

Effectiveness of electroacupuncture (EA) for the treatment of urinary incontinence (UI) in patients with spinal cord injury (SCI)

A protocol of systematic review of randomized controlled trials

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Abstract

Background: The objective of this study is to examine the effectiveness and safety of electroacupuncture (EA) in the treatment of urinary incontinence (UI) in patients with spinal cord injury (SCI).

Methods: All potential studies will be retrieved from the electronic databases of MEDLINE, EMBASE, Cochrane Library, PsycINFO, Web of Science, CBM, and China National Knowledge Infrastructure from origin of each database up to January 31, 2020. Additionally, we will check other resources, such as Google scholar, dissertations, conference proceedings, and reference lists of included studies. No language and publication date limitations will be considered in the literature resources search. All randomized controlled trials using EA for the treatment of UI in patients with SCI will be included. Two independent investigators will perform study selection, data extraction and study quality assessment. If any conflicts occur, we will invite a third investigator to solve them. Cochrane risk of bias will be used for study quality assessment, and RevMan 5.3 software will be employed for statistical analysis.

Results: This study will summarize the most recent evidence to assess the effectiveness and safety of EA for the treatment of UI in patients with SCI.

Conclusion: The results of this study will provide helpful evidence to determine whether EA is effective and safety for the treatment of UI in patients with SCI or not.

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Abbreviations: EA = electroacupuncture, RCTs = randomized controlled trials, SCI = spinal cord injury, UI = urinary incontinence.

Keywords: effectiveness, electroacupuncture, spinal cord injury, urinary incontinence

TSW and ZMW contributed equally to this study.

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1. Introduction

Spinal cord injury (SCI) is a serious and debilitating central nervous system neurological disorder.^[1–3] It is reported that about 250,000 and 500,000 new cases annually and most of them are traumatic, with male-to-female of 2:1.^[4,5] Several factors result in SCI, such as traffic accidents, violence, sports, and falls.^[6–11] Patients with SCI often experience a variety of complications, including pain, spasticity, pressure ulcers, respiratory, cardiovascular, and urinary and bowel disorders, especially urinary incontinence (UI), which leads to very poor quality of life.^[12–16]

Electroacupuncture (EA) has been widely used to treat numerous diseases around the world.^[17–22] Studies suggested that it can effectively manage UI in patients with SCI.^[23–30] However, no systematic review has been conducted on this subject. Thus, this study aims to supply sufficient evidence for the clinical application of EA for the treatment of UI following SCI.

2. Methods

2.1. Study registration

This study was funded and registered on PROSPERO (CRD42020165562). It is reported according to the guidelines

of the preferred reporting items for systematic reviews and meta-analysis protocol statement.^[31,32]

2.2. Criteria for including studies

2.2.1. Types of studies. This study will only consider randomized controlled trials (RCTs) assessing the effectiveness and safety of EA for the treatment of UI in patients with SCI for inclusion. We will not limit their language and publication date to all included RCTs.

2.2.2. Types of interventions. The intervention of the trial group only used EA for the treatment of UI in patients with SCI.

The intervention of the control group could use any treatments, such as conventional therapy, medication, and any others. However, we will exclude EA or EA combined with other therapies as comparators.

2.2.3. Types of patients. Regardless of ethnicity, age, sex, educational background, any SCI patients who were diagnosed as UI will be included in this study.

2.2.4. Types of outcome measurements. The primary outcome is the change from baseline in the amount of urine leakage, as measured by the pad-weighing test or other tests.

The secondary outcomes are urination diary, bladder capacity, severity of UI, a 72-hour incontinence episode frequency, clinical symptom scores, the number of participants healed completely within study period and adverse events.

2.3. Data sources and search

We will comprehensively search the electronic databases of MEDLINE, EMBASE, Cochrane Library, PsycINFO, Web of Science, CBM, and China National Knowledge Infrastructure from origin of each database up to January 31, 2020. All literature resources will be searched regardless language and publication date. The detailed search strategy of MEDLINE is built (Table 1). Similar search strategies of other electronic databases will be modified.

In addition, we will search other sources, such as Google scholar, dissertations, conference proceedings, and reference lists of eligible trials.

2.4. Data collection and analysis

2.4.1. Study selection. All retrieved literatures will be imported into Endnote X7 and all duplicates will be removed. Two investigators will independently screen the titles and abstracts of all searched literatures, and any unconnected studies will be excluded. Then, full-texts of the remaining studies will be obtained and read cautiously against all inclusion criteria. Any uncertainty between two investigators will be resolved through consulting a third investigator. The procedure of study selection will be exerted in a flow diagram.

2.4.2. Data extraction. Two investigators will independently extract all essential data from each included trial using a predefined data extraction form. Any divergences will be figured out with the help of a third investigator through discussion. We will extract the following information:

Study information: first author, publication year, country, et al.

Patient information: gender, age, race, diagnostic criteria, inclusion and exclusion criteria, et al.

Table 1

Search strategy for MEDLINE.

Number	Search terms
1	spinal cord
2	spinal canal
3	injury
4	injuries
5	traumatic
6	Or 1–5
7	urinary incontinence
8	loss of bladder control
9	loss of urine
10	urine leakage
11	urination frequency
12	Or 7–11
13	electroacupuncture
14	acupuncture
15	manual acupuncture
16	alternative medicine
17	traditional Chinese medicine
18	ear acupuncture
19	auricular acupuncture
20	Or 13–19
21	randomized controlled trials
22	clinical trial
23	clinical study
24	randomly
25	random
26	allocation
27	placebo
28	blind
29	trial
30	control
31	comparator
32	Or 21–31
33	6 and 12 and 20 and 32

Trial methods: details of randomization, concealment, blind, et al.

Specifics of intervention and controls: treatment duration, dosage, frequency, et al.

Outcome details: primary and secondary outcomes, adverse events, et al.

2.4.3. Missing data dealing with. If there is unclear or insufficient data, we will contact primary authors to request it. If we cannot receive those data, we will only analyze available data. If necessary, we will discuss its potential effects on the study findings.

2.4.4. Study quality assessment. Two investigators will independently appraise study quality using Cochrane risk of bias tool through 7 fields. Each item is graded as high, unclear or low risk of bias. Any differences will be solved by a third investigator through discussion and a consensus will be reached after discussion.

2.4.5. Subgroup analysis. We will carry out subgroup analysis to identify the possible factors that may result in significant heterogeneity based on the different interventions, controls and outcome indicators.

2.4.6. Sensitivity analysis. We will perform sensitivity analysis to test the robustness and stability of study findings by excluding low quality trials.

2.4.7. Reporting bias. We will examine the reporting bias using funnel plot and Egger regression test if more than 10 included trials are included.^[33,34]

2.5. Data synthesis

RevMan 5.3 software will be used to undertake statistical analysis. To assess the extracted data, mean difference or standardized mean difference and 95% confidence intervals will be used for continuous data. For dichotomous data, we will use risk ratio and 95% confidence intervals. Statistical heterogeneity across eligible trials will be inspected using I^2 statistics. $I^2 \leq 50\%$ means fair heterogeneity, and a fixed-effect model will be examined. If sufficient outcome data is extracted, we will conduct a meta-analysis. $I^2 > 50\%$ suggests apparent heterogeneity, and a random-effect model will be used. We will carry out subgroup analysis to investigate the sources of heterogeneity. If the sources of heterogeneity cannot be identified, synthetic analysis will not be performed and descriptive analysis will be adopted.

2.5.1. Quality of evidence. The quality of evidence for major outcomes will be appraised by 2 independent investigators using grading of recommendations assessment, development and evaluation.^[35] Any disagreements will be disentangled by another investigator through consultation.

2.6. Dissemination and ethics

We expect to publish this study on a peer-reviewed journal. This study will not inquire ethic approval because it will not collect individual patient data.

3. Discussion

UI is a progressive disorder in patients with SCI.^[23–30] EA is currently used in the treatment of UI after SCI, relieving clinical symptoms, frequency and severity of UI. Although previous clinical studies have reported that EA has positive therapeutic effects on UI following SCI, all conclusions drawn are based on the individual trial. Thus, this study is designed to systematically and comprehensively assess the effectiveness and safety of EA for the treatment of UI in patients with SCI. The results of this study will provide evidence to determine whether EA is an effective and safety treatment for UI following SCI, which may benefit clinical practice and patients.

Author contributions

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