

Comparing 1-L and 2-L Polyethylene Glycol with Ascorbic Acid for Small Bowel Capsule Endoscopy: A Randomized Controlled Trial

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Sang Pyo Lee ORCID https://orcid.org/0000-0002-4495-3714 E-mail ultra_pyo@hanmail.net **Background/Aims:** Small bowel capsule endoscopy (SBCE) has become the standard for initial evaluation in the diagnosis of small bowel lesions. Although optimal visualization of the mucosa is important, patients experience difficulty in consuming a large volume of bowel preparation agents. This study aimed to compare the efficacy and safety of 1-L polyethylene glycol (PEG) with ascorbic acid (AA) and 2-L PEG with AA.

Methods: In this prospective, multicenter, non-inferiority study, patients who received SBCE were randomly assigned to consume 1-L PEG with AA or 2-L PEG with AA for small bowel preparation. The primary outcome was adequate small bowel visibility quality (SBVQ). The secondary outcomes included diagnostic yield, cecal complete rate, and adverse events.

Results: One hundred and forty patients were enrolled in this study, 70 patients per group. In the per-protocol analysis, there were no significant differences in the adequate SBVQ rate (94.0% vs 94.3%; risk difference, -0.3; 95% confidence interval, -8.1 to 7.6; p=1.000), diagnostic yield rate (49.3% vs 48.6%, p=0.936), or cecal complete rate (88.1% vs 92.9%, p=0.338) between the 1-L PEG with AA group and 2-L PEG with AA group. The incidence of adverse events did not differ significantly between the groups (12.9% vs 11.9%, p=0.871).

Conclusions: One liter-PEG with AA is not inferior to 2-L PEG with AA in terms of adequate SBVQ for SBCE. One liter-PEG with AA can be recommended as the standard method for bowel cleansing for SBCE. (Gut Liver 2025;19:87-94)

Key Words: Capsule endoscopes; Video capsule endoscopes; Bowel preparation solutions; Polyethylene glycols

INTRODUCTION

Small bowel capsule endoscopy (SBCE) is a noninvasive diagnostic technique for visualizing the small bowel mucosa. It is currently a useful method for the initial evaluation of suspected small bowel bleeding and various small bowel diseases.^{1,2}

As with other endoscopic examinations, the quality of SBCE is important for visualizing the mucosa. In particular,

bile or slurry can significantly impact small bowel visibility quality (SBVQ) and diagnostic yield (DY) in SBCE observing long small bowel transit time (SBTT). Recent guidelines from the European Society of Gastrointestinal Endoscopy recommend that patients take 2 L of polyethylene glycol (PEG) before SBCE to improve visualization; however, evidence regarding completion rate and DY is lacking.³ The American Gastroenterological Association guidelines do not recommend specific types of bowel preparation but ac-

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knowledge that bowel preparation improves visualization.⁴ A small volume of bowel preparation agent can enhance patient convenience, improve compliance, mitigate vomiting, and reduce adverse events such as Mallory-Weiss tear.⁵⁻⁷

In Korean SBCE guidelines, the administration of 2-L PEG and ascorbic acid (AA) is recommended.⁸ However, there have been relatively few studies on the efficacy and safety of 1-L PEG with AA, which is widely used in colon preparation, as a SBCE preparation.^{9,10} Our study aimed to compare 1-L PEG with AA with 2-L PEG with AA for SBCE.

MATERIALS AND METHODS

1. Study design

This was a prospective, randomized, controlled, non-inferiority, multicenter trial. The study was conducted at four Hallym University-affiliated hospitals (Dongtan Sacred Heart Hospital, Kangnam Sacred Heart Hospital, Kangdong Sacred Heart Hospital, and Chuncheon Sacred Heart Hospital). Patients undergoing SBCE for SB evaluation were randomly assigned to two groups, 1-L PEG with AA and 2-L PEG with AA, as bowel preparation methods. All procedures were conducted in accordance with the Declaration of Helsinki, and the study protocol was approved by the Institutional Review Board of Hallym University School of Medicine (IRB number: HDT 2020-06-019-002). All patients provided written informed consent before participating in the study. The study was reported following the CONSORT guidelines and registered with the International Clinical Trials Registry Platform (KCT0005347).

2. Study participants

Participants were prospectively recruited from four Hallym University-affiliated hospitals from August 2020 to January 2024. Patients were excluded if they: (1) had undergone small bowel resection or had a history of gastrointestinal surgery; (2) were using antispasmodic, analgesic, or prokinetic agents; (3) had a history of diarrhea, thyroid disease, diabetes mellitus, congestive heart failure, or chronic renal failure; (4) had a known or suspected small bowel obstruction or stricture; (5) had a swallowing disorder, a PEG allergy, were pregnant; or (6) were under 20 or over 90 years of age, or declined to sign the consent form. The baseline characteristics of the eligible participants including demographic data were collected.

3. Interventions

Eligible patients were admitted to hospital and randomly assigned to receive either a 1 L dose of PEG with AA (Cleanviewal[®], Taejoon Pharmaceutical Co., Seoul, Korea) or a 2 L dose of PEG with AA (Coolprep[®], Taejoon Pharmaceutical Co.). Blood tests and radiographs were conducted on the day before and day after SBCE to check for adverse events. All the procedures were performed using a SBCE system (MiroCam[®], IntroMedic, Seoul, Korea; PillCam[™] SB 3, Medtronic, Minneapolis, MN, USA).

The patients in the 1-L PEG with AA group were in-

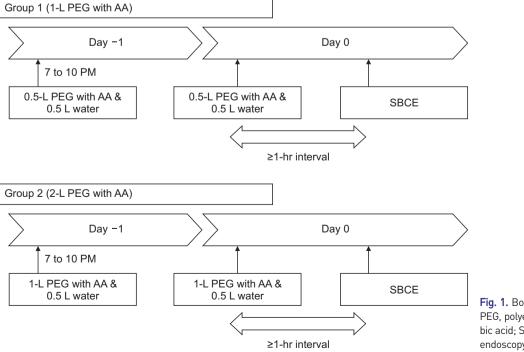


Fig. 1. Bowel preparation protocol. PEG, polyethylene glycol; AA, ascorbic acid; SBCE, small bowel capsule endoscopy. structed to drink 500 mL of 1-L PEG with AA, and then consume 500 mL of water from 7 to 10 PM. On the inspection day, they were instructed to consume 500 mL of 1-L PEG with AA and a further 500 mL of water 1 hour before SBCE (Fig. 1).

In the 2-L PEG with AA group, the patients were instructed to drink 1 L of 2-L PEG with AA and drink 500 mL of water from 7 to 10 PM. On the inspection day, they were instructed to finish ingestion 1 L of 2-L PEG with AA and 500 mL of water 1 hour before SBCE.

The day before the procedure, all patients abstained from solid food. They were allowed to have white porridge around 5 PM. SBCE was performed within 1 hour after bowel preparation. SBCE results were interpreted by experts who has been interpreting SBCE for more than 5 years.

4. Outcome parameters

The primary outcome was adequate SBVQ, categorized as either excellent or good SBVQ. As there is no standardized scoring system for SBVQ in SBCE, we used the assessment method employed in previous studies, in which the intestinal mucosa is defined as "clean" if less than 25% of the mucosal surface is covered by contaminants. "Excellent" is then defined as at least 90% of the small bowel mucosa clean; "good" as at least 75% to 90% of the small bowel mucosa clean, and "fair" as at least 50% to 75% of the overall small bowel mucosa clean; "poor" is defined as at least 25% to 50% of the overall small bowel mucosa clean.^{11,12}

Secondary outcomes were DY, SBTT, cecal complete rate (CR), and adverse events. DY was considered "positive" if the SBCE findings were able to account for a patient's signs or symptoms and help in planning further management, or were confirmed by further examinations. SBCE findings consisted of: erosions or ulcers, petechiae or red spots, varix, lymphangiectasia, angiodysplasia, small bowel tumor, subepithelial lesion, and diverticulum. Small bowel bleeding grade was classified as: grade 1, active bleeding with clear focus, grade 2, active bleeding with obscure focus, grade 3, old blood clot, and grade 4, no evidence of gastrointestinal bleeding. SBTT was defined as the time between the first duodenal image and the first cecal image. Cecal CR was defined as whether SBCE reached the cecum for each patient. All patients were checked for adverse events after bowel preparation. They were also asked whether they had experienced nausea, vomiting, dizziness, abdominal pain, or bloating. Previous studies have reported that there was no significant difference in DY between SBCE devices.¹³ In this study, there was no adjustment between MiroCam and PillCam.

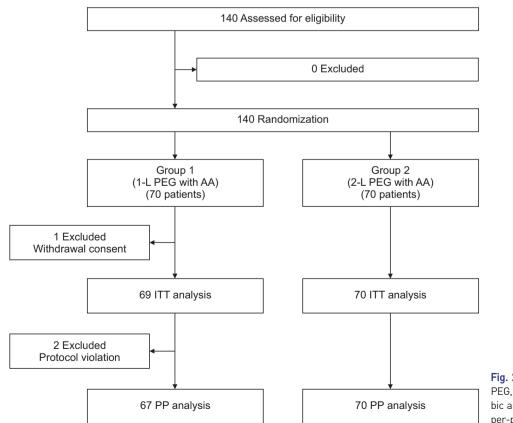


Fig. 2. Flow diagram of the study. PEG, polyethylene glycol; AA, ascorbic acid; ITT, intention-to-treat; PP, per-protocol.

5. Calculation of sample size

Assuming an overall cleansing success rate of 90% for each group, a non-inferiority margin of 15%, an alpha level of 2.5% (two-sided), and a drop rate of 15%, a sample size of 70 patients per group was needed to provide a power of at least 80% for demonstrating the non-inferiority of the 1-L PEG with AA group. Thus, the total number of subjects needed was calculated to be 140.

6. Randomization and monitoring

The stratified permuted block randomization method was used. A research assistant who did not participate in the clinical procedures generated the randomization sequence, and the information was concealed until the intervention group had been assigned at the time of preparation. Additionally, the endoscopists did not know which group a patient was in when interpreting the endoscopic findings.

7. Statistics

The primary outcome was analyzed by per-protocol (PP) analysis. Categorical outcomes are presented as relative risks and risk differences with 95% confidence intervals (CIs). Continuous outcomes are presented as mean differences with 95% CIs. p<0.05 was considered to indicate significance. Non-inferiority of the 1-L PEG with AA group (henceforth referred to as group 1) to the 2-L PEG with AA group (henceforth referred to as group 2) was determined if the lower limit of its two-sided 95% CI was larger than the non-inferiority margin of -15%. Therefore, non-inferiority would be established if the lower boundary of the 95% CI for the between-group difference was not less than 0.85. All statistical analyses were carried out with R Statistical Software (version 4.3.1; R Core Team, 2023, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

1. Baseline characteristics

A total of 140 patients were initially included in the study between October 2020 and January 2024 (Fig. 2). Finally, 140 patients were randomly allocated to the 1-L PEG with AA (group 1) and 2-L PEG with AA group (group 2). One patient in group 1 withdrew consent and was excluded from the intention-to-treat analysis, and two patients were excluded from the PP analysis due to protocol violations. Finally, PP analysis was conducted on 67 and 70 patients, respectively, in groups 1 and 2.

Table 1 shows the baseline characteristics of the patients in the two groups. Median ages (interquartile range) were 59 years (38 to 67) and 52 years (38 to 69) in groups 1 and 2, respectively, and there were 67.2% and 62.9% males, respectively, in the two groups. There were no significant differences between the groups in use of alcohol, smoking, underlying disease, use of medication, or indications for SBCE.

2. Clinical outcomes

SBVQ was classified as excellent in 44.8 % and 48.6% of groups 1 and 2, respectively, good in 49.2% and 45.7%, and fair in 6.0% and 5.7%, and no patients were classified as poor in either group (p=0.923). In the PP analysis, adequate SBVQ rates were similar in the two groups (94.0% vs 94.3%; risk difference, -0.3; 95% CI, -8.1 to 7.6; p=1.000) (Fig. 3). This indicates non-inferiority of

Table 1. Baseline Characteristics

Characteristic	Group 1 (n=67)	Group 2 (n=70)	p-value
Age, yr	59 (38–67)	52 (38–69)	0.995
Male sex	45 (67.2)	44 (62.9)	0.597
Alcohol			0.835
None	35 (52.2)	36 (51.4)	
≤4 weekly	30 (44.8)	30 (42.9)	
≥5 weekly	2 (3.0)	4 (5.7)	
Smoking			0.615
Never	45 (67.2)	42 (60.0)	
Cessation	14 (20.9)	16 (22.9)	
Current	8 (11.9)	12 (17.1)	
Underlying disease			
Hypertension	29 (43.3)	25 (35.7)	0.365
Dyslipidemia	19 (28.4)	13 (18.6)	0.176
COPD	4 (6.0)	2 (2.9)	0.434
Stroke	4 (6.0)	4 (5.7)	1.000
Liver cirrhosis	1 (1.5)	2 (2.9)	1.000
Ischemic heart disease	4 (6.0)	6 (8.6)	0.745
Medication			
Aspirin	9 (13.4)	8 (11.4)	0.722
Warfarin	0	1 (1.4)	1.000
Clopidogrel	4 (6.0)	4 (5.7)	1.000
DOAC	7 (10.4)	3 (4.3)	0.201
NSAIDs	4 (6.0)	5 (7.1)	1.000
Indication			0.651
Suspected gastrointestinal bleeding	36 (53.7)	34 (48.6)	
Unexplained chronic abdominal pain	16 (23.9)	14 (20.0)	
Abnormal findings on diagnostic imaging	3 (4.5)	6 (8.6)	
Evaluation of known or suspected disease	12 (17.9)	16 (22.9)	

Data are presented as median (interquartile range) or number (%). Group 1 is 1-L PEG with AA and Group 2 is 2-L PEG with AA.

PEG, polyethylene glycol; AA, ascorbic acid; COPD, chronic obstructive pulmonary disease; DOAC, direct oral anticoagulant; NSAID, nonsteroidal anti-inflammatory drug. group 1 with respect to group 2 because the CIs did not include the predefined inferiority margin. DYs for the two groups were 49.3 % versus 48.6 % (p=0.936), mean SBTTs (interquartile range) were 330 minutes (247 to 420) and 307 minutes (230 to 397) (p=0.778), and cecal CRs were 88.1% and 92.9% (p=0.338), respectively. There were no significant differences between the groups with respect to SBCE findings (ulcer or erosion, 52.2% vs 50.0%, p=0.793;

red spot or petechiae, 41.8% vs 41.4%, p=0.966; varix, 0% vs 0%; lymphangiectasia, 3.0% vs 0%, p=0.237; angiodysplasia, 3.0% vs 1.4%, p=0.614; small bowel tumor, 6.0% vs 4.3%, p=0.714; subepithelial lesion, 0% vs 1.4%, p=1.000; diverticulum, 0% vs 1.4%, p=1.000) and small bowel bleeding grade (p=0.871). Adverse events are shown in Table 2. Nausea, abdominal pain, bloating, and electrolyte imbalance were reported in 1.5%, 0%, 9.0%, and 1.5%, respec-

Population	(Group 2 (2-L PEG with AA) tients (%)		R	tisk difference (95% CI) in adequate SBVQ
			ninferiori margin	ty Treatment differen	се
PP analysis	63/67 (94.0%)	66/70 (94.3%)			-0.3 (-8.1 to 7.6)
ITT analysis	65/69 (94.2%)	66/70 (94.3%)			-0.1 (-7.8 to 7.6)
			-15	0	10

Fig. 3. Treatment differences between bowel preparation with 1-L PEG AA and 2-L PEG AA. PEG, polyethylene glycol; AA, ascorbic acid; SBVQ, small bowel visibility quality; CI, confidence interval; PP, perprotocol; ITT, intention-to-treat.

Table 2. Study Outcomes for the Per-Protocol Population

N/ 11	Per-protocol analysis			Intention-to-treat analysis		
Variable	Group 1 (n=67)	Group 2 (n=70)	p-value	Group 1 (n=69)	Group 2 (n=70)	p-value
Adequate SBVQ	63 (94.0)	66 (94.3)	1.000	65 (94.2)	66 (94.3)	1.000
SBVQ			0.923			0.888
Excellent	30 (44.8)	34 (48.6)		30 (43.5)	34 (48.6)	
Good	33 (49.2)	32 (45.7)		35 (50.7)	32 (45.7)	
Fair	4 (6.0)	4 (5.7)		4 (5.8)	4 (5.7)	
Poor	0	0		0	0	
Diagnostic yield	33 (49.3)	34 (48.6)	0.936	33 (47.8)	34 (48.6)	0.930
SBCE finding						
Ulcer or erosion	35 (52.2)	35 (50.0)	0.793	35 (50.7)	35 (50.0)	0.932
Red spot or petechiae	28 (41.8)	29 (41.4)	0.966	28 (40.6)	29 (41.4)	0.919
Varix	0	0		0	0	
Lymphangiectasia	2 (3.0)	0	0.237	2 (2.9)	0	0.245
Angiodysplasia	2 (3.0)	1 (1.4)	0.614	2 (2.9)	1 (1.4)	0.620
Small bowel tumor	4 (6.0)	3 (4.3)	0.714	4 (5.8)	3 (4.3)	0.718
SEL	0	1 (1.4)	1.000	0	1 (1.4)	1.000
Diverticulum	0	1 (1.4)	1.000	0	1 (100)	1.000
SBB			0.871			0.827
Grade 1	4 (6.0)	5 (7.1)		4 (5.8)	5 (7.1)	
Grade 2	1 (1.5)	1 (1.4)		1 (1.4)	1 (1.4)	
Grade 3	3 (4.5)	6 (8.6)		3 (4.3)	6 (8.6)	
Grade 4	59 (88.0)	58 (82.9)		61 (88.5)	58 (82.9)	
SBTT	330 (247–420)	307 (230–397)	0.778	330 (245–420)	307 (230–397)	0.415
Cecal CR	59 (88.1)	65 (92.9)	0.338	61 (88.4)	65 (92.9)	0.367
Adverse event	8 (11.9)	9 (12.9)	0.871	8 (11.6)	9 (12.9)	0.820
Nausea	1 (1.5)	2 (2.9)	1.000	1 (1.4)	2 (2.9)	1.000
Abdominal pain	0	3 (4.3)	0.245	0	3 (4.3)	0.245
Bloating	6 (9.0)	5 (7.1)	0.696	6 (8.7)	5 (7.1)	0.735
Electrolyte imbalance	1 (1.5)	0	0.489	1 (1.4)	0	0.496

Data are presented as number (%) or median (interquartile range). Group 1 is 1-L PEG with AA and Group 2 is 2-L PEG with AA. PEG, polyethylene glycol; AA, ascorbic acid; SBVQ, small bowel visibility quality; SBCE, small bowel capsule endoscopy; SEL, subepithelial lesion; SBB, small bowel bleeding; SBTT, small bowel transit time; CR, complete rate. tively, of the group 1 patients, and 2.9%, 4.3%, 7.1%, and 0%, respectively, of the group 2 patients. Overall adverse events were 11.9% vs 12.9% (p=0.871), respectively.

In the intention-to-treat analysis, adequate SBVQ rates were similar in the two groups (94.2 % vs 94.3 %; risk difference, -0.1; 95% CI, -7.8 to 7.6) (Fig. 3). These CIs again did not include the non-inferiority margin. There were also no significant differences between the groups with respect to other outcomes and adverse events (Table 2).

DISCUSSION

In the present study, we found that the frequency of adequate SBVQ was similar in the two groups. Therefore, we conclude that the use of 1-L PEG with AA for bowel preparation in SBCE is non-inferior to the use of 2-L PEG with AA. Additionally, there were no significant differences between the two groups in SBVQ, DY, cecal CR, SBTT, and adverse events.

Clear visualization of the mucosa is crucial in gastrointestinal endoscopy. Currently, there is debate over bowel preparation for SBCE,^{9,10,14-20} although the American Gastroenterological Association and European Society of Gastrointestinal Endoscopy clearly acknowledge its benefit for mucosal visualization.^{3,4} Several studies have reported improved DY rates with bowel preparation in SBCE,^{16,17,20} and DY is a clinically relevant outcome for bowel preparation. Furthermore, SBCE has limited insurance coverage and is relatively expensive compared to other gastrointestinal endoscopic procedures in Korea, so that missing a diagnosis due to inadequate bowel preparation is a significant burden on the patient. In our study, the use of bowel preparation agents resulted in high rates of adequate SBVQ and DY in both groups.

Recently, Choi *et al.*²¹ reported that SBVQ depends on the timing of SBCE following bowel preparation: SBVQ was higher when SBCE was performed within 6 hours of the completion of bowel preparation, and other studies have also reported that DY tends to be higher when SBCE is performed as soon as possible after bowel preparations.^{11,19,22} Clear visualization of the small bowel mucosa can improve the DY of SBCE since a high Boston Bowel Preparation Scale score leads to a high adenoma detection rate in colonoscopy. In our study, SBCE was performed within 1 hour of completion of bowel preparation. This probably contributed to the high DY compared to other studies.

In our study, the frequency of adverse events was low compared to other studies.^{10,23} We speculate that this was because all patients were hospitalized and received con-

tinuous guidance on the bowel preparation protocol from medical staff, as well as auxiliary therapy such as intravenous fluids, and they were familiar with the use of bowel preparation agents because colonoscopy is relatively frequently performed in Korea.

Several meta-analyses have shown that there is no significant difference in DY in SBCE depending on the type of bowel preparation.^{18,19} Furthermore, the results of bowel preparation using 2-L PEG are similar to those obtained using 4 L-PEG in terms of SBVQ. To date, meta-analyses have suggested that intake of 2-L PEG before SBCE leads to an improvement in SBVQ.^{16,17,19} Therefore, clinical guidelines recommend 2-L PEG prior to SBCE for better visualization.^{3,8}

Large-volume bowel preparation may decrease compliance with bowel preparation and result in inadequate bowel preparation. Inadequate bowel preparation is also associated with diagnostic failure, unsatisfactory patient experience, inadequate small bowel visualization, and increased medical costs. Just as 2-L PEG has replaced 4-L PEG, we may assume that administering 1-L PEG with AA might further increase patient compliance. However, the use of 1-L PEG might lead to patient non-compliance if adverse events were frequent. In our study, however, 1-L PEG with AA resulted in a similar frequency of adverse events to 2-L PEG with AA. Furthermore, 1-L PEG with AA had similar outcomes to 2-L PEG with AA in terms of adequate SBVQ, DY, cecal CR, and SBTT.

Our study has several limitations. First, simethicone was not used. A study evaluating the efficacy of simethicone found a significant improvement in visualization quality compared to overnight fasting or laxative use alone.²⁴ This is probably because simethicone prevents the formation of bubbles that impair visualization. However, in our study, neither group used simethicone, so SBVQ or DY may have been underestimated. Second, although SBVQ is widely used, it has not been as well validated as the Boston Bowel Preparation Scale, and there is heterogeneity in evaluating SBVQ across studies.^{11,12,14,25,26} This may make direct comparison with other studies difficult. Third, while it is presumed that the good results obtained were the consequence of performing the SBCE within 1 hour after completion of bowel preparation, further study is needed to compare different time intervals to confirm this inference.

In conclusion, our study demonstrates that 1-L PEG with AA is non-inferior in terms of adequate SBVQ compared to 2-L PEG with AA. The use of 1-L PEG with AA may improve patient compliance while being as effective as 2-L PEG with AA in preparing the SB. Therefore, administering 1-L PEG before SBCE may be preferable to administering 2-L PEG with AA.

CONFLICTS OF INTEREST

This research was supported by a grant from Taejoon Pharmaceutical Co., Republic of Korea (TJG-2004-501). Except for that, no potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Study concept and design: S.P.L. Data acquisition: C.K.O., S.P.L., J.G.L., Y.J.Y., S.I.S., C.S.B., Y.J.K., W.G.S., J.B.K., H.J.J., S.H.K., G.H.B. Data analysis and interpretation: C.K.O., S.P.L. Drafting of the manuscript: C.K.O., S.P.L. Study supervision: S.P.L. Critical revision of the manuscript for important intellectual content: C.K.O., S.P.L. Statistical analysis: S.P.L. Obtained funding: S.P.L. Approval of final manuscript: all authors.

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