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Efficacy and Acceptability of 1 Liter of Polyethylene Glycol with Ascorbic Acid *vs.* 2 Liters of Polyethylene Glycol Plus Mosapride and Sennoside for Colonoscopy Preparation

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Background: Bowel preparation is an important factor for an optimal outcome of colonoscopy. Recently, polyethylene glycol (PEG) solution has been in common use for bowel cleansing for colonoscopy, but some patients are intolerant of PEG because of taste or volume. A low-volume PEG administered with ascorbic acid solution (PEG-Asc) was designed to improve tolerability, but the administration of this method is more complex than that with PEG alone. This study aimed to compare bowel cleansing efficacy, safety, and tolerability of 1 L PEG-Asc with a 2 L PEG preparation with use of sennosides and mosapride.

Material/Methods: This was a prospective, single-center, non-inferiority trial that included 112 patients (PEG-Asc group, 68; PEG group, 44). The primary endpoint was the efficacy of colon cleansing assessed by endoscopists using a validated 4-point scale according to the Aronchick scale and was verified by a blinded investigator. Acceptability, tolerability, and adenoma detection rate (ADR) of these 2 regimens were secondary endpoints.

Results: We found no statistically significant differences between the groups in colon-cleansing efficacy or in the adenoma detection rate (ADR). Moreover, overall, patients significantly favored PEG-Asc over PEG, reflecting better acceptance of PEG-Asc. Additionally, more patients favored PEG-Asc over PEG for a hypothetical future colonoscopy.

Conclusions: The alternate 1 L PEG-Asc regimen and standard 2 L PEG regimen were clinically equivalent with respect to cleansing efficacy, safety, and ADR, and more patients favored PEG-Asc than PEG. This alternate regimen may improve patient compliance and acceptance of surveillance colonoscopy.

MeSH Keywords: Ascorbic Acid • Cathartics • Colonoscopy • Detergents • Polyethylene Glycols

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Background

Recently, the incidence of colorectal cancer (CRC) has been increasing worldwide [1,2]. Accordingly, the performance of colonoscopy has been increasing. Colonoscopy is an established procedure for surveillance and evaluation of the gut status and can reduce the risk of death from CRC through detection of tumors at an earlier and more treatable stage and through the removal of precancerous adenomas [3–6]. A previous study indicated that the detection of 1 or more adenomas (adenoma detection rate; ADR) was recommended to assess the quality of screening colonoscopy, and that each 1.0% increase in the ADR was associated with a 3.0% decrease in the risk of cancer [3]. To perform a successful colonoscopy, optimal bowel preparation is required. There are many methods and preparations for bowel cleansing. PEG-based solutions have become mainstream in Japan and have been evaluated for efficacy and safety in Japan and in the United States [7]. However, a significant fraction of patients are intolerant of PEG solutions due to their unpleasant taste, which may lead to inadequate colon cleansing and even discontinuation of the colonoscopy. Because of this, we can now prescribe a PEG-based solution combined with ascorbic acid (PEG-Asc). In 2013, the bowel-cleansing effect and maintenance of the electrolyte balance were shown to be equal compared with isotonic PEG.

Before its approval in Japan, PEG-Asc was used for more than 6 500 000 patients overseas, and its validity and safety were confirmed [8–10]. Previous studies showed that the low-volume PEG-Asc was better tolerated and had a superior bowel-cleansing capacity than the larger volume of PEG. However, if the liquid discharge does not become clear after 1 L of PEG-ASC, additional half-liter increments of PEG-Asc and 250 mL of clear liquid are required until the discharge becomes clear. Therefore, PEG-Asc usage can become complicated and in all cases it is highly convenient for the patient. On the other hand, the volume of lavage solution can be decreased by using it together with a laxative and an enterokinesis-promoting agent [11,12]. If the dose of PEG-Asc could be reduce to 1 L, its use would be simplified. This would be desirable for medical professionals and patients.

Material and Methods

Patients and setting

This was a prospective, single-center, non-inferiority trial that compared 1 L PEG-Asc with 2 L PEG in patients who underwent colonoscopy as outpatients. The study was conducted at Juntendo University, Tokyo, from August 2011 to July 2014. The protocol for this study was reviewed and approved by the Institutional Review Board of Juntendo University School of Medicine (the study site). All patients provided signed written informed consent. A total of 112 patients were included in this study. The age range of participating patients was 21–70 years (median age, 45.5 years). Exclusion criteria were gastrointestinal obstruction or perforation, delayed gastric emptying, toxic megacolon, over 70 years of age, and dysphasia.

Procedures

On the day before colonoscopy, patients in both groups took a 5-mg mosapride citrate hydrate tablet (Gasmotin®) before each meal and 24 mg sennoside (Pursennid®) at bedtime. There was no food restriction on the day before colonoscopy. At almost 4 h prior to the colonoscopy, PEG-Asc or PEG was taken as follows.

In the PEG-Asc group, each patient drank PEG-Asc solution (Moviprep®, Ajinomoto Pharmaceuticals, Tokyo, Japan) at a rate of approximately 1 L/h. Patients were advised to drink 0.5 L of additional clear fluid after completion. We decided not to prescribe more than 1 L of PEG-Asc solution. In the PEG group, each patient drank PEG solution (NIFLEC®, Ajinomoto Pharmaceuticals) at a rate of approximately 1 L/h up to a total of 2 L.

Study design

The primary endpoint of this study was overall colon cleansing. The efficacy of the bowel preparation was evaluated by 2 gastroenterologists for each colonic segment (cecum to ascending, transverse, descending, sigmoid colon, and rectum) (Figure 1) using a 4-point scale: “excellent” (greater than 90% of the mucosa was clearly seen, with mostly liquid stool with minimal suctioning needed for adequate visualization); “good” (greater than 90% of the mucosa was clearly seen, with mostly liquid stool, but significant suctioning needed for adequate visualization); “fair” (greater than 90% of the mucosa was clearly seen, and a mixture of liquid and semisolid stool could be suctioned or washed); and “poor” (less than 90% of the mucosa was seen, together with a mixture of semisolid and solid stool that could not be suctioned or washed) according to a modified version of the Aronchick scale (Figure 1). These ratings were classified as ‘adequate’ (excellent or good) and ‘inadequate’ (fair or poor) for the analysis. Efficacy was assessed by 2 independent gastroenterologists, one who performed the colonoscopy and another who was blinded to the method of bowel preparation. The latter was the same individual throughout the study. The secondary endpoints of each bowel preparation method were patients’ acceptance and tolerance, adenoma detection rate (ADR), and safety for ulcerative colitis (UC) evaluation.

Evaluations of patients’ acceptance and tolerance was acquired via a standardized questionnaire provided to the patients on the day of colonoscopy. The questionnaire required “Yes”, “No”, or ordinal scale answers. Information was requested on: A) ease

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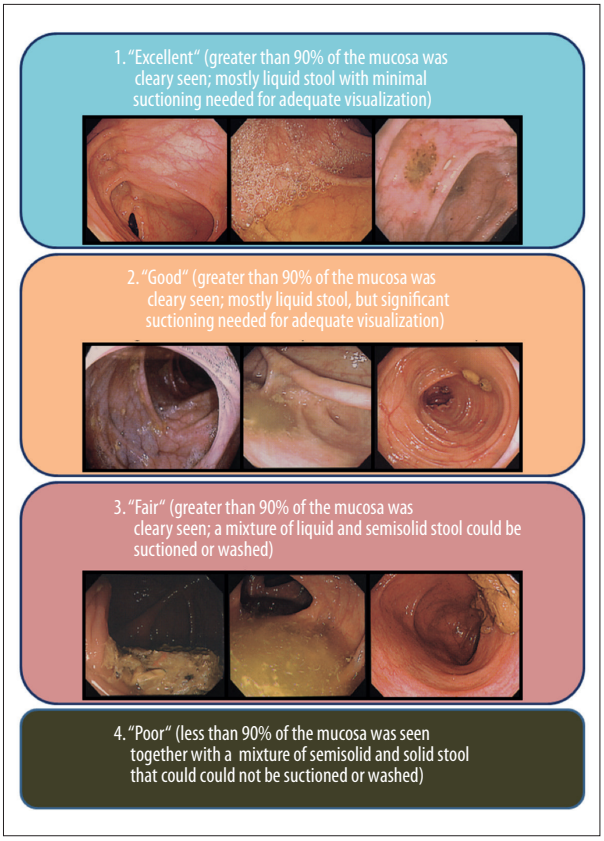

Figure 1. Method of evaluation of colon cleansing efficacy.

of ingestion, B) fluid volume, C) if the patient would choose the same preparation again, and D) physical condition (Table 1). The ADR was calculated according to the number of cases of colonoscopy in which 1 or more adenomas were detected divided by the total number of cases of colonoscopy except inflammatory bowel disease (IBD) follow-up patients. Ulcerative colitis (UC) patients often report symptom flare-ups after colonoscopy [13]. Thus, special arrangements have to be made for patients with UC to ensure safety. Our other concern was whether the PEG-Asc solution contributes to disease progression. We retrospectively examined the medical chart of patients with a history of UC to obtain information on symptoms before and after colonoscopy. All UC patients included in this study were in remission or had no more than moderate disease.

Ethical considerations

Prior to the initiation of the study, our investigation protocol was reviewed and approved by the Juntendo University Hospital Ethics Committee (IRB No.24-027, 25-183). Further, all participating patients provided written informed consent after being informed of the purpose of the study and the nature of the procedures involved. The study was conducted with strict adherence to the Helsinki Declaration, with extra care taken to avoid undue suffering.

Statistics

To compare differences in patients' demographic variables, we used the *t* test (for age, disease duration, intubation time, and total examination time), the χ^2 test (for sex), Fisher's exact test (for purpose), and Mann-Whitney test (for examination frequency). The primary outcome was the results of the comparison between the 2 groups based on the Fisher's exact test. For secondary endpoints, the Fisher's exact test and Wilcoxon signed rank test were used. A P value <0.05 was considered statistically significant. All analyses were done using SPSS Statistics Version 22 (IBM, Armonk, NY, USA).

Results

Study groups

A total of 112 patients were included this study. Patients were divided into 2 groups depending on the timing of the

Table 1. Standardized questionnaire administered to study patients.

A) How easy or difficult was it to ingest the preparations?
1. Very easy. 2. Easy. 3. Tolerable. 4. Difficut. 5. Very difficult.
B) How did you feel about the fluid volume?
1. Not too much. 2. A little too much. 3. Too much.
C) If you needed a colonoscopy again in the future, do you want to use the same preparation reagent regimen?
1. Fervently hope for the same preparation. 2. Hope for the same preparation. 3. Hope for another preparation. 4. Fervently hope for another preparation.
D) Did you feel a change in your physical condition?
1. Yes (what was your adverse event?) 2. No.

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Table 2. Patients' demographic features and indications for surveillance colonoscopy.

	PEG-Asc group	PEG group	P-value
Number	68	44	
Mean age (range)	48.8±1.4 (21–70)	45.2±1.9 (25–70)	Mean ±sem 0.4088 (t-test)
Mean: Women	42: 26	25: 19	0.2720 (χ^2-test)
Intubation time (range)	7.8±0.1 (2–30)	9.7±0.1 (2–20)	Mean ±sem 0.0297 (t-test)
Total examination (range)	17.6±0.1 (8–44)	17.4±0.1 (10–30)	Mean ±sem 0.8675 (t-test)
Purpose			
Cancer surveillance or screening	20	24	0.0151 (χ^2-test)
Positive fecal accult blood test or rectal bleeding	10	7	
Inflammatory bowel disease	38	13	
Examinal frequency			
First time	9	10	0.0012 (Mann-Whitney test)
Second time	7	8	
Third time	8	13	
Over four times	43	12	

examination. Patients did not choose the cleansing regimen. The PEG-Asc group included 68 patients and the PEG group included 44 patients. The 2 groups were similar in age, sex, and total examination time. Insertion time was significantly reduced in the PEG-Asc group. In the PEG-Asc group, there were more IBD follow-up patients and patients who underwent a multiple examination than in the PEG group (Table 2).

Evaluation of bowel cleansing by endoscopists

From the cecum to the ascending colon, adequate bowel preparation rates were 96% in the PEG-Asc group and 81% in the PEG group, with the cleansing score in the PEG-Asc group being significantly better than in the PEG group (P=0.0201). On the other hand, the cleansing rates for the transverse colon (PEG-Asc 99% *vs.* PEG 90%), descending colon (97% *vs.* 95%), sigmoid colon (99% *vs.* 93%), and rectum (99% *vs.* 93%) did not differ significantly between these 2 groups (Figure 2A).

Evaluation of endoscopic images

As stated above, endoscopic images were evaluated by a second independent endoscopist (blinded investigator). Adequate bowel preparation rates were not significantly different between the PEG-Asc and PEG groups in any segment of the colon (79% *vs.* 82% in the ascending colon, 88% *vs.* 98% in the transverse colon, 97% *vs.* 100% in the descending colon, 99% *vs.* 100% in the sigmoid colon, and 97% *vs.* 100% in the rectum) (Figure 2B). Because there was a difference in the number of IBD patients in the 2 groups, which could bias the results, we performed a sub-analysis excluding all IBD patients and found no significant between-group differences in cleansing of each segment according to the judgment of the endoscopists who performed the procedure and the second endoscopist who evaluated the endoscopic images.

Patients' acceptance and tolerance of the 2 bowel preparation reagents

Figure 3A shows that with regard to the ease of ingestion of the bowel preparation, a greater fraction of patients in the PEG-Asc group rated the reagent as "very easy" or "easy" to ingest than patients in the PEG group: 40% *vs.* 23% (N.S.). Further, Figure 3B shows that with regard to fluid volume, 33% of patients in the PEG group reported that the ingested volume was too large, compared with 5% in the PEG-Asc group (P<0.001).

Patient preference

In the PEG-Asc group, 86% of patients preferred to receive the same preparation in the future (34% strongly hoped and 52% hoped) compared with 47% of the patients in the PEG group (12% strongly hoped and 35% hoped) (P<0.001). Overall, the distributions of ratings of acceptability and tolerability for PEG-Asc were significantly better than for PEG regardless of the difference in fluid volume (Figure 3C).

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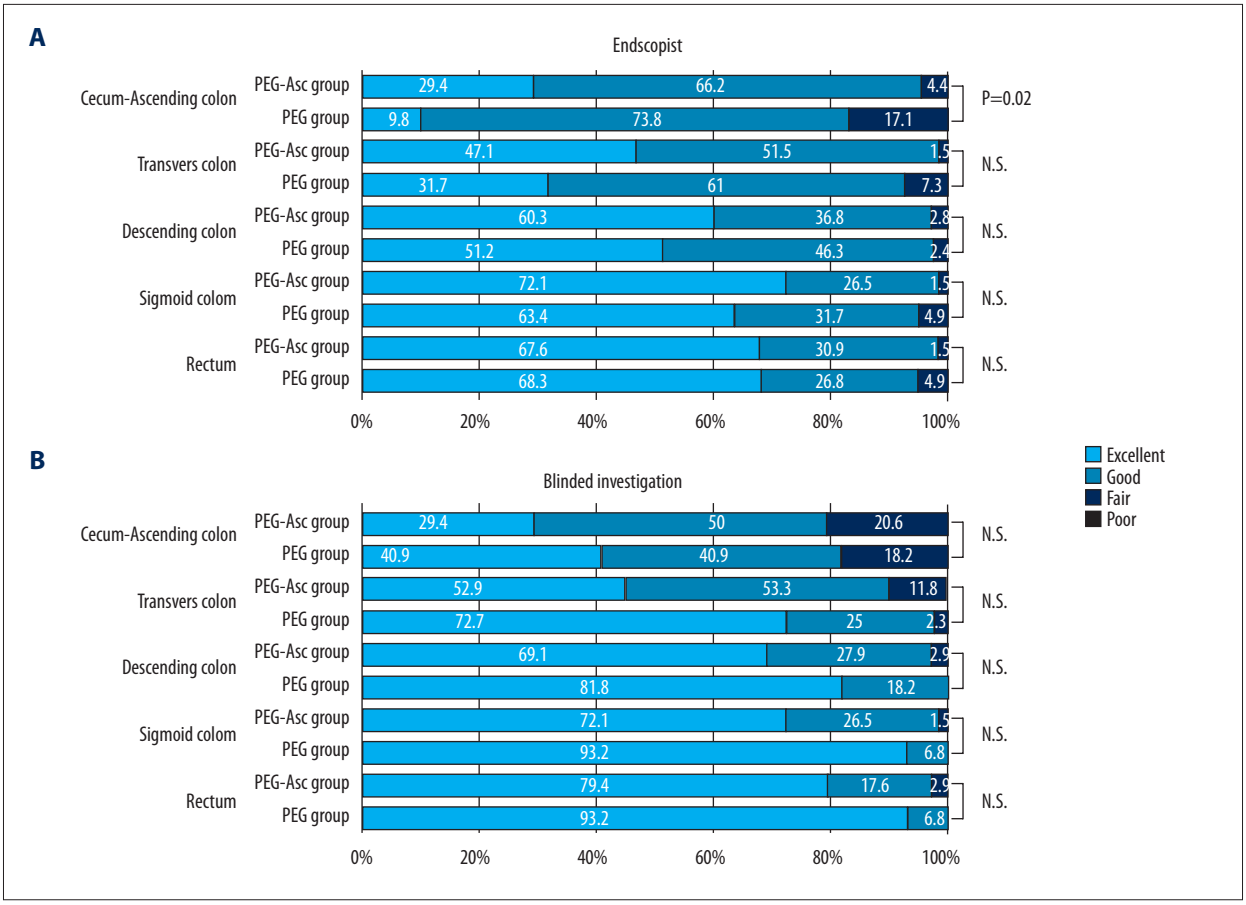

Figure 2. (**A, B**) Efficiency of bowel cleansing in patients undergoing colonoscopy. Colon cleansing was evaluated by endoscopists and a blinded investigator. For the colon-cleansing effect in the cecum-ascending colon, PEG-Asc was rated as superior to PEG. There were no significant differences in the other segments between the 2 regimens.

Safety

No adverse event requiring medical intervention occurred in either group. The PEG-Asc group included fewer patients with an adverse event than the PEG group (P<0.05) (Figure 3D). The most common adverse events were "nausea", "vomiting", "abdominal pain", "abdominal distension", "dry mouth feeling" and "a languorous feeling". Among these, "nausea and vomiting" (13.2% *vs.* 40.9%; p<0.01), "abdominal pain" (0.0% *vs.* 9.1%; p<0.05), and "abdominal distension" (0.0% *vs.* 11.4%; p<0.01) were more common in the PEG group than in the PEG-Asc group. On the other hand, "dry mouth feeling" (11.8% *vs.* 0.0%; P<0.05) and "a languorous feeling" (4.4% *vs.* 0.0%; N.S.) were more common in the PEG-Asc group than in the PEG group.

ADR

The ADR was examined only among patients who did not have IBD [14]. The PEG-Asc group had a similar ADR compared to the PEG group, suggesting that similar degrees of visualization were ultimately achieved with similar procedure times (33.3% *vs.* 25.8%; N.S.).

Safety for UC evaluation

With respect to mean value of the clinical activity index for the evaluation of patients with UC among patients with a previous history of UC, there was no significant difference between before and after colonoscopy (N.S.). Therefore, we can infer that PEG-Asc had no influence on the mucosal inflammation status of UC patients.

Discussion

Proper and safe bowel cleansing is needed for optimal outcomes of colonoscopy. Poor or incomplete bowel cleansing due to intolerance of the cleansing reagent is not only detrimental in that patients are exposed to the risk of repeated unnecessary colonoscopies, but also presents a danger in terms of missed lesions or polyps [15,16]. Clinical experience indicates

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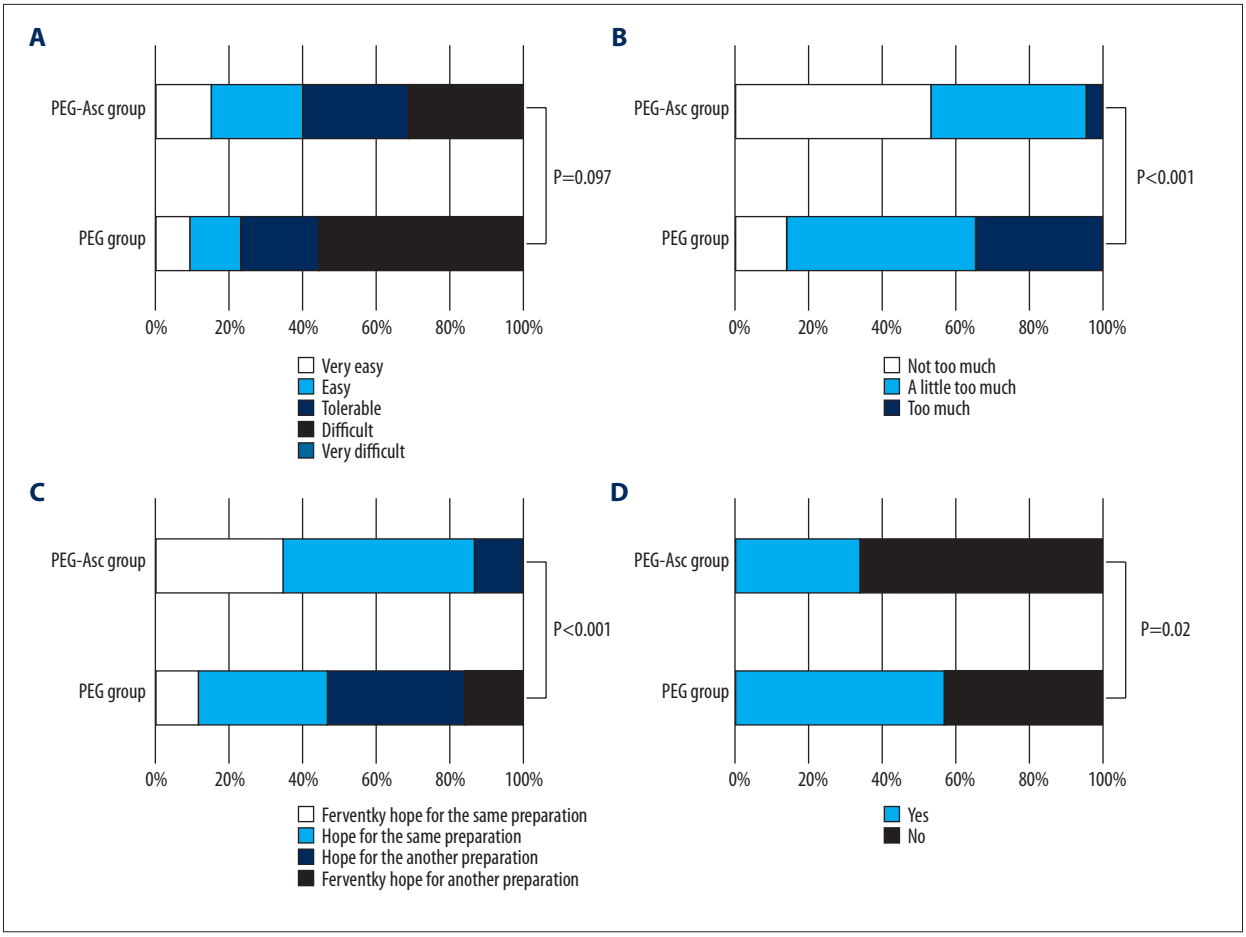

Figure 3. Outcomes of assessments of acceptability, tolerability, and safety. (**A**) Ease of ingestion of bowel preparation. (**B**) Feedback on fluid volume. (**C**) Preference for future colonoscopy. (**D**) Adverse events.

that patients may respond unfavorably to the taste, odor, or the large volume of cleansing reagents that need to be ingested prior to colonoscopy. This may lead to low patient compliance and lack of acceptance of surveillance colonoscopy. PEG solution has been used worldwide because of its proven efficacy and favorable safety profile [17–19]. Since 2013, PEG-Asc has been available in Japan. However, the standard regimen requires drinking a large volume of PEG-Asc, often 2 L, over a short period of time. The cleansing procedure in Japan is as follows: patients are instructed to drink the first 1 L of PEG-Asc slowly over a period of 1 h, followed by drinking 0.5 L of clear fluids; after that, they are instructed to begin drinking 0.5 L of PEG-Asc, followed by 0.25 L of clear fluid. Then, if clear bowel excretion is not confirmed, they are finally instructed to drink 0.5 L of PEG-Acs and 0.25 L of clear liquid (all at a rate of 0.25 L every 15 min). This regimen was noted to be poorly tolerated and was reported to be overly complicated for many patients [20].

To the best of our knowledge, this is the first study to evaluate the clinical relevance of use of 1 L PEG-Asc for bowel cleansing prior to colonoscopy without food restriction on the day before the examination. It was reported that co-administration of sennoside and mosapride with L-NaP tablets has allowed not only a reduction in the clear fluid volume without decreasing cleansing efficiency, but also produced better patient acceptability and tolerability [12]. Based on these results, we co-administered sennoside and mosapride in our alternate regimen. Other studies have shown the efficacy of modified versions of bowel cleansing regimens. One study indicated the efficacy of an alternate regimen of 0.5 L of PEG-Asc followed by 0.25 L of clear fluids, repeated 3 times, in comparison with the standard regimen under the same conditions of a low-residue diet and sodium picosulfate hydrate on the day before colonoscopy [11]. Their regimen reduced the requirement of intake of the first 1 L of PEG-Asc at the same time. These results are good news for patients who have difficulty drinking 1 L of PEG-Asc. However, the entire fluid intake, including clear water, was 2.25 L, and there was also a food restriction, so the overall fluid intake is greater than 2 L. Our regimen compared favorably with their regimen in the successful cleansing rate (75.1% *vs.* 92.1%) and there was no food restriction

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on the day before colonoscopy, even though the volume of cleansing fluid was lower.

Generally speaking, requiring patients to drink a large volume of fluid contributes to lower tolerability and compliance. Accordingly, we considered that there was a need to reduce the fluid volume to improve acceptability and tolerability without compromising the cleansing effect. Our alternate regimen seems to have accomplished this aim. In the present study, we found that a 1-L PEG-Asc preparation had a similar bowel-cleansing efficacy to that of a PEG-based preparation, but with better tolerability. We also focused on symptom flares in patients with UC after colonoscopy, because such symptom flairs after this examination have been experienced. Our present study found no exacerbation of UC after colonoscopy that appeared to be related to the examination. Therefore, our alternate regimen appears to be safe for UC patients.

The ADR is considered one of the most important quality indicators for colonoscopy [21]. In our study, there was no significant difference in the ADR between the PEG group and PEG-Asc group. An ADR >20% satisfies the benchmark for screening colonoscopy in the current literature [22]. Since the ADR has been shown to be an important measure of the ability of colonoscopy to decrease the future incidence and mortality from CRC [21], the finding of the similarity of ADR between the 2 groups is certainly reassuring.

Altogether, low volume of fluid is administered in the PEG-Asc group, whereas larger volume is used in the PEG group. Although, there is no advantage of the former preparation over the latter with regard to such important issues as colon cleansing and adenoma detection rate, the former preparation is better tolerated compared to the latter. As a result, the number of surveillance colonoscopies could increase with better survival rate in CRC.

There are a few limitations of this study. First, this study involved a small number of ambulatory patients referred to a single hospital. Thus, our patient population may not be representative of the community setting. Further larger studies are warranted to fully evaluate the colon-cleansing effect and acceptability of PEG-Asc. The second limitation of this study is that in both groups there were only a few patients with severe constipation. For patients with severe constipation, low-dose PEG-Asc may not always be adequate. We suggest that taking a full dose of bowel preparation from the beginning should be recommended for patients with severe constipation. The third limitation is that this study has done only among Japanese patients. The colonoscopy preparation varies in particular countries depending on body dimensions or eating habit. Therefore, this result might not always apply in countries other than Japan. Finally, there was a bias in the patients' background and examination frequency. Thus, a comparison was made among non-IBD patients, and we showed there was no significant difference. In respect to examination frequency, significantly more patients had undergone colonoscopy more than 4 times in the 1-L PEG-Asc group than in the PEG group; therefore, we should regard both their opinions and conditions as more important than those of patients undergoing a single colonoscopy.

Conclusions

In conclusion, 1-L PEG-Asc and 2-L PEG preparation are clinically equivalent with respect to cleansing efficacy, including ADR, but the 1-L PEG-Asc regimen had better tolerability profiles without food restriction. We also suggest that the 1-L PEG-Asc preparation does not seem to influence the mucosal inflammation status of UC patients. However, limitations may apply in using the 1-L PEG-Asc preparation in patients with severe constipation. With these restrictions in mind, these results support the recommendation of a 1-L PEG-Asc regimen as a valid regimen in compliant patients with a previous history of inadequate bowel preparation.

Conflicts of interest.

None.

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