

Feasibility of a novel low-volume and sodium phosphate-free bowel preparation regimen for colon capsule endoscopy

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Abstract. Bowel preparation regimens for colon capsule endoscopy are not yet standardized since they are not well optimized. The aim of the present study was to evaluate the feasibility of a novel low-volume and sodium phosphate-free bowel preparation regimen for colon capsule endoscopy. A total of 31 patients were prospectively enrolled. In the novel regimen, on the day prior to examination, a low-fiber diet was permitted, 5 mg mosapride citrate was administered twice (1 h prior to lunch and supper) and 1 l polyethylene glycol was administered in the evening. On the day of the examination, an additional 1 l polyethylene glycol, 5 mg mosapride citrate and 200 mg simethicone were administered before capsule ingestion. Polyethylene glycol booster (0.5 l) was administered twice, at 1 and 4 h following capsule ingestion. Colon cleansing levels, ileocecal valve transit time and completion rate were evaluated. A total of 29 patients were included in the final analysis, 90% of whom achieved adequate preparation of the overall colon. Ileocecal valve transit time was 2.35 ± 0.82 h and completion rate was 79.3%. The results revealed that the novel low-volume and sodium phosphate-free bowel preparation regimen for colon capsule endoscopy was feasible, with adequate colon cleansing and completion rates, and has the potential to be used as an alternative regimen.

Introduction

Colorectal cancer (CRC) is the second most common type of cancer in western countries and has exhibited an increasing

incidence in many Asian countries in recent decades (1,2). A recent study demonstrated that screening for CRC in average-risk adults was effective in reducing the mortality rate (3). A satisfactory screening method for CRC must be safe, non-invasive, cost-effective, easily acceptable and possess a high diagnostic accuracy (4).

The PillCam colon capsule endoscopy (CCE) may achieve direct visualization of the entire colon without sedation, radiation or air insufflation, which represents a non-invasive imaging system for exploring the colon (5). Although colonoscopy is currently considered to be the gold standard method for CRC screening and the diagnosis of most colonic diseases (4), the PillCam colon capsule endoscopy has been developed as the most promising approach to CRC screening in recent years, which is an alternative for patients with incomplete colonoscopy or who are reluctant to accept colonoscopy examination due to discomfort or embarrassment (6).

The effectiveness of CCE partly depends on the cleanliness of the colon. An optimal bowel preparation regimen for CCE is required for a clean intestine, capsule propulsion and visualization of the whole large intestine. Previous studies have demonstrated bowel preparation regimens for CCE that generally consist of a split-dosage of polyethylene glycol (PEG) with the volume of 4 l, prokinetic agents and sodium phosphate (NaP) boosters (5,7-9). However, large volumes of laxatives may reduce patient compliance. Furthermore, NaP is associated with certain adverse events, such as electrolyte disturbance, acute nephropathy and kidney failure (10), and should be avoided in patients at increased risk of NaP toxicity. Therefore, there is a requirement for the current bowel preparation regimen to be improved.

The present study aimed to evaluate a novel low-volume and NaP-free bowel preparation regimen for CCE. In this regimen, the volume of PEG was reduced to 2 l and NaP was substituted with PEG as the booster. Colon cleansing quality and completion rate were assessed.

Patients and methods

Patients. Between July 2013 and July 2014, a total of 31 patients were enrolled to the current prospective study at the Department of Gastroenterology, Nanfang Hospital, Southern Medical University (Guangzhou, China) in accordance with the

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Table I. Conventional (4) and novel bowel preparation regimens for colon capsule endoscopy.

Time	Regimen	
	Conventional	Novel
Day before examination		
All day	Clear liquids only	Low-fiber diet
1 h before lunch		5 mg mosapride citrate
1 h before supper		5 mg mosapride citrate
6:00-9:00 p.m.	3 l PEG	1 l PEG
Examination day		
6:00 a.m.		1 l PEG
6:00-7:00 a.m.	1 l PEG	
7:30 a.m.		5 mg mosapride citrate
7:45 a.m.	20 mg domperidone	
8:00 a.m.	Capsule ingestion	200 mg simethicone
8:30 a.m.		Capsule ingestion
9:30 a.m.		0.5 l PEG
10:00 a.m.	45 ml NaP + 1 l water	
12:30 p.m.		0.5 l PEG
2:00 p.m.	30 ml NaP + 1 l water	
3:00 p.m.	Snack (optional)	
3:30 p.m.		Snack (optional)
4:30 p.m.	10 mg bisacodyl	

PEG, polyethylene glycol; NaP, sodium phosphate.

following inclusion criteria: Aged 18-75 years, willing to accept CCE examination and providing signed informed consent. According to the criteria in a previously published study, exclusion criteria were as follows: Dysphagia or swallowing disorder, prior major abdominal surgery of the gastrointestinal tract, known or suspected bowel obstruction, presence of a cardiac pacemaker or other implanted electromedical devices and pregnancy (11). The methodology was approved by the Ethics Committee of Nanfang hospital.

PillCam colon capsule endoscopy. The PillCam CCE (PillCam COLON, Given Imaging; Medtronic, Dublin, Ireland) was 11x31 mm in size and had two cameras, one at each end of the capsule, each capturing 2 images/sec. The angle of view for each imager was 156°. The capsule enters a 1 h delay mode following a 3-min initial function, then the system automatically restarts and functions for an additional 9 h. Captured images were transmitted to the data recorder via eight sensors. A rapid real-time viewer allowed a real-time view during a PillCam procedure. Following the examination, the recorded data was downloaded into the Given Imaging RAPID 4 workstation (Medtronic). Captured videos were reviewed by two physicians who had prior experience with colonoscopy and small intestine capsule endoscopy. Colon cleansing levels were then assessed, as described below.

Bowel preparation regimens. As shown in Table I, the conventional regimen of bowel preparation for CCE includes 4 l of an oral preparation of PEG (Colopeg; Roche Laboratories,

Gaillard, France), 1-2 oral boosters of NaP at a dosage of 30-45 ml (Fleet Phospho Soda®; Wolf, Fleet, Lynchburg, VA, USA) and a suppository of bisacodyl as necessary (Dulcolax®, Boehringer Ingelheim, Scherer, Aprilia, Italy) (4). In order to avoid adverse events associated with NaP, improve patient compliance and maintain the quality of bowel cleansing, the current study evaluated a modified regimen. In the novel bowel preparation regimen, on one day prior to examination, a low-fiber diet was permitted, 5 mg mosapride citrate (Gasmotin; Sumitomo Dainippon Pharma Co., Ltd., Osaka, Japan) was orally administered twice (1 h before lunch and 1 h before supper) and 1 l of an oral preparation of PEG (Fortrans; Ipsen, Paris, France) at 6:00-9:00 p.m. On the day of the examination, an additional 1 l PEG, 5 mg mosapride citrate and 200 mg simethicone (Espumisan; Berlin-Chemie AG, Berlin, Germany) were orally administered at 2.5, 1 and 0.5 h prior capsule ingestion, respectively. PEG booster (0.5 l) was orally administered twice, 1 and 4 h following capsule ingestion. The detailed procedure of the novel regimen is presented in Table I. Patient education concerning the bowel preparation procedure for CCE was delivered by physicians prior to the examination, in order to improve the efficacy of the regimen. Any adverse effects were recorded, including nausea, vomiting, abdominal pain, dizziness, headache and allergy.

Performance evaluation. The four-point grading scale system reported by Leighton and Rex (12) was applied to evaluate colon cleansing levels. A 'poor' level of colon cleansing was

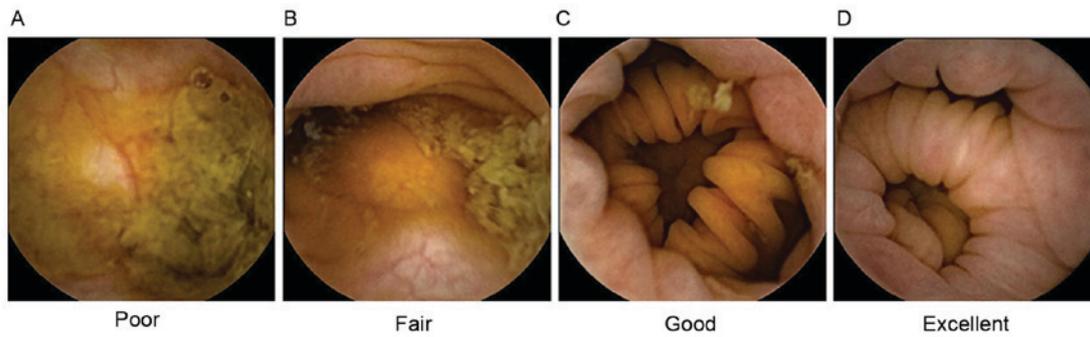


Figure 1. Images of colon cleansing levels rated by a four-point scale grading system. Cleansing levels were rated as (A) poor, (B) fair, (C) good or (D) excellent.

Table II. Clinical indications of patients undergoing colon capsule endoscopy (n=33)^a.

Clinical indication	n	Percentage
Physical examination	8	24.2
Constipation	6	18.2
Abdominal pain	5	15.2
Diarrhea	4	12.1
Abdominal distension	3	9.1
Hematochezia	2	6.1
Acid reflux and heartburn	2	6.1
Recent change of bowel habits	1	3.0
Prior ulcer in terminal ileum	1	3.0
Crohn's disease	1	3.0

^aA total of 29 patients were in the final analyses and as 4 of these patients suffered from two clinical indications, the sum of indications was 33.

defined as a large amount of fecal residue. 'Fair' was defined as a sufficient amount of feces or turbid fluid to prevent reliable examination. 'Good' was defined as a small amount of feces or turbid fluid not interfering with examination. 'Excellent' was defined only small pieces of adherent feces (Fig. 1). For subsequent analysis, the grades of excellent and good were defined as 'adequate preparation', whereas fair and poor were defined as 'inadequate preparation'. The video footage was divided into five segments: Cecum, ascending colon, transverse colon, descending colon and rectosigmoid colon. Subsequently, overall cleansing levels and cleansing levels of each segment were assessed. Ileocecal valve transit time was defined as the time from capsule ingestion to the first image of the cecum. The examination was considered to be completed when the haemorrhoidal plexus was visualized.

Results

Study participants. A total of 29 patients were included in the final analysis (male/female, 13/16; mean age, 35 years; age range, 24-61 years). Two patients (6%) were excluded as data was not acquired due to technical failure. Major clinical indications included physical examination, constipation, abdominal pain and diarrhea (Table II). All enrolled patients

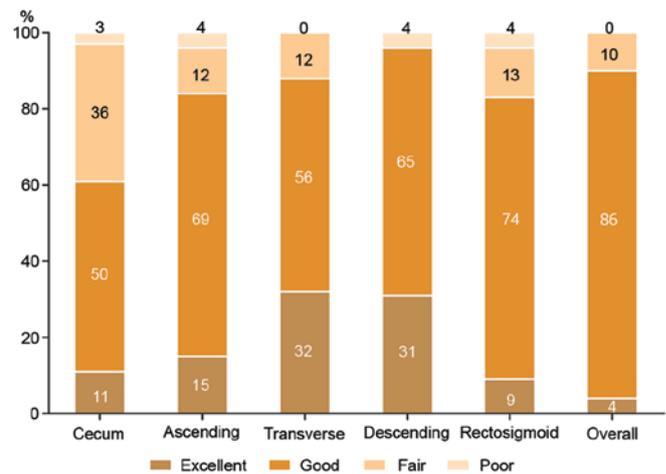


Figure 2. Colon cleansing levels in different colon segments and overall colon. Adequate levels (rated as good or excellent on a four-point scale grading system) were as follows: cecum, 61%; ascending colon, 84%; transverse colon, 88%; descending colon, 96%; rectosigmoid colon, 83%; and overall colon, 90%.

complied with the novel bowel preparation. No adverse effects associated with CCE occurred.

Colon cleansing levels. According to the four-point scale grading system, the results indicated that overall colon cleansing levels were rated as excellent in 1 patient (4%), good in 25 patients (86%) and fair in 3 patients (10%). No patients were rated as poor (Fig. 2). In total, 90% of the patients exhibited adequate colon preparation (ratings of excellent or good). In the individual colon segments, the descending colonic mucosa exhibited the highest quality of cleansing (adequate cleansing level in 96% of patients), whereas the cecum exhibited the poorest quality (adequate cleansing level in 61%). As for bubbles in the large intestine, overall the images were not evidently affected by bubbles and only a small number were observed (Fig. 2).

Colon capsule transmit time and completion rate. Ileocecal valve transit time (time from capsule ingestion to the first image of cecum) was 2.35±0.82 h. Furthermore, 93.1% (27/29) of capsules were located in the small intestine when they restarted following the 1 h delay mode. Two capsules were still in the stomach at this point and successfully travelled into the small intestine after the patients drank some water. Examination completion occurred in 79.3% (23/29) of patients.

Table III. Location of colon capsule endoscopy at different time points (n=29).

Time	Location	Patients (n)	Percentage
Restart after 1 h delay	Stomach	2	6.9
	Small intestine	27	93.1
End of examination	Haemorrhoidal plexus (visible)	23	79.3
	Descending colon	2	6.9
	Transverse colon	1	3.4
	Ascending colon	2	6.9
	Cecum	1	3.4

At the end of CCE examination in 2 cases, the capsule was in the descending colon, in 1 case it was in the transverse colon, in 2 cases it was in the ascending colon and in 1 case it was in the cecum (Table III).

Discussion

At present, a standardized bowel preparation regimen is still not available. In previous studies, large volumes of PEG combined with a NaP booster regimen was most commonly applied (4,5,7-9). However, this remains controversial due to low patient compliance and safety concerns surrounding NaP (13,14). In the present study, a novel low-volume and NaP-free bowel preparation regimen was provided for CCE, which was demonstrated to be feasible.

Different bowel preparation regimens for CCE in previous studies have reported variable results; adequate colon cleansing ranged from 35 to 84% and completion rates ranged from 64 to 100% (4,7-9,14-24). More recently, modified regimens with low dosage PEG have been researched. Hartmann *et al* (14) reported that a 2 l PEG plus ascorbic acid regimen yielded adequate cleansing levels in 82% of patients and Kakugawa *et al* (23) reported that a 2.3-2.6 l polyethylene glycol electrolyte lavage solution (PEG-ELS) regimen yielded adequate cleansing levels in 94% of patients. However, Usui *et al* (24) evaluated a lower volume regimen with 0.7 l PEG in second-generation colon capsule endoscopy, which yielded lower adequate cleansing levels of 60%. According to the four-point grading scale system, 90% of patients achieved adequate colon cleansing level in the present study with a 2 l PEG regimen. Consistent with the results reported by Spada *et al* (19), the current data revealed that the cecum was the segment with the lowest quality of cleansing (adequate level in 61%) and the descending colon had the highest quality of cleansing (adequate level in 94%). The current study demonstrated that a low-volume regimen could also achieve a high quality of colon cleansing.

A booster is necessary for cleaning the colonic mucosa and improving capsule excretion. The efficacy of NaP as booster has been reported in previous studies (5,19,22), however it has associated adverse effects, including electrolyte disturbance, acute nephropathy and kidney failure. Guidelines established in Europe (UK National Patient Safety Agency and European Society of Gastrointestinal Endoscopy) advised against the routine use of NaP for bowel preparation due to

safety concerns (13,25), and an equivalent recommendation is suggested by the Guidelines published by Chinese society of digestive endoscopy in China (26). Therefore, there is an urgent requirement for a safe substitute for NaP. Without side effects such as electrolyte disturbance and renal damage, PEG has been demonstrated to be a safe booster. Spada *et al* (21) and Hartmann *et al* (14) reported PEG booster regimens obtained completion rate in 75 and 76% of cases, respectively. The regimen in the current study achieved a completion rate in 79.3% of cases. Compared with NaP-based regimens, the completion rate is lower, yet the application of PEG as booster is still promising for its safety and further studies should be performed to evaluate how completion rate may be increased. Previously, magnesium citrate was applied as an emerging booster with completion rates of 55-85% (23,24). These fluctuating results emphasize the need for further research on magnesium citrate as a booster.

There are other strategies that are favorable for improving the quality of colon cleansing and increasing completion rate. Several types of prokinetic agent have been used, such as tegaserod (8), domperidone (4,6,15,18), metoclopramide (22) and mosapride (23,27). Mosapride is an emerging prokinetic agent, working as a 5-hydroxytryptamine receptor 4 agonist and accelerating both gastric emptying and peristalsis of the small intestine (28). Wei *et al* (29) and Ida *et al* (30) recommended that patients received 10 mg mosapride citrate 30-60 min prior to capsule ingestion. However, the dosage and administration time of mosapride remain to be evaluated. In the present study, to assist bowel cleansing and reduce the dosage of PEG, 5 mg mosapride citrate was administered 1 h prior to lunch and supper on the day prior to examination and 1 h prior to capsule ingestion. The present results revealed that in 93.1% (27/29) of patients, capsules were located in the small intestine when the capsules activated following the 1 h delay and the average ileocecal valve transit time was 2.35 h. Although evidence from a controlled study is not available, this time was notably shorter than the 5-8 h exhibited in small intestine capsule endoscopy (31). In addition, simethicone is also considered to have an auxiliary effect for bowel preparation. In the studies of Kakugawa *et al* (23) and Usui *et al* (24), simethicone was applied, but its necessity was not discussed. In the present study, to decrease the number of bubbles in the large intestine, 200 mg simethicone was ingested 30 min prior to capsule endoscopy. Ultimately, bisacodyl suppository was optional in previous studies (4,14). In order to reduce the embarrassment

of patients and maintain patient compliance, bisacodyl was not administered.

The present study demonstrated that a low-volume and NaP-free bowel preparation regimen was effective for colon capsule endoscopy. However, there were some limitations to the study, including the limited sample size and the absence of a controlled comparison with conventional colonoscopy. Furthermore, the study would be optimized if consecutive patients were included.

In conclusion, a novel low-volume and NaP-free bowel preparation regimen for CCE has been demonstrated to be feasible, with adequate colon cleansing levels and completion rate, and could therefore be used as an alternative regimen. Further studies should be performed in order to evaluate whether the completion rate can be increased, and the accuracy of CCE with the novel regimen should be compared with traditional colonoscopy in a randomized, controlled trial.

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