

INPLASY PROTOCOL

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Corresponding author:
Huaiyu Li

1021504702@qq.com

Author Affiliation:
Jiangxi University of
Traditional Chinese Medicine

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The authors have no conflicts of interest to disclose.

Effectiveness of acupuncture for the recovery of gastrointestinal function of patients with gastric cancer in the postoperative period: a protocol for systematic review and meta-analysis

Li, HY¹; Ye, J²; Hu, ZY³; Li, RL⁴; Jiang, JW⁵; Qiu, QJ⁶; Chen, Y⁷.

Review question / Objective: Gastric cancer (GC) is the most common malignant tumors in the world and surgical resection remains the primary treatment for it. Postoperative patients often have gastrointestinal function as the most common side effects of surgery for GC patients. Acupuncture has a regulatory effect on gastrointestinal function. We conducted this study to assess the effectiveness of acupuncture on the restoration of gastrointestinal function of postoperative patients with GC.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2020 and was last updated on 17 November 2020 (registration number INPLASY2020110066).

INTRODUCTION

Review question / Objective: Gastric cancer (GC) is the most common malignant tumors in the world and surgical resection remains the primary treatment for it.

Postoperative patients often have gastrointestinal function as the most common side effects of surgery for GC patients. Acupuncture has a regulatory effect on gastrointestinal function. We conducted this study to assess the

effectiveness of acupuncture on the restoration of gastrointestinal function of postoperative patients with GC.

Condition being studied: Gastric cancer (GC) largely derives from the glands of the most superficial layer, or the mucosa, of the stomach. The vast majority of GC are designated as adenocarcinomas from gastric antrum, gastric body and cardia. the pathogenesis of GC is currently multifactorial, and it is mainly related to risk factors such as age, gender, *Helicobacter pylori*, Low consumption of fruits and vegetables, and Cigarette smoking. According to data from the Global Cancer Epidemiology Database (GLOBOCAN) in 2018, GC of which the global incidence was 5.7% and the mortality rate was 8.2%, has become the fifth most common cancer in the world and the third leading cause of cancer deaths. Surgical resection currently remains the primary treatment for GC. The early surgical treatment of GC is endoscopic resection, including endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD). A D1 lymphadenectomy is indicated for T1a tumors that not meet the standards for EMR/ESD, and for cT1bN0 tumors that are histologically differentiated type and 1.5 cm or smaller in diameter. The 5-year survival rate of postoperative patients with early GC is proved more than 90.00%. Standard gastrectomy for advanced GC is the main surgical method of radical surgery.

METHODS

Participant or population: All Postoperative patients with GC, regardless the age, gender, race, country and GC type.

Intervention: Any type of acupuncture treatment will be included, such as body acupuncture, electro-acupuncture, auricular acupuncture, warm acupuncture, fire needling, elongated needle and moxibustion. Neither the number of treatments nor the length of treatment will be restricted in this review.

Comparator: Control interventions may include one of the following treatment methods: general care, sham acupuncture, placebo, physical/mental training therapy, adjuvant chemotherapy or other pharmacotherapy.

Study designs to be included: All randomised controlled trials (RCTs) reported will be included without regional and language restrictions. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

Eligibility criteria: 1.Type of studies. All randomised controlled trials (RCTs) reported will be included without regional and language restrictions. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded. 2.Type of participants. All Postoperative patients with GC, regardless the age, gender, race, country and GC type. 3. Type of interventions. Any type of acupuncture treatment will be included, such as body acupuncture, electro-acupuncture, auricular acupuncture, warm acupuncture, fire needling, elongated needle and moxibustion. Neither the number of treatments nor the length of treatment will be restricted in this review. 4.Type of comparators. Control interventions may include one of the following treatment methods: general care, sham acupuncture, placebo, physical/mental training therapy, adjuvant chemotherapy or other pharmacotherapy. 5.Types of outcome measures. The primary outcome measure will be the Time to First Flatus. Secondary outcome measures include the time of first defecation and the quality of life (QOL). The number of patients with abdominal distention will be employed as one of adverse events (AEs).

Information sources: The following electronic databases will be searched from inception to 31 November 2020 to identify any relevant study: Medline, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature

Database (CBM) and Chinese Scientific Journal Database (VIP database). An equivalent translation of the same search terms will be used to search in the Chinese databases. No restriction on time and language will be applied.

Main outcome(s): The primary outcome measure will be the Time to First Flatus.

Additional outcome(s): Secondary outcome measures include the time of first defecation and the quality of life (QOL). The number of patients with abdominal distention will be employed as one of adverse events (AEs).

Quality assessment / Risk of bias analysis: The Risk of bias assessment form developed by the Cochrane Collaboration will be used as the assessment of methodological quality by two reviewers. It includes the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. Each domain includes a judgement of low (meeting all criteria), high (meeting none of criteria) and unclear (insufficient information to judge) risk of bias according to information provided by authors. Disagreements between reviewers will be resolved through discussion with a third reviewer.

Strategy of data synthesis: The meta-analysis will be conducted using the Review Manager (RevMan) software (V.5.3). If the result of heterogeneity in $I^2 \geq 40\%$, the fixed-effects model will be used for data synthesis and analysis; If $I^2 < 40\%$ and $< 75\%$, the random-effects model will be implied; If $I^2 \geq 75\%$, it means there is considerable heterogeneity between studies and the narrative summary of the studies will be done.

Subgroup analysis: If there is substantial heterogeneity between the study results, subgroup analysis will be performed, following items will be considered: type of

acupuncture, gender, age, and outcome styles.

Sensibility analysis: When sufficient data are available, sensitivity analysis will be conducted to verify the robustness of the results. It includes the impact of methodological quality, study design and sample size.

Country(ies) involved: China.

Keywords: gastric cancer, acupuncture, gastrointestinal function, effectiveness.

Contributions of each author:

Author 1 - Huaiyu Li - Conceptualization; Data curation; Writing; original draft.

Email: 1021504702@qq.com

Author 2 - Jing Ye - Conceptualization; Methodology; Supervision; Writing; original draft; Writing; review & editing.

Email: yejing1016@163.com

Author 3 - Ziyi Hu - Data curation; Methodology.

Email: huziyi0829@163.com

Author 4 - Renliang Li - Formal analysis; Software; Writing; review & editing.

Email: 1051545802@qq.com

Author 5 - Jiawang Jiang - Data curation; Software; supervision; Writing; original draft.

Email: 1137298371@qq.com

Author 6 - Qianjie Qiu - Formal analysis; Software; Writing; review & editing.

Email: 820380634@qq.com

Author 7 - Yun Chen - Formal analysis; Methodology.

Email: 1021504702@qq.com