


## ORIGINAL ARTICLE

# 5G-based remote magnetically controlled capsule endoscopy for examination of the stomach and small bowel

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## Abstract

**Background and aims:** Remote endoscopy can improve diagnostic efficiency of gastrointestinal (GI) diseases for patients in remote areas. A novel remote magnetically controlled capsule endoscopy (MCE) system based on a 5G network was developed for real-time remote GI examinations. We aimed to evaluate the feasibility and safety of the 5G-based remote MCE for examination of the stomach and small bowel.

**Methods:** This was a prospective, nonrandomized, comparative study. Consecutive participants enrolled in the First People's Hospital of Yinchuan underwent remote MCE examinations performed by an endoscopist located in Changhai Hospital. Consecutive participants enrolled in Changhai Hospital underwent conventional MCE examinations performed by the same endoscopist. The main outcomes included the complete visualization rate of the stomach and small bowel, safety assessment and network latency time of remote MCE examinations.

**Results:** From March 2021 to June 2021, 20 participants in each group were enrolled. The complete visualization rate of the stomach and small bowel was 100% in both groups ( $p > 0.999$ ) without any adverse event. The median network latency time of remote MCE group was 19.948 ms. Gastric examination time (8.96 vs. 8.92 min,  $p = 0.234$ ), maneuverability (15.00 vs. 15.00,  $p = 0.317$ ), image quality (1.00 vs. 1.00,  $p > 0.999$ ) and diagnostic yields in the stomach and small bowel (55% vs. 30%, 5% vs. 0%, both  $p > 0.05$ ) were comparable between remote and conventional MCE groups. All participants in remote MCE group considered remote MCE acceptable and necessary.

**Conclusions:** 5G-based remote MCE was a feasible and safe method for viewing the stomach and small bowel.

## KEYWORDS

5G, magnetically controlled capsule endoscopy, remote endoscopy, small bowel, stomach, telemedicine, videocapsule investigation of gastroduodenum

Ting Zhang, Yi-Zhi Chen, Xi Jiang and Chen He these authors contributed equally to this work

Clinical Trial Registration, [ClinicalTrials.gov](https://clinicaltrials.gov), ID: NCT04670692.

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## INTRODUCTION

Telemedicine is the provision of medical information and services through the use of telecommunications, which has allowed many patients worldwide to access remote healthcare and played an increasingly important role in the past decade.<sup>1,2</sup> In the field of gastrointestinal (GI) endoscopy, remote endoscopy is an important direction of telemedicine. Because of limited medical resources and lack of local expertise,<sup>3</sup> endoscopy has not been widely carried out at remote areas in China, which may lead to delayed diagnosis and treatment of GI diseases. Besides, the COVID-19 pandemic further hinders the access for endoscopy due to the high infection risk during the face-to-face procedure.<sup>4</sup> Remote endoscopy could be an effective solution to these problems, improve the popularization and convenience of endoscopy, and thus improve the efficiency of endoscopic diagnosis.

However, few studies have explored the possibility of real-time remote endoscopy because of limited availability of endoscopic robots. Some new endoscopic robots based on the conventional endoscopes have been developed and tested.<sup>5-7</sup> Unlike current robotic systems using a rigid endoscope in the surgical field, robotic systems using conventional flexible endoscopes increase operation difficulty and the remote control of conventional gastroscopy still remain unresolved. In addition, network delay and instability has invariably been an obstacle to real-time remote operation.<sup>8</sup> Therefore, the use of telemedicine has mainly played a role in remote consultation, training and triaging of endoscopic procedures in endoscopy area.<sup>9-11</sup>

Magnetically controlled capsule endoscopy (MCE), with equally favorable diagnostic accuracy as conventional gastroscopy, has become an efficient and comfortable diagnostic modality for GI diseases.<sup>12,13</sup> The endoscopist could control the movement of the capsule inside human body precisely through the manipulation of the magnetic robot arm. The non-invasive capsule endoscope, which allows image acquisition after being swallowed, works separately from the control parts of the MCE system. The separable and robotic characteristics of the MCE system provide the technical foundation for remote operation. Moreover, the recent development of the fifth generation of wireless system (5G), with its high speed, low latency, and wide bandwidth, has further supported real-time telemedicine with reliable networks.<sup>14</sup> Some real-time remote examinations and surgeries, such as teleultrasound, telerobotic spinal surgery and laparoscopic telesurgery, have been explored and successfully carried out.<sup>15-19</sup> Here, we present a 5G-based remote MCE system that the remote endoscopist can directly perform the MCE examination on the patient through a remote control system and the application of 5G network. This study aimed to evaluate the feasibility and safety of the 5G-based remote MCE system.

## MATERIALS AND METHODS

### Study design

This was a prospective, nonrandomized, interventional study performed between Changhai Hospital in Shanghai, China and the First

### Key summary

#### Summarise the established knowledge on this subject

- Unbalanced medical resources result in limited access for gastrointestinal (GI) examinations in remote areas.
- Magnetically controlled capsule endoscopy (MCE) is an effective diagnostic modality for GI diseases and has been widely used in examinations of the stomach and small bowel.
- The advent of the fifth generation of wireless system (5G) is promoting the development of real-time telemedicine.

#### What are the significant and/or new findings of this study?

- This is the first study to evaluate and confirm the feasibility and safety of remote capsule endoscopy for viewing both the stomach and small bowel.
- The 5G-based remote MCE has the potential to be widely used in clinic and improve the efficiency of endoscopic diagnosis in remote areas.

People's Hospital of Yinchuan in Ningxia, China. Consecutive participants who underwent 5G-based remote MCE were compared with the same number of consecutive participants who underwent conventional MCE during the same period. The study protocol was approved by Institutional Review Board of Changhai Hospital and the First People's Hospital of Yinchuan and registered at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT04670692). Written informed consent was obtained from each enrolled participant.

### Study patients

Inclusion criteria for both groups were the same. Adult participants with abdominal complaints or asymptomatic individuals for physical examination who were scheduled to undergo MCE were eligible for this study. Participants prospectively enrolled in the First People's Hospital of Yinchuan underwent remote MCE examinations performed by a remote endoscopist located in Changhai Hospital (remote MCE group). Participants prospectively enrolled in Changhai Hospital underwent conventional MCE examinations locally performed by the same endoscopist (conventional MCE group). Participants with any of the following contraindications for MCE were excluded: dysphagia; have implanted pacemakers, electromedical devices or magnetic metal foreign bodies which are incompatible with magnetic field; known or suspected GI obstruction, stenosis, fistula; pregnancy; and any other contraindications as determined by endoscopists.

### Devices

The remote MCE system included a doctor terminal (based in Changhai Hospital) and a patient terminal (based in the First People's

Hospital of Yinchuan). And this system was composed of four parts: (1) the conventional MCE system<sup>20</sup>; (2) remote control modules for remote manipulation of the capsule, including a remote console and remote software (NaviRemoteCtrl and NaviRemoteConn); (3) a remote audio-visual system for communications between two terminals, consisting of a video camera and a microphone; (4) an additional computer workstation at the doctor terminal. Besides, a 5G wireless network was used for high-speed data transmission, which was provided and established by China Telecom (Beijing, China).

**Patient terminal** Devices at the patient terminal included the MCE system and a video camera (Figure 1a). The MCE system (Ankon Technologies, Shanghai, China) consists of an endoscopic capsule, a capsule locator, a data recorder, a guidance magnet robot, and a computer workstation with ESNavi and NaviRemoteConn.<sup>13,20</sup> The remote connection software NaviRemoteConn was used to connect the ESNvai software to the remote console and NaviRemoteCtrl software at the doctor terminal. A general overview of the patient terminal was recorded with the video camera, enabling the endoscopist at the doctor terminal to view what was occurring in the patient terminal.

**Doctor terminal** Devices at the doctor terminal included a computer workstation with NaviRemoteCtrl software, a remote console and a microphone (Figure 1b). The NaviRemoteCtrl software, which was connected to the MCE system and video camera at the patient terminal through the 5G network, provided two interfaces to display the real-time capsule images, capsule posture and general overview of the patient terminal. The remote console consists of two joysticks and a touchscreen. The joysticks could control the motion of the capsule position and the orientation of the capsule lens inside human body, and functional buttons on the touchscreen could be used for the rotation of the video camera and swift movement of the capsule and guidance magnet robot at the patient terminal. Thus the real-time viewing and capsule control functions of ESNavi (in the patient terminal) were completely replaced by NaviRemoteCtrl and the remote console (in the doctor terminal). In addition, real-time audio-visual communications between the two terminals were also realized through the interface of NaviRemoteCtrl.

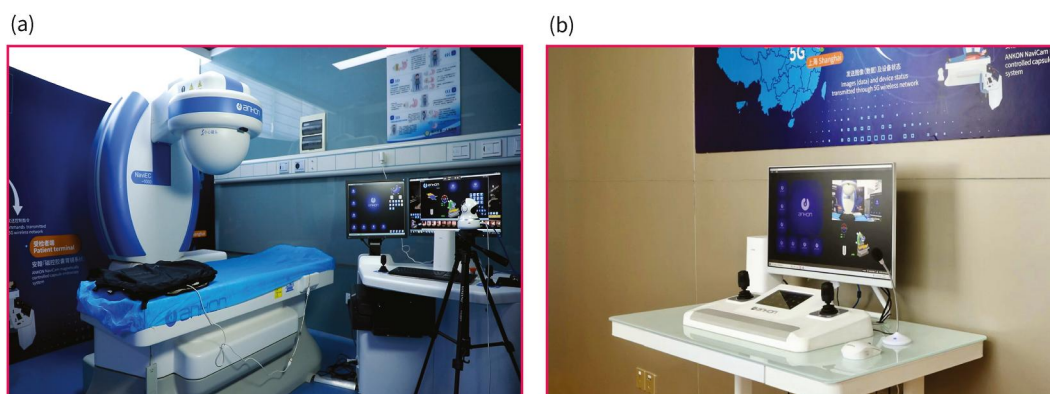
## Magnetically controlled capsule endoscopy procedures

Remote MCE procedures were performed by an endoscopist (W.Z.) with an experience of >500 cases of MCE operation in Changhai Hospital, Shanghai. Before the examination, the assistant at the patient terminal opened ESNavi and NaviRemoteConn for remote connection, and the remote endoscopist opened NaviRemoteCtrl to build connections with the MCE system and video camera at the patient terminal. Then the participant entered the examination room and put on the data recorder, and the assistant activated the capsule with the capsule locator. After receiving the remote endoscopist's order to start examination, the patient swallowed the capsule under the assistant's instruction, and then the stomach examination was performed by the endoscopist remotely. During the examination, the endoscopist controlled the movement of the capsule with the remote console and monitored the gastric images, device and patient's status in real time through the NaviRemoteCtrl software. Communications between the two terminals were established through the remote audio-visual communication system. After completing the stomach examination, if the pylorus opened, the capsule would be dragged to the duodenum and examine the duodenum under magnetic control. If the capsule did not pass through the pylorus under magnetic control, the capsule would directly be switched to "small intestine mode". Stomach examination and small-bowel examination were carried out according to standardized protocol.<sup>20</sup> The remote MCE procedure Supporting Information S1 is shown schematically in Figure 2.

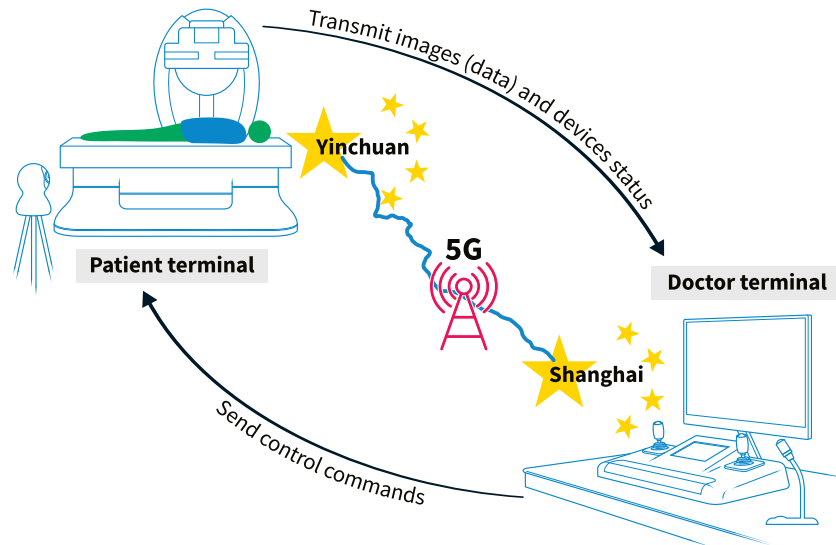
Conventional MCE procedures were performed by the same endoscopist (W.Z.) and carried out according to standardized protocol<sup>20</sup> at Changhai Hospital.

## Study outcomes

The primary outcome was the complete visualization rate of the stomach and small bowel, measured by complete visualization of the gastric mucosa in the 6 anatomic landmarks (cardia, fundus,



**FIGURE 1** 5G-based remote magnetically controlled capsule endoscopy (MCE) system. (a) general view of devices at the patient terminal. (b) general view of devices at the doctor terminal



**FIGURE 2** Schematic diagram of the remote magnetically controlled capsule endoscopy (MCE) procedure

body, angulus, antrum, and pylorus)<sup>13</sup> and complete small bowel examination.

Secondary outcomes included (1) safety, measured by incidence of adverse events; (2) network latency time of remote MCE examinations; (3) GI transit times, including 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), small bowel transit time (SBTT; defined as the time between the first duodenal image and the first cecal image), and magnetically gastric transit rate; (4) maneuverability of MCE (on a scale of 1–5; 1, the worst; 5, the best) on three indicators (fluency, comfort and stability); (5) image quality (on a scale of 1–3; 1, clear; 2, a little fuzzy; 3, fuzzy); (6) diagnostic yield of positive findings; (7) participants' awareness and acceptability of telemedicine.

All the MCE videos obtained from two groups were independently and blindly interpreted by two experienced MCE readers. If there was an inconsistency in the results, a third reader carried out an evaluation for a final decision. The maneuverability of MCE was scored by the operating endoscopist (W.Z.). Participants' awareness and acceptability of telemedicine were surveyed among participants of the remote MCE group through a questionnaire.

### Statistical analysis

Quantitative data with a normal distribution were summarized with mean and standard deviation and compared using independent *t*-test. Non-normally distributed data were summarized with median and interquartile range and compared using Wilcoxon test. Categorical variables were presented as frequency (percentage) and compared between arms by the Chi-square test or the Fisher's exact test. Statistical analyses were performed with Statistical Product and Service Solutions 26 software (IBM Corp, Armonk, NY, USA).

## RESULTS

### Patient characteristics

From March 2021 to June 2021, a total of 40 participants were prospectively enrolled in this study: 20 in the remote MCE group and 20 in the conventional MCE group. The two groups were well matched for age, gender, body mass index and indications for MCE (Table 1).

### Visualization of the stomach and small bowel and safety

Magnetically controlled capsule endoscopy procedures were successfully performed on all the 40 participants with 100% complete visualization rate of the stomach and small bowel in both groups. Table 2 included the results concerning the visualization of the stomach and small bowel in the two groups. Visualization of the gastric mucosa was assessed as complete in the 6 anatomic landmarks in all participants of two groups. The rate of complete small bowel examination of both groups was 100%. No adverse event was observed. Representative images of anatomic landmarks under remote MCE are shown in Figure 3.

### Latency time and gastrointestinal transit times

For latency time of remote MCE group and GI transit times, detailed data are illustrated in Table 2. The median network latency time of remote MCE group was 19.948 ms (17.481–52.363 ms). GTT (57.90 vs. 79.29 min,  $p = 0.433$ ), GET (8.96 vs. 8.92 min,  $p = 0.234$ ) and SBTT (5.53 vs. 4.86 h,  $p = 0.202$ ) were similar between remote MCE and conventional MCE groups. The gastric transit of the capsule under magnetic control was successfully performed on

**TABLE 1** Demographic data and indications for magnetically controlled capsule endoscopy (MCE) examination of enrolled participants in 2 groups

Characteristics	Remote MCE (n = 20)	Conventional MCE (n = 20)	p value
<b>Baseline characteristics</b>			
Age, y	46.35 ± 15.500	42.95 ± 6.428	0.373
Sex, M/F	11/9	12/8	0.749
Body mass index, kg/m <sup>2</sup>	24.25 ± 3.74	23.09 ± 1.63	0.219
History of GI diseases	2	0	0.468
PPI	1	0	>0.999
Smoking history	8	3	0.077
Drinking history	6	3	0.449
<b>Indications</b>			
Abdominal pain or distension	3	8	0.077
Acid reflux	4	2	0.658
Physical examination	12	6	0.057
Others <sup>a</sup>	1	4	0.339

Abbreviation: PPI, proton pump inhibitors.

<sup>a</sup>includes nausea, chronic diarrhea and melena.

12 participants in remote MCE group and 8 participants in conventional group (60% vs. 40%,  $p = 0.206$ ).

### Maneuverability and image quality

Maneuverability and image quality were summarized in Table 2. Maneuverability assessment on comfort and stability of MCE was evaluated as the best in all the participants between the two groups (100%). Fluency of operation was graded as the best in all participants but one in the remote MCE group (scored 4). There was no statistical difference on maneuverability (15.00 vs. 15.00,  $p = 0.317$ ). All images from two groups were graded as clear (1.00 vs. 1.00,  $p > 0.999$ ).

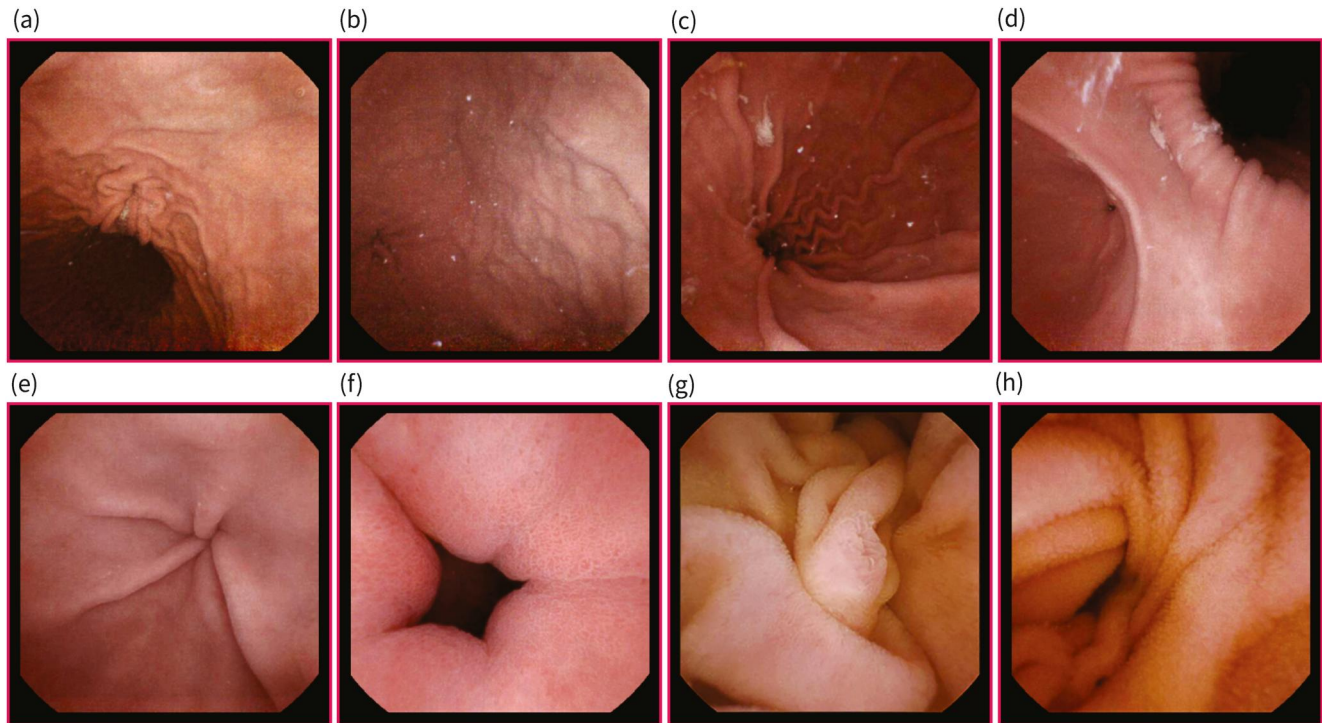
### Diagnostic yields

A comparison of findings identified in two groups is shown in Table 3. There was no difference in the diagnostic yields of positive findings in the esophagus (5% vs. 0%,  $p > 0.999$ ), stomach (55% vs. 30%,  $p = 0.110$ ), duodenum (15% vs. 5%,  $p = 0.598$ ) and small bowel (5% vs. 0%,  $p > 0.999$ ). Typical GI lesions observed under remote MCE are shown in Figure 4.

**TABLE 2** Efficacy analysis between remote magnetically controlled capsule endoscopy (MCE) and conventional MCE

Characteristics	Remote MCE (n = 20)	Conventional MCE (n = 20)	p value
<b>Complete gastric mucosal visualization</b>			
Cardia	20 (100%)	20 (100%)	>0.999
Fundus	20 (100%)	20 (100%)	>0.999
Body	20 (100%)	20 (100%)	>0.999
Angulus	20 (100%)	20 (100%)	>0.999
Antrum	20 (100%)	20 (100%)	>0.999
Pylorus	20 (100%)	20 (100%)	>0.999
Complete small bowel examination	20 (100%)	20 (100%)	>0.999
Complete visualization of stomach and small bowel	20 (100%)	20 (100%)	>0.999
<b>GI transit times</b>			
GET, min	8.96 (5.97-10.05)	8.92 (7.95-13.34)	0.234
GTT, min	57.90 (21.54-95.35)	79.29 (46.50-96.43)	0.433
SBTT, hour	5.53 ± 1.54	4.86 ± 1.71	0.202
Magnetically gastric transit rate	12 (60%)	8 (40%)	0.206
<b>Maneuverability score</b>			
Fluency	5.00 (5.00,5.00)	5.00 (5.00,5.00)	0.317
Comfortableness	5.00 (5.00,5.00)	5.00 (5.00,5.00)	>0.999
Stability	5.00 (5.00,5.00)	5.00 (5.00,5.00)	>0.999
Total	15.00 (15.00,15.00)	15.00 (15.00,15.00)	0.317
Image quality score	1.00 (1.00,1.00)	1.00 (1.00,1.00)	>0.999

Abbreviations: GET, gastric examination time; GTT, gastric transit time; SBTT, small bowel transit time.



**FIGURE 3** Representative images of anatomic landmarks under remote magnetically controlled capsule endoscopy (MCE). (a) gastric cardia, (b) fundus, (c) gastric body, (d) angulus, (e) antrum, (f) pylorus (g) duodenal papilla, (h) small intestine

**TABLE 3** Comparison of positive findings in esophagus, stomach and small bowel

Lesions	Remote MCE (n = 20)	Conventional MCE (n = 20)	p value
Esophageal disease	1 (5%)	0 (0%)	>0.999
Fungal esophagitis	1	0	
Gastric diseases	11 (55%)	6 (30%)	0.110
Inflammation	7	6	
Gastric polyp	3	0	
Ulcer	1	0	
Duodenum diseases	3 (15%)	1 (5%)	0.598
Duodenitis	3	1	
Small bowel diseases	1 (5%)	0 (0%)	>0.999
Small bowel ulcer	1	0	

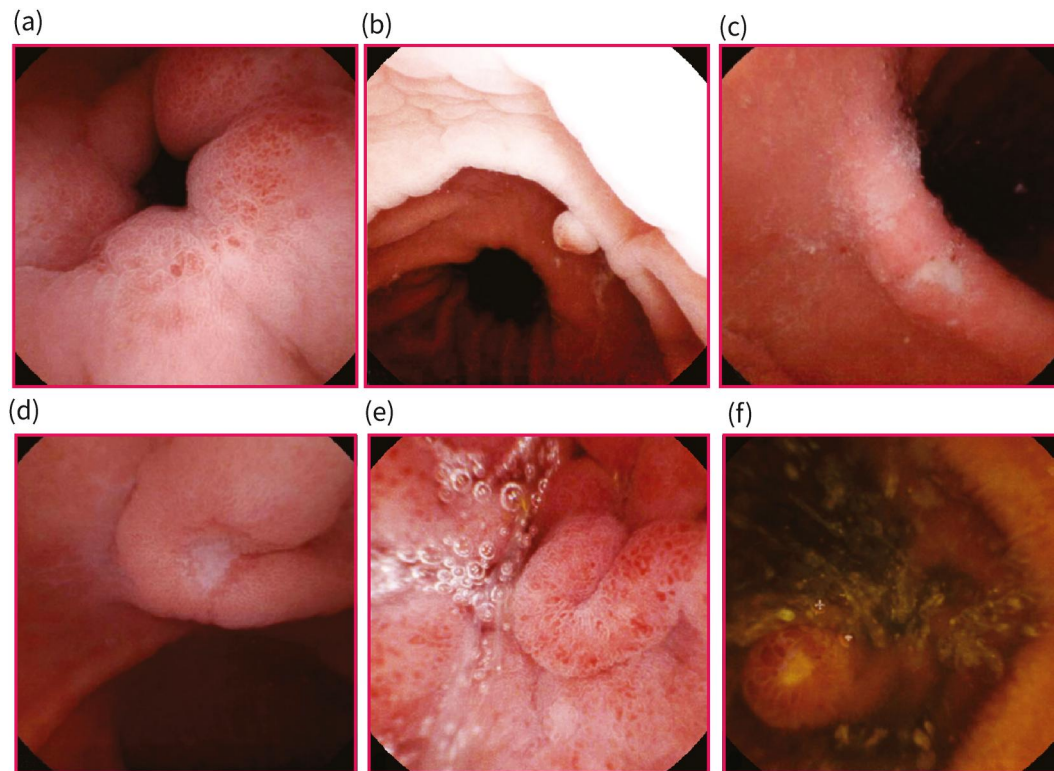
### Awareness and acceptability

According to the questionnaires from the 20 participants in remote MCE group, only 4 participants (20%) were familiar with telemedicine and more than half of the participants (55%) did not know much about telemedicine before this trial. After taking remote MCE examinations, all participants found this novel method acceptable, with 80% of the participants considering telemedicine very necessary and the other 20% considering it necessary.

### DISCUSSION

This pilot study provided an assessment of a novel remote MCE system over the 5G network. Remote MCE examinations were successfully performed on all the participants without any adverse event. To the best of our knowledge, our study is the first trial to evaluate and confirm the feasibility and safety of remote endoscopy for stomach and small bowel examinations.

Owing to technical constraints, real-time remote endoscopy is seldom reported. Several studies have explored the possibility of robotic operation systems based on the conventional colonoscopy.<sup>5,6,21</sup> In 2018, a robot-assisted system named YunSRobot was reported to realize the remote manipulation of gastroscopy for the first time.<sup>7</sup> However, all these robotic systems based on the conventional flexible endoscopes were on the preclinical stage and further studies were warranted. As for capsule endoscopes, a magnetically guided capsule endoscope (MGCE) has also been evaluated and approved to be feasible for gastric examinations,<sup>22,23</sup> whereas the follow-up study demonstrated a limited sensitivity of MGCE for gastric lesions.<sup>24</sup> Recently, Li et al developed a fully automated MCE and mentioned that the examination could be performed remotely after a 5G module was installed.<sup>25</sup> However, the feasibility and safety of remote endoscopy were not evaluated in the research. Besides, as the entire gastric examination was performed automatically, the procedure may preclude an adequate and complete visualization of gastric lesions without the chance of focusing and re-examining a particular area of interest.



**FIGURE 4** Typical gastrointestinal (GI) lesions observed under remote magnetically controlled capsule endoscopy (MCE). (a) gastritis, (b) gastric polyp, (c) gastric angulus ulcer, (d) gastric antrum ulcer, (e) duodenitis, (f) small bowel ulcer

In this present remote MCE system, the remote console can remotely control the capsule movement through remote software, and the remote audio-visual system was an effective bidirectional communication channel for efficient interaction between the two sides. The 5G network with its low latency guaranteed real-time data transmission between the two ends. The median network latency time of remote MCE group was 19.948 ms and the maximum was 229.098 ms. Such a short delay should have no meaningful effect on actual manipulation. Relying on this 5G-based remote MCE system, remote MCE was successfully and safely performed with complete gastric visualization. Subsequent small bowel examinations were also complete in all participants, thus the scope of remote MCE covered the stomach and small bowel. The transit times and maneuverability were similar between two groups. Whether considered from the perspective of visualization of GI tract, image quality, or the diagnostic yields of lesions, the results in this study demonstrated that remote MCE was feasible and could reach a comparable diagnostic efficacy as the conventional MCE. In addition, according to the questionnaire results, this new method of telemedicine was widely accepted and considered necessary by participants.

Our study serves as an important step forward in the endoscopy field of telemedicine and has significance in current medical environment. Firstly, remote MCE offers an effective solution to problems that arise from unbalanced medical resources. Without long-distance transport, GI examinations could be performed on patients in remote areas by experienced endoscopists from major hospitals. In addition to providing access to healthcare for patients,

remote MCE procedures could also offer a new training approach for local endoscopists. Secondly, the current COVID-19 pandemic is causing striking to the conventional endoscopy practice.<sup>26</sup> As the faeces of COVID-19 patients are potentially infectious, both upper and lower GI endoscopies are considered high-risk procedures for disease transmission.<sup>4</sup> Thus, focus has been given to the use of non-invasive or less-invasive diagnostic procedures such as video capsule and radiological imaging.<sup>27</sup> Besides, a significant number of patients are turning to telemedicine because of the high infection risk of COVID-19 and the need for social distancing.<sup>26</sup> To these ends, remote MCE meet the present needs and is expected to exert a long-lasting influence on endoscopy practice in the post COVID-19 era. Thirdly, actual realization of this new technology in clinic is promising. At the patient terminal, a MCE system and an assistant who is familiar with the standardized MCE procedure are essential. The main task of the assistant includes assisting the patient in GI preparation, cooperating with the remote endoscopist during the examination and providing after-procedure instructions to patients. The training of assistants is relatively undemanding in comparison to that of endoscopists. Experienced nurses or local endoscopists who have received training of standardized MCE procedure could be the assistants. In addition, as the devices of the doctor terminal are portable and could be packed into a suitcase, the endoscopist could perform GI examinations anywhere at any time with a 5G wireless network. The high mobility of the doctor-side expands the application scene of remote MCE and provides more convenience for endoscopists.

There were several limitations in our study. Firstly, the current study was a nonrandomized trial with a small sample size. As participants of the two groups were recruited at two different places, randomization was not implemented. The remote MCE group was enrolled in Yinchuan. Whereas, the conventional MCE group was enrolled in Shanghai, because there was no experienced MCE endoscopist in Yinchuan and the design of the same endoscopist for both groups was used to limit subject bias. Further large-sample trials using esophagogastroduodenoscopy as a gold standard are warranted to validate the efficacy of remote MCE. Secondly, there was concern in the practical use of remote MCE. As more than one hospital is involved in the remote MCE procedures, responsibilities need to be clarified in case of medical accidents and disputes. And new technologies, such as artificial intelligence for video reading,<sup>28,29</sup> are expected to be incorporated to decrease workload for endoscopists.

In conclusion, our study demonstrated that the remote MCE system over a 5G wireless network is feasible and safe for remote GI examinations, which has the potential to be widely used in clinic and improve the efficiency of endoscopic diagnosis in remote areas.

#### AUTHOR CONTRIBUTIONS

*Study concept and design:* Zhuan Liao, Jian-Ping Hu and Zhao-Shen Li. *Conduct of the study:* Ting Zhang, Yi-Zhi Chen, Xi Jiang, Chen He, Jun Pan and Wei Zhou. *Acquisition of data:* Ting Zhang, Yi-Zhi Chen, Xi Jiang, Chen He and Jun Pan. *Analysis and interpretation of data:* Ting Zhang, Chen He. *Drafting of the manuscript:* Ting Zhang, Yi-Zhi Chen, Xi Jiang. *Critical revision of the manuscript for important intellectual content:* All authors. *Obtained funding:* Zhuan Liao. *Final approval:* All authors.

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#### CONFLICT OF INTEREST

The authors declared no conflict of interest.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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