INPLASY PROTOCOL

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None declared.

Vibrating Capsules in The Treatment of Chronic Functional Constipation: A Systematic Review and Meta-Analysis

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Review question / Objective: **Participant：patients diagnosed with chronic functional constipation. Intervention：patients treated with vibrating capsules. Comparison：patients treated with sham capsules. Outcome：an increase of at least one complete spontaneous bowel movement per week (CSBM≥1/wk) during treatment compared to baseline. Study：RCTs.**

Eligibility criteria: **Inclusion criteria: a) study type: RCTs; b) participants: patients diagnosed with chronic functional constipation; c) intervention: patients treated with vibrating capsules and sham capsules; d) clinical outcomes: endpoints collected were: an increase of at least one complete spontaneous bowel movement per week (CSBM≥1/wk) during treatment compared to baseline. safety outcomes: treatment-related adverse events. All of the above outcomes were not required for the included RCTs. exclusion criteria: a) Study type: retrospective studies, cohort studies, case reviews and case reports; b) Animal studies; c) Control: active control (i.e., known effective treatment is experimental compared to placebo; d) Patients with any significant intestinal structural abnormality.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 September 2022 and was last updated on 03 September 2022 (registration number INPLASY202290012).

INTRODUCTION

Review question / Objective: **Participant：patients diagnosed with chronic functional constipation. Intervention：patients treated with vibrating capsules. Comparison：patients treated with sham capsules. Outcome：an increase of at least one complete spontaneous bowel movement per week (CSBM≥1/wk) during treatment compared to baseline. Study：RCTs.**

Condition being studied: Chronic constipation is one of the most common gastrointestinal disorders, accounting for approximately 16% (varies between 0.7% and 79%) of the global population , with a high incidence and unsatisfactory outcome , with a significantly higher incidence in women than in men, accounting for approximately 75% . However, the majority of patients with chronic constipation belong to functional disorders, which are classified according to the Rome criteria IV : Functional Constipation (FC), Irritable Bowel Syndrome-Constipation (IBS-C), Obstructed Defecation Syndrome (ODs), and Opioid-Induced Constipation (OIC). Among them, FC is one of the common functional gastrointestinal disorders (FGIDs), which is defined by the Rome Criteria IV as a functional disorder without organic pathology in which defecation is difficult, less frequent or incomplete, with or without abdominal pain or diarrhea, and the above symptoms have been present for at least 6 months . In recent years, there are various methods for treating chronic functional constipation, but the efficacy is not satisfactory. With the advent of vibrating capsules (VC), its response in randomized controlled trials (RCTs) has not been confirmed, Therefore, we performed a meta-analysis to research the value of VC in the treatment of chronic fnctional constipation.

METHODS

Search strategy: 41 studies were systematically investigated by two researchers from Pubmed, Cochrane Library, Embase, Web of science and Clinical Trials.gov to meet the consistency between results searched and our goal of identifying till June 2022. The keywords for searching were as follows: "vibrating capsule"[Title/Abstract] AND ("Colonic Inertia"[Title/Abstract] OR "Dyschezia"[Title/Abstract] OR "Constipation"[Title/Abstract]). In addition, relevant systematic reviews and meta-analyses of RCTs were independently and manually screened to ensure a more comprehensive search..

Participant or population: Patients diagnosed with chronic functional constipation.

Intervention: Treated with vibrating capsules.

Comparator: Treated with sham capsules.

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

Eligibility criteria: Inclusion criteria: a) study type: RCTs; b) participants: patients diagnosed with chronic functional constipation; c) intervention: patients treated with vibrating capsules and sham capsules; d) clinical outcomes: endpoints collected were: an increase of at least one complete spontaneous bowel movement per week (CSBM≥1/wk) during treatment compared to baseline. safety outcomes: treatment-related adverse events. All of the above outcomes were not required for the included RCTs. exclusion criteria: a) Study type: retrospective studies, cohort studies, case reviews and case reports; b) Animal studies; c) Control: active control (i.e., known effective treatment is experimental compared to placebo; d) Patients with any significant intestinal structural abnormality.

Information sources: Pubmed, Cochrane Library, Embase, Web of science and Clinical Trials.gov

Main outcome(s): A total of 3 RCTs with 452 patients met our inclusion criteria and were included in this meta-analysis. VC can significantly improve chronic functional constipation (OR:2.18,95%CI:1.47-3.25,P=0.0001). However, subgroup analyses found that weekly doses will affected efficacy, 2 capsules per week have obvious therapeutic effects (OR:3.18,95%CI:1.83-5.52,p<0.001) , but 5 capsules a week is not sure (OR:1.42,95%CI:0.79-2.54, p=0.24) . The most common adverse event associated with VC was diarrhea, abdominal discomfort and other adverse effects including vibration discomfort(11.5%),

fever(0.93%), and fecal occult blood(4.67%). Diarrhea (OR=0.20, 95%CI: 0.02-1.72, P=0.14) and abdominal discomfort (OR=0.73, 95%CI: 0.14-3.78, P=0.7) caused by vibrating capsules were not significantly different from the sham capsules (SC) group, and all patients can tolerate and adapt it.

Quality assessment / Risk of bias analysis: Risk of bias maps for individual studies were assessed using Review Manager 5.4 software. The Cochrane Collaboration's uniform criteria for assessing the risk of bias in RCTs were used, which included: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential bias. Each bias criterion was categorized as classified as "low", "high", or "unclear". If a difference occurred, the difference was resolved through discussion with a third researcher.

Strategy of data synthesis: Statistical analysis of the data was performed by two researchers by used RevMan 5.4 software and the heterogeneity between studies was analyzed before Mate analysis: if I2 > 50% and p-values < 0.05 indicated heterogeneity between studies, a random-effects model was used for combination; if I2 < 50% and p-values > 0.05 indicated no heterogeneity between studies, a fixed-effects model was used for combination. Subgroup analysis was then performed. The Odds ratio of the experimental groups and control groups was used as the combined statistic, and its 95% Confidence Interval (CI) was calculated, and forest plots were generated. Differences were considered statistically significant at p-values <0.05. Funnel plots were generated to analyze whether there was publishing bias.

Subgroup analysis: We separately conducted a comparative analysis of weekly doses about their efficacy. The results showed that 2 capsules per week have obvious therapeutic effects (OR:3.18,95%CI:1.83-5.52,p<0.001), but 5 capsules per week have not significant difference in the SC group compared to the VC group (OR:1.42,95%CI:0.79-2.54, p=0.24).

Sensitivity analysis: None.

Language restriction: English only.

Country(ies) involved: China.

Keywords: vibrating capsule; chronic functional constipation; treatment; meta-analysis.

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