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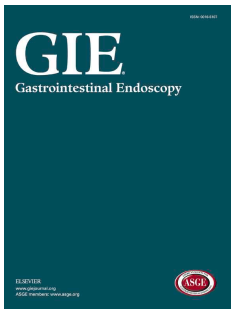

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Gian Eugenio Tontini, MD, PhD, Felix Wiedbrauck, MD, OA, Flaminia Cavallaro, MD, PhD, Anastasios Koulaouzidis, MD, FEBG, FRSPH, FRCP, Roberta Marino, MD, Luca Pastorelli, MD, PhD, Luisa Spina, MD, PhD, Mark E. McAlindon, BM, BS, BMed Sci, MRCP, PhD, Piera Leoni, MD, Pasquale Vitagliano, MD, Sergio Cadoni, MD, Emanuele Rondonotti, MD, PhD, Maurizio Vecchi, MD, Prof.

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Small-bowel capsule endoscopy with panoramic view: results of the first multicenter, observational study (with videos)

Gian Eugenio Tontini[1], MD, PhD; Felix Wiedbrauck[2], MD, OA; Flaminia Cavallaro[1], MD, PhD; Anastasios Koulaouzidis[3], MD, FEBG, FRSPH, FRCP; Roberta Marino[4], MD; Luca Pastorelli[1,5], MD, PhD; Luisa Spina[1], MD, PhD; Mark E McAlindon[6], BM, BS, BMed Sci, MRCP, PhD; Piera Leoni[4], MD; Pasquale Vitagliano[7], MD; Sergio Cadoni[8], MD; Emanuele Rondonotti[9], MD, PhD; Maurizio Vecchi[1,5] MD, Prof.

[1]Gastroenterology & Digestive Endoscopy Unit, IRCCS Policlinico San Donato, San Donato Milanese, Milano, Italy; [2]Klinik für Gastroenterologie/GI-Onkologie, Allgemeines Krankenhaus Celle, Celle, Germany; [3]Centre for Liver & Digestive Disorders, The Royal Infirmary of Edinburgh, Edinburgh, United Kingdom; [4]Gastroenterology & Digestive Endoscopy Unit, AO Lodi, Lodi, Italy; [5]Department of Biomedical Sciences for Health, University of Milan, Milano, Italy; [6]Gastroenterology, Royal Hallamshire Hospital, Sheffield, United Kingdom; [7]Gastroenterology & Digestive Endoscopy Unit, A.O. di Melegnano, Milano, Italy; [8]Digestive Endoscopy Unit, St. Barbara Hospital, Iglesias, Carbonia-Iglesias, Italy; [9]Gastroenterology Unit, Valduce Hospital, Como, Italy.

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Authors' contribution

Gian Eugenio Tontini, Flaminia Cavallaro: study concept and design, acquisition of data, analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript.

Felix Wiedbrauck, Roberta Marino, Luca Pastorelli, Luisa Spina, Mark E McAlindon, Piera Leoni, Pasquale Vitagliano, Sergio Cadoni: acquisition of data and critical revision of the manuscript for important intellectual content.

Anastasios Koulaouzidis: acquisition of data, drafting of the manuscript, and critical revision of the manuscript for important intellectual content.

Emanuele Rondonotti: drafting of the manuscript, critical revision of the manuscript for important intellectual content.

Maurizio Vecchi: study concept and design, drafting of the manuscript, critical revision of the manuscript for important intellectual content, study supervision.

Corresponding Author:

Gian Eugenio Tontini, MD, PhD.

Gastroenterology & Digestive Endoscopy Unit, IRCCS Policlinico San Donato,

Via Morandi 30, 20097, San Donato Milanese, Milano, Italy

Tel/Fax: +39 02 52774655; e-mail: gianeugeniotontini@gmail.com

Abstract

Background and Aims

The first small-bowel video-capsule endoscopy (VCE) with 360° panoramic view has been recently developed. This new capsule has a wire-free technology, 4 high frame-rate cameras, and a long-lasting battery life. The present study was aimed at assessing performances and the safety profile of the 360° panoramic-view capsule in a large series of patients from a multicenter clinical practice setting.

Methods

Consecutive patients undergoing a 360° panoramic-view capsule procedure in 7 European Institutions between January 2011 and November 2015 were included. Both technical (ie, technical failures, completion rate) and clinical (ie, indication, findings, retention rate) data were collected by means of a structured questionnaire. VCE findings were classified according to the likelihood to explain reason for referral: P0-low, P1-intermediate and P2-high.

Results

Among 172 patients (94 men; median age: 68 years, IQR: 53-75), 142 underwent VCE for obscure (32 overt, 110 occult) GI bleeding (OGIB) and 28 for suspected (17) or established (2) Crohn's disease (CD). Overall, 560 findings were detected; 252 of them were P2. The overall diagnostic yield was 40.1%; 42.2% and 30.0% in patients with OGIB and CD, respectively. The rate of complete enteroscopy was 90.2%. All of the patients but one, who experienced capsule retention (1/172: 0.6%), excreted and retrieved the capsule. VCE failure occurred in 4 of 172 (2.3%) cases for technical problems.

Conclusion

The present multicenter study, conducted in clinical practice setting and based on a large consecutive series of patients, showed that DY and safety profile of 360° panoramic-view capsule are similar to those of forward-view VCEs.

INTRODUCTION

Video capsule endoscopy (VCE), first introduced in clinical practice in 2001, has rapidly gained a definite role in the diagnostic work-up of small-bowel disorders [1-3]. Currently, VCE is the first-line procedure for the evaluation of patients with obscure GI bleeding (OGIB) [1-3]. Furthermore, VCE is performed for a number of additional indications including suspected and/or known small-bowel Crohn's disease (CD), suspected small-bowel tumors, inherited polyposis syndromes, and refractory celiac disease [1-5].

Nonetheless, several studies demonstrated that the visualization of the small bowel with forward-viewing capsules is suboptimal [1-3,6-14]. First, the exploration of the entire small bowel can be achieved only in about 80% of patients [1-3,6]. Furthermore, VCE can miss about 30% of discrete lesions, especially in the proximal segments where passive capsules are rapidly propelled by gut motility [7-10]. Finally, image interpretation for lesions appearing in a single frame, mucosal bulges and/or segments with inadequate bowel cleansing can be challenging even for expert readers [11-14].

Nevertheless, VCE remains an evolving technology, undergoing continuous technical improvements aimed to overcome the limitations of available capsule models [15,16]. In 2011, a new VCE platform (CapsoCam SV, Capso-Vision, Inc. Saratoga, Calif, USA) was introduced in clinical practice, **Figure 1**. It is equipped with 4 cameras, placed at the middle of the capsule, at 90 degrees to each other, and provides a lateral 360° panoramic-view of the small-bowel mucosa. CapsoCam SV is able to acquire a high number of frames (12-20 frames/second), with optimized battery power consumption, due to a dedicated Smart Motion Sense technology that captures images only when the capsule is in motion. Therefore, the system allows for a long battery life (>15 hours). Furthermore, CapsoCam SV is the only completely wire-free VCE platform because the acquired images are not transmitted to an external recorder but stored inside the capsule (on-board

data storage system) and retrieved after capsule excretion and retrieval. Technical characteristics of CapsoCam SV are shown in **Table 1**.

Data about the use of CapsoCam SV in clinical practice are scarce; at present, only one pilot [17] and one comparative study [18], including overall 91 patients, are available. Interestingly, these initial studies demonstrated that although CapsoCam SV can identify more lesions than frontal-view capsules, the diagnostic yield (DY) remains comparable. On the other hand, the need to retrieve the capsule remains a possible limitation of this VCE platform. In that sense, if the patient fails to retrieve the capsule (7% in the study by Pioche *et al.* [18]) or capsule retention occurs, no video recording can be generated, thus delaying a non-invasive endoscopic evaluation of the small bowel with all the relevant consequences.

We performed the present observational study to assess the performances of CapsoCam SV and its safety profile, in a clinical practice setting, based on large series of consecutive patients undergoing VCE.

MATERIALS AND METHODS

Study population and VCE procedure

All consecutive patients undergoing VCE with CapsoCam SV for suspected small-bowel bleeding, without ongoing overt bleeding, or for Crohn's disease at 4 Italian, 2 British, and 1 German institution were enrolled. For each patient, technical (eg, transit times, completion rate, technical failure rate), clinical (eg, findings and DY) and safety data (eg, retention rate, capsule aspiration) were collected, with a structured data entry.

Patients undergoing the procedure between January 2011 and January 2015 received CapsoCam SV1 (first generation CapsoCam SV), whereas those investigated between January and November 2015 CapsoCam SV2 (second generation CapsoCam SV). When compared with the first CapsoCam SV generation, SV2 includes minor software changes and a fully automated downloading system. Nevertheless, there are no major differences in image acquisition, data processing and image quality between the 2 models. Therefore, no major clinical differences are expected, and all patients were analyzed together, whichever capsule model was used.

Patients received 2 to 4 L of polyethylene glycol solution 2 to 8 hours before capsule ingestion as per local VCE protocol at each center. Patients were instructed by the local investigator on how to check for capsule excretion and on how to retrieve it by means of a dedicated magnetic wand used to facilitate its extraction from the feces. If capsule excretion was not noticed within 15 days, the patient underwent an abdominal radiograph to exclude the retention of the device.

As a part of routine diagnostic work-up, the local investigator evaluated VCE recordings but no central reading was performed; therefore, no intraobserver or interobserver agreement was assessed. All VCE readers involved in the study had a large experience in frontal-view VCE (>100 VCEs/reader for several years) and, at the beginning of the present study, all of them had limited experience with lateral-view capsules (<3 procedures/reader).

The small-bowel cleansing was scored by estimating the amount of clearly visible mucosa. For this purpose, we simplified the scoring system proposed by Esaki et al. [19], developing a new score, the “Small Bowel Mucosal Visibility Scoring System.” This newly proposed scoring system focuses on mucosal visibility and takes into account dark fluids only when affecting mucosal visibility (Supplementary Table 1). Incomplete VCE

examinations were excluded from the assessment of small-bowel mucosal visibility because it was impossible to divide the small bowel in 3 tertiles.

Patients provided informed consent before undergoing VCE, as per routine clinical care in each center. This study was carried out in accordance with the World Medical Association Declaration of Helsinki adopted in 1964 incorporating all later amendments.

Clinical outcomes

To assess the clinical performances of VCE with CapsoCam SV, the following parameters were evaluated:

i) **VCE findings:** location, endoscopic features and clinical significance were systematically recorded for each identified lesion. All endoscopic findings were classified according to the clinical significance, in relation to procedure indications, as P0 (low probability), P1 (intermediate probability), or P2 (high probability) [20].

ii) **Diagnostic Yield (DY):** VCE was defined as 'positive' when at least one clinically significant finding (P2) was identified; the rate of "positive" VCE (ie, DY) was therefore calculated. The study covers a 4-year timeframe; therefore, a possible learning curve effect on DY cannot be excluded. All VCE readers had similar expertise in both frontal- and lateral-view VCE at the beginning of the study. Therefore, at the end of the study, we selected those readers with at least 20 lateral-view VCEs to compare the DY observed within the first 10 examinations with the DY obtained during the subsequent set of lateral-view VCEs.

Technical outcomes

To evaluate the technical performances of CapsoCam SV, the following data were collected:

1. **CapsoCam SV system technical failure:** it was defined as any technical problem occurring to one or more system components (ie capsule device, downloading system, and/or workstation) preventing the generation of the video. In CapsoCam SV the image storage device is built-in; therefore, any failure in retrieving the capsule results in recording loss. Hence, In case of capsule non-retrieval, the examination was considered as a technical failure. The capsule was defined as non-retrieved when the patient did not realize capsule excretion 15 days post-ingestion and the abdominal radiograph excluded capsule retention.

2. **Transit and operating times**: gastric transit time (GTT), defined as the time between the first and the last gastric image; small-bowel transit time (SBTT), defined as the timeframe between the first and the last small-bowel image; and, operating time, defined as the time between the first and the last image captured by the capsule.

3. **Completion rate:** the number of patients in which the colon was reached during the operating time over the overall number of patients undergoing VCE.

4. **Ampulla of Vater detection rate:** the number of examinations in which the ampulla was clearly identified over the number of completed VCE examinations.

5. **Video record reliability:** we developed a new quantitative scoring system, aimed at evaluating the possible amount of damaged (ie, dark, non-readable, blurred, distorted) images due to interference with other electronic devices in order to assess the video record reliability. This score is detailed **Supplementary Table 2**. Incomplete VCE examinations were excluded from the assessment of video record reliability.

Safety profile

As reported in previous studies on front-viewing capsules [1,21], we focused our attention on capsule aspiration, at time of ingestion, and/or on capsule retention. The latter was defined as the persistence of the capsule within the patient's intestinal tract, demonstrated by means of an abdominal radiograph, 15 days after capsule ingestion. Patients in whom the capsule was retrieved by elective surgery and/or by endoscopic procedures were also counted as cases of capsule retention. Any other incident and/or adverse event, reported as potentially related to VCE by the local investigator, were documented and classified according to previously published international guidelines [22].

Statistical analysis

The median with inter-quartile range (IQR) and range is provided for non-normally distributed variables, whereas the mean ± standard deviation (SD) for normally distributed variables. The 2-tailed Student *t*-test for unpaired samples was used to compare CapsoCam SV1 and SV2 technical outcomes (ie, operative time and video records reliability). The 2-tailed Fisher exact test was used to compare the DY reported in the first 10 capsules with the DY reported for capsules subsequently performed in the per-reader analysis. All statistical analyses were performed using PASW Statistics 18 (SPSS, Inc., Chicago, Ill, USA). Given the nature of the present descriptive, observational study, no sample size calculation was performed.

RESULTS

Overall, 172 patients (94 men; median age 68 years, IQR 53-75 years; range 9-97 years) were collected. Clinical indications for VCE are listed in **Table 2**.

In patients with suspected small-bowel bleeding without ongoing hemorrhage, the time interval from symptoms onset or recurrence to VCE ranged between 2 and 30 days. When VCE with CapsoCam SV was performed for suspected or established CD, patients underwent radiologic patency tests to reduce the risk of capsule retention in line with the European Crohn's and Colitis Organization consensus [4].

CapsoCam SV1 and SV2 were used in 137 (79.6%) and 35 patients (20.4%), respectively. The enteroscopic mucosal visibility according to bowel preparation was adequate in most patients (127/152, 84%). The mucosal visibility score, calculated for each small-bowel tertile and for the entire small bowel, is reported in **Table 3**.

Clinical outcomes

VCE findings

Overall, in a total of 172 VCEs, 685 lesions were found. Interestingly, 125 small-bowel lesions were reported in a single patient with pan-enteric CD [23]. Barring this case as an outlier, in the remaining 171 patients, 560 lesions were reported. Among them, 252 (45%) were classified as P2 findings. Most lesions were located in the small bowel (448/560: 80%) (**Figure 2**, **Video 1-4**). Nonetheless, VCE identified a number of relevant findings in the upper (95/560, 34 of them classified as P2) (**Figure 3**, **Video 5**) and lower GI tract (17/560, 12 of them being classified as P2) (**Video 6**).

Diagnostic yield

The VCEs containing at least one P2 finding were 69 (DY: 69/172, 40.1%). The DY varied according to VCE indication, being 30% (9/30) in patients with suspected or established CD, and 42.2% (60/142) in those with OGIB (**Table 2**). Different types of P2 lesions and

their location among these 69 patients with a positive video capsule endoscopy are shown in **Figure 4**. Among the 69 patients with at least one P2 lesion, 34 had vascular lesions further classified as related to portal hypertension (n=5) and to angioectasias (n=29). Fourteen patients had a single angioectatic lesion and 14 multiple angioectasias. The mean number of vascular lesions in those having at least one angioectasia (n=29) and in the 14 patients with multiple angioectasias were 2.9 and 4.9, respectively. In the remaining 103 patients with no P2 lesion, we found at least one P1 lesion in 32 patients (18.6%), and P0 lesions in 14 (8.1%).

Four readers involved in this study reviewed more than 20 lateral-viewing VCEs (mean number per reader: 32, range 20-51). The overall DY of the first 10 lateral-viewing VCEs was similar to that of the subsequent VCEs. When the per-reader analysis was performed, all but one showed a DY in the first set of 10 capsules consistent with the set of subsequent capsules (detailed results are reported in **Supplementary Table 3**).

Technical outcomes

CapsoCam® SV system failure

All patients who excreted the capsule (n =171) were able to return the capsule for the downloading process. Failure of CapsoCam SV system occurred in 4 cases (4/171: 2.3%): three capsules (1/137 SV1 and 2/35 SV2) had technical problems; in the remaining case the investigator damaged the capsule while handling it during the downloading process.

Transit and operating times

As far as transit and operative times, completion rate, and ampulla of Vater detection rate are concerned, 8 cases (including 4 patients with system failures and the 4 patients in

which the capsule was delivered in the small bowel under endoscopic assistance) were excluded from calculations.

Median GTT and SBTT were 30 minutes (IQR 14-66 min; range 1-1070 min) and 268 minutes (IQR 224-350 min; range 86-855 min), respectively. Overall, median CapsoCam SV operating time was 16.4 hours (IQR 14.2-17.7 hours; range 3.7-23.4 hours). Capsule excretion occurred after a median time of 36 hours (IQR 24-47 hours; range 7-120 hours) after ingestion.

Completion rate

The rate of complete enteroscopy was 90.2% (148/164). Incomplete enteroscopy occurred due to organic strictures: 3 cases; prolonged GTT (ie, >120 min[24]): 3 cases; capsules with short battery life (ie, < 7 hours): 2 cases; duodenal diverticulosis: 1 case; undefined reasons: 7 cases.

Detection rate of the ampulla of Vater

Among the 164 patients in whom technical parameters were calculated, 2 were eventually excluded because the capsule failed to pass the pylorus. The ampulla of Vater was clearly identified in 53 to 162 patients (32.7%) and recorded in a mean of 2.5 frames (range 1-29 frames), **Figure 5**.

Video records reliability

The CapsoCam SV video records reliability was adequate in 151 patients (151/152; 99%). The video reliability was comparable between the 2 capsule models: it was adequate in 119 out of 120 and 32 out of 32 patients receiving CapsoCam SV1 and CapsoCam SV2,

respectively (*P*=0.607). The video records reliability scores calculated for each small-bowel tertile and for the entire small-bowel video are reported in **Table 3**.

Safety profile

In 4 patients, the VCE was released under endoscopic assistance according to the history of gastric surgery or previous VCE affected by prolonged GTT. The remaining patients swallowed the capsule uneventfully. Capsule retention occurred in one patient (1/172: 0.58%) undergoing VCE for non-active OGIB. This patient did not develop obstruction. Because CapsoCam SV was visualized by abdominal radiograph examination 15 days after ingestion, the patients underwent CT, thereby showing a stricturing small-bowel mass. The capsule was retrieved at time of surgical intervention; the pathological evaluation of the resected specimen showed a neuroendocrine tumor. No additional incident or adverse events were reported.

DISCUSSION

This multicenter, observational study shows that both diagnostic and technical performance of CapsoCam SV are similar to that reported in studies where VCE is performed using forward-viewing capsules. To the best of our knowledge, this is the first study presenting a large consecutive patient-series, in a clinical practice setting, undergoing VCE with CapsoCam SV. It should be noted however that in patients with positive VCE, 25% of P2 lesions were located in the upper GI tract, whereas the distribution of P2 lesions along the small bowel was similar to that described in previous studies [25,26]. Although it is well known that upper GI lesions may be missed by conventional gastroscopy and identified at the time of VCE, the frequency reported in studies using forward-viewing cameras is lower than that observed in our study (range 4-

17%)[27,28]. Although selection bias is an issue, the brand-new image acquisition mode that CapsoCam SV offers (high frame rate cameras, located at the side of the capsule and covering a 360° angle) could have played a role in increasing the diagnostic yield of the capsule in the upper GI tract. The lateral-panoramic-view can potentially improve the visualisation of flat diminutive lesions, such as vascular findings, throughout the entire GI tract. However, as with frontal-viewing VCE, anterograde and retrograde movements may result in an overestimation of the number of lesions. Therefore, the exact number and location of vascular findings remains challenging even with the use of lateral-panoramic-view VCE.

In the present study, we have also calculated the ampulla of Vater detection rate. According to previous studies [7-10], the visualization of this landmark of the proximal small bowel is regarded as a surrogate marker of an adequate visualization of the proximal small bowel overall. Interestingly, in our study the ampulla of Vater was identified in 33% of patients. Although this is lower to the detection rate (71%) reported by Friedrich et al [17], it is still substantially higher to the rate observed in studies performed with frontal-view VCEs irrespectively of field of view, number of cameras and/or frame-rate [7-10]. Nevertheless, it should be noted that in our study, no central reading was performed and no specific instructions about ampulla of Vater reporting were provided. Whether further head-to-head large studies would confirm a higher detection rate of upper GI findings and a more effective inspection of the proximal small bowel with lateral-view capsules remains to be confirmed.

In addition, the completion rate was relevant (90.2%) and consistent with those reported by previous studies based on the use of CapsoCam SV [17,18]. The very long operating time of this new VCE system, coupled with low number of capsule retentions and relatively short mean GTT observed in our study may have contributed to achieve such an excellent

rate of complete small-bowel evaluation as compared to that usually reported with frontal-view capsules [13,29].

As the CapsoCam SV system has been recently developed and is characterized by brand-new technical features, we also focused our attention on technical issues. To this purpose, we developed the first dedicated scoring system aimed at assessing the overall reliability of the system in generating high-quality videos. In detail, counting the number of images that could not be analysed because of technical defects (ie, blurred images, gaps in the recording) over the total number of images for each tertile, we found that the video recording was unreliable in less than 1% of patients. The most relevant technical issue, reported in previous studies, was the rate of patients with technical failure; this requires repeat testing, thereby leading to an increase in costs and possibly to delayed diagnosis.

Although the technical failure rate observed in our study (2.3%) is considerably lower than that reported by Pioche et al (7%), it remains consistently high and similar to the technical problems rate (2.9%) occurring in the early phase (2001-2005) of the use of frontal-view capsules [30]. In the study by Pioche et al. [18], technical failures were mostly due to non-retrieved capsules, whereas in our study all patients except the one with capsule retention retrieved the capsule. Therefore, our data seem to suggest that capsule retrieval is no longer a problem, when patients are adequately informed. On the other hand, because of the strictly technical nature of the problems detected in our study, one might expect that they will be resolved in the near future through further system improvement.

As far as the safety of the system is concerned, only one case of (asymptomatic) capsule retention occurred and none of capsule aspiration. Notably, patients reported no discomfort in swallowing this 31 mm-length capsule device. This low adverse event rate confirms the safety profile of CapsoCam SV, as reported in previous studies [17,18]. Nevertheless, the retention that occurred in our study highlights that the absence of an

external recorder might be a significant limitation. Indeed, recent guidelines suggest that in case of capsule retention, capsule findings have a key role in driving further diagnostic and/or therapeutic work-up, especially when a clear diagnosis of small-bowel tumour (ulcerated, bleeding mass lesion, stenosis) is reached [1]. Given its peculiarities, CapsoCam SV might have either pros or cons in clinical practice (Supplementary table 4) when compared with standard frontal-view VCE systems.

Our study has some inherent limitations. Given the observational design, all results are merely descriptive, and because data of frontal-view capsule examinations performed in the study timeframe at the participating centers have not been systematically collected, we cannot perform any head-to-head comparison of lateral-view and standard frontal-view VCE systems. In addition, we restricted our data collection to two most common clinical indications for capsule endoscopy. It is possible that this approach generated a selection bias. However, there are several robust studies [31-33] reporting the performances of frontal-view capsule endoscopy for these 2 indications that we can reliably compare with. Furthermore, although the number of involved centers allowed for a large series of patients, the different expertise in capsule endoscopy, as well as the differences in facilities and local procedure protocols, might have influenced our results. Finally, no data were collected concerning reading time and interobserver agreement.

In conclusion, this first multicenter study conducted in routine clinical practice with the largest series of CapsoCam SV collected so far, confirms that VCE with 360° panoramic-view is safe and provides clinical and technical performances similar to those reported in the literature with frontal-view VCEs [17,18,31-33]. Our data also suggest that CapsoCam SV seems to be particularly effective in scoping some areas of the GI tract (ie, the proximal small bowel and the upper GI tract). After the ongoing technical improvements of

the CapsoCam SV system, larger studies, possibly with head-to head comparison with the most recently released frontal-view cameras, are warranted.

VIDEO LEGEND

Video 1. A 4 to 6 mm nonsteroidal anti-inflammatory drugs related ileal ulcer in 84-year-old man with occult obscure GI bleeding.

Video 2. Diffuse and severe portal hypertension enteropathy in 66-year-old man presenting for occult obscure GI bleeding in liver cirrhosis.

Video 3. Diffuse ulcerative enteritis in 55-year-old woman later diagnosed with Crohn's disease.

Video 4. Ulcerated non-bleeding mass of the proximal jejunum later diagnosed as adenocarcinoma in a 52-year-old man with iron deficiency anemia and history of obscure overt bleeding.

Video 5. Fresh blood in 83-year-old woman with recent overt obscure GI bleeding, further diagnosed as a bleeding angectasia.

Video 6. Large cecal angectasia hidden behind the ileo-cecal valve, in a 76-year-old woman with a severe iron deficiency anemia during anticoagulant therapy.

FIGURE LEGEND

Figure 1. The CapsoCam SV device.

Figure 2. Small-bowel lesions case series: A, edema, hyperemia and lymphangectasia of proximal jejunum. B, A 6 to 8 mm nonbleeding angectasia of the proximal jejunum. C,

Fresh blood and aphtous ulcers in the proximal ileum. D, Ulcerative enteritis of the ileum, later diagnosed as ischemic.

Figure 3. Upper GI lesions: A, diffuse and severe gastropathy related to portal hypertension; B, hyperemic duodenitis with one aphtous ulcer.

Figure 4. Different locations and types of lesions with high bleeding potential in patients with positive video capsule endoscopy.

Figure 5. A clear image depicting a native Vater's ampulla.

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Tables

Table 1

Capsule details	CapsoCam SV Capso-Vision
Lenght (mm)	31
Diameter (mm)	11
Weight (gr)	4
Battery life (h)	≥ 15
Field of view	360°
Depth of view (mm)	0-20
Frame rate per second	12-20 (3-5 per camera)
Resolution (pixel)	896X128
EMA-certified / FDA-approved	Yes / Yes

Capsule specifications referring to both the CapsoCam SV1 model.

Table 2

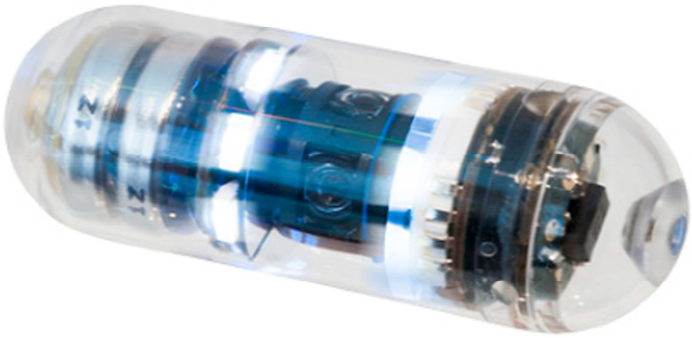
CapsoCam SV Video-Capsule Endoscopy	Patients	Positive Tests (%)
All indications	**172**	**69 (40%)**
o **Obscure GI Bleeding (OGIB)**	**142**	**60 (42%)**
Non-Active Overt OGIB	32	14 (44%)
Occult OGIB	110	46 (42%)
o **Crohn's Disease**	**30**	**9 (30%)**

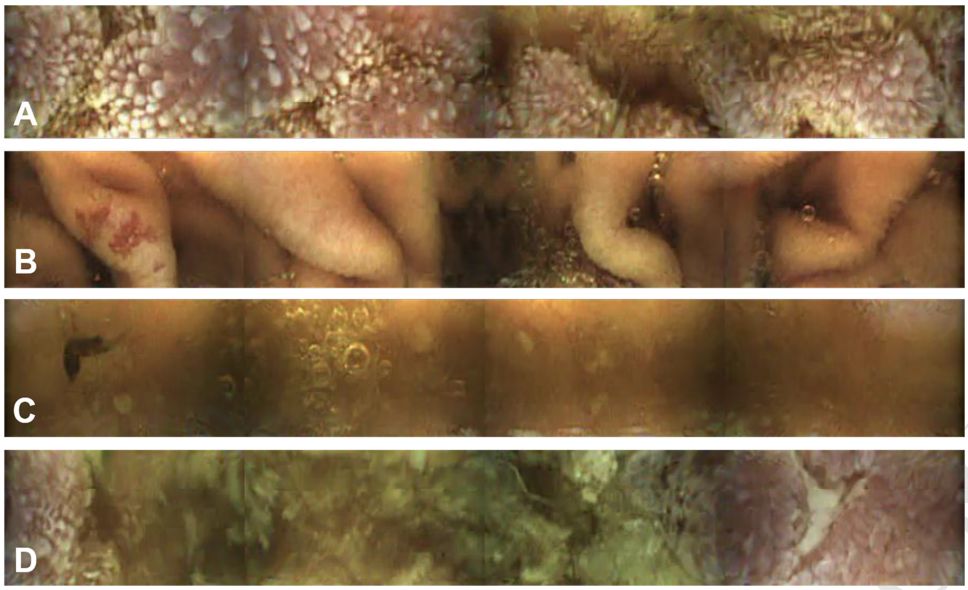
Consecutive small-bowel video capsule endoscopy indications and diagnostic yields according to the intention-to-treat analysis.

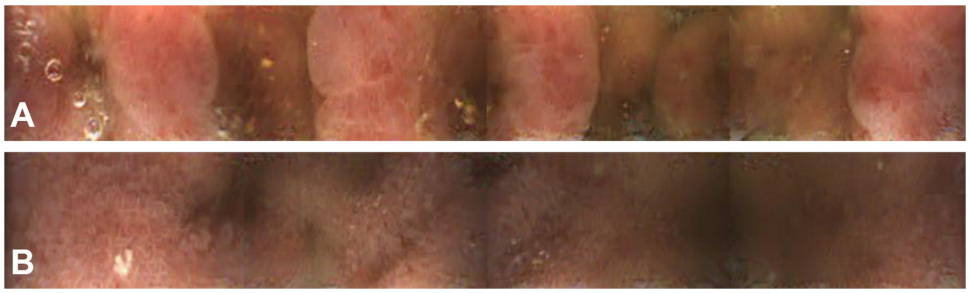
Table 3

GI tract	Small Bowel Mucosal Visibility			
	Excellent	Good	Fair	Poor
Proximal tertile	125/152 (82%)	21/152 (14%)	4/152 (3%)	2/152 (1%)
Middle tertile	101/152 (66%)	44/152 (29%)	5/152 (3%)	2/152 (1%)
Distal tertile	69/152 (45%)	63/152 (41%)	17/152 (11%)	3/152 (2%)
Entire small bowel	Adequate in 127/152 (84%)			
	Small-Bowel Capsule Endoscopy Video Recording Reliability			
	Excellent	Good	Fair	Poor
Proximal tertile	140/152 (92%)	12/152 (8%)	0	0
Middle tertile	140/152 (92%)	11/152 (7%)	1/152 (1%)	0
Distal tertile	141/152 (93%)	11/152 (7%)	0	0
Entire small bowel	Adequate in 151/152 (99%)			

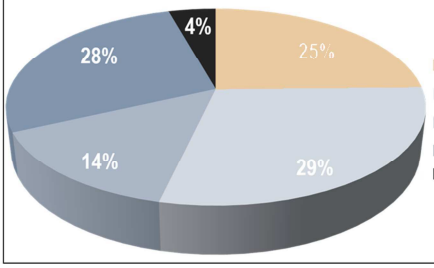
Small-bowel mucosal visibility and video recording reliability in complete video-capsule endoscopy with 360°panoramic-view.



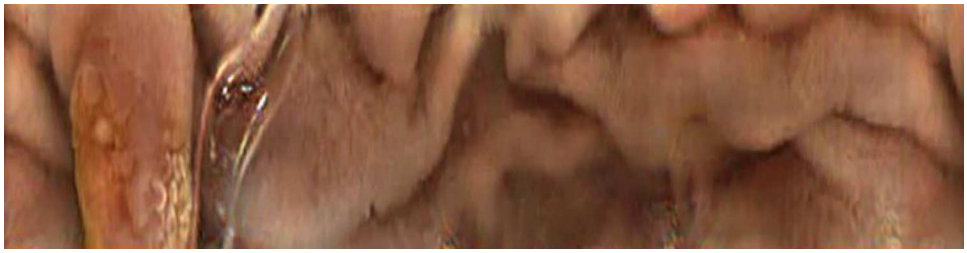




Lesions location and type



	Vascular	Inflammatory	Mass
Upper GI	41%	59%	0
Proximal SB tertile	55%	20%	25%
Middle SB tertile	80%	20%	0
Distal SB tertile	26%	63%	11%
Lower GI	100%	0	0
Entire GI tract	49%	41%	10%



Supplementary Materials

Supplementary table 1

Small-Bowel Mucosal Visibility Scoring System	
Step 1	Divide the entire small-bowel length into 3 standard small bowel tertiles (ie, proximal, middle, and distal) according to the entire small-bowel transit time.
Step 2	Assigns a score ranging from 0 to 3 points to each small-bowel tertile depending on the relative amount of video-recording during which any kind of residue (including air bubbles and dark liquids) affects the correct visualization of at least 50% of mucosal surface: • 3 points – excellent: when the mucosal visualization is affected for less than 5% of each small-bowel tertile video-recording. • 2 points – good: when the mucosal visualization is affected for ≥5 to <15% of each small-bowel tertile video-recording. • 1 point – fair: when the mucosal visualization is affected for ≥15 to <25% of each small-bowel tertile video-recording. • 0 points – poor: when the mucosal visualization is affected for more than 25% of each small-bowel tertile video-recording.

The small bowel mucosal visibility of the entire video-capsule endoscopy was defined as "inadequate" when at least one tertile was scored as poor or fair; otherwise, it was considered as "adequate." Incomplete enteroscopic examinations were excluded from the assessment of the small-bowel mucosal visibility.

Supplementary table 2

Small-Bowel Capsule Endoscopy Video-Record Reliability Scoring System	
Step 1	Divide the entire small-bowel length into 3 standard small bowel tertiles (ie, proximal, middle, and distal) according to the entire small-bowel transit time.
Step 2	Assigns a score ranging from 0 to 3 points to each small-bowel tertile depending on the relative amount of frames, which were not clearly evaluable for clinical purposes (ie, blurred image, image entirely grey or dark): • 3 points – excellent: when less than 5 total frames and no consecutive non-evaluable frames were observed. • 2 points – good: when ≥5 to <10 total frames or one sequence with <5 consecutive non-evaluable frames were observed. • 1 point – fair: when ≥10 to <15 total frames, or one sequence with <10 consecutive non-evaluable frames were observed. • 0 points – poor: when ≥15 total frames, or multiple sequences, or one sequence with ≥10 consecutive non-evaluable frames were observed.

The small-bowel capsule endoscopy video-record reliability was defined as "inadequate" when at least one tertile was scored as poor or fair; otherwise, it was considered as "adequate." Incomplete enteroscopic examinations were excluded from the assessment of the small-bowel capsule endoscopy video-record reliability.

Supplementary table 3

	Diagnostic yield			*P* value*
	First 10 VCEs (group A)	Over the first 10 VCEs (group B)	All VCEs	
Investigator 1	40% (4/10)	32% (13/41)	33%	0.71
Investigator 2	70% (7/10)	23% (6/26)	36%	0.02
Investigator 3	40% (4/10)	70% (7/10)	55%	0.36
Investigator 4	50% (5/10)	60% (6/10)	55%	1.0
All investigators	50% (20/40)	37% (32/87)	41%	0.17

**P value calculated by two-tailed Fisher exact test comparing the diagnostic yield in the group A and in the group B*

VCE: videocapsule enteroscopy.

Supplementary table 4

CapsoCam SV peculiarities	Pros & Cons
Four high-frame rate cameras resulting in a lateral panoramic view	**PROS:** potential to detect more lesions, landmarks, frames per landmark/lesion, especially in the proximal small bowel, upper/lower GI. **CONS:** time consuming (additional reading time: 5.8 min on average [18]); difficult differentiation between masses and bulges and possible difficulties in strictures' detection; difficult reading in patients with poor bowel preparation.
Very long battery life (16.4 ± 3.4 hours)	**PROS:** high completion rate (90.5%) without the need of real time control or remotely record suspension; suitable for panenteric endoscopy in Crohn's disease. **CONS**: potentially longer reading time
Wire-free technology (ie, on-board data storage)	**PROS:** safe and effective in patients with electronic implants; no record problem in obese patients; ready for use at the bedside without the need of any computerized support/initialization; increased outpatient comfort. **CONS:** need of capsule retrieval; absence of real time view and external recorder might result in diagnostic delay in patients with ongoing overt bleeding or capsule retention.

Acronyms' List

VCE:	video-capsule endoscopy
IQR:	interquartile range
CD:	Crohn's disease
OGIB:	obscure gastro-intestinal bleeding
DY:	diagnostic yield
GGT:	gastric transit time
SBTT:	small bowel transit time