INPLASY PROTOCOL

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None declared.

The Efficacy and Safety of Transcutaneous Electrical Acupoint Stimulation (TEAS) for Postoperative Pain in Laparoscopy: A Protocol for Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) on postoperative pain of laparoscopy.**
Information sources: **We will search articles in PubMed, the Cochrane Library (CENTRAL), Embase, and four Chinese databases (China National Knowledge Infrastructure, Chongqing VIP Information, and WanFang Data, Chinese Biomedical Database) from their inception up to November 30, 2020. For the literature to be difficult to obtain the full text, we will check and identify the ongoing or unpublished studies through the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, Chinese Clinical Trial Registry (Chi CTR), and the reference list of eligible RCTs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2021 and was last updated on 28 May 2021 (registration number INPLASY202150101).

INTRODUCTION

Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) on postoperative pain of laparoscopy.**

Condition being studied: **Laparoscopic surgery is widely used in clinics because of its advantages of small trauma, light pain and quick recovery. But the artificial**

pneumoperitoneum in laparoscopic surgery will make the visual field clear, will aggravate the postoperative pain and other stress reactions. However, the artificial pneumoperitoneum in laparoscopic surgery will make the visual field clear and aggravate the postoperative pain and other stress reactions. Transcutaneous electrical acupoint stimulation(TEAS) is to make the specific pulse current input into the human body through the appropriate skin electrode on the surface of acupoints and stimulate the acupoints to achieve certain therapeutic effect. Studies have shown that TEAS not only has analgesic effect, but also can reduce stress response and postoperative complications. However, there is a lack of systematic evaluation of the effect of TEAS on postoperative pain. Therefore, it is of great significance to carry out relevant research on the application of TEAS in laparoscopic surgery.

METHODS

Search strategy: We will search articles in PubMed, the Cochrane Library (CENTRAL), Embase, and four Chinese databases (China National Knowledge Infrastructure, Chongqing VIP Information, and WanFang Data, Chinese Biomedical Database) from their inception up to November 30, 2020. We performed an initial search of PubMed as follows(Table 1): #1 "transcutaneous electrical acupoint stimulation" OR "transcutaneous acupoint electrical stimulation" OR "electr* stimulat*" OR "electr* acustimul*" OR "electroacupuncture*" OR "electro-acupuncture" OR "TEAS"; #2 "Laparoscopy[Mesh]" OR "laparoscop*" OR "coelioscop*" OR "celioscop*" OR "peritoneoscop*"; #3 "Pain, Postoperative[Mesh]" OR "postoperative pain" OR "postoperative analgesi*" OR "pain management" OR "ache*" OR "suffering*" OR "discomfort". We also further searched the grey literature and the retrieved references to avoid omission. For the literature to be difficult to obtain the full text, we checked and identify the ongoing or unpublished studies through the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, Chinese Clinical Trial Registry (Chi CTR), and the reference list of eligible RCTs.

Participant or population: Inclusion criteria: 1.Patients receiving laparoscopic surgery ; 2.There is no limitation on sex, age, race, disease category,et al. Exclusion criteria: Patients who did not receive general anesthesia.

Intervention: 1.Patients receiving laparoscopic surgery with general anesthesia; 2.The intervention measures in the experimental group include transcutaneous electrical acupoint stimulation (e.g. TEAS, TEAS combined with PCIA or analgesic medicine) 3.The intervention time, frequency, and the wave of transcutaneous electrical acupoint stimulation(TEAS) is not limited.

Comparator: Inclusion criteria: The control group underwent mock-TEAS or blank control or combined with other anesthesia methods, such as general anesthesia combined with the transverse abdominal plane block or postoperative routine analgesia nursing or placebo group or patient-controlled intravenous analgesia after the operation(PCIA) or combination of the above several methods. Exclusion criteria: Compared with the treatment group, underwent different frequency, waveform, intervention time, and other percutaneous acupoints electrical stimulation treatment.

Study designs to be included: Inclusion criteria:Randomized controlled trials (RCTs) will be included. Exclusion criteria: 1.Animal experiments; 2.No acupoints are involved.

Eligibility criteria: Inclusion criteria:Randomized controlled trials (RCTs) will be included. Exclusion criteria: 1.Animal experiments; 2.No acupoints are involved.

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databases (China National Knowledge Infrastructure, Chongqing VIP Information, and WanFang Data, Chinese Biomedical Database) from their inception up to November 30, 2020. For the literature to be difficult to obtain the full text, we will check and identify the ongoing or unpublished studies through the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, Chinese Clinical Trial Registry (Chi CTR), and the reference list of eligible RCTs.

Main outcome(s): Visual analysis scale (VAS) at different time points The dosage of postoperative analgesia or analgesic pump.

Additional outcome(s): Recovery quality scale(QoR-40), Time of the first ambulation after operation, First defecation time after operation, The first exhaust time after operation, The first postoperative bowel sounds, residence time in the anesthesia recovery room.

Data management: Meta-analysis was carried out based on Stata 15.0 software. Relative Risk(RR)/Odds Ratios(OR) was used for secondary classification data, and weighted mean difference (WMD) or standard mean difference (SMD) was used to combine effect values for continuous variables, and corresponding 95% confidence interval (95% CI) was calculated. Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. After gradually finalizing the screening results, the author, year of publication, sample size, demographic indicators, course of the disease, intervention measures, course of treatment, Intervention time, observation indicators, outcome indicators, and other information were extracted to excel and cross-checked, and the data in doubt were submitted to group discussion or expert arbitration. The total sample size and the number of events were collected for binary variables, and the total sample size, the sample mean, standard deviation or standard error were collected for continuous variables.

Quality assessment / Risk of bias analysis: The "process-based evaluation table" attached to the Cochrane Collaboration Network was used to test the quality of literature. Selection risk: to judge the accuracy of the randomized scheme and the concealment of the allocation scheme; implementation risk: to judge whether the blinding of the participants is perfect; measurement risk: to judge whether the analyst blinding is successful; follow up bias: whether the results are reported completely, such as loss of follow-up, exit, and other information; reporting risk: the possibility of selective reporting; other bias: judging whether there are other factors High risk of bias. When the number of studies was more than 10, a funnel plot was drawn to analyze publication bias. If there was significant publication bias, the influence of publication bias on outcome indicators was evaluated by Egger's test; if the number was less than 10, publication bias analysis was not conducted.

Strategy of data synthesis: Meta-analysis was carried out based on Stata 15.0 software. Relative risk (RR) or odds ratio (OR)was used for secondary classification data, and weighted mean difference (WMD) or standard mean difference (SMD) were used to combine effect values for continuous variables, and corresponding 95% confidence interval (95% CI) was calculated. When $p > 0.10$ and $I2 < 50\%$, fixed effect model was selected; when $p < 0.10$ or $I2 > 50\%$, random effect model was selected, and I2 had higher priority than p-value. Test level $\alpha = 0.05$. When heterogeneity exists, the first review whether the data extraction is correct, draw a Galbraith diagram to verify the heterogeneity, explore the source of heterogeneity, continue to use subgroup analysis or meta-regression, and determine the stability of the effect value by sensitivity analysis after eliminating the heterogeneity points. If the heterogeneity is very significant, meta-analysis is not appropriate, and only a qualitative description is made. When the number of

studies was more than 10, a funnel plot was drawn to analyze publication bias. If there was significant publication bias, the influence of publication bias on outcome indicators was evaluated by Egger's test; if the number was less than 10, publication bias analysis was not conducted.

Subgroup analysis: 1.There are no restrictions on the duration of TEAS and the timing of its implementation (preoperative, intraoperative, and postoperative). Therefore, subgroup analysis should consider whether TEAS can be divided according to the duration of TEAS (long-term, short-term) and the implementation timing (before, during and after the operation). Considering that this factor may be the source of heterogeneity, different action time may have different effects on postoperative pain. 2.According to the VAS scores at different time points after operation, the effect of TEAS on postoperative pain was evaluated. 3.The effect of TEAS on postoperative pain was evaluated according to the amount of postoperative analgesia pump or analgesia analgesic. 4.Predicting the effect of waveform and frequency of TEAS on postoperative pain.

Sensitivity analysis: When heterogeneity exists, the first review whether the data extraction is correct, draw a Galbraith diagram to verify the heterogeneity, explore the source of heterogeneity, continue to use subgroup analysis or meta-regression, and determine the stability of the effect value by sensitivity analysis after eliminating the heterogeneity points. If the heterogeneity is very significant, meta-analysis is not appropriate, and only a qualitative description is made.

Language: All the publications will be searched without any restriction of countries.

Country(ies) involved: In China.

Keywords: Efficacy; Safety; TEAS; Postoperative Pain in Laparoscopy; Protocol; Systematic Review and Meta-Analysis.

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