ORIGINAL ARTICLE

# Magnetically Guided Capsule Versus Conventional Gastroscopy for Upper Abdominal Complaints

## *A Prospective Blinded Study*

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**Objectives:** Upper gastrointestinal endoscopy is mostly performed under sedation and has a low yield of relevant gastric lesions in patients without alarm symptoms. Simpler screening tests such as capsule endoscopy could be helpful, but gastric visualization is insufficient with the current passive capsules. A magnetically guided gastric capsule was prospectively evaluated in patients with routine indications for gastroscopy.

**Methods:** A total of 189 symptomatic patients (105 male; mean age 53 y) from 2 French centers subsequently and blindly underwent capsule and conventional gastroscopy by 9 and 6 examiners, respectively. The final gold standard was unblinded conventional gastroscopy with biopsy under propofol sedation. Main outcome was accuracy (sensitivity/specificity) of capsule gastroscopy for diagnosis of major gastric lesions, defined as those lesions requiring conventional gastroscopy for biopsy or removal.

**Results:** Twenty-three major lesions were found in 21 patients. Capsule accuracy was 90.5% [95% confidence interval (CI), 85.4%-94.3%] with a specificity of 94.1% (95% CI, 89.3%-97.1%) and a sensitivity of 61.9% (95% CI, 38%-82%). Accuracy did not correlate with lesion location, gastric luminal visibility, examiner case volume, or examination time. Of the remaining 168 patients, 94% had minor and mostly multiple lesions; the capsule made a correct diagnosis in 88.1% (95% CI, 82.2%-92.6%), with gastric visibility and lesion location in the proximal stomach having significant influence. All patients preferred capsule gastroscopy.

**Conclusions:** In a prospective and strictly blinded study, magnetically guided capsule gastroscopy was shown to be feasible in clinical practice and was clearly preferred by patients. Improvements in capsule technology may render this technique a future alternative to gastroscopy.

**Key Words:** gastroscopy, capsule endoscopy, gastric cancer screening

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Flexible endoscopy has been established for the diagnosis and treatment of a large and increasing number of gastrointestinal (GI) disorders during the past 30 years. However, depending on patient characteristics and symptoms, endoscopy detects relevant lesions in only a minority of cases and involves costs and expenditure as well as certain risks mostly related to sedation.[1–4] Thus, similar to colorectal cancer screening, a simple and reliable filter test would be helpful to stratify patients into those without relevant lesions not requiring further invasive methods and a minority of cases in whom flexible endoscopy has to be performed for biopsy or treatment of detected lesions. In countries with gastric cancer screening such as Japan, noninvasive methods such as serum pepsinogen tests have been evaluated, but have not replaced image-based screening by endoscopy or barium swallow.[5,6] For symptomatic patients with upper abdominal complaints, several nonendoscopic strategies outside of cancer screening have been evaluated, such as *Helicobacter pylori* testing and treatment,[7] but these have not been implemented into most national guidelines.

Capsule endoscopy was introduced into gastroenterologic diagnostics primarily for small-bowel imaging, in which conventional endoscopy and radiology have traditionally failed to detect lesions especially if they are smaller and more discrete.[8,9] Attempts to expand the indications for capsule endoscopy to the esophagus[10] and colon[11] have met several obstacles in performance, preparation, organization, and costs, thereby preventing widespread capsule use in these areas. In the stomach, occasional lesions have been detected after esophageal capsule endoscopy or before small-bowel imaging, but the consensus is that the stomach is not a good target organ for passive capsule endoscopy.[12]

Thus, there may be a need for guided capsule gastroscopy to allow for complete visualization of all areas of the stomach. After promising initial results using a capsule guided by a simple external magnet[13,14] or by a more sophisticated magnetic guidance system,[15,16] the current prospective study systematically evaluated the diagnostic accuracy of the latter system of capsule gastroscopy. It was compared with conventional flexible gastroscopy in patients examined for upper GI complaints. Examination of the esophagus and duodenum was not included in this comparative study.

## PATIENTS AND METHODS

### Patients

During a 6-month period (October 2011 to March 2012), patients with abdominal complaints requiring upper GI endoscopy were included in this prospective comparative trial after providing informed consent. Patients with the following were excluded: dysphagia or symptoms of gastric outlet obstruction, suspected or known intestinal stenoses, postabdominal radiation, overt GI bleeding, known large (> 2 cm) and obstructing tumors (cardia/pylorus) of the upper GI tract, status after upper GI surgery or abdominal surgery altering GI anatomy, under therapeutic anticoagulation, in poor general condition (American Society of Anesthesiologists class III/IV), patients with claustrophobia, metallic parts, electronic implants, artificial heart valves, pregnancy or suspected pregnancy.

The study was approved by the Local Ethical Committee (Comité de Protection des Personnes – Sud Mediterranée V; Scientific study: No. 2010-A01442-37; P reference 11.006) and was performed at the Institut Arnault Tzanck, St. Laurent du Var/France, where the magnetic guidance equipment was installed. Patients were recruited from both gastroenterologic departments at the Institut Arnault Tzanck and the Centre Hospitalier Universitaire of Nice. Examinations were performed by 9 and 6 different examiners for capsule and conventional gastroscopy, respectively, who were all very experienced in upper GI endoscopy (> 10,000 examinations). All capsule examiners received special training in capsule gastroscopy, participating in at least 10 gastric capsule endoscopies. Three of 9 capsule examiners had precious experience with the small-bowel capsule. The training was part of prestudies, which also evaluated different preparation regimens[16]; these examinations were not included in the present study. All authors had access to the study data and reviewed and approved the final manuscript.

Examiners were blinded to previous findings, suspected diagnoses, and patient history, but only received a standardized indication list. Patients were cared for by 2 study fellows (M.A.-H., B.H.). Capsule and conventional gastroscopies were always performed by different examiners who were blinded to the results of the other test.

### Capsule Gastroscopy

#### Guidance System, MGCE Capsule, and MGCE Navigation

The capsule gastroscopy setup has been described in detail elsewhere.[10,17] The magnet of the guidance system has a footprint of 1 × 2 m and generates dynamic magnetic fields and field gradients in 3-dimensional space over the entire stomach at very low intensity. The low magnetic field has a maximum of 100 mT, which is 15 times smaller than the standard 1.5 T magnetic resonance imaging field. Because of the low intensity of the magnetic field, a cooling system is not required and possible side effects for patients with metallic internal devices are reduced.

The capsule measures 31 × 11 mm and contains a permanent magnet to enable guided movements by the magnetic field applied by the guidance system. The capsule is equipped with 2 image sensors—1 at each end—that use a charge-coupled device. It generates images from the forward and backward direction of the capsule movement with image transmission at 4 frames/s. The optics obtain high-quality images of the stomach using a wider field of view and a deeper field of depth compared with the current small-bowel capsule. Comparable to the small-bowel capsule, images are recorded by means of multiple antennas attached to the patient.

In real-time gastric imaging, the capsule images and data are displayed on a dual-monitor panel. The images of both capsule optic sensors are shown simultaneously on the right monitor, whereas the left monitor displays the information about the capsule orientation assessed by the magnetic field. The physician controls capsule movements using 2 joysticks with 5 independent mechanical degrees of freedom. The magnetically guided capsule endoscope (MGCE) can be navigated forward, backward, tilting, which is equivalent to the large–steering wheel movements of an endoscope, or rotating, which is equivalent to the endoscopic small-wheel movements. Movements are possible floating at the water surface or diving at the bottom of the stomach. If the capsule is blocked between the gastric folds it can be dislocated using the jumping function.

Capsule transmission time is about 30 to 40 minutes.

#### Capsule Procedure

Capsule gastroscopy was always performed first. After overnight fasting, patient preparation included administration of 500 mL of clear water at room temperature and 300 mg simethicone about 1 hour before the procedure. this was followed by 2 × 400 mL of tap water at near body temperature (35°C) within 15 to 20 minutes, to provide an air-water interface in the stomach for capsule navigation. Image receiving antennae were attached to the patient, and the patient was positioned inside the low-field magnetic resonance imaging. Capsule was ingested in a sitting position to facilitate the esophageal passage. The examination was then undertaken with the patient lying in subsequent positions of left lateral, supine, and finally right lateral. In cases of difficulty in capsule navigation, the patient was turned to a different position, sometimes even prone. If necessary, additional water was ingested to create optimal conditions (the capsule requires some water volume for

proper navigation). Findings were documented immediately after capsule gastroscopy without later review by the examiner and/or the research fellow.

### Conventional Gastroscopy

Conventional upper GI endoscopy was performed after MGCE with a maximum delay of 1 day but a minimum delay of 4 hours due to water filling of the stomach with the capsule examination. The examination was carried out first blinded and then unblinded (Olympus gastroscopes 180 series; Olympus Corp., Hamburg, Germany) with patients in the left lateral position and under propofol sedation monitored by an anesthesiologist. Only the stomach was inspected for the present study; the esophagus and duodenum were examined for clinical routine reasons, but findings were not noted on the study case report form. Upper GI endoscopy was terminated when the examiner felt the stomach had been adequately inspected, and findings were documented at this stage by the research fellow as dictated by the examiner. Biopsies were taken whenever felt to be appropriate. After this, results of capsule gastroscopy or other clinical or imaging information relevant for the case were revealed by the research fellow to allow reinspection in the case of discrepancy between capsule gastroscopy and blinded gastroscopy. With this information, unblinded gastroscopy was performed in the same gastroscopy session. The combined endoscopic assessment (blinded and unblinded gastroscopy) including biopsy was used as the final gold standard and is called unblinded gastroscopy in the following sections.

### Data Recording and Definitions

The following parameters were recorded:

- patient age and sex
- indication for upper GI endoscopy
- details of capsule gastroscopy performance such as
  - examination time
  - assessment of examination quality consisting of
    - (i) overall gastric visibility on a visual analog scale (VAS) of 1 to 10 (1 = excellent; 10 = no visualization)
    - (ii) overall clarity of capsule image 1 to 3 (1 = completely clear; 2 = slightly turbid, no impairment; 3 = turbid, impairment of visibility)
    - (iii) gastric contractile activity 1 to 3 (1 = ignorable; 2 = mild; 3 = strong)
    - (iv) gastric expansion during examination (sufficient/insufficient)
- findings; major findings were defined as localized lesions with diagnostic or therapeutic relevance (ie, those requiring subsequent conventional gastroscopy for biopsy or therapy). Major lesions thus included tumors (adenomas, carcinomas, singular hyperplastic polyps), ulcers, and angiodysplasia. Minor findings were multiple and diffuse findings such as fundic gland polyps, erosions, and marked gastric atrophy. Location (proximal = fundus + cardia; distal = body, antrum + pylorus) and size were noted for major lesions, and location only was noted for minor lesions. The case load of participating examiners within the study was also recorded.

Patient acceptance of capsule gastroscopy (no sedation) versus conventional gastroscopy (including sedation), on a VAS scale of 1 (excellent, no problem) to 10 (very poor, hardly tolerable, interrupted) was recorded, as well as the answer to the question of which examination patients would prefer in the case of further gastroscopy becoming necessary.

### Outcome Parameters

The primary outcome parameters were the accuracy (all true positives and negatives/all cases) and the sensitivity, specificity, and predictive values of capsule gastroscopy compared with unblinded gastroscopy with biopsy with regard to major lesions on a per-patient and per-lesion basis, respectively. This definition was chosen, as the concept of capsule gastroscopy as a filter test for gastroscopy is based on the assumption that the imaging function should be equivalent to conventional gastroscopy, which should then be reserved for biopsy or therapy. We thus choose lesions that would require biopsy or removal as major lesions, the precise diagnosis of which can be regarded as the major outcome parameter. Only these major lesions require conventional gastroscopy, whereas minor lesions contribute to the diagnosis but do not require subsequent gastroscopy.

Secondary outcome parameters were: the accuracy (sensitivity, specificity, predictive values) of capsule gastroscopy compared with unblinded gastroscopy with biopsy with regard to minor lesions, on a per-patient and per-lesion basis, respectively; analysis of factors with possible influence (patient characteristics, overall visibility, examination time, examiner case volume, lesion location) on the accuracy of diagnosing major and minor lesions; complications of both examinations; comparison of blinded and unblinded gastroscopy.

### Case Number Calculation

Because of limited availability of capsules (n = 220), it was decided to enrich the population with positive findings under conditions of strict blindness for both capsule and gastroscopy examiners to reach a prevalence of major lesions of 20% to 25%. Under these circumstances, the case number of 220, including a dropout rate of 10%, would provide the following confidence intervals (CIs) for sensitivity and specificity: 25% prevalence of major lesions: for sensitivity 90% CI 78%-97%, 80% CI 66%-90%; for specificity 95% CI 91%-98%, 85% CI 78%-90%. These assumptions were partially based on 2 previously published pilot studies.[15,16]

### Statistical Analysis

Discrete variables are given as counts and percentages, and continuous variables are given as mean ± SD. Specificity, sensitivity, and positive and negative predictive values along with their exact 95% CIs are given. Hierarchical logistic regression analyses were applied to analyze the effect of various factors of the true positivity of capsule findings. A nominal $P$-value of $<0.05$, 2 tailed, was considered statistically significant. No adjustment for multiplicity was performed. Analyses were performed using statistical software SAS v 9.3 (SAS Institute Inc., Cary, NC).

## RESULTS

### Patient Characteristics and Examination Details

A total of 215 patients were initially included, but 26 had to be excluded because of secondary refusal of study

TABLE 1. Accuracy Values of Capsule Gastroscopy Compared With Unblinded Gastroscopy as the Final Gold Standard for the Diagnosis of Major Lesions on a Per-Patient (n = 21) and Per-Lesion (n = 23) Basis

| | Per Patient (%) | 95% CI | Per Lesion (%) | 95% CI |
|---|---|---|---|---|
| Accuracy | 90.5 | 85.4-94.3 | 89.5 | 84.3-93.5 |
| Sensitivity | 61.9 | 38.4-81.9 | 56.5 | 34.5-76.8 |
| Specificity | 94.1 | 89.3-97.1 | 94.1 | 89.3-97.1 |
| PPV | 56.5 | 34.5-76.8 | 56.5 | 34.5-76.8 |
| NPV | 95.2 | 90.7-97.9 | 94.1 | 89.3-97.1 |

There were 21 cases with major lesions and 168 without major lesions (ie, 10 normal cases and 158 cases with minor lesions).
CI indicates confidence interval; NPV, negative predictive value; PPV, positive predictive value.

participation (n = 14), capsule impaction in the esophagus during scanning time (n = 3), technical problems (n = 5), protocol violation (n = 2), and inability to swallow the capsule (n = 1). The remaining 189 patients (105 male, 84 female; mean age 53.0 ± 13.7 y) with an indication for upper GI endoscopy such as upper abdominal pain and/or anemia were included in the study.

### Major Lesions

The planned enrichment failed to reach the desired level of 20% to 25% patients with major lesions, but ended at a rate of 11%. These 23 major lesions found in 21 patients were 2 adenocarcinomas (tumor size 1.2 and 10.0 cm, both located in the gastric body), 4 submucosal tumors (size/location 1.5 and 0.8 cm in the gastric body, 0.9 cm in the cardia, and 1.0 cm in the antrum), 9 gastric ulcers [mean size 0.8 cm (range, 0.5 to 1.5 cm]; location cardia (n = 2), fundus (n = 1), antrum (n = 6)], 3 single hyperplastic polyps with a maximum size of 5 mm [location fundus (n = 2), pylorus (n = 1)], and 5 focal angiodysplasias [location antrum (n = 2), gastric body (n = 2), cardia (n = 1)]. Two patients each showed 2 lesions (each patient with 1 ulcer and 1 hyperplastic polyp).

### Minor Lesions

Minor lesions were marked inflammatory changes with erosions (n = 165), multiple fundic gland polyps (n = 55), gastric atrophy (n = 16), and others (n = 7). Only 10 patients had no minor lesions found on unblinded gastroscopy.

### Complications

No complications of capsule or conventional endoscopy were encountered. In the 3 patients who were excluded from the analysis due to capsule entrapment in the esophagus during the scanning time, subsequent upper GI endoscopy found the capsules still in the esophagus; the capsules were pushed gently into the stomach without problems. These patients had no symptoms either before gastroscopy or on follow-up.

### Test Performance

Capsule gastroscopy was performed by a total of 9 examiners and upper GI endoscopy by 6. The mean examination time was 10.6 minutes (95% CI, 10.1-11.1) for capsule gastroscopy and 4.0 minutes (95% CI, 3.7-4.2) for blinded gastroscopy, with an additional 1.7 minutes (95% CI, 1.6-1.9) for the unblinded part of gastroscopy. On capsule gastroscopy, examiners' subjective assessment rated 96.3% of all 189 gastric capsule examinations as complete, with rates for pylorus, antrum, body, and cardia ranging from 93.1% to 98.9%, with significant differences between locations favoring the proximal stomach ($P = 0.007$). In addition, subjective ratings for overall visibility, clarity, and absence of significant gastric contractile activity were 80.3% (visibility VAS 1 to 2), 93.1% (clarity 1 to 2 with 67.2% completely clear), and 79.9% (absence of contractile activity; an additional 12.7% had mild contractile activity), respectively. There was no complication with any of the tests performed.

## Capsule Gastroscopy Accuracy Compared With Unblinded Gastroscopy

Tables 1–3 show the accuracy results of capsule gastroscopy with regard to major and minor lesions, respectively. Sensitivity was limited for major lesions. Of the responsible factors that could be analyzed, sex was not found to be of relevance in the univariate analysis and was not considered further. None of the other factors analyzed with respect to capsule accuracy for major lesions had significant influence (Fig. 1). Because of the limited case number of major lesions, further factors documented but not shown in Figures 1 and 2 could not be analyzed in this model. With respect to minor lesions, only proximal location had significant influence (Fig. 2). Examples of major findings seen on capsule endoscopy are displayed in Figure 3.

## Blinded Versus Unblinded Gastroscopy

Of the 21 patients with major lesions, 1 angiodysplastic lesion seen on capsule gastroscopy was not detected on blinded gastroscopy but was confirmed on subsequent unblinded gastroscopy. In all other patients with major lesions, findings had already been detected by blinded gastroscopy. For minor lesions, blinded gastroscopy was 89.8% to 98.0% sensitive depending on the lesion type and also very specific in the 3 subgroups when compared with

TABLE 2. Accuracy Values of Capsule Gastroscopy Compared With Unblinded Gastroscopy as the Final Gold Standard for the Diagnosis of Minor Lesions on a Per-Patient Basis (n = 168)

| | Per Patient (%) | 95% CI |
|---|---|---|
| Accuracy | 88.1 | 82.2-92.6 |
| Sensitivity | 89.2 | 83.3-93.6 |
| Specificity | 70.0 | 34.8-93.3 |
| PPV | 97.9 | 94.0-99.6 |
| NPV | 29.2 | 12.6-51.1 |

There were 158 with 1 or (mostly) several minor lesions and 10 cases with normal stomach (ie, the 21 cases with major lesions are not included).
CI indicates confidence interval; NPV, negative predictive value; PPV, positive predictive value.

TABLE 3. Accuracy Values of Capsule Gastroscopy Compared With Unblinded Gastroscopy for the Diagnosis of Subgroups of Minor Lesions on a Per-Patient Basis

| | Fundic Gland Polyps | | Erosions and Hemorrhagic Gastritis | | Gastric Atrophy | |
|---|---|---|---|---|---|---|
| | % (n = 49) | 95% CI | % (n = 148) | 95% CI | % (n = 17) | 95% CI |
| Accuracy | 83.9 | 77.5-89.1 | 91.7 | 86.4-95.4 | 91.7 | 86.4-95.4 |
| Sensitivity | 75.5 | 61.1-86.7 | 93.9 | 88.8-97.2 | 29.4 | 10.3-56.0 |
| Specificity | 87.4 | 80.1-92.8 | 75.0 | 50.9-91.3 | 98.7 | 95.3-99.8 |
| PPV | 71.2 | 56.9-82.9 | 96.5 | 92.1-98.9 | 71.4 | 29.0-96.3 |
| NPV | 89.7 | 82.6-94.5 | 62.5 | 40.6-81.2 | 92.6 | 87.3-96.1 |

This calculation was based on the 168 patients without major lesions (overlap between groups possible), of whom 158 had 1 or more minor lesion and 10 had none.

CI indicates confidence interval; NPV, negative predictive value; PPV, positive predictive value.

unblinded gastroscopy, although the number of negative cases was small (n = 10) (Table 4).

## Patient Acceptance

The mean patient rating was 1.17 (95% CI, 1.11-1.23) for capsule gastroscopy and 1.67 (95% CI, 1.55-1.79) for conventional gastroscopy under sedation ($P < 0.001$). Preference for the type of future gastroscopy if indicated was capsule in all cases (100%).

## DISCUSSION

The present study is the first large study to systematically evaluate guided capsule gastroscopy in patients with upper abdominal symptoms. The main outcome was defined as the accuracy of capsule gastroscopy in the diagnosis of major lesions because these lesions would require subsequent conventional endoscopy for biopsy and/or therapy, such as endoscopic biopsy and/or removal for (early) tumors, endoscopic ultrasound for suspected submucosal tumors, biopsy including *H. pylori* testing for ulcers, and coagulation in angiodysplasias. Unfortunately, we could not fully reach our goal of case enrichment of major lesions, which would have allowed for smaller CIs for sensitivity calculation. However, the present rate of 11% major lesions is more realistic for an average gastroscopy setting, and the limited sensitivity of only 62% is unlikely to become substantially better with more lesions; the multivariate analysis showed that examiner experience and case load did not play a role. Thus, it has to be concluded that at the present stage of development, guided capsule gastroscopy would have to be substantially improved before it could be considered as a filter test to stratify patients to undergo conventional gastroscopy, irrespective of cost issues. Previous studies with a different technology only involved small numbers of volunteers as feasibility trials[13,14] or—using the same capsule in a pilot trial and in prestudy testings—did not systematically evaluate a similar patient collective of the same size and did not rigorously test accuracy.[15,16]

There would be several ways of improvements related to both influencing stomach characteristics and modifying capsule technology. Among the former, limited expansion of the stomach yielded by drinking water in capsule gastroscopy compared with air expansion in gastroscopy was probably the most important one. Sufficient intragastric volume of clear fluid is required for good visualization and capsule maneuvering,[15] but ingested water left the stomach too quickly; adding water during the examination did not substantially improve the results as outflow was similarly rapid. The fact that the visibility rating by examiners yielded excellent results, yet detection of focal lesions was poor, points toward the fact that the subjective impression of examiners of visibility probably represents an overjudgment of their own performance. This conclusion is also supported by the low detection rate of singular major lesions versus the high detection rate of minor lesions, which were mostly multiple and thus did not readily escape gastric inspection. That the visualization of minor lesions was significantly better in the proximal stomach was mostly due to antral motility leading to a pushback of the capsule, which could not be counteracted by active capsule maneuvering.

Therefore, future technical requirements for capsule gastroscopy include implementation of a lens-cleaning system, as is available with conventional endoscopy, and a stronger guidance system, which currently appears to be too weak and requires faster speed of movement with stronger force, but also a better capability of keeping the capsule in place more steadily. More force would probably also help to actively pass the pylorus and to keep the capsule in the esophagus. The latter appears to be particularly important, as detection of esophageal lesions such as reflux erosions, Barrett esophagus, or varices will be important indications for upper GI endoscopy performed by guided capsules in the future.

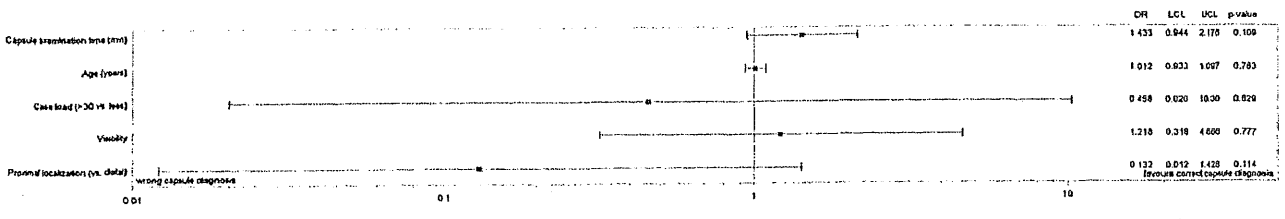


FIGURE 1. Factors influencing sensitivity in the diagnosis of major lesions; lesion-based analysis (see also Table 1). For definitions see text. LCL indicates lower confidence limit; OR, odds ratio; UCL, upper confidence limit.

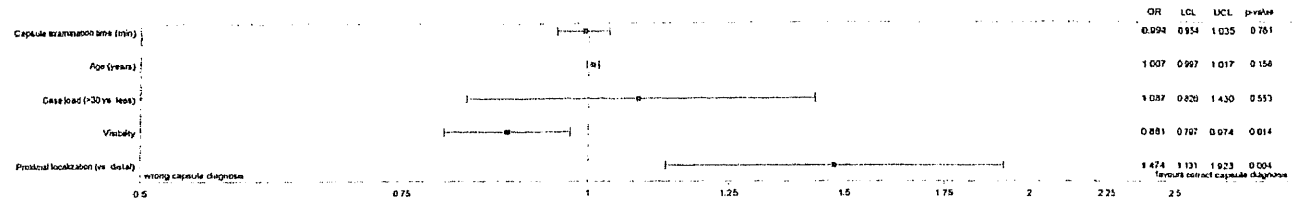


FIGURE 2. Factors influencing sensitivity in the diagnosis of minor lesions: lesion-based analysis (see also Table 2). For definitions see text. LCL indicates lower confidence limit; OR, odds ratio; UCL, upper confidence limit.

In 3 cases the capsule was still found in the esophagus on subsequent conventional endoscopy; patients did not have any symptoms nor any esophageal pathology, and the examiners decided to push the capsule into the stomach during gastroscopy. Capsule entrapment in the esophagus has been described with esophageal stenosis,[18] and despite the fact that passage times of small-bowel capsules are very rapid in most patients, they are significantly delayed in a few cases.[19] Thus, it can be assumed that capsules would have passed spontaneously in these 3 cases. In contrast, a special technical modification would be required to perform capsule endoscopy in the esophagus, one that keeps the capsule in the esophagus for longer on a regular basis.[10,17]

In conclusion, current models of steerable capsules should be improved to be further studied as a filter test in clinical routine for gastric examination, such as for gastric cancer screening in Japan. Only then would it make sense to discuss cost issues, including equipment and time needed for performance and reading as well as other factors such as nurse performance, etc. Further refinements are to be

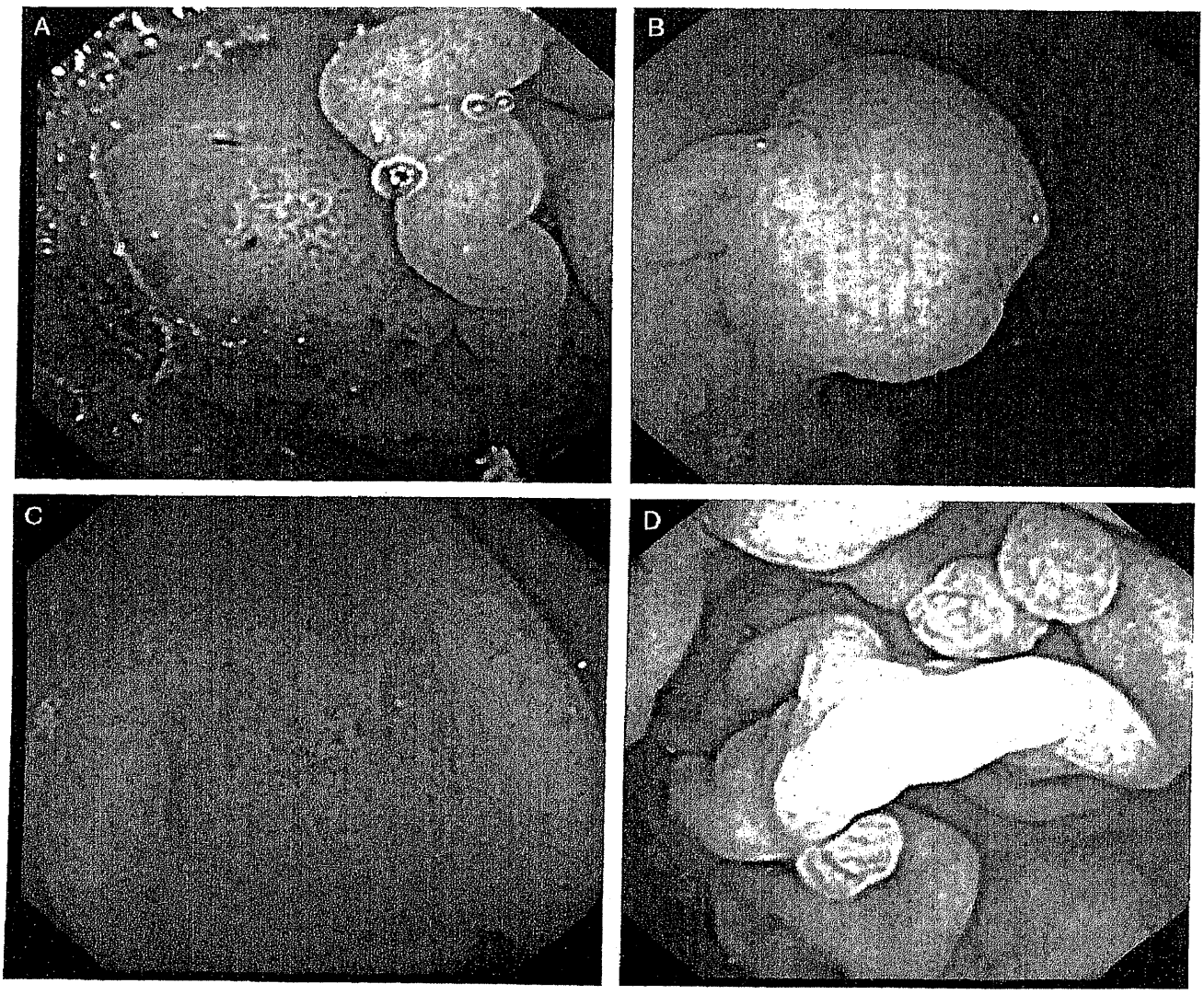


FIGURE 3. Examples of gastric pathology on capsule gastroscopy: (A) gastric cancer; (B) submucosal tumor; (C) diffuse erosions; and (D) multiple fundic gland polyps.

TABLE 4. Sensitivity and Specificity Values of Blinded Compared With Unblinded Gastroscopy as Gold Standard

| | Sensitivity | 95% CI | Specificity | 95% CI |
|---|---|---|---|---|
| Major lesions (per lesion) (n = 23) | 95.6 | 78.1-99.9 | — | — |
| Minor lesions (per patient) (n = 168) | 98.1 | 94.6-99.6 | 100 | 69.2-100 |
| Subgroups | | | | |
| Fundic gland polyps (n = 49) | 89.8 | 77.8-96.6 | 100 | 97.0-100 |
| Erosions and hemorrhagic gastritis (n = 148) | 98.0 | 94.2-99.6 | 95.0 | 75.1-99.9 |
| Gastric atrophy (n = 17) | 94.2 | 71.3-99.9 | 99.3 | 96.4-100 |

CI indicates confidence interval.

expected and then studies with similar methodology as well as patient uptake and outcome studies have to be conducted to define the role of guided upper GI capsule endoscopy in the clinical setting.

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