# Capsule endoscopy performed across the pediatric age range: indications, incomplete studies, and utility in management of inflammatory bowel disease

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**Background:** Capsule endoscopy (CE) is used increasingly to evaluate the small bowel in children. An upper GI series is recommended before CE to evaluate the risk of obstruction. Despite normal findings on an upper GI series, CE may still be incomplete. Although large adult studies have demonstrated the safety and diagnostic yield of CE, similar pediatric studies have not been available.

**Objective:** To identify factors associated with incomplete studies and the diagnostic yield in pediatric patients.

**Design:** Retrospective review of consecutive CE studies from February 2005 through June 2008.

**Setting:** Large tertiary children's hospital.

**Patients:** A total of 123 CE studies in 117 patients; median age 12.9 years (range 0.8-22.4 years).

**Main Outcome Measurements:** Demographic information, indication, placement technique, pre-CE imaging results, and cecal completion status were recorded. Risk factors were analyzed with bivariate and multivariate regression analysis.

**Results:** There were 27 (22%) incomplete studies; of these, there were normal pre-CE radiologic study findings in 12 (44%), and findings requiring medical, endoscopic, or operative intervention in 6. Of the 117 patients, CE produced a new diagnosis in 21 (18%). Abnormal findings on previous imaging (odds ratio [OR] 3.0; 95% CI, 1.2-8.0), endoscopic placement (OR 3.1; 95% CI, 1.1-8.4), and female sex (OR 3.3; 95% CI, 1.2-9.4) were associated with incomplete studies.

**Limitations:** Retrospective, incomplete follow-up.

**Conclusions:** CE may be performed in children as small as 11.5 kg, with 18% yield in all studies, and 28% in pediatric known inflammatory bowel disease. Capsule retention requiring retrieval did not pose life-threatening risk in our series, and CE may be used to identify disease-associated small-bowel stenosis. (Gastrointest Endosc 2010;72:95-102.)

Wireless capsule endoscopy (CE) was approved by the U.S. Food and Drug Administration in 2001 for the evaluation of small-bowel disease in adults and in January 2004 for patients 10 to 18 years old. For patients unable to swallow the capsule, endoscopic placement has been described.[1] Since approval, CE is used regularly to evaluate the small bowel. Multiple studies have shown that the diagnostic yield varies based on the indication. In the setting of occult GI bleeding (OGIB), the diagnostic yield ranges from 55% to 81%.[2] When evaluating for small-

*Abbreviations: CD, Crohn's disease; CE, capsule endoscopy; IBD, inflammatory bowel disease; IC, indeterminate colitis; OR, odds ratio; OGIB, occult GI bleeding; SBO, small-bowel obstruction.*

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bowel Crohn's disease (CD), CE has proved more effective than small-bowel follow-through, slightly better than ileoscopy, and better than CT.[3]

Because of the increased incidence of small-bowel stenosis in patients with CD, special care is taken to avoid capsule retention. The 2005 International Council on Capsule Endoscopy consensus statement reported a 0% to 6.7% frequency of capsule retention, with 90% to 100% of these patients having had a normal small-bowel series before CE, but also commented on the increased risk of capsule retention in CD versus suspected CD (5% and 1.2%, respectively).[4] Importantly, only one of these studies was a pediatric series in which there was capsule retention in 1 of 20 cases.[5] A recent pediatric study reported that adverse events may occur in nearly 20% of patients, including 2 endoscopic capsule retrievals and 3 surgical resections,[6] and the largest pediatric series to date showed a 1.4% risk of capsule retention.[7] The patency capsule (Given Imaging, Yoqneam, Israel) was developed to address this risk. A case series describes 3 patients in whom acute obstructive symptoms developed after taking the single-opening M2A patency capsule (Given Imaging), 2 of whom required emergency surgery. The authors concluded that the patency capsule may not detect stenoses not seen on small-bowel imaging, and extra caution should be taken when using CE in patients with CD.[8]

Unless a patient is symptomatic, the first clue of a retained capsule is the discovery of an incomplete study, in which the capsule does not reach the cecum at the conclusion of the study. Although not thoroughly described, incomplete studies caused by inadequate transit or visualization have been reported to occur in 20% to 30% of all CE studies,[9] a frequency that has produced discussion in the gastroenterology billing literature.[10]

Because of the limited information on pediatric patients, we review our experience with CE to provide more data on the utility and diagnostic yield and to identify factors associated with incomplete studies. Furthermore, we describe an alternative indication for CE that has proved useful in patient care.

**Take-home Message**

- This study demonstrates that capsule endoscopy can be performed safely in children, including patients as small as 11.5 kg. The diagnostic impact was similar to that of adult series and was higher for the evaluation of suspected or known inflammatory bowel disease. The incidence of incomplete studies in which the capsule was not in the colon within 8 hours was 22%, and associated factors included endoscopic placement and female sex. Last, our data support the utility of the capsule in the localization of subclinical stenosis that can be operatively managed in an elective manner without untoward risk to the patient.

## METHODS

The study was approved by the Human Research Review Board at the Children's Hospital of Wisconsin (Milwaukee, Wisconsin). All CE studies performed at the Children's Hospital of Wisconsin from February 2005 through June 2008 were reviewed retrospectively. Demographic data and radiographic, endoscopic, histologic, and CE results were abstracted from medical records.

### CE procedures

Before CE, patients had radiologic studies to evaluate for the risk of obstruction. Exceptions were made for patients with DNA repair defects and those in whom fluoroscopic screening was not feasible based on clinical judgment. The results were classified as normal when the findings of all imaging studies were normal, abnormal when all radiologic studies produced mucosal findings, and mixed if multiple studies had differing results. A patency capsule prescreening system is not used at our institution.

All patients were prepared for CE in a standard manner; consuming an unrestricted diet until 1400 hours the day before CE, after which they were restricted to clear, nonred liquids, and placed completely nil per os after 0400 hours on the day of the procedure. The patients swallowed the Given capsule (Given Imaging) according to a standard protocol, or the capsule was placed in the proximal duodenum by an experienced endoscopist using the AdvanCE capsule endoscope delivery device (US Endoscopy, Mentor, Ohio). The patients were allowed to drink clear liquids 2 hours after the procedure and to have a light snack 4 hours after, but to avoid red foods and red liquids. The recording continued for 8 hours after which the images were downloaded and read by 1 of 3 physicians who had access to clinical information as well as the endoscopic and radiologic results.

In patients in whom the capsule failed to reach the cecum within 8 hours, the study was considered incomplete. Abdominal radiographs were used to evaluate capsule location if the capsule was not observed in the stool after 5 days (Fig. 1).

### Statistical methods

The effect of CE on diagnosis and/or management was limited to only those patients with follow-up. Only the first CE study for all patients was included for analysis of factors affecting completion status. Differences between patients were evaluated using the Fisher exact test. Multivariate logistic regression was used to identify variables associated with an incomplete study or a change in diagnosis. For significant predictors without an obvious biological association, further analysis was performed to determine where differences may exist. Goodness-of-fit analysis was used to evaluate model adequacy. A statistical

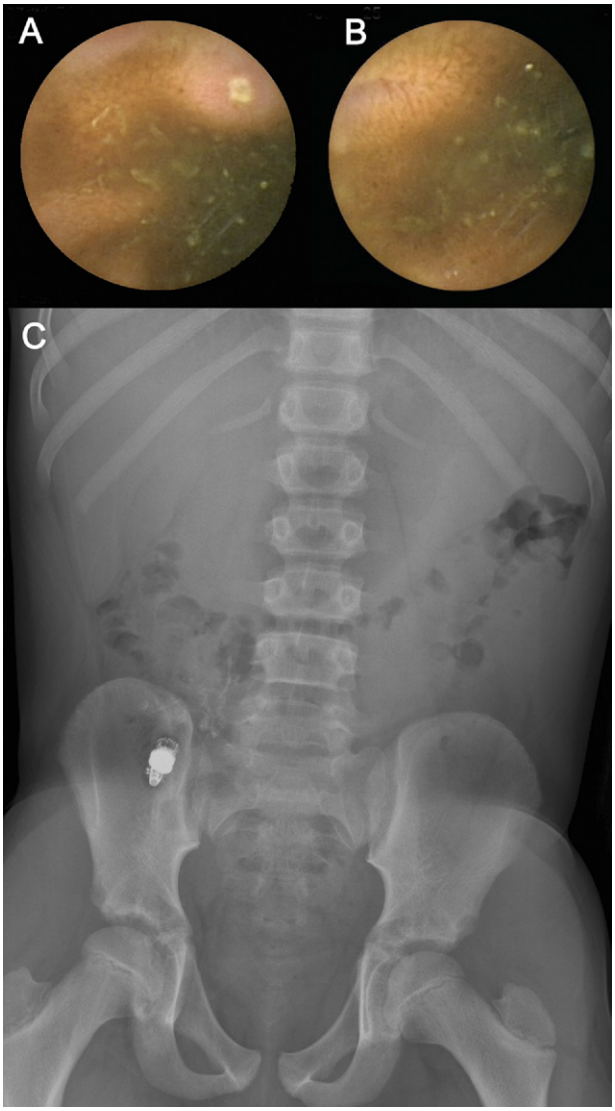


**Figure 1.** Final CE images and abdominal radiograph of retained capsule in 14-year-old with CD (patient 1, Table 4). **A**, The final CE images show an aphthous ulcer consistent with the patient's CD diagnosis seen at 7:31:54 hours. **B**, The final image at 7:44:25 hours showed retained fluid and ileal mucosa. **C**, Radiograph obtained 10 days after ingestion. The capsule was retained proximal to a fibrotic stricture. Elective operative capsule retrieval and bowel resection were performed 4 days after the radiograph was obtained.

significance level ($\alpha$) of .05 was used throughout; 95% confidence intervals were calculated. SAS Learning Edition, version 4.1 (SAS Institute, Cary, NC) was used for all statistical analyses.

## RESULTS

Table 1 lists patient characteristics and study indications. A total of 123 studies were performed in 117 patients, of whom 112 had follow-up. The youngest patient was 10 months old, weighed 11.5 kg, and underwent CE for multifocal lymphangioendotheliomatosis with thrombocytopenia, a rare vascular condition with recurrent life-threatening GI bleeds.[11] A majority of the patients (70%) swallowed the capsule, the youngest being 5.8 years of age. Repeat studies were performed 1 week to 27 months later for incomplete studies (n = 4), inadequate visualization (n = 1), and assessment of small-bowel disease (n = 1).

**TABLE 1. Patient population and indications for CE (N = 117)**

| Total population | Frequency (%) or median (IQR) (range) |
|---|---|
| Male | 65 (56) |
| Median age (y) | 12.9 (6.5) (0.8–22.4) |
| Median weight (kg) | 47 (34.7) (11.5–123.7) |
| Indication, no. (%) | |
| Suspected IBD | 71 (60.7) |
| Known IBD | 18 (15.4) |
| Occult GI bleeding | 18 (15.4) |
| Survey of known polyposis syndrome | 6 (4.9) |
| Persistent vomiting/possible stricture | 3 (2.5) |
| Evaluation of PTLD | 2 (1.7) |

*IQR*, Interquartile range; *IBD*, inflammatory bowel disease; *PTLD*, posttransplantation lymphoproliferative disease.

## CE findings

In the 112 patients with follow-up, 118 studies were performed. Mucosal abnormalities were seen in 61 (51.7%) of 118 CEs, of which 28 were nonspecific. Table 2 summarizes the abnormal mucosal findings. Three capsules remained in the stomach, and 54 (46%) were normal or had only minimal findings.

Based on chart review, a new diagnosis or a change in management occurred in 20 of 112 patients, indicating a diagnostic yield of 18%. In subjects with suspected OGIB (n = 18), 5 had a diagnosis of arteriovenous malformation, 5 had nonspecific enteropathy, 5 were normal, 1 suggested graft versus host disease, 1 diagnosed lymphangiectasia, and 1 had an incomplete study with gastric capsule retention.

When the indication for CE was suspected CD based on clinical symptoms (n = 71), 69 (97%) of 71 subjects had a diagnostic result. New diagnoses were made in 12 (17%) of 71, including CD (n = 9), vascular abnormalities (n = 1), celiac disease (n = 1), and ulcerative colitis (n = 1), and CD was excluded in 59 (83%). Two subjects with suspected CD had incomplete studies. Findings in subjects

**TABLE 2. Findings and outcome based on indication**

| | No. (%) |
|---|---|
| Known IBD, n = 18* | |
| Unremarkable small bowel | 6 (33) |
| Uncontrolled small-bowel disease with CD | 6 (33) |
| Enteropathy not considered classic for CD | 2 (11) |
| Identification of postoperative caliber change | 1 (6) |
| Identification of stricture not seen on previous imaging | 1 (6) |
| Newly diagnosed small-bowel disease with previous IC | 1 (6) |
| Normal small bowel in previous IC | 1 (6) |
| Suspected IBD, n = 71 | |
| Excluded small-bowel CD | 59 (83) |
| New diagnosis of CD | 9 (13) |
| Vascular abnormality | 1 (1.4) |
| Celiac disease | 1 (1.4) |
| Suggestive of UC in patient with colitis | 1 (1.4) |
| Occult GI bleeding, n = 18 | |
| Arteriovenous malformation | 5 (28) |
| Nonspecific enteropathy | 5 (28) |
| Normal small bowel | 5 (28) |
| Consistent with GVHD | 1 (5.6) |
| Lymphangiectasia | 1 (5.6) |
| Polyposis syndromes, n = 6 | |
| No small-bowel polyps | 3 (50) |
| Gastric polyps only | 1 |
| Gastric and duodenal polyps | 1 |
| Shaggy villi and single large jejunal polyp[12] | 1 |

*IBD*, Inflammatory bowel disease; *CD*, Crohn's disease; *IC*, indeterminate colitis; *UC*, ulcerative colitis, *GVHD*, graft-versus-host disease.
*One patient with 2 studies.

with known inflammatory bowel disease (IBD) are listed in Table 2. No indications for CE were significantly associated with an increased likelihood of change in diagnosis or management.

## Patients with polyposis

In 6 patients with polyposis syndromes who underwent CE, 3 had small-bowel polyps seen and 3 had a normal small bowel. One patient with known gastric polyps had no small-bowel polyps seen, whereas a second patient with known gastric and duodenal polyps had an additional small polyp along with adenomatous changes seen in the jejunum. The findings of 1 patient with Peutz-Jeghers syndrome were previously described.[12]

## Capsule completion

Overall, 26 (22%) of 117 primary CE studies were incomplete, including 3 patients in whom the capsule never left the stomach and 4 with no identified disease who simply had slow gastric and/or small-bowel transit. Four (15%) of 26 studies were repeated and successfully completed. Only 1 patient with polyposis had an incomplete study; no intervention was required. Table 3 lists the characteristics of subjects with incomplete studies. Female sex (odds ratio [OR] 2.4; 95% CI, 1.0-6.0) and an abnormal imaging result (OR 3.0; 95% CI, 1.2-8.0) were significant factors for incomplete CE studies, whereas age and weight were not. The only difference between sexes was that males were younger (median age 12.6 years, range 0.8-22.4 years vs 13.9 years, range 4.1-19.2 years; $P = .04$). Endoscopic placement was only moderately associated (OR 2.5; 95% CI, 1.0-6.3) with incomplete studies.

Multivariate analysis evaluated all factors together; endoscopic placement (OR 2.9; 95% CI, 1.1-8.0) and female sex (OR 3.0; 95% CI, 1.1-8.7) were significant predictors of having an incomplete study. Multivariate analysis also showed that mixed imaging versus normal imaging is associated with incomplete studies (OR 11.5; 95% CI, 2.7-49.2).

## Outcomes in children with incomplete studies

Of the 27 incomplete studies, most capsules passed spontaneously, but 6 (22% of incomplete studies and 4.9% of all studies) required intervention (Table 4). Three patients required operative retrieval: 2 with CD-related stenosis and 1 with an ileal myofibroblastic tumor obstructing capsule transit. Two other patients had endoscopic retrieval: 1 from the stomach after 5 days and the second from a tunneled ileostomy that prevented spontaneous evacuation. A sixth patient with severe enteropathy but no discrete stricturing disease evacuated a capsule after bowel lavage with GoLytely (Braintree Laboratories, Inc, Braintree, Massachusetts) after 22 days of retention. All retrievals were performed electively without signs of acute bowel obstruction, perforation, or ischemic compromise.

# DISCUSSION

CE has proved useful for many indications across a wide age range. Our data highlight some of the differ-

**TABLE 3. Capsule endoscopy study completion status by patient characteristics (first capsule endoscopy, n = 117)**

| Characteristic, no. (%) | Incomplete, no. (%) | Complete, no. (%) | *P* value |
|---|---|---|---|
| Sex | | | .07 |
| Male, 65 (56) | 10 (15.4) | 55 (84.6) | |
| Female, 52 (44) | 16 (30.8) | 36 (69.2) | |
| Screening imaging results* | | | .008 |
| No imaging, 12 (10.3) | 3 (25.0) | 9 (75.0) | |
| Normal, 75 (64.1) | 12 (16.0) | 63 (84.0) | |
| Abnormal, 19 (16.2) | 4 (21.0) | 15 (79.0) | |
| Mixed, 11 (9.4) | 7 (63.6) | 4 (36.4) | |
| Placement technique | | | .053 |
| Swallowed, 82 (70) | 14 (17) | 68 (83) | |
| Endoscopic, 35 (30) | 12 (34) | 23 (66) | |
| CE indications | | | |
| Suspected IBD, 74 (63.5) | 15 (20) | 59 (80) | .5 |
| Known IBD, 17 (15) | 4 (24) | 13 (76) | 1.0 |
| OGIB, 17 (15) | 3 (18) | 14 (82) | .76 |
| Polyposis, 6 (5) | 1 (17) | 5 (83) | 1.0 |
| Other,† 4 (3) | 3 (75) | 1 (25) | .03 |
| | **Incomplete** | **Complete** | |
| Age (y), median (IQR), range | 13.8 (8.8), 3.1–19.3 | 12.8 (6.3), 0.8–22.4) | .81 |
| Weight (kg), median (IQR), range | 43.3 (44.7), 15.2–82.1 | 47.2 (34.5), 11.5–123.7 | .53 |

*CE*, Capsule endoscopy; *IBD*, inflammatory bowel disease; *OGIB*, occult GI bleeding; *IQR*, interquartile range.
*Results of screening fluoroscopic and/or CT scanning where applicable; mixed results denote cases in which one study was unremarkable and the other suggested mucosal disease.
†Three cases of persistent vomiting and suspected stricture and 1 evaluation for possible posttransplantation lymphoproliferative disease.

ences between CE in adults and children. Similar to other pediatric series,[5-7] suspected IBD was the most common indication for CE. OGIB is the most common indication in most adult series, but accounted for only 18 (15.4%) of our cases. Our yield for OGIB is somewhat lower than that of previous pediatric studies in which a source was located in 60% to 100% of patients,[5,13,14] but these studies only had 4 to 10 patients. Additional etiologies of OGIB that CE may identify include hemangiomas and lymphoid hyperplasia.[15,16] An adult meta-analysis comparing CE with other diagnostic modalities showed a higher yield for CE than other techniques, including push enteroscopy and small-bowel imaging. The study also showed a higher yield with CE for vascular lesions as well as inflammatory lesions compared with push enteroscopy.[17]

Our most frequent indication was the evaluation of children with known or suspected IBD. CE has proved effective in guiding therapy, including immunosuppression and surgery, when standard endoscopy may not show evidence of increased disease.[6] In our series, 71 (60.7%) studies were performed for suspected CD, based on symptoms and laboratory test results, of which 18% had a new diagnosis obtained. Arguably as important is the ability to use CE to rule out IBD in cases in which it is strongly suspected despite unremarkable findings on EGD and colonoscopy. In our study, 84% of the subjects with suspected IBD based on clinical symptoms had the diagnosis of IBD excluded based on negative CE results, thus avoiding the unnecessary risks of immunosuppression.[18-20]

An additional indication related to IBD involves patients with indeterminate colitis (IC), which is reported to occur in 10% to 15% of adult patients, but in as many as 30% of children with IBD.[21] Other studies have also shown that nearly 50% of adult patients and 25% of pediatric patients with an initial diagnosis of IC will have their diagnosis reclassified in the future.[21] In the 3

**TABLE 4. Characteristics of patients requiring interventions for incomplete capsule endoscopy**

| Patient | Age (y) | Indications | SBFT* | CT* | Intervention | Timing† |
|---|---|---|---|---|---|---|
| 1 | 14.2 | CD with previous TI surgery, growth failure | No areas of stenosis, dilation, or bowel wall thickening, ileal disease | None | Operative resection of fibrotic stricture | 14 |
| 2 | 17.1 | CD with nausea and bilious emesis | Mild fold thickening of TI, no evidence of stricture | Transmural inflammation of the distal ileum, narrowing of the TI | Operative resection of stricture | 6 |
| 3 | 8 | Vomiting, abdominal distention | Mid and distal small bowel appear featureless, suggestive of mucosal disease, no obstruction identified | No obstruction, mild prominence of the small bowel | Operative resection of myofibroblastic tumor | 2 |
| 4 | 14.2 | OGIB after chemotherapy | None | Normal | Endoscopic retrieval from stomach | 5 |
| 5 | 18.8 | Vomiting and increased ostomy output | Normal | No obstruction (CT enterography) | Endoscopic retrieval from narrow ileostomy | 2 |
| 6‡ | 5.3 | PLE, anemia, hematochezia | None | None | Polyethylene glycol bowel prep | 22 |

*SBFT*, Small-bowel follow-through; *CD*, Crohn's disease; *TI*, terminal ileum; *OGIB*, occult GI bleeding; *PLE*, protein-losing enteropathy.
*Screening imaging study before CE.
†Days after CE study when intervention was performed.
‡Patient with radiation sensitivity secondary to known DNA repair defect.

children with IC in our study, 1 was reclassified as having CD, a second had an unremarkable CE study, and the third had nonspecific small-bowel abnormalities thought to be insufficient to change the diagnosis. These data are similar to those of Cohen et al,[22] who reported that 4 of 5 patients with ulcerative colitis and 1 of 2 patients with IC had their disease reclassified to CD based on small-bowel findings.

With incomplete studies or when CE is used in known or suspected IBD, increased caution is emphasized to avoid retained capsules. In our series, there were 27 (22%) incomplete studies, which were associated with prestudy imaging, placement technique, and sex, but not age or weight. A recent pediatric study reported a 14% incomplete rate.[7] In this study, however, only 75 (36%) of 207 subjects had small-bowel imaging before CE, 13 (17%) of whom had abnormal results, including 5 of 13 with luminal narrowing;[7] it is unclear whether the patients with retained capsules underwent previous imaging. Furthermore, none of the patients in this series required endoscopic placement for CE[7] compared with 32% in our series. Capsule retention is most frequently cited to occur in less than 1% of patients, most of whom were evaluated for OGIB and had normal results on small-bowel series before CE.[23,24] Smaller series report incidences of 3.6% in patients with OGIB and 13% in patients with known CD,[24-26] despite unremarkable prestudy imaging screens. A pediatric series found a 5% risk of retained capsules in CD patients compared with 1.4% overall.[7] Other series demonstrated that screening with small-bowel follow-through or CT scan may not detect all strictures and does not prevent capsule retention.[5,6,23,27]

Endoscopic placement was associated with an increased likelihood of an incomplete study in our series (OR 2.9; 95% CI, 1.1–8.0), which partially explains our completion rate. The role of placement technique, however, is only seen when multivariate analysis evaluates all factors associated with incomplete studies simultaneously. Endoscopic placement alone is only marginally responsible for incomplete studies as reflected by the bivariate analysis (OR 2.5; 95% CI, 1.0-6.3). Potential etiologies for these observations include the use of general anesthesia and patient positioning. Neither is solely responsible, and both factors likely contribute. The effect of positioning on completion status in adult studies has produced conflicting results.[28,29] Furthermore, an adult series identified risk factors associated with incomplete studies and found that surgery, hospitalization, bowel preparation, and delayed gastric transit

all influence study completion.[9] These factors, however, have only limited application to pediatric patients.

The more unusual finding was that female patients were twice as likely to have an incomplete study as male patients. Female patients tended to be older, but weight, indications, or placement technique, did not differ significantly between sexes. Possible explanations include nonspecific decreased motility in females, coinciding with increased irritable bowel syndrome prevalence, or simply the effect of our sample size. This finding should be investigated in additional studies.

The *intentional* use of CE to evaluate suspected small-bowel obstruction (SBO) has also been described with CE retention in 21% of adults with SBO, all of whom were managed surgically without complications.[26] In a series of 19 cases of suspected SBO, CE definitively identified the obstructive site, in which the capsule was retained proximal to a stricture in 3 cases. All these patients had elective surgical resection without complications; moreover, there was no case in which CE led to acute SBO.[30] These data are concordant with our experience in the pediatric population; capsule retention and delayed operative retrieval did not result in any retention-related morbidity. In another pediatric series, with 3 retained capsules, symptoms were concerning for obstruction, but urgent intervention was not required.[7] A smaller pediatric series, however, reported that acute obstructive symptoms requiring urgent surgical intervention developed in 2 of 4 patients with capsule retention. In that study, patients with capsule retention were older than those who experienced no adverse event.[6]

Our series demonstrates that CE may be performed safely across the spectrum of the pediatric population, from infancy to adulthood and with a weight as low as 11.5 kg. A majority of patients, as young as 6 years old, can swallow the capsule. Diagnostic yield is similar to that of published pediatric and adult studies and is particularly valuable in the evaluation and management of pediatric IBD. Retention requiring retrieval did not pose life-threatening risk in our series. CE may be used as a technique to identify stenotic disease beyond traditional endoscopic and radiographic reach.

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