INPLASY PROTOCOL

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All authors involved in this work have no conflicts of interest.

Therapies for diabetic gastroparesis: a protocol for a systematic review and network meta-analysis

Wang, S[1]; Wang, R[2]; Zhang, Y[3]; Zhang, X[4]; Cai, B[5]; Lu, Y[6]; Xia, Y[7]; Chen, Q[8].

Review question / Objective: What is the best intervention for diabetic patients with gastroparesis?

Condition being studied: The protocol of this systematic review and network meta-analysis will be written in accordance with the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) guidance. The completed systematic review will be written using the PRISMA-NMA extension statement to structure the contents of the final report. Published trial from inception to May 2021 in the English and Chinese language.

Information sources: We will retrieve other resources to complete the deficiencies of the electronic databases, mainly searching for the clinical trial registries and grey literature about treatments for DG on the corresponding website.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2020 and was last updated on 26 April 2020 (registration number INPLASY202040176).

INTRODUCTION

Review question / Objective: What is the best intervention for diabetic patients with gastroparesis?

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METHODS

Participant or population: Studies that enrolled patients (from 18 years of age, regardless of gender and ethnicity) were diagnosed as diabetes with dyspeptic symptoms excluding gastric outlet obstruction or ulceration.

Intervention: Interventions and comparisons: medication (metoclopramide, domperidone, erythromycin, azithromycin, mitemcinal, camicinal, cisapride, tegaserod, revexepride, TZP101, TZP102, relamorelin, aprepitant, prochlorperazine, promethazinc, meclizine, transdermal scopolamine, ondansetron), venting gastrostomy, jejunostomy, transpyloric stenting, gastric per-oral endoscopic myotomy, compared among them or to placebo; botulinum toxin intrapyloric injections compared to saline solution, surgical treatments (laparoscopic pyloroplasty, gastrectomy, antrectomy, pancreatic transplantation), gastric electrical stimulation, traditional Chinese medicine, acupuncture (electroacupuncture, scalp acupuncture, eye acupuncture, abdomen acupuncture, ear acupuncture).

Comparator: Reduction of symptoms (e.g. early satiety, fullness, nausea, vomiting, anorexia, bloating, abdominal pain, either self-reported or through PAGI-SYM and GCSI), improvement of gastric emptying (through scintigraphy or radio-opaque markers), and the quality of life (through PAGI-QOL), the psychological measurements (depression, anxiety, through BDI and STAI).

Study designs to be included: Randomized controlled trials (RCTs) and controlled clinical trials (CCTs).

Eligibility criteria: Studies that enrolled patients (from 18 years of age, regardless of gender and ethnicity) were diagnosed as diabetes with dyspeptic symptoms excluding gastric outlet obstruction or ulceration. According to the literature, treatments for DG are of wide variation and can be divided into the following groups: (1) medicine therapies: Macrolides, Substituted Benzamides, Serotonin Antagonists, phenothiazines, Antihistamines, Butyrophenones, Antidepressants, Benzodiazepines; (2) endoscopic therapies: botulinum toxin A intrapyloric injections, balloon dilation of pylorus, radiofrequency ablation at LES (lower esophageal sphincter); (3) electric therapies: gastric electric stimulation, gastric pacing; (4) diet therapies: gastroparesis diet, high-protein drinks, total parenteral nutrition; (5) traditional Chinese medicine: Xiangshaliujunzi Decoction; (6) acupuncture: electroacupuncture, scalp acupuncture, eye acupuncture, abdomen acupuncture, ear acupuncture; (7) surgical treatments (laparoscopic pyloroplasty, gastrectomy, antrectomy, pancreatic transplantation) (8) others: alternative or support therapies (transpyloric stenting, gastric per-oral endoscopic myotomy). We will include RCTs and CCTs. Review papers, expert opinions, case reports, and series of case reports will be excluded. The bibliographies of relevant systematic reviews will be studied to identify any studies missed by our literature search.

Information sources: We will retrieve other resources to complete the deficiencies of the electronic databases, mainly searching for the clinical trial registries and grey literature about treatments for DG on the corresponding website.

Main outcome(s): Reduction of symptoms (e.g. early satiety, fullness, nausea, vomiting, anorexia, bloating, abdominal pain, either self-reported or through PAGI-SYM and GCSI), improvement of gastric emptying (through scintigraphy or radio-opaque markers).

Quality assessment / Risk of bias analysis: The evidence will be interpreted according to the GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. This approach is based on four steps considering direct and indirect treatment estimates for each comparison of the evidence network, rating the quality of

each direct and indirect effect estimate, rating the network meta-analysis (NMA) estimate for each comparison of the evidence network and quality of each network meta-analysis effect estimate . Studies will be assessed for bias using the Cochrane risk of bias tool considering the judgment of the random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias as "Low risk" of bias, "High risk" of bias, or "Unclear risk" of bias.

Strategy of data synthesis: An overview of all selected studies will be narratively displayed. Once data are obtained, a sheet will be made to tabulate data for the different outcomes. Classification according to the population and study characteristics and nature of the therapy will be made. Both traditional pairwise meta-analyses and network meta-analyses will be conducted.

Subgroup analysis: Possible violation of transitivity could be associated with inclusion of patients with different health conditions and different habits. We will explore this through a subgroup and meta-regression analyses.

Sensibility analysis: Sensitivity analysis is mainly used to evaluate the robustness of the primary outcome measures. The method is that removing the low-level quality study one by one and then merge the data to assess the impact of sample size, study quality, statistical method, and missing data on results of network meta-analysis and traditional meta-analysis.

Country(ies) involved: China.

Keywords: Diabetic gastroparesis; network meta-analysis; systematic review; protocol.