Comparison of bowel cleansing efficacy, safety, bowel movement kinetics, and patient tolerability of same-day and split-dose bowel preparation using 4 L polyethylene glycol: a prospective randomized study

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MATERIALS AND METHODS

Study Population and Protocol

This was a single-center, prospective, assessor-blinded, noninferiority, randomized controlled study conducted at a tertiary referral center (Incheon St. Mary's Hospital, Incheon, Korea). Individuals who underwent colonoscopy with or without esophagogastroduodenoscopy (EGD) for various indications were eligible for inclusion. Study subjects were enrolled between November 2017 and February 2018. Individuals who met all of the following criteria were included: (1) age 40–75 years; (2) American Society of Anesthesiologists (ASA) class I or II; (3) outpatients; and (4) no previous history of bowel resection or gastrectomy. Exclusion criteria were as follows: (1) cancellation, (2) violation of protocol for bowel preparation, such as subjects in the SDD group ingesting a purgative the previous day or as an SPD; or subjects in the SPD group ingesting a purgative the previous day or as an SDD. After informed consent was obtained, study subjects were randomly assigned to the SDD or SPD group. Randomization was performed using a block size of four, stratified by colonoscopy time (morning vs afternoon) and sex, using a computer-generated randomization list.

The protocol for bowel preparation is shown in Figure 1. Subjects underwent bowel preparation at home. Study subjects were encouraged to finish 2 L PEG within 1 h. If ingestion was difficult, 2 L PEG was consumed within 1.5 h. Hence, 2 to 3 h were required to fully ingest the 4 L PEG. Individuals in the SDD group ingested PEG on the day of the colonoscopy. For those who underwent morning colonoscopy, ingestion of 4 L PEG was started at 5 a.m. Individuals who were scheduled to undergo afternoon colonoscopy were instructed to take 2 L PEG starting at 7 a.m., then after a 2-h break, the remaining 2 L PEG was ingested starting at 10 a.m. Individuals in the SPD were instructed to begin ingesting 2 L

PEG at 9 p.m., 1 day before the colonoscopy. The remaining 2 L PEG was ingested from 7 a.m. for morning colonoscopy or from 10 a.m. for afternoon colonoscopy. We encouraged the participants to ingest additional water until their bowel effluent was clear. Consumption of fibers and seeds was restricted for 2 days before colonoscopy. Soft food was allowed for dinner the day before colonoscopy. Colonoscopy was performed between 10 a.m. and 5 p.m. (morning colonoscopy 10 a.m.–12 p.m.; afternoon colonoscopy 1:30 p.m.–5 p.m.) by three board-certified colonoscopists with experience of more than 2000 cases. The colonoscopists were blinded to the bowel cleansing regimen. This study was approved by the Institutional Review Board of Incheon St. Mary's Hospital and registered at ClinicalTrials.gov (NCT03315949).

Bowel Cleansing Efficacy, Bowel Movement Kinetics, and Colonoscopy Results

The primary endpoint of this study was the bowel cleansing efficacy assessed by the Boston bowel preparation scale (BBPS). The BBPS score is the sum of three segmental scores (range 0–9).[18] Each segment is graded on a 4-point scale: 0, inadequate; 1, poor; 2, good; and 3, excellent. The rates of cleansing success, defined as all segments ≥2 and total BBPS score, were compared between groups. The bowel cleansing efficacy was also assessed by the Aronchick scale, which has scores of excellent, good, fair, poor, and very poor; details of the Aronchick scale are described elsewhere.[19,20]

Bowel movement kinetics included the number of defecations, the start and finish time of bowel preparation, and the last defecation time. The amount of PEG and additional water ingested were recorded.

The results of the colonoscopy were analyzed. The cecal intubation time, colonoscopy withdrawal time, polyp detection rate (PDR), ADR, and the number of adenomas per patient

were recorded. For those who underwent EGD, fluid in the stomach was suctioned and its volume was measured.

Safety and Tolerability

The composite safety profile included vital signs and questionnaire findings. Vital signs were checked on the day of randomization and at colonoscopy. Before the colonoscopy, all study subjects completed a questionnaire asking about adverse events, tolerability, and bowel movement kinetics.[17,20] The questionnaire contained the following items: (1) adverse events related to the ingestion of the purgative; (2) number of sleep disturbances during the night before colonoscopy; (3) overall satisfaction with the bowel cleansing regimen (very satisfied, satisfied, intermediate, dissatisfied, very dissatisfied); and (4) willingness to use the bowel preparation regimen again. The patients used a checklist of possible adverse events to report whether they had experienced any of the following during or after ingestion of the bowel cleanser: nausea, vomiting, bloating, abdominal pain, dizziness, headache, and/or any other symptoms.

Statistical Analysis

We assumed a bowel cleansing success rate for SPD of 85% and set the inferior margin at 10%. With 80% power and a type I error of 0.05, the required sample size for each group was calculated to be 158. A total of 176 subjects in each group was required, considering a 10% drop-out rate. Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as number and percent. The demographic characteristics, bowel cleansing efficacy, safety profile, tolerability, bowel movement kinetics, and results of colonoscopy were compared between the two groups. For this analysis, we used Student's *t* test for continuous variables, and the chi-square or Fisher's exact test for categorical variables. A *p*-value <0.05 was considered significant. The safety analysis of safety and

tolerability included all subjects except those who were excluded for cancellation or protocol violation. Per-protocol (PP) analysis was used for the patients who completed colonoscopy. Bowel cleansing efficacy and bowel movement kinetics were investigated in the PP analysis. All statistical analyses were conducted using SAS software (9.0; SAS Institute, Cary, NC, USA).