Incidence, Outcomes and Risk Factors for Mortality of Symptomatic upper Gastrointestinal Hemorrhage in Surgical Critical Ill Patients (THAI SICU Study)

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Objective: This multicenter university-based study reports the incidence, outcomes and defined risk factors for mortality of upper gastrointestinal hemorrhage (UGIH) patients in the surgical intensive care units (ICU) patients in Thailand. **Material and Method:** This is part of a multicenter prospective observational study in the ICU in Thailand (THAI-SICU study). Patients who had a clinical presentation of upper gastrointestinal hemorrhage or an endoscopic diagnosis from April 2011 to January 2013 were enrolled into this sub-study.

Results: A total of 4,652 patients were analyzed. Fifty-five patients (1.18%) had symptomatic UGIH during ICU admission. The median age (interquartile range, IQR) was 72 (63-78) years old and the median APACHE II score (IQR) was 17 (13-22). In a comparison between the UGIH patients who survived and those who non-survived APACHE II score were higher in the non-survivors. The ICU mortality rate and 28-day mortality rate in these patients were 30.91% and 40%, respectively. In multivariable model, UGIH was significantly associated with 28-day mortality [adjusted odds ratio, OR, (95% confidence interval, CI): 1.99 (1.02 to 3.88); p = 0.043] and ICU length of stay [adjusted coefficient (95% CI): 9.36 (8.03 to 10.70); p < 0.001]. Regarding the exploratory model, the significant risk factors for non-survived of UGIH patients were coagulopathy especially platelet count < 50,000 [OR (95% CI): 3.96 (1.07-14.67); p = 0.039] and INR > 1.5 [5 (1.04-23.98); p = 0.044], renal failure [6.48 (1.37-30.61); p = 0.018], APACHE II score [1.11 (1.02-1.22); p = 0.020] and vasopressor use [5.78 (1.6-37.18); p = 0.013].

Conclusion: The incidence of symptomatic UGIH in the THAI-SICU study was 1.18% and UGIH was associated with higher 28-day mortality rate and prolonged ICU length of stay. The risk factors for mortality were coagulopathy, renal failure, APACHE II score and vasopressor use.

Keywords: Upper gastrointestinal hemorrhage, Critical care, Mortality, Incidence, Risk factors

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Upper gastrointestinal hemorrhage (UGIH) is a common problem in critically ill patients that can be a life-threatening condition and is also an economic burden. In the United States, the annual incidence of UGIH ranges from 48 to 160 cases per 100,000 individuals with an estimated cost of \$2.5 billion annually^(1,2). Even though the incidence of UGIH is a small proportion, GI hemorrhage is the symptom most significantly associated with a poor outcome

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or mortality⁽³⁾. Over the past few decades, despite an advance in therapy and a significantly decreased incidence rate of upper GI bleeding, the risk of rebleeding or mortality in these patients has not improved⁽⁴⁾. The mortality rate is from 10 to 14% and it increases among elderly patients and patients with co-morbidities^(1,2,4,5).

Clinical manifestation of UGIH commonly presents with coffee grounds in the nasogastric aspirate, hematemesis, or melena. It may coexist with anemia, hypotension or shock in case of life-threatening bleeding. The major cause of hemorrhage is peptic ulcer and almost one half of all patients with peptic ulcer bleeding were using non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin. Thus, prevention of ulcer

bleeding is the most effective strategy and preferable management^(4,6).

Early recognition of UGIH and urgent assessment of bleeding severity are important for resuscitation. A multidisciplinary team of specialists including an intensivist, gastroenterologist, surgeon and interventional radiologist improves patient management and outcomes of treatment. From the point of view of management for UGIH patients, the first priority is to treat hemodynamic instability rather than to identify the source of bleeding. Endoscopy is undertaken once resuscitation has been achieved⁽⁷⁾.

Population-based epidemiology data of UGIH in critically ill patients is important to give insight in the healthcare problem and to determine the risk factors. In Thailand, the data of UGIH in critically ill patients are poorly understood. The purpose of this multicenter university-based study was to report the incidence, outcomes and defined risk factors for mortality of UGIH in the surgical intensive care units (SICU) patients in Thailand.

Material and Method

This is part of a multicenter prospective observational study in 9 university-based surgical intensive care units in Thailand (THAI-SICU Study). The data collection was performed after the ethics committee or Institutional Review Board approved the study. Patients who were ≥18 years old who had an SICU admission period ≥6 hours from April 2011 to January 2013 were enrolled in this study. The patients were followed until they were discharged from the SICU or up to 28 days of their SICU admission and up to 28 days following discharge from the SICU if they survived. The details of methodology were described in a previous publication(8). The patients who had a clinical presentation of UGIH or had an endoscopic diagnosis which occurred after admission to SICU were enrolled into this sub-study. Patients who were admitted to SICU due to UGIH were not included in this study. The diagnosis methods, characteristics, risk factors and final treatments and outcome were observed and recorded in a specially designed form. Diagnosis method, bleeding site, cause of UGIH, risk factors, final treatments and outcome were collected.

Statistical analysis

The statistical program used in this study was STATA, version 11.0 (STATA Inc., College Station, TX, USA). Descriptive data were reported as percentages and mean \pm standard deviation (SD) or median and

interquartile range (IQR) for continuous data. Univariable analysis was used to detect the differences between the groups using the Student's t-test or Mann-Whitney U test for continuous variables. The Chisquare or Fisher exact probability test was used for categorical data. Relationships between the factors and mortality were analyzed by regression analysis with univariable and multivariable analysis. The risk factors of mortality were described in odds ratio. Statistically significant differences were defined as *p*-value <0.05.

Results

After a period of 19.7 months of recruitment, a total of 4,652 patients were analyzed. The study flow and analysis sequence were demonstrated as Fig. 1. Fifty-five patients (1.18%) were reported to have UGIH. The median age (IQR) was 72 (63-78) years old. The median APACHE II score (IQR) was 17 (13-22). Nonsurvived UGIH patients had a significantly higher median APACHE II score (p = 0.007). The demographic characteristics are described in Table 1.

The specially designed form had complete data in only 44 cases. Most of the patients were diagnosed by bloody or coffee ground like nasogastric lavage (72.73%), melena (20.45%) or witnessed bloody gastric content (15.91%). Only one case (2.27%) was diagnosed by esophagogastroduodenoscopy (EGD). From the characteristics of the UGIH in these patients, the bleeding site of most patients was unknown. The major cause of UGIH in this study was stress ulcer (34.09%). The other causes were drug induced, portal hypertension, trauma or post-surgery and tumors.

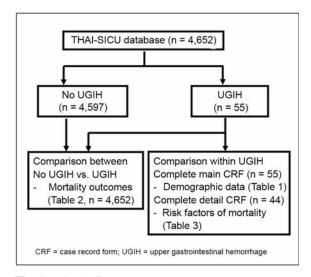


Fig. 1 Study flow.

The ICU mortality and 28-day mortality rate in these patients were 30.91% and 40%, respectively. Regarding the multivariable analysis, the UGIH was associated with higher 28-day mortality rates: the adjusted odds ratios were 1.99 (1.02 to 3.88; p = 0.043) and ICU length of stay: the adjusted coefficient was 9.36 (8.03 to 10.70); p < 0.001) (Table 2). Since a completed form was required, only 44 patients were analyzed from the available data. The univariate analysis of risk factors for mortality in UGIH patients showed that

the significant risk factors were coagulopathy (platelet count <50,000 or INR >1.5) (odds ratio, OR, (95% CI): 3.96 (1.07-14.67); p=0.039 and 5.00 (1.04-23.98), p=0.044, respectively), renal failure (OR 6.48, 95% CI 1.37-30.61, p=0.018), APACHE II score (OR 1.11, 95% CI 1.02-1.22, p=0.02) and use vasopressor (OR 5.78 (1.6-37.18), p=0.013) (Table 3). The authors did not perform the multivariable analysis due to the small sample size on the detail case record form of UGIH.

Of the three types of treatment, 34 patients

Table 1. Demographic characteristics of UGIH patients

Variable	Survivors $(n = 33)$	Non-survivors $(n = 22)$	All (n = 55)	<i>p</i> -value
Female (%)	11 (33.33)	10 (45.45)	21 (38.18)	0.365
Average age years, (IQR)	70 (64-76)	73.5 (63-80)	72 (63-78)	0.525
Underlying disease (%)				
Cardiovascular disease	23 (69.70)	9 (40.10)	32 (58.18)	0.034
Respiratory disease	4 (12.12)	7 (31.82)	11 (20.0)	0.074
Previous stroke	5 (15.15)	3 (13.64)	8 (14.55)	0.876
Diabetes	7 (21.21)	6 (27.27)	13 (23.64)	0.604
Chronic renal failure	5 (15.15)	3 (13.64)	8 (14.55)	0.876
Malignancy	3 (9.09)	4 (18.18)	7 (12.73)	0.322
Low immune status	2 (6.06)	2 (9.09)	4 (7.27)	0.672
Previous drug use				
Antiplatelet	10 (30.30)	4 (18.18)	14 (25.45)	0.312
Anticoagulant	2 (6.06)	2 (9.09)	4 (7.27)	0.672
NSAIDs	1 (3.03)	0 (0.00)	1 (1.82)	1.000
Steroid	1 (3.03)	1 (4.55)	2 (3.64)	0.769
Median APACHE II score (IQR)	14.5 (10.5,18)	20.5 (16.5,25)	17 (13-22)	0.007
GI prophylaxis (%)				
No	9 (45.45)	3 (13.64)	12 (21.82)	0.230
Ranitidine	1 (3.03)	0 (0.00)	1 (1.82)	1.000
PPIs	32 (96.97)	22 (100)	54 (98.18)	0.410
Sucralfate	5 (15.15)	6 (27.27)	11 (20.0)	0.271
Other	1 (3.03)	1 (4.55)	2 (3.64)	0.769

Data are presented as n (%) unless otherwise stated.

NSAIDs = Nonsteroidal anti-inflammatory drugs; APACHE II = Acute Physiology and Chronic Health Evaluation II; PPIs = Proton pump inhibitors

Table 2. Mortality rates comparing no UGIH and UGIH patients

Variable	No UGIH (n = 4,597)	UGIH (n = 55)	Adjusted value*	Value (95% CI)	<i>p</i> -value
ICU mortality (%) 28-day mortality (%) ICU length of stay (IQR) Hospital length of stay (IQR)	430 (9.35)	17 (30.91)	Odds ratio	1.88 (0.89 to 3.98)	0.097
	620 (13.49)	22 (40.00)	Odds ratio	1.99 (1.02 to 3.88)	0.043
	2 (1-4)	11 (6-26)	Coefficient	9.36 (8.03 to 10.70)	<0.001
	15 (9-26)	23 (15-34)	Coefficient	6.76 (-0.29 to 13.80)	0.060

^{*} Adjusted by underlying heart disease, underlying lung disease, and APACHE II score

(77.27%) were treated by medication only, unsuccessful of 6 patients (13.64%) had endoscopic intervention and 4 patients (9.09%) underwent surgery for treatment. Of these, the improved outcomes after treatment of medication, endoscopic intervention and surgery accounted for 70.59%, 66.67%, and 75%, respectively (Fig. 2).

Discussion

Gastrointestinal complications frequently occur in patients admitted to the intensive care unit.

Ulceration and bleeding related to stress-related mucosal disease (SRMD) can prolong hospitalization, and increase healthcare costs and are associated with a high mortality rate. The incidences of UGIH from several recent studies demonstrate a large variation due to the different populations, cause of bleeding, management, and treatment. The incidence of UGIH of the present study was similar to a prospective multicenter cohort study by Cook et al⁽⁹⁾ that reported an incidence of clinically significant bleeding of 1.5% in 2,252 critically ill patients. Nowadays, the

Table 3. Risk factors of 28 day mortality in UGIH patients

Risk factors	Survivors (n = 28)	Non-survivors (n = 16)	Odds ratio (95% CI)	<i>p</i> -value
Mechanical ventilation >48 hours (%)	24 (85.71)	14 (87.50)	1.54 (0.26-9.26)	0.638
Coagulopathy (%)	2 (10 =1)	- (0- 0)		0.000
Platelet < 50,000	3 (10.71)	6 (37.50)	3.96 (1.07-14.67)	0.039
INR >1.5	3 (10.71)	6 (37.50)	5.00 (1.04-23.98)	0.044
aPTT >2	3 (10.71)	2 (12.50)	1.19 (0.18-8.00)	0.858
Shock (%)	3 (10.71)	3 (18.75)	1.92 (0.34-10.90)	0.460
Sepsis (%)	7 (25.00)	8 (50.00)	3.00 (0.82-11.02)	0.098
Hepatic failure (%)	2 (7.14)	2 (12.50)	1.86 (0.23-14.64)	0.557
Renal failure (%)	3 (10.71)	7 (43.75)	6.48 (1.37-30.61)	0.018
Glucocorticoid (%)	1 (3.57)	1 (6.25)	1.80 (0.02-146.4)	0.682
APACHE II score (IQR)	14.5 (10.5-18)	20.5 (16.5-25)	1.11 (1.02-1.22)	0.020
Vasopressor use (%)	12 (42.86)	13 (81.25)	5.78 (1.6-37.18)	0.013

Data are presented as n (%) unless otherwise stated.

NSAIDs = Nonsteroidal anti-inflammatory drugs; APACHE II = Acute Physiology and Chronic Health Evaluation II

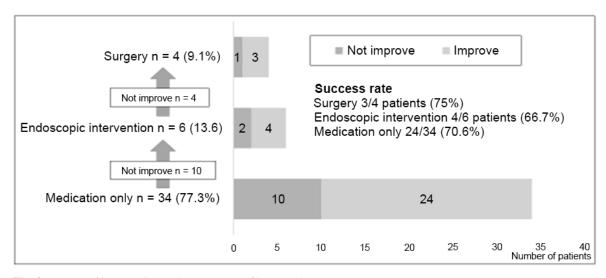


Fig. 2 Type of intervention and success rate of intervention.

incidence of UGIH tends to decrease because of the improvements in ICU management and the widespread use of prophylaxis therapy in high risk patients⁽¹⁰⁾. In a comparison between the UGIH patients who survived and those who died, the average age and APACHE II score were higher in the non-survivors but only the APACHE II score was statistically significant. According to a study by Kaplan RC et al(11), elderly patients had a higher incidence of UGIH because of their comorbidities and the use of antiplatelet or anticoagulant agents. In the APACHE II score, which is one of several ICU scoring systems, higher scores correspond to more severe disease and a higher risk of death. Schein M, Gecelter G(12) studied the prognostic value of APACHE II score in patients who underwent emergency operations for bleeding peptic ulcers and found that the mean APACHE II score in survivors and in patients who died were 10.8 and 17.5, respectively.

In this study, stress ulcer was the major cause of bleeding which was the as same as many recent studies and the other main causes were varices, Mallory-Weiss tear, reflux esophagitis(4,6,13,14). The bleeding site was unknown because EGD was not performed in most patients. Although the advantage of endoscopy is not only the accuracy that defines the cause of bleeding, it also provides prognostic information about the risk of rebleeding and offers therapeutic potential. The role of endoscopic therapy in SRMD may be limited because the lesions are usually diffuse and not amenable to directed therapy(10,15,16). However, endoscopic treatment will be considered if the UGIH is clinically important bleeding defined as overt bleeding with one of the following: 1) a spontaneous decrease of \geq 20 mmHg in the systolic blood pressure; 2) an increased heart rate of \geq 20 beats per minute, or a decreased systolic blood pressure of >10 mmHg measured in the upright position; or 3) a decrease hemoglobin level of ≥ 2 g per deciliter and subsequent transfusion after which the hemoglobin does not increase by a value defined as the number of units transfused minus 2 g per deciliter⁽⁹⁾. Regarding the adjusted model, the 28-day mortality in UGIH were significant higher than no UGIH patients. Lewis JD found the in-hospital mortality rate in critically ill patients with UGIH was 42% (6) and the data of Djibril AM et al showed that the mortality in the ICU was 45% (17). These results was similar to the report of Reintam BA et al⁽³⁾ as well. In addition, we found that UGIH was associated with higher 28-day mortality rates and ICU length of stay. Regarding the previous report, the gastrointestinal bleeding from any cause in the ICU is associated with a fivefold increase in mortality $^{(9,10)}$. The predictors for mortality in UGIH patients were revealed in previous studies. Lanas et al $^{(19)}$ demonstrated that age >65 years, number of comorbidities, history of ulcer bleeding, in-hospital bleeding, and the type of concomitant medication especially ASA were predictors of death. In Thailand, Thanapirom K et al $^{(18)}$ reported that use of vasoactive agent, INR \geq 1.8 and serum creatinine \geq 1.8 were predictors of 30-day mortality which were close to our study.

Laine L, McQuaid KR(21) reported proton pump inhibitors (PPIs) therapy without endoscopic treatment may be sufficient in patients at low risk for rebleeding. Some recent studies (5,10,14,20-22) suggested that administration of PPIs only downstaged the lesion but didn't reduce mortality and no pharmacologic therapy had a significant benefit once hemorrhage begins. Early endoscopic therapy was recommended in most UGIH patients because the results indicated reduced morbidity, rebleeding, and the need for surgery. Surgical treatment carries high morbidity and mortality so it becomes necessary only if non-operative therapy such as medication or endoscopic treatment fails in uncontrolled hemorrhage. In this study, the fewer number of endoscopic interventions probably resulted in missing data.

A limitation of this study was the small proportion of the incidence of UGIH. Therefore, some risk factors, such as mechanical ventilation ≥48 hours, shock, sepsis, hepatic failure, or burn, were not statistically significant, which was the same as in previous studies. In addition, because there were a missing data of some variables which may affect the survival rate such as intraoperative massive bleeding or massive blood transfusion, the author could not use these variables for data analysis.

Conclusion

The incidence of UGIH in the THAI-SICU study was 1.18% and SICU patients with UGIH had higher ICU mortality and 28-day mortality rates than those without UGIH. The risk factors for mortality were coagulopathy (platelet count <50,000 or INR >1.5), renal failure, high APACHE II score and use of vasopressor. Because UGIH is one of the causes of higher mortality in critically ill patients, the strategies should be focused on the prevention of UGIH rather than treatment after the fact. Proper management may minimize complications associated with UGIH and ideally improve outcomes.

What is already known on this topic?

Upper gastrointestinal hemorrhage (UGIH) is a common problem in critically ill patients that can be a life-threatening condition and is also an economic burden. GI hemorrhage is the symptom most significantly associated with a poor outcome or mortality⁽³⁾. Over the past few decades, despite an advance in therapy and a significantly decreased incidence rate of upper GI bleeding, the risk of rebleeding or mortality in these patients has not improved⁽⁴⁾. The mortality rate increases among elderly patients and patients with co-morbidities^(1,2,4,5).

What this study adds?

In Thailand, the data of UGIH in critically ill patients is poorly understood. The present study is a pioneer study to illustrate overall treatment outcomes, incidence of adverse events and factor associated with adverse events in 9 university-based surgical intensive care units (SICUs) in Thailand. Furthermore, the results of this study gave an insight into a healthcare problem and in the future, it can be used to develop the policies, strategies and management of critically ill patients.

This study demonstrated that the incidence of UGIH in the THAI-SICU Study was 1.18%. In multivariable model, UGIH was associated with higher mortality in critically ill patients and ICU length of stay. Univariate analysis showed that the significant risk factors for non-survived UGIH patients were coagulopathy (platelet count <50,000 or INR >1.5), renal failure, high APACHE II score and vasopressor use.

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Potential conflicts of interest

None.

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อุบัติการณ์, ผลการรักษาและปัจจัยเสี่ยงที่ทำให้เกิดการเสียชีวิตของผู้ป่วยที่มีภาวะเลือดออกในระบบทางเดินอาหารสวนบนใน หออภิบาลผู้ป่วยวิกฤตศัลยกรรม

ชณัฐี กิจสิริพันธ, กวีศักดิ์ จิตตวัฒนรัตน, สุนิสา ฉัตรมงคลชาติ, โอสรี อัครบวร, กลุ่มศึกษา THAI-SICU

วัตลุประสงค์: เพื่อรายงานอุบัติการณ์ของภาวะเลือดออกในระบบทางเดินอาหารส่วนบน, ผลการรักษา และปัจจัยเสี่ยงที่ทำให้เกิดการเสียชีวิตที่เกิดขึ้น กับผู้ป่วยวิกฤตสัลยกรรมในโรงพยาบาลมหาวิทยาลัยระดับตติยภูมิของประเทศไทย

วัสดุและวิธีการ: การศึกษานี้เป็นการนำข้อมูลของโครงการวิจัยสหสถาบันเพื่อศึกษาผลลัพธ์และภาวะแทรกซ้อนของผู้ป่วยในหออภิบาลผู้ป่วย วิกฤตศัลยกรรมในโรงพยาบาลมหาวิทยาลัยมาวิเคราะห์เพิ่มเติม ระหวางการเก็บข้อมูลตั้งแต่เดือนเมษายน พ.ศ. 2554 จนถึงเดือนมกราคม พ.ศ. 2556 ผุป่วยที่ไดรับการวินิจฉัยวามีภาวะเลือดออกในระบบทางเดินอาหารส่วนบนจะไดรับการติดตามและลงบันทึกตามแบบฟอร์มยอย

ผลการศึกษา: ผู้ป่ายจำนวน 55 รายจากทั้งหมด 4,652 รายเกิดภาวะเลือดออกในระบบทางเดินอาหารส่วนบน ซึ่งคิดเป็นร้อยละ 1.18 ของผู้ป่าย ที่เข้ารับการรักษาในหออกิบาล อายุมัธยฐานของผู้ป่ายกลุ่มนี้คือ 72 ปี (ค่าพิสัยควอไทส์ 63-78) และค่ามัธยฐานของคะแนน APACHE II คือ 17 (ค่าพิสัยควอไทส์ 13-22) และเมื่อเปรียบเทียบระหว่างผู้ป่ายกาวะเลือดออกในระบบทางเดินอาหารส่วนบนที่เสียชีวิตและรอดชีวิต พบว่ากลุ่มที่เสียชีวิต มีอายุและคะแนน APACHE II ที่สูงกว่าอัตราการเสียชีวิตในหออกิบาลและที่ 28 วัน ร้อยละ 30.91 และ 40 ตามลำดับ จากการวิเคราะห์พหุตัวแปรพบว่า ภาวะเลือดออกในทางเดินอาหารส่วนบนมีความเกี่ยวข้องกับการเสียชีวิตที่ 28 วัน (ค่าความเสี่ยงสัมพัทธ์ 1.99, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.02-3.38, ค่านัยสำคัญทางสถิติ 0.043) และระยะเวลาที่รักษาในหออกิบาล (ค่าความเสี่ยงสัมพัทธ์ 9.36, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 8.03-10.70, มีนัยสำคัญทางสถิติ 0.043) และระยะเวลาที่รักษาในหออกิบาล (ค่าความเสี่ยงสัมพัทธ์ 3.96, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.07-14.67, ค่านัยสำคัญทางสถิติ 0.039) และค่า INR มากกว่า 1.5 (ค่าความเสี่ยงสัมพัทธ์ 5, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.04-23.98, ค่านัยสำคัญทางสถิติ 0.044), ภาวะไดวาย (ค่าความเสี่ยงสัมพัทธ์ 6.48, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.37-30.61, ค่านัยสำคัญทางสถิติ 0.018), มีคะแนน APACHE II (ค่าความเสี่ยงสัมพัทธ์ 1.11, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.02-1.22, ค่านัยสำคัญทางสถิติ 0.020) และการใช้ยาหดหลอดเลือด เพื่อเพิ่มความดันโลทิต (ค่าความเสี่ยงสัมพัทธ์ 5.78, ความเชื่อมั่นที่ร้อยละ 95 ระหว่าง 1.6-37.18, ค่านัยสำคัญทางสถิติ 0.013)

สรุป: อุบัติการณ์การเกิดภาวะเลือดออกในระบบทางเดินอาหารส่วนบนในหออภิบาลผู้ป่วยวิกฤตศัลยกรรมในโรงพยาบาลมหาวิทยาลัยคิดเป็นร้อยละ 1.18 ซึ่งมีความสัมพันธ์กับการเพิ่มขึ้นของอัตราการเสียชีวิตที่ 28 วันและระยะเวลาการรักษาตัวในหออภิบาล ปัจจัยเสี่ยงของการเสียชีวิตจากภาวะเลือดออก ในระบบทางเดินอาหารส่วนบน ได้แก่ ผู้ป่วยที่มีภาวะแข็งตัวของเลือดผิดปกติ (โดยเฉพาะเกร็ดเลือดต่ำกว่า 50,000 หรือ ค่า INR มากกว่า 1.5), ภาวะไตวาย, คะแนน APACHE II และการใช้ยาหดหลอดเลือดเพื่อเพิ่มความดันโลทิต