INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) as an analgesic therapy in labor pain: A systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **The purpose of this study is to evaluate the status of transcutaneous electrical acupoint stimulation (TEAS) in the pain relief of labor pain, with the aim of illustrating the effectiveness and safety of this non-invasive treatment, which is a treatment combined acupuncture with electro stimulation.**
Condition being studied: **In the process of delivery, labor pain is a kind of unbearable experience for parturients that brings a huge burden on their spirits and bodies. As a result of labor pain, the health of newborns and the progress of labor would be affected seriously. Transcutaneous electrical acupoint stimulation (TEAS) is a noninvasive therapy via putting electro tabs or pens with regulated stimulation modes on certain acupoints to exert the double efficacy of acupuncture and transcutaneous electrical nerve stimulation. The purpose of this study is to evaluate the efficacy and safety of TEAS therapy in the reduction of labor pain for parturients, as well as summarize the relevant studies and literature with RCTs, for providing a certain reference for clinical trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 May 2022 and was last updated on 09 May 2022 (registration number INPLASY202250050).

INTRODUCTION

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METHODS

Participant or population: Healthy laboring parturients without being used TEAS, TENS, acupuncture, or other analgesia methods before starting the intervention.

Intervention: The intervention group underwent TEAS (received electrical stimulation on the target acupoints. The stimulation was provided by an electrical stimulator through electrode tabs or acupuncture pens on the target acupoints, normal electroacupuncture was not included as it is invasive. The electrical stimulator was set at certain modes, frequency, and intensity accordingly) or TEAS combined with other anesthesia methods such as PCEA. There is no restriction on the time of starting the intervention, duration of stimulation, acupoints, frequency, waveform, mode, intensity and pulse duration of the treatment, etc.

Comparator: Sham TEAS (received a very low electrical stimulation with less than 5mA); blank control; routine care; some other forms of analgesia; combined with other treatment methods which are the same as the intervention group or combination of the above several methods. However, if the control group underwent different frequency, waveform, mode, intervention time, and other forms of TEAS compared with the treatment group, it will be excluded.

Study designs to be included: Randomized controlled trials (RCTs) in English and Chinese.

Eligibility criteria: Inclusion criteria:Participants: Healthy laboring parturients without being used TEAS, TENS, acupuncture, or other analgesia methods before starting the intervention. (2) Intervention: the intervention group underwent TEAS (received electrical stimulation on the target acupoints. The stimulation was provided by an electrical stimulator through electrode tabs or acupuncture pens on the target acupoints, normal electroacupuncture was not included as it is invasive. The electrical stimulator was set at certain modes, frequency, and intensity accordingly) or TEAS combined with other anesthesia methods such as epidural analgesia and intraspinal block anesthesia. There is no restriction on the time of starting the intervention, duration of stimulation, acupoints, frequency, waveform, mode, intensity and pulse duration of the treatment, etc. (3) Comparator: sham TEAS (received a very low electrical stimulation with less than 5mA); blank control; routine care; some other forms of analgesia; combined with other treatment methods which are the same as the intervention group or combination of the above several methods. However, if the control group underwent different frequency, waveform, mode, intervention time, and other forms of TEAS compared with the treatment group, it will be excluded. (4) Study designs: Randomized controlled trials (RCTs) in English and Chinese. (5) Outcomes: the indicator of the pain intensity (visual analog scale, VAS) .Exclusion criteria:(1) Non-RCTs, quasi-randomized trials, crossover trials, cohort studies, retrospective studies, case reports, protocols, conference summaries, reviews, animal experimental research studies, and ongoing trials without results.(2) Studies difficult to identify the research types or did not specify the type clearly.(3) Duplicate publications.(4) Vague descriptions of intervention and comparison methods.(5) Literature without full text or difficult to extract studied outcomes.(6) Irrelative

interventions and outcomes were excluded. (7) The studied participants were pregnant women who had received oxytocin injections before the study will be excluded.

Information sources: PubMed, EMBASE, Cochrane Library, Web of science, Sinomed, China National Knowledge Infrastructure (CNKI), VIP, Wanfang databases, Clinical Trials.gov, and Chinese Clinical Trial Registry (Chi CTR) from their respective inception dates to 23rd April 2022.

Main outcome(s): The indicator of the pain intensity (visual analog scale, VAS).

Additional outcome(s): Secondary outcomes: duration of labor, modes of delivery, the amount of bleeding within 2h after the delivery, Apgar scores (1 and 5min) Additional outcomes: β-endorphin (EP) levels of parturients, oxytocin use rate, the incidence of maternal and neonatal side effects, participants' satisfaction towards the intervention experience.

Quality assessment / Risk of bias analysis: Two reviewers will assess the risk of bias of all included RCTs independently via the Cochrane Handbook for Systematic Reviews of Interventions tool, which contains the following 7 items: 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) and others bias. Each item is classified as "Low risk", "High risk," or "Unclear risk". Disagreements between these 2 reviewers will be resolved via consensus or after the discussion with the third researcher.

Strategy of data synthesis: Review Manager 5.4 software from the Cochrane collaboration will be used to analyze data from included RCTs. For the dichotomous data, a Mantel-Haenszel (M-H) method will be used to calculate RRs with 95% CI. For continuous data, the inverse variance (IV) method will be used to calculate their mean difference (MD) or standard mean difference (SMD) with 95% CI. The magnitude of heterogeneity of included studies will be performed through the software illustrated above. We will select a random-effect model or fixed-effect model to pool the data according to the results of the heterogeneity test. If I2<50% then the fixed-effect model will be applied for data synthesis. Otherwise, the random-effect model will be conducted if the heterogeneity is significant (I2≥50%).

Subgroup analysis: If significant heterogeneity exists and the necessary data are available, subgroup analyses will be performed based on the different duration of intervention, the different starting time of intervention, different stages of labor duration, different waveforms or frequencies or modes, and different sample sizes, etc.

Sensitivity analysis: Sensitivity analyses will be applied by removing certain studies and recalculating the significance of results to investigate the robustness of main decisions made during the review process to evaluate the stability of our results.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: labor pain; TEAS (transcutaneous electrical acupoint stimulation); electro stimulation; acupoint; systematic review and meta-analysis.

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