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Small Bowel Capsule Endoscopy: Experience from a single large tertiary care centre

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Authors
Neeraj Singla[1], Pradev Inavolu[1], Nitin Jagtap[1], Aniruddha Pratap Singh[1], Rakesh Kalapala[1], Sana Fathima Memon[1], Gowtham Reddy Katukuri[1], Partha Pal[1], Zaheer Nabi[1], Mohan Ramchandani[1], Sundeep Lakhtakia[1], Rupa Banerjee[1], Palle Manohar Reddy[1], Manu Tandan[1], Nageshwar Reddy[1]

Institutions
1 Gastroenterology, Asian Institute of Gastroenterology, Hyderabad, India

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Corresponding author
Dr. Neeraj Singla, MD, DM, Asian Institute of Gastroenterology, Gastroenterology, Mindspace Road, 500032 Hyderabad, India
dr.neerajsingla@gmail.com
docneersk@gmail.com

ABSTRACT

Background and study aims Capsule endoscopy (CE) has transformed examination of the small bowel (SB), once considered a dark continent. The present study aimed to describe the indications, diagnostic yield, practical issues and complications of CE in one of the largest tertiary center in India.

Patients and methods This retrospective analysis from a prospectively maintained database, conducted from January 2013 to June 2021 included 1155 CEs performed during this period. Patient medical records were reviewed for indications, results, and complications of CE.

Results A total of 1154 patients (809 males and 345 females), mean age 53 years (range 6–87 years), one capsule got stuck in the esophagus, were included in the study. Active SB bleeding had no effect on SB transit time (324.7 ±161 minutes, n = 137 patients with active bleed vs 310.6 ±166.9 minutes, n = 1017 patients without active bleed; P = 0.35). The indication and diagnostic yield (DY) of CE were potential overt SB bleed (68.6% & 43.9%), potential occult SB bleed (8.2% and 40%), chronic diarrhea (7.9% and 28.4%), abdominal pain (6.5% and 21.3%), anemia (5.9% and 57.9%), and suspected/known case of Crohn's disease (2.3% & 56.5%) respectively. The DY for patients with age ≥60 years was similar to those with age < 60 years (61.9% vs. 51.8% respectively; P = 0.4). 21 patients (1.8%) had capsule retention of which six (0.5%) had to be referred for surgery.

Conclusions CE is a safe and effective investigation with ever increasing range of indications. Potential SB bleed remains the most common indication for CE with high detection rate.

Introduction

Endoscopic evaluation and treatment of the small bowel (SB) is a challenge because of its length, angulation, and limited tools. Advances in the previous two decades have provided a new armamentarium for evaluation and treatment of SB diseases. Capsule endoscopy (CE) allows direct visualization of the entire length of the SB [1]. It is an investigation of choice to evaluate SB bleeding, Crohn's disease (CD), celiac disease, and polyposis syndrome. CE delivers a high diagnostic yield compared with other technologies in the range of 38% to 87% depending on the indication [2]. Although there are a few limitations of CE, such as suboptimal visualization and inability to acquire tissue or provide treatment, it has shown superiority over convention-

al methods like SB follow through, push enteroscopy (PE) and comparable efficacy to device-assisted enteroscopy (DAE) for the evaluation of the SB [2].

CE has a pivotal role in evaluation of patients with suspected SB diseases such as potential obscure SB bleeding, iron deficiency anemia (IDA), CD, tumors, and celiac disease. In the current study, we aimed to share our center's experience with SB CE [3, 4, 5].

Patients and methods

Patient collection and capsule system

This was a retrospective analysis from a prospectively maintained database, conducted over 8 years, from January 2013 to June 2021, at AIG hospitals, Hyderabad, India. Eleven hundred and fifty-five CEs were performed during the study period. As the CE system was upgraded during the study period, CE was performed on 835 patients with Pillcam SB2 capsules. In the other 320 patients, CE was performed using Pillcam SB3 capsules.

Inclusion and exclusion criteria

All patients who underwent CE in AIG Hospitals Hyderabad up to June 30, 2021 fo any indication were enrolled in the study. Patients in whom the CE did not enter the SB were excluded from the study. In patients with a high index of suspicion for retention, computed tomography enterography was performed before referral for CE.

Bowel preparation

CE was performed in an ambulatory outpatient setting with some inpatients too. Patients were kept fasting for at least 12 hours before the procedure. Each patient was administered 2 L of polyethylene-glycol solution for bowel cleansing. Patients were allowed to drink clear liquids 2 hours after ingestion of the capsule, and eat a light meal after 4 hours and were observed for at least 8 hours in the hospital.

CE procedure

CE was performed using a standard protocol in an ambulatory outpatient setting with some inpatients too. The GIVEN Video Capsule system (Given Imaging, Yoqneam, Israel) with Rapid v8.0 International software was used for CE. A total of six endoscopists analyzed all CE over period of 8 years. Each CE procedure was analyzed by two endoscopists with a minimum of 5 years of experience in the field of gastroenterology who had reviewed a minimum of 100 capsule studies under guidance. CE findings were labeled as per international Delphi consensus on nomenclature and description of SB vascular lesions [6]. The term "erythematous patch" was used for small (few mm) and flat reddish area, without any vessel appearance, within the mucosal layer. The term "red spot" was used for less than 1 mm, punctuate, and flat lesion with a bright-red area, without linear or vessel appearance, within the mucosal layer.

Statistical analysis

All data were entered in standardized format in spreadsheets using Microsoft excel. Continuous variables were expressed as mean and standard deviation or median and interquartile range wherever appropriate. Categorical variables were expressed as a percentage. Categorical variables were compared using Chi-square test or Fisher exact test wherever appropriate. Continuous variables were compared using student's t test or Mann-Whitney tests wherever appropriate. $P < 0.05$ was considered as statistically significant. The SPSS version 25 (IBM Corp., Armonk, New York, United States) was used for statistical analysis.

Ethics

The study was approved by the institutional ethical committee vide AIG/IEC-BH&R 17 108,2A21 -02 (August 25, 2021). Because this was a retrospective observational study, no written informed consent was required from patients for participation in this study. However, all patient-identifiable data were kept anonymous during collection and CE was performed after informed consent. The study is registered on clinical trials.gov with ID: NCT05228379.

Results

Patient characteristics

CE examination was performed in 1155 patients over 8 years. In one patient, the capsule was retained in the esophagus, subsequently diagnosed as Achalasia cardia, was excluded from analysis. The study consisted of 1154 patients with 809 males (70.1%) and 345 females (29.9%). The mean age was 53 years (range 6–87 years).

Indications for CE

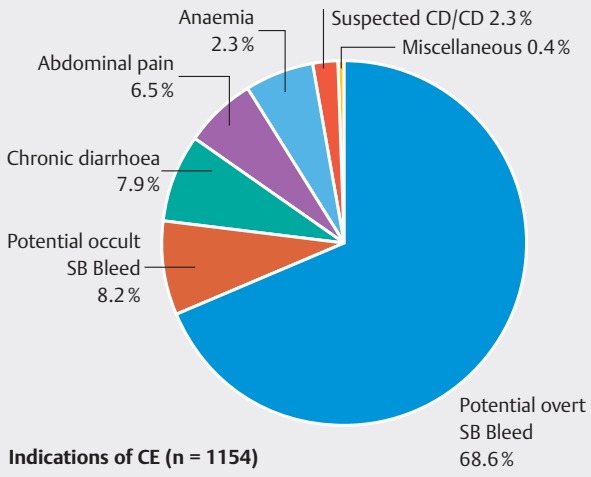
The most common indication for doing CE was potential overt SB bleeding (n = 792; 68.6%) followed by potential occult SB bleeding (n = 95; 8.2%). Other indications were chronic diarrhea (n = 91; 7.9%), abdominal pain (n = 75; 6.5%) and anemia (n = 69; 5.9%) (▶ **Fig. 1**).

Gastric and small bowel transit time

The median gastric emptying time was 16 minutes (range, 1–647 minutes) while the mean SB transit time was 270 minutes (range, 6–840 minutes). There was no significant effect of active SB bleeding on the transit time (324.7±161 minutes, n = 137 for patients with active bleeding vs. 310.6±166.9 minutes, n = 1017 for patients without active bleeding; $P = 0.35$).

Findings visualized on CE

SB erythematous patch/red spots were the most common finding on CE, seen in 744 patients (64.47%). Ulcers were the second most common finding with 189 patients (16.37%) having jejunal and 226 patients (19.58%) having ileal ulcers. SB stricture was seen in 88 patients (7.62%) and angioectasias in 187 patients (16.20%). Polyps were noted in 61 patients (5.28%) pa-



▶ **Fig. 1** Indications for doing capsule endoscopy.

tients, worms in 34 patients (2.94%), diverticulum in 25 patients (2.16%) and mass/growth in 14 patients (1.21%).

Potential overt SB bleeding

Seven hundred and twenty-six patients (91.7%) had some lesion found on CE including non-specific findings. An erythematous patch/red spot (63.79% patients) was the most common lesion, but it was not considered a definite source of overt gastrointestinal bleeding. A specific lesion explaining the cause of potential overt SB bleeding was detected in 348 of 792 patients (43.9%). These include a combination of findings such as ulcers in the jejunum or ileum, angioectasias, mass/growth and polyps >10 mm size. Suspicious lesions such as strictures, diverticuli, and polyps ≤10 mm size were seen in 49 patients (6.2%). A total of 129 patients (16.3%) were found to have active bleeding on CE and were referred for enteroscopy or angio-embolization to manage the bleeding (▶ **Fig. 2**, ▶ **Fig. 3a**).

Potential occult SB bleeding

Of the 95 patients referred for potential occult SB gastrointestinal bleeding, 38 (40%) had a definite lesion found on CE. Three patients were found to have mild active bleeding with one patient having a jejunal ulcer and another patient having angioectasias as the cause of bleeding. The cause of bleeding could not be ascertained in the third patient. Ileal ulcers and jejunal ulcers were noted in 17.9% and 13.7% of patients, respectively.

SB erythematous patch/red spots (72.63% of patients) were found to be the most common finding and were not considered a definite source of occult SB bleeding in the present study (▶ **Fig. 3b**, ▶ **Fig. 3c**, ▶ **Fig. 3d**, ▶ **Fig. 4**).

Suspected Crohn's disease/Crohn's disease

CE showed findings typical of CD in 13 of 23 patients referred for suspicion of CD (56.5%) with five patients having both jejunal and ileal ulcers and four patients having jejunal and ileal ulcers alone each.

Of the seven patients with known CD, four patients had both jejunal and ileal ulcers, while one patient had only jejunal ulcers. Stricture was noted in one of the patients, while one patient had a normal CE (▶ **Fig. 5a**, ▶ **Fig. 5b**).

Iron deficiency anemia

This group of patients had a negative fecal occult blood test (FOBT) as compared to patients with potential SB bleeding in whom FOBT was positive. Of the 69 patients with IDA referred for CE, 27 patients were age ≥ 60 years and 42 were age < 60 years. The diagnostic yield (DY) of CE for IDA was found to be 57.9%. The DY for patients aged ≥ 60 years was found to statistically similar to those aged <60 years (61.9% vs. 51.8% respectively; $P = 0.4$). The most common findings were combinations of lesions such as jejunal or ileal ulcers: 14 patients had either a jejunal ulcer or an ileal ulcer and six patients had both jejunal and ileal ulcers. Other significant diagnoses included angioectasias (10.1%, n = 7), polyps (7.2%, n = 5), stricture (4.3%, n = 3) and worm infestation (1.4%, n = 1) (▶ **Fig. 5c**, ▶ **Fig. 5d**).

Abdominal pain

The most common findings were found to be erythematous patch, seen in 48 patients (64%), but definite lesions (ulcers, stricture, polyp size > 10 mm, mass/growth) which could explain the pain were seen in 16 patients (21.3%; n = 75). The most common definite lesions were ileal ulcers, seen in 12 patients (16%), while other findings were jejunal ulcers (10.6%, n = 8), stricture (2.25%, n = 3), polyps ≤ 10 mm (1.3%, n = 1) with some patients having a combination of findings.

Chronic diarrhea

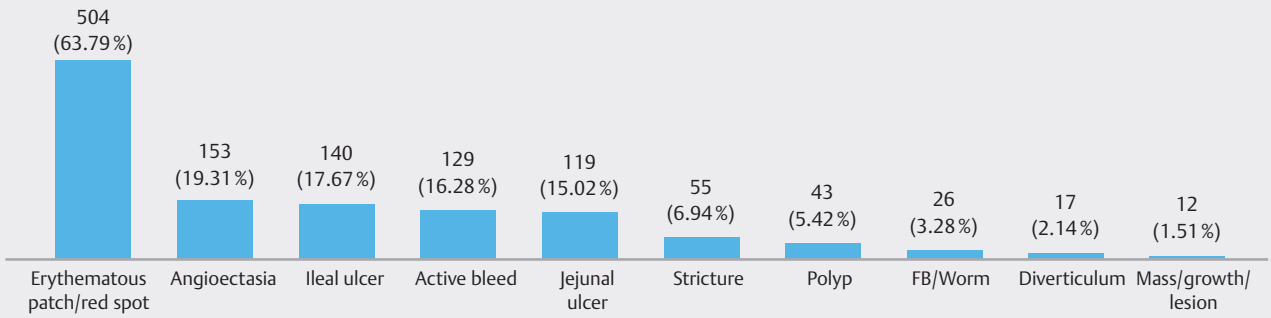
The DY of CE for chronic diarrhea was found to be 28.4% with 25 patients (n = 88) having definite lesions that could explain the disease. Twenty-two patients had ulcers in the jejunum and/or ileum, while three patients were reported to have stricture.

Capsule retention/ Incomplete SB examination

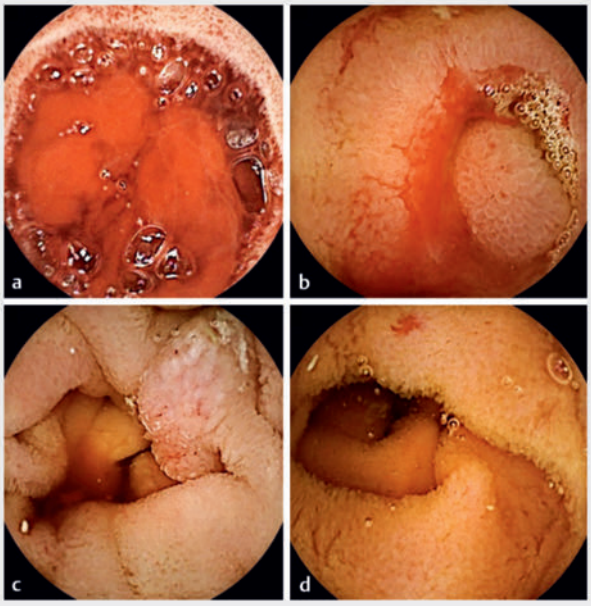
The SB capsule completion rate was 91.3%. Of the 101 patients in whom the capsule did not reach cecum, 21 (1.8%) had capsule retention, i. e., presence of the capsule in the digestive tract for a minimum of 2 weeks or more. Of these 21 patients, 13 had jejunal or ileal stricture, three patients had diverticulum, four had postsurgical status and one patient had growth as the cause of retention. In 15 patients, the capsule could be retrieved through enteroscopy, while six patients (0.5%) had to be referred for surgery. Eighty patients had incomplete SB transit; i. e. the capsule did not reach the cecum during recording time. Of these 80 patients, 16 (20%) had partial jejunal/ileal stricture, 15 had diverticulum (18.8%), slow gastric transit was noted in 12 patients (n = 9, 11.3%) in whom the capsule remained in the stomach for a majority of recording time, seven patients (8.8%) had either polyps or tumor, while CE was normal in 33 patients (41.3%).

Role of drugs in CE findings

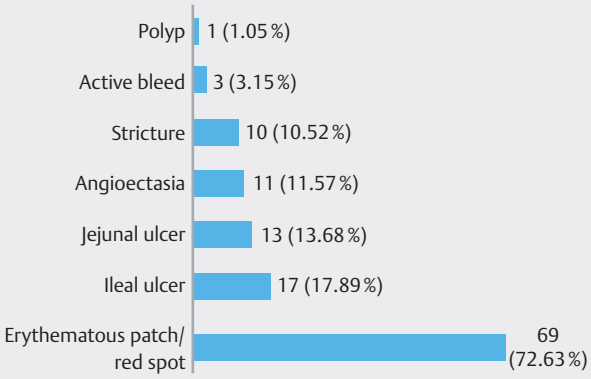
A history of nonsteroidal anti-inflammatory drug (NSAID) use was noted in 80 patients. Of them, only four had jejunal/ileal ul-



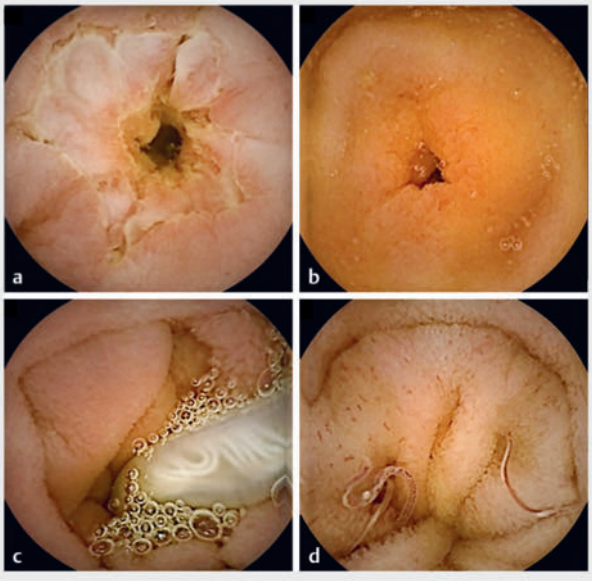
▶ **Fig. 2** Lesions detected by CE in patients with potential overt SB bleeding.



▶ **Fig. 3** Capsule endoscopy images. **a** Active oozing of blood from jejunum noted in a patient with potential overt SB bleeding. **b** Ileal polyp with oozing noted in a patient with potential occult SB bleeding. **c** Pedunculated polyp in proximal jejunum in a patient with potential occult SB bleeding. **d** Telangiectasias noted in patient with potential occult SB bleeding.



▶ **Fig. 4** Lesions detected by CE in patients with potential occult SB gastrointestinal bleeding.



▶ **Fig. 5** Capsule endoscopy images. **a** Circumferential mucosal ulceration with stricture in a patient with Crohn's disease. **b** Complete stricture in a patient with Crohn's disease. **c** Ascariasis infestation in jejunum in a patient with iron deficiency anemia. **d** Hookworms noted in the jejunum of a patient with iron deficiency anemia.

cers with no active bleeding. Forty-five patients had erythematous patch, while 31 patients had no findings. Anticoagulant use was noted in 42 patients while 127 patients had a history of antiplatelet therapy.

Discussion

CE has become an important diagnostic tool in the algorithmic evaluation of SB diseases. It is a well-tolerated and safe procedure with limited contraindications such as intestinal obstruction, fistulas and strictures.

Potential SB bleeding is the most common indication for CE worldwide, similar to our study in which 76.8% of patients were

subjected to CE. Other common indications for CE include chronic diarrhea, suspected CD and occasionally evaluation of anemia and abdominal pain.

In the present study, DY of CE for potential SB bleeding was 43.9% for potential overt SB bleeding, while it was 40% for potential occult SB bleeding. Previous studies have shown DY ranging between 40% and 65% [7, 8, 9, 10, 11]. There is no standardization in reporting of SB lesions with the definition of a positive finding still ambiguous. We believe gastroduodenal and colonic findings should not be included in the DY of SB CE, because esophagogastroduodenoscopy and colonoscopy are mandatory before doing a CE. Besides, non-specific findings such as erythematous patch, red spots, and polyps less than 10 mm size cannot be attributed as a definite source for obscure gastrointestinal bleeding or any other symptom [12, 13]. Our results are similar to another multicenter study of 172 patients, in which the DY of CE for obscure gastrointestinal bleeding was found to be 40.1% for high-probability lesions. This study categorized lesions into low, intermediate and high probability with high-probability lesions being considered to calculate the DY [10]. For the purpose of the current study, erythematous patch, red spots, and polyps ≤10 mm size were considered suspicious lesions, while ulcers, strictures, polyps size > 10 mm, mass lesions, and angioectasias were considered as definitive lesions.

CE has shown similar DY to double balloon enteroscopy (DBE) in evaluation of SB diseases including potential SB bleeding. A meta-analysis of 10 studies with 651 subjects undergoing CE and 642 subjects DBE showed similar DY (62% vs. 56% respectively; $P = 0.16$). The study revealed that DY for DBE performed after a previously positive CE was 75.0% as compared to 27.5% for previously negative CE [14]. Another meta-analysis of 11 studies comprising 757 subjects revealed no significant difference in DY between CE and DBE (60% vs. 57% respectively) [15].

CE is usually a safe procedure with minimal complication rate. Capsule retention is a major complication of CE and is different from "incomplete examination" in which the capsule stays in the ileum for a long time but ultimately passes on its own. The completion rate for CE (91.3%) in the current study was similar to previous studies. The risk of capsule retention is high in patients with CD, diverticulum, SB tumors, radiation enteritis, exposure to NSAIDS, and postsurgical anatomy. The capsule retention rate of 1.8% in the current study was also relevant and consistent with other studies [10, 16, 17].

CE has proven to be an important tool in management of CD. It has shown superiority over other modalities such as CT/magnetic resonance enterography, SB enteroclysis, barium contrast radiography, PE and ileocolonoscopy in diagnosing non-stricturing CD in numerous studies [16, 17, 18, 19]. Two meta-analyses comprising nine and 12 trials, respectively, found the DY of CE for CD to be 52% to 71%, which is comparable to our study [18, 20].

IDA is often caused by potential SB bleeding and is a common reason for patient referral to gastroenterologists. The DY of CE for IDA has been found to vary between 28% and 60% [21, 22, 23]. The wide variation may be a reflection of CE being routinely performed in some centers as compared to the stringent criteria set in other centers. CE being a costly investigation, it is advisable to have stringent criteria as in our center, which led to the higher overall DY (57.9%) in our study. The DY of CE for IDA increases progressively with advancing age [24, 25]. The results in the present study resonate with the previous studies where patients aged ≥ 60 years had a higher DY than those aged < 60 years.

Our results underscore that the evidence for utility of CE for non-specific findings such as abdominal pain and chronic diarrhea is low. Our study reported the DY for chronic diarrhea to be 28.4%, while it was 21.3% for abdominal pain. Previous studies have also found low DY of CE for chronic diarrhea (28%-46%) and abdominal pain (15%-41%) [8, 26]. CE should be performed using stricter criteria when evaluating patients for chronic diarrhea and abdominal pain.

The present study has several limitations. First, it was retrospective and single-center. Second, as the technology changed over the study period, SB3 capsules were used instead of the SB2 capsules, beginning in 2017. But multiples studies have established that there is no significant difference in DY with SB3 over SB2 capsules [27, 28, 29]. Third, this study did not include follow-up of the patients who had lesions found on CE to reach a conclusion about the etiology of the disease.

Conclusions

In summary, CE has been established as a safe and effective investigation with ever-increasing range of indications for which it has proven utility. In this study, we have shown that the DY of CE for potential SB bleeding is not that high, as reported in small case series in the past, but still comparable to DAE. With an inability to take tissue samples, CE cannot be considered a replacement for SB enteroscopy, but it can definitely be used a supplementary procedure for localizing the lesion. CE has also shown efficacy in early diagnosis and prognostication of CD patients. Future prospective studies are required to identify factors that might help increase the DY of CE in potential SB bleeding as well as other non-specific indications such as IDA, chronic diarrhea and abdominal pain.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Clinical trial

Trial registry: ClinicalTrials.gov (http://www.clinicaltrials.gov/)
Registration number (trial ID): NCT05228379
Type of Study: Retrospective observational

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