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A randomized, prospective trial on efficacy and tolerability of low-volume bowel preparation methods for colonoscopy

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ABSTRACT

Background: Low-volume bowel preparations have been shown to provide an equivalent cleansing effect as that of a standard 4 L polyethylene glycol. However, studies comparing the efficacy of low-volume bowel preparations are few, and the results have been controversial. This study aimed to compare the bowel cleansing quality and tolerability between sodium picosulfate/magnesium citrate and polyethylene glycol with ascorbic acid.

Methods: A randomized study was performed with two hundred outpatients who were prospectively enrolled. The Boston Bowel Preparation Scale and the Aronchick scale were used to evaluate the bowel cleansing quality, and bubble scoring was also performed to back up both results. To investigate patients' preferences and tolerability, a questionnaire was administered.

Results: Sodium picosulfate/magnesium citrate was not inferior to polyethylene glycol with ascorbic acid in terms of successful bowel preparation ($\geq$6 Boston scale score: 80% vs. 82%; $p = 0.718$, adequate Aronchick grade: 93% vs. 96%; $p = 0.352$). In addition, sodium picosulfate/magnesium citrate caused fewer gastrointestinal symptoms, and tasted better than polyethylene glycol with ascorbic acid.

Conclusions: Sodium picosulfate/magnesium citrate was not inferior to polyethylene glycol with ascorbic acid in cleansing efficacy, and was found to have higher tolerability.

1. Introduction

Colonoscopy is a common screening method to detect polyps and CRC [1–3]. With the early detection of CRC through screening colonoscopy, patients could have better therapeutic effects and outcomes. The reluctance of participants to undergo bowel preparation results in the relatively low rate of detection of polyps and CRC, because poor preparation interferes with successful colon mucosa examination during a colonoscopy.

Large volumes of colon-cleansing preparation solutions have been used for a long time [4–8], typically up to 4 L of a polyethylene glycol (PEG) solution. However, the large amount of solution often causes dissatisfaction among patients [9,10]. Therefore, poor compliance in taking the preparation solution has led to a decreased quality of colon cleansing.

Recently, low-volume hyperosmolar preparations have emerged. These preparations improved patient tolerability through use of solutions with a reduced amount and improved taste while having a similar cleansing effect. A commonly used solution is oral sodium picosulfate/magnesium citrate (SPMC) (Picolight®; Phambio, Korea Co., Ltd., Seoul, Korea). Sodium picosulfate is a stimulant laxative. Magnesium citrate, which is a solution of magnesium oxide and anhydrous citric acid, is an osmotic laxative [11]. This formulation was recently approved by the US Food and Drug Administration and is also available in Korea. Another preparation solution is polyethylene glycol with ascorbic acid (PEG-Asc) (Coolprep®; TaeJoon Pharmaceuticals, Seoul, Korea), which combines PEG with high-dose ascorbic acid. The excessively high dose of ascorbic acid, which cannot be absorbed, functions as an osmotic laxative, thereby reducing the effective volume of the colon-cleansing solution to 2 L [12]. These two preparations have become market leaders among low-volume preparations [13].

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There are few data comparing the superiority between low-volume bowel preparation methods, and controversy exists among studies.

The aim of this study is to compare split-dose methods of SPMC and PEG-Asc in the aspect of bowel preparation quality and patient tolerability.

2. Materials and methods

2.1. Study design

A single-centre, randomized, observer-blinded study was performed from March 2013 to September 2013 at Korea University Hospital in Anam. In total, 200 outpatients receiving the split-dose method of low-volume bowel preparation were prospectively enrolled and underwent colonoscopy. This study was approved by the institutional review board (ED12144) of Korea University Hospital. All participating patients provided written informed consent. The study is registered with ClinicalTrials.gov, number NCT02250196.

2.2. Patients

All patients between the ages of 18 and 80 years who were scheduled to undergo colonoscopy were included. The exclusion criteria included the following: patients who had (i) chronic kidney disease, (ii) severe heart failure (New York Heart Association [NYHA] class III or IV), (iii) uncontrolled hypertension (systolic pressure ≥170 mm Hg, diastolic pressure ≥100 mm Hg), (iv) severe constipation, (v) any bowel resection, (vi) significant gastroparesis, or (vii) suspected bowel obstruction or perforation.

2.3. Randomization

In total, 200 outpatients were randomly allocated to receive one of the two bowel preparations either SPMC or PEG-Asc on a 1:1 basis. A randomized computer-generated list with a block size of 4 was prepared by a qualified statistician. Eligible patients were consecutively assigned to the next available randomization number. Study medications were provided by investigator. The endoscopists were not allowed to participate in the randomization. Patients were instructed not to discuss their type of preparation kit with any staff member.

2.4. Sample size

A sample size of at least 99 patients per treatment group was required in order to detect a difference in treatment success at a 5% type-I error rate and 80% power for a two-tailed χ^2 test. Because most of the published data regarding reduced volume bowel preparation methods target Westerners, no formal sample size was calculated to assess the primary outcome measure in Asian patients. Therefore, our sample size was based upon the results from a pilot study that was conducted in our hospital with 30 patients per group. It was estimated that the efficacy for excellent treatment success would be 45% with SPMC and 26% with PEG-Asc.

2.5. Preparation method

The participants were given instructions on how to prepare and ingest the bowel preparation solution, as well as dietary advice. The patients were not allowed to eat nondigestible food such as fruits, vegetables, or cereals for three days before the procedure.

Patients allocated to the SPMC one-day diet received two sachets of Picolight, each containing 10 mg sodium picosulfate hydrate, 3.5 g magnesium oxide, and 12 mg citric acid. On the day before their colonoscopies, patients randomized to this group were instructed to dissolve one sachet in 150 mL water and drink it with 1 L water at 7:00 pm. Then, 5 h before the colonoscopy, they were to ingest the second sachet. Patients were advised to take at least 1 L additional clear fluid after each dose.

Patients allocated to the PEG-Asc group (100 g macrogol 3350 per sachet plus ascorbic acid/ascorbate and electrolytes) were presented with two sachets of powder to be reconstituted as PEG-Asc solution in water. The first 1 L solution was taken at 7:00 pm on the day before the colonoscopy, and the second 1 L solution was taken 5 h before the colonoscopy. Each litre had to be consumed between 1 and 2 h, and patients were advised to take at least 500 mL of additional clear fluid after each dose.

In both groups, patients had to finish dinner a minimum of 1 h before drinking the preparation solution, and solid food was not permitted until the end of the colonoscopy. Clear fluids were permitted until midnight. Colonoscopies were performed between 8:00 am and 1:00 pm.

2.6. Assessments

To assess the cleansing quality of the bowel preparations, the Boston Bowel Preparation Scale (BBPS), the Aronchick scale, and the bubble score were used. Experienced endoscopists who were blinded to the preparation method scored the bowel cleansing. A questionnaire was administered before the colonoscopy to evaluate the patient's preference and tolerability.

2.6.1. Assessment of cleansing quality

2.6.1.1. BBPS. Endoscopists rated the quality of the bowel preparation according to the BBPS [14], a 4-point scoring system applied to each of the three broad regions of the colon: the right colon, transverse colon, and left colon. The points were assigned as follows: 0 (inadequate: unprepared colon segment with the mucosa not visible because of solid stool that could not be cleared); 1 (poor: portion of the mucosa of the colon segment visible, but other areas of the colon segment not well visualized because of staining, residual stool, and/or opaque liquid); 2 (good: minor amount of residual staining, small fragments of stool and/or opaque liquid, but the mucosa of the colon segment well visualized); and 3 (excellent: entire mucosa of the colon segment well visualized with no residual staining, small fragments of stool, or opaque liquid). Each region of the colon received a "segment score" from 0 to 3, and these segment scores were summed for a total BBPS score ranging from 0 (completely unprepared) to 9 (perfect).

2.6.1.2. Aronchick scale. The Aronchick scale [15] was classified in the following manner: excellent (>95% of the mucosa visualized, small amount of clear liquid); good (>90% of the mucosa visualized, large volume of clear liquid covering 5–25% of surface); fair (>90% of the mucosa visualized, some semisolid stool that could be suctioned or washed away); poor (<90% of the mucosa visualized, semisolid stool that could not be suctioned or washed away); or inadequate (repreparation required, large amount of faecal residue precluded a complete examination).

2.6.1.3. Bubble score. The bubble score was based on the criteria categorized according to the obscuration by bubbles, debris, bile, and other materials, as follows: 3 (<5%, no obscuration); good (5–20%, mild obscuration); 1 (25–50%, moderate obscuration); and 0 (≥50%, severe obscuration).

2.6.2. Assessment of patient tolerability

Patients completed questionnaires before the colonoscopy regarding their symptoms associated with the preparations to assess tolerability. Patients were asked about any of the following: