INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Acupotomy for shoulder pain: a systematic review protocol

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Review question / Objective: **This systematic review aims to evaluate the effectiveness of acupotomy for shoulder pain. Is acupotomy a safe treatment for shoulder pain?**
Condition being studied: **Shoulder pain is a common disease that reduced range of motion, which seriously affects the quality of life of patients. Current conventional treatments include non-pharmacological measures, medication, and surgical procedures. Limited evidence suggests that acupotomy may be beneficial for it.**
Information sources: **Relevant studies will be searched from the databases of PubMed, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database, Weipu Database for Chinese Technical Periodicals, SinoMed, and Wanfang Database**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 March 2021 and was last updated on 01 March 2021 (registration number INPLASY202130002).

INTRODUCTION

Review question / Objective: **This systematic review aims to evaluate the effectiveness of acupotomy for shoulder pain. Is acupotomy a safe treatment for shoulder pain?**

Condition being studied: **Shoulder pain is a common disease that reduced range of motion, which seriously affects the quality of life of patients. Current conventional treatments include non-pharmacological measures, medication, and surgical**

procedures. Limited evidence suggests that acupotomy may be beneficial for it.

METHODS

Participant or population: Participants with shoulder pain must be diagnosed with a standard diagnostic criteria. There are no limits to research subjects' age, gender, race, condition duration or intensity.

Intervention: The treatment group will be treated with acupotomy (there is no limit on the needle materials, treatment methods, and course of treatment). Mixed therapies including acupotomy will be excluded.

Comparator: Because there is no false acupotomy reported in the literature and acupotomy commonly used in the acupuncture-moxibustion department, the control group will adopt the internationally recognized therapy such as block therapy or no treatment, acupuncture will also be included. Acupotomy with another active therapy versus the same therapy alone will also be investigated. Studies comparing 2 different types of acupotomy procedures will be expelled.

Study designs to be included: Only randomized controlled clinical trials (RCTs) related to the effects of acupotomy for treating shoulder pain will be included in this systematic review. Trials published in the form of dissertations will be also selected as eligible studies.

Eligibility criteria: Interventions will include any type of acupotomy for shoulder pain patients.

Information sources: Relevant studies will be searched from the databases of PubMed, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database, Weipu Database for Chinese Technical Periodicals, SinoMed, and Wanfang Database.

Main outcome(s): Shoulder pain intensity, as measured by using any validated pain scales. Constant-Murley Score.

Quality assessment / Risk of bias analysis: We will use the Cochrane Collaboration's tool which is recommended by the Cochrane Reviewer's Handbook to assess risk of bias for quality assessment of the included studies. The studies will be graded based on: (i) random sequence generation; (ii) allocation concealment; (iii) blinding; (iv) incomplete outcome data; (v) selective outcome reporting; (vi) other sources of bias.

Strategy of data synthesis: Comparisons will be made between any form of acupotomy and placebo or sham or no treatment with/without same additional treatment is given to both groups. The data of the study included may be divided into two cases, depending on whether the data are suitable for meta-analysis. If the meta-analysis will not be performed because of heterogeneity, interventions, comparisons, outcomes etc., we will make forms for a qualitative description. If the data is suitable for meta-analysis, we will perform the meta-analysis using software RevMan 5.3 (Review Manager). For dichotomous data, we will present the results as risk ratios (RR) with 95% confidence intervals (CIs). For continuous data, the mean difference (MD) will be presented. If outcome variables are measured on different scales, standard mean differences (SMD) analysis with 95% CIs will be performed. For the datas will be done with the meta-analysis, the heterogeneity will be tested by a standard I^2 test. If there is no statistic heterogeneity among the results, the fixed effects model is employed for meta-analysis. If there is a statistic heterogeneity, the source of the heterogeneity should be further analyzed. If there is obvious clinical heterogeneity, the subgroup or sensitivity analysis, or only descriptive analysis can be performed.

Subgroup analysis: If there is a significant heterogeneity in the included trials, we will conduct subgroup analysis based on the severity of shoulder pain and types of acupotomy.

Sensitivity analysis: When there are sufficient studies, we will carry out

sensitivity analysis to test the robustness of studies according to the quality of method, the sample size and the selection of missing data. And the fluctuation of results will be observed.

Language: Without any language or publication status restrictions.

Country(ies) involved: China.

Other relevant information: When data are missing, we will look for the reason. Then, we will contact the corresponding author to obtain and verify the data if possible. If this does not work, we will only analyze the available data.

Keywords: acupotomy, shoulder pain, protocol, systematic review.

Dissemination plans: The results of this systematic review will be published in a peer-reviewed journal.

Contributions of each author:
Author 1 - Zhu Yongda - The author drafted the manuscript.
Author 2 - Zhu Yiwen - The author provided statistical expertise.
Author 3 - Hua Danyun - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Ye Renying - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 5 - Shen Cimin - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.