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Gastric preparation for magnetically controlled capsule endoscopy: A prospective, randomized single-blinded controlled trial

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ABSTRACT

Background and aims: Magnetically controlled capsule endoscopy (MCE) is a novel technique for which there is no agreed gastric preparation. We aimed to determine an optimal standardized gastric preparation regimen.
Methods: 120 patients referred for MCE were randomly assigned to gastric preparation with either water alone (A), water with simethicone (B) or water, simethicone and pronase (C). Image quality was assessed using cleanliness and visualization scores, higher scores equating to better image quality.
Results: The total cleanliness scores were (mean ± SD) 15.83 ± 2.41 (A), 21.35 ± 1.23 (B), and 20.82 ± 1.90 (C). The total visualization scores (mean ± SD) were 10.75 ± 2.02 (A), 15.20 ± 1.32 (B), and 15.08 ± 1.86 (C). While the image quality of the whole stomach in groups B and C were significantly better than group A ($P < 0.0001$), there was no statistical difference between group B and C ($P > 0.05$). MCE detected positive findings in 21 (52.5%), 27 (67.5%) and 21 (53.8%) patients in group A, B and C respectively, with no significant difference between groups ($P > 0.5$).
Conclusions: Simethicone swallowed with water prior to MCE produced the optimal gastric mucosal image quality. The addition of pronase had no demonstrable additional benefit.

1. Introduction

Capsule endoscopy (CE) was first introduced as a non-invasive small bowel imaging modality, better tolerated than conventional endoscopy and therefore possibly improving patients' compliance [1–3]. Given these advantages, CE has been rapidly applied to clinical practice. Whilst capsule endoscopy is now standard practice in small bowel examination, gastric examination remains a challenge because of the capacity and unusual anatomy of the stomach. Recently, several capsules manoeuvred with external magnetic fields, so-called magnetically controlled capsule endoscopy (MCE) or magnetic assisted capsule endoscopy (MACE), have been designed to make non-invasive exploration of the whole stomach possible [4–15]. From 2013 to date, more than 600 MCE have been performed in our center and MCE is widely accepted in China. The feasibility and safety of MCE has already been demonstrated [9,12]. Moreover, the diagnostic accuracy of MCE for gastric focal lesions was reported to be comparable with conventional gastroscopy in a large multi-center study [13].

In clinical practice, diagnostic accuracy may be hampered by the presence of intraluminal air bubbles, mucus, bile and chyme. Many investigators have already used detergents in the preparation of small bowel and colon examination procedures. Simethicone, a defoaming substance and pronase, a mucolytic agent, have been used in gastric preparation for conventional endoscopy with favourable results [16–20]. However, neither of them has been utilized in MCE and there is no agreed standardized regimen for gastric preparation. Therefore, this prospective, randomized, controlled study was performed to determine an optimal standardized gastric preparation regimen for MCE.

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2. Materials and methods

2.1. Study design

This study was a prospective, randomized physician-blinded controlled study. The study protocol was approved by the institutional review board of Shanghai Changhai Hospital and informed consent was obtained from each enrolled patient before the procedure.

2.2. Study patients

Consecutive patients referred for MCE in Changhai Hospital from June to October 2016 were enrolled and analyzed. Adult patients with upper abdominal complaints aged 18–75 years were eligible for this study. Patients with any of the following conditions [13] 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 post-abdominal radiation; (2) congestive heart failure, renal insufficiency, use of anticoagulant medication, poor general condition (American Society of Anesthesiologists class III/IV) or claustrophobia; (3) implanted metallic devices such as pacemakers, defibrillators, artificial heart valves or joint prostheses (although the low magnetic field used technically should not interfere with such devices); (4) pregnancy; (5) currently participating in another clinical study.

2.3. Study intervention

2.3.1. Magnetically controlled capsule endoscopy system

The MCE 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 (by altering the distance of the magnet from the patient) and the polarity of the magnet. Relevant detailed parameters are referred to in previous studies [9,12–13].

2.3.2. Gastric preparation regimen and MCE examination protocol

Based on experience in clinical practice, simethicone (Espumisan; Berlin-Chemie, Germany, containing 40 mg simethicone in 1 mL emulsion) was applied as a defoaming agent to improve gastric mucosal visualization, and pronase granules (Deyou; Beijing Tide Pharmaceutical Co, China, containing 20,000 iu pronase) as a mucolytic [17,21–23]. All patients attended after overnight fasting (>8 h). The patients were equally randomized to one of three study groups according to a computer-generated random number table. Fifty minutes before swallowing the capsule, patients in the water control group (A) ingested 1 l of tap water at near body temperature (35 °C) to provide an air-water interface in the stomach for capsule navigation; patients in the simethicone group (B) ingested 950 ml of water and 400 mg simethicone; patients in the S-P group (C) ingested 900 ml of water, 400 mg simethicone and 20,000 iu pronase granules combined with 1 g $NaHCO_3$ to maintain the intragastric PH at 6–8 [17].

After attaching the data recorder, patients were asked to sit on the examination couch beneath the guidance magnet robot. The capsule was ingested in a left lateral position to facilitate esophageal passage. The examination was conducted with the patient lying in left lateral, supine, and finally right lateral positions. If difficulties in navigation were encountered, further positional change (including the prone position) was tried. If distension was insufficient, the patient was asked to drink more water. When the capsule reached the stomach, the investigator lifted the capsule away from the posterior wall, rotated and advanced the capsule to the fundus and cardiac regions, and then to the gastric body, angulus, antrum, and pylorus. The mean time of MCE examination was 15 min with a maximum of 20 min.

All patients were followed up for up to 2 weeks to confirm capsule excretion and document any adverse events [13].

Conventional gastroscopy to obtain biopsy or for therapeutic intervention was performed according to standard practice if lesions were identified by MCE.

2.4. Randomization

Eligible patients were randomly assigned in a 1:1:1 ratio to one of the three preparation groups, A, B or C, which they drank in the presence of a nurse uninvolved in the treatments or assessments. The randomization was based on a computer-generated list of random numbers using SPSS Statistics software.

2.5. Study outcomes

The primary outcome was the quality of MCE videos. Secondary outcomes included the safety of MCE and pathology detected by MCE including superficial gastritis, chronic erosive gastritis, polyps and ulcers.

To evaluate the quality of MCE videos, scores of gastric cleanliness and mucosal visualization in six primary anatomical landmarks of the stomach (cardia, fundus, body, angulus, antrum, and pylorus) were recorded. A 4-point grading scale (Supplementary Fig. S1 in the online version at DOI: 10.1016/j.dld.2017.09.129) was introduced to define the cleanliness as excellent (no more than small bits of adherent mucus and foam: score 4), good (small amount of mucus and foam, but not enough to interfere with the examination: score 3), fair (considerable amount of mucus or foam present precluding a completely reliable examination: score 2) and poor (large amount of mucus or foam residue: score 1) [13,17,19–20,24]. As for mucosal visualization, a 3-point grading scale was introduced as good (>90% of the mucosa observed: score 3), fair (70–90% of the mucosa observed: score 2) and poor (<70% of the mucosa observed: score 1) as used in our previous study [13]. Scores for total gastric cleanliness and total mucosal visualization were obtained by summating the individual scores of the six anatomical landmarks.

Adverse events, defined as symptoms or signs such as abdominal distension, nausea, or vomiting, were monitored closely during the MCE procedure. Capsule retention (i.e., a capsule endoscope remaining in the gastrointestinal tract for more than two weeks or a capsule endoscope that requires directed intervention or therapy to aid its expulsion) was monitored and followed up for up to two weeks.

In this study, a qualified capsule endoscopist with an experience of more than 500 cases of MCE operation performed the MCE. A second endoscopist with over five years' reading experience, who was blinded to the type of gastric preparation, independently graded the quality of the images captured by MCE.

2.6. Statistical analysis

In the absence of previous studies of MCE preparation regimens, a pilot study was performed to obtain data on which to base a sample size calculation. Total gastric cleanliness scores were assessed for eight patients enrolled into each gastric preparation group, A, B and C. Our study assumed that the preparation regimen of simethicone/simethicone plus pronase granules would be better than clear water. It was calculated that 108 patients (36 per treatment

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