INPLASY PROTOCOL

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No conflict of interest.

Efficacy and Safety of Complementary and Alternative Medicine Therapy for gastroparesis: A protocol for systematic review and meta-analysis

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Review question / Objective: 1. Type of Participants - Patients with a diagnosis of gastroparesis. Patients with postprandial epigastric discomfort (such as nausea, vomiting, postprandial fullness, abdominal distension, and epigastric pain) and with delayed gastric emptying or dysregulation of the stomach as assessed by the gastric exercise test. We excluded those patients whose upper gastrointestinal endoscopy revealed significant pathological changes. 2. Interventions - We include all complementary and alternative therapies that exclude oral and surgical treatments which have been shown to have no significant therapeutic effect or to pose a significant safety risk. Now known complementary and alternative therapies may include acupuncture, moxibustion, acupoint application and so on. 3. Type of Controls - The control group can be neither on-treatment or standard treatment, as long as it does not receive specific complementary and alternative therapy corresponding to the experimental group. 4. Outcomes - We focused on assessing the symptoms of gastroparesis reported by patients in the current clinical study, including the Gastroparesis symptom Index (GCSI), the Comprehensive Patient Assessment of symptoms of Upper gastrointestinal disease (PAGI-SYMP), and a revised GCSI-DAILY Diary (GCSI-DD). We also assessed changes in patients' quality of life (through PAGI-QOL), and psychosomatic changes (through BDI and STAI). All treatment-related adverse events will be recorded, summarized, and evaluated. 5. Type of Study designs - We only include Randomized controlled trials (RCTs) or controlled clinical trials (CCTs), which aimed to evaluate the efficacy of complementary and alternative therapies in the treatment of gastroparesis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 October 2020 and was last updated on 10 October 2020 (registration number INPLASY2020100033).

INTRODUCTION

Review question / Objective: 1. Type of Participants - Patients with a diagnosis of gastroparesis. Patients with postprandial epigastric discomfort (such as nausea, vomiting, postprandial fullness, abdominal distension, and epigastric pain) and with

delayed gastric emptying or dysregulation of the stomach as assessed by the gastric exercise test. We excluded those patients whose upper gastrointestinal endoscopy revealed significant pathological changes. 2. Interventions - We include all complementary and alternative therapies that exclude oral and surgical treatments which have been shown to have no significant therapeutic effect or to pose a significant safety risk. Now known complementary and alternative therapies may include acupuncture, moxibustion, acupoint application and so on. 3. Type of Controls - The control group can be neither on-treatment or standard treatment, as long as it does not receive specific complementary and alternative therapy corresponding to the experimental group. 4. Outcomes - We focused on assessing the symptoms of gastroparesis reported by patients in the current clinical study, including the Gastroparesis symptom Index (GCSI), the Comprehensive Patient Assessment of symptoms of Upper gastrointestinal disease (PAGI-SYMP), and a revised GCSI-DAILY Diary (GCSI-DD). We also assessed changes in patients' quality of life (through PAGI-QOL), and psychosomatic changes (through BDI and STAI). All treatment-related adverse events will be recorded, summarized, and evaluated. 5. Type of Study designs - We only include Randomized controlled trials (RCTs) or controlled clinical trials (CCTs), which aimed to evaluate the efficacy of complementary and alternative therapies in the treatment of gastroparesis.

Condition being studied: Gastroparesis is a pathological condition characterized by delayed gastric emptying of solid food in the absence of mechanical obstruction of the stomach, which could result in some clinical signs and symptoms, such as early satiety, post-meal satiety, nausea, vomiting, burping and bloating, upper abdominal discomfort or pain. The principles of treatment for gastroparesis include correcting the deficiency or imbalance of electrolyte and nutrient, finding and treating the original cause of delayed gastric empting, and treating specific symptoms. The treatment strategies currently rely mainly on dietary adjustments, withdrawal of medications that affect the normal function of the stomach, use of antiemetic medications, and non-pharmacological measures such as endoscopic or surgical interventions or gastric electrical stimulation. However, in clinical practice, accelerating or normalizing gastric empting may not improve patients' clinical symptoms, and many patients often do not respond to pharmacological treatments. Current alternative non-drug therapy strategies, such as endoscopy, electrical stimulation, or surgery, are mainly used in patients with severe gastroparesis.

METHODS

Participant or population: Patients with a diagnosis of gastroparesis. Patients with postprandial epigastric discomfort (such as nausea, vomiting, postprandial fullness, abdominal distension, and epigastric pain) and with delayed gastric emptying or dysregulation of the stomach as assessed by the gastric exercise test. We excluded those patients whose upper gastrointestinal endoscopy revealed significant pathological changes.

Intervention: We include all complementary and alternative therapies that exclude oral and surgical treatments which have been shown to have no significant therapeutic effect or to pose a significant safety risk. Now known complementary and alternative therapies may include acupuncture, moxibustion, acupoint application and so on.

Comparator: The control group can be neither on-treatment or standard treatment, as long as it does not receive specific complementary and alternative therapy corresponding to the experimental group.

Study designs to be included: We only include Randomized controlled trials (RCTs) or controlled clinical trials (CCTs), which aimed to evaluate the efficacy of complementary and alternative therapies in the treatment of gastroparesis.

Eligibility criteria: We will use EndNote X9 (USA) to manage all the retrieved documents. First, duplicate literature from different databases was excluded, and then that literature that was irrelevant to this study was excluded by reading the titles and abstracts of the literature, and then full-text reading and screening were conducted according to the pre-determined inclusion and exclusion criteria. This process will be independently reviewed and screened by two investigators. Any differences will be discussed between the two reviewers, and further differences will be arbitrated by the third author.

Information sources: We will retrieve literature using the following data sources: Medline (through PubMed), Embase, the Cochrane Library database (Cochrane Central Register of Controlled Trials), Web of science, as well as four Chinese databases (China National Knowledge Infrastructure, VIP Database for Chinese Technical Periodicals, Chinese Biomedical Literature Database, and WanFang). Other resources will be searched to make up for the deficiency of the electronic database, mainly on the corresponding website for clinical trial registration and grey literature on gastroplegia treatment.

Main outcome(s): We focused on assessing the symptoms of gastroparesis reported by patients in the current clinical study, including the Gastroparesis Symptom Index (GCSI), the Comprehensive Patient Assessment of symptoms of Upper gastrointestinal disease (PAGI-SYMP), and a revised GCSI-DAILY Diary (GCSI-DD).

Quality assessment / Risk of bias analysis: The deviation risk Cochrane collaboration tools (http://methods.cochrane.org/bias/assessing-risk-bias- include - studies) will be used to evaluate all potential sources of relative deviation. We summarize the individual and overall bias risk data included in the study. The main evaluation areas include random sequence generation; Allocation hiding; Blind testing of patients, researchers, and outcome assessors; Bias in reporting; Frayed prejudices; And other possible sources of deviation, such as those related to trial design, contamination risks, or cross-risks between the two groups.

Strategy of data synthesis: Meta-analysis was used to summarize treatment outcomes. For dichotomous results, the results are expressed as a 95% confidence interval (CI) risk ratio (RR). For continuous variables, we will use the weighted mean difference (WMD) or standardized mean difference (SMD). If a result measure contains less than 2 trials, we will summarize the results descriptively. We will use I^2 statistical analysis to estimate the percentage of variability due to non-random heterogeneity in the study. We will use the following rules to classify the heterogeneity. A value of 0% to 25% for I^2 indicates low heterogeneity. A value of I^2 between 25% and 50% indicates moderate heterogeneity. A value of I^2 between 75% and 100% indicates high heterogeneity. When the heterogeneity of the results is low, the fixed-effect model will be used for the meta- analysis analysis. The RevMan 5.0.16 (Nordic Cochrane Centre, Cochrane Collaboration) and STATA 14.0 (STATA Corp LP) were used for statistical analysis.

Subgroup analysis: When aggregated results show significant heterogeneity, we first use subgroup analysis to find the source of heterogeneity. The pre-set grouping mainly includes age, gender, different intervention methods, different control methods, treatment time, patients' grade of gastroparesis, combined with other diseases, and the quality of the study.

Sensibility analysis: Each study included in the results will be excluded one by one, then the remaining study data will be re-analyzed and pooled, and the differences between the re-obtained effect and the original effect will be compared to test the stability of the results. The entire process is performed using STATA 14.0 software.

Country(ies) involved: China.

Keywords: complementary and alternative medicine, meta-analysis, systematic review, gastroparesis.

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