Repetitive position change improves gastric cleanliness for magnetically controlled capsule gastroscopy

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Study Design and Patients

We conducted a single-blind, randomized controlled trial approved by the institutional review board of Shanghai Changhai Hospital (ClinicalTrials.gov. ID: NCT03514966). From May 7 to May 31 2018, consecutive patients (aged ≥ 18 years) with upper abdominal complaints requiring MCCG in Changhai Hospital were included after providing informed consent. Patients with the following [7] 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, 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 [6].

Examination were performed by one qualified capsule endoscopist with an experience of more than 500 cases of MCCG operation. Other two endoscopists (J.P., X.J.S.) was blinded to the type of gastric preparation, independently graded the quality by reviewing the images captured by MCCG. When discrepancies arise over the grading results, this will be resolved by consensus discussion between the two endoscopists, with arbitration by a third endoscopist (Z.L.) and made the final decision.

Study intervention

Magnetically controlled capsule gastroscopy system

The MCCG system used in this study includes an endoscopic capsule, a portable external data recorder, a guidance magnet robot, and a computer workstation with software for real-time viewing and controlling, all provided by Ankon Technologies Co. Ltd (Shanghai, China). The endoscopic capsule has a size of 27 * 11.8 mm, with light-emitting diodes surrounding two metal oxide chip cameras placed at both ends. Images are captured and

recorded at a rate of 2 frame/s, and information sent wirelessly to the data recorder. The view angle of capsule is 140°, and view distance is 0 to 30 mm. It is powered by two silver oxide batteries for up to 10-12 hours. In addition, a permanent magnet was also contained within the dome of capsule, which is guided by the C-arm type guidance magnet robot with five degrees of freedom—two rotational degrees and three translational degrees. Through simulation on the basis of the magnetic field generated by the magnet guidance system, the magnetic field can be adjusted and reaches a maximum of 200 mT. Using two joysticks, the examiner can control capsule movement to varying the strength of magnetic field by altering the distance of the magnet from the patient and change the polarity of the magnet. The size of lesions could be measured by the ESNavi software [5, 6].

Gastric preparation regimen and MCCG examination protocol

After overnight fasting (> 8h), subjects receiving magnetically controlled capsule gastroscopy at the institution who met the inclusion criteria will be randomly allocated into 1 of 2 groups (1:1): position change or conventional groups. An independent research assistant generated the computerized random number sequence. The sequence was concealed in an opaque envelope until the intervention was obtained from eligible subjects, study nurses telephoned the independent research assistant, and then informed the patient's intervention allocation. Right after ingesting 5 g dimethicone (Zigong Honghe Pharmaceutical Co.,Ltd; Sichuan, China) mixed with 100 ml of water, subjects in the conventional group were allowed to walk freely; while subjects in the position change group were instructed by the study nurses to repeatedly change the body position according to a pre-specified protocol for a period of 15 min: in the order of supine position, left lateral position, three cycles of prone, left lateral, supine, and right lateral positions, and finally supine position, with a duration of 1 min for each position. Thirty and forty min after dimethicone administration, subjects in both groups would additionally take 200 ml and 800 ml water, respectively before undergoing MCCG examination (Supplementary Figure S1).

After attaching the data recorder, patients were asked to lie down on the examination couch beneath the guidance magnet robot. Then the capsule was swallowed in a supine position with approximately 100 ml of water for investigating the esophagus. The patient

remained sat upright to facilitate the esophageal passage if capsule stop in the esophagus more than one minute. 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. Additional water was needed if distension was insufficient. 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 gastric examination time of MCCG was recorded. If lesions were identified during MCCG examination, conventional EGD was performed according to standard practice to obtain biopsy or for therapeutic intervention.

Outcome parameters

Primary Outcome Measure

The primary outcome was gastric cleanliness score (GCS). Six primary anatomical landmarks of the stomach (cardia, fundus, body, angulus, antrum, and pylorus) were recorded for evaluation. A 4-point grading scale was introduced to define the cleanliness as excellent (no adherent mucus and foam: score 4), good (mild mucus and foam but does not obscure vision: 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 needing water to clear it: score 1) (Supplementary Figure S2) [6, 7]. GCS was the total scores of all six landmarks, ranging from 6 (completely unprepared) to 24 (perfect). GCS of ≥ 18 was regarded as acceptable.

Secondary Outcome Measure

Secondary outcomes included detection rate of positive findings, number of lesions per patient (NLPP), gastric examination time, and safety of MCCG. Positive findings defined as any pathology detected by MCCG, including polyp, ulcer, gastric fundus varices, submucosal tumor, and carditis. The diffuse lesions such as superficial, atrophic, and erosive gastritis were defined as negative findings [6]. NLPP was defined as the number of positive findings divided by the total number of patients, the location of NLPP were also recorded. Gastric examination time was determined using digital stopwatch in the ESNavi software. Safety of

MCCG, or adverse events, defined as symptoms or signs such as abdominal distention, nausea, or vomiting, were monitored closely during the MCCG 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.