INPLASY PROTOCOL

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Conflicts of interest: None declared. Effectiveness and safety of electroacupuncture for myocardial protection in cardiopulmonary bypass patients with myocardial ischemiareperfusion injury: a protocol for a systematic review and meta-analysis

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Review question / Objective: P:Adult patients requiring cardiopulmonary bypass (CPB) for cardiac surgery; I:electroacupuncture; C: Placebo acupuncture, false electroacupuncture, blank control; O:Effectiveness indicators: main myocardial injury markers (CK-MB, LDH, cTn I), arrhythmia score, myocardial contractility score, autorepulse rate at the end of the bypass, related inflammatory factors (IF-2, IF-6, IF-8, IF-10, TNF- α), related oxidative stress indexes (SOD, NO, MDA); Safety measure: incidence of adverse events;S: randomized controlled trials.

Condition being studied: Myocardial protection in cardiopulmonary bypass patients with myocardial ischemia-reperfusion injury. We have a strong evidence-based medicine research team, and our teachers and students have been engaged in evidence-based research in the field of integrated Chinese and Western medicine for a long time, and have received national and provincial funding support.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 April 2021 and was last updated on 08 April 2021 (registration number INPLASY202140045).

INTRODUCTION

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Rationale: Study showed that myocardial tissue after ischemia oxygen for a long time to restore blood perfusion, myocardial damage may be more serious earlier, main performance for oxygen utilization obstacle, speed up the consumption rate of ATP, the energy utilization rate of myocardial cells decreased, reduced myocardial systolic function and myocardial edema, and compliance, is the 'ischemia/reperfusion injury '. It has been reported that in severe cases, fatal damage to the myocardium may result in prolonged operation time, difficulties in weaning, postoperative low cardiac output syndrome, and malignant arrhythmias. The degree of myocardial ischemia/reperfusion injury during cardiopulmonary bypass directly determines the operative quality and patient prognosis. Therefore, myocardium protection during cardiopulmonary bypass is particularly important. Different from traditional acupuncture and moxibustion therapy, electroacupuncture therapy is combined with modern electricity on the basis of acupuncture and moxibustion to stimulate the meridians and acupoints of the human body, regulate the physiological functions of the human body, so as to promote the circulation of gi and blood, so as to achieve the purpose of treating diseases. It is becoming more and more popular in many countries. Moreover, animal experimental studies have shown that electroacupuncture can reduce ischemiareperfusion injury after cardiac surgery. Therefore, we conducted a systematic review and meta-analysis of the benefits of electroacupuncture in clinical cardiac surgery, and summarized its effectiveness and safety in terms of myocardial protection, which is more conducive to the clinical promotion of electroacupuncture in cardiac surgery.

Condition being studied: Myocardial protection in cardiopulmonary bypass patients with myocardial ischemiareperfusion injury. We have a strong evidence-based medicine research team, and our teachers and students have been engaged in evidence-based research in the field of integrated Chinese and Western medicine for a long time, and have received national and provincial funding support.

METHODS

Participant or population: Adult patients requiring cardiopulmonary bypass (CPB) for cardiac surgery.

Intervention: Electroacupuncture.

Comparator: Placebo acupuncture, false electroacupuncture, blank control.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: P:Adult patients requiring cardiopulmonary bypass (CPB) for cardiac surgery; I:electroacupuncture; C: Placebo acupuncture, false electroacupuncture, blank control; O:Effectiveness indicators: main myocardial injury markers (CK-MB, LDH, cTn I), arrhythmia score, myocardial contractility score, auto-repulse rate at the end of the bypass, related inflammatory factors (IF-2, IF-6, IF-8, IF-10, TNF-a), related oxidative stress indexes (SOD, NO, MDA); Safety measure: incidence of adverse events;S: randomized controlled trials.

Information sources: We will search the following electronic databases without restrictions for publication status: Chinese National Knowledge Infrastructure (CNKI), Wanfang database, Chinese Science and Technology Periodical Database (VIP), China Biology Medicine Database (CBM), PubMed, EMBASE, the Cochrane Library and Web of Science from inception to April 2021. In addition, we will also identify any additional qualified articles by searching reference lists of retrieved literature. Main outcome(s): Main myocardial injury markers (CK-MB, LDH, cTn I), arrhythmia score, myocardial contractility score, autorepulse rate at the end of the bypass, related inflammatory factors (IF-2, IF-6, IF-8, IF-10, TNF- α), related oxidative stress indexes (SOD, NO, MDA).

Additional outcome(s): Incidence of adverse events.

Quality assessment / Risk of bias analysis: Tools recommended by the Cochrane Collaboration will be used to assess the risk of bias in included studies, including: Random sequence generation, Allocation concealment, Blinding of participants and personnel, Blinding of outcome assessment, Incomplete outcome data, Selective reporting, Other bias.

Strategy of data synthesis: RevMan V.5.3.3 will be used for data analysis of the included studies. The X² test and I²statistic will be used to test the heterogeneity of the included literature: when P < 0.05 or $I^2 >$ 50%, it means that the heterogeneity between the studies is significant, and a random-effects model will be used to synthesize the data. We should look for sources of heterogeneity actively. And the obvious clinical heterogeneity will be treated by the method of subgroup analysis or sensitivity analysis or just descriptive analysis. When P > 0.05 and $I^2 < 50\%$. use a fixed-effects model. Dichotomous variables are expressed by relative risk (RR) with 95% confidence intervals (CIs); continuous variables are expressed by mean difference(MD) or standardized mean difference (SMD) with 95% CIs.

Subgroup analysis: When sufficient data is available, we will conduct the following subgroup analysis to investigate the source of heterogeneity: ischemia time, reperfusion time, electroacupuncture methods and time, methods of anesthesia, Type of operation, treatment methods in the control group.

Sensitivity analysis: After conducting a quality assessment of the included studies,

we can perform a sensitivity analysis if there exist studies of low quality. Sensitivity analysis will also be conducted when there exists considerable heterogeneity between the studies. We will remove the low-quality literature for further analysis to explore the source of heterogeneity, then we can acquire a stable result of our study.

Language: In both Chinese and English.

Country(ies) involved: China.

Keywords: Electroacupuncture; Myocardial Reperfusion Injury; Cardiac Surgical Procedures; cardioprotective; systematic review and meta-analysis.

Contributions of each author:

Author 1 - Xiaoyu QIN. Author 2 - Chunai WANG. Author 3 - Jie ZHANG. Author 4 - Shuwei WANG. Author 5 - Weigi ZHANG.