Indications and detection, completion, and retention rates of small-bowel capsule endoscopy: a systematic review

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Background: Capsule endoscopy (CE) has been widely used in clinical practice.

Objective: To provide systematically pooled results on the indications and detection, completion, and retention rates of small-bowel CE.

Design: A systematic review.

Main Outcome Measurements: We searched the PubMed database (2000-2008) for original articles relevant to small-bowel CE for the evaluation of patients with small-bowel signs and symptoms. Data on the total number of capsule procedures, the distribution of different indications for the procedures, the percentages of procedures with positive detection (detection rate), complete examination (completion rate), or capsule retention (retention rate) were extracted and/or calculated, respectively. In addition, the detection, completion, and retention rates were also extracted and/or calculated in relation to indications such as obscure GI bleeding (OGIB), definite or suspected Crohn's disease (CD), and neoplastic lesions.

Results: A total of 227 English-language original articles involving 22,840 procedures were included. OGIB was the most common indication (66.0%), followed by the indication of only clinical symptoms reported (10.6%), and definite or suspected CD (10.4%). The pooled detection rates were 59.4%; 60.5%, 55.3%, and 55.9%, respectively, for overall, OGIB, CD, and neoplastic lesions. Angiodysplasia was the most common reason (50.0%) for OGIB. The pooled completion rate was 83.5%, with the rates being 83.6%, 85.4%, and 84.2%, respectively, for the 3 indications. The pooled retention rates were 1.4%, 1.2%, 2.6%, and 2.1%, respectively, for overall and the 3 indications.

Limitations: Inclusion and exclusion criteria were loosely defined.

Conclusions: The pooled detection, completion, and retention rates are acceptable for total procedures. OGIB is the most common indication for small-bowel CE, with a high detection rate and low retention rate. In addition, angiodysplasia is the most common finding in patients with OGIB. A relatively high retention rate is associated with definite or suspected CD and neoplasms. (Gastrointest Endosc 2010;71:280-6.)

Since the first brief communication published in *Nature* in 2000 introducing capsule endoscopy (CE),[1] CE has been widely used in clinical practice. Until now, more than 600,000 capsules had been deployed worldwide.[2] Small-bowel CE has been performed in many studies for the evaluation of patients with small-bowel signs and symptoms or for the determination of performance such as positive detection, complete examination, limitations, and complications of this new diagnostic technique. Although CE is a useful tool for evaluating small-bowel disease, it is impossible to view the entire small-bowel in all patients because some capsules have not passed the ileocecal valve before battery exhaustion because of various reasons. Moreover, capsule retention, one of its severe complications, has long perplexed physicians because surgical intervention is usually required to remove the retained capsule.[3]

Abbreviations: CD, Crohn's disease; CE, capsule endoscopy; OGIB, obscure GI bleeding.

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So far, there have been several published original articles addressing the indications and detection, completion, and retention rates of CE for small-bowel diseases; however, the results of the distribution of indications and detection, completion, and retention rates varied among the different studies and different countries.[4-10] Accurate assessments of these parameters are apparently essential and beneficial to the physicians and patients who need to undergo CE. Therefore, we performed this systematic review of global literature to provide current state-of-the-art data on the number and type of CE-related publications, the indications, the detection, completion, and retention rates, and the consequence of retained capsules in evaluating small-bowel diseases.

Capsule Summary

What is already known on this topic

- Capsule endoscopy (CE) is a useful tool for evaluating small-bowel disease, but appropriate indications and rates of detection, completion, and retention vary.

What this study adds to our knowledge

- Obscure GI bleeding is the most common indication for CE, yielding high detection and low retention rates.
- Crohn's disease and neoplasia are the most common reasons for capsule retention; most retained capsules are surgically removed.

MATERIALS AND METHODS

Literature search strategy

The literature search was conducted in the PubMed database in January 2009, and all English-language publications on CE since 2000 were retrieved. The search terms that we selected were ''video capsule endoscopy OR capsule endoscopy OR wireless capsule endoscopy OR wireless capsule endoscope OR capsule endoscope OR video capsule endoscope OR video capsule OR M2A OR PillCam,'' which were mainly based on the official thesaurus (MeSH).

Study selection

All initial search results were reviewed by title and abstracts. Then, the potential original articles mainly focusing on small-bowel diseases were all identified, and full texts were obtained and reviewed for further hand data retrieving. Studies in which CE was performed to evaluate esophageal, gastric, or colonic diseases were excluded, whereas studies in which CE was used alone or with other diagnostic tools for indications of small-bowel diseases were all included. However, in studies in which other diagnostic tools were used, only CE results were collected. In the case of multiple publications of the same study or data set, we selected only the most recent version for analysis.

Definitions

OGIB was defined as bleeding of unknown origin that persists or recurs after an initial or primary endoscopy with negative findings (upper and/or lower GI endoscopy); overt or occult bleeding recurring in the GI tract and persistent iron deficiency anemia with negative findings on the initial endoscopy were all considered as OGIB.[11] The indications of CD or celiac disease were defined as definite or suspected CD or celiac disease. Surveillance or screening for small-bowel tumors or polyposis attributed to a family history of familial polyposis or Peutz-Jeghers syndrome or alarming signs and symptoms was defined as the indication of neoplastic lesions.[2] Other clinical symptoms such as pain, diarrhea, and weight loss without OGIB, definite or suspected CD, and neoplastic lesions were categorized as the indication of only clinical symptoms reported (ie, clinical symptoms only). Subjects without GI symptoms who underwent CE for health examination or for validation of a new CE were defined as healthy subjects. Any signs and symptoms in the small-bowel that were not included in the previously defined 6 indications were categorized as other.

Positive CE procedures were described in different ways in different articles. In this review, data were extracted according to the following criteria: (1) positive-detection CE procedures, which were referred to as CE procedures that were able to produce a diagnosis, including normal or abnormal (such as clinically significant findings or lesions) diagnosis and (2) the diagnoses produced by CE procedures included clinically significant findings or lesions in the entire GI tract, although most lesions were reported in the small-bowel. Thus, the detection rate was calculated as the ratio of the positive-detection procedures over the total CE procedures, which were referred to as the procedures in which capsules were successfully swallowed by the patients or placed by endoscopy.

Data on complete examination and capsule retention were also extracted from those studies in which complete examination results and complications were reported. Complete examination was defined as capsule passing through the ileocecal valve or into the colon in the images during its working time and capsule being excreted in 2 weeks, regardless of technical failure or poor small-bowel preparation. Capsule retention was defined as a capsule endoscope remaining in the digestive tract for a minimum of 2 weeks or one that required directed intervention or therapy to aid its passage.[12] Reasons for retention and interventions for the retained capsules were also collected. Correspondingly, the completion rate was calculated as the ratio of the successfully complete procedures to the total CE procedures, and the retention rate was the ratio of the procedures with retention of capsules to the total CE procedures.

Data extraction

All selected articles were categorized into prospective or retrospective studies according to their study design at first. Then the total CE procedures were collected, followed by collection of the indication data. Because not all studies reported indications, indications were categorized based on most original and review articles with detailed indications data divided into 7 categories, namely, OGIB, CD, neoplastic lesions, celiac disease, only clinical symptoms reported, other, and healthy subjects, as defined previously.

Then, studies that met either of the following 2 criteria were selected for further analysis: (1) studies whose aim was to evaluate 1 or more of the 3 indications (OGIB, CD, and neoplastic lesions) and (2) studies that included patients with miscellaneous indications, and the results of positive detection, complete examination, or retention were produced according to the indications. Only results for the indications of OGIB, CD, and/or neoplastic lesions were separately extracted for further analyses. The total procedures and the detection, completion, and retention rates for the 3 indications were all collected or calculated respectively. When detected, OGIB was further classified into 5 categories based on the most articles, ie, angiodysplasia (including artery, vein, and capillary angioectasia), inflammatory/ulcers (including erythema, edema, erosions, ulcers, and ulceration), neoplastic lesions (including polyps, masses, and tumors), fresh blood (fresh blood only without definite lesions), and other (findings not included in the previous 4 categories).[13]

Two of the authors (Z.L., R.G.) identified the relevant original articles and extracted the data independently, whereas another author (Z.-S.L.) checked the results. If a disagreement existed, the relevant procedures were repeated until a consensus was achieved between the reviewers.

Statistical analysis

Meta-analysis for the pooled results of detection rate, complete examination rate, and retention rate were performed. Statistical heterogeneity was measured by using Cochran's Q test; a P value $<.05$ was considered significant for heterogeneity. The random effects model was used when there was significant heterogeneity, and the 95% confidence interval was also calculated. All analyses were performed with StatDirect Statistical software, version 2.7.0.2 (http://www.statsdirect.com).

RESULTS

Bibliometrics

A total of 227 original articles (149 prospective studies, 78 retrospective studies) involving 22,840 procedures (22,753 patients) using "PillCam SB CE" were finally included in our analysis. Both the total number of articles and the selected original articles on CE increased significantly with time (Fig. 1). Full texts of all 227 articles were successfully obtained from the online access, the authors, or the libraries. Of these articles, 73 (32.2%), 53 (23.3%), 52 (22.9%), and 49 (21.6%) reported of 0 to 30, 31 to 50, 51 to 100, and more than 100 CE procedures, respectively (Table 1).

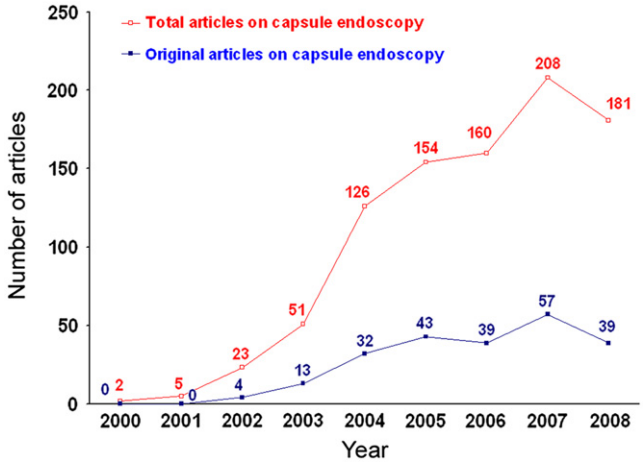

Figure 1. Trends of total number of articles (n = 910) and final included original articles (n = 227) on CE from 2000 to 2008.

Indications

Detailed indications were described in 147 prospective studies with 8518 procedures and 77 retrospective studies with 13,654 procedures, with 224 studies with 22,172 procedures in total. Of these, OGIB was the most common indication, accounting for 14,623 procedures (66.0%), followed by clinical symptoms only, CD, other, neoplastic lesions, celiac disease, and healthy subjects, respectively accounting for 2538 procedures (10.6%), 2295 (10.4%), 1555 (7%), 786 (3.5%), 381 (1.7%), and 174 (0.8%) (Table 1).

Detection rates

Detection rates were reported in 121 prospective studies with 6501 procedures and 51 retrospective studies with 5868 procedures, giving a total of 172 studies involving 12,369 procedures. The pooled detection rate was 59.4% ($P < .0001$; 95% CI, 56.5%-62.2%) in total; the detection rates in prospective studies and retrospective studies were 58.8% ($P < .0001$; 95% CI, 55.4%-62.2%) and 60.5% ($P < .0001$; 95% CI, 55.5%-65.5%), respectively.

Detection rates for the indications of OGIB, CD, and neoplastic lesions were specifically reported in 84, 38, and 17 studies, with rates of 60.5% ($P < .0001$; 95% CI, 57.2%-63.9%), 55.3% ($P < .0001$; 95% CI, 48.0%-62.4%), and 55.9% ($P < .0001$; 95% CI, 46.0%-65.6%), respectively. In addition, detailed CE findings in OGIB were described in 64 studies with 4828 procedures. Among these, 2751 CE procedures had positive findings; angiodysplasia was the

TABLE 1. Indications of capsule endoscopy in the final included original articles

Study type	Procedures, range	Studies	Procedures (patients)	Detailed indications reported	OGIB	Crohn's disease	Neoplastic lesions	Celiac disease	Clinical symptoms only	Other	Healthy subjects
Prospective	0-30	59	1116 (1103)	1086	413	314	175	57	80	38	9
	31-50	44	1793 (1749)	1793	1048	393	92	97	101	62	0
	51-100	29	2118 (2117)	2118	1505	109	55	3	152	294	0
	>100	17	3521 (3493)	3521	2454	252	50	47	117	541	60
	Total (%)	149	8547 (8462)	8518	5420 (63.6)	1068 (12.5)	372 (4.4)	204 (2.4)	450 (5.3)	935 (11.0)	69 (0.8)
Retrospective	0-30	14	254 (254)	254	115	47	9	15	50	18	0
	31-50	9	405 (403)	405	279	84	11	0	28	3	0
	51-100	23	1812 (1809)	1812	1284	191	51	11	226	47	2
	>100	32	11,820 (11,737)	11,183	7525	905	343	151	1604	552	103
	Total (%)	78	14,293 (14,291)	13,654	9203 (67.4)	1227 (9.0)	414 (3.0)	177 (1.3)	1908 (14.0)	620 (4.5)	105 (0.8)
Total (%)		227	22,840 (22,753)	22,172	14,623 (66.0)	2295 (10.4)	786 (3.5)	381 (1.7)	2358 (10.6)	1555 (7.0)	174 (0.8)

OGIB, Obscure GI bleeding.

TABLE 2. Detection rate, complete examination, and retention rate of capsule endoscopy in patients with different indications

Study type	Subgroup	Detection rate (%)	Completion rate (%)	Retention rate (%)
Prospective	Overall	58.8 (55.4-62.2)	84.8 (82.9-86.6)	1.0 (0.7-1.3)
	OGIB subgroup	58.6 (54.3-62.8)	84.4 (81.3-87.2)	0.9 (0.5-1.4)
	Crohn's disease subgroup	58.8 (51.3-66.0)	89.3 (82.8-94.4)	2.8 (1.6-4.5)
	Neoplastic lesions subgroup	56.5 (43.5-69.0)	85.6 (75.8-93.2)	1.8 (0.5-4.0)
Retrospective	Overall	60.5 (55.5-65.5)	81.3 (78.7-83.8)	1.7 (1.3-2.1)
	OGIB subgroup	63.9 (58.5-69.1)	82.0 (76.7-86.7)	1.7 (1.1-2.4)
	Crohn's disease subgroup	45.5 (30.6-60.9)	74.6 (69.2-79.7)	2.8 (3.1-7.6)
	Neoplastic lesions subgroup	54.9 (38.2-71.1)	79.1 (64.1-90.9)	5.7 (1.8-18.3)
Sum	Overall	59.4 (56.5-62.2)	83.5 (82.0-85.0)	1.4 (1.2-1.6)
	OGIB subgroup	60.5 (57.2-63.9)	83.6 (80.9-86.0)	1.2 (0.9-1.6)
	Crohn's disease subgroup	55.3 (48.0-62.4)	85.4 (79.0-90.8)	2.6 (1.6-3.9)
	Neoplastic lesions subgroup	55.9 (46.0-65.6)	84.2 (75.8-91.1)	2.1 (0.7-4.3)

OGIB, Obscure GI bleeding.

most common diagnosis, with a rate of 50.0% (n = 1375), followed by inflammatory/ulcers, neoplastic lesions, fresh blood, and other with rates of 26.8% (n = 736), 8.8% (n = 243), 6.7% (n = 184), and 7.7% (n = 213), respectively (Table 3).

Complete examination rate

Complete examination was reported in 98 prospective studies with 5372 procedures and 44 retrospective studies with 6607 procedures, in which 9905 capsules had passed through the ileocecal valve or into the colon judging from the images, giving a pooled completion rate of 83.5% ($P <$ .0001; 95% CI, 82.0%-85.0%). The completion rates were 84.8% ($P <$ .0001; 95% CI, 82.9%-86.6%) and 81.3% ($P <$ .0001; 95% CI, 78.7%-83.8%) in prospective studies and retrospective studies, respectively. In addition, 37, 17, and 12 studies reported complete examination for indications of OGIB, CD, and neoplastic lesions, with rates of

TABLE 3. Detailed clinically significant findings by capsule endoscopy in the patients with obscure GI bleeding

Study type	Procedure range	Studies	Procedures (patients)	Positive procedures	Detailed findings/ total procedures reported	Angiodysplasia	Inflammation/ ulcer	Neoplastic lesion	Fresh blood	Other
Prospective	0-30	19	316 (305)	181	167/275	81	48	11	23	4
	31-50	18	773 (730)	468	439/690	238	93	39	53	16
	51-100	11	804 (804)	454	398/734	205	115	35	25	18
	>100	8	1425 (1425)	791	327/708	198	59	36	7	27
	Total (%)	56	3318 (3264)	1894	1331/2407	722 (54.2)	315 (23.7)	121 (9.1)	108 (8.1)	65 (4.9)
Retrospective	0-30	4	64 (64)	37	32/48	7	13	8	3	1
	31-50	3	129 (129)	73	24/48	17	3	2	0	2
	51-100	10	843 (840)	577	333/502	136	118	33	30	16
	>100	11	2760 (2760)	1737	1031/1823	493	287	79	43	129
	Total (%)	28	3796 (3793)	2424	1420/2421	653 (46.0)	421 (29.6)	122 (8.6)	76 (5.4)	148 (10.4)
Total		84	7114 (7057)	4318	2751/4828	1375 (50.0)	736 (26.8)	243 (8.8)	184 (6.7)	213 (7.7)

P value: prospective studies versus retrospective studies.

83.6% ($P < .0001$; 95% CI, 80.9%-86.0%), 85.4% ($P < .0001$; 95% CI, 79.0%-90.8%), and 84.2% ($P = .0013$; 95% CI, 75.8%-91.1%), respectively.

Capsule retention, symptom, reason, and intervention

Overall, 184 capsules were reported to be retained in 104 prospective studies and in 46 retrospective studies, giving a pooled retention rate of 1.4% ($P = .2133$; 95% CI, 1.2%-1.6%) with the fixed-effects model. The retention rates in prospective studies and retrospective studies were 1.0% ($P = .2133$; 95% CI, 0.7%-1.3%) and 1.7% ($P = .0102$; 95% CI, 1.3%-2.1%), respectively. Retention rates for indications of OGIB, CD, and neoplastic lesions were reported in 47, 23, and 12 studies, with rates of 1.2% ($P = .6014$; 95% CI, 0.9%-1.6%), 2.6% ($P = .231$; 95% CI, 1.6%-3.9%), and 2.1% ($P = .9021$; 95% CI, 0.7%-4.3%), respectively.

According to the full texts of 128 articles, of the 104 retained capsules with clinical symptoms mentioned in the articles, 88 were symptomless, and only 16 were associated with partial or complete intestinal obstruction symptoms. The possible or definite causes of lesions responsible for the retained capsules were reported in 109 studies with 136 retained capsules. CD was the most common reason for capsule retention (35.3%, n = 48) (Table 4). Among the 164 retained capsules reported in 122 articles, most were surgically removed (58.7%, n = 108) (Fig. 2). There were no serious adverse events or other complications reported among all the studies.

DISCUSSION

The strength of this review is that it collected all the CE procedures in the original articles published in the past 9 years relevant to CE in evaluating patients with indications of small-bowel diseases to identify the common indications and determine the pooled rates of detection, completion, and capsule retention. In addition, because OGIB, CD, and neoplastic lesions were identified as the most common indications for CE, we further determined the performance (ie, rates of detection, completion, and capsule retention) of CE for these indications specifically.

In the 227 studies included in this report, OGIB was the most common indication. It has been reported that OGIB accounts for approximately 5% of all cases of GI bleeding.[11] Since CE was first developed, it has shown its advantage in evaluating OGIB, even when compared with other conventional diagnostic tools,[14-16] and its diagnostic capability for OGIB has been accepted worldwide.[17] Detection rates of CE for OGIB in the large sample size studies (>100) were 41.6% to 61.4%, and the completion and capsule retention rates were 56.0% to 88.1% and 0 to 5%, respectively.[4,18-25] Angiodysplasia and inflammatory/ulcers were the main findings of CE procedures for OGIB,

TABLE 4. Factors/lesions responsible for or associated with capsule retention

Reasons (diseases)	Prospective studies, no. (%)	Retrospective studies, no. (%)	Total, no. (%)
Total	39	145	184
Not reported	15	33	48
Reported	24	112	136
Crohn's disease	6 (25.0)	42 (37.5)	48 (35.3)
Neoplastic lesions	9 (37.5)	21 (18.8)	30 (22.1)
NSAID-induced enteropathy	2 (8.3)	23 (20.5)	25 (18.4)
Postsurgical stenosis	2 (8.3)	8 (7.1)	10 (7.4)
Intestinal adhesion	0 (0)	4 (3.6)	4 (2.9)
Tuberculosis	0 (0)	3 (2.7)	3 (2.2)
Ischemia-induced stenosis	0 (0)	2 (1.8)	2 (1.5)
Radiation enteritis	1 (4.2)	2 (1.8)	3 (2.2)
Meckel's diverticulum	1 (4.2)	1 (0.9)	2 (1.5)
Pouch	1 (4.2)	1 (0.9)	2 (1.5)
Peptic ulcer scar with stricture	0 (0)	1 (0.9)	2 (0.7)
Cryptogenic multifocal ulcerous stenosing enteritis	0 (0)	1 (0.9)	1 (0.7)
Ulceration	2 (8.3)	3 (2.7)	5 (3.7)

NSAID, Nonsteroidal anti-inflammatory drug.

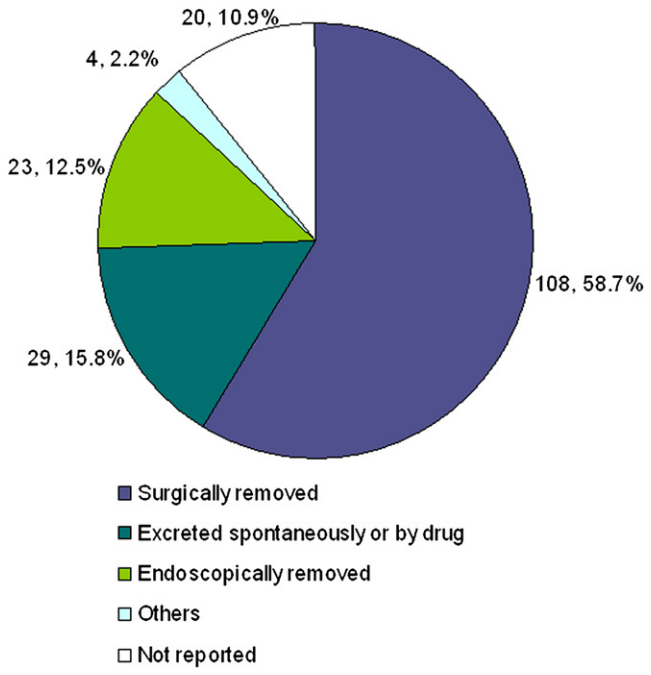

Figure 2. Further interventions for the retained capsule endoscopes. Other included capsule endoscopes that remained in the GI tract at the time of the article preparation (n = 2), laparoscopically removed (n = 1), and vomited out (n = 1).

with angiodysplasias accounting for nearly half of patients who underwent CE for OGIB.

CE has been shown to be superior to small-bowel barium radiography, colonoscopy with ileoscopy, and CT in detecting CD.[26] In our review, the pooled detection rates varied among the studies; we propose that the main reason was that most patients included in some studies were screened for CD and thus the positive results were mostly diagnostic of CD on CE images.[27,28] However, most studies on neoplastic lesions were performed for patients with polyposis syndromes, and the detection rate, completion rate, and retention rate all were similar to those for the CD indication.

The completion rate and capsule retention rate of CE have attracted much attention of both physicians and patients. Completion rates in the large sample size studies ranged from 75.1% to 95.6%.[4-10,29] The several factors account for incomplete examination, of which battery exhaustion is the most common reason, followed by capsule retention, technical failure, and poor small-bowel preparation.[4-10,25,29] Battery exhaustion can easily occur in patients with delayed gastric emptying, with the capsule failing to enter the duodenum or remaining in the stomach for more than 1.5 hours. Therefore, efforts should be made to identify patients who are more likely to have delayed gastric emptying. Bowel preparation is also an influencing factor for battery exhaustion, although this finding has not been consistent.[10,30]

CE has proved to be an extraordinarily safe device with few adverse events and complications. There has been no reported death from CE so far. Retention, perforation, aspiration, and small-bowel obstruction are reported complications of CE.[31-34] Among these, capsule retention is the most common complication. The retained capsules are usually asymptomatic but may cause partial or complete intestinal obstruction symptoms in some patients. The retained capsule can be excreted spontaneously or by drug promotion in a few patients, but for most cases, it needs to be removed by surgical intervention because of underlying lesions such as CD and neoplastic lesions.[5,6-10] Retention rates reported in the large sample size studies ranged from 0 to 2.4%.[3,4-10,25] The risk of retention is high in patients with prolonged nonsteroidal anti-inflammatory drug use, abdominal radiation injury, extensive CD,[35] and previous major abdominal surgery or small-bowel resection.[36] In a recent large study evaluating the capsule retention, Li et al[3] found that the retention rate was 1.4%, the same as the pooled rate of this review, but the most common reason in their study was nonsteroidal anti-inflammatory drug–induced enteropathy (11 of 14), whereas CD was the most common reason in

this review. Moreover, a larger sample size study of CD (102 cases) observed that the retention rate was 13% (5/38) in patients with known CD, but only 1.6% (1/64) in patients with suspected CD.[35]

In conclusion, the pooled detection rate, completion rate and capsule retention rate are acceptable for CE procedures. OGIB is the most common indication for CE, with a high detection rate, and the most common finding in these patients is angiodysplasia. There is a relatively high capsule retention rate in patients with definite or suspected CD and neoplasms. These findings provide further useful and instructive information for physicians in clinical practice.

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