Feasibility of patency capsule and colon capsule endoscopy in patients with suspected gastrointestinal stenosis: a prospective study

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ABSTRACT

Patency capsule (PC) can evaluate the patency of gastrointestinal (GI) tract. We hypothesized preceding patient selection using PC would improve the successful rate of colon capsule endoscopy (CCE). Therefore, a prospective single-arm study using PC followed by CCE was conducted with a control group of CCE alone. Patients with suspected or known GI stenosis scheduled for CCE were enrolled. CCE was performed only when the PC was excreted out of the body within 33 hours of ingestion. Primary endpoint was the rate of observation of the entire GI tract within the duration of examination. The secondary endpoints were complications and CCE findings. Twenty-three patients (17 men) were enrolled. The mean age was 50.5±19.8 years. Suspected stenotic sites were 8, 5, and 10 in the small, large, and small and large bowel, respectively. Sixteen, 12, and 10 patients had abdominal pain, active inflammatory bowel disease, and history of surgery for suspected stenosis, respectively. Patency of GI tract was confirmed in 96% (22/23) of the patients by administered PC. Of the 22 patients who underwent CCE, the entire GI tract was observed in 86% (19/22). No complications were observed. The median transit times in the small bowel and colon were 99 (21–682) and 160 (5–328) minutes, respectively. CCE findings revealed ulcers, erosions, and diverticula in 5, 9, and 4 patients, respectively. In conclusion, CCE with PC might be a safer and useful modality to observe the large colon for patients with suspected GI stenosis.

Keywords: colon capsule endoscopy, stenosis, retention, Crohn’s disease

Abbreviations:
SBCE: small bowel capsule endoscopy
CCE: colon capsule endoscopy
GI: gastrointestinal
PC: patency capsule
CD: Crohn’s disease
AFR: adaptive frame rate function
PEG: polyethylene glycol
NSAIDs: non-steroidal anti-inflammatory drugs

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INTRODUCTION

With the advent of small bowel capsule endoscopy (SBCE) in 2000, there has been a dramatic change and advancement in the management of the small bowel diseases. Currently, colon capsule endoscopy (CCE) is also available in Japan. The most common complication of SBCE and CCE is the retention of the capsule in strictures at the oral end of the gastrointestinal (GI) tract for up to 2 weeks. To avoid the retention of the SBCE capsule, a patency capsule (PC), which is of the same size as the capsule endoscope and collapses in the GI tract within 100 to 200 hours, was introduced in Japan in July 2012. In cases where the patency of the entire GI tract is confirmed by ingestion of the PC, subsequent SBCE can be safely performed. With the introduction of PC, SBCE can be performed in patients with GI stenosis such as patients with Crohn’s disease (CD) and those who have undergone abdominal radiotherapy. Previously, these conditions were contraindications for SBCE.

CCE is one of the most valuable tools for investigating the entire colon, although colonoscopy is still the gold standard. The rate of observation of the entire colorectum on CCE has been reported to be 70–100%, which is comparable with that of colonoscopy. CCE is expected to become increasingly popular and further develop in the future. In CCE, it is possible to observe the entire GI tract, including the small bowel, using the adaptive frame rate function (AFR), by which the capture image rate changes from 4 to 35 frames per second when the system determines that the capsule is moving more quickly. However, CCE also has the potential risk of capsule retention in any part of the GI tract, and there is no other device to check the patency of the GI tract. In this prospective study, we examined the feasibility of PC to predict the possible retention of CCE in patients with suspected or known GI stenosis.

METHODS

Patients

Patients were recruited from February 2016 to April 2018. The inclusion criteria were: patients who were aged 18 years and above, and wished to undergo CCE despite suspected GI stenosis. The exclusion criteria were as follows: history of hypersensitivity to any medicines used for bowel preparation, swallowing disorder, implantation of cardiac pacemaker or an electro-medical device, suspected acute abdomen, and severe constipation. The study protocol was approved by the local ethics committee (Nagoya University Hospital ethic committee ID 2015-372), registered at UMIN-CTR (UMIN000019632) and written informed consent was obtained from all patients who met the inclusion criteria and agreed to participate in the study.

Methods

Details of the PC plus CCE regimen are shown in Table 1. Patients were administered 24 mg of sennoside and PC before bedtime, two days before the examination. Bowel preparation was initiated from breakfast on the day before the examination. Patients had low residue meals at breakfast, lunch, and dinner and took 50 g of magnesium citrate, 180 ml of water, and 24 mg of sennoside before going to bed. Patients drank 500 ml of MOVIPREP™, which is a polyethylene glycol (PEG) solution plus ascorbic acid, and 250 ml of water at 8:30 am on the day of the CCE examination. All patients swallowed the capsule after 1 hour at 9:30 am in the AFR mode. The
patients drank 30 ml of castor oil with 100 ml of water as the 1st boost, 1500 ml of PEG with 1500 ml of water as the 2nd boost, 30 ml of castor oil with 100 ml of water as the 3rd boost, and 50 g magnesium citrate with 900 ml of water as the 4th boost. This regimen is currently one of the standard regimens in Japan because sodium phosphate is not available in Japan and MOVIPREP™ is used as the main booster.

Table 1 Regimen of patency capsule and colon capsule endoscopy

| Day 0 | Bedtime | 24 mg Sennosides, PC ingestion |
|-------|---------|-------------------------------|
| Day 1 | (Each meal) | Low fiber diets |
| PM 7–10 | | 50 g magnesium citrate, 180 ml water and 24 mg Sennoside |
| Day 2 | AM 8:00 | (checking the PC excretion) |
| AM 8:30 | | 500 ml MOVIPREP™ and 250 ml water |
| AM 9:30 | CCE ingestion, adapted framed rate started at the same time |
| 1st booster | | 30 ml castor oil and 100 ml water |
| 2nd booster | | 1500 ml MOVIPREP™ and 1500 ml water |
| 3rd booster | | 30 ml castor oil and 100 ml water |
| 4th booster | | 50 g magnesium citrate, 900 ml water |

PC: PillCam patency capsule
CCE: colon capsule endoscopy
* PEG solution plus ascorbic acid (MOVIPREP®, EA Pharma Co., Ltd, Tokyo, Japan)

The CCE, PillCam COLON 2 capsule (GIVEN Imaging, Ltd., Yokneam, Israel), is a minimally invasive technology that does not require sedation or intubation. The capsule measures 31.5 × 11.6 mm and has a camera at each end. Each camera can obtain two images per second. Similar to the SBCE, the PillCam COLON 2 capsule transmits captured images to an external data recorder that later downloads the data to the RAPID 8 (GIVEN Imaging, Ltd., Yokneam, Israel) workstation.

PC, PillCam patency capsule (GIVEN Imaging, Ltd., Yokneam, Israel), is a self-dissolving dummy capsule with exactly the same size as that of SBCE and of the similar size as that of CCE. The capsule is primarily composed of barium sulphate and lactose anhydrous. When a patient swallows the PC, it advances through the GI tract by peristaltic movement. When there is no severe stenosis to trap the PC in the GI tract, it is naturally excreted in the feces. Thirty hours after ingestion of the PC, a built-in timer opens two small holes on the capsule’s surface. The digestive juice enters the capsule and starts dissolving it, which is useful to test the possibility of retention of the real capsule endoscope without complications. The longest diameter of the PC (26.0 mm) is shorter than that of the CCE (31.5 mm); however, the shortest diameter of PC (11.0 mm) is nearly equal to that of the CCE (11.6 mm).

In accordance with a previous study, we used “excellent/good/fair/poor” to categorize the colon cleansing level. “Excellent/good” levels were considered as adequate, and “fair/poor” as inadequate. We evaluated the colon cleansing level in four segments: right colon (cecum, ascending colon), transverse colon, left colon (descending colon, sigmoid colon), and rectum.

Evaluation

Results of the PC and CCE procedures, including the duration of each procedure, were
recorded. Regular CCEs in clinical practice conducted during the same period as that of this study were reviewed. Examination results between the regular CCE and PC plus CCE were retrospectively compared. The primary endpoint was the total GI tract observation rate within the duration of examination in cases with confirmed patency of the GI tract. The secondary endpoints were the complications of the procedures and CCE findings.

Statistical analysis
All data were analyzed using the SPSS version 24.0 statistical software (IBM, Tokyo, Japan). Mann-Whitney U test and Pearson’s Chi-square test were used for comparisons of the patients’ background between the regular CCE and PC plus CCE groups. Mann-Whitney U test, Pearson’s Chi-square test and Fisher’s exact test were used for comparisons of the results between the regular CCE and PC plus CCE groups. Differences with values of p < 0.05 were considered statistically significant.

RESULTS

PC plus CCE results
The flowchart of the study design is shown in Fig. 1. In all, 23 patients were registered in the study (Tables 2, 3), and the confirmation rate of the patency of GI tract was 96% (22/23) by PC examination. One patient with CD did not excrete the PC within 33 hours from ingestion because of stenosis in the ascending colon (Fig. 2). The rate of complete examination with the CCE was 86% (19/22). Three patients did not expel the capsule within the duration of the battery life. CCE findings revealed ulcers, erosions, and diverticula in 5, 9, and 4 patients, respectively (Fig. 3, 4, Table 4).

Fig. 1 Flowchart of the study
Colon capsule endoscopy for stenosis

Table 2  Patient characteristics

| PC plus CCE performed | n=23 |
|-----------------------|------|
| Age, mean ±SD (years) | 50.5±19.8 |
| Male/female           | 17/6 |
| BMI (%)               | 20.6±3.4 |
| Constipation (%)      | 2 (8.6) |
| Use of laxative (%)   | 2 (8.6) |
| Previous abdominal surgery (%) | 10 (43.4) |
| Abdominal symptoms (%)| 16 (69.5) |
| Diabetes (%)          | 5 (21.7) |

BMI: body mass index

Table 3  Reason for using PC in the patients

| Suspected stenotic part | n=23 | Details |
|-------------------------|------|---------|
| Small bowel             | 8    | 2 with stenotic symptoms, 1 amyloidosis, 1 radiation enteritis, 1 intestinal tuberculosis, 1 long-term user of NSAIDs, 1 lupus enteritis, 1 previous small bowel obstruction |
| Colon                   | 5    | 2 sigmoid diverticulum, 2 ulcerative colitis, 1 severe constipation |
| Small bowel and colon   | 10   | 10 Crohn’s disease |

PC: patency capsule  
NSAIDs: non-steroidal anti-inflammatory drugs

Fig. 2  Patency capsule was retained at the oral side of the stenosis in the ascending colon due to Crohn’s disease

Fig. 2a: Coronal image on plain CT.  
Fig. 2b: Axial image on plain CT.
Fig. 3 A patient of Crohn’s disease with anal pain and suspected anal stenosis (patency capsule was excreted out of the body)

Fig. 3a: Colon capsule endoscopy revealed ulcers in the small bowel and large bowel.

Fig. 3b: A couple of longitudinal ulcers were detected from the rectum to the anal canal.
Fig. 4a

A patient with wall thickness in the sigmoid colon

Fig. 4a: Since a sigmoid colon tumor was suspected, colonoscopy was attempted. However, it could not be inserted into the target area due to the narrow lumen.

Fig. 4b: Plain CT scan revealed the wall thickness and multiple diverticula in the sigmoid colon.

Fig. 4c: Patency capsule was excreted out of the body. Colon capsule endoscopy revealed the diverticula and absence of tumor.
Comparison between the outcomes with Regular CCE and PC plus CCE

Regular CCE was performed in 52 patients during the same period (Table 5). Comparisons of the procedures between the regular CCE and PC plus CCE groups revealed no significant differences in the capsule discharge rate and duration until discharge. The median colorectal transit time in the regular CCE and PC plus CCE groups was 87 and 160 minutes, respectively; however, the difference was not statistically significant (Table 6). The median transit time in the small intestine showed a significant difference between the regular CCE and PC plus CCE groups (58 vs. 99 minutes, p=0.004). Bowel cleansing was adequate (excellent/good) in 82% of the patients in the PC and CCE group (Fig. 5). Adequate patients showed decrease in the left side of colon and rectum in both groups.

Table 4  CCE results

| Procedure                                      | PC and CCE |
|------------------------------------------------|------------|
|                                                 | n=22       |
| Number of excreted CCE (%)                     | 19 (86.3)  |
| Gastric transit time, median (min)             | 18 (4–186) |
| Small bowel transit time, median (min)         | 99 (21–682)|
| Colorectal transit time, median (min)          | 160 (5–328)|
| right-side colon transit time, median (min)    | 17 (1–341) |
| transverse colon transit time, median (min)    | 4 (1–85)   |
| left-side colon transit time, median (min)     | 57.5 (1–313)|
| Total transit time, median (min)               | 345 (158–1037)|

Findings (no. of patients)

- Diverticulum: 4
- Erosion: 9
- Ulcer: 5

Adverse events

- CCE retention: 0
- Swallow disorder: 0

CCE: colon capsule endoscopy
PC: patency capsule
Colon capsule endoscopy for stenosis

Table 5  Comparison of patients’ backgrounds between regular CCE and PC plus CCE groups

|                      | CCE (n=52) | PC plus CCE (n=23) | p-value |
|----------------------|------------|--------------------|---------|
| N                    | 52         | 23                 |         |
| Age, mean ±SD (years)| 54.1 ±16.8 | 50.5 ±19.8         | *0.331  |
| Male/female          | 32 / 20    | 17 / 6             | **0.436 |
| BMI (%)              | 23.5 ±3.5  | 20.6 ±3.4          | *0.004  |
| Constipation (%)     | 7 (13.4)   | 2 (8.6)            | **0.713 |
| Use of laxative (%)  | 5 (9.6)    | 2 (8.6)            | **0.999 |
| Previous abdominal surgery (%) | 17 (32.6) | 10 (43.4)          | **0.522 |
| Abdominal symptoms (%) | 15 (28.8) | 16 (69.5)          | **0.002 |
| Diabetes (%)         | 2 (3.8)    | 5 (21.7)           | **0.025 |

Indications
- activity of IBD
- hematochezia
- abdominal pain
- bowel movement disorder
- follow-up post polypectomy
- fecal immunological test
- others

* Mann-Whitney U test
** Pearson’s Chi-square test
CCE: colon capsule endoscopy
PC: patency capsule
IBD: inflammatory bowel disease

Table 6  Comparison of results between the regular CCE and PC plus CCE groups

|                      | Regular CCE (n=52) | PC plus CCE (n=22) | p-Value  |
|----------------------|--------------------|--------------------|----------|
| Number of excreted CCE (%) | 39 (75.0)         | 19 (86.3)          | **0.364  |
| Number of adverse events (%) | 0 (0%)           | 0 (0%)             | ***1.000 |
| Gastric transit time, median (min) | 35 (1–262)     | 18 (4–186)         | *0.653   |
| Small bowel transit time, median (min) | 58 (18–428)  | 99 (21–682)        | *0.004   |
| Colorectal transit time, median (min) | 87 (16–420)   | 160 (5–328)        | *0.422   |
| right-side colon transit time, median (min) | 22 (1–226)    | 17 (1–341)         | *0.528   |
| transverse colon transit time, median (min) | 3.5 (1–286)   | 4 (1–85)           | *0.700   |
| left-side colon transit time, median (min) | 34 (1–415)    | 57.5 (1–313)       | *0.398   |
| Total transit time, median (min) | 276 (68–997)  | 345 (158–1037)     | *0.132   |

* Mann-Whitney U test
** Pearson’s Chi-square test
*** Fisher’s exact test
CCE: colon capsule endoscopy
PC: patency capsule
IBD: inflammatory bowel disease
Currently, there is no PC which has the same size as that of the CCE. CCE has a wider diameter and usually goes through the entire small bowel, just like the SBCE. However, the CCE might be retained by a stenotic lesion. The aim of this study was to highlight the feasibility of checking the presence of lesions that cause intestinal stenosis, such as advanced colorectal cancer and Crohn’s disease, by evaluating the patency of the GI tract using PC prior to CCE. Else, the indication for CCE would have a limited scope. In the clinical setting, CCE is usually performed for the detection of colorectal polyps and evaluation of the endoscopic activity in ulcerative colitis; however, there is a potential risk of retention of the CCE at the stenotic site in the small and large bowels. This is because even advanced colorectal cancer might not exhibit any symptoms, and active ulcerative colitis can cause deep ulcerations, resulting in large bowel stenosis. Therefore, we evaluated the patency of the GI tract before the CCE to avoid CCE retention, with a focus on safety and feasibility. SBCE and CCE are similar in shape and diameter, and their lateral diameter is almost the same, which is an important factor for evaluating the patency. Hence, we assumed that CCE can be evacuated from the same passage as the PC. According to our preliminary results, PC and CCE appeared to be safe.

To compare the results between regular CCE and PC plus CCE, we evaluated the CCE transit time. This is essential for the diagnosis and complete examination using CCE. Rapid passage of the CCE in the colon has the advantage of complete examination; however, it has a risk of missing the lesions. Small bowel transit time was significantly longer in the PC plus CCE group, and obstruction to the transit of the CCE might depend on small bowel lesions. We found that

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**DISCUSSION**

![Colon cleansing level in the regular CCE and PC plus CCE groups](image)

PC: patency capsule
CCE: colon capsule endoscopy
Colon capsule endoscopy for stenosis

CCE was able to detect all findings, once the bowel preparation was adequate. CCE is not the primary examination tool to evaluate lesions in the large colon; rather, it is a complementary tool. In the Japanese population, multiple diverticular lesions are seen in the sigmoid colon, rather than in the ascending colon. It might be challenging to diagnose advanced cancer of the sigmoid colon complicated by multiple diverticula at the same site. As seen in Fig. 4, CCE detected the diverticular lesion in a patient with GI stenosis, which developed from multiple diverticula while the colonoscopy data were not available. In some cases of stenosis in the large colon, an antegrade approach might be better than a retrograde approach.

CD involves ulcers in the colon and rectum, as well as in the small bowel. Although the usefulness of CCE for CD was reported in the previous studies,\textsuperscript{18-20} they did not use PC. Since patients with CD have a potential risk of unexpected CCE retention, PC should be recommended, especially, in patients with obstructive symptoms, history of intestinal obstruction or surgery, or according to the treating physician’s request.\textsuperscript{21-23}

Prior to the CCE examination, it is necessary to evaluate the patency of GI tract by any method, including an interview, which can prevent the retention of the CCE that can occur due to NSAIDs-induced stricture, intestinal tuberculosis, or stenosis at an anastomotic site. Our study demonstrated the usefulness of PC as another evaluation tool before CCE. In the future, we suggest that evaluation of the patency of the GI tract will be more frequently required for CCE, as the number of patients with suspected GI stenosis increase. For an accurate evaluation of the patency, the development of a PC with a size corresponding to that of the CCE is awaited.

This study has several limitations. This was a preliminary prospective study, conducted in a single-center, and had a small sample size. The size of the PC used was similar to that of CCE but not exactly the same. This study included only 22 patients and further study with a large sample size is necessary to evaluate the differences between PC and CCE.

In conclusion, this study indicates that colorectal lesions can be evaluated by CCE in patients with suspected GI stenosis, by using a PC. This will significantly benefit patients with CD, which is otherwise a contraindication for CCE.

CONFLICT OF INTEREST

None of the authors have a conflict of interest regarding the work in the manuscript.

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