INPLASY PROTOCOL

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Efficacy of acupuncture treatment for ovulatory disorder infertility A systematic review and meta-analysis

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Review question / Objective: Efficacy of Acupuncture for ovulatory disorder infertility: A Systematic Review and Meta-Analysis of randomized controlled trials.

Condition being studied: Those who do not have contraception after marriage, have a normal sexual life, and cohabitation for 1 year without pregnancy are called infertility, and those who have no history of pregnancy are called primary infertility. Those with a history of previous pregnancy are called secondary infertility. Infertility is a global reproductive health problem that affects about 10% of married women. Ovulatory infertility ranked second only to fallopian tube abnormalities in the proportion of all infertility, accounting for 25%-30%. Ovulation induction drugs are commonly used in western medicine, but long-term use often causes side effects such as follicular hyperstimulation. Modern clinical studies have shown that traditional Chinese medicine and acupuncture have good effects on follicle development and ovulation induction, with few side effects. This article systematically reviews the clinical efficacy of acupuncture and moxibustion in the treatment of ovulatory infertility by searching the clinical research literature and conducting Meta-analysis, so as to provide an evidencebased basis for clinical decision-making.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2023 and was last updated on 25 April 2023 (registration number INPLASY202340088).

INTRODUCTION

Review question / Objective: Efficacy of Acupuncture for ovulatory disorder infertility: A Systematic Review and Meta-Analysis of randomized controlled trials.

Condition being studied: Those who do not have contraception after marriage, have a

normal sexual life, and cohabitation for 1 year without pregnancy are called infertility, and those who have no history of pregnancy are called primary infertility. Those with a history of previous pregnancy are called secondary infertility. Infertility is a global reproductive health problem that affects about 10% of married women. Ovulatory infertility ranked second only to fallopian tube abnormalities in the proportion of all infertility, accounting for 25%-30%. Ovulation induction drugs are commonly used in western medicine, but long-term use often causes side effects such as follicular hyperstimulation. Modern clinical studies have shown that traditional Chinese medicine and acupuncture have good effects on follicle development and ovulation induction, with few side effects. This article systematically reviews the clinical efficacy of acupuncture and moxibustion in the treatment of ovulatory infertility by searching the clinical research literature and conducting Meta-analysis, so as to provide an evidence-based basis for clinical decision-making.

METHODS

Search strategy: Pubmed, Embase, Cochrane Library, CNKI, Wanfang database, VIP and CBM database were searched from inception to Feb 2023.

Participant or population: Patients diagnosed with ovulatory disorder infertility.

Intervention: Intervention groups that received acupuncture alone or acupuncture combined with clomiphene.

Comparator: Control groups should be clomiphene.

Study designs to be included: Randomised controlled trials(RCTs) published will be eligible for inclusion.

Eligibility criteria: 1. Type of studies. All randomized controlled trials (RCTs) that evaluate the effectiveness acupuncture for ovulatory disorder infertility will be included. 2. Types of participants. Pediatric. Patients diagnosed with ovulatory disorder infertility. 3. Types of intervention. Intervention groups that received acupuncture alone or acupuncture combined with clomiphene. Control groups should be clomiphene. 4. Types of outcome measures. Outcomes include pregnancy rate, ovulation rate, pregnancy loss rate, follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), progesterone (P), and endometrial thickness.

Information sources: Pubmed, Embase, Cochrane Library, CNKI, Wanfang database, VIP and CBM database were searched from inception to Feb 2023.

Main outcome(s): Outcomes include pregnancy rate, ovulation rate, pregnancy loss rate, follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), progesterone (P), and endometrial thickness.

Quality assessment / Risk of bias analysis: The quality of the included studies was evaluated using the Cochrane Collaboration's tool for assessing the risk of bias in systematic reviews, including random sequence, allocation concealment, blinding (including blinding of researchers and participants, and blind evaluation of study results), the integrity of the results, selective reporting of study results, and other biases.

Strategy of data synthesis: Revman 5.4 software was used for Meta-analysis. Relative risk (RR) was used as the effect indicator for binary variables, and standardized mean difference (SMD) was used as the effect indicator for continuous variables. For each effect size, its point estimate and 95%CI were presented. Heterogeneity test was performed by χ^2 test, and the test level was $\alpha = 0.05$. There was no statistical heterogeneity among the studies (P > 0.10, I2 < 50%), and the fixed effect model was used for the analysis. Otherwise, the random effects model was used for analysis. When the heterogeneity of the pooled studies was large, the

subgroup analysis was performed by combining different interventions.

Subgroup analysis: If the included studies are highly heterogeneous, we will perform a subgroup analysis based on age, sample size, methodological quality, etc.

Sensitivity analysis: If heterogeneity is significant, we will conduct a sensitivity analysis to assess the robustness and quality of the findings by excluding each included study individually and varying the study's impact scale.

Language restriction: Chinese and English.

Country(ies) involved: China.

Keywords: acupuncture, ovulatory disorder infertility, meta-analysis, systematic review.

Contributions of each author:

Author 1 - Chen Yuqi - Author 1 drafted the manuscript. Email: gochenyq@163.com