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Validation of same-day bowel preparation regimen using 4L polyethylene glycol

Comparison of morning and afternoon colonoscopy

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Abstract

A split-dose regimen is the recommended method of bowel preparation for colonoscopy. However, for colonoscopy performed in the afternoon, same-day preparation is recommended rather than a split-dose regimen. No study has compared the efficacy of same-day bowel-cleansing for morning colonoscopy (MC) and afternoon colonoscopy (AC). The aims of this study were to evaluate the bowel-cleansing efficacy, adverse events, and patient tolerability of same-day bowel preparation for colonoscopy using 4L polyethylene glycol (PEG).

The medical records of consecutive patients who underwent colonoscopy at our healthcare center over 3 months were retrospectively reviewed. Colonoscopy was performed between 10:00 and 16:00. Study subjects were assigned to the MC or AC group according to their colonoscopy start time (MC group, before 12:00; AC group, after 12:00). Study subjects were instructed to drink 500-mL PEG every 15 minutes. In the MC group, bowel cleansing was started at 05:00 and finished at 07:00. For the AC group, 2L PEG was consumed from 07:00, and the remaining 2L PEG was started 3 hours before colonoscopy. The composite safety profile included vital signs, laboratory test results, and questionnaire findings. Laboratory testing of subjects and completion of the questionnaire were performed before colonoscopy. The questionnaire asked about adverse events and tolerability of the bowel cleansing regimen. Bowel-cleansing efficacy was assessed using the Boston bowel preparation scale (BBPS). Bowel-cleansing efficacy, tolerability, and safety profile were compared between the 2 groups.

Two hundred and ninety-one subjects were included (MC group, 169; AC group, 122).The BBPS did not differ between the 2 groups (7.3 ± 0.8 vs. 7.3 ± 0.8, $P = .68$). There were no instances of electrolyte imbalance or hemodynamic instability in either group. The tolerability of the bowel-cleansing regimen did not differ between the 2 groups ($P = .59$).

The bowel-cleansing efficacy, safety profile, and patient tolerability of MC and AC were comparable. A same-day dose of 4L PEG is a feasible bowel preparation method.

Abbreviations: AC = afternoon colonoscopy, ADR = adenoma detection rate, BBPS = Boston Bowel Preparation Scale, BUN = blood urea nitrogen, EGD = esophagogastroduodenoscopy, GI = gastrointestinal, MC = morning colonoscopy, PDR = polyp detection rate, PEG = polyethylene glycol, WBC = white blood cell.

Keywords: boston bowel preparation scale, bowel-cleansing efficacy, colonoscopy, polyethylene glycol, same-day bowel preparation

1. Introduction

Proper bowel cleansing is essential for the precise detection of colorectal neoplasia.[1,2] Poor bowel preparation is associated with a low adenoma detection rate (ADR).[3,4] Reexamination is recommended in patients with poor bowel preparation, which is inconvenient for the patients and increases medical costs.[5] Therefore, proper bowel cleansing of >85% to 90% is a quality indicator for colonoscopy.[6–8]

Polyethylene glycol (PEG) is an osmotic laxative that is widely used in bowel preparation.[9] High volume (4L) PEG shows better bowel-cleansing efficacy than other bowel cleansers.[10,11] PEG can be used safely in patients with comorbidities,[1,11,12] and the European Society of Gastrointestinal Endoscopy guideline recommends 4L PEG for routine bowel preparation.[1]

A split-dose bowel preparation is recommended for proper bowel cleansing.[1,6,13] A split-dose regimen shows better bowel-cleansing efficacy and better ADR than a previous-day regimen.[13–15] For afternoon colonoscopy (AC), a same-day dose is recommended as an alternative to split-dose.[1] A same-day dose of bowel cleanser has several benefits compared with split-dose or previous-day dose: the fasting time is shorter and there is no sleep disturbance, which can be associated with split-dose or previous-day regimens.[13,16]

No previous study has investigated the bowel-cleansing efficacy of a same-day dose of 4L PEG for individuals who undergo colonoscopy in the morning. The aims of the present study were to evaluate the bowel-cleansing efficacy, safety, and patient tolerability of same-day bowel preparation using 4L PEG

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for morning colonoscopy (MC) by comparing it with the same regimen for those undergoing AC.

2. Materials and methods

2.1. Study population and procedure

We retrospectively reviewed the medical records of consecutive patients who underwent screening colonoscopy with or without esophagogastroduodenoscopy (EGD), performed by 3 experienced colonoscopists at the health promotion center of Incheon St. Mary's Hospital, South Korea, between March 2017 and May 2017. All colonoscopy examinations were performed by colonoscopists with patients under conscious sedation using midazolam and pethidine. Individuals who met the following criteria were included: age 35 to 75 years, ingestion of the bowel cleanser on the same-day as the colonoscopy. Exclusion criteria were: age <35 or >75; previous history of bowel resection; patients who were found to have advanced gastrointestinal (GI) cancer at either EGD or colonoscopy; patients who ingested bowel cleanser as a split-dose or 1 day before colonoscopy; and cecal intubation failure.

Study subjects were allocated to the MC or AC group according to their colonoscopy start time (MC group, before 12:00; AC group, after 12:00). Bowel cleansing was done using 4L PEG. One sachet of PEG mixed with 500-mL of water was ingested every 15 minutes. Individuals who were scheduled to receive colonoscopy in the morning (MC group) were instructed to begin ingesting PEG at 05:00 on the day of the colonoscopy and finish the PEG at 07:00. If ingestion was difficult, bowel preparation was finished before 08:00. Individuals in the AC group were instructed to take 2L PEG starting at 07:00 and to finish within 1 hour. After a break, the remaining 2L PEG was ingested starting 3 hours before the scheduled colonoscopy start time. Ingestion of additional water was encouraged until the bowel effluent was clear. Patients were not permitted to consume fibers and seeds for 2 days before colonoscopy. Two days before their colonoscopy, they were reminded by phone of the method of bowel cleansing, the time of their colonoscopy examination, and advised to arrive at the hospital 1 hour before colonoscopy. Up on their arrival, we checked the patients' bowel-cleansing status by asking them about the color of the bowel effluent. If the effluent was turbid or mixed with solid particles, they were instructed to take an additional 500 mL PEG. Colonoscopy was performed between 10:00 and 16:00. Most patients underwent EGD before colonoscopy. Colonoscopy was performed in the left-lateral position. Position change was allowed in cases of difficult insertion. During EGD and colonoscopy, all bowel fluid was suctioned and collected in a bottle. The study protocol was approved by the Institutional Review Board of Incheon St. Mary's Hospital.

2.2. Bowel-cleansing efficacy

The primary endpoint was the bowel cleansing efficacy, assessed using the Boston bowel preparation scale (BBPS).[17] The BBPS score was assessed during withdrawal of the colonoscope, and to allow precise assessment of the BBPS score, bowel fluid suction was not allowed during insertion of the colonoscope. The BBPS score is the sum of the segmental scores. The colon is divided into 3 segments: right colon (cecum and ascending colon); midcolon (hepatic flexure, transverse colon, and splenic flexure); and left colon (descending colon, sigmoid colon, and rectum), and each segment is graded on a 4-point scale: 0, inadequate; 1, poor; 2, good; and 3, excellent. The BBPS score ranges from 0 to 9. Successful cleansing was defined as a score ≥2 for all segments.

2.3. Secondary endpoints: safety, tolerability, and outcome of colonoscopy

The composite safety profile included vital signs, laboratory test results, and questionnaire findings.[18] Vital signs and laboratory parameters included in the health check-up program were checked on the day of colonoscopy. Serum hemoglobin concentration, hematocrit, white blood cell (WBC) count, and concentrations of glucose, sodium, potassium, chloride, calcium, phosphorus, creatinine, and blood urea nitrogen (BUN) were checked. Before the colonoscopy, all study subjects completed a questionnaire about adverse events and the tolerability of the bowel cleanser. The questionnaire contained the following items: overall satisfaction with the bowel cleansing regimen (rated on a 5-point scale [1, very easy; 2, easy; 3, intermediate; 4, difficult; 5, very difficult]); willingness to use the bowel cleansing regimen again; and adverse events during and after the ingestion of the bowel cleanser. The patients used a checklist of possible adverse events to report whether they had experienced any during or after ingestion of the bowel cleanser. Adverse events included on the list were nausea, vomiting, abdominal pain, dizziness, tingling sensation, bloating, and/or any other symptoms.

The outcome and parameters related to the colonoscopy were assessed. Any position change during the colonoscopy was recorded. The volume of water in the stomach and the colon was measured. The polyp detection rate (PDR), ADR, and the number of adenomas per patient were analyzed. The complications of colonoscopy were analyzed.

2.4. Statistical analysis

Continuous variables were expressed as mean ± standard deviation. The demographic characteristics, bowel cleansing efficacy, safety profile, tolerability, and results of endoscopy were compared between the 2 groups. To compare the bowel-cleansing efficacy, the total BBPS, each segmental score, and the cleansing success rate were compared. The success rate for bowel cleansing (%) was calculated as the (number of individuals with successful cleansing)/(number of individuals included in the study) × 100. For this analysis, we used Student t test for continuous variables, and the χ^2 or Fisher exact test for categorical variables. A P value <.05 was considered significant. All statistical analyses were conducted using SAS 9.0 software (SAS Institute, Cary, NC).

3. Results

3.1. Enrollment and demographic characteristics of the study subjects

During the study period, 341 subjects were scheduled to receive colonoscopy. Three subjects (2 in the morning; 1 in the afternoon) were unable to complete the ingestion of PEG. Among 338 subjects who underwent colonoscopy, 47 were excluded for the following reasons: age <35 or >75 (n = 33); previous bowel resection (n = 4); advanced GI cancer (n = 2); ingestion of PEG on the day before the colonoscopy or split-dose regimen (n = 6); cecal intubation failure (n = 2). Finally, 291 subjects were included in this study: 169 in the MC group and 122 in the AC group (Fig. 1). The demographic characteristics of

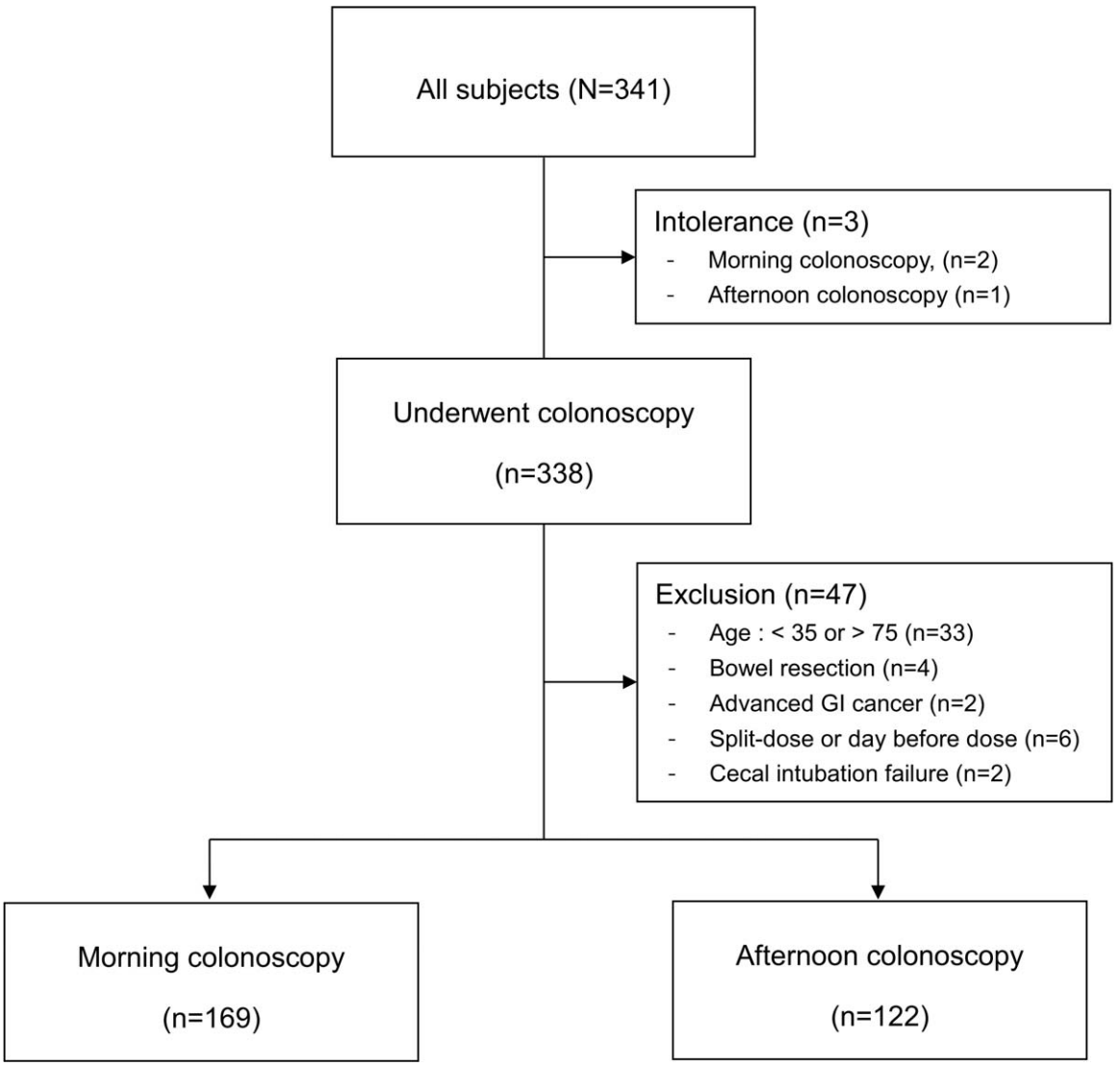

Figure 1. Enrollment of the study subjects.

the 2 groups are shown in Table 1. Sex, age, and body mass index did not differ between the 2 groups. The characteristics that affect bowel-cleansing efficacy (number of defecations, medical history, and surgical history) did not differ between the 2 groups.

3.2. Bowel-cleansing efficacy

A comparison of bowel-cleansing efficacy in the 2 groups is shown in Table 2. The total BBPS score and each segmental score did not differ between the MC group and the AC group (total BBPS score, 7.3 ± 0.8 vs. 7.3 ± 0.8, $P = .68$; right colon, 2.3 ± 0.5 vs. 2.4 ± 0.5, $P = .72$; mid colon 2.8 ± 0.4 vs. 2.8 ± 0.4, $P = .91$; left colon, 2.1 ± 0.3 vs. 2.1 ± 0.3, $P = .74$). The overall regional scores for all patients in the right colon, mid colon, and left colon were 2.3 ± 0.5, 2.8 ± 0.4, and 2.1 ± 0.3, respectively. Mid colon showed better cleansing efficacy than the other segments (all patients: mid colon vs. right colon, $P < .01$; mid colon vs. left colon, $P < .01$). The percentage of successful bowel cleansing in the MC group was 98.8% and that in the AC group was 99.2% ($P = .80$).

3.3. Laboratory testing, adverse events, and tolerability

The results of the laboratory tests are shown in Table 3. The hemoglobin concentration, hematocrit, WBC count, and concentrations of electrolytes did not differ between the 2 groups. Glucose levels were higher in the MC group than in the AC group (106.3 ± 30.7 mg/dL vs. 98.0 ± 14.2 mg/dL, $P < .01$), but no hypoglycemia was observed in either group. All values were within normal range. No hemodynamic instability after bowel preparation was observed in either group.

The findings of the questionnaire, including adverse events and tolerability related to ingestion of bowel cleanser, are shown in Table 4. The percentage of subjects with no adverse symptoms was 52.7% in the MC group, and 56.6% in the AC group ($P = .51$). The percentage of subjects who developed nausea, vomiting, abdominal pain, dizziness, tingling sensation, bloating, and/or other symptoms did not differ between the 2 groups. The overall satisfaction score and willingness to reuse the bowel cleansing regimen did not differ between the 2 groups (satisfaction score, 3.4 ± 1.0 vs. 3.2 ± 1.0, $P = .59$; willingness to reuse, 54.4% vs.61.5%, $P = .23$).

Table 1

Baseline characteristics.

Characteristics	Morning colonoscopy (n = 169)	Afternoon colonoscopy (n = 122)	P
Male, n (%)	102 (60.4)	74 (60.7)	.96
Age	54.3 (±11.2)	55.7 (±9.8)	.26
BMI, kg/m^2	24.5 (±3.0)	24.3 (±3.8)	.59
Number of defecation, n (%)			.21
1/day	93 (55.0)	58 (47.5)	
>1/day	55 (32.5)	39 (32.0)	
4–6/week	16 (9.5)	16 (13.1)	
≤3/week	5 (3.0)	9 (7.4)	
Medical history, n (%)			.59
None	96 (56.8)	65 (53.3)	
Diabetes	17 (10.1)	8 (6.6)	
Hypertension	24 (14.2)	25 (20.5)	
Hypercholesterolemia	16 (9.5)	11 (9.0)	
Constipation	5 (3.0)	6 (4.9)	
Arthritis	4 (2.4)	1 (0.8)	
Others	7 (4.1)	6 (4.9)	
Surgical history, n (%)			.95
None	125 (74.0)	94 (77.0)	
Appendectomy	14 (8.3)	8 (6.6)	
Cholecystectomy	4 (2.4)	2 (1.6)	
Hysterectomy	10 (5.9)	7 (5.7%)	
Cesarean section	11 (6.5)	9 (7.4)	
Others	5 (3.0)	2 (1.6)	

BMI = body mass index.

3.4. Outcomes and parameters of colonoscopy

Table 5 shows the outcomes and parameters of colonoscopy. The percentage of subjects who underwent EGD before colonoscopy was 94.7% in the MC group, and 96.7% in the AC group ($P = .57$). The volume of gastric fluid collected during EGD in the MC and AC groups was 22.8 and 21.0 mL, respectively ($P = .17$). The volume of water collected in the colon for each group was 227.5 and 231.5 mL, respectively ($P = .21$). The percentage of subjects who required a position change did not differ between the 2 groups (MC group, 22.5% vs. AC group, 30.3%, $P = .13$).

The PDR and ADR did not differ between the MC and AC groups (PDR, 37.9% vs. 41.0%, $P = .40$; ADR, 31.4% vs.36.1%, $P = .40$).The number of adenomas per patient was 0.5 ± 1.1 in the MC group and 0.5 ± 0.8 in the AC group ($P = .26$). There were no instances in either group of complications related to colonoscopy, such as aspiration or post-polypectomy bleeding.

4. Discussion

In the present study, we compared the bowel-cleansing efficacy, safety profile, and tolerability in patients who underwent colonoscopy in the morning with that in patients who underwent colonoscopy in the afternoon, when 4L PEG was administered on the same-day as colonoscopy. The bowel-cleansing efficacy was comparable in each group. There were no instances of hemodynamic instability or electrolyte imbalance. Adverse events, patient satisfaction, and willingness to reuse the bowel-cleansing regimen did not differ between the two groups. To our knowledge, this is the first study to investigate the bowel-cleansing efficacy of a same-day dose of 4L PEG in individuals who undergo colonoscopy in the morning.

We found no difference between the 2 groups in relation to bowel-cleansing efficacy assessed by total BBPS score or each segmental score. The mid colon showed better bowel-cleansing efficacy than the other segments. This was related to the patient's position during the examination: colonoscopy was performed in the left-lateral position. Therefore, most fluid was observed in the left colon because of gravity. A position change might affect the distribution of fluid in the colon, which is related to the bowel-cleansing efficacy in each region, but the proportion of patients whose position was changed during the colonoscopy did not differ between groups (22.5% and 30.3%, $P = .13$). Most patients completed the colonoscopy without requiring a position change. In this study, we did not exclude patients with a surgical history, except for bowel resection. Although abdominal surgery is related to poor bowel preparation,[19] cleansing failure was observed in only 2 of 169 subjects in the MC group and 1 of 122 subjects in the AC group, a cleansing success rate >95%. All

Table 2

Comparison of bowel cleansing efficacy.

Bowel-cleansing efficacy	All subjects (n = 291)	Morning colonoscopy (n = 169)	Afternoon colonoscopy (n = 122)	P
Total BBPS score	7.3 (±0.8)	7.3 (±0.8)	7.3 (±0.8)	.68
Rt. colon score	2.3 (±0.5)	2.3 (±0.5)	2.4 (±0.5)	.72
Mid colon score	2.8 (±0.4)	2.8 (±0.4)	2.8 (±0.4)	.91
Lt. colon score	2.1 (±0.3)	2.1 (±0.3)	2.1 (±0.3)	.74
Success rate, n (%)	167 (99.0)	167 (98.8)	121 (99.2)	.76

BBPS = Boston Bowel Preparation Scale, SD = standard deviation.

Table 3

Post bowel preparation laboratory tests.

Characteristics	Morning colonoscopy (n = 169)	Afternoon colonoscopy (n = 122)	P
Hemoglobin, g/dL	14.3 (±1.8)	14.2 (±1.6)	.50
Hematocrit, %	43.4 (±3.7)	42.9 (±4.5)	.36
WBC, cells/mm^3	5975.7 (±1815.5)	6101.2 (±1904.4)	.61
BUN, mg/dL	13.2 (±3.5)	13.5 (±3.6)	.23
Creatinine, mg/dL	0.9 (±0.2)	0.9 (±0.2)	.15
Na, mEq/L	140.9 (±2.0)	140.9 (±1.9)	.39
K, mEq/L	4.2 (±0.3)	4.1 (±0.3)	.29
Cl, mEq/L	104.5 (±2.0)	104.6 (±2.1)	.24
Ca, mg/dL	9.1 (±0.4)	9.1 (±0.4)	.62
P, mg/dL	3.4 (±0.4)	3.4 (±0.5)	.48
Glucose, mg/dL	106.3 (±30.7)	98.0 (±14.2)	.01

BUN = blood urea nitrogen, WBC = white blood cell.

Table 4

Adverse events and tolerability.

Characteristics	Morning colonoscopy (n = 169)	Afternoon colonoscopy (n = 122)	P
Adverse events, n (%)			
None	89 (52.7)	69 (56.6)	.51
Nausea	39 (23.1)	30 (24.6)	.77
Vomiting	28 (16.6)	14 (11.5)	.22
Abdominal pain	2 (1.2)	1 (0.8)	1
Dizziness	9 (5.3)	11 (9.0)	.22
Tingling sensation	1 (0.6)	0 (0)	1
Bloating	16 (9.5)	14 (11.5)	.58
Others	2 (1.2)	1 (0.8)	1
Satisfaction with regimen	3.4 (±1.0)	3.2 (±1.0)	.59
Willingness to re-use, n (%)	92 (54.4)	75 (61.5)	.23

Table 5

Outcomes and parameters of colonoscopy.

Characteristics	Morning colonoscopy (n = 169)	Afternoon colonoscopy (n = 122)	P
EGD before colonoscopy, n (%)	160 (94.7)	118 (96.7)	.57
Gastric water*, mL	22.8 (±20.0)	21.0 (±9.9)	.17
Colon water, mL	227.5 (±106.4)	231.5 (±134.8)	.21
Position change, n (%)	38 (22.5)	37 (30.3)	.13
Polyp detection rate, n (%)	64 (37.9)	50 (41.0)	.59
Adenoma detection rate, n (%)	53 (31.4)	44 (36.1)	.40
Number of adenoma	0.5 (±1.1)	0.5 (±0.8)	.26

EGD = esophagogastroduodenoscopy.
* missing data: morning colonoscopy (n = 9); afternoon colonoscopy (n = 4).

colonoscopies were performed at a health care promotion center, so most participants were healthy without significant comorbidities. Furthermore, we intensively instructed the patients about the bowel-cleansing method and the importance of a low-residue diet. The study subjects were encouraged to ingest more water when turbid effluent was evacuated after bowel cleansing. Two days before colonoscopy, we contacted the subjects by phone to remind them of the procedure, and we checked their bowel preparation before colonoscopy. This intensified instruction resulted in better bowel preparation compared with patients given conventional instructions.[20–22]

Safety was investigated using vital signs, laboratory findings, and questionnaire responses. Rapid bowel preparation has the potential to cause electrolyte imbalance and hemodynamic instability, but no hemodynamic instability or electrolyte imbalance after bowel preparation was seen in this study. The results of all laboratory tests, except the glucose level, were similar in the 2 groups. PEG is a widely used bowel-cleansing agent for which electrolyte imbalance has rarely been reported.[12,23] The glucose levels were higher in the MC than the AC group because of their shorter fasting time. However, neither group showed any hypoglycemia. The American Society for Gastrointestinal Endoscopy guideline recommends that bowel preparation should be finished within 4 to 8 hours of colonoscopy.[6] In our study, patients finished bowel preparation 2 hours before colonoscopy. Although this short time interval between the end of bowel preparation and colonoscopy showed better bowel cleansing efficacy,[24] it has the potential to cause aspiration. However, several previous studies reported no aspiration when bowel preparation was finished 2 hours before colonoscopy.[18,22] To investigate aspiration risk, we measured the volume of fluid in the stomach, which was <30 mL and did not differ between the 2 groups. The American Society of Anesthesiologists recommends at least 2 hours of fasting from the intake of clear liquids to before sedation.[25] Almost half of the subjects reported at least 1 adverse event. The incidence of nausea, vomiting, abdominal pain, dizziness, tingling sensation, bloating, and/or other symptoms did not differ between the 2 groups. The percentage of patients with no adverse symptoms related to ingestion of bowel cleanser was similar for the 2 groups. Therefore, the high rate of adverse events was related to the large volume of PEG rather than its rapid ingestion. Satisfaction with the regimen and willingness to reuse did not differ between the 2 groups. Hence, the tolerability of MC was not inferior to that of AC. Although willingness to reuse the cleansing regimen was lower than reported in previous studies,[15,22] in this study we used 4L PEG, which was related to patient inconvenience because of the large volume.[18] Future studies should compare the safety and tolerability of same-day dosing with PEG with those of split-dose regimen.

For colonoscopy performed by qualified colonoscopists, the minimum cecal intubation rate was 90% and ADR was 25%.[8,26] In our study, all colonoscopists were qualified. The cecal intubation rate was >95% and ADR was >30% (MC group, 31.4% vs. AC group,36.1%, $P = .40$).

This study has several limitations. First, it is a retrospective observational study. However, we enrolled consecutive subjects during the study period and collected data prospectively. Second, we could not investigate the safety and tolerability of the procedure in subjects who stopped bowel preparation because the questionnaire was completed only by those who underwent colonoscopy. Intolerance to the bowel-cleansing agent or regimen is an important issue for bowel cleansing. The rate of intolerance to a same-day dose of PEG, especially among those who undergo colonoscopy in the morning, should be investigated in future studies. Third, all patients were healthy subjects without comorbidities, and colonoscopy was done for screening purposes. The use of a same-day dose of PEG for MC should be validated in patients with various comorbidities and various conditions. Fourth, colonoscopy was started from 10:00. Because 2 hours are required for ingestion of the bowel cleanser, it is challenging to prescribe a same-day dose for colonoscopy starting earlier than 10:00. Therefore, a same-day dose should be suggested selectively for individuals who receive colonoscopy in the morning.

In conclusion, we showed that the bowel-cleansing efficacy, safety profile, and patient tolerability of MC are comparable to those of AC. The same-day dose of 4L PEG is a feasible bowel preparation method, but this should be validated in future prospective studies.

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