

Is there a role for second-look capsule endoscopy in patients with obscure GI bleeding after a nondiagnostic first test?

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Background: Long-term follow-up data on patients with obscure GI bleeding subjected to capsule endoscopy (CE) are missing.

Objective: Our purpose was to follow up patients with a nondiagnostic test and determine whether a second-look CE would be beneficial.

Patients: We enrolled 293 subjects. CE studies were classified as diagnostic (positive findings) or nondiagnostic (findings of uncertain significance/no findings). Patients were followed up for a mean (SD) 24.8 (5.2) months. Outcome was defined as continued or complete resolution of bleeding.

Interventions: Patients with a nondiagnostic test were subjected to a repeat CE if they manifested a new bleeding episode or a drop in hemoglobin ≥ 2 g/dL.

Results: Positive findings, findings of uncertain significance, and no findings were identified in 41.6%, 16.0%, and 42.3% of our patients, respectively. Therapeutic intervention was possible in 72.1% of those with positive findings and in 30% of those with findings of uncertain significance. Complete resolution of bleeding occurred more often in patients with a diagnostic test (65.2%) compared with those with a nondiagnostic test (35.4%, $P < .001$). Second-look CE was performed in a subgroup of our patients ($n = 76$) and was diagnostic in those whose presentation changed from occult to overt or those whose hemoglobin dropped ≥ 4 g/dL.

Conclusions: In patients with obscure GI bleeding, a diagnostic CE leads to therapeutic interventions and a favorable outcome. Patients with a nondiagnostic test would definitely benefit from a second-look CE if the bleeding presentation changes from occult to overt or if the hemoglobin value drops ≥ 4 g/dL. (Gastrointest Endosc 2009;69:850-6.)

Obscure GI bleeding (OGIB) remains a major clinical challenge. The majority of OGIB cases originate from the small intestine; therefore, wireless capsule endoscopy (CE) is a valuable tool in the investigation of these patients.¹⁻³

Although sound literature data have proven the superiority of CE compared with all other diagnostic modalities in identifying bleeding lesions,⁴⁻¹² the true diagnostic yield of this test in patients with OGIB is still not known. Numerous previous reports have reported conflicting results, and according to the available data the diagnostic yield of CE

ranges from 45% to 75%, clearly reflecting differences in image interpretation and the diagnostic criteria used for the identification of the bleeding condition.⁴⁻¹²

We have previously reported that positive findings, defined by strict diagnostic criteria, were identified in 41.7% of patients subjected to CE for the investigation of OGIB.¹³ After a median follow-up period of 14 months, those patients were more likely to receive some kind of therapeutic intervention for their lesions and eventually had a favorable outcome. On the contrary, the outcome of those patients with findings of uncertain significance or no findings on CE was not changed in a positive way. In clinical practice, the most appropriate management of patients with OGIB and a nondiagnostic CE test remains elusive, and we do not know whether these subjects would benefit from a second-look CE. Meanwhile, data on follow-up longer than 1 year are sparse in the literature, further obscuring our knowledge on the best therapeutic algorithm that needs to be followed in these cases.

Abbreviations: CE, capsule endoscopy; DBE, double-balloon enteroscopy; NSAIDs, nonsteroidal anti-inflammatory drugs; OGIB, obscure GI bleeding.

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TABLE 1. Characteristics of the study population

Age (y) (mean [SD])	59.5 (14.4)
Male/female	169:124
Hemoglobin (g/dL) (mean [SD], minimum-maximum)	9.9 (1.68), 7.2-12.4
Overt GI bleeding of obscure origin	146
Hematochezia	61
Melena	85
Occult GI bleeding of obscure origin	147
Iron deficiency anemia	108
Positive fecal occult blood test	39

We therefore prospectively evaluated all patients with OGIB who underwent CE at our institution to determine their outcomes and to investigate whether those with a nondiagnostic test would benefit from a second-look CE.

PATIENTS AND METHODS

From September 2002 to January 2007, all patients referred to our unit for CE because of overt or occult OGIB were considered for entry into the study. We excluded patients with known or suspected GI obstruction, strictures or fistulae; patients with a cardiac pacemaker, defibrillator, or other implanted electromedical device; pregnant women; patients under 18 years of age; and patients who refused consent. Patients with suspected GI obstruction were excluded because the capsule can become stuck at points of luminal narrowing, with resultant acute bowel obstruction. Patients with a pacemaker were excluded because of fear of interference of the pacemaker by the capsule, although, so far, such an incidence has not been reported.

We defined bleeding of obscure origin as bleeding of unknown origin that persists or recurs (ie, recurrent or persistent iron deficiency anemia, fecal occult blood test positivity, or visible bleeding) after a negative initial work-out including gastroscopy, colonoscopy, small bowel barium follow-through or enteroclysis, and push enteroscopy. Bleeding of obscure origin was further subdivided in 2 clinical entities: (1) obscure: occult, as manifested by recurrent iron-deficiency anemia or recurrent positive fecal occult blood test results and (2) obscure: overt, with recurrent passage of visible blood (hematochezia/melena).

CE was performed with the Given M2A video capsule system (Given Imaging, Yotneam, Israel), as reported previously.¹⁴ All patients ingested the capsule at 9 AM after an

Capsule Summary

What is already known on this topic

- Despite capsule endoscopy (CE), a substantial number of patients with occult GI bleeding (OGIB) do not receive a diagnosis, and a second CE may be used.

What this study adds to our knowledge

- In 293 subjects at a single institution, 65% of individuals with a nondiagnostic initial CE continued to manifest OGIB after a mean follow-up period of 24 months.
- Development of overt bleeding and a hemoglobin drop of 4 g/dL or more were significant predictive factors of a diagnostic second CE.

overnight fast. They were also given a bowel preparation with 2 L of polyethylene glycol electrolyte lavage solution 16 hours before the investigation because this has been shown to increase the diagnostic yield of CE.¹⁵ In addition, they were advised to consume clear liquids from the time they started receiving the bowel purge until the time they went to bed that same night. After ingestion, nonhospitalized patients were free to go home and continue their usual activities, but they were asked to contact us if they noted abdominal pain, nausea, or vomiting. All patients were advised not to drink and eat for a 3- and a 4-hour period, respectively. At the end of the recording period, the equipment was removed.

Two investigators (N. V., K. P.) independently evaluated the video capsule endoscopy images at a movie speed of 10 frames per second. The investigators were blinded as to whether the patients were referred for the evaluation of overt or occult bleeding of obscure origin.

Findings were considered positive if the investigators could explain the patient's symptoms or help further management or if the findings were later confirmed by other diagnostic modalities. Findings were considered of uncertain significance if they failed to completely explain the patient's symptoms, thus necessitating further investigation. Finally, when no abnormality was detected, despite a definite indication of an existing lesion, the test was considered as having no findings.

All patients were monitored closely at 3- and 6- month intervals and every 6 months thereafter for a survey of their final outcome. Outcome was described as either continued bleeding or complete resolution of bleeding (regardless of whether treatment was given). For all patients the following follow-up information was obtained: use of medical, endoscopic, or surgical treatment; further bleeding episodes; persistence of iron deficiency anemia; or positivity of fecal occult blood testing. This information was sought through telephone interviews, contact of the referring physicians, or follow-up visits of the patients themselves.

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