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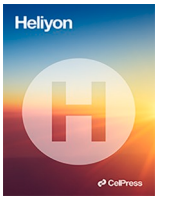

Efficacy and safety of acupuncture for pregnancy-related low back pain: A systematic review and meta-analysis

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ABSTRACT

Background: Pregnancy-related low back pain (PLBP) is a common musculoskeletal disorder, affecting people's physical and psychological health. Acupuncture is widely used in clinical practice as a treatment for PLBP. This study aimed to evaluate the efficacy and safety of acupuncture or acupuncture combined with other treatments for PLBP patients.

Methods: The Cochrane Library, PubMed, EMBASE, Web of Science, the Chinese Biological Medicine Database, China National Knowledge Infrastructure, WanFang Database, and VIP information database were searched from inception to January 31, 2022. Randomized controlled trials (RCTs) were eligible, without blinding and language restriction. Cochrane's risk of bias tool was used to assess the methodological quality. Meta-analysis was performed using RevMan 5.3.

Results: Twelve randomized controlled trials involving 1302 patients were included. The results showed that compared to the control group, the VAS score was significantly decreased after acupuncture treatment. In addition, no significant difference was found in the preterm delivery rate (RR = 0.38, 95%CI: 0.24 to 0.61, P = 0.97) after acupuncture treatment. Compared with other therapies, acupuncture or acupuncture plus other therapies revealed a significant increase in the effective rate (OR: 6.92, 95%CI: 2.44 to 19.67, $I^2 = 0\%$). No serious adverse events owing to acupuncture were reported.

Conclusion: Acupuncture or acupuncture combined with other interventions was a safe and effective therapy for treating PLBP. However, the methodological quality of the RCTs was low. More rigorous and well-designed trials should be conducted.

1. Introduction

Pregnancy-related low back pain (PLBP) is a recurrent or constant pain, lasting for more than one week from the lumbar spine or pelvis [1]. PLBP occurs frequently in the middle and 3rd trimesters. Besides, these symptoms persist during the all postpartum period.

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The prevalence of PLBP ranges from 20% to 90%, and its severe form affects 1/3 of pregnant women across the globe [2–6]. PLBP results in maternal health outcomes, including sleep interference, prolonged sick leave, low quality of life, increased adverse delivery outcomes, and postpartum depression [3,7–12]. Up to now, the underlying pathogenesis and etiology of PLBP remain unclear. Furthermore, clinical treatment is filled with difficulty and repeated medical treatment is common. Which brings great difficulties to clinical treatment, resulting in repeated medical treatment. PLBP is a chronic disease associated with mechanical strain and pelvic ligament laxity. Its occurrence is associated with an intense physical workload, pre-pregnancy body mass, the body's center of gravity forward, PLBP history, old age, amniotic fluid index (AFI), and depression [13–15].

PLBP often develops due to poor management during pregnancy. Treatment focuses on controlling pain and improving quality of life. From the last decades, medication, non-pharmacological treatments, exercise, complementary and alternative therapy psychotherapy, physical technology, and multidisciplinary rehabilitation have been used in the management of PLBP [16–19]. Acetaminophen and NSAIDs are common first-line treatment options for PLBP [20]. The users are very commonly at elevated risk of the gastrointestinal tract, kidneys, and cardiovascular adverse effects [21–23]. Nonetheless, they have poor acceptability and transient analgesia. As such, there is a need for more effective therapies.

Acupuncture is a non-pharmacological treatment widely used in musculoskeletal pain management [24–28]. The efficacy of acupuncture has been confirmed in recent clinical trials [29–35]. Moreover, a middle or strong level of evidence was provided in previous systematic reviews, indicating that acupuncture ameliorates pregnancy-related pelvic pain, causing mild adverse events which include needling pain and bleeding [7,32,36,37]. However, the pure effect of acupuncture on PLBP remains elusive. Therefore, this work aims to systematically collect and review the available evidence on the efficacy and safety of acupuncture in patients with PLBP. This is geared towards providing evidence-based insights for related patients, physicians, and investigators.

2. Materials and methods

This meta-analysis was conducted using Review Manager as per the Cochrane Handbook for Systematic Reviews of Interventions (Version 5.3) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. This study was registered on PROSPERO (CRD42022307865).

2.1. Search for literature

This systematic review was conducted via an online literature search of the 8 following databases from their inception to January 31, 2022: The Cochrane Library, PubMed, EMBASE, Web of Science, the Chinese Biological Medicine Database, China National Knowledge Infrastructure, Wan-fag Database, and VIP information databases. The search strategies were applied to each database using MeSH terms and natural language associated with the keywords "low back pain," "pregnancy," "postpartum period," and "acupuncture". No restriction was required on language or publication period. Table 1 shows the full electronic search strategy for the PubMed database. The search strategy for each database (MeSH term) was detailed in Supplementary Material (S1).

Table 1
Search strategy for PubMed.

Query	Search term
#1	"low back pain"[MeSH Terms]
#2	"pelvic pain"[Title/Abstract] OR "back discomfort"[Title/Abstract] OR "back ache"[Title/Abstract] OR "back pain"[Title/Abstract] OR "low back pain"[Title/Abstract] OR "pelvic girdle pain"[Title/Abstract]
#3	#1 OR #2
#4	"pregnancy"[MeSH Terms]
#5	"pregnant*"[All Fields] OR "gestation"[Title/Abstract]
#6	"postpartum period"[MeSH Terms]
#7	"postnatal"[Title/Abstract] OR "post natal"[Title/Abstract] OR "Natal"[Title/Abstract]
#8	#4 OR #5 O R#6 OR #7
#9	"acupuncture"[MeSH Terms] OR "acupuncture therapy"[MeSH Terms] "acupoint"[Title/Abstract] OR "needling"[Title/Abstract] OR "electroacupuncture"[Title/Abstract] OR "electric acupuncture"[Title/Abstract] OR "hand acupuncture"[Title/Abstract] OR "scalp acupuncture"[Title/Abstract] OR "auricular acupuncture"[Title/Abstract] OR "ear acupuncture"[Title/Abstract] OR "warm acupuncture"[Title/Abstract] OR "dry needling"[Title/Abstract] OR "acupoint injection"[Title/Abstract] OR "acupressure"[Title/Abstract] OR "acupoint catgut embedding"[Title/Abstract] OR "transcutaneous electrical acupoint stimulation"[Title/Abstract]
#10	randomized controlled trial as a topic [MeSH Terms]
#11	controlled clinical trial [Title/Abstract]
#12	clinical trials, randomized [Title/Abstract]
#13	random* [Title/Abstract]
#14	#10 OR #11 OR #12 OR #13
#15	#3 AND #8 AND #14

2.2. Eligibility criteria

2.2.1. Types of studies

Only RCTs were included, regardless of the blinding method used. No language limitation was used.

2.2.2. Types of participants

According to the existing diagnostic criteria, women with a diagnosis of low back pain and pelvic pain during pregnancy or postpartum would be included. The gender, age, race, nationality, duration of the disease, etc., were not restricted.

2.2.3. Types of interventions

Acupuncture or acupuncture plus conventional therapy as an intervention for PLBP was included. No restriction was imposed regarding the conventional regimen. In addition to intervention measurements, other background treatment measurements were identical in both groups.

2.2.4. Types of comparators

The following interventions were considered in the control group: conventional treatments (the same conventional regimen as the intervention group in the same original trial), medication, physiotherapy, herbal formulations, placebo, or no treatment (e.g., waiting list).

2.2.5. Types of outcome measures

The primary outcome was the change in the Visual Analog Scale (VAS). Secondary outcomes included effective rate, preterm delivery rate, and adverse events.

2.2.6. Exclusion criteria

The following criteria were excluded: animal experiments, literature review, case reports, case series, observational studies; opinion trials and conference proceedings; incomplete original data or full trail; duplicated publications.

2.3. Selection of studies

Two investigators (RL and LPC) independently checked the titles and abstracts of the included RCTs by using EndNote software (X.9.3.3). They excluded studies that did not refer to acupuncture and PLBP. Identified studies were retrieved for full-text assessment. Any discrepancy was resolved by a third party (Prof. R) or by contacting the authors of the original article. Study selection was summarized in a PRISMA flow diagram [38].

2.4. Data extraction

Data were extracted using a predefined data-extraction form (Excel software) that assessed RCTs details (publication year, nationality, journal, year of publication, study design), patient demographics (sample size per arm, median age of patients, gender, height, weight, gestational weeks), treatment information (duration, frequency, types of acupuncture, acupuncture points, types of comparators), primary and secondary outcomes, and adverse reactions. Two independent investigators (RL and LPC) extracted the data in duplicate. Any disagreements were arbitrated by a third party (Prof. R). If any of the study information was unclear or missing, the corresponding author was contacted through email.

2.5. Risk of bias assessment

The Cochrane Handbook for Systematic Reviews of Interventions was utilized to evaluate the methodological quality of the included studies [39]. The following items were assessed: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. Each domain was assessed and graded as “low risk”, “unclear”, or “high risk”. The evaluation was performed independently by two investigators (RL and LPC). Any difference encountered was arbitrated by a third investigator (Prof. R).

2.6. Statistical analysis

Statistical analyses were performed using the Review Manager (V.5.3.0) and Stata (17.0). A risk ratio or odds ratio with 95% confidence intervals was utilized for dichotomous data, whereas a mean difference or standardized mean difference with 95% confidence intervals was used for continuous data. The Chi-square and I^2 statistics were applied to investigate statistical heterogeneity. The fixed-effects model was used for low heterogeneity (I^2 <50%), and the random-effects model was applied if heterogeneity was moderate (50% <I^2 <75%). $\alpha = 0.05$, $P < 0.05$ was considered a statistically significant difference. A meta-analysis would not be performed when heterogeneity was considerably high (I^2 >75%). Sensitivity analysis was conducted based on different levels of bias in the included studies to validate the robustness of our findings. Funnel plots were used to evaluate the publication bias of the primary outcome indicators when more than ten eligible studies were included.

Table 2
Characteristics of the eligible trials included.

Including studies	Location	Sample size (T/C)	Initial gestational weeks (T/C)	Intervention type	Acupoints	Frequency and Period	Control type	Outcome	Adverse event(T/C)
Kaj 2000[41]	Sweden	60/60	T:24.2 ± 3 C:24.2 ± 2.25	Acupuncture	BL26-30, BL60, Cw2, and local points.	Session: 3 times a week during the first two weeks and then twice a week Stimulation: 30 min Period: 4 weeks	Physiotherapy	VAS the effective rate adverse events	local hematoma (2/0)
João 2004[42]	Brazil	79/61	T:19.9 ± 4.6 C:21.0 ± 4.4	Acupuncture	KI3, SI3, BL62, BL40, TE5, GB30, GB41, and the Jiaji points.	Session: once a week, twice a week if necessary Stimulation: NR Period: 8 weeks	Conventional treatment and the antispasmodic drug	VAS neonatal weight	None
Nina 2004[43]	Sweden	100/72	30 ± 4.2	Acupuncture	LR3, GV20, BL60, SI3, BL22-26.	Session: 2 times a week during the first two weeks and then 1 per week Stimulation: NR Period: NR	No treatment	VAS adverse events	local pain (6), heat or sweating (5), local hematoma (2), tiredness (2), nausea(2), and weakness (1)
Long 2014[45]	China	82/82	T:18.3 ± 2.3 C:20.1 ± 3.1	Acupuncture	BL23, BL25, Ashi points.	Session: 2 times a week Stimulation: 20 times, within 30 min before meals Period: 8 weeks	Conventional treatment (No treatment)	VAS neonatal weight neonatal height preterm delivery rate cesarean section rate adverse events	Drowsiness or Calmness (11/0)
Jia 2015[46]	China	94/94	–	Acupuncture	BL23, BL25, Ashi points.	Session: 1 per week Stimulation: 30 min Period: 5 weeks	Conventional treatment	VAS neonatal weight neonatal height preterm delivery rate cesarean section rate adverse events	Drowsiness(9/0)
Luo 2019[48]	China	80/80	T:25.4 ± 3.2 C:24.9 ± 3.3	Acupuncture	BL25, BL23, Ashi points.	Session: 1 per week Stimulation: 30 min Period: 4 weeks	Attention diversion method of analgesic drugs	VAS preterm delivery rate cesarean section rate adverse events	NR
Zhang 2020[51]	China	148/148	T:39.44 ± 2.56 C:38.68 ± 2.32	Acupuncture	BL23, BL25, Ashi points.	Session: 1 per day Stimulation: 30 min Period: 4 weeks	Comfort treatment	Pain score preterm delivery rate	NR
Li 2019[49]	China	60/60	–	Warm acupuncture	BL23, BL31-34, ST36, SP6.	Session: 5 times a week Stimulation:30 min Period: 10 weeks	Eight Jane granules	VAS the effective rate	NR

(*continued on next page*)

Table 2 (*continued*)

Including studies	Location	Sample size (T/ C)	Initial gestational weeks (T/C)	Intervention type	Acupoints	Frequency and Period	Control type	Outcome	Adverse event(T/C)
Feng 2017[47]	China	60/60	–	Acupuncture + Duhuo Jisheng Tang	BL23, BL31-34, BL40, BL57, GB30, GB31, GB32, GV3, EX-B2, Ashi points.	Session: 4 times a week Stimulation:20 min Period: 7 times	Duhuo Jisheng Tang	Pain score the effective rate recurrence rate	NR
Stephanie 2019[50]	Canada	200/199	T:28 ± 4.7 C:27.4 ± 4.2	Acupuncture + standard care	BL40, BL26, BL23, BL32, BL57, SP10, KI9, KI11, LR6, GB30, LR3, Ashi points.	Session: 2 times a week during the first week and then 3 times a week Stimulation: 30 min Period: 5 weeks	Standard care	VAS adverse events	bruising (24), fatigue (9), dizziness (1), and headache (1)
Liu 2021[52]	China	120/120	–	Acupuncture + WIRA irradiation	Trigger point	Session:1 per day Stimulation: 25 min Period: 4 weeks	Conventional treatment	VAS the effective rate	NR
Helen 2008[44]	Sweden	386/386	T:24 ± 3 C:24 ± 3/T:39.2 ± 1.7 C:39.5 ± 1.6	Acupuncture + standard treatment	GV20, LI 4, BL26, BL32 -33, BL60, BL54, KI 11, EX-B7, GB30, SP12, ST36.	Session: 2 times a week Stimulation: 40 min Period: 6 weeks	Standard treatment/ Standard treatment plus stabilizing exercises	VAS adverse events neonatal weight	Headache plus severe drowsiness(1), headache(1), rash(2), severe nausea with feeling faint, sweating and Dizziness(4)

*T, treatment group; *C, control group; *NR, not reported; *VAS, Visual Analog Scale; *Cw2, Location of this point was not described in the article.

Table 3
Characteristics of the adverse events.

Adverse events	Experiment group	Control group	Risk Ratio
Preterm delivery	20	53	$P = 0.97$
Local hematoma	28	0	
Drowsiness	21	0	
Tiredness	11	0	
Weakness	1	0	
Dizziness	*5*	*0*	
Headache	*3*	*0*	
Nausea	*6*	*0*	

Local hematoma, tiredness, weakness, drowsiness, nausea, and headache were considered adverse events (AEs) of acupuncture. Among them, no significant difference was found in the preterm delivery rate after acupuncture or not ($P = 0.97$). No serious adverse events occurred.

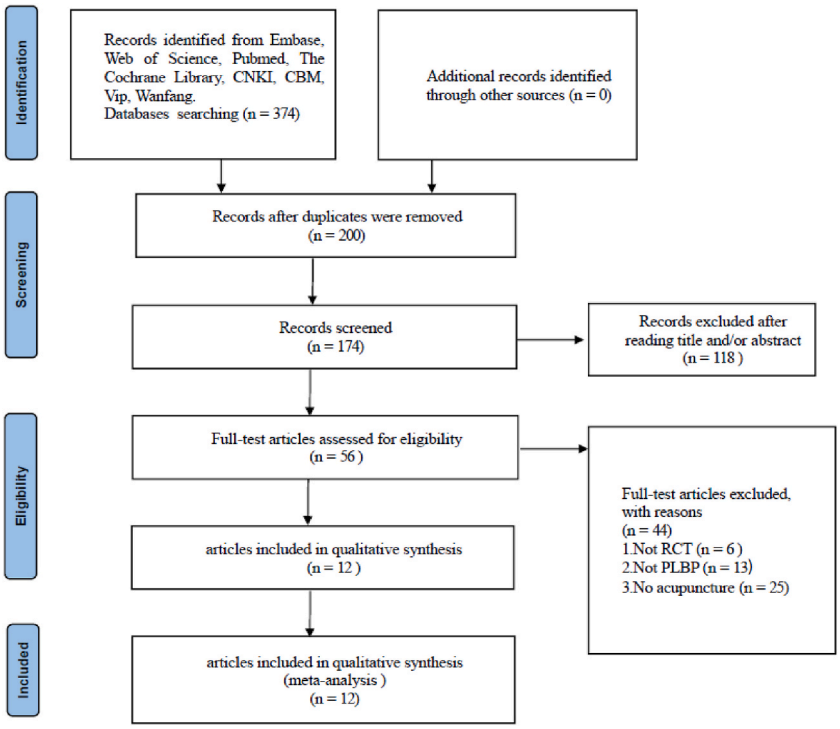

Fig. 1. The PRISMA flowchart of the study selection.

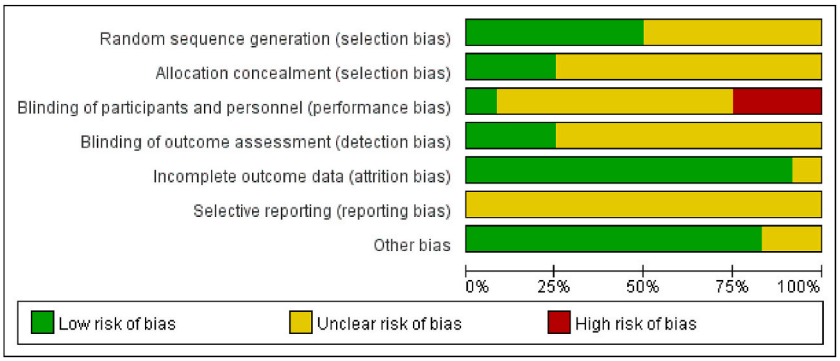

Fig. 2. Risk of bias graph.

2.7. Subgroup analyses

To further explore the potential resource of heterogeneity, subgroup analysis was explored based on the different treatment periods, gestational weeks, and age of the patient.

2.8. Assessment of evidence strength and certainty

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was used for assessments of the quality of primary outcomes [40]. In detail, a general "confidence of evidence" rating that was split into 4 categories (ie, high, moderate, low, and extremely low) will be used to characterize the strength and certainty of the evidence.

3. Result

3.1. Eligible studies and characteristics

A total of 374 records were initially detected, and 174 studies were deduplicated with the Note Express software. By browsing the abstract and reading the full text, they were screened according to the inclusion and exclusion criteria, and finally, 12 RCTs were included, with a total of 1302 patients (634 in experimental groups and 646 in control groups) [41–52]. The characteristics of the included RCTs were outlined in Table 2. The detailed research flow chart was shown in Fig. 1 (see Table 3).

3.2. Risk of bias of included studies

12 RCTs were included, all trials having a comparable baseline. Cochrane risk of bias assessment was performed on the included literature. Adequate methods of random sequence generation were described in 6 trials. Specifically, these procedures were random number tables such as computer random number generators, a coin toss random sampling, or shuffling sealed envelopes. The remaining 6 trials were assessed as unclear without the specific randomization method. Single-blinded was used in two trials [43,44], double-blinded was used in one trial [50], and then the remaining trials did not describe blinding. No reporting bias was found. In terms of other risks of bias, two RCTs were assessed as unclear, due to unclear baseline between groups. Figs. 2 and 3 demonstrated the risk of bias in the included trials.

3.3. VAS

The VAS of the seven trials was evaluated, two of which were postpartum trials [47,52], and five were post-pregnancy trials [44–46,48,50]. The summary results revealed that acupuncture was more effective than other therapies (MD = −1.60, 95% CI [−1.76, −1.45], P ≤ 0.05). Due to high heterogeneity (I^2 = 93%), we performed a subgroup analysis based on whether the women were postpartum or post-pregnancy. Pregnant women as participants in 5 trials showed high heterogeneity (I^2 = 95%) (see Fig. 4).

3.4. The effective rate

The effective rate of acupuncture was evaluated in four trials [41,47,49,52]. The heterogeneity test showed that there was no significant difference between the postpartum group and the pregnant group (OR = 7.08, 95% CI [2.51, 20.00], $P > 0.05$). Subgroup analysis suggested that the effectiveness rate was improved in both the pregnant groups (OR:7.71, 95%CI: 0.79 to 75.75, P = 0.08) and postpartum groups (OR: 6.94, 95%CI: 2.17 to 22.22, P = 0.001). (see Fig. 5).

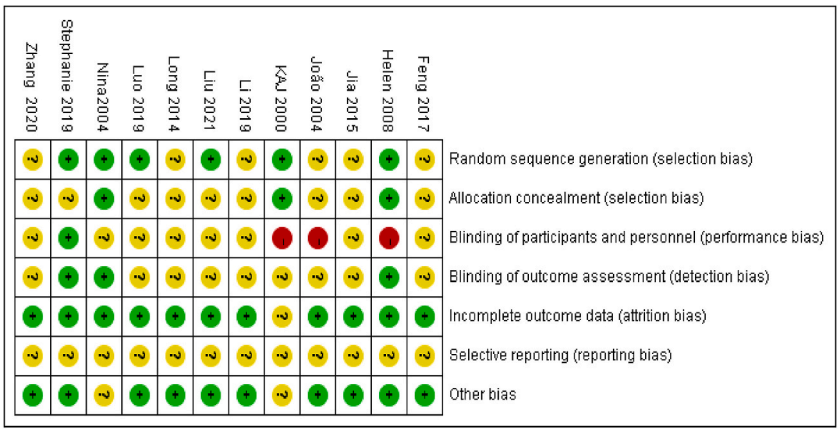

Fig. 3. Risk of bias summary.

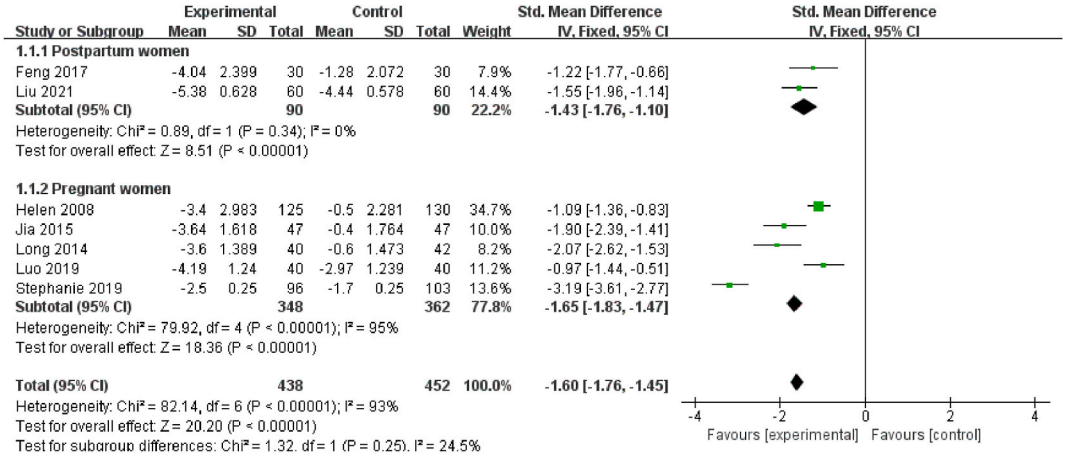

Fig. 4. Forest plot for the VAS between the experimental and control group.

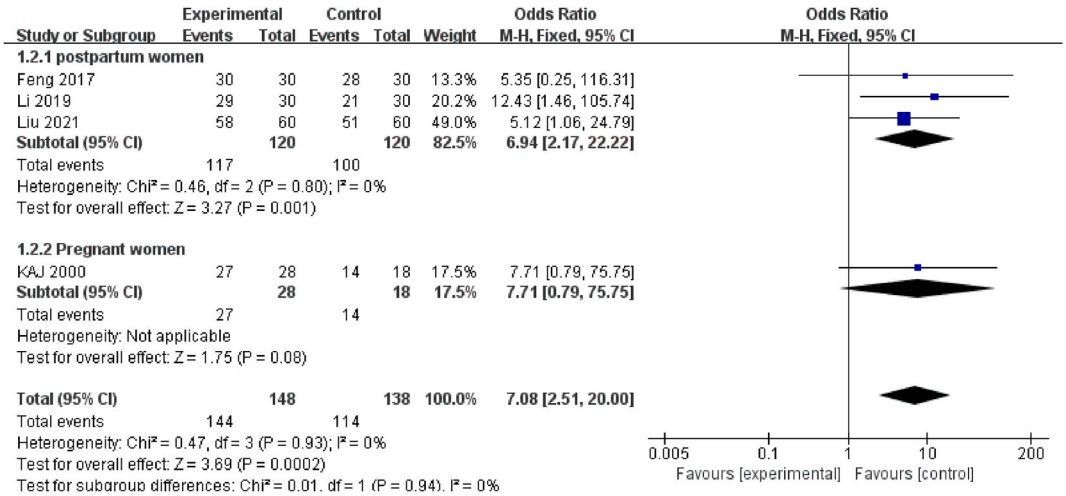

Fig. 5. Forest plot for the effective rate between the experimental and control group.

3.5. Adverse effects

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3.6. The quality of evidence

The GRADE tool was used to assess each outcome's certainty evidence of quality. The evidence quality of the effective rate was moderate. For serious limitations: most trials were assessed as an unclear or low bias of risk, so the evidence was downgraded. No serious inconsistency: no statistically significant heterogeneities were found ($P > 0.05$). The effective rate was directly associated with clinical outcomes. No serious imprecision: the effect size (OR) was significantly different ($P > 0.05$). No serious other considerations were found. For the VAS, the evidence quality was assessed as moderate. Most trials were assessed as an unclear or low bias of risk, therefore the evidence was downgraded. The VAS was used to measure PLBP pain intensity directly. No serious inconsistency or serious imprecision was found in those trials.

4. Discussion

In this systematic review with meta-analyses, we present evidence of the efficacy and safety of PLBP, based on 12 RCTs including 1302 patients. The pooled results revealed that the therapeutic effect of acupuncture was superior to physiotherapy, conventional treatment, stabilizing exercise, or other drug treatment. In addition, acupuncture or acupuncture combined with other therapies has better efficacy in relieving the pain of PLBP. Besides, no significant adverse events were reported to have been treated with

acupuncture during pregnancy. In recent years, acupuncture had been confirmed as a safe therapy.

The American Academy of Family Physicians (AAFP) endorsed the American College of Physicians (ACP) Guidelines recommending acupuncture as a first option for acute, subacute, and chronic low back pain [53]. Acupuncture provides analgesia for several types of chronic pain with lower cost, lower risk, and higher patient satisfaction than drug treatment [54,55]. Acupuncture analgesia is a manifestation of integrative processes at different levels in the CNS between afferent impulses from pain regions and impulses from acupoints. Extensive experimental evidence indicates that acupuncture stimulates endogenous pain-control mechanisms. Diverse signal molecules promote acupuncture analgesias, including opioid peptides, glutamate, 5-hydroxytryptamine, and cholecystokinin octapeptide [3]. Among these, the opioid peptides and their receptors modulate acupuncture analgesia. Opioids desensitize peripheral nociceptors, decrease proinflammatory cytokines in peripheral sites, cytokines, and SP in the spinal cord as well as promote pain inhibition. Acupuncture has also been shown to reduce inflammation locally which in turn impacts pain processing by the central nervous system [56–58]. Besides, acupuncture downregulates GluN1 phosphorylation to inhibit pain by inducing serotonin and norepinephrine.

Low back pain (LBP) refers to muscle tension or stiffness that is localized below the costal margin and above the inferior gluteal folds [59]. On the other hand, pelvic girdle pain (PGP) is a type of pain between the posterior iliac crest and the gluteal fold, specifically in the vicinity of sacroiliac joints (SIJ) [60]. The painful nature of LBP and PGP are usually similar and overlapping. Both are associated with lumbopelvic stabilization. In our study, based on the contention and uncertainty of etiology and treatment, we selected people with low back pain and pelvic girdle pain as participants [14,61], as many investigators do.

Pain is a subjective experience and clinicians often rely on patients' verbal reports [62,63]. The change in pain intensity is the primary outcome in trials of pain-specific therapies, managing and detecting the patient's life. In a recent survey, clinicians and patients preferred the VAS to other scales for measuring LBP pain intensity [64]. The VAS is a continuous scale that quantifies pain intensity. It comprises a 10 cm horizontal or vertical line with anchor points of 0 (no pain) and 10 (extreme pain) [65]. The pain intensity and pain affect were key dimensions of the pain experience. So far, VAS is the most commonly used in LBP clinical trials to measure pain intensity and assess "unpleasant" feelings. We confirmed its reliability and efficacy in pain assessment [66], including cancer pain, degenerative joint pain, and other chronic pain. Thus, VAS represents the primary outcome of this work.

In line with our current report, the efficacy of acupuncture had been proven in previous systematic reviews. Complementary and Alternative Medicine (CAM) is a mainstream therapy for PLBP [18] and has been verified its efficacy [32,36,37,67]. Nevertheless, acupuncture is only effective as a supplementary therapy. In our analysis, we discovered that acupuncture or integrated with other treatments for PLBP is effective and safe.

In conclusion, acupuncture effectively ameliorates pain in PLBP patients compared to the control group. For AEs, no adverse effects occurred in the trials. In contrast with the two groups in the trial, the preterm delivery rate does not increase after acupuncture treatment.

5. Study limitations

There were several limitations should be considered in the study. Firstly, considering different diagnostic criteria and gestational weeks, which might result in high heterogeneity. Besides, due to the small sample size and low quality of RCTs, the results might be inconclusive. Acupuncture was usually an adjunct therapy and rarely used in isolation. Further research needs to improve the methodology. More large-scale and high-quality RCTs will be needed. The high quality of acupuncture trials requires to be reported. The future study design should use acupuncture in isolation to explore the efficacy of PLBP.

6. Conclusions

In summary, this meta-analysis found that acupuncture may be a potential adjustive option for PLBP with minimal side effects. Acupuncture can relieve pain and improve the effective rate. However more well-designed research will be needed to support our findings.

Author contribution statement

Rong Li: conceived and designed the experiments; Wrote the paper.
Yulan Ren: conceived and designed the experiments.
Liping Chen performed the experiments; Wrote the paper.
Xiaoding Lin; Yuqi Xu: analyzed and interpreted the data.
Runchen Zhen; Jinzhu Huang: Contributed reagents, materials, analysis tools or data.

Data availability statement

Data associated with this study has been deposited at PROSPERO under the accession number CRD42022307865.

Declaration of competing interest

The authors have no competing interests to declare for this review.

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