INPLASY PROTOCOL

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Acupuncture for diabetic neurogenic bladder: A protocol for systematic review and meta-analysis

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Review question / Objective: The question is whether acupuncture is effective and safe for diabetic neurogenic bladder.

Condition being studied: Diabetic neurogenic bladder (DNB) or diabetic bladder dysfunction (DBD) is one of the common complications of diabetes mellitus, which has a high prevalence rate, and study has shown that diabetic patients have a 40% - 80% chance of developing DNB.some researches suggested that acupuncture can improve the clinical symptoms of diabetic neurogenic bladder patients.Although acupuncture can treat DNB, there is no systematic review or meta analysis to investigate its safety and effectiveness.Therefore, it is necessary to carry out a systematic review of the literatures concerning the safety and efficacy of acupuncture for treatment of DNB.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 December 2020 and was last updated on 13 December 2020 (registration number INPLASY2020120076).

INTRODUCTION

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METHODS

Participant or population: Adults with diabetic neurogenic bladder (as diagnosed by a clinician, or using any recognized diagnostic criteria) will be included.

Intervention: Simple acupuncture or acupuncture combined with other conventional therapy (such as Chinese herbal, western medicine) used to manage patients with DNB.

Comparator: The control group was treated with other conventional treatment and not undergoing any acuouncture therapy(as auricular acupuncture, electroacupuncture, warm acupuncture, acupoint injection, acupoint catgut embedding, etc).

Study designs to be included: Randomized controlled trials and quasi-randomized controlled trials of acupuncture for DNB will be included.

Eligibility criteria: Inclusion criteria: **1.Types of participants:Participants** diagnosed as diabetes with bladdear dysfuction wii be included., and their age were older than 18 years. 2.Types of study:Randomized controlled trials and quasi-randomized controlled trials of acupuncture for DNB will be included. Case report, animal studies, Meta analysis, reviews, conference articles will be excluded. 3.Types of interventions and comparisons:Simple acupuncture or acupuncture combined with other conventional therapyt (such as Chinese herbal, western medicine) used to manage patients with DNB will be included in the observation group. The control group was treated with other conventional treatment and not undergoing any acupuncture therapy (as auricular acupuncture, electroacupuncture, warm acupuncture,

acupoint injection, acupoint catgut embedding, etc) 4. The primary outcome is the total effective rate. Secondary outcomes include urodynamic parameters (such as daily micturition frequency, residual bladder volume, maximum urine flow rate), and adverse events.

Information sources: We will search electronic databases including the Cochrane Library, Web of Science, PubMed, MEDLINE, EMBASE, China National Knowledge Infrastructure (CNKI), Wan-Fang and Baidu Scholar Database.

Main outcome(s): We will use Revman 5.3 software which is provided by Cochrane assistance network to perform data analysis. For continuous outcomes, we will use mean difference (MD) with 95% confidence intervals (CIs) to measure the treatment effect, and we will use risk ratio (RR) with 95% CIs to analyzed dichotomous data.

Quality assessment / Risk of bias analysis: We will use the Cochrane risk of bias tool to assess seven aspects of risk of bias, including sequence generation, allocation concealment, blinding of participants and assessors, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias, which can evaluate the risk of bias of the final included studies.

Strategy of data synthesis: Selection of study, extraction of data, and assessment of study quality will be performed independently by two researchers, and we will use Revman 5.3 software which is provided by Cochrane assistance network to perform data analysis.

Subgroup analysis: When heterogeneity exists, if the source of heterogeneity can be determined, we will perform subgroup analysis according to heterogeneity factors; if the source of heterogeneity cannot be determined, the random effects model will be used to merge the data.

Sensibility analysis: Sensitivity is an important index to measure the quality and

heterogeneity of studies. Therefore, we will carry out the sensitivity analysis to access the stability and reliability of the research results.

Country(ies) involved: China.

Keywords: Diabetic neurogenic bladder; acupuncture

Contributions of each author:

Author 1 - Yu Dai. Author 2 - Qing Ye. Author 3 - Yi-ming Sun. Author 4 - Xin-ru Liu. Author 5 - Lu Li. Author 6 - Quan Wen. Author 7 - Tian-min Zhu.