

Original Article

Standing-type magnetically guided capsule endoscopy versus gastroscopy for gastric examination: multicenter blinded comparative trial

Hua-sheng Lai,¹ Xin-ke Wang,¹ Jian-qun Cai,¹ Xin-mei Zhao,¹ Ze-long Han,¹ Jie Zhang,¹ Zhen-yu Chen,¹ Zhi-zhao Lin,¹ Ping-hong Zhou,² Bing Hu,³ Ai-min Li¹ and Si-de Liu¹¹Guangdong Provincial Key Laboratory of Gastroenterology, Department of Gastroenterology, Nanfang Hospital, Southern Medical University, Guangzhou, ²Department of Gastroenterology, Zhongshan Hospital, Fudan University, Shanghai, and ³Department of Gastroenterology, West China Hospital, Sichuan University, Chengdu, China**Aim:** To compare feasibility and safety after gastrointestinal checkup by standing-type magnetically controlled capsule endoscopy (SMCE) and conventional gastroscopy.**Methods:** This was a prospective multicenter, blinded study that compared SMCE with gastroscopy in patients from April 2018 to July 2018. All patients first underwent SMCE and then subsequently had gastroscopy with i.v. anesthesia. We calculated the compliance rates of gastric lesion detection by SMCE using gastroscopy as the standard. Capsule retention rate, incidence of adverse events, and patient satisfaction were documented throughout the study.**Results:** One hundred and sixty-one patients who completed SMCE and gastroscopy were included in the analysis. Positive compliance rate among SMCE and gastroscopy was 92.0% (95% CI: 80.77%–97.78%). Negative compliance rate was 95.5%

(89.80%, 98.52%). Moreover, overall compliance rate was 94.41% (89.65%, 97.41%). Sixty-four pathological outcomes were identified. Of these 64 outcomes, 50 were detected by both procedures. The gastroscopy method neglected seven findings (such as five erosions, one polyp, and one ulcer). Furthermore, SMCE also overlooked seven lesions (i.e. one erosion, two polyps, one atrophy, and three submucosal tumors). Capsule retention or related adverse events were not reported.

Conclusion: Standing-type magnetically controlled capsule endoscopy provides equivalent agreement with gastroscopy and may be useful for screening of gastric illnesses without any anesthesia.**Key words:** compliance rate, conventional gastroscopy, gastric disease, gastric examination, standing-type magnetically guided capsule

INTRODUCTION

CONVENTIONAL GASTROSCOPY IS uncomfortable and has poor patient compliance. Although anesthesia can improve patient compliance, patients feel discomfort and may suffer from anesthesia-related adverse events after gastroscopy.¹Capsule endoscopy (CE) has been used for decades and represents a comfortable alternative gastroscopy method.^{2,3} A newly developed method called magnetically controlled CE (MCE) is currently used for gastric examination.^{4–6} According to the latest expert consensus on MCE, advantages of MCE are that it does not require sedation, iscomfortable and safe, has high diagnostic accuracy and is easily accepted by the population.⁷Recently, a new standing-type MCE (SMCE) system has been developed. Except for the SMCE system, three lying types of gastric capsule systems are currently used for medical assessment globally: the handle style, the MRI style, and the robotic style.^{5,8–10} When compared with other similar products such as Olympus (Olympus Medical Systems Co. Ltd., Tokyo, Japan) and NaviCam (ANKON Technologies Co. Ltd., Wuhan, China) magnetic capsule,^{8,11} SMCE does not require patients to be equipped with multiple antennae to record the images so the procedure is more convenient. Also, SMCE is more maneuverable, as the guidance magnet robot in this study could produce a maximum magnetic field of 250 mT, which is greater than the 100 mT of Olympus and the 200 mT of NaviCam.^{8,11}

However, the safety and feasibility of SMCE system remain to be determined. We carried out a multicenter comparison trial to confirm the effectiveness of SMCE, allowing patients to undergo a preliminary gastric SMCE examination before

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Registry and the registration number: The Chinese Clinical Trials Registry (ChiCTR1800018346).
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Received 27 June 2019; accepted 27 August 2019.

carrying out gastroscopy with sedation. Primary outcome was the compliance rate of stomach lesions detection by SMCE using gastroscopy as the standard.

METHODS

Study type and ethical approval

THIS STUDY WAS approved by the Institutional Review Board of participating centers. Written informed consent was obtained from all patients.

Patient enrolment

This trial was carried out in three tertiary hospitals between 17 April 2018 and 9 July 2018. Adult patients between 18 and 70 years who had upper abdominal complaints and were scheduled for gastroscopy were eligible.

Patients with any of the following were excluded: (i) various acute types of enteritis, such as bacterial dysentery, acute ulcerative colitis, asphyxia etc.; (ii) known or suspected gastrointestinal obstruction, stenosis, and fistula; (iii) acute phase of upper gastrointestinal perforation; (iv) severe throat disease; (v) acute phase of corrosive esophagitis; (vi) severe gastric dysmotility; (vii) electronic device implanted; (viii) previous history of allergy; and (ix) pregnancy.

Study intervention

First SMCE was conducted and subsequent gastroscopy was done with i.v. anesthesia after 4 h. Ability to detect gastric lesions was compared between SMCE and gastroscopy.

Standing-type magnetically controlled capsule endoscopy system

The SMCE system (JIFU Medical Technologies Co., Ltd, Shenzhen, China) comprises a capsule endoscope, a guidance magnetic robot, and imaging computer. The capsule is 27 × 12 mm (Fig. 1), weighs 2.7 g, and contains a permanent magnet (Fig. S1). Pictures are taken at 4 frames/s. Observation distance is 0–50 mm and viewing angle is 136°. The magnetic robot is a standing-type system without arms (Fig. 1) and contains wireless receivers.

Stomach preparation procedure and magnetically controlled capsule endoscopy procedure

Patients were asked to fast overnight (>8 h) before arriving at the hospital. Dimethyl silicone oil (10 mL; Berlin-Chemie AG, Berlin, Germany) was used as a defoamer 30 min

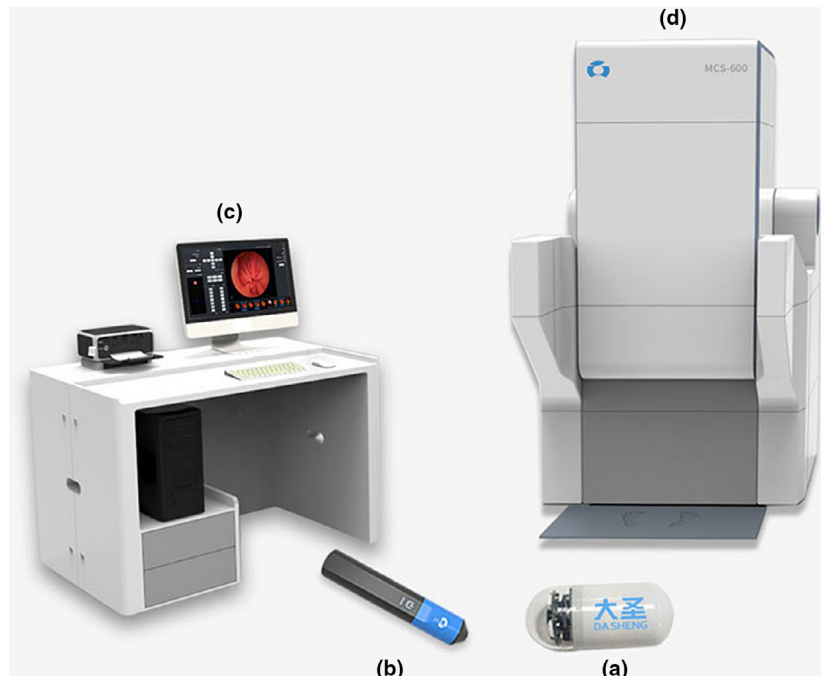


Figure 1 Guidance equipment: guidance magnet robot and control station. Four single images are shown: (a) capsule endoscopy, (b) capsule activator, (c) control station, (d) standing-type guidance magnet robot.

before inspection and 20 000 units pronase granules were used 15 min before inspection (Beijing Tide Pharmaceutical Co., Ltd, Beijing, China) to eliminate mucus. Patients were requested to consume 500 mL to 1 L of water to a feeling of fullness.

Six anatomical landmarks (cardia, fundus, body, angulus, antrum, and pylorus) were observed. When the patient stood with his/her left side close to the machine, the capsule moved to the fundus, cardia and body; when the patient stood with the abdomen stood close to the machine, the capsule moved to the angulus, antrum, and pylorus (Video S1).

Gastroscopy

Gastroscopy (Olympus GIF-H260; Tokyo, Japan) was carried out 4 h after SMCE. It was done by two other endoscopists with experience of more than 1000 gastroscopies, both of whom were unaware of the previous SMCE results. Six landmarks were observed and photographed. If clinically necessary, pathological biopsy specimens were taken. Operator recorded all the results of gastroscopy, including lesion location, size, and characteristics, which were confirmed by two doctors. A second gastroscopy of the patient was required within 1 week after a lesion was determined by SMCE but not by gastroscopy, but the results were not included in the final evaluation. Esophagus and duodenum were also inspected by gastroscopy, but the results were not included in the final evaluation.

Gastric mucosal cleanliness and visualization

Mucosal cleanliness of major anatomical landmarks of the stomach was assessed and recorded in real time by two reviewers who were maneuvering the capsule. Four review subscales were used to subjectively rate the cleanliness, namely excellent, good, fair, or poor (Fig. S2).¹²

A five-level subscale was applied to subjectively define visualization of the six landmarks, as follows: level 1, >90% of the mucosa was observed; level 2, 75–90% of the mucosa was observed; level 3, 60–74% of the mucosa was observed; level 4, 50–59% of the mucosa was observed; and level 5, <50% of the mucosa was observed.

Evaluation of study findings

Evaluation of SMCE was operated by two experienced physicians with experience of more than 100 MCE. Positive findings were defined as focal lesions such as erosion, polyp, ulcer, and others (i.e. submucosal tumor [SMT], heterotopic pancreas etc.), or a diffuse lesion such as atrophic gastritis. Normal gastric mucosa or mild

inflammation was defined as a negative finding. Results from both examinations were consistent when the location, characteristics, and sizes of the lesions were consistent. If more than one lesion was noticed in a patient, the most critical lesion was selected, and the ulcer, polyp, SMT, etc. was considered the final analysis. Images of each patient were independently assessed by two investigators. If the results between the two investigators were inconsistent, an independent investigator made a final diagnosis. They were blinded to each other's test results.

Evaluation of safety and maneuverability of SMCE

If the capsule was not found in stool within 1 week, patients were instructed to return to the respective center for abdominal X-ray. If patients had not found the capsule in 2 weeks, they were instructed to return to hospital for surgery or other treatment for capsule removal as suggested by the investigator. Adverse events were defined as symptoms such as bloating, nausea, or vomiting during the trial. Overall maneuverability of the SMCE capsule was subjectively rated by the endoscopists.

Statistical analysis

We assumed that SMCE has at least a 96% positive compliance rate and a 78% negative compliance rate in detecting gastric lesions.⁶ With a significance level of 0.05 (two-sided) and tolerance error of 8%, the formula for calculating sample size was $n = Z_{1-\alpha/2}^2 P(1-P)/\Delta^2$ (Δ is the allowable error). After calculation, the number of positive-finding subjects was estimated to be 23, and negative-finding subjects was 104. At least 127 patients were needed. With a projected drop-out rate of 10%, at least 140 patients were required.

Descriptive statistics for continuous variables were recorded as mean \pm SD or median and range values. A chance-adjusted kappa statistic (κ) was calculated to assess the strength of compliance between SMCE and gastroscopy. Statistical analysis was done by SAS software version 9.4 (SAS, Cary, NC, USA).

RESULTS

Patients

A TOTAL OF 171 patients were registered in the three participating centers. After SMCE, three patients declined further follow up, one patient's capsule was removed by gastroscopy and therefore violated the protocol. One patient had unexplained skin allergy before SMCE, one

patient encountered menstrual period before the endoscopy period, one patient refused to return the capsule, and three patients voluntarily withdrew during the trial. Thus, 10 patients were not involved in the final analysis (5.8%). Hence, 161 patients who finished both tests were included in the analysis (Fig. 2). One hundred and sixty-five subjects who completed both methods were included in the safety set (SS). Ninety-four (57.0%) patients were male and 71 (43.0%) were female with a mean age of 30.02 ± 9.73 years (range, 18–69 years). Average time to conduct SMCE was 24.17 ± 7.48 min (range, 7–47 min), whereas average time to conduct the gastroscopy was 7.06 ± 4.18 min (range, 2–32 min).

Negative versus positive gastric areas determined by gastroscopy and SMCE

One hundred and six patients were determined as negative and 55 as positive (Table 1). These findings lead to a positive agreement of 92.0% (95% CI: 80.77%–97.78%), a negative agreement of 95.5% (89.80%, 98.52%), an overall agreement of 94.41% (89.65%, 97.41%), and a κ -value of 0.870 (two-sided exact, $P < 0.0001$). McNemar's test indicated a P -value of 0.11 ($P = 0.74$), suggesting that the results obtained from both investigations were not significantly different.

Table 2 and Table 3 show the lesions found by SMCE and gastroscopy. Sixty-four pathological findings were identified, of which 50 lesions were detected by both procedures. Among the diagnoses, there were 23 erosions, 15 polyps, nine SMT, one heterotopic pancreas, and two atrophic gastritis (Figs 3 and 4). Gastroscopy identified seven extra lesions that were overlooked by SMCE, together with one erosion, two polyps,

one atrophic gastritis, and three SMT. SMCE also detected seven lesions that were overlooked by gastroscopy including five erosions, one polyp, and one ulcer. The polyps not detected by gastroscopy were confirmed and treated by another endoscopic procedure.

Safety of SMCE and patient preference

Abdominal X-ray confirmed that there was no capsule retention during follow up. Of the 165 subjects included in the safety set (SS), 152 (92.1%) subjects had confirmed capsule excretion in the feces during the follow-up period (2 weeks), and the remaining 13 (7.9%) subjects finally confirmed excretion within 2 weeks by X-ray.

Adverse reactions were reported in three (1.8%) of the 165 patients who finished the study. One patient had nausea and vomiting, one patient had oral pain, and one patient had dizziness. Nausea and vomiting were considered a result of the gastric preparation procedure. All described symptoms disappeared within 24 h after the SMCE procedure. Among the 165 patients, 99 (60.0%) preferred SMCE, and 66 (40.0%) patients preferred gastroscopy.

Gastric cleanliness, mucosal visualization and maneuverability of SMCE

Gastric cleanliness in the cardia, fundus, body, angulus, antrum, and pylorus of the stomach was regarded as good in 82.6%, 84.2%, 93.9%, 96.0%, 97.6%, and 97.6% of patients who underwent SMCE, respectively. Gastric mucosa visualization in the above-mentioned six landmarks was good (level 1 or level 2) in 99.4%, 93.4%, 99.4%, 100.0%, 99.4%, and 99.4% of patients, respectively. Perfect visibility

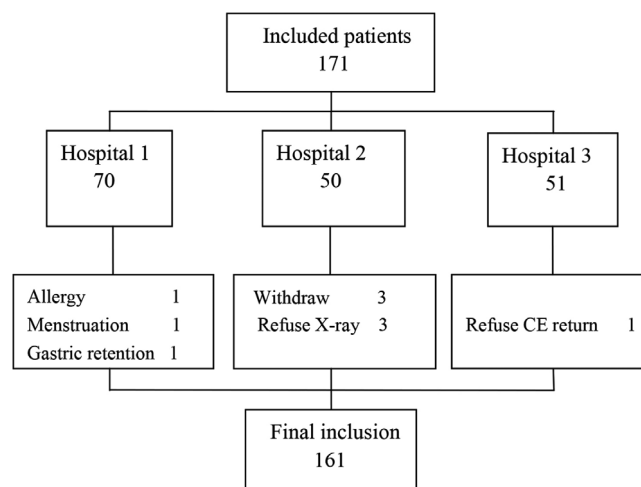


Figure 2 Flow chart of patients included in the present study.

Table 1 Initial readings of negative vs positive findings in patients who underwent SMCE and standard gastroscopy

SMCE, n (%)	Gastroscopy, n (%)		
	Positive	Negative	Total, n
Positive	46 (28.58)	5 (3.11)	51 (31.68)
Negative	4 (2.48)	106 (65.83)	110 (68.32)
Total	50 (31.06)	111 (68.94)	161 (100.00)

SMCE, standing-type magnetically controlled capsule endoscopy.

Table 2 Classification of 64 lesions diagnosed by SMCE and standard gastroscopy

Lesion	SMCE only, n	Gastroscopy only, n	Both SMCE and gastroscopy, n
Erosion	5	1	23
Polyp	1	2	15
Ulcer	1	0	0
Atrophic gastritis	0	1	2
Protuberance	0	3	9
Heterotopic pancreas	0	0	1
Bleeding	0	0	0
Total (abnormal)	7	7	50

SMCE, standing-type magnetically controlled capsule endoscopy.

(level 1) in the above-mentioned six landmarks accounted for 49.7%, 47.9%, 61.2%, 68.5%, 63.0% and 63.6% of patients, respectively. In nearly all subjects (164, 99.4%), maneuverability was graded as good or moderate.

DISCUSSION

STANDING-TYPE MAGNETICALLY CONTROLLED capsule endoscopy and gastroscopy show similar diagnostic consistency with overall consistency of 94.41%, positive agreement of 92.0% and negative agreement of 95.5%. A previous similarly designed study on a similar product⁶ showed overall consistency of 91.2% (95% CI: 84.4%–97.9%), positive agreement of 96.0% and negative agreement of 77.8%. Compared to the latter study, SMCE was slightly better in overall agreement rate and it seemed that SMCE was significantly better in negative agreement rate. Possible reasons for this advantage are that the SMCE capsule was able to distinguish greater detail of the mucosal pattern of the stomach and had a better ability to distinguish between normal mucosa and mucosal lesions. In the present study, both methods missed focal lesions. However, SMCE appears to have a small benefit over

Table 3 Per location and per lesion analyses of lesions diagnosed by SMCE and standard gastroscopy

		Gastroscopy only, n	SMCE only, n	Both SMCE and gastroscopy, n
Antrum	Atrophic gastritis	1	0	1
	Polyp	0	0	1
	Ulcer	0	0	0
Body	Atrophic gastritis	0	1	0
	Polyp	1	0	11
	Ulcer	1	0	0
Fundus	Atrophic gastritis	0	0	0
	Polyp	0	1	2
	Ulcer	0	0	0
Cardia	Atrophic gastritis	0	0	0
	Polyp	1	0	1
	Ulcer	0	0	0
Angulus	Atrophic gastritis	1	0	1
	Polyp	0	0	1
	Ulcer	0	0	0

SMCE, standing-type magnetically controlled capsule endoscopy.

gastroscopy in finding mild erosion (five lesions vs one lesion). These findings are consistent with other findings.^{4,5,13} Possible reasons for this advantage are the magnifying effect of water and, as a result of this, the capsule was able to inspect the mucosal surface for an extended time due to better patient tolerability of capsule.

Standing-type magnetically controlled capsule endoscopy is a promising alternative screening method for gastric disease. First, SMCE could be a reliable screening method for patients who do not require further invasive procedures. In this trial, only 30 patients (18.2%) needed biopsy by gastroscopy. Hence, more than 80% of patients did not require invasive gastroscopy after SMCE investigation. Second, SMCE takes up less space, which is more acceptable in medical institutions than lying-type devices.^{12,14,15} Third, another benefit of SMCE is its comparatively lower price.^{11,12} The cost of each SMCE examination appears to be cheaper than that of the other MCE system in China (\$436.13 vs \$581.51), but still higher than sedation gastroscopy (\$145.38).

Adverse events described by patients were infrequent and mild, and none of the reported events were due to the capsule itself. In the present study, patients suspected of having small-bowel disease were excluded, and the retention rate of the capsule in these excluded patients is supposed to

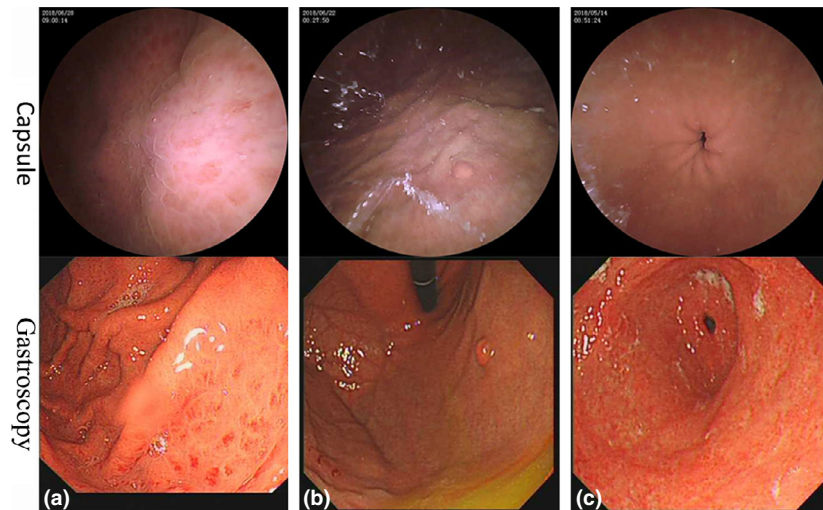


Figure 3 Representative images taken by both magnetically controlled capsule endoscopy and gastroscopy. (a) Erosive gastritis. (b) Gastric polyp. (c) Atrophic gastritis.

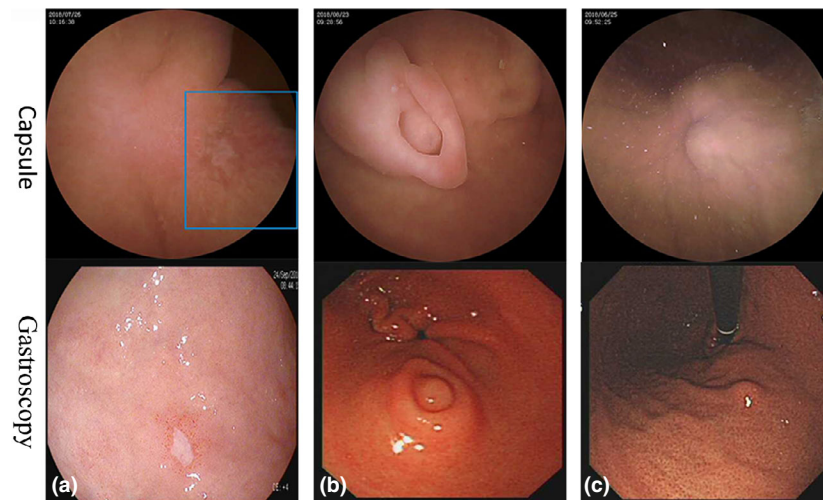


Figure 4 Representative images taken by both magnetically controlled capsule endoscopy and gastroscopy. (a) Ulcer. (b) Heterotopic pancreas. (c) Submucosal tumors.

be low.¹⁶ No retention occurred in our study. Our findings support that SMCE, specified for identifying upper gastrointestinal diseases, is safe with a very low complication rate.

Maneuverability of the SMCE was graded as good in 105 (63.6%) patients and moderate in 59 (35.8%) patients. Maneuverability is the most important factor in determining whether CE can be effectively controlled in the gastrointestinal tract.^{10,14,17} In the present study, the SMCE device was advanced to the entire cardia and fundus, which were considered to be extremely challenging regions for active control in other studies.^{8,18}

In the present study, cleanliness in six landmarks was good in more than 80% of patients who underwent SMCE. Most studies used simethicone as an antifoaming agent to improve visualization of the gastric mucosa and removal of gastric mucus by pronase granules.^{5,12,19} In our study, gastric mucus reduced capsule visualization in nine patients. Current or past *Helicobacter pylori* infection status is considered to be a cause of excessive and/or sticky mucus.^{20,21} However, only one hospital in our study had assessed *H. pylori* infection status. Elimination of mucus by pronase²² has been shown to eliminate this problem, and this result was consistent with a previous study.⁴

Although SMCE was as good as gastroscopy in investigative agreement, certain limitations of SMCE must be considered. First, SMCE examination time was longer than the time needed for gastroscopy (24 min to 7 min); however, in the future, the time required will be less when the image is automatically analyzed using artificial intelligence.^{23–27} SMCE requires less time than does a similar product, which requires approximately 30 min.⁵ Second, SMCE examination time varied from 7 min to 47 min. Reasons for this are as follows: First, the SMCE capsule moved in the liquid by means of rolling and rotating. So, when moving the same distance, the path of the capsule's lens was much longer than that of gastroscopy. Second, the visual field of the capsule in the motion state changed rapidly, which made manipulation of the capsule more difficult and thus increased operation time. Also, the structure of each person's stomach cavity is different, resulting in different trajectories of capsule movement. Third, the discomfort caused by standing may limit the use of SMCE in certain patients, but, in the future, a sitting method will solve this problem. In addition, upper gastrointestinal endoscopy generally includes examination of the entire esophagus, stomach, and duodenum. Thus, SMCE targeted for stomach only may limit its use in clinical practice.

Standing-type magnetically controlled capsule endoscopy system produces approximately 20 000 images per inspection and 30–60 min are required for a doctor to read them. With the application of artificial intelligence, SMCE system has been able to screen 80–90% of similar images, greatly reducing the burden on doctors. Similar to published studies,^{28–32} doctor's reading time will further shorten with the application of computer-assisted diagnosis. Image-processing technologies have also been applied to CE.^{33,34} A recent meta-analysis showed that improved delineation was seen in 89% of angioectasias and in 45% of ulcer/erosions using flexible spectral imaging color enhancement.³⁵ However, imaging processing technology has not been applied in this study, but it will be implemented in the next generation of SMCE.

In conclusion, this new SMCE method may be a promising alternative for noninvasive screening for gastric diseases. Technical modifications are needed, and trials with larger sample sizes in a high-risk population need to be done.

ACKNOWLEDGMENTS

THIS STUDY WAS supported by Science and Technology Project of Guangdong, No. 2015B020233007 and No. 2018A070701005 and Guangdong Gastrointestinal Disease Research Center, No. 2017B020209003.

CONFLICTS OF INTEREST

AUTHOR H.L. IS a consultant for JIFU Technologies beginning September 2018. The other authors have no conflicts of interest or financial ties to disclose.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Figure S1 Magnetically controlled capsule endoscope (JIFU Medical Technologies Co., Ltd, Shenzhen, China). The capsule has a size of 27 × 12 mm and has a permanent magnet inside its dome. Viewing angle of the capsule is 136°, and the viewing distance is 0–50 mm.

Figure S2 Symbolic images indicating the use of 4-point grading scale to accurately explain the cleanliness of the stomach for the duration of the examination. (A) Excellent, no more than small bits of adherent mucus and foam. (B) Good, a small amount of mucus and foam, but not enough to interfere with the examination. (C) Fair, a considerable amount of mucus or foam present to preclude a completely reliable examination. (D) Poor, large amount of mucus or foam residue.

Video S1 Inspection procedure of standing-type magnetically controlled capsule endoscopy.