

## Clinical consequences of videocapsule endoscopy in GI bleeding and Crohn's disease

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**Background:** Videocapsule endoscopy (VCE) has a high diagnostic yield in the analysis of GI bleeding and Crohn's disease. Little information is available on the impact of VCE findings on clinical care.

**Objective:** Assess the impact of VCE findings on clinical management and outcome.

**Design:** Retrospective descriptive study.

**Setting:** General hospital.

**Patients:** VCE was performed in 150 patients for GI bleeding (n = 97), Crohn's disease (n = 36), and miscellaneous reasons (n = 17).

**Main Outcome Measurements:** Clinical consequences were evaluated by using a questionnaire and were divided into change of management or unchanged management. Change of medication, endoscopic procedures, surgical procedures, other consequences, and avoidance of additional investigations were considered a change of management. For all patients, an assessment of the actual clinical condition and the most recent Hb level were registered.

**Results:** A definite diagnosis was established in 34%, a probable diagnosis in 34%, and no diagnosis in 32%. Management was changed in 38% of patients, increasing to 59% if a definite diagnosis was established at VCE. No relation between change of management and clinical improvement or increased Hb level could be established.

**Limitations:** The start of ethinylestradiol/norethisterone in case of telangiectasia was considered a change of management, although controversy on the rationale of this treatment exists. A more detailed and objective evaluation of the clinical condition should be performed to assess the clinical outcome.

**Conclusions:** VCE findings have a serious impact on clinical practice. VCE in particular leads to a change of management in 59% of the patients in whom a definite diagnosis is established. (Gastrointest Endosc 2007;66:1164-70.)

Until recently, complete endoscopic examination of the small intestine was only achieved by intraoperative enteroscopy. The only endoscopic access to the small intestine was obtained by ileocolonoscopy or fluoroscopy-guided push enteroscopy. Both approaches offered a limited view of the small-intestinal mucosa. Videocapsule endoscopy (VCE) is a new, noninvasive diagnostic tool to visualize the entire small intestine. The system consists of a wireless capsule that can be swallowed and that is propelled by

peristalsis. It obtains sequential endoscopic images of the small intestine that can be reviewed as a movie.

The main indications for visualization of the small intestine are GI bleeding (GIB), small-bowel Crohn's disease (CD), and intestinal tumors. Various studies on the diagnostic yield and clinical applicability of VCE have been performed in highly selected groups of patients. These studies reported a diagnostic yield of 55% to 85%.<sup>1-8</sup> VCE was compared with other diagnostic modalities for the small intestine in a large meta-analysis that demonstrated that VCE is superior to push enteroscopy and enteroclysis in both the analysis of occult GIB and suspected small-intestinal CD.<sup>9</sup> This led to the increasing implementation of VCE in clinical practice for the investigation of GI blood loss or small-intestinal CD. Little

Abbreviations: CD, Crohn's disease; GIB, GI bleeding; n.s., not significant; SD, standard deviation; VCE, videocapsule endoscopy.

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information is available, however, on the clinical implications of VCE. Frequently, VCE reveals minor abnormalities of which it is not clear whether they have a causal relation with the patient's symptoms. Even in case of abnormalities at VCE that can reasonably be the cause of the clinical symptoms under investigation, the impact on treatment and outcome is largely unknown. To assess the clinical usefulness of VCE, not only the diagnostic yield but also the clinical relevance and consequences should be investigated. In the present study, we, therefore, analyzed the direct clinical consequences of VCE findings and the current clinical status of the patients 1 year after the procedure.

## PATIENTS AND METHODS

### Patients

For all patients who underwent VCE in the period between January 2002 and January 2005, data were collected regarding age, sex, and the indication of VCE. None of the patients previously underwent major GI surgery. The indication of GIB was divided into occult GIB in the case of iron deficiency anemia in the absence of visible blood and overt GIB if blood loss was visualized.<sup>10</sup> In patients with GIB, the lowest Hb in the year preceding VCE was registered. The time delay between the most recent bleeding episode and VCE was registered in the case of overt bleeding and was categorized as less than 2 weeks or more than 2 weeks. Patients with CD were categorized into 2 groups. Patients with known CD were classified as established CD and patients with diarrhea combined with abdominal pain and laboratory abnormalities that suggested CD were classified as suspected CD. All other indications were classified as other.

### VCE

VCE was performed by using a wireless capsule (M2A; Given Imaging, Yoqneam, Israel), as previously described.<sup>11,12</sup> All images were analyzed by 1 of 4 experienced gastroenterologists who each had reviewed at least 50 VCE procedures before the study. Gastric and small-intestinal transit time was calculated, and the percentage of complete small-bowel evaluations was registered.

Findings were considered a definite diagnosis if the observed finding could explain the symptoms of the patient. Findings were considered suspicious and were registered as a probable diagnosis if an observed finding failed to completely explain the symptoms of the patient. In case of multiple findings, the most relevant finding determined whether they were considered a definite diagnosis or suspicious findings. If no relevant abnormalities were found and in case of an insufficient investigation, then VCE was classified as "no diagnosis."<sup>1</sup>

### Questionnaire

One year after VCE, a questionnaire was sent to the referring physician. The questionnaire evaluated the impact of VCE findings on clinical care. Clinical consequences

### Capsule Summary

#### What is already known on this topic

- Videocapsule endoscopy (VCE) is a noninvasive diagnostic tool that may visualize the entire small intestine and evaluate GI bleeding, small-bowel Crohn's disease, and intestinal tumors.

#### What this study adds to our knowledge

- In a retrospective review of 150 patients who underwent VCE, a definite diagnosis was established in 34%, a probable diagnosis in 34%, and no diagnosis in 32%.
- VCE changed management in 38% of patients.

were categorized as change or no change of management. Change of medication, endoscopic procedures, surgical procedures, avoidance of additional investigations (eg, push enteroscopy, CT enteroclysis, or nuclear imaging), and other clinical consequences were considered a change of management. In case of patients referred for VCE by one of the investigators, the clinical impact was assessed by an independent physician.

The treating physician was asked to judge the present clinical condition of the patient as worse, better, or equal compared with the moment of referral for VCE based on general clinical parameters. If VCE had been performed for GIB, then the Hb level 1 year after VCE was registered. All referring physicians were asked whether they would refer their patients for VCE for the same indication in the future.

For the assessment of the relation of consequences of VCE findings and clinical outcome, consequences were divided in change of treatment or unchanged treatment. The major differences with the assessment of management changes concerned the categories, avoiding additional investigation and the performance of endoscopic procedures in patients with inflammatory bowel disease. These categories were categorized as unchanged treatment, because this will not influence the clinical outcome. The other clinical consequences were considered a change of treatment.

### Statistics

Parametric results were compared by 2-sided Student *t* test. Data from multiple groups were compared by analysis of variance. Group proportions were compared with the  $\chi^2$  test or the Fisher exact test where appropriate. A 2-sided *P* < .05 was considered significant.

## RESULTS

### Questionnaire

One year after the performance of VCE, 166 questionnaires were sent to the referring physicians. The response rate was 90.4% (*n* = 150).

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