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Preliminary study of magnetically controlled capsule gastroscopy for diagnosing superficial gastric neoplasia

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ABSTRACT

Background: Magnetically controlled capsule gastroscopy (MCCG) is a newly developed non-invasive method designed for gastric examination. Although favorable diagnostic accuracy has been reported, there is little if any data about its ability to diagnose gastric cancer.
Aims: To compare the detectability of superficial gastric neoplasia by MCCG and gastroscopy.
Methods: This study was a self-controlled comparison study. Ten subjects diagnosed with superficial gastric neoplasia and scheduled to undergo endoscopic submucosal dissection (ESD) at a tertiary hospital were prospectively invited for an MCCG examination. The diagnostic agreement of MCCG, ESD and pathology were compared, including location, size and endoscopic appearance of the lesions.
Results: Of the 10 enrolled patients, 6 were confirmed as having early gastric cancer/high-grade intraepithelial neoplasia, 2 gastric low-grade intraepithelial neoplasia (LGIN), 1 tubular adenoma with LGIN and 1 neuroendocrine tumor. The per-patient and per-lesion sensitivities of MCCG for superficial gastric neoplasia detection were 100% and 91.7%. Location and size of the lesions were compared favorably to gastroscopy whilst one cardiac lesion was missed. Endoscopic appearances of these lesions observed on MCCG and EGD demonstrated good consistency. No adverse events were observed.
Conclusion: With good gastric preparation and careful examination of stomach, MCCG is able to detect superficial gastric neoplasms.

1. Introduction

Gastric cancer (GC) has become the third leading cause of cancer-related death worldwide [1] and is particularly prevalent in East Asia. Early detection and accurate preoperative staging of GC can improve the prognosis which reinforces the importance of screening and diagnosis of early gastric cancer (EGC) [2–4]. However, esophagogastroduodenoscopy (EGD) may be uncomfortable and poorly tolerated and incurs the risks of intravenous sedation and endoscopic intubation [5,6]. Magnetically controlled capsule endoscopy (MCCG), a newly developed method of gastric examination may represent a more acceptable approach for gastric diseases screening. It is non-invasive and does not require patient sedation, does not incur the risk of cross infection and is easy to perform. Furthermore, our recently published randomized controlled trial demonstrated a diagnostic accuracy approaching that of conventional gastroscopy [7]. However, there are few data illustrating the diagnostic value of MCCG for GC, especially EGC, the early detection and management of which are of vital importance. To investigate the diagnostic yield of MCCG for superficial gastric neoplasia, we conducted this pilot study.

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2. Patients and methods

2.1. Study design

This study was a prospective, self-controlled, single-centered comparison pilot study of the feasibility of MCCG in the detection of superficial gastric neoplastic lesions. The study protocol was approved by the institutional review board of Shanghai Changhai Hospital with strict adherence to the principles outlined in the 1975 Declaration of Helsinki (6th revision, 2008) as reflected in a priori approval by the institution's human research committee, and written informed consent was obtained from each enrolled patient.

2.2. Study patients

This study was conducted between June and December 2016 in Changhai Hospital. Patients invited to participate were 18–75 years, were known to have superficial gastric neoplasia and were scheduled to undergo endoscopic submucosal dissection (ESD). Exclusion criteria included contraindications to capsule endoscopy as previously published [7]. Results of gastroscopy and biopsies were obtained and documented. Of note, the diagnosis criteria met the updated Paris classification of superficial neoplastic lesions in the digestive tract [8].

2.3. Study intervention

After enrollment, patients underwent the gastric preparation regimen prior to MCCG examination. On completion of MCCG, EGD was performed during which the lesion was resected by ESD and sent for pathological examination.

2.3.1. Gastric preparation regimen

Patients arrived at the hospital after an overnight fast (>8 h). Fifty minutes before capsule ingestion, all patients swallowed 50 ml clear water containing 400 mg simethicone (Espumisan; Berlin-Chemie, Germany, containing 40 mg simethicone in 1 ml emulsion). They were encouraged to mobilise in order to maximize intragastric distribution of the simethicone. A further 950 ml clear water was then swallowed in order to flush out any residual mucus and foam 30 min before the MCCG examination [9].

Any patients who additionally required examination of the small bowel during the same procedure had 2 l of polyethylene glycol 5 h before the MCCG examination as per normal protocol.

2.3.2. MCCG system

The MCCG system was provided by Ankon Technologies Co. Ltd (Shanghai, China). The system consists of a guidance magnet robot, an endoscopic capsule, a data recorder, and a computer workstation with software for real-time viewing and controlling. The examiner uses two joysticks which control capsule movement by varying the strength of the magnetic field, which can reach a maximum of 200 mT (by altering the distance of the magnet from the patient) and the polarity of the magnet. The capsule endoscope is 26.8 mm in length, 11.6 mm in width, 4.8 g in weight and has a field of view of 151° from one end. Images are captured at a rate of two frames per second with a resolution of 480 × 480 pixels. LED light exposure time is adjusted automatically in response to the signal of the CMOS image sensor to optimize the brightness and contrast of the images [7,10,11].

During the examination, patients swallowed capsules with a small amount of water in the left lateral decubitus to observe the esophagus and dentate line effectively. When the capsule reached the stomach, the capsule was controlled magnetically according to the standardized examination protocol, from the fundus to the cardiac regions, and then to the gastric body, angulus, antrum, and finally to the pylorus. Water ingestion would be repeated in case of insufficient gastric distention. After completing gastric examination, the operation of the capsule was adjusted to "small bowel mode" (without magnetic control) for those patients also requiring a small bowel examination. These patients were discharged with the data recorder in situ after the capsule had passed into the duodenum, and were asked to return the recorder the next day.

All patients were followed up to 2 weeks to confirm capsule excretion and any adverse events. MCCG was performed by an endoscopist with an experience of >500 cases of MCCG operation. All the images obtained by MCCG were monitored in real time and reviewed by one of two high qualified endoscopists. MCCG operation videos were available in Supplementary videos.

2.3.3. Endoscopic submucosal dissection

Lesion resection was performed on the day after MCCG examination by a single experienced endoscopist certified as having performed ESD on at least 100 patients. Procedures were video recorded and archived for purposes of future reference and audit.

2.3.4. Gross and pathological evaluation

MCCG findings were compared to those of EGD and the pathological specimen obtained by ESD in terms of location, size and endoscopic appearance of the lesion. Lesion location was defined as being present in one of six primary anatomic landmarks of the stomach: cardia, fundus, body, angulus, antrum and pylorus. Lesion size measurement on MCCG is presented in Fig. 1. Endoscopic appearance of a superficial neoplastic lesion was described according to the Paris classification. One-dimensional lesion size was defined as the longest diameter of the lesion and two-dimensional lesion size was defined as the product of the longest lesion diameter multiplied by its longest perpendicular diameter. Lesion size (in one- and two-dimensions) measured by the two endoscopic modalities was compared using a paired t test. A value of $P < 0.05$ was considered significant. The pathological specimen was regarded as the gold standard.

2.4. Study outcomes

The main purpose of this pilot study was to investigate the clinical application of MCCG in the detection of superficial gastric neoplasia. The primary outcome was to evaluate the diagnostic yield of superficial gastric neoplasia by MCCG as assessed by the location, size, endoscopic appearance of the lesions in comparison to EGD and pathological results.

Safety outcomes assessed included adverse events, defined as symptoms or signs such as abdominal distention, nausea, or vomiting occurring during the MCCG procedure. Patients were observed for up to 2 weeks to exclude the possibility of capsule retention (defined as a capsule endoscope remaining in the digestive tract for more than 2 weeks or a capsule endoscope that requires directed intervention or therapy to aid its passage).

3. Results

Ten consecutive adult patients evaluated at the time of diagnosis of superficial gastric neoplasia and scheduled to undergo ESD for lesion resection and diagnosis at our hospital were invited to participate in this study. The mean age of the study subjects was 61, ranging from 46 to 75 years, and 9 of them were male. All patients were symptomatic, 5 had a family history of GC and H. pylori infection, 7 were smokers and 5 consumed alcohol. The mean time of MCCG examination was 15 min (maximum 20 min).

MCCG and ESD were successfully performed in all 10 patients. Following pathological assessment, 6 were diagnosed as EGC/high-grade intraepithelial neoplasia (HGIN), 2 gastric low-grade

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