INPLASY PROTOCOL

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Review question / Objective: P: Adult patients with digestive system diseases undergoing abdominal surgical treatment, regardless gender or race. I: The patients were treated by Enema with traditional Chinese medicine during perioperative period. C: Addition of Enema with traditional Chinese medicine during perioperative period versus Routine treatment in perioperative period. O: Main outcomes: Recovery time of bowel sounds after operation; First anal exhaust time after operation; First defecation time after operation; Additional outcomes: Evaluation of abdominal distension; Surgical incision infection; Length of hospitalization S: Randomized or quasi- randomized trials regardless of blinding.

Information sources: Electronic databases: CNKI, Wanfang Data, VIP, CBM, Pubmed, Embase, Web of science, cochrane library.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 June 2021 and was last updated on 13 June 2021 (registration number INPLASY202160039).

INTRODUCTION

Review question / Objective: P: Adult patients with digestive system diseases undergoing abdominal surgical treatment, regardless gender or race. I: The patients were treated by Enema with traditional Chinese medicine during perioperative period. C: Addition of Enema with traditional Chinese medicine during perioperative period versus Routine treatment in perioperative period. O: Main outcomes: Recovery time of bowel sounds after operation; First anal exhaust time after operation; First defecation time after operation; Additional outcomes: Evaluation of abdominal distension; Surgical incision infection; Length of hospitalization S: Randomized or quasi- randomized trials regardless of blinding.

Condition being studied: Surgical treatment of gastrointestinal diseases is accompanied by a series of complications, of which gastrointestinal dysfunction is the most common complication. Under normal conditions, the recovery time of gastric motility was 1-2 days, the recovery time of intestinal motility was 0.5-1 days, and the recovery time of colonic motility was 3-5 days. When gastrointestinal peristalsis slows down, gastrointestinal dysfunction occurs, resulting in nausea, vomiting, abdominal distension, prolonged exhaust and defecation time. More serious gastrointestinal dysfunction may even cause systemic inflammatory reaction. Gastrointestinal dysfunction after gastrointestinal surgery will not only cause obvious adverse consequences for the prognosis of patients, but also prolong the hospitalization time of patients, bring heavy economic burden to patients. Therefore, how to effectively prevent the occurrence of gastrointestinal dysfunction after gastrointestinal surgery is one of the focuses of clinical attention. At present, there is no unified standard for the treatment of gastrointestinal dysfunction, so the clinical effect is not good. In recent years, we try to use traditional Chinese medicine therapy to prevent gastrointestinal dysfunction after gastrointestinal surgery. Enema can make the traditional Chinese medicine absorbed from the mucosal venous plexus, act directly on the gastrointestinal tract, reduce the first pass effect of liver, improve the local drug bioavailability, and play a fast role. Many studies have shown that traditional Chinese medicine enema after laparoscopic surgery can effectively promote the recovery of gastrointestinal function, which is conducive to the prognosis of patients. However, the number of patients included in a single article is not enough to provide sufficient treatment basis for clinicians. In order to provide evidence-based basis for clinicians, we made strict inclusion criteria and searched the research in this field to further compare and analyze the effect of traditional Chinese medicine enema on the recovery of gastrointestinal function in patients after laparoscopic surgery.12. Hospitalized patients with digestive system diseases undergoing abdominal surgical treatment.

METHODS

Participant or population: Adult patients with digestive system diseases undergoing abdominal surgical treatment, regardless gender or race.

Intervention: The patients were treated by Enema with traditional Chinese medicine during perioperative period.

Comparator: Addition of Enema with traditional Chinese medicine during perioperative period versus Routine treatment in perioperative period.

Study designs to be included: Randomized or quasi- randomized trials regardless of blinding.

Eligibility criteria: 1. All patients were hospitalized for digestive system diseases; 2. All patients received surgical treatment; 3. The patients in the experimental group were treated with traditional Chinese medicine enema during the perioperative period, while the patients in the control group were treated with routine treatment; 4. The results included one or more of the following indicators: main outcome measures: bowel sounds recovery time, postoperative exhaust time, postoperative defecation time; Secondary outcome measures: postoperative complications: abdominal distension, incidence of incision sensation and length of hospital stay.

Information sources: Electronic databases: CNKI, Wanfang Data, VIP, CBM, Pubmed, Embase, Web of science, cochrane library. Main outcome(s): Recovery time of bowel sounds after operation; First anal exhaust time after operation; First defecation time after operation.

Quality assessment / Risk of bias analysis:

According to the Cochrane risk of bias tool (Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0), the included studies are examined in 6 aspects by two independent investigators. Discrepancies were resolved either by consensus or through adjudication by a third investigator. The quality evaluation items of each trial included selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting), and other bias. These items were scored as low, high, or unclear risk of bias.

Strategy of data synthesis: 1.Quantitative data synthesis. We will use Reyman 5.3 software to conduct meta analysis. If it is continuous data, it will be calculated based on the mean difference (MD) of the 95% confidence interval(CI) ,and the dichotomous data will be calculated based on the risk ratio (RR) of the 95% CI. 2.Assessment of heterogeneity. Chi-square test and I2 test were used to test the heterogeneity of the included literature. When P>0.1and I2<50%, it indicates that there is no statistical heterogeneity between the studies; conversely, when P50%, it is considered that there is statistics heterogeneity between the studies. 3. Assessment of reporting biases. Less than 10 studies will not be analyzed for reporting bias. If more than 10 studies are included, the symmetry of the funnel chart will be used to detect potential reporting bias.

Subgroup analysis: Subgroup analysis was performed according to the operation mode, i.e. open surgery or laparoscopic surgery. Sensitivity analysis: In order to evaluate the robustness of data analysis, sensitivity analysis will be performed.

Country(ies) involved: China.

Keywords: abdominal operation, enema, complication.

Contributions of each author:

Author 1 - Miao Yu. Author 2 - Hong Yu. Author 3 - Jianrong Li.