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Efficacy and safety of acupuncture in the treatment of urinary incontinence after prostate surgery: protocol for a systematic review and meta-analysis

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ABSTRACT

Background Urinary incontinence (UI) is a common complication after prostate surgery. Acupuncture treatment (AT) has been proposed as an alternative therapy for this condition. The purpose of this protocol aims to outline a systematic review and meta-analysis that aims to evaluate the effectiveness and safety of AT in patients with postprostate surgery UI.

Methods We will search for randomised controlled trials (RCTs) in eight databases including PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wanfang database, SinoMed and VIP database. Additionally, we will search two clinical trial registration platforms, namely the WHO's International Clinical Trials Registry Platform and the Chinese Clinical Trial Registry. The search will include articles from the inception of these databases until 30 September 2023. The extracted data will then be imported into the Stata V.15.0 software. Two authors will independently review the literature, collect data and use the Grades of Recommendation, Assessment, Development and Evaluation and the Cochrane Risk of Bias 2 tool to evaluate the risk of bias and the quality of the evidence. Outcomes for RCTs will include at least one of the following: International Consultation Incontinence Questionnaire-Urinary Incontinence Short Form, Individualised Care for People with long-term health conditions–Capability measure for Adults, Score of Frequency Incontinence Quality of Life Questionnaire, Patient Global Impression of Improvement, Visual Analogue Scale, Numeric Rating Scale, 1- hour pad test, Self-Rating Anxiety Scale, total efficiency and adverse event. We will use random or fixed effect models to analyse data according to heterogeneity. If significant heterogeneity exists along with sufficient data, we will perform subgroup analyses to identify the source of heterogeneity.

Ethics and dissemination Ethical approval is not required for this study because the data we will extract are from published articles. The results will be published in a peer-reviewed journal.

PROSPERO registration number CRD42022382806.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We will conduct a comprehensive search of the included studies by not only searching eight databases using a broad search strategy but also considering the clinical trial registration platforms for planned and ongoing randomised controlled trials.
⇒ Our study uses outcome indicators compliant with clinical practice, including International Consultation Incontinence Questionnaire-Urinary Incontinence (UI) Short Form, 1-hour pad test and Self-Rating Anxiety Scale. These indicators provide a comprehensive evaluation of the therapeutic effect of acupuncture treatment (AT).
⇒ To investigate the placebo effect of AT, we will include sham acupuncture, as some suggest that AT may work partly through a placebo effect.
⇒ Due to the unique characteristics of acupuncture, our research focuses solely on acupuncture therapy without providing further details such as the acupuncturist's experience and skill, specific acupuncture points or the frequency of acupuncture.
⇒ The discussion of the mechanisms of AT for UI after prostate surgery in this paper cannot delve deeper due to the limited existing literature on the subject.

INTRODUCTION

Urinary incontinence (UI) is a prevalent postprostatectomy complication and a distressing symptom for patients.[1] The International Continence Society has estimated the incidence of UI to be as high as 80%.[2] UI can manifest as stress UI (SUI), urge UI (UUI) or a combination of both (mixed UI).[3] According to a review by the European Association of Urology, pelvic innervation and anatomical support are believed to be fundamental causes of UI, while postoperative fibrosis-induced loss of pliability also contributes to the condition.[4 5] Incidence rates vary depending on factors such as body mass index (BMI), age and surgical techniques.[6–8] A study reported that the average age of men with UI is around 70 years, and meta-analysis results indicated a significant correlation between obesity (BMI≥30 kg/m^2) and UI.[9 10] UI accounts for approximately 2% of medical expenditure in the USA and Switzerland. Studies have demonstrated a close association

between UI and depression, which significantly impacts patients' recovery and quality of life after surgery.[11 12]

Current clinical treatments for UI include pelvic floor muscle training (PFMT), artificial urinary sphincter, male sling and drug therapy.[6 13] However, these treatment methods have notable limitations. Previous evidence suggests that PFMT is effective when performed regularly over an extended period, but poor patient compliance can hinder its long-term efficacy.[14 15] In some cases, PFMT improved the function of striated muscles in male patients but did not contribute to UI recovery.[16] Furthermore, surgical interventions such as the artificial urinary sphincter and a male sling may exacerbate pain and increase the risk of infection and urethral atrophy.[17] Duloxetine, a pharmacological therapy for UI, has shown short-term improvement of incontinence symptoms in men undergoing prostatectomy; however, adverse events such as fatigue and nausea often lead to medication discontinuation in 21% of patients.[18 19]

Acupuncture, as a traditional Chinese medicine therapy, has been clinically applied for over 3000 years, known for its simplicity, high efficiency and safety.[20 21] A reanalysis of a randomised non-inferiority controlled trial demonstrated that electroacupuncture (EA) had similar effectiveness to PFMT combined with solifenacin in treating UI, with EA exhibiting better safety profiles.[22] A prospective case series on sacral EA as a treatment for UUI indicated a significant and statistically favourable association between EA targeting the lumbosacral region and UUI improvement.[23]

Although a previous systematic review has been conducted in this field,[24] ongoing randomised controlled trials (RCTs) continue to generate more evidence. The previous review only qualitatively analysed the potential of acupuncture treatment (AT) for UI after prostate surgery (UIP), lacking further analysis of its safety and typology of different types of incontinence.[24] A Cochrane article reported unclear efficacy of AT for SUI; however, a recent RCT demonstrated the effectiveness of AT for post-prostate surgery patients with SUI, UUI or mixed UI.[25 26] Given the remaining controversies, we aim to update the existing evidence and address the limitations of previous studies to investigate the safety and effectiveness of AT for UIP.

METHODS

The systematic review and meta-analysis are scheduled to commence on 1 October 2023 and end on 1 June 2024. This study will adhere to the guidelines established by the Cochrane Collaboration[27] and will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol checklist.[28] To enhance the protocol's transparency and accountability, we have registered the meta-analysis protocol under the CRD42022382806 number on the International Prospective Register of Systematic Reviews (PROSPERO) website.

Eligibility criteria

We will employ the population, interventions, comparisons, outcomes, study design principle to rigorously screen the literature for our systematic review and meta-analysis.

Types of participants

This study will include participants who exhibit symptoms of UI or experience 'leakage' during rest or activities such as coughing, standing, lifting heavy objects or walking after prostate surgery.[29–31]

We will exclude participants who already have UI resulting from urological conditions (eg, prostatic hyperplasia) or neurological disorders (eg, cerebral atrophy, lateral sclerosis) unrelated to prostate surgery.

Types of interventions

Interventions in the experimental group

In the experimental group, the treatment will be strictly limited to AT. To ensure consistency and reliability of the results, clear definitions of AT and specific intervention requirements will be established. For this study, we define AT as the insertion of needles into acupuncture points in humans. This definition encompasses various techniques and approaches, including the use of microacupuncture needles (such as intradermal acupuncture, auricular acupuncture and acupuncture point burial), standard acupuncture needles (such as manual acupuncture, warm acupuncture and fire acupuncture), as well as modern techniques and theories (such as EA). However, our definition of AT will exclude non-invasive methods such as moxibustion, laser acupuncture, acupressure and transcutaneous electrical stimulation. By applying this clear definition, we aim to reduce heterogeneity in data synthesis and enhance the reliability of the study results.

Interventions in the control group

For the control group, we will include non-surgical (PFMT, drug therapy, sham acupuncture) and surgical treatments (artificial urethral sphincter, male slings) that align with current standard treatment measures, as recommended by guidelines and supported by clinical experience.[32]

Types of study

Only RCTs that meet the criteria will be included in our systematic review and meta-analysis, regardless of language or publication date. We will specifically include RCTs investigating the effects of AT on UIP. Furthermore, if cross-over randomised trials are available, we will include them in our study. However, we will only consider the precross-over data to avoid carryover effects. This decision is based on the potential long-lasting impact of acupuncture interventions, which could influence the trial's latter phase if the effect persists.[33] Non-RCTs, such as case reports, reviews, conference papers or animal experiments, will be excluded from our analysis.

Types of outcomes

Based on the importance of each outcome, we will classify the outcome indicators into primary and secondary

outcomes. The included original studies must have at least one of the following outcome measures.

Primary outcome measures

1. International Consultation Incontinence Questionnaire-UI Short Form (ICIQ-UI-SF): Patient questionnaires play a significant role in the diagnosis of UI. The International Consultation on Incontinence (ICI) recommends the use of their modular questionnaire (ICIQ) as a worldwide standard for assessing UI in research studies.[34] This questionnaire includes items related to the number of urine leaks, the impact on quality of life and the timing of leaks. The overall ICIQ score, derived from the first three questions, ranges from 0 to 21. It is categorised into four levels to evaluate the severity of UI: mild (0–5), moderate (6–12), severe (13–18) and very severe (19–21).[35]
2. Score of Frequency Incontinence Quality of Life Questionnaire (I-QOL): The I-QOL is a scoring system used to evaluate the quality of life in patients with UI. It encompasses four dimensions, namely physical functioning, social aspects, emotional well-being and independence, and discomfort related to bathroom usage.[36]
3. Patient Global Impression of Improvement (PGI-I): The PGI-I is a single-item questionnaire that asks patients to rate the change in their condition following treatment on a 7-point scale ranging from 'very much worse' to 'very much improved'. The PGI-I is widely used as a tool to assess the perceived effectiveness of treatment and the degree of improvement experienced by patients.[37]
4. Individualised Care for People with long-term health conditions-Capability Measure for Adults (ICeCAP-A): The ICeCAP-A evaluates patients' capability in five domains: Stability, Attachment and Love, Achievement, Enjoyment and Happiness, and Control. It is designed to evaluate the overall health status and quality of life of patients.[38]

Secondary outcome measures

1. 1-hour pad test: The 1-hour pad test measures urine leakage by assessing the weight increase of a urine pad after a period of holding back urination through specific exercises. The severity of leakage is classified as mild (1–10 g), moderate (11–50 g) or severe (more than 50 g).[39]
2. Self-Rating Anxiety Scale: UIP patients often experience significant anxiety during the treatment process, adding to their distress.[15] A 20-item scale is used to measure subjective anxiety sensations, with each item categorised into four frequency-based categories. This scale effectively evaluates the intensity of anxiety symptoms and helps guide treatment modifications.[40]
3. Total effective rate (defined by outcome indicators): Clear criteria have been established to define the effectiveness, improvement, cure and ineffectiveness of outcome indicators included in the literature. To assess these indicators, we will calculate the number of patients who achieved effectiveness, improvement and cure by dividing it by the total number of patients.
4. *V*isual Analogue Scale (VAS): The VAS allows patients to self-assess the severity of their UI symptoms on a scale ranging from 0 to 10. For patients with UI, patients can mark a continuum of 'no symptoms' and 'most severe symptoms' based on their level of symptoms.[41]
5. Numeric Rating Scale (NRS): The NRS can be used to assess the severity of a patient's UI. A score of 0 on the scale represents the absence of symptoms, while a score of 10 represents the most severe symptoms.[42]
6. Adverse event: To assess the safety of AT for UIP, we will record the occurrence of adverse events in both the test and control groups within the included RCTs.

Information sources

We will conduct a comprehensive search for available RCTs by exploring eight prominent databases and two clinical trial registry platforms. These include four English databases: PubMed, EMBASE, the Cochrane Library and Web of Science, as well as four Chinese databases: China National Knowledge Infrastructure, Wanfang Database, SinoMed and VIP Database. Furthermore, we will also retrieve ongoing RCTs from the WHO's International Clinical Trials Registry Platform and the Chinese Clinical Trial Registry.

Search strategy

The search strategy will be used as follows (online supplemental material 1): (1) Acupuncture, combined exploded versions of Medical Subject Headings (Mesh) acupuncture, electroacupuncture, Pharmacopuncture, needling, fire acupuncture, warm acupuncture, auricular acupuncture, acupuncture point burial; (2) Urinary Incontinence combined exploded versions of Mesh Incontinence, Urinary; (3) Prostatectomy, combined exploded versions of Mesh Suprapubic Prostatectomies, Retropubic Prostatectomy, Prostatectomy, after prostate surgery (4) Randomised controlled trials; We will combine these terms as follows: 1 and 2 and 3 and 4. In the Chinese database, we will search '针灸' or '针' or '针刺' or '电针' or '微针' or '皮内针' or '耳针' or '穴位埋线' or '手针' or '温针' or '三棱针' or '火针' and '尿失禁'and '前列腺术后' and '随机对照试验'. Online supplemental material 1 demonstrates the complete search strategy. To ensure the article's completeness and rigour, we will review the reference list of included studies and related reviews for grey literature. Additional team members (M-YT and C-YM) will check significant acupuncture and urology journals to identify other studies. The corresponding author (QZ) will search the clinical trial registration platforms for planned and ongoing RCTs (WHO's International Clinical Trials Registry Platform: https://www.who.int/clinical-trials-registry-platform; Chinese Clinical Trial Registry: http://www.chictr.org.cn).

Study selection process

To ensure the comprehensive inclusion of potential RCTs and minimise the subjective influence, two authors (M-YT and C-YM) will independently screen the literature. The data from each database will be imported into Endnote (V.X20, Clarivate, USA) to eliminate duplicate documents. The imported literature will then undergo a title and abstract screening to exclude non-compliant articles based on predetermined inclusion and exclusion criteria. The remaining papers will undergo a full-text assessment to determine eligibility. In case of any disagreements, the third author (QZ) will provide evaluation and facilitate consensus (online supplemental material 2).

Data extraction and management

Before proceeding with data extraction, three tables will be prepared to collect relevant information. Initially, two authors (M-YT and C-YM) will independently extract data including the first author, age, trial and control interventions, sample size, type of incontinence, duration of disease, treatment duration, randomisation and blinding methods, and outcome measures. The extraction will follow the table provided in online supplemental material 3. Additionally, online supplemental material 4 will be utilised, based on the Standards for Reporting Interventions in Controlled Trials of Acupuncture checklist, to extract more comprehensive details from the eligible RCTs included in the analysis. Subsequently, data collection will follow the guidelines presented in online supplemental material 5, using Stata V.15.0 software (Stata). For continuous variables, mean and SD will be recorded. In cases where only the median is provided, the mean, SD and range will be calculated using the method described by Hozo *et al*.[43] Dichotomous variables will be analysed using the risk ratio (RR) effect values, extracting the number of occurrences and non-occurrences of patients. Any disagreements during the data extraction process will be resolved through team negotiation. If the data is incomplete or missing in the included RCTs, we will contact the respective first or corresponding authors to obtain the required information.

Risk of bias assessment

Two authors (M-YT and C-YM) will independently evaluate the included studies using the Cochrane Risk of Bias 2.0 (RoB 2.0) tool.[44] The RoB 2.0 tool consists of six items for assessment: (1) random sequence generation, (2) deviations from intended interventions, (3) missing outcome data, (4) outcome measurement, (5) selection of reported results and (6) overall bias. Each item will be classified as 'low risk of bias', 'unclear risk of bias' or 'high risk of bias' based on the specific circumstances of the study.

It should be noted that achieving double-blinding in acupuncture studies is challenging due to the nature of the intervention. Although certain devices claim to enable double-blinding of acupuncturists and patients, they may not be suitable for investigating the effects of acupuncture.[45] However, double-blinding for participants and outcome assessors has been widely implemented in clinical trials. If necessary, the third author (QZ) will participate in discussions to reach a consensus on any arisen discrepancies.

Data synthesis and statistical analysis

Measures of treatment effect

The meta-analysis will be conducted using Stata V.15.0 software (Stata). For dichotomous variables, the results will be reported using RR and 95% CIs. For continuous variables, if the assessment tools used in the included RCTs are consistent, the outcomes will be expressed as weighted mean difference and 95% CI. However, if different assessment tools are used, the final results will be presented as standardised mean difference and 95% CI.

Assessment of heterogeneity

Heterogeneity will be detected with the Q test with the associated I^2 test and p value. If p>0.1 and $I^2$50%, the fixed-effects model will be used. If p <0.1 and $I^2 \geq 50\%$, the random effects model will be adopted in our study.

Assessment of reporting biases

When the number of included articles reaches at least 10, we will assess the potential publication bias by conducting an informal visual examination of a funnel plot. To further evaluate publication bias accurately, we will perform Begg's and Egger's tests.[46 47] If publication bias is detected, we will use the trim-and-fill method to assess whether it influences the overall results of the study.[48] The presence of publication bias, if identified, will be discussed and explained in detail in the discussion section of the paper.

Data synthesis

If multiple RCTs include the same outcome indicator, we will extract the data and conduct a meta-analysis using Stata V.15.0 software (Stata). However, if only a single literature or outcome is available, we will perform a descriptive analysis without conducting a meta-analysis.

Sensitivity analysis

If the data in the articles allow for quantitative analysis, we will conduct a sensitivity analysis. This analysis can be performed by systematically removing one included study at a time to assess the stability of the results or by conducting a descriptive analysis only. In cases where the exclusion of certain studies leads to unstable results, we will discuss the experimental design and potential reasons for the instability in the discussion section of the paper.

Subgroup analysis

If sufficient data are available, we will conduct subgroup analyses based on the following criteria:

1. For Patient: duration of disease, age, course of treatment.
2. For Interventions: type of acupuncture, acupuncture points, frequency of acupuncture.

3. For the type of UI: SUI, UUI or a combination of both (mixed UI).
4. Severity of UI according to ICIQ-UI-SF: mild, moderate, severe or very severe.

Grades of Recommendation, Assessment, Development and Evaluation evaluation

Two independent reviewers (M-YT and C-YM) will use the Grading of Recommendations Assessment, Development and Evaluation method to assess the quality of evidence and the strength of recommendations.[49] The quality of evidence will be categorised as 'high' (further research is highly unlikely to alter the confidence in the effect estimate), 'moderate' (further research is likely to have an impact on the confidence in the effect estimate and may change the estimate), 'low' (further research is highly likely to have an impact on the confidence in the effect estimate and is likely to change the estimate) or 'very low' (there is very limited certainty in the effect estimate). In case of any disagreements, the third author (QZ) will participate in the evaluation process until a consensus is reached.

Patient and public involvement

None.

Ethics and dissemination

Secondary data analysis does not require ethical approval. The study's findings will be made available to the public by being published in a peer-reviewed journal.

DISCUSSION

AT has demonstrated unique advantages in the treatment of UI as a traditional Chinese medicine approach. However, the underlying mechanism is still not fully understood. In the treatment of SUI with AT, acupuncture points in the lumbosacral region are commonly selected (39.4%), including BL33, BL35, RN3 and RN4.[50] BL33 is located at the passage of the posterior branch of the third sacral nerve and is surrounded by sympathetic nerve fibres, while BL35 is situated in the sacral nerve segment with the deep pudendal nerve trunk. From a modern anatomical perspective, the sacral nerve plays a significant role in voiding function.[51] The third sacral nerve primarily innervates the detrusor muscle of the bladder, while the second sacral nerve mainly innervates the external urethral sphincter.[52] Clinical studies have shown that needle stimulation of BL33 and BL35 can directly regulate the function of the lumbosacral autonomic nerves, inhibit detrusor muscle overactivity and improve bladder compliance, leading to a reduction in UI symptoms.[53] Furthermore, stimulation of BL32 and BL35 has been suggested to activate the pubic nerves, inducing rhythmic contractions of pelvic floor muscles through PFMT, thereby enhancing pelvic floor muscle strength and improving urinary control, effectively treating SUI and UUI.[26]

According to traditional Chinese medicine theory, UI is attributed to deficiencies in kidney energy, middle energy and bladder control. Stimulating acupuncture points along the bladder meridian can regulate bladder qi and enhance the bladder's capacity to retain urine. Additionally, stimulating points related to the kidney meridian, such as KI3, can tonify kidney energy and improve symptoms of UI.[54] However, further research is required to explore the mechanism due to the current limitations in the existing literature.

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Competing interests None declared.

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