

Which model of small bowel capsule endoscopy has a better diagnostic yield? A systematic review and meta-analysis

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Abstract

Background and study aims: Small-bowel capsule endoscopy (SBCE) is a safe and efficient method for diagnosis of small-bowel diseases. Since its development, different models have appeared. The aim of this study was to analyze which of the different models of SBCE has the best diagnostic yield.

Patients and methods: Extensive medical literature research was reviewed, using MESH terms, searching studies comparing different SBCE types. We analyzed the diagnostic yield of all the comparisons and when there were 2 or more studies that compared the same model of SBCEs, a meta-analysis was performed.

Results: Ten eligible studies including 1065 SBCEs procedures were identified. The main indication was occult gastrointestinal bleeding in 9/10 studies. Two of them included anemia, chronic diarrhea and/or chronic abdominal pain. The indication in one article was celiac disease. In 9 studies, different types of SBCEs (MiroCam, Endocapsule, OMOM and CapsoCam) were compared with PillCam (SB, SB2 and SB3). Three studies compared MiroCam vs PillCam and CapsoCam vs PillCam, while two studies contrast Endocapsule vs PillCam. None of the SBCEs show superiority over PillCam [OR 0.78 (95%CI;0.60-1.01)]. One study compared SBCEs other than PillCam (MiroCam vs Endocapsule). Nine studies did not find statistical differences between SBCEs, one showed better diagnostic yield of Mirocam compared with PillCam SB3 ($p=0.02$). The difference between these SBCE was not replayed in the meta-analysis [OR 0.77 (95%CI;0.49-1.21)].

Conclusions: Despite the appearance of new SBCE models, there are no differences in diagnostic yield; therefore, SBCE endoscopist's performance should be based on experience and availability. (*Acta gastroenterol. belg.*, 2022, 85, 1-9).

Keywords : Small bowel, capsule endoscopy, occult gastrointestinal bleeding.

Introduction

In 1997, two groups of entrepreneurs from Israel and London, that independently had initiated small bowel capsule endoscopy (SBCE) development, joined forces for its creation (1,2). This allowed the first publication on SBCE in *Nature* journal in 2001 (3). Since then, the SBCE has evolved, with technological advances, achieving higher quality imaging, extended battery life and growing intelligence in pathology recognition software (4). SBCE has become the first-line endoscopic study for the small-bowel, increasing the number of indications and being the gold standard in some of them (5). At the present time, different models of SBCE are commercially available, but only 5 are involved in head-to-head comparisons. These are: PillCamâ SB, SB2 and SB3 (Given Imaging Ltd, Yoqneam, Israel),

Endocapsuleâ (Olympus, Tokyo, Japan), MiroCamâ (Intromedic Ltd, Seoul, Korea), OMOMâ (Jinshan Science and Technology Co Ltd, Chongqing, China) and CapsoCamâ CV2 and Plus (Capsovision Inc., California, USA) (1,6,7) (Table 1).

PillCam SB

Given Imaging Limited was established in 1998, and with the effort and union of the two pioneering groups, they managed to develop the first SBCE, known as M2A capsule (8). Later, the M2A capsule was renamed PillCam SB. The size of the PillCam SB is the same as the second and third generation capsules (11 mm x 26 mm). PillCam SB can takes 2 frames per second and has a 140° field view, with a battery life of 8 hours (9). The second-generation capsule, named PillCam SB2, takes the same frames per second as the PillCam SB, but provides a larger field of vision (156°), automatic light control and a new lens that resulted in better visualization of the mucosa. Years later, a new second-generation capsule, called SB2-ex, extended battery life of the capsule to 12 hours (10). PillCam SB3, the third-generation capsule, has a greater image resolution and an adaptative frame rate technology that increases the frame rate from 2 to 6 frames per second when the capsule is moving faster (11). The RAPID[®] SBCE reading software used by Given, develops technical features to make SBCE video analysis easier and quicker. The first software feature designed was the Suspected Blood Indicator (SBI), which is an image selection feature that detects video frames with red pixels that possibly represent areas of hemorrhage in the gastrointestinal tract. Other software additional tools introduced were the QuickView and the electronic chromo-endoscopy (1,12). The usefulness of these software tools is controversial (13,14). The PillCam software v9 is the latest generation software and includes new tools, such as the Top 100, which is an improved

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Table 1. — Specifications of the latest current generations of small bowel capsule endoscopy systems

Capsule Endoscopy	PillCam SB3	Endocapsule 10	MiroCam MC 1600	OMOM HD	CapsoCam Plus
Manufacturer	Medtronic	Olympus	IntroMedic	Jinshan Science and Technology	CapsoVision
Length (mm)	26.2	26	24	25.4	31
Diameter (mm)	11.4	11	11	11	11
Weight (g)	3	3.3	3.2	3	4
Frames per second	2-6	2	6	2-10	12-20
LEDs	4	4	6	4	16
Field of View (degree)	156	160	170	172	360
Battery life (h)	12	12	12	12	15
Transmission	Radiofrequency	Radiofrequency	Human Body Communication	Radiofrequency	Onboard Storage System
Software	PillCam Software v9	Endocapsule Software 10	MiroView 4.0 Software	Vue Smart Software	CapsoView

map and atlas, including a faster read time compared with other versions.

Endocapsule

The Olympus capsule endoscope named Endocapsule EC type 1, was first reported in 2006 (15). The second-generation and actual generation of SBCE is the Endocapsule 10, which has a new sensor with a wider angle of view (160°), better image quality, and longer battery life (minimum 12 hours) compared to its predecessor (16). The dimensions of the Endocapsule 10 are 11 mm (diameter) × 26 mm (length) and a weight of 3.3 g. The Endocapsule 10 System provides functions such as a 3D Track and the Omni Mode, that reduces the amount of time spent on the reading process by an average of 40%, without reduction in clinical accuracy (17).

MiroCam

Intromedic first reported MiroCam CE in 2009. Unlike other SBCEs that uses radiofrequency transmission, these use electric-field propagation, where the human body acts as a conductive medium for data transmission (18). MiroCam has a 170° field view with an operation time of up to 12 hours, with a frame rate of 3 or 6 frames per second depending on the model (MC 1200 or MC 1600, respectively). One of the software tools to enhance the characterization, called Express-View, reduces SBCE reading time by suppressing repetitive small-bowel images, with good accuracy results (19).

OMOM

OMOM SBCE belongs to Jinshan Science & Technology and has developed three generations of SBCE.

OMOM SBCE has evolved from a size of 13 × 27.9 mm with a field view of 140° and 2 frames per second in its first-generation (20), to a size of 11 × 25.4 mm, a 172° field view and a 2 to 10 frame rate per second in the OMOM HD, which is the third-generation capsule. This SBCE improved its resolution to a 512 × 512 Pixel image.

CapsoCam

CapsoCam from Capsovision, is a different SBCE compared to the previous ones. It consists of four cameras that face the side of the capsule. Each camera can take from 5 frames per second in the first 2 hours, to 3 frames per second in the rest of the study, with a battery life of 15 hours. The captured images are stored on a microchip, making the system truly wire-free. Finally, the capsule is open and placed in a Docking Station to download examination data to a standard PC workstation (21). Three generations have been developed SV-1, SV-2 and Plus.

The aim of this meta-analysis was to compare the diagnostic yield of the different SBCEs available nowadays.

Material and methods

a. – Literature search strategy

A search was performed in the Cochrane Central Register of Controlled Trials, Pubmed/Medline, EMBASE and Scopus databases to identified studies published until November 2021. With the intention to capture as many articles as possible, a broad search strategy was employed, using the MeSH term ‘capsule endoscopy’ added to a simple search string, with the

following term precede by “AND”. The terms we used were: ‘comparison’, ‘versus’, ‘head-to-head’, ‘against’, ‘contrast’, ‘match’, ‘measure’ and ‘sequential’. A search was also done with each name of the models of SBCE.

b. – Selection criteria

The conditions to include the articles in this meta-analysis were the following:

- published as full articles (prospective or retrospective)
- comparing two or more models of SBCE from different trademarks.
- following data was explained: how SBCE were administered, indications, number of patients, same or different patients, diagnostic yield with each SBCE.
- administration of SBCE only when small bowel pathology was suspected

The studies that compared different generations of the same CE were excluded from the meta-analysis.

c. – Statistical analysis

An analysis was performed only when there were two or more articles that compared different models of SBCE regardless of their generation. The weight, odds ratio and the 95% confidence intervals were calculated by using the fixed-effects model with the Mantel-Haenszel method. Inconsistency index (I^2) and chi-square (X^2) test were assessed for heterogeneity. Forest plot graphical displays were constructed for visualization of odds ratios between selected studies. Data synthesis was performed using the program Cochrane Review Manager software (RevMan 5.0).

Results

A total of 18 studies were identified. Seven of them were excluded because they compared different generations of the same CE. In 6 studies the comparison was between PillCam SB2 and PillCam SB3, and in another article, PillCam SB2 was compared to PillCamSB2-ex. In other study, Mirocam was compared with Pillcam SB, but the aim of this study was to evaluate the abilities of both SBCE to detect Z-line and duodenal papillae, so it was also excluded (Fig. 1). Therefore, 10 articles that included 1065 CEs ingested by 609 patients, met the inclusion and exclusion criteria, and entered this meta-analysis (Table 2). The indication was only occult gastrointestinal bleeding (OGIB) in 7 studies, in 2 articles in addition to OGIB, patients with other indications were included (anemia, chronic diarrhea or chronic abdominal pain), and in only one study, the indication for the SBCE procedure was celiac disease. In 9 studies, some generation of Pillcam SBCE (SB, SB2 or SB3) was compared to another SBCE (Fig. 2). Only one study compared SBCEs other than Pillcam, MiroCam vs Endocapsule. In 9 studies, a head-to-head comparison

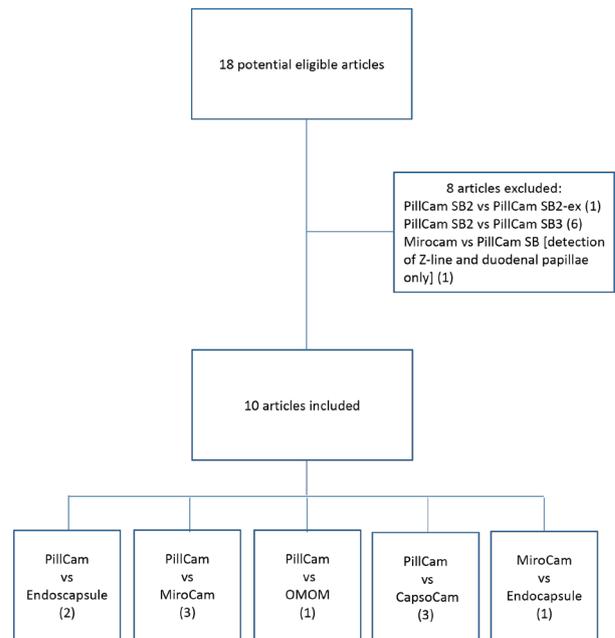


Figure 1. — Flow diagram of the eligible studies and the selection process of this review and meta-analysis.

was done using SBCE in the same patient, but one study, comparing PillCam SB3 vs CapsoCam included different groups of patients who ingested one of the two SBCE.

PillCam vs Endocapsule

Two studies compared these SBCE. Both were a prospective head-to-head comparison that included 40 and 51 patients that ingested the two SBCEs (PillCam SB and Endocapsule) (22,23). In both studies the Endocapsule SBCE identified more lesions (26 vs 29 and 17 vs 24 lesions, respectively) without a statistical difference. In the meta-analysis of both studies, there was no evidence of heterogeneity between the studies ($I^2=0\%$; $P=0.72$) and the pooled OR was 0.62 [95%CI; 0.33-1.14].

PillCam vs MiroCam

Three studies analyzed the diagnostic yield of either PillCam SB or PillCam SB2 vs Mirocam. The first one, realized by Kim et al. (24), included 24 patients that randomly swallowed both capsules. The rate of complete examination of the small bowel was higher with MiroCam (83.3% vs 58.3%; $p=0.031$), but the diagnostic yields were similar (MiroCam 45.8% vs PillCam SB 41.7%; $p>0.05$). A second study compared MiroCam and PillCam SB2 in 73 patients. Each patient ingested the 2 SBCE at 1-hour interval in a random order. A positive diagnosis was found in 46.6% of the cases using PillCam SB2 and in 56.2% with MiroCam. In patients with both SBCE films available MiroCam identified 95.2% of the positive cases, while PillCam SB2 did it in 78.6% ($p=0.02$) (25). The last study also compared MiroCam and PillCam SB2

Table 2. — Study characteristics

Authors (year)	Country	Study type	Centre	# Patients included (Ingested CE)	CE compared	Evaluated Outcomes	Outcomes	Significant difference between CE?
Hartmann et al. (2007) ³⁰	Germany	Prospective	Single center	40 (80)	PSB & EC	-Lesion detection in OGIB (Saurin's classification). -Recording time. -Complete SB examination.	-Lesion Detection: PSB: P2 55% EC: P2 52.5% PSB: P1 86.8% EC: P1 87% -Recording time: PSB: 471 +/- 27 min EC: 591 +/- 52 min -Complete SB evaluation: PSB: 82.5% EC: 100%	No
Cave et al. (2008) ³¹	USA	Prospective	Multicenter	51 (102)	PSB & EC	-Agreement proportion between normal and abnormal studies for both CE systems in OGIB patients. -SB Transit time. -Reading time. -Image quality.	-Overall agreement 74.5%, k 0.48 -SB transit time: PSB 3.93 hours EC: 4.32 hours -Reading time: PSB: 48.9 min EC: 47.0 min -Subjective image quality favors EC	No
Kim et al. (2010) ³²	Korea	Prospective	Single center	24 (48)	PSB & MC	-Diagnostic yield in patients with SB diseases (OGIB, chronic abdominal pain and chronic diarrhea). -Agreement rate. -Complete SB examination. -Operational time.	-Diagnostic yield: PSB: 45.8% MC: 41.7% -Agreement rate: 87.5%, k 0.74 -Complete SB examination: PSB: 58.3% MC: 83.3% -Operational time: PSB: 11 h, 44 min MC: 7 h, 26 min	-Higher rates of complete SB examination for MC (p<0.031) -Longer operation time favors MC (p<0.001)
Pioche et al. (2011) ³³	France	Prospective	Multicenter	73 (146)	PSB2&MC	-Diagnostic yield in OGIB. -SB Transit time. -Reading time. -Quality image.	-Diagnostic yield: PSB2: 78.6% MC: 95.2% -Transit time: PSB2: 234.5 min MC: 268.1 min -Reading time: PSB2: 25.4 min MC: 40.3 min	-Higher diagnostic yield for MC in detection of positive CE (p<0.02) -Lower SB transit & reading times favors PSB2 (p<0.05)
Dolak et al. (2012) ³⁴	Austria	Prospective	Single center	50 (50)	MC&EC2	-Diagnostic yield in patients with SB diseases (OGIB, chronic diarrhea and anemia). -Agreement rate. -Complete SB examination. -SB Transit time.	-Diagnostic Yield MC: 50% EC: 48% -Agreement rate: 68%, k 0.50 -Complete SB examination MC: 96% EC2: 90% -SB Transit Time MC: 319 min EC2 316 min	No

Choi et al. (2013) ³⁴	USA	Prospective	Multicenter	89 (178)	PSB & MC	-Agreement rate in OGIB. -Complete SB examination. -Operational times.	-Agreement rate: 78.7%, k 0.55 -Complete examination: PSB: 84.3 MC: 93.3% -Capture time: PSB: 7.8 hours MC: 11.1 hours	-Longer capture time for MC (p<0.001)
Pioche et al. (2014) ³⁵	France	Prospective	Multicenter	60 (120)	PSB2& CCSV1	-Diagnostic agreement in patients with OGIB. -Diagnostic yield. -Image quality.	-Agreement rate: k 0.63 -Diagnostic yield: PSB2: 48.3% CCSV1: 46.7% -Image quality: Similar for both systems	No
Zwinger et al. (2018) ³⁶	Germany	Prospective	Multicenter	153 (153)	PSB3 & CCSV1	-Diagnostic yield in OGIB. -Transit time -Reading time. -Adverse events.	-Diagnostic yield in SBB PSB3 34.6% CCSV1 39.7% -Transit time PSB3:256 min CCSV1 : 244 min -Reading time PSB3 27 min CCSV1 40 min -Adverse events PSB3 1.3% min CCSV1 0% min	No
Blanco et al. (2020) ⁷	Mexico	Prospective	Single centre	44 (88)	PSB3 & OMOM2	-Diagnostic yield OGIB. -Agreement rate. -Battery time. -Download time.	-Diagnostic yield: PSB3:88.6% OMOM2:77.3% -Agreement rate: k 0.62 -Battery time: PSB3 700.5 min OMOM2 816.5 min -Download time: PSB3 132 min. OMOM2 33 min.	-Longer battery time for PSB3 (p<0.001) -Shorter download time for OMOM2 (p<0.001)
Branchi et al. (2020) ³⁷	Italy	Prospective	Single centre	25 (50)	PSB3 & CCPlus	- Diagnostic yield in Celiac disease.	- Diagnostic yield in Celiac disease: PSB3 : 52% CCPlus:65%	No

CCSV1: CapsoCam SV-1; CCPlus: Capsocam Plus; EC: Endocapsule; EC2: Endocapsule 2; OGIB: obscure gastrointestinal bleeding; MC: MiroCam; PSB: PillCam SB; PSB2: PillCam SB2; PSB3: PillCam SB3; SB: small bowel, Saurin Classification: P0 no bleeding potential, P1 uncertain bleeding potential, P2 high bleeding potential.

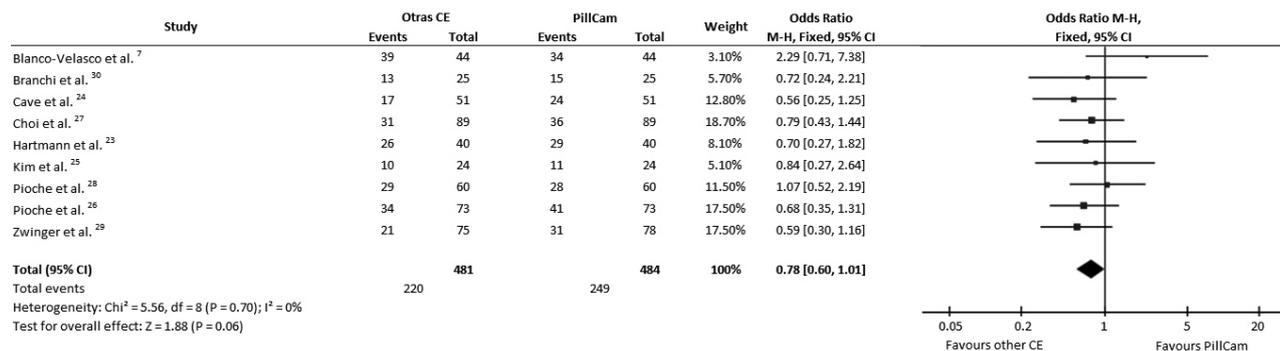


Figure 2. — Forest plot comparing Pillcam versus other small bowel capsules endoscopy.

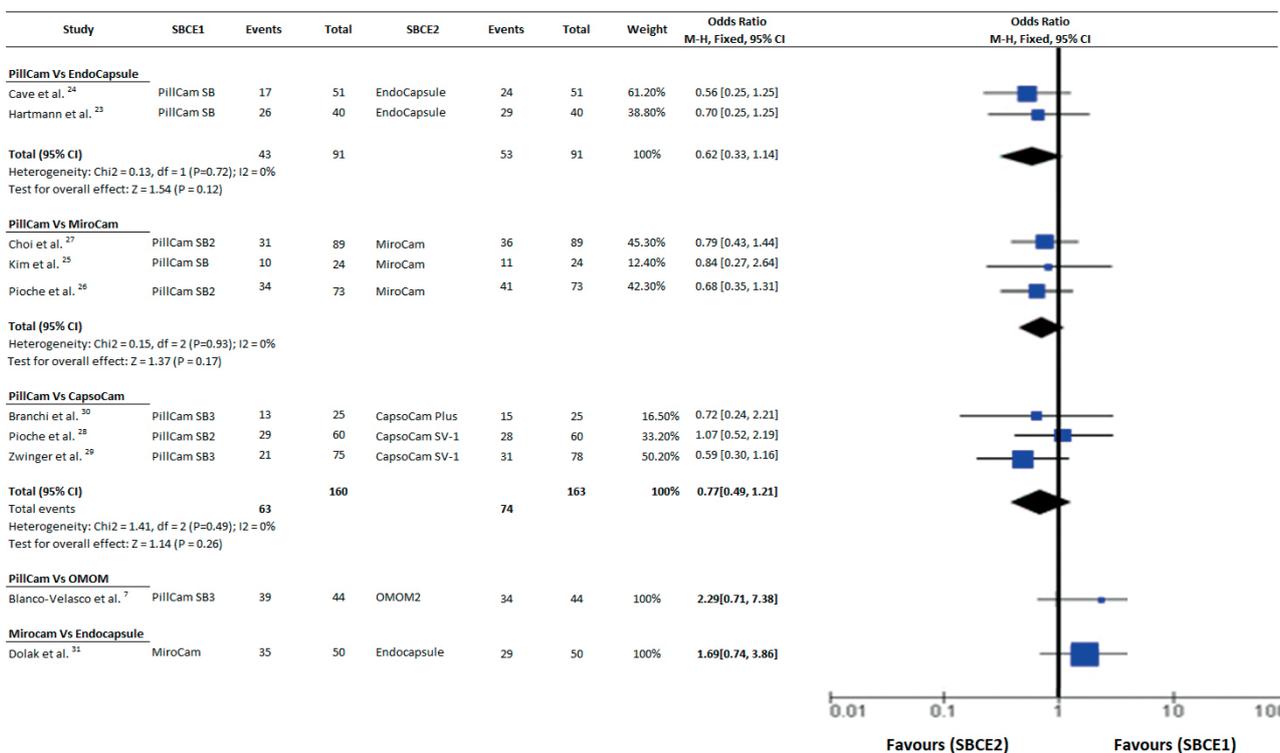


Figure 3. — Forest plot comparing different types of small bowel capsule endoscopy.

in 89 patients, who randomly swallowed both SBCEs with an interval of 30 minutes. MiroCam found abnormal results in the SBCE in 36 patients and PillCam SB2 in 31, without statistical difference (26). The meta-analysis of the three studies together did not show a preference for either of the models, with a pooled OR of 0.75 [CI 95%; 0.49-1.13]. Neither was their heterogeneity between studies (I²=0%; p=0.17).

PillCam vs OMOM

There was only one study that compared PillCam SB3 vs OMOM2 in 44 patients with suspected small bowel bleeding. The cause of bleeding was identified in 88.6% with Pillcam SB3 and in 77.3% with OMOM2, without a statistical difference. In this study, all the patients ingested

both SBCEs randomly with a 24 hour-interval, due to the radiofrequency interference found with the SBCEs (7).

PillCam vs CapsoCam

Three studies analyzed the diagnostic yield between PillCam and CapsoCam. The first one compared PillCam SB2 and CapsoCam SV-1 in 60 patients that ingested the two SBCEs, with one hour between and in a randomized order. Both SBCEs show a comparable efficacy; CapsoCam made a diagnosis in 46.7% of the SBCE and PillCam SB2 in 48.3% (6). A second study evaluated PillCam SB3 vs CapsoCam SV-1 in different patients. A total of 75 patients ingested PillCam SB3 and 78 CapsoCam SV-1. CapsoCam detected more lesions than PillCam SB3 (31 vs 26) without a statistical difference

(27). The last study that compared these SBCEs included 25 patients that randomly ingested, in an interval of 3 hours, a PillCam SB3 and a Capsocam Plus. The results show that the axial view system found positive findings in 13 cases and the lateral/panoramic view system in 15 SBCE, which was not statistically significant (28). The final analysis showed no differences in diagnostic yield favoring a specific SBCE: pooled OR of 0.77 [95%CI; 0.49-1.21]. There was no heterogeneity between the studies ($I^2=0\%$; $p=0.26$).

Endocapsule vs MiroCam

The only study that did not compare a PillCam SBCE included 50 patients that swallowed, in an interval of 2 hours, a MiroCam SBCE and an Endocapsule SBCE. The diagnostic yield in the small bowel with the MiroCam was done in 25 SBCE and in 24 with the Endocapsule, although the MiroCam device had a video recording time 2 hours longer (29). No differences in diagnostic yield between both was found [OR 1.69(95%CI;0.74-3.86)]

Discussion

Capsule endoscopy has become an important tool for the study of the gastrointestinal tract beyond the small bowel, finding utility also in the esophagus, stomach, and colon (30). Its excellent results have encouraged the creation and improvement of the SBCE, with evident differences between models and trademarks (31). For this reason, comparison between them has been an important issue. In this meta-analysis we did not find differences in diagnostic yield among the different SBCEs (Fig 3).

Because PillCam was the first created SBCE, it has been considered as the gold standard up to now and has been the object of multiple comparisons with others SBCEs. The differences with the second developed SBCE, Endocapsule, are minimal and are observed mainly in the reading software. Endocapsule was compared with PillCam SB in two studies included in this review. In both, Endocapsule showed a higher diagnostic yield than PillCam, but without reaching a statistically significant difference. The potential advantages that the first-generation Olympus SBCE had over PillCam's first generation were a higher field of view (145° vs 140°) and a longer battery life (10 h vs 8 h) (1,23). However, these technical differences were not significant in the clinical scenario.

MiroCam SBCE presents important changes compared to the first generations of PillCam. It uses an electric-field propagation, has a wider field view (170°), a longer battery life (12 hours) and can take 3 frames per second (32). Of the studies analyzed in this revision, only the study of Pioche et al. showed a statistically significant difference favoring MiroCam over PillCam SB2(26), identify more of the positive cases observed with both CE (95.2% vs 78.6%; $p=0.02$). However, no statistical difference was found in the diagnostic yield of SBCEs

in patients with OGIB, although a higher case detection was observed with MiroCam (56.2% vs 46.6%). This difference may be due, according to the authors, to the fact that the small bowel transit time of MiroCam was inexplicably longer (268.1 minutes vs 234.5 minutes), and that it takes more frames per second than the PillCam SB2. In the other two articles that compared MiroCam against PillCam SB and SB2, no statistical differences were found in the diagnostic yield, although MiroCam detected a greater number of lesions as well. We can conclude that despite improvements in technical aspects presented by MiroCam, compared to PillCam, these were also not translated in a better diagnostic yield.

Only one study compared PillCam SB3 vs OMOM2. Apparently PillCam's SBCE would have an advantage due to its ability to take 2 to 6 frames per second compared to OMOM2's 2 frames per second and its longer battery life (12 h vs 10 h) (33). But nevertheless, no statistically significant differences in the diagnostic yield were found, despite the greater lesion detection in the PillCam group.

Capsocam is a revolutionary SBCE that unlike the others, allows a 360° field view thanks to its 4 cameras (21). It has also been compared against PillCam SB3 with different results in the diagnostic yield of lesions favoring each SBCE, but without statistically significant difference in favor of either of the two SBCEs. It seems that changing from axial to lateral view does not increase the diagnostic yield, despite having a panoramic view of the small bowel. One possible disadvantage of the Capsocam is that the patient must recover the capsule, and if it is lost or retained, the images will not be accessible to the endoscopist. This problem was found in the three studies that compared Capsocam.

Finally, the only study that compared SBCEs other than PillCam included Endocapsule and MiroCam without finding statistical differences in the diagnostic yield between them.

Although safety was a variable that was not analyzed in this study, complications associated with SBCE were identified in none of the articles analyzed, except for few technical problems that did not affect the diagnostic yield of the SBCEs.

The present study has some limitations. Like in other meta-analysis, the conclusions are related with the available evidence. Some of the articles included have a low population, probably due to the high costs of using two SBCEs in one patient. Although most of the studies used small bowel bleeding as their main indication, few articles included other indications, causing a variation in the diagnostic yield. Also, not all the studies tested SBCEs in the same patients. However, this is the first meta-analysis that directly compares different SBCEs and, as we can observe, no superiority was found in the diagnostic yield between the SBCEs analyzed. We think that despite the improvements in technical features since the first SBCE was created, this could not be considered as the main factor of success (increasing diagnostic yield). This can be explained because of the complex

pathology and endoscopic access to the small bowel and probably to other important factors such as the operator's experience and the inherent patient's specific conditions. It will be important to evaluate the technical advances that the different SBCEs and their software may present in the future, mainly the use of artificial intelligence that could increase their diagnostic yield, making one brand superior to another.

In conclusion, because no superiority in diagnostic yield was observed with the available SBCEs, we suggest that the rational use of a specific SBCE should be based on the operator's experience, cost, and availability. However, as technology is evolving, further studies should be performed to clarify if new generations of SBCEs could increase diagnostic yield of small bowel pathologies.

Author Contributions

Gerardo Blanco-Velasco: Substantial contributions to the conception, acquisition, analysis, or interpretation of data for the work

Oscar Victor Hernández-Mondragón: Substantial contributions to the conception and acquisition of data for the work and final approval of the version to be published

Omar Michel Solórzano-Pineda: Substantial contributions to the analysis, or interpretation of data for the work

Luis Fernando García-Contreras: Substantial contributions to the analysis, or interpretation of data for the work

Claudia Martínez-Camacho: Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Enrique Murcio-Pérez: Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Competing interests

Gerardo Blanco-Velasco, Omar M Solórzano-Pineda, and Oscar V Hernández-Mondragón were the authors of two studies included in this review [7,10]. Gerardo Blanco-Velasco is a speaker for Medtronic. The remaining authors have no conflicts of interest to declare. The authors have no financial relationships relevant to this article to disclose.

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