MISSED INJURIES DURING THE INITIAL ASSESSMENT OF TRAUMA PATIENTS IN RED ZONE EMERGENCY DEPARTMENT HOSPITAL UNIVERSITI SAINS MALAYSIA

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LIST OF SYMBOLS, ABBREVIATIONS, AND ACRONYMS

ACL	Anterior Cruciate Ligament
AIS	Abbreviated Injury Scale
ATLS	Advanced Trauma Life Support
BPI	Brachial Plexus Injury
CT-SCAN	Computed Tomography Scan
DDI	Delay in diagnosis
ED	Emergency Department
EDH	Extradural hemorrhage
FDP	Flexor Digitorum Profundus tendon
FDS	Flexor Digitorum Superficialis tendon
GCS	Glasgow Coma Scale
ICD-10	10th Revision of the International Statistical Classification of Diseases and related Health Problems
ICU	Intensive Care Unit
ISS	Injury Severity Score
MI/MIs	Missed injury / Missed injuries
PCL	Posterior Cruciate Ligament
SAH	Subarachnoid hemorrhage
SBP	Systolic Blood Pressure
SCI	Spinal Cord Injury
SDH	Subdural hemorrhage
SPSS	Statistical Package for Social Science
TTS	Tertiary Trauma Survey
USM	Universiti Sains Malaysia
WHO	World Health Organization

KECEDERAAN YANG TIDAK DIKESAN SEMASA PENILAIAN AWAL PESAKIT TRAUMA DI ZON MERAH JABATAN KECEMASAN HOSPITAL UNIVERSITI SAINS MALAYSIA

ABSTRAK

Pengenalan:

Menguruskan pesakit trauma di Jabatan Kecemasan merupakan cabaran yang besar. Walaupun mempunyai sistem penilaian awal yang sistematik, risiko kecederaan yang tidak dikesan daripada penilaian awal masih sukar untuk dielakkan. Kajian ini dijalankan untuk menentukan kadar kejadian (*incidence rate*), menilai faktor-faktor risiko dan menjelaskan kecederaan-kecederaan yang tidak dikesan semasa penilaian awal pesakit trauma di Zon Merah Jabatan Kecemasan Hospital Universiti Sains Malaysia.

Kaedah:

Penilaian secara retrospektif terhadap 485 rekod pesakit trauma yang dimasukkan ke zon merah untuk tempoh masa setahun (daripada bulan Jun 2016 ke bulan Mei 2017) telah dijalankan. Kecederaan yang tidak dikesan ditakrifkan sebagai kecederaan baru yang dikenalpasti hanya selepas pesakit melepasi saringan penilaian di Jabatan Kecemasan dan telah dimasukkan ke wad khusus selama mana pesakit tersebut masih berada di wad hospital. Takrifan ini juga meliputi kecederaan baru yang dilaporkan dalam laporan rasmi ujian-ujian radiologi dan juga kecederaan yang dikenalpasti ketika pembedahan dilakukan. Kecederaan yang tidak dikesan dan membawa kesan klinikal yang signifikan (*clinically significant missed injury*) pula ditakrifkan sebagai kecederaan yang memerlukan prosedur rawatan tambahan dan mempunyai skor *Abbreviated Injury Scale (AIS)* 3 ataupun lebih.

Keputusan:

Sebanyak 135 kecederaan yang tidak dikesan dikenalpasti daripada 94 orang pesakit dengan kelaziman (*prevalence*) sebanyak 19.4% dan kadar kejadian sebanyak 2.75 setiap 100 orang-jam (*person-hours*). Bahagian badan yang kerap terlibat adalah bahagian muka (35%) diikuti dengan anggota tangan dan kaki (20%), bahagian kepala (11%), toraks & abdomen (masing-masing 10%), tulang belakang (9%). Sebanyak 46 kecederaan yang tidak dikesan dan membawa kesan klinikal yang signifikan tetapi hanya memerlukan rawatan konservatif (81%). Sebanyak 46% kecederaan yang tidak dikesan ditemui daripada ujian radiologi, 45% daripada penilaian klinikal dan 9% daripada rawatan pembedahan. Pesakit yang diintubasi ($p=0.007$), mempunyai skor GCS ≤ 10 ($p=0.022$), mempunyai skor ISS tinggi ($p<0.001$), menerima transfusi darah dalam tempoh masa 24 jam ($p=0.001$) dan mempunyai tempoh masa yang lebih panjang berada di Jabatan kecemasan ($p=0.007$) adalah dikaitkan dengan risiko kecederaan yang tidak dikesan daripada penilaian awal.

Kesimpulan:

Kecederaan yang tidak dikesan semasa penilaian awal di Jabatan Kecemasan Hospital USM berada di dalam lingkungan sama seperti kajian-kajian sebelum ini. Strategi untuk megurangkan kadar kecederaan terlepas ini harus difokuskan kepada penilaian yang lebih aktif untuk pesakit-pesakit yang berisiko, baik daripada anggota klinikal di Jabatan Kecemasan sendiri ataupun anggota klinikal primari yang menerima pesakit dan juga mendapatkan input awal berkenaan laporan rasmi pengimejan daripada jabatan radiologi.

Kata Kunci:

Kecederaan yang tidak dikesan**,** Jabatan Kecemasan, Trauma, Malaysia

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ABSTRACT

Introduction:

Dealing with trauma patient in Emergency department (ED) is a major challenge. Despite a systematic initial assessment, the risk of missing injuries is still inevitable. This study is conducted to determine the incidence rate, evaluate the risk factors and described the injuries missed after initial assessment in red zone ED Hospital Universiti Sains Malaysia (Hospital USM).

Materials & Methods:

Hospital records of 485 patients presented to red zone over one-year period (June 2016 to May 2017) were retrospectively reviewed. Missed injuries (MIs) were defined as any new injury identified after disposition from ED to a period before hospital discharge which also includes injuries reported from formal radiological reports and injuries found after surgical exploration. A clinically significant MI is an injury that require operative treatment and injury with Abbreviated Injury Scale (AIS) ≥3.

Results:

There were 135 MIs were discovered in 94 patients with a prevalence of 19.4% and incidence rate of 2.75 per 100 person-hours. Most common involved body regions were the face (35%), followed by upper & lower extremities (20%), head (11%), thorax & abdomen (10% each), spine (9%). 46 injuries were clinically significant, but majority MIs

were treated conservatively (81%). 46 % injuries were missed radiologically, 45% clinically and 9% intraoperatively. Patient who were intubated (p=0.007), had GCS ≤10 (p=0.022), had higher ISS score (p<0.001), transfused with blood within 24 hours (p=0.001) and stayed longer in ED (p=0.007) were associated with MIs.

Conclusion:

MI rate after initial assessment in ED Hospital USM is within the range of previous reported literatures. Strategies to reduce MIs should focus on active reassessment of a high-risk patients by ED team and by subsequent managing team as well as early radiological input.

Keywords:

Missed injuries, Emergency department, Trauma, Malaysia

CHAPTER 1

INTRODUCTION

1.1 Trauma survey

Dealing with trauma patient is a major challenge to any Emergency department (ED). The challenge is more profound when dealing with multiply injured patient in which resuscitation and precise diagnosis proceed at the same time. The complex tasks of diagnosing and treating at the same time impose the risk of missing injuries or a delay in diagnosis and subsequently may contribute to a significant morbidity and mortality.

ED team management of trauma patients follows the gold standard principles of assessment as recommended by the American College of Surgeons in the Advanced Trauma Life Support Course (ATLS). It starts with a primary survey to identify life threatening injuries and treating them according to priority. In primary survey, resuscitation effort will be focused on the airway, breathing, circulation, neurological status and lifesaving interventions. A secondary survey is an assessment in which a meticulous physical examination from head to toes to be performed together with the adjunct of imaging studies to detect any associated injuries but only after the life-threatening injuries have been assuredly cleared. The time spent to complete both assessments will depend on complexity of the trauma case. It must be completed in a timely manner, but not to exceed "golden hour" or the period of opportunity during which a positive impact is still possible on the morbidity and mortality associated with the injuries. The initial assessment of resuscitation emphasizes a more prominent and life-threatening injuries and may overlook other non-life-threatening injuries. A tertiary trauma survey (TTS) which was introduced in the early nineties, is a repetition of the secondary survey, was aimed to pick up injuries missed from initial assessment (primary and secondary survey).

1.2 Missed injury in trauma

Missed injury (MI) may stand out as the patient's bad experience in an institution despite the heroic efforts of the trauma team, giving out negative impression to an institution, result in suboptimal outcome for patient and lead to a loss of confidence in the health provider and a reason for litigation.

There are numerous studies conducted to identify the causative factors contributing to the missed injuries (MIs) or a delay in diagnosis (DDI) in trauma patients. Despite the abundance of available literatures, the data involving developing countries especially Malaysia are still lacking. Besides, there were discrepancies in the findings which warrant a further evaluation. Considering the need for further study involving this area of concern, this research was conducted to identify variety of factors contributing to the MIs and the results is hoped to improve the standard of care and clinical service.

1.3 Hospital USM trauma case approach

Hospital USM is a teaching hospital under the Malaysia Ministry of Higher Education. It is recognized as the regional tertiary referral center for the east coast region of Peninsular Malaysia. The Emergency department (ED) receives up to 60,000 presentations annually and is well equipped with modern infrastructures to compliment trauma services in north-east Malaysia. This hospital however has no dedicated trauma team. ED team is the first team to encounter trauma cases and referring the cases to respective disciplines which is known as vertical approach. In fact, there is no standardized or formalized process for the reassessment of admitted trauma patients by the primary team. Patients were managed at the discretion of the admitting team. In an ideal situation, a trauma center is ideally organized with a team approach, comprises a multidisciplinary group of individuals drawn from the specialties of emergency medicine, surgery, orthopaedic, anaesthesia and supporting staff, each of whom provide simultaneous inputs into the assessment and

management of the trauma patient and their actions being coordinated by a team leader. This is a concept of horizontal approach to trauma care aims to provide rapid input to a critically injured patient without the need to contact and request the presence of individual team members. An effective trauma system has been shown to reduce mortality amongst the victims of trauma.

1.4 Justification of study

The initial phase of hospital care in the ED has been identified as the area where most preventable problems in trauma care. In this case, overlooked MIs may happen at the expense of prioritizing life threatening injuries during initial resuscitation of trauma cases in ED. Studying the factors which contribute to MIs from patient arrival in ED is valuable in order to identify high-risk groups, improve clinicians' diagnostic accuracy and patients' outcome, minimize potential medico-legal problems and improve the service provided.

An institution may be reluctant to expose occurrence of MIs in their center to avoid depreciation to their institution, and related departments managing same trauma case may have not communicate well and giving feedback to ED on MIs cases. Therefore, reported case of MIs are largely unexposed, poses risk to potential litigation and ED may not be able to appreciate their performance. But nowadays, more institutions worldwide have contributed to the literatures to address this issue and subsequently find solutions to improve the service.

There are ample literatures studying into this global problem, but data involving Malaysia population is still lacking. In addition, different centers have their own settings and population hence may yields different results as compared to previous studies.

CHAPTER 2

STUDY PROTOCOL

2.1 Introduction

Dealing with trauma patient is a major challenge to any Emergency department (ED). The challenge is more profound when dealing with multiply injured patient in which resuscitation and precise diagnosis proceed at the same time. The complex tasks of diagnosing and treating at the same time impose the risk of missing injuries or a delay in diagnosis and subsequently may contribute to a significant morbidity and mortality.

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and secondary survey). Missed injury (MI) may stand out as the patient's bad experience in an institution despite the heroic efforts of the trauma team, giving out negative impression to an institution, result in suboptimal outcome for patient and lead to a loss of confidence in the health provider and a reason for litigation.

There are numerous studies conducted to identify the causative factors contributing to the missed injuries (MIs) or a delay in diagnosis (DDI) in trauma patients. Despite the abundance of available literatures, the data involving developing countries especially Malaysia are still lacking. Besides, there were discrepancies in the findings which warrant a further evaluation. Considering the need for further study involving this area of concern, this research was conducted to determine the prevalence and incidence rate of MI, evaluate the risk factors and described types of MI found after initial assessment in red zone ED Hospital USM.

2.2 Literature review

The term "delay in diagnosis of injury" (DDI) is often interchangeably used with the term "missed injury" (MI). To date, there is no consensus on specific criteria to define missed injury. A review on missed traumatic injuries done by (Stawicki *et al.*, 2009) had define DDI as an injury identified after the initial diagnostic phase of resuscitation, but before the injury manifests itself as a clinical problem, whereas, a MI is an injury which is not diagnosed in a timely fashion, but is discovered after it causes clinical symptoms. Both situations lead into same understanding which is an injury that has present from the beginning, resulted from the traumatic event, that would be normally have been detected in an awake and alert patient if an appropriate clinical investigation and diagnostic studies were performed.

There is ample amount of literatures describing the problem of MIs but only a few studies that address the problem of MIs with the relation to the primary, secondary, and tertiary trauma surveys. An earlier study by (Rizoli *et al.*, 1994) defined MI as any injury recorded after the initial 24 hours, that is, in the hospital or trauma file but not recorded on the resuscitation room forms. (Guly *et al.*, 2001) defined MI as an injury diagnosed after the patient had left the ED which could and should have been made while the patient was still in the department. Whereas, a study by (Adam Brooks *et al.*, 2003) conducted in Adult Intensive Care Unit (AICU) patient defined MI as an injury not discovered nor suspected upon admission to the (AICU) following the initial resuscitation, diagnostic studies or surgery. One military study done in Turkey by (Kalemoglu *et al.*, 2006) defined MI as any injury that was not discovered or suspected upon admission and not documented in either the trauma resuscitation notes or admission notes. A Taiwan study by (Chen *et al.*, 2010) defined MI as any injury which was not identified prior to the tertiary trauma survey performed upon Intensive Care Unit (ICU) admission. This study identified diagnoses of new injuries made after ICU admission. In contrast to an ICU diagnosis, any incomplete documentation or vague description of an anatomic region of injuries in the ED diagnosis (i.e., primary and secondary surveys) was a missed diagnosis. A similar definition was used by (Giannakopoulos *et al.*, 2011), in which MIs were defined as new injuries (sustained during the initial trauma) diagnosed after the primary and secondary survey. Either an injury was not suspected on clinical grounds, a radiological abnormality was not recognized as such, or no specific evaluation for that injury had yet been performed. (Thomson *et al*., 2008) in their literature review had proposed a definition MI as an injury, undiagnosed in the ED but recognized in subsequent admissions as one of standard for reporting of missed injury. The above-mentioned studies defined secondary survey as a cut off by which any new diagnosis made beyond this period is considered missed. In

other words, any new injuries recorded in disposition unit/ward during reassessment are considered missed from initial assessment in ED or resuscitation room.

The tertiary trauma survey (TTS) was introduced in the early 90s to specifically identify injuries missed during primary and secondary survey. This survey is basically a repetition of the secondary survey including a complete review of diagnostic imaging and blood results. Though introduced earlier, there is no standardized way on performing TTS. Only after recent years there are growing evidences to support its formal use and advantages. TTS should be done either on arrival in the intensive care unit (ICU) or after 24 hours after admission to a ward (Hardcastle, 2011). A study by (Enderson *et al.*, 1990) after performing re-examination of patients identified increase incidence of MIs to 9% rather than performing primary and secondary ATLS surveys alone (2%). Study by (Janjua *et al.*, 1998) performed a prospective evaluation of early MIs by completing a TTS within 24 hours of admission, a 39% of the total number of injuries went undetected after the primary and secondary surveys. However, after conducting a TTS within 24 hours, 56% MIs were detected from previous injuries. Another study by (Biffl *et al.*, 2003) after formalizing a TTS in trauma intensive care unit (TICU) within 24 hours decreased MIs by 36% and advocates routine TTS use in trauma centers.

MIs detection begins right after initial assessment up to a period after hospital discharge. A systematic review by (Keijzers *et al.*, 2012) who analyzed studies which are using TTS to identify MI had classified MIs into 3 types; Type I is an injury missed at initial assessment (primary and secondary survey) but detected by performing a TTS with a rates varying from 9.3 to 19.3% in 8 studies. Type II is an injury missed at initial assessment and TTS but still detected upon hospital stay with a rate of 1.51% reported by one study. Whereas, Type III injury is an injury missed at initial assessment, TTS and hospital stay but discovered after hospital discharge. However, there were no studies were identified

which met this definition during the review period. It can be predicted that detection rate will be different depending on which definition of MIs being used. An increase in detection of MIs would be expected using Type I definition but decrease using Type II or III.

TTS is recommended to done either on arrival in the ICU or 24 hours after admission to a ward, as this gives time to get all the relevant documentation and allows the resuscitation phase to be completed. It is a team-based review, which ideally should include at least one unbiased senior staff member, preferably not previously involved with the case (Hardcastle, 2011).

Incidence of MI ranges between 0.4% to 65%. This wide range was due a difference in study populations, study methods (retrospective vs. prospective) and used definition of MIs of the included studies. However**,** the majority of these may not be clinically significant. This significant missed injury ranges between 15 to 22.3% (Pfeifer *et al*., 2008). Different studies defined clinically significance missed injury differently. (Houshian *et al*., 2002) and (Buduhan *et al*., 2000) defined it as MIs that were associated with high morbidity and mortality. (Robertson *et al*., 2000) defined further surgical procedures as criteria to define clinically significant MIs. (Janjua *et al*., 1998) defined significant pain, complications, residual disability and death in the definition of a clinically significant MI. (C.-W. Chen *et al.*, 2010) defined it objectively using Abbreviated Injury Scale (AIS) in which AIS moderate score (more than 2) were defined as clinically significant. But in general, most studies report MIs to be clinically significant if they cause an alteration in therapy.

Injuries can be missed in all body regions, but it appears that certain groups of injuries are more likely to be unrecognized. Most studies found that typical body regions injuries are commonly missed include musculoskeletal injuries especially fractures involving

extremities, head and neck, chest (Buduhan *et al*., 2000; Houshian *et al.*, 2002). A literature review by (Hardcastle, 2011) described up to 50% of MIs in several studies involving the extremities and other bony tissue such as small bones of the hands and feet, knee ligaments to facial bones. Spinal injuries involving cervical is commonly missed. Pneumothorax or hemothorax are commonly missed chest injuries. Other chest injuries like diaphragm, aortic and occasionally cardiac injury were missed particularly in penetrating injuries. Missed abdominal organ injuries particularly bowel injuries deemed to be clinically significant as it causes significant morbidity like ICU admission, multiple re-laparotomies, and poses risk of multiple organ dysfunction or sepsis. Incidence of bowel injuries is even higher in conservatively managed solid intraabdominal organ injury. Neurovascular injuries and peripheral nerve deficits often missed in head or spinal injury as this group of patients are difficult to evaluate.

It is interesting to study the factors affecting the MIs in order to identify high risk groups and subsequently be more vigilant in performing clinical assessment in these group. Demographic data including age and gender were studied in most of studies. Studies by (Janjua *et al*., 1998; Houshian *et al*., 2002; Okello *et al*., 2007; Giannakopoulos *et a*l., 2011) had shown that age has no significant difference affecting MIs. However, a study by (Chen *et al.*, 2010) clarified age as a parameter that has a physiological explanation which is worth being studied as a risk factor for MI. Elderly patients do not tolerate trauma due to aged physiological functions and organ systems. An earlier presentation of neurological or cardiopulmonary decompensation in elderly patients can easily arouse physician caution and examinations compared to younger patients. The elderly might also receive more frequent and detailed examinations because physicians usually have special concerns due to their frailty and comorbid conditions as compared to young patient. This study had found that younger patients are more susceptible to MIs than older patients.

The risk of a missed injury occurring was significantly associated with a younger age (hazards ratio (HR) = 0.99; 95% CI, 0.98–1.00). However, gender difference showed no significant association (Okello *et al*., 2006; Chen *et al.*, 2010).

Impaired alertness or mental status may hinder clinician to detect injuries as compared to an awake patient. Significance of impaired alertness or mental status on arrival was differently proven by different studies. Study by (Giannakopoulos *et al*., 2011) showed an impaired alertness represented by Glasgow Coma Scale (GCS) less than 8 to be significantly associated with MIs (OR of 2.19 (95% CI 1.23–3.88) with p value of 0.006. A military study by (Kalemoglu *et al*., 2006) admission GCS < 8 was 14.2% in MI group vs. 4.2% in non-MI group ($p < 0.05$) was significantly different. Whereas, study by (Okello *et al*., 2006; Montmany *et al*., 2007) had shown that GCS did not affect this relationship significantly.

Hospital intubation during initial assessment may have a similar role as impaired alertness. This parameter is also studied in previous studies but failed to prove significant relationship to MI (Buduhan *et al.*, 2000; Houshian *et al.*, 2002; Kalemoglu *et al*., 2006; Chen *et al.*, 2010). But a study by (Montmany *et al*., 2008) showed 51.5% of MI group was intubated in hospital as compared to 25% which is not intubated in non-MI group (p value of 0.009).

It is possible that patients with polytrauma or severe injuries distract clinicians from carrying out a comprehensive examination in order to focus on more life-threatening injuries and provide rapid treatment. Higher severity of injury, represented by injury severity score (ISS) more than 16 had been shown to be significantly associated with MIs in previous studies by (Buduhan *et al*., 2000; Houshian *et al*., 2002). More recent study by (Giannakopoulos *et a*l., 2011) showed the MI population had significantly higher

median ISS 15 (8–22) versus 5 (1–13), p < 0.001). (Okello *et al*., 2006) also had shown median ISS in MI compared to in non-MI (25 vs. 14, P < 0.001).

Study by (Giannakopoulos *et a*l., 2011) described initial assessment management including blood transfusion and emergency intervention associated with MI are intriguing. This study found that 21.6% patients with MIs received blood transfusion within the first 24 hours as compared to 10.2% patients with no MIs (OR of 2.61 (95% CI 1.54–4.42) with p value of 0.001 is significant. Whereas, for emergency interventions, defined as an operation or angiography within 6 hours after initial assessment in the resuscitation room, this study found that 23.9% patients with MIs underwent emergency interventions as compared to 12.3% patients with no MIs (OR of 2.24 (95% CI 1.34–3.74) with p value of 0.030. P-values <0.05 were considered statistically significant in this study. The reason for emergency interventions causing unavoidable factor causing MIs is that in accordance with the ATLS guidelines, in which the most life-threatening injuries are diagnosed and treated first. Only after emergency interventions, additional radiography will be performed to detect minor or non-life-threatening injuries.

With regards to circumstantial factor such as patient's time of arrival, one could speculate that outside office hours or during the nighttime and weekends, less experienced clinician or consultant on call combined with less attentiveness and ability to concentrate during the night could be reasons for MIs. This was proven by (Chen *et al.*, 2010) in which 31.3% of patients with MIs were admitted during the nighttime shift vs. 22.1% of those without MIs the difference was statistically significant. (Okello *et al*., 2006) also found that 52 (29%) patients with MIs had been admitted during the night, compared with 26 (11.6%) admitted during the day which is statistically significant (p value of <0.001). But this result was confounded by the mean waiting time between arrival and assessment was 66 min during the night period and 28 min during the day period. (C.-W. Chen *et al.*, 2010)

found that there is no statistically significant difference for waiting time in ED for both group of patients. With regards to patient primary disposition, study by (Giannakopoulos *et a*l., 2011) found that patients who were directly admitted to the ICU following trauma room evaluation had the highest chance for MIs (OR 3.2 (95% C.I. 2.0–5.1; $p < 0.001$)).

(Chen *et al.*, 2010) also studied the medical outcome between patients without and those with MIs but had found no significant differences in terms of complications, length of hospital stays, or in-hospital mortality. Study by (Giannakopoulos *et a*l., 2011) also found no significant differences in mortality.

As compared to previous studies, study by (Chen *et al.*, 2010) has the advantages of studying additional circumstances such as work experience of attending staff in years and clinician in charge of trauma shift (Trauma surgeon vs. Emergency physician) but had found no significant differences contributing to missed injury. With regards to mechanism leading to injuries, patients severely injured in road traffic accidents are more likely to have MIs or DDI. (Janjua *et al*., 1998; Houshian *et al*., 2002).

2.3 Research questions

1. Would there be any difference in the incidence of MIs as compared to reported literatures in a hospital without a dedicated trauma team or formalized process for review of admitted trauma patients like Hospital USM?
2. What are the types of MIs during initial assessment in ED Hospital USM?
3. What are the contributing factors to MIs could be predicted from initial assessment?

2.4 Objectives

2.4.1 General Objective

To study the frequency, risk factors and descriptions of missed injuries in trauma patients admitted to Hospital USM.

2.4.2 Specific Objectives

1. To determine the prevalence and incidence rate of MIs
2. To determine risk factors of MIs from patient's demography and injury-related characteristics
3. To describe types of MIs

2.5 Research hypothesis

The incidence of MIs in Hospital USM is high as compared to reported literatures

2.6 Research Methodology

2.6.1 Research design

This is an observational, case control study that includes trauma patients presented to ED Hospital USM and fulfill all inclusion and exclusion criteria

2.6.2 Study population

Reference population

All trauma patients who presented to emergency department in Kelantan

Source population

All trauma patients who presented to emergency department in Hospital USM

Target population

All trauma patients who presented to red zone emergency department in Hospital USM during the study period, fulfilled the inclusion and exclusion criteria and admitted to intensive care units or wards.

2.6.3 Subject criteria

Inclusion criteria

1. Trauma cases presented to red zone with age more than 12 years old and require admission
2. Referred trauma cases from other hospital or centers for admission and receive initial assessment in ED Hospital USM
3. Patient who died in ED after initial assessment and has a complete clinical postmortem performed

Exclusion criteria

1. Patient who died on arrival before completion of initial assessment
2. Patient who opted discharge against medical advice or transferred to another center from ED Hospital USM
3. Patient who opted discharge against medical advice or transferred to other center from ICU or wards before reassessment. This is because comparison between injuries during initial assessment in ED and new injury detected during reassessment in ICU or wards (up to a period before hospital discharge) will not be possibly made if patient opted discharge against medical advice or transferred to other center from those ICU or wards.

2.6.4 Sample size calculation

For 1st specific objective: **To determine the prevalence and incidence rate of MIs**

Sample size required is **401** (after considering 10% drop-out rate). Sample size is calculated using single proportion formula, $\mathbf{n = (z/\Delta)^2\ p\ (1\text{-}p)}$ where (z_α=critical value for α, α= 0.05, therefore z_α = 1.96, precision, Δ=0. 05, p=expected proportion of individual in the sample size with missed injuries. A literature review from (Pfeifer

et al., 2008) summarizes the available literature on missed injuries found prevalence of **1.3% to 39%.** Therefore, p=0.39 which is closest to 0.5 is used.

For 2nd specific objective**: To determine risk factors of MIs injuries from patient's demography and injury-related characteristics**.

Sample size calculation was done using ***PS Power and Sample Size Calculations Version 3.0.*** (Dupont, 2009). Parameters used in sample size calculation are; α = 0.05, power = 0.8, M (ratio) = 7, P_0 = the probability of exposure in non-MI group (control), P_1**=** the probability of exposure in MI group (case). The highest calculated sample size is **485** and is used to study cases of MIs among trauma patient admitted to red zone ED HUSM during the study period

For 1st specific objective: **To describe types of Mis**

Sample size calculation is not necessary for descriptive analysis

2.6.5 Sampling method

Samples will be selected using simple random sampling method. According to red zone ED Hospital USM census database from June 2016 to May 2017, there are total 750 patients age more than 12 years old registered in red zone registry and admitted to the wards or ICU. Patient's ID from the registry will be entered into the Statistical Package for Social Science (SPSS) for windows, version 24.0, 485 sample will be randomly selected.

2.7 Data collection

Eligible subjects will be identified from the red zone registry book for the study period between Jun 2016 and May 2017. Each subject will be assigned with a unique study ID to maintain patient's confidentiality with a separate list of names containing relevant identification data will be only held available to the investigator. Medical record will be

traced in the record unit and relevant data will be extracted into the data collection form in Appendix 2.

Information on demographic and injury-related characteristics of interest to this study will be extracted by the investigator from the case notes. Variables recorded from medical records were categorized into patient-related factors, circumstantial factors and medical outcomes. Under patient-related factors, variables recorded includes; age, gender, intubation status, Glasgow coma scale (GCS), mechanism of injury, Injury Severity Score (ISS), blood transfusion within first 24 hours, systolic blood pressure on arrival and surgical intervention from ED within 6 hours. Circumstantial factors recorded includes; length of stay in ED, day and time of arrival, primary disposition. Whereas for medical outcomes, in-hospital mortality and length of hospital stay were recorded

Diagnoses documented in the ED clerking notes by ED team and diagnoses in the admission notes by related on call teams were recorded and both were regarded as diagnoses after the initial assessment. New diagnosis of injury related to the trauma which was detected after admission until patient's discharge (following reassessment, diagnostic studies or surgeries) were recorded and evaluated by investigators whether it is classified as missed injury or not. For each injury (diagnosed injuries and MIs), the severity will be assessed according to AIS-2015 (version 7, June 2017) and overall severity will be represented by injury severity score (ISS) which will be calculated from the AIS score. Injuries will be described according to the ICD-10 (revision 2016) and subcategorized accordingly into eight AIS anatomical regions.

2.8 Data entry and analysis

2.8.1 Data entry

Data entry and statistical analysis were entered using Statistical Packages for Social Science (SPSS) version 24.0

2.8.2 Statistical analysis

Data were explored and analysed using SPSS software version 24. Numerical variables were presented using mean and standard deviation. Categorical variables were presented as frequency and percentage. Distributions of continuous variables between patients with and without missed injuries were compared using Student's t tests; Pearson's chi-square tests or Fisher's exact tests were used for distributions of categorical variables. Statistical significance was defined by a P value of less than 0.05. Simple Logistic Regression and Multiple Logistic Regression were used to determine the risk factors associated with MIs in trauma patients. All odd ratios (ORs) are presented with 95% confidence intervals (CI).

The incidence of MIs is represented by incidence rate (per 100 person-hours). Incidence rate was preferred as patients had different exposure time periods. The incidence rate is computed by dividing the number of newly diagnosed injuries by the person-time (person-hours) during the ED stay. Person-time is defined as sum of total time contributed by all subjects.

2.8.3 Dummy tables

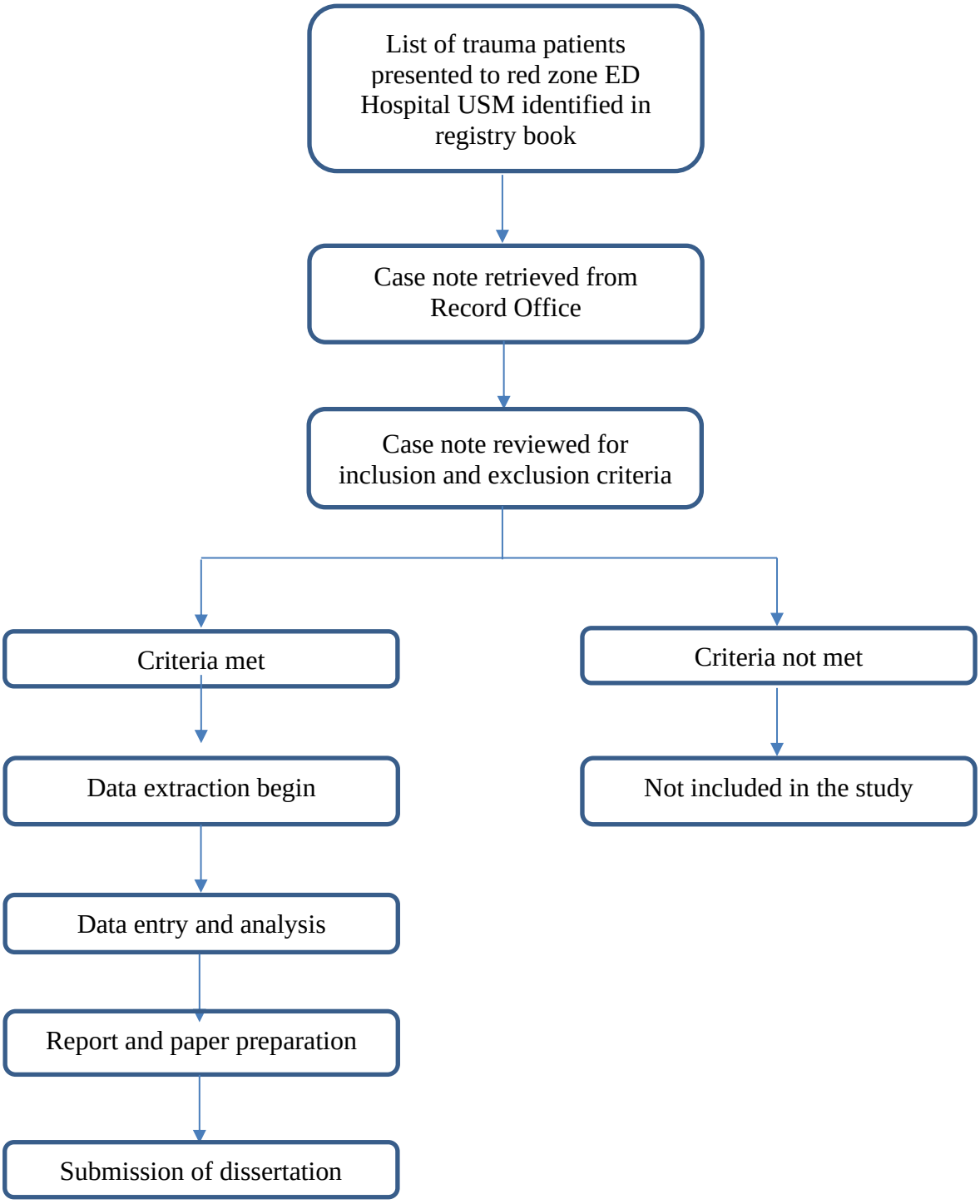
Table 1. Distribution of demographics and injury-related characteristics among patients without and with missed injuries

Characteristic	Without missed injuries (N) Mean (SD) n (%)	With missed injuries (N) Mean (SD) n (%)	p-Value
Medical outcomes *1. In-hospital mortality* *2. Length of hospital stay (day)*			
Patient-related factors *1. Age (year)* *2. Gender (male)* *3. Intubation status Impaired alertness (GCS≤8)* *4. Mechanism of injury (MVA)* *5. ISS* *6. Blood transfusion within first 24 hour* *7. SBP on arrival (<90mmHg)* *8. Surgical intervention from ED within 6 hours*			
Circumstantial factors *1. Length of stay in ED* *2. Time of arrival* *Weekends/public holiday* *Nighttime* *3. Disposition to ICU*			

Table 2. Location, numbers & descriptions of missed injuries

AIS location	Injuries	n	Median AIS	Median day detection	Suspicion to detection	Treatment
Head						
Face						
Neck						
Thorax						
Abdomen						
Spine						
Extremities						
External						

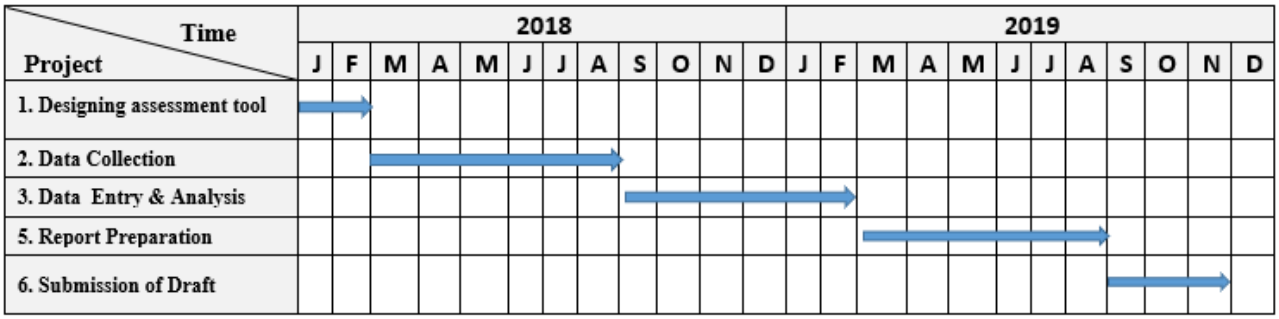
2.9 Flow chart



2.10 Ethical consideration

Approval from University Ethical and Research Committee, Hospital USM is sought (USM/JEPeM/17110596). The confidentiality of the data is ensured. Researches declared no conflict of interest in this study.

2.11 Gantt chart



2.12 Project milestone

1. Designing the assessment tools is expected to be completed by the end of February 2018.
2. Data collection is expected to be completed by the end of August 2018.
3. Data entry and data analysis are expected to be completed by the end of February 2019.
4. Report preparation is expected to be completed by the end of August 2019.
5. Submission of draft is expected to be done by November 2019.

2.13 References

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2.14 Appendices

2.14.1 Appendix 1: Sample size calculation using PS software

1. Gender (male) (Chen *et al*., 2010)

Gender (male)	
P0	0.678
P1	0.85
Significance level (α)	0.050
Power (1-ß)	0.800
M	7
Sample size	399
10% Drop-out rate	**439**