ORIGINAL ARTICLE

Use of capsule endoscopy in the emergency department as a triage of patients with GI bleeding

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Background and Aims: Upper GI bleeding (UGIB) still constitutes one of the major hospital admissions through emergency departments (EDs). This feasibility study aims to test whether capsule endoscopy (CE) can reduce unnecessary hospital admissions in patients with suspected UGIB.

Methods: This was a prospective randomized controlled trial in which patients who presented with symptoms or signs suggestive of UGIB were randomized to receive either the standard treatment (ST) of hospital management or receive CE, after which hospital admission was determined by the findings of CE. Patients were also graded by Glasgow Blatchford score (GBS) at the ED for assessment of need of hospital admission.

Results: Seventy-one patients fulfilled the recruitment criteria, with 37 subjects enrolled into the CE group and 34 subjects into the ST group. Seven CE patients with active bleeding or significant endoscopic findings were admitted to the hospital compared with the ST group in which all 34 patients were admitted. There was no difference in the clinical outcome in terms of recurrent bleeding and 30-day mortality. Hospital admission was also greatly reduced if CE instead of GBS was used to triage patients in the ED.

Conclusions: This feasibility study shows that CE offers a safe and effective method in triaging patients presenting with symptoms of UGIB that do not require hospital admission. (Clinical trial registration number: NCT02446678.) (Gastrointest Endosc 2016;■:1-7.)

Patients coming to the hospital with "coffee ground" vomiting or "tarry stools" may not actually have active upper GI bleeding (UGIB). Hospital admission can be avoided if active UGIB or high-risk lesions are excluded in the emergency department (ED). To date, the only useful tool to triage patients for hospital admission with UGIB is by using a clinical score such as the Rockall score[1] or Glasgow Blatchford score (GBS),[2] but these scoring systems can only exclude the most benign cases. In a large cohort study using the GBS, 22% of patients who were seen with UGIB were considered low risk and could be managed as outpatients.[3] Subsequent studies show that most patients with suspected UGIB are still admitted to the hospital unnecessarily.[4] The number of patients who can avoid early endoscopy is only modest.[5]

Capsule endoscopy (CE) can be used to identify patients with fresh blood and "coffee ground" substance in the stomach and is superior to nasogastric tubes for this purpose. In a previous cohort study, we reported that CE detected 9 cases of fresh blood or "coffee grounds" in the duodenum, whereas nasogastric tube aspirate was reported to be bilious or clear in 7 of these 9 cases.[6] We concluded that in an ED setting, CE is feasible and safe in patients presenting with acute UGIB. CE may facilitate patient triage and earlier endoscopy. It was also suggested that Pillcam ESO (Given Imaging Ltd., Yoqneam, Israel) is more accurate than a clinical scoring system in risk stratification of patients presenting to the ED with acute UGIB.[7]

The objective of the current study is to validate CE as an effective tool in diagnosing patients with UGIB and identifying those who require hospital admission. It is our aim to study whether CE can reduce unnecessary hospital

Abbreviations: CE, capsule endoscopy; ED, emergency department; GBS, Glasgow Blatchford score; ST, standard treatment; UGIB, upper GI bleeding.

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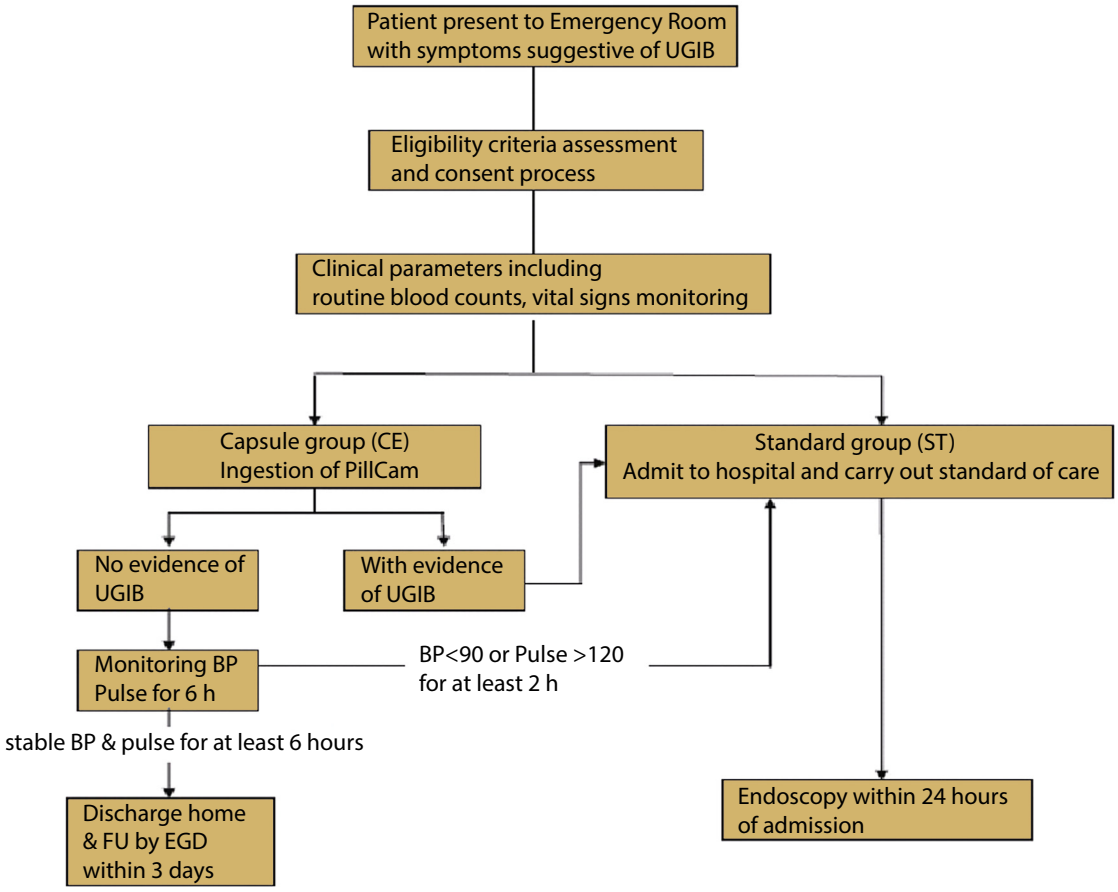

Figure 1. Study flow diagram. *BP,* blood pressure; *FU,* follow-up.

admissions in patients with suspected UGIB. We also aim to compare the effectiveness of CE against the GBS in identifying patients with UGIB who may require early endoscopic intervention.

METHODS

This prospective randomized controlled trial was approved by the university hospital clinical research ethics committee and registered at the Clinical Trial Registry (NCT02446678). Written informed consent was obtained from patients who met inclusion criteria before study enrollment. Patients who were recruited into this study had to be at least 18 years of age or older. They presented to the ED of hospitals with symptoms of acute overt UGIB, namely "coffee ground" vomiting and/or melena. Exclusion criteria included (1) those who had hemodynamic shock (systolic blood pressure below 90 mm Hg and pulse rate over 120/min); (2) those who presented with fresh hematemesis; (3) those who had dysphagia, odynophagia, swallowing disorder, and/or Zenker's diverticulum; (4) those who had conditions that might contraindicate the use of CE (eg, suspected bowel obstruction and/or perforation, Crohn's disease, previous GI surgery); (5) those who had altered mental status; (6) pregnant and/or lactating women; and (7) those with a known history of esophageal varices or gastric varices with or without prior bleeding history. Patients who had upper or lower GI malignancy were also excluded. Before randomization, 10 mL of blood was taken from patients for a complete blood count, coagulation profile, renal tests, and liver function tests. Other demographic data and parameters for GBS calculation were also collected.

The primary outcome was the number of patients requiring hospital admission, and the secondary outcomes included safety, clinical rebleeding, and mortality. Comparing the effectiveness of CE against the GBS in identifying patients with UGIB who may require endoscopic intervention was also a secondary outcome of this study.

Eligible patients were randomized to receive either CE or standard-of-care treatment (ST). Based on the current standard practice of the hospital, patients presenting with clinical or biochemical evidence of UGIB were admitted to the hospital for monitoring and early endoscopic evaluation (hence included in the ST group). On the other hand, patients who were not confirmed to have UGIB symptoms, who had stable hemodynamic measurements, and who showed no drop in hemoglobin levels were

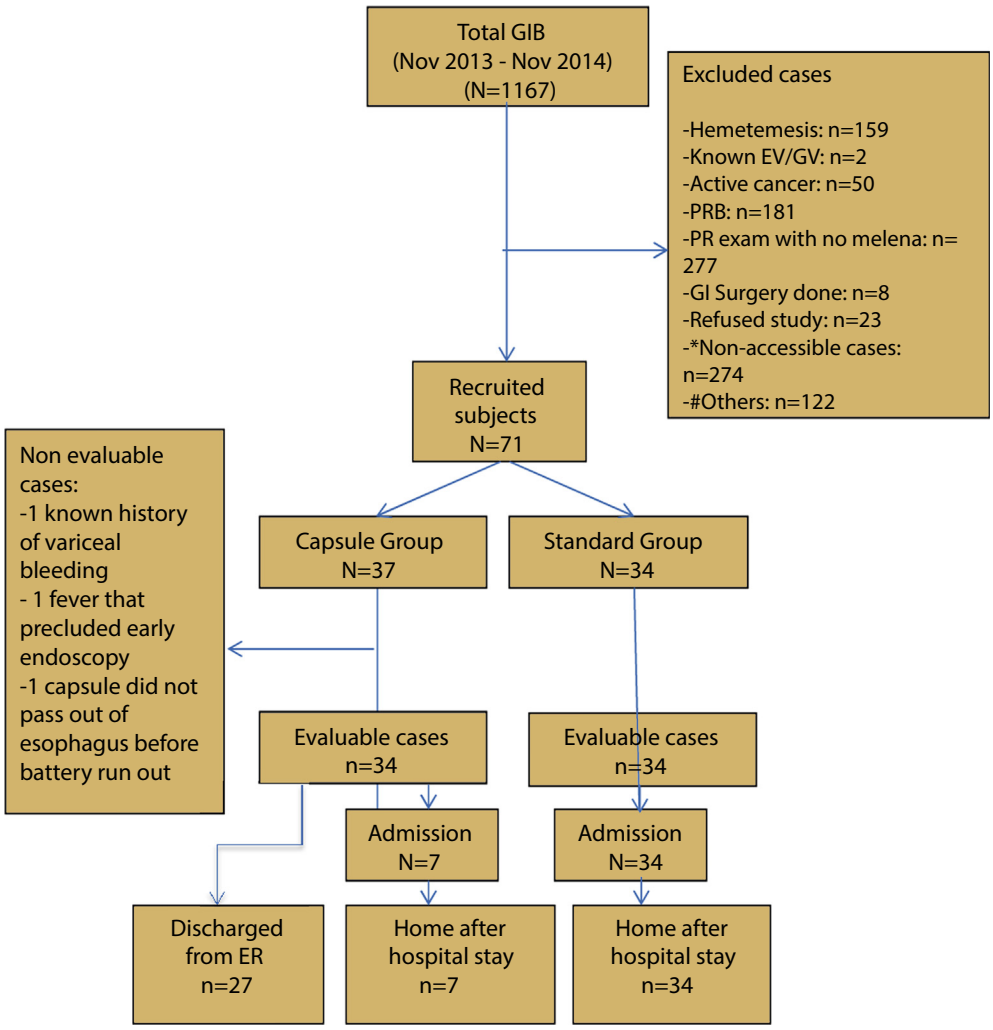

Figure 2. Randomization of subjects into the 2 treatment groups: capsule endoscopy (CE) or standard treatment (ST). *EV*, esophageal varices; *GV*, gastric varices; *PRB*, per rectal bleeding; *PR*, per rectal; *ED*, emergency department.

discharged from the ED. All patients in the ST group were admitted to the hospital by ED physicians within 24 hours. Endoscopic examination of the upper GI tract was offered to all patients within 24 hours, and hemostasis therapy was applied as necessary (Fig. 1).

In the CE group, hospital admission was determined by the findings of CE. After confirming that the patient had fasted for at least 5 hours, patients in the CE group ingested the PillCam ESO 2 using the simplified ingestion procedure. Thirty to 60 minutes before capsule ingestion, each patient received a single dose of intravenous metoclopramide 10 mg, which helped to promote gastric motility and improved visualization of the gastric mucosa at endoscopy. Upper GI tract images (esophagus to the second portion of the duodenum) were obtained in real time at the patient's bedside. The video images that were transmitted by the PillCam ESO 2 were displayed in real time on the tablet computer screen (REAL time viewer, Given Imaging Ltd., Yoqneam, Israel). A full-length CE video recording was obtained for subsequent capsule workstation downloading and complete review.

The CE videos received a 2-tier review: initial bedside real-time review by trained research personnel for obvious fresh blood, blood clots, or "coffee ground" material, followed by a formal review after completion of the CE by a staff gastroenterologist with extensive experience in CEs of the small bowel, colon, and esophagus. Both research personnel and the gastroenterologist underwent a 2-day capsule training program organized by Given Imaging Ltd and received accreditation after the training.

A formal CE report was produced within 2 hours after capsule ingestion. The finding of fresh blood or "coffee

grounds" was documented. Upper GI pathologies that might lead to bleeding were also recorded. Patients in the CE group were admitted to the hospital based on significant findings defined as either evidence of significant bleeding or findings of serious GI lesions by CE that might be related to UGIB. Evidence of significant bleeding included (1) finding of more than 5 mL "coffee ground" material (by estimation) in the upper GI tract, (2) finding of fresh blood in the stomach without active bleeding, or (3) finding of fresh blood in the stomach with active bleeding from an identifiable upper GI lesion. Serious endoscopic findings included (1) peptic ulcer showing Forrest I/II stigmata, (2) esophageal or gastric varices, or (3) malignancy of the stomach or esophagus. Patients who had no sign of active bleeding, showed no serious endoscopic findings, and had stable blood pressure and heart rate for at least 6 hours were discharged from the ED.

All admitted patients in the CE group underwent EGD within 24 hours after completion of CE. Discharged CE patients were scheduled to have an outpatient EGD within 3 days after discharge. Findings of the EGD were recorded, and corresponding treatment was delivered according to standard practice. All patients were followed up by phone call on day 30 to assess the recurrent bleeding episode.

Sample size calculation

Based on the assumption that all patients in the ST group were admitted to the hospital, CE can reduce hospital admission by 30% (ie, from 100% to 70%). To achieve an alpha of .05 and beta of .1, the study needed no fewer than 34 patients in each treatment group. Hence, a minimum of 68 patients were required.

Statistical analysis

Descriptive statistics of demographic data, CE findings, conventional endoscopy findings, clinical rebleeding, and mortality are presented. The 95% confidence interval (CI) for single proportion was calculated as described by the Wilson method.

RESULTS

Seventy-one patients fulfilled the recruitment criteria, with 37 subjects enrolled into the CE group and 34 subjects into the ST group. Three subjects in the CE group were subsequently excluded after identifying a history of variceal bleeding in one and fever after admission that precluded early endoscopy in another (both had no CE done). One patient, after swallowing the capsule, refused to ingest 15 mL of water per 30 seconds until the capsule entered into the stomach. The capsule did not pass out of the esophagus before the battery ran out. However, the capsule was excreted smoothly on the same day without causing any adverse events. Therefore, data for 34 patients in each treatment group were analyzed (Fig. 2). Age, sex, baseline systolic and diastolic blood pressure, pulse rate, initial hemoglobin levels, serum urea level, prothrombin time, and international normalized ratio were comparable (Table 1).

TABLE 1. Patient demographics

	CE group (n = 34)	ST group (n = 34)
Male	21 (61.8)	24 (70. 6)
Age (mean ± SD), y	55.2 ± 18.7	54.9 ± 21.71
Baseline (mean ± SD)		
Systolic blood pressure	132.4 ± 21.0	133.7 ± 24.4
Diastolic blood pressure	78.4 ± 8.8	72.9 ± 12.6
Pulse	85.2 ± 17.5	83.8 ± 16.3
Hemoglobin	12.8 ± 1.6	11.7 ± 2.7
Urea	7.0 ± 3.4	8.3 ± 4.8
Prothrombin time	10.5 ± 1.8	11.8 ± 4.0
INR	1.0 ± .07	1.1 ± .4
Presenting symptoms		
"Coffee ground" vomiting	10 (29.4)	5 (14.7)
Melena	22 (64.7)	29 (85.3)
Both CG and melena	2 (5.9)	0 (0)

Values are number of cases with percents in parentheses, unless otherwise noted.
CE, Capsule endoscopy; *ST*, standard treatment; *SD*, standard deviation; *INR*, international normalized ratio; *CG*, "coffee ground" vomiting.

Seven patients in the CE group were considered to have evidence of bleeding or significant clinical findings. This included "coffee ground" material in 2 (5.9%), peptic ulcer with Forrest Ib stigmata in 2 (5.9%), Forrest IIa in 2 (5.9%), and esophageal varix in 1 (3%). No evidence of bleeding or significant endoscopic findings were reported in 27 of 34 patients (79.4%). Subsequently, conventional endoscopy in this group revealed 11 peptic ulcers (including 5 gastric ulcers, 4 duodenal ulcers, and 2 with both gastric and duodenal ulcers), 1 esophageal varix, 7 gastritis/duodenitis, 5 gastric/duodenal erosions, and 1 case of gastrointestinal stromal tumor (GIST). There was no malignancy reported in this group (Table 2). In the ST group, endoscopy findings included peptic ulcers in 14 (2 gastric ulcers [GU] and 12 duodenal ulcers [DU]), gastritis/duodenitis in 10, gastric or duodenal erosions in 5, and Mallory Weiss tear in 1. No varix or malignancy was found (Table 3). Assuming the 3 patients randomized to the CE group who were excluded (1 with known history of variceal bleeding, 1 with fever, and 1 with failed CE examination) were admitted to the hospital, the number of patients admitted was 10 of 37. The discharged-from-ED rate decreased from 79.4% (27/34) to 73.0% (27/37).

Seven patients in the CE group with active bleeding or significant endoscopic findings were admitted to the hospital after initial assessment in the ED. Three (42.9%; 95% CI, 15.8%-75.0%) were subsequently confirmed to have high-risk lesions (1 esophageal varix, 1

TABLE 2. Endoscopy findings in the CE group

	Capsule findings	EGD findings
No evidence of significant bleeding	27*	30
Evidence of bleeding		
>5 mL "coffee ground" material in stomach	2	1 (GIST)
Fresh blood in stomach but no active bleeding	0	0
Fresh blood and evidence of active bleeding	0	0
Endoscopic findings		
Peptic ulcer Forrest I/II	4 (11.8%) (2 oozing + 2 v.v.)	2 (1 GU with fresh blood + 1* GU with v.v.)
Peptic ulcer Forrest III	0	9 (3 GU, 4 DU, 2 GU+DU)
EV or GV (with or without SRH)	1 (EV)	1 (EV)
Malignancy of stomach or esophagus	0	0

CE, Capsule endoscopy; *EGD,* esophagogastroduodenoscopy; *GIST,* gastrointestinal stromal tumor; *v.v.,* visible vessel; *GU,* gastric ulcer; *DU,* duodenal ulcer; *EV,* esophageal varices; *GV,* gastric varices; *SRH,* stigmata of recent hemorrhage.
*One GU with visible vessel was missed by CE.

gastrointestinal stromal tumor (GIST) with coffee ground, and 1 gastric ulcer with fresh blood) (Table 2). All were treated by endoscopy, with no recurrent bleeding within 30 days of follow-up. Among the 27 patients in the CE group showing no evidence of significant bleeding by CE who were sent home, 1 patient (3.7%; 95% CI, .7%-18.3%) was subsequently found to have a gastric ulcer with a visible vessel. His case was uneventful in the 3-day follow-up until endoscopy found the gastric ulcer. None of these 27 cases developed clinical bleeding at home requiring admission. All 34 patients in the ST group were admitted. Five (14.7%) were found to have Forrest I/II peptic ulcers and 1 (2.9%) had a Mallory Weiss tear with a visible vessel (17.6%; 95% CI, 8.3%-33.5%) (Table 3). Patients were treated by a standard endoscopic method, and none had recurrent bleeding within the 30-day follow-up. There was no mortality in both the CE and ST groups in this study.

The average attendance time for the CE group was 6 hours and for the ST group, 2.5 hours. The CE procedure was done by 2 endoscopy nurse specialists. After swallowing, patients were observed for 10 minutes to monitor capsule entry into the stomach. Once the capsule entered the stomach, no close observation was needed at bedside. The video was then downloaded for the physician's reviewing. The capsule videos were reviewed by a physician within 15 minutes after completion of video data downloading.

Based on the GBS of the patients undergoing CE while in the ED, 6 patients scored 0 and 3 scored 1. In the ST group, none scored 0 and 7 patients scored 1. Therefore, if we adopt the admission criteria of admitting any patient with a GBS over 1 (ie, 2 or above), 25 patients (73.5%; 95% CI, 56.9%-85.4%) in the CE group and 27 patients (79.4%; 95% CI, 63.2%-89.7%) in the ST group required hospital admission (Table 4). Applying CE in the 2 groups obviated hospital admission by 16 of 68 and reduced the admission rate by 76.5%.

TABLE 3. Endoscopy findings in the ST group

	EGD findings
Decisions	
Admitted	34
Early discharge	0
Endoscopy findings	
Esophageal ulcer	2
GU/DU	14 (5* DU)
GV/EV	0
Gastritis/duodenitis	10
Gastric/duodenal erosions	5
"Coffee grounds" only	0
Normal	1
Other	2 (1* MWT with v.v.)
Discharge outcome	
Recurrent bleeding within 30 days	0
Mortality within 30 days	0

ST, Standard treatment; *EGD,* esophagogastroduodenoscopy; *GU,* gastric ulcer; *DU,* duodenal ulcer; *GV,* gastric varices; *EV,* esophageal varices; *v.v.,* visible vessel.
*Denotes significant bleeding.

DISCUSSION

A recent study has shown that in emergency CE in patients with acute severe GI bleeding, even upper endoscopy failed to detect the source of bleeding.[8] This is the first randomized study to show that CE can be used safely to identify which patients presenting with symptoms suggestive of UGIB are high-risk individuals

TABLE 4. GBS of patients in the CE and ST groups

	Overall		CE group		ST group	
GBS	n	%	n	%	n	%
0	6	8.8	6	17.6	0	0.0
1	10	14.7	3	8.8	7	20.6
2	10	14.7	6	17.6	4	11.8
3	6	8.8	2	5.9	4	11.8
4	5	7.4	3	8.8	2	5.9
5	7	10.3	4	11.8	3	8.8
6	3	4.4	1	2.9	2	5.9
7	4	5.9	4	11.8	0	.0
8	8	11.8	4	11.8	4	11.8
9	1	1.5	0	.0	1	2.9
10	2	2.9	1	2.9	1	2.9
11	4	5.9	0	.0	4	11.8
12	1	1.5	0	.0	1	2.9
16	1	1.5	0	.0	1	2.9

CE, Capsule endoscopy; *ST*, standard treatment; *GBS*, Glasgow Blatchford score.

requiring hospital admission. It is safe in the sense that swallowing the capsule endoscope in these patients did not create any problems or adverse events. In the single patient who failed to follow protocol (and hence the capsule did not enter the stomach before the battery ran out), the capsule passed within 1 day, causing no adverse events. Moreover, CE also accurately identified esophageal varices, most of the Forrest I or II peptic ulcers, and a case of gastrointestinal stromal tumor (GIST) that produced "coffee ground" vomiting. One case of Forrest II gastric ulcer was missed by CE. With the use of CE, this study showed that triaging patients can be done effectively because hospital admission has been reduced by almost 80%. This is a large reduction in hospital work, which carries a significant impact on the financial and workload burden of the hospital system. This result, however, is related to the emergency setting. Gastroscopy and colonoscopy are still needed during follow-up to discover the source of bleeding.

We have to point out that this triage algorithm did not use CE alone; other clinical judgment was applied. Patients with obvious signs of massive UGIB should be admitted to the hospital without going through the capsule test. Therefore, all patients who had hemodynamic shock (systolic blood pressure below 90 mm Hg and pulse rate over 120/min) and those who presented with fresh hematemesis were excluded from the study because they obviously required hospital admission. In fact, in this study 159 patients were admitted because of hematemesis (Fig. 2). On the other hand, if we used the conventional criteria in which all patients presenting with hematemesis and/or melena were admitted indiscriminately, most patients who did not actually require hospitalization and urgent endoscopy would have been admitted. Therefore, CE does not preclude clinical discretion, and common sense still applies.

The GBS is among the most validated and popular clinical scoring systems used to triage patients who require hospital-based intervention. Recent studies have shown that a GBS $\leq$ 1 or 2 can effectively identify patients with low-risk UGIB, and hence those patients can be managed on an outpatient basis.[9,10] In prospective observational studies, only 11% to 14% of patients were found to have a GBS score equal to zero and considered safe to send home.[3,4] When GBS is used as a triage tool, hospital admission can be reduced by 15% to 20%.[9] On the other hand, high GBS at admission is associated with a high risk of recurrent bleeding from the upper GI tract after hospitalization.[11]

A previous small-scale nonrandomized study showed that pre-endoscopy GBS and Rockall scores were inferior to CE in differentiating high-risk from low-risk patients with acute UGIB.[10] In the current study in which patients were randomized to receive either CE or ST, when comparing the results of CE with the GBS, the former can exclude more low-risk patients for unnecessary admission. Applying the GBS to the CE group, only 26.4% of patients had a score of 1 or below (a similar percentage of patients randomized to the ST group had a score of 1 or below). According to our previous study, 75% of patients will be admitted to the hospital. However, only 7 of 34 cases were admitted to the hospital using CE as the triage tool, reducing hospital admission by nearly 80%. As long as the patients could be contacted and recalled for upper endoscopy, this triage method appears to be quite safe because none of the patients recruited had recurrent bleeding or died in the 30-day follow-up period. This current study suggests that using when CE, especially in communities where hospital beds are limited and/or expensive, UGIB can be managed efficiently, reducing hospital workload.

This study was designed to test whether applying CE in the ED can reduce hospital admissions. In the control arm of ST, all patients with strong clinical or biochemical evidence of UGIB were admitted, and conventional endoscopy was arranged. One might argue that a more relevant comparison would be CE at ED against early upper endoscopy and early discharge from ED. In many centers, early endoscopy can only be done after the patient has been admitted to the hospital. Endoscopy in the setting of the ED is not widely available. Furthermore, in some centers, even after hospital admission, endoscopy cannot be arranged over holidays and weekends, and hence hospitalization is prolonged. The result of this study may therefore suggest an alternative approach that could minimize unnecessary hospital admission and shorten the waiting time for endoscopic examinations.

There are several limitations to this study. This is a small-scale study with only 34 subjects randomized to each group. With a larger sample size, would there be

cases of serious UGIB missed by CE and sent home, inadvertently leading to disastrous consequences? We cannot rule out this possibility. The sample size was based on the assumption that all patients in the ST group were admitted to the hospital and CE could reduce hospital admission by 30% (ie, from 100% to 70%). A large-scale study should be considered to prove the efficacy and safety of this protocol.

One could also argue that the cost of CE is relatively high or even prohibitive to be used for such screening purposes. Compared with hospital admission and early endoscopy, we are not sure which is more cost-effective. This could be answered by conducting a cost-effectiveness analysis using the local cost of hospital fees, endoscopy charges, and various cost structures. The only study available in the literature addressing the cost-effectiveness analysis of CE compared with other strategies to manage acute UGIB favors the use of CE in low- and moderate-risk patients.[12] This model was constructed primarily based on a healthcare system in Western developed countries. If the cost of CE falls, as it would when technology further matures and market competition increases, the use of CE as a triage tool may become more cost-effective.

Finally, the use of CE requires training and expertise so significant lesions are not missed. Would this be possible in a busy hospital ED? One needs to realize that in this scenario, capsules are used primarily to detect fresh blood and a significant amount of "coffee ground" material. Other important lesions that lead to major bleeding such as large gastric or duodenal ulcers, varices, and upper GI cancer are relatively easy to find. The training of ED doctors, or even endoscopy nurses, for this is feasible. However, the capsule images should subsequently be examined by endoscopists experienced in upper endoscopy and CE to avoid missing significant lesions. Nevertheless, further studies on validation and training requirements are necessary.

In conclusion, this feasibility study shows that CE offers a safe and effective method in triaging patients presenting with symptoms of UGIB who do not require hospital admission. This may potentially relieve the burden on hospital admissions.

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