

**COMPARISON OF PREHOSPITAL INDEX WITH MGAP
SCORE TO DETERMINE OUTCOME IN TRAUMA
PATIENTS PRESENTED TO EMERGENCY DEPARTMENT
HOSPITAL TENGKU AMPUAN RAHIMAH KLANG,
SELANGOR**

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LIST OF SYMBOLS, ABBREVIATIONS OR NONMENCLATURE

ED – Emergency Department

PHI – Prehospital Index

MGAP – Mechanism, Glasgow coma scale, Age, Pressure

MTC – Malaysian Triage Criteria

ADL – Activities of Daily Living

HTAR – Hospital Tengku Ampuan Rahimah

ISS – Injury Severity Score

GAP – Glasgow coma scale, Age, Pressure

RTS - Revised Trauma Score

T-RTS - Triage Revised Trauma Score

TRISS - Trauma Injury Severity Score

BHT – Bed Head Ticket

AIS - Abbreviated Injury Score

GCS – Glasgow Coma Scale

BP – Blood pressure

ABSTRAK

Pengenalan

Trauma adalah salah satu penyebab utama kematian di seluruh dunia termasuk di Malaysia. Kematian akibat trauma boleh dijelaskan oleh Model Kematian Trimodal, kematian berlaku seurus selepas trauma, kematian pertengahan iaitu beberapa jam setelah trauma dan kematian yang tertunda beberapa minggu setelah trauma. Kepentingan sistem skor pra-hospital adalah untuk mengurangkan kematian dalam kumpulan pertengahan yang mana kematian dapat dicegah jika diberi rawatan tepat pada waktu yang tepat.

Kaedah Kajian

Ini adalah kajian pemerhatian keratan rentas, menggunakan data retrospektif dari Mei 2019 hingga April 2020. Sebanyak 502 pesakit direkrut, skor PHI dan MGAP dikira berdasarkan dokumentasi pra hospital yang dilakukan oleh responden di tempat kejadian atau dalam perjalanan ke hospital. Persampelan yang mudah digunakan dengan penyelidik merekrut pesakit semasa pesakit tiba di ED dan menindaklanjuti pesakit sehingga mereka keluar atau sehingga maksimum 30 hari selepas trauma untuk kes-kes hospital yang berpanjangan.

Keputusan

Semua 502 data pesakit dianalisis. Pearson chi square digunakan untuk mengukur penemuan kedua-dua skor. Kedua-dua skor PHI dan MGAP adalah signifikan dengan nilai $p < 0.01$ dalam menentukan hasil umum pesakit (kematian, morbiditi, tinggal di hospital yang berpanjangan, ramalan pembedahan major). Walau bagaimanapun, PHI mempunyai kepekaan dan kekhususan yang lebih tinggi 72.97% dan 95.91%, sementara skor MGAP adalah 24.32% dan 2.64%. Kappa

digunakan untuk membandingkan hubungan antara skor dengan skor standard untuk meramalkan hasil kematian, morbiditi, tinggal di hospital yang berpanjangan dan ramalan pembedahan major. Kedua-dua skor gagal meramalkan kemasukan ke hospital yang berpanjangan. Untuk ramalan pembedahan major juga kedua skor gagal menunjukkan hasil yang signifikan dan skor Kappa kurang dari 0, MGAP (-0.012) dan PHI (0.060). Dalam ramalan morbiditi dan kematian skor PHI menunjukkan sedikit persetujuan dengan skor ISS, morbiditi (0,299) dan kematian (0,431), sementara MGAP tidak menunjukkan kesepakatan morbiditas (-0,051) dan kematian (-0,060).

Kesimpulan

Kami menyimpulkan bahawa, di antara kedua sistem pemarkahan, PHI mempunyai kekhususan dan kepekaan yang lebih baik antara kedua-dua sistem pemarkahan dalam menentukan hasil pesakit trauma. Walau bagaimanapun, kedua-dua skor rendah atau tidak ada kesepakatan dengan skor ISS dalam meramalkan kemasukan ke hospital, ramalan pembedahan major, morbiditi, dan kematian. PHI dapat digunakan sebagai alat pemeriksaan untuk mempermudah dan melancarkan pengurusan pesakit trauma dari tempat kejadian hingga tiba di hospital.

Kata Kunci

Skor pra-hospital; Skor PHI; Skor MGAP; Trauma; Hasil; kematian; morbiditi; tinggal di hospital yang berpanjangan; ramalan pembedahan major

ABSTRACT

Background

Trauma is one of the leading causes of death worldwide including Malaysia. Death due to trauma is best explained by the Trimodal Death Model, death occurring immediately after trauma, intermediate death several hours after trauma and delayed death. The importance and significance of prehospital score system is to reduce the death rate in the intermediate group which can be prevented if given treatment in a timely manner.

Methods

This was a cross sectional observational study, using retrospective data from May 2019 till April 2020. A total of 502 patients were recruited, PHI and MGAP scores were calculated based on prehospital clerking done by responder at the scene or en route to the hospital. Convenient sampling was used with the researcher recruiting upon patient arrival in ED and follow up patient until they are discharged or until maximum 30 days post trauma for prolonged hospitalization cases.

Results

All 502 patient's data were analysed. Pearson chi square was used to measure the finding of both scores. Both PHI and MGAP score were significant with a p value of <0.01 in determining patient's general outcome (mortality, morbidity, prolonged hospital stay, major surgery prediction). However, PHI has higher sensitivity and specificity 72.97% and 95.91%, whilst MGAP score is 24.32% and 2.64%. Kappa was used to compare the association between the scores with the standard score to predict individual outcome of mortality, morbidity, prolonged hospital stay and prediction of major surgery. Both scores failed to predict prolonged hospitalization. For major

surgery prediction also both scores failed to show significant result and Kappa score was less than 0, MGAP (-0.012) and PHI (0.060). In the prediction of morbidity and mortality PHI score showed slight agreement with ISS score, morbidity (0.299) and mortality (0.431), whilst MGAP showed no agreement for morbidity (-0.051) and mortality (-0.060).

Conclusion

We conclude that, between both scoring system, PHI has a better specificity and sensitivity in determining the outcome of trauma patients. However, both scores have low to no agreement with ISS score in predicting prolonged hospitalization, major surgery prediction, morbidity, and mortality. PHI can be used as screening tool to facilitate and tighten the management of trauma patients from the scene till arrival of patient to the hospital.

Keywords; Prehospital score; PHI score; MGAP score; Trauma; Outcome; mortality; morbidity; prolonged hospital stay; major surgery prediction

CHAPTER 1.0 INTRODUCTION

1.1 OVERVIEW OF TRAUMA AND PREHOSPITAL CARE

Trauma is one of the leading cause of deaths worldwide. According to World Health Organization statistics, over 5 million people die from trauma worldwide each year⁶. It is an ever-increasing problem and it is the leading cause of morbidity and mortality in the under 40 years old of age in most developed country including Malaysia.⁷

Prehospital care services have been the backbone in transporting patients from the scene to the hospital. In prehospital care setting, providers should be able to identify life threatening injuries sustained and subsequently give the first aid treatment to the patient at the scene or en route to the hospital. Another important step is to identify the severity of injury and in developed countries they will be sent to trauma centres directly from the scene. This is to ensure fast treatment is given to the patient to improve the outcome of patients. As for in Malaysia, we do not have that kind of system implemented yet. Patients will be assessed and taken to the nearest hospital for further management.

The knowledge, skills and decision making by the paramedics are very important in prehospital services. Appropriate initial management and triaging of patients is crucial for the appropriate continuation of treatment in a timely manner at the hospital. Adequate triage of severe trauma patients is one of the key issues for trauma care.⁸ Appropriate triage aims at directing the most severe patients to level-1 trauma center with high level technical facilities and expertise to decrease intra-hospital mortality.⁸ Apart from specific algorithms, prehospital trauma scores have been implemented to predict intra-hospital mortality and can therefore be used as a prehospital triage.

CHAPTER 2.0 STUDY PROTOCOL

2.1 INTRODUCTION

Trauma is an ever-increasing problem occurring worldwide, including in Malaysia. The increase usage of transport by the increasing average age increases the possibility of trauma to occur. The first Malaysian National Trauma Database was launched in May 2006, with five tertiary referral centres to determine the fundamental data on major trauma, subsequently to evaluate the major trauma management and to come up with guidelines for improved trauma care.⁷ A prospective study, using standardized and validated questionnaires, was carried out from May 2006 till April 2007 for all cases admitted and referred to the participating hospitals.⁷ From this study, it was successfully demonstrated its significance in giving essential data on major trauma in Malaysia.

Adequate triage of severe trauma patients is one of the key issues for trauma care.⁸ Appropriate triage aims at directing the most severe patients in level-1 trauma centre with high level technical facilities and expertise to decrease intra-hospital mortality.⁸ For this purpose, prehospital organization including decision scheme for triage has been developed in many countries.⁸ In many developed countries, prehospital scoring system is one of the tools used to determine the severity of the trauma patients. It is crucial to determine the severity for appropriate routing of patients to the appropriate trauma centre or hospital for a better definitive care.

Patients arriving via prehospital team have advantage compared to other modes of transportation as treatment will always start at the scene, as simple as starting IV fluids for hypotensive patients will reflect the outcome of the patient. Prehospital score can be used as an objective calculation in determining the severity of each trauma patient. This can be used to alert

the receiving end to prepare for the incoming of trauma patients, and if appropriate to activate trauma team and alert the blood bank.

This study was a cross sectional observational study, using retrospective data to calculate the prehospital score in determining the outcome of trauma patients.

2.2 LITERATURE REVIEW

Trauma care involves a chain of services, and its effectiveness depends on quality and cooperation between each individual service. Broadly, major trauma is defined as those injuries with the highest severity in terms of requiring time critical specialist care. Although the major impact of lowering the trauma morbidity and mortality is through prevention of injury, there is considerable evidence that early correction (resuscitation) and definitive management will result in better outcome.

The major benefits of prehospital care are realized during the second phase of trauma, when the timely provision of care can limit or halt the cascade of events that otherwise quickly leads to death or lifelong disability. Without prehospital care, many people who might otherwise survive their injuries may die at the scene or en route to the hospital.⁹ Many fatal injuries may be prevented, or their severity reduced by adequate prehospital trauma care.

The concept of prehospital trauma scoring, among numerous recent advances in the care of trauma patients, has been developed out of the need to use prehospital data more effectively for appropriate triage, prehospital management, and emergency department preparation.¹⁰ In Malaysia, there are no specific scoring system is used. The prehospital triage scoring should be simple and precise to be used. Many trauma scoring systems have been developed and used, there is no gold standard for this system to till today. Most scoring systems incorporate several types of

criteria to differentiate major from minor trauma including, physiologic, anatomic, mechanics, age and comorbidities.

Mechanism, Glasgow coma scale, Age, Systolic Pressure (MGAP) was developed by Sartorius et al. in 2010.¹¹ A multicentre prospective observational study done in France. 1360 trauma patients receiving care from a prehospital mobile intensive care unit in 22 centers in France during 2002 were evaluated. It involved 22 centres (14 university and eight nonuniversity centers) in France and each center was asked to record consecutive cases of trauma patients from January 1 through December 31, 2002.¹¹

There are many studies done to compare multiple scoring system which is more accurate in predicting intra-hospital mortality and outcome of trauma patients. A recent study done in China, was to evaluate the prognostic value of PHI score for hospitalized patients with acute trauma. The sensitivity of the PHI was superior to the ISS ($\chi^2=6.975$, $P=0.008$), but the specificity and the accuracy of the PHI and ISS showed no significant difference ($P>0.05$). The PHI is valuable in prognostic prediction of hospitalized patients with acute trauma, and it is superior to the ISS.¹²

In 2014, a study conducted to validate and reclassify the MGAP and GAP score. This is a cohort study with 30-day mortality as the primary outcome to validate two new trauma scores using data from the UK Trauma Audit and Research Network. A total of 79,807 adult major trauma patients were included; 5,474 (6.9%) died. In conclusion it is found that both scores to be valid triage tools to stratify emergency department patients, according to their risk of death. MGAP calibrated better, but GAP slightly improved discrimination.¹³ Another study done in 2015 to compare MGAP score with Revised Trauma Score (RTS) showed that MGAP score was statistically significant in comparison to RTS score in predicting in-hospital mortality.¹⁵ The study also quoted that MGAP score is easier than RTS score to calculate and has few parameters, it is

advantageous for providing fast results, allowing quick decision making in major poly-trauma patients including head injuries.

¹⁵ MGAP score is an easily calculable system both in the field and at the time of admission to the ED that can suggest future decision-making schemes to ED physicians by predicting patient mortality. ¹⁵ MGAP score is a simple scoring system that can guide healthcare staff at the scene and enable the transfer of trauma patients to trauma centres, which may reduce the loss of time. ¹⁵

2.3 PROBLEM STATEMENT

Prehospital services have the advantage when transporting trauma patients to the hospital. The appropriate triaging of trauma patients can reflect the outcome of trauma patients. A more objective screening of trauma patients can be done when prehospital score system is used. This will help to determine the appropriate triaging of the patients. It is known that; prehospital services do not have a standard protocol or score to determine the severity of trauma cases at the scene or prior to arrival to the hospital. The use of standard objective assessment is important so that appropriate triaging and management of patient is carried out in a timely manner.

2.4 STUDY JUSTIFICATION AND BENEFIT OF THIS STUDY

This study is to determine which score is more sensitive and specific to determine outcome of trauma patients. In developed countries many prehospital score system is used to determine the severity or category of trauma to determine the level of hospital the patient needed to be sent to. This is important so that the appropriate team is present to treat the patient without the need of transferring of patients to other centres.

In Malaysian setting, the application of prehospital scoring system can be used for the preparedness of the emergency department to receive patient. It is a more objective score where patients can be categorized and simply identified as major trauma or high-risk patients. Many tertiary centres in Malaysia had been implement 'Trauma Team' system which is a multidisciplinary team approach for a trauma patient. This is to ensure fast decision and adequate resuscitation is being carried out without any further delay. In hospitals with this practice we can alert and activate the team prior to patient arrival.

There are many trauma scores which had been developed in predicting mortality and other outcomes of trauma patients. PHI is one of the oldest score that had been developed and is purely based on physiological parameters whilst MGAP score has an additional two parameters age and mechanism of injury blunt or penetrating included in the calculation of the score. MGAP will have significant result in prediction of outcome comparatively to PHI score in view of the age factor which is known to be one of the major predictors of trauma outcome. The comparison of two scoring system will help determine which scoring system is more specific and sensitive to determine the outcome of patients. Currently there no study done to compare PHI and MGAP score.

2.5 RESEARCH QUESTION(S)

1. What is the outcome (mortality, length of hospital stay, morbidity, major surgery) of trauma patients, based MGAP Score?
2. What is the outcome (mortality, length of hospital stay, morbidity, major surgery) of trauma patients, based on Prehospital Index Score?
3. Between Prehospital Index and MGAP Score, which score is more sensitive and specific in predicting in-hospital mortality for trauma patients?

4. Is there any difference of outcome (mortality, length of hospital stay, morbidity, major surgery) in relation to calculation of Prehospital Index and MGAP Score?

2.6 OBJECTIVE

2.6.1 General objective

To determine the outcome (mortality, length of hospital stay, major surgery and morbidity) of patients in relation to the score calculated using Prehospital Index Score and Mechanism, Glasgow coma scale (GCS), age, systolic blood pressure (MGAP) Score in trauma patients

2.6.2 Specific objectives

1. To determine specificity and sensitivity of Prehospital Index Score in predicting outcome (mortality, length of hospital stay, major surgery and morbidity) of trauma patients
2. To determine the specificity and sensitivity of MGAP Score in predicting outcome (mortality, length of hospital stay, major surgery and morbidity) of trauma patients
3. To compare between Prehospital Index and MGAP Score sensitivity and specificity in determining outcome (length of hospital stay, major surgery and morbidity) of trauma patients
4. To compare between Prehospital Index and MGAP Score sensitivity and specificity in determining 30 days in-hospital mortality.

2.7 METHODOLOGY

2.7.1 Study Design

- Cross sectional observational study, using retrospective data

2.7.2 Study Location

- Emergency Department, Hospital Tengku Ampuan Rahimah, Klang, Selangor.

2.7.3 Study Population

- Reference population
 - Patients who receive treatment in Emergency Department HTAR via ambulance
- Study Population
 - Trauma patients who receive treatment in Emergency Department, HTAR
- Study Participants
 - Trauma patients who receive treatment in Emergency Department HTAR arriving via prehospital care services who fulfil the inclusion and exclusion criteria
 - Data of trauma patients seen in ED from May 2019 till May 2020

2.7.4 Subject Criteria

Inclusion Criteria

- All trauma patients receiving treatment in Emergency Department HTAR, brought in alive by prehospital care services age more than 18 years old

Exclusion Criteria

- Trauma patients presented to Emergency Department, HTAR via other modes of transportation.
- Trauma patients pronounced dead at scene.
- Trauma transfer in cases from other hospitals.

Sample Size Estimation

For this study sample size calculation will be using the 2-proportion formula. Using the PS software, sample size collection are as follows:

	A	power	p₀	p₁	M	n	Reference
Prehospital Index	0.08	0.9	0.11	0.35	1	55	¹²
MGAP	0.09	0.9	0.12	0.04	1	202	¹⁴

For this calculation, 1 arm is as mentioned above, for 2 arms and additional of 10% dropout calculation is as follow:

	n calculated	2 arm	10% dropout	n
Prehospital Index	55	110	11	121
MGAP	202	404	40	444

This calculation is based to reference as mentioned above for the calculation of objective number 2 to predict mortality of patients depending on the score calculated. For objective number 3 and 4 for the specificity and sensitivity of each score is also using the same sample size.

For objective number 2 which is to look at the outcome of trauma patients, morbidity, major surgery and length of hospital stay, no sample size calculation can be done as there are no previous study to look at these outcomes. The highest number of sample size 444 will be chosen as the sample size for this study.

2.8 DATA COLLECTION METHOD

- Patients who fulfil the inclusion criteria will be scored using MGAP Score and Prehospital Index Score.
- Patients who fulfil the inclusion criteria will be selected by convenient sampling based on registration to the Emergency Department.
- All data will be collected by PI from the prehospital care form which are filled by paramedics responding to the case, after the patient has arrived in ED and received their appropriate management.
- There will be no interference with patients care and paramedics duty.
- The outcome of patients also will be traced from the BHT of patients along their hospital course if admitted to the ward.

2.8.1 Data Entry

Data to be compiled and analysed using SPSS statistic 24 which is licensed to the School of Medical Sciences, Universiti Sains Malaysia.

2.8.2 Variables

Prehospital Index (PHI) Score, MGAP Score, Major Surgery, Length of hospital stay > 30 days, Morbidity ADL independent or dependent, Mortality, Triaging

2.8.3 Statistical Analysis

Data collected will be analysed using chi square to calculate the sensitivity and specificity of each scoring system. The total score of each scoring system is categorized into a few categories. The Prehospital Index (PHI) Score, is a triage-oriented trauma severity scoring systems, comprising of four components, systolic BP, pulse, respiratory status and level of consciousness, each score 0-5.¹⁰ and divided into two categories which is Major trauma and Minor Trauma. Major trauma is categorized with score of 4-20 and minor trauma score 0-3. For MGAP Score, it is categorized into three categories as follow, Low risk (23-29), Intermediate risk (18-22) and High risk (<18). After discussion with statistician and board meeting it is agreed that the MGAP score to be categorized into two groups, severe and non-severe for statistical analysis. MGAP score of 18-29 as non-severe and less than 18 into severe category.

The MGAP and PHI score will be compared to the Injury Severity Score (ISS) which is calculated when patient is in the ward or after investigations are completed. ISS is used as the gold standard in calculating the patient's severity of injury. This score can only be calculated once patient have completed the examination and all the investigations are done. This is to ensure that the score calculated in prehospital care is validated. ISS will be categorized into major and minor trauma to make a 2x2 table for calculation of sensitivity and specificity of both scores.

The ISS score is an anatomical scoring system that provides an overall score for patients with multiple injuries. Each injury is assigned an Abbreviated Injury Score (AIS) and is allocated to one of the six body regions (head, face, chest, abdomen, extremities, external). Only the highest AIS score in each region is used and only 3 most severely injured body regions have their score squared and added together to get the ISS score. Major trauma is considered when the ISS score is more than 15.

2.8.4 Dummy Table

Prehospital Index Score				
	Death	Alive	X ²	P value
Major Trauma				
Minor Trauma				

MGAP Score				
	Death	Alive	X ²	P value
Severe				
Non-severe				

	ISS		
MGAP	Major	Minor	Total
Severe	a	b	
Non-severe	c	d	
Total			

Sensitivity: $a/a+b$

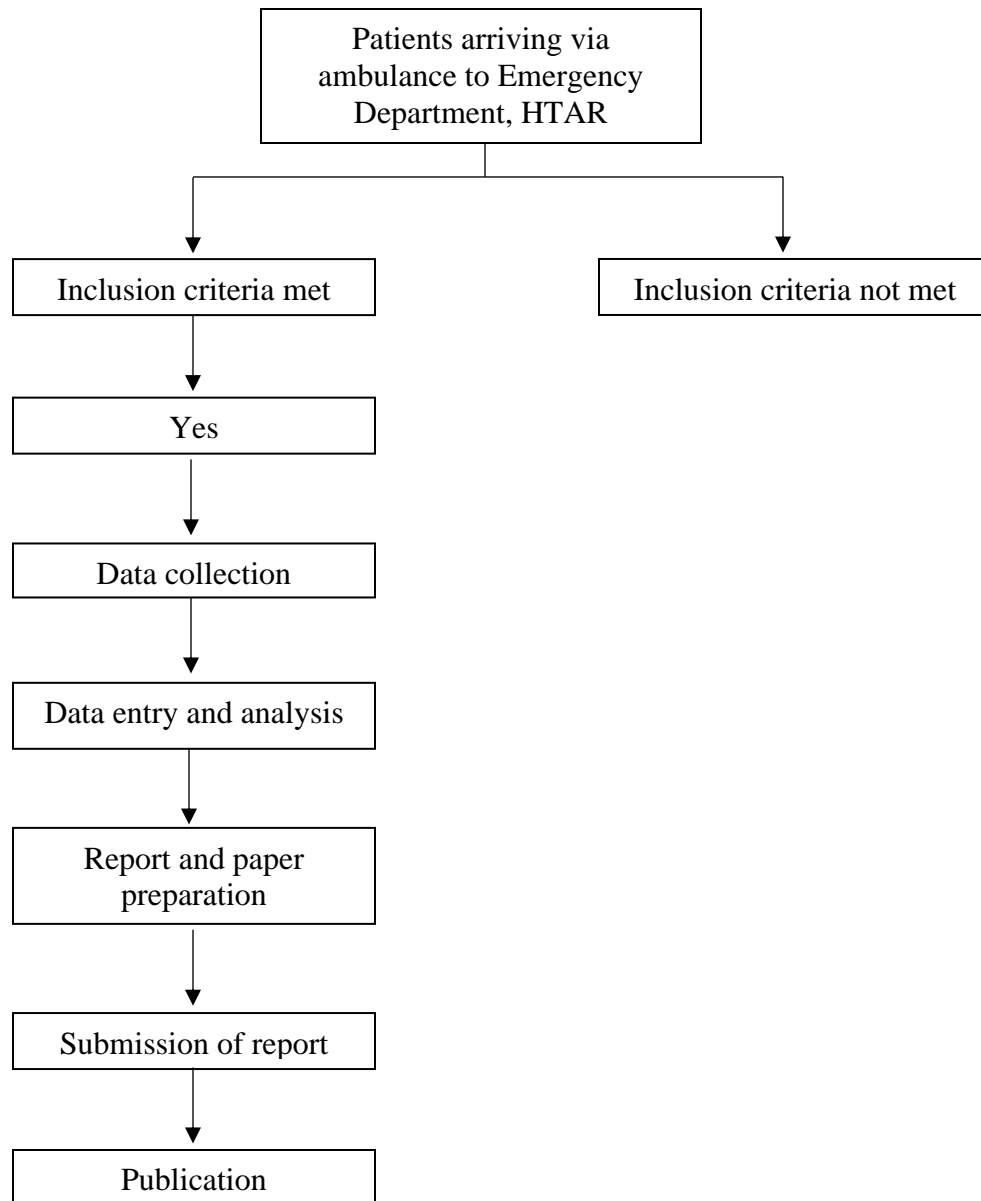
Specificity: $d/c+d$

	ISS		
PHI	Major	Minor	Total
Major Trauma	a	b	
Minor Trauma	c	d	
Total			

Sensitivity: $a/a+b$

Specificity: $d/c+d$

2.9 STUDY FLOW CHART



No	Milestones	Date	Semester
1.	Draft research proposal to supervisor	July 2018	Semester 1 2018/2019
2.	Present research proposal to department	August 2018	
3.	Submit proposal to ethics committee	September 2018	
4.	Anticipated date for ethics approval	March 2019	Semester 2 2018/2019
5.	Data collection commencement	May 2019	
6.	Data collection complete	May 2020	Semester 2 2019/2020
7.	Data entry & analysis commencement	April 2020	
8.	Data entry & analysis complete	June 2020	Semester 1 2020/2021
9.	Review findings with supervisor	July 2020	
10.	Dissertation report write up	August 2020	
11.	Review draft final report with supervisor & corrections	October 2020	
12.	Submit final report	November 2020	

2.11 ETHICS OF STUDY

The quality and integrity of the research will be ensured. The study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. Approval to conduct the study will be obtained from the institutional ethic committee; Human Research Ethics Committee USM (HREC/ JePEM), National Medical Research Registry (NMRR) and the hospital management. The participants will take part voluntarily. Any harm towards the participants will be avoided.

This study will benefit the community by able to be appropriately triage and appropriate preparation be done be the arrival of patient to the emergency department.

2.12 PRIVACY AND CONFIDENTIALITY

All forms are anonymous and will be entered into the SPSS software. Only the research team members can access the data. The data will be presented as a grouped data and will not identify the responders individually. The confidentiality and anonymity of the research respondents will be respected.

2.13 CONFLICT OF INTEREST

The investigators declared that they have no conflict of interest.

2.14 PUBLICATION POLICY

No personal information will be disclosed, and subjects will not be identified when the findings of the study is published.

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2.16 ETHICAL APPROVAL LETTER

 <p style="text-align: center;">8th April 2019</p> <p>Dr. Adila Hana Mohd Mustamam Department of Emergency Medicine School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan.</p> <p>JEPeM Code : USM/JEPeM/18090411 Protocol Title : Comparison of Prehospital Index with MGAP Score to Determine Outcome in Trauma Patients Presented to Emergency Department Hospital Tengku Ampuan Rahimah, Klang, Selangor.</p> <p>Dear Dr.,</p> <p>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/18090411, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from 8th April 2019 until 7th April 2020.</p> <p>Study Site: Hospital Tengku Ampuan Rahimah, Klang, Selangor.</p> <p>The following researchers also involve in this study:</p> <ol style="list-style-type: none"> 1. Dr. Mimi Azliha Abu Bakar 2. Assoc. Prof. Dr. Tuan Hairulnizam Tuan Kamauzaman <p>The following documents have been approved for use in the study.</p> <ol style="list-style-type: none"> 1. Research Proposal <p>In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:</p> <ol style="list-style-type: none"> 1. Data Collection Form <p>Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.</p> <p>While the study is in progress, we request you to submit to us the following documents:</p> <ol style="list-style-type: none"> 1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form. Subsequently this need to be done yearly as long as the research goes on. 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) 2019: Study Protocol Amendment Submission Form. 3. Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form. 	<p>Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)</p> <p>Universiti Sains Malaysia Kampus Kesihatan 16150 Kubang Kerian, Kelantan, Malaysia Tel. : +6 09-767 3000/2354/2362 Fax. : +6 09-767 2351 Emel : jepem@usm.my Laman Web : www.jepem.kk.usm.my www.usm.my</p>
 <p>JEPeM JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA</p>	



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Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

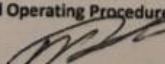
Date of meeting : 18th December 2018
Venue : Main Conference Room (BPU), School of Medical Sciences,
USM Health Campus.
Time : 9.00 a.m – 2.00 p.m
Meeting No : 408

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

Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Chairperson: Professor Dr. Hans Amin Van Rostenberghe	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim	Science Officer	M	✓
Members :			
1. Dr. Juhaida Daud	Representative of Hospital USM	F	✓
2. Mr. Khairul Ithma Mahdi	Assistant Registry, School of Health Sciences	M	✓
3. Dr. Mohammad Farris Iman Leong Abdullah	Lecturer, Advanced Medical and Dental Institute (AMDI)	M	✓
4. Prof. Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
5. Dr. Nazri Mustaffa @ Mohamed	Lecturer, School of Medical Sciences	M	✓
6. Dr. Noor Aman A. Hamid	Lecturer, School of Medical Sciences	M	✓
7. Assoc. Prof. Dr. Norhayati Mohd Noor	Lecturer, School of Medical Sciences	F	✓
8. Mrs. Norleha Mohd Noor	Executive Secretary, School of Dental Sciences	F	✓
9. Mrs. Normah Salleh	Community Representatives	F	✓
10. Dr. Surini Yusoff	Lecturer, School of Medical Sciences	F	✓

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

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4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
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) 2019: Final Report Form.**

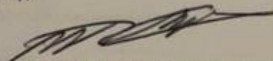
Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

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"

Sincerely,



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