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# Usefulness of capsule endoscopy for small intestinal obstruction: a dual-center prospective observational study

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**How to cite this article:** Imai M, Niikura R, Yamada A, Suzuki H, Nakada A, Mitsuno Y, Yamamoto S, Aoki T, Hayakawa Y, Kawai T, Fujishiro M. Usefulness of capsule endoscopy for small intestinal obstruction: a dual-center prospective observational study. *Mini-invasive Surg* 2024;8:2. <https://dx.doi.org/10.20517/2574-1225.2023.67>

**Received:** 21 Jun 2023 **First Decision:** 13 Nov 2023 **Revised:** 12 Jan 2024 **Accepted:** 22 Jan 2024 **Published:** 29 Jan 2024

**Academic Editor:** Jean François Rey **Copy Editor:** Dong-Li Li **Production Editor:** Dong-Li Li

## Abstract

**Aim:** To evaluate whether capsule endoscopy can identify causes of small intestinal obstruction and determine the appropriate patient population for capsule endoscopy.

**Methods:** In this prospective observational study, we performed a tag-less patency capsule endoscopy for patients with small intestinal obstruction. After confirming the patency of the small intestine, capsule endoscopy was performed using Pill Cam SB2. The study endpoint was recurrence of small intestinal obstruction within 1 year.

**Results:** Of the 31 study patients, 8 were excluded. The remaining 23 patients, including 13 with a history of surgery and 3 with band adhesions on contrast-enhanced CT, were analyzed. Subsequently, 18 of the 23 study patients underwent tag-less patency capsule endoscopy to evaluate the small intestinal patency. Capsule endoscopy revealed redness in six patients, erosions and ulcers in three patients, small intestinal diverticulum in one patient, and tumor in one patient. One patient with Meckel's diverticulum and another with small intestinal ganglioneuroma underwent surgical resection. No recurrence of small intestinal obstruction was observed at 1 year.

**Conclusion:** This prospective observational study demonstrated that capsule endoscopy can determine the cause of small intestinal obstruction after the obstruction is relieved.

**Keywords:** Small intestinal obstruction, patency capsule endoscopy, capsule endoscopy



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## INTRODUCTION

Intestinal obstruction accounts for more than 10% of cases requiring surgical intervention, with over 300,000 surgeries performed annually in developed countries<sup>[1]</sup>. The causes of intestinal obstruction include postoperative adhesions, malignant tumors, Crohn's disease, nonsteroidal anti-inflammatory drug (NSAID)-related enteritis, and radiation-induced enteritis<sup>[2]</sup>. Moreover, intestinal obstruction has a high recurrence rate<sup>[3]</sup>. Postoperative intestinal obstruction recurs in 23% of cases within one year and in 30% within five years<sup>[4]</sup>.

Over the past 20 years, contrast-enhanced CT has been used to diagnose and treat small bowel obstruction. It allows the identification of the obstruction site and severity, aiding in treatment decisions, including the timing of surgical intervention<sup>[1]</sup>. However, CT cannot accurately determine the causes of intestinal obstruction<sup>[5]</sup>. Conversely, capsule endoscopy<sup>[6]</sup> enables the direct visualization of the entire small intestine and provides useful information regarding the underlying cause of small intestinal obstruction. To evaluate the usefulness of capsule endoscopy, we performed a preliminary single-arm prospective observational study of patients with small intestinal obstruction after the obstruction was relieved.

The objective of this study was to evaluate whether capsule endoscopy can identify the causes of small intestinal obstruction and to determine the appropriate patient population for capsule endoscopy.

## METHODS

### Trial design and setting

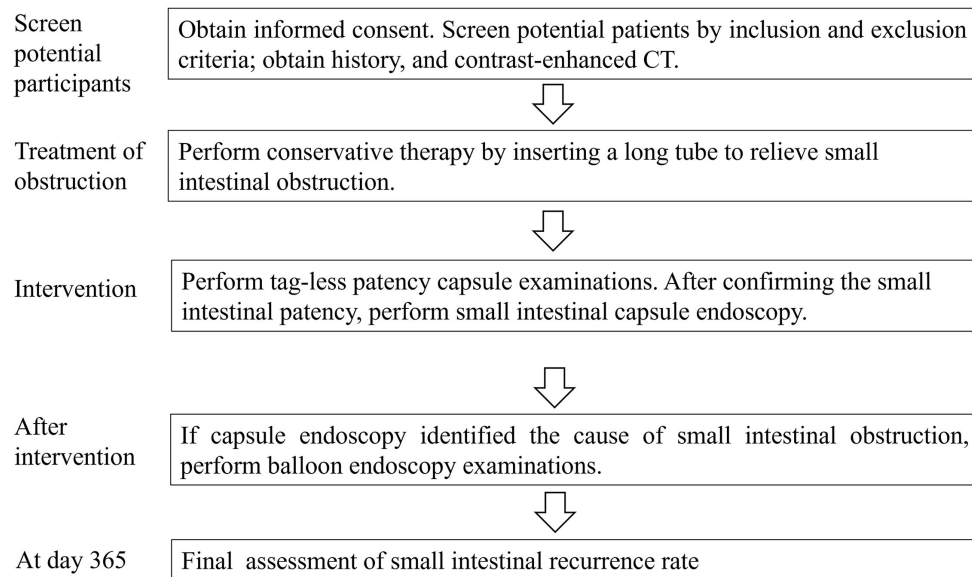
Between September 2013 and October 2016, we performed a prospective observational study at two centers: the Graduate School of Medicine, The University of Tokyo and the Japanese Red Cross Medical Center. We obtained written informed consent from all patients before enrollment. The study protocol was approved by the institutional review boards of The University of Tokyo (No. 10252) and Japanese Red Cross Medical Center (No. 487) and registered at UMIN-CTR (UMIN000011831).

### Patients

This study included patients aged  $\geq 20$  years who presented with vomiting, absent bowel movements, or abdominal pain and were diagnosed with small intestinal obstruction on contrast-enhanced CT. For the contrast-enhanced CT, 2 mL/kg of iodinated contrast media (370 mg/mL) was administered intravenously. The arterial- and venous-phase images were obtained after a delay of 30 and 60 s, respectively. Patients with contrast medium allergy or estimated glomerular filtration rate  $< 45$  mL/min/1.73 m<sup>2</sup> underwent non-contrast CT. The study excluded patients with small intestinal obstruction that was not relieved with conservative treatment or long tube placement, suspected perforation or peritonitis, Crohn's disease, dysphagia, or pacemaker placement.

### Variables

We evaluated the age, sex, history of abdominal surgery (colectomy, ovariectomy, hysterectomy, gastrectomy, appendectomy, cholecystectomy, hepatectomy, or pancreatectomy), regular medication use for at least 30 days before enrollment (NSAIDs, antiplatelets, anticoagulants, steroids, proton pump inhibitors, and histamine-2 receptor antagonists), and contrast-enhanced CT findings (such as band adhesions, single band with length  $> 1$  cm and diameter  $< 1$  cm, matted adhesions, multiple bands with length  $< 1$  cm and diameter  $> 1$  cm<sup>[7]</sup>, small intestinal tumors, ischemic enteritis, and Meckel's diverticulum).



**Figure 1.** Eligibility criteria, intervention, follow-up, and analysis of patients.

## Intervention

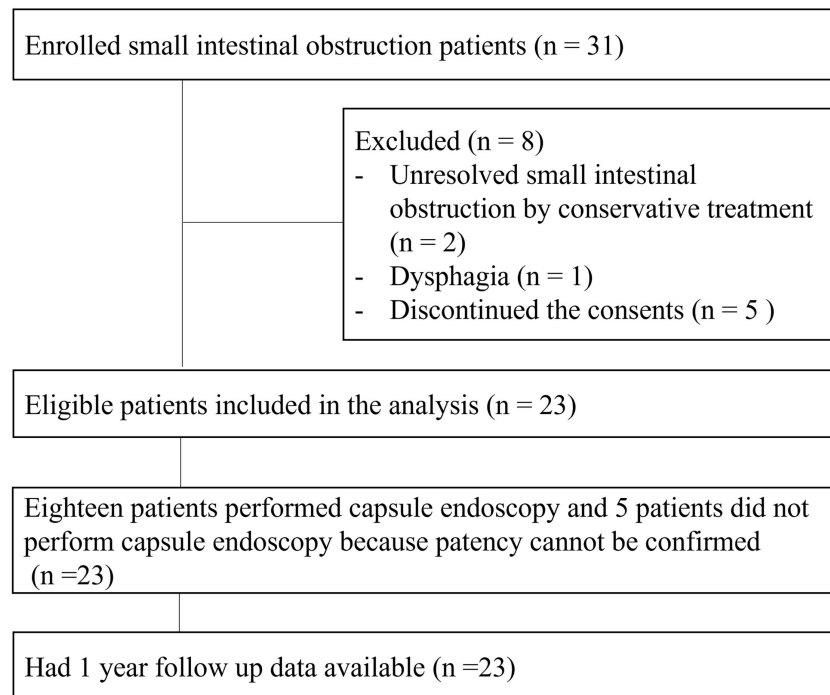
**Figure 1** presents the eligibility criteria, intervention, follow-up, and analysis of patients.

The patients were treated with conservative therapy by inserting a long tube to relieve small intestinal obstruction. After relieving the obstruction, we performed tag-less patency capsule examination using a tag-less Pill Cam patency capsule (Medtronic, Minneapolis, MN, USA) to evaluate small intestinal patency. Small intestinal patency was determined at 30–33 h after the Pill Cam patency capsule examination<sup>[8]</sup> based on capsule excretion without transformation or detection of the capsule in the colon on abdominal X-ray, ultrasound, or non-contrast CT.

After confirming the small intestine patency, capsule endoscopy was performed using Pill Cam SB2 (Medtronic). The patients were administered 40 mg of oral simethicone before the examination<sup>[9]</sup>. Two experienced gastroenterologists independently assessed the capsule endoscopy images at The University of Tokyo Hospital and Japanese Red Cross Medical Center.

In cases where the cause of small intestinal obstruction was identified on capsule endoscopy, double-balloon endoscopy was performed using an electronic video endoscope (Fujifilm Wako Pure Chemical, Tokyo, Japan). Before the double-balloon endoscopy, the bowel was prepared by administering polyethylene glycol solution via an oral or anal approach. The approach used for double-balloon endoscopy is determined according to the site of the suspected lesions detected on capsule endoscopy. In cases where the lesion site could not be reached during the initial balloon endoscopy, we performed tattooing at the deepest position and performed a second balloon endoscopy examination on the next day. In cases where balloon endoscopy diagnosed the cause underlying the small intestinal obstruction, surgical intervention was performed.

After discharge, follow-up visits were performed every three months for one year. At each visit, in-person interviews were conducted, including an assessment of abdominal symptoms. Furthermore, abdominal X-ray was conducted to evaluate the recurrence of small intestinal obstruction. Failure to follow-up indicated no further visits within six months after the last visit.



**Figure 2.** Flowchart for patient selection.

### Outcomes

The study outcomes included patency capsule findings (excretion, excretion time, capsule transformation, colonic or intestinal lesions, and modality used to detect lesions), capsule endoscopy findings (small intestine transit time, redness, erosions and ulcers, angioectasia, stenosis, tumor, and diverticulum), and capsule endoscopy-related adverse events (including abdominal pain, gastrointestinal bleeding, retention, and cardiovascular events). The study endpoints included recurrence of small intestinal obstruction, defined as abdominal symptoms, such as vomiting or abdominal pain, and contrast-enhanced CT findings of small intestinal obstruction.

### Statistical analysis

The primary statistical analysis was performed for all eligible patients. The study endpoint was small intestinal obstruction recurrence. Data were censored one year after enrollment or loss to follow-up. The Kaplan-Meier curve was used to estimate the cumulative incidence of small intestinal obstruction recurrence at three months to one year. Statistical analyses were performed using SAS software (version 9.4; SAS Institute Inc., Cary, NC, USA).

## RESULTS

Of the 31 patients enrolled, eight were excluded, and the remaining 23 were enrolled, including 14 with adhesive ileus and three with band ileus on contrast-enhanced CT [Figure 2].

Table 1 presents the baseline characteristics of patients. The mean age of the patients was 62.13 years, and 14 (60.87%) were males. Thirteen patients (56.52%) had a history of surgery. Contrast-enhanced CT revealed band adhesions in three patients and a small intestinal tumor in one patient.

**Table 1. Baseline characteristics (n = 23)**

	No. of patients (%)
<b>Authors</b>	
Sex, Male	14 (60.87)
Mean age (years)	62.13 ± 16.40
Current smoking	11 (47.83)
Regular alcohol use	10 (43.48)
<b>History of surgery<sup>#</sup></b>	13 (56.52)
Colectomy	2 (8.70)
Ovariectomy or hysterectomy	5 (21.74)
Gastrectomy	2 (8.70)
Appendectomy	3 (13.04)
Hepatectomy	0 (0.00)
Cholecystectomy	1 (4.35)
Pancreatectomy	1 (4.35)
<b>Medications</b>	
NSAIDs	2 (8.70)
Antiplatelets <sup>*</sup>	5 (21.74)
Anticoagulants <sup>§</sup>	0 (0.00)
Steroids	0 (0.00)
PPIs	4 (17.93)
H2RAs	4 (17.93)
<b>Contrast-enhanced CT findings</b>	
Band adhesions	3 (13.04)
Matted adhesions	0 (0.00)
Ileum intussusception	1 (4.35)
Ischemic enteritis	0 (0.00)
Ileum dilation	1 (4.35)

"±" indicates standard deviation; <sup>#</sup>duplicate results were allowed; <sup>\*</sup>including aspirin, clopidogrel, ticlopidine, icosapentaene, sarpogrelate, beraprost sodium, limaprost alfadex, Girazep, dipyridamole, and ozagrel sodium; <sup>§</sup>including warfarin. NSAID: Nonsteroidal anti-inflammatory drug; PPI: proton pump inhibitor; H2RA: histamine 2 receptor antagonist.

Of the 23 eligible patients, 18 underwent patency capsule endoscopy at  $13.9 \pm 15.9$  days after the diagnosis of small bowel obstruction. Capsule endoscopy was not performed in five patients in whom small intestinal patency could not be confirmed. Of the 18 patients who underwent patency capsule endoscopy, seven excreted the capsules without transformation after  $22.2 \pm 9.47$  h, whereas 11 had confirmed small intestinal patency on X-ray, ultrasound, or non-contrast CT. In nine patients, X-ray revealed small intestinal patency. In two patients, the patency capsule could not be identified on X-ray, and non-contrast CT was performed [Table 2].

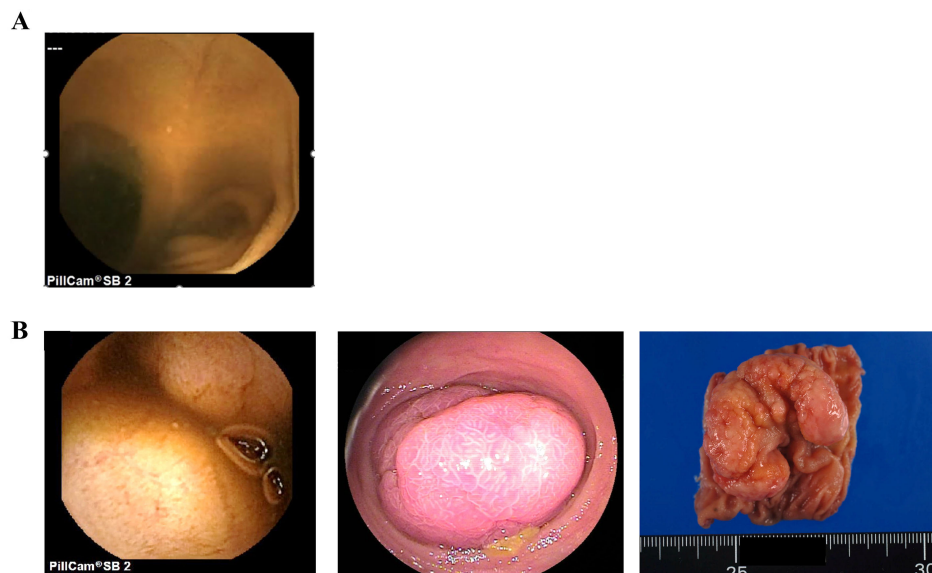
In total, 18 patients underwent small intestinal capsule endoscopy at  $15.7 \pm 16.8$  days after the diagnosis of small bowel obstruction. The enteroscopy rate based on capsule endoscopy was 94.4% (17/18 patients) over  $296 \pm 133$  min. Capsule endoscopy revealed redness in six patients, erosions and ulcers in three patients, small intestinal diverticulum in one patient, tumor in one patient, and normal examination in seven patients. No capsule endoscopy-related adverse events were observed.

In four of the 18 patients who underwent capsule endoscopy, subsequent balloon endoscopy was also performed, which revealed Meckel's diverticulum and ileum ganglioneuroma in one patient each

**Table 2. Small intestinal patency in patients who did not excrete patency capsules (n = 11)**

Patient	X-ray findings	Ultrasound findings	CT findings
Case 1	×	×	Detected
Case 2	Detected	Detected	Detected
Case 3	×	×	Detected
Case 4	Detected	×	Detected
Case 5	Detected	Detected	Detected
Case 6	Detected	Detected	Detected
Case 7	Detected	Detected	Detected
Case 8	Detected	×	Detected
Case 9	Detected	×	Detected
Case 10	Detected	Detected	Detected
Case 11	Detected	Detected	Detected

“×”: indicates that patency was not detected.



**Figure 3.** Patients with Meckel's diverticulum and ileum ganglioneuroma. (A) Capsule endoscopy revealed a double lumen, indicating Meckel's diverticulum; (B) Capsule endoscopy (left panel) and balloon endoscopy (middle tumor) revealed a small intestinal tumor, which was resected (right panel).

[Figure 3]. Of the remaining two patients, one had a history of catheter insertion for peritoneal dialysis, and another had no history of surgery. Contrast-enhanced CT revealed ileum dilation and ileum intussusception in these patients, respectively. These patients underwent surgical resection. Sixteen of the 23 patients completed the one-year follow-up, whereas seven patients were lost to follow-up. During a mean follow-up period of  $292 \pm 121$  days, no cases of recurrence of small intestinal obstruction were observed.

## DISCUSSION

This preliminary, prospective observational study demonstrated that capsule endoscopy can determine the cause of small intestinal obstruction after the obstruction is relieved. Confirmation of small intestinal patency before capsule endoscopy is crucial to ensure patient safety. The identification of small intestinal obstruction by capsule endoscopy can prevent short-term recurrence.

Although most of our patients had a history of surgery, one (1/18, approximately 5%) did not have a history of abdominal surgery and was diagnosed with a small bowel tumor. However, our study may have overestimated the frequency of small bowel tumors as most of our patients had a history of surgery. Furthermore, one patient with Meckel's diverticulum on capsule endoscopy had a history of catheter insertion for peritoneal dialysis. Interestingly, CT and capsule endoscopy revealed variable findings in our study, which may be attributable to the small sample size. We speculate that the cause of small intestinal obstruction is typically related to the small intestinal tract; thus, endoscopic visualization of the small intestinal lumen might be more important for determining the cause of obstruction than contrast-enhanced CT-based evaluation of the surrounding regions. Therefore, capsule endoscopy may be useful for patients with an unclear cause of obstruction on CT. Nevertheless, CT is the gold standard investigation for the diagnosis of small intestinal obstruction and provides useful information. Additionally, the resolution of CT has significantly improved over time. Randomized clinical trials are needed to compare the diagnostic performance between CT and capsule endoscopy for small intestinal obstruction.

It is crucial to accurately determine small intestinal patency before performing capsule endoscopy. In the present study, X-ray could not detect small intestinal patency in all patients. Previous large-scale studies have demonstrated that approximately 30% of patients require CT to determine the small intestinal patency<sup>[10,11]</sup>, which is consistent with our results. Compared with X-ray, non-contrast CT can accurately distinguish between small and large intestines and can identify patency capsules in the colon. Therefore, non-contrast CT should be considered in cases where the patency capsule cannot be identified on X-ray. Patency capsules are associated with important adverse events. A previous study demonstrated that the outer wall of the patency capsule remains undissolved in patients with Crohn's disease, which can lead to small intestinal obstruction<sup>[12]</sup>.

The main strength of the present study was that it was a prospective observational study that evaluated the cause of small intestinal obstruction in patients with a high risk of obstruction recurrence. However, this study also had several limitations. First, the sample size was small; Second, we did not compare the diagnostic accuracy between capsule endoscopy and other investigations; Third, the follow-up duration was short. Finally, most patients had a history of surgery. Therefore, our findings have limited generalizability to the general patient population and those without a history of abdominal surgery.

In conclusion, capsule endoscopy and subsequent balloon endoscopy, after confirming the intestinal patency, revealed the cause of obstruction in our small patient population. Capsule endoscopy may be useful for these patients after the obstruction has been relieved. However, further large-scale comparative trials are needed.

## **DECLARATIONS**

### **Acknowledgments**

We thank all patients and their families.

### **Authors' contributions**

Conceptualized the trial design: Niikura R, Yamada A

Collected the data: Niikura R, Yamada A, Suzuki H, Nakada A, Mitsuno Y, Yamamoto S

Analyzed the data and drafted the manuscript: Imai M, Niikura R

Edited the manuscript: Imai M, Niikura R, Aoki T, Hayakawa Y, Kawai T, Fujishiro M

All authors approved the final version of the manuscript.

### Availability of data and materials

Data supporting the trial findings are unavailable because of our institutional review board policy.

### Financial support and sponsorship

None.

### Conflicts of interest

All authors declared that there are no conflicts of interest.

### Ethical approval and consent to participate

The study was performed in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional review boards of The University of Tokyo and the Japanese Red Cross Medical Center. We obtained written informed consent from all patients before enrollment.

### Consent for publication

We obtained written informed consent from patients before enrollment.

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