INPLASY PROTOCOL

To cite: Liu et al. Effectiveness and safety of moxibustion for De Quervain disease: a protocol for systematic review and meta-analysis. Inplasy protocol 2020100111. doi: 10.37766/inplasy2020.10.0111

Received: 28 October 2020

Published: 28 October 2020

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Support: **Science and Technology Project.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
The authors have no conflicts of interest to disclose.

Effectiveness and safety of moxibustion for De Quervain disease: a protocol for systematic review and meta-analysis

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Review question / Objective: **The purpose of this study is to evaluate the effectiveness and safety of moxibustion for De Quervain disease.**

Condition being studied: **De Quervain disease (DQD) is a clinical symptom caused by frequent movement of the thumb or wrist, local exudation, oedema and fibrosis of the tendon and tendon sheath, resulting in obstruction of the sliding of the tendon in the tendon sheath. The disease mostly occurs in people between 30 and 50 years old, The incidence rate of men is 0.05% and the incidence rate of women is 1.3%. The clinical manifestations are finger-snapping with obvious pain., in severe cases, the affected finger flexes and dare not move. Pain is often on the palm side of the metacarpo-phalangeal joints. Painful nodules can be palpated at the distal palmar transverse lines during physical examination. It moves up and down with the flexor tendons during physical examination and can cause bounce.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 October 2020 and was last updated on 28 October 2020 (registration number INPLASY2020100111).

INTRODUCTION

Review question / Objective: **The purpose of this study is to evaluate the effectiveness and safety of moxibustion for De Quervain disease**

Rationale: **A large number of clinical studies have reported that moxibustion has a good effect on the treatment of DQD, but there is no relevant systematic review.**

Condition being studied: **De Quervain disease (DQD) is a clinical symptom**

caused by frequent movement of the thumb or wrist, local exudation, oedema and fibrosis of the tendon and tendon sheath, resulting in obstruction of the sliding of the tendon in the tendon sheath. The disease mostly occurs in people between 30 and 50 years old, The incidence rate of men is 0.05% and the incidence rate of women is 1.3%. The clinical manifestations are finger-snapping with obvious pain., in severe cases, the affected finger flexes and dare not move. Pain is often on the palm side of the metacarpophalangeal joints. Painful nodules can be palpated at the distal palmar transverse lines during physical examination. It moves up and down with the flexor tendons during physical examination and can cause bounce.

METHODS

Search strategy: The following 8 electronic databases will be searched including PubMed, Embase, the Cochrane Library, China National Knowledge Infrastructure (CNKI), Web of Science, Chinese Scientific Journal Database(VIP), Wanfang Database and Chinese Biomedical Literatures Database (CBM) from their inception to 1 October 2020 without any restrictions.

Participant or population: The patients who are diagnosed with de Quervain disease regardless of ethnic group, severity, syndrome type and source of cases clinically will be included. Studies that de Quervain disease combined with other basic diseases will be excluded.

Intervention: The studies that used various forms of moxibustion (e.g. direct or indirect moxibustion, heat-sensitive moxibustion, warm needling moxibustion, or salt-separated moxibustion, etc.) as the single therapy or as the main part of a combination treatment with other interventions (e.g. western medicine, etc) will be considered. And the studies that moxibustion was used as an ancillary treatment will be excluded.

Comparator: The control interventions will include: positive interventions (e.g. western medicine), no intervention, placebo or sham moxibustion. The choice of specific forms, as follows:(1). Moxibustion VS positive interventions;(2). Moxibustion+ positive interventions VS positive interventions; (3) . Moxibustion VS no intervention;(4). Moxibustion VS placebo; (5). Moxibustion VS sham moxibustion.

Study designs to be included: All relevant randomised controlled trials (RCTs) or quasi-RCTs will be included.

Eligibility criteria: All the RCTs or quasi-RCTs of moxibustion for patients with DQD will be included without publication status restriction, review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded.

Information sources: We will electronically search the randomized controlled trials in the following databases: including the PubMed, Embase, the Cochrane Library, China National Knowledge Infrastructure (CNKI), Web of Science, Chinese Scientific Journal Database(VIP), Wanfang Database and Chinese Biomedical Literatures Database (CBM) from their inception to 1 October 2020 without any restrictions. The search strategy that will be run in the PubMed and adjusted to fit the other database when necessary.

Main outcome(s): 1. The effective rate.2. Visual analogue scale.

Additional outcome(s): 1.Finkelstein's 2. Resisted thumb extension. 3. Incidence of any adverse events.

Quality assessment / Risk of bias analysis: Based on the Cochrane Handbook for Systematic Reviews of Interventions, the risk of bias in all studies will be assessed by 2 authors independently using the Cochrane risk of a bias assessment tool. Six areas of each trial will be evaluated: generation of random sequences, allocation concealment, blinding method, incomplete outcome data, selective

reporting and other bias. Each domain will be divided into three levels of bias: unclear risk, high risk and low risk and "Risk of bias" will be filled in. And any differences will be resolved through negotiation or consulting with other reviewers.

Strategy of data synthesis: We will use RevMan 5.3.0 software to perform the meta-analysis. We will summarize data using risk ratios (RR) with 95% CI for binary outcomes or mean difference (MD) with 95% CI for continuous outcomes. I^2 value and P-value will be used to test the degree of heterogeneity. When $P > 0.1$, $I^2 < 50\%$, no heterogeneity was considered between the studies and the fixed effect model will be used for statistical analysis; otherwise, the random effect model will be used. If there was significant clinical heterogeneity between studies, only descriptive analysis was performed. For a study with incomplete result data, we will try to contact the first author.

Subgroup analysis: In order to explore the possible causes of heterogeneity, we will conduct subgroup analysis if there are a sufficient number of studies (at least 10 trials). In addition, if we do not observe the predicted effect in all the subjects, the subgroup analysis can help us find out whether the treatment is effective in some subgroups.

Sensibility analysis: In order to assure the robustness of our results, We will conduct sensitivity analysis to eliminate the impact of low-quality studies, with the premise of significant heterogeneity still exists right after validation of inputted data and subgroup analysis. We will contrast the results of these two meta-analyses and decide whether to exclude low-quality researches based on impact on the pooled effect size, sample size and strength of evidence. Nevertheless, if all included studies are at high risk of bias, we will not conduct sensitivity analysis.

Language: English.

Country(ies) involved: China.

Keywords: De Quervain disease, moxibustion, randomized controlled trial, systematic review and meta-analysis, protocol.

Dissemination plans: We have no dissemination plans.

Contributions of each author:
Author 1 - Liu Min - drafted the manuscript.
Author 2 - Liu Meinian - provided statistical expertise.
Author 3 - Yang Wenlong - contributed to the development of the selection criteria.
Author 4 - Mei Ou - contributed to the risk of the bias assessment strategy.
Author 5 - Xia Hanting - read, provided feedback and approved the final manuscript.
Author 6 - Tu Hong - use the software to analyze the data.
Author 7 - Wang Li - write the original draft.
Author 8 - Deng Xuyong - review and edit the manuscript.