



Changes in performance of small bowel capsule endoscopy based on nationwide data from a Korean Capsule Endoscopy Registry

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Background/Aims: Capsule endoscopy (CE) is widely used for the diagnosis of small bowel diseases. The clinical performance and complications of small bowel CE, including completion rate, capsule retention rate, and indications, have been previously described in Korea. This study aimed at estimating the recent changes in clinical performance and complications of small bowel CE based on 17-year data from a Korean Capsule Endoscopy Registry.

Methods: CE registry data from 35 hospitals were retrospectively analyzed. Clinical information, including completion rate, capsule retention rate, and indications, was collected and analyzed. In addition, the most recent 5-year data for CE examinations were compared with the previous 12-year data.

Results: A total of 4,650 CE examinations were analyzed. The most common indication for CE was obscure gastrointestinal bleeding (OGIB). The overall incomplete examination rate was 16% and the capsule retention rate was 3%. Crohn's disease was a risk factor for capsule retention. Inadequate bowel preparation was significantly associated with capsule retention and incomplete examination. An indication other than OGIB was a risk factor for incomplete examination. A recent increasing trend of CE diagnosis of Crohn's disease was observed. The most recent 5-year incomplete examination rate for CE examinations decreased compared with that of the previous 12 years.

Conclusions: The 17-year data suggested that CE is a useful and safe tool for diagnosing small bowel diseases. The incomplete examination rate of CE decreased with time, and OGIB was consistently the main indication for CE. Inadequate bowel preparation was significantly associated with capsule retention and incomplete examination.

Keywords: Capsule endoscopy; Intestine, small; Retention; Bowel preparation

INTRODUCTION

Since Capsule endoscopy (CE) was introduced in 2000, it has been widely used as the main tool for diagnosing small bowel diseases [1]. Although CE is useful for diag-

nosing small bowel diseases, it has some limitations including incomplete examinations and capsule retention [2-4]. Occasionally, capsules cannot reach the cecum due to various causes, thus leading to incomplete examination of the small bowel. Another problem is capsule re-

tention. Most patients in whom capsule retention occurs are asymptomatic; however, some require surgical or enteroscopic capsule removal [4-9]. The clinical performance and complications of small bowel CE include completion rate, capsule retention rate, and indications [2,3]; these have also been described in Korea [10]. This study aimed to investigate the clinical performance and complications of small bowel CE based on 17-year data from a Korean Capsule Endoscopy Registry. Furthermore, recent changes in the clinical performance and complications of small bowel CE were also evaluated.

METHODS

CE registry data from 35 hospitals, collected between October 2002 and April 2019, were retrospectively analyzed. Clinical information, including demographic data, completion rate, capsule retention rate, indications, CE diagnosis, and bowel preparation data, was collected and analyzed. From September 2014, health insurance benefits were provided to patients with obscure gastrointestinal bleeding (OGIB) in Korea. However, for patients with small bowel tumor(s), Crohn's disease, and other small bowel diseases, a patient burden of 80% was applied. As such, data from the most recent 5 years (September 2014 to April 2019) were compared with those from the previous 12 years (October 2002 to August 2014).

Indications for CE included OGIB, abdominal pain, chronic diarrhea, small bowel tumor(s), Crohn's disease, weight loss, protein-losing enteropathy, and screening. OGIB was defined as bleeding of unknown cause that persisted or recurred after initial upper gastrointestinal endoscopy and colonoscopy with negative results [11,12]. In addition to overt bleeding (melena or hematochezia), occult bleeding (persistent iron deficiency anemia or positive stool occult blood) was also considered OGIB [12,13].

Before CE examinations, patients were offered a bowel preparation regimen according to clinician preferences. Options for the bowel preparation included *nil per os* (NPO), polyethylene glycol (PEG), PEG + ascorbic acid, sodium phosphate (NaP), picosulfate, or others. Bowel preparation quality was categorized by independent examiners as follows: excellent, $\geq 75\%$ of the mucosa visualized; good, 50% to 74% of the mucosa visualized; fair,

25% to 49% of the mucosa visualized; poor, $\leq 24\%$ of the mucosa visualized [14]. For the purpose of study analysis, excellent or good bowel preparation were deemed adequate, and fair or poor preparation were deemed inadequate [15]. Comparison was performed between adequate and inadequate bowel preparation quality.

CE diagnoses were based on CE structured terminology. Complete examination was defined when the capsule reached the cecum during the recording time [2,3]. Capsule retention was defined when the capsule remained in the digestive tract for > 2 weeks [2,10]. Completion and capsule retention rates were calculated, and risk factors affecting incomplete examination and capsule retention were also investigated. Acquisition of informed consent was exempted and the study design was approved by the Institutional Review Board of Seoul Metropolitan Government Seoul National University Boramae Medical Center (approval number: 20190802/10-2019-62/091).

Data are expressed as mean \pm standard deviation (SD) for continuous variables and number (%) for categorical variables. Risk factors for incomplete examination and capsule retention were analyzed using logistic regression models. Statistical analysis was performed using SPSS version 20.0 (IBM Corporation, Armonk, NY, USA).

RESULTS

Demographics and indications

A total of 4,650 CE examinations were analyzed. The mean \pm SD age of the study population was 53.5 ± 18.8 years, and 60.3% was male. The overall incomplete examination rate was 16.3%, and the capsule retention rate was 3%. The incomplete examination rate of recent CE examinations (from September 2014 to April 2019) decreased compared with that of previous examinations (9.4% vs. 18.9%, $p < 0.001$) (Table 1). The most common indication for CE was OGIB (64.4%). Patients in whom the indication for CE was OGIB accounted for 68.8% in recent CE examinations and 62.7% in previous CE examinations ($p < 0.001$) (Table 2).

CE diagnoses

Positive CE diagnosis was obtained in 63.8% CE examinations, while negative (normal) CE diagnosis was ob-

Table 1. Demographic information and incomplete examination and retention rates

Variable	Total	~Aug. 31, 2014	Sep. 1, 2014~
Age	53.5 ± 18.8	53.1 ± 18.1	55.0 ± 20.5
Male sex	2,804 (60.3)	2,067 (61.1)	681 (58.2)
Incompletion	678 (16.3)	570 (18.9)	108 (9.4) ^a
Retention	125 (3.0)	105 (3.2)	20 (2.6)

Values are presented as mean ± SD or number (%).

^aDecreased trend.

Table 2. Indications for capsule endoscopy

Variable	Total	~Aug. 31, 2014	Sep. 1, 2014~
Obscure GI bleeding	2,965 (64.4)	2,110 (62.7)	790 (68.8) ^a
Overt	2,445 (53.1)	1,755 (52.2)	638 (55.6)
Occult	520 (11.3)	355 (10.5)	152 (13.2)
Abdominal pain	724 (15.7)	594 (17.7)	117 (10.2)
Crohn's disease	212 (4.6)	119 (3.5)	86 (7.5) ^a
Small bowel tumor	166 (3.6)	122 (3.6)	42 (3.7)
Chronic diarrhea	171 (3.7)	118 (3.5)	51 (4.4)
Weight loss	19 (0.4)	18 (0.5)	1 (0.1)
Cancer of unknown primary site	4 (0.1)	3 (0.1)	0
Protein-losing enteropathy	15 (0.3)	6 (0.2)	7 (0.6)
Behcet's disease, TB enteritis	44 (1.0)	21 (0.6)	23 (2.0)
Ileus	13 (0.3)	5 (0.1)	8 (0.7)
Screening	214 (4.6)	209 (6.2)	2 (0.2)

Values are presented as number (%).

GI, gastrointestinal; TB, tuberculous.

^aIncreased trend.

tained in 36.2% CE examinations. Recent CE examinations yielded normal results in 28.4%, which was lower than the normal results in previous CE examinations (38.5%) ($p < 0.001$). CE diagnoses are summarized in Table 3. A recent increasing trend of CE diagnosis of Crohn's disease was observed (6.3% vs. 8.5%, $p = 0.014$). Regarding nonsteroidal anti-inflammatory drug (NSAID) enteropathy, significant changes with time were not observed (5.7% vs. 6.5%, $p = 0.305$).

Factors associated with incomplete examination and capsule retention

Factors associated with incomplete examination includ-

ed inadequate bowel preparation and an indication other than OGIB (Table 4). Crohn's disease was a risk factor for capsule retention, and inadequate bowel preparation was significantly associated with capsule retention (Table 5). The capsule retention rate was the highest among patients with Crohn's disease (Table 6).

Bowel preparation

The quality of bowel preparation significantly differed according to bowel preparation regimen (Table 7). When the proportion of adequate bowel preparation after ingesting the bowel preparation regimen was compared pairwise with that after NPO, significant differences

Table 3. Capsule endoscopic diagnosis

Variable	Total	~Aug. 31, 2014	Sep. 1, 2014~
Normal	1,647 (36.2)	1,285 (38.5)	322 (28.4) ^a
Vascular lesions			
Angiodysplasia, telangiectasia, Dieulafoy's lesion	442 (9.7)	349 (10.4)	87 (7.7)
Bleeding of unidentified origin	234 (5.1)	122 (3.7)	109 (9.6)
Varices	12 (0.3)	10 (0.3)	2 (0.2)
Inflammatory lesions			
Erosion, not signified	365 (8.0)	233 (7)	130 (11.5)
Ulcer, not signified	469 (10.3)	352 (10.5)	112 (9.9)
Hemorrhagic enteropathy	31 (0.7)	28 (0.8)	3 (0.3)
Congestive enteropathy	13 (0.3)	13 (0.4)	6 (0.5)
H-S purpura, vasculitis	11 (0.2)	10 (0.3)	1 (0.1)
Ischemic enteritis	9 (0.2)	6 (0.2)	3 (0.3)
NSAID enteropathy	267 (5.9)	190 (5.7)	74 (6.5)
TB enteritis	30 (0.7)	16 (0.5)	12 (1.1)
Behcet's enteritis	33 (0.7)	22 (0.7)	11 (1.0)
Radiation enteritis	9 (0.2)	8 (0.2)	0
Eosinophilic enteritis	18 (0.4)	10 (0.3)	6 (0.5)
Crohn's disease	316 (6.9)	211 (6.3)	96 (8.5) ^b
CMUSE	3 (0.1)	1 (0)	2 (0.2)
Tumor lesions			
Lymphoid hyperplasia	25 (0.5)	22 (0.7)	3 (0.3)
Lymphangiectasia	30 (0.7)	17 (0.5)	12 (1.1)
Malignant tumor	50 (1.1)	40 (1.2)	9 (0.8)
Submucosal tumor	146 (3.2)	120 (3.6)	24 (2.1)
Polyp, adenomatous	25 (0.5)	21 (0.6)	4 (0.4)
Polyp, non-neoplastic	134 (2.9)	105 (3.1)	25 (2.2)
Peutz-Jeghers syndrome	10 (0.2)	7 (0.2)	3 (0.3)
Hemangioma	4 (0.1)	2 (0.1)	2 (0.2)
Lymphangioma	3 (0.1)	2 (0.1)	1 (0.1)
Others	220 (4.8)	138 (4.1)	82 (7.2)

Values are presented as number (%).

H-S, Henoch-Schönlein; NSAID, nonsteroidal anti-inflammatory drug; TB, tuberculous; CMUSE, cryptogenic multifocal ulcerous stenosing enteritis.

^aDecreased trend.

^bIncreased trend.

were identified for PEG 4 L, PEG + ascorbic acid 2 L, and NaP ($p = 0.017$, $p < 0.001$, $p = 0.028$, respectively). When

Bonferroni correction was applied for multiple comparisons ($p < 0.0125$), the proportion of adequate bowel

Table 4. Factors associated with incomplete examination

Variable	Crude			Age and sex adjusted		
	OR	95% CI	p value	OR	95% CI	p value
Age	1.005	1.001–1.009	0.026			
Male sex	0.911	0.771–1.076	0.274			
Indication for capsule endoscopy						
OGIB vs. others	0.761	0.642–0.902	0.002	0.712	0.597–0.850	< 0.001
Crohn's disease vs. others	0.864	0.574–1.301	0.484	0.966	0.636–1.467	0.871
Small bowel tumor vs. others	0.827	0.523–1.308	0.418	0.868	0.548–1.375	0.548
Bowel preparation						
Inadequate vs. adequate	1.757	1.479–2.086	< 0.001	1.750	1.472–2.080	< 0.001

OR, odds ratio; CI, confidence interval; OGIB, obscure gastrointestinal bleeding.

Table 5. Factors associated with capsule retention

Variable	Crude			Age and sex adjusted		
	OR	95% CI	p value	OR	95% CI	p value
Age	0.999	0.989–1.008	0.814			
Male sex	0.83	0.580–1.188	0.309			
Indication for capsule endoscopy						
OGIB vs. others	1.083	0.745–1.575	0.677	1.092	0.743–1.604	0.654
Crohn's disease vs. others	2.264	1.226–4.182	0.009	2.380	1.258–4.505	0.008
Small bowel tumor vs. others	0.213	0.030–1.533	0.124	0.209	0.029–1.506	0.120
Bowel preparation						
Inadequate vs. adequate	2.434	1.677–3.533	< 0.001	2.412	1.657–3.510	< 0.001

OR, odds ratio; CI, confidence interval; OGIB, obscure gastrointestinal bleeding.

Table 6. Capsule retention rates according to indications for capsule endoscopy

Indications of capsule endoscopy	No. (%)
Obscure GI bleeding	82 (3.1)
Abdominal pain	20 (3.0)
Crohn's disease	12 (6.3)
Small bowel tumor	1 (0.7)
Screening	0
Chronic diarrhea	2 (1.3)

GI, gastrointestinal.

preparation was different only between PEG + ascorbic acid 2 L and NPO. PEG 2 L was previously the most commonly used regimen (47.9%); however, recently, the PEG + ascorbic acid regimen has become the most popular (58.1%) (Table 8).

DISCUSSION

In this registry-based study including 4,650 CE examinations, the incomplete examination and capsule retention rates were determined. This study revealed an incomplete examination rate of 16%, which is similar to that reported in previous studies [2,3]. The capsule retention rate was 3%, which is slightly higher than that reported in previous studies [2,3]. The incomplete examination rate of recent CE (September 2014 to April 2019) decreased compared with that of previous CE (October 2002 to August 2014). With the extended battery life of newer CE technologies, more capsules have reached the ileocecal valve and cecum, leading to a decrease in the number of incomplete examinations [16,17]. With technical advances in radiological examinations, such as computed tomography enterography and magnet-

Table 7. Bowel preparation quality according to bowel preparation method

Variable	NPO	PEG 4 L	PEG 2 L	PEG + Asc 2 L	NaP	p value
Quality						< 0.001
Excellent	149 (21.4)	104 (16.1)	165 (10.8)	92 (13.5)	89 (30.3)	
Good	340 (48.9)	388 (60.1)	874 (57.5)	289 (42.6)	138 (46.9)	
Fair	161 (23.2)	119 (18.4)	368 (24.2)	215 (31.7)	53 (18.0)	
Poor	45 (6.5)	35 (5.4)	114 (7.5)	83 (12.2)	14 (4.8)	
Acceptability						< 0.001
Adequate	489 (70.4)	492 ^a (76.2)	1,039 (68.3)	381 ^a (56.1)	227 ^a (77.2)	
Inadequate	206 (29.6)	154 (23.8)	482 (31.7)	298 (43.9)	67 (22.8)	
p value vs. NPO	Reference	0.017	0.333	< 0.001	0.028	

Values are presented as number (%).

NPO, *nil per os*; PEG, polyethylene glycol; Asc, ascorbic acid; NaP, sodium phosphate.

^aStatistically significant in comparison with NPO ($p < 0.05$).

Table 8. Trends in bowel preparation methods

Variable	Total	~Aug. 31, 2014	Sep. 1, 2014~
NPO	704 (17.5)	560 (19.2)	144 (12.9)
PEG 4 L	658 (16.3)	546 (18.7)	111 (10.0)
PEG 2 L	1,553 (38.5)	1,398 (47.9)	155 (13.9)
PEG + Asc 2 L	681 (16.9)	34 (1.2)	646 (58.1)
NaP	297 (7.4)	297 (10.2)	0
Picosulfate	64 (1.6)	8 (0.3)	56 (4.8)
Others	77 (1.9)	77 (2.7)	0

Values are presented as number (%).

NPO, *nil per os*; PEG, polyethylene glycol; Asc, ascorbic acid; NaP, sodium phosphate.

ic resonance enterography, more patients with small bowel stricture(s) can be diagnosed before undergoing CE. However, the decrease in capsule retention rate over time was not statistically significant in our study. Moreover, our data lacked radiological examination results and, thus, analysis in this regard was not possible. The most common indication for CE was OGIB (64.4%), which is consistent with results reported in previous studies [2,3,10]. In our study, recent CE examinations had more OGIB indications than previous CE examinations ($p < 0.001$), which can be explained by the inception of health insurance coverage for patients with OGIB in September 2014.

Recently, the incidence of Crohn's disease has been

found to be increasing in Korea [18]. Our study revealed a recent increasing tendency of indications and CE diagnosis of Crohn's disease. CE diagnosis of NSAID enteropathy demonstrated an increasing tendency without statistical significance. The increase in NSAID enteropathy can be attributed to the aging population. In our study, the proportion of normal results was smaller in recent CE examinations than in previous examinations. Recent advances in CE technology with improved resolution may have led to more lesion detection and fewer patients diagnosed with normal findings.

Our study revealed that factors associated with incomplete examination were inadequate bowel preparation and indications other than OGIB, which is consistent

with the results of a previous study [10]. With adequate bowel preparation, CE is more likely to be completed. Blood materials in patients with gastrointestinal bleeding appear to act as laxatives, thus helping the capsule proceed through the ileocecal valve. In our study, inadequate bowel preparation was significantly associated with capsule retention, which is also consistent with the results of previous studies [2,10]. The presence of stenotic portions in the small bowel may lead to both inadequate bowel preparation and capsule retention. Additionally, fecal materials stuck in the stenotic portion may result in capsule retention. Although causality was difficult to determine, our study revealed that inadequate bowel preparation was significantly associated with capsule retention. Crohn's disease was a risk factor for capsule retention and the capsule retention rate was the highest among patients with the indication of Crohn's disease. Special caution or using a patency capsule will be needed in patients with Crohn's disease.

In this study, bowel preparation quality was affected by the bowel preparation regimen. PEG 4 L or NaP more favorably affected bowel preparation than NPO; however, PEG + ascorbic acid resulted in worse bowel preparation than NPO. In our study, the recent data revealed that PEG + ascorbic acid regimen was the most widely used. This can be explained by the fact that recent guidelines recommend that CE should be performed as soon as possible (generally after colonoscopy) in patients with overt, obscure bleeding [11], and PEG + ascorbic acid has recently become the most popular regimen for colonoscopy in Korea [19]. The time interval from the ingestion of the bowel preparation regimen to performing CE can be delayed because performing colonoscopy and clinician's decision-making to perform CE after colonoscopy can take time. This time delay may adversely affect bowel preparation quality [20,21], because debris and intestinal fluid can affect preparation of the distal small bowel [22].

Our study had some limitations, the first of which was its retrospective design and, as such, may have been susceptible to selection bias. Moreover, our data may have been susceptible to the under-reporting of complications. Second, our investigation was a multi-center, registry-based study, and the data collection methods used at each institution were not monitored. There was no auditing system to control data collection. However, this was a large study based on 17-year registry data.

Time trends were also investigated between recent and previous data.

In conclusion, our 17-year data suggest that CE is a useful and safe tool for diagnosing small bowel diseases. The incomplete examination rate of CE decreased with time and OGIB was consistently the primary indication for CE. Inadequate bowel preparation was significantly associated with capsule retention and incomplete examination.

KEY MESSAGE

1. The incomplete examination rate of capsule endoscopy decreased over time.
2. Obscure gastrointestinal bleeding was consistently the primary indication for capsule endoscopy.
3. Inadequate bowel preparation was significantly associated with capsule retention and incomplete examination.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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