Impact of magnetic steering on gastric transit time of a capsule endoscopy (with video)

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Backgrounds and Aims: Delayed gastric transit of the capsule may lead to incomplete small bowel examination, reducing the diagnostic yield. Thus, this study was designed to determine if magnetic steering could enhance capsule gastric emptying and mucosal visualization within the duodenum.

Methods: The intervention group comprised 100 patients undergoing magnetic-controlled capsule endoscopy between May to September 2017 in whom magnetic control was used to assist transpyloric passage of the capsule and duodenal inspection. A cohort of 100 patients who had undergone the procedure before May 2017 was randomly selected from the database as an historic control group in whom transpyloric movement of the capsule occurred spontaneously (without magnetic assistance). The difference in the pyloric transit time (PTT) and duodenal papilla detection rate (DPDR) between the 2 groups were compared, and related factors were also investigated.

Results: Transpyloric passage of the capsule under magnetic control was successfully performed in 59 patients (59%). Median PTT was greatly reduced in the intervention group from 58.38 minutes (range, 13.45-87.47) to 4.69 minutes (range, 1.56-55.00; $P < .001$), and DPDR was also greatly improved with magnetic steering (30.5% vs 9%, $P < .001$). Magnetic steering, male gender, and higher body mass index were independently associated with reduced gastric transit time and magnetic steering with an enhanced DPDR.

Conclusions: Magnetic steering of the capsule can enhance gastric emptying of the capsule and may prove useful in nonobese and female patients who appeared to have longer gastric transit time and achieved a better DPDR than that under the action of peristalsis alone. (Clinical trial registration number: NCT03441945.)

(footnotes appear on last page of article)

Capsule endoscopy (CE) is noninvasive, painless, and safe and is a valuable diagnostic tool for small bowel diseases, including inflammatory bowel disease, suspected polyposis syndromes, unexplained abdominal pain, celiac disease, and obscure GI bleeding.[1] However, incomplete examination of the small bowel may reduce the diagnostic sensitivity. According to previous reports, the noncompletion rate of small-bowel examination can be up to 13%,[2-5] in part because of slow gastric transit, limited battery life, and poor bowel preparation. Delayed gastric emptying is believed to account for 30% of the incomplete small-bowel CE procedures.[4]

Furthermore, there is concern about the diagnostic sensitivity of CE in the duodenum. The major duodenal papilla, 7 to 10 cm from the pylorus on the posteromedial wall of the descending part of duodenum, is a landmark in the duodenum, and the detection of the duodenal papilla has been regarded as a surrogate indicator of diagnostic yield in the proximal small bowel. However, it was infrequently identified by CE.[6-8] Furthermore, the detection of the duodenal papilla played a significant role in the detection of adenomatous polyposis[9] and intestinal type intraductal papillary mucinous neoplasm of the pancreas.[10] Thus, enhancing capsule gastric emptying and duodenal papilla detection

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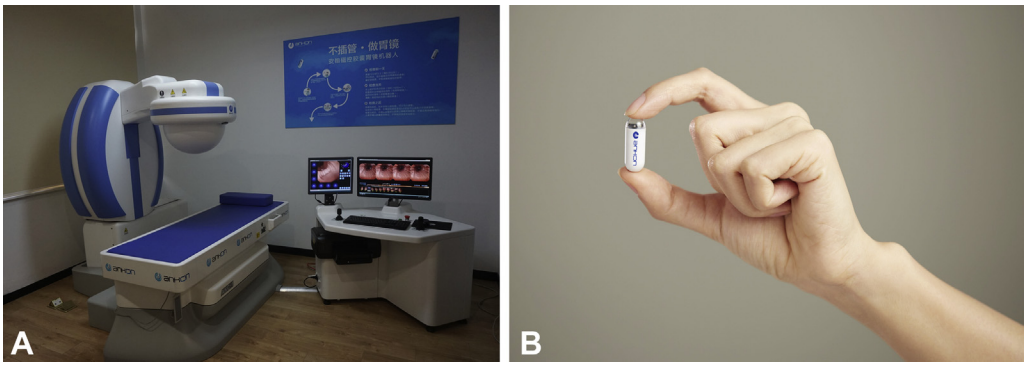

Figure 1. The Navicam magnetic control system (Ankon). It contains an endoscopic capsule, a data recorder, a guidance magnet robot, and a computer workstation. **A,** Guidance magnet robot and workstation. The magnetic field generated can be adjusted and can reach a maximum of 200 mT. The capsule can be controlled with the synchronized rotation of the external magnetic robot and the variable magnetic field. The computer workstation is designed for real-time viewing and controlling. The capsule can be controlled either manually by a magnet robot through a joystick or automatically by default mode on the control panel. **B,** The capsule endoscope. The capsule has a size of 26.8 × 11.6 mm, with a weight of 4.8 g. It has a battery life of more than 8 hours, offering a viewing field of 151 degrees. Images are captured at a rate of 2 frames per second with a resolution of 480 × 480 pixels. It contains a CMOS image sensor; with that the LED light exposure time are adjusted automatically to optimize the brightness and contrast of the images. *CMOS*, Complementary metal oxide semiconductor; *LED* to light emitting diode.

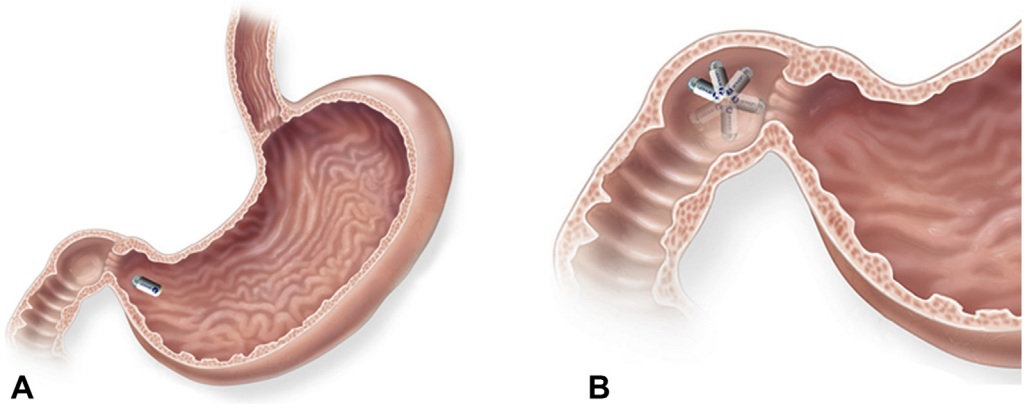

Figure 2. Schematic diagram showing magnetic control of the capsule. **A,** The endoscopist rotated the capsule until the camera end faced the pylorus. **B,** In the duodenal bulb, the "360-degree automatic scanning" model was used during the procedure.

may improve visualization and completion of small-bowel examination. Approaches aimed at achieving these goals to date include the development of a wider angle of view,[9] faster adaptable frame rate,[7,8] longer battery life,[11] positional change,[12] prokinetics,[13,14] chromoendoscopy,[15] and a 3-dimensional localization method.[16]

Magnetic-controlled CE (MCE) has been used in clinical practice since 2010. With external magnetic fields to guide and orientate the capsule in a fluid-distended stomach, it is noninvasive, requires no sedation, incurs no risk of cross-infection, is easy to perform, and has comparable diagnostic accuracy with EGD in gastric examination.[17,18] Therefore, this study was performed to determine whether magnetic steering could improve small-bowel examination by enhancing gastric emptying and detection of the major duodenal papilla, which may help to improve the completion and mucosal visualization during small-bowel examination.

METHODS

Study design

Consecutive patients undergoing MCE were compared with the same number of historical control subjects. The study was approved by the ethics committees at Changhai Hospital, Shanghai, China, according to the Helsinki Declaration. Written informed consent was obtained from all patients.

Patients

From May 2017, 100 consecutive patients over age 18 years undergoing MCE examination in Changhai Hospital were prospectively enrolled as the intervention group. Patients with any of the following conditions were excluded: (1) pregnancy or suspected pregnancy, (2) suspected or known intestinal stenosis or other known risk factors for capsule retention, (3) pacemaker or other implanted

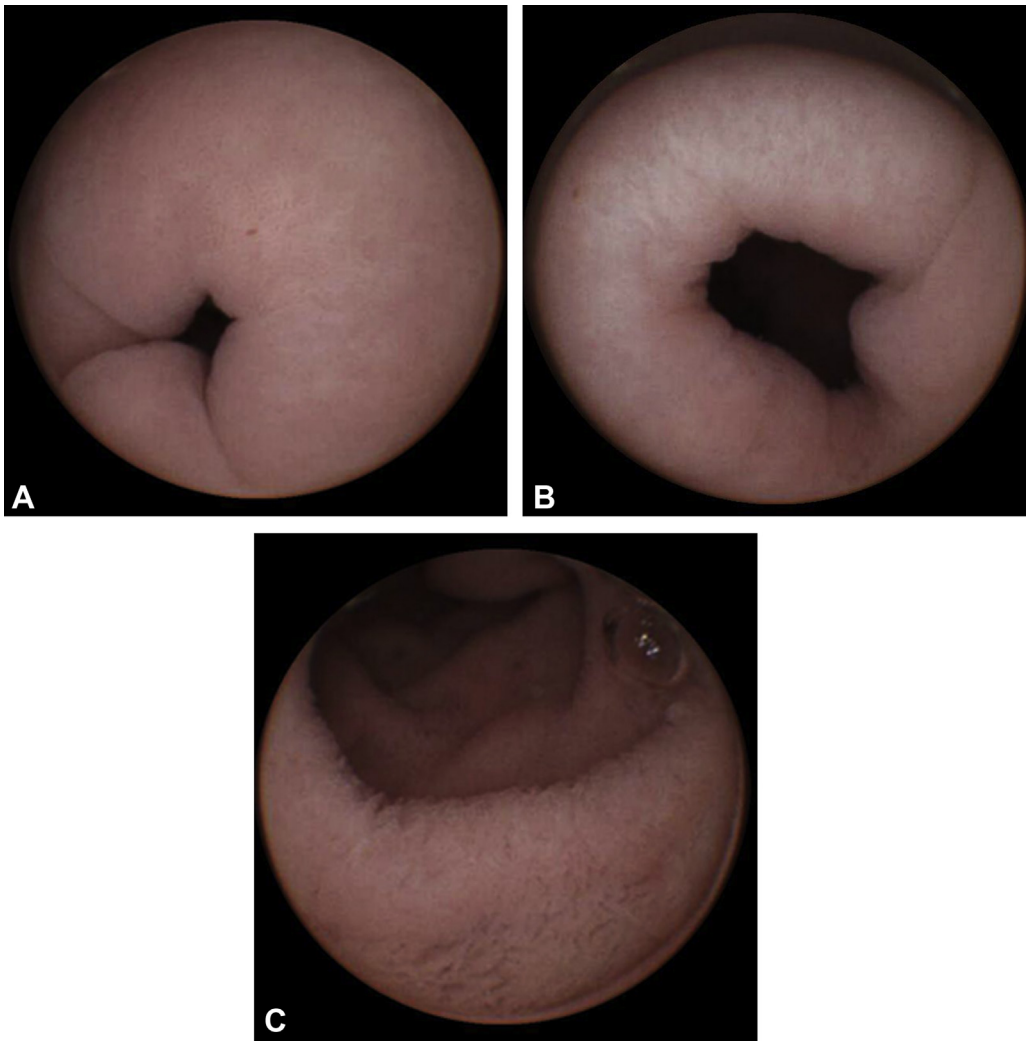

Figure 3. Transpyloric passage of the capsule. **A,** Capsule was dragged close to the pylorus, waiting for the opening of the pylorus. **B,** Pylorus opened. **C,** Capsule entered the duodenum.

electromedical devices that could interfere with magnetic resonance, and (4) prior duodenal resection. MCE studies of these patients were compared with those of 100 patients undergoing MCE before May 2017 who were randomly selected from the MCE database using simple random sampling.

Study intervention

The MCE system (Ankon Technologies Co, Ltd, Shanghai, China) consists of an endoscopic capsule, a data recorder, a guidance magnet robot, and a computer workstation with software for real-time viewing and magnet control (Fig. 1). The capsule has a size of 26.8 × 11.6 mm and weighs 4.8 g. It has a battery life of more than 8 hours, offering a viewing field of 151 degrees. Images are captured at a rate of 2 frames per second with a resolution of 480 × 480 pixels. The capsule can be controlled either manually by a magnet robot using 2 joysticks or automatically using a default mode. Magnetic steering mode facilitates movement of the capsule to different gastric locations and allows orientation of the imaging end of the capsule. Relevant detailed parameters can be found in previous studies.[17]

All patients enrolled consumed a liquid diet the day before the examination and fasted overnight (>8 hours). No colored drinks or medications were allowed on the morning of the procedure. The standard protocol for small-bowel CE was followed, and patients received 2 L polyethylene glycol 5 hours before the MCE examination. Forty minutes before the examination, patients were asked to ingest 400 mg simethicone suspension, (Espumisan, 40 mg/mL; Berlin-Chemie, Berlin, Germany) dissolved in 50 mL water.[19] Patients were encouraged to mobilize and swallowed 1000 mL water 10 minutes before the examination to provide an air–water interface in the stomach for capsule navigation. Water ingestion was repeated to optimize distension during the examination. Retrospectively reviewed patients were enrolled into the control protocol, whereas prospectively enrolled patients entered into the intervention protocol.

TABLE 1. Demographic data and indication for MCE

Characteristics	Control group (n = 100)	Intervention group (n = 100)	*P* value
Baseline characteristics			
Sex, M/F	64/36	67/33	.655
Age, y	46.15 ± 14.06	45.48 ± 12.73	.724
Body mass index, kg/m^2	23.35 ± 3.90	23.58 ± 3.82	.668
Diabetes mellitus	7/100	7/100	1.000
History of abdominal surgery	18/100	9/100	.063
Indication for MCE			
GI symptoms	78	75	.617
Abdominal pain or distension	57	55	.776
Acid reflux or nausea /vomit	5	9	.268
Chronic diarrhea	7	6	.774
Others*	9	5	.268
Asymptomatic individuals	22	25	.617
Medical examination	14	20	.259
History of GI diseases	8	5	.390

MCE, Magnetic-controlled capsule endoscopy.
*Includes obscure GI bleeding, suspicion of inflammatory bowel disease, or malignancies, etc.

Control protocol

Patients were placed in the left lateral decubitus position and swallowed the capsules with a small amount of water. The position of the capsule was established using a real-time viewer. Once the capsule entered the stomach, approximation of the magnet toward the abdomen lifted away from the posterior wall, after which it was rotated if necessary and advanced to the fundus and cardiac regions, and then to the gastric body, angulus, antrum, and pylorus. After completing the stomach examination, operation of the capsule was switched to "small-bowel mode" without magnetic control. The capsule entered the duodenum under physiologic peristalsis. If the capsule failed to enter the duodenum after 1 hour, domperidone (10 mg) was orally administered. If the capsule remained in the stomach after a further 3 hours, gastroscopy was used to assist transpyloric passage. After the capsule moved into the duodenum, patients left the hospital with the data recorder if small-bowel (in addition to upper GI) examination was required and returned the recorder the following day.

Intervention protocol

After completing the stomach examination in the same manner as described in the control protocol, an endoscopist lifted the capsule off the dependent part of the posterior wall by moving the magnetic ball toward the abdomen over the gastric antrum. The capsule was then rotated until the camera end faced the pylorus. Next, the endoscopist dragged the capsule close to the pylorus with the guidance magnet robot and waited until the pylorus opened. After doing so, peristalsis propelled the capsule into the duodenum. A gastric transit time (GTT) of more than 30 minutes was defined as a failed procedure, and the patient would transfer to the relevant section of the control protocol.

After entering the duodenal bulb, the capsule was held stationary by advancing the magnet to as near the abdominal wall as possible (the maximum position of "Z"), and a duodenal bulb examination was performed automatically using the "360-degree automatic scanning" mode in which a preset computer algorithm alters the magnet polarity to rotate the capsule (Figs. 2 and 3). With transit beyond the bulb, capture of the capsule in the second part of the duodenum was attempted by approximating the magnet toward the abdominal wall and the major papilla sought by capsule rotation using the joysticks to alter magnet polarity. After the capsule passed through the duodenum, a "small-bowel mode" was started to complete the small-bowel examination (if needed) under the natural action of peristalsis. Under these maneuvers required for capsule transpyloric passage, the gastric mucosa, capsule transpyloric passage, and duodenum including the duodenal papilla were visualized clearly (Video 1, available online at www.giejournal.org). All patients were followed for up to 2 weeks to confirm capsule excretion and identify any adverse events.

Study outcomes

The primary outcome was the pyloric transit time (PTT) of the capsule. Patient-related characteristics and CE-related parameters were retrospectively reviewed and prospectively collected. Patient-related characteristics included age, sex, body mass index (BMI), indication for

TABLE 2. Comparison of manipulation related parameters

Variables	Control group	Intervention group	*P* value
Median ETT, min	1.06 (.49-1.83)	1.10 (.63-2.17)	.345
Median GET, min	14.25 (10.97-20.38)	14.08 (10.04-20.36)	.614
Median GTT, min	84.53 (42.13-115.45)	22.37 (13.32-77.52)	<.001
Median PTT, min	58.38 (13.45-87.47)	4.69 (1.56-55.00)	<.001

Values in parentheses are interquartile ranges.
ETT, Esophageal transit time; *GET*, gastric examination time; *GTT*, gastric transit time; *PTT*, pyloric transit time.

MCE, and a history of diabetes or previous abdominal surgery. CE-related parameters included esophageal transit time (time from the capsule entering to leaving the esophagus), gastric examination time (time taken for the endoscopist to complete the gastric examination to his or her satisfaction), GTT (time from the capsule entering to leaving the stomach), and PTT (time from completion of the gastric examination to the capsule entering the duodenum). Duodenal papilla detection rate (DPDR) and upper GI findings including ulcers, polyps, inflammation, and ectopic pancreas were also recorded and compared.

Statistical analysis

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). The unpaired *t* test was used to compare age and BMI between the 2 study groups, and the χ^2 test was used to compare sex, diabetes mellitus, history of abdominal surgery, and indication for the procedure between 2 study groups. CE-related parameters were not normally distributed; thus, the Mann-Whitney test was used to compare the difference between the 2 groups. The statistical differences of DPDR and rate of GTT $\leq$30 minutes were analyzed by the χ^2 test. Factors affecting PTT and DPDR were assessed using univariate analysis with the χ^2 test. Factors with a value of $P < .05$ were included in a multivariate logistic regression model. Odds ratios estimated by the model are presented along with the 95% confidence intervals (CIs). A value of $P < .05$ was considered significant. All data were analyzed with SPSS version 21 software (IBM Corp, Armonk, NY).

RESULTS

Enrollment and baseline characteristics of the patients

In total, 200 patients referred for investigation of symptoms or a screening procedure aged from 22 to 81 years were enrolled. Patient demographics and indications for MCE are shown in Table 1. There was no statistical difference in any of the baseline characteristics or indications for MCE between these 2 study groups. All except 7 patients (4 in the control group and 3 in the intervention group) were ambulatory outpatients at the time of the procedure.

TABLE 3. Comparison of the gastric transit time within 30 minutes and the detection of duodenal papilla

	Control group n/N (%)	Intervention group n/N (%)	*P* value
Gastric transit time $\leq$30 min	17/100 (17)	59/100 (59)	<.001
DPDR	9/100 (9)	18/59 (30.5)	<.001

DPDR, Duodenal papilla detection rate.

Transit times through esophagus, stomach, and pylorus

As illustrated in Table 2, no significant difference in median esophageal transit time and gastric examination time existed between the 2 groups ($P = .345$ and .614, respectively). Magnetic intervention greatly reduced the mean PTT from 58.38 minutes (IQR, 13.45-87.47), 4.69 minutes (IQR, 1.56-55.00), 84.53 minutes (IQR, 42.13-115.45) and 22.37 minutes (IQR,13.32-77.52); $P < .001$).

Comparisons of the rate of GTT within 30 minutes and duodenal papilla detection

In the intervention group, 59% of capsules could be manipulated into the duodenum within 30 minutes of swallowing using magnetic control compared with 17% in the control group ($P < .001$). Under magnetic control, the DPDR was 30.5% (18/59) compared with only 9% in the control group ($P < .001$; Table 3). As shown in Figure 4, the duodenal papilla could often be clearly visualized.

Influence factors of GTT within 30 minutes and DPDR

Tables 4 and 5 show the influence of factors studied. As for GTT within 30 minutes, univariate analysis revealed an association with magnetic steering, male sex, and high BMI. Multivariate analysis showed that a more rapid GTT was independently associated with magnetic steering (odds ratio, 3.73; 95% CI, 2.01-6.91), male sex (odds ratio, 2.54; 95% CI, 1.32-4.89), and a high BMI (odds ratio, 1.14; 95% CI, 1.05-1.24). However, only magnetic steering was significantly associated with DPDR in univariate analysis.

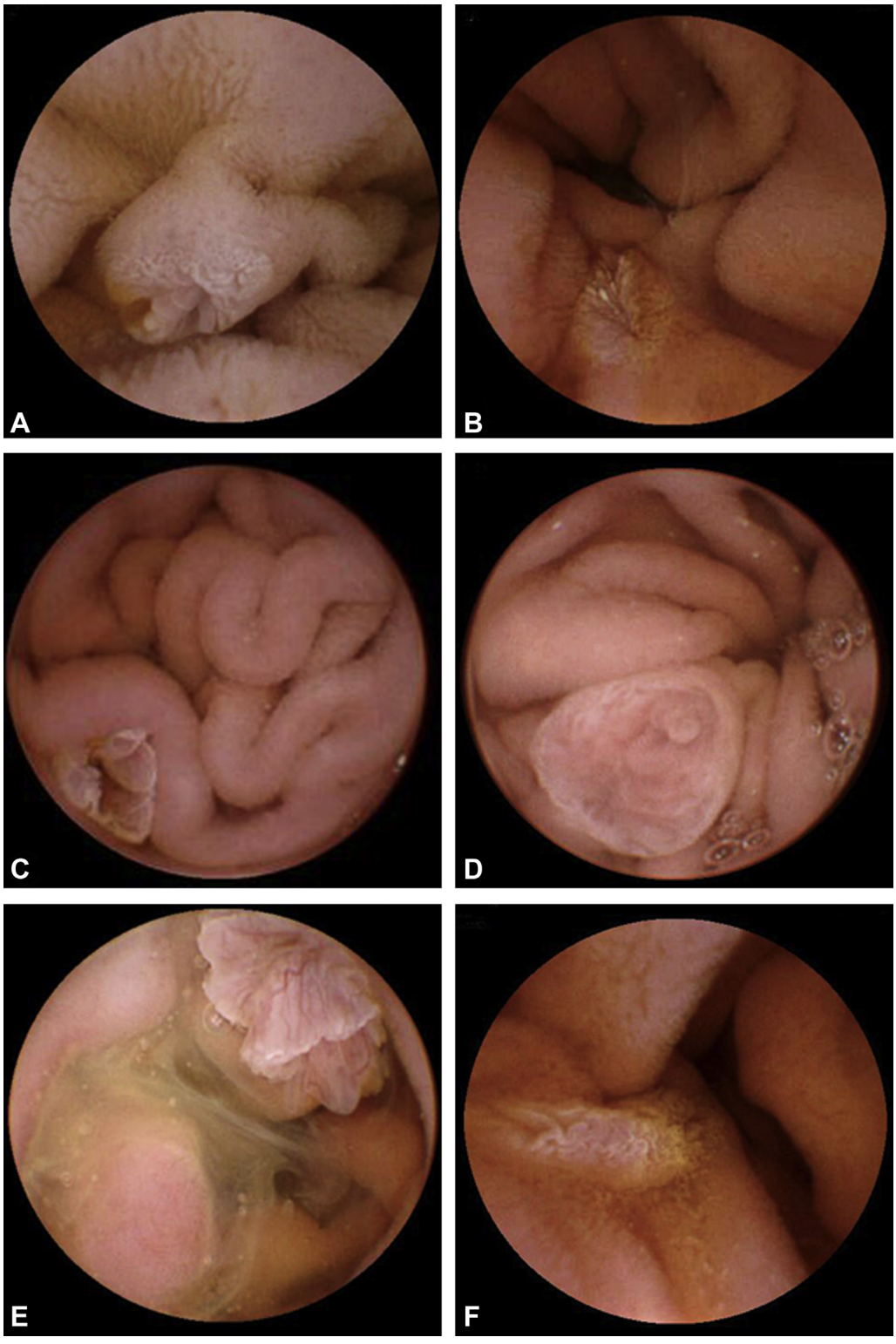

Figure 4. Representative view of the duodenal papilla during the magnetic-controlled capsule endoscopy examination (**A-F**).

Positive findings in upper GI tract and safety outcomes

A comparison of findings identified using the intervention and control protocols is shown in Table 6. There was no difference in the detection of polyps, ulcers, inflammation, or other pathologies. This was also the case in the duodenum, in which 11 pathologies were identified in the intervention group and 10 in the control

TABLE 4. Univariate and multivariate analysis of factors affecting the gastric transit time

Variables	Univariate *P* value	Multivariate *P* value	Odds ratio (95% confidence interval)
Magnetic steering	<.001	<.001	3.73 (2.01-6.91)
Age	.785		
Sex (male)	.003	.005	2.54 (1.32-4.89)
Body mass index	.002	.002	1.14 (1.05-1.24)
Diabetes mellitus	.877		
History of abdominal surgery	.224		
Gastrointestinal symptoms	.572		
Gastric positive findings	.506		

TABLE 5. Univariate and multivariate analysis of factors affecting the detection of duodenal papilla

Variables	Univariate *P* value	Odds ratio (95% confidence interval)
Magnetic steering	.021	.372 (.161-.859)
Age	.271	1.017 (.987-1.048)
Sex	.574	1.273 (.548-2.954)
Body mass index	.211	1.072 (.961-1.195)
Diabetes mellitus	.999	(0,∞)
History of abdominal surgery	.583	1.345 (.466-3.881)
Gastrointestinal symptoms	.624	1.271 (.486-3.324)
Gastric positive findings	.299	.649 (.286-1.469)

TABLE 6. Comparisons of positive findings in esophagus, stomach, and duodenum

	Control group n (%)	Interventional group n (%)	*P* value
Polyps	6 (6)	4 (4)	.516
Ulcers	6 (6)	2 (2)	.149
Inflammation	40 (40)	35 (35)	.465
Others	3 (3)	2 (2)	.651

group. No serious adverse events were reported during MCE examination and follow-up. All patients excreted the capsules spontaneously.

DISCUSSION

Our study is by far the largest trial with 200 patients enrolled to validate that the use of an external magnet robot to capture the capsule just proximal to the pylorus and launch it on a peristaltic wave into the duodenal bulb reduces PTT and in doing so also improves gastric transit. This may help improve the completion rate of small-bowel CE. Furthermore, magnetic control also allows the capsule to be captured in the duodenum in a position that is sufficiently stable to allow a better examination, as measured by an improved DPDR.

In the present study, the median GTT and PTT were significantly improved in the intervention group compared with those in the control group. Thus, our study first showed that magnetic steering achieved transpyloric passage in 59% of patients compared with a spontaneous passage rate of only 17%. This is in contrast to the findings in the prospective trial conducted by Hale et al.[4] The joystick-controlled guidance magnetic robot used in our study allows continuous, subtle adjustments of capsule position and orientation and may therefore provide a more stable capsule position than the handheld magnet used by Hale et al, the control of which is affected by operator fatigue.

CE is a first-line examination modality for the small intestine, but the low detection rate of the duodenal papilla raises concerns about its reliability in detecting periampullary lesions.[6,20,21] The detection of the duodenal papilla has been regarded as a surrogate indicator of diagnostic yield in the proximal small bowel. Clarke et al[6] detected the major duodenal papilla in 10.4% of patients, a rather limited sensitivity, which was similar to the result in the control group in our study. Panoramic imaging capsule,[6] higher frame rate image,[7] and improved image resolution[8] have been developed to improve the DPDR and proved positive results. The large diameter of the duodenum offers the possibility of external control of the capsule within it, which may contribute to better identification of duodenal lesions. In this study, we were able to show that magnetic control was associated with a DPDR of 30.5%, 3 times the value of the control group. The DPDR by PillCam SB3 (Medtronic, Dublin, Ireland) was reported as 42.7% in a small retrospective series and by the Capsocam SV (Capsovision, Saratoga, Fla) as

32.7%.[22] The former has a higher frame acquisition rate of between 2 and 6 per second, compared with 2 per second for the Ankon capsule (Ankon, Shanghai, China), and the latter acquires 3 to 5 frames per second from each of 4 lenses in the side (rather than the ends) of the capsule, which are presented together as a 360-degree panoramic view into the mucosa. Our study is the first to show that in addition to frame rate and orientation of cameras, magnetic control may also contribute to more complete duodenal imaging.

Based on the logistic regression model, our study demonstrated that magnetic steering, male sex, and higher BMI were independent factors associated with more rapid GTT whereas magnetic steering was the only factor affecting DPDR, consistent with previous studies.[23-25] These findings highlight the potential role of the guidance magnetic robot in enhancing GTT and DPDR, especially in female and nonobese patients, in whom delayed gastric emptying is more common. Higher BMI was reported to be significantly associated with CE completion and shorter bowel transit times.[24] Metabolic differences between obese and nonobese patients may affect GI motility literature because being underweight has been linked to slower bowel transit times.[25]

This study has limitations. Selection bias may occur in a study using historical control subjects. Second, the small sample size may explain why no detection difference of duodenal lesions existed between these 2 groups. Finally, we were unable to compare small-bowel completion rates because some patients only had a gastric examination. Thus, further prospective randomized studies of duodenal imaging and small-bowel completion rates are needed to clarify the role for magnetic robot control.

In summary, our study demonstrated that magnetic steering greatly facilitated capsule transpyloric passage and duodenal papilla detection, thus enhancing capsule gastric emptying and improving the visualization of the duodenum. It may be especially helpful in female and nonobese patients who tended to have slower gastric transit.

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Abbreviations: BMI, body mass index; CE, capsule endoscopy; DPDR, duodenal papilla detection rate; GTT, gastric transit time; MCE, magnetic-controlled capsule endoscopy; PTT, pyloric transit time.

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