

INPLASY PROTOCOL

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submission:** Data extraction.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: Postsurgical gastroparesis syndrome (PGS) after gastrointestinal tumors surgery impact patients' nutritional status, follow-up

The effectiveness of the external therapy of Traditional Chinese Medicine in postsurgical gastroparesis syndrome after gastrointestinal tumors surgery –A systematic review and meta-analysis

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Review question / Objective: Postsurgical gastroparesis syndrome (PGS) after gastrointestinal tumors surgery impact patients' nutritional status, follow-up treatment and quality of life. The current treatments seem not satisfactory or need invasive interventions. The search of external therapy of Traditional Chinese Medicine (TCM) has been of increasing interest. Based on the background, we plan to conduct such a meta-analysis: **P:** Patients diagnosed with PGS after gastrointestinal tumors. **I:** External therapy of TCM included all forms of acupuncture, moxibustion, acupoint injection, sticking therapy, massage, Chinese medicine enema, Chinese herbal ointment. **C:** Western medicinal treatment, active control, and placebo are acceptable, but no external therapy of TCM. **O:** Total effective rate is the primary outcome measures. **S:** Randomized controlled trails.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 November 2022 and was last updated on 25 November 2022 (registration number INPLASY2022110134).

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Condition being studied: Postsurgical gastroparesis syndrome is a complex disorder characterized by the presence of postprandial nausea, vomiting, and gastric atony in the absence of mechanical gastric outlet obstruction. Patients of PGS after gastrointestinal tumors surgery frequently suffer marked weight loss, malnutrition required hospitalization and delayed follow-up treatment like adjuvant chemotherapy. At present, there are no specific treatment for PGS. The current treatments seem not satisfactory or need invasive interventions. A multidisciplinary step-wise approach included dietary modifications, patient education, pharmaceutical interventions, Gastric electrical stimulation (GES) and surgical interventions is the common treatment. Patients of PGS after gastrointestinal tumors surgery need rapid recovery to prepare for follow-up treatment. A number of clinical trails have shown that external treatment of TCM may help PGS recover quickly.

METHODS

Participant or population: Patients diagnosed with PGS after gastrointestinal tumors.

Intervention: External therapy of TCM included all forms of acupuncture, moxibustion, acupoint injection, sticking therapy, massage, Chinese medicine enema, Chinese herbal ointment.

Comparator: Western medicinal treatment, active control, and placebo are acceptable, but no external therapy of TCM.

Study designs to be included: Randomized controlled trails.

Eligibility criteria: The diagnostic criteria of PGS we used are those recommended by the International Study Group of Pancreatic Surgery (ISGPS). The criteria are as follows: (1) Absence of mechanical gastric outlet obstruction identified by one or more medical examination modalities; (2) A volume of gastric juice aspirate exceeding 800 mL/d that sustained for more than 10 d; (3) No abnormalities in water, electrolytes, or acid-alkali balance. (4) Absence of underlying diseases causing gastroparesis, such as diabetes, chorionitis, hypothyrosis, etc. (5) No history of using such agents as morphine, atropine, etc. that affected contraction function of the smooth muscle. The diagnostic criteria of PGS we used are those recommended by the International Study Group of Pancreatic Surgery (ISGPS).

Information sources: Pub med, Em base, Cochrane Library, Web of Science, China National Knowledge Infrastructure database, Wan fang Data Knowledge Service Platform, VIP information resource integration service platform and the China Biology Medicine disc.

Main outcome(s): We considered efficacy outcomes as primary outcome measures.

Additional outcome(s): Additional outcomes were gastric fluid drainage, gastric tube retention time, gastrointestinal motility recovery time and safety evaluation.

Quality assessment / Risk of bias analysis: The risk of bias will be assessed according to the "Risk of bias assessment criteria of the risk of bias assessment tool" in the Cochrane Reviewers Handbook version 6.1, which included the following: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessors (detection bias), incomplete outcome data (attrition bias), selective

reporting (reporting bias). Two investigators independently evaluated the risk of bias of the included literature, and described it in three levels: low risk, high risk, and unclear risk (lack of relevant information or uncertainty).

Strategy of data synthesis: Meta-analysis will be performed using RevMan 5.4 provided by the Cochrane Collaboration. Categorical variables such as the total effective rate are expressed as Relative Risk (RR), and continuous variables such as the gastric fluid drainage are expressed as Mean difference (MD) and 95% Confidence interval (CI). Inter-study heterogeneity are assessed using the I² value test: when $I^2 \leq 50\%$, $p > 0.05$, it indicates that statistical heterogeneity between studies is small and a fixed-effects model will be used, otherwise a random-effects model will be used. When ≥ 10 papers are included for an outcome indicator, funnel plots will be drawn to determine the presence of publication bias.

Subgroup analysis: We plan to conduct subgroup analysis according to different external treatment methods of TCM in the intervention measures, such as acupoint injection, acupuncture, etc. to observe whether there are differences in the therapeutic effects of different external treatment methods of TCM. We also perform subgroup analyses according to the different criteria for judging efficacy.

Sensitivity analysis: We will use STATA software for sensitivity analysis to reflect the sensitivity of the article by the change in effect size after removing one of the articles.

Language restriction: There is no language limits.

Country(ies) involved: China.

Keywords: Traditional Chinese Medicine; External therapy; Gastroparesis syndrome after gastrointestinal tumors surgery; Systematic review; Meta-analysis

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