

INPLASY PROTOCOL

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None declared.

Acupuncture for Postoperative Gastroparesis

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Review question / Objective: Population: the patients with postoperative gastroparesis syndrome. Intervention: acupuncture therapy based on needle manipulation. Comparison: basic medical care. Outcome: The primary outcome was overall efficacy appraised through the improvements of symptoms including nausea, vomiting, abdominal pain or distension, and recovery time of gastrointestinal motility. The secondary outcomes were (a) serum motilin level; (b) gastric tube indwelling time; (c) gastric juice draining amount; (d) recovery time of gastrointestinal motility. Study design: RCTs.

Condition being studied: Postoperative gastroparesis syndrome (PGS), frequently caused by abdominal or thoracic surgery, is a common postsurgical complication. The most common symptoms are early satiety, fullness after eating, nausea and vomiting, while its main manifestations of gastroscopy are gastric fluid retention, weakened gastric peristalsis, anastomotic edema and chronic inflammation, without difficulty passing through the anastomotic stoma. PGS is most frequently seen after upper abdominal surgery, particularly gastric and pancreatic surgery, but can also occur after lower abdominal surgery or thoracic surgery, leading to a long-time course with disturbing symptoms.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 February 2023 and was last updated on 08 February 2023 (registration number INPLASY202320035).

INTRODUCTION

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acupuncture therapy based on needle manipulation. Comparison: basic medical care. Outcome: The primary outcome was overall efficacy appraised through the improvements of symptoms including

nausea, vomiting, abdominal pain or distension, and recovery time of gastrointestinal motility. The secondary outcomes were (a) serum motilin level; (b) gastric tube indwelling time; (c) gastric juice draining amount; (d) recovery time of gastrointestinal motility. Study design: RCTs.

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METHODS

Participant or population: Subjects must meet the clinical diagnosis of PGS, regardless of source of case, , but must be comparable at baseline.

Intervention: The acupuncture intervention included in this study refer to penetration of skin or muscle by needles. Acupuncture in conjunction with topical herbal patches and new types of acupuncture such as warm acupuncture, electro-acupuncture can also be included ,combined ancillary techniques of which is considered to enhance the stimulation of acupoints. For the studies applying the acupoint injection, the same drug should also be administrated in the control group ,either orally or Intravenously.

Comparator: conventional treatment (including gastrointestinal decompression, fasting, semi-recumbent position, application of prokinetic drugs, etc).

Study designs to be included: Random controlled trials.

Eligibility criteria: Inclusion criteria(1) Types of studies: Only randomized controlled trials testing the efficacy and safety of acupuncture for PGS were included, with or without blinding. There was no limitation of publication status and language.(2) Research subjects: Subjects must meet the clinical diagnosis of PGS, regardless of demographic indexes and source of case, , but must be comparable at baseline(3) Interventions: The control group was given conventional treatment (including gastrointestinal decompression, fasting, semi-recumbent position, application of prokinetic drugs, etc), while the experimental group was given conventional treatment combined with acupuncture therapy. The acupuncture intervention included in this study refer to penetration of skin or muscle by needles. Acupuncture in conjunction with topical herbal patches and new types of acupuncture such as warm acupuncture, electro-acupuncture can also be included ,combined ancillary techniques of which is considered to enhance the stimulation of acupoints. For the studies applying the acupoint injection, the same drug should also be administrated in the control group ,either orally or Intravenously. However, studies that did not involve the participation of needle manipulation were excluded, as well as studies in which acupuncture was combined with oral herbal decoction , which also contributed to some of the efficacy in the study.; Exclusion criteria Following piece were excluded : (a) repeated literature; (b) the literature data is incomplete or the full text cannot be retrieved ;(c) abstracts, conference papers, dissertations and other documents.

Information sources: We searched electronic databases. English and Chinese databases were searched for relevant literature. We searched three English databases including PubMed, EMBASE and CENTRAL, and three Chinese databases, including China National Knowledge Infrastructure (CNKI), VIP Database for

Chinese Technical Periodicals, and WanFang Data.

Main outcome(s): The primary outcome was overall efficacy appraised through the improvements of symptoms including nausea, vomiting, abdominal pain or distension, recovery time of gastrointestinal motility .

Additional outcome(s): The secondary outcomes were (a) serum motilin level; (b) Gastric tube withdrawal time; (c) gastric juice draining amount.

Quality assessment / Risk of bias analysis: The methodological quality of RCTs was assessed using the Cochrane Risk of bias assessment tool. [Higgins JP, Altman DG. The Cochrane Collaboration. Chapter 8: assessing risk of bias in included studies. In: Higgins JP, Altman DG, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. (2011). Available online at: <http://www.cochrane-handbook.org> (accessed January, 2021).] A grade of “high”, “unclear” or “low” was allocated to following items: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. Assessment progress was independently performed by two reviewers(XYC and LPH). Any disagreements were brought up for discussion until a consensus was reached. When the methods in some studies were not demonstrated clearly such as the strategy of randomization, we tried to contact the first or corresponding author by letters or e-mails for concrete information .

Strategy of data synthesis: We carried out the meta-analysis of the data through Review Manager software V5.4. Dichotomous data was presented as relative risk (RR) with statistical method Mantel-Haenszel (M-H), while continuous data as mean difference (MD) with inverse variance (IV) method, both with 95% confidence interval (CI). Heterogeneity test was performed on the included literature. $I^2 \leq 50\%$ and $P > 0.1$ indicated no significant

statistical heterogeneity, and a fixed effect model was used. $I^2 > 50\%$ and $P \leq 0.1$ indicated statistical heterogeneity, the source of which would be further analyzed by subgroup analysis or sensitivity analysis. If $50\% \leq I^2 \leq 75\%$, a random effect model would be used for combined analysis. Descriptive analyses were provided if the heterogeneity was too great to be suitable for pooling the results. A funnel plot was used to intuitively demonstrate publication bias for the outcome indicators with more than 10 included studies.

Subgroup analysis: We will conduct subgroup analysis according to different acupuncture intervention methods.

Sensitivity analysis: If there exists significant heterogeneity, sensitivity analysis will be carried out.

Country(ies) involved: All authors are from China.

Keywords: acupuncture; postoperative gastroparesis; systematic review.

Contributions of each author:

Author 1 - Yichuan Xv.

Author 2 - Peihong Li.

Author 3 - Jing Ni.

Author 4 - Jiang Lin.