^{9,13,14,47} 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.^{8,25,29,52}

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.⁴ This is not uncommon in acupuncture research,^{18,37} 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.¹⁹ 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.^{10,38} 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.²⁰

More recently new methodology for conducting acupuncture RCTs has been developed using the Delphi approach.³⁴ 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.³¹ 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.^{2,12,27,39}

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.²⁰ 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

four to ten (or more) acupuncture points given in each of six (or more) acupuncture treatments.^{38,5}

As mentioned, most acupuncture-IVF RCTs used two acupuncture treatments – 25 min before and after ET. Some of the RCTs did add additional treatments, but most only included one or two additional treatments within the IVF cycle. This is a very low dosage of acupuncture. The number of points used in each treatment was adequate, but the total number of treatments was sub-optimal. What compounds this issue is the fact that infertility is a complex medical issue, often associated with either significant previous gynecological issues/pathology (e.g., fibroids, endometriosis, fallopian tube adhesions, autoimmune disease etc.) and/or with patients whose age (often late 30s/early 40s) brings significant additional physiological challenges. It is therefore debatable whether a couple of acupuncture treatments using fixed protocols will have a significant impact on the outcome of an IVF cycle.

4. Mechanistic considerations

To be more realistic in our assessment and expectations of acupuncture when used in conjunction with IVF we need to consider possible mechanisms by which acupuncture could improve IVF outcomes. Several have been proposed: improving blood circulation to the ovaries and uterus; neuro-hormonal modulation; cytokine modulation and improving implantation; and reducing stress, anxiety and depression.^{3,29,46} These mechanisms can be thought of in terms of short-term and longer-term benefits, and correspondingly the likelihood to benefit during a single IVF cycle or more focused on longer-term benefits for either assisted or natural conception.

4.1. Treatment duration

Women that seek out acupuncture during IVF generally fall into two categories: those that only seek treatment during an IVF cycle (and often only receive something similar to the Paulus protocol – 25 min before and after ET); and those that seek out Chinese medicine to help with infertility over a longer time period. In the latter category acupuncture is used before, during, and between IVF cycles to create an improvement in both reproductive and overall health and thereby increase the likelihood that conception could occur either naturally or through the use of assisted reproductive technologies (ART).

4.2. Short-term treatment

Patients that receive a small number of treatments during an IVF cycle are most likely benefiting from acupuncture due to the improved blood circulation to the uterus and ovaries, and by facilitating lowered stress levels and improved relaxation. This effect of acupuncture has been observed in several studies^{6,12,16,41,43–45} However it is also possible that if women have not had acupuncture before, the treatment could raise stress levels, as was demonstrated in one clinical trial.²⁷ This is likely due to the concern around an unknown procedure involving needles that is likely to engender some degree of pain. So advising women to receive acupuncture before and after ET should take into consideration their perceptions about acupuncture and the possibility that this may raise stress levels. From this perspective better advice would seem to be suggesting acupuncture treatments before an IVF cycle to determine if the patient is comfortable with the intervention. In addition, the Paulus protocol model of using acupuncture 25 min before and after ET may be introducing new stresses that reduce efficacy. One study showed that when patients were rushing through Seattle, WA, traffic trying to get their acupuncture

25 min before and after the ET, the pregnancy rates were lower than without acupuncture.¹¹ Again from the perspective of reducing stress levels and improving relaxation, this could be counterproductive.

Important additional short-term benefits are to ameliorate the side effects of IVF medications. Hormonal stimulation of the ovaries to produce multiple follicles is often associated with significant abdominal bloating and discomfort. The associated increased estrogen levels also often leads to fluid retention, headaches, and mood swings. A fundamental effect of acupuncture is to reduce stagnation both energetically and in terms of facilitating the reduction of fluid, gas, and digestive accumulations. This impact can bring significant amelioration of IVF medication side effects including ovarian hyperstimulation syndrome.

4.3. Longer-term treatment

Patients that seek out longer-term treatment often want to improve their general state of health before starting IVF to increase their chances of success and reduce the required number of IVF cycles. Other patients begin by just seeking out acupuncture during an IVF cycle (before and after ET) and find that they notice benefits from it and then decide to continue regular treatment in subsequent IVF cycles and/or into their pregnancy. Some patients decide to take breaks between IVF cycles and often will continue their acupuncture treatments with the goal of improving their overall and reproductive health to get ready for future IVF cycles or to try to conceive naturally. In these longer treatment situations, a different spectrum of mechanistic possibilities becomes evident.

Acupuncture treatment may be beneficial for preexisting gynecological conditions that can be a significant factor preventing conception or rendering patients ineligible for IVF. Patients and biomedical practitioners are often unaware that acupuncture can address a wide variety of gynecological conditions, an area very well documented in the classical and modern Chinese medicine literature.^{22,24,28} Some examples of conditions that can be treated with acupuncture and are commonly seen in women undergoing IVF include: endometriosis, fibroids, PCOS, elevated FSH, adhesions, and ovarian cysts. Acupuncture is unlikely to resolve advanced cases of gynecological pathology where surgery may be necessary. However, in such cases treatment can often alleviate symptoms, work synergistically with biomedical treatments, and facilitate successful conception. Mechanistic studies have demonstrated that acupuncture can induce regular ovulation in women diagnosed with PCOS⁴² through modulation of endogenous regulatory systems, including the sympathetic nervous system, the endocrine system and the neuroendocrine system.⁴⁶

Patients receiving longer-term treatment also benefit from the effects of regular acupuncture on their other health issues. Chinese medicine is holistic in the sense that treatment benefits the whole body and addresses all imbalances. This is why acupuncture clinical trials that have included quality of life measurements often show that patients receiving acupuncture experience a wide range of benefits and often have a general improvement in their feelings of well being,^{1,17,23,30,50} even if their main complaint did not significantly improve. This is attributable to the acupuncture treatment and also to lifestyle modifications that acupuncturists routinely recommend. For fertility patients important lifestyle recommendations often include dietary changes consistent with their Chinese medicine diagnosis, increasing sleep duration and quality, finding appropriate forms and intensity of exercise, incorporating relaxation techniques, and reducing excessive work hours.

Longer-term treatment also provides for significant psycho-emotional factors to come into play. Patients undergoing IVF are faced with understanding a complex medical procedure with many

unknown outcomes. Patients are often very knowledgeable about the process and experience considerable anxiety over their progress and its implications for their ability to conceive. Visiting their acupuncturist at least once per week, and usually twice per week during the stimulation phase and ET, provides an opportunity to discuss progress, choices, and outcome possibilities with an experienced clinician who can provide emotional support and information. For many women going through IVF, emotional endurance and retaining a sense of hope are central to eventual success. Their acupuncturist can become like a coach who partners with them through the arduous journey. All of this reduces stress and imparts all the physiological and psychological benefits associated with stress reduction.

5. Significance of the research to clinical practice

Despite the fact that the Paulus protocol has been accepted as the gold standard for acupuncture practice during an IVF cycle, we really do not know if this is the most optimal approach to impart short-term benefits. What becomes especially difficult from a practical standpoint in clinical practice is how critical it is for treatments to be given 25 min before and after ET. This has never been tested against any other time frame, leading many patients to insist on trying to have acupuncture within this narrow time frame and likely causing undue stress that could be counterproductive. For this reason, many acupuncturists will recommend 24 h before and after ET to facilitate scheduling and reduce stress. If the primary short-term benefits are to improve blood flow to the reproductive system and reduce stress, then it would seem logical that treatment throughout the entire cycle would also be beneficial, especially during the stimulation phase. Increased blood circulation to the ovaries during hormonal stimulation could potentially improve follicular development and reduce medication side effects. For this reason acupuncturists may also recommend a treatment 24 h before egg retrieval, and many recommend twice weekly treatments during the whole IVF cycle up until ET.

The question of whether acupuncture is more beneficial if undertaken for longer durations both before and throughout an IVF cycle remains untested and unanswered. However many women (and quite possibly the majority) who have acupuncture in conjunction with IVF do more than just before and after ET. Most common is acupuncture throughout the entire IVF cycle, often twice per week, and then into pregnancy, or prior to and throughout the next IVF cycle. Considering the possible mechanisms by which acupuncture may benefit women trying to conceive (as discussed above), especially the modulation of endogenous regulatory systems, a logical argument can be proposed in support of the use of acupuncture before, during and between IVF cycles. If circumstances permit it is most advisable to start acupuncture (and Chinese herbal medicine) 3–6 months before undergoing ART. This is discussed below in the section on Chinese herbal medicine, which is often seen to significantly enhance the effect of acupuncture.

When acupuncture is performed throughout the entire IVF cycle and into pregnancy, it is important to carefully consider using acupuncture points that are contraindicated during pregnancy⁷ following ET. This decision should be made based on the patient's Chinese medicine diagnosis. Many of the acupuncture-IVF RCTs have included contraindicated points following ET.⁴ One such trial, showed that the group that received an additional acupuncture treatment 2 days post ET⁵¹ had a greater early pregnancy loss. This is an aspect of the current research that requires further investigation.

6. Chinese herbal medicine

Chinese Herbal medicine is used extensively to treat a wide range of gynecological conditions including both female and male infertility.^{22,24} However there is relatively little research available to make evidence informed decisions about the use of Chinese herbal medicine for treating infertility. A recent systematic review³³ investigating the effect of Chinese herbal medicine upon pregnancy rates compared with ART intervention showed that Chinese herbal medicine improved pregnancy rates 2-fold within a 4 month period compared with fertility drug therapy or IVF. A non-randomized trial³⁵ showed that the combination of Chinese herbal medicine with intrauterine insemination (IUI) resulted in statistically significant higher pregnancy and live birth rates as compared to IUI alone. A recent systematic review has also demonstrated the effectiveness of Chinese herbal medicine for endometriosis.¹⁵

Combining Chinese herbal medicine with fertility medications must be done with caution because Chinese herbs can potentiate or negate the effect of drugs,⁴⁰ and be potentially unsafe or detrimental. There are differing opinions within the Chinese medicine community about the use of herbs together with IVF drugs. Some advocate the use of Chinese herbs²¹ while others recommend herbs only during times when women are not taking any fertility medications (before starting IVF and between IVF cycles). Despite the relatively small amount of evidence in support of the efficacy of Chinese herbs for improving the success of ART, some additional guidelines for clinical practice based on experience and mechanistic considerations are given below.

When there is significant preexisting gynecological pathology and/or the patient is in her late thirties/early forties long-term treatment with acupuncture and/or Chinese herbal medicine is ideally at least 3–6 months. The 3–6 month duration has been observed clinically to be the time required to see beneficial outcomes in terms of parameters such as better follicular response to gonadotropin stimulation during IVF and significant lowering of FSH levels. The effect upon follicular response may be related to the length of time it takes for a secondary follicle to develop into a dominant follicle, which is approximately 3 months.⁴⁸ The 3–6 months of treatment may be undertaken before (if inclusive of Chinese herbal medicine) or in conjunction with ART (if acupuncture alone). Delaying ART to include Chinese herbal medicine treatment needs to be carefully considered in relation to the age of the patient and the potential disadvantages of delaying ART intervention.

Shorter duration treatment with Chinese herbal medicine can also be quite effective, especially in cases of milder pathology of recent onset. This is relevant for women who have breaks between IVF cycles, which may be opportune times to take Chinese herbal medicine. A common situation is where a woman has been through one or more unsuccessful IVF cycles and then has elevated FSH, such that she is not able to start another cycle. This provides an opportunity to add Chinese herbal medicine to her treatment regime, which is often more successful in reducing FSH levels than acupuncture treatment alone. Women who have a history of recurrent miscarriage following IVF also often benefit from even brief periods of Chinese herbal medicine treatment, which again is usually better than acupuncture alone.

7. Conclusions

There is a pressing need for further research into the effectiveness of acupuncture for improving IVF outcomes. Such research needs to examine acupuncture treatment within a context that more closely resembles real world clinical practice. Given that

many women undergoing IVF are utilizing acupuncture and deriving benefits in addition to improving IVF outcomes,³⁶ current research does not adequately inform patients or clinicians. Possible mechanisms by which acupuncture may treat gynecological conditions requires further exploration, and may well represent general mechanisms by which acupuncture modulates physiology and treats a broad spectrum of pathology.

Conflict of interest statement

None.

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