

A Clear Liquid Diet Is Not Mandatory for Polyethylene Glycol-Based Bowel Preparation for Afternoon Colonoscopy in Healthy Outpatients

Yoon Suk Jung*, Hyo Sun Seok*, Dong II Park*, Chang Seok Song*, Seong Eun Kim[†], Suck Ho Lee[‡], Chang Soo Eun[§], Dong Soo Han[§], Yong Soo Kim[§], and Chang Kyun Lee^{||}

*Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, [†]Department of Internal Medicine, Ewha Womans University School of Medicine, [†]Department of Internal Medicine, Soonchunhyang University College of Medicine, Seoul, [§]Department of Internal Medicine, Hanyang University Guri Hospital, Hanyang University College of Medicine, Guri, and [§]Department of Internal Medicine, Kyung Hee University School of Medicine, Seoul, Korea

Background/Aims: A dietary regimen consisting of a clear liquid diet (CLD) for at least 24 hours is recommended for colonoscopy preparation. However, this requirement results in problems in patient compliance with bowel preparation. The aim of this study was to evaluate the efficacy of a CLD compared with a regular diet (RD) for colonoscopy preparation using a polyethylene glycol (PEG) solution. Methods: This was a multicenter, randomized, investigator-blind prospective study. A total of 801 healthy outpatients undergoing afternoon colonoscopy were randomized to either a CLD or RD in addition to a 4 L PEG regimen. Results: The quality of bowel cleansing was not different between the CLD and RD groups in terms of the proportion with excellent or good preparation. In addition, no significant differences were observed between the two groups for polyp and adenoma detection rates and overall adverse events. Good compliance with bowel preparation was higher in the RD group than in the CLD group. **Conclusions:** A CLD for a full day prior to colonoscopy should not be mandatory for PEG-based bowel preparation. Dietary education concerning the avoidance of high-fiber foods for 3 days before colonoscopy is sufficient, at least for healthy outpatients. (Gut Liver 2013;7:681-687)

Key Words: Clear liquid diet; Regular diet; Afternoon colonoscopy; Bowel preparation

INTRODUCTION

Colonoscopy is currently regarded as the gold standard for the detection of colorectal neoplasms and is recommended for colorectal cancer (CRC) screening of average-risk individuals over the age of 50 years. However, early studies have shown that 4% to 5% of cancers may be missed on a single colonoscopic examination. One of the main reasons for missed CRCs is incomplete bowel cleaning. Several studies have reported that poor bowel preparation reduces detection of polyps that may have the potential to be cancerous. In response, professional societies have proposed measuring the quality of bowel preparation as an important quality indicator for colonoscopy.

Polyethylene glycol (PEG) has become the most commonly used agent for colon cleansing because it does not cause fluid exchange across the mucosal membrane and thereby limits fluid and electrolyte disturbances.⁸ However, the need to ingest a large volume of fluid reduces patient compliance. Moreover, patients usually complain of having to adhere to a clear liquid diet (CLD) for a full day before the colonoscopy in addition to the large volume (4 L) of the preparation.

Although diet restriction is an important factor influencing patient compliance, the majority of previous studies regarding bowel preparation have focused on comparing the effects of different purgative regimens, including the types, timing, and quantities of cathartics. 9-19 Only a few studies have evaluated the effects of different diet types on bowel preparation under controlled circumstances. 20-22 Currently, a dietary regimen incorporating a CLD for at least 24 hours is recommended for improving the quality of preparation. However, evidence for the efficacy of a CLD in bowel preparation is lacking, which led us to question whether it is reasonable to recommend a CLD for 24 hours prior to colonoscopy as part of a PEG-based bowel preparation in healthy outpatients. This study was designed to test

Correspondence to: Dong Il Park

Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, 29 Saemunan-ro, Jongno-gu, Seoul 110-746, Korea

Tel: +82-2-2001-2059, Fax: +82-2-2001-2049, E-mail: diksmc.park@samsung.com

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the hypothesis that education to avoid high-fiber foods without strict dietary restriction is sufficient for preparation for bowel cleansing of healthy outpatients. As part of an effort to increase patient compliance with the bowel preparation for colonoscopy using a PEG solution, we evaluated the effect of a regular diet (RD) for the 24-hour period prior to colonoscopy, which allowed patients to eat their usual diet instead of the difficult to follow CLD. In short, the aim of this study was to compare the efficacy of and patient compliance with a CLD versus a RD as part of a PEG-based bowel preparation in healthy outpatients who were instructed to avoid high-fiber foods for 3 days before colonoscopy.

MATERIALS AND METHODS

1. Patients

This was a prospective, investigator-blinded, randomized, multicenter study that was conducted at five university hospitals (Kangbuk Samsung Hospital, Ewha Womans University Hospital, Soonchunhyang University Hospital, Hanyang University Guri Hospital, and Kyung Hee University Hospital) in Korea, between March 2010 and August 2011. The study protocol was approved by the institutional review boards at the participating medical centers. All patients who agreed to participate in the study signed a written informed consent form.

Adult outpatients (range, 18 to 80 years old) undergoing colonoscopy for CRC screening or with nonspecific gastrointestinal symptoms were candidates for inclusion in the study. Exclusion criteria were as follows: inpatient status; serious medical conditions, such as severe cardiac, renal, liver, or metabolic disease; stroke or dementia; major psychiatric illness; known allergy to PEG; a previous colon resection; incomplete colonoscopy examination (failure of cecal intubation); or functional constipation defined by Rome III diagnostic criteria.

2. Bowel preparation protocol

After determination of patient enrollment, clinical research coordinators at each participating center randomized the patients using a computer-generated random sequence and then they interviewed the patients and provided each with oral and written instruction on one of two diet types. On the day before the scheduled colonoscopy (until 8:00 PM), patients in the first group were asked to eat a CLD for all three meals, and the patients in the second group were allowed to have their usual diet (RD) for all three meals. Patients in both groups were instructed to avoid foods that contain a lot of fiber, such as vegetables, seaweeds, mushrooms, and fruits for 3 days before the scheduled colonoscopy. The method of bowel cleansing, as well as the type and intensity of instruction, was the same for both groups. All participants were asked to drink 4 L of PEG solution (Taejoon Pharm Inc., Seoul, Korea; 236 g PEG, 22.7 g Na₂So₄, 6.74 g NaHCO₃, 5.86 g NaCl, and 2.97 g KCl) between 6:00 and 10:00 AM on the morning of the day of the colonoscopy at a rate of 240 mL every 10 minutes. All colonoscopies were performed between 1:00 PM and 6:00 PM. Also, all colonoscopies were performed between 2 and 7 hours after last ingestion of PEG.

3. Evaluation of patient compliance and colonoscopy quality

Before colonoscopy, we collected patient information which included age, gender, weight, height, body mass index (BMI), functional constipation according to Rome III diagnostic criteria, indications for colonoscopy, and history of previous operation and colonoscopy. Just before colonoscopy, patients completed a questionnaire regarding their preparation experience (the start and end time for PEG solution ingestion; the amount of PEG solution ingested; any associated adverse effects, including abdominal pain, nausea, vomiting, headache, dizziness, and others; and willingness to repeat the same preparation in the future) with the help of an endoscopy nurse who was blinded to the dietary randomization. Patients who were instructed to eat a CLD were asked about the actual number of CLD meals (range, 0 to 3 times). We categorized participants into subgroups with regard to compliance; good compliance was defined as less than 25% of the PEG solution remaining, and poor compliance was defined as 25% or more of the PEG solution remaining.

Colonoscopies were performed under conscious sedation by experienced staff endoscopists who were blinded to the results of dietary randomization using conventional videoendoscopes. At the end of the procedure, the endoscopists were asked to grade the overall quality of bowel cleansing as excellent, good, fair, or poor, according to a previously described scale (Table 1). 19,23 The endoscopists were also asked about details of the procedure, including start time of colonoscopy, cecal intubation time, withdrawal time, and number of polyps. Prior to study commencement, all endoscopists performed calibration exercises involving 20 colonoscopies, based on their interpretations of bowel cleansing quality, to ensure consensus. The assessments of bowel cleansing were classified as satisfactory (excellent or good) or unsatisfactory (fair or poor). The polyp detection rate

Table 1. Grading of Bowel Cleansing Quality 19,23

Grade	Description	
Excellent	No fecal matter or nearly none in the colon; small to moderate amounts of clear liquid	
Good	Small amounts of thin, liquid fecal matter seen and suctioned easily, mainly distal to splenic flexure; all mucosa seen	
Fair	Moderate amounts of thick liquid to semisolid fecal matter seen and suctioned, including proximal to splenic flexure; small lesions may be missed; >90% mucosa seen	
Poor	Large amounts of solid fecal matter found, precluding a satisfactory study; unacceptable preparation; <90% mucosa seen	

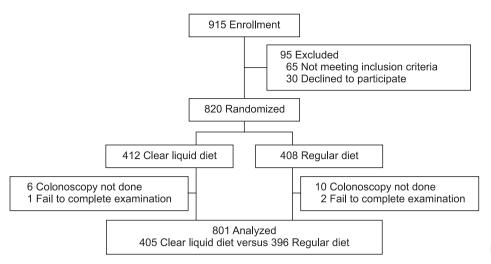


Fig. 1. Enrollment flow chart.

(PDR) was defined as the proportion of procedures in which at least one polyp was seen. Most of the polyps detected were sent for pathologic examination after biopsy or snare removal. The adenoma detection rate (ADR) was defined as the proportion of procedures in which at least one adenoma was documentated by the pathology report.

4. Statistical analysis

This study was designed to test wheather a CLD is superior to a RD for colonoscopy preparation. The sample size calculation was based on the assumption of 15% unsatisfactory preparations in the CLD group versus 25% in the RD group. Considering a 20% dropout rate, the estimated sample size per group was 371 with an α -value of 0.05 and a power of 80%.

The software program SPSS version 12 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. Student t-test was used to compare numerical variables between groups. The chisquare or Fisher exact test was used to compare categorical variables. The p<0.05 were considered statistically significant.

RESULTS

1. Patients

Fig. 1 shows a flow diagram of the study. A total of 915 patients from five university hospitals were enrolled in this study. Of these, 95 were excluded for the following reasons: not meeting inclusion criteria (n=65) and refusal to participate (n=30). Patients were randomized to either the CLD group (n=412) or the RD group (n=408). Ultimately, 801 patients (405 in the CLD group and 396 in the RD group) who had a complete examination (cecal intubation) were analyzed per protocol. Of the 801 patients, 406 (50.7%) were men and the age of patients ranged from 18 to 80 years with a mean of 54.8±12.7 years.

No significant differences were observed between the two groups in terms of age, sex, BMI, prior experience with colonoscopy, and surgical history. Stool caliber change was more

Table 2. Demographic Data and Indication for Colonoscopy

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	Clear liquid diet (n=405)	Regular diet (n=396)	p-value
Mean age, yr	55.6 <u>+</u> 12.1	54.0±13.3	0.071
Male	192 (47.4)	214 (54.0)	0.060
BMI	23.5±3.2	23.7±3.4	0.600
Experience of colonoscopy	218 (53.8)	239 (60.4)	0.062
Surgical history	102 (25.2)	103 (26.0)	0.789
Indication for colonoscopy	<i>I</i>		
Screening	217 (53.6)	199 (50.3)	0.346
Bowel habit change	39 (9.6)	34 (8.6)	0.608
Stool caliber change	26 (6.4)	12 (3.0)	0.024
Melena/hematochezia	23 (5.7)	29 (7.3)	0.345
Tenesmus	0	1 (0.3)	0.312
Abdominal pain	45 (11.1)	34 (8.6)	0.231
Anemia	4 (1.0)	5 (1.3)	0.712
P/Hx of CRN	38 (9.4)	62 (15.7)	0.007
F/Hx of CRC	3 (0.7)	5 (1.3)	0.458
Others	10 (2.5)	15 (3.8)	0.238

Data are presented as mean+SD or number (%).

BMI, body mass index; P/Hx, past history; CRN, colorectal neoplasm; F/Hx, family history; CRC, colorectal cancer.

frequent as the indication for colonoscopy in the CLD group, whereas past history of colorectal neoplasm was more frequent in the RD group (Table 2).

2. Clinical outcomes according to diet

The clinical outcomes according to diet are shown in Table 3. When the evaluations of bowel cleansing were classified as satisfactory (excellent or good) and unsatisfactory (fair or poor), the RD group showed a similar rate of satisfactory preparation compared to the CLD group (83.3% vs 83.5%, p=0.963). An excellent bowel preparation was more common in the CLD group

than in the RD group (31.6% vs 23.7%, p=0.013), whereas a good bowel preparation was more common in the RD group than in the CLD group (59.6% vs 51.9%, p=0.027). The compli-

Table 3. Clinical Outcomes according to Diet Type

	Clear liquid diet (n=405)	Regular diet (n=396)	p-value
Bowel cleansing			
Satisfactory (excellent or good)	338 (83.5)	330 (83.3)	0.963
Excellent	128 (31.6)	94 (23.7)	0.013
Good	210 (51.9)	236 (59.6)	0.027
Fair	45 (11.1)	51 (12.9)	0.441
Poor	22 (5.4)	15 (3.8)	0.268
Good compliance (PEG \geq 3 L)	364 (89.9)	379 (95.7)	0.001
Patients who would repeat the preparation in future	362 (89.4)	353 (89.1)	0.912
Cecal insertion time, min	7.4 <u>+</u> 7.9	7.4 <u>±</u> 6.8	0.917
Withdrawal time, min	9.0 <u>+</u> 4.2	10.4 <u>±</u> 6.3	<0.001
Total colonoscopy time, min	17.0 <u>+</u> 8.8	19.6±10.4	<0.001
Polyp detection rate	209 (51.6)	195 (49.2)	0.504
No. of polyp	1.3 <u>+</u> 2.0	1.2 ± 1.8	0.668
Adenoma detection rate	136 (33.6)	139 (35.1)	0.650
No. of adenoma	0.7±1.4	0.8±1.4	0.480

Data are presented as number (%) or mean±SD.

PEG, polyethylene glycol.

Table 4. Clinical Outcomes according to the Actual Frequency of Clear Liquid Diet (CLD) in the CLD Group

	CLD ≤2 (n=194)	CLD=3 (n=211)	p-value
Bowel cleansing			
Satisfactory (excellent or good)	163 (84.0)	175 (82.9)	0.770
Excellent	63 (32.5)	65 (30.8)	0.718
Good	100 (51.5)	110 (52.1)	0.906
Fair	17 (8.8)	28 (13.3)	0.149
Poor	14 (7.2)	8 (3.8)	0.129
Good compliance (PEG ≥3 L)	178 (91.8)	186 (88.2)	0.230
Patients who would repeat preparation in future	175 (90.2)	187 (88.6)	0.606
Cecal insertion time, min	8.0 <u>+</u> 9.5	6.8 <u>±</u> 6.1	0.118
Withdrawal time, min	9.0 <u>±</u> 3.9	9.0 <u>±</u> 4.4	0.928
Total colonoscopy time, min	17.0 <u>±</u> 8.8	17.1 <u>±</u> 8.8	0.927
Polyp detection rate	98 (50.5)	111 (52.6)	0.674
No. of polyp	1.2±1.8	1.3±2.1	0.566
Adenoam detection rate	66 (34.0)	70 (33.2)	0.857
No. of adenoma	0.6±1.3	0.7±1.6	0.434

Data are presented as number (%) or mean±SD.

PEG, polyethylene glycol.

ance with the bowel preparation was higher in the RD group, as shown by the number of patients who drank more than 3L of PEG solution: 379 (95.7%) in the RD group compared with 364 (89.9%) in CLD group (p=0.001). Withdrawal (10.4 minutes vs 9.0 minutes, p<0.001) and total colonoscopy time (19.6 minutes vs 17.0 minutes, p<0.001) were prolonged in the RD group compared to the CLD group. There were no significant differences in willingness to repeat the same preparation in the future, cecal insertion time, PDR, ADR, and mean number of polyps or adenomas between the two groups.

3. Clinical outcomes according to the actual frequency of CLD within the CLD group

Of patients in the CLD group, only 211 (52.1%) adhered to the diet instructions to consume three meals of CLD. Among the 194 patients who did not eat a CLD for all three meals, 12, 52, and 130 patients had 0, 1, and 2 CLD meals on the day before colonoscopy, respectively. To accurately evaluate the efficacy of CLD, we conducted an additional analysis of patients in the CLD group according to the actual frequency of CLD meals (range, 0 to 3 times). We categorized patients in the CLD group into two subgroups with regard to actual frequency of CLD meals (\leq 2 vs 3) and compared the clinical outcomes of the two subgroups. No significant differences were observed between the two subgroups in terms of bowel cleansing quality, patient compliance, cecal insertion time, withdrawal time, PDR, ADR, and mean number of polyps or adenomas (Table 4).

4. Adverse events

In the both groups, the most common complaint was nausea and vomiting. The frequency of reported adverse events, including abdominal pain, nausea, vomiting, headache, and dizziness, was similar for both groups (total 33.3% vs 33.3%, p=1.000) (Table 5).

DISCUSSION

In the present study, we found that a CLD was not superior to a RD with regards to bowel cleansing quality (satisfactory prep-

Table 5. Adverse Events

Adverse events	Clear liquid diet (n=405)	Regular diet (n=396)	p-value
Abdominal pain	7 (1.7)	7 (1.8)	0.966
Nausea	63 (15.6)	64 (16.2)	0.814
Vomiting	59 (14.6)	55 (13.9)	0.783
Headache	2 (0.5)	1 (0.3)	1.000
Dizziness	4 (1.0)	4 (1.0)	1.000
Others	0	1 (0.3)	0.494
Total	135 (33.3)	132 (33.3)	1.000

Data are presented as number (%).

aration), PDR, and ADR in patients undergoing PEG solution bowel preparation for afternoon colonoscopy. A greater number of patients in the RD group than in the CLD group drank more than 3 L of PEG solution, and this may be one of the reasons why a CLD was not superior to a RD. In addition, it is possible that patients in the CLD group did not strictly adhere to the three meals of the CLD. Our results showed that only 52.1% of the CLD group patients were in compliance with the three meals of the CLD. Considering the possibility that low compliance with the CLD led to an underestimation of the efficacy of bowel preparation in CLD group, we investigated clinical efficacy according to the actual frequency of CLD among patients in the CLD group because low compliance with the CLD might reduce the efficacy of bowel preparation. However, the number of CLD meals was not associated with the efficacy of colonoscopy preparation. Our results suggest that healthy outpatients need not necessarily have a CLD on the day before afternoon colonoscopy and that it is sufficient to simply receive diet education to avoid high-fiber foods for 3 days before colonoscopy.

In addition to dietary restriction, the timing of the colonoscopy preparation is an important factor for bowel cleansing. 9,10,13 Because our study was conducted in the setting of bowel preparation on the morning of planned afternoon colonoscopy, the time between completion of the preparation and the performance of colonoscopy was less than 7 hours in all participants. A relatively short interval of time between last ingestion of PEG solution and the beginning of colonoscopy in our study might have improved the bowel cleansing quality, and thus the difference in efficacy of bowel cleansing between the RD and CLD groups might be offset. One recent study showed that if >7 hours elapse after ingestion of PEG, the quality of bowel preparation for afternoon colonoscopy is poor. 24 Unlike previous studies, we included only healthy outpatients, excluding patients with constipation as well as patients with serious medical problems that could affect bowel preparation quality. Ness

et al.25 reported that inpatient status, a procedural indication of constipation, and a history of cirrhosis, stroke, or dementia were independent predictors of inadequate colon preparation. In another study by Kim et al.,26 a walking exercise was found to improve colonoscopic bowel cleansing. In our study, one of reasons why the bowel cleansing efficacy of a CLD was not superior to that of a RD might be because we enrolled only healthy outpatients, namely patients who had no comorbidities and no limitations in physical activity.

Interestingly, our study showed that although the satisfactory preparation was similar in both groups, excellent bowel preparation is more common in the CLD group and colonoscopy withdrawal time was longer in the RD group. These results may imply that the bowel preparation in the RD group was slightly worse than in the CLD group. In other words, the bowel cleaning during withdrawal in the RD group might have partially accounted for the significantly longer times. Therefore, our suggestion that a CLD is not mandatory for PEG-based bowel preparation shoud be carefully applied to only healthy outpatients and should not be misinterpreted to mean that a RD has no affect on the preparation.

There have been several studies investigating the impact of diet liberalization on bowel preparation (Table 6).9-12,20-22 All of these studies demonstrated that colonic preparation with fewer dietary restrictions did not diminish the quality of colon cleansing compared to preparations that included a CLD. However, the results of some studies were difficult to attribute to a diet effect because the preparation regimens consisted of different cathartics or different dosing intervals.9-12 To date, only a few studies have been conducted to evaluate only the effect of diet on bowel preparation in the setting of a uniform preparation regimen utilizing the same type, dose, and timing of cathartics. 20-22 Scott et al.21 reported that diet liberalization did not influence the bowel cleansing efficacy. Our previous study also demonstrated that a prepackaged low residue test meal and 4 L PEG regimen

Table 6. Several Studies Investigating the Impact of Diet Liberalization on Bowel Preparation

Strict dietary restriction (group A) diet type/cathartics	Fewer dietary restriction (group B) diet type/cathartics	Better quality colon cleansing	Higher compliance or tolerability
CLD ¹¹ whole dose PEG	RD except for a light liquid dinner split-dose PEG+bisacodyl	Group B	Group B
CLD ¹² whole dose PEG	RD split-dose PEG	Group B	No difference
CLD ¹³ standard sodium phosphate cathartic	Prepackaged, low fiber diet low sodium, magnesium citrate cathartic+bisocodyl tablets+a bisacodyl suppository	Group B	Group B
CLD ¹⁴ magnesium citrate+bisacodyl	Low-residue diet kit magnesium citrate+bisacodyl and low-residue diet kit PEG	No difference	No difference
A light breakfast followed by clear liquids ²² sodium phosphates oral solution	A normal breakfast followed by a low-residue lunch sodium phosphates oral solution	No difference	Group B
CLD ²¹ 4 L PEG solution	Prepackaged low residue test meal 4 L PEG solution	No difference	Group B
CLD ²³ 4 L PEG solution	Fiber-free diet 4 L PEG solution	Group B	Group B

CLD, clear liquid diet; PEG, polyethylene glycol; RD, regular diet.

provided cleansing efficacy similar to that of a CLD and 4 L PEG regimen.²⁰ Similarly, Soweid *et al.*²² revealed that a fiberfree diet given with 4 L of PEG solution was a more effective regimen than the standard CLD regimen.

To our knowledge, the current study is the first randomized, prospective clinical study to investigate the effect of diet liberalization (RD vs CLD) during bowel preparation using 4 L of PEG solution on the morning of afternoon colonoscopy in healthy outpatients. Furthermore, our study had several distinct advantages over previous studies. First, our study compared PDR and ADR, which are accepted as some of the most important quality indicators for colonoscopy, as well as bowel cleansing quality between two diet groups. Secondly, our study analyzed the efficacy according to the actual frequency of CLD meals and thus clarified the effect of CLD on colonoscopy preparation. Finally, our study included a relatively larger number of patients than previous studies.

Nonetheless, our study had several limitations. First, we only included outpatients without serious comorbidities and patients undergoing afternoon colonoscopy. Therefore, our results cannot be applied to inpatients with comorbidities or patients undergoing morning colonoscopy. Secondly, interobserver bias may have occurred because several endoscopists performed the colonoscopies and scored the bowel preparation quality on a multicenter-basis. However, all endoscopists performed calibration exercises involving 20 colonoscopies prior to study commencement, based on their interpretations of bowel cleansing quality, to ensure that their findings agreed. Although the kappa statistics or interclass correlation coefficient statistics were not calculated, these trainings were intended to reduce interobserver bias. Finally, we did not use validated scales such as Boston or Ottawa scales and thus did not assess the quality of bowel cleansing in each segment.

In conclusion, a CLD was not superior to a RD with regards to bowel cleansing efficacy, PDR, and ADR among healthy outpatients undergoing PEG-based bowel preparation for afternoon colonoscopy. Furthermore, the sum of the number of CLD meals was not associated with quality improvement for colonoscopy, and a RD offered the benefit of improved compliance compared to a CLD. We suggest that a CLD for 24 hours prior to colonoscopy should not be compulsory for PEG-based bowel preparation and that it is sufficient for patients to receive diet education to avoid high-fiber foods for 3 days before colonoscopy, at least in healthy outpatients. This could make the overall bowel preparation less burdensome and allow for higher patient participation in screening programs.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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