Clinical Gastroenterology and Hepatology 2016;14:1266–1273

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.

Most current article

1542-3565
http://dx.doi.org/10.1016/j.cgh.2016.05.013

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.