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Formulation and Management of Poor Bowel Preparation: A Survey Study

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Background/Aims: There are no established guidelines for bowel preparation formulation for bowel cleansing, nor is there an optimal method of dealing with inadequate bowel cleansing. This study investigated bowel preparation formulation preferences and responses to bowel preparation situations using surveys.

Methods: The study surveyed 221 Korean lower gastrointestinal endoscopists from January to March 2015 and assessed their responses.

Results: The analysis indicated that 2-L polyethylene glycol (PEG) plus ascorbic acid (Asc) was the preferred method (76.5%) and most responders expressed satisfaction with the formulation in both potency and safety. To address poor bowel preparation on the day of colonoscopy, the majority of physicians chose to order ingestion of additional preparations and proceed with the colonoscopy as scheduled (56.6%). In addition, concerns about renal safety and electrolyte stability were raised regarding oral sodium phosphate.

Conclusions: This study found that 2-L PEG+Asc was preferred for potency and safety, and that Korean endoscopists preferred to proceed with colonoscopy in poor bowel preparation situations rather than choose an alternate diagnostic modality. (Korean J Gastroenterol 2016;68:70-76)

Key Words: Colonoscopy; Cathartics

INTRODUCTION

Colonoscopy is the most effective screening method for identifying and preventing colorectal cancer, and polypectomy performed with colonoscopy effectively resects precancerous adenomas. Adequate bowel cleansing is essential for accurate colonoscopy and requires an optimal balance of diet control and bowel preparation formulation. An ideal bowel preparation formulation should provide an excellent bowel cleansing effect while preventing electrolyte

imbalance, and should also be affordable and well-tolerated by patients.³ However, no bowel preparation formulation currently available meets all of these criteria, and the choice of bowel preparation formulation largely depends on the patient's condition and the physician's preference and experience with the agents. A 4-L polyethylene glycol (PEG) preparation has minimal influence on serum volume or electrolyte balance, allowing it to be used safely in patients with other comorbidities, such as renal, cardiac, and liver diseases.⁴ Unfortunately, 5% to 15% of patients that ingest 4-L PEG do

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not completely finish because of the large volume formulation required (up to 4 L), the bad taste, and the odor, leading to inadequate cleansing.^{3,5} Improving the flavor or fragrance of the formulation has been attempted to address the limitations of PEG and to increase patient compliance.6 The 2-L PEG plus ascorbic acid (Asc) has a lower required ingestion volume (2 L) and the flavor is more tolerable, increasing compliance and satisfaction while retaining the effectiveness of 4-L PEG.7

Oral sodium phosphate (OSP) is advantageous because of the small ingestion amount required and overall convenience; some reports have concluded that it is as effective as 2-L PEG + Asc in bowel cleansing.8 However, OSP may cause temporary shifts in electrolyte balance, which may lead to complications in patients with a history of fluid-electrolyte balance, heart failure, unstable angina, renal disease, or liver disease with ascites. 9,10 Additional bowel preparation formulations that are available for patients include magnesium citrate combined with sodium picosulfate, which synergistically stimulates bowel motility for adequate bowel cleansing and also provides improved taste and smell. 11

There are no established guidelines for optimal bowel preparation formulation, bowel cleansing or an optimal method for addressing inadequate bowel cleansing. This study surveyed physicians that were performing colonoscopies in clinical fields to investigate the preferred formulation for bowel preparation, and the solution most commonly related to inadequate bowel preparation. Based on these data, this study discusses optimal bowel cleansing procedures and appropriate response to inadequate bowel preparation.

SUBJECTS AND METHODS

1. Subjects

This study was based on questionnaires that included 12 questions. The survey questionnaires were approved by Institutional Review Board of Wonju Severance Christian Hospital in October 2014 (WCH-2014-0149). The subjects were physicians that routinely performed colonoscopy in private clinics, secondary and tertiary hospitals. Physicians that were contacted by Taejoon Pharmaceuticals (Seoul, Korea) responded to this questionnaire. The survey was conducted with subjects that worked in tertiary hospitals between

January 7th and 21st, 2015, and was conducted with physicians that worked in private clinics and secondary hospitals from March 2nd to 18th, 2015.

2. Survey items

The physicians received questionnaires that included 12 questions, for which multiple responses were allowed (Table 1): the most important factor in choosing bowel preparation formulation and the most preferred formulation of choice, addition of bisacodyl (and if yes, the condition for bisacodyl addition), approach for patients with severe constipation, response to inadequate bowel cleansing on the day of colonoscopy, the most probable cause of inadequate bowel preparation, incidence of electrolyte imbalance due to use of bowel preparation formulations, bowel preparation formulation that most frequently resulted in complications, the most concerning issues regarding prescription of bowel preparation formulas, and the characteristics of various bowel preparation formulations (2-L PEG + Asc, OSP, and magnesium citrate combined with sodium picosulfate).

3. Statistics

The subjects were categorized according to their employment institution (tertiary university hospitals vs. private clinics and secondary hospitals) and according to their location (Seoul and neighboring areas vs. others). Statistical comparisons on the responses were made between those categories, type of institution and location, with a chi-square test (Fisher's exact test) using Statistical Analysis System version 9.2 (SAS Inc., Cary, NC, USA). Null hypotheses of no difference were rejected if p-values were less than 0.05.

RESULTS

Two hundred and twenty-one physicians who routinely performed colonoscopy (109 in tertiary hospitals, 59 in secondary hospitals, 53 in private clinics) responded to this survey. The geographical distribution of the responders was as follows: 127 (57.5%) in Seoul and its neighboring area, 20 (9.1%) in Daegu, 20 (9.1%) in the Kyeongbuk Province and so on. In choosing a bowel preparation agent, 67.4% selected potency as the most influential factor (71.6% of tertiary hospitals, 63.4% of private clinics/secondary hospitals, p=0.1953), with no significant difference between groups, and 19.5% se-

Table 1. Questionnaire Results

Questionnaire	Tertiary (n=109)	Private/secondary (n=112)	Total (n=221)	p-value
What is the most important factor in choosing bowel preparation formulation?	. ,	· · · ·	. ,	
1. Bowel preparation potency	78 (71.6)	71 (63.4)	149 (67.4)	0.1953
2. Possible complications (safety)	15 (13.8)	28 (25.0)	43 (19.5)	0.0349
3. Patient compliance	16 (14.7)	15 (13.4)	31 (14.0)	0.7831
2. Which bowel preparation formulation do you prefer?				
1. 4-L PEG	35 (32.1)	18 (16.1)	53 (24.0)	0.0052
2. 2-L PEG+Asc	76 (69.7)	93 (83.0)	169 (76.5)	0.0197
3. Magnesium citrate combined with sodium picosulfate	4 (3.7)	5 (4.5)	9 (4.1)	0.7651
4. Oral sodium phosphate	1 (0.9)	2 (1.8)	3 (1.4)	0.5771
5. I don't have a preferred formula.	1 (0.9)	1 (0.9)	2 (0.9)	0.9846
3. Do you prescribe laxatives such as bisacodyl in conjunction with bowel preparati				
1. No, I do not prescribe additional laxatives.	56 (51.4)	, ,	117 (52.9)	0.6456
Yes, but only to those expected to show poor bowel cleansing (severe constipation, elderly patients, etc.).	47 (43.1)	35 (31.3)	82 (37.1)	0.0678
3. Yes, to all patients, to improve the degree of bowel preparation.	6 (5.5)	16 (14.3)	22 (10.0)	0.0293
4. Which additional bowel preparation method do you employ in patients with seve	-			
1. I order the bowel preparation formulas to be taken in divided doses.	22 (20.2)	, ,	57 (25.8)	0.0601
I prescribe laxatives (such as bisacodyl) in addition to bowel preparation formulas.	60 (55.0)	48 (42.9)	108 (48.9)	0.0699
3. I increase the dose of bowel preparation formula.	42 (38.5)	, ,	79 (35.7)	0.394
4. I extend the duration of diet control prior to colonoscopy.	62 (56.9)	,	109 (49.3)	0.0266
5. I don't find additional methods to be necessary.	4 (3.7)	6 (5.4)	10 (4.5)	0.5462
5. How do you respond to poor bowel preparation status (solid feces remaining) or	•			
 Order additional ingestion of the same formula and perform colonoscopy as scheduled 	60 (55.0)	65 (58.0)	125 (56.6)	0.6539
Order additional ingestion of a different formula and perform colonoscopy as scheduled	6 (5.5)	12 (10.7)	18 (8.1)	0.1569
3. Reschedule colonoscopy and prescribe a different formula	10 (9.2)	5 (4.5)	15 (6.8)	0.164
Reschedule colonoscopy, prescribe the same formula, add bisacodyl laxatives, and order tighter diet control	37 (33.9)	26 (23.2)	63 (28.5)	0.0773
Administer additional formula through colonoscopy and perform colonoscopy as scheduled	0 (0.0)	6 (5.4)	6 (2.7)	0.0143
6. Perform additional enema and proceed with colonoscopy as scheduled	4 (3.7)	7 (6.3)	11 (5.0)	0.3779
 Choose alternate diagnostic modality (double barium contrast or CT colonography) 	0 (0.0)	1 (0.9)	1 (0.5)	0.3228
8. Do not perform colonoscopy at all.	0 (0.0)	0 (0.0)	0 (0.0)	
9. Others	2 (1.8)	3 (2.7)	5 (2.3)	0.0673
6. What is the most frequent cause of poor bowel preparation, based on your experience	erience?			
Poor compliance with bowel preparation formulation (Failure to ingest full dose of formula)	42 (38.5)	43 (38.4)	85 (38.5)	0.9830
2. Failure to follow the instructions on formula ingestion (incorrect preparation of formula, etc.)	32 (29.4)	31 (27.7)	63 (28.5)	0.7822
3. Underlying comorbidities of the examinee (old age, severe constipation, chronic diseases, etc.)	33 (30.3)	26 (23.2)	59 (26.7)	0.2355
4. Inadequate potency of the prescribed bowel preparation formula	2 (1.8)	6 (5.4)	8 (3.6)	0.1611
5. Poor diet control prior to colonoscopy	13 (11.9)		21 (9.5)	0.2253
6. Others	1 (0.9)	3 (2.7)	4 (1.8)	0.3262
7. Have you experienced electrolyte imbalance following the use of bowel preparation		- ()	. (=.0)	2.2 2.2
1. No	80 (73.4)	86 (76.8)	166 (75.1)	0.5599
2. Yes	27 (24.8)		53 (24.0)	0.7865
8. If so, choose all bowel preparation formula that have resulted in electrolyte imba		, ,	. ,	
1. 4-L PEG	10 (9.2)	6 (5.4)	16 (7.2)	0.2736
2. 2-L PEG + Asc	8 (7.3)	4 (3.6)	12 (5.4)	0.2165
3. Magnesium citrate combined with sodium picosulfate	14 (12.8)	, ,	28 (12.7)	0.9387
4. Oral sodium phosphate	11 (10.1)	14 (12.5)	25 (11.3)	0.5720

Table 1. Continued

Questionnaire	Tertiary (n=109)	Private/secondary (n=112)	Total (n=221)	p-value			
9. What is the safety issue of most concern when prescribing bowel preparation fo	rmula?						
1. Most complications are dismissable. I am concerned about nausea	62 (56.9)	69 (61.6)	131 (59.3)	0.4746			
and vomiting, which prevents complete ingestion of formula.							
2. I am concerened about the possibility of electrolyte imbalance.	37 (33.9)	43 (38.4)	80 (36.2)	0.4915			
3. I am concerned about bowel inflammation, which may mask colonic lesions.	13 (11.9)	0 (0.0)	13 (5.9)	0.0002			
4. Others	2 (1.8)	1 (0.9)	3 (1.4)	0.5452			
10. Based on your experience, choose all the items that are relevanat with the use of 2-L PEG+Asc (Coolprep; Taejoon Pharmaceuticals).							
1. I have never prescribed it.	4 (3.7)	12 (10.7)	16 (7.2)	0.0433			
2. It is satisfactory in terms of bowel preparation potency.	69 (63.3)	80 (71.4)	149 (67.4)	0.1975			
3. It appears to be less potent than 4-L PEG.	28 (25.7)	15 (13.4)	43 (19.5)	0.0210			
4. It is a safe formula that can be recommended to patients with renal failure.	31 (28.4)	28 (25.0)	59 (26.7)	0.5633			
It is appropriate for elderly patients with various comorbidities (renal disease, heart disease, etc.).	39 (35.8)	40 (35.7)	79 (35.7)	0.9919			
It requires less amount of ingestion and provides better patient compliance compared to 4-L PEG.	63 (57.8)	54 (48.2)	117 (52.9)	0.1536			
7. Others	1 (0.9)	0 (0.0)	1 (0.5)	0.3096			
11. Based on your experience, choose all the items that are relevant with the use	of oral NaF	(Clicolon; Korea	Pharma).				
1. I have never prescribed it.	59 (54.1)	63 (56.3)	122 (55.2)	0.7512			
2. It is satisfactory in terms of bowel preparation potency.	7 (6.4)	11 (9.8)	18 (8.1)	0.3556			
3. It appears to be less potent than 4-L PEG.	20 (18.3)	13 (11.6)	33 (14.9)	0.1598			
It can be used safely in patients with renal failure despite the risk of electrolyte imbalance.	3 (2.8)	1 (0.9)	4 (1.8)	0.2999			
It should be used only in healthy adults due to the risk of electrolyte imbalance.	30 (27.5)	34 (30.4)	64 (29.0)	0.6423			
6. I avoid the use of oral NaP becauses of concerns with nephropathy.	26 (23.9)	27 (24.1)	53 (24.0)	0.9647			
7. I avoid the use of oral NaP becauses of concerns with bowel inflammation.	7 (6.4)	5 (4.5)	12 (5.4)	0.5208			
8. Others	2 (1.8)	3 (2.7)	5 (2.3)	0.6732			
12. Based on your experience, choose all the items that are relevant with the use of PSMC (Picolyte; Pharmbio Korea).							
1. I have never prescribed it.	43 (39.4)	44 (39.3)	87 (39.4)	0.9801			
2. It is satisfactory in terms of bowel preparation potency.	10 (9.2)	13 (11.6)	23 (10.4)	0.5537			
3. It appears to be less potent than 4-L PEG.	41 (37.6)	45 (40.2)	86 (38.9)	0.6959			
 When used cautiously, it is a safe formula that can be recommended to patients with renal failure. 	12 (11.0)	8 (7.1)	20 (9.0)	0.3165			
5. It can be used safely in patients with renal failure despite	6 (5.5)	9 (8.0)	15 (6.8)	0.4545			
the risk of electrolyte imbalance.	0 (3.3)	9 (6.0)	13 (0.8)				
It should be used only in healthy adults due to the risk of electrolyte imbalance.	38 (34.9)	24 (21.4)	62 (28.1)	0.0263			
7. I avoid the use of PSMC becauses of concerns with bowel inflammation.	6 (5.5)	4 (3.6)	10 (4.5)	0.4894			
8. Others	1 (0.9)	1 (0.9)	149 (67.4)	0.9846			

Values are presented as n (%).

A 12-item questionnaire on formulation preference and management of poor bowel preparation was distributed to 221 South Korean endoscopists. Multiple answers were allowed. Null hypotheses of no difference were rejected if p-values were less than 0.05. PEG, polyethylene glycol; ASc, ascorbic acid; NaP, sodium phosphate; PSMC, sodium picosulfate magnesium oxide citric acid.

lected the safety of the formulation (13.8% vs. 25.0%, p=0.0349) and compliance as the most influential factor.

The analysis indicated that 76.5% of the responders preferred 2-L PEG + Asc (69.7% vs. 83.0%, p=0.0197), followed by 4-L PEG, selected by 24.0% of the responders (32.1% vs.16.1%, p=0.0052). There was a significant difference in formulation preference between the responder groups. We found that 52.9% of the physicians responded that they did not prescribe bisacodyl in conjunction with bowel preparation formulation (51.4% vs. 54.5%, p=0.6456). When bisacodyl was prescribed, it was selectively given to patient groups in which the degree of bowel preparation was expected to be poorer (i.e., severe constipation, elderly patients).

For patients with severe constipation, 48.9% of the responders preferred to add laxatives such bisacodyl (55.0% vs. 42.9%, p=0.0699) while another 49.3% chose to prolong the duration of diet control prior to colonoscopy (56.9% vs.

42.0%, p=0.0266). Other responses included, in the order of frequency, increasing the dose of formulation, dividing the formulation dose, and no additional preparation.

When met with inadequate bowel preparation on the day of colonoscopy, 56.6% of the physicians decided to order additional ingestion of the same formulation on the examination day and perform the colonoscopy as scheduled (55.0% vs. 58.0%, p=0.6539), followed by 28.5% of physicians that opted to reschedule the colonoscopy and prescribe the same formulation, in addition to laxatives and diet control (33.9% vs. 23.2%, p=0.0773). The following options were selected at similar rates: add another type of formulation and perform the colonoscopy as scheduled, reschedule the colonoscopy and prescribe another type of formulation, perform an additional enema and perform the colonoscopy as scheduled, and add a bowel preparation formulation through an endoscopic approach. None of the physicians selected an alternative method of colonic evaluation (such as double-contrast barium series or computed tomography scan of the abdomen).

The results indicated that 38.5% of the responders listed poor compliance as the most frequent cause of inadequate bowel preparation (38.5% vs. 38.4%, p=0.9830), while 28.5% suggested inappropriate ingestion of formulation, such as incorrectly following the directions on the formulation package (29.4% vs. 27.7%, p=0.7822). Finally, 26.7% also indicated that an underlying comorbidity was a major cause of poor compliance (30.3% vs. 23.2%, p=0.2355) and others indicated that failed dietary control and ineffectiveness of bowel preparation formulation were also problematic.

The majority of the physicians (75.1%) responded that they did not have any cases with electrolyte imbalance that resulted from bowel preparation formulation (73.4% vs. 76.8%, p=0.5599). For those who did have electrolyte imbalance in their patients, 12.7% listed magnesium citrate combined with sodium picosulfate as the problematic formula (12.8% vs. 12.5%, p=0.9387), and 11.3% chose OSP (10.1% vs. 12.5%, p=0.5720), and the 4-L PEG and 2-L PEG + Asc were the next most frequent formulations. We found that 59.3% of the responders expressed no serious concerns with the safety of bowel preparation formulations (56.9% vs. 61.6%, p=0.4746), but 36.2% did mention the possibility of electrolyte imbalance (33.9% vs. 38.4%, p=0.4915) and

bowel inflammation affecting accurate diagnosis.

When asked about the 2-L PEG + Asc formula, 67.4% indicated that it provided a satisfactory bowel cleansing effect (63.3% vs. 71.4%, p=0.1975), and 52.9% reported that it improved compliance through reduced doses and improved flavor (57.8% vs. 48.2%, p=0.1536). Other descriptions included "appropriate for elderly patients with other comorbidities (such as renal and cardiac dysfunction)" and "recommended for patients with kidney diseases". However, 19.5% of the responders suggested that 2-L PEG + Asc was not as effective as 4-L PEG for bowel cleansing.

Approximately half of the responders did not have any experience in prescribing OSP (54.1% vs. 56.3%, p=0.7512). In those who did, most of the providers limited its prescription to healthy adults due to concerns regarding electrolyte imbalance (27.5% vs. 30.4%, p=0.6423). Other comments on OSP included, in the order of frequency, concerns about renal complications, insufficient bowel preparation compared to 4-L PEG, and satisfactory bowel preparation.

In regards to the magnesium citrate combined with sodium picosulfate, 39.4% of the physicians did not have any experience with the formulation (39.4% vs. 39.3%, p=0.9801). Among the physicians that had experience with the formulation, 38.9% described it as having an inferior bowel cleansing effect compared to 4-L PEG (37.6% vs. 40.2%, p= 0.6959) and 28.1% indicated that it could cause electrolyte imbalance (34.9% vs. 21.4%, p=0.0263). Response rates were compared between tertiary university hospitals and private clinic/secondary hospitals, but there was no significant difference between the two groups in the majority of the items. A significant difference in the order of frequency was found in only one question: bowel preparation in patients with severe constipation.

The responses from Seoul (and the neighboring area) and other areas were compared, and significant differences were found in the response rates of several items, but there was no difference in the overall trend, and the order of frequency mirrored the other responses.

DISCUSSION

Most physicians chose bowel cleansing potency, rather than safety or compliance, as the most important factor for selecting the bowel preparation formulation. This may be because the degree of bowel cleansing directly influences the completion and complications of colonoscopy. In addition, poor bowel preparation can occur despite good compliance, and the risk of complications from bowel preparation formulation is low. Poor bowel preparation extends the duration of the colonoscopy, increasing patient discomfort and adversely affecting the diagnostic rate of colonic disease.⁵ Furthermore, it hinders the cecal insertion rate (greater than 90%), which is an essential component of colonoscopy quality assurance. 12 Among the available bowel preparation formulas, the combination of 2-L PEG + Asc was preferred compared to other formulas because it required a lower ingestion volume than 4-L PEG, while providing similar bowel cleansing potency⁷ and better compliance due to improved flavor. These advantages were also reflected in the responses to this survey.

In patients with severe constipation, most responders preferred to add laxatives such as bisacodyl or to extend the duration of diet control prior to colonoscopy, rather than dividing the dosage of the bowel preparation formulation. While there are reports that restricting dietary fiber leads to improved bowel preparation, 13 there is insufficient evidence of the association between dietary control and the degree of bowel preparation. Adding bisacodyl to standard dosages of bowel preparation formulation has not been thoroughly investigated and the approach remains controversial. One domestic study reported that the addition of bisacodyl did not result in a significant difference compared to the conventional bowel preparation protocol. 4 In comparison, guidelines published by the European Society of Gastrointestinal Endoscopy recommended divided intake of bowel preparation formula since it can improve both compliance and the degree of bowel cleansing. However, this approach was the least preferred method in this survey.

In cases of inadequate bowel preparation on the day of colonoscopy, most preferred to order additional ingestion of the same formula and perform the examination as scheduled, possibly because of difficulty in rescheduling the examination: patients often find it difficult to take another day off from work for a colonoscopy and do not wish to undergo bowel preparation again. The results indicated that 2.7% of the responders chose to administer an extra dose of bowel preparation formula through colonoscopy. Direct administration of the bowel preparation formula to the hepatic flexure with colonoscopy requires approximately two hours, and is reported to achieve adequate bowel preparation in 96.2% of patients. 15 However, because this is such a time-consuming procedure, it is unfeasible under National Health Service medical reimbursement policy conditions in South Korea. None of the responders preferred to substitute another diagnostic method for the colonoscopy, such as a double barium contrast or CT colonography. One report indicated that the CT colonography had higher sensitivity than conventional colonoscopy for detecting colorectal carcinoma, 16 although the approach is not as effective for detecting flat lesions, hyperemia, and superficial mucosal erosion. However, this may be an appropriate alternative when colonoscopy fails.

Sodium phosphate solution was removed from the market in 2008 due to demonstrated renal toxicity, and currently only an OSP solution is available. 17 A study that compared OSP to 2-L PEG + Asc concluded that the two formulas were nearly equivalent in efficacy or safety. 18 Nonetheless, most physicians reported that they had limited experience prescribing OSP due to concerns that OSP could cause complications similar to the sodium phosphate solution.

Several formulas are available for patients for bowel preparation, and the formula is selected after considering bowel preparation potency, safety, and compliance, among other factors.

This study has several limitations. First, our study is limited in clinical application. This study was designed to investigate the preference on bowel preparation agent and preferred strategies on poor bowel preparation. As it is not an evidence-based study, its results have limited novel value for suggesting clinical application. Second, there is potential bias toward a certain bowel preparation agent since the questionnaire was performed by a private company that markets the agents. While the participants in secondary and tertiary hospitals were directly contacted by the research team once, participants in tertiary hospitals who joined academic meetings were further contacted and asked to respond to preliminary questionnaires to maintain objectiveness. Third, this study compared the differences in colonoscopy practice between tertiary hospitals and private/secondary hospitals. However, a more detailed sub-analysis could not be done because of private information act policy. Last, this study lacks data on bowel preparation scale such as Boston scale or Otawa scale, resulting in a more subjective analysis of the

bowel preparation status. However, this study focused on poorly prepared bowels only, especially the cases that impeded colonoscopy. While a detailed scale was not provided, there would have been little disagreement among endoscopists on the degree of poor bowel preparations of the subjects included in this study.

To our knowledge, this is the first study that conducted a large-scale survey of physicians that prescribe bowel preparation formulations. This investigation allowed us to determine current preferences for bowel preparation and management of poor bowel preparations. While this does not represent the entire population of physicians that perform colonoscopies in South Korea, this study was able to capture current trends in treatment approaches, which is important for establishing guidelines and optimizing outcomes.

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