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Tenth People's Hospital,  
Tongji University, Shanghai, China.**ADMINISTRATIVE INFORMATION****Support** - Key Discipline Construction Project of Shanghai Chongming District Municipal Health Commission.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202480017**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 August 2024 and was last updated on 03 August 2024.**INTRODUCTION**

**Review question / Objective** The purpose of this systematic review and network meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of acupuncture for treating renal colic.

**Condition being studied** Renal colic is a common and extremely painful condition that leads to millions of emergency department visits annually. The incidence of urinary stones varies widely worldwide, from 1% to 20%, influenced by factors such as geography, climate, ethnicity, diet, and genetics. The financial burden is significant; for instance, the National Health Service in England estimated the cost of renal colic management at nearly £20 million in 2012-2013.

Given the severe distress associated with renal colic, the prompt provision of safe and effective analgesia is a primary concern. However, delivering quick and effective pain relief in emergency departments can be challenging due to the high patient volume and diverse populations being

treated simultaneously. The European Association of Urology (EAU) recommends nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids as standard analgesics for renal colic management. Despite their efficacy, these medications come with significant side effects, including gastrointestinal bleeding, kidney failure, and risks of addiction and abuse.

Traditional Chinese medicine, particularly acupuncture, has been employed for thousands of years to treat various pain conditions. Substantial evidence supports the effectiveness of acupuncture in managing both acute and chronic pain. Acupuncture is believed to alleviate pain by correcting and eliminating pathological factors and by blocking maladaptive pain pathways. Despite this, skepticism exists regarding its efficacy, with some studies suggesting acupuncture may not be more effective than placebo.

Recent research indicates that acupuncture can provide rapid pain relief for acute renal colic caused by urinary calculi, offering reliable therapeutic effects without toxic side effects. However, these studies often involve small sample

sizes, which may lead to overly optimistic conclusions. Previous evaluations of the efficacy and safety of manual acupuncture for treating acute renal colic in adults have used traditional meta-analyses. In contrast, this study employs a Bayesian network meta-analysis to systematically evaluate the efficacy and safety of manual acupuncture in treating acute renal colic caused by urinary calculi in adults. By incorporating evidence from randomized controlled trials (RCTs) and utilizing this advanced methodological approach, we aim to provide more robust and comprehensive evidence to support the clinical application of acupuncture in managing renal colic.

## METHODS

**Search strategy** The free texts and medical subject headings (i.e., MeSH terms in Medline) that were combined for searching included: (“renal colic” or “kidney stone” or “renal stone” or “urinary calculi” or “urinary calculus” or “ureteral Colic” or “urolithiasis” or “nephrolithiasis” or “Ureteral calculi”) and (“Acupuncture” or “Electro acupuncture” or “Laser acupuncture” or “Needle acupuncture” or “auricular acupuncture”).

**Participant or population** Adult patients diagnosed with renal colic are of all genders and races.

**Intervention** The interventions in the treatment group were acupuncture alone or in combination.

**Comparator** The control group was treated with commonly used analgesics and antispasmodics (e.g., diclofenac, indomethacin, ibuprofen, morphine, pethidine, tramadol, atropine, anisodamine, and acetaminophen).

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

**Eligibility criteria** All studies were randomized controlled trials (RCTs), regardless of language, with or without assignment concealment and blinding. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

**Information sources** PubMed, the Cochrane Library (CENTRAL), Embase, Web of Science, China National Knowledge Infrastructure (CNKI), Chongqing VIP Information (VIP), and WanFang Data, China Biomedical Literature Database (CBM), ClinicalTrials.gov and Chinese Clinical Trial Registry (ChiCTR).

**Main outcome(s)** The primary observations were the efficacy response rate and the time duration before pain remission. The efficacy response rate was defined as the percentage of effective cases relative to the total number of cases.

The effectiveness of acupuncture in treating renal colic was determined by: A reduction in the patient's pain score (using the Visual Analog Scale (VAS) or Numeric Rating Scale (NRS)) of at least 50% within 30 minutes of receiving acupuncture treatment.

The time duration before pain remission, which refers to the time at which pain begins to relieve or the onset of pain relief.

**Additional outcome(s)** Secondary outcome measures include incidence of adverse reactions.

**Quality assessment / Risk of bias analysis** Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: low risk of bias, unclear risk of bias, and high risk of bias. The following seven characteristics will be assessed:

Random Sequence Generation (Selection Bias): Evaluating the method used to generate the randomization sequence.

Allocation Concealment (Selection Bias): Assessing whether the allocation to interventions was adequately concealed.

Blinding of Participants and Personnel (Performance Bias): Determining whether participants and study personnel were sufficiently blinded to the intervention allocations.

Blinding of Outcome Assessment (Detection Bias): Assessing the blinding of outcome assessors.

Incomplete Outcome Data (Attrition Bias): Evaluating the completeness of outcome data, including attrition and exclusions from the analysis. Selective Reporting (Reporting Bias): Assessing whether all pre-specified outcomes and analyses were reported.

Other Biases: Considering any additional biases that may be relevant to the specific study.

The results from these assessments will be graphed and analyzed using Review Manager 5.4. Discrepancies between the two reviewers will be resolved through discussion, and if necessary, consultation with a third reviewer.

Additionally, an overall risk of bias judgment for each study will be determined by considering the risk of bias across all domains. Studies will be categorized as having:

Low Risk of Bias: All domains are rated as low risk. Unclear Risk of Bias: At least one domain is rated as unclear risk, but no domain is rated as high risk.

High Risk of Bias: At least one domain is rated as high risk, or multiple domains are rated as unclear risk.

To ensure the robustness of our findings, sensitivity analyses will be conducted by excluding studies with a high risk of bias and comparing the results with those of the full dataset. The overall quality of evidence will also be assessed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach.

**Strategy of data synthesis** The network meta-analysis will be conducted using Review Manager 5.4 software and the Aggregate Data Drug Information System (ADDIS) version 1.16.5. Dichotomous variables will be assessed using risk ratios (RR) with 95% confidence intervals (95% CIs), while continuous variables will be analyzed using mean differences (MD) or standardized mean differences (SMD) with 95% CIs.

Heterogeneity among studies will be assessed using the  $\chi^2$  test and the  $I^2$  statistic. According to the heterogeneity test results:

If  $I^2 < 50\%$ , a fixed-effect model will be used for data synthesis.

If  $I^2 \geq 50\%$ , indicating significant heterogeneity, a random-effect model will be applied.

The Bayesian network meta-analysis approach will incorporate direct and indirect comparisons of multiple interventions to assess the relative efficacy and safety of acupuncture for treating renal colic. The outcomes will be calculated using P values, with  $P < 0.05$  considered statistically significant.

Additionally, the consistency between direct and indirect evidence will be assessed, and sensitivity analyses will be conducted to ensure the robustness of the findings. The results will be presented as network diagrams, ranking plots, and league tables to provide a comprehensive comparison of the treatments evaluated.

**Subgroup analysis** Subgroup analyses will be performed if the necessary data are available to investigate differences based on specific factors. These analyses will include:

Gender: Evaluating the efficacy and safety of acupuncture for renal colic separately for male and female patients.

Age: Assessing differences in outcomes based on age groups (e.g., younger adults vs. older adults).

Site of Needling: Analyzing the effects of different acupuncture needling sites on the treatment outcomes.

**Sensitivity analysis** Sensitivity analysis will be conducted to assess the stability and robustness of the findings. This will include examining the

influence of various factors such as study quality, study design, and sample size. Specifically, we will: Study Quality: Evaluate how the inclusion or exclusion of studies with different levels of risk of bias (as assessed by the Cochrane Risk of Bias tool) impacts the overall results.

Study Design: Assess the effects of different study designs (e.g., parallel-group versus crossover trials) on the outcomes.

Sample Size: Analyze the influence of studies with small sample sizes compared to larger studies to determine if results are disproportionately affected by smaller studies.

The results of the sensitivity analysis will be presented in a summary table, highlighting any variations in the findings when different subsets of data are considered.

**Country(ies) involved** China (Chongming Branch of Shanghai Tenth People's Hospital, TongjiUniversity, Shanghai).

**Keywords** Acupuncture, Renal Colic, Systematic Review, Network Meta-Analysis.

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