UNIVERSITE DE LAUSANNE – FACULTE DE BIOLOGIE ET DE MEDECINE
DEPARTEMENT DE MEDECINE

Service de gastro-entérologie et d'hépatologie
Chef de service : Professeur Pierre Michetti

Is Early Endoscopy in the Emergency Room Beneficial in Patients with Bleeding Peptic Ulcer ?

A « Fortuitously Controlled » Study

THESE

Préparée sous la direction du

Professeur honoraire André L. Blum

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par

Gerold Schacher

Médecin diplômé de la Confédération Suisse
Originaire de Lucerne et Escholzmatt/LU

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Est-ce qu'une endoscopie précoce en salle de réanimation est bénéfique pour les patients avec une hémorragie digestive sur ulcère peptique ?
Une étude « fortuitement contrôlée »

Introduction et objectifs : les études randomisées antérieures montrent qu'une endoscopie précoce améliore les résultats cliniques chez les patients qui présentent une hémorragie sur ulcère peptique. Toutefois, dans la plupart de ces études, le terme « précoce » s'applique aux endoscopies pratiquées dans les 24 heures après l'admission. En utilisant la durée d'hospitalisation comme paramètre principal de l'évolution clinique, nous avons comparé les résultats d'une endoscopie pratiquée immédiatement après l'admission (endoscopie précoce en salle de réanimation : EPR) à ceux d'une endoscopie pratiquée au cours des premières 24 heures d'hospitalisation dans le centre endoscopie mais pendant les heures de travail normales (endoscopie différée au centre d'endoscopie : EDC).

Patients et méthodes : nous avons effectué une analyse rétrospective des données concernant 81 patients consécutifs qui ont été admis en 1997 et 1998 pour une hémorragie sur ulcère peptique (âge compris entre 16 et 90 ans). De ces 81 patients, 38 ont subi une EDC (le traitement standard à l'hôpital) et 43 ont subi une EPR. Les patients dans les deux groupes étaient comparables concernant les critères d'admission et ils présentaient un risque égal en ce qui concerne leur risque d'évolution défavorable (évalué par le « Baylor Bleeding Score » et par le score de Rockall). Ils ne se distinguaient que par le traitement reçu. Une hémostase endoscopique était pratiquée à chaque fois que cela était possible et dans tous les patients avec une hémorragie d'ulcère de type Forrest I, IIa et IIb.

Résultats : dans les deux groupes nous avons trouvé des taux similaires pour les récidives d'hémorragie (16 % chez les patients EDC vs. 14 % chez les patients EPR) et pour les saignements persistants (8 % chez le patients EDC vs. aucun des patients EPR) ainsi qu'une durée d'hospitalisation comparable (5,1 jours pour les patients EDC vs. 5,9 jours pour les patients EPR). Entre les deux groupes, aucune des différences dans ces paramètres n'était statistiquement significative. Aucun des patients n'est décédé.

Conclusions : l'endoscopie précoce en salle de réanimation n'a pas amélioré l'évolution clinique chez nos 81 patients consécutifs avec un ulcère peptique hémorragique.

Endoscopy

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Address:
ESGE Technical Secretariat
c/o Medconnect GmbH
Brünnsteinstr. 10
81541 Munich, Germany
Phone: + 49-89-4141-9241
Fax: + 49-89-4141-9245
E-mail: ESGE@medc.de

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Is Early Endoscopy in the Emergency Room Beneficial in Patients with Bleeding Peptic Ulcer? A "Fortuitously Controlled" Study

G. M. Schacher[1]
D. Lesbros-Pantoflickova[1]
M. A. Ortner[1]
J. B. Wasserfallen[2]
A. L. Blum[3]
G. Dorta[1]

Background and Study Aims: In previous randomized trials, early endoscopy improved the outcome in patients with bleeding peptic ulcer, though most of these studies defined "early" as endoscopy performed within 24 hours after admission. Using the length of hospital stay as the primary criterion for the clinical outcome, we compared the results of endoscopy done immediately after admission (early endoscopy in the emergency room, EEE) with endoscopy postponed to a time within the first 24 hours after hospitalization, but still during normal working hours ("delayed" endoscopy in the endoscopy unit, DEU).

Patients and Methods: We conducted a retrospective analysis of data from 81 consecutive patients with bleeding peptic ulcer admitted in 1997 and 1998 (age range 16–90 years). Of these 81 patients, 38 underwent DEU (the standard therapy at the hospital) and 43 underwent EEE. Patients in the two groups were comparable with regard to admission criteria, were equally distributed with respect to their risk of adverse outcome (assessed using the Baylor bleeding score and the Rockall score), and differed only in the treatment they received. Endoscopic hemostasis was performed whenever possible in all patients with Forrest types I, IIa, and IIb ulcer bleeding.

Results: We found similar rates in the two groups for recurrent bleeding (16% in DEU patients vs. 14% in EEE patients), persistent bleeding (8% in DEU patients vs. none in EEE patients), medical complications (21% in DEU patients vs. 26% in EEE patients), the need for surgery (8% in DEU patients vs. 9% in EEE patients), and the length of hospital stay (5.1 days for DEU patients vs. 5.9 days for EEE patients). None of the differences between the two groups in these parameters were statistically significant. None of the patients died.

Conclusions: Early endoscopy in an emergency room did not improve the clinical outcome in our 81 consecutive patients with bleeding peptic ulcer.

Introduction

Endoscopic hemostasis has been shown to improve the outcome for patients presenting with ulcer bleeding. It favorably affects recurrent bleeding, the need for surgery, and, probably, survival [1–4]. The question of whether endoscopic hemostasis should be performed early after hospital admission has also been examined in randomized trials [5,6], in observational cohort studies [7–9], and in a systematic review [10], and these papers have described early endoscopy as advantageous. However, it is difficult to interpret these studies as the definitions of "early" and "late" endoscopy vary widely. In most studies, "early" endoscopies were defined as examinations which were performed within the first 24 hours, compared with "late" endoscopies, which were performed after several days, although this distinction is not in fact a relevant one in most hospitals. Rather, endoscopists want to know if endoscopic hemostasis needs to be performed by an emergency team in an emergency room, immediately after hospital admission, as soon as the diagnosis of upper gastrointestinal bleeding has been made (early endoscopy in the emergency room, EEE). The alternative to this emergency procedure is an endoscopy performed within the first 24 hours by the normal endoscopy team in an endoscopy unit (delayed endoscopy in an endoscopy unit, DEU). Using this approach, the patient is assigned to the normal endoscopy department. During the delay of several hours' duration before endoscopy, these patients are closely supervised in the emergency department and receive treatment for blood loss. EEE requires that a special team is available around the clock; DEU does not. To the best of our knowledge, the question of which of these two courses of action proves more beneficial to the patient has not yet been examined.

We had an opportunity to investigate this very question because, in 1997 and 1998, the gastroenterologists of the Lausanne University Hospital held differing opinions about the benefits of EEE.

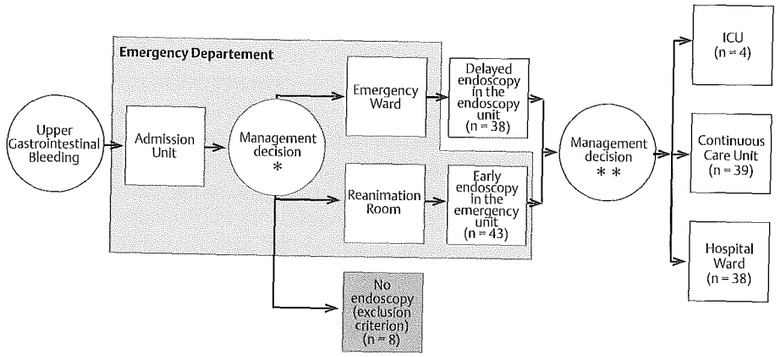

Figure **1** Flow chart showing how management decisions affected when and where patients underwent endoscopy and their aftercare after an upper gastrointestinal bleed. In the emergency department, patients were assigned to undergo either "early" endoscopy in the emergency room (EEE group) or "delayed" endoscopy in the endsocopy unit (DEU group). After endoscopy, patients were sent to the intensive care unit (ICU), the continuous care unit, or a hospital ward, depending on clinical and endoscopic outcome predictors.

* attribution to EEE and DEU by gastroenterologist on duty according to his opinion on the usefulness of EEE
** choice of the appropriate hospital unit according to clinical and endoscopic outcome predictors

Patients and Methods

This study reports on a retrospective analysis made of data gathered from 81 consecutive patients with bleeding peptic ulcer who were admitted to the Lausanne University Hospital in 1997 and 1998 (age range 16–90 years). The hospital's five attending gastroenterologists agreed on the use and techniques of endoscopic hemostasis and second-look endoscopy, but their views on EEE differed strongly. After examination in the admission unit, patients with suspected ulcer bleeding were assigned, depending on the preference of the gastroenterologist on duty, to undergo either EEE or DEU. Of the 81 patients who presented in this way to the admission unit, 38 underwent DEU (the consistent preference of three gastroenterologists and the standard, or "control", treatment at the hospital at the time), and 43 others underwent EEE (the option always used by the other two attending gastroenterologists). The decision on whether patients were assigned to treatment by EEE or DEU depended solely and randomly on which gastroenterologist was on call and was independent of the patient's condition. As a consequence, patients in the two groups were comparable with respect to admission criteria, were equally distributed with respect to their risk of adverse outcome (assessed using the Baylor bleeding score and the Rockall score), and differed only in the treatment they received. This constituted a "fortuitously controlled" study, a clinical trial in which it was possible to compare two similar groups [11]: by comparing the two groups, we were therefore able to formulate and test the hypothesis that EEE is better than DEU.

In EEE patients, endoscopy was performed after a delay of up to 3 hours by an emergency team in an endoscopy unit situated near the resuscitation room of the emergency department (Figure **1**). DEU patients remained in the emergency ward and were monitored with respect to hemodynamic parameters until their endoscopy, which was performed in the endoscopy unit by the normal endoscopy team. This was done within 24 hours in 84% of the DEU patients; 16% of the DEU patients arrived on a Saturday and had their endoscopy within 48 hours. After endoscopy (EEE or DEU), patients were sent to the intensive care unit, the continuous care unit, or a hospital ward, as appropriate. Identical internal guidelines were followed by all gastroenterologists for hemostatic procedures and follow-up after endoscopy. Endoscopic hemostasis was indicated whenever technically feasible in patients presenting with Forrest types I, IIa and IIb ulcer bleeding. Hemostasis was performed with combined injection of fibrin glue and epinephrine or with epinephrine alone. Second-look endoscopy was usually performed on the day following endoscopic treatment. Discharge decisions were made by the internist in charge of the hospital units.

Identification of Patients and Inclusion and Exclusion Criteria

The hospital database was screened using the appropriate ICD-10 codes. Medical records were extracted using a standardized data collection form. All patients who presented at the Emergency Department of the Lausanne University Hospital for bleeding peptic ulcer in 1997 and 1998 were identified. Inclusion criteria were: a) ulcer hemorrhage diagnosed by endoscopy; b) bleeding on admission and/or within 10 days prior to admission; and c) age between 16 and 90 years. We excluded patients whose first episode of hemorrhage had started during hospitalization and those who were referred from other hospitals more than 12 hours after initial presentation. Patients who were bleeding but who did not undergo endoscopy were also excluded.

Assessment of Clinical Parameters

The Baylor bleeding score was established for all patients [12,13]. This score is used to predict the risk of rebleeding. It scores three

Institution
[1] Service de Gastroentérologie, Centre Hospitalier et Universitaire Vaudois, Lausanne, Switzerland
[2] Département de Médecine A, Centre Hospitalier et Universitaire Vaudois, Lausanne, Switzerland
[3] Faculty of Biology and Medicine, University of Lausanne, Lausanne, Switzerland

Corresponding Author
G. Dorta, M.D. · Gastroentérologie, CHUV BH 10/535 · Rue du Bugnon 47 · CH-1011 Lausanne · Switzerland · Fax: +41-21-314-0707 · E-mail: gian.dorta@hospvd.ch

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pre- and two postendoscopic risk factors: age, the number of concurrent illnesses, the severity of these illnesses (chronic, acute, or life-threatening), endoscopic bleeding site, and endoscopic stigmata of bleeding. We defined a low-risk group (Baylor pre-endoscopic score of 5 or less, postendoscopic score of 10 or less), and a high-risk group (pre-endoscopic score over 5 and/or postendoscopic score over 10).

We also established the Rockall score for all patients [7,14,15]. This score can be used in all types of upper gastrointestinal hemorrhage and is made up of three pre- and two postendoscopic risk factors: age, the presence of co-morbidity, shock, diagnosis (Mallory–Weiss, malignancy, "all other diagnoses"), and endoscopic stigmata of recent hemorrhage. Pre-endoscopic scores were determined immediately on admission of the patients to the hospital in both EEE and DEU groups, whereas postendoscopic scores were determined 10 hours later in DEU patients than they were in EEE patients.

Upper gastrointestinal hemorrhage was defined as hematemesis, melena or hematochezia of upper gastrointestinal origin. Recurrent bleeding was defined as upper gastrointestinal hemorrhage which occurred within 14 days after initial presentation and after a symptom-free interval of more than 6 hours following endoscopically documented hemostasis.

Shock on admission was defined according to the Rockall score as the recording of a systolic blood pressure of less than 100 mm Hg. Shock during hospital follow-up was defined as a systolic blood pressure recording of less than 80 mm Hg, or a systolic blood pressure of less than 90 mm Hg plus a heart rate greater than the systolic blood pressure, and/or the need for vasoactive amines.

Outcomes

In this comparison of EEE and DEU, the primary outcome parameter was the length of hospital stay. Secondary outcome parameters were recurrent bleeding, the need for surgery, medical complications (any acute illness or worsening of a co-morbid condition), and mortality. All of these events were only considered as significant when they occurred during hospitalization and within 14 days of the initial episode of bleeding.

Statistical Analysis

For quantitative data, the deviation from normal was assessed by the Kolmogorov–Smirnov test, using Lilliefors' correction. Normally distributed data were compared using *t*-tests. When a departure from the norm was detected, comparisons were made using the Mann–Whitney test. Categorical and contingency table data were compared using Fisher's exact test or a chi-squared test with Yates' correction for continuity, as appropriate. For quantitative data, the summary statistics are presented as means (and standard deviation) or as medians (and interquartile range), depending on whether the data were analyzed by parametric or by nonparametric techniques, respectively. *P* values of less than 0.05 were considered to be statistically significant [16].

Results

Study Population

Our ICD-10-based data search identified 81 patients with peptic ulcer bleeding: 38 of these underwent DEU (21 men, 17 women; mean age 71), and 43 underwent EEE (23 men, 20 women; mean age 68). The differences between the groups with respect to these demographic characteristics were not statistically different. A history of nonsteroidal anti-inflammatory drug use preceded bleeding in 53% of DEU patients and 60% of EEE patients (not a statistically significant difference). The two groups were also similar regarding a history of previous ulcer disease (32% in the DEU group vs. 23% in the EEE group), previous upper gastrointestinal bleeding (26% in DEU patients vs. 14% in EEE patients), and the clinical manifestations of bleeding (hematemesis occurred in 58% of DEU patients and in 56% of EEE patients). The median delay from the onset of the bleeding episode to hospital admission was shorter in patients in the DEU group than in the EEE patients (20.7 hours vs. 36.2 hours, $P = 0.1$). The last bleeding episode occurred within the 12 hours before hospital admission in 29/33 (88%) of DEU patients and in 26/32 (81%) of EEE patients (there being no statistically significant difference between these rates). Exact data were not recorded in 16 patients (20%).

Clinical and Laboratory Results

Low- and high-risk patients, as assessed by their Baylor bleeding score and their Rockall score, were equally distributed in the two groups (see Table **1**). Abnormal hemodynamic parameters on admission (shock, tachycardia) were also similarly distributed in the two groups.

The median delay from admission to initial endoscopic examination was longer in the DEU group than in the EEE group (12.0 hours vs. 2.1 hours, $P < 0.001$). There was no statistically significant difference between the groups with respect to the prevalence of gastric and duodenal ulcers: 44.7% of DEU patients and 46.5% of EEE patients had a gastric ulcer; 44.7% of DEU patients and 48.8% of EEE patients had a duodenal ulcer; 7.9% of DEU and 4.9% of EEE patients had a combined gastroduodenal ulcer; and an anastomotic ulcer was found in 2.6% of DEU patients but in no EEE patients. Forrest type Ia ulcer bleeding was less common in the DEU group than it was in the EEE group, while Forrest types IIc and III ulcer bleeding were more common in the DEU group than in the EEE group (Table **2**). Data on *Helicobacter pylori* status (established by urease testing and/or histological examination) were available in 80% of the patients and there was no statistically significant difference between the two groups, with positive tests in 47% of DEU patients and 42% of EEE patients.

Table **1** Upper gastrointestinal bleeding was assessed in the study patients by establishing their Baylor bleeding scores and Rockall scores, comparing the DEU patients (who underwent "delayed" endoscopy in the endoscopy unit) with the EEE patients (who underwent "early" endoscopy in the emergency room)

	DEU group	*EEE group*	P
Baylor bleeding score			
Age (mean score)	3.9	3.8	0.65
No. of illnesses (mean score)	0.9	1.1	0.5
Severity of illnesses (mean score)	0.9	0.7	0.6
Baylor pre-endoscopy score	5.7	5.5	0.8
Site of bleeding (mean score)	0.7	0.6	0.6
Stigmata of bleeding (mean score)	1.8	3.1	0.07
Baylor postendoscopy score	8.3	9.1	0.3
Rockall score			
Age	1.11	1.02	
Shock	0.39	0.51	
Co-morbidity	1.11	0.98	
Rockall pre-endoscopy score	2.61	2.51	0.77
Diagnosis	1.0	1.0	
Stigmata of recent hemorrhage	1.16	1.72	
Rockall postendoscopy score	4.76	5.23	0.3

Table **2** Forrest classification of ulcer bleeding in the DEU and EEE patient groups

	DEU group (n = 38)		*EEE group (n = 43)*		*P*
	n	*%*	*n*	*%*	
1Active bleeding	9	24	17	40	0.1
Forrest Ia	1	3	8	19	0.022
Forrest Ib	8	21	9	21	0.99
No active bleeding	29	76	26	60	0.1
Forrest IIa	6	16	10	23	0.4
Forrest IIb	3	8	8	18	0.2
Forrest IIc	7	18	2	5	0.05
Forrest III	13	34	6	14	0.03

Table **3** Features of the endoscopies carried out in the DEU patients and in the EEE patients

	DEU group (n = 38)	*EEE group (n = 43)*	P
Median delay from admission to first endoscopy, hours	12.0	2.1	0.001
Mean no. of upper endoscopies performed during hospitalization	2.1	2.3	0.3
No. of patients who underwent therapeutic endoscopy (%)	18 (47.4%)	33 (76.7%)	0.006
No. of endoscopically treated patients with active bleeding (%)	9/18 (50%)	17/33 (51.5%)	0.9

Endoscopic Treatment

Table **3** summarizes the endoscopic treatments performed. Endoscopic treatment was performed more often in the EEE group patients than in the DEU group patients (77% vs. 47%, $P = 0.006$). All DEU and EEE patients with active bleeding (Forrest types Ia and Ib) received endocopic treatment. All DEU and EEE patients with visible vessels (Forrest IIa) underwent endoscopic treatment except for one patient in the DEU group, whose endoscopy was complicated by technical problems. Adherent clots were removed and endoscopic treatment of the underlying lesion was performed in all patients with Forrest IIb ulcer bleeding, except for one patient in the EEE group, again because there were technical problems. The proportion of endoscopically treated patients who did not have active bleeding at initial endoscopy was 50% in the DEU group and 48% in the EEE group (not a statistically significant difference).

Table **4** Clinical outcomes according to whether the initial endoscopy was carried out in the endoscopy unit after a delay (DEU) or in the emergency room (EEE)

	DEU group (n = 38)	*EEE group (n = 43)*	P
Primary outcome parameter			
Median length of hospital stay, days	5.1	5.9	0.8
Secondary outcome parameters, n (%)			
Failure of hemostasis			
Recurrent bleeding	6 (15.8%)	6 (14%)	0.8
Persistent bleeding	3 (7.9%)	0	0.06
Complications			
Medical complications	8 (21.1%)	11 (25.6%)	0.6
Endoscopy-related complications	0/18	1/33 (3.0%)	1.0
Surgery required	3 (7.9%)	4 (9.3%)	0.8
Death	0	0	1.0

Outcome in Low-Risk and High-Risk Patients

When comparing low-risk and high-risk patients, stratified according to the Baylor bleeding score and independent of where the initial endoscopy was carried out, the hospital stay was longer in the high-risk group than in the low-risk group (6.6 days vs. 4.2 days, $P = 0.002$). The incidence of medical complications was also higher in this group (36% vs. 9%, $P = 0.004$). No significant difference between the two risk groups was found with respect to the need for surgery.

Outcome According to Where the Endoscopy was Carried Out

We found no significant difference in length of hospital stay between DEU and EEE patients (Table **4**). Regarding the other outcome parameters we analyzed, no statistically significant differences were found between the two groups (Table **4**): after the initial ulcer bleeding, three patients fulfilled the criteria for persistent bleeding (these patients were all from the DEU group, $P = 0.06$, but still not significant); 12 patients had recurrent bleeding (16% in the DEU group vs. 14% in the EEE group); medical complications occurred with the same frequency in the two groups; and the need for surgery was also similar (8% in the DEU group vs. 9% in the EEE group). Indications for surgery were failure of initial endoscopic treatment in one patient (in the EEE group) and rebleeding in six patients (three in the DEU group, three in the EEE group). None of the patients died.

Discussion

To test our hypothesis that "early" endoscopy in the emergency room (EEE) is more advantageous to the patient than "delayed" endoscopy in the endoscopy unit (DEU), we analyzed data from patients with ulcer bleeding who underwent endoscopy with an average delay of 2 hours after hospital admission by an emergency team (the EEE group). This rapid intervention did not shorten the hospital stay when compared with patients undergoing endoscopy in an endoscopy unit during normal working hours, performed after an median delay of 12 hours (the DEU group). The outcomes in EEE and DEU patients were also similar with respect to recurrent bleeding, endoscopy-related complications, medical complications, the need for surgery, and mortality. We were

therefore unable to detect an advantage of EEE for patients presenting with bleeding peptic ulcers.

In our retrospective comparison, EEE and DEU patients were similar with respect to gender, intake of nonsteroidal anti-inflammatory drugs, *H. pylori* status, and Baylor and Rockall scores. On the basis of these entry parameters, the two groups were well matched and thus comparable. However, there was a major difference between the two groups with respect to the incidence of actively bleeding ulcers diagnosed at endoscopy: this led to a greater incidence of therapeutic hemostatic procedures at endoscopy in the EEE patients. It is possible that this difference was due to a selection bias which favored patients with actively bleeding ulcers on admission being placed into the EEE group. However, this seems less likely when the similar hemodynamic parameters recorded on admission and the similar pre-endoscopic Baylor and Rockall scores recorded in the two groups are taken into consideration. It could therefore be argued that many actively bleeding ulcers in patients in the DEU group stopped bleeding while the patient waited for endoscopy (with hemodynamic monitoring) and that a 12-hour delay diminishes the need for therapeutic intervention without unfavorably affecting the outcome.

Our study does not argue against the usefulness of EEE in all patients who are bleeding because we only considered patients with ulcer bleeding in this study. It could be claimed, for example, that EEE is life-saving in variceal bleeding: because the source of bleeding is unknown before endoscopy, EEE would then be necessary in order to identify and adequately treat variceal bleeding. Nevertheless, the necessity for EEE even in these circumstances is still not proved because sclerotherapy shows no benefit compared with vasoactive drugs alone, as shown in a recent meta-analysis [17]. Other studies have shown that combined pharmacological and endoscopic treatment is superior to endoscopic treatment alone, but does not increase the 15-day survival in variceal bleeding [18,19]. Furthermore, the same critisisms apply to all prospective trials of ulcer bleeding which attempt to address strategies for diagnostic and therapeutic endoscopy [5,6]. A study of patients with all types of upper gastrointestinal bleeding needs to be done in order to address the question of the overall value of EEE.

On the basis of the Baylor bleeding score, the Rockall score, and the severity of the endoscopic findings, our 81 consecutive patients were at least as severely ill as the patients in other trials [14,15]. In spite of this, the need for surgery and the mortality were low in our study (8.6% and zero respectively). The lack of any difference in outcomes between patients in the EEE and DEU groups is not therefore due to a lack of expertise with the procedures used.

In conclusion, based on the results of our study, the emergency treatment of bleeding ulcers is not a valid argument for performing endoscopy by an emergency team within a few hours after hospital admission. However, our results are preliminary and need to be tested in a prospective randomized trial: they serve as an ethical background for such a study. Furthermore, studies in patients with other types of upper gastrointestinal bleeding are needed in order to further assess the validity of emergency endoscopy.

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