Prospective study of factors important to achieve observation of the entire colon on colon capsule endoscopy

Ther Adv Gastroenterol
2017, Vol. 10(1) 20–31
DOI: 10.1177/1756283X16673556

Junichi Sato, Masanao Nakamura, Osamu Watanabe, Takeshi Yamamura, Kohei Funasaka, Eizaburo Ohno, Ryoji Miyahara, Hiroki Kawashima, Hidemi Goto and Yoshiki Hirooka

Abstract

Background: Colon capsule endoscopy (CCE) is a procedure in which capsule swallowing facilitates observation of the lumen of the entire digestive tract. It does not require an air supply, and is a noninvasive procedure with a markedly low risk of adverse events in comparison with conventional colonoscopy (CS). It reduces patient stress, and may be acceptable to patients. A limitation of this procedure is that the entire colon observation rate (CCE excretion rate, completed CCE rate) is not 100%. In this study, we prospectively investigated clinical factors important to achieve observation of the entire colon on CCE.

Methods: The participants were 70 patients for whom CCE was scheduled, and from whom written informed consent regarding participation in this study was obtained. We selected patient background/examination factors, and analyzed all factors involved in observation of the entire colon and factors for completion of the CCE within 4 h after the start of examination using multivariate analysis.

Results: Of the 70 enrolled patients, 64 were analyzed, excluding 6. On multiple logistic analysis, only a water intake of ⩾12.0 ml/min during examination [$p = 0.025$, odds ratio (OR): 46.753, 95% confidence interval (CI): 1.630–1341.248] was identified as an independent predictive factor involved in observation of the entire colon. With respect to factors involved in the completion of CCE within 4 h, multiple logistic analysis showed that a body mass index (BMI) of ⩾25 ($p = 0.039$, OR: 13.723, 95% CI: 1.135–165.913), the absence of constipation ($p = 0.030$, OR: 13.988, 95% CI: 1.287–152.047), and a water intake of ⩾12.0 ml/min during examination ($p = 0.004$, OR: 12.028, 95% CI: 2.225–65.029) were independent predictive factors.

Conclusions: Completion of a CCE was most closely related to water intake per hour. In addition to water intake, CCE-promoting factors included a high BMI and the absence of constipation.

Keywords: body mass index, capsule endoscopy, colon, constipation, gastrointestinal endoscopy, water intake

Correspondence to:
Masanao Nakamura, MD, PhD
Department of Gastroenterology and Hepatology, Nagoya University Graduate School of Medicine, 65 Tsuruma-cho, Showa-ku, Nagoya, 466-8550, Japan
makamura@med.nagoya-u.ac.jp

Junichi Sato, MD
Osamu Watanabe, MD, PhD
Kohei Funasaka, MD, PhD
Eizaburo Ohno, MD, PhD
Ryoji Miyahara, MD, PhD
Hiroki Kawashima, MD, PhD
Hidemi Goto, MD, PhD
Nagoya University Graduate School of Medicine, Department of Gastroenterology and Hepatology, Nagoya, Japan

Takeshi Yamamura, MD, PhD
Yoshiki Hirooka, MD, PhD
Nagoya University Hospital, Department of Endoscopy, Nagoya, Japan

Introduction

Colonoscopy (CS) is a gold standard for the diagnosis of colorectal diseases such as colorectal cancer or inflammatory bowel disease. However, it is difficult to perform complete CS in some patients, and others hesitate to undergo CS. The cecal intubation rates on CS are reportedly 85– 95% [Anderson *et al.* 2000; Shah *et al.* 2007; Aljarallah and Alshammari, 2011; Koido *et al.* 2014; Dafnis *et al.* 2005; Fasoli *et al.* 2002], and other procedures will be suggested in patients with incomplete CS.

Colon capsule endoscopy (CCE) is a procedure in which capsule swallowing facilitates observation of the lumen of the entire digestive tract. It does not require an air supply, and is a noninvasive procedure with a markedly low risk of adverse

events in comparison with conventional CS. It reduces patient stress, and may be acceptable to patients [Saito *et al.* 2015].

Another option of colorectal examination is computerized tomography (CT) colonography (CTC). The sensitivity and specificity of CTC is high in the diagnostic yield of colorectal polyps, suggesting the usefulness of CTC [Johnson *et al.* 2008; Graser *et al.* 2009; Regge *et al.* 2009]. On the other hand, a study indicated that the sensitivity and specificity of CCE for colorectal polyp detection were favorable in patients with incomplete CS, and that the colorectal polyp detection rate was higher than that of CTC [Spada *et al.* 2015]. As such, demands for CCE have been increasing and the role of CCE will become more important in the future.

However, issues to be clinically resolved have been raised: the entire colon observation rate on CCE (excretion rate, completed CCE rate) is not 100%. According to previous clinical studies, the rate ranges from 70–90% [Eliakim *et al.* 2006; Schoofs *et al.* 2006; van Gossum *et al.* 2009; Herrerías-Gutiérrez *et al.* 2011; Spada *et al.* 2011a]. To improve the excretion rate, preparation regimens have been discussed. However, no clinical study has been conducted into the types of patient that can complete CCE. In other words, factors influencing complete CCE have not been reviewed. It is essential to select the patient who is suitable for CCE.

Even CS could not achieve total colon observation in all patients, though it is the gold standard of colon examination. Factors associated with incomplete CS have been reported in the literature: sex (female) [Anderson *et al.* 2000; Shah *et al.* 2007; Koido *et al.* 2014; Dafnis *et al.* 2005; Cirocco and Rusin 1995], age (elderly) [Shah *et al.* 2007; Aljarallah and Alshammari 2011; Koido *et al.* 2014; Dafnis *et al.* 2005], previous abdominal or pelvic surgery [Shah *et al.* 2007; Koido *et al.* 2014; Cirocco and Rusin 1995], and diverticulum [Dafnis *et al.* 2005]. However, considering the characteristics of CCE, factors involved in difficulty in CCE excretion may differ from these factors. These factors should be investigated to understand whether the patient is suitable for CCE. If factors influencing complete CCE are clarified, patients in whom a CCE can be readily excreted can be selected; for such patients, the dose of a cleaning liquid can be reduced. It may be possible to establish order-made regimens appropriate for individual patients in the future. For patients in whom completion of the CCE procedure is difficult, and who do not wish to undergo CS, other colorectal examinations, such as CTC, may be adequately performed, and this may finally increase the proportion of patients undergoing CS.

The purpose of this study was to investigate clinical factors important to prospectively achieving completion of the CCE procedure and find CCE-matched patients.

Material and methods

Patients

We selected patients that were at least 20 years old, for whom a CCE was scheduled between June 2015 and February 2016, and from whom written informed consent regarding participation in this study was obtained, regardless of sex. We excluded patients with stenosis of the digestive tract, those definitively diagnosed with Crohn's disease, those who had undergone abdominal radiotherapy, those with pacemaker insertion, those with dysphagia, those with a history of hypersensitivity to drugs for examination, those in whom acute abdomen was suspected, those with spastic constipation, those with severely hard stools, and those with an electrolyte imbalance. The primary endpoint of this study was to prospectively clarify factors important to achieve completion of the CCE procedure. Its secondary endpoint was to clarify factors involved in the completion of a CCE within 4 h. The protocol of this study was approved by the Ethics Review Board of Nagoya University Hospital, Japan (2014-0255), and registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN000015277).

To patients for whom a CCE was scheduled, the purpose and contents of this study were explained, and informed consent was obtained. We took a blood test for checking the electrolyte imbalance related to the oral administration of several kinds of cleaning liquids and prokinetics. Prior to this study, a questionnaire survey of each patient's background regarding factors involved in entire colon observation was conducted. A pedometer (Lifecorder GS; Suzuken Co. Ltd, Nagoya, Japan) was attached to a waist belt immediately

Table 1. Schedule of bowel preparation used in the study.

Schedule	Intake
Day 2, before bedtime	2 Senna tablets, 12 mg each
Day 1, all day	3 meals: low-fiber diet, sugar supplementation if necessary
20:00	Magnesium citrate 50 g (180 ml): hypertonic method
Before bedtime	2 Senna tablets
Day of examination	
08:30	1.5 l PEG
10:00	Capsule ingestion with mosapride citrate 20 mg. Attachment of a pedometer
11:00	Real-time monitoring
	• If CCE remains in the stomach, additional examination should be conducted after 1 h. If it still remains in the stomach at that point, metoclopramide 10 mg should be intramuscularly injected.
	• If it is present in the small intestine, the 1st booster should be started.
1st boost (within 2 h)	Each patient drinks a mixture of PEG 1000 ml and water 1000 ml. Candies and gum are permitted.
	• Real-time monitoring
	The right colon or lumen seems to be dilated.
	If the left colon or wall is reached, left abdominal compression (5 s × 5 sets)/ using stairs/walking/postural changes/exercise to strengthen the abdominal muscles* should be conducted.
	→2nd boost
2nd boost	Sodium picosulfate 48 mg
	• Real-time monitoring (30 min after the completion of the 2nd boost)
	The * items should be performed. →3rd boost
3rd boost (within 1–2 h)	Magnesium citrate 50 g (900 ml): isotonic method
	If necessary, The * items should be performed.
	• Subsequently, additional drinks, light meals, irritating suppositories, enema, or the muscular injection of metoclopramide 10 mg should be decided after consultation with each patient.

CCE, colon capsule endoscope; PEG, polyethylene glycol.

before examination. A CCE was performed according to the bowel preparation regimen presented in Table 1. This regimen is currently one of the Japanese standards because sodium phosphate (NaP) is not available in Japan. Polyethylene glycol (PEG) is frequently used as the main booster in Japan.

Definitions in this study

'Non-CCE excretion' refers to cases in which a CCE is not excreted within the battery time, and does not mean retention of the capsule. Patients receiving any laxatives regularly, regardless of fecal property or frequency, were regarded as having 'constipation'. 'Previous abdominal surgery' refers to abdominal surgery without intestinal resection. In this study, there was no patient who had undergone intestinal resection. 'Abdominal symptoms' refer to the presence of symptoms, such as abdominal pain, distension or discomfort, for 3 days or more per month, within the past 3 months. Patients receiving drug therapy for diabetes regardless of HbA1c or those with an HbA1c of $\geqslant$6.5% were regarded as having diabetes. The number of steps during examination and amount of water intake involving cleaning liquids were calculated every hour and reviewed in the analysis.

Colon cleansing level

In accordance with a previous article, we used 'excellent/good/fair/poor' to categorize the colon cleansing level [Leighton and Rex 2011]. 'Excellent/good' levels were evaluated

Table 2. Patient characteristics.

Number of patients	64
Mean age (years)	57.8 (25–87)
Male/female	36/28
BMI (%)	22.7 (16.2–31.6)
Constipation (%)	16 (25.0)
Previous abdominal surgery (%)	23 (35.9)
Abdominal symptoms (%)	26 (40.6)
Diabetes (%)	8 (12.5)
Ulcerative colitis (%)	10 (15.6)
Charlson comorbidity index	0.66 (0–4)

BMI, body mass index.

as adequate, and 'fair/poor' as inadequate. We evaluated the colon cleansing level by dividing the colon into four segments: right colon (cecum, ascending colon), transverse colon, left colon (descending colon, sigmoid colon), and rectum.

Statistical analysis

All data were analyzed using SPSS version 23.0 statistical software (IBM, Tokyo, Japan). Logistic regression was used to estimate the hazard ratio (HR) and the 95% confidence interval (CI) of various factors associated with achieving completion of the CCE. Differences with values of $p < 0.05$ were considered statistically significant.

Results

Patient characteristics

During the study period, 70 patients were enrolled. This analysis was performed in 64 patients. Of the 6 that were excluded, 2 were excluded because the capsule could not reach the cecum within the examination time, 2 dropped out during examination because they were unable to take the amount of cleaning liquids, and 2 were excluded due to machinery problems.

Concerning the patient background, the mean age was 57.8 years, and the patients consisted of 36 males and 28 females, with a mean body mass index (BMI) of 22.7. The proportion of patients with constipation was 25.0%. Those who had undergone abdominal surgery accounted for 35.9%, those with abdominal symptoms accounted for 40.6%, those with diabetes accounted for 12.5%, and those with ulcerative colitis accounted for 15.6%. To assess the severity of comorbidity, we used Charlson comorbidity index [Charlson *et al.* 1987], and the mean index was 0.66 (Table 2).

CCE results

With respect to the results of CCE, overall, the excretion rate (completed CCE rate) was 81.3% (52/64). The mean gastric transit time was 44.6 min, and the mean small intestinal transit time was 61.0 min [Hejazi *et al.* 2016]; shorter than conventional small intestinal capsule endoscopy. The mean colorectal transit time was 134.7 min, and the mean duration of all examinations was 355.5 min. Concerning the colon cleansing level, right colonic, transverse colonic, left colonic, and rectal levels were evaluated as adequate in 95.9%, 98.0%, 95.9%, and 89.8% of the patients, respectively. Patients with any findings accounted for 95.3%: diverticulum was observed in 62.5%, and colorectal polyps in 50.0%. There were no CCE-related adverse event, such as retention, or adverse reaction to cleansing liquids, such as nausea, vomiting or abdominal pain, in any patient. In the nonexcretion group, the final sites of CCE arrival were the left colon in 96.3% (11/12) of the patients and right colon in 8.7% (1/12). The mean total water intake was 3895.8 ml (Table 3).

Comparison of excretion and nonexcretion group

Factors that may influence excretion during a CCE were compared between the excretion and nonexcretion groups, as shown in Table 4. There were no significant differences in the age, sex, BMI, previous abdominal surgery, presence or absence of ulcerative colitis, Charlson comorbidity index, number of steps during examination, gastric transit time, small intestinal transit time, presence or absence of colorectal polyps, or presence or absence of diverticulum. There were significant differences for complete CCE excretion in the factors, constipation, abdominal symptoms, diabetes, and water intake during examination between the two groups.

Univariate and multivariate analyses using logistic regression

The results of a review to clarify factors important to achieve completion of CCE are shown in Table 5. On univariate analysis, 4 factors were

Table 3. Results of CCE procedure.

Number of excreted CCE (%)	52 (81.3)
Gastric transit time (min)	44.6 (1–205)
Small intestinal transit time (min)	61.0 (6–177)
Colorectal transit time (min)	134.7 (3–529)
Duration of examination (min)	355.5 (75–999)
Colon cleansing level	
Adequate (%)	
Right colon	95.9
Transverse colon	98.0
Left colon	95.9
Rectum	89.8
Proportion of patients with findings (%)	95.3
Primary findings (%)	
Diverticulum	62.5
Colorectal polyp	50.0
Erosion/flare	35.9
Hemorrhoid	21.9
Ulcerative colitis	15.6
Adverse events (%)	0
Final site of CCE arrival in the nonexcretion group (%)	
Left colon	91.7
Right colon	8.3
Total water intake (ml)	3895.8 (2000–7700)

CCE, colon capsule endoscope.

significantly associated with the excretion rate: the absence of constipation [$p = 0.022$, odds ratio (OR): 4.778, 95% CI: 1.251–18.254], absence of abdominal symptoms ($p = 0.050$, OR: 3.778, 95% CI: 1.000–14.273), a step count of ⩾5.0 per minute during examination ($p = 0.034$, OR: 4.200, 95% CI: 1.116–15.804), and a water intake of ⩾12.0 ml/min during examination ($p = 0.015$, OR: 13.870, 95% CI: 1.666–115.434). When performing multiple logistic analysis on all items, only a water intake of ⩾12.0 ml/min during examination ($p = 0.025$, OR: 46.753, 95% CI: 1.630–1341.248) was identified as an independent predictive factor.

The results of a review to clarify factors contributing to the completion of CCE within 4 h are shown in Table 6. On univariate analysis, four factors were significantly associated with CCE excretion within 4 h: the absence of constipation ($p = 0.018$, OR: 5.333, 95% CI: 1.334–21.325), ulcerative colitis ($p = 0.044$, OR: 5.391, 95% CI: 1.045–27.812), a water intake of ⩾12.0 ml/min during examination ($p > 0.001$, OR: 10.679, 95% CI: 3.350–34.036), and a short intestinal transit time of <60 min ($p = 0.045$, OR: 2.850, 95% CI: 1.026–7.916). When performing multiple logistic analysis in all items, a BMI of ⩾25 ($p = 0.039$, OR: 13.723, 95% CI: 1.135–165.913), the absence of constipation ($p = 0.030$, OR: 13.988, 95% CI: 1.287–152.047), and a water intake of ⩾12.0 ml/min during examination ($p = 0.004$, OR: 12.028, 95% CI: 2.225–65.029) were identified as independent predictive factors.

Discussion

The morbidity and mortality rates of colorectal cancer remain high. To prevent colorectal cancer development and colorectal cancer-related death, it may be important to positively undergo colorectal examination. The sensitivity and specificity of second-generation CCE for detecting colorectal polyps measuring ⩾6 mm is 63–91% and 64–94%, respectively; this procedure proves to be useful [Spada *et al.* 2011b, 2011c, 2012; Eliakim *et al.* 2009; Hartmann *et al.* 2012]. On the other hand, several issues to be clinically resolved have been raised. In particular, the most important issue is that the entire colon observation rate (excretion rate, completed CCE rate) is not 100%. One idea for improving completed CCE rates was to identify the patients most suitable for CCE. Therefore, we conducted a prospective study to clarify factors important to achieve completion of CCE (Table 5).

Water intake per hour during examination was identified as an independent predictive factor important to achieve completion of CCE. This suggests that if water is not ingested at a specific speed or faster, it is not effective in achieving completion of CCE. PEG solution, which was used in this study, is isotonic, and does not cause any colonic membrane-mediated changes [Keeffe, 1996]. Briefly, the oral administration of PEG solution at a specific speed or faster and intestinal retention of water involving PEG solution, may be important for CCE excretion. To achieve a complete CCE, it may also be important to select the patients who can drink enough cleansing liquids at a satisfactory speed.

Factors associated with incomplete CS, sex (female), age (elderly), previous abdominal or pelvic surgery, and diverticulum have been indicated,

Table 4. Comparison of excretion and nonexcretion group.

	Excretion group	Nonexcretion group	*p* value
Number of patients	52	12	
Mean age (years)	56.2 (25–84)	64.7 (39–87)	*0.121
Male/female	32/20	4/8	**0.108
BMI	22.8 (16.2–31.6)	22.1 (17.2–27.3)	*0.705
Constipation (%)	9 (17.3)	6 (50.0)	**0.016
Previous abdominal surgery (%)	17 (32.7)	6 (50.0)	**0.260
Abdominal symptoms (%)	18 (34.6)	8 (66.7)	**0.042
Diabetes (%)	4 (7.7)	4 (33.3)	**0.015
Ulcerative colitis (%)	9 (17.3)	1 (8.3)	**0.440
Charlson comorbidity index	0.60 (0–4)	0.92 (0–2)	*0.231
Number of steps during examination (steps/min)	9.46 (2.57–25.24)	6.63 (0.071–17.4)	*0.090
Water intake during examination (ml/min)	13.6 (3.94–43.8)	6.45 (3.11–13.8)	*<0.001
Gastric transit time (min)	44.4 (5–205)	45.6 (1–94)	*0.380
Small intestinal transit time (min)	60.4 (6–177)	63.6 (21–132)	*0.731
Diverticulum	31 (59.6)	9 (75.0)	**0.258
Colorectal polyp	26 (50.0)	6 (50.0)	**0.625

*Mann–Whitney test **Fisher's exact method.
BMI, Body mass index.

but, of these, no factor was identified as a factor that makes CCE excretion difficult, though both CS and CCE belong to the category of colorectal examination. One reason was that we could understand the relationship between constipation and late CCE excretion, since constipation patients have a long, spastic or very relaxed colon. Another reason was speculated that water intake during CCE significantly affected the completion of CCE with a high OR and therefore the other factors could not affect it. Our results provide useful information for selecting the colorectal examinations; for those with factors associated with incomplete CS, such as sex (female), age (elderly), previous abdominal or pelvic surgery, and diverticulum, CCE may be positively recommended, because these factors do not make CCE excretion difficult. For those who are unable to drink a sufficient volume of water, involving cleansing liquids, CS should be selected rather than CCE. For those who refuse CS despite the above conditions, appropriate examinations, such as CTC, may be selected with reference to the individuals' characteristics.

We also reviewed factors excreting the capsule within 4 h (Table 6). A BMI of $\geqslant$25, the absence of constipation, and enough water intake during examination were identified as independent predictive factors.

Constipation affected CCE excretion time. We defined constipation as the status of the patient who used any laxative regularly. When selecting CCE, the regular use of laxative should be ascertained prior to examination.

A BMI of $\geqslant$25 as an independent predictive factor reflects that a CCE is more readily excreted in patients with a higher abdominal and visceral fat level. A study reported lower BMI as a factor associated with incomplete CS [Anderson *et al.* 2000], suggesting that abdominal wall and visceral fat prevents loop formation on colonoscope insertion, facilitating endoscope insertion in the obese patient. There may also be similar mechanism in CCE. In patients with a BMI $\geqslant$ 25, that is, obese patients, visceral fat-related abdominal pressure may always be loaded on the intestinal tract in comparison with thin patients. This abdominal pressure can contribute to early CCE excretion. In this study, the capsule was left in the left colon, especially the sigmoid colon, in most patients in whom a CCE was not excreted out of the body. In such patients, real-time monitoring or imaging showed flexions of the sigmoid colon for a long duration. This may have been related to curvatures, and the flexions may have made it impossible for the capsule to go through the sigmoid colon. A study reviewed CTC findings in

Table 5. Logistic analysis of factors influencing complete CCE.

	Number of patients	Excreted (%)	Univariate analysis		Multivariate analysis	
			P-value	Odds ratio (95% confidence interval)	P-value	Odds ratio (95% confidence interval)
Age			0.081			
⩾65	23	16 (69.6)		0.317 (0.087–1.153)	0.158	0.151 (0.011–2.086)
<65	41	36 (87.8)		1.000		
Sex			0.085			
Male	36	32 (88.9)		3.200 (0.852–12.026)	0.445	2.346 (0.263–20.884)
Female	28	20 (71.4)		1.000		
BMI			0.838			
25⩽	12	10 (83.3)		1.190 (0.225–6.308)	0.409	5.937 (0.087–406.249)
<25	52	42 (80.8)		1.000		
Constipation			0.022			
Yes	15	9 (60.0)		1.000	0.898	1.197 (0.076–18.779)
No	49	43 (87.8)		4.778 (1.251–18.254)		
Previous abdominal surgery			0.266			
Yes	23	17 (73.9)		0.486 (0.136–1.732)	0.526	0.461 (0.042–5.027)
No	41	35 (85.4)		1.000		
Abdominal symptoms			0.050			
Yes	26	18 (69.2)		1.000	0.197	4.220 (0.473–37.657)
No	38	34 (89.5)		3.778 (1.000–14.273)		
Diabetes			0.026			
Yes	8	4 (50.0)		1.000	0.149	30.015 (0.295–3054.065)
No	56	48 (85.7)		6.000 (1.242–28.987)		
Ulcerative colitis			0.451			
Yes	10	9 (90.0)		2.302 (0.263–20.155)	0.864	0.750 (0.028–20.270)
No	54	43 (79.6)		1.000		
Charlson's comorbidity index			0.266			
⩾1	23	17 (73.9)		0.486 (0.136–1.732)	0.204	9.751 (0.291–327.046)
0	41	35 (85.4)		1.000		

(Continued)

Table 5. (Continued)

	Number of patients	Excreted (%)	Univariate analysis		Multivariate analysis	
			P-value	Odds ratio (95% confidence interval)	P-value	Odds ratio (95% confidence interval)
Number of steps during examination (steps/min)			0.034			
⩾5.0	48	42 (87.5)		4.200 (1.116–15.804)	0.313	5.933 (0.186–188.770)
<5.0	16	10 (62.5)		1.000		
Water intake during examination (mL/min)			0.015			
⩾12.0	30	29 (96.7)		13.870 (1.666–115.434)	0.025	46.753 (1.630–1341.248)
<12.0	34	23 (67.6)		1.000		
Gastric transit time (min)			0.201			
⩾30	21	19 (90.5)		2.879 (0.570–14.543)	0.326	3.984 (0.253–62.676)
<30	43	33 (76.7)		1.000		
Small intestinal transit time (min)			0.718			
⩾60	29	23 (79.3)		1.000	0.255	0.277 (0.030–2.527)
<60	35	29 (82.9)		1.261 (0.359–4.432)		
Diverticulum			0.327			
Yes	40	31 (77.5)		0.492 (0.119–2.034)	0.438	2.640 (0.227–30.638)
No	24	21 (87.5)		1.000		
Colorectal polyp			1.000			
Yes	32	26 (81.3)		1.000 (0.285–3.509)	0.793	1.307 (0.177–9.627)
No	32	26 (81.3)		1.000		

Table 6. Logistic analysis of factors influencing complete CCE within 4 hours.

	Number of patients	Achieved (%)	Univariate analysis		Multivariate analysis	
			P-value	Odds ratio (95% confidence interval)	P-value	Odds ratio (95% confidence interval)
Age			0.942			
⩾65	23	11 (47.8)		0.963 (0.346–2.674)	0.168	3.826 (0.567–25.807)
<65	41	20 (48.8)		1.000		
Sex			0.198			
Male	36	20 (55.6)		1.932 (0.708–5.271)	0.538	0.564 (0.091–3.497)
Female	28	11 (39.3)		1.000		
BMI			0.169			
25⩽	12	8 (66.7)		2.522 (0.674–9.431)	0.039	13.723 (1.135–165.913)
<25	52	23 (44.2)		1.000		
Constipation			0.018			
Yes	15	3 (20.0)		1.000	0.030	13.988 (1.287–152.047)
No	49	28 (57.1)		5.333 (1.334–21.325)		
Previous abdominal surgery			0.942			
Yes	23	11 (47.8)		0.963 (0.346–2.674)	0.918	0.904 (0.132–6.199)
No	41	20 (48.8)		1.000		
Abdominal symptoms			0.762			
Yes	26	12 (46.2)		1.000	0.684	0.714 (0.141–3.608)
No	38	19 (50.0)		1.167 (0.429–3.170)		
Diabetes			0.173			
Yes	8	2 (25.0)		1.000	0.256	4.500 (0.335–60.406)
No	56	29 (51.8)		3.222 (0.598–17.358)		
Ulcerative colitis			0.044			
Yes	10	8 (80.0)		5.391 (1.045–27.812)	0.065	18.129 (0.834–394.029)
No	54	23 (42.6)		1.000		
Charlson's comorbidity index			0.942			
⩾1	23	11 (47.8)		0.963 (0.346–2.674)	0.981	1.023 (0.155–6.737)
0	41	20 (48.8)		1.000		

(Continued)

Table 6. (Continued)

	Number of patients	Achieved (%)	Univariate analysis		Multivariate analysis	
			P-value	Odds ratio (95% confidence interval)	P-value	Odds ratio (95% confidence interval)
Number of steps during examination (steps/min)			0.665			
⩾5.0	48	24 (50.0)		1.286 (0.412-4.013)	0.427	0.414 (0.047-3.655)
<5.0	16	7 (43.8)		1.000		
Water intake during examination (mL/min)			>0.001			
⩾12.0	30	23 (76.7)		10.679 (3.350-34.036)	0.004	12.028 (2.225-65.029)
<12.0	34	8 (23.5)		1.000		
Gastric transit time (min)			0.332			
⩾30	21	12 (57.1)		1.684 (0.587-4.828)	0.629	1.515 (0.282-8.141)
<30	43	19 (44.2)		1.000		
Small intestinal transit time (min)			0.045			
⩾60	29	10 (34.5)		1.000	0.590	1.603 (0.288-8.940)
<60	35	21 (60.0)		2.850 (1.026-7.916)		
Diverticulum			0.084			
Yes	40	16 (40.0)		0.400 (0.141-1.132)	0.656	0.665 (0.111-3.990)
No	24	15 (62.5)		1.000		
Colorectal polyp			0.803			
Yes	32	16 (50.0)		1.133 (0.425-3.023)	0.731	1.307 (0.284-6.005)
No	32	15 (46.9)		1.000		

patients with incomplete CS, and indicated the length of the colon, that of the transverse colon, that of the sigmoid colon, number of curvatures, and diverticulum as factors associated with incomplete CS [Hanson *et al.* 2007]. The number of sigmoid colon curvatures should be examined in the future. Furthermore, another study investigated the length, maximal diameter, and surface area of the intestinal tract through enema, and reported that the maximal diameter of the sigmoid colon was the second shortest, following that of the descending colon, and that the length and surface area of the sigmoid colon were the second longest and largest, following those of the transverse colon [Sadahiro *et al.* 1992].

A main limitation of this study was the types of boosters. Boosters were the important factors to achieve completion of the CCE. NaP and sodium sulfate (Suprep) were not used in this regimen. Although NaP and Suprep are useful as a booster [Spada *et al.* 2011c; Singhal *et al.* 2014], they are not available in Japan; PEG is mainly used as a booster in Japan. Nevertheless, a paper reports that PEG has been proven to have a poor effect as a booster [Spada *et al.* 2011c]. PEG acts as a booster due to a cascade effect, whereas other boosters can act through an activation of colonic movements. With the NaP and Suprep regimen, it will be necessary to review examination-related factors along with the number of steps and water intake during examination. Furthermore, the number of patients, which was relatively small despite being a prospective study, also had limitations. The target sample size on the trial registry was 100 patients; however we analyzed the data of 70 patients and obtained significant results, and so patient recruitment was stopped. In the future, a larger number of patients should be investigated by using other regimens.

In conclusion, the completion of CCE was most closely related to water intake per hour in regimens including PEG as a booster. In addition, excretion-accelerating factors included a high BMI and the absence of constipation. However, the results of this study cannot be directly translated to regimens of preparations containing different boosters.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors declare that there is no conflict of interest.

References

Aljarallah, B. and Alshammari, B. (2011) Colonoscopy completion rates and reasons for incompletion. *Int J Health Sci (Qassim)* 5: 102–107.

Anderson, J., Gonzalez, J., Messina, C. and Pollack, B. (2000) Factors that predict incomplete colonoscopy: thinner is not always better. *Am J Gastroenterol* 95: 2784–2787.

Charlson, M., Pompei, P., Ales, K. and MacKenzie, C. (1987) A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 40: 373–383.

Cirocco, W. and Rusin, L. (1995) Factors that predict incomplete colonoscopy. *Dis Colon Rectum* 38: 964–968.

Dafnis, G., Granath, F., Påhlman, L., Ekbom, A. and Blomqvist, P. (2005) Patient factors influencing the completion rate in colonoscopy. *Dig Liver Dis* 37: 113–118.

Eliakim, R., Fireman, Z., Gralnek, I., Yassin, K., Waterman, M., Kopelman, Y. *et al.* (2006) Evaluation of the PillCam Colon Capsule in the detection of colonic pathology: results of the first multicenter, prospective, comparative study. *Endoscopy* 38: 963–970.

Eliakim, R., Yassin, K., Niv, Y., Metzger, Y., Lachter, J., Gal, E. *et al.* (2009) Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. *Endoscopy* 41: 1026–1031.

Fasoli, R., Repaci, G., Comin, U. and Minoli, G. (2002) A multi-centre North Italian prospective survey on some quality parameters in lower gastrointestinal endoscopy. *Dig Liver Dis* 34: 833–841.

Graser, A., Stieber, P., Nagel, D., Schafer, C., Horst, D., Becker, C. *et al.* (2009) Comparison of CT colonography, colonoscopy, sigmoidoscopy and faecal occult blood tests for the detection of advanced adenoma in an average risk population. *Gut* 58: 241–248.

Hanson, M., Pickhardt, P., Kim, D. and Pfau, P. (2007) Anatomic factors predictive of incomplete colonoscopy based on findings at CT colonography. *AJR Am J Roentgenol* 189: 774–779.

Hartmann, D., Keuchel, M., Philipper, M., Gralnek, I., Jakobs, R., Hagenmuller, F. *et al.* (2012) A pilot study evaluating a new low-volume colon cleansing

procedure for capsule colonoscopy. *Endoscopy* 44: 482–486.

Hejazi, R., Bashashati, M., Saadi, M., Mulla, Z., Sarosiek, I., McCallum, R. *et al.* (2016) Video capsule endoscopy: a tool for the assessment of small bowel transit time. *Front Med (Lausanne)* 3: 6.

Herrerías-Gutiérrez, J., Argüelles-Arias, F., Caunedo-Álvarez, A., San-Juan-Acosta, Romero-Vazquez, J., Garcia-Montes, J. *et al.* (2011) PillCam Colon Capsule for the study of colonic pathology in clinical practice. Study of agreement with colonoscopy. *Rev Esp Enferm Dig* 103: 69–75.

Johnson, C., Chen, M., Toledano, A., Heiken, J., Dachman, A., Kuo, M. *et al.* (2008) Accuracy of CT colonography for detection of large adenomas and cancers. *N Engl J Med* 359: 1207–1217.

Keeffe, E. (1996) Colonoscopy preps: what's best? *Gastrointest Endosc* 43: 524–528.

Koido, S., Ohkusa, T., Nakae, K., Yokoyama, T., Shibuya, T., Sakamoto, N. *et al.* (2014) Factors associated with incomplete colonoscopy at a Japanese academic hospital. *World J Gastroenterol* 20: 6961–6967.

Leighton, J. and Rex, D. (2011) A grading scale to evaluate colon cleansing for the PillCam Colon Capsule: a reliability study. *Endoscopy* 43: 123–127.

Regge, D., Laudi, C., Galatola, G., Monica, P., Bonelli, L., Angelelli, G. *et al.* (2009) Diagnostic accuracy of computed tomographic colonography for the detection of advanced neoplasia in individuals at increased risk of colorectal cancer. *JAMA* 301: 2453–2461.

Sadahiro, S., Ohmura, T., Yamada, Y., Saito, T. and Taki, Y. (1992) Analysis of length and surface area of each segment of the large intestine according to age, sex and physique. *Surg Radiol Anat* 14: 251–257.

Saito, Y., Saito, S., Oka, S., Kakugawa, Y., Matsumoto, M., Aihara, H. *et al.* (2015) Evaluation of the clinical efficacy of colon capsule endoscopy in the detection of lesions of the colon: prospective, multicenter, open study. *Gastrointest Endosc* 82: 861–869.

Schoofs, N., Devière, J. and Van Gossum, A. (2006) PillCam Colon Capsule endoscopy compared with colonoscopy for colorectal tumor diagnosis: a prospective pilot study. *Endoscopy* 38: 971–977.

Shah, H., Paszat, L., Saskin, R., Stukel, T. and Rabeneck, L. (2007) Factors associated with incomplete colonoscopy: a population-based study. *Gastroenterology* 132: 2297–2303.

Singhal, S., Nigar, S., Paleti, V., Lane, D. and Duddempudi, S. (2014) Bowel preparation regimens for colon capsule endoscopy: a review. *Therap Adv Gastroenterol* 7: 115–122.

Spada, C., de Vincentis, F., Cesaro, P., Hassan, C., Riccioni, M., Grazioli, L. *et al.* (2012) Accuracy and safety of second-generation PillCam Colon Capsule for colorectal polyp detection. *Therap Adv Gastroenterol* 5: 173–178.

Spada, C., Hassan, C., Barbaro, B., Iafrate, F., Cesaro, P., Petruzziello, L. *et al.* (2015) Colon capsule versus CT colonography in patients with incomplete colonoscopy: a prospective, comparative trial. *Gut* 64: 272–281.

Spada, C., Hassan, C., Ingrosso, M., Repici, A., Riccioni, M., Pennazio, M. *et al.* (2011a) A new regimen of bowel preparation for PillCam Colon Capsule endoscopy: a pilot study. *Dig Liver Dis* 43: 300–304.

Spada, C., Hassan, C., Munoz-Navas, M., Neuhaus, H., Deviere, J., Fockens, P. *et al.* (2011b) Second-generation colon capsule endoscopy compared with colonoscopy. *Gastrointest Endosc* 74: 581–589.

Spada, C., Riccioni, M., Hassan, C., Petruzziello, L., Cesaro, P. and Costamagna, G. (2011c) PillCam Colon Capsule endoscopy: a prospective, randomized trial comparing two regimens of preparation. *J Clin Gastroenterol* 45: 119–124.

Van Gossum, A., Munoz-Navas, M., Fernandez-Urien, I., Carretero, C., Gay, G., Delvaux, M. *et al.* (2009) Capsule endoscopy versus colonoscopy for the detection of polyps and cancer. *N Engl J Med* 361: 264–270.