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ORIGINAL ARTICLE

Outcomes and Management Strategies for Capsule Retention: A Korean Capsule Endoscopy Nationwide Database Registry Study

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Abstract

Background The most concerning complication of capsule endoscopy (CE) is capsule retention (CR) in the gastrointestinal (GI) tract; however, the clinical outcomes and management of patients with CR are still uncertain.

Aims This study aimed to investigate the clinical outcomes and management of CR.

Methods The outcomes of CR in multiple centers between October 2002 and June 2018 were retrospectively reviewed. Data on CE indication, findings, and management details were analyzed.

Results A total of 2705 consecutive small-bowel CE procedures were performed. CR was detected in 20 cases (0.7%). The most common site of CR was the small bowel (19 cases), followed by the esophagus (one case). In patients who underwent CE, CR was detected in nine (0.6%) of 1397 patients with obscure GI bleeding. Further, CR occurred in 11 (6.5%) of 169 patients with Crohn's disease based on the final diagnoses after CE. Capsule retrieval was safely performed surgically in nine cases and endoscopically in six cases. The retained capsules dislodged after steroid treatment in two cases, whereas three cases of CR resolved without any intervention. In multivariate analysis, the development of abdominal symptoms after CR was a significant predictive factor for requiring endoscopic or surgical interventions for capsule extraction.

Conclusions This large multicenter study shows that CR is a rare complication with favorable clinical outcomes. Three-fourths of the patients with CR were managed with endoscopic or surgical intervention, which was required particularly in patients with abdominal symptoms after CR.

Keywords Capsule endoscopy · Small bowel · Retention

Introduction

Capsule endoscopy (CE) is a primary method for evaluating small-bowel (SB) disorders. CE is useful in cases of obscure gastrointestinal (GI) bleeding and in the evaluation of suspected or known Crohn's disease (CD) [1]. Although CE is usually considered a noninvasive and safe technology, one of the main risks associated with this procedure is capsule retention (CR). CR has been reported in approximately 1.4% of CE procedures [2–7]. Factors related to a higher risk of CR include established CD, SB strictures, or abdominal radiation exposure [6, 8]. Conservative observation is a therapeutic choice for the management of CR in most cases, because CR is usually asymptomatic; however, endoscopic or surgical intervention may be required for capsule retrieval [7]. In clinical practice, it might be difficult to decide whether endoscopic or surgical intervention is needed in CR, particularly in cases in which the CR duration is <2 weeks, which does not yet meet the definition of CR.

Thus, we aimed to analyze the clinical outcomes of CR and to determine for which subgroup of patients endoscopic or surgical intervention would be a necessary strategy.

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Methods

Patients

We investigated the records in the Korean CE nationwide database registry of patients who underwent CE for various reasons in 16 tertiary referral centers from October 2002 to June 2018. PillCam (SB 1 to 3; Medtronic, Minneapolis, MN, USA) or Mirocam (Intromedic, Seoul, South Korea) was used for CE examinations. The study was performed in accordance with the guidelines of the Declaration of Helsinki and was approved by the institutional review boards.

Patients were evaluated by experienced gastroenterologists before the CE study. It was not available to perform magnetic resonance enterography (MRE), which was not covered by the national medical insurance during most of the study period. Abdominal computed tomography (CT) or CT enterography (CTE) was usually performed before CE procedure [9]. Patients with potential contraindications to CE, such as severe SB stricture on the abdominal CT or CTE, or obstructive symptoms, did not undergo CE. However, as a limitation of the retrospective study, all patients with CR did not undergo abdominal CT or CTE before CE procedures.

In preparation for the CE procedure, the patients were not allowed to ingest anything by mouth for 8 h before the procedure. Each patient received bowel preparation according to clinician preference. The various methods of bowel preparation included nothing per os (NPO) or use of purgative agents such as 2 or 4 L polyethylene glycol (PEG) conducted in each hospital.

After swallowing the capsule, the patients were allowed liquid food after 2 h and solid food after 4 h. Examinations with a patency capsule could not be performed in this study because it was not available in Korea at the time of the study.

All CE studies were evaluated by gastroenterologists experienced in CE. If the video did not show that the capsule reached the colon or if the patient did not visualize the passage of the capsule with the stool, abdominal radiography was recommended about ≤ 14 days after the CE examination to confirm CR.

Capsule Retention

CR was defined as capsule remaining in the GI tract for at least 2 weeks after ingestion with retention confirmed with abdominal radiography or when endoscopic or surgical interventions were required to remove the capsule [5, 10]. When CR was identified, the patients were examined by a gastroenterologist to determine whether obstructive symptoms were present and whether the capsule needed to be removed.

We analyzed the reasons for CE and evaluated the sites, causes, management, and clinical outcomes of CR in a nationwide patient cohort. Abdominal symptoms after CR were defined as the newly occurred symptoms of abdominal pain or vomiting after capsule ingestion. To identify the subgroup of patients with CR who would need to be indicated for endoscopic or surgical intervention, we compared the clinical features between patients who underwent endoscopic or surgical interventions for capsule extraction (intervention group) and those who showed spontaneous resolution or needed drug treatment (control group). In clinical practice, there are many cases in which the clinicians may need to explain the situation and prognosis to the patients and their guardians. Therefore, the clinicians should decide whether endoscopic or surgical intervention would be required for CR, particularly in cases in which the CR duration is <2 weeks. Thus, to compare the two patient groups, asymptomatic patients with CR for >1 day and <14 days were additionally included in the control group, although they do not yet meet the definition of CR.

Statistical Analysis

Values are presented as mean ± standard deviation for quantitative data and as frequencies (percentages) for categorical data. A Student's t test was conducted to analyze the continuous variables, and a Chi-square test was performed to evaluate the categorical variables. Multivariate analysis was conducted with logistic regression to identify the risk factors for requiring endoscopic or surgical interventions for capsule extraction. All statistical analyses were performed using SPSS version 14.0 (SPSS Inc., Chicago, IL, USA). The confidence interval (CI) was set at 95%, and p values of <0.05 were considered statistically significant.

Results

Outcomes and Management for Capsule Retention

Among 2705 patients who underwent CE, 20 (0.7%) patients showed CR according to the definition. The SB was the most common site for CR (19 cases, with nine at the jejunum and ten at the ileum) followed by the esophagus (1 case; Table 1). In patients who underwent CE, CR occurred in four (4.0%) of 101 patients with suspected and known CD based on the reasons for CE procedure. Further, CR was detected in nine (0.6%) of 1397 patients with obscure GI bleeding. Based on the final diagnoses after CE examination, CR occurred in 11 (6.5%) of 169 patients with CD, two (1.4%) of 140 patients with nonsteroidal anti-inflammatory drug (NSAID) enteropathy, one (4.3%) of 23 patients with

Table 1 Site of capsule retention ($n=20$)

Site	*n* (%)
Esophagus	1 (5.0)
Stomach	0 (0)
Small bowel	19 (95.0)
Jejunum	9 (45.0)
Ileum	10 (50.0)
Colon	0 (0)

Table 2 Management of capsule retention ($n=20$)

Management	*n* (%)
Spontaneous resolution	3 (15.0)
Drug treatment	2 (10.0)
Endoscopic removal	6 (30.0)
EGD	1 (5.0)
Enteroscopy	5 (25.0)
Surgery	9 (45.0)

EGD esophagogastroduodenoscopy

SB cancer, and one (4.8%) of 21 patients with intestinal tuberculosis.

Spontaneous resolution of the retained capsule was observed in three (15.0%; 18, 75, 85 days, respectively, on the duration of CR) of the 20 patients with CR (Table 2), whereas two (10.0%) capsules dislodged after drug treatment with steroids. Endoscopic capsule removal was performed in six (30.0%) cases (one by esophagogastroduodenoscopy and five by double-balloon enteroscopy (DBE)), and surgical intervention was performed in nine (45.0%) cases. There was no CR-related death.

The details of patients with CR are shown in Supplementary Table 1A. We found that two (10.5%) of the 19 patients with CR at the SB did not show SB stricture on abdominal CT. The reason for CE in both patients was obscure GI bleeding. In one of the two patients, CE showed SB ulcer with stricture, and surgical intervention for capsule extraction was performed on the patient 9 days after CR. In the other patient, who was diagnosed with NSAID enteropathy in the ileum, and then stopped taking NSAIDs, the capsule spontaneously passed 75 days after CR. Details of asymptomatic patients with the retained capsule for > 1 day and < 14 days are shown in Supplementary Table 1B.

The clinical features of patients with CR that required endoscopic or surgical intervention for capsule extraction (intervention group, $n=15$) are summarized in Table 3 and were compared with those of patients with spontaneous resolution or drug treatment after CR (control group, $n=21$). As previously mentioned, the control group included patients ($n=5$) with true CR according to the definition and asymptomatic patients ($n=16$) with the retained capsule for < 14 days. The mean age was 53.1 years in the intervention group and 51.4 years in the control group. A history of previous GI surgery was noted in 11 (13.3%) patients in the intervention group and in four (19.0%) patients in the control group. The reasons for CE in the intervention group were obscure GI bleeding ($n=7$), suspected CD ($n=3$), and others ($n=5$). There were no significant differences in age, sex, history of previous GI surgery, and reasons for CE between the two groups. SB wall thickening on abdominal CT was more frequent in the intervention group than in the control group (11 [73.3%] vs. 8 [38.1%]; $p=0.037$). The development of abdominal

Table 3 Clinical features of patients with capsule retention that required endoscopic or surgical intervention for capsule extraction

Variables	Endoscopic or surgical interventions after CR ($n=15$)	Spontaneous resolution or drug treatment after CR ($n=21$) (true CR by definition ($n=5$) and CR duration less than 14 days ($n=16$))	*p* value
Age, y (SD)	53.1 (23.9)	51.4 (24.0)	0.836
Male, *n* (%)	11 (73.3)	12 (57.1)	0.319
Previous GI surgery, *n* (%)	2 (13.3)	4 (19.0)	0.650
Reasons for capsule endoscopy			
Obscure GI bleeding	7 (46.7)	10 (47.6)	0.955
Suspected Crohn's disease	3 (20.0)	5 (23.8)	0.786
Known Crohn's disease	0 (0)	2 (9.5)	0.219
Others	5 (33.3)	4 (19.0)	0.329
Previous abdominal radiation therapy, *n* (%)	0 (0)	0 (0)	N/A
Small-bowel wall thickening on CT, *n* (%)	11 (73.3)	8 (38.1)	0.037
Abdominal symptoms after capsule retention, *n* (%)	8 (53.3)	1 (4.8)	0.001
Duration from capsule intake to discharge of the capsule, d (SD)	35.3 (51.2)	15.0 (24.4)	0.122

CR capsule retention, *GI* gastrointestinal, *CT* computed tomography

symptoms after CR was more frequent in the intervention group than in the control group (8 [53.3%] vs. 1 [4.8%]; $p = 0.001$).

Factors Associated with the Requirement for Interventions for Capsule Extraction

We performed univariate and multivariate analyses for factors associated with the requirement for endoscopic or surgical intervention for capsule extraction after CR, compared with spontaneous resolution or drug treatment after CR (Table 4). In univariate analyses, SB wall thickening on abdominal CT ($p = 0.042$) and abdominal symptoms after CR ($p = 0.006$) were statistically significant; however, age, sex, history of previous GI surgery, and reasons for CE were not statistically significant.

In multivariate analyses, the presence of abdominal symptoms after CR (odds ratio 18.56, 95% CI 1.87–183.82; $p = 0.013$) was statistically significant.

Discussion

The present study demonstrated the clinical outcomes and management strategies for CR in a nationwide multicenter cohort. The rate of CR was very low (0.7%), and the SB was the location of CR in almost all cases except for one case of CR in the esophagus. In the previous studies, CR has been reported in about 1.4% of CE examinations [2–7]. In a recent study in a large tertiary hospital with 5593 CE procedures, CR occurred in only 0.3% of patients without obstructive symptoms [11]. More recently, a large single-center retrospective study including 2401 patients reported a CR rate of 1.0% [12]. These findings were similar to the results of our study.

Patient factors related to a higher risk of CR include a suspected tumor, abdominal or pelvic radiation exposure, established CD, or strictures [6, 8, 11]. Although strictures are usually considered a contraindication for CE, not all strictures cause sufficient obstruction to prevent the passage of the capsule [6]. Studies have reported that passage of an intact patency capsule is predictive of successful passage of CE in most patients with known or suspected strictures [6, 13–15]. However, in our study, a patency capsule could not be used before CE examination because it is not yet available in Korea. Nevertheless, in a previous retrospective, multicenter study including 406 CE procedures, the risk of CR was similar between patients who underwent CE without a patency capsule test (1.5%) and those who underwent CE after a negative patency capsule test (2.1%; $p = 0.9$). The patients who underwent CE after a positive patency capsule test showed a high CR rate of 11.1% [16]. The major concern associated with the use of a patency capsule is that false-positive results could occur in patients with delayed transit without obstruction, which would preclude the use of CE [15]. Moreover, there is no established method for determining the location of the patency capsule in the bowel [17]. A recent study showed that localization of a patency capsule on plain abdominal films is unreliable, and abdominal CT is often additionally needed [18].

Most cases of CR occur in the SB; however, CR can occur at any level of the GI tract [19]. In our study, one capsule was retained in the esophageal diverticulum in a patient with obscure GI bleeding. The retained capsule was extracted, and a second capsule was delivered to the duodenum through a gastroscopy. A recent study reported four cases of CR in the esophagus, two in the stomach, and two in the duodenum [12]. These results suggest that careful esophagogastroduodenoscopy should be performed before a CE procedure to reduce the risk of CR in the upper GI tract, and endoscopic delivery of the capsule to the duodenum is an optimal method in patients with a high risk of CR [9].

In our study, two cases of CR involved patients with a history of previous abdominal surgery. One patient had

Table 4 Univariate and multivariate analysis of factors associated with the requirement for endoscopic or surgical intervention for capsule extraction after capsule retention compared with spontaneous resolution or drug treatment after capsule retention

Variable	Univariate		Multivariate	
	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)	*p* value
Age	1.00 (0.98–1.03)	0.831		
Sex, male	0.49 (0.12–2.03)	0.322		
Previous GI surgery	0.65 (0.10–4.14)	0.652		
Reasons for capsule endoscopy				
Obscure GI bleeding	0.96 (0.26–3.63)	0.955		
Suspected or Known Crohn's disease	2.0 (0.42–9.49)	0.383		
Small-bowel wall thickening on CT	4.47 (1.05–18.94)	0.042	3.17 (0.60–16.69)	0.174
Abdominal symptoms after capsule retention	22.86 (2.41–216.86)	0.006	18.56 (1.87–183.82)	0.013

CI confidence interval, *GI* gastrointestinal, *CT* computed tomography

undergone total hysterectomy before the CE examination, and surgical intervention was performed to extract the capsule retained owing to postoperative stenosis in the ileum. The other patient had undergone umbilical hernia repair before the CE procedure, and surgical resection was performed to remove the capsule retained, owing to postoperative stenosis in the SB. A previous study showed that CE was safe in patients who had undergone surgical resection of the SB [20]. However, a recent systematic review reported that postsurgical stenosis and intestinal adhesion were associated with CR [4]. We found that previous GI surgery and even non-GI abdominal surgery such as hysterectomy could be related to CR.

The CR rate in our study was 0.7% (20 of 2705) in the entire GI tract, and it was still 0.7% (19 of 2705) in the SB excluding one case of CR in the esophagus. This is similar to the result of a recent study that also reported a 0.7% CR rate in the SB [12]. In the previous studies, the most common cause of CR was CD, with CR rates of 1.0–8.2% in the SB, and CD was also the reason for a high proportion of CE examinations [4, 10, 12]. Similarly, the most common cause of CR in our study was CD, with a rate of 6.5% based on the final diagnoses after CE, although the most common reason for CE examinations was obscure GI bleeding. Compared with Western studies, it is likely that patients in Korea are more often evaluated for CD through cross-sectional imaging studies because of the considerable concern about CR.

In a Swedish study based on 2300 CE procedures, CE was considered a safe examination, although CR occurred in 1.3% ($n=31$) and complications of CR were acute obstructive symptoms in six patients [5]. Those are quite similar to the results in our study that CR occurred in 0.7% and abdominal symptoms after CR occurred in eight patients.

Either conservative observation or treatment with steroids can be considered for CR [9]. According to patient's symptoms or physician preference in our study, treating the underlying disease, in some patients with CD, with corticosteroids, induced spontaneous passage of the capsule [9, 17, 21]. When capsule retrieval is required, both endoscopy and surgery may be viable alternatives [6, 9, 21]. In our study, five (25.0%) patients underwent endoscopic intervention with DBE for capsule retrieval and nine (45.0%) patients underwent surgical intervention including one patient, in whom removal of the retained capsule with DBE had failed. In our study, the decision depended on patient's symptoms or availability of DBE [9]. If abdominal symptoms after CR occurred, endoscopic or surgical interventions were usually performed in this study, as multivariate analysis demonstrated it. Abdominal CT findings did not show a significant association with the requirement for interventions for capsule retrieval. It might be due to a small number of CR patients. If DBE was available in the institute, DBE was initially performed to remove the retained capsule. When DBE failed to remove it, surgical intervention was performed [6, 17, 21]. Although DBE was available in the hospital, there were some cases that surgical interventions without initial DBE were performed, according to the factors including the feasibility of DBE for the removal of the retained capsule and patients with a history of previous abdominal surgery [9, 22]. If DBE was not available in the hospital, surgical intervention was performed.

In the endoscopic or surgical intervention group, there were seven (46.7%) asymptomatic patients after CR, including one CR case in the esophagus. In a 35-year-old patient with CD, capsule removal was performed with DBE after 21 days of CR, based on patient and physician preferences. In a 27-year-old patient with CD, capsule removal was performed with DBE after 27 days of CR, as a subsequent investigation. A 41-year-old male with CD was transferred to one of the hospitals in our registry, to remove capsule although he did not have a related symptom of CR, based on patient and physician preferences. He finally underwent surgical intervention after the failed DBE procedure. A 39-year-old male showed recurrent GI bleeding, and it was difficult to diagnose the SB lesion by abdominal CT and CE. He underwent surgical resection and was finally diagnosed with Meckel's diverticulum. A 59-year-old male had a history of intestinal tuberculosis 30 years prior to CE. It was difficult to differentiate between intestinal tuberculosis and CD, based on CE results of SB ulcers and stricture. He underwent surgical intervention and was finally diagnosed with intestinal tuberculosis.

This study has a few limitations. First, a patency capsule could not be used before CE examination, as previously mentioned. Second, this was a retrospective study. Patient selection bias might have existed. However, we collected data from a nationwide database registry to minimize selection bias. Third, MRE was not used to rule out SB stenosis before the CE procedure because MRE was not covered by the government health insurance system during most of the study period. Nevertheless, negative MRE examinations did not exclude all cases of SB stenosis in a previous study [12]. Although abdominal CT or CTE was usually performed before CE in this study [9], all patients with CR did not undergo abdominal CT or CTE before CE procedures. Fourth, the study design and management strategies for CR might be imprecise and flawed in this study, because this was a retrospective study and the decision for the management depended on patient's symptoms, physician preference, or circumstances of each institution. Finally, in terms of the reasons for CE, CD was not strictly classified as suspected or known, before CE in this registry. The CR of suspected and known CD could not be shown independently.

In conclusion, this large multicenter study shows that CR is a rare complication with favorable clinical outcomes. Three-fourths of the patients with CR were managed with

endoscopic or surgical intervention. We also found that the requirement for these interventions for capsule retrieval was associated with the presence of abdominal symptoms after CR. Thus, these methods would be required particularly in patients with abdominal symptoms after CR.

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Compliance with ethical standards

Conflict of Interest The authors declare that they have no conflict of interest.

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