

Blinded nonrandomized comparative study of gastric examination with a magnetically guided capsule endoscope and standard videoendoscope

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Background: Passive video capsule endoscopy is the criterion standard for small-bowel exploration but cannot be used for the large gastric cavity. We report the first blinded comparative clinical trial in humans comparing a magnetically guided capsule endoscope (MGCE) and a conventional high-definition gastroscope.

Objective: To assess the potential of gastric examination with a guided capsule.

Design: Blinded, nonrandomized comparative study.

Setting: Single endoscopy center.

Methods: The trial involved 61 patients included in a blinded capsule and gastroscopy comparative study. MGCE examination was performed 24 hours after patients had undergone gastroscopy. To remove food residue or mucus, patients drank 900 mL of water in 2 portions. Then to provide the air-water interface required by the guidance system, they drank 400 mL of water at 35°C.

Results: Visualization of the gastric pylorus, antrum, body, fundus, and cardia was evaluated as complete in 88.5%, 86.9%, 93.4%, 85.2%, and 88.5% of patients, respectively. Of gastric lesions, 58.3% were detected by both gastroscopy and MGCE at immediate assessment and review of recorded data. Capsule examination missed 14 findings and gastroscopy missed 31 findings seen with MGCE. Overall diagnostic yield was similar for both modalities.

Limitation: Pilot study.

Conclusions: Diagnostic results were similar for the 2 methods. After some technical difficulties related to gastric expansion or presence of mucus had been overcome, this study opened a new field for noninvasive gastric examination in countries where high gastric cancer incidence demands a screening tool. (*Gastrointest Endosc* 2012;75:373-81.)

Gastric cancer remains the second leading cause of cancer mortality worldwide. Combatting the disease is a national priority in Japan and other countries of Eastern Asia, and in the West, changes in the gastric mucosa remain an important reason for referral for upper GI en-

Abbreviations: MGCE, magnetically guided capsule endoscope; MRI, magnetic resonance imaging.

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doscopy. Even with the development of nasal insertion,¹ most gastroscopies are performed by using local anesthesia and with some level of sedation. Since 2001 when the U.S. Food and Drug Administration approved video capsule endoscopy for small-bowel examination, it has rap-

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Figure 1. General overview of the guidance equipment: magnetic guidance system and control panel.

idly become the criterion standard in that field.²⁻⁴ Capsules for the esophagus^{5,6} and colon⁷ have subsequently been developed with promising but not yet definitive results.⁸ Examination of the stomach, however, remained a hurdle because of the impossibility of thorough exploration of the gastric cavity with a passive capsule that was propelled only by gastric motility. A magnetically guided capsule endoscope (MGCE) has been designed to fill this gap, providing a new tool that allows noninvasive exploration of the stomach. Availability of a stomach capsule would increase acceptance by patients, could reduce overall costs, and could open up a completely new area for gastric diagnosis. The effectiveness of the new MGCE had to be proved in comparison with high-definition videoendoscopy, which is considered to be the criterion standard for gastric examination. We report the first comparative blinded clinical trial of gastric examination with an MGCE (Fig. 1).

METHODS

Materials

The MGCE was developed in a joint project between Olympus Medical Systems Corporation (Tokyo, Japan) and Siemens Healthcare AG (Erlangen, Germany) to create a prototype device that provides endoscopic visualization of the stomach. Olympus imaging technology has been combined with a guidance system from Siemens that is used to move the capsule in the gastric cavity. The guidance system is not used to move the capsule to the stomach. Passage through the esophagus is obtained simply by gravity and esophageal motility. The Siemens guidance system, based on magnetic technology, was installed in the building used for CT and magnetic resonance imaging (MRI) procedures, next to the endoscopy unit, at the Institut Arnault Tzanck in Saint Laurent du Var, France.

MGCE capsule. The MGCE capsule (Fig. 1) is custom made for observation of the stomach. It is 31 mm long and

Take-home Message

- This study opens a totally new field for noninvasive gastric examination and allows the examiner to see a more physiologic aspect of the stomach (no sedation, no air inflation).
- This type of examination gives details of the gastric mucosal aspect and minute abnormalities not seen with high-definition gastroscopy and could be important for further studies of gastric motility.

11 mm in diameter and equipped with 2 image sensors. The images are captured and recorded at 4 frames/second.

The MGCE capsule is equipped with optics designed to obtain sufficiently high quality images of the relatively larger stomach space, with a wider field of view and deeper depth of field compared with the current small-bowel capsule (Olympus EC Type 1).

In addition, to enable guided and more extensive observation of the stomach, the MGCE capsule contains a permanent magnet. This allows the capsule to be guided inside the stomach by a magnetic field that is applied externally by the guidance system.

Furthermore, because the MGCE capsule has 2 sensors, images from both the forward and backward directions of the capsule movement are shown.

These features are expected to enable effective examination of an organ such as the stomach that has a relatively large luminal area.

As with the small-bowel capsule, the patient is equipped with multiple antennae to record the images from the MGCE capsule. Standard imaging is done in real time. The images from both sensors are displayed simultaneously on 1 monitor of a dual-monitor panel.

Guidance system. The guidance system uses a very low level magnetic field. As a result, in a phantom stomach, it is possible to stop the capsule with minimal force. In a human stomach, that means that the capsule may be trapped by gastric mucus but, on the other hand, avoids dangerous potential hazards such as perforation.

The low magnetic field of the guidance system has a theoretical maximum of 100 mT; for comparison, this is 2000 times greater than the Earth's magnetic field and 15 times smaller than the standard 1.5-T MRI field. The typical magnetic fields used for navigation (3-10 mT) are actually 60 to 200 times greater than the Earth's magnetic field and 150 to 500 times smaller than the 1.5-T MRI field. The low level of the magnetic field means that the equipment does not require a substantial cooling system, and it is very quiet compared with the usual MRI machine. This also reduces the potential side effects for patients with any metallic internal medical device.

MGCE navigation. The practitioner stands in front of the dual monitors (Fig. 2). The right monitor shows the images from both sensors of the MGCE capsule and also

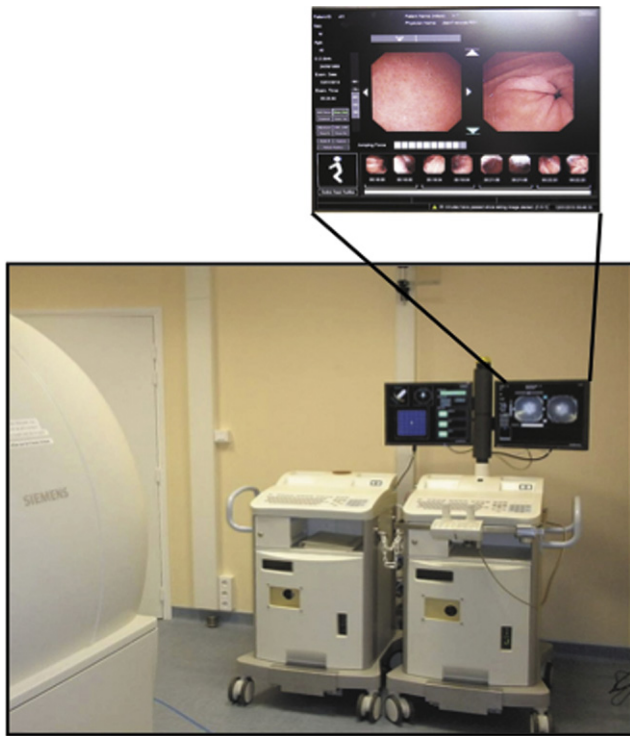


Figure 2. Details of the control panel.

displays the possible capsule maneuvers and settings (forward, backward, rotating, diving, tilting, jumping). The left monitor displays information about the orientation of the MGCE capsule as assessed on the basis of the magnetic field generated by the guidance system. Two joysticks that in effect control the magnetic field applied to the MGCE capsule are in front of the dual monitors (Fig. 2). The physician responsible for guiding the device chooses which screen should be the “active” one for directing the capsule and controls the motion of the capsule by using the 2 joysticks.

Capsule maneuverability. The capsule can be moved with 5 independent mechanical degrees of freedom: 2 rotational and 3 translational (ie, in 3 dimensions). It can be tilted (equivalent to the large steering-wheel movements of an endoscope tip) and rotated (equivalent to the small steering-wheel movements). The tilting command allows the position of the capsule at a fixed point to be oriented. The MGCE can be navigated at a water surface in the stomach or can be made to dive to the bottom of the stomach. When the capsule is lying on the stomach wall, it can be made to crawl, and if the capsule is blocked between gastric folds, it can be dislodged by being made to “jump” (Fig. 3).

Operators’ learning curve. Initially the operators gained in vitro experience in using the technology. The use of plastic “stomachs” with labeled areas and pig stomachs allowed them to understand how the basic handling worked and to become familiar with the possibilities of the guided video capsule. This stage provided information

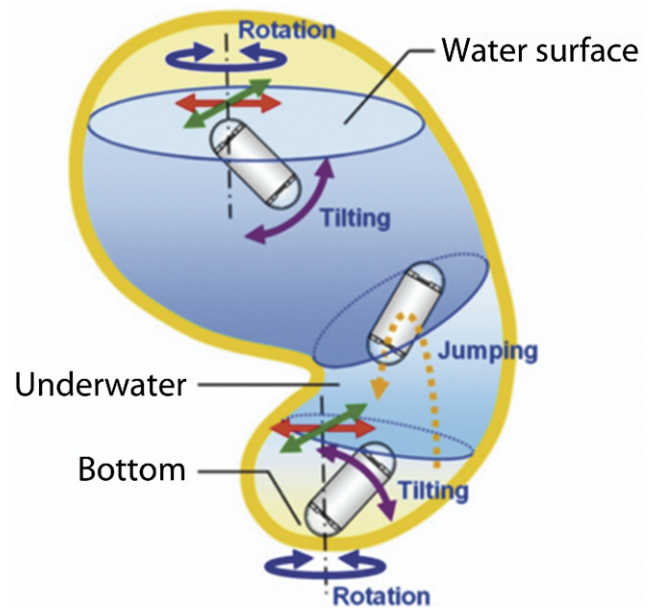


Figure 3. Possible maneuvers of the video capsule by using magnetic guidance.

about the effectiveness of low-level magnetic field guidance and its limitations but also safety for patients. This stage was completed by using simulation software because the practitioners were not familiar with joystick handling. The stage was useful but limited because only the basic functions were tested.

To complete our learning curve, before the beginning of this comparative trial, 24 patients had been included in a pilot study.⁹ In this pilot study, the capsule operators were aware of the gastroscopy findings and tried to identify the known lesions by using the capsule. Initially, because of the unfamiliar appearance of the uninflated stomach, it was difficult to identify some structures, such as the closed cardia.

Patients

Patients with indications for upper GI examination, of ages ranging from 18 to 75 years, were enrolled for capsule examination. All had been given written information about the capsule endoscopy procedure and had signed a consent form. Approval for the study had been obtained from the Nice Hospital Ethics Committee (Comité de Protection des Personnes no. 09.041, November 2, 2009 and Agence Française de sécurité sanitaire des produits de santé no. 2009-A00714-53, November 19, 2009). The exclusion criteria included all clinical conditions that might involve potential hazards (impaired bowel movement from ileus or organic digestive diseases, previous digestive tract surgery, poor general condition, pregnancy). They also included the exclusion criteria for standard MRI examinations, in particular, the presence of surgical metallic devices, even though technically the low magnetic field would not interfere with such devices.

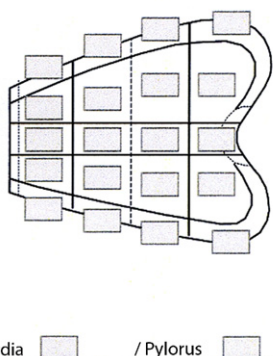
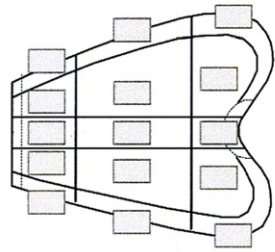
Observation area C : complete / I : incomplete / M : impossible exploration	Observed lesions / comment
 <p style="text-align: center;">Cardia <input type="checkbox"/> / Pylorus <input type="checkbox"/></p>	<p>[1] Atrophy [2] Bleeding [3] Erosion [4] Inflammation [5] Polyp [6] Ulcer [7] Others: _____</p> 

Figure 4. Report sheet for data collection.

Gastroscopy

High-definition gastroscopy was performed at least 1 day before the MGCE examination by an examiner who would not be performing MGCE on the same patient. If necessary, biopsy specimens were obtained.

MGCE

Clinical protocol. Gastric examination with the MGCE was performed by using the following protocol. After overnight fasting, patients drank 500 mL of clear water at room temperature. One hour later, they drank another 400 mL of clear water at room temperature. This was followed by light exercise for approximately 15 minutes to obtain a clean stomach. Then patients drank another 400 mL of clear water at near body temperature (35°C). This was done to provide enough space in the stomach for capsule navigation, with the creation of an air-water interface. At that point, image-receiving antennae were attached to the patient's body, and the patient was settled inside the magnetic guidance system. The patient's position on the table was predetermined to allow for optimal gastric imaging and maximal effect of the magnetic force for capsule navigation. Capsule imaging was initiated, and the patient ingested the capsule in a sitting position before lying down in the guidance system when the capsule had reached the stomach by gravity and esophageal motility. No drugs were used to modify gastric motility.

MGCE examination. At the beginning of the examination, the position of the patient was left lateral; this was then changed to supine and finally right lateral. When it was difficult to move or navigate the capsule in a particular position, the patient was moved into another position. If necessary, additional water was ingested during the examination to create optimal conditions because the MGCE requires an air-water interface for guidance. The MGCE examination was conducted by the 2 main operators (I.P,

J.-F.R) who were blinded to the results of gastroscopy. The visualization of the gastric surface in the antrum, body, and fundus and identification of the 2 well-known landmarks of the cardia and pylorus were checked by the examiners.

Data analysis and evaluation of outcomes. Overall evaluations of the quality of stomach visualization, including all stomach areas, were documented immediately on a detailed report sheet by the operator (Fig. 4). The examiner assessed these subjectively. Examination time and abnormal findings were also recorded. The capsule recordings were then reviewed by the operator immediately after the capsule examinations. All data recordings were minutely reassessed by the panel of other physicians who were also blinded to the gastroscopy findings. This step helped to avoid duplicate counting of capsule findings. Later on, in case of unclear description of abnormalities, all data were reviewed and assessed jointly to ensure a homogeneous analysis. Acceptability to patients was assessed by means of a questionnaire, with ratings on a scale of 0 to 10, completed in the recovery room immediately after capsule examination.

The main outcome parameters were the percentage of patients in whom there was complete visualization of the gastric surface in the antrum, body, and fundus and identification of the cardia and pylorus. Secondary outcomes were examination time and the percentage of abnormal findings seen on gastroscopy that were reproducible by capsule endoscopy and vice versa. All statistical analyses were done on a per-protocol basis.

RESULTS

The main indications for gastroscopy were epigastric pain and/or reflux symptoms. Seventy-one patients were enrolled for the comparative blinded study, and examina-

tions were completed in 61 patients. Concerning the 10 patients who did not complete the trial, 1 patient was unable to swallow the capsule (because of previous ENT carcinoma), 1 patient began to vomit, and 8 patients did not wish to undergo a new procedure with a magnetic machine after reading the detailed patient information form. Thus, 61 patients (39 men, 22 women; mean age 52.7 years, range 21-75 years), eventually completed the study. The capsule was swallowed and water ingested (overall volume 1300 mL as described in the protocol) without any problem in all cases except 2. A few patients ($n = 5$) needed to drink additional water at body temperature to keep the stomach distended. No technical defect occurred, and we were able to analyze completely comparative examinations in the 61 patients. No premedication was given or thought to be necessary by any of the patients. On follow-up, 1 patient had temporary abdominal pain, which subsided spontaneously and has not recurred. In another patient, left lower quadrant pain was finally related to recurrent sigmoid diverticulitis.

The capsule could be maneuvered at the water surface or made to dive to the bottom of the stomach (Fig. 3). On close-up view, the mucosal pattern could be seen clearly as it was magnified because of refraction by the water and the fixed-focus imaging (Fig. 5). Results of complete visualization of the different parts of the stomach are shown in Table 1. In summary, visualization of the gastric pylorus, antrum, body, fundus, and cardia was thought to be complete in 88.5%, 86.9%, 93.4%, 85.2%, and 88.5% of patients, respectively. Incomplete gastric visualization was caused by resistant mucus in 7 patients, excessive gastric motility in 2 patients, early pyloric passage of the capsule in 4 patients, and incomplete distention of gastric walls in 2 patients (Fig. 6). Capsule examination was achieved in a mean total examination time of 17.4 minutes (range 9.9-26.4 minutes) versus 5.3 minutes (range 4.4-6.3 minutes) for conventional gastroscopy. Capsule endoscopy examination time decreased with increasing skill in navigation but also as new knowledge was gained of gastric aspects such as a previously unfamiliar appearance of the lesser curve or closed cardia.

The results of blinded capsule endoscopy and conventional gastroscopy with regard to pathological findings are shown in Table 2. A total of 108 pathological findings were detected. Of these, 63 were identified at both conventional gastroscopy and capsule endoscopy: there were 44 cases of diffuse inflammation or erosion, 8 polyps, 3 ulcers, 4 cases of atrophy, 2 cases of antral metaplasia, 1 case of external compression, and 1 case of fundic varices. Gastroscopy detected 14 additional lesions not identified at capsule endoscopy: 2 polyps, 1 case of inflammation, 2 angiodysplasias, 2 ulcers, 2 cases of atrophy, 1 case of important bile reflux, 2 cases of hypertrophic folds, and 2 of antral metaplasia. On the other hand, 31 lesions were detected only by capsule endoscopy and missed by conventional endoscopy: 11 polyps, 10 cases of inflammation,

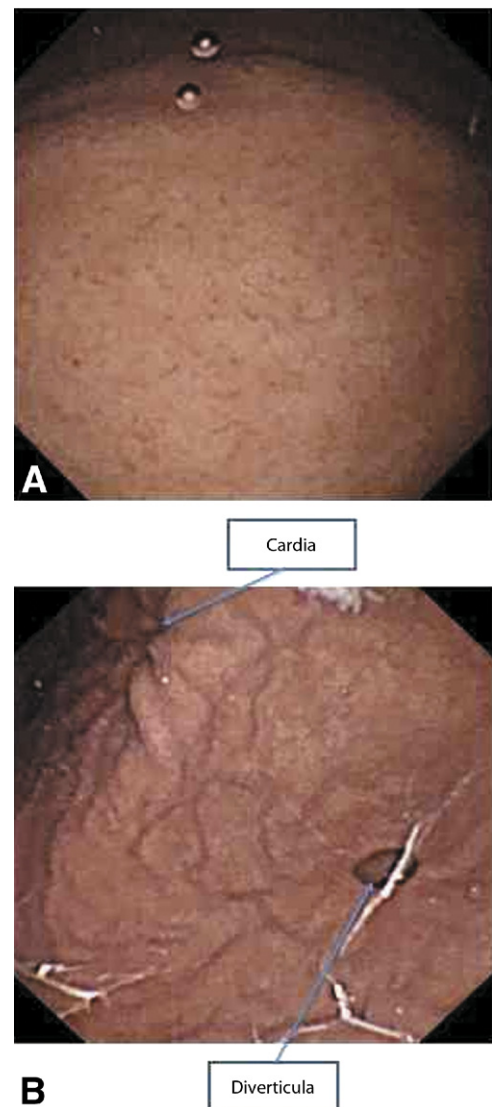


Figure 5. Capsule images. **A**, Front sensor (*left*): detail of fundus mucosa. **B**, Rear sensor (*right*): fornix and closed cardia with diverticula.

1 angiodysplasia, 5 ulcers, 1 metaplasia, 2 bleeding lesions, and 1 hiatal hernia.

DISCUSSION

Since early 2000, capsule endoscopic examination has become increasingly attractive to both patients and physicians. It is now the criterion standard for small-bowel examination,¹⁻³ and attempts have been made to extend the clinical indications to the esophagus^{4,5} and colon,^{6,7} with encouraging results. However, because of the large size of the gastric cavity, complete gastric examination with a passive capsule seemed impossible. Thus, the steering of capsule endoscopes has been a matter for intensive research,¹⁰⁻¹² and, in fact, a self-experiment by the capsule pioneer Paul Swain was recently reported.¹³ Although it is too early to assess the overall clinical benefit of MGCE

TABLE 1. Results for complete visualization of the stomach

Gastric area	Complete visualization, 61 patients	
	No.	%
Cardia	54	88.5
Fundus	52	85.2
Body	57	93.4
Antrum	53	86.9
Pylorus	54	88.5

compared with traditional endoscopy, this is the first clinical study to carry out a blinded comparison of conventional gastroscopy with MGCE in patients with gastric pain. It represents a first crucial step in defining the potential of gastric examination with MGCE and assessing and overcoming the technical difficulties.

Patient position

To obtain a complete stomach examination, it was important to move the patient from one position to another, allowing the water to fill the different gastric areas and facilitate MGCE movements. Patients were initially in the left lateral position, where, in most cases, the cardia, fornix, fundus, and part of the antrum were visible; this part of the examination generally took approximately 10 minutes. The patient was then moved to a supine position for a more complete examination of the fundus and antrum. The right lateral position was useful only for obtaining the general and close-up appearances of the antrum and pylorus, but in many cases, it was also possible to navigate the MGCE back to the cardia. The magnetic steering function does not depend on patient position, but changing the position is needed to fill each part of the stomach with water; this facilitates navigation, just as a submarine capsule needs to be in water for its movement to be guided.

Gastric visualization

The first challenge was the identification of gastric anatomic structures because the MGCE records appearances with the device in various positions and without insufflation of the stomach. The capsule movement differs from that of the conventional endoscope because capsule guidance allows rotation in 4 directions with 2 views provided simultaneously from the sensors at each end of the capsule. Traditional gastroscopy is simpler with the examination done in the forward direction in a distended stomach or in retroversion for observation of the cardia, fornix, or fundus. MGCE gives an excellent new panoramic view of the lesser curve (Fig. 7). This is one of the main advantages when the MGCE is made to dive near the greater curve in

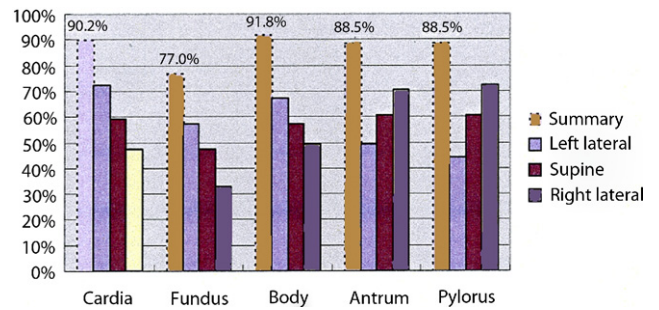


Figure 6. Proportion of complete observations in each stomach area.

TABLE 2. 108 lesions diagnosed at magnetically guided capsule endoscopy (MGCE) and EGD

Finding	MGCE only	EGD only	Both EGD and MGCE
Polyps	11	2	8
Inflammation/erosion	10	1	44
Angioma	1	2	0
Ulceration	5	2	3
Atrophy	0	2	4
Important bile reflux	0	1	0
Hypertrophic folds	0	2	0
External compression	0	0	1
Fundic varices	0	0	1
Metaplasia	1	2	2
Bleeding	2	0	0
Hiatal hernia	1	0	0
Total	31	14	63

MGCE, Magnetically guided capsule endoscopy.

front of the angulus, giving an overview of the lesser curve anatomy for diagnosis and orientation. The fundus and antrum are easy to assess in a larger or close-up view. The well-established differences in mucosal pattern were also a major aid to navigating the capsule. Although the pylorus was easily identifiable, one needs to be aware that a cardia that is closed or only slightly open most of the time presents an unfamiliar aspect on capsule visualization. In conventional endoscopy, this landmark is easily visible, seen in retroversion with the gastroscope going through the cardinal orifice.

Gastric motility was another difficulty because capsule forces were too low to counteract gastric movements. This was especially notable on the antrum where strong gastric contractions did not allow navigation to the area of the pylorus. In a few cases, there was the opposite problem



Figure 7. Capsule image: overview of the gastric fundus.

when antral motility moved the capsule forward to the duodenal bulb. To give another example, it was impossible to get through the pylorus by using the MGCE forces. When the MGCE passed spontaneously through the pylorus, it could not be navigated back into the stomach. On the other hand, because the MGCE did not interfere with gastric motility, during the MGCE examination, we were able in 2 patients to assess clear and strong fundal gastric contractions that were uncomfortable to the patient. This is a totally new field for studying gastric motility disorders. MGCE might be used to investigate this field because the current technical possibilities are limited.

Image quality

Compared with conventional endoscopy, the video capsule images are closer to those provided by the endoscopes without high definition that were marketed in the early years of this century. The brightness needs to be improved to extend the depth of field, but close-up views show excellent details of the gastric mucosal pattern. In some cases, there was a foggy appearance at the beginning of examination, but this rapidly disappeared, allowing a clear view of the gastric cavity. In some examinations, oral mucus stuck to the front of the MGCE lens; it was possible to remove it by using capsule movement or a special “capsule-shaking” command, but it remains the most important drawback.

Diagnostic yield of MGCE compared with gastroscopy

At this stage, high-definition gastroscopy remains the criterion standard for gastric examinations because use of the capsule could not provide complete visualization (Table 1). Only 58.3% of gastric lesions (63/108) were detected with both modalities. This result is very positive for a first human trial and encouraging for further technical improvement. Moreover, some results of this first trial

were particularly unexpected. As we considered high-definition endoscopy to be the criterion standard for gastric examination and that the guided capsule was an early prototype, the number of missed diagnoses with use of the capsule was the main point of this trial. As shown in Table 2, this occurred for 14 findings. But, more surprisingly, the number of findings observed only with the capsule, as many as 31, was even more notable. In all cases, these numbers do not have important clinical consequences as they relate to multiple benign gastric polyps or angiomas.

The greater detection of minute lesions, such as a small hyperplastic polyp and angioma, by the capsule compared with conventional gastroscopy might be linked to the length of the examination; this was longer with the capsule as we were testing our guidance ability. In our study, high-definition gastroscopy was done in less than 6 minutes compared with more than 18 minutes for capsule examination. Because 1 of the capsule sensors almost touches the gastric mucosa, this could explain the high percentage of minute lesion findings during capsule examination. Focusing on the details of the findings, the major discrepancy between the 2 methods relates to findings of inflammation/erosion. At this stage, we can only suggest 2 reasons for this: the capsule technology and examination length, as just mentioned, but also bias linked to the sequence of the examinations in the protocol. During a previous gastroscopy, minute trauma could have occurred, and also antral biopsies were performed in 31 patients to assess *Helicobacter pylori* status; the latter procedure induces macroerosion. However, for the main diagnostic outcomes in this trial, gastroscopy and MGCE gave very similar results.

Overall assessments

After operators had acquired their initial learning experience, the overall maneuverability of the capsule was impressive. Of course, improvements are required; in particular, an increase in magnetic force is needed to get a closer and steady position in relation to the cardia or to pass through the pylorus in both directions. Gastric folds are not usually a problem because of the jumping command and the possibility of moving the capsule at the water surface or in a diving position. The current design of the joystick also needs to be improved so that it looks more like a flight simulator joystick. The comparative study of gastroscopy and capsule examination was made possible by immediate documentation of findings by using the Japanese endoscopic reporting method. This allows very accurate assessment of each part of the stomach examination and also precise location of any abnormality. Furthermore, all recordings of capsule images were reviewed immediately by the physician, and later on, gastroscopy and capsule images from each patient were re-inspected, in particular, to check the differences in findings between the gastroscopy and capsule procedures (Table 2). The recording and review of images were part

of the planned protocol. It is important to emphasize that gastroscopy, which is considered to be the criterion standard, can miss some lesions as is already well accepted with regard to colonoscopy.¹⁴

Patient acceptability

Whether considered as a major factor in acceptance of digestive tract examination or as a minor issue from a medical point of view, the high level of patient acceptability in this study is based on the absence of sedation and its drawbacks (such as fear of anesthesia or the inability to drive or work on the day of the procedure). Even with the development of less uncomfortable gastroscopy examinations, by using various types of sedation or ultrathin gastroscopes for nasal insertion, acceptability to patients and their compliance in the case of repeated examinations need improvement. It should be noted that in this trial, all gastroscopies were done with propofol sedation. Even though currently the time for capsule examination is longer than that for gastroscopy, the acceptability of the noninvasive MGCE was very high. This noninvasive method of gastric examination is of particular potential importance in countries where the use of a gastric screening tool is essential because of the high incidence of gastric cancer.

Adverse effects

Impaction or retention may be a concern with capsule gastroscopy, as it has been with capsule endoscopy in general. Reports in patients, mostly with obscure bleeding, have described a low risk.^{15,16} In our trial, it could be speculated that temporarily obstructed passage was the cause in 1 patient of pain that subsided spontaneously after some hours. Further studies will show what the overall risk of capsule gastroscopy will be; it may seem wise, for the time being, to exclude from initial trials those patients with suspected or known strictures and perhaps those with previous small-bowel surgery. In our trial, only 1 patient was unable to swallow the capsule and another started vomiting after ingestion of still water at 35°C.

Study limitations

Technical limitations. The first requirement for MGCE capsule examination is to obtain a clean stomach distended with still mineral water. In most cases, the amount of mucus remained minimal. Impaired visualization caused by gastric mucus or remaining debris in the water could be overcome by changing the patient's position or in a few cases by ingestion of more water. Nevertheless, gastric mucus reduced capsule navigability in 7 patients. The removal of mucus by drugs will need further research because it is a critical issue with regard to capsule navigation and visibility. When the capsule was lodged between folds on the gastric wall, we could move the capsule by using the jumping and floating functions.

Ingestion of a large amount of water. The ingestion of the large amount of water that was required was well tolerated by the patients, but in a future study, we intend to reduce, by means of gastric cleaning, the amount of liquid required. On the other hand, an air–water interface is required for navigation of the capsule. Of course, this will limit the use of the MGCE in elderly patients or in those with esophageal disorders, but, on the other hand, regarding patient acceptability, 59 patients showed a clear preference for capsule examination, 2 found both procedures equally acceptable, and none preferred conventional gastroscopy.

Protocol limitations. For reasons of patient safety, at the request of the Comité de Protection des Personnes, in this trial it was decided not to randomize the order of the 2 gastric examinations; therefore, it is possible that the capsule detected minute erosions caused by the gastroscopy that had been performed the previous day. To clarify this important consideration, we should conduct a future evaluation with a different protocol in which the capsule examination is performed before the gastroscopy.

We should emphasize that capsule findings were not only diagnosed immediately but also by review of the recorded data by using reading software; this could explain the high number of hyperplastic polyps or minute erosions detected by the capsule, given that the overall time for diagnosis was much longer than for conventional gastroscopy. Further clinical studies should also include high-definition gastroscopy with new technological enhancements such as narrow-band imaging.

Future outcomes

The development of capsule technology is also well adapted to the limited resources for gastroenterology in the future in most countries. When images are recorded and then analyzed by using software that reduces the reading time, future capsule examinations could be performed by nurses or assistants with the practitioner simply reading the recordings. This is an important point, especially if this technology is applied in a screening program for early gastric cancer such as the one in Japan. Since the completion of this trial, Swain et al¹³ published a report on a magnetically maneuverable capsule limited to 1 volunteer examination. The maneuverability of the capsule was monitored by using a gastroscope.

Financial perspectives

When this new technology is widely used, the cost of the capsule will decrease, as has happened for example with digital cameras. However, an initial investment in the magnetic guidance system will be needed; this will be similar to the relatively low cost of the machines recently introduced for low-field or extremity MRI in rheumatology. For endoscopists, it also entails a new business model and a new way of organizing work, similar to those applied by radiologists for MRI and CT scanning. At the

current stage, the costs of sedation and of the use of the endoscopy suite are saved. The indirect costs of the patient's being unable to drive or to work normally on the day of the gastric examination are also avoided. The inconvenience of gastroscopy, with the need for sedation and loss of normal activity for 1 day as well as fear of pain itself will lead to reluctance to undergo the examination, so that diagnosis is delayed with consequent poor prognosis. Patients will not have the same hesitation about a less-invasive examination; this will help with early detection and better prognosis. MGCE might also be a more cost-effective use of medical and social resources.

CONCLUSION

The first human trial of gastric examination with a guided capsule opens a new field for digestive endoscopy. It represents 1 new possibility among many others for minimally invasive gastric examination techniques. Technical improvements are required, but the manipulation of the current device was easier than expected. Physicians need to be trained in this new modality of gastric examination and would need to learn about various image appearances that are sometimes different from those obtained with conventional gastroscopic imaging.

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