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Original Article

Comparative Study of MiroCam MC2000 and PillCam SB3 in Detecting Small Bowel Bleeding: A Multicenter Prospective Randomized Crossover Study

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Background/Aims: The MiroCam MC2000 (MC2000) is a double-tip capsule with a camera on each side. It is designed to provide more extensive visualization of the small bowel mucosa, potentially reducing the chance of missing lesions. This study aimed to compare the detection rates for lesions in the ampulla of Vater (AoV) and the small bowel of the MC2000 and the PillCam SB3 (SB3) for patients with suspected small bowel bleeding.

Methods: This prospective, multicenter, randomized crossover trial compared the lesion detection capabilities of the MC2000 and SB3 capsules, ingested one hour apart by patients with suspected small bowel bleeding. The primary outcome was the detection of lesions in the AoV, while the secondary outcome was the assessment of the detection of P1 and P2 lesions, known underlying causes of small bowel bleeding.

Results: There was no significant difference in AoV lesion detection rates between the devices. However, MC2000 demonstrated significantly greater detection of red spots in patients with visible bleeding (p=0.018) and tended to detect a greater number of small bowel lesions, including P2 lesions. Minor complications included device stasis, with fewer incidents with the MC2000 than with the SB3, and one instance of small bowel retention due to ulcers.

Conclusions: The MC2000's dual-camera system appears to enhance the detection of small bowel lesions over the SB3, especially for more important lesions. These findings suggest that the MC2000 may offer superior diagnostic capabilities for patients with suspected small bowel bleeding, potentially leading to better clinical outcomes (this trial registered KCT0005591). **(Gut Liver, 2025;19:569-578)**

Key Words: Capsule endoscopy; Obscure gastrointestinal bleeding; Ampulla of Vater; Angioectasia; Diverticulum

INTRODUCTION

Historically, diseases of the small bowel were considered rare; however, the prevalence of conditions such as Crohn's disease and small bowel tumors has significantly increased.[1-8] Additionally, the aging population has experienced an increase in antiplatelet and anti-inflammatory drug use for conditions such as cerebral infarction, ischemic heart disease, and degenerative arthritis, thereby increasing the risk of gastrointestinal (GI) bleeding of uncertain origin.[9-11]

With the advancement of capsule endoscopy, comprehensive visualization of the entire small bowel through endoscopic images has become feasible.[11,12] This innovative technique has emerged as a valuable tool for diagnosing and monitoring various conditions affecting the small

bowel, including hereditary GI polyposis, Crohn's disease, small bowel tumors, and ailments in patients experiencing unexplained bleeding, chronic iron deficiency anemia, abdominal pain, or unexplained weight loss.[13,14] However, capsule endoscopes (CE) traverse the intestine passively, potentially leading to limitations such as restricted perspectives, low frame rates, or inadequate bowel cleansing.[15,16] Previous studies have attempted to address these limitations; however, missed lesions are still reported.[17,18]

Recently, dual-camera CE, such as the MiroCam MC2000 (IntroMedic, Seoul, Korea; MC2000), expanded the field of view from 170° to 340°, reducing blind spots and potentially improving diagnostic accuracy.[19] However, comparative studies between dual- and single-camera CEs are limited. In this study, we aimed to evaluate the usefulness of MC2000, a double-headed capsule, by comparing the detection rate of the ampulla of Vater (AoV) and small bowel lesions in patients with suspected small bowel bleeding with PillCam SB3 (Given Imaging, Yokneam, Israel; SB3) with a unidirectional camera and MC2000.

MATERIALS AND METHODS

1. Participants

This prospective, multicenter, randomized, crossover trial was conducted at six academic medical centers affiliated with the Capsule Artificial Intelligence Imaging Research Society of the Korean Society of Gastrointestinal Endoscopy. Patients were enrolled between January 2021 and June 2022. Eligible participants included: (1) individuals with recurrent or persistent iron deficiency anemia, positive fecal occult blood tests, or visible bleeding recommended for CE; (2) patients who had undergone gastroscopy and colonoscopy within 6 months prior to CE, with no definitive cause of bleeding found, warranting further evaluation with CE; and (3) patients older than 19 who provided written consent. The indications for capsule endoscopy are shown in Supplementary Table 1.

Exclusion criteria for this study included cases of hemodynamic instability, patients previously unable to undergo complete small bowel evaluation via CE, patients with GI paralysis or suspected fistula, individuals with swallowing disorders, those with a history of Zenker's diverticulum, individuals with prior small bowel resection, patients diagnosed with hereditary GI polyposis or inflammatory bowel diseases, pregnant women, and patients unable to provide voluntary consent.

2. Ethical approval

The study protocol was reviewed and approved by the institutional review boards of six academic medical centers (IRB numbers: HDT 2020-06-024, SMC 2020-06-179, 1-2020-0065, YUMC 2020-06-085, SEUMC 2020-06-038, CHUNCHEON 2020-06-014). This study was conducted in accordance with the principles of the Declaration of Helsinki. This trial was registered as KCT0005591, and informed consent was obtained from all participants.

3. Study design and data collection

Standard bowel preparation was performed on the patient group before CE. The specifications of the two capsules are provided in Supplementary Table 2. Enrolled patients fasted for 8 hours and were prepared with polyethylene glycol-based laxatives 1 hour before the examination. MC2000 and SB3 capsules were ingested at 1-hour intervals, with the order of ingestion randomly assigned using a randomization table. The SB3 was ingested first in 77 cases, while the MC2000 was ingested first in 74 cases. Briefly, 1 hour after the ingestion of the first CE, its location was confirmed using a real-time viewer. Upon verification that the first CE had passed into the small bowel, the second CE was then ingested. If the first CE remained in the stomach after 1 hour, the real-time viewer was checked again after 1 hour to confirm entry into the small bowel. If the first CE was observed on the real-time viewer to have passed through the small bowel 2 hours after ingestion, the second CE was then ingested. If it did not enter the small bowel and remained in the stomach, the CE was passed from the stomach to the duodenum using an endoscope, after which the second CE was ingested.

If the CE did not reach the cecum, the retention rate was assessed through abdominal radiographs. If CE retention was confirmed on abdominal X-ray on the third day, a follow-up X-ray was performed 2 weeks later in asymptomatic cases to assess for ongoing retention, with removal planned if retention persisted. If patients experienced symptoms such as abdominal pain or vomiting, an abdominal computed tomography scan was promptly performed for evaluation. Each capsule endoscopy image was interpreted by two specialists (GI endoscopy experts with experience in over 100 CEs). CE videos were reviewed at a rate of 10 to 25 frames per second. If the results were consistent, discrepancies between MC2000 and SB3 diagnostic results were analyzed. If the reading results did not match, a third specialist analyzed the results (Fig. 1). The third reading was conducted by the principal investigator at each institution.

4. Assessment of the quality of small bowel image and cleanliness

To assess various aspects of CE performance, several

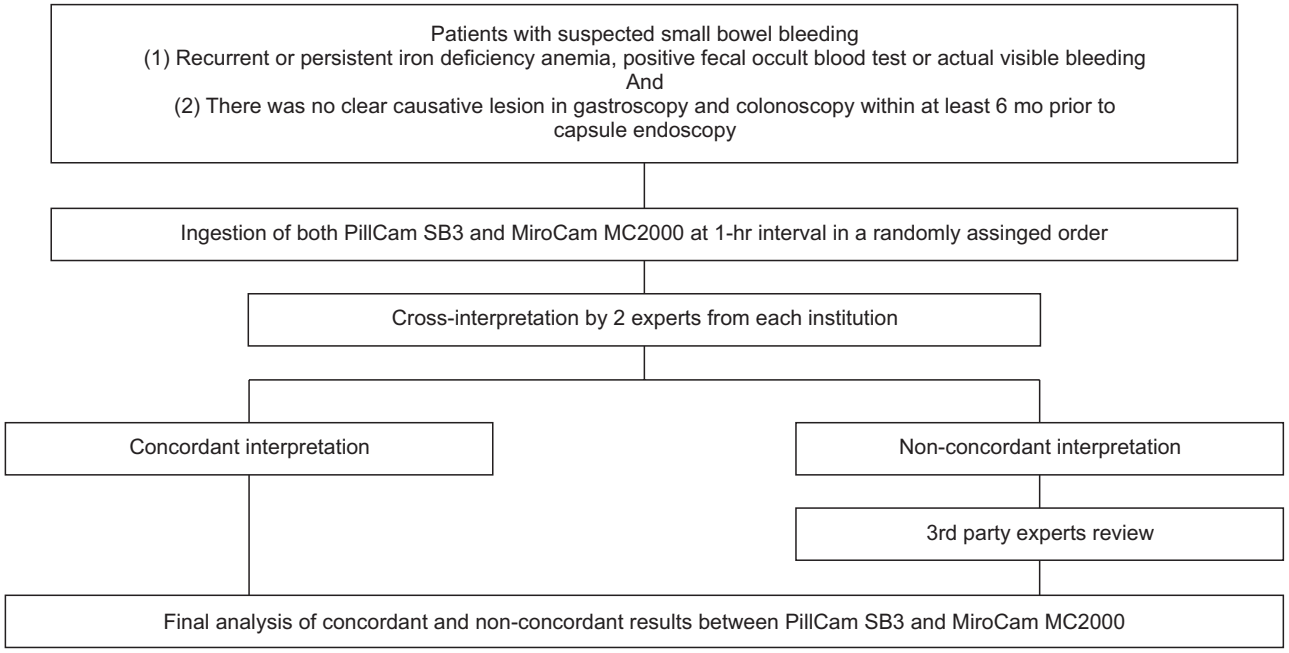

Fig. 1. Flowchart of this study.

parameters were recorded, including the duration of the CE procedure, gastric transit time, small bowel transit time, interpretation time, and completeness of small bowel transit. The imaging quality was examined in terms of the degree of illumination.

The quality of small bowel images was assessed using three parameters adapted from the esophageal grading scale: (1) image quality, categorized as poor, adequate, or good based on resolution and focus; (2) illumination, assessing brightness and darkness, classified as poor, adequate, or good; (3) classification of artifacts such as interferences, bubbles, food materials, and bile contents into three categories: (1) all four, (2) any one or two, (3) none.

The effectiveness of small bowel cleansing was determined using a scale that classified overall bowel preparation as excellent, good, fair, or poor. Mucosal visibility was further categorized based on the fraction of the observed range, using a 4-point scale: more than 75% visualized bowel, 50% to 75% visualized bowel, 25% to 49% visualized bowel, and less than 25% visualized bowel.[20]

5. Outcomes

The primary outcome was to assess the detection rate of AoV. The secondary objective was to determine the detection rate of underlying causes of small bowel bleeding. To evaluate the causes of bleeding, small bowel lesions were classified using Saurin's classification, which categorizes lesions based on their potential to cause bleeding. In this system, lesions were classified from P0 to P2 based on criteria established in the existing literature. P0 indicated normal findings, while P1 represented abnormalities with hemorrhagic potential, such as red spots, erosions, and polyps. Lesions with a high potential for bleeding, including angioectasia, ulceration, tumors, and varices, were categorized as P2.[21-23]

6. Statistical analysis

Anticipating a diagnosis rate of 45% for SB3 and an expectation of over 55% for MC2000, a discrepancy of 20% between the two tests was assumed based on a previous study.[24] The ratio between individuals diagnosed with MC2000 but not with SB3 and those diagnosed with SB3 but not with MC2000 was estimated to have a 10% difference. McNemar's test was used to compare the diagnostic rates between the two tests, with a significance level of 5% and a power of 80%. In total, 155 participants were required for the study, considering an expected dropout rate of 7%. Consequently, the final enrollment was calculated to be 165 subjects. Finally, data from 151 of the 165 enrolled patients were analyzed. Fourteen patients were excluded for technical reasons or withdrawal of informed consent.

Values are expressed as the median (interquartile range) for continuous variables and as the number (%) for categorical variables. The Wilcoxon signed-rank test or McNemar's test was used to compare the variables between the MC2000 CE and the SB3 CE. The agreement for lesions was examined using Cohen's kappa coefficient in the study. All statistical analyses were performed using R Statistical

Software (version 3.6.3; Foundation for Statistical Computing, Vienna, Austria).

RESULTS

1. Baseline characteristics of patients

Data were analyzed from 151 of the 165 patients enrolled. Table 1 provides a summary of the clinical characteristics of the enrolled patients. The median age was 65 years, with 93 patients (61.6%) were male. Among the patients, 66 (43.7%) had hypertension, 37 (24.5%) had cardiac disease, and 14 (9.3%) had cerebrovascular disease.

The use of anticoagulants was observed in 18 patients (11.9%), while 26 patients (17.2%) were using antiplatelet agents, and 15 patients (9.9%) were using nonsteroidal anti-inflammatory drugs. The mean hemoglobin level was measured at 9.5±2.4 g/dL, with 60 patients (39.7%) receiving blood transfusions during the study. Of the enrolled patients, 78.1% were inpatients, and 76.8% presented with visible bleeding (Supplementary Fig. 1).

2. Detection rate of AoV and small bowel lesions

AoV was detected in 32 cases (21.2%) with MC2000 and 27 cases (17.9%) with SB3 (Table 2). AoV was observed in both groups in 12 cases. The MC2000 detected more AoV than the SB3 (20 vs 15); however, the difference was not statistically significant (p=0.499). The MC2000 tended to detect a higher number of red spots and erosions among P1 lesions, and more angioectasias among P2 lesions in the overall cohort; however, these differences were not statistically significant. Among the 116 patients with visible bleeding, the MC2000 showed a tendency to detect lesions more effectively, though this was not statistically significant. Notably, the MC2000 demonstrated a statistically significant improvement in detecting red spots among P1 lesions (Table 3). An additional 12.1% to 59.4% of small bowel lesions were found by individual cameras on MC2000, with only

Table 1. Baseline Characteristics of the Enrolled Patients

Variable	Value (n=151)
Age, median (IQR), yr	65 (50–75)
Male sex, No. (%)	93 (61.6)
BMI, median (IQR), kg/m^2	24.2 (21.5–26.6)
Comorbidities, No. (%)	
Hypertension	66 (43.7)
Diabetes mellitus	34 (22.5)
Cardiovascular disease	37 (24.5)
Cerebrovascular disease	14 (9.3)
Chronic liver disease	5 (3.3)
Chronic kidney disease	19 (12.6)
History of abdominal surgery, No. (%)	26 (17.2)
History of drug use, No. (%)	
Anti-coagulant	18 (11.9)
Antiplatelets	26 (17.2)
NSAIDs	15 (9.9)
Blood transfusion, No. (%)	60 (39.7)
Amount of blood transfusion, median (IQR), unit	2 (2–3)
Laboratory findings	
Initial hemoglobin level, mean±SD, g/dL	9.5±2.4
Iron, median (IQR), μg/dL	42 (23–84)
Ferritin, median (IQR), ng/mL	39 (12.1–121.5)
TIBC, mean±SD, μg/dL	312.1±84.6
Reticulocyte, median (IQR), %	2.1 (1.6–3.6)
Creatinine, median (IQR), mg/dL	0.9 (0.7–1.1)
Albumin, mean±SD, g/dL	4.0±0.6

IQR, interquartile range; BMI, body mass index; NSAIDs, nonsteroidal anti-inflammatory drugs; TIBC, total iron binding capacity.

Table 2. Detection Rate of AoV Lesions (n=151)

	MC2000	SB3	p-value
Detection of AoV	32 (21.2)	27 (17.9)	0.499
Both	12 (7.9)	12 (7.9)	
MC2000 only	20 (13.2)	-	
SB3 only	-	15 (9.9)	

Data are presented as number (%).
AoV, ampulla of Vater; MC2000, MiroCam MC2000; SB3, PillCam SB3.

Table 3. Detection Rate of Small Bowel Lesions for the MC2000 and SB3

Variable	MC2000	SB3	p-value
Total, No. (%) (n=151)			
Normal	59 (39.1)	69 (45.7)	0.058
P1 lesion			0.183
Red spots	48 (31.8)	40 (26.5)	0.103
Erosions	33 (21.9)	31 (20.5)	0.670
Polyp	9 (6.0)	10 (6.6)	0.706
P2 lesion			0.197
Angioectasia	22 (14.6)	16 (10.6)	0.109
Ulcer	24 (15.9)	24 (15.9)	<0.999
Tumor	2 (1.3)	2 (1.3)	NA
SMT	3 (2.0)	2 (1.3)	0.317
Varix	0	0	NA
Diverticulum	6 (4.0)	3 (2.0)	0.083
Visible bleeding, No. (%) (n=116)			
Normal	43 (37.1)	53 (45.7)	0.041
P1 lesion			0.101
Red spots	37 (31.9)	27 (23.3)	0.018
Erosions	25 (21.6)	25 (21.6)	<0.999
Polyp	7 (6.0)	7 (6.0)	<0.999
P2 lesion			0.333
Angioectasia	17 (14.7)	14 (12.1)	0.366
Ulcer	19 (16.4)	18 (15.5)	0.706
Tumor	2 (1.7)	2 (1.7)	NA
SMT	2 (1.7)	1 (0.9)	0.317
Varix	0	0	NA
Diverticulum	6 (5.2)	3 (2.6)	0.083

MC2000, MiroCam MC2000; SB3, PillCam SB3; P1 lesion, red spots+erosions+polyps; P2 lesion, angioectasia+ulcer+tumor+SMT+varix; SMT, submucosal tumor; NA, not available.

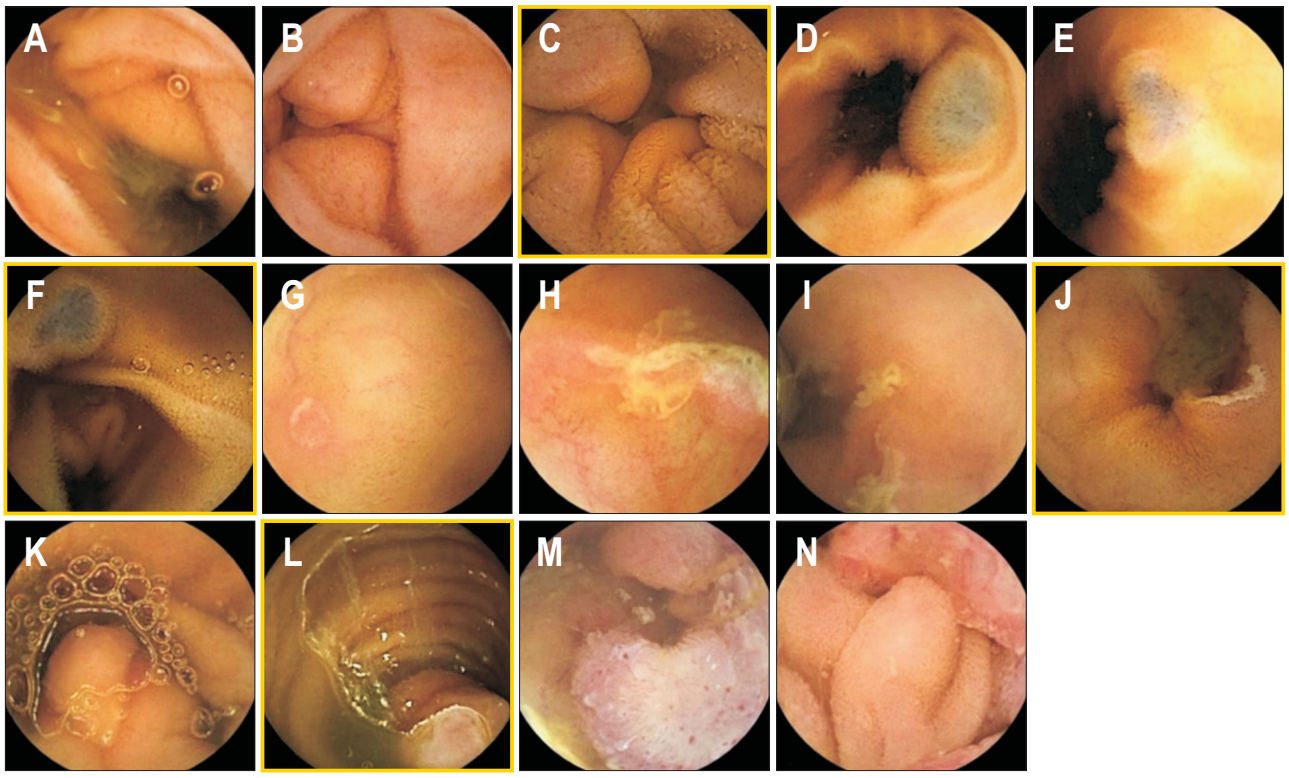

Fig. 2. Images of ampulla of Vater (AoV) and small bowel lesions from MiroCam MC2000 (MC2000) and the PillCam SB3 (SB3). (A) AoV from right camera of MC2000. (B) AoV from left camera of MC2000. (C) AoV from SB3. (D) Hemangioma from left camera of MC2000. (E) Hemangioma from right camera of MC2000. (F) Hemangioma from SB3. (G) Ulcer from right camera of MC2000. (H) Ulcer from right camera of MC2000. (I) Ulcer from left camera of MC2000. (J) Ulcer from SB3. (K) Ulcer on protruding lesion from left camera of MC2000. (L) Ulcer on protruding lesion from SB3. (M) Tumor from right camera of MC2000. (N) Tumor from left camera of MC2000.

15.6% of AoV observed on both cameras (Supplementary Table 3). Fig. 2 shows AoV and small bowel lesion images from MC2000 and SB3. Fig. 2A and B show AoV images from right and left cameras of the MC2000 in a patient. Fig. 2C shows an AoV image from SB3. Fig. 2D-F show hemangioma images from left and right cameras of MC2000 (D, and E), and SB3 (F) in a patient. Fig. 2E and F were the same lesion. The hemangioma of the image (D) was not observed in SB3. Fig. 2G-J show ulcer images from right camera (G, H) and left camera (I) of MC2000, and SB3 (J) in a patient. More ulcers were observed in the MC2000. Fig. 2K and L show ulcer on protruding lesion from left camera of MC2000 (K) and SB3 (L). This lesion was not observed in right camera of MC2000. Fig. 2M and N show tumor images from right camera (M) and left camera (N) of MC2000. The appearance of the tumor was observed differently depending on the location of the camera.

3. Agreement analysis between the SB lesions detected in both groups

When assessing Cohen's kappa coefficient, the kappa coefficient between the two groups showed moderate to excellent agreement in P1 and P2 lesions (range of coefficient, 0.56 to 1.00) (Table 4). The degree of agreement was good in both P1 and P2 lesions. The degree of agreement of erosions and angioectasia was lower compared to the rest of the P1 and P2 lesions. In the case of diverticulum, the kappa coefficient was 0.66, indicating moderate agreement between the two groups, and it was higher compared to P1 (0.62) but lower than P2 lesions (0.72) (Table 4). The kappa coefficient of AoV was 0.26, representing the lowest agreement of all lesions.

Supplementary Fig. 1 is a schematic showing the concordance and discordance of small bowel lesions detected in MC2000 and SB3. The area of small bowel lesions detected only in MC2000 was more widely distributed than that of small bowel lesions detected only in SB3.

4. Assessment of camera performance

The operating time of MC2000 was significantly shorter by approximately 100 min than that of SB3 ($p<0.001$). However, the SB transit time was slightly longer in MC2000 than in SB3 (364 minutes vs 359 minutes, $p=0.704$). The median interpretation time was 39.5 minutes (interquartile range, 35 to 53 minutes), which was longer than that of SB3 at 30 minutes (interquartile range, 25 to 42 minutes)

Table 4. Agreement Analysis for the Small Bowel Lesions Detected with the MC2000 and the SB3

Lesion type	Both detected	Only MC2000	Only SB3	Both undetected	Concordant	Discordant	Cohen's Kappa		
							Estimate	95% LCL	95% UCL
AoV	12 (7.9)	20 (13.2)	15 (9.9)	104 (68.9)	116 (76.8)	35 (23.2)	0.26	0.08	0.45
Red spots	32 (21.2)	16 (10.6)	8 (5.3)	95 (62.9)	127 (84.1)	24 (15.9)	0.62	0.48	0.75
Erosions	21 (13.9)	12 (7.9)	10 (6.6)	108 (71.5)	129 (85.4)	22 (14.6)	0.56	0.40	0.73
Polyp	6 (4.0)	3 (2.0)	4 (2.6)	138 (91.4)	144 (95.4)	7 (4.6)	0.61	0.34	0.87
Angioectasia	12 (7.9)	10 (6.6)	4 (2.6)	125 (82.8)	137 (90.7)	14 (9.3)	0.58	0.38	0.78
Ulcer	19 (12.6)	5 (3.3)	5 (3.3)	122 (80.8)	141 (93.4)	10 (6.6)	0.75	0.61	0.90
Tumor	2 (1.3)	0	0	149 (98.7)	151 (100)	0	1.00	1.00	1.00
SMT	2 (1.3)	1 (0.7)	0	148 (98.0)	150 (99.3)	1 (0.7)	0.80	0.41	1.00
Varix	0	0	0	151 (100)	151 (100)	0	-	-	-
Diverticulum	3 (2.0)	3 (2.0)	0	145 (96.0)	148 (98)	3 (2.0)	0.66	0.30	1.00
P1 lesion	59 (13)	31 (6.8)	22 (4.9)	341 (75.3)	400 (88.3)	53 (11.7)	0.62	0.52	0.71
P2 lesion	35 (4.6)	16 (2.1)	9 (1.2)	695 (92.1)	730 (96.7)	25 (3.3)	0.72	0.61	0.82

Data are presented as number (%).
MC2000, MiroCam MC2000; SB3, PillCam SB3; LCL, lower confidence limit; UCL, upper confidence limit; AoV, ampulla of Vater; SMT, submucosal tumor; P1 lesion, red spots+erosions+polyps; P2 lesion, angioectasia+ulcer+tumor+SMT+varix.

(p<0.001). The completeness of small bowel transit was lower for MC2000 at 87% than for SB3 at 93.4% (p<0.001) (Table 5). The small bowel cleaning scale was mostly adequate or good, with no difference between the two groups. Additionally, no significant difference was observed in the quality of SB images between the two groups (p=0.336).

5. Adverse event

In a total of 23 cases, stasis of the first CE occurred in the esophagus or stomach, and they were transferred to the duodenum using an endoscope. Stasis occurred in nine cases with MC2000 and 14 cases with SB3. Among the nine MC2000 cases transferred to the duodenum by endoscopy, one did not reach the cecum. The SB3 taken following this MC2000 also did not reach the cecum. Of the 14 SB3 cases transferred to the duodenum endoscopically, three cases did not reach the cecum. Two of the MC2000 cases taken following these three SB3 cases did not reach the cecum, and one was stagnant in the diverticulum.

Additionally, small bowel retention occurred in one case, caused by stricture owing to small bowel ulcers. It was removed by small bowel endoscopy, and the stricture extended to the ileum.

DISCUSSION

This study presents evidence that demonstrates the superiority of using MC2000 with a dual camera over SB3 with a single camera in detecting small bowel structures such as AoV and diverticulum, as well as potential lesions for small bowel bleeding.

Numerous efforts have been made to enhance the diagnostic yield of capsule endoscopy for patients with chronic and obscure GI bleeding, supported by extensive research. In a study involving 32 patients with chronic GI bleeding, a definite source such as angiodysplasia was identified in 21 patients (66%) through capsule endoscopy (p<0.001).[19] A pilot study comparing capsule endoscopy with push enteroscopy in patients suspected of small bowel bleeding demonstrated a marginally statistically significant high diagnostic yield of 55% compared to 30% (p=0.065).[25] The third-generation SB3, with improved optics and adaptive frame rate of up to six frames per second, was developed to enhance diagnostic yield. However, a study of 260 patients found no significant difference between PillCam SB3 and SB2 in detecting relevant GI lesions (46.2% vs 51.5%, p=0.385).[26] The introduction of MC2000 and subsequent studies comparing it with SB3 showed no statistically significant difference in diagnostic yield, with rates of 45.8% and 41.7%, respectively.[27] This was true for the earlier sin-

Table 5. Comparison between MC2000 and SB3 According to Bowel Preparations and Interpretation

	MC2000	SB3	p-value
Capsule endoscopy operation time, median (IQR), min	720.1 (720–720.1)	822.9 (786.5–848.1)	<0.001
Gastric transit time, median (IQR), min	29.7 (14.7–63.5)	27 (12.9–70.9)	0.765
Small bowel transit time, median (IQR), min	364 (284–476.1)	359 (263.5–498)	0.704
Interpretation time, median (IQR), min	39.5 (35–53)	30.0 (25–42)	<0.001
Completeness of SB transit (approach to cecum)	131 (86.8)	141 (93.4)	<0.001
Quality of small bowel image, No. (%)			
Artifacts (interferences, bubbles, food materials, bile contents)			0.457
All four	17 (11.3)	19 (12.6)	
Any 1 or 2	123 (81.5)	122 (80.8)	
None	11 (7.3)	10 (6.6)	
Illumination (brightness/darkness)			0.442
Poor	8 (5.3)	8 (5.3)	
Adequate	59 (39.1)	55 (36.4)	
Good	84 (55.6)	88 (58.3)	
Image quality (resolution/focus)			0.162
Poor	9 (6)	10 (6.6)	
Adequate	60 (39.7)	49 (32.5)	
Good	82 (54.3)	92 (60.9)	
Small bowel cleansing scale, No. (%)			
Overall bowel preparation			0.336
Excellent	37 (24.5)	42 (27.8)	
Good	73 (48.3)	70 (46.4)	
Fair	31 (20.5)	31 (20.5)	
Poor	8 (5.3)	7 (4.6)	
Proportion of mucosa visualized			0.635
>75%	91 (60.3)	89 (58.9)	
50%–75%	41 (27.2)	42 (27.8)	
25%–49%	10 (6.6)	15 (9.9)	
<25%	7 (4.6)	4 (2.6)	

MC2000, MiroCam MC2000; SB3, PillCam SB3; IQR, interquartile range; SB, small bowel.

gle-direction camera models of MC2000; however, studies using the dual-camera developed in 2017 reported detection rates for the MC2000 as high as 75% and increased diagnostic yields for neoplastic lesions.[28,29] In our study, among 116 patients with visible bleeding, the diagnostic yields of SB3 and MC2000 were 54.7% and 62.9%, respectively, which is consistent with previous findings.

In the case of lesions detected by the MC2000, significantly more small bowel lesions were visible only on one of the single cameras (left camera or right camera) than those visible on both, as detailed in Supplementary Table 3. If only one camera had been present, lesions detected by the opposite camera would have been missed. Indeed, the low diagnostic yield of the SB3, which employs a unidirectional camera, appears to be attributable to this limitation. The MC2000 captures bidirectional images, whereas the SB3 captures images in a single direction, either forward or backward. As the capsule traverses the GI tract, bowel movements may alter its orientation, resulting in random forward or backward image acquisition. This may lead to a potential risk of missing individual lesions.

Although the SB3's battery lasted slightly longer than the MC2000, the MC2000's battery life was sufficient for evaluating the small bowel, considering transit times. The MC2000 requires longer interpretation time due to the need to review images from both directional cameras, consistent with this study. However, as the median difference in interpretation time is under 10 minutes, the additional diagnostic yield from dual cameras justifies the extra time.

The quality of small bowel images did not significantly differ between the two groups, and both were deemed to provide sufficient quality for interpretation, according to comparisons with previous studies.[27,28,30] In reaching the cecum, MC2000 had a rate of 86.8%, and SB3 achieved a higher rate of 93.4%. The completeness of SB transit reaching the cecum was 131 cases (86.8%) for MC2000 and 141 cases (93.4%) for SB3, showing a statistically significant difference (Table 5). This difference can be interpreted in light of the capsule endoscopy operation times, as MC2000 operates for 12 hours compared to 15 hours for SB3. However, in practical terms, the cases of retention were limited to specific instances: one where the capsule was temporarily retained in a diverticulum but exited spontaneously, and another where retention occurred due to edema from

an ulcer. In the latter case, both MC2000 and SB3 capsules were simultaneously removed via enteroscopy. These were the only events reported as adverse events. Previous studies reported 82% for SB3 in a trial comparing it with endocapsule among 40 patients with occult GI bleeding, where 32 reached the cecum. In a head-to-head trial, MC2000 showed 83% completion among 24 patients (20 reaching the cecum), while SB3 showed 59% (14 reaching the cecum), indicating a statistically significant difference.[31] According to a meta-analysis conducted in 2009, the overall completion rate was established at 83.7%.[32] In our study, the completion rate for the MC2000 was comparable to or higher than this benchmark, while the SB3 showed a comparatively higher rate. However, despite the higher completion rate of the SB3 than that of the MC2000, there were more instances where the CE remained in the stomach for more than 2 hours post-ingestion, requiring endoscopic assistance to enter the small bowel: nine cases for MC2000 and 14 cases for SB3. Therefore, considering the high rate of gastric retention with the SB3, the final completion rates between the two groups are likely to be similar.

This multicenter, randomized study involved many patients, allowing an accurate comparison of diagnostic yields for small bowel lesions by performing both capsule endoscopies in the same patients. With 76.8% of patients exhibiting visible bleeding, the study primarily included those with a high likelihood of small bowel lesions. This facilitated comparing diagnostic yields between the two capsule types and assessing the practical utility of capsule endoscopy in the most commonly indicated patient population.

Although this study involved the sequential administration of two capsule endoscopies with a 1- to 2-hour interval, occasionally resulting in interference phenomena owing to variations in small bowel transit times of each capsule, this interference did not compromise the diagnosis of small bowel lesions upon review of the images.

In conclusion, the MC2000, equipped with cameras at both ends, has the potential to reduce the visual blind spots associated with the single-camera SB3, thereby improving the detection of small bowel lesions. This dual-camera configuration may provide valuable support in the diagnosis of patients with small bowel disorders.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Study concept and design: H.J.J. Data acquisition: J.E.K., E.R.K., J.J.P., K.O.K., Y.P., Y.J.Y. Data analysis and interpretation: J.E.K., E.R.K. Drafting of the manuscript: J.E.K. Critical revision of the manuscript for important intellectual content: E.R.K. Statistical analysis: E.R.K. Administrative, technical, or material support; study supervision: H.J.J. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

Supplementary materials can be accessed at https://doi.org/10.5009/gnl240541.

DATA AVAILABILITY STATEMENT

The data underlying this article cannot be shared publicly, given the privacy expectations of the individuals who participated in the study. The data will be shared upon reasonable request to the corresponding author.

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