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ORIGINAL ARTICLE

Magnetic Steering of Capsule Endoscopy Improves Small Bowel Capsule Endoscopy Completion Rate

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Abstract

Background Capsule endoscopy is currently available as a noninvasive and effective diagnostic modality to identify small bowel abnormalities, with a completion rate to the cecum between 75.1 and 95.6%. A novel magnetically controlled capsule endoscopy (MCE) system could facilitate passage of the capsule through the pylorus, thereby reducing the gastric transit time (GTT).

Objective We performed this study to determine whether magnetic steering could improve the capsule endoscopy completion rate (CECR) compared to standard protocol.

Methods Patients referred for MCE in our center from June 2017 to November 2017 were prospectively enrolled. Magnetic steering of the capsule through the pylorus was performed after standard gastric examination. CECR, GTT, pyloric transit time (PTT), and rapid gastric transit (GTT ≤ 30 min) rate were compared with a historical control group enrolled from January 2017 to May 2017.

Results CECR was significantly higher in the intervention group ($n = 107$) than control group ($n = 120$) (100% vs. 94.2%, $P = 0.02$), with a significantly shorter GTT (22.2 vs. 84.5 min, $P < 0.001$) and PTT (4.4 vs. 56.7 min, $P < 0.001$). Rapid gastric transit rate in the intervention group was significantly higher than the control group (58.9% vs. 15.0%, $P < 0.001$). There were no statistical differences in the diagnostic yields between the two groups.

Conclusions Magnetic steering of capsule endoscopy improves small bowel CECR by reducing GTT, adding further support to MCE as a practical tool for noninvasive examination of both the stomach and small bowel.

Trial registration ClinicalTrials.gov, ID: NCT03482661.

Keywords Magnetic steering · Capsule endoscopy · Small bowel · Completion rate

Introduction

Capsule endoscopy (CE) is a noninvasive small bowel imaging modality used to investigate unexplained gastrointestinal bleeding, suspected inflammatory bowel disease, tumors, complications of celiac disease, and obstruction [1–3]. Of these indications, CE is the first-line diagnostic modality for obscure gastrointestinal bleeding [4]. However, due to battery exhaustion, capsule retention, technical failure, or poor small bowel preparation, small bowel examination completion rate in large studies ranged from 75.1 to 95.6%, leading to an increased miss rate of small bowel lesions [5].

A number of studies have focused on the issue of delayed gastric emptying, the most common cause of small bowel incomplete examination [5]. However, the effect of promoting gastric peristalsis is less than ideal: Prokinetic agents

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may have side effects [6], and results of cephalic phase stimulation studies (e.g., sham feeding, gum chewing) are conflicting [7, 8]. Therefore, control of movement of the capsule using magnetic steering to assist in transpyloric passage of the capsule may be an alternative option.

The magnetically controlled capsule endoscopy (MCE) system NaviCam (Ankon), as demonstrated in our previous studies showing a diagnostic accuracy comparable to conventional gastroscopy [9–12], has also been reported outside China to allow excellent control, provide good gastric views, and be extremely well tolerated [13]. The MCE system enables complete examination of the stomach and small bowel, which may avoid the need for multiple diagnostic procedures. It can facilitate pyloric transit of the capsule after full gastric examination, following which small bowel examination is performed during passive transit of the capsule. In our recent study, we successfully steered the capsule through the pylorus under magnetic guidance [14]. We therefore aim to evaluate the potential role of magnetic steering of the NaviCam through the pylorus on reducing gastric transit time (GTT) and finally improving capsule endoscopy completion rate (CECR) of the small bowel.

Methods

Study Design

This was a historically controlled study. The study protocol was approved by the institutional review board of Changhai Hospital (Second Military Medical University, Shanghai, China) with strict adherence to the principles outlined in the Declaration of Helsinki, and written informed consent was obtained from each enrolled patient.

Study Patients

The intervention group comprised consecutive patients prospectively enrolled in Changhai Hospital from June 2017 to November 2017. Patients aged over 18 with gastrointestinal complaints who were scheduled to undergo CE for both stomach and small bowel examination were eligible for this study. Patients with any of the following conditions were excluded: (1) unfit for, or not prepared to have surgery, in the event of capsule retention; (2) implanted pacemaker (except where compatible with C); (3) other implanted electromedical devices or magnetic metal foreign bodies; and (4) pregnancy or suspected pregnancy. Demographic and clinical characteristics, such as age, sex, BMI, medication use, and indications for MCE, were recorded. The historical control group were consecutive patients who underwent MCE between January 2017 and May 2017.

Study Intervention

MCE System

Procedures were performed using the NaviCam magnetic capsule guidance system (Ankon Technologies, Shanghai, China), which includes an endoscopic capsule, a data recorder, a guidance magnet robot, and a computer workstation with software for real-time viewing and controlling (Supplemental Figure 1). The capsule is 28×12 mm in size with a permanent magnet inside its dome and has a battery life of over 8 h. The weight of the MCE is 2 g, the view angle is $(140.0 \pm 14.0)^\circ$, and the depth of illumination is up to 60 mm. Images are captured at a rate of two frames per second (fps) under "stomach mode," and 1 fps under "small bowel mode." The robot used to guide the magnet is a C-arm type with five degrees of freedom (two rotational and three translational). The capsule can be controlled either manually by a magnet robot through a joystick or automatically using a default operating mode [9–12].

Gastric and Small Bowel Preparation Regimen

Patients followed a liquid diet the day before the procedure, were asked to refrain from colored drinks and medications, and fasted overnight (> 8 h). A total of 2 L polyethylene glycol was administered the night before the examination. Forty minutes before capsule ingestion, all patients swallowed 50 ml clear water containing 400 mg simethicone following which they were encouraged to mobilize to maximize contact with the gastric mucosa. An additional 950 ml clear water was drunk to wash out any residual mucus and bubbles before the MCE examination. During the examination, water ingestion was repeated if there was insufficient distention [9–12].

Standard Examination Protocol (Control Group)

MCE was performed by an endoscopist (W. Z.) with an experience of > 500 MCE operation cases. The patients swallowed the capsule with water in the supine position. When the capsule reached the stomach, approximation of the magnet toward the abdomen lifted the capsule away from the posterior wall. It was then rotated and advanced to the fundus and cardiac regions, and subsequently to the gastric body, angulus, antrum, and pylorus. After completing the stomach examination, the capsule was switched to "small bowel mode" following which no further magnetic interventions were undertaken such that the capsule entered the duodenum under normal physiological conditions. The position of the capsule was verified through the real-time

viewer. If the capsule was detained in the stomach for over 30 min, 10 mg domperidone was administered orally. After the capsule entered the duodenum, patients left the hospital with the data recorder for further collection of small bowel information and returned it the following day [9–12].

Transpyloric Magnetic Steering of the Capsule (Intervention Group)

After completing the stomach examination in the same way as was performed in the control group, the endoscopist moved the magnet ball above the position of the gastric antrum to lift the capsule and then guided the capsule camera toward and immediately proximal to the pylorus, holding it with the pyloric orifice in view. Once the pylorus opened, the capsule moved into the duodenum with gastric peristalsis (Fig. 1). The intervention was considered to have failed if the capsule did not pass through the pylorus within 30 min.

Study Outcomes

The primary outcome was small bowel CECR. Further outcomes included esophageal transit time (ETT: defined as the time between the first esophageal image and the first gastric image), gastric transit time (GTT: defined as the time between the first gastric image and the first duodenal image), gastric examination time (GET: defined as the time for the endoscopist to complete the gastric examination), rapid gastric transit rate (defined as the percentage of patients with GTT $\leq$ 30 min), pyloric transit time (PTT: defined as the time between the first pyloric image and the first duodenal image), small bowel transit time (SBTT: defined as the time between the first duodenal image and the first cecal image), and total transit time (TTT: defined as the sum of ETT, GTT, and SBTT). In cases of incomplete small bowel examination, SBTT and TTT were not calculated. Secondary outcomes included diagnostic yields of esophageal, gastric, small bowel and colon diseases, capsule retention rate, and adverse events. Patients were observed for up to 2 weeks to exclude the possibility of capsule retention. Adverse events were defined as symptoms or signs such as abdominal distention, nausea, or vomiting monitored closely during MCE procedure.

Statistical Analysis

Assuming a CECR of 80% using standard protocol, 100 patients per group were needed to detect a 7% improvement in CECR with a one-sided significance level of 5% and a power of 80%. All the images obtained by MCE were monitored in real time and reviewed by one of two qualified endoscopists. Normal distribution data were expressed as the mean, mean $\pm$ SD, range values and summarized with unpaired t test. Abnormal distribution data were expressed as the median. The Mann–Whitney test was used to compare the statistical differences in these variables between the two groups. The statistical differences between the two groups of CECR, rapid gastric transit rate, sex, and indications for MCE were analyzed by Chi-square test. All authors had access to the study data and reviewed and approved the final manuscript.

Results

Patient Characteristics

A total of 227 patients were enrolled in the study: 120 in the control group and 107 in the intervention group. All but nine patients (five in the control group and four in the intervention group) were ambulatory outpatients at the time of the procedure. The two groups were well matched for age, gender, BMI, history of diabetes, history of abdominal surgery, and indications for capsule endoscopy (Table 1). There were six

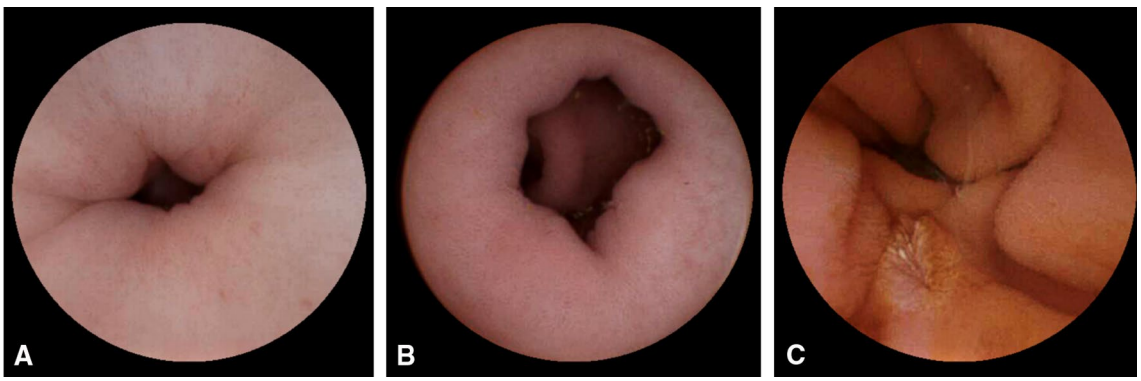

Fig. 1 Transpyloric passage of the capsule under magnetic steering. **a** Capsule was magnetically steered in close observation to the pylorus, waiting for its opening; **b** pylorus opened; and **c** capsule entered the duodenum through gastric peristalsis

Table 1 Patient characteristics

Parameter, *n* (%)	Control group ($n=120$)	Intervention group ($n=107$)	*P*
Male gender	73 (60.8%)	72 (67.3%)	0.31
Mean (SD) age (years)	46.4 ± 14.0	45.6 ± 12.8	0.66
Mean (SD) BMI (kg/m^2)	23.0 ± 3.9	23.6 ± 3.8	0.24
Diabetes mellitus	7 (5.8%)	8 (7.5%)	0.62
History of abdominal surgery	19 (15.8%)	9 (8.4%)	0.09
Indications for MCE			
Abdominal pain	38 (31.7%)	29 (27.1%)	0.45
Abdominal distension	19 (15.8%)	16 (15.0%)	0.86
Diarrhea	5 (4.2%)	7 (6.5%)	0.43
Health checkup	13 (10.8%)	20 (18.7%)	0.09
Gastrointestinal disease history	23 (19.2%)	18 (16.8%)	0.65
Others[a]	22 (18.3%)	17 (15.9%)	0.63

[a]Other indications included obscure gastrointestinal bleeding, suspicion of inflammatory bowel diseases, elevated tumor markers, constipation, heartburn, acid reflux, etc

categories of indications for capsule endoscopy: abdominal pain, abdominal distension, diarrhea, health checkup, gastrointestinal disease history, and other indications (obscure gastrointestinal bleeding, suspicion of inflammatory bowel diseases, elevated tumor markers, constipation, heartburn, acid reflux, etc.).

CECR and Transit Time

As shown in Table 2, the intervention group had a significantly higher CECR than the control group (100% vs. 94.2%, $P=0.02$), with significantly shorter GTT (22.2 vs. 84.5 min, $P<0.001$), PTT (4.4 vs. 56.7 min, $P<0.001$), and TTT (347.1 vs. 388.7 min, $P=0.01$) in the intervention group. ETT (1.1 vs. 1.0 min, $P=0.35$), GET (14.4 vs 14.7 min, $P=0.791$), and SBTT (294.3 vs. 293.5 min, $P=0.998$) were similar between intervention and control groups. Rapid gastric transit (GTT ≤ 30 min) rate was significantly higher in the intervention group than the control group (58.9% vs. 15.0%, $P<0.001$).

As for the seven cases of incomplete examination, both GTT and PTT were somewhat longer than the remaining 113 cases of complete examination in the control group, but the differences between the two subgroups were not statistically significant ($P=0.14$ and 0.08, respectively) (Table 3). Small bowel strictures or capsule retention was not observed in both subgroups. No differences were found in terms of battery life, baseline characteristics (age, sex, BMI, history of diabetes, and history of abdominal surgery), and indications for capsule endoscopy (except for obscure GI bleeding).

Diagnostic Yields of MCE

Table 4 summarizes the diagnostic cases in esophagus, stomach (Supplemental Figure 2), small bowel (Fig. 2), and colon (Supplemental Figure 3). There were no statistical differences in diagnostic yields between the control and intervention groups. Interestingly, five cases of colon diseases were found (four and one cases in intervention and control groups, respectively): colonic polyps ($n=2$), parasites ($n=1$) and colitis ($n=2$). No significant adverse events and no capsule retention were observed in either group.

Discussion

Capsule endoscopy is considered to be one of the most effective methods to assess small bowel pathology. A major unresolved issue is that completion rate to the cecum may be as little as 83.5% [5]. According to a previous study, a considerable number of patients had significant ileal lesions, raising the possibility of missed pathology in the uninvestigated bowel segment in incomplete examinations [15]. This uncertainty may result in further invasive investigations and increased expenditure.

Table 2 Comparisons of CECR and transit time between control and intervention groups

Parameter	Control group ($n=120$)	Intervention group ($n=107$)	*P*
CECR	94.2% (113/120)	100% (107/107)	0.02
Transit time			
Median ETT (min)	1.0	1.1	0.35
Median GTT (min)	84.5	22.2	<0.001
Median GET(min)	14.7	14.4	0.791
Median PTT (min)	56.7	4.4	<0.001
Median SBTT (min)	293.5	294.3	0.998
Mean TTT (min)	388.7	347.1	0.01
Rapid gastric transit rate	15.0% (18/120)	58.9% (63/107)	<0.001

CECR capsule endoscopy completion rate; *ETT* esophageal transit time; *GTT* gastric transit time; *GET* gastric examination time; *PTT* pyloric transit time; *SBTT* small bowel transit time; and *TTT* total transit time

Table 3 Incomplete and complete examination of small bowel in the control group

Parameter, *n* (%)	Incomplete examination (*n* = 7)	Complete examination (*n* = 113)	*P*
Male gender	5 (71.4%)	68 (60.2%)	0.70
Mean (SD) age (years)	43.9 ± 26.0	46.6 ± 13.1	0.79
Mean (SD) BMI (kg/m^2)	23.1 ± 3.0	23.0 ± 4.0	0.92
Diabetes mellitus	0 (0.0%)	7 (6.2%)	1.00
History of abdominal surgery	1 (14.3%)	18 (15.9%)	1.00
Indications for MCE			
Abdominal pain	3 (42.9%)	35 (31.0%)	0.68
Gastrointestinal disease history	1 (14.3%)	22 (19.5%)	1.00
Obscure gastrointestinal bleeding	3 (42.9%)	7 (6.2%)	0.01
Transit time			
Median ETT (min)	1.3	1.0	0.30
Median GTT (min)	159.0	83.0	0.14
Median PTT (min)	139.9	56.2	0.08
Mean battery life of MCE (hours)	11.0	11.6	0.56
Small bowel strictures	0 (0.0%)	0 (0.0%)	1.00
Capsule retention	0 (0.0%)	0 (0.0%)	1.00

ETT esophageal transit time; *GTT* gastric transit time; and *PTT* pyloric transit time

Table 4 Diagnostic yields by MCE in control and intervention groups

	Control group Patients, *n* (%)	Intervention group Patients, *n* (%)	*P*
Total diagnosis cases	89 (74.2%)	78 (72.9%)	0.83
Esophageal diseases	3 (2.5%)	3 (2.8%)	1.00
Esophagitis	3	2	
Esophageal varices	0	1	
Gastric diseases	47 (39.2%)	39 (36.4%)	0.67
Chronic non-atrophic gastritis	19	24	
Erosive gastritis	12	3	
Gastric polyp	4	4	
Gastric submucosal lesion	2	3	
Other gastric diseases	10	5	
Small bowel diseases	39 (32.5%)	32(29.9%)	0.67
Small bowel inflammation	7	17	
Small bowel ulcer	6	4	
Small bowel submucosal tumor	2	2	
Small bowel polyp	4	3	
Small bowel erosion	5	0	
Lymphangioma/lymphofollicular hyperplasia	6	3	
Other small bowel diseases	9	3	
Colon diseases	1 (0.8%)	4 (3.7%)	0.19
Colonic polyp	0	2	
Parasite	0	1	
Colitis	1	1	

Technological advances have improved this situation with the highest completion rate reported as 97% using the PillCam SB3 which has a prolonged battery life of 12 h [16]. However, incomplete examinations may still occur. Besides active locomotion of CE, gastric peristalsis has been stimulated either directly using prokinetic agents or indirectly by

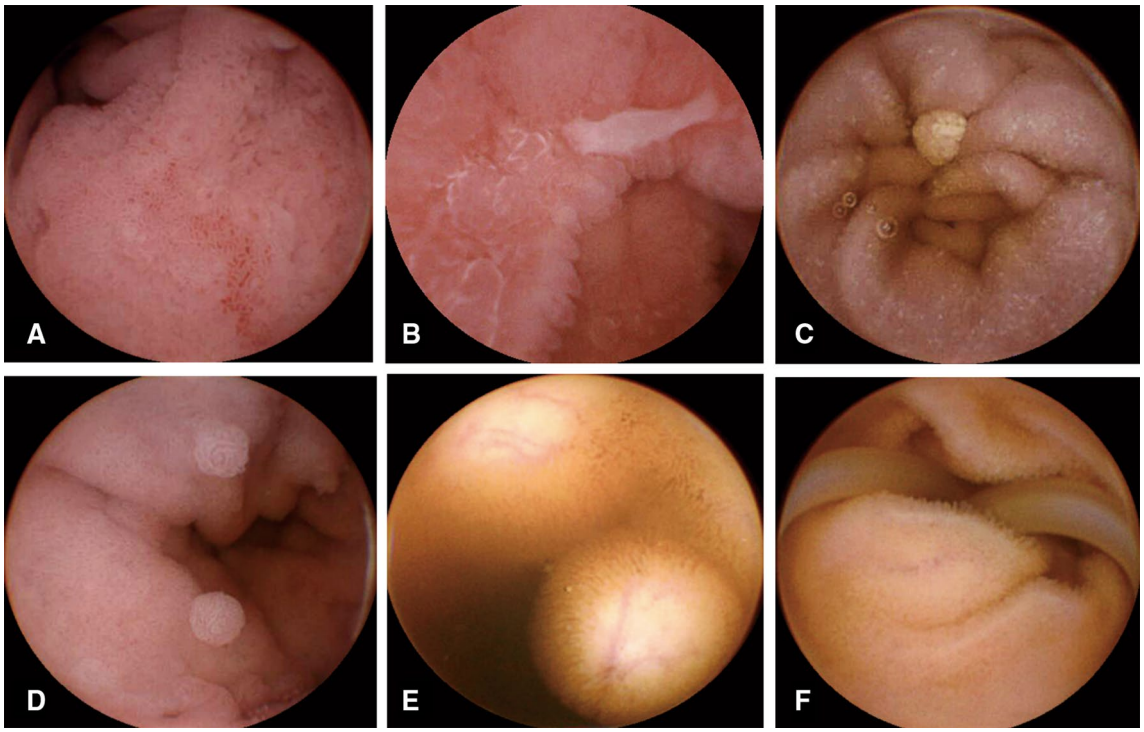

Fig. 2 MCE findings of the small bowel. **a** duodenitis; **b** small bowel ulcer; **c** lymphangioma; **d** small bowel polyp; **e** small bowel submucosal tumor; and **f** parasite

physiological cephalic phase stimulation [7, 8]. In addition to exposing patients to the risks of drug side effects, the routine use of prokinetic agents may actually lower the diagnostic yield of capsule endoscopy by reducing the examination time [17]. The impact of bowel preparation on small bowel completion rate was always controversial. In a large Korean study, the overall incomplete examination rate was as high as 33%, especially in the elderly and those with poor bowel preparation [18]. However, a recent meta-analysis demonstrated that purgative preparation was not useful for improving completion rate [19].

Our study has proved that magnetic control of the NaviCam capsule endoscopy is clinically useful in improving CECR by facilitating pyloric transit of the capsule. GTT and PTT have been reduced to 22 and 4 min, respectively. Although the magnetic navigation system is not capable of moving the capsule against gastric peristalsis, i.e., directly "dragging" the capsule through the pylorus, it is possible to hold the capsule immediately proximal to the pylorus ready to ride the next peristaltic wave into the duodenal bulb. This had an impact on CECR as all patients in the intervention group had a complete small bowel examination. The timely guidance of the capsule endoscopy through the pylorus benefits those with delayed gastric emptying and avoids additional EGD placement. In addition, patients with obscure gastrointestinal bleeding were more frequently observed in cases of incomplete examination. All these patients were relatively older and had gastrointestinal inflammation, which may be associated with poor gastrointestinal motility.

In a previous study, Hale et al. manually controlled the MiroCam-Navi capsule using a handheld magnet moved over the abdominal wall, but failed to improve CECR [20]. The control by handheld magnets relies on subtle movements of the controlling arm which is subject to fatigue, and the magnetic strength is limited [21]. However, joystick control is easier and more sensitive, and the magnetic field generated by the MCE system can reach a maximum of 200 mT [9]. To the best of our knowledge, our study is the first to demonstrate a definite role of magnetic steering to improve CECR. A decade ago, our group demonstrated that right lateral position improves CECR in a gravity-controlled manner [22]. This is somewhat similar to our current study, but magnetic control by robotic system is more adequate, precise, and replicable. Moreover, our study further supports the use of MCE as a sound diagnostic modality for both the small bowel and stomach.

Saving battery life may offer another solution. Our previous study demonstrated an improvement of CECR for CE adjusted from 2 to 1 fps after entering the duodenum [23]. However, increasing battery life from 8 to 12 h still resulted in an incomplete examination rate of approximately 5%, suggesting that increasing GTT may still have

a role in addressing this problem. Although the diagnostic yield in the magnetic steering group is not significantly different from the control group, this might be explained by the small sample size. Interestingly, four cases of colon diseases were detected in the intervention group, implying promise of indication expansion of NaviCam after further improvement in the future. Our study has limitations. The sample size is limited, and a randomized controlled trial is less likely to have introduced bias than a historically controlled study [24]. Therefore, larger randomized controlled trials are warranted. Besides, measurement bias might be introduced as the two endoscopists reviewing the images were not blinded to the clinical data. Although MCE has been proven to enhance gastric transit of the capsule and improve CECR in this study, there were still some disadvantages of the MCE system. First, patients with any pacemaker or other implanted electromedical devices which could interfere with magnetic resonance have to be excluded from MCE examination. Second, magnetic resonance examination is forbidden before the capsule is discharged. Third, the current cost of MCE examination is high. However, the cost will decrease if it is used widely in the future.

In conclusion, magnetic steering of the MCE NaviCam significantly enhances gastric transit of the capsule and improves CECR. This offers a precise remote control modality which addresses the issue of incomplete small bowel examination, avoids additional EGD placement for those with delayed gastric emptying, and further supports the use of the MCE NaviCam as an effective diagnostic tool for both the stomach and small bowel.

Author's contribution ZL was involved in study concept and design; YYL and JP contributed to registration of the study; YYL, JP, and YZC conducted the study; YYL, XJ, WBZ, YYQ, WZ, and XL contributed to acquisition of data; YYL, JP, and YZC analyzed and interpreted data; JP and YZC drafted the manuscript; YYL contributed to statistical analysis; ZL and ZSL critically revised the manuscript for important intellectual content; and ZL and JP contributed to the funding. All authors had access to the study data and reviewed and approved the final manuscript.

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Compliance with ethical standards

Conflicts of interest None.

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