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ALIMENTARY TRACT

Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases

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BACKGROUND & AIMS: Diseases of the stomach, including gastric cancer and peptic ulcer, are the most common digestive diseases. It is impossible to visualize the entire stomach with the passive capsule currently used in practice because of the large size of the gastric cavity. A magnetically controlled capsule endoscopy (MCE) system has been designed to explore the stomach. We performed a prospective study to compare the accuracy of detection of gastric focal lesions by MCE vs conventional gastroscopy (the standard method).

METHODS: We performed a multicenter blinded study comparing MCE with conventional gastroscopy in 350 patients (mean age, 46.6 y), with upper abdominal complaints scheduled to undergo gastroscopy at a tertiary center in China from August 2014 through December 2014. All patients underwent MCE, followed by conventional gastroscopy 2 hours later, without sedation. We calculated the sensitivity, specificity, positive predictive value, and negative predictive value of detection of gastric focal lesions by MCE, using gastroscopy as the standard.

RESULTS: MCE detected gastric focal lesions in the whole stomach with 90.4% sensitivity (95% confidence interval [CI], 84.7%–96.1%), 94.7% specificity (95% CI, 91.9%–97.5%), a positive predictive value of 87.9% (95% CI, 81.7%–94.0%), a negative predictive value of 95.9% (95% CI, 93.4%–98.4%), and 93.4% accuracy (95% CI, 90.83%–96.02%). MCE detected focal lesions in the upper stomach (cardia, fundus, and body) with 90.2% sensitivity (95% CI, 82.0%–98.4%) and 96.7% specificity (95% CI, 94.4%–98.9%). MCE detected focal lesions in the lower stomach (angulus, antrum, and pylorus) with 90.6% sensitivity (95% CI, 82.7%–98.4%) and 97.9% specificity (95% CI, 96.1%–99.7%). MCE detected 1 advanced gastric carcinoma, 2 malignant lymphomas, and 1 early stage gastric tumor. MCE did not miss any lesions of significance (including tumors or large ulcers). Among the 350 patients, 5 reported 9 adverse events (1.4%) and 335 preferred MCE over gastroscopy (95.7%).

CONCLUSIONS: MCE detects focal lesions in the upper and lower stomach with comparable accuracy with conventional gastroscopy. MCE is preferred by almost all patients, compared with gastroscopy, and can be used to screen gastric diseases without sedation. Clinicaltrials.gov number: NCT02219529.

Keywords: Magnetically Controlled Capsule Endoscopy; Gastroscopy; Gastric Diseases; Diagnostic Accuracy; Screening.

[b]Authors share co-senior authorship.

Abbreviations used in this paper: CE, capsule endoscopy; CI, confidence interval; CMOS, complementary metal-oxide semiconductor; MCE, magnetically controlled capsule endoscopy; SMT, submucosal tumor.

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Diseases of the stomach, including gastric cancer and peptic ulcer, are the most common digestive diseases. Gastric cancer is the fourth most common cancer globally, and is the second most common cause of death from cancer worldwide.[1] Almost 4% to 17% of the world population has or has had a peptic ulcer of the stomach or duodenum.[2] Conventional gastroscopy allows for the accurate localization of lesions, and is the most effective diagnostic modality for gastric diseases. Unfortunately, it is invasive and uncomfortable under nonsedated situations, leading to low patient compliance. Although sedation can improve patient compliance, its cost has been a major concern, as well as discomfort and anesthesia-related adverse events that are encountered in a few patients after the procedure.[3]

Capsule endoscopy (CE) was first introduced in 2000, and represents a more patient-friendly alternative method of examination without significant discomfort, which has been widely applied in clinical practice.[4,5] However, complete gastric visualization with the passive capsule currently used in clinical practice is impossible because of the large size of the gastric cavity. Recently, studies have shown that the use of capsules maneuvered with an external magnetic field, so-called magnetically controlled capsule endoscopy (MCE), may represent a more reliable approach for gastric examination; several trials have reported promising results.[6–9] However, most of these studies were pilot studies with a small sample size, and no large multicenter study has been reported.

A novel MCE system was developed and approved by the China State Food and Drug Administration in 2013, which uses a permanent magnetic field generated by an external industrial robot to allow for noninvasive exploration of the stomach. Two pilot studies have shown that the MCE system was safe and feasible in healthy volunteers and a small number of patients.[10,11] However, the diagnostic accuracy of MCE for gastric diseases needs to be confirmed in a large-scale trial. Therefore, this large prospective multicenter study was performed to compare the performance of MCE with conventional gastroscopy in detecting gastric lesions.

Materials and Methods

Study Design

This study was a prospective, self-controlled, multicenter, blinded comparison study. The study protocol was approved by the institutional review board of each participating center. Written informed consent was obtained from all patients.

Study Patients

This multicenter comparative study was conducted at 7 tertiary referral centers between August 2014 and December 2014. Adult patients with upper abdominal complaints aged 18 to 75 years, who were scheduled to undergo a gastroscopy, were eligible for this study. Patients with any of the following conditions were excluded: (1) dysphagia or symptoms of gastric outlet obstruction, suspected or known intestinal stenosis, overt gastrointestinal bleeding, history of upper gastrointestinal surgery or abdominal surgery altering gastrointestinal anatomy, or postabdominal radiation; (2) congestive heart failure, renal insufficiency, under therapeutic anticoagulation, in poor general condition (American Society of Anesthesiologists class III/IV), claustrophobia, metallic parts, a pacemaker or other implanted electromedical devices, or artificial heart valves; (3) pregnancy or suspected pregnancy; (4) exclusion criteria for standard magnetic resonance imaging examination such as the presence of surgical metallic devices, even though its low magnetic field technically would not interfere with such devices; or (5) currently participating in another clinical study.

Study Intervention

MCE was performed, followed by conventional gastroscopy 2 hours later, without sedation in eligible patients. The performance in detecting gastric focal lesions between MCE and conventional gastroscopy was compared.

Magnetically controlled capsule endoscopy system. The MCE system was provided by Ankon Technologies Co, Ltd (Wuhan, Shanghai, China). This system consists of an endoscopic capsule, a guidance magnet robot, a data recorder, and a computer workstation with software for real-time viewing and controlling. The capsule has a size of 28×12 mm, and contains a permanent magnet inside its dome. Images are captured and recorded at 2 frames/s (Supplementary Figure 1*A*). The view angle of the MCE is 140°, and the view distance is 0 to 60 mm. A CMOS image sensor is used in the MCE. The LED light exposure time and signal gain of CMOS sensor are adjusted automatically by measuring the histogram of the image to optimize brightness and contrast the images. The robot used to guide the magnet was a C-arm type with 5 *df*, 2 rotational degrees and 3 translational degrees. The capsule can be controlled either manually by a guidance magnet robot through a joystick or automatically by default mode. The size of lesions could be measured by the ESNavi software (Ankon Technologies Co, Ltd, Wuhan, China). Recording and downloading data are similar to other CEs (Supplementary Figure 1*B*).

Gastric preparation regimen and magnetically controlled capsule endoscopy examination protocol. Patients arrived at the hospital in the morning after overnight fasting (>8 hours). In clinical practice, we used simethicone (Menarini Group, Florence, Italy) as a defoaming agent to improve gastric mucosal visualization, and pronase granules (Beijing Tide Pharmaceutical Co, Ltd, Beijing, China) to remove gastric mucus.[12–15] During the MCE examination, patients were asked to drink 500 to 1000 mL of water on demand.

When the capsule reached the stomach, the capsule was lifted away from the posterior wall, rotated, and advanced to the fundus and cardiac regions, and then to the gastric body, angulus, antrum, and pylorus. If distension was insufficient, water ingestion was repeated. The MCE gastric examination time was limited to 30 minutes. All patients were followed up for up to 2 weeks to confirm capsule excretion and any adverse events. The patients were asked to document the excretion time of the capsule if they found the capsule in the stool. If the patients did not found the capsule in 2 weeks, they should come back to the center for confirmation by magnetic scanning or abdominal plain radiograph examination.

Gastric mucosal cleanliness and visualization. Gastric mucosal cleanliness and visualization in primary anatomic landmarks of the stomach including the cardia, fundus, body, angulus, antrum, and pylorus of the stomach were evaluated and scored, respectively. A 4-point grading scale was used to objectively describe the cleanliness of the stomach during MCE as excellent, good, fair, or poor (Supplementary Figure 2).[16,17]

A 3-point grading scale was used to objectively describe the complete visualization of the gastric mucosa in the 6 anatomic landmarks in the stomach. The 3-point grading scale described the visualization of the gastric mucosa as good (>90% of the mucosa was observed), fair (70%–90% of the mucosa was observed), and poor (<70% of the mucosa was observed).

Gastroscopy. Conventional gastroscopy without sedation was performed by a second experienced physician who was blinded to the capsule results 2 hours after capsule ingestion on the same day, and this was introduced as the standard diagnostic method with which MCE was compared. Gastric focal lesions were diagnosed, and their size was measured by either visual estimation or estimation with the use of open biopsy forceps during gastroscopy. Gastric biopsy specimens were obtained if the endoscopist performing the examination considered the procedure to be clinically necessary. If a focal lesion was obtained by MCE, but not by the subsequent gastroscopy, a second gastroscopy was performed 1 week after MCE by a senior endoscopist, who was informed of the false-positive finding by MCE. We only used the first gastroscopy result for the final data analysis, the second gastroscopy was performed only for ensuring whether or not there was a focal gastric lesion.

After MCE and gastroscopy, all the patients were asked if they preferred MCE or gastroscopy. The physician who performed the MCE and read the real-time gastric capsule videos and the other physician who performed the gastroscopy were unaware of each other's findings until completion of the examinations and reports.

Study Outcomes

The primary outcome in the present study was gastric focal lesion, which was defined as any of the positive findings including polyp, ulcers, submucosal tumor (SMT), and others (ie, xanthoma, diverticulum, and so forth). Erosion, gastritis, and gastric atrophy were defined as negative findings because they are diffuse lesions that can be diagnosed easily by MCE. Secondary outcomes included gastric cleanliness and mucosal visualization during MCE, patient compliance, and safety of MCE.

Evacuation of gastric focal lesions, patient compliance, and safety of MCE. Selected reading speed initially was set and fixed at 4 frames per second. Evaluation of MCE was performed by a well-trained physician with experience of at least 400 capsule endoscopies. CE videos of the gastrointestinal tract, together with videos of the small bowel if available, were read and analyzed carefully in real time and after the procedure. All the findings in the esophagus, small bowel, and colon by MCE also were recorded and disclosed to patients, but we did not report those data in this article because of the specificity of the research design.

Patient compliance for MCE, defined as the tolerance to procedures of the MCE examination including swallowing of the capsule, drinking plenty of water, and lying down for at least half an hour, was monitored. Adverse events, defined as symptoms or signs such as abdominal distension, nausea, or vomiting, were monitored closely and recorded by interviewing the patient as an outpatient or by telephone 1, 3, 5, and 7 days, and 2 weeks after the MCE procedure. Capsule retention (ie, a capsule endoscope remaining in the digestive tract for a minimum of 2 weeks or a capsule endoscope that requires directed intervention or therapy to aid its passage) also carefully was monitored and managed for up to 2 weeks.

Statistical Analysis

For sample size calculation, considering conventional gastroscopy as the gold standard, our study assumed that gastric CE has at least 87% sensitivity and 52% specificity in detecting patients with gastric focal lesions, which were separately the lower limit values of the 95% confidence interval (CI) of 96.00% sensitivity and 77.78% specificity according to our previous study results.[11] To maintain that hypothesis, as well as the significance level of 5% (2-sided) and tolerance error of 6%, the required positive findings were estimated to be 60. In addition, the prevalence of gastric focal lesions was assumed to be 20% in a population that underwent routine gastroscopy (according to an unpublished analysis of gastroscopy results at Changhai Hospital in 2013). We chose 300 as the study sample size. With an estimated drop-out rate of 15%, a total study size of 345 patients was required.

Per-patient comparisons between conventional gastroscopy and MCE were performed according to the type, location, and size of the lesions. If more than 1 focal lesion was detected in a patient, the most important clinical-related finding with the priority of ulcer, SMT, polyp, and others was chosen as the final diagnosis.

Descriptive statistics for continuous variables are expressed as the mean ± SD or median and range values, where appropriate. Variables pertaining to accuracy were calculated with a 95% CI (normal approximate) based on a binomial distribution, in which conventional gastroscopy was considered to be the standard procedure for detecting focal lesions, and gastroscopy combined with biopsy was considered the gold standard procedure for detecting ulcers and cancer. Sensitivity was calculated as the percentage of patients who had positive findings on MCE (of a specified category) among those patients who had positive findings on gastroscopy (of the same category). Specificity was calculated as the percentage of patients who had negative findings on MCE (of a specified category) among patients with negative findings on gastroscopy (of the same category), and this corresponded to 1-the false-positive rate. Statistical analyses were performed with SAS software version 9.3 (SAS Institute, Inc, Cary, NC).

All authors had access to the study data and reviewed and approved the final manuscript.

Results

Patients

A total of 353 patients were enrolled in the 7 participating centers. Three patients (0.8%) refused further conventional gastroscopy after MCE and were not included in the analysis. Therefore, 350 patients who completed the MCE and conventional gastroscopy were included in the analysis. Among these patients, 186 (53.1%) were male and 164 (46.9%) were female; and the mean age was 46.6 ± 13.3 years (range, 18–75 y). A total of 110 patients (31.4%) who were diagnosed with focal lesions or/and atrophic gastritis required biopsy under gastroscopy. The mean time of the MCE studies was 26.4 ± 5.1 minutes (range, 20–33 min).

Primary Outcome

Prevalence of gastric focal lesions by gastroscopy and magnetically controlled capsule endoscopy. Table 1 shows the per-patient prevalence of gastric focal lesions detected by conventional gastroscopy and the performance of MCE for detecting lesions (Figures 1 and 2).

For gastroscopy, 121 focal lesions including polyp ($n = 53$), ulcer ($n = 34$), SMT ($n = 19$), and others ($n = 15$) were found in 104 patients, which represents 29.7% of the patients studied; 85 patients had only 1 kind of focal lesion and 19 patients had at least 2 kinds of focal lesions in the stomach. Various types of gastritis were present in the remaining 246 patients.

Among the 104 patients, 24 (23.1%), 27 (26.0%), and 53 (51.0%) patients had focal lesions (the most clinically related lesion chosen as the final diagnosis) located at the cardia/fundus, body, and angulus/antrum, respectively. Sixty-four (61.5%) patients had lesions less than 5 mm in size, and 40 (38.5%) patients had lesions more than 5 mm in size. MCE detected 128 focal lesions including polyp ($n = 57$), ulcer ($n = 32$), SMT ($n = 17$), and others ($n = 22$) in 107 patients. Gastritis was present in the remaining 243 patients. Gastric focal lesions were observed in 10 patients by gastroscopy, whereas gastric focal lesions were observed in 13 patients by MCE (Tables 1 and 2).

Performance of magnetically controlled capsule endoscopy in detecting gastric focal lesions. With conventional gastroscopy as the gold standard, the sensitivity, specificity, positive predictive value, and negative predictive

Table 1. Prevalence of Gastric Focal Lesions Detected by Conventional Gastroscopy and MCE in 350 Patients With Upper Gastrointestinal Complaints, and the Performance of MCE Compared With Gastroscopy

	Gastroscopy	MCE		
Lesions	Patients, n (%)	Patients, n (%)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Type[a]				
Overall	104 (29.7)	107 (30.6)	90.4 (84.7–96.1)	94.7 (91.9–97.5)
Polyp	43 (12.3)	47 (13.4)	90.7 (82.0–99.4)	96.7 (94.4–98.9)
Ulcer[b]	30 (8.6)	28 (8.0)	90.0 (73.5–97.9)	99.6 (97.6–99.9)
Submucosal tumor	18 (5.1)	17 (4.9)	88.9 (65.3–98.6)	99.6 (97.6–99.9)
Others[c]	13 (3.7)	15 (4.3)	92.3 (64.0–99.8)	98.7 (96.3–99.7)
Location[d]				
Upper stomach	51 (14.5)	54 (15.4)	90.2 (82.0–98.4)	96.7 (94.4–98.9)
Lower stomach	53 (15.1)	53 (15.1)	90.6 (82.7–98.4)	97.9 (96.1–99.7)
Size				
<5 mm	64 (18.3)	71 (20.3)	92.2 (85.6–98.8)	95.1 (92.4–97.8)
≥5 mm	40 (11.4)	36 (10.3)	87.5 (77.3–97.8)	99.6 (97.6–99.9)

[a] If a patient has more than 1 focal lesion, the most important clinical-related finding with the priority of ulcer, submucosal tumor, polyp, and others was chosen as the final diagnosis.
[b] Including 3 malignant ulcer cases.
[c] Including early gastric cancer, xanthoma, diverticulum, venous aneurysm, telangiectasia, and ectopic pancreas.
[d] Upper stomach includes the cardia, fundus, and body, and lower stomach includes the angulus, antrum, and pylorus.

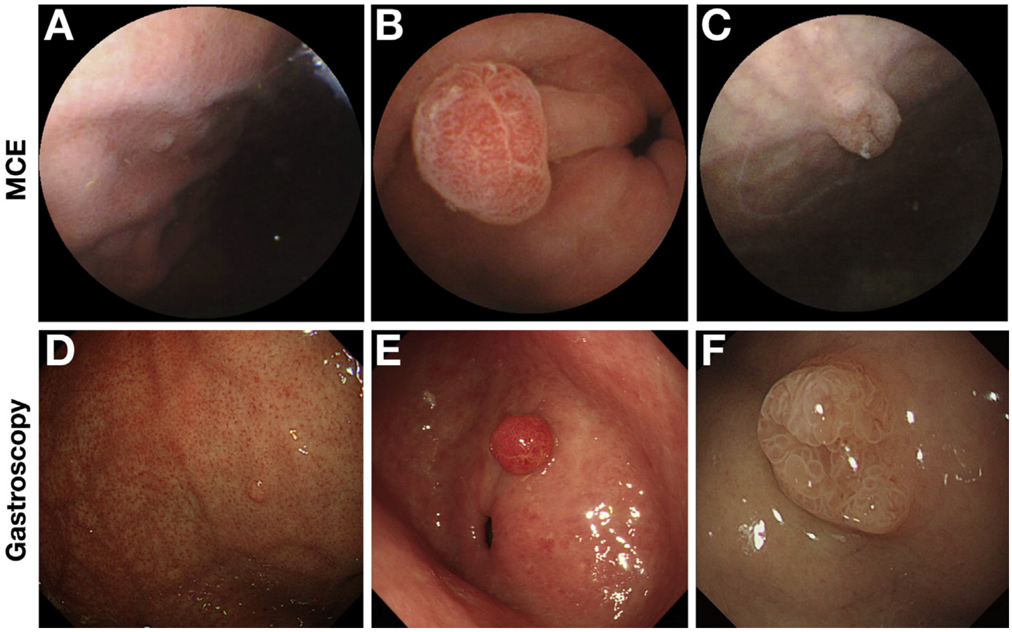

Figure 1. Representative polyps observed on conventional gastroscopy and MCE. (*A–C*) MCE examination and (*D–F*) gastroscopy.

value of MCE in detecting all gastric focal lesions were 90.4% (95% CI, 84.7–96.1), 94.7% (95% CI, 91.9–97.5), 87.9% (95% CI, 81.7–94.0), and 95.9% (95% CI, 93.4–98.4), respectively. Diagnostic accuracy was 93.4% (95% CI, 90.83–96.02) (Table 1).

The sensitivity and specificity of MCE in detecting focal lesions in the upper stomach (including the cardia, fundus, and body) were 90.2% (95% CI, 82.0–98.4) and 96.7% (95% CI, 94.4–98.9), respectively; whereas the sensitivity and specificity of MCE in detecting focal lesions in the lower stomach (including the angulus, antrum, and pylorus) were 90.6% (95% CI, 82.7–98.4) and 97.9% (95% CI, 96.1–99.7), respectively. The sensitivity and specificity of MCE in detecting focal lesions less than 5 mm were 92.2% (95% CI, 85.6–98.8) and 95.1% (95% CI, 92.4–97.8), respectively; and the sensitivity and specificity of MCE in detecting focal lesions that are 5 mm or larger were 87.5% (95% CI, 77.3–97.8) and 99.6% (95% CI, 97.6–99.9), respectively (Table 1).

Large gastric ulcers (>10 mm) were detected by conventional gastroscopy in 3 cases; wherein 2 were diagnosed with malignant lymphoma and 1 was diagnosed with gastric cancer by pathologic examination. Ulcers also were detected by MCE in all 3 cases. An early gastric cancer in the gastric antrum was detected by both MCE and gastroscopy in a 68-year-old man, and the 0.5 $\times$ 0.6 cm lesion was removed successfully by endoscopic submucosal dissection. Pathologic results suggest that it was high-grade intraepithelial neoplasia and focal

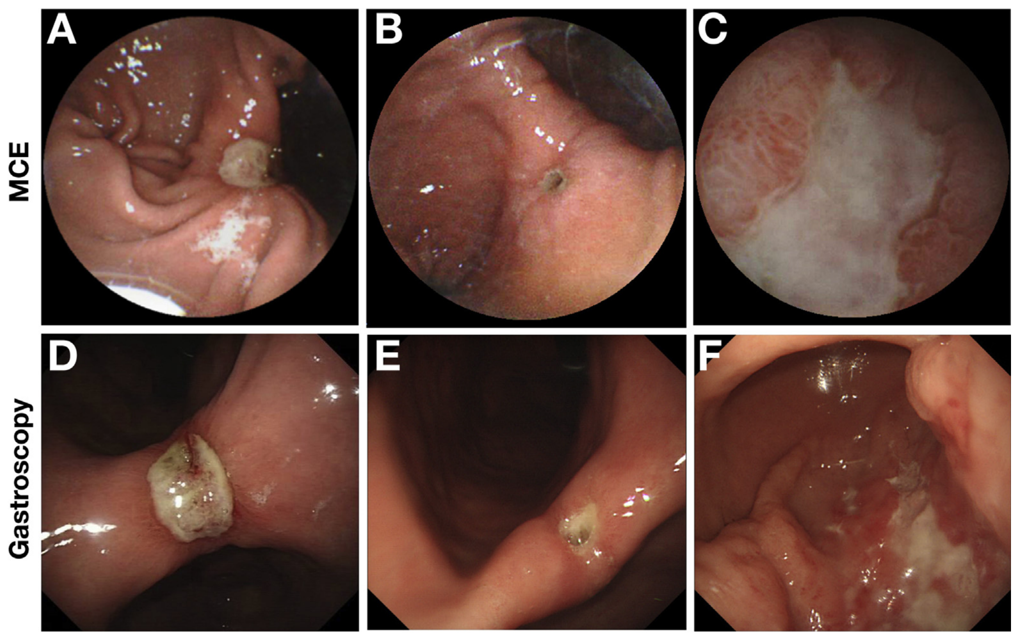

Figure 2. Representative ulcers observed on conventional gastroscopy and MCE. (*A* and *B*) Benign ulcers observed by MCE, (*C*) malignant ulcers observed by MCE, and (*D–F*) the corresponding ulcer images observed by gastroscopy.

Table 2. The Four-Fold Table Showing the Results of Gastric Focal Lesions and Gastritis Detected by Conventional Gastroscopy and MCE in the 350 Patients

		Gastroscopy		
		Focal lesions, n (%)	Gastritis, n (%)	Total, n (%)
MCE	Focal lesions	94 (26.9%)	13 (3.7%)	107 (30.6%)
	Gastritis	10 (2.8%)	233 (66.6%)	243 (69.4%)
	Total	104 (29.7%)	246 (70.3%)	350 (100%)

adenocarcinoma in the gastric mucosa. The patient recovered well (Figure 3).

Among the 10 false-negative cases, MCE missed SMTs in the fundus in 2 cases, ulcers in 3 cases (9.7%, one each in the antrum, body, and angulus), polyps in 4 cases (2 in the antrum, 1 each in the body and fundus), and mucosal uplift in 1 case (in gastric fundus, inflammation confirmed by pathologic examination). In addition, 5 (50%) of these missed lesions were less than 5 mm in size, and 4 (40%) were located in gastric fundus.

Among the 13 false-positive cases, MCE detected 13 lesions: 8 polyps, 1 SMT, 1 ulcer (3.2%), 2 xanthomas, and 1 diverticulum. Among these 13 lesions, 11 (84.6%) lesions were confirmed by a second gastroscopy including 7 polyps, 1 SMT, 1 ulcer, 1 xanthoma, and 1 diverticulum (Figure 4).

Safety Outcomes

Patient compliance and adverse events of magnetically controlled capsule endoscopy. All patients were able to swallow the capsule. No capsule retention occurred during the 2-week follow-up period, which was confirmed by magnetic scanning or abdominal plain radiograph examination. All patients excreted the capsule spontaneously, except for 1 patient who had duodenal ulcer complicated with stenosis. The retained capsule was extracted endoscopically on the same day by gastroscopy.

A total of 9 adverse events were reported in 5 (1.4%) of the 350 patients who completed this study. Three patients had abdominal distension and nausea, 1 patient had headache and vomiting, and 1 patient had foreign body sensations. In 4 of these 5 patients, adverse events including abdominal distension, nausea, vomiting, and headache were considered to be related to gastric preparation. All reported symptoms were resolved within 24 hours after ingestion of the capsule. Among the 350 patients, 335 (95.7%) preferred MCE, 4 (1.1%) preferred conventional gastroscopy, and 11 (3.1%) had no preference.

Secondary Outcomes

Gastric cleanliness and mucosal visualization during magnetically controlled capsule endoscopy. Gastric cleanliness was considered to be excellent or good in the cardia, fundus, body, angulus, antrum, and pylorus of the stomach in 80.9%, 87.2%, 90.9%, 96.0%, 96.6%, and 97.7% of patients undergoing MCE, respectively. Gastric mucosa visualization was considered to be good in 75.2%, 73.2%, 88.7%, 92.3%, 96.6%, and 97.4% of patients, respectively, in the 6 primary anatomic landmarks.

Discussion

This large, prospective, multicenter, blinded study showed that MCE is a safe method of visualizing the gastric mucosa through remote magnetic manipulation without the need for intubation or sedation. Sensitivity and specificity of MCE for detecting gastric focal lesions were acceptable in comparison with gastroscopy. Moreover, because of the noninvasiveness, more than 95% of patients preferred MCE as an initial diagnostic method.

MCE would be a promising alternative examination for gastric diseases.[7,18–21] First, MCE could be a reliable

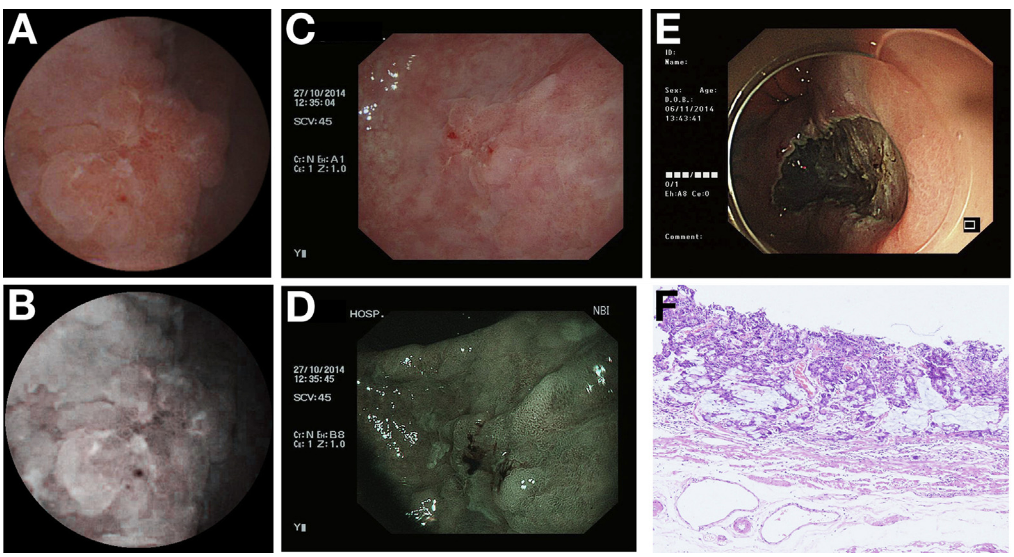

Figure 3. Early gastric cancer was observed on MCE and conventional gastroscopy. (*A*) MCE, (*B*) narrow-band imaging by MCE, (*C*) gastroscopy, (*D*) narrow-band imaging by gastroscopy, (*E*) endoscopic submucosal dissection, and (*F*) pathology.

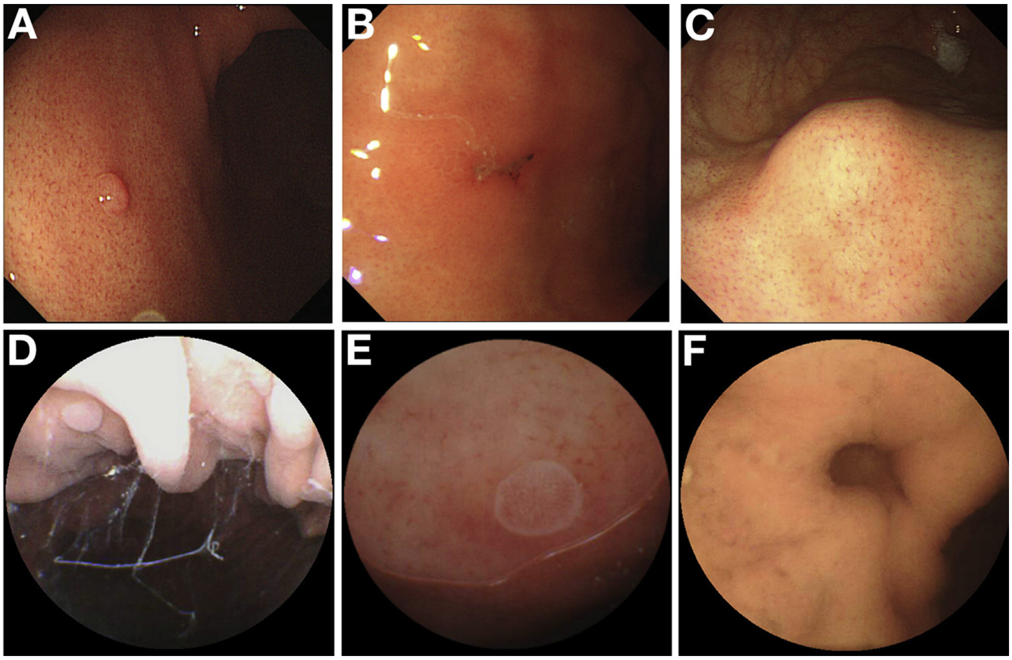

Figure 4. Representative images illustrating gastric focal lesions missed by MCE or gastroscopy. *Upper panel*: lesions missed by MCE. (*A*) Polyp, (*B*) small ulcer, and (*C*) submucosal tumor. *Lower panel*: lesions missed by the first gastroscopy. (*D* and *E*) Polyps and (*F*) gastric diverticulum.

filter test to stratify patients into those without relevant lesions not requiring further invasive methods, such as gastroscopy. In this study, there were 110 patients (31.4%) who required biopsy by gastroscopy. Therefore, nearly 70% of patients did not need an invasive gastroscopy after MCE examination. Second, MCE would be a promising alternative for high-risk patients with peptic ulcers or gastric cancer, ensuring that early lesions would be detected. Interestingly, an early gastric cancer was detected by MCE in this study. The most important lesion for esophagogastroduodenoscopy, at least in Asia, appears to be early gastric cancer. Images of early gastric cancer shown by Asian investigators often show a very subtle flat lesion. MCE seems to be more sensitive than conventional gastroscopy. However, the possibility of whether MCE could represent an effective tool for early gastric cancer screening needs to be validated by further studies. Third, even in regions with a lower expected prevalence rate of gastric pathologies, some patients who may have a contraindication for sedation are afraid of or reluctant to undergo gastroscopy, MCE could be a very patient-friendly examination.

A prevalence rate of approximately 30% for gastric focal lesions is more realistic for an average-risk population in a routine gastroscopy setting. In the present study, all types of gastritis were defined as a negative finding because almost all types of gastritis are diffuse lesions, and diagnosing these diseases was not a challenge for MCE. Although conventional gastroscopy is the gold standard for diagnosing gastric lesions, 13 focal lesions were detected by MCE, which was missed by gastroscopy. Taking into account the painlessness and high acceptance rate, MCE is a good filter test routine that has high sensitivity and specificity in clinical practice for gastric examinations such as gastric cancer screening.

Adverse events reported by the patients were rare and mild, and most of these were attributed to the preparation, in which patients ingested plenty of water. In the present study, only patients with upper abdominal complaints were included, and the retention rate of the capsule in those patients is believed to be lower than in patients who were suspected of small-bowel diseases. Taken together, our results support that MCE, indicated for detecting gastric diseases, is safe and has a very low complication rate.[22]

Although MCE in this study has proven to be comparable in diagnostic accuracy with conventional gastroscopy, there were still some limitations or disadvantages. First, the preparation for MCE is more complicated than that for conventional gastroscopy. Second, it takes 30 minutes to finish the MCE process, which is slightly longer than conventional gastroscopy, and this requires more strict training and experience for endoscopists. Third, the current cost of MCE is a little higher than conventional gastroscopy but the cost will decrease if it is used widely in the future. Fourth, the higher acceptability of MCE observed in this study might be biased by the fact that gastroscopy was performed without sedation.

In summary, this novel MCE has high diagnostic accuracy compared with conventional gastroscopy, and is a promising alternative for patient-friendly screening for gastric diseases.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Clinical Gastroenterology and Hepatology* at www.cghjournal.org, and at http://dx.doi.org/10.1016/j.cgh.2016.05.013.

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Conflicts of interest
The authors disclose no conflicts.

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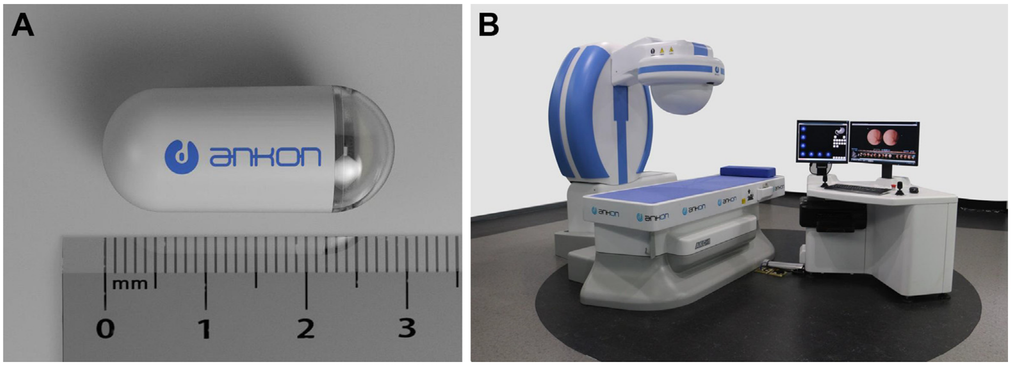
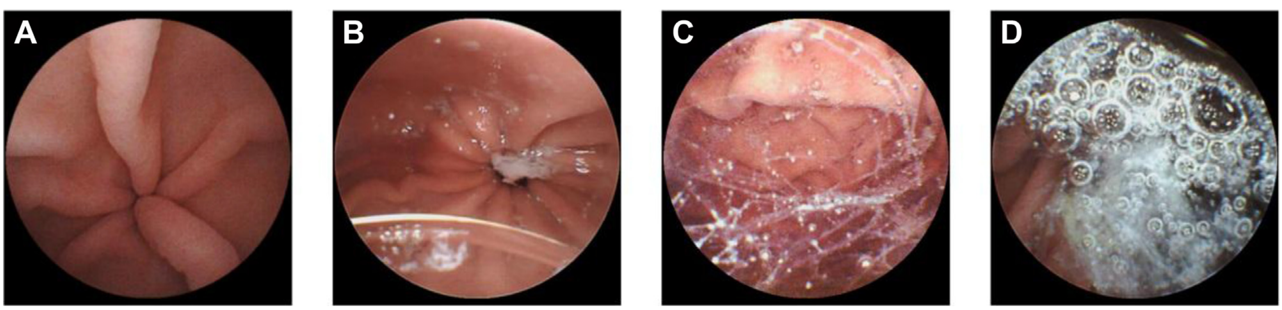


Supplementary Figure 1. The NaviCam capsule endoscope and magnetic control system. (*A*) The NaviCam capsule endoscope (Ankon Technologies Co, Ltd, Wuhan, China). The capsule has a size of 28 $\times$ 12 mm, and contains a permanent magnet inside its dome. The view angle of the MCE is 140°, and the view distance is 0–60 mm. A CMOS image sensor is used in the MCE. The LED light exposure time and signal gain of the CMOS sensor are adjusted automatically by measuring the histogram of the image to optimize brightness and contrast of the images. (*B*) The NaviCam magnetic control system. The magnetic field generated by the MCE can be adjusted, and can reach a maximum of 200 mT. The capsule location was obtained through a simulation, based on the magnetic field generated by the guidance system. There are gravity and magnetic sensors inside the capsule. The gravity sensor can be used to measure the angle between the orientation of the capsule and the direction of gravity, the magnetic sensor can measure the external magnetic field. The external magnet with its magnetization direction along the direction of gravity moves around by the robot, and the MCE sensor values are read and transmitted to the computer. By a programmed search process, the external magnet can be located just above the capsule. At this synchronization position, while the external magnet rotates, the capsule also rotates, and the capsule's orientation and location can be calculated. The external magnet moves according to the calculation results so that it always stays just above the small magnet of the capsule. In case the external magnet and the capsule are out of location synchronization, the search process can be used to find the capsule again. Although the robot can be controlled manually, this automatic process greatly can reduce the complexity to navigate the capsule inside the stomach.



Supplementary Figure 2. Representative images showing the 4-point grading scale used to objectively describe the cleanliness of the stomach during magnetic capsule endoscopy. (*A*) Excellent, no more than small bits of adherent mucus and foam. (*B*) Good, small amount of mucus and foam, but not enough to interfere with the examination. (*C*) Fair, considerable amount of mucus or foam present to preclude a completely reliable examination. (*D*) Poor, large amount of mucus or foam residue.