

**Title:**

**Clinical factors influencing patency capsule excretion and confirmation in patients with intestinal patency**

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## Clinical factors influencing patency capsule excretion and confirmation in patients with intestinal patency

### Study Population & Methods

#### Participants:

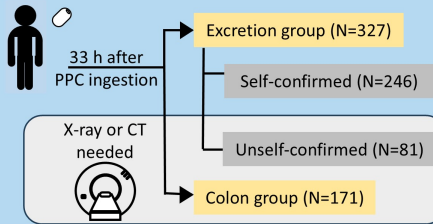
- ✓ 498 patients who underwent PPC examination before SBCE
- ✓ Between January 2017 - April 2023

#### Exclusion criteria:

- ✓ Patients below 18 years of age
- ✓ Small bowel stoma or total colectomy
- ✓ Allergic to barium
- ✓ PPC retention in the esophagus, stomach, or small intestine.

#### Study design:

- ✓ Retrospective observational study
- #### Endpoints:
- ✓ Factors associated with colon group
  - ✓ Factors associated with unself-confirmed group



### Outcomes

#### Colon group factor

- ✓ Female sex
- ✓ Inpatients
- ✓ Constipation
- ✓ PPC retained in the colon in the previous test



#### Unself-confirmed group factor

- ✓ Male sex
- ✓ Younger age

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## Clinical factors influencing patency capsule excretion and confirmation in patients with intestinal patency

**Running title:** Patency Capsule Excretion

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**Keywords:** Capsule endoscopy. Intestinal elimination. Capsule.

### List of abbreviations

ADL	Activities of daily living
AXR	Abdominal X-ray
CD	Crohn's disease
CT	Computed tomography
DM	Diabetes mellitus
GTT	Gastric transit time
PPC	Pillcam™ Patency Capsule
SBCE	Small bowel capsule endoscopy
SBTT	Small bowel transit time
SC	Self-confirmed
UNSC	Unself-confirmed

### Statement of Ethics

This study was conducted in accordance with the principles embodied in the 1975 Declaration of Helsinki (2013 revision) and was approved by the Ethics Committee of Nagoya University Hospital (IRB ID: 2015-0485). The requirement for the acquisition of informed consent from patients was waived owing to the retrospective nature of this study.

### Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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**Authors' contributions:** **Investigation:** T.Y., and M.N.; **Writing-original draft:** S.I.; **writing-review and editing:** K.M., T.S., and E.I.; **Guarantor of the article:** H.K.; **Study design:** S.I., and T.Y.; **Drafting of the manuscript:** S.I., and T.Y.; **Statistical analyses and interpretation:** T.I., K.F., and T.H.; **Data acquisition and critical review of the manuscript:** S.I., and T.Y.

#### **Data Availability Statement**

The datasets analyzed in this study are not publicly available owing to privacy and ethical considerations. However, upon reasonable request, they may be obtained from the corresponding author.

#### **Statement of Generative AI and AI-assisted technologies in the writing process**

The authors declare that they did not use artificial intelligence (AI) or any AI-assisted technologies in the article's elaboration.

## Lay summary

The PillCam™ patency capsule helps prevent issues with capsule endoscopes getting stuck in the intestines, but some patients struggle to confirm when the capsule has exited their body visually. This study looked at factors influencing whether the capsule remains in the colon after 33 hours and why some patients cannot visually confirm its excretion. Analyzing data from 498 patients, researchers found that 49% could visually confirm capsule excretion, while 51% required radiological checks. Factors like being female, being an inpatient, having constipation, and having a previous capsule remaining in the colon were linked to a higher likelihood of the capsule staying in the colon. Men and younger patients were more likely to have trouble confirming capsule excretion visually. The study suggests that new methods are needed to help ensure the reliable exit of capsules from the body and the confirmation of this fact by patients, reducing the need for additional imaging and radiation exposure.

## Abstract

**Introduction:** The PillCam™ patency capsule is useful in preventing capsule endoscope retention; however, visual confirmation of patency capsule excretion is challenging for many patients.

**Objective:** We investigated the factors related to the patency capsule remaining in the colon after 33 h and the factors hindering the visual confirmation of its excretion.

**Methods:** We retrospectively analyzed 498 patients with intestinal patency who underwent patency capsule examination. Patients were categorized into the “excretion group” and “colon group,” depending on whether the capsule was excreted or remained in the colon after 33 h, respectively. Patients were further classified into self-confirmed and unself-confirmed groups within the excretion group. Univariate and multivariate logistic regression analyses were used to analyze the factors associated with the colon and unself-confirmed groups.

**Results:** Overall, 49% of patients visually confirmed capsule excretion within 33 h, whereas 51% did not and required radiological examination. Among those without capsule excretion, 34% of patients had a detectable capsule in the colon, whereas 16% had no detectable capsule. In the excretion group, 75% and 25% of patients were self-

confirmed and unself-confirmed, respectively. Female sex, inpatient status, constipation, and capsule in the colon during the previous examination were the independent factors associated with the colon group. Male sex and younger age were the independent factors associated with the unself-confirmed group.

**Conclusions:** Our findings highlight the need for new approaches to facilitate patency capsule excretion to avoid radiation exposure, especially in females, inpatients, those with constipation, and those with capsule remaining in the colon on the previous examination.

### Introduction

Small bowel capsule endoscopy (SBCE) is a useful modality for evaluating small bowel diseases, including obscure gastrointestinal bleeding, small bowel tumors, polyposis syndrome, and inflammatory bowel diseases such as Crohn's disease (CD) (1). However, capsule retention, defined as the presence of a capsule endoscope in the gastrointestinal tract for at least two weeks after ingestion or requiring medical, endoscopic, or surgical procedures for removal (2), represents a major problem in patients with small bowel stricture (3).

The Agile™ patency capsule is a dummy capsule with a radiofrequency identification tag that can be detected using an external scanner. This device was developed to assess the functional patency of the small bowel to prevent capsule retention and is widely used in Western countries (4); however, it is not accurate in detecting and localizing the capsule (5). Additionally, there is a potential risk of small bowel obstruction owing to the impact of the radiofrequency identification tag on stenotic lesions (6). Thus, the use of a tag-less PillCam™ patency capsule (PPC) for gastrointestinal patency assessment before SBCE was approved in Japan in 2012 (7).

Small bowel patency assessment is based on visual confirmation of intact PPC excretion within 30–33 h after ingestion (8,9). If extracorporeal PPC excretion cannot be confirmed, abdominal X-ray (AXR), computed tomography (CT), X-ray tomosynthesis, or abdominal ultrasonography is performed to verify the passage of the capsule into the colon or its expulsion from the body (10). However, more than

half of the patients undergoing PPC examination fail to identify intact capsule excretion within the specified timeframe, whereas others cannot visually confirm PPC excretion despite expulsion from the body; hence, radiological examination is required (7,11). AXR or CT is reportedly performed in 40–50% of cases to confirm the location and excretion of PPC, even in patients with intestinal patency, with 30–40% of patients having PPC in the colon at 33 h after ingestion (9,12), leading to concerns about radiation exposure and cost. Moreover, there is a paucity of studies investigating patients with intestinal patency who retain the PPC in the colon at 33 h after ingestion and identifying patients who cannot visually confirm PPC excretion.

Therefore, the current study aimed to explore the clinical factors related to PPC remaining in the colon after 33 h and factors hindering the visual confirmation of PPC excretion.

## **Methods**

### **Patients and PPC indications and protocol**

We retrospectively enrolled 637 consecutive patients who underwent PPC examination (PillCam™ patency capsule, Covidien Japan Inc., Tokyo, Japan) before SBCE (PillCam™ SB3, Covidien Japan Inc., Tokyo, Japan) at Nagoya University Hospital between January 2017 and April 2023. The indications for PPC in our hospital are as follows: (i) suspected tumor or stenosis on imaging; (ii) established and suspected CD; (iii) long-term use of non-steroidal anti-inflammatory drugs (>6 months); (iv) previous history of abdominal surgery or abdominal radiation therapy; (v) previous small bowel obstruction; and (vi) obstructive symptoms. A history of abdominal surgery included bowel resection, gynecological surgery, and other surgeries that could potentially cause anastomotic strictures or impaired transit owing to postoperative adhesions. Patients who (i) were below 18 years of age, (ii) had small bowel stomas, (iii) underwent total colectomy, (iv) were allergic to barium, or (v) had PPC retention in the esophagus, stomach, or small intestine were excluded.

In our hospital, the PPC protocol involves ingesting the capsule with water at 11:00 PM and confirming PPC excretion 33 h after ingestion, typically at 8 AM, two days after ingestion. During the PPC examination, no restrictions on food or fluids were imposed,



and the patients continued their medications as usual. Patients were instructed to monitor PPC excretion at each bowel movement using the provided kit, which included disposable gloves, spoons, and toilet seat bags for PPC collection. Patients who did not excrete the PPC within 33 h underwent radiography to confirm the location of the capsule. If radiography alone was inconclusive, CT was performed. Patients with confirmed small bowel patency by radiological examination underwent SBCE and were evaluated for gastric transit time (GTT) and small bowel transit time (SBTT) in SBCE. This study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Ethics Committee of Nagoya University Hospital (IRB ID: 2015-0485).

### **Definition of terms**

Patients visually confirming intact PPC excretion within 33 h or showing no PPC on radiological examination after 33 h were categorized into the “excretion group,” whereas those with PPC located in the colon on radiological examination were categorized into the “colon group.” Within the excretion group, patients who were able to visually confirm PPC excretion were classified as the “self-confirmed (SC) group,” whereas those who could not confirm PPC excretion were classified as the “unself-confirmed (UNSC) group.” Constipation was defined as spontaneous bowel movements occurring fewer than three times a week according to the Rome IV diagnostic criteria (13). Patients with low activities of daily living (ADL) were defined as bedridden patients with poor general condition during the PPC examination. Fasting during the examination was defined as the state of fasting until 33 hours after PPC ingestion.

### **Endpoints**

The primary endpoint was evaluating factors associated with the colon group in patients with confirmed intestinal patency. The secondary endpoint was to identify factors associated with the UNSC group.

## Statistical analysis

Continuous and categorical variables were expressed as means with standard deviations and as percentages, respectively. Between-group differences were evaluated using the Student's *t*-test for continuous variables and Fisher's exact test for categorical variables. Univariate and multivariate logistic regression analyses were conducted to explore the factors associated with the colon group and SC group. All statistical analyses were performed using IBM SPSS version 29.0 (IBM Corp., Armonk, NY, USA), and statistical significance was set at  $P < 0.05$ .

## Results

### Participant flow and clinical characteristics

The study protocol is illustrated in Figure 1. Overall, 139 of the 637 consecutive patients who underwent PPC examination between January 2017 and April 2023 were excluded for the following reasons: underwent total colectomy ( $n=26$ ), had small bowel stomas ( $n=26$ ), were  $< 18$  years old ( $n=46$ ), and had PPC located in the small intestine ( $n=39$ ) or stomach ( $n=2$ ) after 33 h. Consequently, a total of 498 patients were included in the final analysis.

Table 1 summarizes the clinical characteristics of the patients.

Among the 498 patients, 246 (49%) had visually confirmed PPC within 33 h after ingestion, whereas the remaining 252 (51%) did not. Patients who did not excrete the PPC within 33 h underwent radiological examinations, including AXR (22%,  $n=112$ ), abdominal CT (16%,  $n=78$ ), or both (12%,  $n=62$ ). Consequently, among patients who did not excrete the PPC within 33 h, 171 (34%) exhibited PPC remaining in the colon, while 81 (16%) demonstrated complete absence of PPC in their bodies. The anatomical distribution of the patency capsule within the colon was as follows: cecum, 8%; ascending colon, 12%; transverse colon, 17%; descending colon, 22%; sigmoid colon, 19%; and rectum, 22%. Thus, 171 (34%) patients were classified into the colon group, while 327 (66%) patients were allocated to the excretion group. Within the excretion group, 246 (49%) patients were classified into the SC group, while 81 (16%) patients were allocated to the UNSC group.

Moreover, 495 of 498 patients underwent SBCE; three patients with PPC in the colon group did not undergo SBCE for their own reasons (Figure 1). Table 2 lists the reasons for undergoing SBCE and PPC. Overall, 264 (53%) patients had inflammatory bowel disease, including CD or suspected CD.

### Endpoints

Table 3 presents the results of univariate and multivariate analyses for factors associated with the colon group. Univariate analysis revealed that female sex, older age, inpatient status, low ADL, CD, history of DM and hemodialysis, constipation, aspirin use, and PPC in the colon during the previous PPC examination were associated with the colon group. In multivariate analysis, female sex, inpatient status, constipation, and PPC in the colon during the previous PPC examination were identified as significant factors. Next, we evaluated the relationship between the number of risk factors and the probability of a patient being categorized into the colon group. The probability rates were 18.8% with no risk factors, 34.6% with one risk factor, 61.7% with two, 84.6% with three, and 100% with four risk factors.

Among the 327 patients in the excretion group, 246 patients with visually confirmed PPC excretion were categorized into the SC group, whereas 81 patients who failed to visually confirm PPC excretion were designated as the UNSC group. As shown in Table 4, univariate and multivariate analyses revealed that male sex and younger age were independent factors associated with the UNSC group, indicating that younger patients and men were less likely to notice PPC excretion.

Table 5 compares GTT and SBTT between the colon group and the excretion group, as well as according to sex, inpatient or outpatient status, and constipation, which were independent factors associated with the colon group. In the colon group, SBTT was significantly longer compared to the excretion group. Additionally, Inpatients had a significantly longer SBTT than outpatients ( $P < 0.001$ ). However, there were no significant differences in GTT and SBTT according to sex or the presence of constipation.

No serious adverse events (e.g., bowel obstruction and aspiration) attributable to PPC examinations were observed during the study period.

## Discussion

Tag-less PPC, approved in Japan in 2012, begins to dissolve at 30–33 h after ingestion (14,15); hence, PPC excretion should be determined within that timeframe. If it cannot be visually confirmed within the specified timeframe (16), the PPC has either been retained in the intestinal tract or has been excreted unnoticed. AXR is considered the simplest method for confirmation of retained PPC; if no PPC is identified in the body, the PPC is deemed to have already been discharged. However, when the PPC is found in the body on AXR, its exact location may not be accurately determined because of stenosis and postoperative changes, particularly in patients with CD or those who undergo bowel resection (5). Although recent studies have suggested the effectiveness of tomosynthesis and low-dose CT for this purpose (10,16,17), there are concerns regarding the cost and radiation exposure associated with these modalities. Furthermore, the effectiveness of abdominal ultrasound for identifying the location of the PPC has also been reported; however, distinguishing between the small intestine and the colon can be challenging, potentially leading to a lack of objectivity (18,19). To address this issue, we explored factors associated with PPC remaining in the colon at 33 h after ingestion and factors hindering visual confirmation despite PPC excretion.

Female sex, inpatient status, constipation, and PPC in the colon during the previous examination were significantly associated with the presence of PPC remaining in the colon after 33 h. Previous studies reported that women showed no change in the SBTT but had a longer colonic transit time than men (20–22) and that patients with normal defecation habits tended to develop constipation during hospitalization (23,24). Furthermore, patients with constipation often exhibit longer colonic transit times and SBTT (14,21), which may hinder PPC excretion within the designated timeframe. The colon group also showed the presence of PPC in the colon during the previous examination, which is likely attributable to the fact that each patient's bowel habits did not change considerably over time.

Our results are consistent with those of previous studies; these studies identified female sex and inpatient status as factors that prevent PPC excretion within 24–30 h of PPC ingestion (12,20). Additionally, using a larger sample size, we identified

constipation and the presence of PPC in the colon during the previous examination as significant factors.

Current guidelines recommend using PPC and SBCE for routine surveillance of patients with CD suspected of having stenosis (25–27). Similarly, the European Society of Gastrointestinal Endoscopy guidelines advocate capsule endoscopy or magnetic resonance imaging for small bowel surveillance starting at the age of 8 years in patients with Peutz–Jeghers syndrome (28). Given the prevalence of these conditions in young individuals and the need for regular monitoring, minimizing radiation exposure for PPC localization is crucial.

One potential option for facilitating PPC excretion may be to extend the examination time. Previous studies reported that the proportion of the colon group at each assessment time was 48.5% at 24 h, 43.1–44.7% at 28 h, and 37.4% at 30 h, as compared to 34% at 33 h in our own cases (12,15,20). This suggests that the longer the examination time for PPC, the easier it is for them to be excreted from the body. Watanabe et al. verified the effectiveness of extending the examination time to 72 h (29). However, considering the onset of PPC dissolution and the rate of excretion from the body, 33 h was considered appropriate.

Our analysis of the SBCE transit time indicated that the colon group showed a significantly longer SBTT than the excretion group; however, the sum of the GTT and SBTT was approximately 6 h in this study (366 min in the colon group and 321 min in the excretion group) (Table 5). This indicates that the remaining time is spent in the colon and that PPC elimination within 33 h mainly depends on the colonic transit time. We observed that 63% of PPCs in the colon group were located distal to the descending colon (cecum, 8%; ascending, 12%; transverse, 17%; descending, 22%; sigmoid, 19%; rectum, 22%), suggesting that the addition of laxatives or prokinetics to shorten colonic transit time may promote PPC excretion and potentially avoid unnecessary radiation exposure, particularly in women, hospitalized patients, patients with constipation, and patients with a history of PPC in the colon during the previous examination.

Our study also reveals a novel finding that, despite timely excretion of PPC, men, and young adults were less likely to confirm the excretion visually. This observation

suggests a potentially significant demographic variation in the confirmation process. The underlying reasons for this result remain unclear; it may be related to reports indicating lower collection rates for fecal occult blood tests among men than among women during health screenings, suggesting a lack of attention to bowel habits (30). Additionally, this result may be related to lifestyle factors such as work obligations, which limit opportunities to check PPC excretion. The examination schedule should be adjusted for such patients to facilitate confirmation of PPC discharge, and it is essential to educate patients regarding their medical condition and to recognize that superfluous tests can result in inefficient use of time and unnecessary radiation exposure.

Our study has some limitations that should be acknowledged. First, it was conducted as a retrospective analysis at a single institution, with a limited number of patients exhibiting certain factors (Liver Cirrhosis: 8 patients, Colostomy: 11 patients, Hemodialysis: 13 patients), potentially affecting the consistency of results in both univariate and multivariate analyses. Second, the methodology for confirming the location of the PPC was not standardized, being left to the discretion of individual examiners. Notably, in cases where only abdominal X-ray imaging was utilized, the precise location of the PPC may not have been accurately determined. Finally, the time from PPC ingestion to excretion was not assessed. This information could potentially elucidate additional factors influencing the efficacy of PPC excretion.

In conclusion, our findings highlight the importance of considering sex, hospitalization status, constipation, and previous PPC results when performing PPC examinations. This also highlights the need for new approaches to facilitate PPC excretion to avoid radiation exposure, especially in patients with the above-mentioned risk factors. Furthermore, it is important to acknowledge that PPC excretion is more likely to be missed in men and younger individuals. The findings presented in our investigation necessitate validation through prospective, multicenter studies with larger sample sizes to confirm the reliability of the results.

## Key points box

### What Was Previously Known

- The PillCam™ patency capsule is effective in preventing capsule endoscope retention.
- Visual confirmation of patency capsule excretion is challenging for many patients.
- When patency capsule excretion is not confirmed by patients, Abdominal X-ray or other tests are mandatory before capsule endoscopy.

### What This Study Contributes

- Identification of factors associated with the patency capsule remaining in the colon after 33 hours.
- Determination of factors hindering the visual confirmation of capsule excretion.

### How the Results Will Influence Clinical Practice

- Female sex, inpatient status, constipation, and prior colon capsule presence as key factors for capsule remaining in the colon.
- Male sex and younger age are linked to difficulties in self-confirming capsule excretion.
- We highlight the need for innovative methods to assist capsule excretion.

## Acknowledgments

None.

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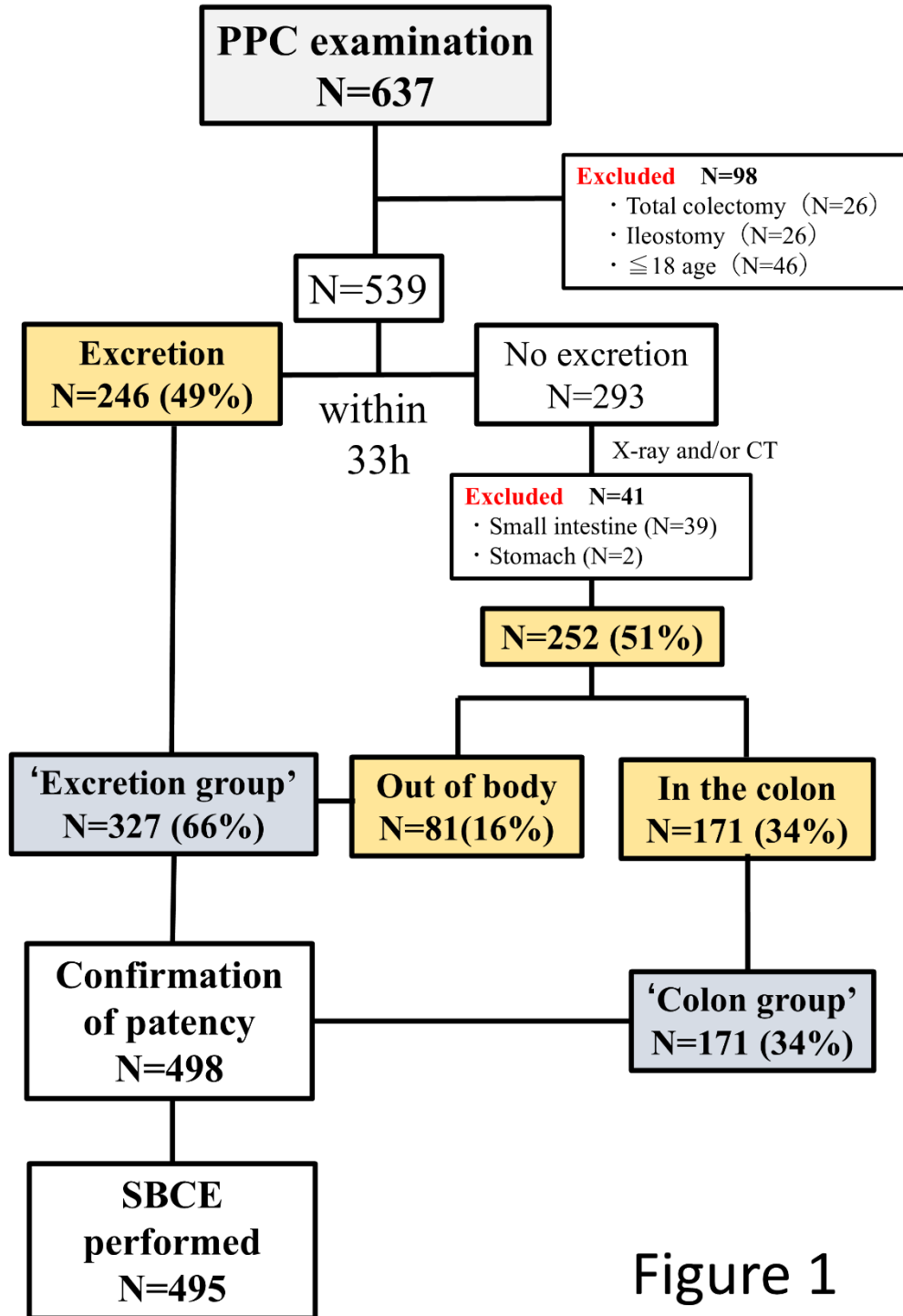


Figure 1

## Figure captions

**Fig. 1.** Study flow.

N=246 (Excretion confirmed by the patient, SC group); N=252 (Excretion not confirmed by the patient); N = 81 (Out of body, not confirmed by the patient, UNSC group); N=171 (Not confirmed by the patient because PPC retained in the colon).

PPC, Patency Pillcam™ Capsule; SC, self-confirmed; UNSC, un-self-confirmed.

**Table 1. Clinical characteristics of patients**

	<b>N=498</b>
<b>Sex (Male/Female)</b>	311/187
<b>Age ± SD</b>	52.3 ± 19.0
<b>Outpatient/inpatient</b>	346/152
<b>Fasting during the examination</b>	40/458
<b>ADL (high/low*)</b>	484/14
<b>History of abdominal surgery</b>	208 (41.8%)
Small bowel surgery, <i>n</i> (%)	115 (23.1%)
Colorectal surgery, <i>n</i> (%)	88 (17.7%)
Others	67 (13.5)
<b>DM, <i>n</i> (%)</b>	46 (9.2%)
<b>HD, <i>n</i> (%)</b>	13 (2.6%)
<b>LC, <i>n</i> (%)</b>	8 (1.6%)
<b>Constipation, <i>n</i> (%)</b>	39 (7.8%)
<b>NSAIDs, <i>n</i> (%)</b>	28 (5.6%)
<b>LDA, <i>n</i> (%)</b>	37 (7.4%)
<b>Colostomy, <i>n</i> (%)</b>	11 (2.2%)
<b>Past history of patency capsule examination, <i>n</i> (%)</b>	146 (29.3%)
PPC location (colon/excreted)	38/108
<b>GTT ± SD, min</b>	43.3 ± 60.5
<b>SBTT ± SD, min</b>	293.0 ± 157.8
<b>GTT+SBTT ± SD, min</b>	336.3 ± 166.8

SD, standard deviation; ADL, activities of daily living; DM, diabetes mellitus; HD, hemodialysis; LC, liver cirrhosis; NSAIDs, non-steroidal anti-inflammatory drugs; LDA, low-dose aspirin; PPC, Patency Pillcam™ Capsule; GTT, gastric transit time; SBTT, small-bowel transit time.

\*Patients with low ADL were defined as bedridden patients with poor general condition during the PPC examination.

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**Table 2. Reasons for SBCE and patency capsule**

<b>N=498</b>	
<b>Reason for SBCE</b>	
CD	168 (33.7%)
Suspected CD	59 (11.8%)
Obscure GIB	41 (8.2%)
Overt GIB	67 (13.5%)
Abdominal pain	43 (8.6%)
Other IBD	37 (7.4%)
Suspected tumor	53 (10.6%)
Follow-up for polyposis	16 (3.2%)
Others	14 (2.8)
<b>Reason for patency capsule</b>	
CD	200 (40.2%)
Suspected IBD	44 (8.8%)
NSAIDs and/or LDA	30 (6.0%)
Thickening on the image	51 (10.2%)
History of abdominal surgery	65 (13.1%)
History of intestinal obstruction	12 (2.4%)
Abdominal symptom	58 (11.6%)
Others	38 (7.6%)

SBCE, small-bowel capsule endoscopy; CD, Crohn's disease; GIB, gastrointestinal bleeding; IBD, inflammatory bowel disease; NSAIDs, non-steroidal anti-inflammatory drugs; LDA, low-dose aspirin.

**Table 3. Univariate and multivariate logistic regression analyses of factors associated with the colon group (N=498)**

	Univariate analysis			Multivariate analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
<b>Sex, female</b>	<b>1.876</b>	<b>1.284–2.741</b>	<b>&lt; 0.001</b>	<b>1.718</b>	<b>1.127–2.619</b>	<b>0.012</b>
<b>Age</b>	<b>1.02</b>	<b>1.01–1.03</b>	<b>&lt; 0.001</b>	1.004	0.991–1.016	0.555
<b>Inpatient</b>	<b>3.245</b>	<b>2.177–4.836</b>	<b>&lt; 0.001</b>	<b>2.753</b>	<b>1.713–4.427</b>	<b>&lt; 0.001</b>
<b>Low ADL (bedridden)</b>	<b>7.425</b>	<b>2.043–26.989</b>	<b>0.002</b>	2.621	0.661–10.388	0.170
<b>CD</b>	<b>0.519</b>	<b>0.344–0.785</b>	<b>0.002</b>	0.925	0.549–1.560	0.771
History of abdominal surgery	1.021	0.702–1.486	0.912			
Small-bowel surgery	0.714	0.453–1.126	0.147			
Colorectal surgery	0.987	0.607–1.604	0.957			
<b>DM</b>	<b>2.495</b>	<b>1.352–4.605</b>	<b>0.003</b>	1.177	0.560–2.474	0.667
<b>HD</b>	<b>3.161</b>	<b>1.018–9.815</b>	<b>0.047</b>	2.265	0.627–8.183	0.212
LC	0.633	0.126–3.171	0.578			
<b>Constipation</b>	<b>5.625</b>	<b>2.725–11.612</b>	<b>&lt; 0.001</b>	<b>4.464</b>	<b>1.977–10.081</b>	<b>&lt; 0.001</b>





NSAIDs	1.467	0.678–3.176	0.331			
<b>LDA</b>	<b>3.071</b>	<b>1.549–6.091</b>	<b>0.001</b>	1.244	0.547–2.8	0.602
					30	
Colostomy	0.418	0.089–1.957	0.268			
<b>Patency capsule in the colon in the previous examination</b>	<b>2.274</b>	<b>1.168–4.425</b>	<b>0.016</b>	<b>3.347</b>	<b>1.602–6.9</b>	<b>0.001</b>
					89	
GTT*	1.001	0.998–1.004	0.693			
<b>SBTT*</b>	<b>1.002</b>	<b>1.001–1.003</b>	<b>0.005</b>	1.001	0.999–1.0	0.309
					02	

ADL, activities of daily living; DM, diabetes mellitus; HD, hemodialysis; LC, liver cirrhosis; NSAIDs, non-steroidal anti-inflammatory drugs; LDA, low-dose aspirin; GTT, gastric transit time; SBTT, small-bowel transit time.

\*N=495 (3 patients in the colon group did not undergo SBCE).

**Table 4. Univariate and multivariate logistic regression analyses of factors associated with the UNSC group (N=327)**

	Univariate analysis			Multivariate analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
<b>Sex, male</b>	<b>2.134</b>	<b>1.178–3.8</b>	<b>0.012</b>	<b>2.04</b>	<b>1.110–3.750</b>	<b>0.022</b>
	<b>68</b>					
<b>Age</b>	<b>0.983</b>	<b>0.969–0.9</b>	<b>0.016</b>	<b>0.984</b>	<b>0.969–1.000</b>	<b>0.045</b>
	<b>97</b>					
Inpatient	0.771	0.409–1.4	0.422			
	55					
Low ADL (bedridden)			0.999			
<b>CD</b>	<b>1.587</b>	<b>0.954–2.6</b>	<b>0.075</b>	1.158	0.664–2.021	0.605
	<b>38</b>					
History of abdominal surgery	0.675	0.400–1.1	0.141			
	38					
Small-bowel surgery	0.813	0.448–1.4	0.495			
	75					
Colorectal surgery	0.854	0.435–1.6	0.647			
	78					
DM	0.487	0.140–1.6	0.259			
	99					
HD	0.756	0.083–6.8	0.804			
	65					
LC	1.532	0.275–8.5	0.626			
	22					
Constipation	1.774	0.506–6.2	0.371			



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		0.506–6.2	
		22	
NSAIDs	1.013	0.317–3.2	0.983
		33	
LDA	0.454	0.100–2.0	0.305
		55	
Colostomy			0.999
GTT*	1.001	0.997–1.0	0.574
		05	
SBTT*	1.000	0.998–1.0	0.704
		01	

UNSC, un-self-confirmed, ADL, activities of daily living; DM, diabetes mellitus; HD, hemodialysis; LC, liver cirrhosis; NSAIDs, non-steroidal anti-inflammatory drugs; LDA, low-dose aspirin; GTT, gastric transit time; SBTT, small-bowel transit time.

\*N=495 (3 patients in the colon group did not undergo SBCE).

**Table 5. Comparison of the GTT and SBTT for each factor (N=495)**

	<b>Group</b>		<b>P-value</b>
	Colon group	Excretion group	
GTT ± SD, min	44.8 ± 55.9*	42.6 ± 62.8	0.693
<b>SBTT ± SD, min</b>	<b>321.0 ± 173.1*</b>	<b>278.5 ± 147.6</b>	<b>0.004</b>
<b>GTT+SBTT ± SD, min</b>	<b>366.0 ± 181.3*</b>	<b>321.0 ± 156.9</b>	<b>0.004</b>
	<b>Sex</b>		<b>P-value</b>
	Male (N=309)	Female (N=186)	
GTT ± SD, min	42.9 ± 55.4	44.2 ± 68.2	0.842
SBTT ± SD, min	282.6 ± 155.9	310.2 ± 159.9	0.060
GTT+SBTT ± SD, min	325.5 ± 163.1	354.2 ± 171.7	0.064
	<b>Patients</b>		<b>P-value</b>
	Inpatients (N=151)	Outpatients (N=344)	
GTT ± SD, min	45.0 ± 60.8	42.6 ± 60.4	0.676
<b>SBTT ± SD, min</b>	<b>345.9 ± 172.0</b>	<b>269.7 ± 145.4</b>	<b>&lt; 0.001</b>
<b>GTT+SBTT ± SD, min</b>	<b>391.0 ± 183.1</b>	<b>312.3 ± 153.3</b>	<b>&lt; 0.001</b>
	<b>Constipation</b>		<b>P-value</b>
	Yes (N=38)	No (N=457)	
GTT ± SD, min	56.4 ± 70.3	42.2 ± 59.5	0.166
SBTT ± SD, min	308.2 ± 187.4	291.7 ± 155.3	0.537
GTT+SBTT ± SD, min	364.6 ± 185.1	334.0 ± 165.2	0.277
	<b>PPC in the colon in the previous test</b>		<b>P-value</b>
	Yes (N=38)	No (N=457)	
GTT ± SD, min	54.9 ± 69.0	42.4 ± 59.7	0.219
SBTT ± SD, min	321.6 ± 164.2	290.6 ± 157.2	0.246
GTT+SBTT ± SD, min	376.5 ± 185.4	333.0 ± 164.9	0.122

GTT, gastric transit time; SBTT, small-bowel transit time. PPC, Patency Pillcam™ Capsule.

\*Three patients in the colon group did not undergo SBCE.



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