INPLASY PROTOCOL

To cite: Peng et al. Effect of acupuncture on ovulation rate and pregnancy outcome in ovulatory disorders of infertility: a systematic evaluation and meta-analysis. Inplasy protocol 202280083. doi: 10.37766/inplasy2022.8.0083

Received: 21 August 2022

Published: 21 August 2022

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Support: **Evidence-based study of acupuncture.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Effect of acupuncture on ovulation rate and pregnancy outcome in ovulatory disorders of infertility: a systematic evaluation and meta-analysis

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Review question / Objective: **To systematically evaluate the effect of acupuncture on ovulation rate and pregnancy outcome in ovulatory disorders of infertility.**
Eligibility criteria: **Patients with a clear diagnosis of ovulatory infertility, aged 20 to 40 years old, from any source. Western medicine diagnostic criteria: refer to the diagnostic criteria of Obstetrics and Gynecology or European Reproductive Society; Chinese medicine diagnostic criteria: "Guidelines for Clinical Research on New Chinese Medicines" or "Gynecology of Chinese Medicine". There will be no restriction on race, nationality or education level.1.1.5Exclusion criteria (i)duplicate publications; (ii) incorrect or unavailable data; (iii) serious primary diseases such as cardiovascular disease; (iv) other factors associated with infertility, such as organic lesions of reproductive organs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 August 2022 and was last updated on 21 August 2022 (registration number INPLASY202280083).

INTRODUCTION

Review question / Objective: **To systematically evaluate the effect of acupuncture on ovulation rate and pregnancy outcome in ovulatory disorders of infertility.**

Rationale: **Computer searches of PubMed, EMbase, The Cochrane Library, CNKI, WanFang Data, CBM, and VIP databases**

were conducted to collect randomized controlled trials (RCTs) of acupuncture for the treatment of ovulatory disorders of infertility, all with a search time frame of August 10, 2022. Meta-analysis was performed using RevMan 5.4 software after 2 investigators independently screened the literature, extracted information, and evaluated the risk of bias of the included studies.

Condition being studied: Ovulatory infertility (AI) is a common gynecological disease with a high incidence and a rising trend, which seriously affects women's physical and mental health.AI clinically the follicles are developed but the dominant follicle is immature, small in diameter or the follicles do not develop, or the follicles are dysplastic and morphologically different and unable to expel an egg.Infertility is a global reproductive health problem with a prevalence of about 10% of married women.Ovulation disorders account for the second largest proportion of all infertility cases after tubal abnormalities, accounting for 25%-30%. The pathogenesis of dysovulatory infertility is still unclear, and most researchers believe that it may be closely related to hypothalamic-pituitary-ovarian axis (HPO) dysfunction, genetics, environment, physical obesity, insulin resistance, and psychosomatic factors.For the treatment of ovulatory disorders of sexual infertility, ovulation promotion and correction of metabolic disorders are now the main focus.However, some patients have poor efficacy and long-term use of the drug is prone to a series of adverse effects such as obesity, ovarian hyperstimulation syndrome, low conception, high miscarriage, and depression.Therefore, the search for active and effective clinical interventions to improve pregnancy and ovulation rates is the focus of clinical research. In recent years, acupuncture, as an exogenous non-pharmacological therapy, has received much attention from researchers because of its clear efficacy and ease of operation.Acupuncture has been shown to promote normalization of HPO axis function and smooth ovulation.However, studies have reported variable efficacy of acupuncture in improving pregnancy outcome and ovulation rate in ovulation-disordered infertility; therefore, this study systematically evaluated the effects of acupuncture on ovulation rate and pregnancy outcome in ovulation-disordered infertility with the aim of providing a basis for clinical decision making.

METHODS

Search strategy: Computer searches of PubMed, EMbase, The Cochrane Library, CNKI, WanFang Data, CBM, and VIP databases were conducted to collect RCTs of acupuncture for the treatment of ovulatory disorders of infertility, all with a search time frame of build to August 10, 2022.Searches are conducted using a combination of subject terms and free words, and are adjusted to the characteristics of each database. References of included studies were also searched to supplement access to relevant literature. Search terms included: ovulation disorders, infertility, acupuncture, acupuncture, electro-acupuncture, auricular acupuncture, acupuncture point injection, etc.

Participant or population: Patients with a clear diagnosis of ovulatory infertility, aged 20 to 40 years old, from any source. Western medicine diagnostic criteria: refer to the diagnostic criteria of Obstetrics and Gynecology or European Reproductive Society; Chinese medicine diagnostic criteria: "Guidelines for Clinical Research on New Chinese Medicines" or "Gynecology of Chinese Medicine". There will be no restriction on race, nationality or education level.

Intervention: Acupuncture.

Comparator: Western medicine.

Study designs to be included: Primary outcome indicators: pregnancy rate, subjects who are still not menstruating 15 days after ovulation will be self-tested with urine human choionic gonadotophin (HCG)

test strips, and if the result is positive, serum HCG and progesterone (P) will be further checked to confirm pregnancy; ovulation rate or cycle ovulation rate. Secondary outcome indicators: miscarriage rate, incidence of adverse effects.

Eligibility criteria: Patients with a clear diagnosis of ovulatory infertility, aged 20 to 40 years old, from any source. Western medicine diagnostic criteria: refer to the diagnostic criteria of Obstetrics and Gynecology or European Reproductive Society; Chinese medicine diagnostic criteria: "Guidelines for Clinical Research on New Chinese Medicines" or "Gynecology of Chinese Medicine". There will be no restriction on race, nationality or education level.1.1.5Exclusion criteria (i)duplicate publications; (ii) incorrect or unavailable data; (iii) serious primary diseases such as cardiovascular disease; (iv) other factors associated with infertility, such as organic lesions of reproductive organs.

Information sources: Computer searches of PubMed, EMbase, The CochraneLibrary, CNKI, WanFang Data, CBM, and VIP databases were conducted to collect RCTs of acupuncture for the treatment of ovulatory disorders of infertility, all with a search time frame of build to August 10, 2022.Searches are conducted using a combination of subject terms and free words, and are adjusted to the characteristics of each database. References of included studies were also searched to supplement access to relevant literature. Search terms included: ovulation disorders, infertility, acupuncture, acupuncture, electroacupuncture, auricular acupuncture, acupuncture point injection, etc.

Main outcome(s): A total of 27 RCTs, including 2275 patients, were included.Meta-analysis results showed that: Acupuncture improves pregnancy rates in patients with ovulatory disorders compared to Western medicine[OR=0.24, 95%CI (0.16, 0.31) , P<0.000, 01]and ovulation rate[OR=4.14, 95%CI (2.52, 6.80) , P<0.00001], Acupuncture + Chinese herbs may improve pregnancy rate[OR=3.01, 95%CI (2.10, 4.31) , P<0.000, 01], The miscarriage rate in the acupuncture group was lower than that in the Western medicine group[OR=0.19, 95%CI (0.07, 0.55) , P=0.002], The incidence of adverse reactions in acupuncture was significantly lower than in the Western medicine group[OR=0.20, 95%CI (0.05, 0.73), P=0.002].

Additional outcome(s): Available evidence suggests that acupuncture alone or in combination with herbal or western medicine for ovulatory disorders of infertility can improve pregnancy and ovulation rates.

Quality assessment / Risk of bias analysis: Two investigators independently evaluated the risk of bias of the included studies and cross-checked the results. The risk of bias was evaluated using the RCT risk of bias assessment tool recommended in Cochrane Handbook 5.4.0.

Strategy of data synthesis: RevMan 5.4 software was used for statistical analysis, and the relative risk ratio (RR) and 95% CI were used for counting data and weighted mean difference (WMD) was used for measurement data to calculate effect sizes.The χ2 test was used to test the heterogeneity among the studies at the level of α=0.1, and then the degree of heterogeneity was estimated according to the I2 value: I2<40% suggested that there was no significant statistical heterogeneity, and the fixed-effect model was selected for the combined analysis; 405% suggested substantial heterogeneity, and the combined analysis was not advocated.If the literature was adequate, funnel plot analysis for publication bias was performed. Intention-to-treat (ITT) analysis was performed on incomplete data to further validate the reliability of the evidence.

Subgroup analysis: No.

Sensitivity analysis: Funnel plotting with the effect on pregnancy rates in ovulatory disorders in the included literature showed that the circles were located around both sides of the midline in an incomplete symmetrical distribution, suggesting a higher possibility of publication bias in this study.

Country(ies) involved: China, France.

Keywords: Acupuncture; Ovulatory disorders; Infertility; Systematic evaluation; Meta-analysis; Randomized controlled trial.

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