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Original Article

Standing-type magnetically guided capsule endoscopy versus gastroscopy for gastric examination: multicenter blinded comparative trial

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Aim: To compare feasibility and safety after gastrointestinal checkup by standing-type magnetically controlled capsule endoscopy (SMCE) and conventional gastroscopy.

Methods: This was a prospective multicenter, blinded study that compared SMCE with gastroscopy in patients from April 2018 to July 2018. All patients first underwent SMCE and then subsequently had gastroscopy with i.v. anesthesia. We calculated the compliance rates of gastric lesion detection by SMCE using gastroscopy as the standard. Capsule retention rate, incidence of adverse events, and patient satisfaction were documented throughout the study.

Results: One hundred and sixty-one patients who completed SMCE and gastroscopy were included in the analysis. Positive compliance rate among SMCE and gastroscopy was 92.0% (95% CI: 80.77%–97.78%). Negative compliance rate was 95.5% (89.80%, 98.52%). Moreover, overall compliance rate was 94.41% (89.65%, 97.41%). Sixty-four pathological outcomes were identified. Of these 64 outcomes, 50 were detected by both procedures. The gastroscopy method neglected seven findings (such as five erosions, one polyp, and one ulcer). Furthermore, SMCE also overlooked seven lesions (i.e. one erosion, two polyps, one atrophy, and three submucosal tumors). Capsule retention or related adverse events were not reported.

Conclusion: Standing-type magnetically controlled capsule endoscopy provides equivalent agreement with gastroscopy and may be useful for screening of gastric illnesses without any anesthesia.

Key words: compliance rate, conventional gastroscopy, gastric disease, gastric examination, standing-type magnetically guided capsule

INTRODUCTION

CONVENTIONAL GASTROSCOPY IS uncomfortable and has poor patient compliance. Although anesthesia can improve patient compliance, patients feel discomfort and may suffer from anesthesia-related adverse events after gastroscopy.[1]

Capsule endoscopy (CE) has been used for decades and represents a comfortable alternative gastroscopy method.[2,3] A newly developed method called magnetically controlled CE (MCE) is currently used for gastric examination.[4–6] According to the latest expert consensus on MCE, advantages of MCE are that it does not require sedation, is comfortable and safe, has high diagnostic accuracy and is easily accepted by the population.[7]

Recently, a new standing-type MCE (SMCE) system has been developed. Except for the SMCE system, three lying types of gastric capsule systems are currently used for medical assessment globally: the handle style, the MRI style, and the robotic style.[5,8–10] When compared with other similar products such as Olympus (Olympus Medical Systems Co. Ltd., Tokyo, Japan) and NaviCam (ANKON Technologies Co. Ltd., Wuhan, China) magnetic capsule, [8,11] SMCE does not require patients to be equipped with multiple antennae to record the images so the procedure is more convenient. Also, SMCE is more maneuverable, as the guidance magnet robot in this study could produce a maximum magnetic field of 250 mT, which is greater than the 100 mT of Olympus and the 200 mT of NaviCam.[8,11]

However, the safety and feasibility of SMCE system remain to be determined. We carried out a multicenter comparison trial to confirm the effectiveness of SMCE, allowing patients to undergo a preliminary gastric SMCE examination before

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carrying out gastroscopy with sedation. Primary outcome was the compliance rate of stomach lesions detection by SMCE using gastroscopy as the standard.

METHODS

Study type and ethical approval

THIS STUDY WAS approved by the Institutional Review Board of participating centers. Written informed consent was obtained from all patients.

Patient enrolment

This trial was carried out in three tertiary hospitals between 17 April 2018 and 9 July 2018. Adult patients between 18 and 70 years who had upper abdominal complaints and were scheduled for gastroscopy were eligible.

Patients with any of the following were excluded: (i) various acute types of enteritis, such as bacterial dysentery, acute ulcerative colitis, asphyxia etc.; (ii) known or suspected gastrointestinal obstruction, stenosis, and fistula; (iii) acute phase of upper gastrointestinal perforation; (iv) severe throat disease; (v) acute phase of corrosive esophagitis; (vi) severe gastric dysmotility; (vii) electronic device implanted; (viii) previous history of allergy; and (ix) pregnancy.

Study intervention

First SMCE was conducted and subsequent gastroscopy was done with i.v. anesthesia after 4 h. Ability to detect gastric lesions was compared between SMCE and gastroscopy.

Standing-type magnetically controlled capsule endoscopy system

The SMCE system (JIFU Medical Technologies Co., Ltd, Shenzhen, China) comprises a capsule endoscope, a guidance magnetic robot, and imaging computer. The capsule is 27 × 12 mm (Fig. 1), weighs 2.7 g, and contains a permanent magnet (Fig. S1). Pictures are taken at 4 frames/s. Observation distance is 0–50 mm and viewing angle is 136°. The magnetic robot is a standing-type system without arms (Fig. 1) and contains wireless receivers.

Stomach preparation procedure and magnetically controlled capsule endoscopy procedure

Patients were asked to fast overnight (>8 h) before arriving at the hospital. Dimethyl silicone oil (10 mL; Berlin-Chemie AG, Berlin, Germany) was used as a defoamer 30 min

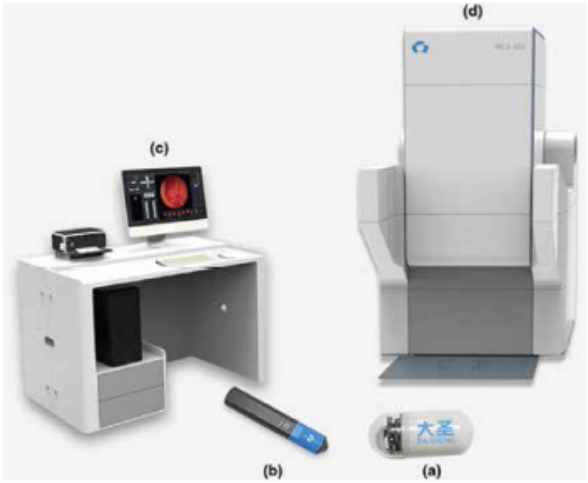

Figure 1 Guidance equipment: guidance magnet robot and control station. Four single images are shown: (a) capsule endoscopy, (b) capsule activator, (c) control station, (d) standing-type guidance magnet robot.

before inspection and 20 000 units pronase granules were used 15 min before inspection (Beijing Tide Pharmaceutical Co., Ltd, Beijing, China) to eliminate mucus. Patients were requested to consume 500 mL to 1 L of water to a feeling of fullness.

Six anatomical landmarks (cardia, fundus, body, angulus, antrum, and pylorus) were observed. When the patient stood with his/her left side close to the machine, the capsule moved to the fundus, cardia and body; when the patient stood with the abdomen stood close to the machine, the capsule moved to the angulus, antrum, and pylorus (Video S1).

Gastroscopy

Gastroscopy (Olympus GIF-H260; Tokyo, Japan) was carried out 4 h after SMCE. It was done by two other endoscopists with experience of more than 1000 gastroscopies, both of whom were unaware of the previous SMCE results. Six landmarks were observed and photographed. If clinically necessary, pathological biopsy specimens were taken. Operator recorded all the results of gastroscopy, including lesion location, size, and characteristics, which were confirmed by two doctors. A second gastroscopy of the patient was required within 1 week after a lesion was determined by SMCE but not by gastroscopy, but the results were not included in the final evaluation. Esophagus and duodenum were also inspected by gastroscopy, but the results were not included in the final evaluation.

Gastric mucosal cleanliness and visualization

Mucosal cleanliness of major anatomical landmarks of the stomach was assessed and recorded in real time by two reviewers who were maneuvering the capsule. Four review subscales were used to subjectively rate the cleanliness, namely excellent, good, fair, or poor (Fig. S2).[12]

A five-level subscale was applied to subjectively define visualization of the six landmarks, as follows: level 1, >90% of the mucosa was observed; level 2, 75–90% of the mucosa was observed; level 3, 60–74% of the mucosa was observed; level 4, 50–59% of the mucosa was observed; and level 5, <50% of the mucosa was observed.

Evaluation of study findings

Evaluation of SMCE was operated by two experienced physicians with experience of more than 100 MCE. Positive findings were defined as focal lesions such as erosion, polyp, ulcer, and others (i.e. submucosal tumor [SMT], heterotopic pancreas etc.), or a diffuse lesion such as atrophic gastritis. Normal gastric mucosa or mild inflammation was defined as a negative finding. Results from both examinations were consistent when the location, characteristics, and sizes of the lesions were consistent. If more than one lesion was noticed in a patient, the most critical lesion was selected, and the ulcer, polyp, SMT, etc. was considered the final analysis. Images of each patient were independently assessed by two investigators. If the results between the two investigators were inconsistent, an independent investigator made a final diagnosis. They were blinded to each other's test results.

Evaluation of safety and maneuverability of SMCE

If the capsule was not found in stool within 1 week, patients were instructed to return to the respective center for abdominal X-ray. If patients had not found the capsule in 2 weeks, they were instructed to return to hospital for surgery or other treatment for capsule removal as suggested by the investigator. Adverse events were defined as symptoms such as bloating, nausea, or vomiting during the trial. Overall maneuverability of the SMCE capsule was subjectively rated by the endoscopists.

Statistical analysis

We assumed that SMCE has at least a 96% positive compliance rate and a 78% negative compliance rate in detecting gastric lesions.[6] With a significance level of 0.05 (two-sided) and tolerance error of 8%, the formula for calculating sample size was $n = Z^2_{1-\alpha/2}P(1-P)/\Delta^2$ (Δ is the allowable error). After calculation, the number of positive-finding subjects was estimated to be 23, and negative-finding subjects was 104. At least 127 patients were needed. With a projected drop-out rate of 10%, at least 140 patients were required.

Descriptive statistics for continuous variables were recorded as mean ± SD or median and range values. A chance-adjusted kappa statistic (κ) was calculated to assess the strength of compliance between SMCE and gastroscopy. Statistical analysis was done by SAS software version 9.4 (SAS, Cary, NC, USA).

RESULTS

Patients

A TOTAL OF 171 patients were registered in the three participating centers. After SMCE, three patients declined further follow up, one patient's capsule was removed by gastroscopy and therefore violated the protocol. One patient had unexplained skin allergy before SMCE, one

patient encountered menstrual period before the endoscopy period, one patient refused to return the capsule, and three patients voluntarily withdrew during the trial. Thus, 10 patients were not involved in the final analysis (5.8%). Hence, 161 patients who finished both tests were included in the analysis (Fig. 2). One hundred and sixty-five subjects who completed both methods were included in the safety set (SS). Ninety-four (57.0%) patients were male and 71 (43.0%) were female with a mean age of 30.02 ± 9.73 years (range, 18–69 years). Average time to conduct SMCE was 24.17 ± 7.48 min (range, 7–47 min), whereas average time to conduct the gastroscopy was 7.06 ± 4.18 min (range, 2–32 min).

Negative versus positive gastric areas determined by gastroscopy and SMCE

One hundred and six patients were determined as negative and 55 as positive (Table 1). These findings lead to a positive agreement of 92.0% (95% CI: 80.77%–97.78%), a negative agreement of 95.5% (89.80%, 98.52%), an overall agreement of 94.41% (89.65%, 97.41%), and a κ-value of 0.870 (two-sided exact, $P < 0.0001$). McNemar's test indicated a P-value of 0.11 ($P = 0.74$), suggesting that the results obtained from both investigations were not significantly different.

Table 2 and Table 3 show the lesions found by SMCE and gastroscopy. Sixty-four pathological findings were identified, of which 50 lesions were detected by both procedures. Among the diagnoses, there were 23 erosions, 15 polyps, nine SMT, one heterotopic pancreas, and two atrophic gastritis (Figs 3 and 4). Gastroscopy identified seven extra lesions that were overlooked by SMCE, together with one erosion, two polyps, one atrophic gastritis, and three SMT. SMCE also detected seven lesions that were overlooked by gastroscopy including five erosions, one polyp, and one ulcer. The polyps not detected by gastroscopy were confirmed and treated by another endoscopic procedure.

Safety of SMCE and patient preference

Abdominal X-ray confirmed that there was no capsule retention during follow up. Of the 165 subjects included in the safety set (SS), 152 (92.1%) subjects had confirmed capsule excretion in the feces during the follow-up period (2 weeks), and the remaining 13 (7.9%) subjects finally confirmed excretion within 2 weeks by X-ray.

Adverse reactions were reported in three (1.8%) of the 165 patients who finished the study. One patient had nausea and vomiting, one patient had oral pain, and one patient had dizziness. Nausea and vomiting were considered a result of the gastric preparation procedure. All described symptoms disappeared within 24 h after the SMCE procedure. Among the 165 patients, 99 (60.0%) preferred SMCE, and 66 (40.0%) patients preferred gastroscopy.

Gastric cleanliness, mucosal visualization and maneuverability of SMCE

Gastric cleanliness in the cardia, fundus, body, angulus, antrum, and pylorus of the stomach was regarded as good in 82.6%, 84.2%, 93.9%, 96.0%, 97.6%, and 97.6% of patients who underwent SMCE, respectively. Gastric mucosa visualization in the above-mentioned six landmarks was good (level 1 or level 2) in 99.4%, 93.4%, 99.4%, 100.0%, 99.4%, and 99.4% of patients, respectively. Perfect visibility

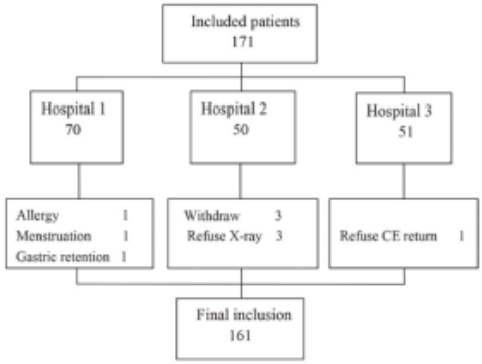

Figure 2 Flow chart of patients included in the present study.

Table 1 Initial readings of negative *vs* positive findings in patients who underwent SMCE and standard gastroscopy

SMCE, *n* (%)	Gastroscopy, *n* (%)		
	Positive	Negative	Total, *n*
Positive	46 (28.58)	5 (3.11)	51 (31.68)
Negative	4 (2.48)	106 (65.83)	110 (68.32)
Total	50 (31.06)	111 (68.94)	161 (100.00)

SMCE, standing-type magnetically controlled capsule endoscopy.

Table 2 Classification of 64 lesions diagnosed by SMCE and standard gastroscopy

Lesion	SMCE only, *n*	Gastroscopy only, *n*	Both SMCE and gastroscopy, *n*
Erosion	5	1	23
Polyp	1	2	15
Ulcer	1	0	0
Atrophic gastritis	0	1	2
Protuberance	0	3	9
Heterotopic pancreas	0	0	1
Bleeding	0	0	0
Total (abnormal)	7	7	50

SMCE, standing-type magnetically controlled capsule endoscopy.

(level 1) in the above-mentioned six landmarks accounted for 49.7%, 47.9%, 61.2%, 68.5%, 63.0% and 63.6% of patients, respectively. In nearly all subjects (164, 99.4%), maneuverability was graded as good or moderate.

DISCUSSION

STANDING-TYPE MAGNETICALLY CONTROLLED capsule endoscopy and gastroscopy show similar diagnostic consistency with overall consistency of 94.41%, positive agreement of 92.0% and negative agreement of 95.5%. A previous similarly designed study on a similar product[6] showed overall consistency of 91.2% (95% CI: 84.4%–97.9%), positive agreement of 96.0% and negative agreement of 77.8%. Compared to the latter study, SMCE was slightly better in overall agreement rate and it seemed that SMCE was significantly better in negative agreement rate. Possible reasons for this advantage are that the SMCE capsule was able to distinguish greater detail of the mucosal pattern of the stomach and had a better ability to distinguish between normal mucosa and mucosal lesions. In the present study, both methods missed focal lesions. However, SMCE appears to have a small benefit over

Table 3 Per location and per lesion analyses of lesions diagnosed by SMCE and standard gastroscopy

		Gastroscopy only, *n*	SMCE only, *n*	Both SMCE and gastroscopy, *n*
Antrum	Atrophic gastritis	1	0	1
	Polyp	0	0	1
	Ulcer	0	0	0
Body	Atrophic gastritis	0	1	0
	Polyp	1	0	11
	Ulcer	1	0	0
Fundus	Atrophic gastritis	0	0	0
	Polyp	0	1	2
	Ulcer	0	0	0
Cardia	Atrophic gastritis	0	0	0
	Polyp	1	0	1
	Ulcer	0	0	0
Angulus	Atrophic gastritis	1	0	1
	Polyp	0	0	1
	Ulcer	0	0	0

SMCE, standing-type magnetically controlled capsule endoscopy.

gastroscopy in finding mild erosion (five lesions *vs* one lesion). These findings are consistent with other findings.[4,5,13] Possible reasons for this advantage are the magnifying effect of water and, as a result of this, the capsule was able to inspect the mucosal surface for an extended time due to better patient tolerability of capsule.

Standing-type magnetically controlled capsule endoscopy is a promising alternative screening method for gastric disease. First, SMCE could be a reliable screening method for patients who do not require further invasive procedures. In this trial, only 30 patients (18.2%) needed biopsy by gastroscopy. Hence, more than 80% of patients did not require invasive gastroscopy after SMCE investigation. Second, SMCE takes up less space, which is more acceptable in medical institutions than lying-type devices.[12,14,15] Third, another benefit of SMCE is its comparatively lower price.[11,12] The cost of each SMCE examination appears to be cheaper than that of the other MCE system in China ($436.13 *vs* $581.51), but still higher than sedation gastroscopy ($145.38).

Adverse events described by patients were infrequent and mild, and none of the reported events were due to the capsule itself. In the present study, patients suspected of having small-bowel disease were excluded, and the retention rate of the capsule in these excluded patients is supposed to

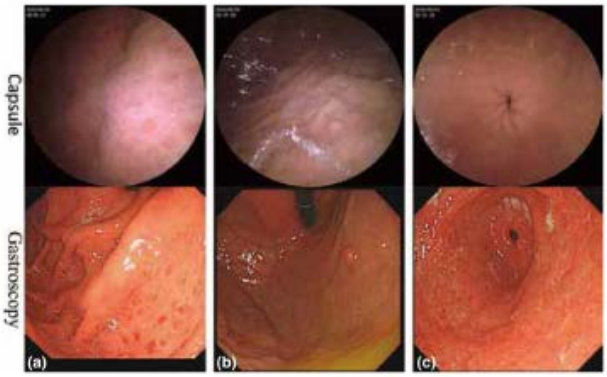

Figure 3 Representative images taken by both magnetically controlled capsule endoscopy and gastroscopy. (a) Erosive gastritis. (b) Gastric polyp. (c) Atrophic gastritis.

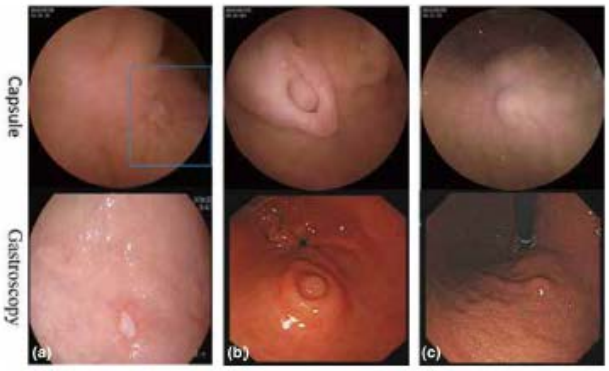

Figure 4 Representative images taken by both magnetically controlled capsule endoscopy and gastroscopy. (a) Ulcer. (b) Heterotopic pancreas. (c) Submucosal tumors.

be low.[16] No retention occurred in our study. Our findings support that SMCE, specified for identifying upper gastrointestinal diseases, is safe with a very low complication rate.

Maneuverability of the SMCE was graded as good in 105 (63.6%) patients and moderate in 59 (35.8%) patients. Maneuverability is the most important factor in determining whether CE can be effectively controlled in the gastrointestinal tract.[10,14,17] In the present study, the SMCE device was advanced to the entire cardia and fundus, which were considered to be extremely challenging regions for active control in other studies.[8,18]

In the present study, cleanliness in six landmarks was good in more than 80% of patients who underwent SMCE. Most studies used simethicone as an antifoaming agent to improve visualization of the gastric mucosa and removal of gastric mucus by pronase granules.[5,12,19] In our study, gastric mucus reduced capsule visualization in nine patients. Current or past *Helicobacter pylori* infection status is considered to be a cause of excessive and/or sticky mucus.[20,21] However, only one hospital in our study had assessed *H. pylori* infection status. Elimination of mucus by pronase[22] has been shown to eliminate this problem, and this result was consistent with a previous study.[4]

Although SMCE was as good as gastroscopy in investigative agreement, certain limitations of SMCE must be considered. First, SMCE examination time was longer than the time needed for gastroscopy (24 min to 7 min); however, in the future, the time required will be less when the image is automatically analyzed using artificial intelligence.[23–27] SMCE requires less time than does a similar product, which requires approximately 30 min.[5] Second, SMCE examination time varied from 7 min to 47 min. Reasons for this are as follows: First, the SMCE capsule moved in the liquid by means of rolling and rotating. So, when moving the same distance, the path of the capsule's lens was much longer than that of gastroscopy. Second, the visual field of the capsule in the motion state changed rapidly, which made manipulation of the capsule more difficult and thus increased operation time. Also, the structure of each person's stomach cavity is different, resulting in different trajectories of capsule movement. Third, the discomfort caused by standing may limit the use of SMCE in certain patients, but, in the future, a sitting method will solve this problem. In addition, upper gastrointestinal endoscopy generally includes examination of the entire esophagus, stomach, and duodenum. Thus, SMCE targeted for stomach only may limit its use in clinical practice.

Standing-type magnetically controlled capsule endoscopy system produces approximately 20 000 images per inspection and 30–60 min are required for a doctor to read them. With the application of artificial intelligence, SMCE system has been able to screen 80–90% of similar images, greatly reducing the burden on doctors. Similar to published studies,[28–32] doctor's reading time will further shorten with the application of computer-assisted diagnosis. Image-processing technologies have also been applied to CE.[33,34] A recent meta-analysis showed that improved delineation was seen in 89% of angioectasias and in 45% of ulcer/erosions using flexible spectral imaging color enhancement.[35] However, imaging processing technology has not been applied in this study, but it will be implemented in the next generation of SMCE.

In conclusion, this new SMCE method may be a promising alternative for noninvasive screening for gastric diseases. Technical modifications are needed, and trials with larger sample sizes in a high-risk population need to be done.

ACKNOWLEDGMENTS

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CONFLICTS OF INTEREST

AUTHOR H.L. IS a consultant for JIFU Technologies beginning September 2018. The other authors have no conflicts of interest or financial ties to disclose.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Figure S1 Magnetically controlled capsule endoscope (JIFU Medical Technologies Co., Ltd, Shenzhen, China). The capsule has a size of 27 × 12 mm and has a permanent magnet inside its dome. Viewing angle of the capsule is 136°, and the viewing distance is 0–50 mm.

Figure S2 Symbolic images indicating the use of 4-point grading scale to accurately explain the cleanliness of the stomach for the duration of the examination. (A) Excellent, no more than small bits of adherent mucus and foam. (B) Good, a small amount of mucus and foam, but not enough to interfere with the examination. (C) Fair, a considerable amount of mucus or foam present to preclude a completely reliable examination. (D) Poor, large amount of mucus or foam residue.

Video S1 Inspection procedure of standing-type magnetically controlled capsule endoscopy.

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原文

站立式磁控胶囊胃镜与传统胃镜的对比：一项多中心盲态比较研究

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摘要

目的:

研究站立式磁控胶囊胃镜（SMCE）与传统胃镜对比在胃肠道检查中的可行性和安全性。

方法:

这是一项前瞻性、 多中心、 盲态比较的研究。 2018年4月至2018年7月期间比较受试者的SMCE和胃镜检查。 受试者先接受SMCE，然后接受静脉麻醉的胃镜检查。 我们以传统胃镜为金标准， 评估通过SMCE检测胃部病变的一致率。 整个研究还记录胶囊滞留率、 不良事件发生率及受试者满意度。

结果:

我们分析了161例完成了SMCE和胃镜检查的受试者。SMCE和胃镜检查的阳性一致率为92.0%（95%CI: 80.77%−97.78%）。阴性一致率为95.5%（89.80%，98.52%）。此外，整体一致率为94.4%（89.65%，97.41%）。整个研究发现了64处病变。在这64处病变中，两种方法均检测到50处。胃镜检查漏诊了7个发现（5处糜烂、1处息肉和1处溃疡）。此外，SMCE也漏诊了7处病变（1处糜烂、2处息肉、1处萎缩和3处黏膜下肿瘤）。研究期间未出现胶囊滞留或相关严重不良事件。

结论:

SMCE与胃镜检查相比具有可靠的一致性，可能实现没有麻醉的情况下用于筛查胃部疾病。

关键词: 站立式磁控胶囊胃镜；传统胃镜；胃部疾病；胃部检查；一致率

临床试验注册地址及编号

中国临床试验注册中心 (ChiCTR1800018346)

前言

常规电子胃镜检查的缺点是不舒适导致患者的依从性差。尽管麻醉可以改善患者的依从性，但受试者在胃镜检查后仍会感到不适并可能出现与麻醉有关的不良反应。[1]

胶囊内窥镜（CE）已经应用了十几年，其代表了一种舒适的替代胃镜检查的方法。[2,3] 近年来，一种新型胃部检查方式—磁控胶囊内窥镜（MCE）应用于胃部检查。[4-6] 根据最新的专家共识，MCE的优点是其不需要镇静或麻醉、舒适、安全、诊断准确性高并且易于被人群接受。[7]

最近，国内开发了一款站立式磁控胶囊胃镜（SMCE）系统。除SMCE系统外，目前全球存在三类卧位式磁控胃镜系统：手柄式、MRI式和机器人式。[5,8-10] 与其他类似产品（例如Olympus和NaviCam）相比，[8,11] SMCE无需患者穿戴复杂的天线来接收图像，因此操作流程更为便捷。此外，SMCE的可操纵性更强，本研究中的磁铁机器人可以产生250mT的最大磁场强度，该磁场强度大于Olympus的100mT和NaviCam的200mT。[8,11]

然而，SMCE系统的安全性及可行性尚未确定。为此，我们进行了一项多中心自身对照的临床研究，以确认SMCE的有效性及安全性。受试者在进行麻醉胃镜检查之前接受SMCE进行初步胃部检查。主要终点指标是以胃镜检查作为金标准下，SMCE检测胃部病变的一致率。

研究方法

伦理审批及知情同意

该研究已获得各参与中心伦理审查委员会的批准。所有受试者均签署了书面知情同意书。

病人招募

该试验于2018年4月17日至2018年7月9日在3家三级甲等医院进行。受试者年龄为18至70岁，具有上腹部主诉且计划进行胃镜检查的成年受试者。

排除标准：(1)各种急性肠炎，如细菌性痢疾，急性溃疡性结肠炎、窒息等；(2)已知或怀疑的胃肠道阻塞、狭窄和瘘管；(3)上消化道穿孔急性期；(4)严重的咽喉疾病；(5)腐蚀性食管炎的急性期；(6)严重的胃动力障碍；(7)体内存在植入电子装置；(8)麻醉药物过敏史；(9)孕妇。

研究干预

受试者先进行SMCE检查，然后在4小时后在静脉麻醉下进行传统胃镜检查。比较SMCE和胃镜检查检测胃部病变的能力。

SMCE系统

SMCE系统（中国深圳市资福医疗技术有限公司）由胶囊内窥镜、磁控机器人和图像工作台组成。胶囊的尺寸为27×12 mm，重量为2.7 g，并包含一永久磁铁。胶囊以4帧/秒的速度拍摄。视距为0–50 mm，视角>136°（补充图1）。磁控机器人是一款无臂式的站立式系统（图1），其内包含无线接收器及永久磁铁。

补充图1.

SMCE胶囊内窥镜（深圳市资福医疗技术有限公司）。胶囊的尺寸为27×12mm，并在其圆顶内包含一块永久磁铁。胶囊的视角为136°，视距为0~50 mm

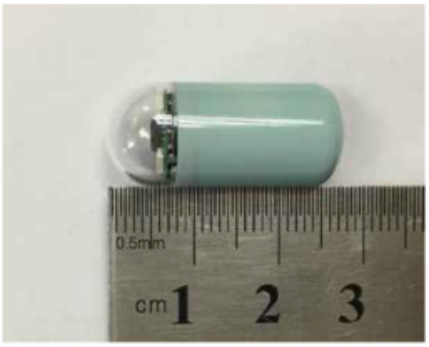


图1.

控制设备：磁控机器人及控制站。显示的四个单张图像：

a）胶囊内窥镜
b）胶囊激活器
c）工作站
d）站立式磁控机器人

胃部准备流程和SMCE检查流程

在到达医院之前，要求受试者禁食一夜（> 8小时）。检查前30 min，将10 ml二甲基硅油（德国柏林化学工业公司）用作祛泡剂，检查前15 min使用20000单位链霉蛋白酶颗粒（北京北京泰德药业有限公司，中国）消除黏液。检查前要求受试者饮用500mL至1L的纯净水，以保持饱腹感。

观察6个解剖标志（贲门、胃底、胃体、胃角、胃窦及幽门）。当受试者的左侧贴近磁控机器人时，将胶囊控制至胃底、贲门和胃体；当腹部侧贴近时，胶囊被移至胃角、胃窦和幽门（补充视频1）。

补充视频1：

详见: https://onlinelibrary.wiley.com/doi/full/10.1111/den.13520

胃镜检查

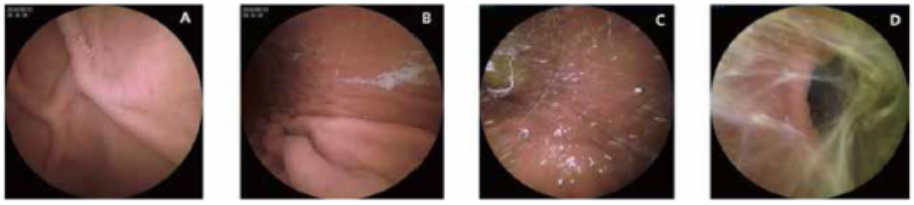
SMCE检查结束4小时后进行胃镜检查（Olympus GIF-H260；日本东京）。由另外2名具有1000次以上胃镜操作经验的医师执行的，且他们不知情SMCE的检查结果。期间观察并拍摄6个标志部位。若临床需要，则取病理活检标本。记录胃镜检查的所有结果，包括病变的位置、大小、性质，需2名医生确认。在发现SMCE检出而胃镜未检出的病变后一周内，需要对受试者进行第二次胃镜检查，但结果不包括在最终评估中。胃镜同时检查食道和十二指肠，但结果不包括在最终评估中。

胃黏膜清洁度及可视化

由2名操作SMCE的医生实时评估和记录主要标志部位的黏膜清洁度。使用4个尺度来主观地评估清洁度，即极好、良好、一般或差。[12]（补充图2）

使用5级量级表来主观定义6个部位的可视化效果：1级，观察到>90%的黏膜； 2级，观察到75～90%的黏膜； 3级，观察到60%～75%的黏膜； 4级，观察到50～60%的黏膜； 5级，观察到<50%的黏膜。

补充图2.



使用4级量表来评估检查期间的胃清洁度。(A) 极好，极少量黏液和泡沫。(B) 良好，少量黏液和泡沫，但不足以影响检查。(C) 一般，存在较多黏液或泡沫，影响检查。(D) 大量黏液或泡沫残留物，无法检查。

评价诊断病变结果

SMCE的评估是由2位经验丰富的医生进行的。他们具有100例以上MCE的操作经验。阳性结果定义的局灶性病变，例如糜烂、息肉、溃疡等（如黏膜下肿瘤（SMT）、异位胰腺等）或弥散性病变如萎缩性胃炎。正常胃黏膜或轻度炎症定义为阴性结果。当两种检查发现的病变位置、性质和大小均一致时，两次检查的结果才算一致。如果在受试者中发现了多个病变，则以最重要的病变为准，并以溃疡、息肉、黏膜下肿物（SMT）等作为最终结果的首选。每位受试者的图像均由2名医生独立评估，如果2个医生之间的结果不一致，则由一名独立研究者参加并做出最终诊断，他们对彼此的诊断结果互不知晓。

评估SMCE的安全性和可操作性

如果受试者1周内未在粪便中发现胶囊，则指示受试者返回医院进行腹部X线检查。如果受试者在2周内仍未发现胶囊，应建议受试者到医院进行手术或其他治疗方法以将其取出。不良事件定义为试验期间受试者出现的症状或体征，例如腹胀、恶心或呕吐等。内镜医师还需对SMCE的可操作性进行主观评估。

统计分析

根据既往报道，假设SMCE在检测胃部病变中至少有96%的阳性一致率和78%的阴性一致率。[6] 显著性水平为0.05（两边），误差为8%，计算样本量的公式为n= $Z^2_{1-\alpha/2}P(1-P)/\Delta^2$（$\Delta$ 是允许误差）。经过计算，阳性受试者人数至少为23名，阴性受试者人数至少为104名，则至少需要127名受试者。预计失访率为10%，则至少需要140名受试者。

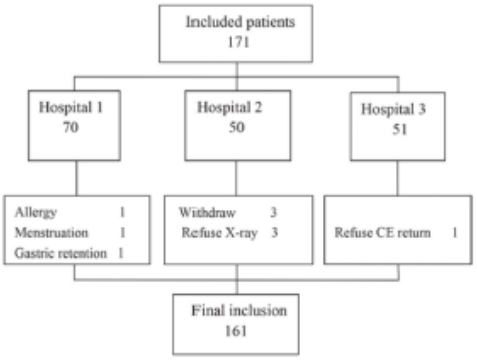
连续变量的描述性统计记录为均值±SD，或中位数、范围。计算机会调整的Kappa统计（κ），以评估SMCE和胃镜检查之间一致性的强度。使用SAS软件（version 9.4, NC, USA）进行统计分析。

结果

受试者

3个参与中心共登记了171名受试者。SMCE后，3例受试者拒绝进一步随访，1名受试者的胶囊通过胃镜检查误取而违背方案，1名受试者在SMCE之前发现了无法解释的皮肤过敏，1名受试者在胃镜检查前遇经期，1名受试者拒绝退回胶囊，3名受试者在试验期间无理由自愿退出。因此，10名受试者未纳入最终分析（5.8%）。因此，将完成这两项检查的161名受试者计入最终分析集中（图2）。165名完成两种检查的受试者被纳入安全分析集(SS)。94名受试者（57.0%）为男性，71名受试者(43.0%)为女性，平均年龄为30.02±9.73岁(范围18–69岁)。SMCE的平均时间为24.17±7.48分钟(范围7–47分钟)，而进行胃镜检查的平均时间为7.06±4.18分钟(范围2–32分钟)。

图2.



受试者纳入流程图

胃镜和SMCE发现的阴性与阳性病变

最终确定106例阴性受试者，55例为阳性受试者（表1）。阳性一致率为92.0%（95%CI: 80.77%–97.78%），阴性一致率为95.5%（89.80%，98.52%），整体一致率为94.41%（89.65%，97.41%），和κ值为0.870（双边，P<0.0001）。McNemar测试表明P值为0.11（P = 0.74），表明两种检查结果的一致性无显着差异。

（表2）和（表3）显示了SMCE和胃镜检查发现的病变。共鉴定出64个病变，两种方法均检测到的有50个病变。其中，有23例糜烂、15例息肉、9例SMT，1例异位胰腺和2例萎缩性胃炎（图3和图4）。胃镜检查发现了SMCE漏诊的7个额外病变，包括1个糜烂、2个息肉、1个萎缩性胃炎和3个SMT。SMCE发现了7处被胃镜检查漏诊的病变，包括5处糜烂、1例息肉和1例溃疡。胃镜检查漏诊的息肉在另一次胃镜检查中得到了确认并进行了治疗。

表1.

接受站立式磁控胶囊胃镜检查和标准胃镜检查的阴性和阳性结果

SMCE, n (%)	胃镜, n (%)		
	阳性	阴性	总计, n (%)
阳性	46 (28.58)	5 (3.11)	51 (31.68)
阴性	4 (2.48)	106 (65.83)	110 (68.32)
总计, n (%)	50 (31.06)	111 (68.94)	161 (100.00)

SMCE, 站立式磁控胶囊胃镜.

表2.

SMCE和标准胃镜检查诊断出的64个病变

病变	仅SMCE, n	仅胃镜, n	SMCE和胃镜, n
糜烂	5	1	23
息肉	1	2	15
溃疡	1	0	0
萎缩性胃炎	0	1	2
黏膜下隆起	0	3	9
异位胰腺	0	0	1
出血	0	0	0
总计（异常）	7	7	50

SMCE, 站立式磁控胶囊胃镜.

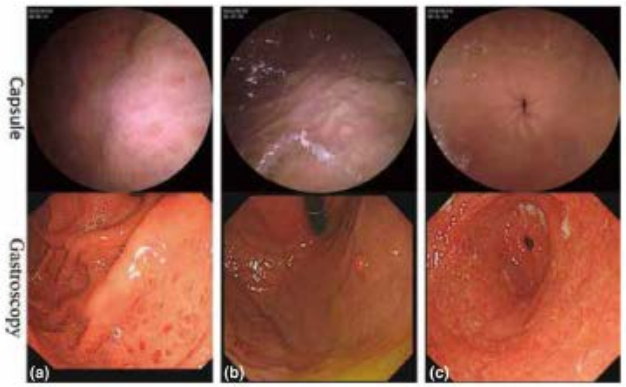
表3.

SMCE和标准胃镜检查诊断病变的单部位分析及单病变分析

		仅胃镜, n	仅SMCE, n	SMCE和胃镜, n
胃窦	萎缩性胃炎	1	0	1
	息肉	0	0	1
	溃疡	0	0	0
胃体	萎缩性胃炎	0	1	0
	息肉	1	0	11
	溃疡	1	0	0
胃底	萎缩性胃炎	0	0	0
	息肉	0	1	2
	溃疡	0	0	0
贲门	萎缩性胃炎	0	0	0
	息肉	1	0	1
	溃疡	0	0	0
胃角	萎缩性胃炎	1	0	1
	息肉	0	0	1
	溃疡	0	0	0

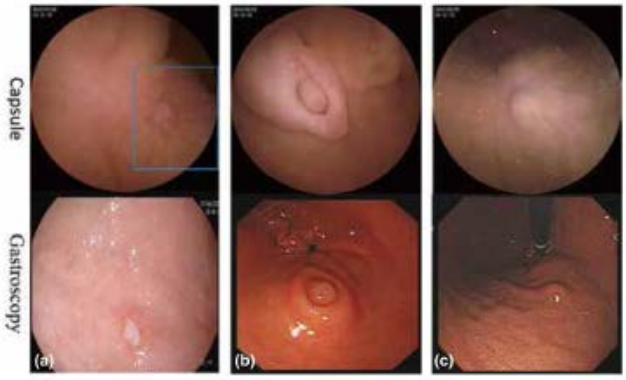
SMCE, 站立式磁控胶囊胃镜.

图3.



SMCE和胃镜均拍摄到的代表性图像: (a) 糜烂性胃炎； (b) 胃息肉； (c) 萎缩性胃炎

图4.



SMCE和胃镜均拍摄到的代表性图像: (a) 溃疡； (b) 异位胰腺； (c) 黏膜下肿瘤

SMCE的安全性和受试者偏好

腹部X线检查证实在随访期间未出现任何胶囊滞留事件。在安全分析集（SS）包括的165名受试者中，有152名（92.1%）受试者在随访期间（2周）内已确认排出胶囊，其余13名（7.9%）受试者在X射线检查后确认排出胶囊。

在完成研究的165名受试者中，有3名（1.8%）出现了不良反应。1例出现恶心和呕吐，1例出现口腔疼痛，1例出现头晕。恶心和呕吐可能是由于胃部准备导致的。但症状都在SMCE后的24小时内消失。在165例受试者中，有99例（60.0%）偏好SMCE检查，而66例（40.0%）偏好胃镜检查。

SMCE的胃清洁度、黏膜可视度和可操作性

接受SMCE的受试者中，82.6%、84.2%、93.9%、96.0%、97.6%和97.6%的贲门、胃底、胃体、胃角、胃窦和幽门的胃清洁度达良好以上。在上述6个标志性区域中，胃黏膜可视化良好（1级或2级）的分别为99.4%、93.4%、99.4%、100.0%、99.4%和99.4%。极好可视化（1级）分别为49.7%、47.9%、61.2%、68.5%、63.0%和63.6%。在几乎所有受试者（164名，99.4%）中，可操纵性被评为中等以上。

讨论

SMCE和胃镜检查显示出相似的诊断一致性，整体一致率为94.41%，阳性一致率为92.0%，阴性一致率为95.5%。与同类产品相比，[6] 其他研究的整体一致率为91.2%（95%CI: 84.4%–97.9%），阳性一致率为96.0%，阴性一致率为77.8%。本研究中SMCE的整体一致率更高，而且SMCE的阴性一致率似乎高得多。这种优势的可能是由于SMCE能够覆盖更多的胃黏膜细节，并且能够更好地区分正常黏膜和病变黏膜。在这项研究中，两种方法均遗漏了病灶。但是，SMCE在发现微小病灶如糜烂（5个病变vs. 1个病变）方面似乎比胃镜检查更好。这些发现与其他研究的结论一致。[4,5,13] 这种优势的可能原因是水的放大作用。此外，由于受试者对胶囊有更好的耐受性，胶囊能够更长时间观察表面黏膜。

SMCE可能是一种有前景的替代性胃部筛查方法。首先，对于不需要进行侵入性手术的受试者，SMCE可能是一种可靠的筛查手段。在该试验中，只有30例受试者（18.2%）需要通过胃镜进行活检。因此，在SMCE检查后，超过80%的受试者并无需进行侵入性的胃镜检查。其次，站立式MCE占用的空间较小，在医疗机构中比卧式设备更容易接受。[12,14,15] 第三，SMCE的另一个好处是费用相对较低。[11,12] 每次SMCE检查的费用似乎比中国另一款MCE系统低（436.13美元 vs. 581.51美元），但仍比麻醉胃镜检查（145.38美元）高。

该研究中受试者描述的不良反应较少见且轻微，报道的不良事件均非明显由胶囊本身引起的。在本研究中，排除了疑似小肠疾病的受试者，经既往报道，排除后的受试者中胶囊的滞留率很低。[16] 本次研究未出现胶囊滞留事件。我们的研究结果表明，该款用于识别上消化道疾病的SMCE是安全的且并发症发生率极低。

SMCE的可操作性在105（63.6%）名受试者中为“良好”，在59（35.8%）名受试者中为“中等”。可操作性是评价胶囊内镜能否在胃肠道中得到有效控制的最重要指标。[10,14,17] 在本研究中，SMCE检查已覆盖到所有的贲门和胃底，贲门和胃底在其他研究中被认为是磁控胶囊胃镜最具挑战性的区域。[8,18]

在本次研究中，接受SMCE检查的80%以上受试者的6个标志性部位的清洁度达良好以上。目前大多数研究使用二甲硅油作为祛泡剂来改善胃黏膜的可视化，使用链霉蛋白酶颗粒去除胃黏液。[5,12,19] 在本次研究中，胃黏液降低了9例受试者的胶囊可视化程度。当前或既往的幽门螺杆菌感染被认为是造成过多和/或胃部黏液的原因。[20,21] 然而，本次研究中仅有南方医院完整地评估了每位受试者的幽门螺杆菌感染状况。目前已证明通过链霉蛋白酶[22] 消除黏液可以解决该问题，并且该结果与既往的研究一致。[4]

尽管SMCE在胃部检查方面尚属满意，但不能忽视其仍存在的局限性。首先，SMCE检查时间比胃镜检查的时间更长（24 min vs. 7 min），但是，将来使用人工智能自动巡航后所需的时间会大大减少。[23–27] 此外，SMCE所需的时间比同类产品所需的30 min略短。[5] 其次，SMCE的检查时间差异大，从7至47 min等。其原因可能如下：首先，SMCE胶囊通过滚动和旋转的方式在液体中移动，因此当移动相同的距离时，胶囊的摄像头经过的路径要比胃镜检查的路径长得多。其次，处于运动状态的胶囊的视野不断变化，这使得胶囊更难被操纵，从而增加了操作时间的不确定性。而且，胃腔结构的个体差异大，从而导致胶囊的运动轨迹存在差异。第三，站立式引起的不适可能会限制某些受试者使用SMCE的依从性，但将来，坐式检查方法将解决该问题。另外，上消化道胃镜检查通常还包括食道、十二指肠的检查。因此，仅针对胃部的SMCE似乎限制其用于临床中。

SMCE系统每次检查可产生大约20,000张图像，医生需要30–60分钟才能阅片完毕。随着人工智能的应用，SMCE系统已能筛除80–90%的相似图像，大大减轻了医生的负担。类似于已发表的研究，随着AI辅助诊断的应用，[28–32] 医生的阅片时间将进一步缩短。图像增强技术也逐渐应用于胶囊内镜检查中。[33,34] 最近的一项胶囊内镜Meta分析显示，使用FICE技术，可以改善89%的血管扩张和45%的溃疡/糜烂的可视轮廓。[35] 然而图像增强技术尚未在本次研究中应用，但将在下一代SMCE中实现。

总之，这款新型的MCE检查可能成为一种无创筛查胃部病变的替代方法。但未来SMCE还需要进行技术改进，并且需要在高风险人群中进行更大样本量的多中心对照研究。

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附录：

附录1. 中英文缩略词对照表

缩略词	英文全称	中文全称
GC	Gastric cancer	胃癌
EGD	Esophagogastroduodenoscopy	食管、胃、十二指肠镜检查
CE	Capsule endoscopy	胶囊内镜
ECE	Esophageal capsule ensoscopy	食管胶囊胃镜
MGCE	Magenetically guided capsule endoscopy	磁控胶囊胃镜
SMCE	Stand-type magnetically controlled capsule endoscopy	站立式磁控胶囊内镜
CCE	Colon capsule endoscopy	结肠胶囊内镜
SMT	Submucosal tumor	黏膜下肿物
AE	Adverse event,	不良事件
SAE	Serious adverse event	严重不良事件
FAS	Full Analysis Set	全分析集
PPS	Per-Protocol Set	符合方案数据集
SS	Safety Set	安全性分析数据集
SAP	Statistic Analysis Plan	统计分析计划