Second-Generation Magnetically Controlled Capsule Gastroscopy with Improved Image Resolution and Frame Rate: Study Protocol for A Randomized Controlled Clinical Trial

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INTRODUCTION

Magnetically controlled capsule gastroscopy (MCCG) provides good visualization of the stomach, and is highly accepted due to the characteristics of painlessness, noninvasiveness and favorable diagnostic accuracy as conventional endoscopy[1,2]. However, the upper gastrointestinal (UGI) tract under capsule endoscopy (CE) continues to present challenges including rapid transit through esophagus and duodenum[3,4], as well as longer gastric examination time[5] compared to conventional endoscopy. Technical improvements in frame rate, field of view, dual camera, image resolution and battery life have been performed to optimize the clinical application of CE, and some turned out to be effective[6,7,8,9].

Therefore, a new-generation MCCG (MCCG-2) highlighted with a higher and adaptive frame rate of 8 frames per second (fps), better image resolution of 720 x 720 pixels, wider field of view of 150°, extended battery life of more than 12 hours and anti-jamming wireless data transmission has been developed. Hence, this pilot study was conducted to determine whether MCCG-2 can further optimize the visualization of UGI tract, thus result in better diagnosis of UGI diseases.

METHODS

Study design

This pilot study was a prospective, single-centered, blinded randomized controlled study, approved by the institutional review board of Shanghai Changhai Hospital and registered at ClinicalTrials.gov. with registration number NCT03977935. Written informed consent was obtained from each enrolled subject.

Patients

From May 2019 to June 2019, 80 consecutive patients aged 18-80 years with or without abdominal complaints referring for MCCG examination were prospectively enrolled and randomly allocated into MCCG-1 group or MCCG-2 group a 1：1 ratio. Patients with any of the following contraindications for MCCG were excluded: pacemakers or electromedical devices implanted which are incompatible with magnetic field; suspected or known gastrointestinal stenosis, obstruction or other known risk factors for capsule retention; scheduled magnetic resonance imaging examination before excretion of capsule; pregnancy or suspected pregnancy; and any other contraindications determined by endoscopists.

Study intervention

The MCCG, a robotic magnetic capsule guidance system, was provided by Ankon Technologies Co. Ltd (Shanghai, China). The MCCG system was consisted of a guidance magnet robot, a capsule endoscopy, a data recorder and a computer workstation with a software for real-time view and two joysticks for capsule orientation control. The guidance magnet robot was of C-arm type with five degrees of freedom: two rotational (horizontal and vertical directions) and three translational (forward/backward, up/down, left/right).

After a standardized gastrointestinal (GI) preparation regimen for MCCG, patients were placed in the left lateral decubitus position and swallowed MCCG-1 or MCCG-2 with a small amount of water according to a random number table with the help of of nurses at the digestive endoscopic center. When MCCG reached the stomach, it would be lifted away from the posterior wall, rotated and advanced to the fundus and cardiac regions, followed by the gastric body, angulus, antrum and the pylorus. During this procedure, position changes such as supine, prone, left and right lateral were also helpful in achieving clear observation and smooth transition. Standardized examination procedure of MCCG was available online at videogie.org[10]. Cases with suspected malignancy were rechecked under conventional endoscopy.

Image capture rate in the esophagus and stomach were 2 fps or 6 fps in MCCG-1 or MCCG-2 group, and standardized operation of MCCG were performed twice for complete gastric examination. After the capsule moved into the duodenum, patients left the hospital with the data recorder to continue with small-bowel examination. In the small bowel, MCCG-2 offered an adaptive frame rate technology which adjusted the image capture rate based on how fast the capsule was moving.

Study outcomes and definition

Basic characteristics of the enrolled patients were prospectively collected. Primary study outcome was efficacy analysis including visualization of the esophagus and duodenum indicated by detection rate of Z-line and duodenal papilla defined as at least one image of Z-line or duodenal papilla was obtained, the number of images captured for esophagus and Z-line, circumferential visualization of Z-line as the number of quadrants observed and cleansing level of Z-line as bubbles/saliva on Z-line[11]. Operation related parameters included esophageal transit time (ETT), gastric examination time (GET), gastric transit time (GTT), small bowel transit time (SBTT) and total running time (TRT). Image quality,

maneuverability and detection of lesions were also prospectively documented. Any procedure related adverse events were closely recorded.

GET was defined as the time for examination of gastric primary anatomical landmarks twice. Image quality ranged from one to ten denoting from the worst to the highest[12]. Maneuverability was classified as fluency (the response to operation and video effect), stability (the ability of holding the capsule at one position for at least one minute) and comfortableness (the operator's fatigue degree during the examination), and each index graded from one to five with one as the worst and five as the best.

All examinations and maneuverability evaluation were performed by an endoscopist (W.Z.) with an experience of more than 1000 cases of MCCG operation. Two other endoscopists blinded to the grouping would independently evaluated the image quality with a mean value as the final score, and a third endoscopist would make the final judgement when there existed a discrepancy more than three. The randomization schedule was generated by the investigator using a random number table, making it possible that patients enrolled and endoscopists involved were all blinded to the treatment protocol assigned.

Statistical analysis

As a pilot study to evaluate the clinical utility of MCCG-2, sample size was not calculated for this study. Quantitative data were summarized with parametric statistics, mean and standard deviation, or with nonparametric statistics, median and interquartile range, whereas categorical data were presented as frequency (percentage). Data with a normal distribution were compared using parametric analysis and non-normally distributed data were compared using nonparametric statistical analyses. Categorical variables were analyzed with the $\chi 2$ exact test and quantitative data were analyzed using the Mann–

Whitney Wilcoxon test with a final two-sided P value of less than 0.05 indicating statistical difference. SPSS 13.0 software was used.

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REFERENCES

1. Liao Z, Hou X, Lin-Hu EQ et al. Accuracy of Magnetically Controlled Capsule Endoscopy, Compared With Conventional Gastroscopy, in Detection of Gastric Diseases. Clin Gastroenterol Hepatol 2016; 14: 1266-1273.
2. Liao Z, Zou WB, Li ZS. Clinical application of magnetically controlled capsule gastroscopy in gastric disease diagnosis: recent advances. Sci China Life Sci 2018; 61: 1304-1309.
3. Hosoe N, Naganuma M, Ogata H. Current status of capsule endoscopy through a whole digestive tract. Digest endosc 2015; 27: 205-215.
4. Ching HL, Healy A, Thurston V et al. Upper gastrointestinal tract capsule endoscopy using a nurse-led protocol: First reported experience. World J Gastroenterol 2018; 24: 2893-2901.
5. Zou WB, Hou XH, Xin L et al. Magnetic-controlled capsule endoscopy vs. gastroscopy for gastric diseases: a two-center self-controlled comparative trial. Endoscopy 2015; 47: 525–528.
6. Tontini GE, Wiedbrauck F, Cavallaro F et al. Small-bowel capsule endoscopy with panoramic view: results of the first multicenter, observational study (with videos). Gastrointest Endosc 2017; 85: 401-408.
7. Monteiro S, de Castro FD, Carvalho PB et al. PillCam® SB3 capsule: Does the increased frame rate eliminate the risk of missing lesions? World J Gastroenterol 2016; 22: 3066-3068.
8. Takamaru H, Yamada M, Sakamoto T et al. Dual camera colon capsule endoscopy increases detection of colorectal lesions. Scand J Gastroenterol 2016; 51: 1532-1533.
9. Ou G, Shahidi N, Galorport C et al. Effect of longer battery life on small bowel capsule endoscopy. World J Gastroenterol 2015; 21: 2677-2682.
10. Jiang X, Pan J, Li ZS et al. Standardized examination procedure of magnetically controlled

capsule endoscopy. VideoGIE 2019; 4: 239-243.

11. Gralnek IM, Adler SN, Yassin K et al. Detecting esophageal disease with second-generation capsule endoscopy: initial evaluation of the PillCam ESO 2. Endoscopy 2008; 40: 275-279.

12. Chen YZ, Pan J, Luo YY et al. Detachable string magnetically controlled capsule endoscopy for complete viewing of the esophagus and stomach. Endoscopy 2019; 51: 360-364.