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ORIGINAL RESEARCH

Evidence-Based Emergency Medicine

Risk stratification with video capsule endoscopy leads to fewer hospital admissions in emergency department patients with low-risk to moderate-risk upper gastrointestinal bleed: A multicenter clinical trial

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Abstract

Objective: In US emergency departments (EDs), the physician has limited ability to evaluate for common and serious conditions of the gastrointestinal (GI) mucosa such as a bleeding peptic ulcer. Although many bleeding lesions are self-limited, the majority of these patients require emergency hospitalization for upper endoscopy (EGD). We conducted a clinical trial to determine if ED risk stratification with video capsule endoscopy (VCE) reduces hospitalization rates for low-risk to moderate-risk patients with suspected upper GI bleeding.

Methods: We conducted a randomized controlled trial at 3 urban academic EDs. Inclusion criteria included signs of upper GI bleeding and a Glasgow Blatchford score <6. Patients were randomly assigned to 1 of the following 2 treatment arms: (1) an experimental arm that included VCE risk stratification and brief ED observation versus (2) a standard care arm that included admission for inpatient EGD. The primary outcome was hospital admission. Patients were followed for 7 and 30 days to assess for rebleeding events and revisits to the hospital.

Results: The trial was terminated early as a result of low accrual. The trial was also terminated early because of a need to repurpose all staff to respond to the coronavirus disease 2019 pandemic. A total of 24 patients were enrolled in the study. In the experimental group, 2/11 (18.2%) patients were admitted to the hospital, and in the standard of care group, 10/13 (76.9%) patients were admitted to the hospital ($P = 0.012$). There was no difference in safety on day 7 and day 30 after the index ED visit.

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Conclusions: VCE is a potential strategy to decrease admissions for upper GI bleeding, though further study with a larger cohort is required before this approach can be recommended.

KEYWORDS
emergency department, hospital admission, risk stratification, upper GI bleed, video capsule endoscopy

1 | INTRODUCTION

1.1 | Background

Gastrointestinal (GI) bleeding is a common presentation in the emergency department (ED) and represents the primary diagnosis for ≈700,000 annual ED visits in the United States.[1] For suspected upper GI bleeds, definitive care is to receive an upper endoscopy (EGD) for diagnosis and possible hemostatic treatment within 24 hours.[2] The challenge is that most US hospitals do not have the resources to perform an EGD on all patients suspected to have an upper GI bleed because of the need for an in-person gastroenterologist, specialized equipment, and anesthesia support. As a result, a significant proportion of patients are admitted to the hospital for observation that does not need an emergent EGD, and others receive delayed care.[3] Established means of performing risk stratification in the ED, such as the Glasgow Blatchford score (GBS) or nasogastric (NG) lavage, have significant limitations regarding sensitivity and specificity.[4,5]

Video capsule endoscopy (VCE), first described by Iddan et al in 2000, is an alternative means to remotely view the lumen of the GI tract.[6] VCE has gained acceptance for several indications, including identifying mucosal lesions of the small intestine, assessing gastric motility, and evaluating occult bleeding.[7–10] In addition, several small studies have described high patient tolerance and accuracy levels similar to traditional EGD to evaluate the upper GI tract for bleeding.[11–15]

1.2 | Importance

VCE offers potential advantages for the ED management of upper GI bleeding. By offering a means to examine the lumen of the GI tract to identify the presence or absence of an active bleed or high-risk lesion, the test can potentially influence the need for admission and/or definitive EGD. Potential advantages of this approach compared with an emergency EGD include that VCE can be administered by a nonspecialist and without anesthesia in the ED setting.[14,16]

1.3 | Goals of this investigation

The objective of this study was to determine if ED risk stratification with VCE reduces hospitalization for low-risk to moderate-risk ED patients with suspected upper GI bleeding as part of a prospective multicenter randomized control trial.

2 | METHODS

2.1 | Study design and setting

We conducted a multicenter randomized control trial comparing VCE versus standard care SC for ED patients with an upper GI bleed. The study was conducted at 3 academic level 1 trauma center EDs with >180,000 annual visits cumulatively (George Washington University Hospital, Washington, DC; Temple University Hospital, Philadelphia, PA; Duke Medical Center, Durham, NC) The sites were selected based on a large diverse patient population with active clinical research programs. Institutional review board approval was obtained at each of the 3 clinical sites, and the trial was registered on clinicaltrials.gov (NCT03458000).

2.2 | Selection of participants

Research assistants prescreened all ED patients for signs of upper GI bleeding, specifically melena, hematemesis, or coffee-ground emesis during mostly weekday daytime hours but specific times varied among the 3 sites. The primary criteria to be in the study included being an ED patient with a suspected upper GI bleed and a GBS <6. The GBS was calculated by the research assistants in the ED both manually and by using an online calculator (Figure 1). Investigators and members of the data safety monitoring board (DSMB) agreed to a GBS of 6 as an appropriate cutoff because of the rationale that it was low enough to prevent the study from inadvertently randomly assigning a patient with a high likelihood of an unstable high-risk bleeding lesion and high enough to potentially affect management change.

Patients were excluded if the study team had concerns about the aspiration of a capsule (eg, altered mental status, dysphagia) or if there were concerns for a bowel obstruction based on clinical judgment or patient history. ED physicians were directly asked if they suspected the patient may have had a bowel obstruction or risk of bowel obstruction (eg, Crohn's disease, GI surgery such as bariatric surgery, complaint of obstipation). Patients were also excluded if they had a cardiac pacemaker or were known or suspected of being pregnant or breastfeeding. In addition, patients were excluded if they were suspected to have a variceal bleed by the clinical team because of the rationale that all patients with variceal bleeds need hospital admission. Finally, patients were excluded if they had no reliable contact information or no permanent address.

2.3 | Interventions

Participants were randomly assigned 1:1 by group via the sequence-generation feature embedded within the Redcap data management software (Developer, Vanderbilt University). Patients were not allowed to be excluded after randomization based on attending concern or based on VCE results. It was not feasible to blind patients or clinicians to the group to which they were allocated.

Participants randomly assigned to the intervention group underwent VCE with the PillCam upper GI capsule EGD, a US Food and Drug Administration (FDA)-cleared device manufactured by Medtronic. The PillCam upper GI system features a variable frame rate that operates at 35 frames per second for the first 10 minutes of the procedure and 18 frames per second for the remainder of the procedure using 2 cameras placed on opposite ends of the capsule. The battery was expected to last between 60 and 90 minutes. The capsule is expelled naturally through the GI tract and not returned to the investigators. The participants who were randomly assigned to the VCE arm received a single dose of intravenous metoclopramide 10 mg at the time of capsule ingestion to promote gastric motility. After ingesting the VCE, progress was monitored at the bedside using a real-time viewer to evaluate for passage through the pylorus. Upon passing through the pylorus, ≈5 more minutes of video was recorded to assess for post-pyloric bleeds before stopping the recording or until the battery died. VCEs were read by an attending gastroenterologist among a rotating group of 4 gastroenterologists from all 3 study sites. The gastroenterologists shared an on-call schedule for the study and were able to interpret the studies remotely. Studies were shared via a health insurance portability and accountability act-secure cloud with a goal of capsule read within 60 minutes of study completion using a structured data collection tool (Appendix 1).

Results of the VCE were shared with the treating emergency physician while the patient was in the ED. All emergency physicians were told of the presence or absence of high-risk lesions based on an attending GI read before disposition. Although hospital admission and inpatient EGD were considered to be SC, ultimate disposition was decided by the treating emergency physician. All physicians were told that the VCE was normal or reassuring before making an ED disposition decision. No additional structured decision support was provided to emergency physicians as part of the protocol regarding disposition decisions. For all participants, a follow-up EGD was recommended. For participants who were admitted, an inpatient EGD was considered to be part of the SC during hospital admission. For participants who were discharged, the EGD was also considered part of SC as part of follow-up. The study coordinator assisted with scheduling the outpatient EGD. Other standard treatments include starting patients on a proton pump inhibitor.

The Bottom Line

This clinical trial tested the utility of video capsule endoscopy (VCE) versus standard care for decision making in patients presenting to the emergency department with upper gastrointestinal bleeding. After screening 506 patients, the trial was terminated after enrolling only 24 patients. Most exclusions were attributed to clinician reluctance to use the results of VCE. Hospital admission was lower in the VCE than the standard care group (18% vs. 77%). This study highlights the challenges of conducting clinical trials and integrating new technology into clinical practice.

2.4 | Measurements

Participant data were collected from the site's electronic health record (EHR) using a standardized data collection tool including the chief

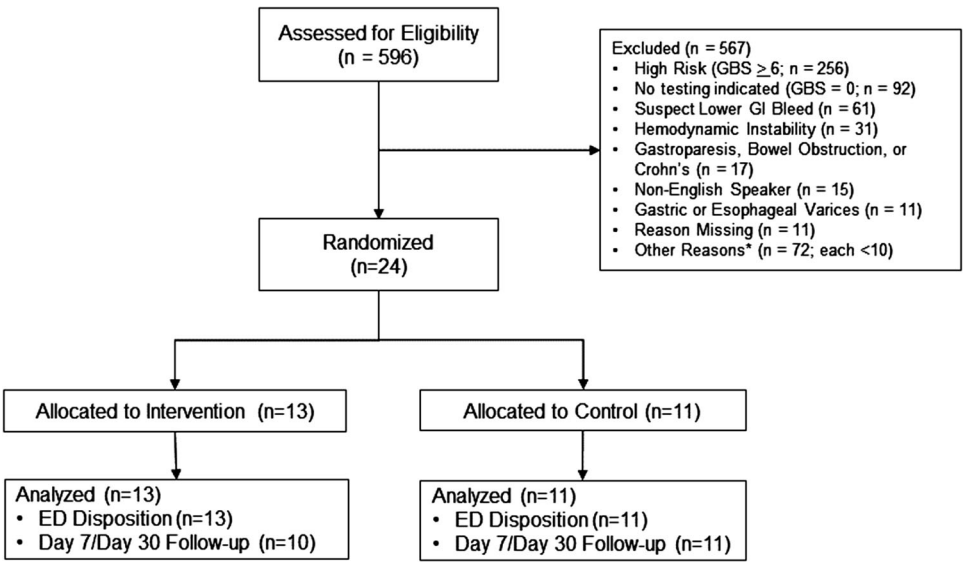

FIGURE 1 Flow of patients in the trial. ED, emergency department; GBS, Glasgow Blatchford score; GI, gastrointestinal

complaint of the patient, prespecified questions regarding the history of present illness (syncope, bloody vomiting, melena, and others), past medical history (ulcers, liver cirrhosis, congestive heart failure, and others), laboratory findings (hemoglobin, blood urea nitrogen, and others), current medications (proton pump inhibitors and non-steroidal anti-inflammatory drugs), vital signs (heart rate and blood pressure), GBS, the ED clinical care (blood transfusion, medication given, and others), and the inpatient clinical care (surgery, EGD, blood transfusion, and others). Data abstractors who collected the outcome variables were not blinded to group allocation. The participants randomly assigned to the VCE arm were monitored for a minimum of 4 hours in the ED; if they had no sign of active bleeding, no high-risk findings on VCE, stable hemoglobin, and stable vital signs, they were considered safe to be discharged from the ED. Hospitalization was ascertained by data abstraction from the EHR and defined as receiving admission orders from an inpatient medical team and a minimum stay of >24 hours in the hospital for evaluation of an upper GI bleed. Physicians who performed the inpatient or outpatient follow-up EGD completed a structured data collection sheet to standardize interpretations. After the VCE, patient satisfaction regarding the VCE was assessed using a standardized form with a 4-question Likert scale (Table 4). Data reported are based on combined positive and negative responses for simplicity.

Participants were called on day 7 and day 30 to assess for patient satisfaction and adverse events such as the need for hospitalization, recurrent bleeding, or any complication attributed to the capsule itself such as non-natural excretion. Patients were also assessed for serious adverse events defined as death, a life-threatening complication, hospitalization, disability, or need for other interventions (FDA, Code of Federal Regulations Title 21[17]). The person assessing for adverse events was not blinded to the group allocation.

2.5 | Outcomes

Our primary outcome was the need for hospitalization. No distinction was made for observation versus admission status. Based on current guidelines, admission was assumed to be the likely result of the SC arm but uncertain in the experimental arm. The final disposition decision was made by the ED treating physician who based his/her decision on the standard data points available to ED physicians, such as hemodynamic estimation, laboratory studies, comorbid conditions, and social stressors. For participants randomly assigned to the VCE arm, their physicians had access to standard data points in addition to the results of the VCE. The secondary outcomes were 7-day and 30-day safety and satisfaction measures assessed by telephone calls.

2.6 | Statistical analysis

SAS 9.4 (SAS Institute) was used for all statistical analyses. In planning this study, a sample size of 100 was estimated assuming a primary outcome rate of 80% admission in the SC group and 55% in the VCE group (ie, a 25% decrease in admissions) with a type I error (2-sided) of 5% and a power of at least 90%. This calculation was based on preliminary data at our site and investigator judgment regarding a meaningful decrease in admissions. Variables were compared between the groups using chi-square/Fisher's exact test for discrete data and Wilcoxon rank sum test for continuous data. As this was an intent-to-treat study, participants were included in the treatment group to which they were randomly assigned regardless of compliance. For analysis, the study statisticians were blinded to the allocation group. All relevant data available from each participant were employed in the analyses. The person doing the statistical analysis was blinded to group allocation.

3 | RESULTS

3.1 | Early termination of the trial

We recruited our first participant for the trial in May 2018. Although we had slower than expected enrollment, the onset of the coronavirus disease 2019 (COVID-19) pandemic forced research teams to discontinue enrollment in March 2020. Clinical trials were suspended at all enrolling sites for studies that were not related to COVID-19. As a result, we performed an interim analysis and presented our results to the DSMB. Because of the uncertainty about the time frame for potentially resuming the study, the sponsor declined to continue funding, and the study was terminated. DSMB concurred with the recommendation for early termination of the trial because of the lack of enrollment.

3.2 | Characteristics of study participants

We screened 506 patients cumulatively at the 3 sites. The majority of patients were excluded because the suspected upper GI bleed was considered too high risk to consider discharge regardless of any bedside diagnostic testing. The next most common reason for exclusion was that the emergency physician considered the patient to be stable enough and, therefore, not require further diagnostic testing. Other patients were excluded because, after further questioning, the bleed was considered most likely to be attributed to a lower GI source. Other patients were excluded as a result of hemodynamic instability or suspicion of a bowel stricture or obstruction.

A total of 24 participants were enrolled in the trial; 11 to the VCE arm and 13 to the SC arm (Figure 1). The treatment groups were well balanced concerning baseline characteristics (Table 1) with the exception that melena was more likely in the VCE arm (91% vs. 31%). No participants withdrew their consent after enrollment. A total of 2 patients in the VCE group and none in the control group were taking anticoagulation medications. No patients required blood transfusions. Of the patients, 1 in the experimental group had a systolic blood pressure of <110 mm Hg, and 5 in the control group had heart rates >100 beats per minute.

TABLE 1 Baseline characteristics of patients

Characteristic	VCE (n = 11)	SC (n = 13)
Age, y, median (IQR)	55 (36.0-58.0)	47.0 (41.0-54.0)
Female sex, n (%)	4 (36.4)	4 (30.8)
Race, n (%)		
Black	9 (81.8)	7 (53.9)
Other	0	2 (15.4)
White	2 (18.2)	4 (30.8)
Ethnicity, n (%)		
Hispanic	0	2 (15.4)
Non-Hispanic	11 (100.0)	11 (84.6)
Bloody or black "tar" stools in the past 24 hours, n (%)	10 (90.9)	4 (30.8)
Bloody or coffee-ground vomit in the past 24 hours, n (%)	2 (18.2)	7 (53.9)
Weak or light-headed in the past 24 hours, n (%)	9 (81.8)	8 (61.5)
How long ago did this episode of the bleeding first start, n (%)		
Between 1 and 2 days	3 (27.3)	3 (23.1)
Between 12 and 24 hours	2 (18.2)	1 (7.7)
Between 4 and 12 hours	0	3 (23.1)
More than 2 days	6 (54.6)	6 (46.2)
GBS, median (IQR)	3.0 (1.0-4.0)	1.0 (1.0-3.0)
PPI medication (Currently taking PPI antacids)?	2 (18.2)	4 (30.8)
On NSAIDS, n (%)	5 (45.5)	3 (23.1)
Taking anticoagulation medications	2 (18.2)	0
Past medical history		
Heart attack or heart disease	1 (9.1)	1 (7.7)
Diabetes mellitus	1 (9.1)	1 (7.7)
Cancer	0	1 (7.7)
Kidney failure or on dialysis	1 (9.1)	0
Previous smoker or active smoker	5 (45.5)	7 (53.9)
Liver disease or liver cirrhosis	0	1 (7.7)
Ulcer or gastritis or reflux	6 (54.6)	9 (69.2)
Hemorrhoids	1 (9.1)	2 (15.4)
Abdominal surgery or pelvic surgery	1 (9.1)	2 (15.4)
History of bowel obstruction	1 (9.1)	1 (7.7)
Initial heart rate, median (IQR)	78.0 (66.0-85.0)	77.0 (65.0-88.0)
Initial hemoglobin, median (IQR)	12.1 (11.1-14.9)	13.3 (12.2-16.0)

Abbreviations: GBS, Glasgow Blatchford score (see Appendix 2); IQR, interquartile range; NSAIDs, non-steroidal anti-inflammatory drugs; PPI, proton pump inhibitor; SC, standard care; VCE, video capsule endoscopy.

3.3 | Main results

For the primary outcome of hospital admission, 2 of 11 participants (18.1%) were admitted to the hospital in the VCE arm, and 10 of 13 (76.9%) were admitted to the hospital in the SC arm ($P = 0.012$, Table 2).

A follow-up EGD was performed in 19/24 (79%) patients. Of the 11 patients in the VCE group, 9 received a follow-up EGD, whereas 10 of 13 in the SC group received a follow-up EGD. (Table 3) The EGD was performed later for the VCE arm compared with the SC arm (median time to EGD: 4 days post index visit in VCE vs. <1 day in SC; $P = 0.006$).

Of the 11 participants in the VCE group, all were contacted at the day 7 and day 30 follow-up calls. No adverse events were elicited at day 7 or day 30 (Table 4). None of the 11 received a follow-up EGD, and none of these participants demonstrated a missed bleeding lesion on follow-up EGD. For the 2 VCE participants admitted, 1 was admitted for a lower esophageal stricture with bleeding and 1 was admitted for a decrease in hemoglobin.

TABLE 2 Primary outcome: hospital admission

Patient disposition from ED	VCE (n = 11)	SC (n = 13)	*P* value*	Difference (95% CI)
Admission to hospital, n (%)	2 (18.1)	10 (76.9)	0.012	−58.7% (−68.1% to −49.4%)
Discharge from ED, n (%)	9 (81.8)	3 (23.1)		58.7% (49.4%–68.1%)

Abbreviations: CI, confidence interval; ED, emergency department; SC, standard care; VCE, video capsule endoscopy.
**P* value was from the chi-square test.

TABLE 3 Disposition and EGD findings for each patient in the trial

Patient identification	Experimental arm	Disposition	EGD findings
1	EXP	Discharged	Peptic ulcer disease
2	EXP	Discharged	Esophagitis
3	EXP	Discharged	Normal
4	EXP	Admission	Lower esophageal stricture
5	EXP	Discharged	Gastritis
6	EXP	Admission	NA
7	EXP	Discharged	NA
8	EXP	Discharged	Upper GI pathology non-causative/incidental
9	EXP	Discharged	Evidence of coffee ground blood; upper GI pathology non-causative/incidental
10	EXP	Discharged	Normal
11	EXP	Discharged	Upper GI pathology non-causative/incidental
12	SC	Discharged	Normal
13	SC	Admission	Gastritis; esophagitis
14	SC	Admission	Other sources of bleeding; esophagitis; adherent clot/mass in distal esophagus
15	SC	Admission	Presence of an ulcer; low-grade non-variceal lesion
16	SC	Admission	Esophagitis
17	SC	Admission	NA
18	SC	Discharged	NA
19	SC	Discharged	NA
20	SC	Admission	Low-grade ulcer
21	SC	Admission	Low-grade ulcer
22	SC	Admission	Gastritis
23	SC	Admission	Low-grade ulcer; gastritis
24	SC	Admission	Ulcer (ungraded), gastritis, hemostasis (2 clips)

Abbreviations: EGD, endoscopy; EXP, experimental arm; GI, gastrointestinal; NA, not administered; SC, standard care.

There was high patient satisfaction in the VCE group (Table 5). In the SC group, 10 of 13 were admitted to the hospital. The 3 patients in the SC group who were discharged were discharged for the following reasons: 1 due to the emergency physician's discretion and the other 2 were due to individual patient requests. Of these 3 participants, 2 were contacted for both the 7-day and 30-day follow-ups. In the SC group, 1 admitted participant received 2 clips during EGD for an ulcer that bled after irrigation. A total of 3 participants from the SC group were lost to follow-up. In the VCE group, 1 participant's VCE revealed a distal esophageal ulceration and stricture and was admitted for endoscopic hemostasis and dilation. This stricture was not known at the time of study enrollment. A second participant in the VCE group was admitted for a decrease in hemoglobin in the ED from 11.7 mg/dL to 10.5 mg/dL. The next-day hemoglobin was 11.8 mg/dL, so the decrease in the ED likely did not represent an active bleed, and the VCE was normal for this participant. An additional participant's VCE revealed gastric erosions and a superficial clean-based gastric ulcer. The follow-up EGD revealed stable peptic ulcer disease. Finally, in 1 participant, the VCE detected portal gastropathy (mosaic appearing mucosa) in the stomach and erosions in the duodenal bulb. The follow-up EGD detected evidence of coffee-ground blood, but no causative upper lesion was detected, and no endoscopic intervention was performed (Table 6).

TABLE 4 Follow-up at 7 and 30 days post-ED visit

	VCE (n = 11)	SC (n = 13)[a]
7-day follow-up, n (%)		
Blood in the stool?	0	1 (7.7)
Vomited any bright red or coffee-ground blood?	1 (9.1)	0
Bloody or black tar stools in the past 24 hours?	1 (9.1)	0
Passed out or lost consciousness in the past 24 hours?	1 (9.1)	0
Seen by a gastroenterologist after ED discharge?	5 (45.5)	2 (15.4)
Received an upper endoscopy after ED visit (either in hospital or as outpatient)	9 (9.1)	10 (76.9)[b]
30-day follow-up, n (%)		
Did you have a return visit to the hospital for recurrent bleeding?[c]	0	0

Abbreviations: ED, emergency department; SC, standard of care; VCE, video capsule endoscopy.
[a]A total of 3 lost to follow-up calls in the SC group.
[b]A total of 2 lost regarding follow-up for upper EGD.
[c]Across both groups, 3 patients returned to the ED within 30 days but none with active bleeding: 1 returned and was diagnosed with anal fissure, the second returned for repeat stricture dilation, and the third returned and received a repeat endoscopy, which showed no recurrent bleeding.

TABLE 5 Satisfaction with VCE (n = 11)

I understood the reason for the VCE (median score/mean score), Likert scale[a]	4.5/5
I understood the VCE procedure (median score/mean score), Likert scale[a]	4.8/5
The video capsule was easy to swallow, yes, n (%)[b]	10 (91)
I would use the video capsule again, yes, n (%)[b]	9 (82)
I had no issues with the video capsule, yes, n (%)[b]	10 (91)
Swallowed VCE with "no" difficulty, n (%)[b]	10 (90.9)
Swallowed with "moderate" difficulty, n (%)[b]	1 (9.1)

Abbreviation: VCE, video capsule endoscopy.
[a]5 = Strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree.
[b]Likert numbers 5 and 4 are combined into 1 compositive score.

TABLE 6 VCE report (VCE arm, n = 11)

Gastroenterologist interpretation	n (%)
Clean stomach and duodenum, that is, no fresh blood/coffee grounds	8 (72.7)
Upper GI pathology non-causative/incidental	1 (9.1)
A low-grade non-variceal lesion, Forrest IIc, III	1 (9.1)
Coffee ground blood	2 (18.2)
Fresh blood or evidence of active bleeding	1 (9.1)
Other sources of non-variceal bleeding/pathology	3 (27.3)
VCE passed the pylorus	9 (81.8)
Needs endoscopic hemostasis	2 (18.2)

Abbreviations: GI, gastrointestinal; VCE, video capsule endoscopy.

4 | LIMITATIONS

Limitations of this study include most notably the small sample size that is unable to more conclusively determine the safety of this approach. The actual sample size was much less than the intended sample size because of a variety of factors but most notably the early suspension of the study because of the COVID-19 pandemic. A second limitation of the study is that emergency physicians were involved in the disposition decision that could be a source of bias regarding admission decisions but also demonstrates the pragmatic nature of the study. A third limitation of the study is that not all participants received a follow-up EGD as part of SC. A total of 5 patients did not receive the follow-up EGD, including 3 who were admitted, which reflects the variability of real-world care even when clear guidelines exist. Given the ≈4 days that elapsed between the VCE and the EGD, we expected differences in gastric findings because of the dynamic nature of gastric lesions. Finally, in 2 of the ED VCE participants, the capsule did not pass the pylorus before the VCE battery ended. Therefore, the duodenum was not directly evaluated in these 2 patients, thus raising the possibility that a post-pyloric bleed could have been missed. This limitation could be addressed in future studies using a longer battery life or with capsule technology that allows an operator to remotely drive the capsule toward the anatomic regions of interest to fully assess the upper GI tract.[18]

5 | DISCUSSION

The major limitation of this study was its early termination. Although the study was ultimately terminated because of the COVID pandemic, recruitment was affected by a variety of factors before termination. A barrier to recruitment was identifying moderate risk patients in whom physicians expressed equipoise regarding the decision to admit. The 2 most common reasons for exclusion were that the patients were either too high risk or too low risk. The rationale for focusing on moderate-risk patients is that high-risk patients were automatically admitted and ultra-low-risk patients should be discharged without further testing.

Although there seemed to be a general willingness by physicians and patients to use new technology to gather information, there was a reluctance to allow the randomization process to change practice,

especially using an unfamiliar technology for an established disease such as upper GI bleed. If we were to redo this project, we would consider changing the methodology to an implementation study and loosening the exclusion criteria. In this way, we could allow more emergency physicians to use VCE as they see fit, record how the new study changed management, and confirm the safety of the VCE evaluation approach.

Although the findings of our trial are preliminary, they offer important insights regarding VCE use in the ED upper GI bleed population. As expected, participants who are risk stratified by VCE were hospitalized less frequently than participants assigned to SC. There was high patient satisfaction with the procedure and few adverse events at 7 and 30 days after the ED visit. This study builds on prior studies of VCE in the ED in which VCE was 88% sensitive at detecting an acute upper GI bleed.[19] Other prior studies limited by small size and risk of bias have shown VCE in the ED to be safe and potentially more informative than a nasogastric lavage and with a similar ability to detect bleeding as traditional EGDs.[11,20–23] Although this study did not address the cost-effectiveness of VCE to risk-stratify GI bleeding in the ED, a prior study has examined the cost-effectiveness for the use of VCE in the ED.[5] In addition, a recent multicenter retrospective study of 146 patients examined the safety of VCE for the initial evaluation of GI bleeding at the peak of the COVID-19 pandemic as the first-line diagnostic test.[24] Finally, it should be reiterated that VCE lacks the therapeutic and interventional abilities of a traditional EGD, but for many low-risk and moderate-risk patients, visualization alone may be the preferred first step.

In summary, this pilot randomized multicenter trial showed that ED patients with low-risk to moderate-risk suspected upper GI bleeds had decreased admissions with an experimental VCE pathway compared with SC. Although no increase in adverse events was noted for patients randomly assigned to VCE in the ED, the sample size of this study was insufficient to confirm the safety of this approach. In addition to safety, future studies will need to address how VCE affects ED workflow, ED length of stay, and overall cost. Moving forward, capsule technology holds promise as a minimally invasive way to evaluate the mucosa of the GI tract in the ED setting.

CONFLICT OF INTEREST

ACM has grant funding from AnX Robotica, Biofire Diagnostics, Medtronic, 1EQ, Centers for Disease Control, and National Institutes of Health.

AUTHOR CONTRIBUTIONS

Andrew C. Meltzer and Anita B. Kumar conceived the study, designed the trial, and obtained research funding. Andrew C. Meltzer, Alexander T. Limkakeng Jr, and Nina T. Gentile supervised the conduct of the trial and data collection. Andrew C. Meltzer, Alexander T. Limkakeng Jr, Nina T. Gentile, Nataly Montano Vargas, David E. Fleischer, Samuel J. Kallus, Zubair Malik, Marie L. Borum, Yan Ma, Anita B. Kumar, and Nicole C. Hall undertook recruitment of participating centers and patients and managed the data, including quality control. Jincong Q. Freeman and Yan Ma provided statistical advice on study design and analyzed the data. Andrew C. Meltzer drafted the manuscript, and all authors contributed substantially to its revision. Andrew C. Meltzer takes responsibility for the article as a whole.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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