INVESTIGATIONS: ORIGINAL ARTICLE

Magnetically controlled capsule for assessment of the gastric mucosa in symptomatic patients: a prospective, single-arm, single-center, comparative study

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Background and Aims: Magnetically controlled capsule endoscopy (MCCE) has the potential to allow an operator to move a video capsule endoscope inside the foregut. The primary objective of this pilot study was to demonstrate that MCCE could visualize the major anatomic regions of the stomach in symptomatic patients before an EGD. Secondary objectives were measuring patient satisfaction, patient safety, and comparing MCCE with a follow-up EGD in the detection of any significant gastric lesions.

Methods: In this prospective, single-arm, single-center, comparative study, adult patients aged ≥18 years who were referred for an EGD as part of a standard evaluation for symptoms were approached for participation in the study. Participants received MCCE before the EGD. MCCE videos were reviewed by 2 independent physicians and compared with subsequent EGD. Patients were followed for 30 days for safety outcomes and satisfaction.

Results: In this study of 40 patients, MCCE detected each of the 6 preidentified major gastric anatomic landmarks with a greater than 95% rate of visualization. Thirty-five patients received a follow-up EGD, and no high-risk lesions were missed with MCCE. Patients preferred MCCE to EGD (80%-13%), and there were no adverse events.

Conclusions: In the first pilot study of MCCE in the United States, a high rate of visualization of all regions of the gastric mucosa was achieved. In addition, high satisfaction and no adverse events were recorded. Future studies will focus on higher-risk cohorts to confirm the accuracy of detection of benign, premalignant, and malignant gastric lesions. (iGIE 2023;■:1-8.)

More than 7 million EGDs are performed annually in the United States, and the main indications include epigastric pain, nausea, anemia, and weight loss.[1,2] Lack of access to an EGD is a health disparity associated with an increased risk of mortality for gastric cancer.[3,4] A less-invasive method to evaluate stable symptomatic patients with upper GI symptoms might be beneficial for patients in the United States and elsewhere, where access to EGDs is limited.

Capsule endoscopy has long been considered an alternative to traditional EGD, but its use is limited by several factors, including the inability to purposefully direct the capsule toward an area of interest in the stomach.[5] Magnetically controlled capsule endoscopy (MCCE) allows an operator to purposefully direct the capsule to regions of interest in the stomach. MCCE shares the advantage of all capsule endoscopy in that it is performed without anesthesia and without a trained endoscopist.[6]

This study is significant because it is the first U.S. study to examine the feasibility of using MCCE in symptomatic patients to visualize the anatomic landmarks of the stomach. The primary objective was to confirm whether an operator was able to visualize all major anatomic regions in the stomach with controlled movement of the capsule endoscope. Secondary objectives were patient satisfaction, patient safety, and a comparison of MCCE with a follow-up EGD to detect any significant mucosal abnormalities. We hypothesized that MCCE will be practical as measured by our ability to implement the study, perform the examination, and share the videos remotely for specialist interpretation; MCCE will be able to visualize the 6 major anatomic landmarks of the stomach in more than 90% of cases; and MCCE will be comparable with EGD at visualizing gastric lesions.

METHODS

Patient selection

In this prospective, single-arm, single-center, comparative study, adult patients aged ≥18 years who required an EGD evaluation as part of a standard evaluation of

relevant symptoms were approached regarding their willingness to have an MCCE examination. Patients needed to have one of several standard indications for EGD such as epigastric pain, bloating, burning, heartburn, excessive belching, nausea and/or vomiting, anemia, or weight loss. Individuals were not eligible for participation in the study if they had any of the following criteria: hemodynamic instability, active hematemesis, dysphagia, a swallowing disorder, suspected bowel obstruction, stricture, fistula or perforation, gastroparesis, Crohn's disease, prior GI tract surgery, presumed pregnancy or trying to conceive, currently breastfeeding, altered mental status (eg, hepatic encephalopathy), a pacemaker or implantable cardiac defibrillator, or a body mass index $\geq$38 kg/m^2. Finally, patients who planned to have a magnetic resonance imaging examination within 30 days were excluded. All patients signed informed consent before undergoing MCCE. The study was approved by the George Washington University Institutional Review Board.

Preparation for MCCE

As preparation for MCCE, patients were asked to refrain from eating after 8 pm the night before their examination. Water was allowed throughout the night or in the morning as needed. Studies were performed around 9 am. On the day of the procedure, the patient was instructed to arrive at the research clinic 30 minutes before the MCCE examination was scheduled to begin to prepare for the examination and sign a consent form. During this time, the patient drank four 8-ounce cups of water (1 L), each containing 40 mg of simethicone, over approximately 20 minutes. Patients were fitted with a data recorder vest on the procedure table beside the magnet.

Approximately 10 minutes after ingestion of the fourth and final cup of water, the patient was asked to swallow the video capsule. During ingestion of the capsule, the patient was asked to use the least amount of water required for swallowing and then immediately lie down on the examination table after the capsule passed the glottis (Fig. 1). The capsule typically passed into the stomach in less than 10 seconds; occasionally, however, the capsule was transiently retained at the lower esophageal sphincter (LES). If retention persisted at the LES for more than 1 minute, we repositioned the patient to the left lateral decubitus position. If the capsule was still present at the LES for 2 minutes, we asked the patient to sip water through a straw in the left lateral position until the capsule passed into the stomach. All swallowed capsules traversed the LES and passed into the stomach within a few minutes.

Operator training

The primary operator for the study was a physician without prior specialty training in endoscopy. Operator training was adapted from a previously designed capsule training curriculum for this purpose.[7] Starting with an in vitro plastic model of a stomach with labeled anatomic landmarks, the operator developed familiarity with the software and the 2-joystick controllers required to direct the capsule. Subsequently, the operator performed MCCE on 20 healthy asymptomatic volunteers with the goal of reproducibly identifying gastric landmarks.

Figure 1. Study volunteer on the procedure table under the magnet wearing the data-recording vest.

Description of MCCE

The NaviCam MCCE (AnX Robotica Corp, Plano, Tex, USA) provides a 160-degree field of view, with an image sensor resolution of 640 $\times$ 480 pixels per inch at a frame per second rate of .5 to 6 through a single camera. Movement of the capsule was controlled with 2 joysticks on the control panel. One joystick controlled the translational movement of the capsule in the *x*-*y*-*z* axes, whereas the other joystick controlled the rotation along either the horizontal or vertical axis.[8] The system provides a continuous video and ability to capture selected still frames for incorporation into a report. The video and images can be transmitted to a remote site in a Health Insurance Portability and Accountability Act–compliant manner.

Performing MCCE

After the patient ingested the capsule, the operator performed MCCE according to protocols previously established with the healthy volunteers. MCCE recorded images of the lower esophagus and the Z-line soon after ingestion. Once the capsule was in the stomach, the operator maneuvered it to visualize all 6 major landmarks of the stomach: cardia, fundus, body, angularis, antrum, and pylorus. If needed, the patient was repositioned alternatively to the left lateral decubitus and right lateral decubitus position for better visualization. Finally, the operator attempted to traverse the pylorus to visualize the duodenum and the ampulla before concluding the examination. The examination was terminated approximately 30 minutes after ingestion or earlier if the capsule traversed the pylorus and the duodenal ampulla was visualized.

After MCCE

After MCCE was performed, a report was generated with photographic documentation of all major landmarks and any mucosal abnormalities. The report was uploaded to a Health Insurance Portability and Accountability Act–secure cloud to allow for remote interpretation by a board-certified gastroenterologist. A follow-up EGD was performed within 5 days of MCCE but ideally as soon as possible; any biopsy samples were taken as part of the standard of care. Patients were contacted at day 7 and day 30 to assess for satisfaction and the development of any adverse events; however, no formal process was performed to confirm excretion.

Interpreting MCCE and EGD results

Interpretation of MCCE results was performed independently by 2 physicians. The first physician was the operator (A.C.M.), whereas the second physician was 1 of 3 rotating board-certified gastroenterologists experienced in traditional and capsule endoscopy (A.K., S.A.S., S.J.K.). The GI physicians had access to the full video captured by the MCCE in addition to the structured report generated by the operator. Both interpretations were recorded on similarly structured data sheets.

Comparison of MCCE and EGD

The research team reviewed the EGD reports in the electronic health record and used the EGD reports to complete the data collection forms. The data sheets for EGD were similar to the data sheets for MCCE. The results of the EGD and biopsy samples were abstracted using structured data sheets from the electronic health record by the research staff.

Analysis

The sample size for this pilot study was chosen to validate the proof of principle of the pilot study protocol. Forty participants were deemed adequate to meet the objectives of the pilot study and to plan for a future noninferiority study of MCCE versus EGD.

RESULTS

The study took place between February 10, 2021 and June 10, 2022, including an approximately 6-month hiatus in enrollment because of delays in capsule delivery related to the global supply chain. Of the patients contacted and screened for eligibility, 43 consented to participate in the study and agreed to have an MCCE evaluation. Three patients were ultimately excluded from final analysis: 2 for an inability to swallow the capsule and 1 for a technical malfunction with the video capture. Demographic information and chief complaints of the study participants are listed in Table 1. Participants were generally healthy and typically had symptoms for more than a month (Table 1).

TABLE 1. Baseline information of study participants (n = 40)

Characteristics	No. of cases	Percentage of cases
Demographics		
Sex		
Men	14	35
Women	26	65
Race/ethnicity		
Black	18	45
White	14	35
Asian	1	2.5
Other race	7	17.5
Hispanic	3	7.5
Non-Hispanic	37	92.5
Medical history		
Diabetes mellitus	2	5
Kidney failure or on dialysis	1	2.5
Previous smoker/active smoker	1	2.5
Ulcer, gastritis, or acid reflux	3	7.5
Hemorrhoids	1	2.5
None	15	37.5
Medications		
Proton pump inhibitors	15	37.5
Nonsteroidal anti-inflammatory drugs	7	17.5
Reason for EGD referral		
Low blood (unexplained anemia)	5	12.5
Upper abdominal or chest pain	15	37.5
Indigestion (dyspepsia)	3	7.5
GERD	9	22.5
Suspected ulcer	2	5
Melena	2	5
Other	10	25

Identification of gastric anatomic regions with MCCE

Each of the 40 MCCE results was reviewed by a minimum of 2 physicians (physician reviewer 1 and physician reviewer 2) for their ability to document 6 gastric landmarks (Table 2). The cardia, fundus, body, angularis, antrum, and pylorus were seen in 95.0% (95% confidence interval, 92.5-97.5) and 96.3% (95% confidence interval, 93.8-98.7) of cases by physician reviewer 1 and physician reviewer 2, respectively (Table 2). The lower esophagus was seen in 97.5% of cases by both physician reviewer 1 and physician reviewer 2, whereas the Z-line was observed in 77.5% and 85% by physician reviewer 1 and physician reviewer 2, respectively. In 13 patients (32.5%), the capsule visualized the duodenum during the examination. Study times ranged between 11 and 65 minutes (mean, 33 minutes).

TABLE 2. Landmarks detected on magnetically controlled capsule endoscopy by 2 physician reviewers

Landmarks	Physician reviewer 1		Physician reviewer 2	
	No. of cases	Percentage of cases	No. of cases	Percentage of cases
Cardia	37	92.5	39	97.5
Fundus	39	97.5	36	90
Body	39	97.5	39	97.5
Angularis	36	90	39	97.5
Antrum	38	95	39	97.5
Pylorus	39	97.5	39	97.5
Lower esophagus	39	97.5	39	97.5
Gastroesophageal junction/Z-line	31	77.5	34	85

Patient satisfaction and patient safety

Among the study participants, 39 of 40 were contacted at day 7 and day 30 by telephone to assess for safety and satisfaction with the MCCE. Two patients reported mild pain with initial swallowing of the MCCE. None of the 40 participants described the swallowing as difficult (all participants described it as either "very easy," "moderately easy," or "neutral"). None of the participants sensed the movement in their stomach or felt pain with internal capsule manipulation. None of the participants described a "negative experience" on the day of the MCCE procedure or at the day-7 and day-30 follow-up calls. All participants were able to immediately return to work or normal daily activities after the procedure and were able to leave the clinic without assistance or an escort. Only 1 participant detected the capsule passage during a bowel movement but described no pain on capsule passage. When the 39 contacted participants were asked which study they preferred ("assuming both studies were equally accurate"), 31 (79.5%) stated they preferred MCCE over traditional EGD, 3 (7.7%) stated they preferred the traditional EGD, and 5 stated they had no preference. At 30 days after MCCE, no adverse reactions, return visits to the hospital, surgery, or second endoscopy were reported (39/40 contacted).

Comparison of MCCE with follow-up EGD to detect any mucosal lesions

Thirty-five of 40 participants ultimately followed up with their scheduled EGD. There was variation in the description of gastritis between the EGD and MCCE. Although chronic gastritis was detected in most patients, only 2 of these patients were found to have active gastritis on the EGD pathology report. Both cases were detected visually by the MCCE (Figs. 2 [patient 13] and 3A [patient 32]). In the second case, both MCCE and EGD detected a diffuse white reticular pattern consistent with a physiologic pit pattern (Fig. 3A and B); gastric biopsy sampling revealed both *Helicobacter pylori* and chronic active gastritis.

In 1 case, MCCE and EGD detected a nonbleeding, linear erosion between 3 mm and 5 mm in the gastric antrum (Fig. 4A and B [patient 21]). In another patient, MCCE recorded a clear gastric antrum but EGD detected a nonbleeding, round, and clean-based medium-sized ulcer in the gastric antrum that was interpreted by pathology as reactive gastropathy (Fig. 5A and B [patient 31]). Thirty-two of 35 patients who received an EGD also underwent biopsy sampling, including 30 participants who underwent biopsy sampling for *H pylori*, of which 2 were positive (Table 3).

Ability to evaluate the LES

Although every capsule was able to visualize the lower esophagus, the Z-line was only visible between 78% and 85% of cases (Table 3). Two patients were tested for Barrett's esophagus as part of the EGD, and 1 was positive on pathology. In the patient who tested positive, an irregular Z-line was clearly visible with no evidence for inflammation (Fig. 6A and B [patient 36]).

DISCUSSION

This pilot study demonstrates high rates of detection of major gastric anatomic landmarks using MCCE. If MCCE can approach the diagnostic capabilities of EGD, there is an opportunity to expand its use and indications for symptomatic patients. The advantage of MCCE versus conventional endoscopy is that it does not require a gastroenterologist at the bedside or sedation of the patient, thus creating the opportunity for visualization of the gastric mucosa in settings such as the emergency department, primary care, or in under-resourced rural settings.[9-12] In addition, MCCE may provide a safe and efficient way to screen low-risk patients for serious disease such as gastric cancer. EGD screening is currently recommended in Japan and Korea but not in the United States and Western Europe because of the very low prevalence of early gastric cancer.[13,14] This trial is significant

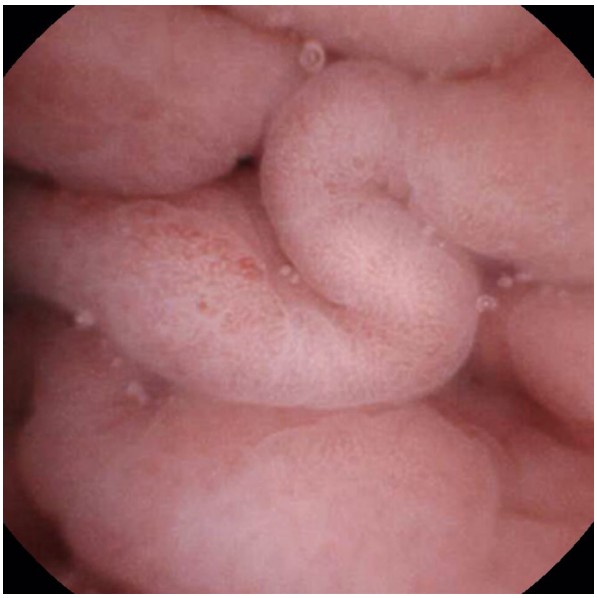

Figure 2. Magnetically controlled capsule endoscopy showing mild gastritis.

because it is the first U.S. study to show the feasibility and potential utility of using MCCE to visualize the entire stomach.

In this study, MCCE generated a video of the gastric mucosa that was shared remotely with a gastroenterologist. The ability to transmit images to a reading center could be important in rural communities or in communities that have limited access to a gastroenterologist or surgeon. The eventual workflow of MCCE may be similar to that of diagnostic tests such as radiology US examinations, which are typically performed by a technician before being read asynchronously by a radiologist.[15] As a diagnostic tool, MCCE may be used to make decisions regarding the need for hospitalization or intervention for GI bleeding. If the diagnostic capabilities of MCCE are comparable with EGD, EGD may evolve to primarily be used for therapeutics or obtaining biopsy samples, similar to the evolution of ERCP. In the future, biopsy sampling may be possible with capsule endoscopy.[16]

The manual operation of MCCE requires familiarity with the joystick controls and the ability to recognize the gastric landmarks. Practice studies and/or training would be anticipated to gain proficiency for both an experienced endoscopist and a nonendoscopist. For this study, the primary operator performed multiple training MCCEs to establish proficiency with visualization and to optimize the preparation protocol. We expect that this training period could be significantly shortened with guidance from an experienced operator or through use of automated software such as the NaviCam GastroScan (AnX Robotica Corp). Formal credentialing for MCCE is not currently established by the major GI societies. In the past, the American Society for Gastrointestinal Endoscopy stated that credentials for capsule endoscopy should be determined independently from other endoscopic procedures such as colonoscopy, sigmoidoscopy, or any other endoscopic procedure.[17] Instead, sound medical training, appropriate patient selection, correct interpretation, and continued medical management for all patients are the major criteria for capsule administration.

Although this is the first U.S. study, the NaviCam has been studied in multiple small international studies, mostly in Asia and Europe. First, in a pilot study of 34 healthy volunteers, visualization of the gastric cardia, fundus, body, angularis, antrum, and pylorus were subjectively assessed as complete in 82.4%, 85.3%, 100.0%, 100.0%, 100.0%, and 100.0%, respectively.[18] Second, in a nonblinded comparative study of 68 patients, the diagnostic accuracy was shown as similar to standard gastroscopy with a positive agreement of 96.0% and negative agreement of 77.8%. In this study, 68 pathologic findings were detected, of which 53 were identified by both MCCE and tube-based endoscopy with a 91.2% overall agreement.[19] Third, in a separate multicenter comparative study in 350 patients, MCCE detected gastric focal lesions in the entire stomach with 90.4% sensitivity, 94.7% specificity, 87.9% positive predictive value, 95.9% negative predictive value, and 93.4% accuracy.[20]

This study illustrates the lack of major abnormalities in 40 patients scheduled for EGD. The optimal role of using MCCE to evaluate patients with dyspepsia is still being established. One strategy is to combine MCCE with a noninvasive *H pylori* test to work up dyspepsia in low-risk patients. Interestingly, over 90% of participants (32/35) in our study who received endoscopy also received tissue testing for *H pylori*, with only 2 positive outcomes. Tissue testing for *H pylori* is more expensive and more invasive than other testing modalities such as urea breath tests or fecal antigen tests. In general, patients with dyspepsia who are under age 45 years without "red flags" can be tested and treated for *H pylori* with antibiotics and without endoscopy.[21]

The safety and cost of MCCE are critical factors when deciding how to incorporate its use in low-risk patients. In general, the safety of capsule endoscopy has been well established over many years, and the only absolute contraindications to capsule endoscopy are intestinal obstruction and significant dysphagia.[22] Multiple studies have shown that capsule endoscopy is well tolerated in patients with acute symptoms.[23-25] MCCE in alternative settings such as the emergency department, urgent care, and primary care is conceivably a cost-effective way to evaluate GI symptoms in an outpatient setting.[26] MCCE may be especially cost-effective if it reduces hospital admissions, need for anesthesia, and missed work days.

Because the yield of EGD in low-risk symptomatic patients is notoriously low, MCCE could serve as an initial diagnostic tool with referral to a formal EGD for anyone

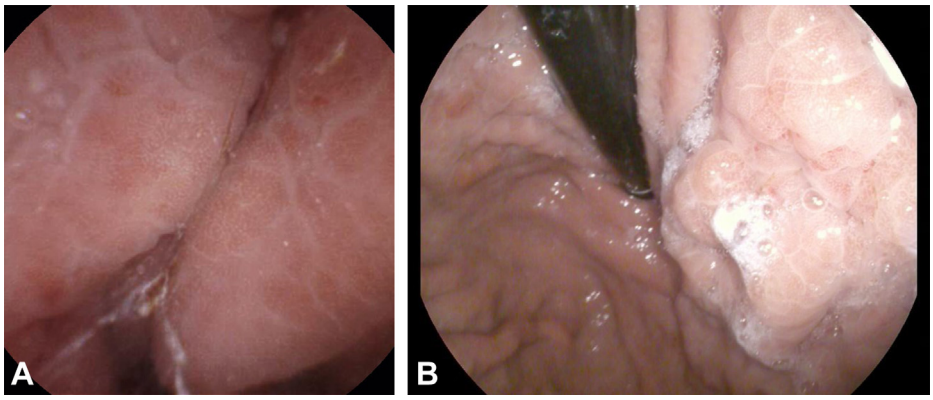

Figure 3. A, Magnetically controlled capsule endoscopy showing mild chronic gastritis. **B,** EGD showing mild gastritis in the fundus.

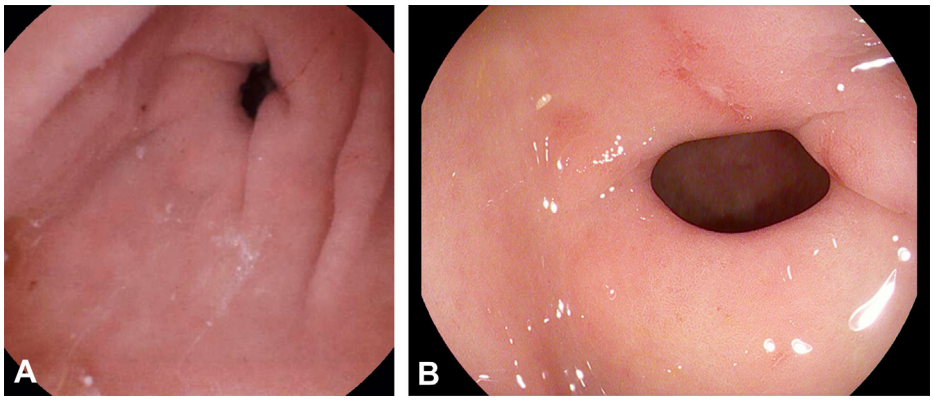

Figure 4. A, Magnetically controlled capsule endoscopy of the gastric antrum with 2 small prepyloric erosions. **B,** EGD of the gastric antrum showing prepyloric erosion.

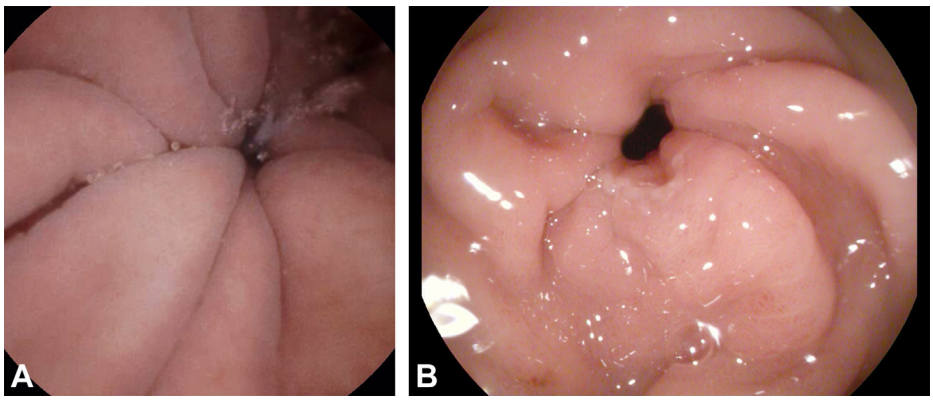

Figure 5. A, Magnetically controlled capsule endoscopy of the gastric antrum. **B,** EGD showing mild antral gastritis.

with positive or equivocal findings. In our study, we asked both MCCE interpreters if they believed endoscopic intervention was needed in each patient after MCCE. In 26 participants (74%), their opinion was that an endoscopic intervention was not needed. Among those 26 patients in whom a follow-up EGD would not have been recommended based on MCCE findings, gastric endoscopic interventions included 6 gastric biopsy samplings that revealed inactive chronic gastritis, including 5 negative *H pylori* biopsy samplings. No ulcers or lesions were detected in the

TABLE 3. Results of gastric biopsy samples (n = 32)

Results	Values
Biopsy for *Helicobacter pylori*	32/32
Positive for *H pylori*	2/32 (6.3)
Presence of gastritis (visual inspection EGD)	24 (75)
Severity of gastritis (pathology report)	
Mild/moderate	24 (75)
Severe	0
Activity of gastritis	
Active	2 (6.3)
Inactive	22 (69)
Chronic gastritis	23 (72)
Reactive gastropathy	11 (34)
Biopsy sampling for Barrett's esophagus	2 (6.3)
Positive for Barrett's esophagus	1 (3.1)
Gastric intestinal metaplasia	0
Gastric polyp(s)	0
Other diagnoses	14 (44)

Values are n/N (%), n (%), or n.

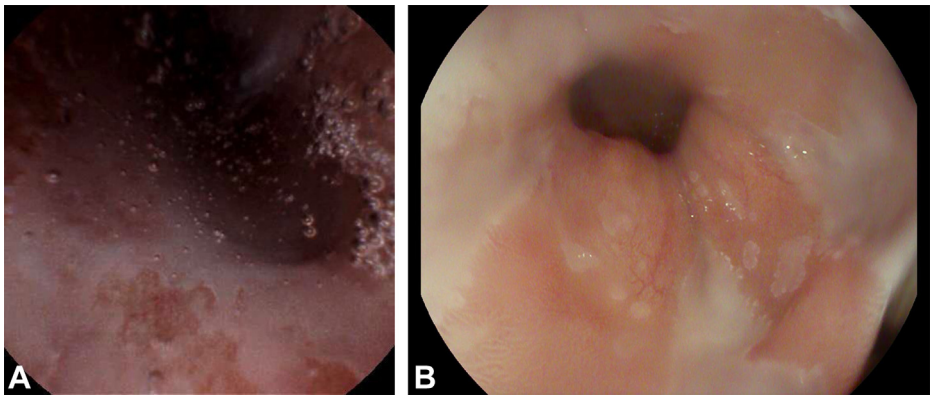

Figure 6. A, Magnetically controlled capsule endoscopy showing an irregular Z-line. **B,** EGD showing an irregular Z-line.

group categorized as "no endoscopic intervention needed" after MCCE interpretation. Assuming that these promising results can be replicated in other settings, it suggests that MCCE may be an effective tool for the initial evaluation for patients without symptoms.

A potential limitation of MCCE is its ability to evaluate the LES and Z-line. The capsule may move quickly through the esophagus because of ingested water, gravity, and peristalsis. In our study, visualization of the Z-line occurred in 78% to 85% of cases. Only 1 patient had Barrett's esophagus, and this was detected as inflammation on MCCE. A current study is ongoing regarding the use of a detachable tether to better visualize the esophagus before continuing on to the gastric examination (clinicaltrials.gov identifier: NCT04605302). The NaviCam Tether (AnX Robotica Corp) has recently received clearance by the U.S. Food and Drug Administration.

Limitations

Current limitations with the MCCE include the time-consuming nature of the procedure and the need for operator training to reliably direct the capsule. However, although EGD itself is very quick, pre- and postprocedural care needs to be considered. In the future, optical diagnosis of mucosal GI pathologies might be assisted with advanced software, including artificial intelligence that drives and interprets MCCE. Software advances are being designed to automate the driving, visualization, and detection of gastric pathology. In addition, future technologic developments

in MCCE may allow operators to collect biopsy samples and perform therapeutic functions such as hemostasis.

The most significant limitation of this pilot study is the small sample size and low number of pathologic lesions. In addition, although the GI endoscopist was blinded to the findings of the MCCE, the second physician interpreting the MCCE (physician reviewer 2) was not blinded to the interpretation of the initial MCCE operator (physician reviewer 1). A follow-up study with a larger sample size is planned to calculate the sensitivity and specificity of MCCE to EGD for pathologically significant lesions as well as to establish noninferiority with EGD for diagnosis.

Conclusion

MCCE is a feasible and effective strategy to visualizing the major anatomic areas of the stomach. Widespread use could increase diagnostic capabilities for evaluating dyspepsia, gastritis, peptic ulcer disease, and other common symptoms related to the gastric mucosa. Future studies need to further establish the accuracy of MCCE compared with EGD for low-risk symptomatic patients.

DISCLOSURE

The following authors disclosed financial relationships: A. C. Meltzer: Research support from AnX Robotica. D. R. Cave: Research support from AnX Robotica; consultant for Medtronic. All other authors disclosed no financial relationships.

Abbreviations: LES, lower esophageal sphincter; MCCE, magnetically controlled capsule endoscopy.

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