INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) as an analgesic intervention in labor pain: A network 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, and compare it to epidural block, the most common analgesic method in the process of labor, 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, compare it to the recognized effective epidural block, 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 10 October 2022 (registration number INPLASY202250050).

INTRODUCTION

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, and compare it to epidural block, the most common analgesic method in the process of labor, with the aim of illustrating the effectiveness and safety of this non-invasive treatment, which is a treatment combined acupuncture with electro stimulation.**

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METHODS

Search strategy: Articles on TEAS, epidural analgesia and labor pain published on electronic databases including PubMed, EMBASE, Web of Science and Cochrane CENTRAL. Ongoing trials or unpublished studies were also searched through Clinical Trials.gov.

Participant or population: Healthy laboring parturients planning natural birth without being used TEAS, TENS, epidural analgesia, acupuncture, or other analgesia interventions 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 epidural analgesia or TEAS combined with other anesthesia interventions. 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) or saline placebo; blank control; routine care; some other forms of analgesia; combined with other treatment interventions which are the same as the intervention group or combination of the above several interventions. However, if the comparison group underwent different frequency, waveform, mode, intervention time, and other forms of TEAS compared with the intervention group, it will be excluded.

Study designs to be included: RCTs without language restriction.

Eligibility criteria: (1) Patients: healthy laboring parturients planning natural birth without being used TEAS, TENS, epidural analgesia, acupuncture, or other analgesia interventions 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 epidural analgesia or TEAS combined with other anesthesia interventions. 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) or saline placebo; blank control; routine care; some other forms of analgesia; combined with other treatment interventions which are the same as the intervention group or combination of the above several interventions. However, if the comparison group underwent different frequency, waveform, mode, intervention time, and other forms of TEAS compared

with the intervention group, it will be excluded.
(4) Outcomes: main outcomes: (a) the indicator of the pain intensity (visual analog scale, VAS); (b)failure to progress natural delivery, including those parturients underwent cesarean section and instrumental deliveries such as forceps and vacuum extraction; (c)adverse events of parturients. Secondary outcomes: Apgar scores of neonates.
(5) Study designs: RCTs without language restriction.

Information sources: PubMed, EMBASE, Web of Science, Cochrane CENTRAL databases, and Clinicaltrials.gov.

Main outcome(s): (a) The indicator of the pain intensity; (b)failure to progress natural delivery; (c)adverse events of parturients.

Additional outcome(s): Apgar scores of neonates.

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: Network plots will be created by StataSE15 (64 bit) that present the connection of the different interventions. We plan to use R software for Heterogeneity analysis. The NMA analysis will be done with ADDIS. The consistency model will be applied when P-value is >0.05, then the potential scale reduction factor (PSRF) analysis will be used to produce the results.

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: No language restriction.

Country(ies) involved: China.

Keywords: transcutaneous electrical acupoint stimulation; epidural analgesia; efficacy; safety; labor pain; network meta-analysis.

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