



Systematic Review

Acupuncture in the Treatment of Infertility due to Luteal Phase Defect: A Meta-Analysis

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Abstract

Background: To systematically evaluate the clinical effect and safety of acupuncture (AC) in the treatment of patients with infertility due to luteal phase defects. **Methods:** We conducted a systematic review and meta-analyses of AC's clinical outcome and safety in treating infertility due to luteal phase defects. We searched for databases, including PubMed, Cochrane Library, Web of Science, EMBASE, CNKI, CBM, Wanfang, Weipu, and VIP, and retrieved articles from inception to February 28, 2022. We used the STATA 12.0 software to conduct the meta-analyses. Egger's test was conducted to assess publication bias. **Results:** A total of 9 randomized controlled trials involving 638 eligible patients were included in our study. The results of the meta-analysis showed that compared with a group of drug treatment, AC-based combination therapeutic regimes can significantly improve total effective rate (TER; odds ratio (OR) = 1.56, 95% confidence interval (95% CI): 1.11–2.18, $p = 0.010$), and pregnancy rate (PR; OR = 1.60, 95% CI: 1.20–2.13, $p = 0.001$) for patients with infertility due to luteal phase defect. Significant differences were observed in serum progesterone (P4) (standardized mean difference (SMD) = 1.52, 95% CI: 1.06–1.98, $p = 0.000$) and estradiol (E2) (SMD = 0.96, 95% CI: 0.47–1.45, $p = 0.000$) levels between AC-based combination therapeutic regimes group and the drug treatment group. **Conclusions:** AC combined with other drug treatments for luteal phase deficiency (LPD) infertility therapy can significantly increase the TER and PR and improve the serum P4 and estradiol (E2) levels of patients compared to drug treatment alone. Considering the low quality of the included studies, the results of this meta-analysis still need to be carefully interpreted. Well-designed clinical studies with large sample sizes are still required to confirm our results. **Registration:** The study has been registered on <https://www.crd.york.ac.uk/prospero/> (registration number: CRD42023472727).

Keywords: acupuncture; infertility; luteal phase defect; randomized controlled trials; meta-analysis

1. Introduction

Luteal phase deficiency (LPD) refers to the hypoplasia or premature degeneration of the corpus luteum during follicular formation after ovulation, which leads to dysfunction, insufficient synthesis, and secretion of progesterone (P4) [1], resulting in delayed development of pregnant endometrium, frequent menstruation, infertility or early abortion [2]. LPD infertility is a common disease among women. Currently, 3.5% to 10% of infertility, 35% of early pregnancy abortion and 23% to 67% of habitual abortion cases are caused by LPD, clinically [3].

Modern medicine mainly uses clomiphene, human menopausal gonadotropin (HMG), gonadotropin (Gn), follicle stimulating-hormone (FSH), and gonadotropin-releasing hormone (GnRH) to promote follicular development [4]. P4 therapy provides exogenous P4 to compensate for endogenous luteal insufficiency. Bromocriptine and dexamethasone improve endocrine disorders [5]. Vitamin E, L-arginine, and human chorionic gonadotropin (HCG)

can improve the blood supply of the corpus luteum and thus, increase blood P4 [6]. Growth hormone (GH) and Gn synergistically promote the secretion of steroid hormones [7]. Estrogen improves the responsiveness of the endometrium to estrogen and P4, and cooperates with luteal replacement therapy to increase its efficacy [8]. However, the current pregnancy outcomes of modern medicine treatments are unsatisfactory. Clinical research has always focused on how to obtain better pregnancy outcomes [9]. Traditional Chinese Medicine (TCM) mainly promotes blood circulation and removes blood stasis, artificial cycles, and acupuncture (AC) [10]. AC and moxibustion therapy are safe and simple, with minor side effects, but the study samples are limited, the symptoms are diverse, and the treatment effects are inconsistent [11]. This study was designed as a meta-analysis to systematically evaluate the clinical outcome and safety of AC in the treatment of infertility due to LPD.



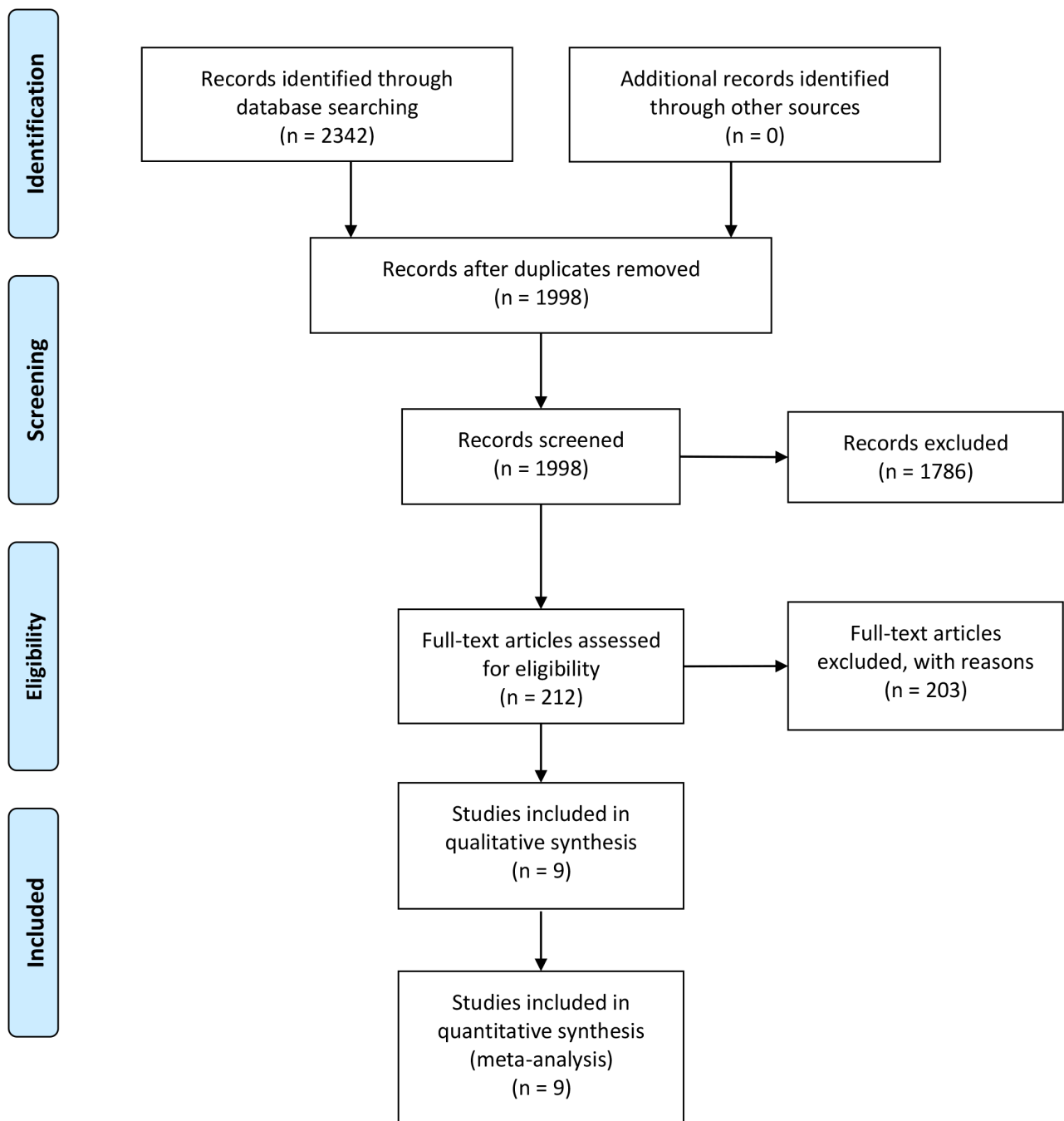


Fig. 1. PRISMA flowchart of literature selection process.

2. Materials and Methods

2.1 Literature Search Strategy

We searched for databases, including PubMed, Cochrane Library, Web of Science, EMBASE, CNKI, CBM, Wanfang, Weipu, and VIP, and retrieved articles from inception to February 28, 2022. Search terms were used as follows: ‘luteal phase defect’, ‘LPD’, ‘infertility’, ‘acupuncture’, ‘clinical trials’, and ‘randomized controlled trials (RCTs)’. The language of the literature search was limited to English and Chinese.

2.2 Inclusion and Exclusion Criteria

Inclusion criteria: (1) patients are more than 18 years old and without serious systemic diseases, (2) research type: RCTs, (3) women of reproductive age who have confirmed infertility due to LPD, (4) intervention groups comprised patients who had received acupuncture AC therapy; control groups had received western medicine or TCM.

Exclusion criteria include: (1) reviews, case reports, retrospective studies, conference abstracts, *in vitro* and animal experimental studies, (2) republished studies, and (3) studies with incomplete original data.

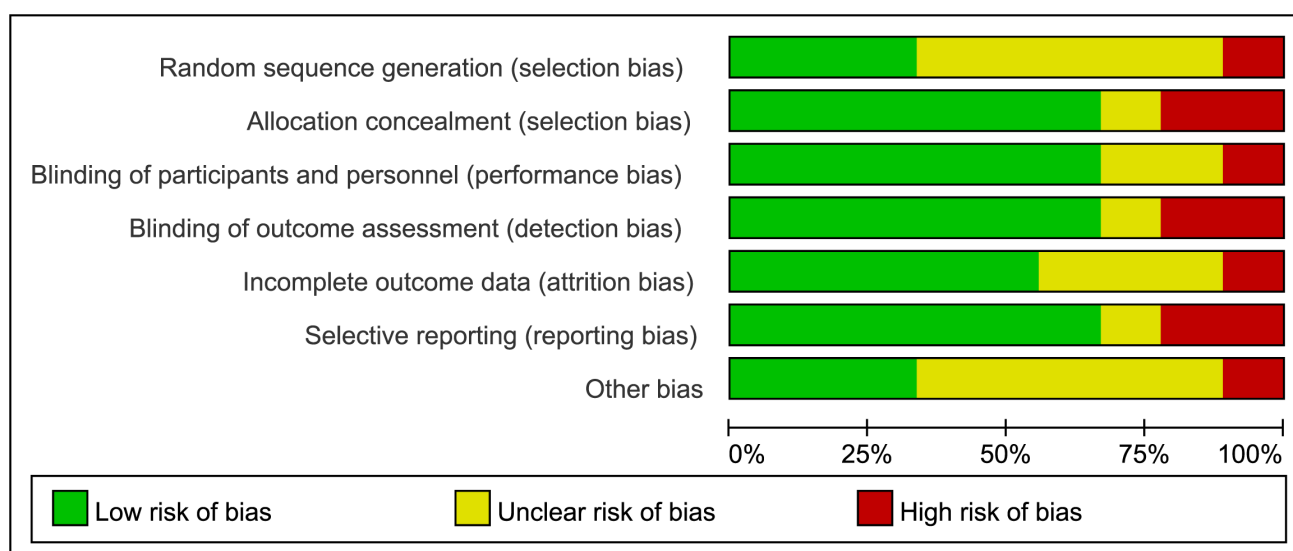


Fig. 2. Risk of bias summary of included studies.

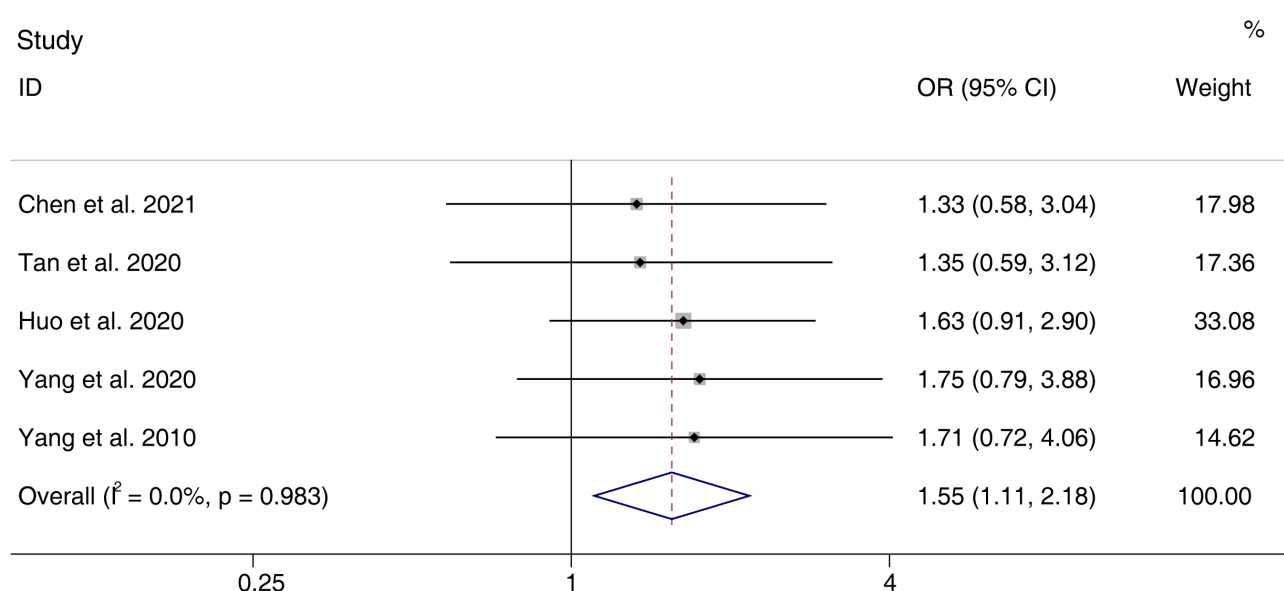


Fig. 3. Forest plot of comparisons between acupuncture (AC) combined therapy and therapy without AC on the TER. TER, total effective rate; OR, odds ratio; 95% CI, 95% confidence interval.

2.3 Data Extraction

According to the inclusion and exclusion criteria, two reviewers independently screened the literature and extracted data, including authors, publication year, age, intervention measures, sample size, and outcomes. The primary outcomes were the total effective rate (TER) and pregnancy rate (PR). The secondary outcomes were serum estradiol (E2) and P4 levels, and adverse events. If there was disagreement, it was discussed and resolved by a third author.

2.4 Quality Assessment

We used the Cochrane bias-of-risk tool to assess the design quality of the included RCTs with RevMan ver-

sion 5.3 software (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). The quality of included RCTs were assessed by 2 reviewers according to the Cochrane Handbook for Systematic Reviews [12]. Each article was evaluated by the following items: allocation concealment, random sequence generation, blinding of researchers, completeness of outcome data, blinding of outcome assessors, selective reporting of studies results, and other sources of bias. Each item was rated as “Yes” (low-risk of bias), “Unclear” or “No” (high-risk of bias).

Table 1. The baseline characteristics of the included studies.

Study	Country	Sample size	Interventions		Course of treatment (months)	Follow-up (months)	Type of AC	Outcomes
			AC group	Control group				
Chen <i>et al.</i> 2021 [13]	China	50	AC + TCM	TCM	3	NR	Abdominal AC	TER, PR, E2, P4
Tan <i>et al.</i> 2020 [14]	China	50	AC + TCM	TCM	3	NR	Electroacupuncture	TER, PR, E2, P4
Wang <i>et al.</i> 2019 [15]	China	120	AC + TCM	TCM	3	12	Normal AC	PR, E2, P4
Zhang <i>et al.</i> 2019 [16]	China	70	AC + luteohormone	luteohormone	3	3	Electroacupuncture	PR, E2, P4
Gao <i>et al.</i> 2020 [17]	China	70	AC + TCM + luteohormone	luteohormone	3	NR	Warming needle moxibustion	E2, P4
Huo <i>et al.</i> 2020 [18]	China	108	AC + TCM + dydrogesterone	dydrogesterone	3	6	Normal AC	PR, E2, P4
Liu <i>et al.</i> 2012 [19]	China	60	AC + TCM	luteohormone	3	NR	Normal AC	PR, E2, P4
Yang <i>et al.</i> 2020 [20]	China	60	AC	luteohormone	3	3	AC and moxibustion	TER, PR
Yang <i>et al.</i> 2010 [21]	China	50	AC	Clomiphene Citrate	6	NR	Normal AC	TER, PR

AC, acupuncture; TCM, Traditional Chinese Medicine; TER, total effective rate; PR, pregnancy rate; P4, serum progesterone; E2, estradiol; NR, not reported.

Table 2. The overall literature quality of each included literature in detail.

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Chen <i>et al.</i> 2021 [13]	Low-risk	Low-risk	Low-risk	High-risk	Unclear-risk	Low-risk	Unclear-risk
Gao <i>et al.</i> 2020 [17]	Unclear-risk	Low-risk	Low-risk	Unclear-risk	Low-risk	Low-risk	Unclear-risk
Huo <i>et al.</i> 2020 [18]	Low-risk	High-risk	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk
Liu <i>et al.</i> 2012 [19]	Unclear-risk	High-risk	High-risk	Low-risk	Low-risk	Low-risk	High-risk
Tan <i>et al.</i> 2020 [14]	Unclear-risk	Low-risk	Low-risk	High-risk	Low-risk	High-risk	Unclear-risk
Wang <i>et al.</i> 2019 [15]	Low-risk	Unclear-risk	Unclear-risk	Low-risk	High-risk	Low-risk	Low-risk
Zhang <i>et al.</i> 2019 [16]	Unclear-risk	Low-risk	Low-risk	Low-risk	Unclear-risk	Unclear-risk	Unclear-risk
Yang <i>et al.</i> 2010 [21]	Unclear-risk	Low-risk	Unclear-risk	Low-risk	Unclear risk	Low-risk	Low-risk
Yang <i>et al.</i> 2020 [20]	High-risk	Low-risk	Low-risk	Low-risk	Low-risk	High-risk	Unclear-risk

2.5 Statistical Analyses

Continuous outcome variables (i.e., luteal function assessment) were pooled with the standardized mean difference (SMD) and its 95% confidence interval (95% CI); dichotomous variables (i.e., PR) were pooled with odds ratios (ORs) and its 95%. Heterogeneity among the trials was evaluated by using I^2 statistics. When $I^2 \leq 50\%$, the fixed-effects model was used for data pooling; otherwise, the random-effects model was adopted. Egger's test was conducted to assess publication bias. We used STATA 12.0 (StataCorp LP, College Station, TX, USA) for meta-analysis. p -value < 0.05 was considered to be statistically significant.

3. Results

3.1 Literature Search

After searching the online databases, 2342 related studies were obtained in the initial search. 1998 were obtained after 354 duplicates were excluded by reading the title and abstract of the literature. 212 literatures were screened by full-text reading, from which 203 full-text articles were excluded. Finally, 9 RCTs [13–21] were included in our meta-analysis, all of which are in Chinese. The literature screening process and results are shown in Fig. 1.

3.2 The Characteristics of Included Studies

2 independent reviewers extracted the included literature data and summarized the results. A total of 638 eligible patients were included, 319 patients were included in the AC group and 319 patients were in the control group. All studies were RCTs. The characteristics of the included studies are shown in Table 1 (Ref. [13–21]).

3.3 Quality Assessment of Included Studies

2 studies mentioned the generation method of random assignment sequence, while the other 7 studies only reported the random assignment object and did not report the specific methodology of random assignment sequence. None of the included studies mentioned the hidden allocation scheme. The blind procedure was described in 6 articles. All of the included analyses completely reported the outcomes without selective report. The risk of bias summary is shown in Fig. 2 and Table 2 (Ref. [13–21]).

3.4 Results of Meta-Analysis

3.4.1 Meta-Analysis of TER

5 included studies reported the TER of AC combined with TCM/luteohormone/dydrogesterone or alone and monotherapy (TCM/luteohormone/dydrogesterone). Meta-analysis in a fixed-effect model ($I^2 = 0.0\%$, $p = 0.983$) showed that AC can significantly improve TER for patients with infertility due to LPD (OR = 1.56, 95% CI: 1.11–2.18, $p = 0.010$), as shown in Fig. 3. No publication bias was detected (Egger's test: $p = 0.610$).

3.4.2 Meta-Analysis of PR

8 included studies reported the PR of AC and monotherapy (TCM/luteohormone/dydrogesterone). Meta-analysis in a fixed-effect model ($I^2 = 0.0\%$, $p = 0.999$) showed that AC can significantly improve PR for patients with infertility due to LPD (OR = 1.60, 95% CI: 1.20–2.13, $p = 0.001$), as shown in Fig. 4. No publication bias was detected (Egger's test: $p = 0.598$).

3.4.3 Meta-Analysis of Serum E2 Level

8 studies reported the serum E2 levels of AC and monotherapy (TCM/luteohormone/dydrogesterone). Meta-analysis in a random-effect model ($I^2 = 85.3\%$, $p = 0.000$) showed that AC can significantly improve serum E2 levels for patients with infertility due to LPD (SMD = 0.96, 95% CI: 0.47–1.45, $p = 0.000$), as shown in Fig. 5. No publication bias was detected (Egger's test: $p = 0.551$).

3.4.4 Meta-Analysis of Serum P4 Level

7 studies reported the serum P4 levels of AC and monotherapy (TCM/luteohormone/dydrogesterone). Meta-analysis in a random-effect model ($I^2 = 81.0\%$, $p = 0.000$) showed that AC can significantly improve serum P4 levels for patients with infertility due to LPD (SMD = 1.52, 95% CI: 1.06–1.98, $p = 0.000$), as shown in Fig. 6. No publication bias was detected (Egger's test: $p = 0.649$).

4. Discussion

This study shows that AC has an apparent clinical effect in the treatment of LPD infertility. AC treatment significantly improved the TER and PR of patients. The TER and PR of AC, combined with TCM, in treating LPD infertility are better than those of TCM alone. The real effective rate of AC combined with effective drugs in the treatment of LPD infertility was too small to be included in the literature for meta-analysis. Still, the PR was better than that of simple, effective drug treatment ($p < 0.05$), and the homogeneity between the studies was not significant. After therapy, the levels of P4 and E2 in the treatment of LPD infertility with AC combined with effective drugs were higher than those with effective drugs alone ($p < 0.05$). Regardless, there was some heterogeneity between the studies.

Currently, there is a study on the mechanism of AC and moxibustion in the treatment of LPD infertility [11]. Researchers have also carried out study on AC and moxibustion in regulating various nerve factors, neurotransmitters and receptors, reproductive endocrine hormone levels, or humoral immune networks [22]. Early studies have shown that after being stimulated by AC and moxibustion, the stimulation signal was transmitted from the acupoints to the central nerve through the peripheral nerve, which caused changes in neurotransmitters and neuropeptides in the brain, led to the release of some bioactive mediators, and activated the target cell function [23,24]. A study by Yu *et al.* [25] found that the effect of neurohumoral factors

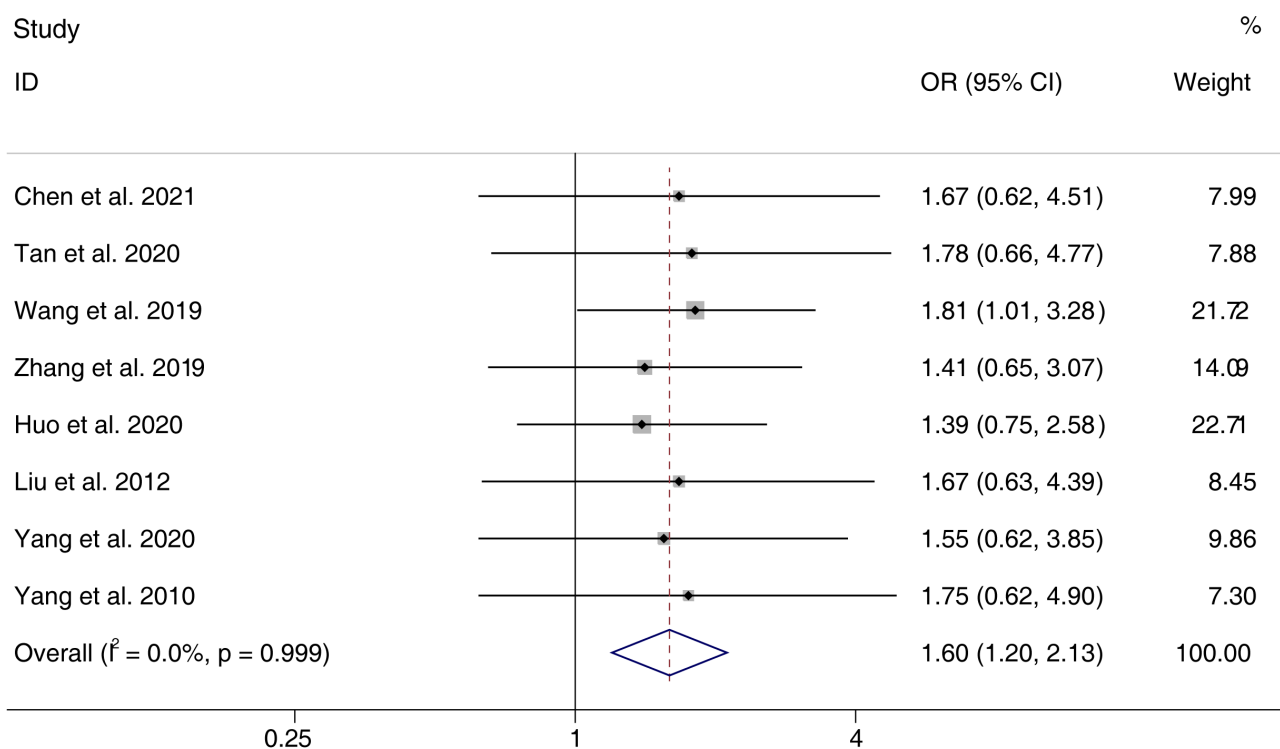


Fig. 4. Forest plot of the comparison between AC combined therapy and therapy without AC on PR results. PR, pregnancy rate; OR, odds ratio; 95% CI, 95% confidence interval.

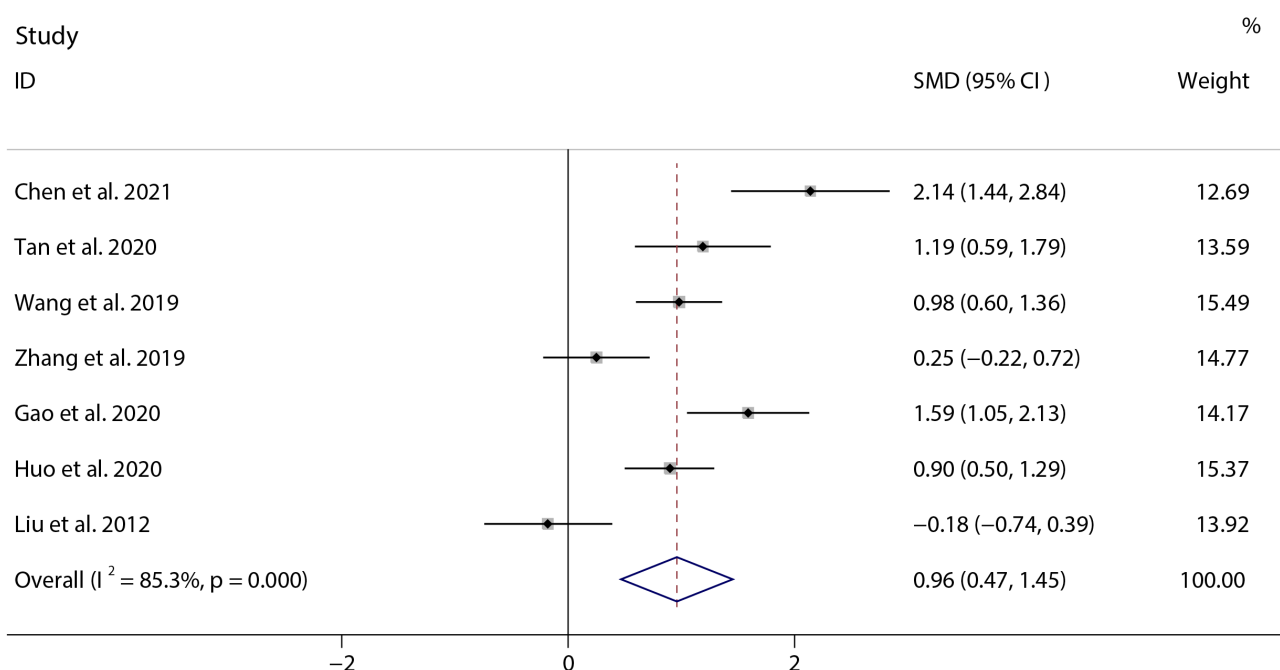


Fig. 5. Forest plot of the comparison between AC combined therapy and therapy without AC on serum E2 levels. AC, acupuncture; E2, estradiol; SMD, standardized mean difference; 95% CI, 95% confidence interval.

can stimulate the activity of the body's neuroendocrine system, adjust the hypothalamus-pituitary-ovary axis, promote follicular development, increase the number of oocytes, and improve ovulation function. Other studies have found that

AC plays a significant role in the regulation of sex hormones, raising the levels of serum P4 and E2, thereby establishing a negative feedback between the ovary and pituitary, and making FSH normal [26–28]. The occurrence of

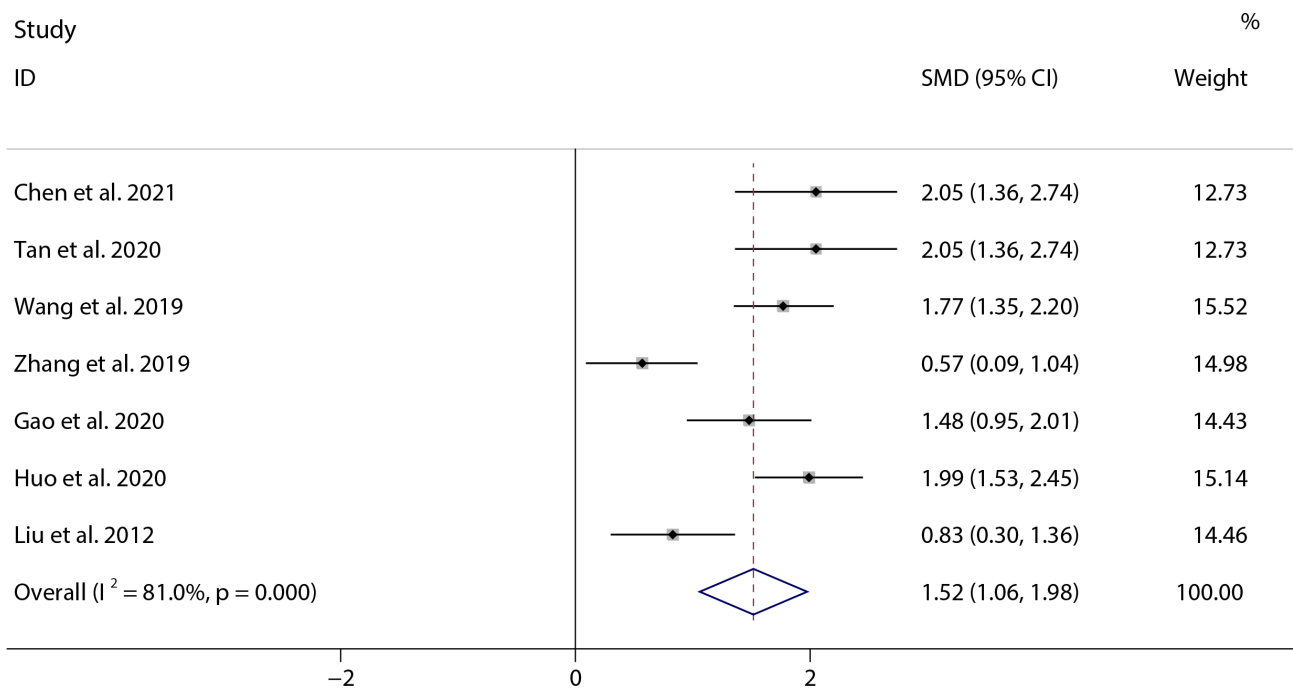


Fig. 6. Forest plot of the comparison between AC combined therapy and therapy without AC on serum P4 levels. AC, acupuncture; P4, progesterone; SMD, standardized mean difference; 95% CI, 95% confidence interval.

LPD is also related to the secretion of gonadotropin [29]. The data shows that the therapeutic effect of AC on LPD is closely related to the abnormal function regulation of the hypothalamus-pituitary-gonad axis of the body [30]. AC and moxibustion can increase serum P4 and E2, and decrease FSH levels [31].

In addition to the patients with infertility due to LPD described in this study, current studies suggest that AC may still be beneficial in infertility patients due to other causes. In infertile patients with obesity and polycystic ovary syndrome, acupoint catgut embedding therapy - a type of long-term AC treatment - could significantly reduce body mass index and total cholesterol levels, and increase the clinical PR compared with the control [32]. The negative emotions of pregnant women will reduce the effect of assisted reproductive surgery, and AC can help infertile patients eliminate depression, anxiety, and other negative emotions, thus increasing the chance of a successful pregnancy [33]. A RCT-designed study also confirmed that AC could improve pregnancy outcomes in infertile patients undergoing *in vitro* fertilization (IVF)/intracytoplasmic sperm injection (ICSI), significantly increasing the clinical PR (33.6% *vs.* 15.6%) and ongoing PR (28.4% *vs.* 13.8%), compared with the control [9].

At present, a meta-analysis has been conducted on AC and moxibustion for infertility related to LPD [34]. The study comprehensively analyzed the therapeutic effects of AC and moxibustion on this condition. However, one included study used only moxibustion intervention [34]. Mechanistically, AC and moxibustion are still different.

The former focuses on physical AC with or without electrical stimulation, while the latter focuses on warming and drug fumigation. Wang *et al.* [35] also conducted a meta-analysis and evaluated the effect of AC in improving the success rate of *in vitro* fertilization and embryo transfer (IVF-ET). The results showed that AC can significantly increase the clinical PR (relative risk = 1.25, 95% CI: 1.11–1.42, $p = 0.0003$), the ongoing PR (relative risk = 1.38, 95% CI: 1.04–1.83, $p = 0.03$), and reducing the miscarriage rate (OR = 1.42, 95% CI: 1.03–1.95, $p = 0.03$) in women IVF-ET, suggesting the advantage of AC in improving the PR [35]. Therefore, this study focuses on analyzing the effect of AC on infertility due to LPD.

In the clinical context, AC therapy is safe and convenient, with a few side effects. This meta-analysis further verified that medical treatment combined with AC intervention can bring additional benefits to infertility patients with LPD. The main adopted acupoints in AC intervention included Guanyuan, Zigong, and Sanyinjiao. However, in actual clinical application, it is necessary for Chinese physicians to select appropriate acupoints and AC methods according to the patient's conditions.

There are certain limitations in this study. The methodological information is limited, and it is not described in detail in the specific implementation details of the random allocation sequence generation method, allocation scheme hiding, and blind method implementation, which affects the judgment of the size of bias risk and the authenticity of the results. The RCTs included in this study need to be improved in terms of randomization, double blindness,

and follow-up. The sample size of the included studies is small, and thus it is necessary to further verify its clinical efficacy and safety by designing a large, randomized, double-blind, placebo-controlled trial.

5. Conclusions

Compared with drug therapy alone, AC treatment of LPD infertility can significantly increase the TER, PR, and improve the serum P4 and E2 levels of patients. Considering the low quality of the included studies, the results of this meta-analysis still need to be carefully interpreted. Well-designed clinical studies with large sample sizes are still required to confirm our results.

Availability of Data and Materials

The datasets used or analyzed during the current study are available from the corresponding author upon reasonable request.

Author Contributions

MX and YK designed and performed the research. YK and JL analyzed data, edited and reviewed manuscript; YK, YC, and XZ researched literature. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.31083/CEOG19928>.

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