UPPER GASTROINTESTINAL NON-VARICEAL BLEEDING: VALIDATION OF GLASGOW BLATCHFORD SCORE AND ITS ASSOCIATION WITH FORREST CLASSIFICATION IN HOSPITAL UNIVERSITI SAINS MALAYSIA

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ABSTRAK

Pengenalan

Pendarahan Gastro Usus Atas yang memerlukan endoskopi adalah senario yang selalu berlaku di hospital. Namun, bukan semua pesakit memerlukan endoskopi kecemasan atau segera. Kajian ini akan mengesahkan dan mengaitkan antara sistem skor Glasgow Blatchford dan klasifikasi Forrest. Ia adalah untuk meramalkan tahap Pendarahan Gastro Usus Atas Bukan Variceal berdasarkan Skor Glasgow Blatchford dan mengesahkan sistem skor ini di Hospital Universiti Sains Malaysia. Kajian ini akan meramalkan kaitan antara dua skor iaitu sistem Glasgow Blatchford dan klasifikasi Forrest. Perkaitan antara pendarahan bukan variceal risiko tinggi dengan pendarahan major serta bukan pendarahan variceal risiko rendah dengan pendarahan minor akan dikaji.

Metodologi

Data dikumpulkan dari Jun 2016 hingga Februari 2017, seramai 113 pesakit dengan pendarahan bukan variceal di mana endoskopi kecemasan OGDS telah dikaji secara retrospektif dan berstrata berdasarkan skor Glasgow Blatchford kepada risiko tinggi dan risiko rendah. Pembahagian kepada risiko telah dikaji dan kaitan bersama klasifikasi Forrest untuk menentukan penemuan endoskopi.

Keputusan

Jumlah majoriti adalah dalam kumpulan berisiko tinggi seramai 107 (94.7%) pesakit dan seramai 6 (5.3%) pesakit adalah kumpulan berisiko rendah. Pesakit yang berada dalam kumpulan berisiko rendah telah menunjukkan tiada komplikasi atau kematian selepas 30 hari rawatan susulan. Secara kesuluruhannya skor median berdasarkan kajian ini adalah 10.27±3.54. Berdasarkan data yang dikumpul, skor ini menunjukkan 95.45% sensitiviti dan spesifisiti sebanyak 5.49%. Penemuan endoskopi menunjukkan jumlah seramai 22 (19.5%) pesakit adalah pendarahan major dan 91 (80.5%) pesakit adalah pendarahan minor.

Berdasarkan kajian ini menggunakan Ujian Fisher Exact, tiada kaitan di antara skor Glasgow Blatchford dan klasifikasi Forrest (p-value > 0.950).

Kesimpulan

Berdasarkan kajian ini, penggunaan Skor Glasgow Blatchford tidak boleh dicadangkan untuk digunakan sebagai peramal untuk keterukan dalam Pendarahan Gastro Usus Atas. Ini telah dibuktikan dalam keputusan, tiada kaitan di antara Skor Glasgow Blatchford dan Klasifikasi Forrest. Namun, keputusan tidak ketara ini disebabkan oleh beberapa factor seperti yang telah dibincangkan. Faktor yang berkaitan adalah pesakit menghidapi Penyakit Buah Pinggang Kronik dan anemia, waktu endoskopi dilakukan dan perberian ubat. Dengan adanya faktor yang telah disahkan, ini boleh dijadikan sebagai bimbingan untuk merangka dan menjalankan kajian yang lebih baik pada masa hadapan untuk mendapatkan kesimpulan yang lebih elok berkenaan Skor Glasgow Blatchford untuk populasi ini.

ABSTRACT

Introduction

Upper Gastrointestinal Bleeding (UGIB) requiring endoscopic intervention is a common scenario in hospitals. However, not all patients require emergency or urgent endoscopy to be done. This study will validate and associate Glasgow-Blatchford Score (GBS) with Forrest classification. This is to predict the severity of Non-Variceal Upper Gastro Intestinal Bleed according to Glasgow Blatchford Score and validate this scoring system in Hospital Universiti Sains Malaysia. This study will also associate between two scoring system of Glasgow Blatchford Score and Forrest Classification between Non-variceal high risk bleeding with major bleed and non-variceal low risk bleeding with minor bleed.

Methodology

Data collected from June 2016 till February 2017, 113 patients with Non-variceal bleed underwent emergency OGDS were retrospectively reviewed and were stratified according to Glasgow Blatchford Score to high and low risk. This stratified risk is associated with Forrest classification to determine its endoscopic findings.

Results

Majority are in the high risk group 107 (94.7%) patients and low risk group 6 (5.3%) patients. Patients in the low risk group was followed up for 30 days and showed no complications or mortality. This study showed patients has a median score of 10.27 ± 3.54 . From the data analysis of Glasgow Blatchford Score showed 95.45% sensitivity and 5.49% specificity. Endoscopic findings showed 22 (19.5%) patients had major bleed and 91 (80.5%) patients had minor bleed. Using Fischer Exact Test, there is no significant association between risk and outcome (p-value > 0.950).

Conclusion

Based on this study alone, we cannot suggest Glasgow Blatchford Score as a predictor for severity of Upper Gastrointestinal Bleeding. This is because as shown in the results, there were no significant association between GBS and Forrest classification. However, this nonsignificant result maybe compounded by several factors as discussed, namely due to underlying Chronic Kidney Disease with anemia, the timing of endoscopy and initiation of medication. With this biases identified, it can be used as a guide in designing and conducting a better study in the future in order to come to a better conclusion about GBS in our population.

A. Study Protocol

a. Document submitted for ethical approval

Introduction and Literature Review

Upper Gastro-Intestinal Bleed (UGIB) remains a common reason for admission to hospitals all over the world (Rockall *et al.*, 1995). The incidence has been reported to range from 50 to 150 per 100,000 adults per year. It has mortality rates ranging between 8% and 14% in the UK (Forrest *et al.*, 1974; Blatchford *et al.*, 2000). Our local Malaysian data shows approximately 72 per 100,000 had mortality due to UGIB (Malaysia, 2003). However, in this past 50 years, hospital mortality due to UGIB has not improved and remains at 10% (Gralnek *et al.*, 2015).

Most patients with UGIB may require OGDS. However, not all patients require emergency or urgent endoscopy to be done. There are many scoring systems that have been created to aid clinicians in making decisions. In order to standardize and improve care, various scoring systems have been developed to identify individuals at high risk of requiring treatment (Atkinson and Hurlstone, 2008). Such scoring system used are Rockall Score (RS), Glasgow-Blatchford Score (GBS), Forrest Classification, Cedars-Sinai Medical Centre Predict Index, Baylor College Scoring System to name a few. Nowadays, the more widely used pre-endoscopic scoring is the RS and GBS. The most common post-endoscopic findings used is the Forrest classification.

Many have compared between these two scoring systems to predict outcomes for better patient care. Both of these scores have been widely validated worldwide. For this study, GBS was chosen because of many factors. GBS stratifies high risk and low risk patients. Hence, assisting clinicians deciding the role of endoscopy as inpatient or outpatient. This scoring system scores patient from 0 to 23. Its criteria consist of urea, hemoglobin level, systolic blood pressure and other parameters such as pulse rate, melena at presentation, syncope and history of liver or cardiac disease (Table 1). If none of the criteria is met it is considered as score of 0 (Table 2). It uses a cut-off point of \geq 1 as high risk and =0 as low risk. It has shown to have identified 99% sensitivity with 32% specificity (Blatchford *et al.*, 2000).

Many studies have been done to compare between RS and GBS in predicting patient outcome. Stanley *et al.*, 2011 studied about risk scoring systems available. The study was done for prediction of clinical end point. It concluded, GBS of zero has been reported to have > 99% sensitivity in identification of those who do not require intervention, re-bleed or die in studies from Hong Kong, United States, Japan, Taiwan and United Kingdom (Stanley *et al.*, 2011). Schiefer *et al.*, 2012 published a paper about predictive validity in GBS in Netherlands. It compared the RS, Haemoglobin–Urea–Pulse–Systolic blood pressure (HUPS) with GBS. In conclusion, GBS showed to be more superior as compared to the other two scoring system. This shows GBS is more accurate than the admission RS for early (pre-endoscopic) prediction of clinically relevant outcomes and is highly sensitive in identifying low risk patients suitable for out-patient management (Laursen *et al.*, 2012; Schiefer *et al.*, 2012; Bryant *et al.*, 2013; Gralnek *et al.*, 2015).

Admission parameter	Score value
Urea (mg/dL)	
<u>></u> 6.5 to ≺8.0	2
<u>≻</u> 8 to ≺10.0	3
<u>≻</u> 10.0 to ≺25.0	4
<u>≥</u> 25.0	6
Haemoglobin (g/dL)	
Men	
<u>≻</u> 12.0 to ≺13	1
<u>≻</u> 10.0 to ≺12.0	3
<10.0	6
Women	
<u>≻</u> 10.0 to ≺12.0	1
<10.0	6
Systolic BP (mmHg)	
100 to 109	1
90 to 99	2
<90	3
Other parameters	
Pulse ≻100 bpm	1
Melena at presentation	1
Syncope	2
Hepatic disease	2
Cardiac failure	2

Table 1 – Glasgow-Blatchford Score Criteria

Table 2 – Glasgow-Blatchford Score of 0

- Hemoglobin level >12.9 g/dL (men) or >11.9 g/dL (women)
- Systolic blood pressure >109 mm Hg
- Pulse <100/minute
- Blood urea nitrogen level <6.5 mg/dL
- No melena or syncope
- No past or present liver disease or heart failure

There has been no validation for GBS in Malaysia and our local hospital population. From previous to recent journals, GBS and RS has been widely validated and many studies shows that GBS is more superior than RS. Hence, the suggestion to validate GBS in our local hospital. In regards, if validation proves to be valid, it can be adapted to our local hospital in the future. This will able to predict the need for intervention and hence reduce mortality or morbidity in UGIB patients.

By having this scoring system, low risk patients can be safely treated as outpatients. Thus, to further improve the possibilities of treating low risk patients, Masaoka *et al.*, 2007 used GBS as a guideline but uses a cut-off value of ≥ 2 as high risk and ≤ 2 as low risk. Furthermore, increased the number of patient being able to be treated as outpatient with a 100% sensitivity and 13% specificity (Masaoka *et al.*, 2007). Srirajakanthan *et al.*, 2010 used a higher cut-off value GBS ≥ 3 to even include more patients being able to be treated as outpatients. This study had a 100% sensitivity and 68% specificity (Srirajaskanthan *et al.*, 2010). Another study by Koksal *et al.*, 2012 also used a higher cut-off value to calculate the sensitivity and specificity to assess the reliability of this score to be used (Koksal *et al.*, 2012).

Adapting this scoring system, Stephens *et al.*, 2009 and McLaughlin *et al.*, 2012 studied regarding low risk patient being able to be treated as outpatient are safe. This study was done to further evaluate the safety of managing low risk patients as outpatient. Both studies concluded that it is safe to treat low risk patients as outpatient (Stephens *et al.*, 2009; McLaughlin *et al.*, 2012). This is being used as a guideline by the European Society Gastroenterology Endoscopy (ESGE) in 2015.

Other than pre-endoscopic scoring system, endoscopic findings have been studied and classified. Forrest classification uses endoscopic findings to predict risk of re bleeding and mortality. Forrest *et al.*, 1974 created a score based on endoscopic findings to stratify risk of re-bleeding. Lesions were classified as acutely bleeding, showing evidence of recent bleeding or criteria of recent bleeding, showing black base, adherent clot, or a protruding artery or no evidence of bleeding (Forrest *et al.*, 1974). High risk lesions include those characterized by spurting haemorrhages (Forrest Ia), oozing haemorrhages (ForrestIb), nonbleeding visible vessels (Forrest IIa), adherent clots (Forrest IIb). Low risk lesions include haematin on the ulcer base (Forrest IIc), and clean ulcer base (Forrest III). Kim *et al.*, 2009 compared between GBS, RS, Cedars-Sinai, American Baylor college, Forrest classification and showed Forrest classification was the most useful scoring system for the prediction of re-bleeding and death in patients with nonvariceal UGIB. Currently, the Forrest classification is being use as the gold standard for post endoscopic findings for risk of re-bleeding (Kim *et al.*, 2009).

It has been proven that high risk patients would require intervention whereas low risk patients are able to be treated as outpatient. However, association between pre-endoscopic and postendoscopic has never been compared. Hence, the importance of this study to further prove safety of patients with high risk would have major bleeding and low risk having minor bleeding.

1.2 Rationale of study

Risk stratification scoring has been used to help and guide clinicians deciding for treatment. Many scoring systems has been developed over the years but only a few are being used widely. This study will focus on non-variceal upper gastrointestinal bleeding and validate GBS in local population and hospital. It will stratify between high risk (>3) and low risk (\leq 2) patients using GBS and associate with endoscopic findings using Forrest Classification. In order to be able to treat low risk score patients as outpatient, we need to ascertain that it is a minor bleed. Likewise for the high risk score patients, we need to ascertain that it is a major bleed. Low risk patients will be able to get an OGDS appointment as outpatient and for high risk patient they would require admission with an urgent or early OGDS. Thus, reduce unnecessary admission and reduce financial burden of the hospital.

General Objective

The objective of this study is to stratify Non-Variceal UGIB patients to high and low risk using pre-endoscopic parameters and its association with severity of bleeding

Specific objectives:

I) Primary objective:

- To validate Glasgow Blatchford Score for non-variceal bleeding for local population in Hospital Universiti Sains Malaysia (HUSM)
- To determine association between non-variceal high risk with major hemorrhage (Ia,Ib,IIa or IIb) and low risk with minor hemorrhage (IIc or III) according to GBS and Forrest Classification

II) Secondary objectives

1. To review demographics of non-variceal UGIB in HUSM, Kubang Kerian

Design

Retrospective study of patients with Non-Variceal Upper Gastro Intestinal Bleeding

Setting

Hospital Universiti Sains Malaysia

Study Population

 All patients presented with UGIB requiring OGDS by General Surgery or Gastroenterology in HUSM, Kubang Kerian

Source population

 All patients from Emergency Department and wards presented with UGIB underwent OGDS within the same admission by General Surgery Department and Gastroenterology in HUSM, Kubang Kerian

Inclusion criteria:

- I. Patients with presentation of UGIB who underwent OGDS in HUSM within the same admission from 1st June 2016 till 28th February 2017
- II. OGDS findings of Non-variceal UGIB
- III. UGIB patients that has complete data for GBS (Follow up for 30 days for low risk patients)

Exclusion criteria:

- I. OGDS findings of Variceal UGIB
- II. Patients presented with UGIB but did not undergo OGDS
- III. Patients with incomplete data from records for GBS
- IV. Anemia for investigations without symptoms of UGIB
- V. Patients age below 18 years old

Sampling size

Two proportions formula is used to obtain the appropriate sample size. The calculation of sample size is done by using Power and Sample Size Calculation (PS) Software. The parameters used are:

```
\alpha = 0.05

Power = 80%

P_0= proportion of high risk group reported in previous study : 40%

P_1= proportion of high risk group based on expert opinion : 55%

Ratio 1:5

Total sample size = 103

Total sample size including 10% dropout = 113
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Data collection

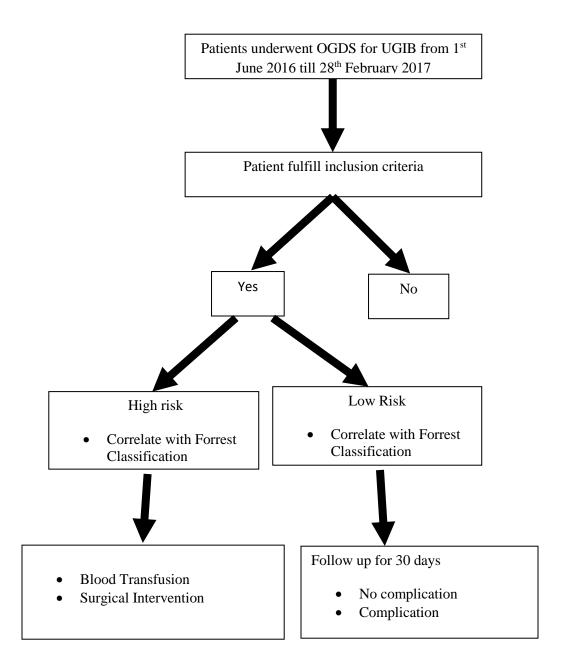
Record of all patients who underwent OGDS for UGIB in HUSM, Kubang Kerian from 1st June 2016 till 28th February 2017 will be reviewed. This will further follow by ensuring patients used for this study will comply to the inclusion and exclusion criteria by reviewing the medical records. The study will focus only on non-variceal bleeding. In the process of validation, it will score patient and subdivide to high risk and low risk. High risk will further be identified if patient requires blood transfusion or surgical intervention. Whereas, the low risk patients will be reviewed up till 30 days whether any signs of re-bleeding for which occurred during the same admission or patient was readmitted, or mortality related to acute UGIB will be recorded. The 30 days is taken from the date of OGDS was done. This will be done by reviewing patient medical records and if required to contact by phone if no documentation is present.

To associate between the GBS and Forrest classification, endoscopic findings of major and minor hemorrhage with high risk and low risk will be documented. Data retrieved will be entered in the data collection form. Subsequently, statistical analysis and report preparation will be done. Research correction and admission of final research will be reviewed.

Data analysis

• SPSS Statistical software, version 22 will be used for data analysis. 1st and 2nd specific objective using univariate analysis Chi-squared test and Fischer Exact Test

Flow Chart



Gantt chart

YEAR		2016						2017			-					
MONTH	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ост	NOV	DEC
PROPOSAL PRESENTATION																
ETHICS APPROVAL																
DISCUSSION WITH SUPERVISOR																
DATA COLLECTION																
DATA ANALYSIS AND REPORT PRESENTATION																
SUBMISSION OF DRAFT AND REVISION																
SUBMISSION OF FINAL RESEARCH																

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Zhong, M., Chen, W. J., Lu, X. Y., Qian, J. & Zhu, C. Q. (2016). Comparison of three scoring systems in predicting clinical outcomes in patients with acute upper gastrointestinal bleeding: a prospective observational study. *Journal of Digestive Diseases*, **17(12)**, 820-828.

II. Ethical approval letter



13th July 2017

Dr. Mohd Razaleigh Yusof Department of Surgery School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan. Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia T: (6)09-767 3000/2354/2362 F: (6)09-767 2351 E: jepem@usm.my L: www.jepem.kk.usm.my www.usm.my

JEPeM Code : USM/JEPeM/17010007 Protocol Title : Upper Gastrointestinal Non-Variceal Bleed: Validation and Correlation Glasgow-Blatchford Score with Forrest Classification.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/17010007**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **13**th **July 2017** until **12**th **July 2018**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

- 1. Dr. Mohd Nizam Md Hashim
- 2. Assoc. Prof. Dr. Andee Dzulkarnaen Zakaria

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Data Collection Sheet

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

- Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of JEPeM-USM FORM 3(B) 2017: Continuing Review Application Form. Subsequently this need to be done yearly as long as the research goes on.
- 2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.





- 3. Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.
- 4. Reports of adverse events including from other study sites (national, international) using the JEPeM-USM FORM 3(G) 2017: Adverse Events Report.
- 5. Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(E) 2017.
- 6. Any event which may have ethical significance.
- 7. Any information which is needed by the JEPeM-USM to do ongoing review.
- 8. Notice of time of completion of the study using JEPeM-USM FORM 3(C) 2017: Final Report Form.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

M

PROF. DR. HANS AMIN VAN ROSTENBERGHE Chairperson Jawatankuasa Etika Penyelidikan (Manusia) JEPeM Universiti Sains Malaysia



: 27th April 2017

: 359

USM Kampus Kesihatan.

: 9.00 a.m - 3.00 p.m

Date of meeting

Venue

Time Meeting No Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia

- Kampus Kesihatan,
- 16150 Kubang Kerian, Kelantan, Malaysia T : (6)09-767 3000/2354/2362 F : (6)09-767 2351
- jepem@usm.my E
- www.jepem.kk.usm.my
- www.usm.my

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

: Meeting Room, Division of Research & Innovation,

	Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were		
Chairr	person:			reviewed (Chairperson)		
Profes		Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	М			
Secretary: Mr. Mohd Bazlan Hafidz Mukrim		Science Officer	Μ	1		
Memb	pers :	I I I I I I I I I I I I I I I I I I I				
1.	Associate Professor Dr. Azlan Husin	М	1			
2.	Professor Dr. Narazah Mohd Yusoff	Deputy Director, Advanced Medical and Dental Institute (AMDI)	F	1		
3.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	М	1		
4.	Mr. Sadasivam Ramiah	Community Representative	М	1		
5.	Associate Professor Siti Hawa Ali	Lecturer, School of Health Sciences	F	~		
6.	Dr. Soon Lean Keng	Lecturer, School of Health Sciences	F	1		
7.	Dr. Surini Yusoff	Lecturer, School of Medical Sciences	F	1		
8.	Mrs. Zawiah Abu Bakar	Community Representative	F	1		

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

PROFESSOR DR. HANS AMIN VAN ROSTENBERGHE Chairperson Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia

MALAYSIA

B. BODY CONTENT

a. Introduction

Upper gastrointestinal bleeding (UGIB) is gastrointestinal bleeding in the upper gastrointestinal tract, commonly defined as bleeding arising from the oesophagus, stomach, or duodenum. Causes of non-variceal UGIB are due to peptic ulcer, Mallory-Weiss tear, erosive gastritis or duodenitis, malignancy, angiodysplasia or vascular malformation. It is known that UGIB remains a common reason for admission to hospitals all over the world (Rockall *et al.*, 1995). The incidence has been reported to range from 50 to 150 per 100,000 adults per year. It has a mortality rates ranging between 8% and 14% in the UK. Our local data shows approximately 72 per 100,000 in Malaysia (Forrest *et al.*, 1974; Blatchford *et al.*, 2000; Malaysia, 2003). However, in this past 50 years, hospital mortality due to UGIB has not improved and remains at 10% (Gralnek *et al.*, 2015).

In order to standardize and improve care, various scoring systems have been developed to identify individuals at high risk of requiring treatment (Atkinson and Hurlstone, 2008). Such scoring system used are RS, GBS, Forrest Classification, Cedars-Sinai Medical Centre Predict Index, Baylor College Scoring System to name a few (Malaysia, 2003). The use of risk scoring systems in early assessment of patients suffering from UGIB may be useful to distinguish high-risks patients, who may need clinical intervention and hospitalization, from low risk patients with a lower chance of developing complications, in which management as outpatients can be considered (Imperiale *et al.*, 2007).

GBS has been shown to identify patients with suspected UGIB and can be used to predict the need for treatment such as blood transfusion, endoscopic therapy or surgical intervention. The

greatest feature of the GBS is its ability to identify low-risk patients who do not need to be admitted into a hospital (Min *et al.*, 2016). By this, reduces duration of hospital stay and admission cost (Girardin *et al.*, 2014; Chatten *et al.*, 2018). Hence, gives a good economical outcome for hospital expenses.

Study Objective

General Objective

The objective of this study was to predict severity of Non-Variceal UGIB to high risk and low risk using pre-endoscopic parameters

Specific objectives:

I) Primary objective:

- 1. To validate GBS for non-variceal bleeding for local population in HUSM
- 2. To associate non-variceal high risk with major hemorrhage (Ia,Ib,IIa or IIb) and low risk with minor hemorrhage (IIc or III) according to GBS and Forrest Classification

II) Secondary objectives

1. To review demographics of non-variceal UGIB in HUSM, Kubang Kerian

b. Rationale for Study

Risk stratification scoring has been used to help and guide clinicians deciding for treatment. Many scoring system has been developed over the years but only a few are being used widely(Monteiro *et al.*, 2016). This study will focus on non-variceal upper gastrointestinal bleeding and validate GBS in local population and hospital. It will stratify and correlate between high risk (>3) and low risk (\leq 2) patients using Glasgow-Blatchford Score with post endoscopic findings using Forrest Classification. High risk represents major hemorrhage (Forrest Ia, Ib, IIa, IIb) and low risk represents minor hemorrhage (Forrest IIc, III). By stratifying the risk, we are able to determine low risk patient and high risk patients. Low risk patients do not need urgent OGDS, therefore don't need admission. Outpatient OGDS appointment may be given, thus, reduce unnecessary admission and reduce financial burden and reduce workload of the hospital.

c. Methodology

Design

Retrospective study of patients with Non-Variceal UGIB

Study Population

 All patients presented with UGIB requiring OGDS by General Surgery or Gastroenterology in Hospital Universiti Sains Malaysia, Kubang Kerian

Source population

 All patients from Emergency department and wards presented with UGIB underwent OGDS within the same admission by General Surgery Department and Gastroenterology in HUSM, Kubang Kerian

Inclusion criteria:

- Patients with presentation of UGIB who underwent OGDS in HUSM within the same admission from 1st June 2016 till 28th February 2017
- 2. OGDS findings of Non-Variceal UGIB
- 3. UGIB patients that has complete data for GBS (Follow up for 30 days for low risk patients)

Exclusion criteria:

- 1 OGDS findings of Variceal UGIB
- 2 Patients presented with UGIB did not underwent OGDS
- 3 Patients with incomplete data from records for GBS
- 4 Anemia for investigations without symptoms of UGIB
- 5 Patients age below 18 years old

Study Design and Data Collection

This study is a retrospective study for all patients which underwent OGDS for UGIB in HUSM, Kubang Kerian from 1st June 2016 till 28th February 2017. Patients will comply to the inclusion and exclusion criteria by reviewing the medical records. The study will focus only on non-variceal bleeding. In the process of validation, it will score patient and subdivide to high risk and low risk. High risk will further be identified if patient requires blood transfusion or surgical intervention. Whereas, the low risk patients will be reviewed up till 30 days whether any signs of re-bleeding for which the patient was readmitted, or mortality related to acute UGIB will be recorded. The 30 days is taken from the date of OGDS was done. This will be done by reviewing patient medical records and if required to contact by phone if no documentation is present. To determine the association between GBS and Forrest classification, endoscopic findings of major and minor hemorrhage with high risk and low risk will be documented. Data retrieved will be entered in the data collection form. Subsequently, statistical analysis and report preparation was done.

d. Results

From June 2016 to February 2017, 132 patients underwent emergency OGDS in Hospital Universiti Sains Malaysia. 113 patients had non-variceal bleeding and fulfilled the inclusion and exclusion criteria. The number of subject that involved in this study fulfilled the calculated sample size requirement.

Demography

The mean age from our study was 61.75 ± 14.95 (Figure 1). From the total data collected, 81 (71.7%) patients were male and 32(28.3%) patients were female (Figure 2). Majority of the patient were from Malay ethnicity with 109 (96.5%) patients with 3 (2.65%) patients were Chinese and 1(0.85%) patients was a foreigner from Indonesia (Figure 3).

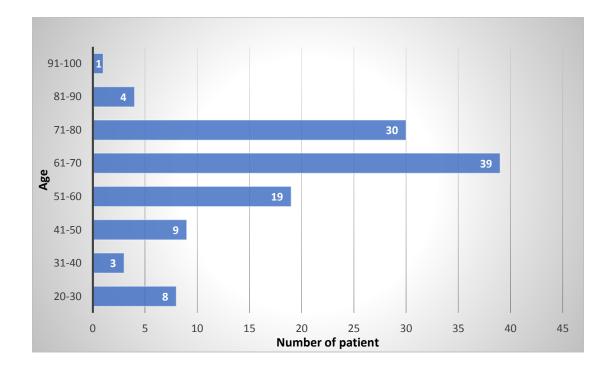


Figure 1: Age Demography in UGIB in HUSM Population