Original Article

Association between patient characteristics and magnetically controlled capsule endoscopy findings

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Abstract

Background/Aim: Magnetically-controlled capsule endoscopy (MCE) is a potential option for the evaluation of gastric diseases in cases that are unsuited for conventional endoscopy, avoiding discomfort, sedation, and related complications. This retrospective study investigated associations between MCE findings and patient gender, age, and inpatient/outpatient status.

Patients and Methods: The data of 580 consecutive patients who underwent MCE from 2015 to 2016 were analyzed. Data included age, gender, indication for MCE, inpatient/outpatient status, overall coverage of gastric anatomical landmarks, and comorbid conditions.

Results: Compared with outpatients, inpatients had a higher rate of overall significant MCE findings ($P = 0.014$), polyp ($P = 0.03$), and ulceration ($P = 0.003$). MCE findings of the inpatient men and women were similar. Considering all patients, the percentage with ulceration was significantly higher in men than in women ($P = 0.004$), and men were younger ($P < 0.001$). Compared with younger patients, those aged ≥60 years had significantly higher rates of overall significant findings, mainly polyp and angiodysplasia.

Conclusions: Compared with outpatients, the inpatients showed higher overall significant findings. Men undergoing MCE were younger than the women, and more likely to have ulcerations. Older patients, whether outpatient or inpatient, had higher rates of significant findings, mainly polyp and angiodysplasia.

Keywords: Gastric diseases, magnetically-controlled capsule endoscopy, patient characteristics

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INTRODUCTION

Gastric diseases such as gastric cancer, gastric polyps, and peptic ulcer are among the most common gastrointestinal (GI) diseases. The predominant and preferred screening modality for gastric disease is conventional gastroscopy, which is also the gold standard to detect gastric lesions. Gastroscopy is also employed during some therapeutic procedures. However, gastroscopy is invasive and uncomfortable for the patient when performed without sedation, and while patients' compliance can be

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facilitated by sedation, procedure-related complications as well as anesthesia-related adverse events can occur.[1]

Gastric capsule endoscopy is a noninvasive technique that allows exploration of the stomach, without requiring sedation or air insufflation. However, most of the commercially available capsules are not useful for gastroscopy, due to the large size of the stomach. In addition, assessment of the gastric mucosal surface by capsule endoscopy is hampered by a collapsed stomach and peristaltic waves,[2] unlike conventional gastroscopy in which clear views are obtained with the stomach distended.

Magnetic-controlled capsule endoscopy (MCE) was first described by Carpi *et al.*[3] in 2006. Currently, three main types of MCE devices are manipulated by hand (Intromedic), robot-assisted (Olympus and Siemens), or by robotic arm (Ankon).[4] In addition, a novel MCE system was developed and approved by the China State Food and Drug Administration in 2013. This MCE system has been demonstrated as viable and safe in healthy volunteers and for a small number of patients.[5-9] However, published studies have been limited by relatively small inpatient cohorts, lack of comparisons between inpatients and outpatients, and lack of data on gender and age as they relate to diagnostic findings on MCE. Previous studies have suggested that outpatients during or directly after clinical episodes are associated with higher diagnostic yields.[10,11] However, the inpatients who underwent MCE are usually sicker than the outpatients. So, it is unclear which status is related to higher diagnostic findings on MCE.

The present large retrospective study compared diagnosis based on MCE examinations of outpatients with that of inpatients, and investigated associations between gender and age and MCE findings.

PATIENTS AND METHODS

The Institutional Review Board at Southern Medical University approved this study. All patients provided written informed consent before undergoing MCE.

Study participants and data collection

This retrospective study included patients undergoing MCE examination between August 2015 and November 2016 at Nanfang Hospital affiliated to Southern Medical University. Patients with upper GI symptoms such as reflux, belching, or abdominal pain were first recommended to receive conventional endoscopy. Patients who refused conventional endoscopy, or who failed conventional endoscopy (due to patient discomfort or inability to confirm lesions in the stomach), were offered MCE. Patients were excluded from receiving MCE for any contraindications, including the following: impaired bowel movement; a known obstructing tumor of the GI tract; history of abdominal surgery; poor general condition; current use of equipment that could be affected by the magnetic field; or pregnancy or suspected pregnancy. Patients who received conventional endoscopy with biopsy were also excluded from this study.

Patient preparation

For MCE examinations, prokinetic drugs were not routinely administered but were used if prescribed by the endoscopist. All patients received bowel preparation with 2 L of polyethylene glycol solution (Golytely; Wanhe Pharmaceutical Factory, Shenzhen) the night before the MCE, in addition to overnight fasting (>8 h). Simethicone (Berlin-Chemie AG, Germany), an anti-foaming agent, was used to improve visualization of the gastric mucosae. During the MCE examination, patients were asked to drink 500 to 1200 ml of water, on demand. There were no significant differences among the subjects that might have influenced the study results such as indications for admission or bowel preparation.

MCE system

The MCE system (Ankon Technologies, Wuhan, Shanghai, China) used consists of an endoscopy capsule, a guidance magnetic robot, a data recorder, and a computer workstation with software for controlling real-time viewing [Figure 1]. The size of the capsule is 28 mm × 12 mm. Images were captured and recorded at 0.5–2 frames/s. The view angle of the MCE was 140° and the view distance 0–60 mm. The lesions were measured using ESNavi software (Ankon Technologies, Wuhan, China).

MCE examination protocol

Image receivers were attached to the patient by wearing a special waistcoat and capsule can be detected by an outside detector [Figure 2]. Capsule was ingested in a sitting position to pass the esophagus. Each patient (inpatient or outpatient) lay on a bed that was attached to the magnetic robot [Figure 3]. When the capsule reached the stomach, the examination was then undertaken with the patient lying in positions of left lateral, supine, and finally right lateral. The robot lifted the capsule away from the posterior wall and then rotated, to guide the capsule. The capsule was guided to the fundus and cardiac regions, and then to the gastric body, incisura angularis, antrum, and pylorus. In cases of difficulty in visualization, sometimes the patient was turned to a different position, even prone. If distension was insufficient, ingestion of water was repeated. The

Figure 1: Robotic arm and capsule

magnetic control was used only during examination of the stomach, and the rest of the examination was similar to video capsule endoscopy.

Patients were followed-up within 2 weeks to confirm capsule excretion and any adverse events. All the procedures were conducted by the same doctor (i.e., ZJ).

Data collection

The following information was collected: patient age, gender, status (inpatient or outpatient), indication for MCE, gastric transit time (GTT), small bowel transit time (SBTT), coverage rate of gastric landmarks, and study findings. The small bowel and colon were not evaluated.

Data regarding the rates of gastric retention or incomplete study of the stomach were collected, defined respectively as the percentage of cases in which the capsule could not reach the small bowel before the battery lost power.

We attempted to collect details regarding comorbid conditions such as pulmonary, cardiac, and renal disease. Most of them were referrals for MCE examination and were interviewed primarily. We also collected information regarding indications for patient admission.

MCE findings were graded based on the P0-P2 grading system [Figures 4-6][12] as follows: P0, normal examination findings; P1, lesions of questionable relevance (red spots, erosions, and submucosal bulges); and P2, indications of major clinical relevance. The latter (P2 findings) included

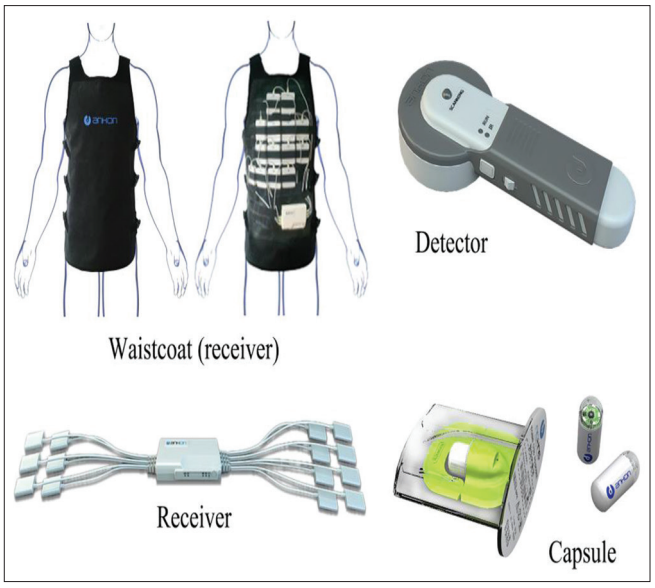

Figure 2: Waistcoat and detector

angiodysplastic lesions, ulcerations, suspected neoplasms or polyps, parasite, fresh blood, and other major lesions in the stomach. Patients with positive MCE findings were advised to receive further conventional endoscopy examination or treatment. Patients who received conventional endoscopy with biopsy were excluded from this study.

Statistical analysis

Data were retrospectively collected, and the parameters are presented as frequencies, percentages, or mean ± standard deviation. We used the Chi-square test for categorical data analysis and Student's *t*-test for continuous data analysis. Analyses were performed with IBM SPSS version 20.0 statistical software (IBM, Armonk, NY). To discover the relationship between patient characteristic and MCE findings, associations between measurement variables were evaluated using Pearson's correlation coefficient, and associations between ordinal variables were evaluated using Spearman's correlation coefficient. Statistical significance was defined as $P < 0.05$.

RESULTS

A total of 580 individuals that underwent MCE at Nanfang Hospital between August 2015 and November 2016 were included: 344 (59.3%) men and 236 (40.7%) women [Table 1]. Among the 580 patients, 456 and 124 had respectively refused or failed conventional endoscopy.

MCE examinations were performed in 168 inpatients (29.0%) and 412 (71.0%) outpatients. There was no significant difference in the gender ratio of the inpatient and outpatient cohorts. Indications for MCE examination

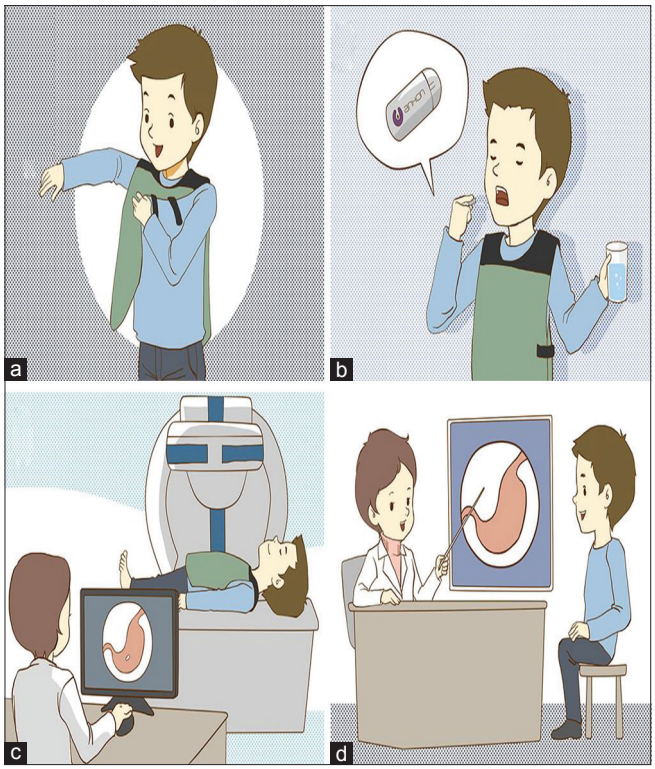

Figure 3: Examination procedures of MCE: (a) wear waistcoat; (b) swallow capsule; (c) examination; (d) diagnosis and reporting

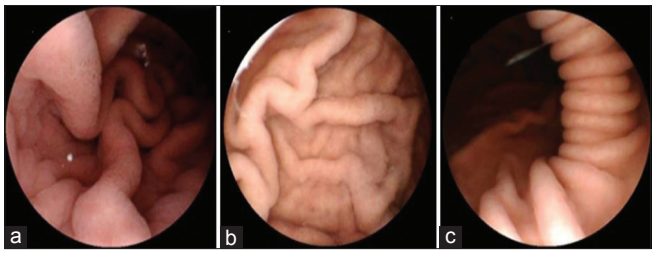

Figure 4: Gastric diagnosis grading P0 (original). (a) Normal gastric body; (b) normal gastric fundus; (c) normal gastric angular

were the following: abdominal pain (319, 55.0%), abdominal distension (55, 9.5%), diarrhea (45, 7.6%), GI bleeding (36, 6.2%), and others (124, 21.4%).

Overall, GTT was 69.9 ± 57.8 min (0–510.4 min); SBTT was 4.8 ± 1.8 h (0.07–10.5 h). The overall rates for gastric retention and incomplete study of the colon were 1.2 and 22.3%, respectively. The rate of P2 lesions in stomach was 35.7%. The overall rates of gastric-anatomical-landmark coverage were: cardia, 82.6%; fundus, 94.0%; gastric body, 97.2%; incisura angularis, 51.1%; antrum, 99.0%; and pylorus, 100%. The terminal ileum was visualized in 82.2% of patients.

No patient experienced any complication associated with the MCE.

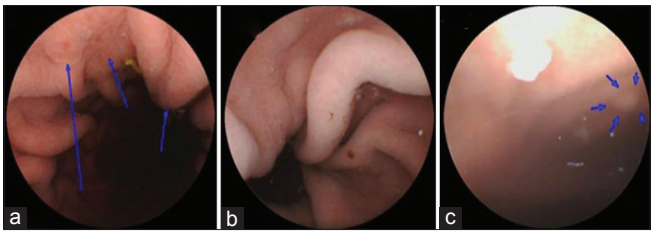

Figure 5: Gastric diagnosis grading P1 (original). (a) Erosions on gastric body; (b) red spots on gastric body; (c) submucosal bulge on gastric fundus

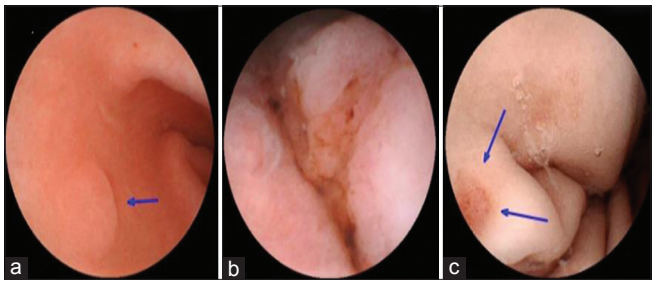

Figure 6: Gastric diagnosis grading P2 (original). (a) Polyp on gastric antrum; (b) ulceration on gastric body; (c) angiodysplastic lesion on gastric antrum

Comparison of MCE findings of inpatients and outpatients

Clinical and procedural data comparing inpatients and outpatients undergoing MCE examinations are shown in Table 2. There was no significant difference in the gender ratio or age ratio of the inpatient and outpatient cohorts. When compared with the outpatients, the hospitalized patients had higher rates of P2 lesions in stomach (44.6% cf. 32.0%, $P = 0.014$); higher rates of polyp, mass, or stricture (20.2% cf. 13.3%, $P = 0.03$), and higher rates of ulceration (20.2% cf. 11.2%, $P = 0.003$). The rates of angiodysplastic or hemorrhage lesions of the two groups were comparable, as were lymphangectasia or follicular hyperplasia.

Gender and age differences on MCE findings

The MCE findings by gender are shown in Table 3. Regardless of inpatient or outpatient status, compared with the women, a higher percentage of the men showed findings of significant ulceration (17.4% men cf. 8.9% women; $P = 0.004$), and the men were significantly younger than the women (42.03 y men cf. 46.5 y women; $P < 0.001$). However, there was no significant difference in the rate of P2 lesion, polyp, or other lesions between the two groups.

The MCE findings by age are shown in Table 4. For analysis, the patients were stratified as <60 or ≥60 years.[13] Compared with the younger patients, the group aged ≥60 years had higher rates of P2 lesion in the stomach (44.8%

Table 1: Baseline characteristic of the patients who underwent MCE*

Subjects, *n*	Total	580
Age, y		43.9±15.0
Gender	Men	344 (59.3)
	Women	236 (40.7)
Patient status	Inpatient	168 (29.0)
	Outpatient	412 (71.0)
Indication	Abdominal pain	320 (55.2)
	Abdominal distension	55 (9.5)
	Diarrhea	45 (7.8)
	Gastrointestinal bleeding	36 (6.2)
	Others	124 (21.4)
Gastric transit time		69.9 (0-510.4 min)
Gastric retention		7 (1.2)
P2 lesions	Stomach	207 (35.7)
Landmark coverage rate	Cardia	479 (82.6)
	Fundus	545 (94.0)
	Body	564 (97.2)
	Angular	296 (51.1)
	Antrum	574 (99.0)
	Pylorus	580 (100.0)
	Terminal ileum	440 (82.2)

*Indicated as *n* (%), unless indicated otherwise

Table 2: Result of inpatient and outpatient MCE examination*

	Inpatient	Outpatient	*P*
Subjects	168	412	-
Age, y	48.64±16.2	41.92±14.1	NS
Male	108 (64.2)	236 (57.3)	NS
Ulceration	34 (20.2)	46 (11.2)	0.003
Polyp, mass, or stricture	34 (20.2)	55 (13.3)	0.03
P2 lesions in stomach	75 (44.6)	132 (32.0)	0.014
Angiodysplasia, hemorrhage	27 (16.1)	52 (12.6)	NS
Lymphangectasia, follicular hyperplasia	28 (16.7)	72 (17.5)	NS

*Reported as *n* (%), unless noted otherwise; NS, not significant

cf. 33.9%, $P = 0.003$); presence of polyp, mass, or stricture (22.9% cf. 14.1%, $P = 0.029$); angiodysplasia (6.2% cf. 2.3%, $P = 0.047$). The two groups were comparable with regard to ulceration and lymphatic disease.

We performed an analysis to determine whether gastric diagnosis grading on inpatient MCE examinations were associated with the prevalence of comorbid conditions including cardiac, pulmonary, and renal disease [Table 5]. Patients who had more than one comorbid conditions were listed separately for each category in Table 5. There were no significant differences between inpatients with P1/P0 findings and those with P2 findings for a variety of comorbid conditions except for GI bleeding (19 vs 26, $P = 0.034$). However, the absolute number of subjects in each category was small.

We performed a separate correlation analysis of patient age and MCE findings (Supplementary table 1). A trend

Table 3: Gender differences in patients undergoing MCE examination*

	Men	Women	*P*
Subjects, *n*	344	236	
Age, y	42.03±15.0	46.5±14.7	<0.001
Inpatient	108 (31.4)	60 (25.4)	NS
Ulceration	60 (17.4)	21 (8.9)	0.004
Polyp, mass, or stricture	51 (14.8)	39 (16.5)	NS
P2 lesions in stomach	124 (36.0)	83 (35.2)	NS
Angiodysplasia, hemorrhage	46 (13.4)	33 (13.9)	NS
Angiodysplasia/hemorrhage in inpatients	19 (18.1)	8 (13.5)	NS
Lymphangectasia, follicular hyperplasia	61 (17.7)	40 (16.9)	NS

*Reported as *n* (%), unless indicated otherwis; NS, not significant

Table 4: Age differences in MCE examination*

	<60 y	≥60 y	*P*
Subjects, *n*	484	96	
Inpatient	124 (25.6)	44 (45.8)	<0.001
Male	296 (61.2)	48 (50)	0.042
Ulceration	67 (13.8)	16 (16.7)	NS
Polyp, mass, or stricture	68 (14.1)	22 (22.9)	0.029
P2 lesions in stomach	164 (33.9)	43 (44.8)	0.003
Angiodysplasia, hemorrhage	11 (2.3)	6 (6.2)	0.047
Lymphangectasia, follicular hyperplasia	85 (17.5)	15 (15.6)	NS

*Reported as *n* (%), unless indicated otherwise NS, not significant

toward a positive correlation was observed between age and gastric diagnosis grading ($r = 0.195$; $P < 0.001$).

DISCUSSION

As reported by Liao *et al.*[6] in 2016, MCE has rapidly become an accepted minimally invasive examination for gastric diseases with an excellent efficacy and safety profile. Compared with conventional gastroscopy, MCE detected gastric focal lesions in the whole stomach with 90.4% sensitivity (95% confidence interval (CI), 84.7–96.1%) and 94.7% specificity (95% CI, 91.9–97.5%), and MCE did not miss any significant lesions (tumors or large ulcers). However, as with other studies in the literature,[5,8,14] none of them mentioned the association between patient characteristics and MCE findings. As such, it is still unclear what the relationship between patient characteristics and MCE findings is.

This retrospective study of 168 inpatients and 412 outpatients who underwent MCE examinations is one of the largest inpatient cohorts to date. To our knowledge, this study is the first to indicate a significant association between patient characteristics (i.e., age, gender, or inpatient/outpatient status) and MCE findings. The strengths of this study are the large number of patients that underwent MCE examinations.

While there have been some studies that investigated an association between inpatient status and the findings

Table 5: Comorbid conditions associated with inpatient MCE examinations

Comorbid condition	P0/P1 finding (*n*=93)	P2 finding (*n*=75)	*P*-value*
Cardiovascular disease, no.	11	9	NS
CAD, no.	9	8	NS
Cardiac arrhythmia, no.	11	12	NS
Cardiomyopathy/CHF, no.	7	4	NS
Pulmonary disease, no.	16	13	NS
CRI/ESRD, no.	9	7	NS
Hepatic cirrhosis, no.	3	3	NS
Admission for overt or occult Gastrointestinal bleeding, no. (%)	17	23	0.034
None or other, no. †	21	18	NS

NS, Not significant; CAD, coronary artery disease; CHF, congestive heart failure; CRI, chronic renal insufficiency; ESRD, end-stage renal disease *P-values adjusted by the Bonferroni correction †Includes patients with hypertension, previous cerebrovascular accident, or none of these condition

of small bowel capsule endoscopy,[10,15,16] none of them reported the association between MCE gastric findings and patient characteristics. In the present study, inpatients experienced higher rates of P2 lesions, higher rates of ulceration and polyps compared with outpatients. Overall, men undergoing MCE studies were younger than the women, and more likely to have ulceration. However, P2 lesions in the stomach were comparable between them. Polyps, P2 lesions, and angiodysplasia occurred more frequently in elderly (≥60 years) patients than in younger (<60 years) patients.

In terms of hospitalization, we found that inpatients experienced higher rates of P2 lesions, higher rates of ulceration and polyps compared with outpatients. The reasons for these results are unclear. There were no significant differences regarding policies for bowel preparation, patient admission, operation methods, or other factors that might have influenced the study results between inpatients and outpatients. Possibilities include that inpatients are sicker and more often hemodynamically unstable than outpatients,[17] both acute and chronic multimorbidity was frequently present in hospitalized older patients,[18] inpatients actually benefit from a more thorough visualization of the stomach, or inpatients were more compliant than outpatients. Our results suggest that MCE readers should consider careful examination of the inpatients in the setting of ulceration and polyps to examine for the presence of missed lesions.

In the present study, we also found that men undergoing MCE studies were younger than the women, and more likely to have ulceration. However, overall P2 lesions in the stomach were comparable between them. It is possible that men are more vulnerable to gastric symptoms which results in earlier consultation to doctors. Men experience more stress than women in our society and male gender is a possible clinical risk factor for aspirin-induced gastric mucosal injury which possibly account for the reasons for higher rate of ulceration.[19] However, no significant difference was found in terms of P2 lesions. This finding has led to the recommendation that clinicians should pay attention to ulceration in men to reduce missed lesions.

We also found that polyps, P2 lesions, and angiodysplasia occurred more frequently in elderly (≥60 years) patients than in younger (<60 years) patients. A trend toward a positive correlation was observed between age and gastric diagnosis grading ($r = 0.195$; $P < 0.001$). As aging induces acceleration of epigenetic aging which is associated with *Helicobacter pylori* infection and chronic atrophic gastritis,[20] the reason for these results is that aging makes the gastric mucosa more vulnerable to damage. Similar to a study describing 2400 subjects receiving small bowel OMOM capsule (Jinshan Science and Technology Group, Chongqing, China),[21] the diagnostic yield also appeared to be higher in patients >60 years. Our study results concur with those of previous VCE studies suggesting that readers should carefully scrutinize older patients in order to avoid missing lesions.

There were no significant differences between inpatients with P1/P0 findings and those with P2 findings for a variety of comorbid conditions except for GI bleeding (19 vs 26, $P = 0.034$). GI angiodysplastic lesions are an important cause of GI bleeding, particularly in elderly persons.[22] As the definition of P2 findings included angiodysplastic lesions or fresh blood in the lumen, the reason for this finding is clear. Our result showed that patients combined with overt or occult GI bleeding were associated with higher gastric diagnosis rate. This finding has led to the recommendation that clinicians should pay attention to angiodysplastic lesions in older patients combined with overt or occult GI bleeding.

The main limitation of this study was its retrospective nature. We could not report on the bowel preparation quality of each patient as this detail was not available. A secondary review of the capsule findings is required. We did not repeat a review of all the MCE studies for potentially missed lesions, but we reported unclear findings if detected by three MCE readers. We did not report the data regarding comorbid conditions for outpatients undergoing MCE. We also did not collect information regarding the use of prokinetic agents that could be associated with shorter GTT and SBTT, including benzamide, cisapride, domperidone, or erythromycin.[23,24]

We could not report the use of medications that may be associated with GI bleeding, including aspirin, nonsteroidal anti-inflammatory agents, warfarin, or other anticoagulant or antiplatelet agents.[25,26]

CONCLUSION

The results of our retrospective study showed that inpatients may experience higher rates of P2 lesions, higher rates of ulceration and polyps compared with outpatients. Overall, men undergoing MCE studies seemed to be younger than the women, and more likely to have ulceration. However, P2 lesions in the stomach were comparable between them. Polyps, P2 lesions, and angiodysplasia may occur more frequently in elderly (≥60 years) patients than in younger (<60 years) patients.

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Conflicts of interest

There are no conflicts of interest.

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