

ORIGINAL ARTICLE

대장 내시경 장정결제 분할 요법의 효능: 2 Liters Polyethylene Glycol with Ascorbic Acid versus Sodium Picosulfate versus Oral Sodium Phosphate Tablets

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Split-dose Bowel Preparation for Colonoscopy: 2 Liters Polyethylene Glycol with Ascorbic Acid versus Sodium Picosulfate versus Oral Sodium Phosphate Tablets

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Background/Aims: Adequate bowel preparation is an essential factor affecting the visibility of colonic mucosa and safety of related therapeutic interventions. The aim of this study was to assess the efficacy, tolerability, and safety of three bowel preparation agents –2 L polyethylene glycol with ascorbic acid (PEGA), sodium picosulfate magnesium citrate (SPMC), and oral sodium phosphate tablet (NaP)– for morning colonoscopy.

Methods: Here, we analyzed the medical records of patients who had taken bowel preparation agents using the split-dose method and undergone colonoscopy in a single hospital. The efficacy of bowel preparation agents was evaluated using the Ottawa bowel preparation assessment tool. The safety and tolerability of the agents were assessed by measuring the renal function and electrolytes prior to and after the procedure as well as by assessing the self-reported questionnaire.

Results: Of the 365 patients (PEGA:163, SPMC: 93, NaP: 109), 98.6% ingested more than 90% of the agents. NaP showed an inferior cleansing efficacy, and serum phosphate elevation was significantly higher in the NaP group. However, the satisfaction score was lowest in the PEGA group. Age (odds ratio [OR] 0.96, 95% confidence interval [CI] 0.92-0.99, $p=0.04$) and preparation agents (OR of PEGA versus NaP 5.0, 95% CI 2.28-10.97, $p<0.001$) (OR of SPMC versus NaP 2.73, 95% CI 1.22-6.08, $p=0.01$) were independently associated with bowel preparation success.

Conclusions: According to our analysis, NaP showed an inferior cleansing efficacy compared with PEGA and SPMC, which may be attributed to the complex administration method and lower water intake. However, large-volume ingestion remains unsatisfactory for patients. Detailed bowel preparation instructions could enhance bowel cleansing efficacy. (Korean J Gastroenterol 2017;70:89-95)

Key Words: Bowel preparation solutions; Colonoscopy; Polyethylene glycols; Picosulfate sodium; Sodium phosphate

INTRODUCTION

Adequate bowel preparation is an essential factor affecting the visibility of colonic mucosa and safety of related ther-

apeutic interventions. It has been reported that poor bowel preparation is found in about 20-25% of colonoscopy exams.^{1,2}

Inadequate bowel preparation not only prolongs the procedure as it requires an addition step of washing the poorly

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cleansed colon, but it also increases the chance of missing mucosal lesions. Ideal bowel preparation agents should be easy to take with minimal effect on the water and electrolyte balance, without inducing mucosal injuries and not requiring an extended duration to finish the preparation.³

The available bowel preparation agents in Korea include polyethylene glycol (PEG), osmotic laxatives, and stimulant laxatives. PEG is the most commonly used agent and is relatively safe because it is not absorbed through the colonic mucosa and does not permit the transposition of water and electrolytes. However, despite its advantages, its disadvantage is that it is not easy to take due to the large volume of agents required (a total of 4 liters of water). PEG 2 L+ascorbic acid (PEGA) has recently been developed and widely adopted in Korea. The stimulant laxative, sodium picosulfate+magnesium citrate (SPMC), is also available in Korea. This laxative stimulates the peristalsis of the bowel, inducing osmotic diarrhea. Another agent, a sodium phosphate (NaP) solution, has been used as an osmotic laxative. However, complications, including acute phosphate nephropathy, which could potentiate chronic kidney disease requiring hemodialysis, had been reported, and as a result, the Korean Food and Drug Administration banned the use of a NaP solution for bowel cleansing in 2009.⁴⁻⁶ However, the oral NaP tablet was permitted in 2012 and is currently being used in Korea.

There have been many studies comparing the efficacy, safety, and tolerability between these bowel preparation agents. However, it remains difficult to determine which agent is most superior. Thus, the aim of this study was to compare the efficacy, safety, and tolerability of PEGA, SPMC, and NaP using the split-dose method in a Korean population.

SUBJECTS AND METHODS

1. Ethics statement

This study was conducted in accordance with the Declaration of Helsinki and approved by the institutional review board of Chuncheon Sacred Heart Hospital prior (2015-23). Patient records and information were anonymized and de-identified prior to analysis.

2. Patient selection

The authors retrospectively analyzed, using the split-dose method, the medical records of patients who had undergone

colonoscopy (for the purpose of screening or surveillance) and taken bowel preparation agents between December 2013 and February 2014 in a single hospital in Korea (split-dose bowel preparation was started in November 2013 in Chuncheon Sacred Heart hospital). Patients with systemic illness or a past history that may have affected the bowel cleansing were excluded. The exclusion criteria were as follows: patients with heart failure (New York Heart Association class>2), renal failure (glomerular filtration rate<60 mL/min/1.73 m²), liver cirrhosis, malignancy, intestinal obstruction, history of parathyroidectomy, history of abdominal surgery, ascites, inflammatory bowel disease, and specific medication use (nonsteroidal anti-inflammatory drugs with the exception of low-dose aspirin, diuretics, angiotensin-converting-enzyme inhibitors, or angiotensin receptor blockers). Patients who underwent colonoscopy in the afternoon were also excluded because the time interval between bowel preparation and colonoscopy may have biased the efficacy of the preparation agents.

3. Bowel preparation method

Three bowel preparation agents were used in this study (Coolprep[®], Taejoon Pharmaceuticals Co., Ltd., Seoul, Korea; Picolight powder[®], Pharmbio Korea Co., Ltd., Chungju, Korea; and Nexcolon tab[®], Nexpharm Korea Co., Ltd., Seoul, Korea). All enrolled patients took these preparation agents following the doctor's instructions. All patients commenced a minimal-residue diet, which was refraining from eating fruits with seeds, sea algae, mixed grains, and foods with high fiber contents, three days prior to colonoscopy. They were also instructed to skip their last dinner. Bowel preparation agents were selected by a prescribing doctor for each patient considering patients' taste preference, cost, and tolerability. Details of patient instruction on specific bowel preparation methods according to each regimen are as follows:

1) PEGA for morning examination

(1) The day before the exam, at 9 p.m., dissolve two sachets of PEGA in 1 L of water and drink 250 mL in each 15-minute period; afterward, drink an additional 500 mL of plain water.

(2) On the following day, at 5 a.m., repeat step (1) using the remaining two sachets.

(3) These steps should be finished at least 3 hours before the colonoscopy.

2) SPMC for morning examination

(1) The day before the exam, at 5 p.m., dissolve one sachet of SPMC in 150-200 mL of water, and drink the solution, and drink an additional 1 L of water or another clear fluid within 1-2 hours. Take the additional sachet in the same manner at 9 p.m.

(2) On the following day, at 5 a.m., repeat step 1 using the remaining sachet.

(3) These steps should be finished at least 3 hours before the colonoscopy.

3) NaP for morning examination

(1) The day before the exam, at 7 p.m., take four tablets of NaP with 240 mL of water in each 15-minute period, until 20 total tablets have been taken (4 tablets×5 times, 1.2 L of water total).

(2) On the following day, at 5 a.m., take four tablets of NaP with 240 mL water in each 15-minute period until 12 total tablets have been taken (4 tablets×3 times, 960 mL of water total).

(3) These steps should be finished at least 3 hours before the colonoscopy.

4. Evaluation of the efficacy of the preparation agents

Bowel cleansing efficacy was assessed at the end of the colonoscopy by endoscopists with an experience of at least 2,000 cases. The Ottawa bowel preparation scale, a reliable and valid tool for assessing bowel cleansing, was used for the assessment. This scale uses ratings from 0-4 (no liquid=0, minimal liquid, no suctioning required=1, suction required to see mucosa=2, wash and suction=3, solid stool, not washable=4) for the right, middle, and rectosigmoid colon, respectively, as well as a score for the overall amount of fluid in the colonic lumen (minimal=0, moderate=1, large=2). These provide a score range between 0 (excellent preparation, no fluid) and 14 (inadequate in all segments with a large amount of fluid). A total score of 7 or less was defined as a successful bowel preparation.⁷

5. Safety and tolerability of bowel preparation agents

The safety of each preparation agent was assessed by comparing the serum level of the electrolytes and creatinine with the estimated glomerular filtration rate on arrival in the endoscopy suite with the baseline (in the same clinic prior to or after booking colonoscopy within 1 month) levels. Of the

365 patients, laboratory data on 247 were available for this study (PEGA, SPMC, NaP=92, 82, 73).

The tolerability was assessed by a self-reported questionnaire. We routinely investigated the tolerability of the bowel preparation agents due to safety concerns in a customer satisfaction campaign. Voluntary participation was requested, and written informed consent was obtained from each participant for the use of their information.

We investigated whether each participant consumed all preparation agents prescribed and their taste; we also evaluated the development of any side effects, including nausea, vomiting, abdominal pain, bloating, or dizziness after completing the bowel preparation. The satisfaction score was assessed via the visual analogue scale (from 0=unsatisfactory to 10=satisfactory). We also investigated the patients' willingness to accept or refuse the same preparation agent in the future.

6. Statistical analysis

Continuous data are expressed as the means and standard deviation, and categorical data are given as frequencies (percentages). The Student's *t* test, ANOVA, and Fisher's exact test were used to evaluate the baseline characteristics (post-hoc analysis using the Bonferroni method), and RM-ANOVA was used to compare the preparation scores of the three agents. A multivariable logistic regression test was used to detect the associated factors of successful bowel preparation. A *p*-value<0.05 was considered statistically significant for all tests. The analysis was performed using SPSS software version 18.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

1. Population characteristics

Among the 402 colonoscopy examinations during study period, 37 cases were excluded. The detailed cause of exclusion is as follows: renal failure (*n*=2), liver cirrhosis (*n*=5), malignancy (*n*=3), history of abdomen surgery (*n*=3), inflammatory bowel disease (*n*=2), medication users (*n*=20), and colonoscopy in the afternoon (*n*=2). Finally, a total of 365 patients (PEGA 163, SPMC 93, NaP 109) were included in this study. The detailed study flow is described in Fig. 1. The mean age of the total population was 49.3±9.3 years. Among the study population, 214 were men (58.6%) and 151 were

women (41.4%). The mean body weight and body mass index were 65.4 ± 11.2 kg and 24.2 ± 3.2 , respectively. Twenty-five patients (6.8%) had diabetes mellitus, and 86 patients

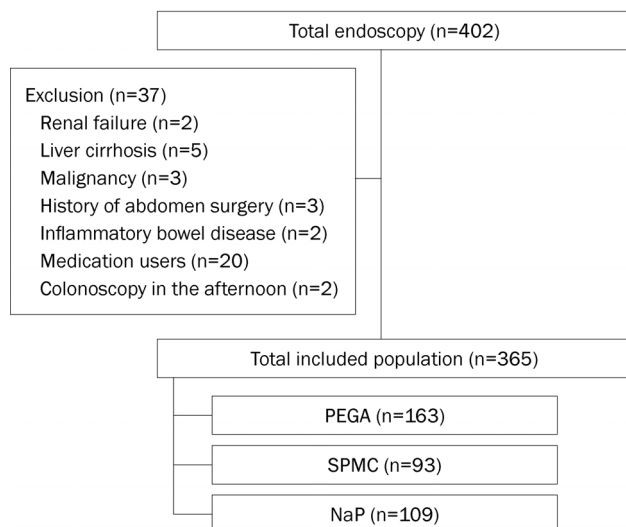


Fig. 1. Flow diagram of study. PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate.

(23.6%) had hypertension. Seventy-eight patients (21.4%) were smokers, and 141 patients (38.6%) were alcoholics. No significant differences in the baseline characteristics were detected between the three preparation groups. Detailed characteristics of the total enrolled population are listed in Table 1.

2. Efficacy of preparation agents

In the enrolled population, 360 patients (98%) ingested more than 90% of the bowel preparation agents. A total of 318 patients (88.3%) showed successful bowel preparation (Ottawa total regional score of 7 or less). Ottawa bowel preparation scale scores were significantly higher in the NaP group than the other groups (PEGA and SPMC) in the right colon, mid colon, and rectosigmoid colon, as well as for the total score (PEGA, SPMC, NaP= 3.57 ± 1.70 , 3.82 ± 2.55 , 4.93 ± 2.96 , respectively, $p < 0.001$) (Table 2). However, there were no significant differences in the colonic fluid score between the groups (PEGA, SPMC, NaP= 1.06 ± 0.37 , 1.09 ± 0.41 , 1.05 ± 0.48 , respectively, $p = 0.77$) (Table 2).

Table 1. Clinical Characteristics of Total Enrolled Population

Characteristics	PEGA (n=163)	SPMC (n=93)	NaP (n=109)	p-value
Age	49.6 ± 9.8	50.7 ± 9.4	47.6 ± 8.3	0.06
Sex				0.27
Male	101 (62.0)	56 (60.2)	57 (52.3)	
Female	62 (38.0)	37 (39.8)	52 (47.7)	
Smoking	33 (20.2)	24 (25.8)	21 (19.3)	0.47
Alcohol	55 (33.7)	36 (38.7)	50 (45.9)	0.13
DM	15 (9.2)	8 (8.6)	2 (1.8)	0.05
HTN	44 (27.0)	24 (25.8)	18 (16.5)	0.12
BMI	24.5 ± 3.1	24.0 ± 3.3	23.8 ± 3.3	0.22

Values are presented as mean \pm standard deviation or n (%).

PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate; DM, diabetes mellitus; HTN, hypertension; BMI, body mass index.

Table 2. Cleansing Efficacy of Bowel Preparation Agents

Component of Ottawa bowel preparation scale	PEGA (n=163)	SPMC (n=93)	NaP (n=109)	p-value
Right colon	0.93 ± 0.69	0.97 ± 0.84	1.51 ± 1.07	$< 0.001^a$
Mid colon	1.01 ± 0.56	1.05 ± 0.81	1.34 ± 0.93	0.005^b
Rectosigmoid colon	0.56 ± 0.64	0.69 ± 0.88	1.04 ± 0.99	$< 0.001^c$
Colonic fluid	1.06 ± 0.37	1.09 ± 0.41	1.05 ± 0.48	0.77
Total score	3.57 ± 1.70	3.82 ± 2.55	4.93 ± 2.96	$< 0.001^d$

Values are presented as mean \pm standard deviation.

PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate.

^aSignificant difference between PEGA and NaP ($p < 0.001$), and between SPMC and NaP ($p < 0.001$); ^bSignificant difference between PEGA and NaP ($p = 0.001$), and between SPMC and NaP ($p = 0.02$); ^cSignificant difference between PEGA and NaP ($p < 0.001$), and between SPMC and NaP ($p = 0.008$); ^dSignificant difference between PEGA and NaP ($p < 0.001$), and between SPMC and NaP ($p = 0.003$).

3. Safety of bowel preparation agents

There were no significant differences in the 3 groups regarding the changes in the serum Na, creatinine level, or estimated glomerular filtration rate ($p=0.91$, 0.91 , and 0.98 , respectively) between the baseline and after bowel preparation (Table 3). However, there were statistically significant differences between the groups regarding changes in the serum phosphate, calcium, and chloride levels. The elevation of the serum phosphate level and a reciprocal decrease in the serum calcium level were statistically significant in the NaP group (PEGA versus NaP: $p<0.001$; SPMC versus NaP: $p<0.001$) (Table 3). A statistically significant serum chloride elevation was observed in the PEGA group compared with the SPMC group ($p=0.03$) (Table 3). Visible mucosal abnormalities, diagnosed as non-specific colitis, were found in 4 patients (0.01%; 2 patients in the PEGA group, 1 patient in the SPMC group, and 1 patient in the NaP group).

4. Tolerability of bowel preparation agents

All the enrolled patients voluntarily participated in completing the self-reported questionnaire. The proportion of patients who complained of abdominal pain, nausea or vomiting after taking bowel preparation agents were not statistically different among the 3 preparation agents (<5% in each

group). There were no significant differences in the proportion of patients who could not drink all preparation agents ($p=0.86$). However, PEGA showed a significantly lower satisfaction score than the other preparation agents (PEGA, SPMC, NaP= 7.29 ± 2.00 , 8.25 ± 1.71 , 8.12 ± 1.60 , respectively, $p<0.001$), and the proportion of refusal for the same bowel preparation agent in the future was highest in the PEGA group (PEGA, SPMC, NaP= 29.4 , 17.2 , 15.6% , respectively, $p=0.012$) (Table 4).

5. Multivariable analysis for the success of bowel preparation

In the analysis of the detection of associated factors for successful bowel preparation, age (odds ratio [OR] 0.96, 95% confidence interval [CI] 0.92-0.99, $p=0.04$) and preparation agents (OR of PEGA versus NaP 5.0, 95% CI 2.28-10.97, $p<0.001$) (OR of SPMC versus NaP 2.73, 95% CI 1.22-6.08, $p=0.01$) showed a significant association with the success of bowel preparation (Ottawa total regional score of 7 or less). Detailed adjusted factors and OR are shown in Table 5.

DISCUSSION

Adequate bowel preparation is an essential factor for a suc-

Table 3. Safety Profile of Bowel Preparation Agents

	PEGA (n=92)	SPMC (n=72)	NaP (n=83)	p-value
Na (mmol/L)	0.40	-0.33	0.81	0.91
Cl (mmol/L)	1.29	-0.80	-0.11	0.03 ^a
P (mg/dL)	-0.07	0.07	3.85	<0.001 ^b
Ca (mg/dL)	0.07	0.14	-0.35	<0.001 ^c
Cr (mg/dL)	0.01	0.01	0.01	0.91
eGFR (mL/min)	-1.10	-0.79	-0.97	0.98

The mean difference between pre & post-bowel preparation of serum electrolyte and eGRF.

PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate; eGFR, estimated glomerular filtration rate.

^aSignificant difference between PEGA and SPMC ($p=0.03$); ^bSignificant difference between PEGA and NaP ($p<0.001$), and between SPMC and NaP ($p<0.001$); ^cSignificant difference between PEGA and NaP ($p<0.001$), and between SPMC and NaP ($p<0.001$).

Table 4. Tolerability of Bowel Preparation Agents

	PEGA (n=163)	SPMC (n=93)	NaP (n=109)	p-value
Could not intake all the preparation agents	3 (1.8)	1 (1.1)	1 (0.9)	0.86
Satisfaction score	7.29 ± 2.00	8.25 ± 1.71	8.12 ± 1.60	<0.001 ^a
Refuse to take the same preparation agent in the future	48 (29.4)	16 (17.2)	17 (15.6)	0.01

Values are presented as mean±standard deviation or n (%).

PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate.

^aSignificant difference between PEGA and SPMC ($p<0.001$), and between PEGA and NaP ($p=0.001$).

Table 5. Multivariable Logistic Regression Analysis Assessing the Associated Factors of Successful Bowel Preparation (Ottawa bowel preparation scale score 7 or less)

Variables	p-value	OR (95% CI)
Age	0.04	0.96 (0.92-0.99)
Sex	0.06	1.93 (0.98-3.91)
Bowel preparation agents		
PEGA	<0.001	5.00 (2.28-10.97)
SPMC	0.01	2.73 (1.22-6.08)
NaP	Control	
Alcohol	0.83	1.09 (0.50-2.33)
Smoking	0.40	1.47 (0.60-3.62)
DM	0.59	1.54 (0.33-7.21)
HTN	0.92	0.96 (0.44-2.10)
BMI	0.30	0.95 (0.86-1.05)

OR, odds ratio; CI, confidence interval; PEGA, polyethylene glycol+ascorbic acid; SPMC, sodium picosulfate magnesium citrate; NaP, sodium phosphate; DM, diabetes mellitus; HTN, hypertension; BMI, body mass index.

successful colonoscopy. The optimum bowel preparation regimen for a colonoscopy should provide excellent cleansing, have a high safety profile, and be well tolerated by patients. In this study, we investigated the cleansing efficacy, safety profile, and patient tolerance of three different agents in a Korean population by using the split-dose method. Moreover, we also aimed to determine which factor was associated with successful bowel preparation.

Regarding bowel cleansing efficacy, previous studies have shown inconsistent results when comparing between available agents.⁸⁻¹⁰ Moreover, comparison data on oral NaP tablets are scarce. In this study, oral NaP tablets showed to be inferior with respect to its efficacy compared with PEGA and SPMC; this was consistent in all bowel segments (Table 2). This result is in agreement with a recent large-scale randomized study in Australia.⁸ The complex administration method and relatively lower water intake are suspected to be the reasons for the low efficacy of oral NaP. Between PEGA and SPMC, efficacy was comparable; this result is in line with previous randomized studies.^{8,11} However, there has also been conflicting reports, indicating a lower efficacy for SPMC compared with PEG.^{12,13} A recent Korean multicenter randomized study also indicated comparable efficacy between SPMC+bisacodyl and 4 L PEG.¹⁴ Heterogeneity between the studies in terms of dietary counseling, total water intake, administration method, and time interval between bowel preparation and colonoscopy may bias the results. It appears that there is an increasing demand by patients for a lower volume of prepara-

tion agents. This prompts the need for more studies focusing on ways to lower the volume of bowel preparation agents. Further studies are also required to confirm the results found in this study.

Regarding the safety profile, hyperphosphatemia and hypocalcemia induced by NaP tablets presented statistically significant differences compared with the other two agents (Table 3). Although no patients with acute kidney injury were found, hyperphosphatemia and hypocalcemia, which are well-known adverse events, were identified at the same levels following the administration of NaP tablets compared with NaP solution. The long-term effects of NaP tablet ingestion were difficult to determine, as this study only focused on the available, immediate biochemical data.

Although superior bowel cleansing efficacy was observed in PEGA compared with NaP, patient satisfaction and tolerability of PEGA were lower. Due to the detailed instruction of the administration method in this study, the proportion of patients who were unable to consume all the preparation agents as instructed was not particularly different between the three groups. However, the satisfaction score was higher in the NaP and SPMC groups than in the PEGA group (Table 4). This highlights the difference in perspective between doctors and patients regarding the selection of bowel preparation agents. The bowel cleansing efficacy and safety profile appear to be more important to doctors, while avoiding large volume of consumption remains to be important to patients. To satisfy this unmet need for patients, an agent that is satisfactory with respect to both safety and volume is necessary.

Several factors have been reported to predict inadequate bowel preparation for colonoscopy, including old age, female sex, diabetes, constipation, history of abdominal or gynecologic surgery, compliance with preparation instructions, diet counseling prior to colonoscopy, and bowel preparation type.^{15,16} Our study also revealed that old age was associated with poor bowel preparation. Previous studies indicated that an age over 60 years was associated with poor bowel preparation.¹⁶⁻¹⁸ Suspected reasons are reduced colon transit time or comorbidities in elderly patients.¹⁹ A complex administration method is a barrier and could be the reason for poor adherence to the instruction of taking preparation agents in elderly patients. Detailed instructions and counseling could promote successful bowel cleansing.

This study has several limitations to consider. It is a retro-

spective study from a single hospital, and a small number of patients was enrolled for statistical analysis. It is possible for selection bias to influence the study results because the prescribing doctor may have changed the preparation agents considering the patient's information. Another limitation was the lack of information regarding the safety profile for the enrolled population. However, contrary to previous studies, this study included a group of those who took the oral NaP tablets. Additionally, the entire enrolled population adhered to split-dosing, which was more effective and better tolerated than the standard 1-day bowel preparation method.²⁰ Another strength of this study was the confirmation of compliance to bowel preparation agents. About 98.6% of the enrolled population ingested more than 90% of the prescribed preparation agents.

In brief, NaP tablets were shown to have an inferior cleansing efficacy compared with PEGA and SPMC in this retrospective, single-center based analysis. A complex administration method with a lower water intake could explain this lower efficacy. However, it is also worth noting that the need to ingest a large volume of preparation agents remains unsatisfactory to patients. Detailed bowel preparation instructions could promote bowel cleansing efficacy.

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