INPLASY PROTOCOL

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INTRODUCTION

Review question / Objective: To systematically compare the bowel cleaning ability, patient tolerance and safety of oral sodium phosphate tablets (NaPTab) and oral polyethylene glycol electrolyte lavage solution (PEGL) to inform clinical decision

Comparison of oral sodium phosphate tablets and polyethylene glycol lavage solution for colonoscopy preparation: A systematic review and meta-analysis of randomized clinical trials

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Review question / Objective: To systematically compare the bowel cleaning ability, patient tolerance and safety of oral sodium phosphate tablets (NaPTab) and oral polyethylene glycol electrolyte lavage solution (PEGL) to inform clinical decision making. Review question include: 1) patient populations with an indication for colonoscopy, including outpatients or inpatients requiring diagnosis or treatment, 2) randomized controlled trial (RCT) study designs, 3) a sodium phosphate tablet intervention group, 4) a control group receiving PEGL administered orally or by nasogastric tube, and 5) outcome measures including cleansing quality, adverse effects, patient acceptance, and changes in serum electrolytes after preparation.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 May 2023 and was last updated on 03 May 2023 (registration number INPLASY202350013).

> making. Review question include: 1) patient populations with an indication for colonoscopy, including outpatients or inpatients requiring diagnosis or treatment, 2) randomized controlled trial (RCT) study designs, 3) a sodium phosphate tablet intervention group, 4) a control group receiving PEGL administered orally or by nasogastric tube, and 5) outcome measures including cleansing quality, adverse effects, patient acceptance, and

changes in serum electrolytes after preparation.

Condition being studied: Ideal bowel preparation allows for a detailed examination of the entire colon and should be safe and acceptable to patients. Insufficient bowel preparation is a cause of incomplete colonoscopy. Oral sodium phosphate (OSP) and Polyethylene glycol electrolyte layage solution (PEGL) are the main methods for bowel preparation. PEGL has been available since 1980 and its efficacy was established compared with older diet and cathartic regimens. PEGL are large-volume(2-4L), osmoticallybalanced nonabsorbable solutions that act as purgatives to evacuate the intestine. Similarly, 2L PEG/bisacodyl preparations are as effective as the standard 4L PEG regimens but are better tolerated. OSP acts as an osmotic purgative, drawing water into the bowel lumen and stimulating peristalsis and evacuation and OSP solution is a low volume laxative.

Oral sodium phosphate tablets (NaPTab) are convenient and associated with a lower incidence and severity of nausea than OSP solution(Aronchick et al., 2000). The current study conducted a meta-analysis of reports conducted to compare the use of NaPTab and PEGL for colonoscopy preparation. Differences in bowel cleaning effect, patient tolerance and safety were assessed to inform strategies for clinical use of the two treatments.

METHODS

Participant or population: Patient populations with an indication for colonoscopy, including outpatients or inpatients requiring diagnosis or treatment (those receiving a sigmoidoscopy were not considered).

Intervention: A sodium phosphate tablet intervention group.

Comparator: A control group receiving **PEGL** administered orally or by nasogastric tube.

Study designs to be included: Randomized controlled trial (RCT) study designs.

Eligibility criteria: The inclusion criteria included 1) patient populations with an indication for colonoscopy, including outpatients or inpatients requiring diagnosis or treatment (those receiving a sigmoidoscopy were not considered), 2) randomized controlled trial (RCT) study designs, 3) a sodium phosphate tablet intervention group, 4) a control group receiving PEGL administered orally or by nasogastric tube, and 5) outcome measures including cleansing quality, adverse effects (incidence of nausea), patient acceptance (taste and willingness to repeat the treatment), and changes in serum electrolytes after preparation. The exclusion criteria included 1) articles that were not rigorous or had incomplete data, 2) trials of bowel preparation treatments other than NaPTab and PEGL, 3) repeated publication of the same study, and 4)not in the English language.

Information sources: A systematic search was performed of several databases, including PubMed, China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Journals Database (VIP), Chinese Biomedical Literature Database (CBM), Wanfang Database, and Embase.

Main outcome(s): outcome measures including cleansing quality, adverse effects (incidence of nausea), patient acceptance (taste and willingness to repeat the treatment), and changes in serum electrolytes after preparation.

Quality assessment / Risk of bias analysis: Quality assessment was performed using the Cochrane risk-of-bias tool, which consists of a random distribution method, a distribution hiding method, a blind method, incomplete results and other deviations. Each study was rated as "yes" (low risk of bias), "no" (high risk of bias) or "unclear" (uncertain risk of bias).

Strategy of data synthesis: Meta-analysis was conducted using RevMan5.3 software.

Quantitative data were presented as the relative risk degree (RR) and 95% confidence interval (Cl). Measurement data included the mean difference (MD) and 95% Cl as the effect index. The chi-square and I-square tests were used to measure heterogeneity in the trials (the test level was ?=0.05). If there was no obvious heterogeneity (p >0.10, I2 <50%) then the fixed effect model was used for analysis. When p 50%, a random effect model was used for analysis. Publication bias was assessed through the visual check of funnel plots.

Subgroup analysis: Subgroup analysis according to different numbers of sodium phosphate tablets or according to different volumes of PEGL were conducted.

Sensitivity analysis: Sensitivity analysis were used to handle obvious clinical heterogeneity. A sensitivity analysis of adequate cleansing quality by omitting one study at a time did not fundamentally influence the pooled RR, suggesting that the combined RR was valid and credible.

Language restriction: Articles in the English language.

Country(ies) involved: U.S.A., France, Japan, Korea.

Keywords: Colonoscopy; Bowel preparation; Sodium phosphate; Polyethylene glycol electrolyte lavage solution; Meta-analysis; Systematic review.

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