



Feasibility of a second-generation colon capsule in visualization of the upper gastrointestinal tract

Gangping Li[#], Yu Jin[^], Tao Bai, Wei Qian, Xiaoping Xie, Xiaohua Hou

Division of Gastroenterology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China

Contributions: (I) Conception and design: X Hou, Y Jin, G Li; (II) Administrative support: X Hou, X Xie; (III) Provision of study materials or patients: X Hou, X Xie; (IV) Collection and assembly of data: Y Jin, G Li, T Bai; (V) Data analysis and interpretation: G Li, Y Jin, T Bai; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Xiaohua Hou; Xiaoping Xie. Division of Gastroenterology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430022, China. Email: houyh@hust.edu.cn; xiexiaoping63@126.com.

Background: Capsule endoscopy for visualization of the entire gastrointestinal tract is a challenge. A second-generation colon capsule endoscopy system (CCE-2) performed well in the colon and small intestine, but its utility in the upper gastrointestinal duct is not clear. We evaluated the use of the CCE-2 in the visualization of the upper gastrointestinal tract.

Methods: We performed a retrospective study and further evaluated CCE-2 images using the typical landmarks of esophagus and stomach. The two imagers located at each end of the CCE-2 system were defined as imager1 (green) and imager2 (yellow). Two endoscopists read the images, and they were blinded to the other reader's results. All of the images from the two imagers were separately reviewed.

Results: Images from 127 subjects were analyzed. This study demonstrated the comprehensive visualization of 71.7% of esophageal landmarks and 89.8% of gastric landmarks using the CCE-2. The two CCE-2 imagers were not identical, and the lighter imager (imager2, yellow) was superior to the heavier imager (imager1, green) (78% *vs.* 33.1%) in the stomach. Compared with the use of one imager, the use of two imagers was superior (two-imager *vs.* imager1, 89.8% *vs.* 33.1%; two-imager *vs.* imager2, 89.8% *vs.* 78%) in the stomach. Two-imager combination analysis detected a total of 160 positive findings. In contrast, single-imager analysis with imager1 and imager2 detected 133 and 137 findings, respectively. Two-imager combination analysis provided 20.3% and 16.8% more findings than imager1 and imager2, respectively. The two imagers complemented each other to detect more lesions.

Conclusions: The CCE-2 system is feasible for use in the upper gastrointestinal tract and may be considered an optional tool for upper gastrointestinal imaging. This system may represent a good choice for complete gastrointestinal duct screening. Compared with the use of one imager, the two-imager combination provided improved upper gastrointestinal tract mucosal visualization.

Keywords: Capsule endoscopy; colon capsule endoscopy system (CCE-2); gastrointestinal imaging

Submitted May 03, 2020. Accepted for publication Nov 13, 2020.

doi: 10.21037/atm-20-3699

View this article at: <http://dx.doi.org/10.21037/atm-20-3699>

[^] ORCID: 0000-0001-5322-1315.

Introduction

Gastrointestinal diseases are very common worldwide. The incidence and mortality of gastrointestinal cancers remain high, and it represents a global public health problem (1,2). Early screening of the gastrointestinal tract is an important measure to effectively prevent and treat gastrointestinal tumors (3).

Although the use of a standard endoscope and endoscopic biopsy is the gold standard for the diagnosis of gastrointestinal cancer, the application of gastroscopy and colonoscopy in the screening, investigation, and monitoring of lesions is limited due to the technical requirements and the unpleasant intubation experience (4-6). The use of anesthesia improves patient acceptance, but it is associated with contraindications and risks of adverse events. Therefore, a painless capsule endoscopy method for detecting gastrointestinal lesions would be particularly beneficial (7,8).

Various types of capsule endoscopy are currently available, and these methods represent first-line diagnostic tools for the detection of small intestinal diseases (9-13). With the development of new techniques and ideas, the indications for capsule endoscopy have been extended to range from the small intestine to the colon. The development of a capsule system for examining the upper gastrointestinal tract has also been a hot topic globally. Rey *et al.* presented the first application of a magnetically navigated capsule in the human stomach (14). In addition, other gastric capsule endoscopy tools, including hand-held MCCG, MRI-based MCCG, robotic MCCG (7,15-18), and PillCamESO, have been developed for examination of the esophagus and stomach (19).

However, some significant restrictions of capsule endoscopy should be noted. First, the successful visualization of gastrointestinal landmarks and lesions is a challenging research hotspot. Second, one type of capsule endoscopy examines only parts of the gastrointestinal tract, but not the entire gastrointestinal tract. Therefore, combined with the high cost, this system is not accepted widely by many people. A capsule endoscopy method that functions as a screening method for the entire gastrointestinal tract has not been reported.

The properties of the PillCamColon2, which was designed for colon examination, provide an opportunity to test its feasibility in complete gastrointestinal imaging. The second-generation colon capsule, known as PillCamColon2, measures 31.5 mm by 11.6 mm and has two imagers that

are separately located at each end of the capsule to view the colonic mucosa. The angle of view from each imager was increased from the 156° angle of the first-generation colon capsule to 172°. This improvement allows for a viewing coverage of approximately 360° (20). It also has an adaptive frame rate function that senses the movement speed of the capsule endoscope, and it captures 4 to 35 images per second to image the mucosa adequately (20). Many studies have suggested that this device is an adequate tool for colorectal imaging (20-23).

Other studies have suggested that the dual cameras complement each other to detect more small-bowel lesions (24-26). Moreover, we observed that some upper gastrointestinal lesions were detected during examination using the PillCamColon2 system, even in patients who did not exhibit significant upper gastrointestinal symptoms. If the system is useful in the upper gastrointestinal tract, then it would be a good choice for complete gastrointestinal screening.

Research on the additional potential of the PillCamColon2 system for observing the esophagus and the stomach is limited. In this study, we visualized esophageal and gastric landmarks using this capsule to evaluate the feasibility of applying this method in the upper gastrointestinal tract. We also viewed the images produced by the two imagers to evaluate their characteristics and advantages.

We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/atm-20-3699>).

Methods

The PillCamColon2 system

Similar to other PillCam systems, the current system consists of an ingestible video capsule that moves through the gastrointestinal tract via the natural effects of peristalsis while transmitting images via an antenna-lead array to a data-recording device that is carried by the patient. The recorded images are transferred to a workstation that is loaded with RAPID software. The new colon capsule measures 31.5 mm by 11.6 mm and has two imagers that are separately located at each end of the capsule to view the colonic mucosa. The angle of view from each imager was increased from the 156° angle of the first-generation colon capsule to 172°. This improvement allows for approximately 360° coverage of the colon. To view more mucosa and save

battery energy, this capsule is equipped with an adaptive frame rate. The device captures 35 images per second when in motion and 4 images per second when in a static state.

Study cohorts

We performed a retrospective study. The study was performed in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (Wuhan, China) approved this study (2017-S313). All personally identifying information was omitted. A total of 127 patients underwent PillCamColon2 examinations in our outpatient department from January 2018 through January 2019. The chief complaints of the patients included lower gastrointestinal symptoms (but not upper gastrointestinal symptoms), including abdominal pain, diarrhea, and changes in the characteristics of the stool, whereas some of the healthy subjects came for a physical examination. The exclusion criteria were dysphagia or any swallowing disorder, life-threatening conditions, current pregnancy, or contraindications for bowel preparation or the prokinetic agents used in the study. We re-read the images of the 127 patients and separately recorded the results of the two imagers at each end of the PillCamColon2.

Gastrointestinal preparation and PillCamColon2 examination protocol

Patients underwent a colon preparation procedure before the examination. An experienced nurse explained the bowel preparation regimen to the patients in an approximately 10-minute time period. A low-residue diet was administered to the patients the day before the examination, and the patients were asked to drink 1,000 mL of water with a polyethylene glycol electrolyte powder (Beaufour Ipsen Industrie, France) in one hour at two separate time points (20:00 and 21:00). On the examination day, the patients were asked to drink 1,000 mL of water with the polyethylene glycol electrolyte powder twice in the morning. Simethicone (Menarini Group, Florence, Italy), which is used as a defoaming agent, was voluntarily administered to patients to drink one hour before the examination. When the capsule reached the small intestine, 1,000 mL of water with simethicone was voluntarily administered to patients to drink within one hour, and a prokinetic drug was used, depending on the condition of

the capsule in the colon. Capsule endoscopy was performed without colon insufflation or sedation.

Patients swallowed the capsules in the left lateral position, which allowed for the esophagus to be viewed. Patients were then asked to assume supine, left lateral, and knee-chest positions for 30 seconds for each location, and the patients repeated this cycle three times.

Cleanliness of the mucosa of the esophagus and stomach

A four-point grading scale was used to subjectively describe the cleanliness of the colon at the time of the capsule endoscopy as being excellent, good, fair, or poor (*Figure 1*).

- A. Excellent, with no more than small bits of adherent foam and mucus.
- B. Good, with a small amount of foam and mucus that did not influence visualization.
- C. Fair, with a considerable amount of mucus or foam present that precluded a completely reliable examination.
- D. Poor, with a large amount of foam and mucus.

Main outcome measures

We specifically defined the following esophageal and gastric landmarks: the superior esophagus, middle esophagus, inferior esophagus, Z-line, cardia, fundus, greater curvature of the body, lesser curvature of the body, anterior gastric body, posterior gastric body, angulus, antrum, and pylorus (*Figure 2*). Visualizations of the esophageal and gastric anatomical landmarks were recorded. Comprehensive visualization of the esophagus was defined as a 100% mucosal visualization of the landmarks of the superior esophagus, middle esophagus, inferior esophagus, Z-line, and cardia. Comprehensive visualization of the stomach was defined as a 100% mucosal visualization of the landmarks of the fundus, greater curvature of the body, lesser curvature of the body, anterior gastric body, posterior gastric body, angulus, antrum, and pylorus. Comprehensive visualization of the upper gastrointestinal tract was defined as a 100% mucosal visualization of all 13 landmarks. A partially viewed image or an unclear image was labeled as “not viewed.” Two endoscopists, who had read images from more than 200 capsule endoscopy cases, read the images and were blinded to each other’s results. If they obtained different results, they would discuss their conflicting results until an agreement was achieved. All of the images for each enrolled patient were separately reviewed from the two imagers and

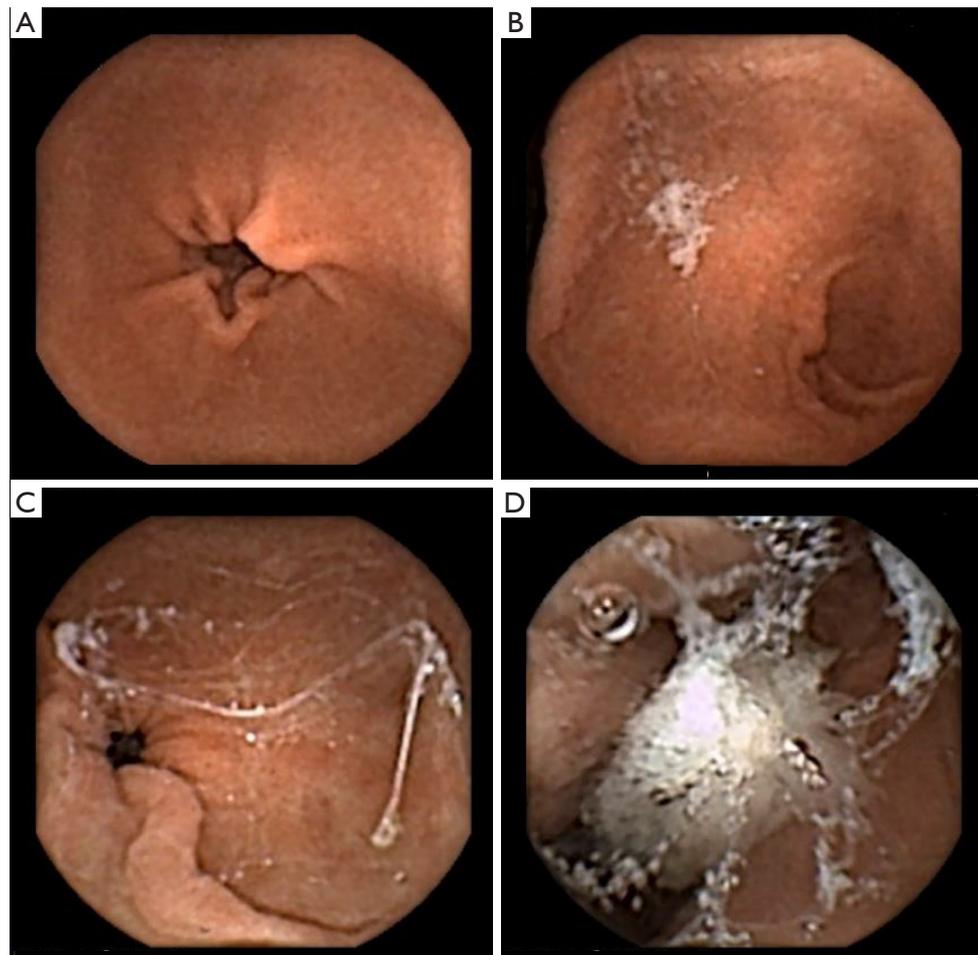


Figure 1 Representative images demonstrating the four-point grading scale used to objectively describe the cleanliness of the mucosa of esophagus and stomach during the examination. (A) Excellent, with no more than small bits of adherent foam and mucus. (B) Good, with a small amount of foam and mucus that did not influence visualization. (C) Fair, with a considerable amount of mucus or foam present that precluded a completely reliable examination. (D) Poor, with a large amount of foam and mucus.

used to identify the landmarks.

Corresponding relationship between the two imagers and the images

Regarding the imager of the different images, imager1 refers to the imager located near the letter “m” of the “PillCam” capsule and corresponds to the recorder’s green frame images. Imager2 refers to the imager near the letter “P” of the “PillCam” capsule and corresponds to the recorder’s yellow frame images (Figure 3). Imager1 was heavier than imager2; thus, when the PillCam was placed in water, imager1 sank and imager2 floated (Figure 3).

Data analysis

The data are expressed as means \pm SDs for the quantitative variables or numbers (percentages) for the qualitative variables. The adjusted regression model included age, sex, location, body mass index (BMI), the esophageal transit time of the capsule, the gastric transit time of the capsule, and cleanliness. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. All of the analyses were performed using EmpowerStats (X&Y solutions, Boston, MA, USA; www.empowerstats.com, accessed December 22nd, 2018) and R (<http://www.R-project.org>, accessed December 22nd, 2018).

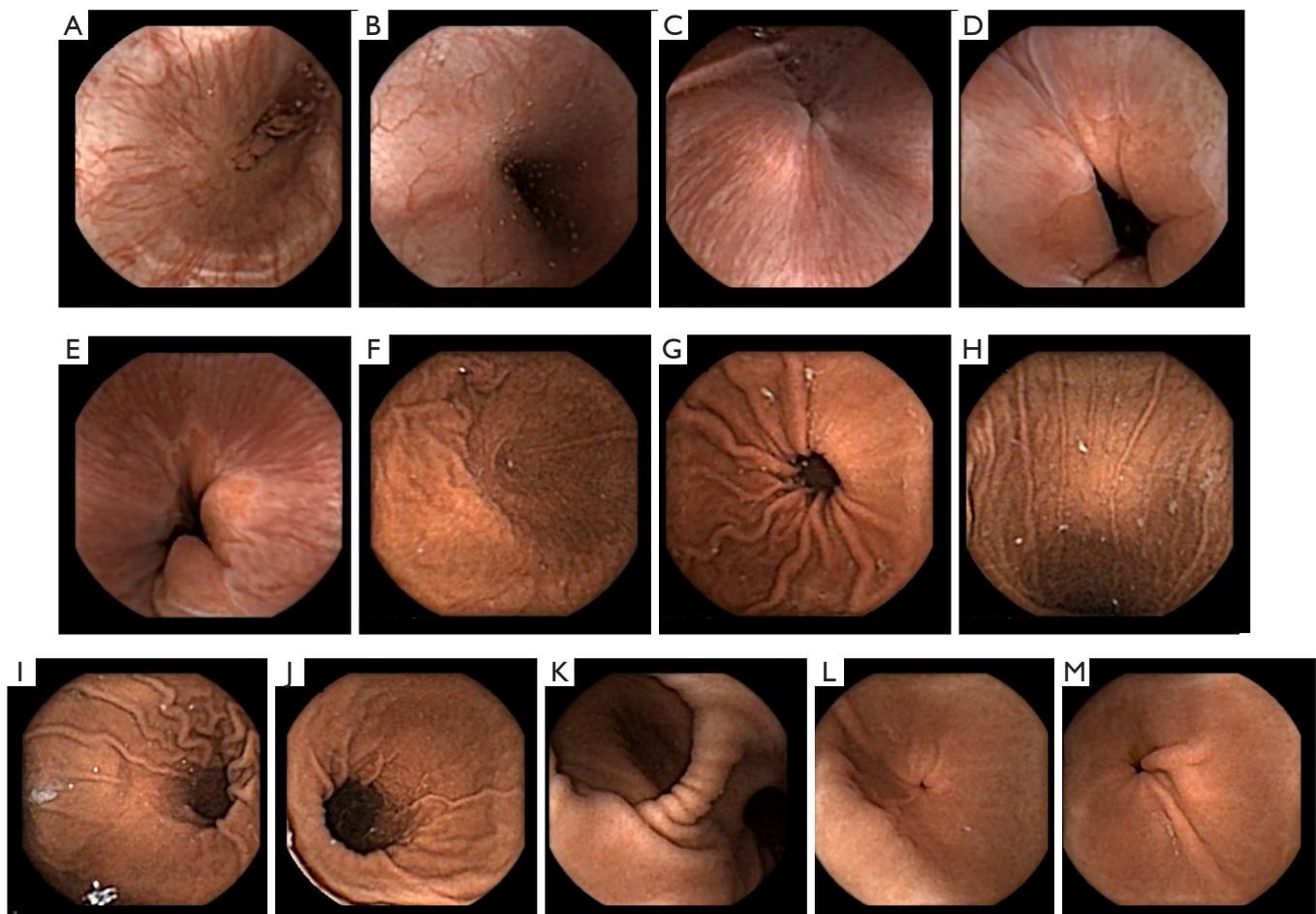


Figure 2 Landmarks of the esophagus and stomach. Esophageal landmarks (A-E): (A) superior esophagus, (B) middle esophagus, (C) inferior esophagus, (D) Z-line, (E) cardia. Gastric landmarks (F-M): (F) fundus, (G) greater curvature of the body, (H) lesser curvature of the body, (I) anterior gastric body, (J) posterior gastric body, (K) angulus, (L) antrum, (M) pylorus.

Results

Study flowchart and symptoms

A total of 127 patients underwent PillCamColon2 examinations in our outpatient department from January 2018 through January 2019. The complaints of these patients involved lower gastrointestinal symptoms only (46.4%) and lower gastrointestinal symptoms combined with upper gastrointestinal symptoms (18.3%). The remaining participants were healthy volunteers (35.3%). Of these patients, 103 patients had positive findings of the upper intestinal duct (*Figure 4*).

Visualization rates of different landmarks by the imagers

The visualization rates of the different landmarks were recorded, as follows: the superior esophagus (92.9%), middle esophagus (99.2%), inferior esophagus (97.6%), Z-line (74%), cardia (93.7%), fundus (98.5%), greater curvature of the body (97.6%), lesser curvature of the body (96.1%), anterior gastric body (96.9%), posterior gastric body (94.5%), angulus (95.3%), antrum (100%), and pylorus (99.2%). The visualization of the Z-line was lower than that of other landmarks of the esophagus and stomach. Regarding the visualization rates of the different imagers, the combined use

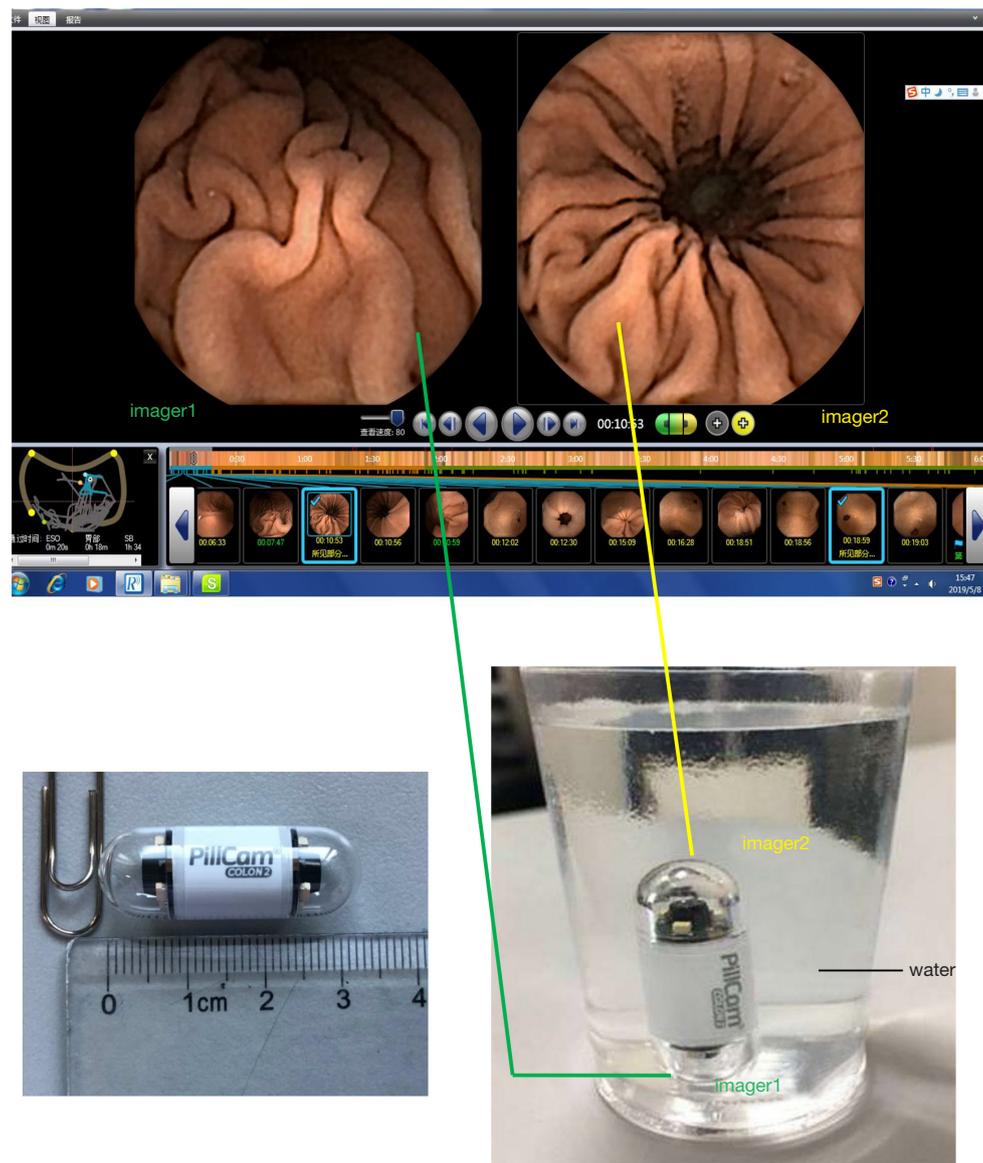


Figure 3 Relationship between the imagers and images. The second-generation CCE-2 capsule measures 31.5 mm × 11.6 mm and has two imagers, one at each end of the capsule. The two imagers collected images separately. Imager1 was heavier than imager2. Imager1 sank and imager2 floated when the capsule was placed into water.

of the imagers performed better than either imager alone. Imager2 provided enhanced visualization in the stomach compared with imager1. The two-imager combination performed better than either imager alone (*Figure 5*).

Positive findings of PillCamColon2

Overall, analysis with the two-imager combination detected a total of 160 positive findings. Single-imager analysis with

imager1 detected 133 findings, and single-imager analysis with imager2 detected 137 findings. Therefore, two-imager combination analysis provided 20.3% and 16.8% more findings than imager1 and imager2, respectively. The types of findings and their locations are summarized in *Table 1*, and the typical lesions are presented in *Figure 6*. An early esophageal cancer was detected when one patient underwent PillCamColon2 examination due to lower gastrointestinal symptoms (*Figure 6*). We did not diagnosis hiatal hernia in

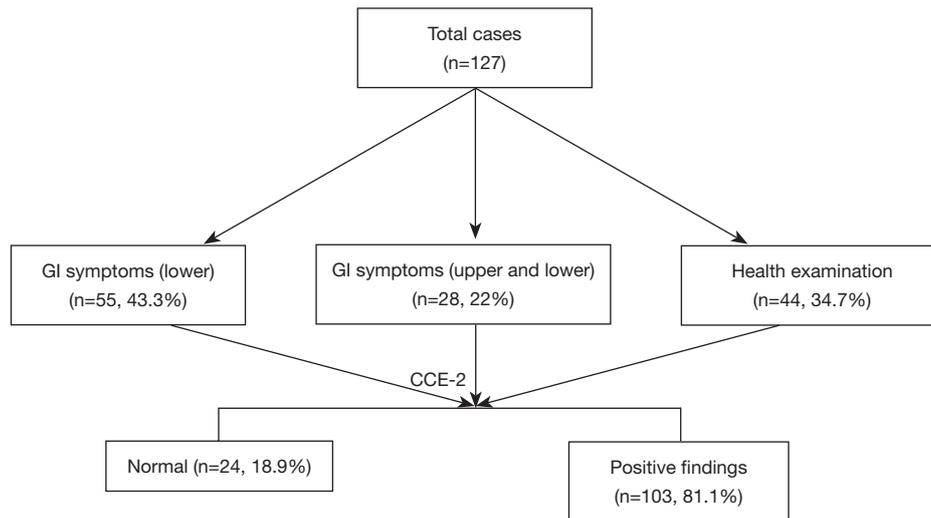


Figure 4 Study flowchart and the symptoms. A total of 127 patients were enrolled. The complaints of these patients involved lower gastrointestinal symptoms only (46.4%), lower combined with upper gastrointestinal symptoms (18.3%), and none (healthy volunteers, 35.3%). A total of 103 patients (81.1%) had positive findings of the upper intestinal duct.

any of the 127 subjects.

Association of basic characteristics with the visualizations from different imagers

Among these patients, 71.7% of the patients were male, and 28.3% were female. The mean age was 50.4 ± 12.7 (range, 10–83) years. The mean esophageal transit time was 31.5 ± 34.0 (range, 1–181) seconds, and the mean time of the stomach examination was 64.6 ± 48.1 (range, 7–237) minutes. Esophageal and gastric mucosa cleanliness was considered excellent in 41 patients, good in 37 patients, fair in 24 patients, and poor in 25 patients. When accounting for various factors, including location, sex, age, BMI, the examination time of the esophagus and stomach, and the cleanliness, the rate of landmark visualization from imager1 alone was considerably reduced compared with that from imager2, and the rates from both imagers alone were less than the rate of both imagers combined ($P < 0.01$) (Table 2).

Multivariate logistic regression analysis of the association of the imagers with the visualizations

Our study demonstrated that the visualizations were independently associated with the imagers ($P < 0.001$), after adjusting for the confounding factors. In the univariate analysis, model I (adjusted for age and sex) and model II

(adjusted for age, sex, location, BMI, Eso-time, Gastro-time, and cleanliness) exhibited significant results (all $P < 0.001$) (Table 3).

Discussion

The present study demonstrated that doctors detected some upper gastrointestinal lesions when patients underwent a PillCamColon2 procedure, including patients without significant upper gastrointestinal symptoms. Notably, the rates of esophageal and gastric landmark visualization were 71.6% and 89.8%, respectively. Similarly, using the MiroCam Navi technique, successful visualization of the main landmarks was achieved at a rate of approximately 88–100%, with a rate of 92% for the esophagogastric junction, 96% for the fundus, 100% for the body, 96% for the incisura, 96% for the antrum, and 100% for the pylorus (15). With the magnetic-guided capsule endoscopy technique, the visualization rates of the cardia and body were 91.7% and 86.7%, respectively, and those of the fundus, angulus, antrum, and pylorus were 91.7%, 80.0%, 90.0%, and 81.7%, respectively (27). The rates of esophageal and gastric landmark visualization were similar between the CCE-2 and other gastric capsule systems. Additionally, in our study, an early esophageal cancer was detected. These results suggest that the use of the PillCamColon2 system in the upper gastrointestinal tract

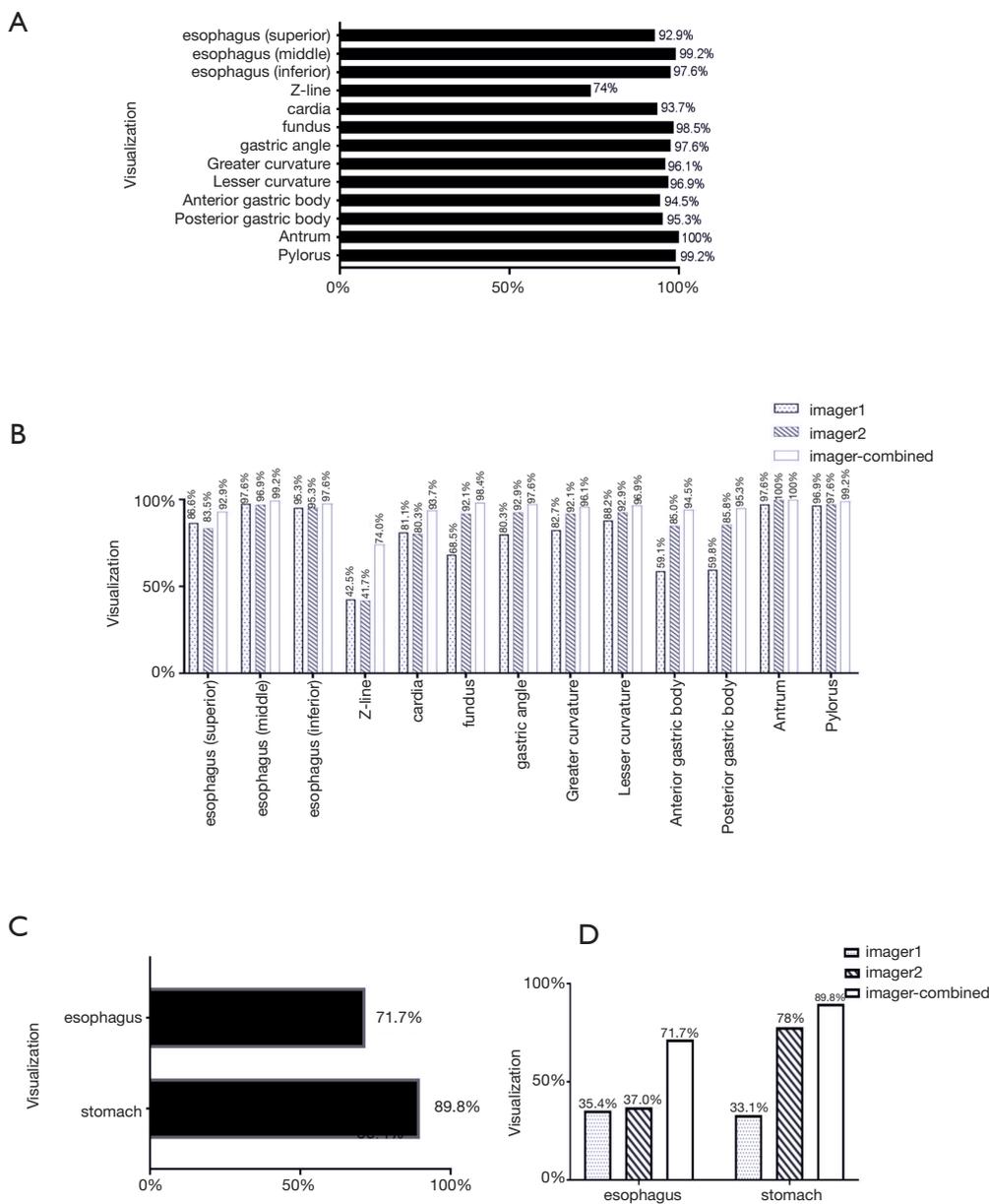


Figure 5 Visualization rates of different landmarks and different imagers. (A) The individual visualization rates of the esophageal and gastric landmarks were as follows: superior esophagus (92.9%), middle esophagus (99.2%), inferior esophagus (97.6%), Z-line (74%), cardia (93.7%), fundus (98.5%), greater curvature of the body (97.6%), lesser curvature of the body (96.1%), anterior gastric body (96.9%), posterior gastric body (94.5%), angulus (95.3%), antrum (100%), and pylorus (99.2%). (B) The visualization rate of the two imagers individually and the imagers combined. (C,D) The comprehensive visualization rates of the esophagus, stomach and upper gastrointestinal tract. Comprehensive visualization of the esophagus and stomach was defined as 100% mucosal visualization of all of the landmarks.

is feasible and that it represents an optional tool for upper gastrointestinal imaging.

These promising data from the PillCamColon2 system may be beneficial for diagnosing esophageal and gastric

diseases, and the two imagers that are located at separate ends of the capsule (which cover nearly a 360° view) may explain the efficacy of this system. Notably, these two imagers are not identical. We analyzed the two imagers of

Table 1 Upper gastrointestinal tract findings detected by the PillCamColon2

Findings	Imager1 (n)	Imager2 (n)	Imager-combined (n)
Total number of findings	133	137	160
Esophageal			
Esophagitis	7	4	10
Early cancer	0	1	1
Barrett esophagus	4	2	5
Esophageal varices	1	0	1
Cardiac			
Carditis	3	1	4
Stomach			
Erosion	93	104	107
Ulcer	4	6	6
Polyp	10	8	14
Atrophic gastritis	9	8	9
Gastric xanthelasma	1	2	2
SMT	1	1	1

Two-imager combination analysis detected 160 positive findings, single-imager analysis with imager1 detected 133 findings, and single-imager analysis with imager2 detected 137 findings. Two-imager combination analysis provided 20.3% and 16.8% more findings than single-imager analysis with imager1 and imager2, respectively. SMT: submucosal tumor.

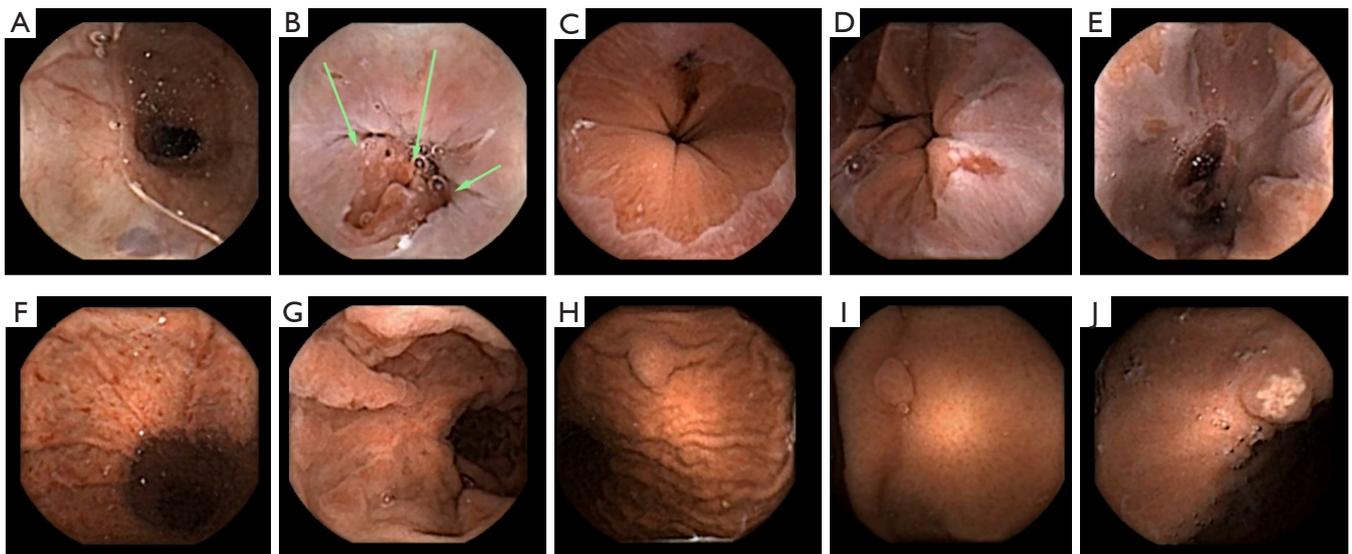


Figure 6 Typical positive findings in the esophagus and stomach. (A) Esophageal venous dilatation, (B) early esophageal cancer, (C) esophagitis, (D) esophagitis, (E) Barrett esophagus, (F) gastritis, (G) atrophic gastritis, (H) submucosa tumor (SMT), (I) polyp, and (J) gastric xanthelasma.

Table 2 Association of basic characteristics with visualization from different imagers

	N	imager1	Imager2		Imager-combined	
			OR (95% CI)	P value	OR (95% CI)	P value
Location						
Esophagus	127	Reference	1.1 (0.6, 1.8)	0.794	4.6 (2.7, 7.8)	<0.001
Gastric	127	Reference	7.2 (4.1, 12.5)	<0.001	17.7 (9.0, 35.1)	<0.001
Gender						
Male	91	Reference	2.0 (1.5, 2.6)	<0.001	5.9 (4.2, 8.4)	<0.001
Female	36	Reference	1.7 (1.1, 2.7)	0.025	4.5 (2.7, 7.4)	<0.001
Age, year						
10–46	42	Reference	1.8 (1.2, 2.7)	0.009	6.4 (3.9, 10.6)	<0.001
47–53	39	Reference	2.9 (1.8, 4.6)	<0.001	11.6 (6.3, 21.3)	<0.001
54–83	46	Reference	1.4 (0.9, 2.1)	0.118	3.0 (2.0, 4.7)	<0.001
BMI, kg/m ²						
16.65–22.41	42	Reference	1.9 (1.2, 2.9)	0.005	6.4 (3.9, 10.6)	<0.001
22.46–25.14	42	Reference	2.2 (1.4, 3.5)	<0.001	6.8 (4.0, 11.4)	<0.001
25.18–34.87	43	Reference	1.6 (1.0, 2.4)	0.031	3.9 (2.4, 6.1)	<0.001
Eso-Time, sec						
1–10	41	Reference	3.0 (1.7, 5.2)	<0.001	9.3 (5.2, 16.7)	<0.001
11–32	43	Reference	2.6 (1.6, 4.5)	<0.001	8.5 (4.8, 14.8)	<0.001
33–181	43	Reference	2.5 (1.5, 4.1)	<0.001	8.9 (5.0, 15.8)	<0.001
Gastro-Time, min						
7–30	41	Reference	4.0 (2.3, 6.9)	<0.001	13.3 (7.2, 24.4)	<0.001
31–77	43	Reference	2.3 (1.4, 3.8)	<0.001	6.0 (3.5, 10.2)	<0.001
82–237	43	Reference	2.2 (1.3, 3.7)	0.004	8.8 (5.0, 15.5)	<0.001
Cleanliness						
Excellent	41	Reference	2.6 (1.5, 4.4)	<0.001	12.0 (6.5, 22.1)	<0.001
Good	37	Reference	3.1 (1.7, 5.4)	<0.001	13.9 (7.2, 26.9)	<0.001
Fair	24	Reference	1.3 (0.7, 2.6)	0.3916	4.9 (2.4, 9.9)	<0.001
Poor	25	Reference	5.9 (2.5, 14.0)	<0.001	9.6 (4.0, 22.7)	<0.001

The significance of differences between groups was evaluated using *t*-tests for normally distributed continuous variables, the Mann-Whitney test for continuous variables with a skewed distribution, and the χ^2 test for categorical variables. BMI: body mass index, which was calculated as weight (kg) divided by height squared (m²). Eso-time: esophageal transit time of the capsule. Gastro-time: gastric transit time of the capsule. Cleanliness: a four-point grading scale was used to objectively describe the cleanliness of the upper gastrointestinal duct during the examination, as described above.

the PillCamColon2 system. After adjusting for confounding factors, we observed that imager2 (yellow) was lighter and exhibited a greater visualization rate than imager2 (green). One possible explanation for why the lighter camera views

more landmarks is that this capsule moved like a tumbler. Specifically, this camera rotated around a central axis, and the lighter imager covered a wider range. We also noticed fewer differences between the two imagers in the esophagus

Table 3 Association of imagers with visualization (multivariate logistic regression)

Y = visualization (yes or no)	Crude model		Model I		Model II	
	OR (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Imager						
Imager1	Reference		Reference		Reference	
Imager2	2.7 (2.0, 3.6)	<0.001	3.2 (2.3, 4.5)	<0.001	3.5 (2.5, 4.9)	<0.001
Imager-combined	8.7 (6.3, 12.1)	<0.001	13.2 (9.1, 19.2)	<0.001	16.0 (10.8, 23.8)	<0.001

Data show odds ratios with 95% confidence intervals in parentheses. Model I was adjusted for age and sex. Model II was adjusted for age, sex, location, BMI, Eso-time, Gastro-time, and cleanliness.

than in the stomach, and the size of the cavity may explain this finding. The rotation axis is smaller in a smaller cavity, and the difference between the two imagers was reduced. We hypothesized that the different designs of the imagers would be more useful in larger cavities. To our knowledge, this study is the first report on the different performances of the two imagers of the PillCamColon2 system in the upper gastrointestinal duct. This result may provide a reference for the use of capsule endoscopy, but more randomized controlled trials are required to validate our findings.

Our study demonstrated that the combined use of two imagers was better than the use of either of the two imagers alone. This is the first study to focus on the visualization provided by CCE-2 in the upper gastrointestinal tract. Similar to our study, other studies showed that capsule endoscopy with dual cameras had the potential to detect more small-bowel lesions by complementing each other (24-26). Other studies, including a prospective multicenter study, demonstrated that the PillCamColon2 was a safe and effective method for visualizing the colon and detecting colonic lesions (28,29). The present results suggest that the PillCamColon2 is a good choice for screening of the entire gastrointestinal tract.

Several limitations in this study should be noted. First, the 13-landmark visualization was not equal to an examination of the entire esophageal and gastric mucosa. We identified some critical lesions that were important. However, this study was a retrospective study, and the participants did not undergo conventional gastroscopy to verify the positive findings. Second, the fact that most of the population comprised healthy subjects or patients without upper gastrointestinal discomfort may decrease the positive findings of this study. Therefore, more prospective studies comparing conventional gastroscopy as the criterion standard to CCE-2 in diagnosing upper

gastrointestinal diseases are needed. However, the use of the colon capsule technique to aid in diagnosing upper gastrointestinal diseases, throughout the gastrointestinal duct, is an important finding. When the PillCamColon2 system was used in patients who reported lower digestive duct complaints, some upper gastrointestinal diseases were detected simultaneously. Subsequently, doctors may suggest that these patients undergo further examinations to screen the upper gastrointestinal duct. The PillCamColon2 system may also be a healthy examination choice for patients who are fearful of conventional gastroscopy and colonoscopy.

Acknowledgments

We thank Dandan Ren for the data collection.

Funding: This project was supported by the National Instrumentation Program (NIP) (No. 2013YQ160439) and the National Science Foundation of China (No. 81800480 and No. 81800465).

Footnote

Reporting Checklist: The authors completed the STROBE reporting checklist. Available at <http://dx.doi.org/10.21037/atm-20-3699>

Data Sharing Statement: Available at <http://dx.doi.org/10.21037/atm-20-3699>

Peer Review File: Available at <http://dx.doi.org/10.21037/atm-20-3699>

Conflicts of Interest: All authors completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/atm-20-3699>). The authors have no conflicts

of interest to declare.

Ethical Statement: The authors are 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. The study was performed in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology approved this study (2017-S313).

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Cite this article as: Li G, Jin Y, Bai T, Qian W, Xie X, Hou X. Feasibility of a second-generation colon capsule in visualization of the upper gastrointestinal tract. *Ann Transl Med* 2021;9(5):411. doi: 10.21037/atm-20-3699