Capsule Endoscopy versus Colonoscopy for the Detection of Polyps and Cancer

André Van Gossum, M.D., Miguel Munoz-Navas, M.D., Iñaqui Fernandez-Urien, M.D., Cristina Carretero, M.D., Gérard Gay, M.D., Michel Delvaux, M.D., Marie Georges Lapalus, M.D., Thierry Ponchon, M.D., Horst Neuhaus, M.D., Michael Philipper, M.D., Guido Costamagna, M.D., Maria Elena Riccioni, M.D., Cristiano Spada, M.D., Lucio Petruzziello, M.D., Chris Fraser, M.D., Aymer Postgate, M.D., Aine Fitzpatrick, M.D., Friedrich Hagenmuller, M.D., Martin Keuchel, M.D., Nathalie Schoofs, M.D., and Jacques Devière, M.D.

From the Department of Gastroenterology, Erasme University Hospital, Université Libre de Bruxelles, Brussels (A.V.G., N.S., J.D.); Digestive Diseases Division, University of Navarra Clinic, Pamplona, Spain (M.M.-N., I.F.-U., C.C.); the Department of Internal Medicine and Digestive Diseases, Hôpital de Brasois, Centre Hospitalier Universitaire de Nancy, Nancy, France (G.G., M.D.); Service d’Hépato-Gastroentérologie, Hôpital Edouard-Herriot, Lyon, France (M.G.L., T.P.); the Department of Internal Medicine, Evangelisches Krankenhaus, Düsseldorf, Germany (H.N., M.P.); the Digestive Endoscopy Unit, Catholic University, A. Gemelli University Hospital, Rome (G.C., M.E.R., G.S., L.P.); Wolfson Unit for Endoscopy, St. Mark’s Hospital, Imperial College, London, London (C.F., A.P., A.F.); and the 1st Medical Department, Asklepios Klinik Altona, Hamburg, Germany (F.H., M.K.). Address reprint requests to Dr. Van Gossum at the Department of Gastroenterology, Hepatopancreatology, and Gastrointestinal Oncology, Erasme University Hospital, Université Libre de Bruxelles, Route de Lennik 808, 1070 Brussels, Belgium, or at andre.vangossum@erasme.ulb.ac.be.


ABSTRACT

BACKGROUND
An ingestible capsule consisting of an endoscope equipped with a video camera at both ends was designed to explore the colon. This study compared capsule endoscopy with optical colonoscopy for the detection of colorectal polyps and cancer.

METHODS
We performed a prospective, multicenter study comparing capsule endoscopy with optical colonoscopy (the standard for comparison) in a cohort of patients with known or suspected colonic disease for the detection of colorectal polyps or cancer. Patients underwent an adapted colon preparation, and colon cleanliness was graded from poor to excellent. We computed the sensitivity and specificity of capsule endoscopy for polyps, advanced adenoma, and cancer.

RESULTS
A total of 328 patients (mean age, 58.6 years) were included in the study. The capsule was excreted within 10 hours after ingestion and before the end of the lifetime of the battery in 92.8% of the patients. The sensitivity and specificity of capsule endoscopy for detecting polyps that were 6 mm in size or bigger were 64% (95% confidence interval [CI], 59 to 72) and 84% (95% CI, 81 to 87), respectively, and for detecting advanced adenoma, the sensitivity and specificity were 73% (95% CI, 61 to 83) and 79% (95% CI, 77 to 81), respectively. Of 19 cancers detected by colonoscopy, 14 were detected by capsule endoscopy (sensitivity, 74%; 95% CI, 52 to 88). For all lesions, the sensitivity of capsule endoscopy was higher in patients with good or excellent colon cleanliness than in those with fair or poor colon cleanliness. Mild-to-moderate adverse events were reported in 26 patients (7.9%) and were mostly related to the colon preparation.

CONCLUSIONS
The use of capsule endoscopy of the colon allows visualization of the colonic mucosa in most patients, but its sensitivity for detecting colonic lesions is low as compared with the use of optical colonoscopy. (ClinicalTrials.gov number, NCT00604162.)
OPTICAL COLONOSCOPY (HENCEFORTH referred to as colonoscopy) is currently considered to be the standard procedure for colon evaluation and screening for colorectal cancer, despite some limitations, such as the invasiveness, the suboptimal performance of colonoscopy, and the poor bowel preparation in selected patients. Moreover, limited endoscopy resources may restrict its use in large, population-based screening programs, and many persons are reluctant to undergo colonoscopy because of its perceived inconvenience, discomfort, or embarrassment.

It seems, therefore, that there is a need for an additional safe, minimally invasive method for visualizing the colon that would complement colonoscopy for patients who have undergone an incomplete examination or those for whom colonoscopy is contraindicated. A less invasive screening tool might serve as an additional screening method for the early detection of colorectal cancer and adenomatous polyps.

On the basis of the technological development and the accumulated clinical experience with the small-bowel capsule endoscope (PillCam SB, Given Imaging), the PillCam COLON capsule endoscope (Given Imaging), an ingestible capsule consisting of an endoscope equipped with a video camera at both ends, was designed especially for visualizing the colon. Two pilot studies have shown the feasibility and safety of capsule endoscopy. We report the findings of a prospective, multicenter study comparing the performance of capsule endoscopy with colonoscopy for the detection of colorectal polyps and cancers.

METHODS

STUDY GROUP
The study protocol was approved by the institutional review board at each of the eight participating centers. Written informed consent was obtained from all patients. Patients were considered for the study if they were scheduled to undergo a colonoscopy because they were either known to have colonic disease (patients ≥18 years of age) or suspected of having colonic disease (patients ≥50 years of age).

The cohort of patients with known colonic disease included patients with a history of colorectal cancer or adenomatous polyps for whom at least 3 years had passed since their last colonoscopy, patients with any positive findings in the colon on the basis of radiographic examinations, and patients with known ulcerative colitis. In the cohort of patients with suspected colonic disease, the patients had at least one of the following symptoms: rectal bleeding, hematochezia, melena, a recent change in bowel habits, or a positive fecal occult-blood test. Exclusion criteria were as follows: an age younger than 18 years; the presence of dysphagia, congestive heart failure, renal insufficiency, intestinal obstruction, a life-threatening condition, or a pacemaker or other implanted electrical medical device; current pregnancy; abdominal surgery in the past 6 months; inability to provide informed consent; or current participation in another clinical study.

STUDY DESIGN
The PillCam COLON capsule is an ingestible capsule equipped with an endoscope (Fig. 1) that has two imagers, enabling it to acquire video images from both ends. The device measures 31 by 11 mm and acquires images at a rate of 4 frames per second. The preprogrammed “sleep” mode allows recording of images from the esophagus and the stomach for 3 minutes before the capsule switches to sleep mode for 1 hour 45 minutes in order to conserve battery life. During this period, the capsule is likely to transit most of the small bowel and reach approximately the level of the terminal ileum. The envelope of the capsule is made of biocompatible materials, sealed with biocompatible adhesives, and produced according to procedures and guidelines that are similar to those for the standard small-bowel capsules. Recording and downloading of data are similar to those of the data for small-bowel capsule endoscopy.

This was a prospective, multicenter study evaluating the use of capsule endoscopy for the visu-
alization of the colon and the accuracy of detecting colonic polyps (defined as a structure arising from the mucosa and projecting into the lumen), advanced adenomas (an adenoma ≥1 cm in size or any adenoma with villous features or high-grade dysplasia), and carcinomas. Colonoscopy was the standard against which capsule endoscopy was compared, and it was performed after capsule endoscopy (after capsule excretion or at least 10 hours after capsule ingestion, whichever came first), on either the same day as ingestion or the next morning. The video from the capsule endoscope was read at a later date in two steps: first the images taken from one end of the device were examined, and then the images taken from the other end were examined. The selected reading speed was approximately 8 frames per second and was adjusted as considered appropriate by the reading physician.

The physician performing the capsule endoscopy and reading the capsule videos and the physician performing the colonoscopy were unaware of each other’s findings until completion of the examinations and reports. After a training session for capsule endoscopy, the participating physicians took a test consisting of six colon-capsule videos. They were required to identify pathological features of the colon in the videos and indicate the type, location, and size of the lesions.

Polyps seen during colonoscopy were recorded according to their location in the colon and size and were then endoscopically removed. Polyp size was measured by either visual estimation or estimation with the use of open biopsy forceps. Colonic-biopsy specimens were obtained if the colonoscopist performing the examination thought it was necessary to do so.

For polyps identified on the videos taken by the capsule endoscope, a visual estimation of the size of the polyp, as explained during the capsule-endoscopy training session, was used. For the purpose of the analysis, we assumed a 50% margin of error for the size of a polyp seen on the video. The recorded size of all lesions was increased by 50% to compensate for errors in measurement. All data were entered into a case-report form by the physician who read the capsule video.

Adverse events were prospectively recorded, by interviewing the patient (asking open-ended questions) by telephone 1 day and 1 week after each procedure. Events were graded as mild, moderate, or severe for the procedures by the investigator assigned to the patient.

The study was designed by the academic investigators in collaboration with Given Imaging, the study sponsor, which donated the PillCams. Data were gathered in each center by the investigators and the local study nurses. Data were centrally collected by Given Imaging and extensively shared and discussed by all the investigators. Statistical analyses were performed by Given Imaging and supervised by the academic investigators; the latter take responsibility for the accuracy and completeness of the recorded data.

**Colon-Preparation Regimen for Capsule Endoscopy**

Patients underwent colon preparation as described previously (Fig. 1 in the Supplementary Appendix). Capsule endoscopy was performed without colon insufflation or sedation, and the capsule traveled through colon fluids. The colon-preparation regimen was explained to the patients in approximately 10 minutes by an experienced nurse.

**Colon Cleanliness**

A four-point grading scale was used to objectively describe the cleanliness of the colon at the time of capsule endoscopy as excellent, good, fair, or poor (Fig. 2 in the Supplementary Appendix). The same classification was used for grading the cleanliness at the time of colonoscopy, which reflected the quality of the preparation after flushing of the colon during colonoscopy.

**Statistical Analysis**

Per-patient comparisons between colonoscopy and capsule endoscopy were performed according to the type and size of the lesions. Descriptive statistics for continuous variables were expressed as the mean, median, and range values. Variables pertaining to accuracy were calculated with a 95% confidence interval that was based on a binomial distribution in which colonoscopy was considered to be the standard procedure for the purpose of detecting polyps and colonoscopy combined with biopsy was considered the standard procedure for the purpose of detecting adenomas and cancer.

Sensitivity was calculated as the percentage of patients who had positive findings on capsule endoscopy (of a specified category) among those...
patients who had positive findings on colonoscopy (of the same category). The false negative rate is equal to 1 – sensitivity and indicates the percentage of lesions missed by capsule endoscopy.

Specificity was calculated as the percentage of patients who had negative findings on capsule endoscopy (of a specified category) among patients with negative findings on colonoscopy (of the same category). This corresponds to 1 – the false positive rate.

A proportions test was performed in order to compare the rates of good and excellent colon cleansing levels in patients who were undergoing capsule endoscopy and those undergoing colonoscopy. A P value of 0.05 or less was considered to indicate statistical significance. All reported P values are two-sided. Statistical analyses were performed with SPSS software, version 15.0.

**RESULTS**

**PATIENTS**

The eight participating centers enrolled 332 patients. Four patients (1.2%) withdrew before completing the study documents and were not included in the analysis. An additional eight patients were not included in the analysis of the accuracy of polyp detection: in five patients (1.5%), the capsule did not reach the colon before the end of the capsule's battery life (two capsules were delayed in the stomach, one was delayed in the small bowel, and two were delayed at the level of a stenosis, which in one case was visualized as a tumor); in two patients (0.6%), the colonoscopy was incomplete because the colonoscope could not be passed beyond the sigmoid colon; and one patient (0.3%) was unable to swallow the capsule. Therefore, 320 patients were included in the accuracy analysis, of whom 144 (45.0%) were women and 176 (55.0%) were men (mean age, 58.5 years; range, 22 to 84). There were 112 patients (35.0%) with known colonic disease (57 were ≥50 years of age) and 208 (65.0%) with suspected colonic disease (201 were ≥50 years of age) (Table 1).

**PROPELLION OF THE CAPSULE**

For analysis of capsule propulsion, seven patients who had been excluded from the accuracy analysis were included (in five patients, the capsule did not reach the colon before the end of the life of the capsule's battery, and in two patients, colonoscopy was incomplete), and seven other patients were excluded (in six patients, the capsule was retrieved during colonoscopy while it was still functioning, and in one patient, the capsule excretion time was not registered).

At 1 hour 45 minutes after ingestion (on “wake up”), the capsule remained proximal to the cecum in 312 of the 320 patients (97.5%). The capsule was already in the cecum in five patients (1.5%), in the ascending colon in two (0.6%), and in the sigmoid colon in one (0.3%). Of the 320 patients, 221 (69.1%) excreted the capsule within 6 hours after ingestion, and 297 (92.8%) within 10 hours. Of the remaining 23 patients, the capsule had reached the descending colon in 3 patients (0.9%) and the rectosigmoid colon in 15 (4.7%) at 10 hours after ingestion. In five patients (1.6%), the capsule did not reach the cecum before the end of the life of the capsule’s battery. All patients — including the 2 with stenosis — excreted the capsule naturally, 319 (99.7%) within 16 hours after ingestion, and 1 (0.3%) during the 4th week after ingestion.

The mean and median capsule transit times in the colon of patients who excreted the capsule within 10 hours after ingestion were 2 hours 8 minutes and 1 hour 18 minutes, respectively (range, 4 minutes to 7 hours 57 minutes). The mean and median transit times in the gastrointestinal tract (from mouth to anus) were 4 hours.

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**Table 1. Known or Suspected Positive Colonic Findings in the 320 Patients Included in the Accuracy Analysis, According to Age.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients (%)</th>
<th>Age Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known positive colonic findings</td>
<td>112 (35)</td>
<td>22–49 Yr (N = 62)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50–84 Yr (N = 258)</td>
</tr>
<tr>
<td></td>
<td>no. of patients</td>
<td></td>
</tr>
<tr>
<td>Colorectal cancer or adenomatous polyps*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive findings in the colon†</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Suspected positive colonic findings‡</td>
<td>208 (65)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>201</td>
</tr>
</tbody>
</table>

* At least 3 years had passed since the last colonoscopy.
† Positive findings were based on radiographic studies and included colonic polyps.
‡ Patients were suspected of having at least one of the following symptoms: rectal bleeding, hematochezia, melena, a recent change in bowel habits, recent onset of diarrhea or constipation, and a positive fecal occult-blood test. Patients with suspected colonic disease were at least 50 years of age. Exceptions to this age requirement were made for seven patients according to the investigator’s discretion on the basis of clinical symptoms.
All colorectal cancers were ≥6 mm or larger (19 were ≥6 mm, and 18 of these were ≥10 mm). A high prevalence of polyps less than 6 mm in size, combined with a low likelihood of histologic features of advanced adenoma, decreased the specificity.

Advanced adenoma was defined as an adenoma 1 cm or larger or an adenoma with villous features or high-grade dysplasia.

Per-patient data are listed. Colonoscopy was the standard criterion. Patients could be included in more than one size category.

Table 2. The Prevalence of Lesions Detected by Colonoscopy in the 320 Patients in the Accuracy Analysis, and the Sensitivity and Specificity of Capsule Endoscopy for the Detection of These Lesions.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Colonoscopy*</th>
<th>Capsule Endoscopy†</th>
<th>Prevalence</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyp</td>
<td></td>
<td></td>
<td>no. of patients (%)</td>
<td>% (95% CI)</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Any size</td>
<td>212 (66.2)</td>
<td>72 (68–75)</td>
<td>78 (71–84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 mm</td>
<td>188 (58.8)</td>
<td>61 (57–64)</td>
<td>82 (76–87)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥6 mm</td>
<td>87 (27.2)</td>
<td>64 (59–72)</td>
<td>84 (81–87)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥10 mm</td>
<td>50 (15.6)</td>
<td>60 (51–66)</td>
<td>98 (96–99)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenoma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥6 mm</td>
<td>71 (22.2)</td>
<td>68 (58–76)</td>
<td>82 (79–84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥10 mm</td>
<td>45 (14.1)</td>
<td>64 (54–72)</td>
<td>97 (96–99)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced adenoma‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any size</td>
<td>52 (16.2)</td>
<td>85 (73–93)</td>
<td>50 (48–51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥6 mm</td>
<td>49 (15.3)</td>
<td>73 (61–83)</td>
<td>79 (77–81)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥10 mm</td>
<td>45 (14.1)</td>
<td>64 (54–72)</td>
<td>97 (96–99)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal cancer¶</td>
<td>19 (5.9)</td>
<td>74 (52–88)</td>
<td>74 (72–75)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Patients could be included in more than one size category.
† Per-patient data are listed. Colonoscopy was the standard criterion.
‡ Advanced adenoma was defined as an adenoma 1 cm or larger or an adenoma with villous features or high-grade dysplasia.
¶ A high prevalence of polyps less than 6 mm in size, combined with a low likelihood of histologic features of advanced adenoma, decreased the specificity.
¶ All colorectal cancers were 6 mm or larger (19 were ≥6 mm, and 18 of these were ≥10 mm).

51 minutes and 4 hours 1 minute, respectively (range, 2 hours 5 minutes to 10 hours 0 minutes); in one patient (not included in the above means and medians) the transit time was more than 500 hours.

**ASSESSMENT OF COLON CLEANLINESS**
According to the four-point grading scale, the overall colon cleanliness was considered to be good or excellent in 72% of the patients for capsule endoscopy (95% confidence interval [CI], 66 to 77) and in 87% for colonoscopy (95% CI, 83 to 91) (P<0.001). Colon cleanliness was not significantly associated with either the capsule transit time in the colon or the age of the patient.

**PREVALENCE AND ACCURACY OF DETECTION OF LESIONS**
Table 2 shows the per-patient prevalence of lesions detected by colonoscopy and the sensitivity and specificity of capsule endoscopy for the detection of these lesions. At colonoscopy, 212 of the patients (66.2%) had at least one polyp, and most polyps were less than 6 mm in size. Fifty patients (15.6%) had at least one polyp that was 10 mm or larger (Fig. 3 in the Supplementary Appendix).

The sensitivity and specificity of capsule endoscopy for detecting polyps 6 mm or larger were 64% (95% CI, 59 to 72) and 84% (95% CI, 81 to 87), respectively, and the sensitivity and specificity for detecting advanced adenomas 6 mm or larger were 73% (95% CI, 61 to 83) and 79% (95% CI, 77 to 81), respectively. Of 19 cancers detected by colonoscopy, 14 were detected by capsule endoscopy (sensitivity, 74%; 95% CI, 52 to 88). Advanced adenomas smaller than 6 mm were detected by both colonoscopy and capsule endoscopy in 4 patients (1.2%), and advanced adenomas of any size were detected by colonoscopy in 52 patients (16.2%) and by capsule endoscopy in 44 patients (13.8%). The various types and sizes of polyps observed at capsule endoscopy and colonoscopy are shown in Figure 2.

The mean reading time of the capsule video was 45 minutes (range, 30 minutes to 1 hour 15 minutes) at a mean selected reading speed of 8 frames per second. No technical problems were reported.

**EFFECT OF CLEANLINESS LEVEL ON THE ACCURACY OF LESION DETECTION**
In order to analyze the effect of the level of cleanliness on the accuracy of lesion detection during capsule endoscopy, we also analyzed the variables that dictated diagnostic accuracy for the patients with good or excellent colon-cleanliness levels (72%) and for the patients with poor or fair colon-cleanliness levels (28%). The sensitivity was significantly higher in the patients with good or excellent cleanliness as compared with the patients with poor or fair cleanliness, with a limited effect on specificity. For example, the sensitivity and specificity for the detection of polyps (≥2 mm) in the 59 patients with good or excellent cleanliness were 75% (95% CI, 65 to 83) and 84% (95% CI, 80 to 87), respectively, and for the detection of such polyps in the 26 patients with poor or fair cleanliness, the sensitivity and specificity were 42% (95% CI, 28 to 56) and 84% (95% CI, 78 to 90), respectively. For patients with advanced adenoma, the sensitivity and specificity in the 33 patients with good or excellent cleanliness were 88% (95% CI, 74 to 95) and 78% (95% CI, 70 to 79), respectively, and in the 16 patients with poor or fair cleanliness,
the sensitivity and specificity were 44% (95% CI, 25 to 64) and 81% (95% CI, 77 to 85), respectively.

**ADVERSE EVENTS**

All patients were able to swallow the capsule except for one patient, who had no identifiable anatomical reason for the inability. A total of 27 adverse events were reported in 26 (7.9%) of the 328 patients who completed the study. In 22 of these 26 patients, adverse events were related to the bowel preparation and included abdominal discomfort, nausea, vomiting, and headache. All reported symptoms were considered to be mild to moderate and resolved within 48 hours.

**DISCUSSION**

This study shows that capsule endoscopy is a safe method of visualizing the colonic mucosa through colon fluids without the need for sedation or insufflation. However, the sensitivity of capsule endoscopy for detecting colonic polyps, advanced adenomas, and colorectal cancer was relatively low in comparison with colonoscopy. It appears that colon cleanliness significantly influences the sensitivity of capsule endoscopy.

The aim of this prospective study was to evaluate the performance of capsule endoscopy in detecting colonic polyps and colorectal cancer. Because the patients we studied were known or suspected to have a colonic disease, our sample was not representative of a typical screening population that has an average risk of colorectal cancer.\(^1\)\(^{19}\)\(^{20}\)

The PillCam COLON capsule, which includes an imager at each end and the sleep mode, functioned appropriately in 97.5% of the patients. Since the capsule was excreted before the end of the life of the capsule's battery in 92.8% of the patients, adequate colonic imaging could be acquired.

Adverse events reported by the patients were mild and attributed to the colon preparation. For capsule endoscopy, the goals of bowel preparation are not only to clean the colon but also to facilitate progression of the capsule through the gastrointestinal tract, to maintain residual clear liquid in the colon for visualization by means of the so-called submarine view, and to avoid the rinse and suction techniques that are used during colonoscopy. Because of these additional goals, the bowel-preparation regimen used for capsule endoscopy was more extensive than that used for colonoscopy.\(^21\)\(^{22}\) Oral sodium phosphate and water administered approximately 2 hours after capsule ingestion in the morning, with an additional portion administered in the early afternoon for patients who did not excrete the capsule at that time, were used to stimulate the progression of the colon capsule through the gastrointestinal tract while maintaining colon cleansing.

We observed that the quality of the colon preparation affected the rate of detection of polyps by capsule endoscopy. Colon preparation has been reported to have a similar effect on the rate of detection by colonoscopy.\(^23\)\(^{25}\) Evaluation of the
effectiveness of the cleansing procedure and its effect on the rate of detection of polyps is required for capsule endoscopy in order to draw appropriate clinical conclusions about the accuracy of the diagnosis. In our study, the sensitivity of capsule endoscopy after adequate colon cleansing was significantly higher than that after inadequate colon cleansing; specificity was minimally affected by the quality of colon cleansing. Efforts should be made to improve the colon-preparation regimen for capsule endoscopy.

In summary, this multicenter study involving patients with known or suspected colonic disease showed that the colon can be visualized with capsule endoscopy, without the need for sedation or air insufflation. However, the sensitivity of capsule endoscopy is lower than the sensitivity of colonoscopy for detecting colonic polyps and adenomas.

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