Long-term follow up of patients with obscure gastrointestinal bleeding examined with video capsule endoscopy

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Abstract

Background: Video capsule endoscopy (VCE) is a commonly used test for the evaluation of obscure gastrointestinal bleeding. However, long-term outcomes of patients undergoing VCE are unclear.

Aims: To evaluate the long-term outcomes in patients undergoing VCE for suspected obscure bleeding including iron deficiency anemia (IDA), and determine the need for additional intervention for persistence or recurrence of symptoms in patients with a diagnostic as well as non-diagnostic VCE.

Design: Retrospective cohort study within a large county hospital system.

Methods: We collected information on indications and findings of VCE and outcomes including further testing, bleeding, and hemoglobin (Hgb) at last follow-up through structured review of the electronic health records. VCE findings were classified as active bleeding or high potential for bleeding (P2), intermediate potential (P1) or without any disruption of the mucosa, and no potential for bleeding (P0). We compared demographic and clinical characteristics between patients with and without normal Hgb at the time of last follow up.

Results: We examined 116 patients who underwent VCEs performed for obscure gastrointestinal (GI) bleeding during 2010 to 2012 with mean duration of follow up after VCE completion of 571 days (standard deviation [SD] = 248). Abnormal VCE findings (37.9% for P1 lesions, 44.8% for P2 lesions) were seen in 106 (87.9%) patients. Additional diagnostic testing was performed in 55/116 (47.4%) (67.7% GI procedures). Hgb was restored to normal range in 59/116 (50.9%) by end of follow up which were attributed to iron supplementation and/or discontinuation of non-steroidal anti-inflammatory drugs (NSAIDs) in a majority. Twenty six of 116 patients experienced rebleeding (22.4%).

Conclusions: The diagnostic yield of VCE is high among patients with obscure GI bleeding. More than 50% of patients achieve normal Hgb in the long term with conservative measures such as iron supplementation and the discontinuation of NSAIDs.

Abbreviations: AVMs = arteriovenous malformations, CI = confidence intervals, EGD = esophagogastroduodenoscopy, GI = gastrointestinal, Hgb = hemoglobin, IDA = iron deficiency anemia, NSAIDs = non-steroidal anti-inflammatory drugs, OR = odds ratios, VCE = video capsule endoscopy.

Keywords: iron deficiency anemia, obscure gastrointestinal bleeding, small bowel bleeding, video capsule endoscopy

1. Introduction

The main utility of video capsule endoscopy (VCE) in clinical practice has been in the evaluation of obscure gastrointestinal bleeding. In a systematic review of 227 published reports including over 20,000 VCE procedures, the primary reason for VCE examination was obscure gastrointestinal (GI) bleeding (66.0%), followed by clinical symptoms (10.6%) and suspected Crohn disease (10.4%). In these studies, the VCE detection of small bowel lesions approached 60%.[1] The diagnostic yield of VCE among patients with small bowel disease is generally higher than that of small bowel radiography or push enteroscopy,[2,3] and not different from balloon assisted enteroscopy.[4]

Few small studies have addressed the long-term outcomes of patients undergoing VCE for obscure GI bleeding with particular emphasis on those with a non-diagnostic study, and arrived at conflicting estimates of rebleeding rates. Lai et al.[4] reported in a series of 49 patients in Hong Kong with obscure GI bleeding a 5.6% (n=1/18) rebleeding rate in those with a negative VCE study during a median follow-up of 19 months (range, 12–31); this rate was significantly lower than rebleeding rate in those with
a positive study; 48.4% (n=16/31), P=.03. Park et al[5] evaluated 51 consecutive patients in Seoul, South Korea who had undergone VCE for obscure GI bleeding, and found no significant difference in the rebleeding rates between patients with a positive (n=23) or negative (n=28) VCE result (34.8% vs 35.7%, respectively, P=.98) during a median follow-up of 32 months. A higher percentage of patients with a positive VCE study received specific treatment (i.e., angiography with embolization, discontinuation of non-steroidal anti-inflammatory drugs [NSAIDs] or anticoagulation, treatment of small bowel Crohn disease) than those with a negative VCE. The calculated yield of VCE in these studies was affected by choice of the comparison tests (i.e., radiography, push enteroscopy, or balloon assisted enteroscopy), and also by the intermittent nature of clinical course of some lesions (e.g., small bowel arteriovenous malformations [AVMs]). There are no similar studies in US populations.

Therefore, rebleeding rates and/or resolution of anemia in patients with suspected obscure GI bleeding with but especially without VCE-detected small bowel pathology, remains unknown, and it is important to evaluate because additional endoscopic, radiologic, or surgical procedures are often taken to investigate small bowel pathology seen on VCE which may otherwise be of no clinical concern. The aims of this study were to evaluate within a large county hospital system the long-term outcomes in patients undergoing VCE for suspected obscure bleeding including iron deficiency anemia (IDA), and determine the need for additional intervention for persistence or recurrence of symptoms in patients with a diagnostic as well as non-diagnostic VCE.

2. Methods

2.1. Study population

We evaluated all consecutive patients who had a request for VCE test placed between January 1, 2010 and December 30, 2012, within the Harris Health System in Houston, TX. We included all adult patients (>18 years of age) for whom a first time VCE request was placed for IDA or obscure overt GI bleeding. We excluded patients in whom the VCE was not performed within 180 days of placing request, test data not available for review, no follow-up visits were recorded within the electronic health records, and/or alternative etiologies for anemia or bleeding (i.e., hemoglobinopathy or abnormal uterine bleeding). We defined obscure overt GI bleeding as melena and/or hematochezia without a source of blood loss identified on esophagogastroduodenoscopy (EGD) and colonoscopy. IDA was defined as hemoglobin (Hgb) <11g/dL for women and 13g/dL for men, and ferritin <30ng/mL, and/or transferrin saturation (<10%) without a source of blood loss on EGD and colonoscopy.

We obtained the information on indications and findings of VCE and follow up outcomes through structured review of the electronic health records. The extracted information included time from VCE order to completion, number and type endoscopic evaluations completed prior to VCE, index blood hemoglobin level obtained within 1 month of VCE, use of anti-platelet or anticoagulant medications, and other major medical comorbidities. We obtained the date of most recent follow-up visit, additional testing related to VCE findings at the time of last follow up, any GI endoscopic tests, further bleeding or need for additional transfusions through June 2015. Resolution of IDA was defined by return of normal blood hemoglobin value (>12g/dL in women, 13g/dL in men). Non-resolution or recurrence of IDA was defined by ongoing anemia and ferritin <30ng/mL and/or iron saturation (<10%).

2.2. VCE Test

We performed VCE using the Pillcam SB, Medtronic Minneapolis, MN (Given Diagnostic Imaging System). Small bowel preparation consisted of a clear liquid diet 1 day prior to the examination and 119g of Miralax mixed with 34 ounces of Gatorade taken 12 hours prior to ingestion of the video capsule. A single endoscopist (RS) reviewed all VCE images for the purpose of the study (>90% concordance with the initial clinical reading). The first duodenal image, first cecal image, and small bowel transit time were recorded. We classified intestinal lesions according to their potential for bleeding, defined by Saurin et al[6] into: lesions with active bleeding or high potential for bleeding based on size or number (P2), intermediate potential for bleeding (P1), and lesions without any disruption of the mucosa and no potential for bleeding (P0). VCE findings were considered diagnostic if P2 or P1 lesions were found and the observed lesions could explain bleeding or IDA, or supported clinical suspicion of small bowel Crohn disease. VCE was considered non-diagnostic if P0 lesions were found and/or findings were not sufficient to explain the signs or symptoms.

2.3. Statistical analysis

We compared the demographic and clinical characteristics between groups using chi-square tests for categorical variables and t tests for continuous variables. We estimated odds ratios (OR) and corresponding 95% confidence intervals (95% CI) using logistic regression models. Variables were included in the final multivariable model using a P-value cut-off of .20 in univariate analysis. All statistical analyses were performed using Stata 13.1 (StataCorp LP, College Station, TX) and a 2-tailed P value of <.05 was considered statistically significant.

The institutional review board of Baylor College of Medicine approved this study.

3. Results

A total of 144 patients had requests for VCE during the study period, of whom 116 completed the test (80.6%) and fulfilled the study inclusion and exclusion criteria (Fig. 1). Table 1 shows selected characteristics of these 116 patients. The mean age of the study cohort was 54.4 years (standard deviation [SD]=11.8), and 56.9% were women. The greatest proportions of patients were Hispanic (53.5%), followed by blacks (26.7%) and non-Hispanic whites (11.2%).

The main indications for VCE were IDA (75, 64.7%), followed by overt GI bleeding (41, 35.3%). The mean Hgb level at the time the VCE request was 8.0g/dL (SD=2.8; range, 3–14). The mean duration between the dates of VCE request and its completion was 42 days (SD=27; range, 7–161). The mean baseline Hgb was 8.7g/dL (SD=2.8) in patients undergoing VCE for IDA, and 6.8g/dL (SD=2.3) in those for overt GI bleeding. NSAIDs intake was reported in 25 patients (21.6%), ASA in 24 patients (20.7%), and either NSAIDs or ASA in 44 (37.9%); 10 patients (8.6%) were on ADP receptor antagonists, 7 (6.0%) on warfarin and 16 (13.8%) on either ADP receptor antagonists or warfarin, whereas 78 (67.2%) patients were on oral iron supplementation preceding VCE.
Among 116 patients, 102 (87.9%) had abnormal VCE findings. The most common VCE finding was <5 small bowel AVMs (38.1%) followed by small bowel erosions (20.6%), small bowel ulcer (19.0%), esophageal or gastric lesions (8.7%), >5 small bowel AVMs (7.1%), and small bowel polyps (6.3%). P2 lesions were identified in 52 (44.8%), P1 lesions in 44 (37.9%), and P0 lesions in 20 patients (17.2%). P2 lesions were detected in 32.7% of patients when VCE was performed ≤30 days versus 53.1% of patients when VCE was performed >30 days the request was made (P = .03).

The mean duration of follow up after VCE completion was 568 days (SD = 257). Additional endoscopic procedures were requested in 53/116 (47.4%) and completed in 44 (12 balloon assisted enteroscopy, 12 repeat EGDs, 10 push enteroscopy, and 10 repeat colonoscopies). The diagnostic yield of single balloon assisted enteroscopy was 5/12 (41.7%) including 1 small bowel adenocarcinoma, 1 jejunal adenoma, and 3 patients with small bowel AVMs. The diagnostic yield of repeat EGD was 6/12 (50.0%). The diagnostic yield of repeat colonoscopy was 2/10 (20.0%), and for push enteroscopy was 5/10 (50.0%). Cauterization of AVMs was performed in 7 patients on subsequent endoscopy. In 11 of the 44 repeated endoscopic procedures, abnormal results were detected on prior VCE (25.0%). The remaining 33 procedures were performed for ongoing anemia or repeated overt GI bleeding. In 4 of the 12 repeated EGDs, abnormal findings were also detected on prior VCE. In 3 of the 12 balloon assisted enteroscopies, abnormal findings were detected on prior VCE. In 4 of the 10 push enteroscopies, abnormal findings were detected on prior VCE. Computed tomography of the abdomen was obtained in 8/116 (6.9%) after VCE was completed. The diagnostic yield was 2/8 (25%) (1 = small bowel adenocarcinoma with liver metastases, 1 = small bowel gastrointestinal stromal tumor).

### Table 1
Baseline demographic and clinical characteristics of the study cohort, overall and stratified by diagnostic versus non-diagnostic VCE.

|                        | All (n = 116) | Non-diagnostic (P0 lesions) (n = 20) | Diagnostic (P2 and P1 lesions) (n = 96) | P value* |
|------------------------|--------------|-------------------------------------|----------------------------------------|---------|
| Age, mean years (SD)   | 54.4 (11.8)  | 48.6 (14.6)                         | 55.6 (10.9)                            | .01     |
| Sex                    |              |                                     |                                        | .76     |
| Male                   | 50 (43.1)    | 8 (40.0)                            | 42 (43.8)                              |         |
| Female                 | 66 (56.9)    | 12 (60.0)                           | 54 (56.2)                              |         |
| Race/Ethnicity         |              |                                     |                                        | .80     |
| Non-Hispanic white     | 13 (11.2)    | 1 (5.0)                             | 12 (12.5)                              |         |
| Black                  | 31 (26.7)    | 6 (30.0)                            | 25 (26.0)                              |         |
| Hispanic               | 62 (53.5)    | 11 (55.0)                           | 51 (53.1)                              |         |
| Other                  | 10 (8.6)     | 2 (10.0)                            | 9 (8.3)                                |         |
| VCE indication         |              |                                     |                                        | .97     |
| IDA                    | 75 (64.7)    | 13 (65.0)                           | 62 (64.6)                              |         |
| Overt GI               | 41 (35.3)    | 7 (35.0)                            | 34 (35.4)                              |         |
| Medication use at time of request |           |                                     |                                        |         |
| Aspirin                | 24 (20.7)    | 1 (5.0)                             | 23 (24.0)                              | .06     |
| NSAIDs                 | 25 (21.6)    | 2 (10.0)                            | 23 (24.0)                              | .17     |
| Anticoagulant          | 10 (8.6)     | 1 (5.0)                             | 9 (9.4)                                | .53     |
| Iron supplement        | 78 (67.2)    | 15 (75.0)                           | 63 (65.6)                              | .42     |

GB = gastrointestinal bleeding, IDA = iron deficiency anemia, NSAIDs = non-steroidal anti-inflammatory drugs, SD = standard deviation, VCE = video capsule endoscopy.

*P-value for chi-square test (categorical variables) or t-test (continuous variables) comparing non-diagnostic (P0 lesions) and diagnostic (P2 and P1 lesions) groups.
In patients with IDA, 42 of the 75 (56.0%) patients had return to normal Hgb range at the end of follow up (Supplementary Table 1, http://links.lww.com/MD/C338). The most common VCE findings in those with IDA was <5 small bowel AVMs followed by small bowel erosion and ulcer. Additional investigation was performed in 12 of the 42 (Supplementary Table 1, http://links.lww.com/MD/C338), and additional therapy in 31 including iron supplementation with (n = 3), duodenal polypectomy (n = 1), colon cancer resection (n = 1), and hemorrhoidectomy (n = 1), additional red blood cell transfusion (n = 7).

In patients with overt GI bleeding, 17 of the 41 (41.5%) patients had resolution of symptoms and return to normal Hgb at the end of follow up (Supplementary Table 2, http://links.lww.com/MD/C338). Additional diagnostic testing was performed in 12 of these 17 patients but the diagnostic yield was low; only 1 was found to have bleeding hemorrhoids. Additional therapy was given in 8 patients; this included iron supplementation (n = 3), hemorrhoidal banding (n = 2), discontinuation of NSAIDs (n = 2), aortic valve repair (n = 1), and 5 of the 17 patients with resolution of anemia required additional red blood cell transfusion. The most common baseline VCE finding in those with overt GI bleeding with resolution was <5 small bowel AVMs.

Overall restoration of normal Hgb range by end of follow up was observed in 59 of 116 (50.9%). On multivariate analysis, female sex, Hispanic ethnicity, and VCE indication of iron deficiency anemia were associated with restoration of normal Hgb at end of follow-up but did not reach statistical significance.

On the other hand, the presence of P1 and P2 lesions were associated with lack of resolution compared with P0 lesions (Table 2). The need for a blood transfusion at the time of presentation was the only significant determinate of rebleeding during the follow-up period (OR 18.9). (Supplementary Table 3, http://links.lww.com/MD/C338).

### Discussion

This is one of the largest single center studies evaluating the diagnostic yield and subsequent follow up of patients undergoing VCE for suspected obscure GI bleeding within a large safety net hospital system. Amongst 116 consecutive VCE procedures performed in unique patients, approximately 87% were abnormal. During a follow up duration of 571 days, 50.9% resolved their baseline anemia. In those undergoing VCE for overt GI bleeding or iron deficiency anemia, 44.8% of patients had P2 lesions. Most achieved normal hemoglobin at the conclusion of follow-up which was attributed to discontinuation of NSAIDS and/or iron supplementation. Only 16% of patients with IDA and subsequent resolution required additional red blood cell transfusion.

VCE has been shown to achieve a higher diagnostic yield in the setting of obscure GI bleeding than angiography, push enteroscopy, or CT-enteroclysis. Detection rates approach 60% in many studies. However, despite the higher yield of abnormal results using VCE, the value of further testing and therapy in restoring return to normal hemoglobin varies. Other studies have also casted doubt on the additional benefit of increased utilization of endoscopic and surgical therapies.

### Table 2

The determinants of resolution of baseline indication among all patients undergoing VCE in the study. Findings from unadjusted and adjusted analyses.

| Age group | Not resolved N = 57 | Resolved N = 59 | Unadjusted OR (95% CI) | Adjusted OR* (95% CI) |
|-----------|---------------------|----------------|------------------------|----------------------|
| <50       | 18 (31.6)           | 16 (27.1)      | 1.00 (Ref)             |                      |
| 50—<60    | 24 (42.1)           | 25 (42.4)      | 1.17 (0.49–2.81)       |                      |
| ≥60       | 15 (26.3)           | 18 (30.5)      | 1.35 (0.52–3.53)       |                      |

**Sex**

| Female   | 29 (50.9) | 37 (62.7) | 1.62 (0.77–3.40) | 1.42 (0.66–3.07) |
| Male     | 28 (49.1) | 22 (37.3) | 1.00 (Ref)       | 1.00 (Ref)       |

**Race/Ethnicity**

| Non-Hispanic | 30 (52.6) | 24 (40.7) | 1.00 (Ref) | 1.00 (Ref) |
| Hispanic    | 27 (47.4) | 35 (59.3) | 1.62 (0.78–3.38) | 1.59 (0.74–3.42) |

**VCE indication**

| IDA       | 33 (57.9) | 42 (71.2) | 1.80 (0.83–3.88) | 1.73 (0.78–3.84) |
| Overt GI bleeding | 24 (42.1) | 17 (28.8) | 1.00 (Ref) | 1.00 (Ref) |

**Aspirin or NSAIDs use**

| No        | 37 (64.9) | 35 (59.3) | 1.00 (Ref) | –          |
| Yes       | 20 (35.1) | 24 (40.7) | 1.27 (0.60–2.69) | –          |

**ADP or anticoagulant**

| No        | 48 (84.2) | 52 (88.1) | 1.00 (Ref) | –          |
| Yes       | 9 (15.8)  | 7 (11.9)  | 0.72 (0.25–2.08) | –          |

**Iron supplement**

| No        | 18 (31.6) | 20 (33.9) | 1.00 (Ref) | –          |
| Yes       | 39 (68.4) | 39 (66.1) | 0.90 (0.41–1.96) | –          |

*Adjusted model includes all variables with P < .20 in unadjusted model (sex, race/ethnicity, VCE indication).

ADP = adenosine diphosphate receptor antagonist, GI = gastrointestinal, IDA = iron deficiency anemia, NSAIDs = non-steroidal anti-inflammatory drugs, VCE = video capsule endoscopy.
Endoscopic cauterization of gastrointestinal AVMs was achieved in over 50% due to iron supplementation and/or the abnormal studies. The most common P2 lesion was the presence of these lesions comprising 44.8% these abnormal studies. The most common P2 lesion was the presence of small bowel angioectasias. Resolution of anemia was achieved in over 50% due to iron supplementation and/or the discontinuation of NSAIDS in the majority of patients. Endoscopic cauterization of gastrointestinal AVMs was performed in 7 patients based on VCE findings with only 2 of the 7 patients returning to normal hemoglobin level on follow up. This high percentage of abnormal VCEs was obtained in our study despite an average wait time of 42 days from VCE request to completion, and all procedures being performed on an outpatient basis. Timing of VCE performance has been shown to affect its diagnostic yield. In a large retrospective series, Singh et al[12] demonstrated a detection rate of 65% among VCE performed in the inpatient setting and 53% for outpatient VCE, but this difference did not reach statistical significance. Similarly, Esaki et al[13] reported a high diagnostic yield (38.2%) when VCE is performed within 7 days of the last bleeding episode compared with VCE performed >7 days (14.7%). In our study’s hospital system all VCEs are performed at a central outpatient location. As a result, the median time to VCE completion was relatively delayed. However, there was a higher detection of P2 lesions when VCE was performed >30 days of the order being placed compared with <30 days.

In this study, 50.9% had resolution of anemia of whom only 10.3% had subsequent endoscopic or invasive therapy, and 56.9% had relatively simple measures such as discontinuing ASA/NSAID and iron supplements. Of those with no resolution, 41.4% had subsequent endoscopic or invasive follow-up, and 51.7% had relatively simple measures such as discontinuing ASA/NSAID and iron supplements. Given the high rate of anemia resolution and low rate of neoplasia a conservative approach is recommended particularly in patients undergoing VCE for IDA, on NSAIDs and/or aspirin, female sex, and the detection of P1 or P0 lesions on VCE.

The weaknesses of our study include the retrospective design and single center safety net hospital. However, the strengths of our study include the number of patients that is larger than previous studies of the same topic. Patient follow up was also sufficiently long to detect the rate of rebleeding, hospitalization, need for further transfusion, and resolution of anemia. Lastly, a single electronic health record allowed complete data capture both in the outpatient and inpatient setting.

In summary, our study found a high diagnostic yield of VCE regardless of time to completion. Long-term outcome of patients undergoing VCE particularly for IDA are favorable with >50% of patients achieving normal hemoglobin. Conservative measures should be considered in those without overt bleeding or transfusion requirement, or on NSAIDs at the time of presentation.

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