

INPLASY PROTOCOL

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None declared.

The efficacy and safety of acupuncture for diabetic gastrointestinal motility disorders: systematic review and meta-analysis

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Review question / Objective: Systematic review and meta-analysis of the efficacy and safety of acupuncture for diabetic gastrointestinal motility disorders.

Condition being studied: Diabetic gastrointestinal motility disorders is a common autonomic neuropathy which affects more than 5% diabetic patients . The prevalence of diabetic gastrointestinal motility disorders is growing with the number of diabetic patients continues to increase. It not only affects nutritional state but also adversely impacts on quality of life in diabetes. It has been demonstrated that traditional Chinese medicine and acupuncture can improve gastrointestinal motility and facilitate gastric emptying in human. During the last 20-30 years, Chinese acupuncturists performed many clinical studies to evaluate the effectiveness of acupuncture for diabetic gastrointestinal motility disorders. A meta-analysis of acupuncture for relieving non-organic dyspeptic symptoms suggestive of diabetic gastroparesis had been published in 2013, Since 2013, a number of new clinical RCT studies have been produced, and the effectiveness of acupuncture in treating diabetic gastrointestinal motility disorders needs to be systematically reevaluated. The present study was therefore conducted to assess the quality of trials and the effect of acupuncture on treating diabetic gastrointestinal motility disorders.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 July 2022 and was last updated on 19 July 2022 (registration number INPLASY202270092).

INTRODUCTION

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common autonomic neuropathy which affects more than 5% diabetic patients . The prevalence of diabetic gastrointestinal motility disorders is growing with the number of diabetic patients continues to increase. It not only affects nutritional state but also adversely impacts on quality of life in diabetes. It has been demonstrated that traditional Chinese medicine and acupuncture can improve gastrointestinal motility and facilitate gastric emptying in human. During the last 20-30 years, Chinese acupuncturists performed many clinical studies to evaluate the effectiveness of acupuncture for diabetic gastrointestinal motility disorders. A meta-analysis of acupuncture for relieving non-organic dyspeptic symptoms suggestive of diabetic gastroparesis had been published in 2013, Since 2013, a number of new clinical RCT studies have been produced, and the effectiveness of acupuncture in treating diabetic gastrointestinal motility disorders needs to be systematically reevaluated. The present study was therefore conducted to assess the quality of trials and the effect of acupuncture on treating diabetic gastrointestinal motility disorders.

METHODS

Participant or population: Patients clearly diagnosed with diabetic gastrointestinal motility disorders, regardless of gender, age or race; and presenting 1 or more of the following symptoms: abdominal bloating, belching, nausea, vomiting, loss of appetite Diarrhea, constipation.

Intervention: Acupuncture-related methods such as acupuncture, electroacupuncture (EA), scalp acupuncture, eye acupuncture, ear acupuncture or abdomen acupuncture, floating acupuncture.

Comparator: The control group was treated with western medication, chinese herbal medication, placebo, sham acupuncture or even with no treatment.

Study designs to be included: Randomized controlled clinical trial.

Eligibility criteria: Randomized Control Trial (RCT) studies meeting PICOS (population, intervention, comparison, outcome, study type) criteria: 1. Population: patients clearly diagnosed with diabetic gastrointestinal motility disorders, regardless of gender, age or race; and presenting 1 or more of the following symptoms: abdominal bloating, belching, nausea, vomiting, loss of appetite, diarrhea, constipation; 2. Intervention measures: The experimental group used acupuncture-related methods such as acupuncture, electroacupuncture (EA), scalp acupuncture, eye acupuncture, ear acupuncture, floating acupuncture or abdomen acupuncture. 3. Control group: the control group was treated with western medication, chinese herbal medication, placebo, sham acupuncture or even with no treatment. 4. Outcome: Main outcome: dyspeptic symptoms scores (Intestinal motility disorders symptoms scores and Gastric motility disorder symptoms scores) ; Clinical response rate; Secondary outcome: The quality of life (through PAGI-QOL); Patient symptom scores: a gastric emptying detected by scintigraphy or radio-opaque markers; adverse reactions. 5. Study type: Randomized controlled trial (RCT). 2.2 Exclusion criteria The following studies were excluded: 1. Duplicate published studies 2. Studies without a control group 3. Experience introduction and basic experimental literature research 4. Non-randomized controlled trials 5. Study subjects with other diseases.

Information sources: We will search several databases, including PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (Wan Fang), Chinese Biomedical Literature Database (CBM), VIP Database for Chinese Technical Periodicals (VIP), Medline, and Clinical Trial Register (CTR) for eligible RCTs. Published trial will be from from their inception to June 2022.

Main outcome(s): As of June 2022, our initial searches identified 293 relevant clinical studies concerning acupuncture and acupuncture-related treatment for diabetes with diabetic gastrointestinal motility disorders. The relevant meta-analysis

studies are presented below: The effectiveness of acupuncture in postoperative gastroparesis syndrome--a systematic review and meta-analysis (2014)
 The efficacy and safety of Tuina for diabetic gastroparesis: A protocol for systematic review and meta-analysis (2021)
 Efficacy and safety of complementary and alternative medicine therapy for gastroparesis: A protocol for systematic review and meta-analysis (2021)
 The efficacy and safety of acupoint injection for diabetic gastroparesis: A protocol for systematic review and meta-analysis (2020)
 Acupoint catgut embedding for diabetic gastroparesis: A protocol of systematic review (2019)
 Meta-analysis of acupuncture for relieving non-organic dyspeptic symptoms suggestive of diabetic gastroparesis (2013)
 Most of the meta-analysis was conducted for the efficacy of acupuncture in the treatment of gastroparesis. The meta-analysis in 2013 was conducted for the symptoms of gastrointestinal dyspepsia. However, since 2013, a number of new clinical RCT studies have been produced, so it is necessary to conduct a new meta-analysis for evaluation.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis: Revman 5.4 software provided by the Cochrane Collaboration was used for analysis. For dichotomous variables, odds ratio (OR) and 95% confidence interval (95% CI) were

used as efficacy analysis statistics; for continuous variables, mean difference(MD) and 95% CI was used. as efficacy analysis statistics; Homoreport test (Q test) was used for heterogeneity test. If there was statistical homogeneity between studies ($I^2 < 50\%$), using the fixed effects model. when there was significant heterogeneity among trials($I^2 > 50\%$), Random effect model was used to calculate the pooled effect . If $I^2 > 75\%$, qualitative description was provided.

Subgroup analysis: Subgroup analysis was conducted in term of symptoms (e.g. intestinal motility disorders and Gastric motility disorder) When there was significant heterogeneity in the included studies, the subgroup analysis will be conducted according to factors such as condition of type of treatment and intervention frequency and other factors.

Sensitivity analysis: Sensitivity analysis was conducted by excluding some studies with low quality, significant weight or results significantly different from other studies. If the number of included studies is greater than 10, funnel plots will be used to detect publication bias.

Country(ies) involved: China.

Keywords: Acupuncture, Diabetic gastrointestinal motility disorders, Systematic review, meta-analysis, Intestinal motility disorders, Gastric motility disorder.

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