INPLASY PROTOCOL

Corresponding author:
Jingyu Wang

724813694@qq.com

Author Affiliation:
Shandong University of Traditional Chinese Medicine.

Conflicts of interest:
None declared.

The effect of acupuncture used for Ureteral calculi A protocol for systematic review and meta-analysis

Wang, JY[1]; Wang, Q[2]; Liu, ZL[3]; Zhang, YC[4]; Jia, HL[5].

Review question / Objective: This meta-analysis aims to evaluate the efficacy and safety of acupuncture in the treatment of US, in order to provide reference and basis for clinical decision-making.

Condition being studied: Ureteral calculi (UC) generally refer to the temporary obstruction of the human body after the ureteral stenosis. Its clinical manifestations include lumbar and abdominal colic, nausea, vomiting and hematuria. In severe cases, renal function can decline or even loss, seriously affecting the quality of life of patients. As one of the characteristic therapies of traditional Chinese medicine, acupuncture has the advantages of obvious analgesic effect, lasting effect and high safety. However, no relevant studies have conducted meta-analysis on the effectiveness of acupuncture in the treatment of UC. Therefore, this study aims to evaluate the efficacy and safety of acupuncture in the treatment of US, in order to provide reference and basis for clinical decision-making.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 December 2022 and was last updated on 19 December 2022 (registration number INPLASY2022120081).

INTRODUCTION

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METHODS

Search strategy: The following electronic databases will be searched: PubMed, Web of Science, Embase, MEDLINE, Cochrane Library, China National Knowledge Infrastructure Database (CNKI), WanFang Database, Chinese Scientific Journals Database (VIP), China Biology Medicine Database (CBM). We will consider articles published between the database initiation and December 2022. We will search WHO International Clinical Trials Registry Platform, Chinese Clinical Trial Registryr, PROSPERO, The US National Institutes of Health registe, relevant conference proceedings, or grey literature for any potential studies.

Participant or population: We will consider patients with a clinical diagnosis of UC, and the age limit is 18~80 years ord, regardless of gender, race, country, and disease duration. Both the patient and the family informed the study and signed a consent form.

Intervention: The experimental group received acupuncture or acupuncture combined with other therapies, which could include one or more treatments, such as body acupuncture, fire acupuncture, electric acupuncture, ear acupuncture, skin acupuncture, scalp acupuncture, warm needling moxibustion, or moxibustion.

Comparator: The control group received conventional symptomatic treatment, surgical treatment, drug treatment, placebo needle, sham needle or no treatment. The experimental group can be given the same basic treatment as the control group. If the experimental group received acupuncture in combination with other therapies, the control group received the same other therapies as the experimental group. The control group using acupuncture-related therapies were excluded.

Study designs to be included: Randomized controlled trials(RCTs).

Eligibility criteria: This review will include randomized controlled trials (RCTs) related to acupuncture for UC published in Chinese and English. Excluding non-RCTs, animal experiments, review studies, and case reports.

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Main outcome(s): The main outcomes included: total clinical effective rate, cure rate, stone complete expulsion rate, and urine test results.

Additional outcome(s): The secondary outcomes included: pain relief time, the amount of painkillers used, calculi expulsion time, incidence of renal colic, and rate of recurrence. At the same time, we should pay close attention to the occurrence of adverse reactions or adverse events to evaluate the efficacy and safety of acupuncture in the treatment of UC.

Data management: The data will be independently extracted by two reviewers (JYW and QW) using a uniform data sheet. The extracted information included not only basic information such as journal name, title, author, and publication year, but also study design, patient characteristics, intervention measures, intervention duration, and outcome indicators. Any disagreement will be resolved by

discussion between the two reviewers. If agreement can't be reached, it will be decided by third-party reviewer (ZLL). All retrieved studies will be imported into Endnote X9.1 for management, and duplicate studies will be removed. Two trained reviewers (JYW and QW) will independently undertake the studies according to the inclusion criteria. First, the retrieved studies will be preliminarily screened according to the title and abstract of the articles. Second, a secondary screening will be performed on the original text included in the primary screening. If necessary, the full text will be read and the excluded studies will be listed in a table giving the reasons for the exclusion. If the first two reviewers have controversial information, the third reviewer (ZLL) will participate in the extraction and discussion.

Quality assessment / Risk of bias analysis: Two reviewers (JYW and QW) will independently use the "bias risk assessment tool" recommended in the Cochran Manual 5.1.0 to assess the quality of RCTs. It includes 7 items: randomized sequence scheme, allocation concealment scheme, blindness of participants and caregivers, blindness of outcome evaluators, incomplete outcome data, selective outcome reporting, and other sources of bias. The assessment of risks of bias will be classified into three levels: high risk of bias, low risk of bias, and unclear risk of bias.

Strategy of data synthesis: According to heterogeneity test, we will use the chi-square test and I2 statistic to evaluate statistical heterogeneity, fixed effect model or random effect model must be selected for effect size combination. When $P > .05$ or $I2 < 50\%$, fixed effect model was selected. When $P < .05$ or $I2 > 50\%$, random effect model was selected. When quantitative synthesis is not applicable, we will conduct descriptive analyses.

Subgroup analysis: We will conduct subgroup analysis among sample size, treatment methods and duration of treatment to explore the causes of heterogeneity.

Sensitivity analysis: We will conduct a sensitivity analysis by eliminating literature one by one to evaluate the stability and reliability of the overall results. If the difference between the results and the overall results is small and there is no essential change after the exclusion, it will be proved that the results have low sensitivity, indicating that the results are robust. Otherwise, it is proved to have high sensitivity, suggesting that the results are not credible. At this time, the results should be interpreted with caution and objectivity.

Language restriction: The language of the publication is limited to Chinese or English.

Country(ies) involved: China.

Keywords: Ureteral calculi, protocol, acupuncture, meta-analysis.

Contributions of each author:
Author 1 - Jingyu Wang.
Email: 724813694@qq.com
Author 2 - Qi Wang.
Author 3 - Ziliang Liu.
Author 4 - Yongchen Zhang.
Author 5 - Hongling Jia.