INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The Application of Acupuncture Therapy in Perioperative Period pain control: A protocol for systematic review and meta-analysis

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Review question / Objective: **The objective of this study was to evaluate the effectiveness and safety of the application of acupuncture in perioperative period pain control by systematic review and meta-analysis and explore the possible factors influencing the specific effect of acupuncture by meta-regression.**
Information sources: **We will search for randomised controlled trials (RCTs) of acupuncture for perioperative pain control from inception to December 2022 in the following databases: Cochrane Central Register of Controlled trials (Central) , PubMed、EMBASE, and four chinese databases including China National Knowledge Infrastructure (CNKI), Wan Fang database, VIP, SinoMed. And we searched the Chinese Clinical Trial Registry to identify completed unpublished studies. There will be no limitations on language.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 December 2022 and was last updated on 14 December 2022 (registration number INPLASY2022120056).

INTRODUCTION

Review question / Objective: **The objective of this study was to evaluate the effectiveness and safety of the application of acupuncture in perioperative period pain control by systematic review and meta-analysis and explore the possible factors influencing the specific effect of acupuncture by meta-regression.**

Condition being studied: **Perioperative period is the period from from the beginning of anesthesia to 24 hours after**

the end of surgery. Postoperative pain is common post-surgical complications of various surgery and is experienced by nearly every patient after surgery, however, evidence suggests that fewer than half of the patients achieve adequate or satisfactory postoperative pain relief[3]. Postoperative pain, especially when managed sub-optimally, leads to unfavorable outcomes like higher incidence of postoperative nausea and vomiting, adverse physiological responses and increased the length of stay in hospital[4] [5].

Chronic postsurgical pain (CPSP) that is defined by the International Association for the Study of Pain (IASP) as pain that develops after a surgical procedure and persists for at least 3 months after surgery, where all other causes of pain[6]. Previous studies suggest that postoperative pain lasting more than 1 month becomes persistent in 10–50% of patients, with 2–10% experiencing moderate to severe chronic pain[7][8]. A study showed that almost one-quarter of children who underwent major surgery developed CPSP of moderate to severe intensity and unpleasantness 1 year after surgery[9]. In another prospective study showed that 19% of patients undergoing colorectal surgery reported CPSP at 6 months, 63% were taking medication for pain relief, and 53% were using opioids to manage their pain[10]. CPSP negatively impacts quality of life, such as mood, walking ability, and normal work. It was found that undertreated acute postoperative pain increases the risk of developing chronic postsurgical pain (CPSP)[11][12]. Previous studies have proved that providing appropriate perioperative analgesia can improve not only patients' satisfaction with pain experience, but also various other patient outcomes, including time to nutritional intake and ambulation, while reducing healthcare resource utilization and a variety complications[13]. Therefore, effective perioperative pain control is an vital part of surgical recovery[1].

Perioperative pain control refers to pain control before, during and after surgery, aiming to reduce postoperative pain and increase the patient outcomes[2]. Various pain control methods have been used to reduce surgical stress response as well as perioperative pain. Opioid drugs are the "gold standard" treatment for perioperative pain, which have been widely used for perioperative analgesia[14]. However, opioid use contributes to treatment-related adverse events in a substantial number of patients[15] and a total of 80% of patients experienced at least one adverse event, most common adverse event is constipation(41%), followed by nausea (32%) and somnolence (29%) [16]. For these reasons, non- pharmacotherapeutic approaches, such as acupuncture, mind–body interventions, and manipulative therapies, can be a good option as either a monotherapy or a concomitant treatment with pharmacotherapy[16].

Acupuncture, as a characteristic therapy of traditional Chinese medicine, can treat systemic diseases through inserting needles into skin to stimulate acupoints in specific body locations to regulate the meridian[18]. Acupuncture therapy has been shown to be effective in treating pain and anxiety among a variety of patient populations[17] and is a promising therapy for perioperative pain control with being regarded as a low-cost, low-risk, limited minor adverse effects therapy.

Previous studies of acupuncture have demonstrated beneficial effects on both pain,anxiety, and postoperative nausea and vomiting[20], such as preoperative anxiety[19], Total Knee Arthroplasty[21], post tonsillectomy [22], neck dissection[23]. However, a comprehensive meta-analysis that covers acupuncture therapy for perioperative pain control in various diseases so far is missing. Our purpose, in this review, is to conduct a systematic review and meta-analysis of the efficacy of acupuncture therapy for perioperative pain control in all types of diseases.

METHODS

Search strategy: A literature search from inception in to December 2022 in the following databases: Cochrane Central Register of Controlled trials（Central）、

PubMed、EMBASE, and four chinese databases including China National Knowledge Infrastructure (CNKI), Wan Fang database, VIP, and SinoMed will be independently performed by two investigators (LYX and ZXH), using terms "Moxibustion", "Acupuncture", "Acupuncture Therapy", "Acupuncture, Ear", "Acupuncture Points", "Acupuncture Analgesia", “perioperative period”, “perioperative pefod”, “Perioperation”, “Peri operation period”, “Post$operat*”, “pre$operat*”, “operat*”, “intra$operat*”, “peri$operat*”, “Post$surgical”, “pre$surgical”, “surger*”, “surgical”.Medical Subject Heading (MeSH) terms were used in PubMed and Emtree terms were used in Embase. In addition, we will search the Chinese Clinical Trial Registry to identify completed unpublished studies. There will be no restriction on publication status, date, and language.

Participant or population: Types of patients of any age or gender in the perioperative environment will be included. All participants patients received the perioperative pain management.

Intervention: Acupuncture treatment using various types of stimulations, including handling (manual acupuncture), electricity (electroacupuncture) and heating (fire or warm needling), and moxibustion (any form of moxibustion) will be included. Acupuncture therapy can be used alone or in combination with an essential therapy, which should be the same as those used in the control groups.

Comparator: The control group included Western medicines, such as morphine and fentanyl, with or without sham acupuncture can be provided for control groups. Patients in the control group can be also given the following treatments, including a placebo, sham acupuncture and usual care.

Study designs to be included: All randomized controlled trials (RCTs) on acupuncture therapy in perioperative period pain control whether blinded or not, will be included. There will be no restrictions on the publication status, language, and date.

Eligibility criteria: Types of studies: All randomized controlled trials (RCTs) on acupuncture therapy in perioperative period pain control whether blinded or not, will be included. There will be no restrictions on the publication status, language, and date. Duplicate publications, no controls, Animal experiment, case reports, editorials, literature reviews, and other irrelevant will be excluded.Types of participants: Types of patients of any age or gender in the perioperative environment will be included. All participants patients received the perioperative pain management.Types of interventions: Acupuncture treatment using various types of stimulations, including handling (manual acupuncture), electricity (electroacupuncture) and heating (fire or warm needling), and moxibustion (any form of moxibustion) will be included. Acupuncture therapy can be used alone or in combination with an essential therapy, which should be the same as those used in the control groups. The control group included Western medicines, such as morphine and fentanyl, with or without sham acupuncture can be provided for control groups. Patients in the control group can be also given the following treatments, including a placebo, sham acupuncture and usual care. Studies that only compared the therapeutic effects of different forms of acupuncture will be excluded.

Information sources: We will search for randomised controlled trials (RCTs) of acupuncture for perioperative pain control from inception to December 2022 in the following databases: Cochrane Central Register of Controlled trials (Central)、PubMed、EMBASE, and four chinese databases including China National Knowledge Infrastructure (CNKI), Wan Fang database, VIP, SinoMed. And we searched the Chinese Clinical Trial Registry to identify completed unpublished studies. There will be no limitations on language.

Main outcome(s): Primary outcomes: Pain scores will be used as the primary outcome and measured with visual analogue scale (VAS) with end-points of 0 “no-pain” to 10 “ intense pain that is unbearable and affects appetite and sleep”.

Additional outcome(s): Secondary outcomes: The secondary outcomes of this review mainly include the following aspects: incidence of adverse reactions, patient satisfaction, the prevalence of analgesic use, length of hospital stay.

Data management: The all titles, abstracts and full text reports of potentially eligible articles will be obtained and independently reviewed by two authors (Li, YX and Xu, LL) to identify included studies. Any disagreements during the selection process will be discussed and resolved through a consensus agreement with a third party (Xiong, J). If there is not enough information to make a judgment, we will contact the original author for original data. Data from each eligible study will be independently extracted by two authors (Li, YX and Zhou, XH) using a predefined electronic data abstraction form, including following information: Study and Patient Characteristics、Interventions、primary outcomes、follow-up period. Data extraction were performed independently by two reviewers (Li, YX and Zhou, XH), and checked by a third reviewer (Xiong, J) against the original studies. If data are missing for some cases, or if the reasons are not reported, we will contact the original study author(s) for clarification, and we will document if the authors could not be contacted or did not respond.

Quality assessment / Risk of bias analysis: Two reviewers(Li, YX; Xiang, J) will independently assess the methodological quality of included RCTs according to the Cochrane Collaboration tool for risk of bias[24], which will be based on six domains: random sequence generation, allocation concealment, blinding of participants, personnel and outcome assessment, incomplete outcome data, selective reporting and other sources of bias. The risk of bias for these items will be evaluated as low, unclear (insufficient information provided) or high. A study will be deemed at low risk of bias if all key domains were judged at low risk of bias; a study will be judged at high risk of bias if high risk for one or more key domains; a study will be judged at unclear risk of bias if unclear risk for one or more key domains[25]. Disagreements between two the researchers will be resolved by discussion and consensus with a third researcher (Xiong, J).

Strategy of data synthesis: Data synthesis and analysis Review Manager Software (RevMan V.5.4) provided by Cochrane Collaboration will be used for data synthesis and analysis. The meta-analysis will be used to combine trials examining same intervention and outcomes in similar populations to estimate pooled intervention effect. We will express dichotomous data as relative risk (RR), and continuous variables as mean difference (MD) with 95% confidence intervals (CIs). When the units of continuous data are different, standardized mean difference (SMD) and 95% CI will be used. Statistical significance will be considered when p was <0.05. x2 test and I2 statistic test will be applied for confirming the heterogeneity of the research results. The fixed effect model will be performed if the assessment of heterogeneity was not significant (I2 0.1), and the random effect model will be performed if significant heterogeneity is identified (P50%).

Subgroup analysis: If there is significant heterogeneity, we would carry out a sensitivity analysis and subgroup analyses to explore the reasons for this. And if there are sufficient and available data, subgroup analysis would have been conducted on studies with different kinds of acupuncture and moxibustion and different disease types to explain the heterogeneity among studies. If quantitative synthesis is not appropriate, we will perform a descriptive analysis to interpret the data.

Sensitivity analysis: We will conduct a sensitivity analyses to identify whether the

conclusions are robust , based on decisions made during the review process.

Country(ies) involved: China.

Keywords: acupuncture, meta analysis protocol, meta regression, Perioperative Period.

Contributions of each author:

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