Randomized pragmatic trial of nasogastric tube placement in patients with upper gastrointestinal tract bleeding

Don C Rockey,[1] Chul Ahn,[2] Silvio W de Melo Jr[3]

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[1]Department of Internal Medicine, Medical University of South Carolina, Charleston, South Carolina, USA
[2]Division of Biostatistics, Department of Clinical Sciences, University of Texas Southwestern Medical Center, Dallas, Texas, USA
[3]Department of Internal Medicine, University of Florida at Jacksonville, Jacksonville, Florida, USA

Correspondence to
Dr Don C Rockey, Department of Internal Medicine, Medical University of South Carolina, 96 Jonathan Lucas Street, Suite 803, Charleston, SC 29425, USA; rockey@musc.edu

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ABSTRACT

The value of nasogastric (NG) tube placement in patients with upper gastrointestinal tract bleeding (UGIB) is unclear. We therefore aimed to determine the usefulness of NG tube placement in patients with UGIB. The study was a single-blind, randomized, prospective, non-inferiority study comparing NG placement (with aspiration and lavage) to no NG placement (control). The primary outcome was the probability that physicians could predict the presence of a high-risk lesion (ie, requiring endoscopic therapy). 140 patients in each arm were included; baseline clinical features were similar in each group. The probability that there would be a high-risk lesion in the control arm was predicted to be 35% compared with 39% in the NG arm (after NG placement)—a probability difference of −4% (95% CI −12% to 3%), which confirmed non-inferiority of the 2 arms (p=0.002). All patients underwent endoscopy and all patients with high-risk lesions had endoscopic therapy. Physicians predicted the specific culprit lesion in 38% (53/140) and 39% (55/140) of patients in the control and NG (after NG placement) groups, respectively. The presence of coffee grounds or red blood in the NG aspirate did not change physician assessments. Pain, nasal bleeding, or failure of NG occurred in 47/140 (34%) patients. There were no differences in rebleeding rates or mortality. In patients with acute UGIB, the ability of physicians to predict culprit bleeding lesions and/or the presence of high-risk lesions was poor. Routine NG placement did not improve physician's predictive ability, did not affect outcomes, and was complicated in one-third of patients.

Trail Registration Number: NCT00689754.

Significance of this study

What is already known about this subject?

- The use of nasogastric (NG) tubes in patients with gastrointestinal (GI) bleeding has been part of the practice of medicine for many years.
- NG tubes are cumbersome and their value has been debated.
- Few studies have evaluated the clinical utility of routine placement of NG tubes in patients with upper GI tract bleeding (UGIB).

What are the new findings?

- This study demonstrated that using an NG tube in patients with routine UGIB did not improve the ability of clinicians to triage care.
- NG tube placement in patients with typical UGIB had no impact on outcomes.
- The placement of NG tubes was often unsuccessful, or associated with discomfort.

How might these results change the focus of research or clinical practice?

- The study findings indicate that NG tubes are of limited value in patients with UGIB.
- The results suggest NG tubes should not be routinely used in patients having UGIB.

INTRODUCTION

Upper gastrointestinal tract bleeding (UGIB) remains a major cause of morbidity and mortality. One of the improvements in the management of UGIB is the recognition that endoscopic treatment of lesions with high-risk stigmata of recent hemorrhage, including for variceal and non-variceal bleeding, reduces rebleeding and improves mortality.[1–4] For patients presenting with UGIB, esophagogastroduodenoscopy is recommended to be performed within 24 hours of presentation,[4] primarily to treat high-risk lesions.

Nasogastric (NG) tube placement and aspiration has long been routinely used in patients with UGIB, and may help triage the acuity and severity of bleeding, or to localize the bleeding source.[5 6] Further, some experts propose that NG lavage helps clear the stomach of blood and clots prior to esophagogastroduodenoscopy,[7–9] which helps facilitate visualization during endoscopy and may help prevent pulmonary aspiration of blood. NG placement is generally considered to be harmless and to be associated with few complications; it can even be performed safely after acute myocardial infarction.[10] A bloody NG aspirate has been reported to be associated with the identification of high-risk lesions, including those with active

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bleeding or visible vessels[11] and may predict rebleeding in non-variceal UGIB.[12] Nonetheless, in clinical practice, routine NG placement for UGIB remains controversial.[13 14]

Here, we have hypothesized that NG lavage provides little additional information to the overall clinical picture in patients with UGIB, and given the controversy regarding the use of NG placement in patients with UGIB, we designed a study to determine whether NG placement assists physicians in identifying high-risk lesions in patients with UGIB, and thus could be helpful in the triage of care. We further assessed whether its use affected outcomes.

METHODS

Study population

The study was conducted at Parkland Memorial Hospital, the safety net hospital for the city of Dallas and a major teaching hospital for the University of Texas Southwestern Medical Center, from 2008 to 2011.

Patients included those older than 18 years who presented to the emergency room within 48 hours of suspected UGIB. UGIB was defined as reported or witnessed hematemesis and/or melena and an abnormal hematocrit and/or decrease in hematocrit of four points below normal.[15] Patients with and without cirrhosis were included. Cirrhosis was defined based on clinical grounds as previously described.[16]

Patients were excluded if they were unable to provide informed consent, had severe comorbid conditions making esophagogastroduodenoscopy hazardous (acute myocardial infarction, hemorrhagic or ischemic stroke, etc), had an expected survival <72 hours as judged by the treating clinician, were prisoners, were pregnant, had ongoing anticoagulation requirements that could not be reversed, had suspected gastrointestinal perforation, or had already participated in the study within 30 days.

The study was approved by the University of Texas Southwestern Medical Center Institutional Review Board (IRB) and adhered to good clinical practice guidelines. All patients gave written informed consent.

Study design

The design was a randomized, pragmatic, single-blinded, non-inferiority trial. Patients assigned to the NG group had an NG placed immediately and lavage (with water) performed until clear or bilious fluid returned as per standard clinical practice. NG tubes ranging from 12 to 16 French (the type was prescribed the primary provider) were placed by the most experienced provider of the care team (ie, nurse, house officer, or faculty member). The character of the initial NG effluent and/or lavage fluid was recorded as follows: red blood, coffee grounds (having the appearance of coffee grounds), bilious (green or yellow–green effluent), or clear liquid. Patients were asked to report their pain along the standard 0–10 hospital pain scale at the time of NG placement (for analysis purposes, a score >5/10 was considered to be associated with pain).

Randomization was computer generated using variable block sizes (allotment group was placed in a sealed envelope by the study coordinator who unsealed envelopes and assigned subjects to intervention group). Given the pragmatic nature of the study, neither patients nor physicians could be blinded to placement of the NG tube. However, all providers were blinded to assessments and questionnaire results.

A validated questionnaire asking the responsible physician(s) to predict the likelihood of a high-risk lesion and thus need for endoscopic therapy (on a 0–100% scale) and in addition, to predict the culprit lesion was completed[17] by the attending physician managing the patient *before* NG placement. For patients randomized to NG placement, the physician reassessed and documented both of the predictions above *after* NG placement. After enrolment, patients underwent esophagogastroduodenoscopy as per standard of care. Use of other medical therapy, such as octreotide, proton pump inhibitor, or other medications, was left at the discretion of the treating physician. Physicians were also asked to record the likely bleeding (culprit) lesion as previously described.[17] Esophagogastroduodenoscopy was performed by a gastrointestinal fellow/attending gastroenterologist team or by an attending gastroenterologist alone. Given the pragmatic design of the trial, the timing of endoscopy was not proscribed.

The Blatchford scoring system was used to help assess the severity of bleeding in individual patients.[18] This validated instrument includes the following variables: hemoglobin, blood urea, pulse, and systolic blood pressure, as well as presentation with syncope or melena, and evidence of hepatic disease or cardiac failure.

Stigmata of bleeding were strictly defined as previously described.[1 4 19] In brief, high-risk stigmata for ulcers included the following: active spurting, a non-bleeding visible vessel, or active oozing. Patients with an adherent clot in which the clot was removed endoscopically and was demonstrated to have the above features were also categorized as having high-risk stigmata requiring therapy. Lesions with flat pigmented spots or a clean base were not considered to be high risk. For varices, high-risk stigmata included active spurting or oozing, a protuberant nipple, or red signs (red wale marks or red spots).[16] Endoscopic therapy was performed according to the standard of care for each lesion discovered at time of evaluation, and in keeping with the pragmatic trial design, the specific type of therapy used was left to the discretion of the attending physician. Implicit in the study design was that high risk lesions (the same as lesions with high risk stigmata) would be expected to undergo endoscopy therapy. Endoscopic findings were also reviewed in a blinded fashion (of still captured images) by each Silvio Melo (SM)/Don Rockey (DR), and lesions were validated as having high-risk stigmata of bleeding.

Statistics and sample size

The primary outcome was the ability to accurately predict the presence of a high-risk lesion (as defined endoscopically above). Using a continuous scale (0–100%), and based on previous literature, we predicted that physicians would be likely to achieve a 70% threshold for prediction. Given this assumption, we determined that 140 patients in each arm (280 patients total) would be required to detect a non-inferiority margin of −15% with a common SD of 50%, 80% power, and a one-sided 5% significance level using a two-sample t-test. The true difference between the means is assumed to be 0. The mean difference in the probability

of detecting a high-risk lesion between the no NG and NG arms along with the 95% CI was computed and non-inferiority of no NG would be declared if the lower limit of the 95% CI was greater than the non inferiority margin of −15%. The sample size was estimated using PASS V.12 software.[20] This sample size calculation represents the revised estimate, after the initiation, but before completion (after ~140 patients had been enrolled and in the absence of any statistical analysis) of the trial. The primary analysis was conducted using an intent-to-treat approach. We additionally performed an analysis using binomial prediction of stigmata, including 'no' for 0–50% and 'yes' for >50%. Secondary outcomes included the rate of complications of NG, the rate of rebleeding, and mortality.

The χ^2 tests or Fisher's exact tests were used to determine whether there were significant differences in categorical demographic and clinical features, and endoscopic lesions between no NG and NG groups. Student's t-tests were conducted to examine whether there were significant differences in continuous demographic and clinical features between no NG and NG groups. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), and diagnostic accuracy with their 95% CIs were calculated by using an exact binomial method.

RESULTS

Baseline characteristics

A total of 753 patients meeting entry criteria were invited to participate. Of those, 434 refused to participate and 319 signed informed consent. Subsequently, 39 patients withdrew consent (figure 1). Each group was assigned 140 patients; in 11 patients in the NG group, the NG tube could not be placed. As in Methods section, analysis was based on intent to treat.

Overall, the clinical features of the study groups were similar (table 1 and online supplementary table S1). Approximately 30% of patients had a clinical diagnosis of cirrhosis. Patients in the NG group had a slightly higher Blatchford score than in the control group (8.8 vs 7.8), although the number with a low Blatchford score was similar. The time to performance of esophagogastroduodenoscopy was similar in the two groups, typical of conventional practice.

Endoscopy and therapy

Endoscopic lesions were those typical of patients with UGIB (table 2). The most common causes of UGIB included gastroduodenal ulcers, esophagitis, and esophageal varices. All patients with high-risk stigmata of bleeding underwent endoscopic therapy, including in 44 (31%) patients in the control group and 48 (34%) patients in the NG arm. Additionally, endoscopic therapy was performed only in those with high-risk stigmata of bleeding. The types of endoscopic therapy used were typical of those used in standard practice (see online supplementary table S2).

Prediction of endoscopic lesions and associations with NG findings

As in Methods section, the need for endoscopic therapy was predicted along a continuum from 0% to 100%. The probability of predicting an endoscopically significant lesion in the no NG arm was 34.6±29.9% compared with 38.8±33.0% in the NG arm (ie, after NG tube placement). The mean difference in the probability of detecting an endoscopically significant lesion between the no NG and NG arms was −4.2% (95% CI −11.6% to 3.2%). Since the lower limit of the 95% CI was greater than the non-inferiority margin of −15%, the data indicated non-inferiority of no NG (p=0.002).

We also analyzed the data using binomial prediction of high-risk stigmata, including 'no' for 0–50% and 'yes' for >50% in order to report sensitivity, specificity, PPV, NPV

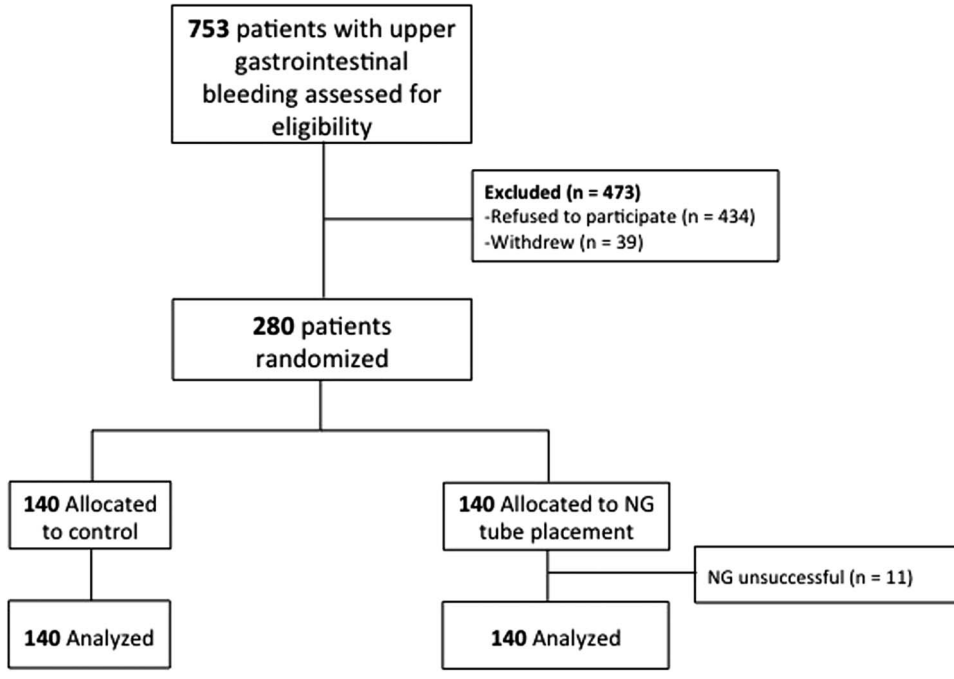

Figure 1 Patient flow. The flow of patient recruitment and enrolment is shown. NG, nasogastric tube with lavage.

Table 1 Demographic and clinical characteristics

Variable	No NG (n=140)	NG (n=140)	p Value
Age (years±SD)	49±12	50±13	0.678
Gender			0.133
Women	55 (39%)	43 (31%)	
Ethnicity			0.536
African-American	34 (24%)	40 (29%)	
Caucasian	40 (29%)	35 (25%)	
Latino	64 (46%)	60 (43%)	
Other	2 (1%)	5 (4%)	
Presentation			0.312
Hematemesis	64 (46%)	53 (38%)	
Melena	44 (31%)	44 (31%)	
Hematochezia only	0 (0%)	1 (1%)	
Hematemesis and melena	32 (23%)	42 (30%)	
Onset of bleeding (from presentation (hours))			0.386
<12	85 (61%)	92 (66%)	
>12	55 (39%)	48 (34%)	
Hemodynamics			
Systolic blood pressure	122±21	121±22	0.943
Diastolic blood pressure	70±15	70±15	0.739
Heart rate	88±18	93±20	0.026
Laboratory data			
Hemoglobin (g/dL)	9.8±2.5	9.2±2.8	0.082
Leucocyte count ($\times 10^3$)	9.0±6.2	11.1±6.7	0.008
Platelet count ($\times 10^3/mm^3$)	186±100	200±119	0.289
INR	1.3±0.6	1.2±0.4	0.582
BUN	29±29	32±32	0.389
Creatinine	1.8±4.1	1.7±3.2	0.746
BUN/Cr ratio	24±13	26±15	0.195
Blatchford score	7.8±4.1	8.8±4.1	0.043
Blatchford score <2	14 (10%)	9 (6%)	0.277
Time to esophagogastroduodenoscopy (hours)	19.2±17.5	17.9±14.3	0.49

BUN, blood urea nitrogen; Cr, creatinine; INR, international normalized ratio; NG, nasogastric tube with lavage.

Table 2 Endoscopic lesions

Lesion	No NG	NG
Gastric ulcer	25 (18%)	25 (18%)
Esophagitis	32 (23%)	24 (17%)
Esophageal varices	23 (16%)	25 (18%)
Duodenal ulcer	11 (8%)	24 (17%)
Mallory-Weiss tear	9 (6%)	4 (3%)
Portal hypertensive gastropathy	8 (6%)	5 (4%)
Gastritis	8 (6%)	4 (3%)
Other	16 (11%)	13 (9%)
No lesion	8 (6%)	16 (11%)

NG, nasogastric tube with lavage.

(table 3). In the control and the NG arms, before NG placement, physicians predicted that high-risk stigmata would be identified in 23/44 (52%) and 29/48 (60%) of patients, respectively (table 3). Notably, after NG placement, there was no change in the prediction of the likelihood that high-risk stigmata would be identified, again, with the same 29 patients being accurately predicted to require therapy (table 3). The ability to predict the absence of high-risk stigmata (specificity) was similar in the control and NG groups before NG placement, and in the NG group after NG placement (table 3). The same was true for PPV and NPV.

As in Methods section, physicians were asked to predict the cause of bleeding (culprit lesion) responsible for bleeding; they accurately predicted these lesions in 38% (53/140) and 39% (55/140) of patients in the control and NG (after NG placement) groups, respectively.

NG aspiration and lavage

In the 129 patients in whom the NG tube was successfully placed, the lavage was clear or bilious in 79 patients (61%), was frankly bloody in 30 (23%) patients, and returned coffee grounds in 20 (16%) patients (see online supplementary table S1 and figure 2). The average lavage volume was 295 mL (range 100–1000 mL). The NG tube could not be placed in 11 subjects; an additional 29 patients (21%) reported pain, and 7 (5%) patients had bleeding from the nares (see online supplementary table S1).

We also assessed whether NG aspirate characteristics played a role in physician assessments. In the group without blood, 21/79 were initially predicted to have a high-risk lesion requiring therapy, while 58/79 were predicted not to have such a lesion. After NG placement, assessments of whether there would be a high-risk lesion changed such that 16 patients were predicted to have a high-risk lesion and 63 were predicted not to have a high-risk lesion. Notably, in patients with coffee grounds and red blood, NG placement did not change any physician assessment. Overall, there were 16, 5 and 18 patients predicted to have high-risk stigmata after NG placement in the no blood, coffee grounds and red blood groups, and 9, 3 and 14 patients had high-risk stigmata, respectively. Although the presence of red blood was associated with a higher predictive ability (78%) than the presence of coffee grounds (60%) or no blood (56%), there were no significant differences in the proportion of patients with high-risk stigmata between no blood and coffee grounds (9/16 vs 3/5, p=1.000), between no blood and red blood (9/16 vs 14/18, p=0.181), and between coffee grounds and red blood (3/5 vs 14/18, p=0.576).

Outcomes

Rebleeding rate and mortality rates were similar in the control and NG groups. Rebleeding occurred in 5% and 4% of patients in the control and NG groups, respectively (p=0.776). Four patients (3%) in each arm died within 30 days.

DISCUSSION

In this single-center, single-blind, randomized, pragmatic, non-inferiority trial, we have demonstrated that NG placement in patients with UGIB did not allow physicians to better predict the presence of a high-risk lesion and thus, the need for endoscopic therapy. It also did not assist in predicting the cause (ie, the culprit lesion) of bleeding. In addition, a large proportion of patients had difficulty with NG tube placement.

Table 3 Prediction of high-risk stigmata

	Pre-NG				Post-NG			
	Sensitivity*	Specificity†	PPV	NPV	Sensitivity*	Specificity†	PPV	NPV
No NG	23/44 (52%)	80/96 (83%)	23/39 (59%)	80/101 (80%)	NA	NA	NA	NA
NG	29/48 (60%)	72/92 (78%)	29/49 (59%)	72/91 (79%)	29/48 (60%)	77/92 (84%)	29/44 (66%)	77/91 (80%)

Data were analyzed using binomial prediction of stigmata; 'no' for 0–50% and 'yes' for >50%.
*Sensitivity=number with high-risk stigmata predicted to have stigmata.
†Specificity=number predicted not to have high-risk stigmata/number without high-risk stigmata.
NA, not available; NG, nasogastric tube with lavage; NPV, negative predictive value; PPV, positive predictive value.

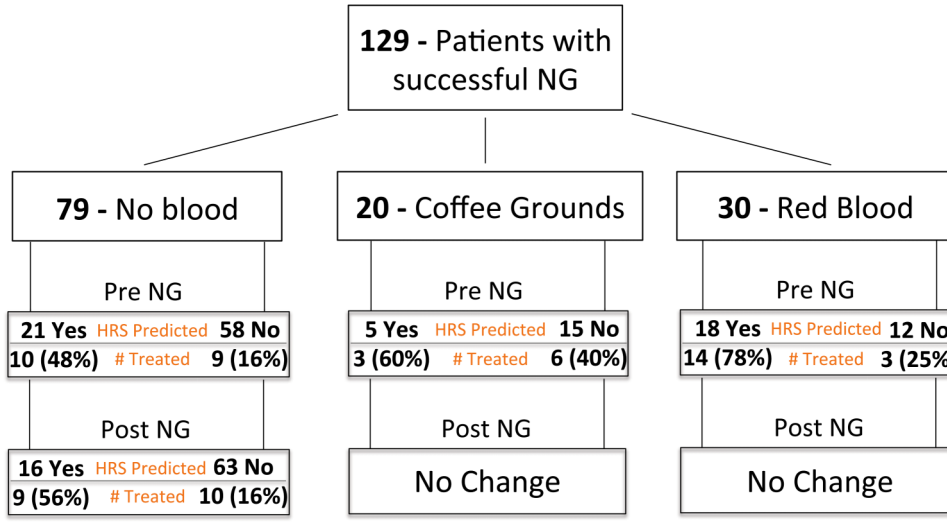

Figure 2 The role of blood in the NG on physician assessments. In patients with a successful NG placement, depending on whether blood (whether coffee ground or red blood) was found in the aspirate, the likelihood of identifying a high-risk stigmata or not is shown. In addition, the prenasogastric and postnasogastric tube probability of identifying a high-risk lesion on the binomial prediction of high-risk stigmata, including 'no' for 0–50% and 'yes' for >50% is shown. NG, nasogastric tube with lavage; HRS, high-risk stigmata.

There are several reasons to perform NG aspiration, including to help triage care, to help localize the source of bleeding, and in some instances to clear the stomach of blood. In a retrospective study, it was reported that a bloody NG lavage was associated with high-risk lesions and that NG lavage was associated with earlier time to endoscopy,[13] but that NG placement did not affect outcomes. The authors concluded that placing an NG tube might promote more timely care. Our results were similar in that a bloody aspirate appeared to be more common in patients with stigmata of bleeding. However, our results bring into question the conclusion as that NG improves care in any manner, since placing an NG did not improve physician's ability to judge the need for endoscopic therapy, the ability to predict the culprit endoscopic lesion, and had no effect on any clinical outcome.

NG tube placement has proposed as an adjunct to help differentiate upper from small bowel or lower gastrointestinal bleeding because it presumably samples the stomach and upper duodenum and thus may detect blood. However, it has been shown that it is difficult to clearly identify bilious fluid by visual inspection alone[6] and some patients with duodenal ulcers may have a clear NG aspirate.[5] Moreover, NG aspiration has a low sensitivity (42–84%) and NPV (0.2–0.62) to rule out an upper gastrointestinal source of bleeding in patients presenting with melena and/or hematochezia without hematemesis.[21] In our experience, a careful history and physical examination are superior to NG tube placement for determining the site—upper, small bowel, or lower gastrointestinal tract—of bleeding.

Another argument in support of placing an NG tube is to clear the stomach of blood and blood clots to facilitate endoscopic visualization.[3 8] A recent multicenter, randomized trial demonstrated that erythromycin, given 30 min before endoscopy, led to 'good' endoscopic visualization in 84% of patients, which was not different than patients having NG lavage alone (82%).[9] In our experience, particularly with the use of endoscopes with large suction channels, there is little difficulty in clearing the stomach of blood, even in patients with substantial blood present.

One of the most remarkable findings of our study was that even in patients with bloody NG aspirates (figure 2), physicians did not change (in particular, increase) their prediction of the likelihood of assessment of high-risk stigmata. We speculate that this is because the patient's clinical presentation and history, including physical examination features such as vital signs, were likely to be viewed to be as or more clinically important than the result of the NG lavage. Another important finding of our study was that NG tube placement could not be successfully completed, was

uncomfortable, caused frank bleeding or pain, and was generally poorly tolerated in many patients. This has been the experience of most clinicians and patients, and is consistent with previous study of procedures commonly performed in the emergency department.[22] Additionally we noted that when patients were asked to participate in this study (prospective participants were provided a simple description of NG tube placement), many patients refused to participate.

We recognize limitations of this study. First, it was designed as a non-inferiority study with prespecified assumptions as to inferiority margins. Thus, it is possible that small differences in outcomes may not have been detected. Second, it was performed at a single hospital, and thus, could be viewed as not generalizable to other populations. On the other hand, the types of patients and lesions seen were typical of most populations with UGIB. Finally, the study intervention could not be blinded. However, it is unlikely that this lack of blinding had an impact on the primary end point because it was measured before the intervention (NG) was performed (ie, obtained prior to endoscopy). Indeed, a specific strength of the study was the manner in which blinding of assessments was planned.

In summary, we have shown that routine NG tube placement does not assist physicians in predicting the need for endoscopic treatment, nor does it assist physicians in predicting culprit bleeding lesions. Further, since NG tube placement appears to be difficult from the patient perspective, our findings bring into question not only its clinical utility, but also the appropriateness of the use of NG tubes in patients with UGIB.

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Contributors DCR and SWdM were involved in study concept and design, and acquisition of data. CA, DCR and SWdM were involved in data analysis and interpretation of data. DCR and SWdM were involved in drafting of the manuscript. DCR, SWdM and CA were involved in critical revision of the manuscript for important intellectual content and statistical analysis. DCR was involved in administrative, technical, and material support, and study supervision.

Competing interests None declared.

Ethics approval Institutional Review Board (IRB).

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