Feasibility and diagnostic yield of small-bowel capsule endoscopy in patients with surgically altered gastric anatomy: the SAGA study

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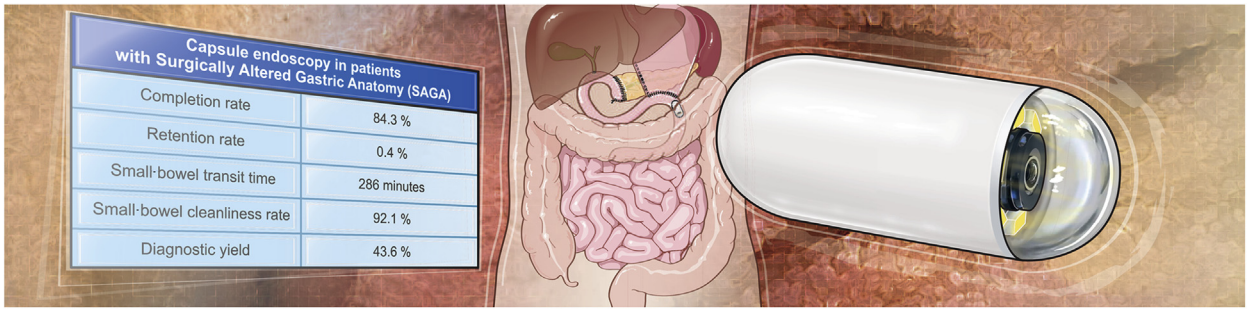
GRAPHICAL ABSTRACT



Background and Aims: Little is known about small-bowel (SB) capsule endoscopy (CE) in patients with a history of gastric surgery. This study aims to evaluate the feasibility and diagnostic yield (DY) of orally ingested SB-CE in patients with surgically altered gastric anatomy.

Methods: Twenty-four European centers retrospectively identified patients who had SB-CE after total or subtotal gastrectomy. The primary outcome was the DY of SB-CE (intermediate P1 to highly P2 relevant findings). Secondary outcomes were gastric and SB transit times, completion, cleanliness, and adverse event rates.

Results: Studied were 248 procedures from 243 patients (mean age, 62 years) with a history of partial gastrectomy (Billroth I, 13.1%; Billroth II, 34.6%), total gastrectomy (7.4%), Whipple procedure (12.8%), sleeve gastrectomy (7.2%), or gastric bypass surgery (24.7%). Obscure GI bleeding was the most frequent indication (85.1%). SB completion rate was 84.3%. One capsule retention in the SB was noted (adverse event rate, .4%). Median SB transit time was 286 minutes (interquartile range [235; 387]). Cleanliness was rated as adequate in 92.1% of procedures. After exclusion of abnormalities found at the upper anastomotic site, the DY was 43.6%, with inflammatory/ulcerated lesions observed more frequently (23.4%) than vascular lesions (21.0%).

Conclusions: SB-CE seems to be feasible and safe in selected patients with a history of major gastric surgery and comes with a high DY. The spectrum of abnormal SB findings in these patients may be different from what is known from the literature in nonoperated patients. (Gastrointest Endosc 2021;94:589-97.)

(footnotes appear on last page of article)

Capsule endoscopy (CE) is a noninvasive modality designed to explore the GI tract. After being swallowed, the capsule device captures frames while traversing the digestive tract. CE has been thoroughly validated in the investigation of the small bowel (SB) in patients with obscure GI bleeding (OGIB) or with suspected Crohn's disease, when upper GI endoscopy and ileocolonoscopy are normal. However, little is known about the feasibility, technical limitations, and diagnostic yield (DY) of SB-CE in patients with surgically altered anatomy.[1] Some clinicians consider a history of major gastric surgery as a contraindication for SB-CE or a call for endoscopic delivery of the CE device to the SB.[2] This study aims to evaluate the use, safety, and the DY of orally ingested SB-CE in patients with surgically altered gastric anatomy (SAGA).

METHODS

We performed a retrospective, multicenter cohort study to investigate the performance of SB-CE in patients with SAGA. Twenty-four European centers were asked to retrospectively identify patients with SAGA who underwent SB-CE (Table 1). Patient data were then deidentified.

Inclusion criteria were (1) a history of total gastrectomy, subtotal gastrectomy (including Billroth I and Billroth II partial gastrectomy, pancreaticoduodenectomy with antrectomy also known as Whipple procedure), sleeve gastrectomy, or exclusion of the stomach (bypass gastric surgery) and (2) an SB-CE examination, irrespective of the use of SB or colon capsule device and manufacturer. Exclusion criteria were CE performed to specifically

TABLE 1. Participating centers, with their standard small-bowel preparation modalities

Institution	City, country	No. of patients (no. of CEs)	Inclusion period	Standard small-bowel preparation
Gemilli Hospital, Catholic University	Rome, Italy	36 (36)	2012-2020	12-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L night before
Skåne University Hospital, Lund University	Malmö, Sweden	33 (33)	2013-2020	Fasting overnight
Altona General Hospital	Hamburg, Germany	23 (23)	2001-2010	<2007: 24-hour liquid low-residue diet, fasting overnight, PEG 4 L split*
				≥2007: 24-hour liquid low-residue diet, fasting overnight, PEG+ASC 2 L split*
Henri Mondor University Hospital	Creteil, France	21 (21)	2017-2019	24-hour liquid low-residue diet, PEG-ELS 2 L night before, fasting overnight
Hôpital Européen Georges Pompidou, Université de Paris	Paris, France	20 (22)	2015-2020	24-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L night before
Hôpital Saint Antoine, Sorbonne Université	Paris, France	15 (15)	2009-2020	<2017: 24-hour liquid low-residue diet, fasting overnight, PEG 1 L night before
				≥2017: 24-hour liquid low-residue diet, fasting overnight, PEG+ASC .5 L, 30 minutes after ingestion
Bethesda Krankenhaus Bergedorf	Hamburg, Germany	14 (15)	2011-2020	24-hour liquid low-residue diet, fasting overnight, PEG+ASC 2 L split*
Complejo Hospitalario de Navarra	Pamplona, Spain	7 (9)	2009-2020	18-hour liquid low-residue diet, fasting overnight
Sheffield Teaching Hospitals	Sheffield, UK	13 (13)	2016-2020	24-hour liquid low-residue diet, PEG-ELS 2 L night before, fasting overnight
South Tyneside District Hospital	South Shields, UK	12 (12)	2010-2020	18-hour liquid low-residue diet, PEG-ELS 2 L night before, fasting overnight
CTO Hospital	Iglesias, Italy	9 (9)	2004-2020	18-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L or PEG+ASC 1 L night before
Trinity College Dublin	Dublin, Ireland	7 (7)	2015-2020	18-hour liquid low-residue diet, fasting overnight, PEG-ELS 1 L night before, fasting overnight, PEG-ELS 1 L same morning
Sheba Medical Center, Tel Aviv University	Tel Aviv, Israel	6 (6)	2016-2020	24-hour liquid low-residue diet, fasting overnight
Amsterdam Universitair Medische Centra	Amsterdam, The Netherlands	6 (6)	2012-2020	<2017: 18-hour liquid low-residue diet + 4 L PEG-ELS night before, fasting overnight

(*continued on the next page*)

TABLE 1. Continued

Institution	City, country	No. of patients (no. of CEs)	Inclusion period	Standard small-bowel preparation
				≥2017: 18-hour liquid low-residue diet + 2 L PEG+ASC night before, fasting overnight
Santa Maria delle Croci Hospital	Ravenna, Italy	5 (5)	2016-2020	18-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L night before or PEG-ELS 2L split*
Università Cattolica del Sacro Cuore, Fondazione Poliambulanza	Rome and Brescia, Italy	3 (3)	2017-2020	18-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L split*
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico	Milan, Italy	3 (3)	2002-2020	2 L PEG and overnight fasting the day before
Attikon University General Hospital, Medical School, National and Kapodistrian University of Athens	Athens, Greece	3 (3)	2015-2020	<2017: 24-hour liquid low-residue diet + 2 L PEG-ELS night before, fasting overnight
				≥2017: 24-hour liquid low-residue diet + fasting overnight
Mater Dei Hospital	Msida, Malta	2 (2)	2014-2020	24-hour liquid low-residue diet, fasting overnight
				PEG-ELS 2 L night before
Morales Meseguer Hospital	Murcia, Spain	2 (2)		24-hour liquid low-residue diet, fasting overnight
Azienda Ospedaliera Città della Salute e della Scienza	Turin, Italy	1 (1)	2016-2020	24-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L or PEG+ASC 1 L night before
Ospedale Valduce	Como, Italy	1 (1)	2011-2020	24-hour liquid low-residue diet, fasting overnight, PEG-ELS 2 L night before
Royal Infirmary of Edinburgh	Edinburgh, UK	1 (1)	2016-2020	24-hour liquid low-residue diet, fasting overnight, sodium picosulfate + magnesium oxide + citric acid, morning and night before
Total	24 institutions	243 (248)	Starting 2001	High variations in the modalities of small-bowel preparation

PEG-ELS, Polyethylene glycol electrolyte lavage solution; *PEG+ASC*, polyethylene glycol containing ascorbic acid; *CE*, capsule endoscopy.
*Night before and same morning.

explore the esophagus, stomach, or colon; endoscopic delivery of the CE in the SB; gastric surgery without surgical anastomosis to the SB, such as suture of a gastric ulcer, gastric ring and antireflux surgery, pancreaticoduodenectomy with pylorus preservation (without antrectomy); and repeat SB-CE examination (ie, performed more than once for the same indication) within 6 months (only the first examination was considered then).

Investigators were asked to retrieve the following data: age at the time of SB-CE, gender, type of surgery (of note, "gastric bypass" was categorized as is with bariatric surgical procedures and not in the "[Roux-en-Y] partial gastrectomy" category), indication(s) of SB-CE, known symptoms of gastric outlet obstruction, capsule retention in the stomach (when stomach present, no passage in the SB during video recording), complete SB evaluation (with ≥1 visible frame of colonic mucosa, anal passage or ileostomy bag), gastric and SB transit times (SBTT), symptoms of ileus during or after SB-CE, capsule retention at day 15, intervention (endoscopy or surgery) for SB-CE retrieval, overall assessment of SB cleanliness (adequate or inadequate, according to the overall adequacy assessment score by Brotz et al[3]), adverse event rate (symptoms and/or a need for the endoscopic or surgical procedure for capsule retrieval), and diagnosis made by SB-CE (type and relevance of findings). Regarding the latter relevance of findings, the Saurin classification[4] was used for indications of OGIB, where P0 findings had no or little potential for bleeding (submucosal veins, diverticula without blood, nodules, lymphagiectasias), P1 findings had an uncertain risk for bleeding (red spots, small or isolated erosions), and P2 findings were presence of blood and/or lesions with a high potential for bleeding (angioectasias, varices, ulcerations, and tumors).

The primary outcome of the study was the DY of SB-CE defined as the proportion of patients with intermediate (P1) or highly (P2) relevant findings.[4] Secondary outcomes were gastric transit time and SBTT, completion rate, adequate cleanliness rate, and adverse event rate.

TABLE 2. Patient characteristics (n = 243)

Characteristics	Values
Gender, M/F	128/115
Age, y, mean ± standard deviation	61.6 ± 13.8
Major gastric surgery	
Total gastrectomy	18 (7.4)
Partial gastrectomy	116 (47.7)
Billroth I	32 (13.1)
Billroth II	84 (34.6)
Whipple's procedure	31 (12.8)
Bypass surgery	60 (24.7)
Sleeve gastrectomy	17 (7.2)
Pyloroduodenectomy	1 (.4)
Indication for SB-CE*	
Obscure GI bleeding	211 (85.1)
Overt	89
Occult	122
Crohn's disease	10 (4.0)
Suspected	8
Known	2
Other	27† (10.9)
SB-CE device (company, brand)*	
Given Imaging/Covidien/Medtronic	213 (94.4)
Pillcam SB1	16
Pillcam SB2	44
Pillcam SB3	134
Pillcam Colon2	40
Intromedic	6 (2.4)
Mirocam 1200	2
Mirocam 1600	2
Mirocam 2000	2
Olympus Endocapsule	7 (2.8)
Jinshan Omom	1 (.4)

Values are n (%) unless otherwise defined.
SB-CE, Small-bowel capsule endoscopy.
*Regarding 248 examinations in 243 patients.
†Investigation for Lynch syndrome (n = 8), familial adenomatous polyposis (n = 2), suspected SB polyp (n = 2), acute intestinal intussusception (n = 2), refractory celiac disease (n = 2), abdominal pain (n = 4), chronic diarrhea (n = 5), and protein-losing enteropathy (n = 2).

Institutional Review Board approval was obtained (Sorbonne University, no. 20200420164535, April 9, 2020) for this retrospective, descriptive study.

Statistical analysis

Descriptive statistics were used to indicate the patients' demographic features and endoscopic findings. Results are expressed as percentages for categorical variables and as means ± standard deviations or medians and interquartile ranges (IQRs) for continuous variables, as appropriate. The Fisher exact test and Mann-Whitney test were used to compare categorical and continuous data between groups, respectively.

RESULTS

Two hundred forty-eight procedures from 243 patients were included in the study. All patients had undergone upper and lower GI endoscopy before SB-CE. Upper GI endoscopy had included inspection of SB loops beyond the gastroenterostomy to a various extent. No complete inspection up to a Billroth II footpoint or Roux-en-Y anastomosis was performed in all patients. Inspection of the afferent loop or of the excluded stomach after gastric bypass surgery by device-assisted enteroscopy had not been performed before SB-CE. Standard SB preparation was highly variable between centers (Table 1).

Patient characteristics are presented in Table 2. There were 128 male patients (52.7%). Mean age was 61.6 ± 13.8 years at first SB-CE examination. Patients had a history of partial gastrectomy in 47.7% of cases (Billroth I, 13.1%; Billroth II, 34.6%), total gastrectomy in 7.4%, Whipple procedure in 12.8%, sleeve gastrectomy in 7.2%, and gastric bypass surgery in 24.7%. OGIB was the most frequent indication of SB-CE (211/248 examinations, 85.1%), being overt in 89 patients (42.2%) and occult in 122 patients (57.8%). SB capsule devices were used in 208 procedures (83.9%) and colon capsules (for SB examination) in 40 procedures (16.1%) (Table 3).

The main results are given in Figure 1 and Table 3. Various CE views of SAGA are given in Figure 2. Overall, the SB completion rate was 84.3% (209/248 procedures). Segmental transit delay (ie, 2 hours or more) in the remnant upper GI tract (esophagus or stomach) was noted in 15 procedures (6.0%). However, no CE retention in the postsurgical upper GI tract was observed in any patient at day 15, and no gastric endoscopic CE retrieval was required. An asymptomatic SB retention was seen in 1 patient (.4%), upstream of an ileocecal anastomosis for Crohn's disease, with successful endoscopic retrieval. The adverse event rate was therefore .4%. Overall, the median SBTT was 286 minutes [IQR, 235; 387]. In the 209 patients with complete SB examination, the median SBTT was 279 minutes [IQR, 233; 369]. In the 229 SB-CEs performed in 225 patients with subtotal gastrectomy, median gastric transit time and SBTT were 2 minutes [IQR, 1; 19] and 281 minutes [IQR, 233; 382], respectively. Cleanliness was rated adequate in 197 of 214 patients (92.1%) (missing data in 34).

Abnormal findings were observed in 155 procedures (62.5%). Findings observed at the upper anastomotic site (with inflamed or ulcerated anastomosis in 14 procedures) were not taken into account for further calculation of the diagnostic performances of the procedure. P0, P1, and P2

TABLE 3. Main results of the study

Outcome	Value
Completion	209 (84.3)
Gastric retention at day 15	0 (.0)
Small-bowel retention rate at day 15	1 (.4)
Small-bowel occlusion rate at day 15	0 (.0)
Intervention for capsule endoscopy retrieval	1 (.4)
Transit time, min	
Stomach, median [interquartile range]	2 [1; 19]*
Small bowel, median [interquartile range]	286 [235; 387]
Small-bowel cleanliness overall adequacy assessment	
Adequate	197/214 (92.1)†
Inadequate	17/214 (7.9)†
Findings in the small bowel‡	
No finding	107 (43.1)
Vascular lesions	52 (21.0)
Typical angiectasia	38 (15.3)
Inflammatory lesions	58 (23.4)
Erosion/ulceration/ulcer	52 (21.0)
Polyps/mass	11 (4.4)
Blood	7 (2.8)
Other	13 (5.2)
Relevance of findings in the small bowel‡	
P0	32 (12.9)
P1	45 (18.1)
P2	63 (25.4)
P1 + P2	108 (43.6)

Values are n or n/N (%) unless otherwise defined.
*Among 229 small-bowel capsule endoscopy procedures in patients for whom gastrectomy was subtotal.
†Calculation based on 204 examinations because of missing data in 34.
‡Per recording. Findings observed at the upper GI anastomotic site (with inflammatory or ulcerative anastomosis in 14 procedures) were not taken into account. Some patients had more than 1 type of finding per small-bowel capsule endoscopy recording. Highest relevance index was noted.

findings in the remaining 141 procedures were calculated to be 13.3%, 18.1%, and 25.4%, respectively (Table 3). Overall, the DY of P1 and P2 lesions was 43.6%. Findings were vascular lesions in 52 procedures (21.0%), with typical angiectasias in 38 (15.3%), inflammatory lesions in 58 (23.4%; with erosion, ulceration, or ulcer in 52 procedures, 21.0%), and polyps or mass in 11 (4.8%), including 1 jejunal adenocarcinoma. Blood was seen in 7 procedures (2.8%) (Table 3). Procedures in patients with a history of bariatric surgery had a lower DY of P1 or P2 lesions (30/77 procedures, 39.0%) compared with those with nonbariatric gastric surgeries (77/171 procedures, 45.0%), but this difference was not statistically significant (Fig. 1). In the subgroup of patients with partial gastrectomy, those with Billroth II operation had a higher DY of P1 or P2 lesions (46/86 procedures, 53.4%) compared with those with Billroth I surgery (14/32 procedures, 43.7%), but this difference did not reach statistical significance ($P = .30$).

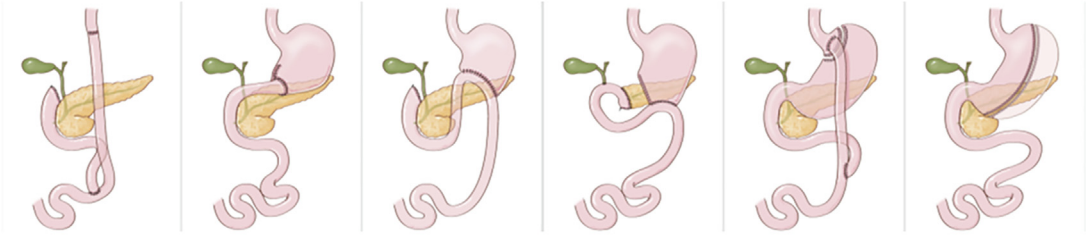
Patients having the CE procedure in centers where the standard SB preparation modalities included a polyethylene glycol–based purge had a longer median gastric transit time (2 minutes vs 1 minute, respectively; $P = .002$) and a significantly lower SB adequate cleanliness rate (89.7% vs 100.0%) (Table 4). Median SBTTs (282 vs 289 minutes, respectively), completion rates (82.7% vs 90.4%), and DY (P1 or P2 lesions, 45.4% vs 36.5%) were not significantly different between the 2 subgroups.

DISCUSSION

To the best of our knowledge, this is the first large retrospective study on oral ingestion of the SB-CE in patients with modified upper GI anatomy. Claiming a theoretical risk of anastomotic stenosis and GI dysmotility in patients with surgically modified anatomy, some practitioners suggest that previous major gastric surgery is a contraindication to the ingestion of SB-CE and recommend endoscopic delivery instead.[2] In 2011, Parikh et al[5] reported SB-CE in 4 consecutive patients with Roux-en-Y gastric bypass for the treatment of morbid obesity. Although none had any documented GI dysmotility, all 4 patients had unsatisfactory studies: 2 incomplete because of gastric and SB retentions, whereas the rest had complete SB recordings but with inadequate cleanliness despite compliance with preprocedure instructions. The authors suggested that patency capsule, endoscopic delivery of SB-CE, or deep enteroscopy should be considered in this group of patients. A few years later, Stanich et al[1] reported on a retrospective series of 24 SB-CEs in 23 patients with a history of gastric surgery. Sixteen capsules were given by the oral route (completion rate, 81.3%) and 8 by endoscopic deployment (completion rate, 62.5%). Although not significant, the median SBTT was longer after endoscopic deployment (364 minutes) than after oral ingestion (291 minutes). No capsule retention occurred. Overall, to date, published data on SB-CE done in patients with altered gastric anatomy are scarce, and international guidelines remain elusive on how to perform the procedure.[6]

The current study shows that orally ingested SB-CE in patients with altered gastric anatomy has a high completion rate (84.3%), a high cleanliness rate (92.1%), a good DY (43.6%), and a low adverse event rate (.4%). These numbers are quite similar to what is reported in various systematic reviews and large surveys (Table 5) regarding the feasibility and DY of SB-CE (which may include both operated and nonoperated patients).[7,8]

The colon (or ileostomy bag) was reached in 84.3% of patients in our series, very similar to the 83.5% completion rate observed among the 22,840 patients in the systematic



Type of surgery	Total gastrectomy	Partial gastrectomy Billroth I	Partial gastrectomy Billroth II	Whipple's surgery	Gastric bypass	Sleeve gastrectomy
Number of procedures	19	32	86	33	60	17
Completion[£] (n, %)	14 (73.7%)	27 (84.4%)	70 (81.4%)	28 (84.8.3%)	54 (90.0%)	15 (88.2%)
P1 + P2 finding* (n, %)	6 (31.6%)	14 (43.7%)	46 (53.5%)	11 (33.3%)	23 (38.3%)	7 (41.2%)
Retention (n, %)	0 (0.0%)	0 (0.0%)	1[#] (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Figure 1. Main outcomes according to the type of major gastric surgery. Completion rate, diagnostic yield (P1 or P2 findings), and retention rate of small-bowel (SB) capsule endoscopy (CE), according to the type of major gastric surgery. [£]A complete SB examination was defined by at least 1 visible frame of colonic mucosa, anal passage, or ileostomy bag. This definition does not take into account the fact that some intestinal loops may be blind to the capsule because of the surgically modified anatomy (as in bypass surgery, Whipple procedure, and Billroth II partial gastrectomy). *Per recording, after exclusion of 14 SB-CE recordings where abnormalities were located in reach of the upper GI endoscopy (at upper GI anastomosis) only. Some patients had more than 1 type of finding per SB-CE recording. Highest relevance index was noted. [#]Capsule retention upstream of an ileocecal anastomosis for Crohn's disease. Successful endoscopic retrieval.

review by Liao et al[8] in 2010. The term "completion" is not appropriate for some patients in our study because of intestinal loops that are blind to the capsule after bypass surgery, Whipple procedure, and Billroth II partial gastrectomy. Unsurprisingly, the median gastric transit time was quick (2 minutes) in those patients with a gastric stump compared with an approximately 20-minute mean gastric transit time in patients with OGIB[9] and healthy control subjects[10] in the literature. The 286-minute median SBTT of patients with altered gastric anatomy is similar to the mean of 291 minutes previously observed in the series of 16 patients by Stanich et al.[1] This SBTT seems significantly longer in our operated patients compared with nonoperated patients in the literature (with medians or means varying from 220 to 250 minutes in the latter).[10] A shorter gastric transit time combined with a longer SBTT (as measured by CE) may lead to a similar "completion" rate in patients with SAGA from our series to what is known in the literature in nonoperated patients.

However, it should be noted that our series is not controlled and that SB-CE is not validated for assessing intestinal motility. Indeed, our results are somehow in contradiction with several demonstrations that the distal stomach plus pylorus exerts an inhibitory mechanism in the regulation of GI movement.[1,11] For instance, a hydrogen breathing testing and scintigraphy imaging have shown that patients with total or subtotal gastrectomy or gastric bypass have a significantly reduced SBTT compared with control subjects.[12-15] Overall, in our study, esophageal and gastric retentions were rare (6.0%) and the completion rate (84.3%) of orally ingested SB-CE satisfactory in patients with a history of gastric surgery. Conversely, limited series suggest that the completion rate with endoscopic capsule delivery is around 63% only,[1,11] whereas the procedure is invasive and expensive for providers and patients. In our opinion, this observation suggests that endoscopic delivery of the capsule is indicated in selected cases only (patients with gastroparesis and gastric outlet obstruction).

The assessment and reporting of SB cleanliness is listed in various guidelines as a performance measure for SB-CE.[16] By means of a widely used scale,[3] we observed in our series a cleanliness rate of 92.1%, close to that recommended (>95%) by the European Society for Gastrointestinal Endoscopy[16] but actually higher compared with that suggested in the literature (10%-40%).[17] Counterintuitively, patients having a CE procedure in centers where the standard SB preparation modalities included a non–polyethylene glycol–based purge had a significantly higher SB adequate cleanliness rate (100.0%) than those from centers where a

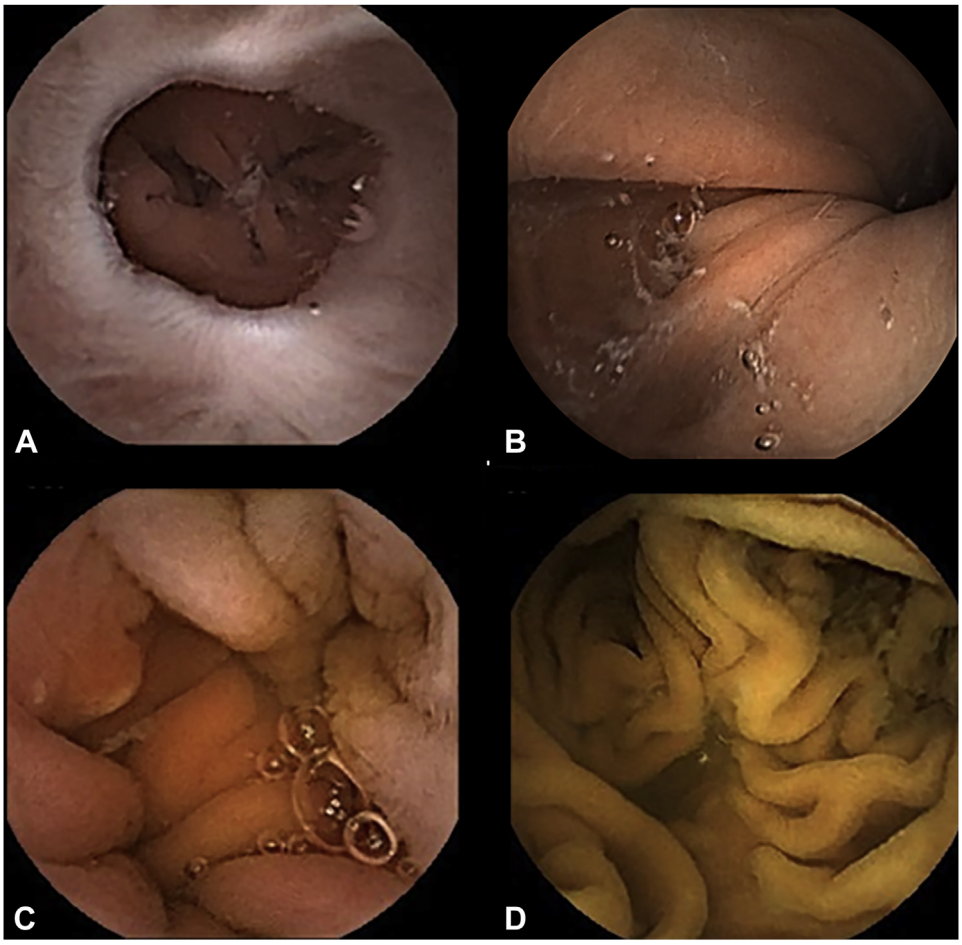


Figure 2. Small-bowel capsule endoscopy images of anastomosis in patients with surgically altered gastric anatomy. **A,** Esophagojejunostomy. **B,** Gastric remnant after gastric bypass. **C,** Billroth II gastroenterostomy. **D,** Roux-en-Y anastomosis.

polyethylene glycol–based preparation was proposed (89.7%, $P = .015$). It is hard to draw conclusions from these results because calculations regarding preparation modalities were center-based (not patient-based) and it is possible that other systematic center-related biases may have influenced this result (bariatric or oncologic referral, CE indications and interpretations, etc). Of note, DYs were not statistically different in these 2 subgroups.

The DY of SB-CE varies from 27% to 77% in the literature, according to the referral population and to the various types and generations of devices.[16] This high variability may also be because of the lack of standardization regarding SB-CE reading and reporting.[16] Overall, our DY of 43.6% in patients with SAGA is in line with previous data and with the estimate of 48.4% observed in an Italian prospective multicenter study.[18] Although these rates are below the expected performance index of 50%,[16] it should be noted that we only considered P1 and P2 lesions as "findings" (thus ruling out 33 examinations with P0 findings). Vascular lesions were found in 21.0% of patients in our series, similar to the 21.6% rate in the Italian prospective multicenter study.[18] Polyps/mass (4.4% in our series) and blood (2.8%) were also in the range of the Italian series (8.3% and 5.4%, respectively). Interestingly, inflammatory/ulcerated lesions were found in 23.4% of our operated patients compared with 12.2% in the Italian prospective multicenter study.[18] Capsule readers should be aware of this particular spectrum of findings in patients with SAGA. Patients with SAGA may have an altered mucosal integrity because of their past (possibly recent) history of surgery and the use of medications (nonsteroidal anti-inflammatory drugs, proton pump inhibitors, and others), with possible microbioma changes, but these data were not collected. Patients with a history of bariatric surgery had a lower DY than nonbariatric patients (39.0% vs 45.0%). Although nonsignificant, this result suggests that different factors may be involved, with iron maldigestion or malabsorption as a direct or additional cause of anemia or because of lesions located in a bypassed stomach or in an intestinal loop blind to CE in patients with Billroth II anastomosis or Whipple procedure. Furthermore, complete upper GI endoscopy in patients with gastric bypass, Whipple procedure, and Roux-en-Y

TABLE 4. Main results according to the center's standard small-bowel preparation modality (PEG-based or not)

	PEG-based	Not PEG-based	*P* value
No. of centers	20*	5*	
No. of procedures	196	52	
Completion	162 (82.7)	47 (90.4)	.20
Transit time, min			
Stomach, median [interquartile range]	2 [1; 23]†	1 [0; 5]†	.002
Small bowel, median [interquartile range]	282 [233; 379]	289 [239; 388]	.45
Small-bowel cleanliness overall adequacy assessment			
Adequate	148/165 (89.7)‡	49/49 (100.0)‡	.015
Inadequate	17/165 (10.3)‡	0/49 (.0)‡	
Relevance of findings in the small bowel§			
P0	29 (14.8)	3 (5.8)	
P1	37 (18.9)	8 (15.4)	
P2	52 (26.5)	11 (21.2)	
P1 + P2	89 (45.4)	19 (36.5)	.27

Values are n or n/N (%) unless otherwise defined.
PEG, Polyethylene glycol.
*Twent-four centers were involved in the study, but 1 center moved from PEG-based to non–PEG-based small-bowel preparation in 2007 (see Table 1).
†Among 229 small-bowel capsule endoscopy procedures in patients for whom gastrectomy was subtotal.
‡Calculation based on 204 examinations because of missing data in 34.
§Per recording. Findings observed at the upper GI anastomotic site (with inflammatory or ulcerative anastomosis in 14 procedures) were not taken into account. Some patients had more than 1 type of finding per small-bowel capsule endoscopy recording. Highest relevance index was noted.

anastomosis may require device-assisted enteroscopy. Hence, it can be assumed that SB-CE had been performed without preceding complete upper GI endoscopy in some patients, resulting in a lower pretest probability.

Regarding safety, the overall adverse event rate of SB-CE is about 1% to 3%[19,20] compared with .4% in our series of operated patients. The most frequent adverse event was capsule retention in the SB, seen in 1.5% to 2.0% of patients[8,19,20] and mostly related to the indication of suspected or definite Crohn's disease (as seen in our patient). This indication was quite low in our series (only 4.0%), whereas it usually accounts for 10% of indications in the largest series,[20] and our patients were possibly selected because of their surgical history, potentially leading to the low adverse event rate observed.

Our study has some limitations. First, it is an open series. In the absence of standardized protocols pre-, peri-, and postprocedure among centers and physicians, patients had various types of devices and preparatory methods, and interpretation of video recordings may differ among readers in terms of cleanliness, diagnosis, and pertinence. In the absence of any control group, we can only compare our results with published data. It would be of great interest to match our series with a paired group of nonoperated patients and with operated patients in whom the capsule was endoscopically deployed. Second, it is a retrospective study, with potential bias. A few data were missing regarding SB cleanliness. It is likely that SB-CE was given in selected patients without any symptom of gastric outlet obstruction. It is also possible that some outcomes were

TABLE 5. Main outcomes of the current study (small-bowel capsule endoscopy in patients with surgically altered gastric anatomy) to those known or recommended from the literature in patients with supposedly nonaltered gastric anatomy

Outcome	Surgically altered gastric anatomy from current series (248 procedures)	Nonaltered anatomy from literature (references)
Completion rate, %	84.3	83.5[8]
Retention rate, %	.4	1.5-2.0[18-20]
Median or mean small-bowel transit time, min	286	220-250[10]
Small-bowel cleanliness, %	92.1	Uncertain (10-40?) European Society of Gastrointestinal Endoscopy recommends > 95%[15,17]
Diagnostic yield, %	43.6	48.4[18]

overlooked, particularly regarding postprocedure adverse events in referred outpatients. However, some strengths should be emphasized as well: To date, it is by far the largest study on the matter and the only multicenter data collection.

Overall, this series suggests that orally ingested SB-CE is feasible and safe in most (but still selected) patients with a history of major gastric surgery and that it comes with a high DY. Of note, the spectrum of findings may be different from what is seen in nonoperated patients.

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Abbreviations: CE, capsule endoscopy; DY, diagnostic yield; IQR, interquartile range; OGIB, obscure GI bleeding; SAGA, surgically altered gastric anatomy; SB, small bowel; SBTT, small-bowel transit time.

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APPENDIX 1

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