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ORIGINAL ARTICLE

Repetitive Position Change Improves Gastric Cleanliness for Magnetically Controlled Capsule Gastroscopy

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Abstract

Background and Aims Good gastric preparation is essential for magnetically controlled capsule gastroscopy (MCCG) examination. This study aims to determine if repetitive position change after dimethicone premedication could further improve gastric cleanliness for MCCG.

Methods Consecutive patients referred for MCCG in our center from May 7 to May 31, 2018 were prospectively enrolled and randomized to undergo repetitive position change for 15 min (position change group) or not (conventional group) after ingesting dimethicone. Primary outcome was gastric cleanliness score and secondary outcomes were detection rate of positive findings, number of lesions per patient, gastric examination time, and safety of MCCG.

Results Totals of 43 and 40 were included in the position change and conventional groups, respectively. Gastric cleanliness score in the position change group was significantly higher than in the conventional group (21.2 ± 1.0 vs. 18.6 ± 2.0, $P < 0.001$), as was the proportion of acceptable gastric cleanliness (gastric cleanliness score ≥ 18) (100% vs. 72.5%, $P < 0.001$). There was no statistical difference in detection rate of positive findings between the two groups (27.9% vs. 27.5%, $P = 0.97$). In the position change group, the gastric examination time was significantly reduced (13.2 ± 4.0 vs. 15.3 ± 5.1, $P = 0.043$). No adverse events were observed.

Conclusions Repetitive position change after dimethicone premedication significantly improves gastric cleanliness for MCCG examination.

Clinical Trial Registration ClinicalTrials.gov, ID: NCT03514966.

Keywords Position change · Gastric cleanliness · Dimethicone · Magnetically controlled capsule gastroscopy

Introduction

Gastric cancer (GC) has become the fourth leading cause of cancer-related death and one of the heaviest cancer burdens worldwide [1, 2]. Mounting evidence has shown that GC screening by upper GI endoscopy is effective in reducing GC incidence and mortality [3]. Compared to conventional esophagogastroduodenoscopy (EGD) with invasiveness and discomfort under unsedated situations, magnetically controlled capsule gastroscopy (MCCG) has recently been accepted as a non-invasive diagnostic modality with comparable diagnostic accuracy [4–9]. However, foam and bubbles usually accumulate in the stomach, obscuring MCCG visibility. Good gastric preparation with little foam and mucus is a key requirement for MCCG, which reduces the possibility of missing subtle lesions [10].

Yuan-Chen Wang, Jun Pan and Xi Jiang have contributed equally to this work.

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Premedication with detergents for upper GI endoscopy improves the visibility of gastric mucosa. As for gastric preparation of MCCG, antifoaming agents (e.g. simethicone [7, 11], dimethicone [10, 12]) and mucolytics (e.g. pronase [13, 14], *N*-acetylcysteine [15–17]) have been commonly used, with the former demonstrated in our previous study as an optimal gastric preparation regime for MCCG examination [7]. However, there was still a less than ideal visibility in the cardia and fundus with opaque gastric contents [15, 18].

Studies have shown that position change affects intragastric content distribution [19], and that a supine position prolongs gastric emptying time copmared with an upright position [20, 21]. In this single-blind randomized controlled trial, we aimed to determine the efficacy of repetitive position change after dimethicone premedication on further improving image quality of MCCG examination.

Materials and Methods

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].

Examinations were performed by one qualified capsule endoscopist with an experience of more than 500 cases of MCCG operation. Two other endoscopists (J.P., X.J.S.) were blinded to the type of gastric preparation and independently graded the quality by reviewing the images captured by MCCG. When discrepancies arose over the grading results, this was resolved by consensus discussion between the two endoscopists, with arbitration by a third endoscopist (Z.L.) who 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 (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 0–30 mm. It is powered by two silver oxide batteries for up to 10–12 h. 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 vary the strength of the 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 (> 8 h), subjects receiving magnetically controlled capsule gastroscopy at the institution , and those who met the inclusion criteria were 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, then study nurses telephoned the independent research assistant, and then informed the patient's intervention allocation. Right after ingesting 5 g dimethicone (Zigong Honghe Pharmaceutical, 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 additionally took 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 to investigate the esophagus. The patient remained sitting upright to facilitate the esophageal passage if the capsule stopped in the esophagus more than 1 min. 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 the MCCG examination, conventional EGD was performed according to standard practice to obtain a 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 do 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 were 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 2 weeks or a capsule endoscope that requires directed intervention or therapy to aid its expulsion) was monitored and followed up for up to 2 weeks.

Statistical Analysis

In order to define the sample size, we carried out an exploratory study enrolling 20 patients in each group. Mean gastric cleanliness score in the position change and conventional groups were 20.1 and 19.4, respectively. This study was a superiority study based on two-sided alpha as 0.05 and the power as 80%, thus 64 patients (32 patients in each group) were required by using NCSS-PASS 11 program (v.11.0.7; NCSS, Kaysville, Utah, USA). Considering a withdrawal rate of 20%, we enrolled at least 80 patients. Statistical analysis was performed using SPSS Statistics software v.18.0. Descriptive statistics were given as mean ± standard deviation (SD). Differences in categorical variables between patient groups were compared by using the Chi square test; differences in means were compared with the independent *t* test. In GCS comparison and subgroup analysis which lack of normal distribution for quantitative data, we used Mann–Whitney test for comparison of the two groups. A P value of < 0.05 was considered to be statistically significant.

Results

Patient Characteristics

From May 7 to May 31 2018, a total of 86 patients were enrolled in this study, of which 3 patients were excluded for declining to participate in the study; therefore, 83 patients (43 position change group, 40 conventional group) were included in the final analysis (Fig. 1). Among these patients, 53 (63.9%) were male and 30 (36.1%) were female, and the mean age was 47.4 years (range, 20–80 years). A total of 19 (22.9%) patients were *Helicobacter pylori*-positive. The main indications for MCCG was gastric cancer screening ($n = 44$, 53.0%), followed by abdominal pain ($n = 14$, 16.9%), abdominal distension ($n = 10$, 12.1%), acid reflux, nausea or vomit ($n = 8$, 9.6%), OGIB or IDA ($n = 2$, 2.4%); others included diarrhea or irritable bowel syndrome ($n = 3$), and surveillance of peptic ulcer ($n = 2$). There was no statistical difference in demographic characteristics or indications between the two groups (Table 1).

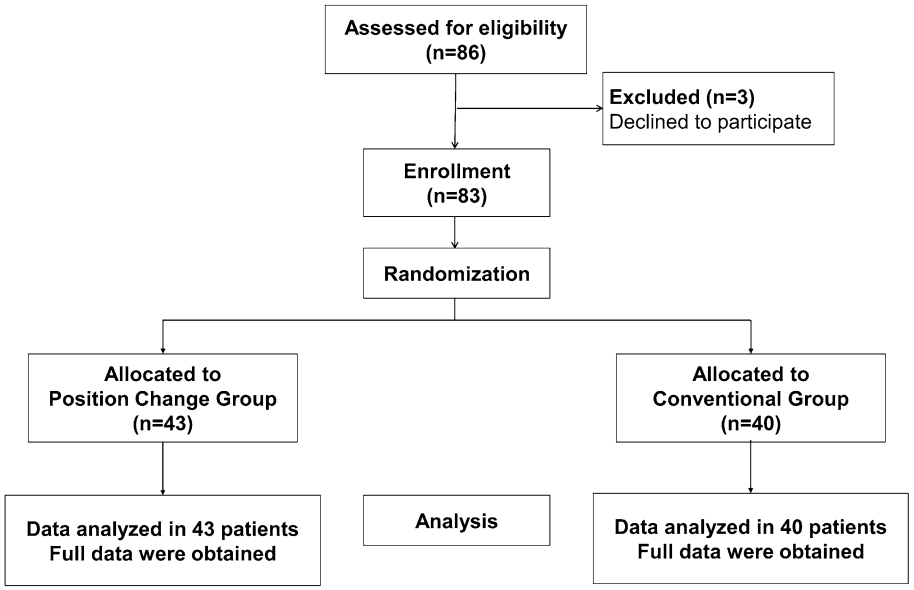

Fig. 1 Schematic flow diagram of the study

Table 1 Patient characteristics and indications for MCCG

	Position change group ($n=43$)	Conventional group ($n=40$)	Total
Male, *n* (%)	23 (53.5%)	30 (75%)	53 (63.9%)
Mean age, year (range)	45.3 (20–69)	49.6 (22–80)	47.5 (20–80)
Mean BMI (SD)	22.9 ± 3.1	24.6 ± 3.7	23.9 ± 3.5
Hp infection, *n* (%)	11 (25.6%)	7 (17.5%)	19 (22.9%)
Indication, *n* (%)			
Abdominal pain	9 (20.9%)	5 (12.5%)	14 (16.9%)
Abdominal distension	5 (11.6%)	5 (12.5%)	10 (12.1%)
Acid reflux, nausea or vomit	4 (9.3%)	4 (10.0%)	8 (9.6%)
OGIB or IDA	0 (0.0%)	2 (5.0%)	2 (2.4%)
Gastric cancer screening	24 (55.8%)	20 (50.0%)	44 (53.0%)
Others	1 (2.3%)	4 (10.0%)	5 (6.0%)

Others included diarrhea or irritable bowel syndrome ($n=3$), and surveillance of peptic ulcer ($n=2$)

BMI Body Mass Index, *SD* standard deviation, *Hp* helicobacter pylori, *OGIB* obscure gastrointestinal bleeding, *IDA* iron deficiency anemia

Primary Outcome

GCS was 21.2 ± 1.0 and 18.6 ± 2.0 in the position change group and conventional group, respectively (Fig. 2). Acceptable gastric cleansing accounted 100% in the position change group and 72.5% in the conventional group ($P<0.001$). Except for the fundus of the conventional group, GCS of each landmark in both groups were good to excellent. Table 2 depicts the results of gastric cleanliness in the six primary anatomic landmarks (Supplementary Figure S3). There were significant differences in cleanliness in each of five primary landmarks except for the pylorus between the two groups. The GCS was improved by position change according to subgroup analysis (Table 3). Additionally, GCS was unrelated to gender, age, alcohol history, and smoking history according to subgroup analysis, whereas BMI stratification showed significant differences between the BMI < 24 group and ≥ 30 group.s. As for comparison of cleanliness in different location, lower stomach was much better than upper stomach, and the differences was statistically significant ($P<0.001$).

Secondary Outcomes

Twelve (27.9%) and 11 (27.5%) lesions were detected in the position change and conventional groups, respectively (Table 4). There was no significant difference in the

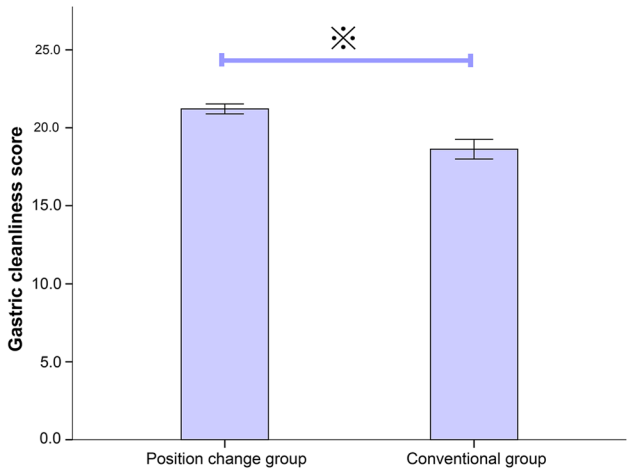

Fig. 2 Total scores of gastric cleanliness in the two groups. The position change group presented a better result than the conventional group ($P < 0.001$)

Table 2 Comparison of gastric cleanliness in the two groups

Location	Gastric cleanliness scores		*P* value
	Position change group	Conventional group	
Cardia	3.5 ± 0.5	3.0 ± 0.6	< 0.001
Fundus	3.0 ± 0.6	2.2 ± 0.7	< 0.001
Body	3.1 ± 0.4	2.7 ± 0.7	0.001
Angulus	3.7 ± 0.5	3.1 ± 0.7	< 0.001
Antrum	4.0 ± 0.0	3.7 ± 0.5	< 0.001
Pylorus	4.0 ± 0.0	3.9 ± 0.3	0.07

P values show the statistical difference between the two groups

detection rate of positive findings between the two groups ($P = 0.97$). In the position change group, the number of lesions per patient (NLPP) were somewhat higher in total (0.49 ± 1.71 vs. 0.28 ± 0.64, $P = 0.736$). Subgroup analysis showed that NLPP of each stomach landmark were somewhat higher in the position change group, and there was a significant difference in the NLPP of the angulus between the groups (0.09 ± 0.29 vs 0.00 ± 0.00, $P = 0.049$) (Table 5). In addition, the mean gastric examination time of the positional change group was significantly reduced (13.2 ± 4.0 min vs. 15.3 ± 5.1 min, $P = 0.043$). In particular, gastric ulcers were detected by MCCG in 5 cases (3 in the conventional group, 2 in the position change group), wherein 1 in the position change group was finally diagnosed with adenocarcinoma by subsequent EGD with biopsy (Supplementary Figure S4). All the patients were able to ingest the capsule without difficulty, and no adverse events were observed in either group.

Table 3 Subgroup analysis of gastric cleanliness

Subgroup	Position change group	Conventional group	*P* value	*P* value for interaction
Location[a]				< 0.001
Upper stomach	9.5 ± 0.8	7.9 ± 1.4	< 0.001	
Lower stomach	11.7 ± 0.5	10.8 ± 1.1	< 0.001	
Gender				0.19
Male	21.1 ± 1.0	18.5 ± 1.9	< 0.001	
Female	21.4 ± 1.0	19.1 ± 2.3	0.004	
Age (year)				0.71
< 40	21.0 ± 1.0	17.3 ± 2.7	0.01	
≥ 40	21.3 ± 1.1	18.9 ± 1.7	< 0.001	
BMI (kg/m^2)[b]				0.03*
< 24	21.2 ± 1.1	18.9 ± 1.8	< 0.001	
24–30	21.3 ± 1.0	18.7 ± 1.8	< 0.001	
≥ 30	21.0 ± 0.0	15.0 ± 2.8	–	
Alcohol history				0.86
No	21.2 ± 1.1	18.6 ± 2.2	< 0.001	
Yes	21.1 ± 1.1	18.6 ± 1.4	0.001	
Smoking				0.71
No	21.4 ± 1.0	18.9 ± 1.9	< 0.001	
Yes	20.7 ± 1.2	17.7 ± 2.1	0.001	

[a]Upper stomach includes the cardia, fundus, and body, and lower stomach includes the angulus, antrum, and pylorus

[b]BMI stratification show significant differences between BMI < 24 group and 24 ≤ BMI < 30 group gastric cleanliness

Table 4 Classification of lesions diagnosed by MCCG

Lesion	Position change group, *n* (%)	Conventional group, *n* (%)	*P*
Superficial gastritis	1 (2.3%)	0 (0.0%)	
Chronic atrophic gastritis	1 (2.3%)	4 (10.0%)	
Chronic erosive gastritis	1 (2.3%)	0 (0.0%)	
Polyps	5 (11.6%)	3 (7.5%)	
Gastric ulcer	1 (2.3%)	3 (7.5%)	
Gastric fundus varices	1 (2.3%)	0 (0.0%)	
Carditis	0 (0.0%)	1 (2.5%)	
Gastric cancer	1 (2.3%)	0 (0.0%)	
Others	1 (2.3%)	0 (0.0%)	
Detection rate of positive findings	12 (27.9%)	11 (27.5%)	0.97

Discussion

This single-blind RCT was the first to investigate the effectiveness of position change after premedication with

Table 5 Number of lesions per patient detected by MCCG

Location	Position change group	Conventional group	*P*
Cardia and fundus	0.14 ± 0.52	0.10 ± 0.50	0.465
Body	0.12 ± 0.50	0.05 ± 0.22	0.691
Angulus	0.09 ± 0.29	0.00 ± 0.00	0.049
Antrum and pylorus	0.50 ± 1.71	0.45 ± 0.69	0.695
Total	0.49 ± 1.71	0.28 ± 0.64	0.736

NLPP number of lesions per patient. NLPP was defined as the number of positive findings (including polyp, ulcer, gastric fundus varices, submucosal tumor, and carditis) divided by the total number of patients. The diffuse lesions such as superficial, atrophic, and erosive gastritis were defined as negative findings

antifoaming agents on improving gastric cleanliness. The image quality of the upper stomach is less ideal than the lower stomach probably due to the decreased contact time between the upper mucosa and detergents, which are affected by gravity effects. In this study, the addition of repetitive position change after ingesting dimethicone resulted in an effective pretreatment that improves gastric cleanliness.

As a feasible and safe diagnostic modality with high patient compliance, MCCG presents a great potential [4–6, 8, 18]. Since clinically relevant abnormalities may be missed because of bubbles and mucus, a clear gastric lumen is necessary to ensure satisfactory visualization of the gastric wall and improve diagnostic efficiency during MCCG examination. Dimethicone, an antifoaming non-absorbable substance, has long been used in routine preparation for capsule gastroscopy with favorable results, and neither drug interactions nor adverse effects have been reported [22, 23]. Chang et al. [15] have proved that a small volume of simethicone used before procedure was effective in significantly improving the visibility of the gastrointestinal tract. Although mucolytics such as pronase and N-acetylcysteine have been reported as effective in conventional EGD, our previous study and that by Asl et al. suggested that simethicone alone produces a significant improvement in gastric cleanliness, and should be the optimal gastric preparation regime for MCCG examination; whereas pronase and *N*-acetylcysteine did not improve visualization by themselves [7, 24]. With this evidence, our study used dimethicone as premedication to improve gastric cleanliness.

Repetitive position change has the following two effects. First, repetitive changes of body positions facilitate dimethicone contact with the gastric mucosa. Postural medicine studies have shown that gravity affects all organ systems in the body, and that intra-gastric content distribution depends on posture [19]. Loots et al. [25] measured the gastric acid pool of subjects (fasted at least 6 h) in the left lateral position (LLP) and right lateral position (RLP), and the results showed that acid accumulates in the upper and lower stomach during LLP, whereas RLP showed one acid pool, presumably in the fundus/cardia of the stomach. Second, repetitive body position change in different lying postures could prolong the exposure time of the gastric mucus to the ingested premedication. Prior studies have suggested that gravity influences gastric emptying of low-nutrient liquids, so that gastric emptying was faster in the upright position compared to lying down [20, 21, 26]. In this study, cleanliness scores for each landmark (except pylorus) in the position change group were significantly higher than in the conventional group ($P < 0.05$).

Although gastric cleanliness improved in the upper stomach after repetitive position change, we found that the fundus had the poorest mucus visibility among all the locations evaluated. This might be explained by the deep mucosal folds of the greater curvature rendering mucus and bubbles relatively inaccessible to the swallowed dimethicone, and therefore making it more difficult to remove. This may be further exacerbated by the reduced motility of the thinner proximal compared to the thicker distal stomach [27]. Gastric physiology indicates the thin upper stomach is less motile than the thick lower stomach [28]. Furthermore, swallowed saliva also contributes to poor cleanliness. Although excess bile might have been expected to interfere with visibility, scores in the distal stomach were good, and there was no difference in GCS between the position change group and the conventional group in the pylorus area. This can be explained by the fact that the upright position was associated with an increase in the amount of drink in the lower stomach, so that dimethicone accumulated in the antral area and fully disrupted the bubbles [21].

Gastric cleanliness is paramount in detecting subtle mucosal abnormalities associated with lesions including early neoplasia during diagnostic EGD, and a clean, well-prepared stomach is associated with higher disease detection rates and also shortened the gastric examination time. In our study, one subject without a history of EGD was diagnosed with adenocarcinoma (confirmed by pathology). Although the differences were not statistically significant between the two groups in the detection rate of positive findings, the NLPP was somewhat higher in total and in each stomach landmark in the position change group. In addition, NLPP in the angulus was significantly increased ($P = 0.049$) and the mean gastric examination time was significantly reduced ($P = 0.043$) in the position change group, probably owing to improved gastric cleanliness.

Several limitations should be considered while interpreting the results of this study. First, although repetitive position change contributes to a better image quality, the lesion detection rate was no different in this study, which is probably due to the small sample size. Second, this trial

was conducted at a single center, and further clinical trials involving a larger number of patients in multiple centers are needed. Last, although upper stomach cleanliness was improved after repetitive position change, the fundus still had the poorest scores in six landmarks within the group. Therefore, studies for a better preparation regime are required to improve upper gastric views.

In conclusion, repetitive position change after ingesting dimethicone significantly improves the quality of MCCG gastric images and achieves satisfactory endoscopic viewing. Further studies evaluating the effect of repetitive position change on MCCG diagnostic yields are warranted.

Author's contribution Study concept and design (ZL); registration of the study (YCW, JP); conduct of the study (YCW, JP); acquisition of data (YCW, XJS, XJ, WBZ, YYQ, WZ, XL, JY, XNY, AJZ); analysis and interpretation of data (YCW, JP); drafting of the manuscript (JP); statistical analysis (YCW); critical revision of the manuscript for important intellectual content (ZL, ZSL); obtained funding (ZL, JP). All authors had access to the study data and reviewed and approved the final manuscript.

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Conflicts of interest The authors have no conflicts of interest or financial ties to disclose.

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