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CLINICAL TRIALS STUDY

Comparison of a novel bedside portable endoscopy device with nasogastric aspiration for identifying upper gastrointestinal bleeding

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Abstract

AIM: To compare outcomes using the novel portable endoscopy with that of nasogastric (NG) aspiration in patients with gastrointestinal bleeding.

METHODS: Patients who underwent NG aspiration for the evaluation of upper gastrointestinal (UGI) bleeding were eligible for the study. After NG aspiration, we performed the portable endoscopy to identify bleeding evidence in the UGI tract. Then, all patients underwent conventional esophagogastroduodenoscopy as the gold-standard test. The sensitivity, specificity, and accuracy of the portable endoscopy for confirming UGI bleeding were compared with those of NG aspiration.

RESULTS: In total, 129 patients who had GI bleeding signs or symptoms were included in the study (age 64.46 ± 13.79, 91 males). The UGI tract (esophagus, stomach, and duodenum) was the most common site of bleeding (81, 62.8%) and the cause of bleeding was not identified in 12 patients (9.3%). Specificity for identifying UGI bleeding was higher with the portable endoscopy than NG aspiration (85.4% *vs* 68.8%, P = 0.008) while accuracy was comparable. The accuracy of the portable endoscopy was significantly higher than that of NG in the subgroup analysis of patients with esophageal bleeding (88.2% *vs* 75%, P = 0.004). Food material could be detected more readily by the portable endoscopy than NG tube aspiration (20.9% *vs* 9.3%, P = 0.014). No serious adverse effect was observed during the portable endoscopy.

CONCLUSION: The portable endoscopy was not superior to NG aspiration for confirming UGI bleeding site. However, this novel portable endoscopy device might provide a benefit over NG aspiration in patients with esophageal bleeding.

Key words: Endoscopy; Gastrointestinal bleeding; Nasogastric aspiration

Core tip: Although nasogastric (NG) tube aspiration is recommended for the potential benefit of risk stratification in upper gastrointestinal (UGI) bleeding, its clinical usefulness is still debatable. Recently, a novel bedside portable endoscopy device (EG scan, IntroMedic Co., Ltd., Seoul, Korea) has been developed to evaluate the esophagogastroduodenal area with high convenience and notable accessibility compared with conventional endoscopy. As far as we know, this is the first study to evaluate the clinical outcomes of this device compared with NG tube aspiration in UGI bleeding identification. We found that EG scan might offer benefits over NG

aspiration in patients with esophageal bleeding.

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INTRODUCTION

Upper gastrointestinal (UGI) bleeding is a common, important emergency situation with an estimated incidence of roughly 100 per 100000 adults[1]. Although advances in medical and endoscopic treatment have had positive effects on the outcomes of UGI bleeding, mortality still remains high, up to 10%[2-5]. A recently reported international consensus on UGI bleeding emphasized the importance of the early risk stratification for rebleeding and mortality[6]. It is recommended to place a nasogastric (NG) tube in patients with UGI bleeding for risk assessment because the findings may have prognostic value[6]. However, the usefulness of NG tube placement in identifying UGI sources of bleeding has not been clarified due to its low sensitivity (42%-84%) and poor negative likelihood ratio (0.62-0.20)[7-9].

A novel bedside portable endoscopy device (EG scan, IntroMedic Co., Ltd., Seoul, Korea) has been developed to evaluate the esophagogastroduodenal area with high convenience and notable accessibility compared with conventional endoscopy[10]. The EG scan comprises four parts: an optical probe, a control handle, a processor that generates air, and a display monitor (Figure 1). The diameter of the probe tip is 6 mm, similar to that of a 16-French NG tube and the shaft of probe is much thinner, with a diameter of 3.6 mm (Figure 2). The probe can reach to the stomach through the nose as easily as an NG tube. The real-time imaging view is visualized via the display monitor. The optical probe tip can be bent 60° upwards or downwards, but not to the right or left side. There has been no previous reported study of the efficacy of this novel endoscopy device compared with that of the NG tube in patients with gastrointestinal bleeding.

The aim of this study was to evaluate the efficacy and safety of this novel bedside portable endoscopy device by comparing the outcome of this scope with that of the NG tube for the identification of the source of gastrointestinal bleeding.

MATERIALS AND METHODS

Adult patients (older than 18 years) presenting with symptoms or signs of gastrointestinal bleeding, including melena, hematemesis, hematochezia, and acute-onset anemia, at a tertiary hospital between January 2012 and

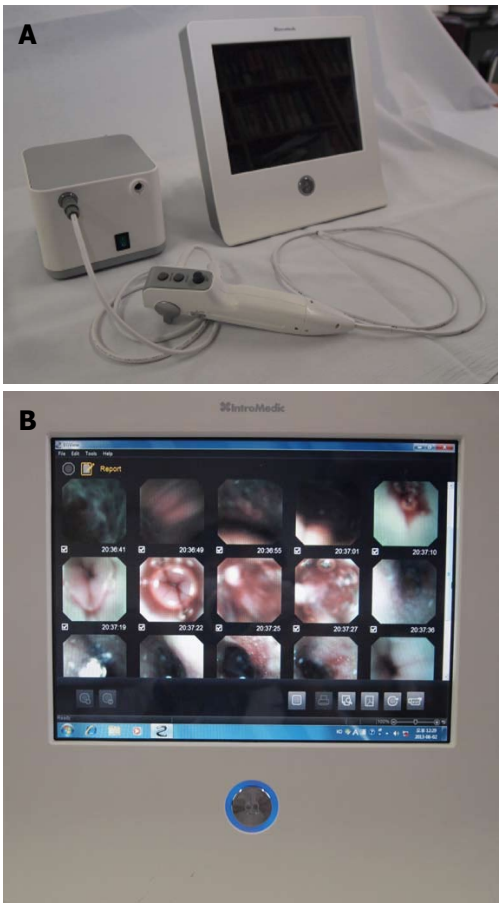

Figure 1 EG scan machine (A) and a display monitor (B).

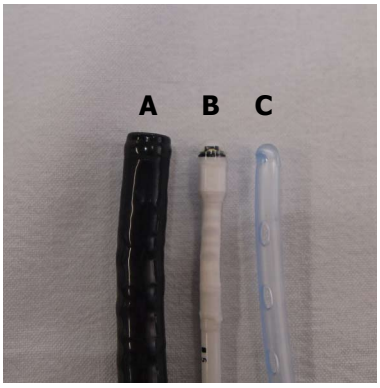

Figure 2 Comparison of the diameters of conventional endoscopy (A, GIF-XQ260, Olympus, Tokyo, Japan), the EG scan (B), and 16F nasogastric tube (C).

September 2012 were eligible for this prospective study. Exclusion criteria included (1) critical vital sign instability; (2) inability to get the NG tube or EG scan device through the nostrils; (3) refusal to undergo the procedure/failure to give consent; and (4) no final esophagogastroduodenoscopy (EGD) evaluation (patients who refuse to undergo EGD for any reason). Patients with hemodynamic instability received crystalloid solutions and blood transfusions. First, patients suspicious for active gastrointestinal (GI) bleeding who visited the emer-

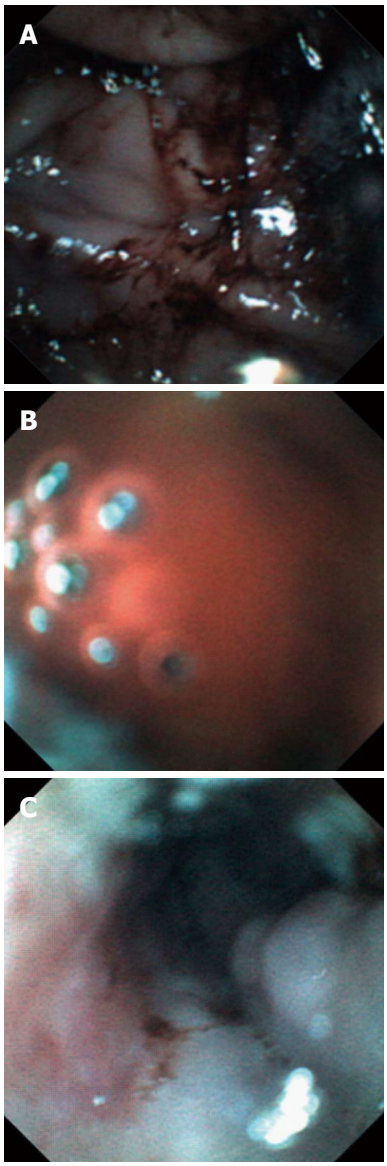

Figure 3 Images of EG scan. A: Dark, coffee-ground colored blood clot; B: bright red fresh blood; C: multiple bluish colored esophageal varices.

gency room received NG tube insertion and aspiration with or without lavage to confirm active UGI bleeding according to the International Consensus Recommendations for patients with UGI bleeding[6]. Then, the EG scan device was inserted within 12 h from NG tube insertion to identify the focus of the UGI bleeding. The scope was inserted through the nose with lubricant jelly and no sedatives or antispasmodics were used during the procedures. The EG scan was performed by three endoscopists with at least 1000 cases of EGD experience (ESK, YJL, and KSP) or three medical personnel with no previous endoscopy experience (JHC, WYC, and JHC) after brief instruction on how to use the EG scan probe. Non-endoscopists learned about luminal lesions, such as varices, ulcers, and erosions, by reviewing endoscopic images before the EG scan. Doctors who performed EG scan did not know the results of NG tube aspiration. Thereafter, all patients underwent EGD as the gold-standard test for the final diagnosis of UGI bleeding.

Informed consent was obtained from patients and the study protocol was approved by the Keimyung University Institutional Review Board. The study was registered on the WHO International Clinical Trials Registry Platform (WHO ICTRP KCT0000298).

Definitions and outcome measures

Dark, coffee ground- or bright red-colored blood seen at NG aspiration was defined as a positive sign of UGI bleeding. During the EG scan procedure, a directly visualized coffee ground-colored blood clot or bright red blood was recorded as a positive sign of UGI bleeding (Figure 3). Additionally, luminal lesions, such as esophageal varices, ulcers or erosions, were evaluated during the EG scan (Figure 3). We attempted to estimate additional findings, including food material, at each procedure. Primary outcome measures were (1) comparison of the accuracy, sensitivity and specificity of the EG scan in identifying UGI bleeding with NG tube insertion; and (2) the rate of adverse event of the EG scan procedure.

Statistical analysis

Sensitivity was the proportion of subjects with UGI bleeding who had a positive test result, and specificity was the proportion of individuals without UGI bleeding who had a negative test result. Accuracy was the proportion of all cases correctly identified by the test. Differences in these categorical variables with matched pairs of subjects were examined with McNemar's test. For comparison of continuous variables, Student's *t*-test was used and the results are presented as means ± standard deviation (SD).

The sample size was calculated on the assumption that accuracy of the EG scan for identifying UGI bleeding would be 60%, while that of NG tube aspiration would be 40%. With a two-tailed test of $\alpha = 0.05$ and $1\text{-}\beta = 0.80$, 117 patients were required. Statistical analysis was performed with the SPSS software (ver. 14.0; SPSS Inc., Chicago, IL, United States). A two-tailed P value < 0.05 was considered to indicate statistical significance.

RESULTS

Among 197 patients with signs or symptoms of gastrointestinal bleeding, 129 were finally included in the study (mean age 64.46 ± 13.79 years, males 70.5%). In total, 68 subjects (34.5%) were excluded for various reasons: 32 refused to participate, 15 skipped the EG scan for an immediate therapeutic endoscopy due to unstable vital signs, and 21 did not undergo final EGD (Figure 4). Baseline characteristics of patients are described in Table 1. The most common co-morbidity was high blood pressure (48, 37.2%), followed by liver cirrhosis (39, 30.2%). Initial systolic blood pressure was 119.52 ± 25.67 mmHg and pulse rate was 85.31 ± 15.78/min. Initial hemoglobin was 9.55 ± 2.62 g/dL. The most common bleeding-

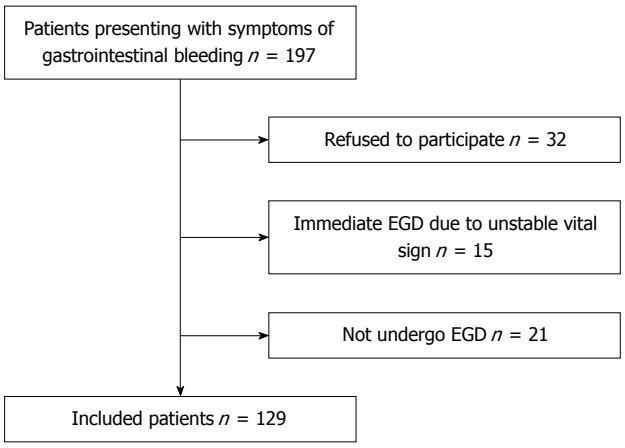

Figure 4 Flow diagram illustrating patients enrolled in the study. EGD: Esophagogastroduodenoscopy.

Table 1 Baseline characteristics of patients with symptoms or signs of gastrointestinal bleeding *n* (%)

Age, mean ± SD, yr	64.46 ± 13.79 (*n* = 129)
Gender, Male	91 (70.5)
Co-morbidities	
Hypertension	48 (37.2)
Diabetes mellitus	33 (25.6)
Cardiovascular disease	17 (13.2)
Liver cirrhosis	39 (30.2)
Chronic kidney disease	14 (10.9)
Cerebrovascular disease	22 (17.1)
Malignancy	25 (19.4)
Initial vital sign	
Systolic blood pressure, mmHg	119.52 ± 25.67
Diastolic blood pressure, mmHg	72.33 ± 17.53
Pulse rate, mean ± SD	85.31 ± 15.78
Initial hemoglobin, g/dL	9.55 ± 2.62
Bleeding related signs or symptoms	
Melena	46 (35.7)
Hematemesis	43 (33.3)
Hematochezia	28 (21.7)
Anemia	12 (9.3)
Non-bleeding related signs or symptoms	
Dizziness	14 (10.9)
Epigastric pain	13 (10.1)
Syncope	2 (1.6)
Dyspnea	2 (1.6)

related symptom was melena (46, 35.7%), followed by hematemesis (43, 33.3%) and hematochezia (28, 21.7%). The major non-bleeding-related symptom was dizziness (14, 10.9%).

EGD confirmed the UGI tract as the source of bleeding in 81 (62.8%) cases (Table 2). Among them, esophageal varices, gastric ulcers and varices, and duodenal ulcers were the major causes of bleeding. The cause of bleeding in 12 (9.3%) was not identified. The mean time interval (min) from NG aspiration to EG scan was 129.5 ± 190.5. The mean time interval (h) from EG scan to EGD was 7.3 ± 7.6. The mean procedure time (min) of the EG scan was 5.49 ± 2.33. The probe was inserted into the stomach in all cases except one while duodenal insertion was possible only in four cases. In six patients, examiners

Table 2 Bleeding sources confirmed by esophagogastroduodenoscopy *n* (%)

	Patients *n* = 129
Upper gastrointestinal bleeding	81 (62.8)
Esophagus	20 (15.5)
Esophageal varices	17 (13.1)
Esophageal ulcers	3 (2.3)
Stomach	53 (41.1)
Gastric ulcers	35 (27.1)
Gastric varices	8 (6.2)
Hemorrhagic gastritis	4 (3.2)
Mallory-Weiss syndrome	3 (2.3)
Cancer	2 (1.5)
Angiodysplasia	1 (0.8)
Duodenum	8 (6.2)
Duodenal ulcers	7 (5.4)
Angiodysplasia	1 (0.8)
Non upper gastrointestinal bleeding	36 (27.9)
Small bowel bleeding	8 (6.2)
Colorectum	23 (17.8)
Colitis	9 (6.9)
Ulcers	7 (5.4)
Cancers	2 (1.5)
Diverticulum	2 (1.5)
Hemorrhoid	1 (0.8)
Rectal varices	1 (0.8)
Radiation colitis	1 (0.8)
Others	5 (4)
Hemoptysis	4 (3.2)
Nasal bleeding	1 (0.8)
No definite focus of bleeding	12 (9.3)

reported that they were not sure whether the probe was inserted into the duodenum due to poor visualization. There was no significant difference in the positive rate for bleeding (detection of blood) between the EG scan and NG tube aspiration (45.7% *vs* 58.1%, $P > 0.05$). Food material could be detected more readily by the EG scan than NG tube aspiration (20.9% *vs* 9.3%, $P = 0.014$). The EG scan provided additional findings of luminal lesions, including varices, ulcers, or erosions. The EG scan showed esophageal lesions in 41 (31.8%) patients (26 varices, 6 ulcers, and 15 erosions; 6 patients had multiple lesions). However, stomach lesions were found only in nine (7%) patients (three ulcers and six erosions), and the EG scan failed to detect any duodenal lesion. Nasal pain and nausea were more frequently observed with the EG scan than NG tube aspiration while epistaxis was more common with NG tube aspiration. Nonetheless, there was no serious adverse effect during or after EG scan (Table 3).

Accuracy for upper gastrointestinal bleeding identification

Overall ($n = 129$), accuracy and sensitivity of the EG scan for UGI bleeding identification was not different from those of NG tube aspiration, whereas the specificity of the EG scan was significantly higher than that of NG aspiration (85.4% *vs* 68.8%, $P = 0.008$). However, when we focused on bleeding in the esophageal area ($n = 68$), the accuracy of the EG scan became significantly better than that of the NG tube (88.2% *vs* 75%, $P = 0.004$; Table 4).

Table 3 Procedural results of EG scan and nasogastric tube aspiration *n* (%)

	Patients *n* = 129		
	EG scan	NG tube aspiration	*P* value
Procedure time, mean ± SD, min	5.49 ± 2.33		
Examiner			
Endoscopist	24 (18.6)	0	
Non-endoscopist	105 (81.4)	129 (100)	
Insertion to stomach	128 (99.2)	129 (100)	
Insertion to duodenum	4 (3.1)		
Main findings			
Blood	59 (45.7)	75 (58.1)	0.061
Food material	27 (20.9)	12 (9.3)	0.014
Esophageal lesions[1]	41 (31.8)		
Stomach lesions[1]	9 (7.0)		
Duodenal lesions	0		
Adverse effects			
Nasal pain	60 (46.5)	40 (31)	0.015
Nausea	26 (20.1)	5 (3.9)	< 0.001
Epistaxis	11 (8.5)	28 (21.7)	0.005
Cough	9 (6.9)	11 (8.5)	0.817
Others	1 (0.7)	2 (1.6)	1.000

[1]Esophageal lesions: varices 26, ulcers 6, erosions 15 (6 patients had multiple lesions); stomach lesions: ulcers 3, erosions 6. NG: Nasogastric.

EG scan outcomes between endoscopists and non-endoscopists

Most cases of the EG scan (105, 81.4%) were performed by non-endoscopists while experts conducted the EG scan in 24 cases (18.6%). The procedure time for endoscopists was shorter than that for non-endoscopists (4.33 ± 1.76 *vs* 5.75 ± 2.36 min; $P = 0.001$). However, the experience of the endoscopist did not make any difference in other procedural outcomes including rate of insertion to duodenum, main findings, and accuracy for UGI bleeding identification (Table 5).

DISCUSSION

For patients suspected of having UGI bleeding, NG aspiration can be useful for determining the management strategy by localizing the source of bleeding[11-13]. Additionally, this practice may enhance risk stratification. For example, patients with a bloody aspirate are more likely to have active bleeding, high-risk lesions, and higher rates of recurrent hemorrhage, leading to a greater mortality[7,14,15]. Thus, the consensus guidelines recommend placing a NG tube for pre-endoscopic evaluation[6]. However, it is still uncertain as to whether NG aspiration improves clinical outcomes in the management of acute gastrointestinal bleeding. A retrospective observational study showed that NG aspiration did not lessen mortality or shorten hospital length of stay suggesting that this practice might be unnecessary in the management of acute gastrointestinal bleeding[16,17]. Furthermore, relatively high false negative rates (10%-18%) in NG aspiration may hinder effective management[18].

This prospective study showed that the EG scan, a novel portable bedside endoscopy device, had better specificity than NG tube aspiration for the identification of bleeding while the overall accuracy was not different between the two procedures. Unexpectedly, the overall sensitivity of the EG scan appeared to be lower than that of NG aspiration (64.2% *vs* 74.1%, $P > 0.05$). In the cases of bleeding in the esophageal area, however, accuracy of the EG scan was superior to that of NG aspiration and the sensitivity increased to 95%. The unexpectedly lower overall sensitivity of the EG scan compared with that of NG aspiration was disappointing in the present study. With this low sensitivity, a negative finding with the EG scan in a patient with suspected UGI bleeding cannot reassure the endoscopist to wait and delay EGD. For screening purposes, a test should have characteristics of high sensitivity or a low false negative value. There are several potential explanations for the low sensitivity of the EG scan. First, the visual imaging quality of the EG scan may be unsatisfactory. As the camera system of this device has been developed technically similar to that of capsule endoscopy (MiroCam, IntroMedic, Seoul, Korea)[10,19], its visibility is substantially limited especially for roomy spaces, such as stomach area, while it can show better quality images in narrower areas, such as the esophagus or small bowel. Our result showing higher sensitivity and accuracy of the EG scan in the esophageal area supports this explanation. Additionally, there is no way to wash the cover glass of the camera, which may cause poor visibility of the EG scan[10]. Second, there was a time interval from NG tube aspiration to EG scan (mean ± SD, min, 129.5 ± 190.5). Although we thought that the time lag between NG tube aspiration and EG scan was not long enough to affect the outcomes of the EG scan, blood might be irrigated and washed away to small bowel, especially after gastric lavage through the NG tube, perhaps leading to the low sensitivity of the EG scan. When we conducted a subgroup analysis of the time intervals of less than 2 h, the sensitivity of the EG scan did increase, to 73.3% from 64.2% (data not shown).

The results of the study indicate the benefit of the EG scan in identifying esophageal lesions as a source of UGI bleeding. This may have significant clinical implications for specific situations requiring prompt recognition of an esophageal source of bleeding, such as patients with liver cirrhosis who are suspicious of acute UGI bleeding. It has been reported that esophageal varices are the cause of bleeding in only half of cirrhotic patients (53%-59%)[20,21]. Thus, it is clinically relevant to differentiate variceal bleeding from non-variceal bleeding in these patients because initial pre-endoscopic treatments are different; the former needs vasoactive agents (somatostatin, octreotide, or terlipressin)[22,23] while a high-dose proton pump inhibitor is recommended in the latter[4,6,24,25]. In our study with 39 cirrhotic patients, esophageal varices were the cause of bleeding in 17 cases (43.6%) of which 12 (88.2%) were correctly localized in the esophagus as the bleeding source by the EG scan. Further study is needed to verify this advantageous effect of EG scan in cirrhotic patients with UGI bleeding.

Compared with NG aspiration, another theoretical

Table 4 Sensitivity, specificity and accuracy of EG scan and nasogastric aspiration for upper gastrointestinal bleeding identification

	Overall n = 129			Esophagus n = 68		
	EG scan	NG tube	P value	EG scan	NG tube	P value
Sensitivity	64.2 (52/81)	74.1 (60/81)	> 0.05	95 (19/20)	90 (18/20)	> 0.05
Specificity	85.4 (41/48)	68.8 (33/48)	0.008	85.4 (41/48)	68.8 (33/48)	0.008
Accuracy	72.1 (93/129)	72.1 (93/129)	> 0.05	88.2 (60/68)	75 (51/68)	0.004

UGI: Upper gastrointestinal.

Table 5 Comparison of EG scan outcomes between endoscopists and non-endoscopists n (%)

	Endoscopists n = 24	Non-endoscopists n = 105	P value
Procedure time, mean ± SD, min	4.33 ± 1.76	5.75 ± 2.36	0.001
Insertion to duodenum	1 (4.2)	3 (2.9)	0.657
Main findings			
Blood	10 (41.7)	49 (46.7)	0.821
Esophageal lesions	6 (25)	35 (33.3)	0.478
Stomach lesions	2 (8.3)	7 (6.7)	0.673
Accuracy for UGI bleeding	16 (66.7)	77 (73.3)	0.614

advantage of the EG scan would be real-time visualization of the lumen, including mucosal ulcers or erosions. However, this benefit also seemed to be limited to the esophageal area. The EG scan found 41 (31.8%) suspicious esophageal lesions, but only 9 (7%) gastric lesions. The EG scan performance was even worse for the duodenal area; it could be inserted through the pylorus in only four (3.1%) cases. These disappointing outcomes in stomach and duodenum might be attributed to the poor visualization of the EG scan, as described above.

Another potential advantage of EG scan over NG aspiration would be confirmation of food material in the stomach, which might cause aspiration pneumonia during or after an emergency EGD procedure. The detection rate of food material with the EG scan was higher than that of NG tube aspiration (20.9% *vs* 9.3%, P = 0.014). Therefore, when an EG scan finds food material without active bleeding evidence, it can delay an unnecessary urgent EGD, possibly resulting in avoiding the risk of aspiration pneumonia.

Our results also indicate no significant difference in the EG scan outcomes between examiners with and without endoscopy experience, except procedure time, and that it had no serious adverse effect, suggesting this practice can be performed easily and safely by medical personnel who do not have specialist endoscopy procedure skills.

There was no major adverse effect such as perforation or aspiration during and after EG scan procedure. Nasal pain and nausea were more common during EG scan than NG tube aspiration. The high rate of complaints during EG scan might be attributed to the slightly large diameters of tip of scan compared to 16 French NG tube (6 mm *vs* 5.3 mm). Interestingly, epistaxis was less frequently observed during EG scan. Although the cause is not clear, we hypothesize that the very thin shaft of the EG scan (3.6 mm) might reduce the proceeding force which was generated during the EG scan tip advancement. A case series study of EG scan showed that there was no epistaxis during EG scan procedures[26].

This study had a limitation that should be noted. We compared the accuracy of the EG scan and NG tube aspiration in a matched pair-wise manner in the same group of patients (NG aspiration then EG scan) rather than a head-to-head comparison in two independent groups of subjects because there might be an ethical issue if we performed the EG scan in a patient without knowing its efficacy or safety. The main reason for the delay between NG and EG scan examination was due to the time taking notification to doctors of gastroenterology division. This design of the study could presumably lead to a poor outcome of the EG scan, such as low sensitivity for detecting blood.

In conclusion, the EG scan is safe and can be as easily performed by non-endoscopists as NG aspiration. Although this novel endoscopy was not superior to NG aspiration for identifying UGI bleeding, it might offer benefits for patients where it is necessary to localize an esophageal source of bleeding. Further study is needed to confirm whether these potential advantages of the EG scan can change the clinical course of patients with acute UGI bleeding.

COMMENTS

Background

Although advances in medical and endoscopic treatment have had positive effects on the outcomes of upper gastrointestinal (UGI) bleeding, mortality still remains high. It is recommended to place a nasogastric (NG) tube in patients with UGI bleeding for risk assessment because the findings may have prognostic value. However, the usefulness of NG tube placement in identifying UGI sources of bleeding has not been clarified due to its low sensitivity (42%-84%) and poor negative likelihood ratio (0.62-0.20).

Research frontiers

A novel bedside portable endoscopy device (EG scan, IntroMedic Co., Ltd., Seoul, Korea) has been developed to evaluate the esophagogastroduodenal area with high convenience and notable accessibility compared with conventional endoscopy. There has been no previous reported study of the efficacy of

this novel endoscopy device compared with that of the NG tube in patients with gastrointestinal bleeding.

Innovations and breakthroughs

In this study, specificity for identifying UGI bleeding was higher with EG scan than NG aspiration (85.4% *vs* 68.8%, $P = 0.008$) while accuracy was comparable. The accuracy of EG scan was significantly higher than that of NG in the subgroup analysis of patients with esophageal bleeding (88.2% *vs* 75%, $P = 0.004$). Food material could be detected more readily by EG scan than NG tube aspiration (20.9% *vs* 9.3%, $P = 0.014$). No serious adverse effect was observed during the portable endoscopy.

Applications

This novel portable endoscopy device might provide a benefit over NG aspiration in patients with esophageal bleeding. Further study is needed to confirm whether these potential advantages of the EG scan can change the clinical course of patients with acute UGI bleeding.

Terminology

Positive sign of UGI bleeding in NG aspiration: Dark, coffee ground- or bright red-colored blood; positive sign of UGI bleeding in the EG scan: A directly visualized coffee ground-colored blood clot or bright red blood; sensitivity: The proportion of subjects with UGI bleeding who had a positive test result; Specificity: The proportion of individuals without UGI bleeding who had a negative test result; accuracy: The proportion of all cases correctly identified by the test.

Peer review

This is a very interesting paper addressing the important clinical problem of triaging upper GI bleeding. The most important advantage of this method that was applied in the manuscript is the statistically significant sensitivity, specificity and accuracy of EG scan in the esophageal lesions. In addition, the useful role of this new tool would be in identifying food in the stomach which may increase aspiration risk with sedation.

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