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Feasibility of stomach exploration with a guided capsule endoscope

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Background and study aims: Video capsule endoscopy has been established in diagnosis of small-bowel disease and has been evaluated for esophageal pathology and recently for colorectal diagnostics. Gastric capsule endoscopy has not hitherto been feasible due to the stomach's large surface area and volume. We present the first application of a magnetically navigated capsule in the human stomach.

Patients and methods: 29 volunteers and 24 patients (men 42, women 11; mean age 47.5 years) were included in a feasibility study. Low-level magnetic fields were used to maneuver the double-sensor video capsule within the human stomach with an air-water interface provided by ingestion of 1300 ml water within 1 hour before examination. Visualization of all parts of the stomach was attempted; time for visualization was recorded, and a subjective assessment of completeness of visualization was documented.

Results: There was technical failure in one individual; thus technical success rate was 98 %. In the 52 remaining cases, examiners assessed that the antrum, body, fundus, and cardia were fully visualized in 98 %, 96 %, 73 % and 75 %, respectively. Mean duration of examinations was 30 minutes (range 8 – 50), with a longer time (mean 37 minutes) for volunteers for study reasons. In total, 30 findings were identified: 14 were detected by both gastroscopy and capsule, 10 lesions were identified by guided capsule examination only, 6 by gastroscopy only. No significant capsule-related adverse events occurred.

Conclusion: Magnetically navigated video capsule endoscopy appears to be feasible and sufficiently accurate for gastric examination. It may permit endoscopic examinations that are more patient-friendly and without sedation. Comparative studies are under way.

Introduction

Video capsule endoscopy (VCE) is considered to be a standard examination in small-bowel diagnostics, especially in cases of obscure bleeding [1 – 3]. Expanded indications using special capsules for esophageal and colonic applications have been evaluated [4 – 10], but their final value has not yet been established. Gastric examination by video capsule endoscopy has however been considered unfeasible, since visualization of the entire stomach appeared to be impossible and would require a steerable capsule. Capsules that can be steered by means of magnets have been reported in model and animal trials [11 – 13] and, recently, in one volunteer [14].

We now report the first use of a magnetically steerable capsule in a human series including both volunteers and patients, where low-intensity magnetic fields were used to maneuver a double-sensor video capsule within stomachs distended by ingestion of water.

Patients and methods

The magnetically navigated video capsule endoscopy project was jointly developed by Olympus Medical Systems Corporation and Siemens Healthcare; a prototype was built for endoscopic examination of the stomach that included an Olympus capsule endoscope and Siemens magnetic guidance equipment for interactively moving the capsule in the gastric cavity. The Siemens guidance system was installed in the building used for computed tomography (CT) and magnetic resonance imaging (MRI) next to the endoscopy unit at the Institut Arnault Tzanck, Saint Laurent du Var, France.

Fig. 1 General overview of equipment for guided capsule endoscopy (GCE).

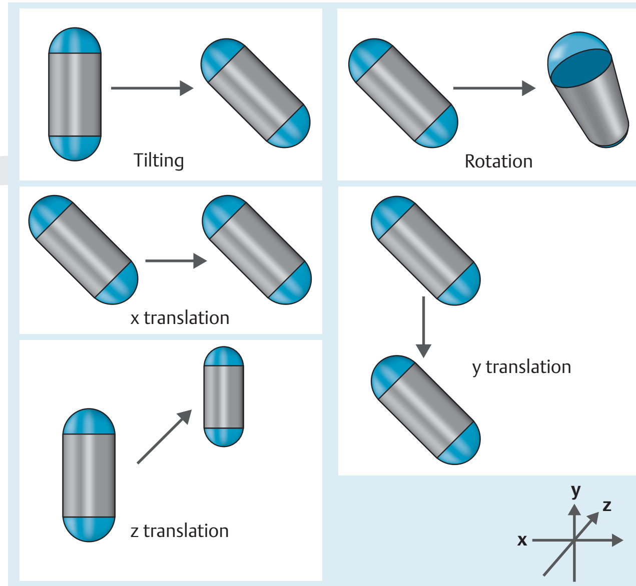

Fig. 2 The capsule can be magnetically steered with five mechanical degrees of freedom (translation in three dimensions, and rotation and tilting).

Guidance system and capsule

The magnet of the guidance system (**Fig. 1**) has a footprint of 1 m × 2 m and generates dynamic magnetic fields and field gradients in three-dimensional space over the entire stomach.

The magnetic field produced is of very low intensity (scores of times smaller than that used for MRI). Thus the potential side effects are lower compared with those of MRI. For example, the capsule may be temporarily trapped between the gastric folds of the human stomach; potential adverse effects for the patient such as heating are avoided. The system works silently, in contrast to conventional MRI machines.

The capsule is 31 mm long and 11 mm in diameter, and has two image sensors that use a charge-coupled device (CCD). Images are visualized and transmitted at 4 frames/sec. As with previous capsule versions, images are recorded by means of multiple antennas attached to the patient.

In real-time gastric imaging, the images from both of the two sensors are displayed simultaneously on a dual-monitor panel, with one screen for each sensor. The panel also indicates the possible maneuvers and settings for moving the capsule (forward, backward, diving, tilting, or "jumping"). The physician responsible for guiding the device can choose which should be the "active" screen for directing the capsule, and controls the motion of the capsule using two joysticks.

Depending on the navigation required, one of the two sensors is chosen for direction of the movement of the capsule. As shown in **Fig. 2**, the capsule can be moved with five independent mechanical degrees of freedom; it can be tilted (equivalent to the large steering-wheel movements of an endoscope tip); and it can be rotated (equivalent to the small steering-wheel movements of an endoscope tip). The tilting and rotation command allows orientation of the capsule at a fixed point.

The surface of the water in the stomach is used to get a baseline position for the capsule, which can then be steered in any direction, including those that are underwater.

Procedure

Patients were enrolled for capsule examination 24 hours after gastroscopy.

The patient or volunteer drank about 500 ml of clear water at body temperature about 1 hour before the procedure, followed by 400 ml of tap water and another 400 ml clear water at body temperature within 15 – 20 minutes; this was to create an air-water interface in the stomach immediately before capsule ingestion.

The participant was then asked to lie down on the table of the guidance equipment. The position of the table in relation to the scanner was predetermined to allow for optimal gastric imaging and maximal magnetic force for capsule navigation. At the beginning of the examination the position of the patient/volunteer was left lateral; this was then changed to supine and finally right lateral. When it was difficult to move or navigate the capsule with a particular position, the participant was turned around to another position or might sometimes even lie prone. If necessary, additional water was ingested to create optimal conditions for examination since the capsule requires some water volume for navigation.

The physician responsible for guiding the capsule used the real-time images and the maneuverability information and settings displayed on the dual-monitor panel to navigate the capsule using the two joysticks.

Follow-up of volunteers and patients was done by telephone after a mean of 30 days, to exclude any adverse events.

The main outcome parameters were percentage of patients in whom there was full visualization of the surface of the antrum, body, and fundus/cardia as judged subjectively by the examiner, the examination time, and the percentage of findings in patients seen on gastroscopy that were reproducible by capsule endoscopy. Assessment was done by the operator (I.P, J.F.R) immediately after the capsule examinations and then reviewed jointly with the one or two co-author physicians present; no blinding with regard to patients was attempted in this pilot trial.

Ethical considerations

The study was approved by the Nice Hospital ethical committee (Comité de Protection des Personnes [CPP] no. 09.041, November 2, 2009), and all participants gave their signed informed consent. Institutional review board (IRB) approval allowed for 55 patients and volunteers to be included in the study.

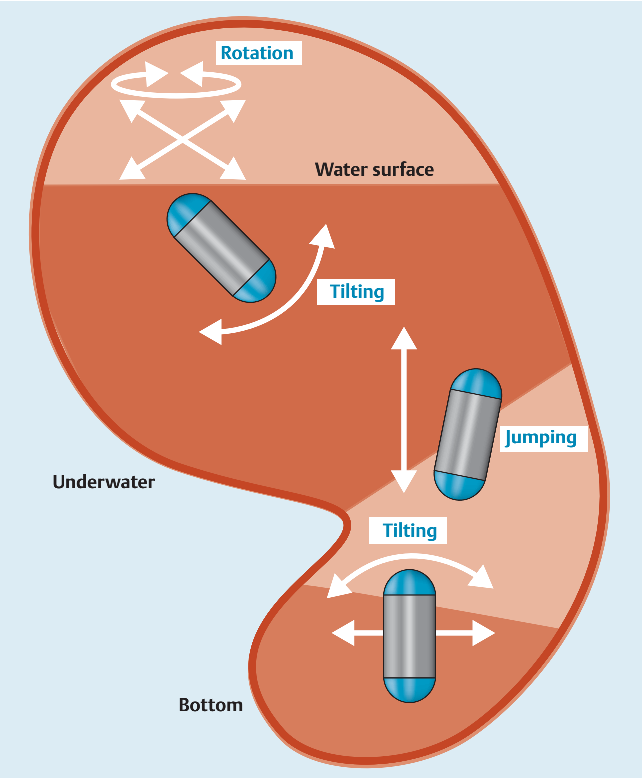

Fig. 3 Possible maneuvers of the video capsule using magnetic guidance.

Fig. 4 A close-up gastric view with guided capsule endoscopy (GCE).

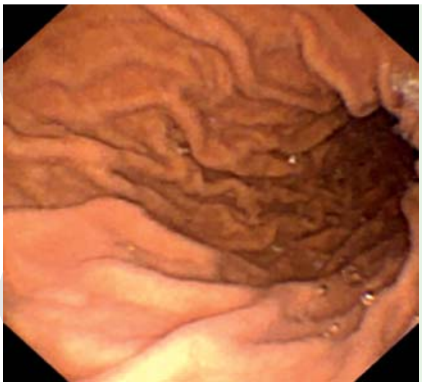

Fig. 5 General appearance of the gastric lesser curvature and body with guided capsule endoscopy (GCE).

Fig. 6 Antral appearance with pylorus seen distally at guided capsule endoscopy (GCE).

Results

The study included 29 volunteers (men 23, women 6; mean age 42 years, range 24 – 60) and 24 patients (men 19, women 5; mean age 52 years, range 25 – 74). Among the patients the indications for gastroscopy were epigastric pain and/or reflux symptoms.
No premedication was given or felt to be necessary by any of the patients or volunteers. Water ingestion and capsule swallowing could be done without any problem in all cases. The standard volume of 1300 ml as described in the methods section was enough for navigation; only a few patients needed to drink small amounts of additional fluid.
Technical defects prevented adequate visualization in one case, so the following results are calculated on the basis of the remaining 28 volunteers and 24 patients.
None of the gastric examinations required any medication. On follow-up one patient had temporary abdominal pain which subsided spontaneously and has not recurred since. 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**).
In close-up view the mucosal pattern could be seen clearly, as it was magnified because of refraction by the water and because of the fixed-focus imaging. When the capsule was stuck between folds on the gastric wall, we could dislodge the capsule by using the "jumping" function. When gastric mucus and remaining debris impaired visualization, this could mostly be overcome by turning the patient and by their swallowing more water. **Figs. 4 – 6** are examples of the images obtained.
Results for 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 subjectively assessed as complete in 96 %, 98 %, 96 %, 73 %, and 75 % of participants, respectively. This was achieved in a mean total examination time of 30 minutes (range 8 – 50). For study reasons, the mean time was longer in volunteers (37 minutes, range 21 – 50) than in patients (21 minutes, range 8 – 30). In three cases incomplete visualization was due to resistant mucus, and in two cases each it was due to excessive gastric motility and early pyloric passage of the capsule.
Regarding pathological findings, the results of unblinded capsule endoscopy and conventional gastroscopy were as follows. Of the 30 pathological findings detected, 14 were identified by conventional gastroscopy and reproduced by capsule endoscopy, comprising 11 cases of diffuse inflammation or erosions, 1 angiodysplasia, 1 diverticulum, and 1 hiatal hernia. Gastroscopy identified 6 additional lesions not found at the capsule examination: 3 cases of inflammation, 2 of atrophy, and 1 of hypertrophic folds. On the other hand, 10 lesions were detected only by capsule endoscopy and missed by conventional endoscopy, comprising 1 polyp, 3 in-

Stomach area	Complete visualization					
	Volunteers n = 28		Patients n = 24		All participants n = 52	
	n	%	n	%	n	%
Cardia	22	78.5	17	71	39	75
Fundus	20	71	18	75	38	73
Body	28	100	22	92	50	96
Antrum	28	100	23	96	51	98
Pylorus	28	100	22	92	50	96

Table 1 Results of gastric magnetically guided capsule endoscopy with regard to visualization of different parts of the stomach. The operators estimated whether or not each area in each participant had been completely visualized. One case with technical difficulties was excluded from calculations.

flammations, 1 angiodysplasia, 3 ulcers, 1 important bile reflux, and 1 hypertrophic fold.

Discussion

Capsule endoscopy has fascinated both physicians and patients from its introduction in 2000, and since then indications for small-bowel diagnostics have been established [1 – 3]. From the very beginning, attempts have been made to use capsule endoscopy for other indications such as esophageal diagnostics [15], with the establishment of esophageal capsule endoscopy in clinical routine [16, 17] being still awaited. Expansion of indications to the stomach has not been possible – in contrast to the colon [10] – since in the larger space of the gastric cavity spontaneous capsule passage does not provide enough information. Thus, steering of capsule endoscopes has been a matter of intensive research [11 – 13], and finally, a self-experiment by the capsule pioneer Paul Swain has recently been reported [14].

Our study uses a new capsule and new magnetic steering technology, developed cooperatively by Olympus and Siemens. Furthermore, it is the first systematic pilot series in a substantial number of volunteers and patients, the latter with mostly minor gastric disease. Although it is clearly too early to assess the overall clinical benefit of capsule relative to traditional gastroscopy, the potential of capsule gastroscopy was clearly demonstrated in this trial, with regard to feasibility, with high rates of gastric visualization and demonstration of (known) lesions, and safety. Two patients had symptoms; in one this was possibly linked to capsule passage, and in the other patient another cause was found (diverticulitis) which was unrelated to capsule endoscopy.

The first difficulty was identification of gastric anatomical structures, as capsule images are obtained with the patient in various positions whereas traditional endoscopies are performed using one position. Capsule endoscopy mostly provided an excellent panoramic view of the lesser curvature, while visualization of the cardia proved to be difficult initially as we are used to looking closely at the cardia in inversion with an endoscope keeping the cardia slightly open. On capsule endoscopy, the cardia was closed in most cases and difficult to approach, and hence identification of detailed structures was often impossible, even if some overview was provided. During our learning phase, we improved our navigating ability in order to assess the fundus and cardia region. One limitation of our pilot study was that assessment of completeness of visualization was done by the examiners and not by independent personnel, let alone with the use of an objective measurement (which is difficult anyway), thus giving rise to some form of bias.

In general, we must bear in mind that the features of capsule imaging are quite different from those of conventional endoscopy. To start with, capsule movements are different as the device as a whole can be rotated with two simultaneous images from the cameras at each end. Usually, one of the sensors allowed a larger view of the stomach while the one at the opposite end provided a close-up of the gastric mucosa with a limited field of view. In order to identify the capsule position, we had to rely on a general overview but also to some extent on mucosal pattern which can vary in different parts of the stomach. The panoramic view of the lesser curvature was mostly very good, when the capsule was made to dive underwater on the greater curvature in front of the angular fold. Antrum and pylorus were comparatively easy to assess in a large or in a close-up view.

Entrapment of the capsule may be a concern with capsule gastroscopy as with capsule endoscopy in general. Reports in patients, mostly with obscure bleeding, have described a very low risk [18, 19], and no entrapment has been reported from the few volunteer studies [20 – 26]. In our trial it could be speculated that temporarily impaired passage was the cause in one patient of pain which subsided spontaneously after some hours. Further studies will show what the overall risk of capsule gastroscopy will be; it may appear wise to exclude patients with suspected and known strictures and perhaps previous small-bowel surgery from initial trials.

The first human trial of gastric examination with a magnetically navigated capsule opens a new field for digestive endoscopy. If this technique proves to be useful in the trial which we are now carrying out using blinded comparison with standard gastroscopy, further technical improvements as well as special training considerations need to be discussed and studied further.

Competing interests: None

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