DETERMINING THE IMPACT OF EARLY AND LATE TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS

BY

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A dissertation submitted in fulfilment of the requirement for the degree of Master of Nursing Science

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ABSTRACT

Introduction: Severe head injury patients require a specific treatment plan and nursing care to achieve an optimal outcome. Mild head injury patients may need a few days of hospitalisation for close monitoring and conservative medical administration. However, in severe head injury cases, the patients may require a more extended period of hospitalisation for a series of complex neuro-medical and neurosurgical management. Tracheostomy may be performed on head injury patients with protracted breathing problems. Early tracheostomy, defined as the tracheostomy done less than seven days after initiation of endotracheal intubation, is believed to improve the patient's functional outcome, health-related quality of life and motivation toward rehabilitation. **Objective:** This study aims to determine the impact of early and late tracheostomy on the functional outcome, quality of life and rehabilitation motivation among severe head injury patients. **Method:** This is a retrospective cohort study involving 45 severe head injury patients with tracheostomy done from two hospitals in the Klang Valley. The participant's functional outcome, quality of life and motivation toward rehabilitation were evaluated using GOSE, QoLIBRI and MoT-Q instruments. In addition, the participant's clinical outcomes, including GCS upon discharge, length of stay in ICU and hospital, the incidence of VAP, duration of mechanical ventilation dependency, and decannulation rate, were recorded to identify the associations with the initiation of early and late tracheostomy. **Results:** There were 45 participants included in this study. Multivariate analyses showed that the association between these variables were significant for the length of stay in the hospital (p=0.035) and duration of mechanical ventilation used (p=0.005). The longitudinal analysis also showed that tracheostomy classification (early and late) had a significant association with the participant's functional outcomes (RR=1.189; 95% CI (1.10-1.28); p=<0.001) and motivation toward rehabilitation (RR=1.470; 95% CI (1.074-2.011); p=0.016). Nevertheless, the analysis did not show a significant association between tracheostomy classification and quality of life (RR=0.470; 95% CI (0.19-1.16); p=0.102). **Conclusions:** The initiation of early tracheostomy contributes to a favourable clinical outcome regarding mechanical ventilation duration and length of stay in the hospital for patients with severe head injury. Early tracheostomy also was significantly associated with functional outcomes and motivation toward rehabilitation, even though the association with health-related quality of life was found otherwise. Continuous follow-up assessment is proposed to reevaluate the impact of early tracheostomy on all variables. A comprehensive and details protocol for the initiation of early tracheostomy is recommended to be devised to maximize its benefit of it for patients with severe head injury.

Keywords: Early Tracheostomy, Late Tracheostomy, Severe Head Injury Patients.

ملخص البحث

مقدمة: يحتاج مرضى إصابات الرأس الشديدة إلى خطة علاجية ورعاية تمريضية خاصة لتحقيق أفضل النتائج. قد يحتاج مرضى إصابات الرأس الخفيفة إلى الإقامة في المستشفى لبضعة أيام تحت الإدارة الطبية المحافظة لمراقبة الحالة عن قرب. على كل حال، في حالات إصابات الرأس الشديدة، ربما يحتاج المرضى إلى فترة أطول من الاستشفاء لإجراء سلسلة معقدة من التدابير الطبية العصبية والجراحية العصبية. يمكن إجراء الفغر الرغامي (ثقب القصبة الهوائية) لمرضى إصابات الرأس الذين يعانون من مشاكل تنفس مديدة. يعتقد أن الفغر الرغامي المبكر، والذي يُعرَّف بأنه الفغر الرغامي الذي يتم إجراؤه خلال أقل من سبعة أيام من بدء التنبيب الرغامي، يحسن كلاً من: النتائج الوظيفية للمريض، ونوعية الحياة المتعلقة بالصحة والدافع نحو إعادة التأهيل. **الهدف:** تهدف هذه الدراسة إلى تحديد تأثير الفغر الرغامي المبكر والمتأخر على النتيجة الوظيفية، ونوعية الحياة، والدافع لإعادة التأهيل بين مرضى إصابات الرأس الشديدة. **المنهجية:** هذه دراسة حشديّة رجعيّة تشمل ٤٥ مريضاً مصاباً بإصابة شديدة في الرأس مع إجراء الفغر الرغامي، من مستشفيين في وادي كلانغ. تم تقييم النتيجة الوظيفية للمشارك، ونوعية الحياة، والدافع نحو إعادة التأهيل باستخدام مقاييس: GOSE وQoLIBRI و MoT-Q أيضا، تم تسجيل النتائج السريرية للمشاركين بما في ذلك: مقياس غلاسكو (GCS)عند الخروج من المشفى، ومدة الإقامة في المشفى و مدة الإقامة في وحدة العناية المركزة، وحدوث الالتهاب

الرئوي المرتبط بجهاز التنفس الصناعي (VAP)، ومدة الاعتماد على التهوية الآلية، ومعدل إزالة أنبوب فغر القصبة الهوائية، لتحديد ارتباطات هذه النتائج مع بدء الفغر الرغامي المبكر والمتأخر. **النتائج:** تضمنت هذه الدراسة ٤٥ مشاركاً، أظهرت التحليلات متعددة المتغيرات أن الارتباط بين هذه المتغيرات كان مهماً: لمدة الإقامة في المستشفى (p=0.035)، ومدة التهوية الألية المطبقة (p=0.005) .كما أظهر التحليل الطولي أن تصنيفات الفغر الرغامي (المبكر والمتأخر) كان لها ارتباطاً كبيرا: بالنتائج الوظيفية للمشارك (RR=1.189; 95% CI (1.10-1.28) ; p=<0.001) والدافع نحو إعادة التأهيل (RR=1.470; 95% CI (1.074-2.011)) ومع ذلك، لم يُظهر التحليل ارتباطًا مهمًا بين الفغر الرغامي ونوعية الحياة (RR=0.470; 95% CI (0.19-1.16) ; p=0.102) .**الاستنتاجات:** إجراء الفغر الرغامي في وقت مبكر يساهم في نتيجة إيجابية فيما يتعلق بمدة التهوية الألية ومدة الإقامة في المشفى عند المرضى المصابين بإصابة شديدة في الرأس، كما ارتبط الفغر الرغامي المبكر بشكل كبير بالنتائج الوظيفية للمرضى والدافع نحو إعادة التأهيل، على الرغم من أن الارتباط بجودة الحياة المتعلقة بالصحة وُجِدَ على خلاف ذلك. يُقترح متابعة التقييم المستمر لإعادة تقييم تأثير الفغر الرغامي المبكر على جميع المتغيرات، ويوصى بوضع بروتوكول شامل وتفصيلي لبدء الفغر لرغامي المبكر للحصول على الاستفادة القصوى منه للمرضى اللذين يعانون من إصابات شديدة في الرأس.

الكلمات المفتاحية: الفغر الرغامي (ثقب القصبة الهوائية) المبكر، الفغر الرغامي (ثقب القصبة الهوائية) المتأخر، مرضى إصابات الرأس الشديدة.

APPROVAL PAGE

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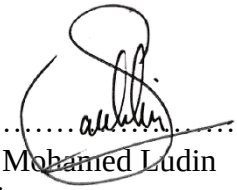

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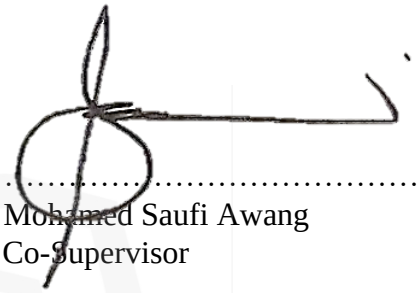

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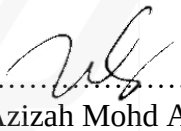

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Muhammad Farhan Bin Mahmud

Signature ..... Date 14/07/2023

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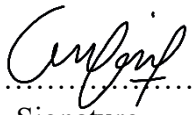

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14/07/2023
…….. Date

This dissertation is dedicated to my beloved parents and siblings, my soulmate Nur Syazwina Mohd Yusof and our bundle of joy Maryam Safiyyah and Muhammad Zayd

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LIST OF ABBREVIATIONS

ADLs	Activity daily living
ARDS	Acute Respiratory Distress Syndrome
CAP	Community-acquired pneumonia
CNE	Continuous Nursing Education
CPG	Clinical Practice Guideline
CRBSI	Catheter related bloodstream infection
CT	Computed tomography
CVA	Cerebrovascular accident
CVC	Central venous catheter
DAI	Diffuse axonal injury
DVT	Deep vein thrombosis
ETT	Endotracheal tube
FRGS	Fundamental Research Grant Scheme
GCS	Glasgow Coma Scale
GEE	Generalized Estimating Equations
GOS	Glasgow Outcome Scale
GOSE	Glasgow Outcome Scale Extended
HAP	Hospital-acquired pneumonia
HDU	High Dependency Unit
HKL	Hospital Kuala Lumpur
ICF	Internal Classification of Functioning, Disability and Health
ICP	Intracranial pressure
ICU	Intensive Care Unit
IREC	International Islamic University Malaysia Research Committee
KNPGRC	Kulliyyah of the Nursing Postgraduate and Research Committee
LOC	Loss of consciousness
LOS	Length of stay
MCO	Movement Control Order
MDG	Millenium Development Goals
MOH	Ministry of Health

MOHE	Ministry of Higher Education
MoT-Q	Motivation for Traumatic Brain Injury Questionnaire
MREC	Medical Review & Ethics Committee
MRIC	Malaysian Registry of Intensive Care
MSEDGE	Neurology Section of the American Physical Therapy Association's Multiple Sclerosis taskforce
MVA	Motor vehicle accident
NMRR	National Medical Research Register
PD EDGE	Parkinson's Taskforce
PDPA	Personal Data Protective Act
PEEP	Positive end-expiratory pressure
PPE	Personal protective Equipments
QoLIBRI	Quality of Life After Brain Injury
RAPS	Risk Assessment Pressure Ulcer Scale
RASS	Richmond Agitation Sedation Scale
SAH	Sub-arachnoid hemorrhage
SAPS II	Simplified Acute Physiology Score
SDG	Sustainable Development Goals
SOFA	Sequential Organ Failure Assessment Score
SPSS	Statistical Package for Social Science
SSI	Surgical site infection
StrokEDGE	Spinal Cord Injury Taskforce
TBI	Traumatic Brain Injury
TBI EDGE	Traumatic Brain Injury Taskforce
UMMC	University Malaya Medical Centre
UTI	Urinary tract infection
VAP	Ventilator-associated pneumonia
VTE	Venous thromboembolism
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Head injury is a medical condition described when the individual has suffered an injury or trauma to the scalp, skull, or brain (Haddad & Arabi, 2012). The injury could be blunt or penetrating trauma to the head accompanied by an episode of alteration in that person's level of consciousness (Maconochie & Ross, 2010). According to Ling et al. (2017), head injury is the most common diagnosis leading to Intensive Care Unit (ICU) admission in Malaysia after severe sepsis, with a percentage of 7.1% of the total population. Patients with a head injury will be assessed on the severity of the injury and will be classified as a mild, moderate, or severe head injury. The Glasgow Coma Score (GCS) assessment is widely used in patients with head injuries due to its high reliability and validity as a universal medical communication tool. According to Orman et al., (2011) and Liew et al., (2017), severe head injuries are classified for patients with GCS of less than 9. Moderate head injury with GCS of 9 to 12, while mild head injury will be classified to the patients with GCS of 13 to 15. Severe head injuries include haematoma, haemorrhage, concussion, cerebral oedema, skull fracture, and diffuse axonal injury (DAI).

In case of severe head injury, establishing an airway is deemed the most critical intervention to maintain adequate oxygenation for the patients (Liew et al., 2017). Patients who experience head injury are among the cases that usually need the support of mechanical ventilation to prevent the condition of hypoxemia or hypercapnia that may lead to secondary insult or further damage to the brain. According to the Malaysian Clinical Practice Guideline (CPG) (2015), a secured airway by tracheal intubation approach should be established among severe traumatic brain injury (TBI) patients with a GCS of less than nine (9) to maintain adequate oxygenation whereby the state of hypoxemia was unable to be corrected by the supplemental oxygen. The regular

breathing rate of the patients should be maintained, and hyperventilation should be avoided (Badjatia et al., 2008).

It is noticeable that the terms head injury and traumatic brain injury (TBI) have been used interchangeably when the researchers explained the cases related to the head injury (Fukuda & Warner, 2007; Liew et al., 2017). TBI usually referred to as an intracranial injury, is a brain injury brought on by an outside force (CDC Injury Centers, 2020). It can be divided into different categories according to the severity (from mild concussion) to severe TBI, its method (closed or penetrating head injury), or other characteristics (e.g., occurring in a specific location or over a widespread area). Meanwhile, the head injury is a more general term that can refer to harm to the skull and other body parts like the scalp (CDC Injury Centers, 2020). As the definition of these two terms is interrelated, thus these terms are used interchangeably in this study to refer to as head injury.

Regarding head injury, Asehnoune et al., (2018) mentioned that severe head injury, intracranial haemorrhage, or stroke are common causes of ICU admission with the initiation of mechanical ventilation therapy. Patients who had a severe TBI that sometimes underwent craniotomy or craniectomy indicated for mechanical ventilation support while they were being fully sedated for cerebral protection. It is an approach of neuroprotection or neuro-resuscitation, described as the therapy commenced before the onset of ischemia (Fukuda & Warner, 2007). For patients likely to have difficulty weaning off from mechanical ventilator support or require re-intubation, the issue arises whether these patients should be preserved with mechanical ventilation support via oral intubation of endotracheal tube (ETT) or proceed with early cannulation of tracheostomy instead.

In the case of patients with severe head injury, the leading physician or neurosurgeon in most healthcare facilities usually will judge for initiating the tracheostomy approach. Franco-Jimenez et al., (2020) mention that the decision to proceed with a tracheostomy should be individualised for each case considering mortality risk, expected duration of mechanical ventilator dependency, and neurological prognosis. The primary consultant or neurosurgical team attending the patient will decide the timing of the tracheostomy to be executed (Franco-Jimenez et al., 2020; Shibahashi et al., 2017; Siddiqui et al., 2015).

The term tracheostomy is subjected to the anterior opening into the trachea via the incision at the neck area to create an artificial surgical airway. This procedure creates

an air passage to help the individual breathing effort if the upper airway is obstructed or impaired (Al-Shathri & Susanto, 2018; Freeman, 2017). The main reason for a tracheostomy to be initiated is due to prolong episodes of mechanical ventilation, when the weaning off the ventilator is challenging to be done, which is quite common in case of head injury, especially in the patient with severe TBI or a massive hemorrhagic stroke (Abe et al., 2018; Qureshi et al., 2020; Vargas et al., 2015).

In Malaysia, according to the ICU Management Protocol for Weaning from Mechanical Ventilation, tracheostomy must be considered if the patient is deemed to have difficulty of weaning and is proven to be prolonged in the weaning process (Meng, 2012). Even though there is some guideline and recommendation for the initiation of tracheostomy among severe head injury patients, there is inconsistency in term of recommendation days after intubation for the tracheostomy recommended to be initiated (Carney et al., 2016). Therefore, the decision on when the time for the patient will be tracheostomised will be discussed on a daily basis between the anaesthesia and neurosurgical team until the tracheostomy is done. However, once the tracheostomy has been done, the verdict for decannulation of the tracheostomy tube in the later stage is only subjected by the attending consultant (Nasir et al., 2015).

It is recognised that prolonged mechanical ventilation support via an endotracheal tube (ETT) may lead to prevalent complications such as ventilator-associated pneumonia (VAP), tracheal and adjacent organs damage, pneumothorax, severe sepsis, acute respiratory distress syndrome (ARDS), and multi-drug resistance infection (Abdelrazik & Salah, 2017; Bösel et al., 2013). These possible complications, which force the patient to experience prolonged ICU stay, will jeopardise the expected time and process of the recovery and rehabilitation phase and will increase the cost. Consequently, if the mechanical ventilation therapy is delivered via the artificial airway – tracheostomy, the weaning process is expected to be smooth and faster, and sedation can be weaned or completely off sooner (Shibahashi et al., 2017).

Tracheostomy is executed not just to assist in a faster weaning process. It is also intended to prevent several complications, such as prolonged ICU stay, preventing VAP, and reducing the risk of long-term mortality. A study by Jeon et al., (2014) among neurosurgical patients in South Korea demonstrates that early tracheostomy significantly reduces the duration of mechanical ventilation. Other related studies also prove that early tracheostomy for head injury patients may reduce the length of stay in ICU, minimise the risk of VAP incidence, reduce long-term mortality, decrease

pulmonary morbidity, and faster weaning off ventilator support (Alali et al., 2014; Arzapalo et al., 2015; Hosokawa et al., 2015; Hyde et al., 2015).

Early cannulation of tracheostomy is believed to offer benefits and positive outcomes for a patient with a head injury. However, whether to perform an early tracheostomy or at a later stage is still uncertain, especially in Malaysian healthcare settings. Thus, the impact of early tracheostomy for severe head injury patients or survivors should be identified and evaluated to discover its significant advantage on the patient's functional outcome, quality of life and rehabilitation compliance.

1.2 PROBLEM STATEMENT

The individual who suffers from a head injury requires a specific plan of treatment which depends on the severity of the injury. Severe head injury may lead to severe physical disability, impaired cognitive function, and poor psychosocial condition, which could be temporary for a more extended period or permanent (Haddad & Arabi, 2012). Patients with mild head injury may be hospitalised for a few days for close observation or administration of specific medication such as an osmotic diuretic agent, anticonvulsant, calcium channel blocker and electrolytes (Olson & Berman, 2018). However, in moderate and severe head injury cases, the patients may require extended period of hospitalisation for a series of complex neuro-medical and neurosurgical management (Rosenfeld et al., 2012). In addition, patients with head injury are at risk experiencing any severe complications after the injury, such as infection, epilepsy, deep vein thrombosis (DVT), muscle spasticity, organ failure, and hydrocephalus (Ahmed et al., 2017). Besides, Stochetti et al., (2016) also mentioned that physical disability experienced by head injury patients during the early phase of a head injury would contribute to significant permanent disability with a minimal chance of returning to their regular and productive life.

In a scenario of severe head injury when the damage has been extended into hypoxemia and cerebral oedema, mechanical ventilation support is essential for cerebral protection (Robba et al., 2020). This approach is taken to avoid further damage to the brain due to secondary injury or insult, thus, the phase of cerebral protection could take a few days before the extubation plan takes place (Asehnoune et al., 2018; Robba et al.,

2020). However, Pelosi et al., (2011) reported that patients with severe head injury accompanied by neurological issues required higher tidal volume and lower positive end-expiratory pressure (PEEP) levels compared to non-neurological patients and eventually required them to have longer mechanical ventilation duration as the faster extubation process is challenging to be done. Even though the process of extubation takes place, Epstein, (2013) mentioned a 45% incidence of re-intubation reported within 24 to 72 hours post-extubation.

In order to assist in reducing the problem of prolonged mechanical ventilation support via ETT, the patient will most likely plan for a tracheostomy procedure to assist in the weaning process from the ventilator support. This surgery will also prevent the incidence of reintubation using the ETT as tracheostomy will provide readily accessible airway passage for oxygen delivery. If the patient is further deteriorating and requires non-invasive or invasive ventilation again, the tracheostomy approach can be used for ventilation delivery (Bice et al., 2015)

Early tracheostomy is believed to offer significant positive impacts on patient prognosis. From the aspect of patient recovery, early tracheostomy will help shorten the duration of ICU stay and duration of mechanical ventilation support (Catalino et al., 2018; Dochi et al., 2019); a significantly reduced time for administration of antibiotics for treatment of pneumonia (Kim et al., 2009); reduced mortality rate (Qureshi et al., 2018); and improve patient neurological and functional outcome (Robba et al., 2020). However, the information about the positive impacts of early tracheostomy on head injury patients is limited, especially in the Malaysian setting. Malaysian neurosurgical CPG in 2015 had yet to discuss the early management of head injury in adults without further discussion on the practice of the tracheostomy approach as the alternative approach was discussed (Liew et al., 2015).

On the contrary, multiple complications or side effects might occur if the initiation of tracheostomy is deferred. It is recognised that delayed tracheostomy with prolonged mechanical ventilation support via an ETT may lead to complications such as VAP, tracheal and adjacent organ damage, pneumothorax, severe sepsis, ARDS, and multi-drug resistance infection (Bösel et al., 2013; El-Anwar et al., 2017). These possible complications may lead to a longer ICU stay, jeopardising the expected time and process of the recovery and rehabilitation phase and increasing the cost financially.

The initiation of tracheostomy was indicated to assist in weaning the mechanical ventilation process and facilitate tracheobronchial hygiene (Huang et al., 2013).

However, if the decision to initiate tracheostomy is deferred, the weaning process will still be inefficient. As reported by Tai et al., (2019), a delay in a decision for a tracheostomy to be done was significantly associated with failure in the weaning process. Furthermore, it is common practice that sedation is administered in mechanically ventilated patients to ensure patient's breath and ventilator support are well synchronised. However, using sedation for a more extended period may also lead to a problematic weaning process as the patient may be over-sedated and compromise the patient's ability to breathe spontaneously. It has been reported by Khammas and Dawood, (2018) that patients with mechanical ventilation support via ETT and had been delayed tracheostomy significantly requires longer period under sedation, and the process of weaning off sedation were slower compared to those with tracheostomy. In addition, delayed tracheostomy also will contribute to longer ICU and hospital stays. Robba et al., (2020) mentioned that every two days for the tracheostomy approach were deferred is associated with an addition of one day in the ICU and two days in the hospital, respectively. The use of ICU monitoring system, invasive mechanical ventilation, infusions pump and staffing in a day are more expensive compared to general ward (Lindermark et al., 2017). The number spent in ICU will add up each day as long as the patient is still ventilated with ETT. Thus, the cost spent for the ICU stay including its the equipment and will rise further.

The timing of tracheostomy for head injury patients with mechanical ventilator support is still inconclusive. Some healthcare practitioners or hospitals will proceed with tracheostomy when weaning off the invasive ventilator is complicated. However, some may proceed with an early tracheostomy to achieve a better outcome (Marra et al., 2021). The decision of the tracheostomy plan also differed from one hospital to another due to multiple considerations such as cost, family dilemma, and neurological outcome. As Sanabria et al., (2013) mentioned, no specific guidance is provided about the issue of prolonging invasive ventilation and tracheostomy. The impact of tracheostomy timing (early and late) is still inconclusive, especially in the Malaysian setting. The evidence-based data and information on this issue are still required. The study to determine the impact of early tracheostomy among severe head injury patients should focus on the outcome during their hospitalization and include other post-discharge outcomes during their recovery phase, such as functional outcome, quality of life and rehabilitation motivation. Thus, this study was conducted to determine the impact of early tracheostomy on patients with a severe head injury.

1.3 SIGNIFICANCE OF THE STUDY

This study was conducted to determine the impact of tracheostomy timing (early and late) on the patient's clinical outcomes, functional outcomes, quality of life and rehabilitation motivation. This study is believed to offer multiple benefits for managing a patient with a severe head injury, given the initiation of early tracheostomy.

1.3.1 Government and Healthcare Setting.

Malaysia is always committed to provide one of the best healthcare services to the people with the vision of a nation working together for better health. The Ministry of Health's (MOH) mission is dedicated to ensuring a high-quality system is delivered to the people that offer a wide variety of services, including health education and promotions, disease prevention, curative treatment, and rehabilitative care via hospitals and clinics (Ministry of Health, 2020). The ICU is also one of the healthcare services available in each hospital in Malaysia. However, from 56 general hospitals under MOH, it had been reported by Ling et al., (2017) that Malaysia still has an inadequate number of ICU beds that are less than one (1) bed per 1,000 000 population.

According to the report by Ling, et al., (2017), there are only 691 operating ICU beds under MOH all over the country. Head injury and cerebrovascular disease are the highest populations of patients in the ICU, with contributed to 10.5% of the total population of ICU admission (Ling et al., 2017). This condition requires using ICU beds efficiently by minimizing unnecessary admissions and enforcing appropriate discharge. Suppose the implementation of early tracheostomy can assist in the extubation process and significantly shorten the ICU stay, the chance for having more immediate vacant ICU beds for the use of other patients will increase (Marra et al., 2021). Therefore, this study is significant because it will provide information on the impact of early tracheostomy in term of the duration mechanical ventilation support, and the length of stay in ICU.

1.3.2 Clinical Practice Guideline (CPG).

The data collected from this study can be used to provide additional information regarding the impact and benefit of early tracheostomy for head injury patients. Furthermore, the finding will suggest whether implementing early tracheostomy practice could improve the patient's prognosis. Recent CPG endorsed by the MOH of Malaysia in 2015 had only enlisted the CPG for Early Management of Head Injury in Adults, which provides evidence-based guidelines to those who are involved in the early management of head injury in primary and secondary/tertiary care which consist of pre-hospital care, medical and surgical intervention until home discharge advice. However, the alternative to tracheostomy practice is still remote. The findings and statistics collected from this study will offer a general overview for the MOH to construct a new evidence-based CPG of tracheostomy approach for severe head injury patients to enhance the good prognosis and better outcome.

1.3.3 Sustainable Development Goals (SDGs) – Goal 3: Good Health and Well-Being.

One of the goals included in the SDGs 2015 is to ensure healthy lives and promote well-being for all ages (Department of Statistics Malaysia, 2018), which consists of nine (9) outcome targets. Target 3.4 in SDGs Goal 3 is to reduce premature mortality from non-communicable diseases through prevention, treatment, mental health, and well-being by 2030. According to the review, 73% of total deaths in Malaysia up to 2014 were caused by non-communicable diseases, with injuries contributing to most. Since 2012, head injury has been one of the non-communicable diseases or conditions that contributed to a high mortality rate (19.7% to 23.1%) after sepsis (Liew et al., 2017). Thille et al. (2019) had recorded that the patients with a head injury who experienced failure in extubation and re-intubation in ICU were significantly associated with a higher mortality rate of 25-50%. Early tracheostomy, which may reduce the patient’s dependency on a mechanical ventilator, will improve the outcome and reduce mortality risk.

SDGs Goal 3 also set a target for universal health coverage, including access to quality essential health care services (Target 3.8). An effective intervention plan and

approach to managing head injury patients are essential to achieve this target. Early tracheostomy is believed to reduce the length of stay in the ICU and prevent complications such as pneumonia (Dochi et al., 2019) and dependency on antibiotic use (Catalino et al., 2018; Kim et al., 2009). A shorter ICU stays with less incidence of pneumonia will assist the government in preserving the costs financially. As You et al., (2018) mentioned, a more prolonged duration of ICU stay will significantly increase the cost by RM 2,645.42 each day, and head injury patients with pneumonia will require a higher mean cost with a difference of RM 31, 100.42 per hospitalisation. The ability to save costs in treating head injury will assist the government in providing the same health coverage services to a larger population. Thus, implementing alternative interventions of early initiation of tracheostomy will aid in achieving SDGs Goal 3 in our country.

1.3.4 Improve Quality of Nursing Care.

The care of patients with tracheostomy consists of tracheal suction via the trach tube, stoma care, dressing of the stoma, prevention of device-related pressure injury, and others. According to (Morris et al., 2013), there are several possible complications, such as infection, tracheomalacia, skin breakdown, and tracheoesophageal fistula, that might happen to patients with tracheostomy if the care is not delivered correctly. Therefore, nurses must equip themselves with a high level of competency and knowledge to perform tracheostomy care and deliver it to the patients regardless of their assigned wards or departments (Sodhi et al., 2014).

Qalawa et al., (2017) mentioned that initiating early tracheostomy, together with high-quality nursing care, improves the likelihood of severe head injury patient's prognosis and neurological outcome. However, a recent study by Alotaibi et al., (2022) recorded that most nurses had poor knowledge of tracheostomy care for patients. Respectively, another study by Gaterega et al., (2021) mentioned that most nurses demonstrated low levels of proper practice in tracheostomy care to patients. Thus, if the initiation of early tracheostomy does help to improve the patient's outcome, the consistency of excellent nursing care is crucial to maximise the benefit of it to the

patients. Thus, all healthcare practitioners, especially nurses, should have exceptional nursing skills in managing tracheostomy patients.

1.4 RESEARCH QUESTIONS.

i. What is the incidence proportion of early and late tracheostomy among severe head injury patients?

ii. What is the level of functional outcome, quality of life and rehabilitation motivation among head injury patients?

iii. What is the association between early and late tracheostomy and the sociodemographic characteristics and clinical outcomes of severe head injury patients?

iv. Is there any association between early and late tracheostomy with the functional outcome, health related quality of life and rehabilitation motivation among head injury patients?

1.5 OBJECTIVE OF THE STUDY

1.5.1 General Objective.

The general objective of this study is:

i. To determine the impact of early tracheostomy on the clinical outcomes, functional outcome, quality of life and rehabilitation motivation among severe head injury patients.

1.5.2 Specific Objective.

The specific objectives of this study are:

i. To determine the incidence proportion of early and late tracheostomy among severe head injury patients.

ii. To determine the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.

iii. To determine the association between early and late tracheostomy and the sociodemographic characteristics and clinical outcomes of severe head injury patients.

iv. To determine the association between early and late tracheostomy with the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.

1.6 HYPOTHESIS.

1.6.1 Null Hypothesis, H_0.

i. There is no significant association between early and late tracheostomy and the sociodemographic characteristics and clinical outcomes of severe head injury patients.

ii. There is no significant association between early and late tracheostomy with the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.

1.6.2 Alternative Hypothesis, H_A.

i. There is a significant association between early and late tracheostomy and the sociodemographic characteristics and clinical outcomes of severe head injury patients.

ii. There is a significant association between early and late tracheostomy with the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.

1.7 OPERATIONAL DEFINITION

1.7.1 Severe Head Injury

Head injury is the condition or damage resulting from blunt and/or penetrating injury to the head and/or brain due to exterior force. This condition might cause a permanent or temporary impaired brain function (Liew et al., 2015). A head injury can be categorized into three types which are mild, moderate, and severe head injuries. To define head injury, external force and alteration with brain physiology must be present with or without anatomical changes such as scalp, hematoma, or swelling. This classification is decided based on the patient's GCS presentation with a total score of three (3) to eight (8) and experiences a loss of consciousness for more than 24 hours (Liew et al., 2017; & Morris et al., 2013). In this study, severe head injury is the diagnosis of the patients diagnosed by a certified physician or neurosurgeon and documented in patient's record.

1.7.2 Tracheostomy

In this study, the term tracheostomy is referred to a surgical procedure whereby an incision is done at the neck area to create an artificial surgical airway in the cervical trachea. This procedure allows an air passage to help the patient breathe if the upper airway is obstructed or impaired (Lindman, 2020). Usually, this procedure is performed on patients to facilitate the ventilator support weaning process, trauma, or appalling neurological insult (Longworth et al., 2016; McGrath et al., 2012; Robba et al. 2020). In this study, the patients who receive tracheostomy intervention were divided into two groups which are early and late tracheostomy. The outcome or impact of early tracheostomy among severe head injury patients will be evaluated.

1.7.3 Tracheostomy Classification (Early and Late)

The participants in this study will include a cohort of severe head injury patients who had undergone a tracheostomy procedure. They are classified into two groups: early tracheostomy and late tracheostomy. According to the recent guideline for the Management of Severe TBI 2016, there is no exact timing or guideline on the timing of tracheostomy to be done. However, it is recommended within fewer than seven days

(Carney et al., 2016). Furthermore, a recent study by Robba et al., (2020) regarding the tracheostomy approach on head injury patients also chose seven-day cut-off points of seven (7) days to differentiate between early and later tracheostomy. Thus, in this study, the patient who had tracheostomy less than 7 days classified as the early tracheostomy group, whereby the patients who had tracheostomy on the seventh day or more classified as the late tracheostomy group.

1.7.4 Glasgow Coma Scale (GCS).

Jain and Iverson (2020) described that GCS is a tool used to portray the impaired consciousness of the individual or patients. This tool measurement consists of three assessment criteria: eye-opening, verbal response, and motor response. It is a measurement or simple summary tool to describe an individual's consciousness level. In this study, the term GCS and its tool will be used as one of the variables to evaluate the impact of early and late tracheostomy. Initial assessment of GCS during the admission and final GCS before the patient's discharge home were recorded and compared accordingly. Patient GCS is one of the clinical outcomes measured in the dependent variables.

1.7.5 Mechanical Ventilation.

Papadakos & Lachmann, (2005) defined *mechanical ventilation* as a method of life support with the help of a machine that overrides the work of breathing of the individual whenever the person cannot do it on his or her own. It is a machine that delivers the therapy called a ventilator, which offers various ventilation support modes, whether invasive or non-invasive. In this study, the selected participants are among those patients who had benefited from mechanical ventilation assistance for their breathing process via ETT or tracheostomy.

1.7.6 Intensive Care Unit (ICU).

The ICU, is a department that organised medical intervention and nursing care for critically ill patients via intensive medical and nursing care, including close observation

and multiple modes of physiologic organ support to sustain an individual's life (Marshall et al., 2017). This unit is operated by a specially trained team of healthcare professionals. In this study, admission to the ICU of Hospital Kuala Lumpur (HKL) and University Malaya Medical Centre (UMMC) is one of the inclusion criteria for the selected participants from both study settings.

1.7.7 Functional Outcome

This study defines functional outcome as a result of specific care delivered to the individual that focuses on their physical ability (Horner, 2018). After episodes of the rehabilitation program are given to the individual, further assessment after the program was evaluated by interviewing the patient and observing their physical ability, also known as performance testing. In this study, the patient's functional outcome with a head injury was assessed using the Glasgow Outcome Scale – Extended instrument to mark their ability to perform a particular dedicated task related to essential daily activity, occupation, and social skills.

1.7.8 Quality of Life

The World Health Organization (WHO) defines the quality of life as the perception of the individual or person regarding their position in life given the culture and value systems they are living on (WHO, 2016). This perception relates to their objectives, goals, expectations, standards, and concerns. In this study, the quality of life of head injury patients is one of the values that was evaluated. This variable was measured using the Quality of Life After Brain Injury (QoLIBRI) instrument created by von Steinbuchel et al., (2010).

1.7.9 Rehabilitation

Rehabilitation is defined as a set of interventions to assist the individual in improving their functioning in contact with the environment that had been affected due to the state disability resulting from certain health conditions (Nas et al., 2015). In this study, rehabilitation is a process to help the patient with a head injury to be independent as

best as they can to perform their activity daily living and enable them to interact in life events among society. Therefore, patient motivation and compliance toward the rehabilitation process was evaluated using the instrument of Motivation for TBI Rehabilitation Questionnaire (MOT-Q) created by Chervinsky et al., (1998).

CHAPTER TWO

LITERATURE REVIEW

2.0 INTRODUCTION

This chapter will consist of four sections. The first section discussed the overview of head injury and tracheostomy procedures. The elaboration on the mechanism of severe head injury is discussed to provide a better understanding regarding its early management and plan of care, which includes ICU care and mechanical ventilation therapy. The second section presents a systematic review to gather and appraise the past studies on the tracheostomy timing approach among head injury patients. The third section discussed the variables included in this study: functional outcomes, quality of life and rehabilitation motivation. The review on the nursing role and responsibilities of tracheostomy management among head injury patients was also included. Lastly, in the final section, the theoretical framework underpinning the study and the conceptual framework also had been discussed and deliberated.

2.1 HEAD INJURY

Head injury, also known as traumatic brain injury (TBI), has affected millions of people around the globe. Individuals would have their fair share of risk in experiencing this unfortunate event due to multiple causes at any point in their age. According to Dewan et al., (2019), 64 to 74 million individuals are estimated to sustain a head injury worldwide due to multiple causes each year. Globally, road traffic accidents are classified as the primary reason for head injury cases besides accidents at home, workplace, and sporting events. The incidence proportion of head injury due to road traffic accidents recorded the highest statistic in Africa and South-East Asia with 56% proportion.

According to a report by Ling et al., (2017), head injury is the second most typical cause of ICU admission in Malaysia, with road traffic accidents mainly the cause contributing to hospital admission. The National Trauma Database Malaysia (NTrD) report reported that nearly 80% of trauma cases occurred in 2009 due to road traffic accidents (Jamaluddin et al., 2011). This statistic is consistent with the research done by Rai et al., (2017), which found that TBI was regarded as one of the top three regular ICU admissions. Abdullah (2011) mentioned that there is 6,872 mortalities recorded from 28 269 head injury incidents in Malaysia, with most of the death occurring in males between the ages of 16 and 30.

The head injury must be present with specific criteria, which are mechanism, physiological, and anatomical. The mechanism, which means the presence of external force and physiological alteration of the brain, must be present with or without anatomical changes such as scalp hematoma or skull fracture (Liew et al., 2017). Some head injuries might not accompany anatomical changes or cannot be visualized in computed tomography (CT) images, such as diffuse axonal injury (DAI).

Head injury can be divided into traumatic brain injury (TBI) and non-traumatic brain injury. TBI is the condition of insult to the brain from an external mechanical force that leads to a temporary or permanent loss of the individual cognitive, physical, and psychosocial functions correlated with an altered mental state (Lindberg, 2019). On the other hand, non-traumatic brain injury (non-TBI) is a comprehensive classification of head injury not resulting from traumatic mechanical forces (Lindberg, 2019). Non-TBI is a condition where the brain injury is not caused by external physical force to the head but could be resulted due to cerebral hypoxia after the event of cardiac arrest, ischemic or hemorrhagic stroke, metabolic disorders, subarachnoid haemorrhage (SAH), or cerebrovascular accident (Giustini et al., 2013). Some conditions of non-external force can lead to brain injury or damage, including lead poisoning and tumours. Generally, the effects of TBI and non-TBI are similar, but some isolated differences may be recognised. Non-TBI could spread to all areas as its mechanism damages the cellular structure of the brain, while TBI typically localizes and affects crucial areas (Barnes & Good, 2013).

2.1.1 Severe Head Injury

The severity of the head injury can be classified into three (3) stages which are mild, moderate, and severe. The interpretation of the severity of the head injury is identified based on the GCS of the patient. For example, the condition of mild head injury is identified in the patient who has a GCS of 13 to 15 with an episode of loss of consciousness (LOC) or amnesia for less than an hour, moderate head injury with a GCS of 9 to 12, and incident of LOC up to 24 hours and severe head injury describe on the patient with the GCS less than nine and LOC for more than 24 hours (Orman et al., 2011; and Liew et al., 2017).

One crucial management of a patient with a severe head injury is preventing secondary insult or secondary brain injury. According to Bridges & Johantgen, (2013), several types of secondary insult could be experienced by the patient even if the early appropriate treatment or intervention had been initiated immediately. Secondary insult or injury includes cerebral oedema, intracranial pressure (ICP) elevation, mitochondrial dysfunction, metabolic dysfunction, oxidative stress, inflammation, cerebral vasospasm, hydrocephalus, and brain herniation (Kaur & Sharma, 2018). It is undeniable that hemodynamic management is crucial in treating severe head injury patients. However, managing a severe head injury is not just limited to that, as an intervention to prevent the occurrence of cerebral hypoxia is also vital. Kim et al., (2011) mentioned that maintaining oxygen delivery is vital to suffice oxidative metabolic needs. Thus, adequate cerebral blood flow is essential to be achieved among severe head injury patients.

2.1.2 ICU Care for Head Injury Patients.

Head injury is one of the unfortunate situations that may lead to a high chance of morbidity and mortality. Internationally, almost 40% of mortality incidents are reported in head injury cases around the globe, specifically in severe TBI, with 20% resulting in permanent major handicapped (Smith, 2014). Therefore, patients with severe head injury are required well-coordinated intensive care with a comprehensive treatment approach to maximise the chance of recovery and minimise morbidity and mortality as much as possible.

For the past two decades, managing a patient with a head injury has evolved into a higher standard of improvement from the initial scene of the pre-hospital setting to the emergency department and ICU (Pelieu et al., 2019). Once the patient is admitted to ICU, further management will be carried out, which consists of close observation and immediate, specific treatment to prevent the occurrence of intracranial hypertension, maintain a stable cerebral perfusion pressure (CPP), prevent secondary brain injury, and enhance cerebral oxygenation (Haddad & Arabi, 2012). Besides the usual management, such as hemodynamic monitoring, cardiac rhythm monitoring, and fluids intake and output charting, a few specific monitoring is required in managing a patient with a head injury, such as radio graphic which includes computed tomography (CT) imaging and magnetic resonance imaging (MRI) and (Chowdhury, 2014).

General ICU care for a patient with a severe head injury is only partially adequate as this vulnerable group of patients requires management in a specific and systematic manner. Ku, (2019) developed an outline of "HEAD" pneumonic for severe head injury management to guide the healthcare practitioner in systematically managing patients with severe head injury without missing out on any details in the ICU. The details are demonstrated in Table 2.1 as follows:

Table 2.1: ICU Management "HEAD"

Item	Description
H	Avoiding the "Hs": Hypotension, Hypoxia, Hyperthermia, Hyperglycemia
E	Head of bed elevation to 30-45 degree.
A	Avoid agitation and irritable with adequate sedation and analgesic.
D	Drug management which includes antibiotic, anti-seizure, analgesic and antacids. DVT prophylaxis.

Additional monitoring capacity, usually only available in a critical area such as ICU, includes intracranial pressure (ICP), cerebral perfusion pressure (CPP), electrophysiological, and regular blood gaseous monitoring. The continuous

neuromonitoring of ICP and CPP is vital for the patient with a severe head injury in detecting and preventing secondary brain damage due to cerebral ischemia (Kinoshita, 2016; Kirkman & Smith, 2014). Severe brain injury patients have a great deal of risk of developing secondary brain insult. Haddad & Arabi (2012) mentioned that about 40% of patients with TBI would deteriorate from secondary insult. This setback will lead to neuron injuries that initially were unharmed in the direct damage. Instead of improving after treatment in a healthcare facility, patient chances of recovery will reduce after each secondary insult. A study by Bridges & Johantgen (2013) recorded that 50% of patients will experience at least one documented event of secondary insult with hyperthermia on top of the list. This condition may be due to post-traumatic cerebral inflammation, hypothalamic injury, or distorted sympathetic tone. Other secondary insults that may happen are hypotension, hyperglycemia, cerebral oedema, hypoxemia, and hypothermia. These conditions might happen in every case of severe head injury despite differences in the mechanism of injury occurs at any point in time during the acute and critical periods. Thus, attentive and diligent intensive care is essential when monitoring and managing severe head injury patients in ICU.

2.1.4 Mechanical Ventilation Therapy.

The ventilator is one of the vital medical devices in higher healthcare facilities, mainly available in critical units such as the ICU and HDU. This medical device will provide mechanical ventilation therapy to those individuals or patients with acute and chronic respiratory problems due to various causes such as severe asthma, drug overdose that interfere with the normal function of ventilatory drive, chronic obstructive pulmonary disease (COPD), autoimmune disease such as Guillan-Barre syndrome and myasthenia gravis (Patel, 2022).

According to Pettenuzzo & Fan (2017), the basic principle of this mechanical ventilation therapy is to enhance pulmonary gas and relieve respiratory distress. Furthermore, this process will heal the lung and the airway while reducing the risk of iatrogenic complications. Furthermore, Tang et al., (2017) suggested that the therapy of mechanical ventilation is classified as the most effective measure in providing support for patients during surgery under the influence of general anaesthesia and a patient who is critically ill in the ICU.

According to a comprehensive multinational survey by Popat & Jones (2012), commonly critically ill patients who are admitted to the ICU due to coma, cerebral protection, respiratory failure, pneumonia, sepsis, postoperative complications, trauma, and neuromuscular disorder were indicated for invasive ventilation. Mechanical ventilation support may be delivered in two categories: non-invasive ventilation (NIV) and invasive ventilation support. Non-invasive ventilator support may be initiated in patients with moderate to severe dyspnea, tachypneic respiration rate of more than 30 breaths per minute, increased work of breathing such as laboured breathing, and drowsiness (Popat & Jones, 2012). On the other hand, invasive ventilation is commonly for those who are critically ill, comatose, experiencing respiratory failure, require cerebral protection, and have other underlying indications. This approach requires the insertion of most commonly ETT that may be done electively or during active cardiac arrest resuscitation events while the initiation of tracheostomy indicated whenever the patient had experiencing failure ETT intubation, prolonged mechanical ventilator support, neuromuscular disease, chronic aspiration and subglottic stenosis (Andersen et al., 2017; Alidad et al., 2019). All patients who receive ventilator support require optimal nursing care and compliance to the guidelines such as ventilator bundle checklist to prevent complications such as ventilator-associated events, infection, ventilator-induced lung trauma, and oxygen toxicity (Haribhai & Mahboobi, 2020; Hassan & Elsaman, 2022). TBI, cerebral haemorrhage, and stroke are severe head injuries that necessitate mechanical ventilation support and ICU admission (Robba et al., 2020). Furthermore, Carney et al., (2016) mentioned that head injury patients required mechanical ventilation support to prevent the risk of hypercapnia and hypoxemia that may lead to secondary insult to the brain. In addition, mechanical ventilation support is necessary for the neurosurgical patient to support or replace an insufficient respiratory drive and to prevent respiratory problems such as atelectasis and aspiration (Asehnoue et al., 2018).

The invasive ventilation ideally is temporary and kept as short as possible to reduce ventilator-related complications (Mora-Caprio & Mora, 2022). This process is recommended during the patients' acute condition; however, it may possess harm than good if the patients were stayed ventilated for a longer period. Hence, continuous evaluation via assessment of Arterial Blood Gaseous (ABG) values and an attempt to wean the patient from ventilator support must be done as soon as possible to avoid later complications. As mentioned by Vetrugno et al., (2020), the weaning process is one of

the ultimate phases that facilitates the recommencement of physiological respiratory function. However, some patients might experience a life-threatening situation throughout the process, and some critically ill patients require reintubation and ventilation support as a result of failed extubation. Beduneau et al., (2017) mentioned that up to 25% of critically ill patients eventually dependence on mechanical ventilation support and prolongs the length of ICU stay.

Given dependency on mechanical ventilation, Jeon et al., (2014) documented in their research retrospectively on 125 critically ill neurosurgical subjects in South Korea who had been separated into two groups based on the time tracheostomy commenced and demonstrated significant findings whereby early tracheostomy reduced the requirement for mechanical ventilation duration with the p-value of 0.001. In addition, this study also showed that the incidences of pneumonia were higher in the group with a late tracheostomy with a p-value <0.05. Another similar research conducted in the United States by Alali et al., (2014) also echoes the outcome. This cohort study was conducted among TBI patients, concluded that early tracheostomy was associated with fewer days of mechanical ventilation support with a 95% confidence interval of 0.66-0.75 and a lower incidence of pneumonia by 21%. However, given hospital mortality, both studies conclude that hospital mortality was found not associated with the initiation of early and late tracheostomy (Alali et al., 2014; Jeon et al., 2014).

According to Deva et al., (2010) in the Malaysian ICU Management Protocol, a patient who requires mechanical ventilation support for more than seven days is considered to experience prolonged ventilation. However, according to the Malaysia Registry of Intensive Care 2017, the average dependency on invasive mechanical ventilation was 4.2 days. Thus, the patient is considered dependent on invasive ventilation if they require ventilator support for more than 5 days, respectively. It is undeniable that mechanical ventilation support is essential for critically ill patients, including those with a severe head injury. However, mechanical ventilation support should be provided as long as it is still needed for the patient and immediately discontinued when the condition allows. Healthcare practitioners, including physicians, anaesthetists, nurses and others, should adhere to the guidelines and standard precautions to reduce the chance of patients having mechanical ventilation complications.

2.1.5 Tracheostomy

Airway management is one of the core managements in lifesaving and emergencies. The management involves planning, basic manoeuvre, therapeutical devices support and interventions, and surgical approach (Avva et al., 2022). The objective of airway management is to ensure that ventilation or gas exchange of the individual remains intact to prevent oxygen depletion or hypoxemia (Sun et al., 2017). As science and technology evolved, multiple interventions and practices have been gazetted and implemented in healthcare facilities worldwide to improve patients' prognoses. For example, the cannulation of tracheostomy is one of the popular interventions implemented in healthcare facilities, especially in the ICU (Vargas et al., 2015). Tracheostomy is usually performed to relieve upper airway obstruction, prevent laryngeal and upper airway damage in the case of prolonged ETT intubation, easy access to the lower airway for tracheal hygiene, and an option to those with prolonged mechanical ventilation (Durbin, 2010).

Different tracheostomy techniques are available and usually will be decided based on the patient's condition. For example, the procedure might include emergent, urgent, or elective tracheostomy. Emergent tracheostomy is where an immediate incision is made through the skin and cricothyroid membrane to establish a patent airway during life-threatening situations, which later will be converted to cannulation tracheostomy when the airway is appropriately secured, and the patient is stabilized (Lindman, 2020). Urgent tracheostomy may be performed on acute respiratory distress patients requiring acute surgical intervention. In contrast, elective tracheostomy is usually performed on patients who are already intubated, chronic and critically ill, and experience prolonged ventilation or other related indications (Lindman, 2020).

There are two approaches of tracheostomy: open surgical tracheostomy and percutaneous dilatational tracheostomy (Kidane & Pierre, 2018). Open surgical tracheostomy is performed in an operating theatre with adequate equipment and a conducive environment. The procedure is performed on patients who cannot tolerate it and requires them to be fully sedated. This surgery will be performed on the patient in a sitting or semi-recumbent position. Percutaneous dilatational tracheostomy, on the other hand, is usually performed ICU bedsides without the influence of general anaesthesia. The process involves dilating the trachea using a guidewire after the pre-

tracheal tissue has been dissected under local anaesthesia or moderate sedation and paralyzing agent usage (Raimondi et al., 2017). This approach was introduced in the 1980s as an alternative to the open surgical tracheostomy and is usually performed on critically ill patients in ICU. Using an assistive device such as bronchoscopy and ultrasound improves the procedure's effectiveness (Mehta & Mehta, 2017).

2.1.6 Early and Late Tracheostomy

Tracheostomy may often be performed as an emergency or elective measure based on individual conditions. Cheung & Napolitano, (2014) stated that the primary purpose of this procedure is to maintain airway patency for the patient with respiratory failure, which requires prolonged mechanical ventilation and airway issues. The commencement of tracheostomy also improves patient comfort, airway clearance, and pulmonary hygiene (Mallick & Bodenham, 2010; Barash & Kurman, 2021; Ghattas et al., 2021).

The ideal timing for tracheostomy had invited a significant debate. The dilemma arises when the unpredicted prognosis of the patients on mechanical ventilator support may require the physician; in this case, majorly the anaesthetist will decide when the best time is for the initiation of the tracheostomy procedure (Arzapelo et al., 2015). On the other hand, some medical practitioners would prefer to wait for some time for the patients on mechanical ventilation via ETT by the weaning process for extubation prior to deciding option for tracheostomy in case the duration of the patient dependent on mechanical ventilation is beyond expectation (Arzapalo et al., 2015). In Malaysia, the tracheostomy procedure will be done by the surgical teams, which include the ENT, general surgeons and neurosurgeons during the emergency. On the other hand, when the tracheostomy is meant to be conducted due to prolonged mechanical ventilation support, a collaborative assessment between the surgeon and anaesthetist should be done (Ministry of Health Malaysia, 2021).

Diaz-Prieto et al., (2014) documented that term early tracheostomy is categorised as the condition where the procedure had been performed less than 10 days after tracheal intubation whereby after the tenth days is considered as late or later tracheostomy. Therefore, a meta-analysis of randomised controlled trials done by Hosokawa et al., (2015) had narrowed the classification of tracheostomy timing into

three very early categories (within four days), moderately early (within 10 days), and late tracheostomy (after 10 days) after initiation of tracheal intubation. The meta-analysis was based on 34 studies from 142 citations from 2002 until 2014. While, based on the meta-analysis Raimondi et al., (2017), early tracheostomy is considered for those patients who perform tracheostomy before or on the sixth day of intubation. Thus, if a tracheostomy is performed beyond six days, it is considered a late tracheostomy.

Various studies have been conducted around the globe to identify the relationship between the effectiveness of tracheostomy - whether to do it early or later towards a few criteria such as its impact on mortality rate, length of ICU stay, acquiring pneumonia and weaning process from mechanical ventilation. Based on Malaysian Registry Intensive Care statistics in 2017, 2, 490 patients had undergone tracheostomy via percutaneous and surgical method, however, the indication of the tracheostomy initiation was not reported. Hosokawa et al., (2015) disclosed that early tracheostomy was associated with better outcomes, includes shorter ICU stay, and reduces long-term mortality compared to late tracheostomy. The finding was parallel to the research done in the same year by Arzapalo et al., (2015) and Hyde et al., (2015), prove that early tracheostomy significantly decreased pulmonary morbidity and better ICU outcome. These findings have been supported by recent research by McCredie et al., (2017), conducted on 503 severe brain injury patients with significant data of $p=0.02$ for decreased risk of long-term mortality and $p=0.01$ for shorter ICU stay.

In contrast, Siempos et al. (2015) research recognised that out of 2 434 patients (which included 648 mortality), the causes of death in the ICU were not significantly lower in patients scheduled for early tracheostomy. In addition, studies other studies also showed no significant relationship between early tracheostomy toward the length of stay in ICU and dependency on ventilator support, and the occurrence of ventilator associated pneumonia (Szakmany et al., 2015; Khammas & Dawood, 2018). Besides, Khammas and Dawood (2018) also claimed that early tracheostomy does not have a significant relationship between the duration of ICU stay and the occurrence of VAP.

Durbin (2010) mentioned that the most common adverse events during tracheostomy are no stranger, especially bleeding. However, it is not life-threatening, and all surgeons who perform the procedure must be familiar with managing tracheostomy-associated complications. Young et al., (2013) concluded in their research in a multicenter in the United Kingdom that from 2004 to 2011, from 909 subjects enrolled, only 6.3% of subjects experienced complications related to

tracheostomy, with 3.1% were due to bleeding. Some studies had compared the complications of tracheostomy with different cases or disciplines. For example, research done by Colomo et al., (2015) compared the complications rate related to tracheostomy between neurocritical care patients and general critical care patients which concludes that there are no significant differences between both samples regarding complications that can delay the weaning and decannulation process.

2.2 SYSTEMATIC REVIEW

The information and past literature about tracheostomy and head injury were identified according to the systematic review approach by using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Page et al., 2021). The following online database, PubMed, Science Direct, Springer Link, and ProQuest, was used to identify literatures that provided evidence related to the topic from 2010 to 2020. The keyword "tracheostomy" and "head injury" was used by using the Boolean term "AND" and "OR". The main objective of this systematic review is to explore the practice and outcome of tracheostomy among head injury patients. The assessment of eligibility for the past studies was conducted in three stages, which are screening for the title, abstract, and full text, as shown in Figure 2.1 of the PRISMA chart with specific assessment tools were analysed.

2.2.1 Search Objective

The objectives of the literature searches are:

i) To identify past studies regarding the evaluation of the tracheostomy approach among head injury patients.

ii) To compare the study on the related topic in terms of variables measured in each study.

iii) To identify the gaps of knowledge regarding past studies on head injury and tracheostomy classification (early and late)

2.2.2 Inclusion Criteria

The inclusion criteria included in this review are:

i) Peer-reviewed articles
ii) Published from 2010 to 2020.
iii) Studies reported on tracheostomy intervention on head injury patients, including TBI, non-TBI and patients who underwent cranial surgery.
iv) Publication in English.

2.2.3 Exclusion Criteria

The exclusion criteria in this review are:

i. Review papers.
ii. Head injury patients were not the subject focus of the study.
iii. Studies do–not indicate the outcome of tracheostomy performed on patients with a head injury.

2.2.4 Results

2.2.4.1 Study Selection

A total of 12 424 articles were identified, and 10 128 were eventually removed as the research articles were not related to the current study interest and were published before 2010 during the screening process. Of the remaining 2296 articles published from 2010 to 2020, 1164 were eliminated due to duplication; the remaining 1132 were engaged in abstract review. From the review, 985 articles were found outside the inclusion criteria of the topic. Most of the studies discussed the issue of tracheostomy concerning other health or medical issues such as respiratory failure, otorhinolaryngological issues, trauma and sepsis. The excluded articles only discuss about the tracheostomy and its indication, tracheostomy care, complications and others. Subsequently, 147 articles left had been retrieved for full-text review. 130 articles were eliminated as the studies were not engaged in discussing the outcome or implication of tracheostomy, were not focused on head injury patients and were review papers. Eventually, 17 articles were included

in the study (Figure 2.1). The data from the articles were extracted consisting of originated country, setting, study design, methodologies, sample size, assessment tool, research objectives, and outcome.

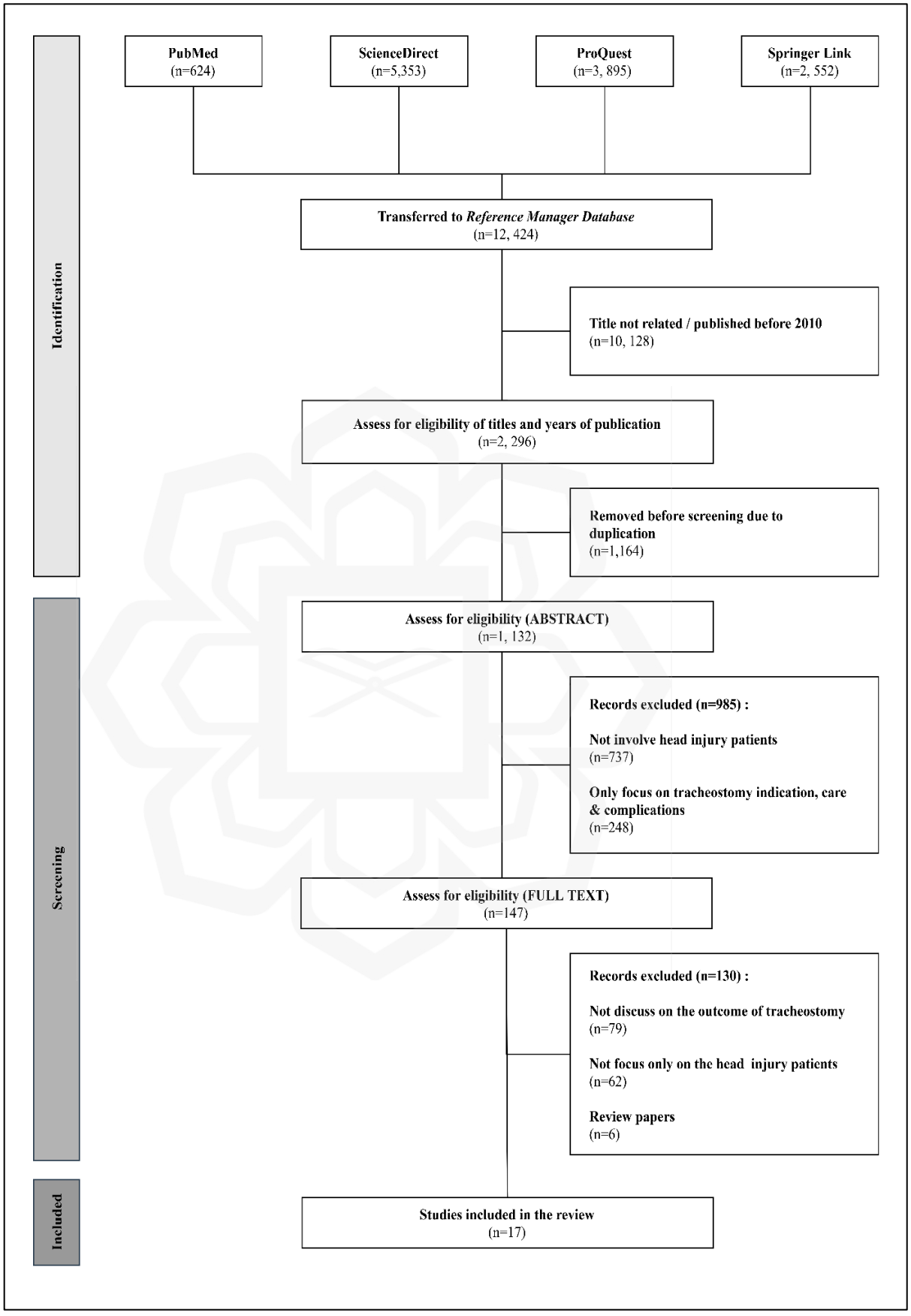


Figure 2.1: PRISMA Flow diagram on the search strategy.

2.2.5 Search Results

2.2.5.1 Definition of Early and Late Tracheostomy.

Out of 17 studies included in the review, 15 were focused on comparing early, and late tracheostomy approaches towards the outcome. The definition of early and late tracheostomy was different between the studies. Five (5) studies contemplate that the initiation of tracheostomy is considered early when it is performed within seven days after oral intubation (Alsherbini et al., 2019; Gessler et al., 2015; Rizk et al., 2011; Robba et al., 2020; Siddiqui et al., 2015). On the other hand, Alali et al., (2014) and Pinheiro et al., (2010) describe early tracheostomy as within eight days post-intubation, and the other four (4) studies by Huang et al., (2013); Jeon et al., (2014); McLaughlin et al., (2019); Qureshi et al., (2018); and Wang et al., (2012) had defined it to be within 10 days.

From the last decade, only one study by Khalili et al., (2017) included in this review uses the timeframe before six days as an early tracheostomy, whereby the procedure performed on the seventh day onward is already considered late. There was a case-control study conducted by Shibahashi et al., (2017) among 91 TBI patients at a tertiary medical centre in Tokyo who had specified the group of early tracheostomies among the patients who underwent the tracheostomy procedure within three days of post-intubation. Rosyidi et al., (2018) also conducted a study in Indonesia to evaluate the outcome of early and later tracheostomy, but the study was not properly disclosing the criteria of early tracheostomy.

From this summary, as demonstrated in Table 2.2, most of the studies conducted in the Asian country had chosen the timeframe of <10 days to > 10 days to categorise between early and late tracheostomy, while the Western and European countries tend to set it between less than seven days to more than seven days. A report by Carney et al., (2017) also concluded a different definition of the timing of tracheostomy from their analysis, but it is within the range of fewer than seven days. On the other hand, a propensity-matched cohort study report by the American College of Surgeons portrayed that less than eight days is considered early tracheostomy and more than eight days is late.

2.2.5.2 Tracheostomy Rate and Study Population.

The tracheostomy rate was significantly higher in the late group compared to the early group in most of the studies included in the review. Except for the study by Rizk et al., (2011), other studies recorded a lower rate of early tracheostomy, with a rate between 24.2% to 48.2% in their respective study. All study was conducted among adult patients with head injury (TBI and non-TBI), SAH, Stroke and neurosurgical cases, except a recent study by McLaughlin et al., (2019), which included children less than 15 years old with TBI. The study recorded 167 (46.2%) children who had been proceeding with early tracheostomy compared to 127 (35.2%) in a later stage.

Multiple reasons lead to the significant result of late tracheostomy reported in the studies. Most studies reported that the attending physician or consultant would decide on tracheostomy (Alsherbini et al., 2019; Gessler et al., 2015; Shibahashi et al., 2017; Schneider et al., 2019; Pinheiro et al., 2010; Khalili et al., 2017; Jeon et al., (2014); Robba et al., 2020). However, the decision to proceed with tracheostomy might be delayed due to the patient's unstable condition, old age, poor expected outcome, and financial constraints (Alali et al., 2014; Franco-Jimenez et al., 2020; Gessler et al., 2015; Jeon et al., 2014; Khalili et al., 2017; and Rizk et al., 2011). All these contraindicated factors will be evaluated on daily basis or during grand round to decide for the tracheostomy to be done (Jeon et al., 2014; Robba et al., 2020; Khalili et al., 2017). If the contraindication is still present, the initiation of tracheostomy will be delayed.

In Table 2.2, the majority of the sample included in all studies were significantly higher (n=4874) in male compared to females (n=1831) except for the study by Alsherbini et al., (2019); Gessler et al., (2015); and Qureshi et al., (2018) which the sample between males (n=171) and females (n=192) was comparable in total. Molayeva and Colantonio (2019) avowed that males have a higher incidence rate of TBI compared to women, especially during early adulthood. This condition resulted since males were the typical road user with a higher risk of getting involved in a head injury due to road traffic collisions (Dunne et al., 2020). Head injury was substantially higher among males, also contributed by the work-related head. However, given sports-related injury, the female population has higher incidents than males. From all the studies reviewed, the sample that had been included were patients subjected to head injury due to falls,

road traffic accidents, work-related injuries, and stroke (Alali et al., 2014; Qureshi et al., 2018; Wang et al., 2012; Khalili et al., 2017; Jeon et al., 2014).

All studies included in this review were conducted among the TBI population except the study by Alsherbini et al., (2019), which contained the data from a patient with stroke, non-TBI and SAH; Gessler et al., (2015) among the patients with poor SAH; and Jeon et al., (2014) with neurosurgical patients following head injury. In addition, three (3) studies from different continents discovered the outcome of early and late tracheostomy among head injury patients in general (Qureshi et al., 2018; Pinheiro et al., 2010; Rizk et al., 2011). These studies did not exclusively differentiate the type of head injury of their participants and group them together as a population with head injury. There are 6 705 patients with various specific diagnoses related to head injury recorded in all 15 studies.

Table 2.2 : Summary of studies included on tracheostomy timing (early and late), population, and rate.

Author	Year published	Origin	Type of study	Definition of ET and LT (days)	Study population	Population Sample (Male/Female)	Tracheostomy Rate ET/LT	Research aim
Pinheiro et al.	2010	Brazil	Retrospective	< 8 vs ≥ 8	Head injury	28 (16/12)	11 (39.3%) 17 (60.7%))	In-hospital outcome
Rizk et al.	2011	USA	Retrospective / Prospective	< 7 vs ≥ 7	Head injury	3104 (2351/753)	1577 (50.8%) 1527 (49.2%)	In-hospital & post discharge outcome.
Wang et al.	2011	Taiwan	Retrospective	< 10 vs ≥ 10	Head injury	66 (47/19)	16 (24.2%) 50 (75.8%)	In-hospital outcome
Alali et al.	2013	Canada	Retrospective	≤ 8 vs >8	TBI	1811 (1345/466)	873 (48.2%) 938 (51.8%)	In-hospital outcome
Huang et al.	2013	Taiwan	Retrospective	< 10 vs ≥10	TBI	38 (24/14)	11 (28.9%) 27 (71.0%)	In-hospital outcome
Jeon et al.	2014	South Korea	Retrospective	< 10 vs ≥10	Neuro-surgical, Head injury	125 (69/56)	39 (31.2%) 86 (68.8%)	In-hospital outcome

Table 3.2 : Summary of studies included on tracheostomy timing (early and late), population, and rate (continued)

Gessler et al.	2015	Germany	Retrospective	≤ 7 vs >7	Poor SAH	148 (54/94)	54 (36.5%) 94 (63.5%)	In-hospital outcome
Siddique et al.	2016	Pakistan	Retrospective	< 7 vs ≥ 7	TBI	100 (55/45)	49 (49%) 51 (51%)	In-hospital outcome
Khalili et al.	2017	Iran	Retrospective / Prospective	< 6 vs ≥ 6	TBI	152 (136/16)	53 (34.8%) 99 (65.1%)	In-hospital & post discharge outcome.
Shibahashi et al.	2017	Japan	Retrospective	< 3 vs ≥ 3	TBI	91 (66/25)	40 (43.9%) 51 (56.1%)	In-hospital outcome
Qureshi et la.	2018	Pakistan	Retrospective	< 10 vs ≥ 10	TBI	48 (21/27)	15 (31.2%) 33 68.8%)	In-hospital outcome
Rosyidi et al.	2018	Indonesia	Retrospective	*Not mentioned / disclosed*	TBI	60 (54/6)	*Not mentioned / disclosed*	In-hospital outcome
Alsherbini et al.	2018	USA	Retrospective	≤ 7 vs >7	Stroke, non-TBI, SAH	140 (69/71)	44 (31.4%) 96 (68.55%)	In-hospital outcome
McLaughlin et al.	2019	USA	Retrospective	< 10 vs ≥ 10	TBI	361 (132/127)	167 (46.2%) 127 (35.8%)	In-hospital outcome
Robba et al.	2020	Europe	Retrospective / Prospective	< 7 vs ≥ 7	TBI	433 (333/100)	180 (41.5%) 253 (58.4%)	In-hospital & post discharge outcome.

ET=early tracheostomy, LT=late tracheostomy, pts=patients, TBI=traumatic brain injury, SAH=subarachnoid hemorrhage.

2.2.5.3 In-Hospital Outcome

Most of the studies in the review focused on the outcome for the hospital's in-patients, such as the duration of mechanical ventilation, length of stay in ICU and hospitalisation, mortality rate, the incidence of pneumonia, and neurological outcome. All 17 studies reported a few patient outcomes during hospitalisation which are duration on mechanical ventilation, LOS in ICU and hospital, mortality rate, incident of pneumonia and nosocomial infection, duration on antibiotic use and neurological outcome as listed in Table 2.3 (Pinheiro et al., 2010; Rizk et al., 2011, Wang et al., 2012; Alali et al., 2013; Huang et al., 2013; Jeon et al., 2014; Gessler et al., 2015; Siddique et al., 2016;B Baron et al., 2016; Khalili et al., 2017; Schneider et al., 2019; Qureshi et al., 2019; Rosyidi et al., 2018; Alsherbini et al., 2018; McLaughlin et al., 2019; Robba et al., 2020). While the report on the duration of mechanical ventilation dependency and ICU length of stay were among the top report included, there are few studies report on specific outcomes related to in-patient matters such as the incident of nosocomial infection (Rizk et al., 2011; Wang et al., 2012), duration on antibiotic usage (Robba et al., 2020; Wang et al., 2012), the incidence of DVT and ulcer (Alali et al., 2014; and McLaughlin et al., 2019), decannulation rate (Gessler et al., 2015; Qureshi et al., 2018; Schneider et al., 2017). In addition, a study by Wang et al., (2012) reported morbidity rates among the sample, and Gessler et al., (2015) included the outcome of sedation usage among the sample population in their study.

2.2.5.3.1 Duration Mechanical Ventilation.

Ten studies had reported on the outcome of the duration required for mechanical ventilation among head injury patients, and nine of them had reported significant findings between early tracheostomy and shorter duration of mechanical ventilation support (Alali et al., 2014; Alsherbini et al., 2019; Gessler et al., 2015; McLaughlin et al., 2019; Qureshi et al., 2018; Schneider et al., 2017; Shibahashi et al., 2017; Siddiqui et al., 2015; Jeon et al., 2014). Alali et al., (2014) and Shibahashi et al., (2017) found that early tracheostomy will have shorter mechanical ventilation days seven days earlier compared to late tracheostomy group while McLaughlin et al., (2019) and Qureshi et al., (2018) reported the shorter duration as early as 11 to 17 days respectively. However, Wang et al., (2012) suggested otherwise in their study among 66 patients with a severe

head injury in Taiwan, which shows an insignificant relationship between early and late tracheostomy with a p-value of 0.58. The other seven studies did not include the duration of mechanical ventilation as one of their measured outcomes, as shown in Table 2.3.

2.2.5.3.2 ICU and Hospital Length of Stay

There are 13 and 11 studies, respectively, that reported the significance of the early tracheostomy approach on the length of stay in the ICU and hospital. All reported studies showed the significant result of fewer ICU length of stay if early tracheostomy had been carried out, with almost all studies showing a significant value of $p<0.0001$. Alsherbini et al., (2019); Jeon et al., (2014); Pinheiro et al., (2010) stated that the difference between ICU length of stay between early and late tracheostomy group could reach the gaps of 12 days average. Baron et al., (2016) mentioned that the early tracheostomy has an advantage in decreasing the ICU length of stay up to 20 days gap. Based on the review indicate that patients with a head injury could stay in the ICU for around 11 to 39 days, with early tracheostomy could narrow it down to five to 26 days.

For the aspect of prolonged hospital stay, there are seven studies (Alali et al., 2013; Baron et al., 2016; Khalili et al., 2017; Shibahashi et al., 2017; Qureshi et al., 2018; Alsherbini et al., 2018; Robba et al., 2020) reported a significant finding of early tracheostomy toward the shorter length of stay from 6 to 22 days. Alali et al., (2014) mentioned that early tracheostomy had shortened the length of stay of TBI patients by 20% over the fourth quartile of the hospital. This condition lowers the patient's odds of developing other hospital-acquired complications, such as pneumonia or nosocomial infection. This outcome was also similar in the paediatric patient with TBI, as mentioned by McLaughlin et al., (2019). Therefore, the children will have low chances of complications and side effects. Patients with a shorter stay due to the early tracheostomy approach also have a higher functional outcome during their six-month regular follow-up, as per the finding by Khalili et al., (2017) with higher GOSE outcome than those with a late tracheostomy. In addition, Robba et al., (2020) mentioned that a late tracheostomy would increase the length of hospital stay by 11.45 days. However, based on the review, four studies by Huang et al., (2013); Wang et al., 2012; Jeon et al.,

(2014); Siddiqui et al., (2015) had proven otherwise. These four studies reported that the tracheostomy timing statistically is not associated with shorter ICU stay.

However, a study by Siddique et al., (2015) reported that the length of the hospital was recorded higher in severe head injury patients with early tracheostomy. In the study, patients with prolonged ETT intubation have fewer days in the hospital by the margin of four days, with the analysis showing an insignificant p-value of 0.279. On the other hand, Jeon et al., (2014) mentioned that early tracheostomy was only associated with reduced length of ICU stay (p=0.000) but not for overall hospital stay (p=0.743).

2.2.5.3.3 Mortality Rate.

The mortality rate is one of the long-term outcomes reported in most studies. Ten studies measured the mortality rate as one of outcomes (Table 2.3). However, only three studies reported a significant association between this early tracheostomy and mortality rate (Pinheiro et al., 2010; Qureshi et al., 2018). In the study by Pinheiro et al., (2010) among 28 head injury patients in one of the teaching hospitals in Brazil, the mortality of patients receiving early (46%) and late (65%) tracheostomy differs by 19% with a p-value of 0.044. On the other hand, another study by Qureshi et al., (2018) among 48 TBI patients indicates a difference of 43.8% between both groups (p=0.013). Other studies in this review show no significant relationship between early and late tracheostomy and mortality rate. In addition, two studies indicate that early tracheostomy contributes to a higher mortality rate even though the margin difference was not too high, around 0.7%-2% (Pinheiro et al., 2010; Qureshi et al., 2018).

2.2.5.3.4 Incidence of Pneumonia.

The relationship between early tracheostomy and the incidence of pneumonia is the most common outcome measured for several studies included in this review. Ten studies reported regarding this association, and seven show a significant relationship, as per Table 2.8.2. Pneumonia could be varied based on its specific categories, such as community-acquired pneumonia (CAP), healthcare-associated pneumonia (HCAP),

hospital-acquired pneumonia (HAP), and VAP (Burnham & Kollef, 2017). Nevertheless, recent guidelines by Kalil et al., (2016) have recommended excluding the term HCAP from medical vocabulary.

However, a few studies did not determine the specific type of pneumonia in their research (Alali et al., 2014; McLaughlin et al., 2019; Wang et al., 2012). All these three studies reported a significant association between early tracheostomy and incident of pneumonia with a p-value of <0.001 (Alali et al., 2013) and 0.04 (Wang et al., 2012). However, McLaughlin et al., (2019) only compared the rate of pneumonia incidents between early (27.2%) and late (41.4%) in their study without inferential statistics. Based on the review, most the studies included the incident of VAP due to its potential risk as the oxygen therapy support delivered by the invasive mechanical ventilation to the severe head injury patients.

The other seven studies specifically discuss VAP, with four studies (Gessler et al., 2015; Jeon et al., 2014; Robba et al., 2020; Siddiqui et al., 2014) describing a significant outcome and three studies (Khalili et al., 2017; Pinheiro et al., 2010; Shibahashi et al., 2017) reported otherwise. However, despite these inconsistent findings, it can be suggested that early tracheostomy might be beneficial in minimising the chances of VAP as the incident rate was low in all studies, with an average of 33.93% compared to the late tracheostomy group (51.86%) calculated from all studies descriptively.

2.2.5.3.5 Nosocomial Infection and Antibiotic Period.

Only four studies discussed the outcome of nosocomial infection incidents and the duration of antibiotic treatment. Wang et al., (2012) reported the incident of nosocomial infection and the duration of antibiotics administered to 66 head injury patients in a tertiary trauma centre in Taiwan. The study enlisted the isolated pathogens on the patient with an early and late tracheostomy, which shows a higher trend of gram-negative pathogens growth, which were *pseudomonas aeruginosa*, *Acinetobacter baumanii*, and *Haemophilis somnus* in the late tracheostomy group (76%) compared to 25% occurrence in the early group even though the association between early tracheostomy and incident of leucocytosis was found insignificant (p=1.00). However, the duration of antibiotic treatment between these two groups was reported to be significant (p<0.001). Robba et al., (2020) reported a significant value of p=0.001 for

antibiotics used between the early and late groups. Rizk et al., (2011) only report the outcome of infection occurrence, which shows that the late tracheostomy group was about a half times more expected to have an infectious rate with $p<0.0001$.

Table 2.4: Summary of Reported Outcome Measured (ET vs LT)

Author (year)	Outcome Measured									
	In-patient							Outpatient		
	Duration on MV	**ICU LOS**	**Hospital LOS**	**Mortality rate**	**Incident of pneumonia**	**Nosocomial infection**	**Duration on antibiotic**	**Neurological outcome**	**Decannulation rate**	**Functional outcome**
Pinheiro et al., (2010)	N/A	*Mean ± SD.* 4.73 ± 2.28 vs 16.94 ± 7.68 (p<0.0001)	N/A	46% vs 65% (*p=0.044)*	54% vs 70% (p=0.44)	N/A	N/A	N/A	N/A	N/A
Rizk et al., (2011)	N/A	*OR (95% CI.* 0.23 (0.20-0.28) (p<0.0001	N/A	N/A	N/A	*OR (95% CI)* 1.52 (1.26-1.83) (p<0.0001)	N/A	3% vs 6% (p<0.0001)	N/A	43% vs 29% (p<0.0001)
Wang et al., (2012)	*Mean ± SD.* 5.1 ± 6.8 vs 5.9 ± 10.6. (p:0.58)	*Mean ± SD.* 14.9 ± 8.9 vs 22.1 ± 7.6 (p<0.0001)	*Mean ± SD.* 38.0 ± 21.4 vs 46.8 ± 22.0 (p=0.62)	N/A	44% vs 76% (p=0.04)	25% vs 24% (p=1.00)	*Mean ± SD.* 2.2 ± 3.4 vs 11.6 ± 8.7 (p<0.0001)	N/A	N/A	N/A
Alali et al. (2013)	*OR (95% CI).* 0.70 (0.66-0.75) (p<0.001)	*OR (95% CI).* 0.70 (0.66-0.75) (p<0.001)	*OR (95% CI).* 0.80 (0.74-0.86) (p<0.001)	8.4% vs 6.8% (p=0.32)	41.7% vs 52.7% (p<0.001)	N/A	N/A	N/A	N/A	N/A

Table 2.5: Summary of Reported Outcome Measured (ET vs LT) (continued)

Huang et al., (2013)	N/A	*SD (days)* 16(8) vs 29(13) (*p*=0.004)	*SD (days)* 50(30) vs 67(33) (*p*=0.15)	9% vs 15% (*p*=1.00)	N/A	N/A	N/A	*Mean (SD)* 2 (1) vs 2 (0) (*p*=1.00)	N/A	N/A
Jeon et al., (2014)	*Mean ± SD.* 4.6 ± 5.5 vs 8.0 ± 14.1 (*p*:0.05)	*Mean ± SD.* 19.9 ± 10.6 vs 31.1 ± 18.2 (*p*:0.000)	*Mean ± SD.* 70.6 ± 48.8 vs 71.6 ± 54.6 (*p*:0.743)	2.6% vs 4,6% (*p*=1.00)	7.7% vs 25.6% (*p*=0.433)	N/A	N/A	N/A	N/A	N/A
Gessler et al., (2015)	*OR (95% CI*) 0.59 (0.38-0.94) (*p*=0.02)	N/A	N/A	7.7% vs 7% (*p*=0.93)	48.7% vs 68.8% (*p*=0.03)	N/A	N/A	*OR (95% CI*) 21 (53.8) vs 98 (62.4) (*p*=0.35)	*HR (95%CI)* 0.5 (0.31-0.79) (*p*=0.003)	N/A
Siddique et al., (2016)	*days* 10 vs 13 (*p*=0.031)	*days* 11 vs 13 (*p*=0.030)	*days* 29 vs 25 (*p*=0.279)	N/A	N/A	N/A	N/A	40.8% vs 27.4% (*p*=N/A)	N/A	N/A
Baron et al., (2016)	N/A	*median (IQR)* 7 (13-14) vs 29 (19-41) (*p*<0.001)	*median (IQR)* 9 (3-17) vs 30 (22-42) (*p*<0.001)	40% vs 38% (*p*=0.86)	N/A	N/A	N/A	N/A	N/A	N/A
Khalili et al., (2017)	N/A	*Mean ± SD.* 26.79 ± 13.16 vs 34.92 ± 20.07 (*p*:0.009)	*Mean ± SD.* 38.58 ± 20.18 vs 46.40 ± 24.56 (*p*:0.048)	18.9% vs 18.2% (*p*>0.99)	52.8% vs 59.6% (*p*=0.492)	N/A	N/A	N/A	N/A	*n (%)* 20 (52.6) vs 43 (43.4) (*p*=0.346)

Table 2.6: Summary of Reported Outcome Measured (ET vs LT) (continued)

Shibahashi et al., (2017)	*n (days)* 5 (4-6) vs 8 (6-10) (*p*<0.001)	*n (days)* 10 (7-13) vs 11 (10-15) (*p=0.021)*	*n (days)* 53 (40-65) vs 57 (45-67) (*p=0.021)*	3% vs 8% (*p*=0.380)	33% vs 41% (*p*=0.51)	N/A	N/A	40% vs 39% (*p*=0.99)	N/A	N/A
Schneider et al., (2017)	n (%) 14 (26.4) vs 2 (10.5) (*p*=0.043)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	*HR (95%CI)* 1.09 (1.01-1.17) (*p*=0.021)	*mRS–median (IQR)* 5 (5-6) vs 5 (4-5) *(p<0.001)*
Qureshi et al., (2018)	*days (%)* 2 (4.2) vs 19 (39.6) (*p=0.004)*)	N/A	days (%) 0 (0) vs 17 (35.4) (*p*=0.001)	20.8% vs 64.6% (p=0.013)	6.3% vs 43.8% (*p*=0.005)	N/A	N/A	N/A	N/A	N/A
Rosyidi et al., (2018)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Alsherbini et al., (2018)	*Mean (SD)* 13.4 (9.4) vs 18.2 (8.3) (*p*=0.005)	*Mean (SD)* 15 (10-20) vs 20.5 (15.8-27) (*p*=0.002)	N/A	N/A	N/A	N/A	N/A	Poor outcome mRS (%) 36 (82%) vs 73 (76%)	N/A	N/A

Table 2.7: Summary of Reported Outcome Measured (ET vs LT) (continued)

McLaughlin et al., (2019)	*RR (95% CI)* 0.55 (0.46–0.65) (*p*=N/A)	*RR (95% CI)* 0.77 (0.63–0.93) (*p*=N/A)	*RR (95% CI)* 0.62 (0.53–0.72) (*p*=N/A)	4.1% vs 3.3% (*p*=N/A)	23.9% vs 41.4% (*p*=N/A)	N/A	N/A	N/A	N/A	N/A
Robba et al., (2020)	N/A	*Coeff. (SE)* 6.89 (1.58) (*p*<0.001)	*Coeff. (SE)* 11.45 (3.35) (*p*<0.001)	N/A	27.2% vs 39.7% (*p*=0.010)	N/A	n (%) 90.3% vs 98% (*p*=).001)	*OR (95% CI.* 1.96 (1.16-3.28) (*p*=0.006)	N/A	*OR (95% CI.* 1.69 (1.07-2.67) (*p*=0.018)

MV=mechanical ventilation, ICU=Intensive Care Unit, LOS=length of stay. mRS=modified Rankin Scale, SD=standard deviation, N/A=not applicable, OR=odd ratio, Coeff. =coefficient, SE=standard error, HR=hazard ratio

2.2.5.4 Post Discharge Outcome.

Research on post-discharge outcomes or outpatient is important among the head injury population to assess their recovery rate and quality of life. However, the study regarding tracheostomy's functional outcome and timing is quite isolated. Based on the studies included in this review, from the last decade, only four studies include the measurement of functional outcome (Khalili et al., 2017; Rizk et al., 2011; Robba et al., 2020; Schneider et al., 2017) while two studies evaluate on decannulation rate (Gessler et al., 2015; and Schneider et al., 2017) and its association with the early tracheostomy timing.

2.2.5.4.1 Decannulation Rate.

Gessler et al., (2015) reported that decannulation of tracheostomy was significantly earlier among the sample of the early tracheostomy group, with a median time of 42 days compared to 54 days in the late tracheostomy group. The multivariate analysis documented in this study found that early tracheostomy is associated with early decannulation with a p-value of 0.03. The study was performed on head injury patients with poor SAH. The other study by Schneider et al., (2017) documented a thorough investigation of the decannulation rate among stroke patients with a significant finding of p=0.021. The decannulation rate was briefly described in this study based on several characteristics, such as the type of tracheostomy approach – percutaneous or surgical approach, complications of tracheostomy during hospitalization, and other clinical conditions.

2.2.5.4.2 Functional Outcome.

Four studies reported on patients' functional outcomes after discharged from the hospital. All studies have found that early tracheostomy is associated with better functional outcomes for patients with a head injury. Khalili et al., (2017) mentioned that early tracheostomy significantly improved the patient's six-month prognosis; however, it was unfavourable among those with older age. This study was evaluated using the GOSE instrument with a score >4 deemed a favourable outcome among TBI patients. This condition is believed to have contributed to the fewer days in ICU and hospitalisation. Robba et al., (2020) also recorded that patients with late tracheostomy will have poor outcomes based on GOSE score compared to the early group with a p-

value of 0.018 and increase the day waiting for tracheostomy will increase the risk of mortality by 6% ($p<0.001$). Rizk et al., (2011) evaluated patient functional status based on the medication of Functional Independence Measure (FIM), finding that early tracheostomy group patients are likely to be functionally independent during discharge ($p<0.001$). On the other hand, Schneider et al., (2017) assessed the respondent's functional outcome at three and 12 months with the modified Rankin Scale (mRS) and Barthel Index Score. For the assessment after 12 months, the patient who had been decannulated showed functional improvement with a median (IQR) Barthel index of 35 (10-80).

2.2.6 Review Summary

This review concludes that initiating early tracheostomy significantly contributes to a good outcome, given the shorter duration of mechanical ventilation dependency and fewer days of ICU stay. However, the association between early tracheostomy, mortality rate, overall hospitalisation duration, and incident of VAP are still inconclusive. The studies included in this review show that early tracheostomy contributes to a good result for decannulation rate and functional outcomes. However, the study was limited during the last decade, especially in the Southeast Asian population. The evaluation of early tracheostomy and head injury survivors' quality of life and the post-discharge neurological outcome is also limited. The overall summary is presented in Table 2.8.1 and Table 2.8.2.

2.3 THE OUTCOMES OF HEAD INJURY

2.3.1 Prolong ICU Stay and Head Injury

The definition of a prolonged ICU stay is inconclusive. It varies in different institutions based on demographic factors, ICU type, the nature of the diseases and facilities offered in the healthcare setting. In addition, different diagnoses or reasons for ICU admission may contribute to the different interpretations of prolonged ICU stay. For instance, a study by Mahesh et al., (2012) in the United Kingdom had enlisted that a total duration of three days or more in the ICU is considered to prolong for patients who underwent

cardiac surgeries. On the other hand, the study by Moitra et al., (2016) stated that they had excluded ICU cases of post-coronary intervention or coronary care; had procured the mean of ICU stay is three to four days and length of stay of more than six days is considered to prolong.

One of the Asian countries, Taiwan, concluded that a more extended stay of more than ten days is considered prolonged in their research among spontaneous intracerebral haemorrhage patients (Chan et al., 2014). In Malaysia, according to the report by the Malaysian Registry of Intensive Care 2017, the average of patients requiring ICU care is around 4.9 days. This statistic has mostly stayed the same over the past five years, initially mentioned by Geok et al., (2015) with a mean of 4.8 days (Figure 2.2). Thus, in Malaysia, prolonged ICU stay is subjected to patients who remain in the ICU for more than 5 days. However, there was no database mentioned about the average LOS in ICU specifically on the head injury or neurosurgical patients in Malaysia.

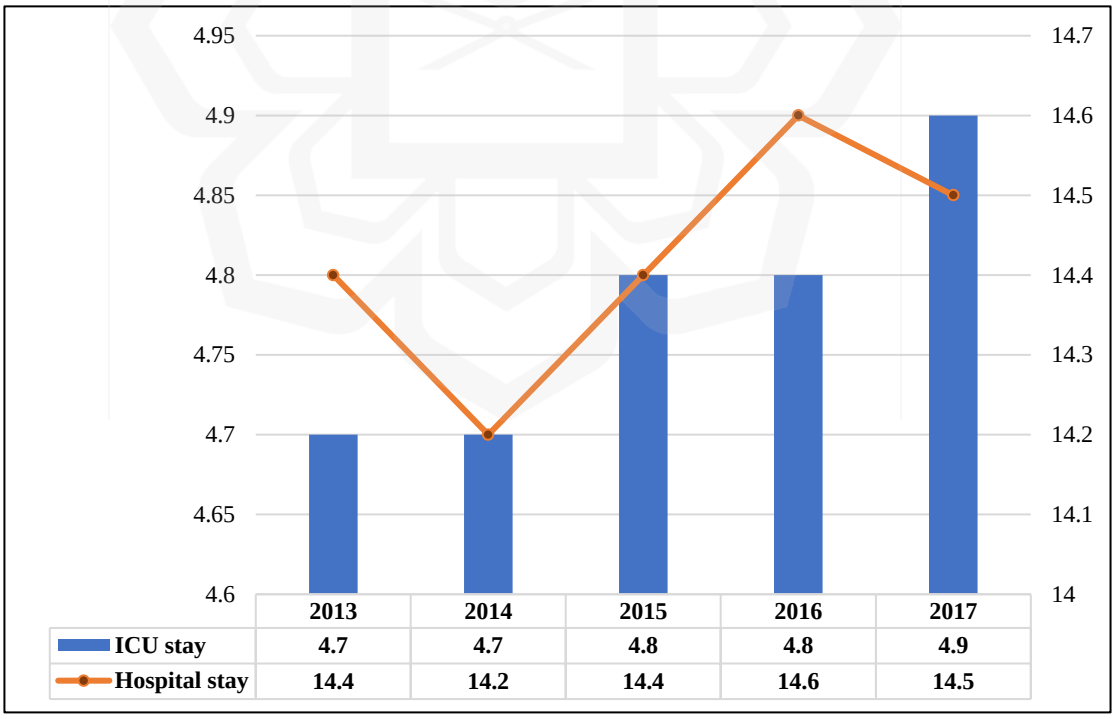


Figure 2.2: Length of Stay in ICU and Hospital (2013-2017)

A prolonged ICU stay is associated with many complications. Possible complications of ICU stay include nosocomial infections, catheter-related bloodstream infections (CRBSI) due to the usage of the central venous catheter (CVC), urinary tract infection (UTI), venous thromboembolism (VTE) and others (Klok et al., 2020; Perez & Azevedo, 2012; Parida, & Mishra, (2013). A conducive environment in ICU is essential in the early phase of treatment. At the same time, the patient is fully sedated and ventilated. However, after the patient regains consciousness and is awake, they might get depressed and fall into a delirium called "ICU psychosis" (Marks, 2021). For most patients entirely dependent on and requiring total nursing care, a few problems, such as the risks of pressure injury, accidental dislodge of medical devices, and nosocomial infection, are highly possible. The risk of pressure injury will be higher for those patients with poor skin integrity, elderly, on infusion of vasopressor and poor nutrition (Alderden et al., 2017). Secondary problems experienced by the patients due to all these possible complications may increase the cost and additional treatment. Therefore, prolonged ICU stay may contribute to additional problems for the patients which include those with head injury. Proper execution of ICU guidelines available in ICU such ventilator bundle checklist, Richmond Agitation Sedation Scale (RASS) score and Risk Assessment Pressure Ulcer Scale (RAPS) may assist in avoiding the problems listed earlier (Brummel et al., 2010; Wahlin et al., 2021; Hellyer et al; 2016).

2.3.2 Functional Outcome

Due to severely impaired cognitive function, head injury patients tend to have impaired or delayed functional outcomes. According to Wabl et al., (2018), functional outcomes are usually assessed as baseline data on the day of discharge. and They are continuously assessed on the first to third month post-discharge and continue at sixth to 12 months, 12 to 24 months, and progressively beyond 36 months post-discharge. Jennet and Bond, (1975) created an instrument to assess the functional outcome of patients following head injury and nontraumatic brain insult known as The Glasgow Outcome Scale (GOS). However, over the years, after several shortcomings of the instrument had been recognized, the instrument was improvised by Wilson et al., (1998).

Khalili et al., (2017) mention that early tracheostomy does help in improving patient functional outcomes during the three and six-months follow-up assessment

using the GOS instrument. On the other hand, Rizk et al., (2011) found that early tracheostomy patients have higher chances of being 1.5 times more likely to be functionally independent before discharge than those with a late tracheostomy. A recent study by Robba et al., (2020) also reported that head injury patients with early tracheostomy would have a better functional outcome based on the GOSE scales. Patients with late tracheostomy would end up otherwise.

According to a meta-analysis report by Arulsamy and Shaikh (2020), most researchers in Malaysia focus on the study of the functional outcome for post-TBI patients using the instrument of GCS, GOS, GOSE, and monitoring of electroencephalography. The analysis documented that past studies have assessed the functional outcome of head injury patient, but, none of them involve in determining the impact of tracheostomy toward the patient's functional outcome. Recent studies on functional outcome assessment include evaluating gait performance, memory processing, cognitive function, neuropsychological performance, and mental health status (Arulsamy & Shaikh, 2020).

2.3.3 Quality of Life

According to Jenkinson (2016), quality of life is when individuals experience good health and are comfortable and able to participate in various activities or life events. The World Health Organization Quality of Life Assessment (1998) defined quality of life as a broad multidimensional perception that includes both positive and negative aspects of life based on subjective evaluations. Individuals suffering from head injury have a higher probability of having a permanent disability or delayed recovery of functional outcomes (Corrigan & Hammond, 2013). Gaddam et al., (2015) mentioned that as the brain plays a significant part in signaling other body parts to function, the injury to the brain will compromise its ability to do that normally. This distressing condition will affect the quality of life of the individual with a head injury, especially in moderate to severe head injury.

Assessing health-related quality of life is vital for patients with a head injury to meet their best possible recovery point. Morbidity rates among head injury patients can be assessed through multiple reliable constructed instruments to assess the severity of disabilities experienced by them. Instruments such as the Extended Glasgow Outcome

Scale (GOSE), Disability Rating Scale (DRS), Quality of Life After Brain Injury (QoLIBRI), Functional Independence Measure (FIM) and Functional Status Examination (FSE) (Nichol et al., 2011). Ghroubi et al., (2016) reported that memory deficit was the main predictor leading to declining quality of life among TBI patients and efforts on neurorehabilitation should be optimized. A study by Vieira et al., (2013) disclosed that despite the injuries lead to irreversible disabilities, the finding still shows that head injury patients had a positive perception of their quality of life. On the other hand, a study by Helene et al., (2013) shows that patient with head injury reflects low self-satisfaction, motivation, and self-esteem 12 months post-injury.

2.3.4 Rehabilitation Motivation and Compliance

One of the significant concerns for patients with a head injury who survive the critical phase is their physical ability to perform daily activities during their recovery period. Early rehabilitation is crucial for this vulnerable group to ensure they can meet the complete physical they could have after the head injury event. Multiple neurorehabilitation programs are available for head injury patients: occupational therapy, rehabilitation psychology, speech and swallowing therapy, vision therapy and language therapy (De Fina et al., 2010; Krucoff et al., 2016). Patients may require a different type of rehabilitation program according to the severity and type of disability they experience. Neurorehabilitation will be separated into two phases: in-hospital and community rehabilitation after the patients are discharged.

With assistance and advice from a physiotherapist, the attending physician will construct the best rehabilitation program for the patient accordingly. For example, Bailey et al., (2007) and Hodgson et al., (2014) mentioned that early rehabilitation that consists of out-of-bed exercise is safe for the patient with ETT. However, Harrold et al., (2015) reported that although the ETT was not contraindicated for this group of patients, the practice of it was lacking, and the healthcare practitioner preferred to wait until tracheostomy in-situ before initiating those rehabilitation programs. As Mallick and Bodenham, (2010) mentioned, the tracheostomy will improve patient comfort, easier suction and oral care which provide a better cooperation from the patients for the rehabilitation activities such as chest physiotherapy and suctioning.

Sutt et al., (2020) reported that early initiation of tracheostomy significantly leads to better efficiency of the rehabilitation program. The patient will be able to communicate and perform out-of-bed exercises earlier than those who do not have tracheostomy or delayed tracheostomy. In addition, as mentioned, a patient with an early tracheostomy will likely be discontinued sedation and analgesic administration. This condition may reduce the risk of delirium, post-traumatic disorder and ICU psychosis and promote better rehabilitation compliance among the patient with head injury (Jackson et al., 2014).

2.3.5 Nursing Role and Responsibility

High-quality nursing care is required to prevent any misfortunate events during the patient's recovery period, including managing head injury patients. However, misfortunate events might still occur due to factors such as prolonged ICU stay and ventilation. Thus, this will lead to severe risks of hospital-acquired pneumonia (HAP), the incidence of VAP, surgical site infection (SSI), and meningitis in the ICU. As mentioned by Kelly et al., (2013), nurses' working environments have been linked to unfortunate situations such as the rising incidence of HAP and VAP. A study by Kourbeti et al., (2015) emphasised that VAP with isolated *Acinetobacter baumanii*. is the most frequent infection developed and transmitted among craniotomy patients and pathogens such as Klebsiella pneumoniae. and Pseudomonas aeruginosa were exhibited higher resistance to several antibiotic groups. Papakonstantinou et al. (2012) mentioned that cross-transmission of microorganisms, mainly in the ICU, spread by colonising the hands of healthcare practitioners, especially when the glove used was not changed. Therefore, nurses who are 24 hours with the patients play a vital role in reducing the risk of cross-infection and VAP (Costa et al., 2016). However, past studies have documented that the nurses' awareness and performance were not up to the optimum level to prevent the incident of HAP and VAP (Aeen et al., 2013). Therefore, despite any approaches to promote the patient's better prognosis, the nurses' awareness and ability to adhere to the high quality of nursing care is one the vital aspects.

Nurses play a vital role as team members to the physician, surgeon or anaesthetist to advise and recommend appropriate interventions toward the care plan to the patients as they may have more information about them (Nagpal et al., 2010). This

is because nurses are the task force that stays with the patient 24 hours and obtains all kinds of information regarding the patient's progress every second (Ramadanov et al., 2020). Nurses input, especially during ward rounds, will be crucial and beneficial for further treatment of the patients, which may also contribute to the decision to initiate tracheostomy.

Nurses are the leading front liners in managing and caring for patients and often become primary witnesses for any chance of deterioration and improvement of the patient. Continuous assessment and discussion among the team members should be more comprehensive than the surgeon and anaesthetist. The team is also comprised of other healthcare practitioners, such as nurses and allied health practitioners, who work passionately hand in hand to make the wisest and faster judgment for the patient, and that includes the decision of whether to do or not to proceed with an early tracheostomy (Bonvento et al., 2017).

Nursing care for patients with tracheostomy and endotracheal tube are crucial to prevent complications such as tube obstruction, bleeding and accidental dislodge and infection (Alotaibi et al., 2022; Sodhi et al., 2014). However, compared to tracheostomy, the management of the patient with an endotracheal tube requires nurses working in the ICU as the patient usually requires the assistance of a mechanical ventilation device (Robba et al., 2021). While on the other hand, tracheostomy care is typically manageable by all qualified registered nurses from all departments, such as the general ward or critical care department, provided they have been appropriately trained and confident to perform it proficiently (Gaterega et al., 2021; Sardesai et al., 2016). The patient who has been tracheostomized will get good nursing care from departments or wards in the hospital from any nurses. Therefore, all nurses must obtain a high level of knowledge and practice in tracheostomy care to prevent any complications for the patient.

2.3.6 Sustainable Development Goals (SDGs)

Since its initiation during the United Nations Conference 2012 in Rio de Janeiro, the Sustainable Development Goals (SDGs) were adopted by all United Member States in 2015 (Department of Statistic Malaysia, 2020). This move replaced Millennium Development Goals (MDGs) that began in 2000 to fight poverty. MDGs' effort,

consisting of eight goals and 21 goal targets, was extended to 17 and 169 targets in the SDGs plan to be achieved by 2030. Malaysia has been involved in this development goal since late 2014, and the Department of Statistics, Malaysia, had agreed to organize the data collection in July 2015. According to the United Nations Development Programme (2020) statistic, every two seconds, one individual between the age of 30 to 70 dies due to a non-communicable disease.

There are seventeen 17 items included in the Malaysian Sustainable Development Goals (SDG) National Review 2017. This plan was developed to ensure that all manhood can live in harmony and prosperity toward the end of the next decade. Currently, only 9.1% Malaysian population aged above 60 years old was recorded in 2015, and the statistic is expected to rise to 15% of the population by 2030. The SDGs plan was engaged with the Ministry of Health in 2016, and one of the goal components included is Goal 3: Good health and well-being to ensure healthy lives and promote well-being for all ages. In Malaysia, 109 163 individuals were reported deceased in 2018. Figure 2.3 portrays the five principal causes of death in Malaysia, with 15.6% of them due to ischemic heart diseases followed by pneumonia (11.8%), cerebrovascular (CVA) diseases (7.8%) and 3.7% due to road-traffic collision (Statistic on Cause of Death, 2020).

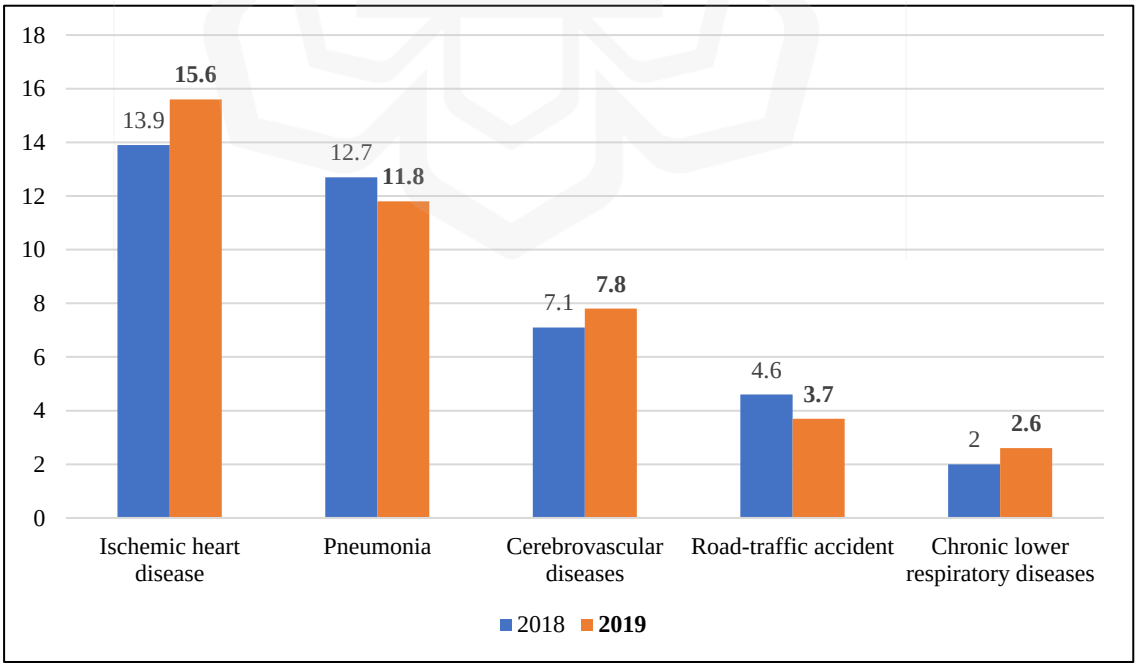


Figure 2.3: Five Principal Cause of Death in Malaysia (2018-2019)

The CVA and road traffic collisions often lead to the individual suffering from a head injury, and this statistic correlates with the common diagnoses leading to ICU admission. Recent statistics in 2017 recorded that head injury is the second most typical reason for ICU admission. One of the critical success factors under the SDGs Goal 3 is to provide adequate public and private investments in healthcare to cater to rising demand in recent days. One of the priorities is to achieve a cost-effective healthcare system (Malaysia Sustainable Development Goals Voluntary National Review, 2017).

Malaysia aims to improve the delivery of healthcare services to establish an excellent public healthcare system accessible even in rural and remote areas, especially to vulnerable groups such as unfortunate citizens with financial constraints, individuals with disabilities, and the elderly. In corresponding to technological advancement in healthcare facilities and improvement of healthcare practitioner services provided, the aim of SDGs to achieve 15% of the population above the age of 60 compared to 9.1% population in 2015 will be significant to be achieved. Suppose the impact of early tracheostomy benefits the patients with severe head injury functional outcome, quality of life and motivation toward rehabilitation. In that case, their prognosis will be much better, reducing the chance of mortality cases and improving community health services satisfaction. For instance, if the early tracheostomy approach contributes to a lesser day required for mechanical ventilation support and length of stay in the ICU and hospital for patients with a severe head injury, the facilities can be readily accessible and available for the use of other patients as well.

2.4 THEORETICAL AND CONCEPTUAL FRAMEWORK

2.4.1 THEORETICAL FRAMEWORK UNDERPINNING THE STUDY

Head injury is an unfortunate condition contributing to a high mortality risk and long-term disability. Even though the acute management for the patient with a head injury has improved over the years, most patients still have some degree of disability affecting their cognitive, psychological, and physical function (Faul & Coronado, 2015). Therefore, this vulnerable group should be supported with an appropriate plan of care

to assist them in adapting to the activity of daily living after the injury following their recent ability.

World Health Organization (WHO) introduced the framework of the Internal Classification of Functioning, Disability and Health (ICF) in 2001, with the approval of 191 WHO members during the 54th World Health Assembly (WHO, 2016). It is a multipurpose classification created to assist various disciplines and different areas. The outline concept of ICF will be adapted as the theoretical framework in this study as ICF explains the conceptual basis for the definition, measurement, and policy formulations for health and disability. Furthermore, the notion of ICF focuses on health and functioning rather than disabilities by providing an incorporated and standard language and framework for explaining health and health-related states. It changed the perception of the "consequences of disease" classification by highlighting the individual disabilities following an unfortunate health problem toward the "component of health" classification by determining the individual's level of health (Sykes, 2006)

The concept of ICF is used in this study as a research tool to measure outcomes, quality of life, and environmental factors and assess the impact of a specific treatment approach. The study intended to measure the impact of early and late tracheostomy initiation among severe head injury patients on their functional outcome, quality of life, and motivation toward rehabilitation. The scope of ICF is contemplating into two main components, which are (1) Functioning and Disability and (2) Contextual Factors. As shown in Figure 2.4, the component of Functioning and Disability consists of body function and structures, activities, and participants. On the other hand, Contextual Factors comprise environmental and personal factors (Cieza et al., 2018).

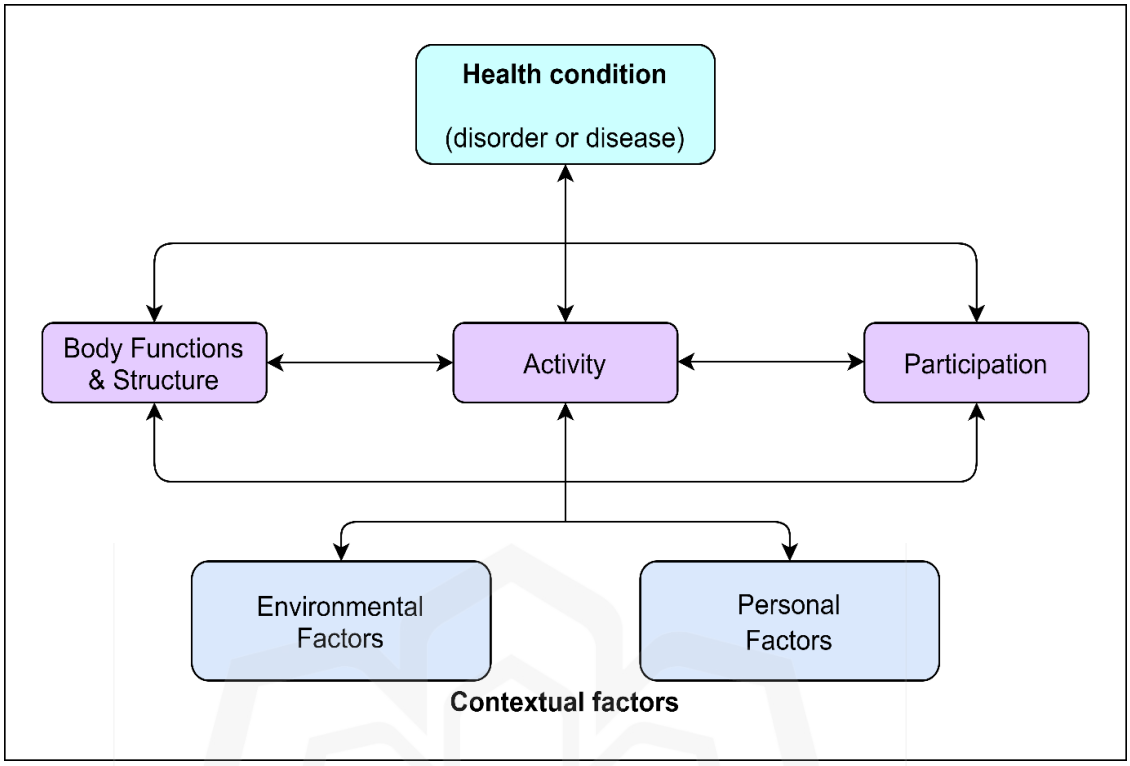


Figure 2.4: Interaction Between ICF Components (Sykes, 2006).

Figure 2.4 also explains the ICF disability and functioning as the outcomes of interactions between health conditions and contextual factors. Body function and body structures are categorised into two different sections but designed to correspond to each other. For instance, the body structure may refer to upper and lower limbs, and it will be related to the body function of the musculoskeletal ability to move. Activity is the action by the individual to perform or complete a task in any daily life situation whereby the term of activity limitation is subjected to any obstacles, restrictions, or difficulties faced by the individual to perform the task or activity. Participation refers to the individual involved in a life situation, whereby participation restriction refers to the problems or difficulties they may experience in a life situation. This condition will be determined by comparing the ability of the individual with a disability to participate with those without a disability in society.

In this study, the health condition discussed is a head injury that affects body structure and functions. Personal factors include the sociodemographic data of each patient, such as age, gender, race, and level of education. In contrast, the environmental factor includes family involvement and community support, social interaction, and

availability of assistive devices and facilities (Sykes, 2006). Environmental factors will interact with the components of Body Structure and Function, Activity, and Participation. A head injury contributes to various types of disability, and the patient suffering from a head injury needs a different adaptation from one patient to another.

Patients may need different needs and abilities, requiring a different assistive device or approach (Kesselring et al., 2008). For example, a patient with a head injury may experience permanent paralysis of paraplegia that requires an assistive device such as a wheelchair to move around; however, in a similar case, other patients with head injury may only be affected with monoplegia with one limb disability that requires the assistance of crutches or walking frame. In addition, some patients at an early age may require assistance in occupational therapy. In contrast, those in old age may only require the ability to perform basic ADL to involve the community. Gray and Hendershot (2000) explained that the environmental factor such as family support, accessible communities, transportation, and supportive attitude of communities would help them to engage in and experience the activity similar to other people. This involvement may allow the patient to improve their functional outcome to be more active and independent.

2.4.2 CONCEPTUAL FRAMEWORK

The conceptual framework for this study is explained in Figure 2.5. This study focused on patients who suffer from severe head injury that undergo tracheostomy intervention. The socio-demographic data of the patients that will be recorded include the patient's age, gender, GCS on the admission, location, and type of head injury. The patient selected in this study will undergo tracheostomy intervention and classified into two groups that differ in the timing of the tracheostomy initiated: early tracheostomy and late tracheostomy.

The impact of early and late tracheostomy was evaluated on the patients in two conditions: primary outcome – during hospitalisation as the in-patient and secondary outcome – after discharge as the out-patient. The first outcome or impact includes days spent in the ICU, duration of mechanical ventilator support, the incidence of VAP, final GCS before they had been discharged, decannulation, and mortality rate. Secondary

impact includes the functional outcome, quality of life, and compliance rate toward the rehabilitation program. On the other hand, the relationship between the primary (clinical outcomes) and secondary outcomes (functional outcomes, health-related quality of life, and motivation toward rehabilitation) was also evaluated.

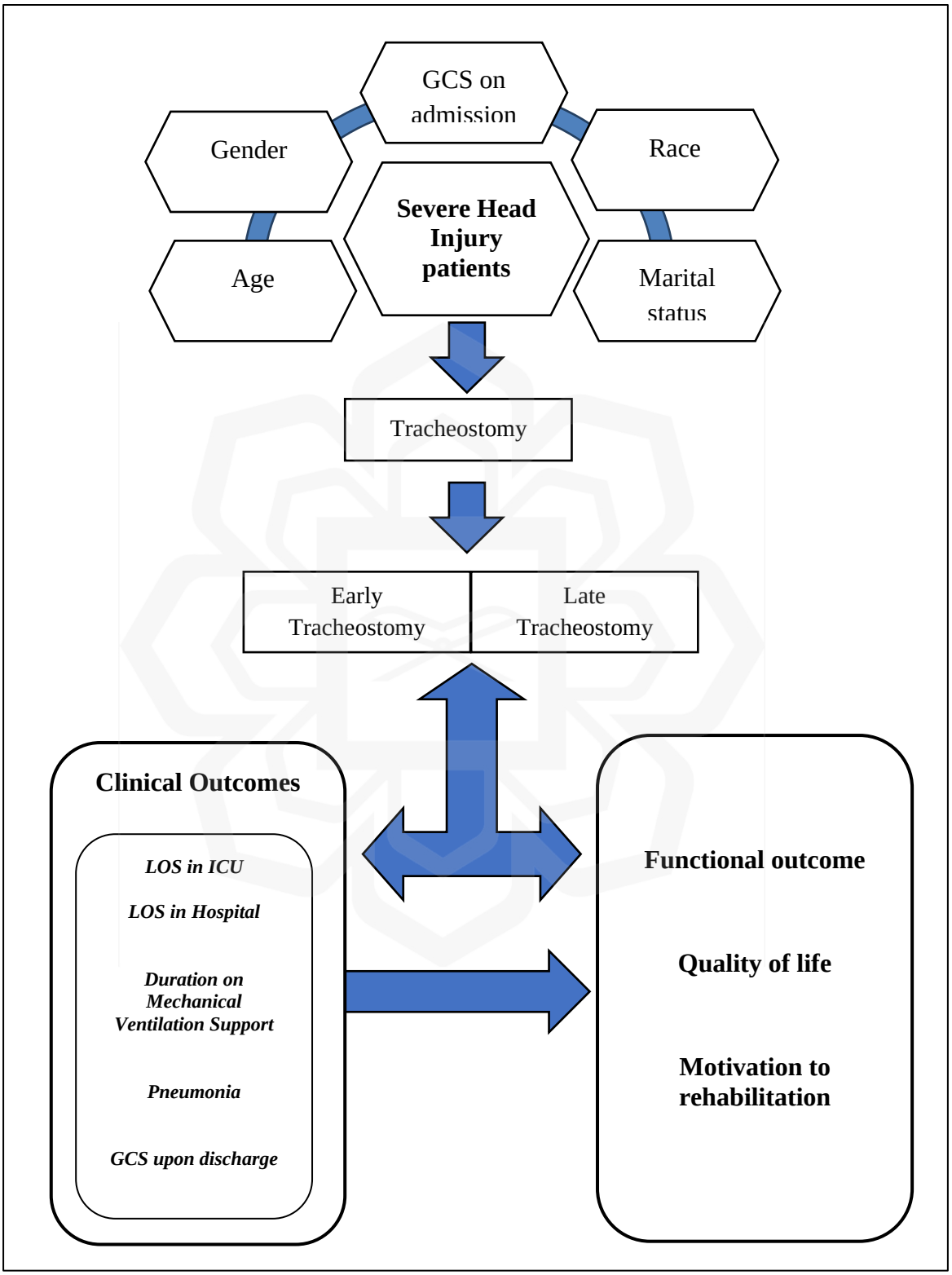


Figure 2.5: Research Conceptual Framework

CHAPTER THREE

RESEARCH METHODOLOGY

3.0 INTRODUCTION

The justification for the methodologies that were used in this study will be discussed in this chapter. The first section introduces the type of study approach, which was a quantitative study approach. Followed by the study design, study setting, population, sampling method, study instruments, and statistical analyses used in this study. Further, this chapter also describes the inclusion and exclusion criteria of the study participants. Finally, the research's ethical considerations are described.

3.1 APPROACH OF THE STUDY

This study applied a quantitative approach of a non-experimental observational cohort study approach. Quantitative research is a technique for collecting data that can be numerically examined and reported. According to Goertzen, (2017), quantitative research uses numbers to analyse information, and the results can be estimated using statistical analysis, where it is possible for the researcher to summarise, generalise, and compare the outcomes. Quantitative research allows researchers to systematically measure variables and test hypotheses by using numbers to analyze the data. In contrast, qualitative research allows researchers to explore concepts and experiences in more detail (Goertzen, 2017).

There are two forms of quantitative research – experimental design and non-experimental design. Due to the nature of the study population and the goal of the study, which was to examine the effects of early tracheostomy on patients with severe head injuries, the researcher decided to use a quantitative approach of a non-experimental observational cohort study design. The researcher will act as an observer and no treatment or manipulation will be performed. This is in contrast to experimental designs,

in which the independent variable is used to control the dependent variable (Frey, 2018). This study aimed to understand the impact of early tracheostomy on the severe head injury patient's functional outcome, quality of life, and rehabilitation motivation. This helped to reduce many uncertainties and make quantitative techniques less subjected to bias by producing objective data and ultimately allowing future research to move forward toward potential solutions with more assurance.

3.2 STUDY DESIGN

The research design can be portrayed as the composition of research that binds all the elements needed in the research process to guide the researcher to answer all the research questions accordingly with great credibility and to handle any encounters arising from the study (Polit & Beck, 2021). Akhtar, (2016) mentioned that research design conveys the concept within the study and includes a blueprint for ~~the~~ data collection, measurement, and analysis. A research design should be constructed once the topic and the problem statement of the study have been identified and formulated and the hypotheses have been appropriately assembled. According to Rothman & Lash (2020), there are four (4) types of observational study design: cross-sectional, case control, cohort, and ecological. This study utilised retrospective observational cohort study design.

3.2.1 Retrospective Observational Cohort Study Design

This study design will allow the researcher to evaluate the association between exposure and outcome for a specific population or group of individuals (a cohort) (MacGill, 2018). The study may be prospective, wherein the examination is conducted by studying the sample population after they have been exposed to a particular element, to examine the outcome beginning now and moving forward. Alternatively, it might be retrospective, with the difference being that the exposure was recorded after the outcome (Akhtar, 2016). According to Rothman and Lash (2020), cohort study designs will yield the highest degree of evidence possible from observational data. Figure 3.1 summarises the direction of the prospective and retrospective approaches in cohort

research design, while Table 3.1 describes the advantages and limitations of this study design.

Table 3.1: Observational Study Design.

Advantages	Disadvantages
i. Exposure is determined before the outcome. ii. Samples can be included in the cohort before having the outcome of interest. iii. Several outcomes can be studied for each exposure. iv. The incidence of outcome can be calculated.	i. Costly and time-consuming ii. Inefficient for atypical diseases with long dormancy. iii. High possibility of attrition rate. iv. Potential of internal validity issue in view of secondary data use. v. Changes in exposure and outcome descriptions over the years.

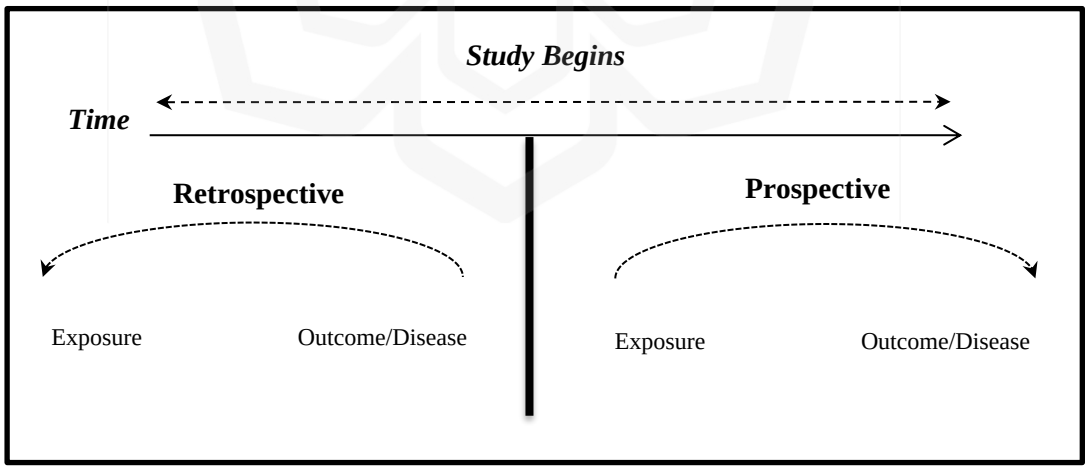


Figure 3.1: Timeline of Prospective and Retrospective Cohort Study Design

This study applied the retrospective observational cohort study design. According to MacGill (2018), a cohort study allows the researcher to establish a causal

relationship between exposure and outcome for a specific population or group of individuals. Therefore, the cohort study design used in this study is most suitable for determining the impact/relationship of early tracheostomy on severe head injury patients toward its outcome. This study consisted of two stages of data collection, as portrayed in Figure 3.2. The first stage took place after ethical approval from related authorities had been acquired and involved data collection on participants' sociodemographic data and clinical outcomes, which includes the information on participant's final GCS score before discharge, length of stay in ICU and hospital, duration of mechanical ventilation support, SOFA and SAPS II scores, the incident of pneumonia and decannulation rate. In this stage, the patients' GOSE, QoLIBRI, and MoT-Q scores were assessed. The second stage involved a follow-up reassessment of participants' GOSE score, QoLIBRI score and MoT-Q scores at three (3) and six (6) months post-discharge.

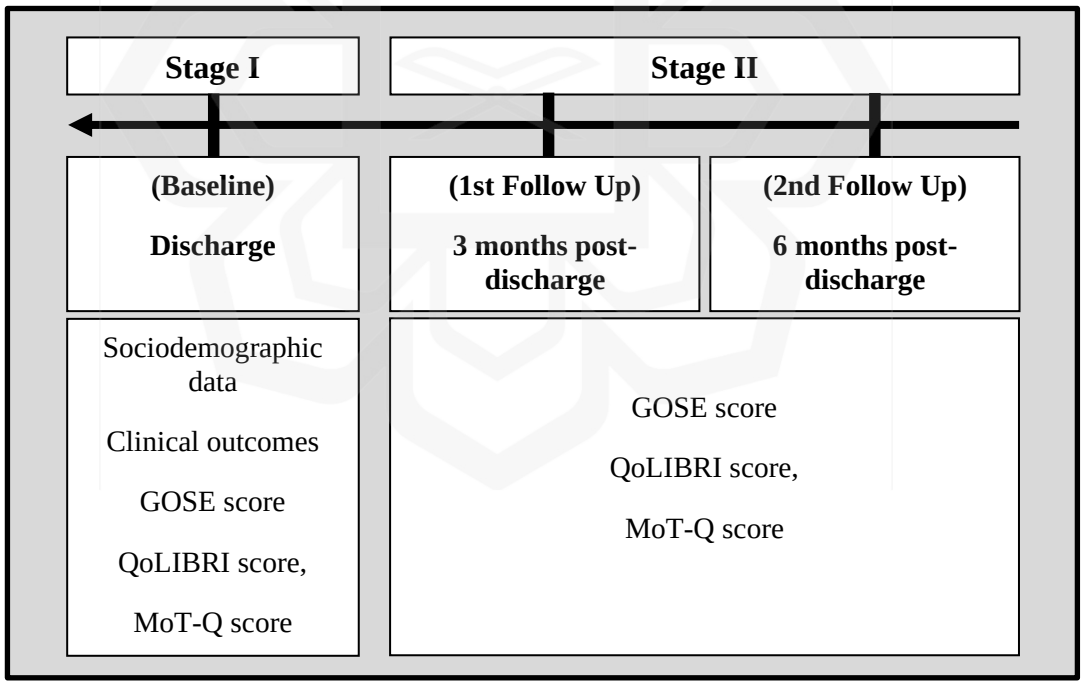


Figure 3.2: Stages of Data Collection

3.3 STUDY SETTING

This study was conducted at tertiary hospitals, which are the University of Malaya Medical Centre (UMMC) and Hospital Kuala Lumpur (HKL). Apart from that, these two hospitals were chosen because: (1) The Department of Neurosurgery in Hospital Kuala Lumpur is the largest in the nation and serves as the National Referral Centre (Abdullah et al., 2016). This facility is in the capital state of Malaysia, where generally, most neurosurgical cases will be referred to for further intervention and management. In addition, HKL is established as the leading Neurosurgical Centre, which is directly involved in the formulation of national policies concerning patient care, education, and research. Currently, HKL is the largest tertiary hospital under the Ministry of Health of Malaysia. (2) While University Malaya Medical Centre (UMMC) is also chosen as it is one of the healthcare facilities in Malaysia that provides advanced neurosurgical facilities and established services of sub-specialized in the respective areas of neurosurgery, including skull base and pituitary, paediatric, endoscopic, vascular, epilepsy, radiosurgery, and functional neurosurgery (UMMC, 2020). This hospital is one of the centres in Malaysia equipped with intraoperative magnetic resonance imaging (MRI) machines used in cranial surgery to ensure sufficient resection of tumours safely.

3.4 STUDY POPULATION AND SAMPLING

3.4.1 Study Population

The study population was patients with severe head injuries who underwent tracheostomy. These severe head injury patients were recruited based on their admission history to the Neurosurgical ICU of the UMMC and HKL within one year from January until December 2021.

3.4.2 Targeted Sample

This study listed the severe head injury patients with the initiation of tracheostomy that fulfill the inclusion and exclusion criteria as the targeted sample to participate in this study. For the participants who were unable to complete the questionnaire by themselves due to certain conditions that limited their participation; they were assisted

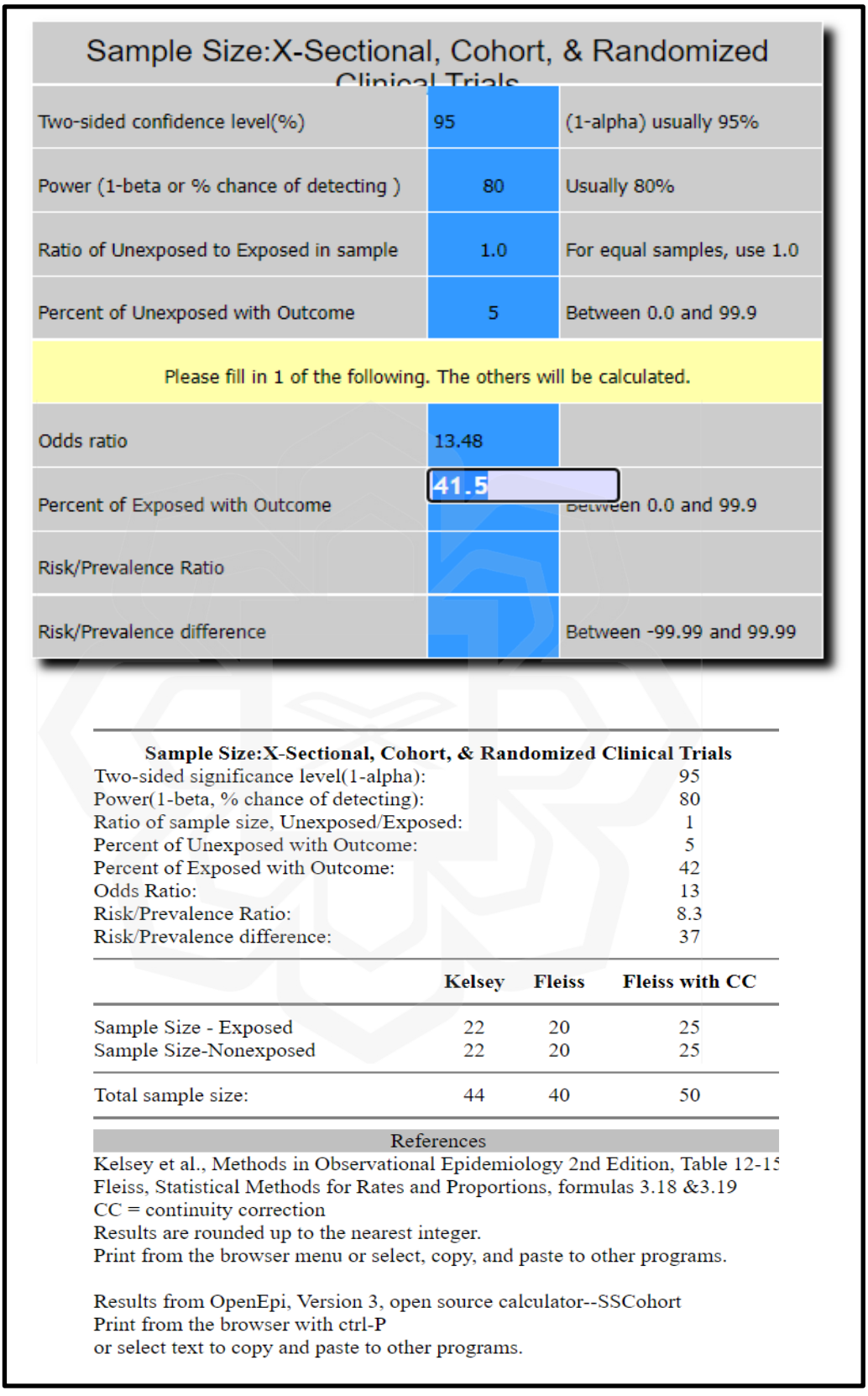
by their proxy to complete the questionnaire. According to Cusick et al., (2000), whenever the participant of the study is allowed to choose their proxy, participant-proxy dependability is sufficient to justify the use of proxies in TBI outcomes. Hart et al. (2010) also emphasised that the implementation of participant proxy reports is acceptable, particularly with regard to the outcomes of productivity and community activities. Thus, in this study the participant-proxy approach was applied to those participants with certain limitations, such as those in a vegetative state, or unfit to respond to the questionnaire by themselves.

3.4.3 Sampling Method

The sampling method applied in this study was the convenience sampling method. Random selection was not possible due to the nature of the study population in the study setting. It was noticeable through the records, patients with severe head injuries who underwent tracheostomy were in small numbers. Given the time constraint and the small number of patients with severe head injuries who underwent tracheostomy a random selection was impossible to apply.

3.4.4 Sample and Sampling Size

The sample size was established based on each research objective. Figure 3.3 depicts the sample size calculation using the Open-Source Epidemiologic Statistics for Public Health (OpenEpi) software (OpenEpi, 2013). The determination of the sample size is detailed in Table 3.2. Following the computation, the recommended first sample size was 50 individuals. After considering all the research objectives and assuming a 40% attrition rate, the required sample size for this study was 70 patients with severe head injuries who underwent tracheostomy. An attrition rate of 40% was applied in this study, considering the probability of dropping out among the participants until the end of the data collection. Death within 90 days of discharge, revocation of the agreement to participate in the middle of the data collection period, failure to appoint a qualified proxy for a participant who is unable to answer the questionnaire, old age, loss of contact, and others may contribute to the dropouts (Agogo et al., 2018; Burket et al., 2019; & Ritchter et al., 2020)



Sample Size:X-Sectional, Cohort, & Randomized Clinical Trials

Two-sided confidence level(%)	95	(1-alpha) usually 95%
Power (1-beta or % chance of detecting)	80	Usually 80%
Ratio of Unexposed to Exposed in sample	1.0	For equal samples, use 1.0
Percent of Unexposed with Outcome	5	Between 0.0 and 99.9
Please fill in 1 of the following. The others will be calculated.		
Odds ratio	13.48	
Percent of Exposed with Outcome	41.5	Between 0.0 and 99.9
Risk/Prevalence Ratio		
Risk/Prevalence difference		Between -99.99 and 99.99

Sample Size:X-Sectional, Cohort, & Randomized Clinical Trials

Two-sided significance level(1-alpha):	95
Power(1-beta, % chance of detecting):	80
Ratio of sample size, Unexposed/Exposed:	1
Percent of Unexposed with Outcome:	5
Percent of Exposed with Outcome:	42
Odds Ratio:	13
Risk/Prevalence Ratio:	8.3
Risk/Prevalence difference:	37

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	22	20	25
Sample Size-Nonexposed	22	20	25
Total sample size:	44	40	50

References

Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15
Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19
CC = continuity correction
Results are rounded up to the nearest integer.
Print from the browser menu or select, copy, and paste to other programs.

Results from OpenEpi, Version 3, open source calculator--SSCohort
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Figure 3.3: Sample size calculation using the OpenEpi software (*OpenEpi*, 2013)

Table 3.2: Sample Size calculation

No.	Objective	Reference previous study	Parameter estimation	Estimated sample size	Inflate %	Desired sample size
1.	To determine the incidence proportion of early and late tracheostomy among severe head injury patients.	Robba et al., (2020)	Prevalence of patients with early tracheostomy (< 7 days): 41.5%	50	40	70
2.	To determine the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.	Ludin et al., (2018)	TBI patients with good recovery (GOSE >6): 48.5%	40	40	56
3.	To determine the association between early and late tracheostomy and the sociodemographic characteristics and clinical outcomes of severe head injury patients.	Alsherbini et al., (2019)	Male respondents with early tracheostomy done: 55%	32	40	45
4.	To determine the association between early and late tracheostomy with the functional outcome, quality of life and rehabilitation motivation among severe head injury patients.	Khalili et al., (2017)	Favourable functional outcome 6-months after discharge, mortality rate and incidence of VAP for early tracheostomy patients: 52.8%	34	40	48

3.5 INCLUSION AND EXCLUSION CRITERIA

3.5.1 Inclusion Criteria

i. Diagnosed with a head injury and admitted or nursed in the ICU.

ii. Age of 18 years old and above.

iii. Had been intubated and ventilated with mechanical ventilator support on the day of admission.

iv. Proceed with tracheostomy during the same admission.

v. Understand English and/or Malay.

3.5.2 Exclusion Criteria

i. Experience a cardiorespiratory arrest event upon admission to the hospital as those with cardiorespiratory arrest event have a higher risk of mortality rate.

ii. Presented with an underlying pulmonary issue before admission to the hospital such as posterior fossa injury, cervical and spine injury as those with this comorbidity have a higher risk of difficult extubation and permanent defendant on mechanical ventilator support.

iii. Presented with multiple trauma and cervical spine injury cases as these patients will have comorbidity such as hypovolemic shock and respiratory failure.

iv. Dead within the 72-hours after admission, which leads to less valuable and limited data collection for further analysis.

v. Referral case from another facility with intubation done earlier as these patients may have inadequate information from their previous hospital.

3.6 VARIABLES

3.6.1 Independent Variables

i) ***Age***

The measurement of the length of time of the participants from the day he/she was born until the present time of the study's recruitment.

ii) ***Gender***

Referring to the participant's sexes of being male or female.

iii) ***Race***

Referring to the participant's ethnicity or self-identification of their social group which comes with a variety such as Malay, Indian, Chinese and others.

iv) ***Marital status***

Referring to the participant's current relationship status of marriage at the recruitment process whether they are single, married or widowed.

v) ***GCS on admission***

Referring to the Glasgow Coma Scale score of the participants assessed during the admission.

vi) ***Tracheostomy classification***

Refer to the timing of tracheostomy was done from the day of endotracheal intubation which is early and late tracheostomy. The early and late tracheostomy was determined on the cut-off time of seven (7) days which indicates <7 days for early tracheostomy and $\geq$7 days indicates late tracheostomy (Carney et al., 2016; Robba et al., 2020).

3.6.2 Dependent Variables

i. ***Clinical outcomes***

The clinical outcomes are also known as the primary outcome for each participant, consist of several measurements, including their length of stay in the ICU and hospital, the duration of mechanical ventilation support given, the incidence of pneumonia, final GCS score upon discharge and their success to be decannulated from the tracheostomy. Inclusive of all these clinical outcomes, the participant's SOFA score and SAPS II score also had been included in the analysis to evaluate the risk of mortality.

ii. ***Functional outcomes***

The participant's functional outcome was measured using the GOSE instrument at three different periods – discharge, three-months post-discharge and six-months post-discharge.

iii. ***Quality of life***

The participant's quality of life was measured using the QoLIBRI instrument at three different periods – discharge, three-months post-discharge and six-months post-discharged.

iv. ***Rehabilitation motivation***

The participant's motivation toward rehabilitation was measured using the MoT-Q instrument at three different periods – discharge, three-months post-discharge and six-months post-discharged

3.6.3 Operational Definition and Coding

The operational definitions and coding of each variable are provided in Table 3.3 below:

Table 3.3: Operational definitions and coding of variables

Variables		Operational definition	Coding
Sociodemographic characteristics	Age	Age (in years) of the participant at the time of recruitment in the year.	NA
	Gender	Refer to the sex's identity (male or female) of the participants.	1: Male 2: Female
	Race	Refer to the primary races/ethnicity groups in Malaysia. During the analysis, it was dichotomous into Malay and non-Malay due to the small number of non-Malay participants (Chinese and Indian).	1: Malay 2: Chinese 3: Indian
	Marital status	Categorized into single, married and widowed. During the analysis, it was dichotomous into Married and Single/Widowed.	1: Single 2: Married 3: Widow
Sociodemographic characteristics	Tracheostomy classification	Refer to the timing of the tracheostomy was done from the day of endotracheal intubation which is early and late tracheostomy. The early and late tracheostomy was determined on the cut-off time of 7 days which indicates <7 days for early tracheostomy and 7 days indicates late tracheostomy (Carney et al., 2016; Robba et al., 2020).	1: Early tracheostomy 2: Late tracheostomy

Table 3.3: Operational definition and coding of variables (continued)

Variables		Operational definition	Coding
	GCS on admission	Refer to the Glasgow Coma Scale of the participant on the day of hospital admission, treated as a continuous variable.	NA
	SAPS II score	Refer to the SAPS II score calculation of the participant to predict the severity of the disease during the first 24 hours of admission to the ICU, treated as a continuous variable.	NA
	Length of stay (LOS) in ICU	Refer to the duration (number of days) of the participant in the ICU from the day of admission until he/she is transferred to the normal ward, treated as a continuous variable.	NA
Clinical outcome	Length of stay (LOS) in the hospital	Refer to the duration (number of days) of the participant in the hospital from the day of admission to ICU until he/she had been discharged from the hospital, treated as a continuous variable.	NA
	Duration of mechanical ventilation (MV)	Indicates the number of days of the participant's dependency on the mechanical ventilation device, treated as a continuous variable.	NA
	Final GCS upon discharge	Refer to the Glasgow Coma Scale of the participant during the day they had been discharged home from the hospital, treated as a continuous variable.	NA
	Decannulation	Inferred to the condition whereby the participant’s tracheostomy-was removed or decannulated without reinsertion of new tracheostomy.	0: no decannulation 1: decannulation done

Table 3.3: Operational definition and coding of variables (continued)

Variables		Operational definition	Coding
	Incidence of pneumonia	Refer to the prevalence of pneumonia that had been experienced by the participants during their hospital stay diagnosed by the field expertise such as physician/surgeon/anaesthetist in charge of the participants.	0: No incidence of pneumonia 1: Incidence of pneumonia
Functional outcome	GOSE score	Refer to the score to categorize the participant's functional outcome (refer to sub-section 3.8.2). The eight domains of the GOSE score had been interpreted into two categorical outcomes – good and poor recovery.	1: Poor recovery 2: good recovery
Quality of life	QoLIBRI score	Refer to the score to categorize the participant's quality of life (refer to sub-section 3.8.3). The seven domains of the QoLIBRI score had been categorized into four interpretations.	1: Above normal 2: Normal 3: Borderline 4: Impaired
Rehabilitation motivation	MoT-Q score	Refer to the total amount of four different sub-scales of the instrument to measure the level of motivation of the participants toward the rehabilitation process, treated as a continuous variable.	NA

3.7 DATA COLLECTION METHOD AND PROCEDURE

3.7.1 Data Collection Method

This study employed a variety of instruments to accomplish all its research objectives. All three data collection periods (discharge, three-months, and six-months post-discharge) utilized three instruments: GOSE, QoLIBRI, and MoT-Q. In addition, a checklist containing sociodemographic information (age, gender, race, marital status, GCS on admission, and tracheostomy classification (early or late)) and clinical outcomes (length of stay in ICU and hospital, duration of mechanical ventilation, incidence of pneumonia, and decannulation of tracheostomy, SOFA score, and SAPS II score) were developed and collected only once during the discharge period.

The use of GOSE was adapted from previous studies on head injury patients to evaluate the functional outcomes of the participants (Ludin et al., 2019; Robba et al., 2020; Khalili et al., 2017). According to Wilson et al., (2021), GOSE is widely used to measure the functional outcomes and disability degree of individuals following head injury. Next, the QoLIBRI instrument was adapted from multiple previous head injury studies (Ludin et al., 2019: Rauen et al., 2021; Born et al., 2018). In addition, von Steinbuchel et al. (2010) stated that the use of QoLIBRI is recognized as a legitimate questionnaire among TBI patients due to its significant association with the usage of GOSE. The MoT-Q was used to measure the participant's motivation toward rehabilitation. This questionnaire was adapted from the study by Chervinsky et al., (1998) among traumatic brain injury (TBI) patients and validated by Boosman et al., (2016) for the use of the acquired brain injury (ABI) patients.

All indicated instruments were consolidated into a self-administered questionnaire completed by the participants or their proxies with the presence of the researcher to assist whenever necessary to clarify any part of the questionnaire that they did not understand or confused. The data collection session between the researcher and participants, with or without proxies, was conducted via face-to-face, phone conversation, and virtual meetings.

3.7.2 Data Collection Procedure

The data collection for this study was divided into two stages – (1) initial assessment during discharge and (2) follow-up for reassessment at three-months and six-months post-discharge. During the first stage, after the ethical approval from all related authorities had been obtained, the participants were identified through a thorough screening process based on inclusion and exclusion criteria extracted from the in-patient records of the ICU admission book, the Patient Information System, and the patient's case note from the Health Information Department of both hospitals for the patients admitted from January 2021 to December 2021 was collected. The data collected consists of information about the participant's independent variables of socio-demographics as per the checklist prepared. Throughout this stage, GCS score during admission and upon discharge, SOFA score, SAPS II score, length of stay in ICU and hospital, duration on mechanical ventilation support, the incident of pneumonia, and decannulation rate.

During stage 2, the patient or their caregivers were contacted by phone call and invited to participate in the study. They were adequately briefed on the objectives of the study. Then, they were given sufficient time to consider their participation in the study. Once they conveyed an interest in participating, written consent from themselves or their closest primary caregiver was obtained (in case the patient is currently in a vegetative state or unfit to administer the questionnaire). The Glasgow Outcome Scale – Extended (GOSE), Quality of Life After Brain Injury (QoLIBRI), and Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MoT-Q) instruments were distributed.

Preceding the COVID-19 pandemic that strikes globally, which limit people's physical interaction, the virtual meeting has become widespread and encouraging. A recent report by Evans (2020) stated that by the end of 2019, video conferencing systems had 10 million subscribers. However, by April 2020, the number had tremendously increased to 300 million every day. This circumstance also impacts academic research and study, with Chuey et al. (2021) emphasised that online data collection is a reasonable alternative to face-to-face data collection. Researchers may benefit from virtual videoconferencing for data collection, as online interviews may be more accessible and feasible (Rashid et al., 2021).

Throughout the survey, participants or their proxies were guided by the researcher to answer all questions via a face-to-face session during a home visit or, alternatively, a virtual meeting platform and phone calls to answer a set of questionnaires which consists of GOSE, QoLIBRI, and MoT-Q. Later, the same set of instruments were asked to be completed again by the participants or their proxies during the first follow-up (three-months post-discharge) and second follow-up (six-months post-discharge). The raw data from the patient's case note had been recorded meticulously for further analysis and interpretation. The data collection process is summarised as shown in Figure 3.3.

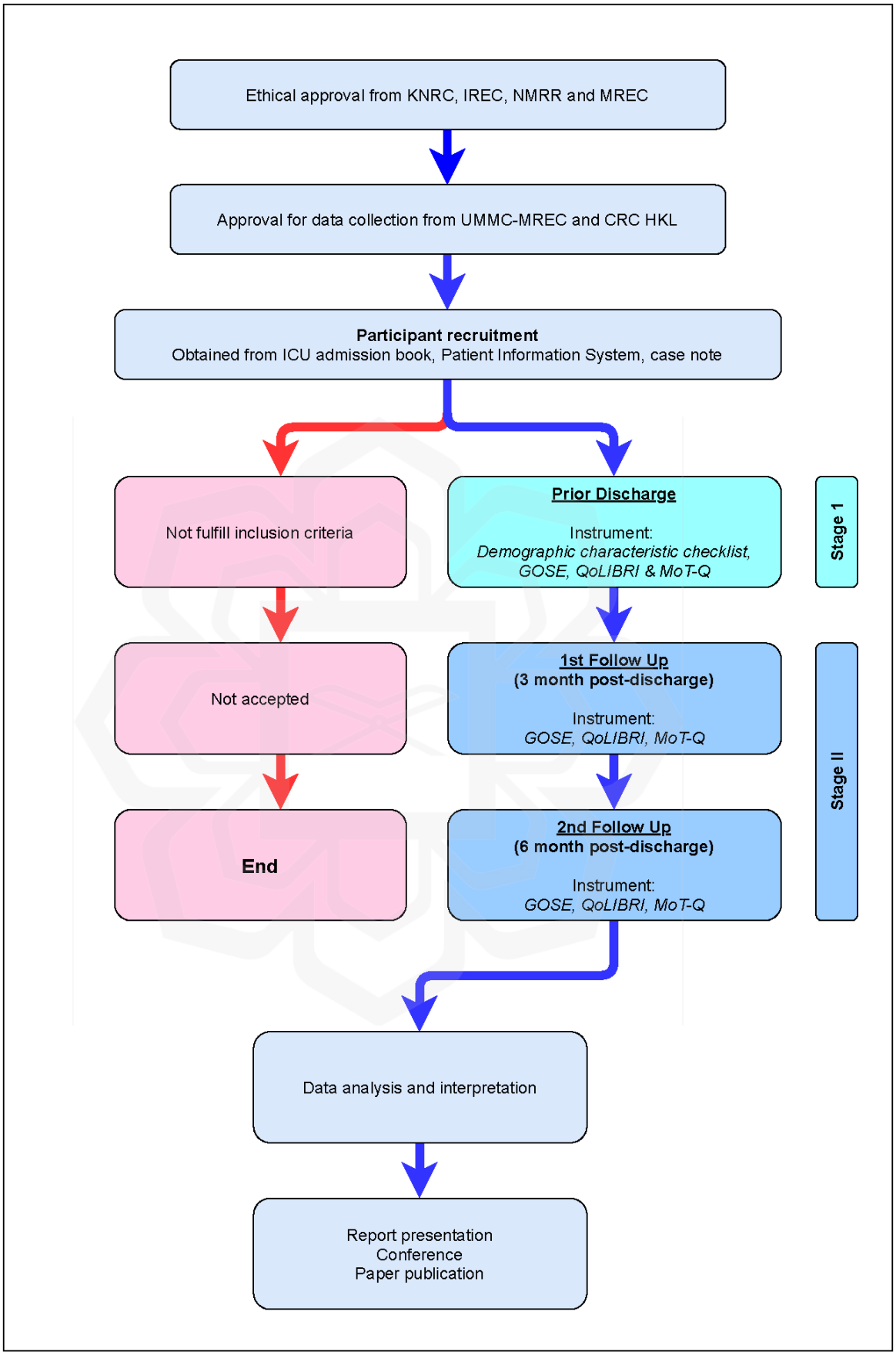


Figure 3.3: Study Flow Chart.

3.8 INSTRUMENT

3.8.1 Glasgow Coma Scale (GCS) Chart.

Glasgow Coma Scale was created by Graham Teasdale and Bryan Jennet back in 1974. The use of this tool is intended to describe the individual consciousness level which consists of three components – eye (4 points), verbal (5 points), and motor (6 points) response. The assessment of GCS is broadly used to guide the initial management of patients with head injuries (Jain & Iverson, 2020). The minimum score is 3/15 and the best score is 15/15. In the case of poor neurological status, a patient with GCS $\leq$ 8 points required urgent intubation for cerebral protection and to avoid aspiration (ATLS, 2013; & Henry, 2018).

3.8.2 Sequential Organ Failure Assessment (SOFA) Score.

According to Velho et al. (2022), the SOFA score may be useful for forecasting long-term outcomes and classifying persons with a high risk of mortality. This score, developed by Jean-Louis Vincent, would aid in predicting ICU mortality based on laboratory information and clinical data. The score ranges from a minimum of 0 to a maximum of +4 on six (6) distinct categories, including the functions of the respiratory system, neurological system, cardiovascular system, liver, and kidneys. Daily evaluations will be conducted to compare patient progress, and the mean SOFA score will be determined. For instance, if the mean score is >5.1 after a few days of evaluation the probability of death could reach 84.4% (Ferreira et al., 2001).

3.8.3 Simplified Acute Physiology Score (SAPS) II

SAPS II is an updated version of SAPS, which was validated for the first time in France in 1984. SAPS II is intended to be administered to ICU-admitted patients older than 18. Le Gall et al. (1993) developed this instrument, known as a score, to estimate mortality after a large-scale investigation was conducted in North America and Europe in 1991. Twelve physiological measures and three disease-related variables comprise the score. The value used to calculate the score is the patient's worst value within the previous 24

hours. Recent research by Czajka et al. (2020) confirmed that the SAPS II score is one of the most accurate predictors of mortality among ICU-admitted patients.

3.8.4 Glasgow Outcome Scale - Extended (GOSE).

The GOSE is a universal evaluation of independent living and social rehabilitation extensively used as an outcome measure in head injury research and to evaluate long-term functional effects (Wilson et al., 2021). Jennet and Bond released the first edition of Glasgow Extended Outcome in 1975 as a global assessment of the outcomes following severe brain injury (GOS). Later, a structured version of the Glasgow Outcome Scale-Extended (GOSE) interview was produced to assist with the standardisation of scoring techniques for both the GOS and GOSE (Wilson et al., 1998). The interview gives a set of guiding questions for assessing the domains or functional areas of the GOSE. This test does not reveal the individual's hardships, provides an overview of the overall outcomes. This systematic interview examination covers consciousness, independence within and outside the home, the maintenance of normal social function, and the remaining symptoms that interfere with daily functioning. Figure 3.4 explains the interpretation of GOSE scores. This instrument's creator had granted permission for its usage in this research (see appendix).

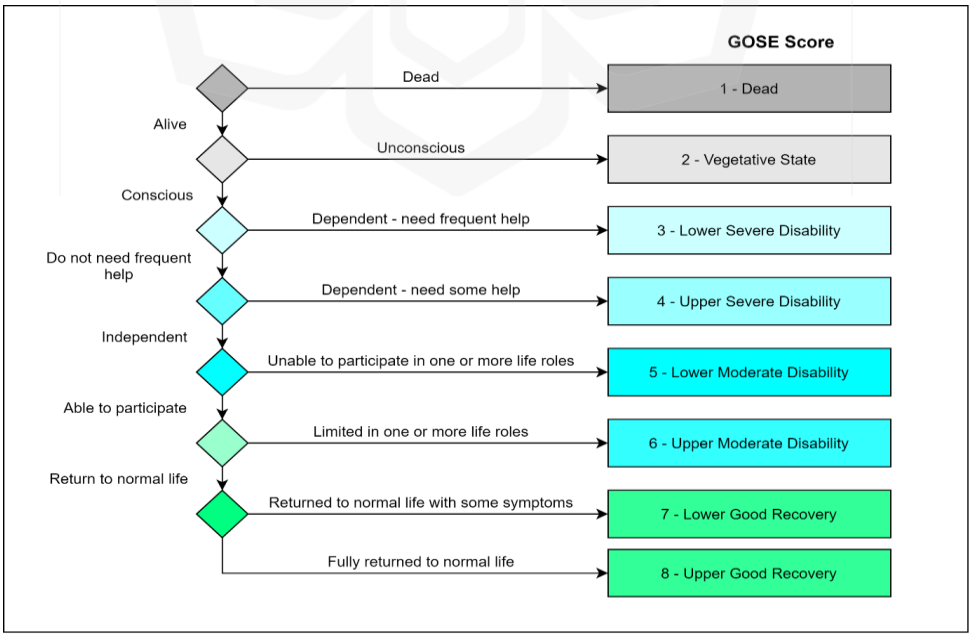


Figure 3.4: Description of GOSE Scales (Wilson et al., 2021)

The participant's functional outcome will be given a score of 1 to 8 in which a score of (1) refers to death, (2) vegetative state, (3) lower severe disability, (4) upper severe disability, (5) lower moderate disability, (6) upper moderate disability, (7) lower good recovery and (8) upper good recovery. The outcome of upper and lower good recovery will be merged into a single category which refers to the good category, and the outcome of the vegetative state until the upper-moderate recovery will be merged to refer to a poor recovery outcome. The good recovery category means that the head injury survivors can restore their functioning at home for daily living activities and at work. These two categories of the GOSE outcome have been used in recent studies (Ludin et al., 2018; Madhok et al., 2020; Stålnacke et al., 2019; and Tsyben et al., 2017). According to Wilson et al., (1998), the GOSE instrument is reliable and applicable over a phone interview or by correspondence using a standard interview structure with a kappa score from 0.85 to 0.89.

3.8.5 Quality of Life After Brain Injury (QoLIBRI).

This study utilizes the QoLIBRI instrument, created specifically to measure patients' health-related quality of life (HRQoL) after brain injury. This tool was derived from Von Steinbüchel et al. (2010) and consisted of a 37-item questionnaire covering six (6) aspects of HRQoL following a head injury or traumatic brain injury. In 2010, this instrument was developed by an international task group in the context of two multilingual studies. Cognitive, self, daily life and autonomy, social interaction, emotional, and physical issues are measured by the QoLIBRI's six (6) assessment scales. All measures will be evaluated using a Likert scale from 0 to 5. Satisfaction was assigned to the cognitive, self, daily life, autonomy, and social connection scales. Alternately, the scales for emotional and physical issues will be scored as "feeling troubled," and the scale will be scored in the opposite direction. Table 3.4 demonstrates the description of the QoLIBRI scale.

Cronbach's alpha, which ranges from 0.75 to 0.89, demonstrates the internal consistency of each QoLIBRI scale (Von Steinbuchel et al., 2010). The initial results were converted to a score range of 0 to 100, with 0 being the poorest quality of life

imaginable and 100 representing the finest quality of life. The scoring percentage was computed by eliminating one from the mean and multiplying the result by 25. The score range was divided into four categories. According to the instrument's developer, a total score of more than 82 indicates "above average," a score between 67 and 82 indicates "normal," a score between 60 and 66 indicates "borderline," and a score below 60 indicates "disabled" (Von Steinbuchel et al., 2010). Table 3.5 explains the scoring range. The author also acknowledged this study's use of this instrument (see Appendix G).

Table 3.4: Description of QOLIBRI scales.

QOLIBRI Scale	**Number of Items**	**Content**
	'Satisfaction'	
Cognition	7	Concentrate, express self, remember, problem solve, decisions, navigate, thinking.
Self	7	Energy, motivation, self-esteem, looks, achievements, self-perception, future.
Daily life & autonomy	7	Independence, getting out, domestic, finances, works, social, feeling in charge.
Social relationship	6	Affection, family, friends, partner, sex life, attitudes of other.
	'Bothered'	
Emotions	5	Loneliness, boredom, anxiety, depression, anger
Physical problems	5	Slow, other injury, pain, see/hear, TBI affects.

Table 3.5: Interpretation of QoLIBRI score (von Steinbuchel et al., 2010)

Range	Score
Above normal	>82
Normal	67 - 82
Borderline	60 - 66
Impaired	<60

3.8.6 Motivation for TBI Rehabilitation Questionnaire (MoT-Q).

This questionnaire was invented by Chervinsky et al., (1998) to evaluate the motivation level toward rehabilitation programs among patients with TBI. The approval to use the questionnaire in this study was also obtained by the creator (see appendix). This instrument consists of four (4) subscales which are (1) interest in rehabilitation, (2) lack of anger, (3) lack of denial, and (4) reliance on professional help, as presented in Table 3.6. The instrument obtains the reliability of Cronbach alpha 0.91 for the total scale. This instrument was not limited to assessing motivation levels among TBI patients only. The study by Boosman et al., (2016) and Bains et al., (2017) also proved that the questionnaire is a valid instrument for the patient with acquired brain injury (ABI) with excellent, consistent internal Cronbach alpha of 0.86.

The Neurology Section of the American Physical Therapy Association's Multiple Sclerosis taskforce (MSEDGE), Parkinson's Taskforce (PD EDGE), Spinal Cord Injury Taskforce (StrokEDGE), and Traumatic Brain Injury Taskforce (TBI EDGE) are among the professional association who recommended the use of this instrument. The questionnaire consists of 31 items with four (4) subscales, as mentioned earlier. The maximum score of 62 points can be achieved by the respondents with the rating made based on the (4) Likert scale of strongly disagree (-2 points), disagree (-1 point), agree (1 point), and strongly disagree (2 points).

Table 3.6: Description of Motivational for TBI Rehabilitation Questionnaire (Chervinsky et al., 1998)

Sub-scales	No. of Item	Measurement
Interest in rehabilitation	7-items	An interest in and positive view on rehabilitation.
Lack of anger	10-items	Evaluates the absence of anger and resentment towards therapists and rehabilitation.
Lack of denial	8-items	Measures the absence of denial of limitations, as well as acceptance and awareness of impairments.
Reliance on professional help	6-items	Assesses the participant's attitude toward experts and their propensity to adhere to treatment and recommendations.

3.9 DATA ANALYSIS

The data collected was analysed using the Statistical Package for Social Science (SPSS) version 26.0 for Windows. The data were analysed with multiple analyses, which include descriptive analysis, univariate analysis, and multivariate analysis as below. All level of significance was set at alpha of 0.005.

3.9.1 Descriptive Analysis

Socio-demographic characteristics data, including classification of tracheostomy duration (early and late tracheostomy), participant's age, gender, race, and marital status, were analysed descriptively. For numerical data, the normality assumptions were verified, and data were reported as mean and standard deviation (SD) (if normally distributed), alternatively median and interquartile range (if not normally distributed). Descriptive findings were reported using row percentage (for categorical variables) and

mean and standard deviation (SD) (for comparing continuous variables between two groups). To identify the incidence proportion of the early tracheostomy and late tracheostomy group as well as the incidence of pneumonia among the participants, the incidence proportion formula (Figure 3. 5) was used.

$$\text{Incident proportion} = \frac{\text{Number of cases during a specific period}}{\text{Population at risk during the same time period}} \times 10^{n}$$

Figure 3.5: Incidence proportion formula (Gertsmen, 2013).

3.9.2 Univariate Analysis

The Pearson chi-square test and Fisher's exact test were performed to assess crude analysis for categorical variables, while the comparisons between two groups for continuous variables were examined using an independent t-test. The Mann-Whitney U test is used for the dependent variables, which were continuous but not normally distributed.-Ordinal regression was used in this study to analyse the association between one or more independent variables with one or more dependent variables with multiple ordered levels. The level of significance was defined as p-value less than 0.05.

3.9.3 Multivariate Analysis

3.9.3.1 Logistic regression

The logistic regression was performed to determine the association between the tracheostomy classification and the participant's clinical outcomes (the SOFA score, SAPS II score, length of stay in ICU, length of stay in the hospital, duration on mechanical ventilator support, the GCS upon discharge, incidence of pneumonia and decannulation of tracheostomy among the participants) by adjusted for participant's

sociodemographic characteristics (age, gender, race, marital status and GCS upon admission).

3.9.3.2 Generalized Estimating Equations (GEE)

Meanwhile, the Generalized Estimating Equations (GEE) was used to assess the longitudinal (discharge, three-months post-discharge and six-months post-discharge) associations of the tracheostomy classification (early and late tracheostomy) and the functional outcome, quality of life and rehabilitation compliance by adjusting the identified confounding factors among severe head injury patients. The main advantage of GEE is that it can estimate population-averaged regression coefficients without bias, even if the correlation structure is not specified correctly (Ghisletta & Spini, 2004). In this study, only participants with complete data throughout all stages were included in the analysis. The final total participants completed were 45 out of initial 70 initial candidates. During the analysis, the distribution of tracheostomy classification (early and late tracheostomy) was set as 'poisson' and the link function as logit where the estimated outcome is the relative risk (RR). The working correlation structure was independent as there was no missing data and the follow-up period for each participant was similar. However, the other options of working correlation structures were tested one by one to determine which gave the lowest quasi-likelihood under the independence model criterion (QIC) value. The analysis showed an independent working correlation structure was the lowest QIC.

3.10 ETHICAL CONSIDERATION

3.10.1 Ethical Approval

This study obtained approval from Kulliyyah of the Nursing Postgraduate and Research Committee, National Medical Research Register (NMRR), and Medical Review & Ethics Committee (MREC). Furthermore, the International Islamic University Malaysia Research Committee (IREC) was also notified. Following the approval from the aforesaid organization, the approval from the authority of both hospitals, the Clinical

Research Centre of Hospital Kuala Lumpur (CRC HKL) and the University Malaya Medical Centre – Medical Research Ethic Committee (UMMC-MREC), had been obtained. The other ethical consideration that had also been stressed throughout the study are:

i) To ensure the confidentiality of the information obtained in accordance with the Personal Data Protective Act (PDPA).
ii) To ensure the research was implemented and the data obtained for academic purposes and improvement for the health industry.

3.10.2 Risk and Benefit to Study Participants

Participation in this study will not affect any further treatment required by the participants, and the risk is minimal. The study may or may not be of any benefit to the participants. The information obtained from this study regarding the impact of early and late tracheostomy will help Malaysian healthcare organizations to develop care management for severe head injury patients.

3.10.3 Informed Consent

The purpose of the study had been explained to the participants and/or their caregivers, and the consent form was enclosed with the information sheet of the study. Participants had been informed that their participation was voluntary. Each participant or caregiver consented to participate by completing the informed consent form as an official agreement to participate in the study. All participant's information details were always kept confidential.

3.10.4 Privacy and Confidentiality

Upon the completion of data collection, all data were stored in a locked cabinet which was only accessible by the investigators only. After that, all data was transferred to a computer that was password protected. Then, data in the computer were copied to CDs while the previous files were erased. CDs and any related documents will be kept for a minimum of five years after the completion of the study. The CDs and data will be destroyed after that period of storage. Participants will not be allowed to view their study data, as it will be consolidated into a database.

3.11 SUMMARY

The methodological approaches of this study have been detailed in this chapter. This retrospective observational cohort study was conducted among severe head injury patients with the initiation of tracheostomy in two study settings – HKL and UMMC. The convenience sampling method was used, and the sample size was calculated according to the study objectives. After considering all the objectives, the minimum size required after the additional 40% attrition rate was 70 participants. The instrument for this study is a set of questionnaires consisting of a few parts: demographic characteristics, GOSE, QoLIBRI and MoT-Q. The next chapter will present the study's findings consisting of the descriptive, univariate and multivariate analyses in line with the research questions and objectives.

CHAPTER FOUR

FINDINGS

4.0 INTRODUCTION

In this chapter, the study's findings will be separated into five sub-sections accordingly. The detailed information on the sub-sections is detailed in Table 4.1.

Table 4.1: The sub-section of the study's findings

Sub-section	Details
4.1	Present the evaluation process comprises of the following: i) Response rate ii) Comparisons of characteristics between enrolled participants versus dropped-out patients in the study.
4.2	Presents the results of the descriptive analyses: i) Descriptive analysis of socio-demographic characteristics of patients' severe head injury in this study ii) Descriptive analysis of characteristics of tracheostomy classification (early and late tracheostomy) among severe head injury patients in this study. iii) Descriptive analysis of the clinical outcomes, functional outcome, quality of life and rehabilitation compliance among severe head injury patients in this study. iv) Descriptive analysis of other clinical outcomes: prevalence of pneumonia and decannulation of tracheostomy among severe head injury patients in this study.

Table 4.1: The sub-section of the study's findings (continued)

4.3	Presents the results of univariate analyses: i) Association between tracheostomy classification (early and late tracheostomy) and clinical outcomes in-hospital and before discharge among severe head injury patients in this study. ii) Association between tracheostomy classification (early and late tracheostomy), and the functional outcome among severe head injury patients in this study. iii) Association between tracheostomy classification (early and late tracheostomy), and quality of life among severe head injury patients in this study. iv) Association between tracheostomy classification (early and late tracheostomy), and rehabilitation compliance among severe head injury patients in this study.
4.4	Presents the results of multivariate analyses: The association of early and late tracheostomy towards the clinical outcomes, functional outcome, quality of life, and rehabilitation compliance by adjusting the confounding factors (sub-section 4.4) among severe head injury patients

4.1 EVALUATION PROCESS

4.1.1 Response Rate

The minimum desired sample size for this study was 70. A total of 105 severe head injury patients were admitted from January 2021 until December 2021 and underwent a tracheostomy from both hospitals. Due to the potential high dropped-out rate of the study sample conditions, the researcher decided to invite all of them to participate in this study. After their case notes were reviewed for eligibility, thirty-five were excluded due to death during hospitalization (n=34) and being underage (n=1). Therefore, only seventy of them met the eligibility criteria which met the minimum desired sample size for this study (70) and were recruited. Before the recruitment, information about the study, and the voluntary basis was explained and informed consent was obtained.

Throughout the study period, twenty-three patients dropped out for various reasons such as being unable to reach due to missing and inconsistency of the contacts available, declining to participate or to complete their participation in the study. The participant had been declared dead within the time frame of desired data collection – less than 90 days post-discharge (Figure 4.1). At the end of the study, only 45 patients completed the study, yielding a 64.3% (45/70) completion rate.

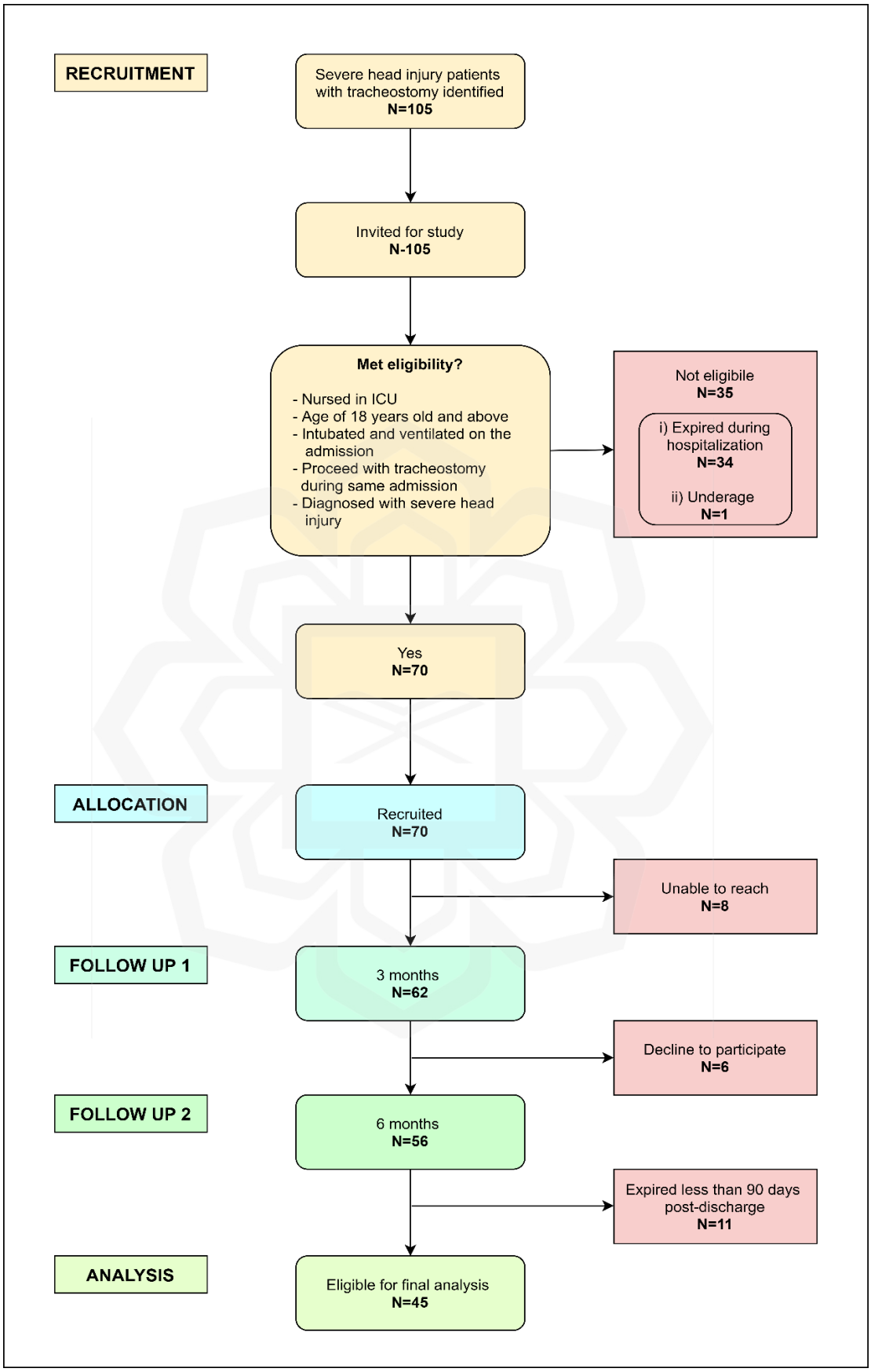


Figure 4.1: The participants' recruitment flow toward the final analysis

4.1.2 Baseline of Characteristics Between Final Participants Group and Those Who Dropped Out

Seventy severe head injury patients with tracheostomy met the eligibility and were recruited in this study. However, only 45 completed the follow-up (3 months and six (6) months post-discharge assessment) in the study and have been included in the final analyses. Table 4.2 shows a comparison of the baseline characteristics of patients who completed the study and those who dropped out of the study. The analyses showed no statistical difference between these two groups regarding their sociodemographic characteristics and tracheostomy classification (early or late). Though Table 4.2 of the sociodemographic characteristics of marital status shows there was a statistical difference between those who completed the study and those who dropped out of the study, the association seemed weak as the p-value was marginally significant 0.049 which nearly violated the pre-set of the significant level of this study (p-value < 0.05).

Table 4.2: Baseline of characteristics between final participants and dropped out.

Variable	**Completed study (n=45) n(%)**	**Dropped out (n=25) n(%)**	**p-value**
Age (years) *(Mean ± SD)*	*49.73±16.82*		0.084
18-29	6(13.3%)	1 (4.0%)	
30-39	8(17.8%)	3 (12.0%)	
40-49	6(13.3%)	3 (12.0%)	0.078
50-59	9(20.0%)	8 (32.0%)	
≥ 60	16(35.6%)	10 (40.0%)	
Gender			
Male	32(71.1%)	15 (60.0%)	0.422
Female	13(28.9%)	10 (40.0%)	
Race			
Malay	25(55.6%)	18 (72.0%)	
Chinese	11(24.4%)	6 (24.0%)	0.187
India	9(20.0%)	1 (4.0%)	
Others	-		
Marital status			
Single	13(28.9%)	4 (16.0%)	
Married	28(62.2%)	14 (56.0%)	0.049
Widowed	4(8.9%)	7 (28.0%)	
Tracheostomy classification			
Early Tracheostomy (< 7 days)	21(46.7%)	9 (36.0%)	0.440
Late Tracheostomy (≥ 7 days)	24(53.3%)	16 (64.0%)	

4.2 DESCRIPTIVE ANALYSES

4.2.1 Sociodemographic Characteristics of Study Participants

The sociodemographic characteristics of the patients recruited in this study were presented in Table 4.3. Respectively, the study patient's mean age (years) was 49.73 (SD=±16.82), varying from 19 to 81 years old. More than half of them were at aged 50 years and above. The majority were male patients (71%, n=32), with most of them being Malay (55.6%, *n*=25), followed by Chinese, (24.4%, n=11), and Indian (20%, n=9). In terms of marital status, most of the participants were married (62.2%, n=28), thirteen of them are still single (28.9%), and the other four participants are widowed (8.9%). Participants were categorized as having a severe head injury when the GCS of less than 9/15 upon admission. In this study, the (median (IQR)) upon admission was 3.00 (3.00).

Table 4.3: Sociodemographic data and GCS score upon admission of the participants (n=45)

Variable	*Mean ± SD*	Frequency (n)	Percentage (%)
Age (years)	*49.73±16.82*	-	-
18-29		6	13.3%
30-39		8	17.8%
40-49		6	13.3%
50-59		9	20.0%
≥ 60		16	35.6%
Gender			
Male		32	71.1%
Female		13	28.9%
Race			
Malay		25	55.6%
Chinese		11	24.4%
India		9	20.0%
Others		0	-
Marital status			
Single		13	28.9%
Married		28	62.2%
Widowed		4	8.9%
GCS upon admission	*3.00 (3.00 [a])*	-	-

[a] = median (IQR)

4.2.2 Patients' Tracheostomy Status

In this study, 46.7% of the participants had undergone early tracheostomy and more than half of the participants (53.3%) had undergone late tracheostomy (Table 4.4). The average day the participants underwent the tracheostomy procedure was at day 10 (±9.66), ranging between day 2 and day 52. This initiation of tracheostomy was delayed for several reasons, including the primary caregiver's reluctance to consent to the procedure, the inconsistent decision between family members regarding whether to

proceed with the procedure, the lengthy period spent waiting for the participant's immediate family members to gather for the family conference, the patient's unstable condition, which rendered them temporarily unfit for the procedure, a financial constraint, and others.

Table 4.4: Classification of Patients' Tracheotomy Status (n=45)

Variable	***Mean* ± *SD***	**Frequency (n)**	**Percentage (%)**
Day of tracheostomy procedure	*10.11±9.663*		
Tracheostomy classification (days)			
Early Tracheostomy (<7 days)		21	46.7%
Late Tracheostomy (≥ 7 days)		24	53.3%

4.2.3 Participants' Clinical Outcomes

Twenty-one participants enrolled in this study are classified into the early tracheostomy (ET) group, whereby the other 24 patients fall under the late tracheostomy (LT) group. The clinical characteristics data of all participants were extracted from the Health Information System of the Medical Record Department of both hospitals, as presented in Table 4.5. The median (IQR range) of the length of stay (LOS) in the Intensive Care Unit (ICU) was 9.76 (9.00) days ranging from 3 to 19 days for the ET group whereby the median (IQR) LOS in ICU for LT group was 27.75 (15.00) days ranging between 9 to 140 days. Consequently, for the LOS in the hospital, the ET group had recorded a median (IQR) of 24.48 (25) days ranging between 10 to 42 days compared to the LT group with a median (IQR) of 49.96 (33.00) days with a range of 18 to 148 days. As the dependency on mechanical ventilation (MV) also play a significant role in the LOS of the participants in ICU, the duration of MV dependency also had been considered. The ET group median (IQR) was 7.14 (7.00) days extending from 3 to 12 days, while the median (IQR) for the LT group was 19.13 (14.50) days with a scale of 9 to 69 days.

Before discharge from the hospital, the final GCS obtained by the participants was also recorded. ET group recorded a median (IQR) score of 10 (11.00), while the LT group with a score of 9.46 (11.00). As for the SOFA score and SAPS II score for the participants, the reading was only recorded within the first 24 hours of hospitalisation. The mean (SD) of the SOFA score for the ET group was 9.14 (2.08), ranging from 6 to 13, whereby the LT group means (SD) was 9.71 (1.55). The median (IQR) of the SAPS II score for the ET group was 43.24 (9.77) and for the LT group 39.63 (10.11).

Table 4.5: The participant's clinical outcomes between ET and LT (*n*=45)

Variable	**Early tracheostomy (n=21)** **Mean (SD)**	**Late tracheostomy (n=24)** **Mean (SD)**
SOFA score	9.14 (2.08)	9.71 (1.55)
SAPS II score	43.24 (9.77)	39.63 (10.11)
LOS in ICU (days)	9.76 (9.00[a])	27.75 (15.00[a])
LOS in hospital (days)	24.48 (25.00[a])	49.96 (33.00[a])
MV duration (days)	7.14 (7.00[a])	19.13 (14.50[a])
Final GCS upon discharge	10.0 (11.00[a])	9.46 (10.00[a])

[a] = median (IQR)
ET = early tracheostomy, LT = late tracheostomy, LOS = length of stay, ICU = Intensive Care Unit, MV = mechanical ventilation, GCS = Glasgow Coma Scale, SOFA = Sequential organ failure score, SAPS II = Simplified acute physiology II score

4.2.4 Functional Outcome Among the Participants

The distribution of GOSE score between all participants is shown in Table 4.6 and Figure 4.2 before it is separated between those in the early tracheostomy group and late tracheostomy group in Table 4.7. Later, the eight available categories were grouped into two primary groups for analysis – poor and good recovery (Table 4.8). This study found that none of the severe head injury patients had a good recovery during the discharge

period, with 51.1% still in a vegetative state (early tracheostomy, n=6; late tracheostomy, n=17) (Table 4.6). Even after three-months post-discharge, only one participant from the early tracheostomy group obtains a good recovery condition, with the other 44 participants still in poor recovery condition. Eventually, there was a substantial improvement, particularly among the early tracheostomy group, with 13 of them and another two individuals from the late tracheostomy group having a good recovery phase (refer to Table 4.6 and Table 4.7).

Table 4.6**:** GOSE score among all participants (n-45)

	Frequency (%)		
	Discharge	**3-month**	**6 -month**
GOSE score			
Death	0 (0)	0 (0)	0 (0)
Vegetative state (VS)	23 (51.1)	15 (33.3)	2 (4.4)
Lower severe disability (SD -)	19 (42.2)	19 (42.2)	5 (11.11)
Upper severe disability (SD +)	0 (0)	1 (2.2)	3 (6.7)
Lower moderate disability (MD -)	3 (6.7)	2 (4.4)	9 (20.0)
Upper moderate disability (MD +)	0 (0)	7 (15.6)	11 (24.4)
Lower good recovery (GR-)	0 (0)	1 (2.2)	10 (22.2)
Upper good recovery (GR +)	0 (0)	0 (0)	5 (11.11)

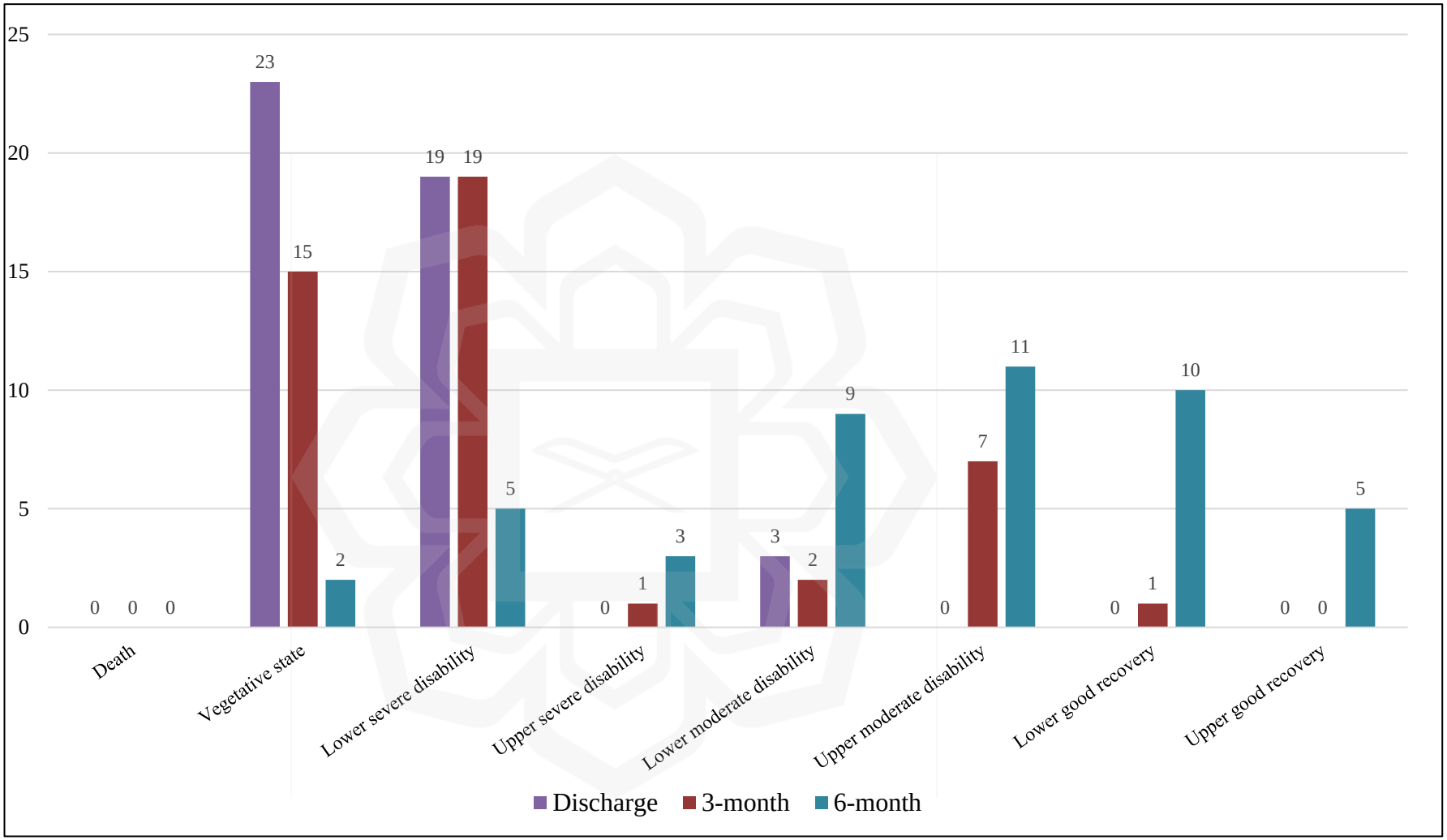


Figure 4.2: Distribution of GOSE outcome among all participants (*n*-45)

Table 4.7: Comparison of GOSE score between ET and LT group.

	Frequency (%)					
	Early tracheostomy (n=21)			Late tracheostomy (n=24)		
	Discharge	**3-month**	**6 -month**	**Discharge**	**3-month**	**6 -month**
GOSE score						
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vegetative state (VS)	6 (28.6)	2 (9.5)	0 (0)	17 (70.1)	13(54.2)	2 (8.3)
Lower severe disability (SD -)	13 (61.9)	11(52.4)	0 (0)	6 (25.0)	8 (33.3)	5 (20.1)
Upper severe disability (SD +)	0 (0)	1 (4.8)	2 (9.5)	0 (0)	0 (0)	1 (4.2)
Lower moderate disability (MD -)	2 (9.5)	0 (0)	0 (0)	1 (4.2)	2 (8.3)	9 (37.5)
Upper moderate disability	0 (0)	6 (28.6)	6 (28.6)	0 (0)	1 (4.2)	5 (20.1)
Lower good recovery	0 (0)	1 (4.8)	9 (9.5)	0 (0)	0 (0)	1 (4.2)
Upper good recovery	0 (0)	0 (0)	4 (19.0)	0 (0)	0 (0)	1 (4.2)

Table 4.8: Overall GOSE score categories across three time periods (discharge, 3 months, and 6 months post-discharge)

	Tracheotomy's classification					
	Early tracheostomy (*n*=21)			**Late tracheostomy (*n*=24)**		
	Discharge n(%)	**3-month n(%)**	**6 -month n(%)**	**Discharge n(%)**	**3-month n(%)**	**6 -month n(%)**
GOSE score						
Poor recovery	21 (100)	20 (95.2)	8 (38.1)	24 (100)	24 (100)	22 (91.7)
Good recovery	0 (0)	1 (4.8)	13 (61.9)	0 (0)	0 (0)	2 (8.3)

4.2.5 Quality of Life Among the Participants

The participant's quality of life was assessed using the QoLIBRI score, which was then classified into four groups: above normal, normal, borderline, and impaired. The evaluation was conducted at three different periods: discharge, three-months post-discharge, and six-months post-discharge. Based on the score shown in Table 4.9, all the patients with severe head injuries had poor quality of life during discharge. Gradually, some of them had improved over time to reach the 'borderline' (n=1) and 'normal' range (n=4) during their 3-month post-discharge. However, only 6.7% of participants (n=3) out of all total 45 participants were able to reach the above-normal range with a score of more than 82 scores. The QoLIBRI scoring across all participants was then separated based on tracheostomy classification as portrayed in Table 4.10.

Table 4.9: The QoLIBRI score interpretation among all participants (n=45)

	Time (follow-up)		
	Discharge n(%)	**3-month n(%)**	**6 -month n(%)**
QoLIBRI Scoring			
Above normal (>82)	0 (0)	0 (0)	3 (6.7)
Normal (67-82)	0 (0)	4 (8.9)	13 (28.9)
Borderline (60-66)	0 (0)	1 (2.2)	5 (11.1)
Impaired (<60)	45 (100)	40 (93.3)	24 (53.3)
Total	**45**	**45**	**45**

Table 4.10 shows that, during the post-discharge period of three months, only four people attain the 'normal' level, with one participant moving to the 'borderline' category. Four out of five individuals were surprisingly from the late tracheostomy group. Eventually, when the time moves on toward 6-months post-discharge, those with early tracheostomy done shows some improvement with 14.3% of them (n=3) achieved ‘above normal’ range and 38.1% (n=8) reached a ‘normal’ range, four participants (19.0%) in the ‘borderline’ range leaving only six participants (28.6%) in ‘impaired’ category. On the-contrary, none of the participants in late tracheostomy able to achieve ‘above normal’ range with only five of them (20.1%) met the ‘normal’ range. One participant (4.2%) in the ‘borderline’ range and 75.0% of them remain in the ‘impaired’ range (n=18).

Table 4.10: The QoLIBRI score interpretation between ET and LT group.

	Tracheostomy's classification					
	Early Tracheostomy (n=21)			**Late Tracheostomy (n=24)**		
QoLIBRI Score	**Discharge n(%)**	**3-month n(%)**	**6-month n(%)**	**Discharge n(%)**	**3-month n(%)**	**6-month n(%)**
Above normal (>82)	0 (0)	0 (0)	3 (14.3)	0 (0)	0 (0)	0 (0)
Normal (67-82)	0 (0)	1 (4.8)	8 (38.1)	0 (0)	3 (12.5)	5 (20.1)
Borderline (60-66)	0 (0)	0 (0)	4 (19.0)	0 (0)	1 (4.2)	1 (4.2)
Impaired (<60)	21 (100)	20 (95.2)	6 (28.6)	24 (100)	20 (83.3)	18 (75.0)
Total	**21 (100)**	**21 (100)**	**21 (100)**	**24 (100)**	**24 (100)**	**24 (100)**

As mentioned earlier, the QoLIBRI score consists of six sub-scales. Based on the distribution of sub-scales QoLIBRI score as shown in Table 4.11, the total mean score was improved from discharge to the final assessment at six months post-discharge for all participants from 15.33 (8.67) to 52.64 (23.88). Based on the score measured at six months post-discharge, the highest mean score was 'social relationship' at 63.06 (21.72), followed by 'self' at 55.87 (25.00), 'physical' was 52.89 (19.93), 'emotion' with 51.11 (22.61) and 'daily life and autonomy' 43.02 (33.92).

Table 4.11: Distribution of QoLIBRI score interpretation among all participants (n=45)

QoLIBRI Scale	**Discharge Mean (SD)**	**3-month Mean (SD)**	**6 -month Mean (SD)**
Cognition	4.13 (8.91)	20.24 (27.01)	51.03 (28.19)
Self	15.80 (12.46)	27.34 (25.37)	55.87 (25.00)
Daily Life and Autonomy	0.95 (2.33)	13.17 (23.18)	43.02 (33.92)
Social Relationship	27.22 (18.94)	40.19 (25.11)	63.06 (21.72)
Emotion	18.11 (15.71)	25.60 (25.16)	51.11 (22.61)
Physical	33.44 (19.88)	35.89 (22.27)	52.89 (19.93)
Average Total Score	**15.33 (8.67)**	**26.08 (21.53)**	**52.64 (23.88)**

The summary of the mean score was then separated to compare early and late tracheostomy participants (Table 4.12). From the average total mean score comparison between these two groups, the total mean score at all periods was higher in the early tracheostomy group compared to the other group. Even though, the finding in this study showed that the mean QoLIBRI score at both three-months and six-months post-discharge for all sub-scales were less than 60 (impaired), but there were some promising improvements occurred within the six-months post-discharge for the early tracheostomy group compared to late tracheostomy group. From the finding, the mean

scores for all sub-scales of the early tracheostomy group had surpassed all mean score for the late tracheostomy group. The mean sub-scale score with the highest increment was ‘cognitive’ from 4.41 to 65.65 compared to the late tracheostomy group with 3.91 to only 35.03.

Table 4.12: Comparison of mean QoLIBRI sub-scale score between early (n=21) and late (n=24) tracheostomy group

	Early Tracheostomy (n=21)			Late Tracheostomy (n=24)		
	Discharge Mean (SD)	**3-month Mean (SD)**	**6 -month Mean (SD)**	**Discharge Mean (SD)**	**3-month Mean (SD)**	**6 -month Mean (SD)**
QoLIBRI Scale						
Cognition	4.42 (8.81)	26.53 (24.55)	65.65 (21.68)	3.91 (9.64)	8.50 (18.09)	35.03 (25.14)
Self	17.52 (10.35)	33.50 (22.40)	69.22 (17.80)	12.59 (13.53)	16.84 (20.30)	40.82 (24.00)
Daily Life & Autonomy	0.68 (1.44)	16.67 (20.28)	60.88 (30.21)	1.36 (3.09)	4.93 (16.35)	23.30 (25.77)
Social Relationship	31.15 (19.92)	51.59 (19.74)	73.41 (14.99)	22.02 (17.54)	25.60 (20.12)	51.19 (22.90)
Emotion	17.38 (14.72)	29.76 (26.00)	56.19 (23.76)	19.05 (17.86)	21.19 (23.71)	44.29 (20.45)
Physical	34.52 (19.99)	38.81 (22.80)	59.05 (17.07)	33.10 (21.42)	33.10 (20.77)	44.76 (21.06)
Average Total Score	***16.34 (8.05)***	***32.14 (20.76)***	***64.51 (20.00)***	***14.44 (9.26)***	***21.23 (21.66)***	***42.26 (22.41)***

4.2.6 Rehabilitation motivation among the participants

The mean (SD) of the participants was reported descriptively in Table 4.13 at three different periods for the two groups – early and late tracheostomy. Overall, all participants (early and late) recorded a mean score of 14.44 during the discharge period, with subsequently decreased to 13.60 (three-months post-discharge) and increased to 14.38 during six-months post-discharge. There was a different curve for the mean score between the early tracheostomy and late tracheostomy groups. The mean score for the early tracheostomy group was 17.95 during the discharge period (ranging from -5 to 42). During the three-month post-discharge, the mean score of the early tracheostomy group had decreased to 16.57, with scores ranging from -5 to 40. However, the score had increased significantly during the six-months post-discharge with a median score of 22.86 (ranging from -8 to 40). On the other hand, those with late tracheostomy had recorded lower mean scores at all periods, which were 11.38 to 11.00 during discharge and three-months post-discharge and further decreased to 6.96 after six-months they had been discharged from the hospital. The participants in LT also documented poorer scores ranging from -17 to 38 across all three periods of assessment time.

Table 4.14 had described the MoT-Q subscales of all participants which shows that the "lack of denial" subscales decreased from the mean score of 11.0 (during the discharge period) to 8.0 and 5.0 after three months and six months post-discharge. The subscales of "interest toward rehabilitation" were 0 during the discharge period and three months post-discharge with some increment to 5.0 at the six months post-discharge. The subscales of "lack of anger" record a mean score of 2.0 during the discharge period which later drop to 1.0 (at 3 months post-discharge) and improve to 4.0 after six months post-discharge. Lastly, the subscales of "reliance on professional help" for all the participants were initially 0 during the discharge period catching a little increment to 1.0 and 2.0 (three-months and six-months post-discharge). Table 4.15 and Table 4.16 differentiated all four subscales scores of the MoT-Q instruments between the early and late tracheostomy groups.

Table 4.13: Total MoT-Q score between ET (n=21) and LT (n=24) groups

	MoT-Q score								
	Discharge			**3-month**			**6-month**		
	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score
Early Tracheostomy (<7 days)	17.95 (13.44)	-5	42	16.57 (14..41)	-5	40	22.86 (13.93)	-8	40
Late Tracheostomy (≥ 7 days)	11.38 (13.19)	-17	38	11.00 (13.16)	-17	33	6.96 (16.00)	-16	37
All participants (Early and Late)	*14.44 (13.57)*	*-17*	*42*	*13.60 (13.90)*	*-17*	*40*	*14.38 (16.92)*	*-16*	*40*

Table 4.14: MoT-Q subscales score among all participants (n=45)

		Discharge			3-month			6-month		
	Possible maximum score	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score
MoT-Q subscales										
Lack of denial	*16*	11.0 (6.0)	-4	16	8.0 (7.0)	-4	16	5.0 (6.0)	-4	13
Interest in rehabilitation	*14*	0 (5.0)	-8	13	0 (6.0)	-8	12	5.0 (10.0)	-8	13
Lack of anger	*20*	2.0 (6.0)	-9	13	1.0 (8.0)	-5	14	4.0 (10.0)	-8	12
Reliance on professional help	*12*	0 (6.0)	-4	9	1.0 (5.0)	-5	9	2.0 (7.0)	-4	9

Table 4.15: MoT-Q subscales score among the participant with ET.

	Discharge			3-month			6-month		
	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score	Mean (SD)	Minimum score	Maximum score
MoT-Q subscales									
Lack of denial	12.0 (7.5)	5	14	5.5(7.25)	1	14	4.5 (8.0)	-1	12
Interest in rehabilitation	3.0 (4.0)	-4	8	4.0 (9.0)	-6	12	8.0 (5.0)	-6	13
Lack of anger	3.0 (7.0)	-4	13	2.0 (9.0)	-4	14	8.0 (7.0)	-4	12
Reliance on professional help	2.0 (7.0)	-4	9	3.0 (6.0)	-4	9	5.0 (4.0)	-4	-9

Table 4.16: MoT-Q subscales score among the participant with LT.

	Discharge			3-month			6-month		
	Mean (SD)	**Minimum score**	**Maximum score**	**Mean (SD)**	**Minimum score**	**Maximum score**	**Mean (SD)**	**Minimum score**	**Maximum score**
MoT-Q subscales									
Lack of denial	9.0 (4.5)	-4	16	8.0(4.75)	-4	16	5.0 (6.0)	-4	13
Interest in rehabilitation	0 (3.75)	-8	11	0 (-1.25)	-8	9	-0.5 (6.75)	-8	11
Lack of anger	1.0 (3.25)	-9	13	0.5(3.75)	-5	9	1.0 (8.25)	-8	11
Reliance on professional help	0 (5.25)	-4	6	0 (2.5)	-4	9	-1.0 (4.25)	-4	9

4.2.7 Other clinical outcomes: Incidence of pneumonia and decannulation of tracheostomy among severe head injury patients

4.2.7.1 Incidence proportion of pneumoniae among the participants

Given pneumonia incidence, 27 participants (60%) from the total number of 45 participants were diagnosed with pneumonia during their hospitalization from the day they had been admitted to ICU until they were transferred to the general ward. Eleven participants from the ET group (52.4%) had experienced pneumonia, whereby 16 of the participants (66.7%) in the LT group had, as shown in Table 4.17. The most popular microorganism that affected the participants during their history of pneumonia was *Klebsiella pneumonia* which appeared in 5 participants from the ET group and eight from the LT group. *Acinetobacter baumannii* became the most common microorganism found in 9 participants, followed by *Pseudomonas aeruginosa* (*n*=5), *Proteus mirabilis, and Staphylococcus aureus* (*n*=2), and one participant affected with *Enterobacter cloacae.* The details distribution of microorganisms found among the participant with pneumonia incidence had shown in Figure 4.3.

Table 4.17: Incidence of pneumonia among the participants.

Variable	Frequency (n)	Percentage (%)
Incidence of pneumonia		
Early tracheostomy (n=21)	11	52.4
Late tracheostomy (n=24)	16	66.7

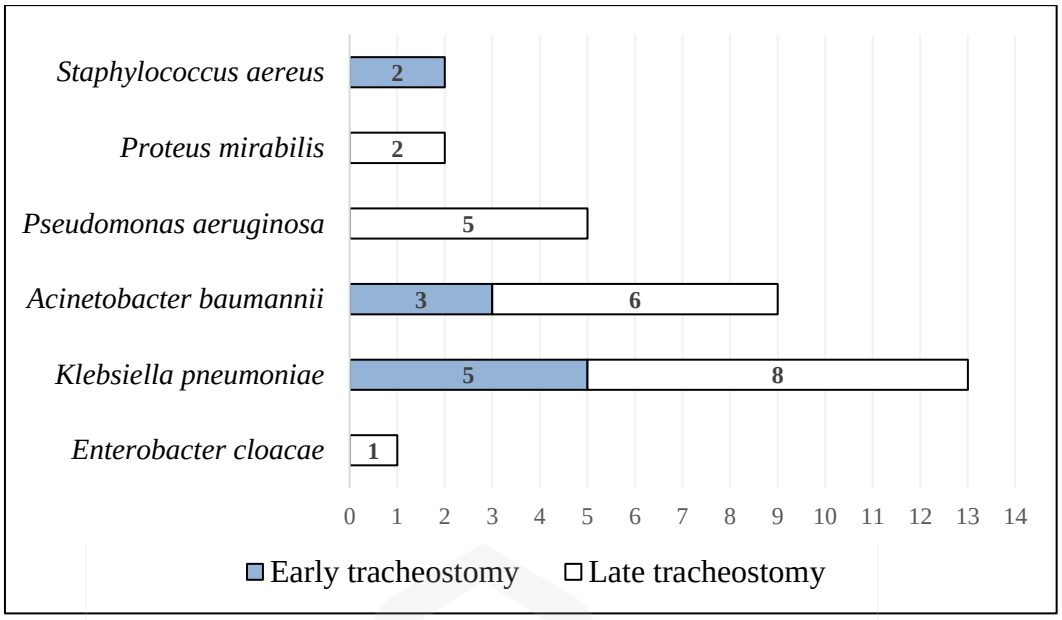


Figure 4.3: Infecting micro-organisms among the participants affected with pneumonia.

4.2.7.2 Decannulation of tracheostomy among the participants

Another aspect that had been observed is the successful decannulation of tracheostomy among all participants. All of them had been discharged home with tracheostomy in situ. The data of them being decannulated at any point within the six-month post-discharge had been recorded. Among 21 participants from the early tracheostomy group, eight of them had successfully done the decannulation of tracheostomy (38.1%) compared to the late tracheostomy group, which recorded only 3 out of 24 participants (12.5%) as shown in Table 4.18.

Table 4.18: Decannulation of tracheostomy among the participants.

Variable	**Frequency (n)**	**Percentage (%)**
Decannulation of tracheostomy		
Early tracheostomy (*n*=21)	8	38.1%
Late tracheostomy (*n*=24)	3	12.5%
Total (*n*=45)	**11**	**24.4%**

4.3 UNIVARIATE ANALYSES

4.3.1 Associations between sociodemographic characteristics and tracheostomy classification (early and late) among the participants

This study recorded several sociodemographic characteristics, including participants' age, gender, race, marital status, and GCS on admission. Due to the small number of single and widowed participants, the analysis was run by merging these two groups, later categorised as single/widowed and married. The same for the participant's race. As the Malay participants recorded most of the sample (55.6%), the other end of the participants was merged between Indian and Chinese. The Independent t-test was performed for the continuous variable of the participant's age by comparing two tracheostomy classification groups. In contrast, the other categorical variables were done with the Pearson chi-square test. Nevertheless, the crude analysis showed that none of the sociodemographics included in this study had a significant association with the tracheostomy classification with a p-value >0.05, as shown in Table 4.19.

Table 4.19: Associations between sociodemographic characteristics and tracheostomy classification (early and late) among the participants (n=45)

		Tracheostomy classification					p value
		Early tracheostomy (<7 days)			Late tracheostomy (≥ 7 days)		
Sociodemographic characteristics		**Frequency (n)**	**Percentage (%)**		**Frequency (n)**	**Percentage (%)**	
Age (years) *Mean ± SD*	*49.52±16.57*	-	-	*49.92±17.38*	-	-	0.939^
Gender							
● Male		14	(43.8%)		18	(56.3%)	0.743#
● Female		7	(53.8%)		6	(46.2%)	
Race							
● Malay		9	(36.0%)		16	(64.0%)	0.140#
● Non-Malay		12	(60.0%)		8	(40.0%)	
Marital status							
● Single/widowed		9	(52.9%)		8	(47.1%)	0.552#
● Married		12	(42.9%)		16	(57.1%)	

^ Independent T-test
# Pearson chi-square test

4.3.2 Associations between tracheostomy classification (early and late tracheostomy) and participant's clinical outcomes

Table 4.20 illustrates the association between tracheostomy classification (early and late) and participants' clinical outcomes. The clinical outcomes included were their SOFA score, SAPS II score, length of stay in ICU, length of stay in the hospital, duration of mechanical ventilation support, GCS score upon discharge, the incidence of pneumonia, and decannulation of the tracheostomy. The analysis performed shows a significant association between tracheostomy classification and LOS in ICU (p=<0.001), LOS in hospital (p=0.002), and duration on mechanical ventilation (p=<0.001). However, the SOFA and SAPS II score, used to assess and predict ICU mortality based on laboratory results and clinical data, show no association with tracheostomy classification (p-value = 0.303; 0.231). The GCS score upon discharge, the incidence of pneumonia, and decannulation of tracheostomy also show no association with the tracheostomy classification despite all variables descriptively recording a better outcome in the early tracheostomy compared to the late tracheostomy group.

Table 4.20: Associations between tracheostomy classification (early and late tracheostomy) and participant's clinical outcomes

	Tracheostomy classification						**p value**
	Early tracheostomy (< 7 days)			**Late tracheostomy (≥ 7 days)**			
Patients' clinical outcomes		**Frequency (n)**	**Percentage (%)**		**Frequency (n)**	**Percentage (%)**	
SOFA score (*Mean ± SD)*	*9.14±2.08*	-	-	*9.71±1.55*	-	-	0.303^
SAPS II score (*Mean ± SD)*	*43.24±9.77*	-	-	*39.63±10.11*	-	-	0.231^
LOS in ICU (*mean rank)*	*14.67*	-	-	*30.29*	-	-	**<0.001***
LOS in hospital (*mean rank)*	*16.81*	-	-	*28.42*	-	-	**0.002***
MV duration (*mean rank)*	*13.86*	-	-	*31.00*	-	-	**<0.001***
GCS upon discharge (*mean rank)*	*26.81*	-	-	*19.67*	-	-	0.057
Pneumonia							
● No		10	55.6%		8	44.4%	0.374#
● Yes		11	40.7%		16	59.3%	
Decanulation							
● No		13	38.2%		21	61.8%	0.081#
● Yes		8	72.7%		3	27.3%	

^ Independent T-test
* Mann-Whitney test
# Pearson chi-square test
Bold- significant p-value< 0.05

4.3.3 Associations between tracheostomy classification (early and late) and functional outcome among the participants

The classification of tracheostomy and functional outcome during the discharge period were excluded from the analysis as all the participants still had a low GOSE score, indicating they were in a poor recovery phase. Later, the analysis performed for the three-months post-discharge showed no significant association between these, two variables with a p-value of 0.467. Eventually, as indicated in Table 4.21, the crude analysis showed that the classification of tracheostomy (early and late) was significantly associated with the functional outcome of severe head injury patients with a p-value of <0.001. Thirteen participants (86.7%) with early tracheostomy performed showed a good recovery in their functional outcome compared to the late tracheostomy group (N=2). Twenty-two participants with late tracheostomy (73.7%) experienced a poor recovery in functional outcome during the six-months post-discharge, however, only eight participants from the early tracheostomy group still had poor recovery.

Table 4.21: Associations between tracheostomy classification (early and late) and functional outcome among the participants (n=45)

	Functional outcome (GOSE score)					
	3-months			**6-months**		
	Poor recovery (n=44) n (%)	**Good recovery (n=1) n (%)**	***p*-value**	**Poor recovery (n=30) n (%)**	**Good recovery (n=15) n (%)**	***p*-value**
Tracheostomy classification						**<0.001#**
● Early tracheostomy	20(95.2%)	1(4.8%)	0.467*	8(38.1%)	13(61.9%)	
● Late tracheostomy	24(100%)	0(0%)		22(91.7%)	2(8.3%)	

* Fisher's exact test
# Pearson chi-square test

4.3.4 Associations between tracheostomy classification (early and late) and quality of life among the participants

The univariate analysis of the classification of tracheostomy and quality of life has only been analysed for the time point of three-months and six-months post-discharge. The discharge time point was not analysed as all participants (n=45) recorded a score of fewer than 60 points, making all of them fall under the 'impaired' category. Nevertheless, the association was not statistically significant at the period of three (3) months post-discharge between tracheostomy classification and the quality of life measured by QoLIBRI score (p=0.465). Meanwhile, the analysis for the six (6) months post-discharge showed there was a significant association between the classification of tracheostomy and the quality of life (p=0.045) as demonstrated in Table 4.22. There were three patients obtain the score more than 82 points (above normal) at the point of 6 months post-discharge from the early tracheostomy group. None of the participants from the late tracheostomy group were able to achieve that (above normal) score at the same period (6 months post-discharge).

Table 4.22: Associations between tracheostomy classification (early and late) and quality of life.

Quality of life outcome	Follow-up (Time)					
	3-month			6-month		
	Early tracheostomy (n=21) n (%)	Late tracheostomy (n=24) n (%)	p-value	Early tracheostomy (n=21) n (%)	Late tracheostomy (n=24) n (%)	p-value
QoLIBRI Score						
● Above normal (>82)	0(0%)	0(0%)	0.465*	3(100.0%)	0(0%)	**0.045***
● Normal (67-82)	1(25.0%)	3(75.0%)		8(61.5%)	5(38.5%)	
● Borderline (60-66)	1(100.0%)	0(0%)		3(60.0%)	2(40.0%)	
● Impaired (<60)	19(47.5%)	21(52.5%)		7(29.2%)	17(70.8%)	

*Fisher's exact test

4.3.5 Univariate analysis: Comparison of rehabilitation motivation based on MoT-Q scores between early tracheostomy and late tracheostomy group

There was no significant difference in the mean of MoT-Q score has been found upon discharge and at the point of three-months post-discharge between those patients who underwent early and late tracheostomy (p-value = 0.105; 0.182). However, a significant difference in the mean of MoT-Q score was found at the point of 6 months post-discharge between participants who underwent early and late tracheostomy (p-value = 0.001). Please refer to Table 4.23.

Table 4.23: Comparison of rehabilitation motivation based on MoT-Q mean score between tracheostomy classification (early and late) groups.

	Discharge			**3-month**			**6-month**		
	Mean ± SD	**T-value**	***p*-value**	**Mean ± SD**	**T-value**	***p*-value**	**Mean ± SD**	**T-value**	**p-value**
Early tracheostomy	17.95±13.44	1.65	0.105^	16.57±14.41	1.35	0.182^	22.86±13.93	3.53	**0.001**^
Late tracheostomy	11.38±13.19			11.00±13.16			6.96±15.99		

^ Independent T-test

4.3.6 Association between sociodemographic characteristics and functional outcomes among the participants

Table 4.24 demonstrates the crude analysis executed between sociodemographic characteristics and the functional outcome of the participant. Based on the analysis, the participant's age shows a significant association with the functional outcome (p=0.047). On the other hand, the other sociodemographic data (gender, race, and marital status) were not significant with the participant's functional outcome with a p-value of >0.005 at both periods – three-months and six-months post-discharge.

Table 4.24: Association between sociodemographic characteristics and the functional outcome of the participants.

	Functional outcome (GOSE score)					
	3-months			**6-months**		
	Poor recovery (n=44) n (%)	**Good recovery (n=1) n (%)**	***P*-value**	**Poor recovery (n=30) n (%)**	**Good recovery (n=15) n (%)**	***P*-value**
Age (years) *Mean ± SD*	*50.14±16.79*	NA	NA	53.23±*17.18*	42.73±*14.08*	**0.047**^
Gender						
● Male	31(96.9%)	1(3.1%)	1.000*	21(65.6%)	11(34.4%)	1.000*
● Female	13(100%)	0(0%)		9(69.2%)	4(30.8%)	
Race						
● Malay	24(96.0%)	1(4.0%)	1.000*	20(80.0%)	5(20.0%)	0.056*
● Non-Malay	20(100%)	0(0%)		10(50.0%)	10(50.0%)	
Marital status						
● Single/widowed	16(94.1%)	1(5.9%)	0.378*	11(64.7%)	6(35.3%)	1.000#
● Married	28(100%)	0(0%)		19(67.9%)	9(32.1%)	

^ Independent T-test
# Pearson chi-square test
*Fisher's exact test
Bold- significant p-value< 0.05

4.3.7 Univariate association between sociodemographic characteristics and quality of life among the participants

4.3.7.1 Association between sociodemographic characteristics and quality of life among participants at three-months post-discharge

The ordinal regression analysis showed no significant association between any sociodemographic characteristics in this study and quality of life among participants three-months post-discharge. The detailed findings are tabulated in Table 4.25 below.

Table 4.25: Association between sociodemographic characteristics and quality of life among participants at 3 months post-discharge

	Estimate	**Standard error**	**Wald**	**Adjusted Odds ratio**	**95% Confidence Interval**	**P-value**
Threshold						
• Normal	1.836	3.423	0.288	6.271	-4.873 – 8.545	0.592
• Borderline	2.102	3.425	0.377	8.183	-4.610 – 8.814	0.539
Age (years) *Mean ± SD*	0.079	0.056	1.988	1.082	-0.031 – 0.189	0.159
Gender	0.925	1.163	0.632	2.522	-1.356 – 3.205	0.427
• Male						
• Female						
Race	-1.013	1.271	0.636	0.363	-3.504 – 1.477	0.425
• Malay						
• Non-Malay						
Marital status	1.823	1.543	1.396	6.190	-1.201 – 4.846	0.237
• Single/widowed						
• Married						

4.3.7.2 Association between sociodemographic characteristics and quality of life among participants at six-months after discharge

Table 4.26 below shows the result of the association between sociodemographic characteristics and quality of life among participants six-months post-discharge. The analysis found that only the age of the participants showed a significant association with the quality of life of participants at six-months after discharge (p-value = 0.028). An increase in one year in the age of participants has a 5.44 % (95% CI 0.006 – 0.10) increase in odds of having an impaired quality of life 6 months post-discharge.

Table 4.26: Association between sociodemographic characteristics and quality of life among participants at 6 months post-discharge

	Estimate	**Standard error**	**Wald**	**Adjusted Odds ratio**	**95% Confidence Interval**	**P-value**
Threshold						
• Above normal	-0.082	1.717	0.002	0.9213	-3.447 – 3.282	0.962
• Normal	2.149	1.692	1.614	8.5763	-1.167 – 5.465	0.204
• Borderline	2.678	1.708	2.458	14.556	-0.670 – 6.026	0.117
Age (years) *Mean ± SD*	0.053	0.024	4.824	1.0544	0.006 – 0.101	**0.028**
Gender	-0.342	0.715	0.229	0.7103	-1.744 – 3.205	1.060
• Male						
• Female						
Race	0.517	0.666	0.603	1.677	-0.789 – 1.824	0.438
• Malay						
• Non-Malay						
Marital status	0.354	0.776	0.208	1.425	-1.167 – 1.875	0.648
• Single/widowed						
• Married						

4.3.8 Univariate associations between sociodemographic characteristics of the participants towards the MoT-Q score (rehabilitation motivation)

The details of the analysis performed to identify the association of sociodemographic characteristics of the participants towards the MoT-Q score (rehabilitation motivation) was tabulated in Table 4.27. The analysis shows a significant association between participant's age and rehabilitation motivation measured by MoT-Q scores at all periods of assessment – discharge, 3 months post-discharge and 6 months post-discharge (p-value = 0.001; <0.001; 0.017). On the other hand, the other sociodemographic characteristics showed no significant association with rehabilitation motivation.

Table 4.27: Association of sociodemographic characteristics of the participants towards the MoT-Q score (rehabilitation motivation)

	Discharge			**3-month**			**6-month**		
	Mean ± SD	**T-value**	**p-value**	**Mean ± SD**	**T-value**	**p-value**	**Mean ± SD**	**T-value**	**p-value**
Age (years)	-	*-0.491*[r]	**0.001**		*-0.588*[r]	**<0.001**	-	*-0.355*[r]	**0.017**
Gender									
● Male	14.53±15.13	0.067	0.947	13.50 ± 16.47	-0.093	0.927	15.66 ± 17.46	0.792	0.433
● Female	14.23±9.15			13.85 ± 9.10			11.23 ± 15.74		
Race									
● Malay	16.68 ± 14.74	1.243	0.220	15.96 ± 13.48	1.284	0.206	14.04 ± 18.39	-0.148	0.883
● Non-Malay	11.65 ± 11.69			10.65 ± 14.16			14.80 ± 15.34		
Marital status									
● Single/widowed.	16.76±16.76	0.892	0.377	17.71±11.48	1.571	0.124	15.65±16.28	0.388	0.700
● Married	13.04±13.04			11.11±14.80			13.61±17.55		

Italic correlation test

[r] *Pearson correlation*

4.3.9 Univariate association between clinical outcomes and functional outcomes among the participants

Table 4.28 shows the univariate analysis between clinical outcomes and participant's functional outcomes. The analysis shows there is no association between clinical outcomes and functional outcomes at the period of 3 months post-discharge. However, the analysis performed at the period of 6 months post-discharge showed significant association between length of stay in ICU (p-value = 0.005) and duration on mechanical ventilation (p-value = 0.004) with the participant's functional outcome.

Table 4.28: Association between clinical outcomes and participant's functional outcomes

	Functional outcome (GOSE score)					
	3-months			**6-months**		
	Poor recovery (n=44) n (%)	**Good recovery (n=1) n (%)**	**p-value**	**Poor recovery (n=30) n (%)**	**Good recovery (n=15) n (%)**	**p-value**
SOFA score (*Mean ± SD)*	*9.41±1.82*	NA	NA	*9.40±1.79*	*9.53±1.92*	0.819^
SAPS II score (*Mean ± SD)*	*41.20±10.10*	NA	NA	*39.67±9.95*	*44.60±9.61*	0.120^
LOS in ICU (*mean rank)*	*23.30*	*10.00*	0.444	*26.72*	*15.57*	**0.005***
LOS in hospital (*mean rank)*	*23.13*	*17.50*	0.756	*25.33*	*18.33*	0.078*
MV duration (*mean rank)*	*23.20*	*14.00*	0.622	*26.70*	*15.60*	**0.004***
GCS upon discharge (*mean rank)*	*22.67*	*37.50*	0.356	*21.0*	*25.20*	0.407*
Pneumonia						
● No	17(94.4%)	1(5.6%)	0.400[F]	11(61.1%)	7(38.9%)	0.519[#]
● Yes	27(100%)	0(0%)		19(70.4%)	8(29.6%)	
Decannulation						
● No	34(100%)	0(0%)	0.244[F]	25(73.5%)	9(26.5%)	0.140[F]
● Yes	10(90.9%)	1(.1%)		5(45.5%)	6(54.5%)	

^ Independent T-test
* Mann-Whitney test
# Pearson chi-square test
[F] Fisher's exact test
Bold- significant p-value< 0.05

4.3.10 Association between clinical outcomes and quality of life among the participants

4.3.10.1 Association between clinical outcomes and quality of life among participants at three- months post-discharge.

The ordinal regression analysis shows no significant association between all clinical outcomes and the quality of life among the participants. The details of the analysis result are described in Table 4.29.

Table 4.29: Association between clinical outcomes and quality of life among the participants at 3 months post discharge

Clinical outcomes	Estimate	Standard error	Wald	Adjusted Odds ratio	95% Confidence Interval	p-value
Threshold						
• Normal	-9.847	6.331	2.419	5.2906	-22.255 – 2.561	0.120
• Borderline	-9.580	6.318	2.299	6.9096	-21.963 – 2.804	0.129
SOFA score	-0.288	0.357	0.651	0.7498	-0.988 – 0.412	0.420
SAPS II score	0.011	0.058	0.035	0.8958	-0.104 – 0.125	0.853
LOS in hospital	-0.331	0.595	0.309	0.7182	-1.498 – 0.836	0.578
MV duration	-0.215	0.568	0.143	0.8065	-1.327 – 0.898	0.705
GCS upon discharge	-0.283	0.393	0.519	0.7535	-1.053 – 0.487	0.471
Pneumonia	-1.358	1.124	1.461	0.2572	-3.562 – 0.845	0.227
• No						
• Yes						

4.3.10.2 Association between clinical outcomes and quality of life among participants at 6 months post discharge

Table 4.30 illustrates the association between clinical outcomes and quality of life among the participants at 6 months post-discharge. The ordinal regression performed also demonstrated that none of the clinical outcomes having a significant association with the participant's quality of life at 6 months post-discharge.

Table 4.30: Association between clinical outcomes and quality of life among the participants

Clinical outcomes	Estimate	Standard error	Wald	Adjusted Odds ratio	95% Confidence Interval	p-value
Threshold						
● Above normal	-1.245	3.719	.112	0.2879	-8.535 – 6.045	0.738
● Normal	1.552	3.689	0.177	4.7209	-5.678 – 8.782	0.674
● Borderline	2.211	3.701	0.357	9.1248	-5.043 – 9.466	0.550
SOFA score	-0.268	0.248	1.173	0.7649	-0.754 – 0.217	0.279
SAPS II score	0.028	0.045	0.396	1.0284	-0.060 – 0.116	0.529
LOS in ICU	1.528	0.835	3.350	4.6089	-0.108 – 3.164	0.067
LOS in hospital	0.263	0.387	0.461	1.3008	-0.496 – 1.021	0.497
MV duration	-0.336	0.734	0.210	0.7146	-1.774 – 1.102	0.647
GCS upon discharge	-0.177	0.232	0.583	0.8378	-0.632 – 0.278	0.445
Pneumonia ● No ● Yes	0.007	0.841	0.000	0.9930	-1.641 – 1.654	0.994
Decannulation ● No ● Yes	1.243	0.954	1.698	3.4659	-0.627 – 3.112	0.193

4.3.11 Association between clinical outcomes of the participants towards the MoT-Q score (rehabilitation motivation)

The univariate analysis of the clinical outcomes towards the rehabilitation motivation measured by the MoT-Q scores was demonstrated in Table 4.31**.** The clinical outcomes of SOFA score, SAPS II score, GCS upon discharge and the incidence of pneumonia shows there is no significant association with the rehabilitation motivation among the participants at all three periods – discharge, 3 months post-discharge and 6 months post-discharge. Meanwhile, the LOS in ICU, length of stay in the hospital and duration on mechanical ventilation support dies to reflect a significant association with rehabilitation motivation at the period of 6 months post-discharge (p-value = 0.004; 0.037; 0.004). Similarly, the clinical outcome of successful tracheostomy decannulation records a significant association with the rehabilitation motivation at the discharge period (p-value = 0.028) however was not significant at the period of 3 months and 6 months post-discharge (p-value = 0.083; 0.082).

Table 4.31: Association between the clinical outcomes towards the participant's MoT-Q score (rehabilitation motivation)

	Discharge			**3-month**			**6-month**		
	Mean ± SD	**T-value**	***p*-value**	**Mean ± SD**	**T-value**	**p-value**	**Mean ± SD**	**T-value**	**p-value**
SOFA score	-	*-0.033*[r]	0.829	-	*-0.032*[r]	0.832	-	*-0.028*[r]	0.856
SAPS II score	-	*-0.050*[r]	0.746	-	*-0.119*[r]	0.438	-	*0.173*[r]	0.256
LOS in ICU	-	*-0.197*[r]	0.196	-	*-0.227*[r]	0.135	-	*-0.425*[r]	**0.004**
LOS in hospital	-	*-0.110*[r]	0.471	-	*-0.162*[r]	0.286	-	*-0.312*[r]	**0.037**
MV duration	-	*-0153*[r]	0.317	-	*-0.194*[r]	0.203	-	*-0.423*[r]	**0.004**
GCS upon discharge	-	*0.119*[r]	0.435	-	*0.084*[r]	0.582	-	*-0.078*[r]	0.163
Pneumonia									
● No	14.94±14.26	0.200	0.843^	13.11 ± 14.37	-0.191	0.850^	12.22 ± 17.11	-0.694	0.492^
● Yes	14.11±13.35			13.93 ± 13.82			15.81 ± 16.97		
Decannulation									
● No	11.94 ± 13.48	-2.277	**0.028**^	15.56 ± 13.58	-1.775	0.083^	11.88 ± 16.26	-1.782	0.082^
● Yes	22.18 ± 11.09			19.91 ± 13.50			22.09 ± 17.35		

Italic correlation test

[r] *Pearson correlation*

^Independent T-test

Bold - significant p value <0.05

4.4 MULTIVARIATE ANALYSIS

4.4.1 The association of early tracheostomy and late tracheostomy towards the clinical outcomes of severe head injuries patients

Table 4.32 shows the association of tracheostomy classification towards the clinical outcomes of severe head injury patients by adjusting for age, gender, race, marital status, and GCS upon admission. The multivariate analysis of logistic regression revealed that the length of stay (LOS) in the hospital and the duration of mechanical ventilation support remained associated with the late tracheostomy (p-value = 0.035; 0.005). The analysis revealed that patients who had undergone the late tracheostomy were more likely to have a longer duration of mechanical ventilation support than those who had early tracheostomy (OR=39.68; p=0.005; 95% CI (3.347 - 95.56). However, although it was significant, the 95% confidence interval was huge between 3.347 - 95.56, potentially due to the sample size issue (small sample size = 45). Therefore, the result needs to be interpreted cautiously. Similarly, the patient who had undergone the late tracheostomy had 5.7 times more likely to have a longer LOS in the hospital than those who had the early tracheostomy (p=0.035; 95% CI (1.126 – 29.229)).

Table 4.32: Association of Tracheostomy Classification towards the Clinical Outcomes

Clinical outcomes	Regression coefficient (B)	Standard error	Wald	Adjusted Odds ratio	95% Confidence Interval	P-value
SOFA score	0.024	0.481	0.003	1.025	0.399 – 2.629	0.960
SAPS II score	-0.038	0.072	0.280	0.962	0.835 – 1.109	0.597
LOS in ICU	0.109	1.557	0.005	1.115	0.053 – 23.580	0.944
LOS in hospital	1.747	0.831	4.421	5.737	1.126 – 29.229	**0.035**
MV duration	4.083	1.467	7.749	39.68	3.347 – 95.56	**0.005**
GCS upon discharge	-0.576	0.411	1.964	0.562	0.251 – 1.258	0.161
Pneumonia						
● No (reference)						
● Yes	-0.597	1.363	0.191	0.551	0.038 – 7.970	0.662
Decannulation						
● No (Reference)						
● Yes	0.204	1.424	0.021	1.226	0.075 – 19.999	0.886

The reference category: Late tracheostomy

Adjusted for age, gender, race, marital status and GCS upon admission.

Bold = p-value < 0.05

4.4.2 The association of early tracheostomy and late tracheostomy towards the functional outcome measured by GOSE score.

Table 4.33 below shows the association of early and late tracheostomy towards the GOSE score by adjusting for time follow-up (discharge, 3-month, 6-month), age, gender, race, marital status, length of stay in the hospital, length of stay in ICU, mechanical ventilation duration, GCS score, SOFA score, SAPS II score, QoLIBRI score, and MoT-Q score. The GEE analysis showed that patients who had early tracheostomy were more likely to have a good recovery at 18.9% higher compared to those patients who had the late tracheostomy.

Table 4.33: Effect of the early tracheotomy to the good recovery measured by GOSE score.

Variables	**B**	**Standard error**	**RR (95% CI)**	***P*-value**
Tracheostomy status ● Early tracheostomy ● Late tracheostomy (reference)	0.173	0.038	1.189 (1.10 – 1.28)	**<0.001**

Quasi-Likelihood Under Independence Model Criterion (QIC)=7.12, Corrected Quasi-Likelihood Under Independence Model Criterion (QICC)=14.68
Adjusted for time follow up (discharge, 3-month, 6-month), age, gender, race, marital status, length of stay (LOS) in hospital, length of stay (LOS) in Intensive Care Unit (ICU), mechanical ventilation duration, Glasgow Coma Scale (GCS) score, Sequential Organ Failure Assessment (SOFA) score, Simplified Acute Physiology II (SAPS II) score, Quality of Life After Brain Injury (QoLIBRI) score, and Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q) score.

4.4.3 The association of early tracheostomy and late tracheostomy towards the quality of life measured by QoLIBRI score

The longitudinal analysis, as portrayed in Table 4.34 below, shows there was no significant association between early or late tracheostomy and quality of life measured by QoLIBRI score among patients with a severe head injury (RR (95% CI); 0.47(0.19 – 1.16) p-value = 0.102).

Table 4.34: Effect of the early tracheotomy on the QoLIBRI score

Variables	**B**	**Standard error**	**RR (95% CI)**	***P*- value**
Tracheostomy status ● Early tracheostomy ● Late tracheostomy (reference)	-0.762	0.465	0.47(0.19 – 1.16)	0.102

Quasi-Likelihood Under Independence Model Criterion (QIC)=23.25, Corrected Quasi-Likelihood Under Independence Model Criterion (QICC)=33.54
Adjusted for time follow up (3- discharge, 3-month, 6-month), age, gender, race, marital status, length of stay (LOS) in hospital, length of stay (LOS) in Intensive Care Unit (ICU), mechanical ventilation duration, Glasgow Coma Scale (GCS) score, Sequential Organ Failure Assessment (SOFA) score, Simplified Acute Physiology II (SAPS II) score, Quality of Life After Brain Injury (QoLIBRI) score, and Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q) score.

4.4.4 The association of early tracheostomy and late tracheostomy towards the rehabilitation motivation measured by MoT-Q score

The GEE analysis shows that the early tracheostomy had a 47% higher MoT-Q score compared the late tracheostomy patients (Table 4.35).

Table 4.35: Impact of the early tracheotomy on the score of MoT-Q

Variables	B	Standard error	RR (95% CI)	*P*- value
Tracheostomy status ● Early tracheostomy ● Late tracheostomy (reference)	0.385	0.160	1.470(1.074 – 2.011)	**0.016**

Quasi-Likelihood Under Independence Model Criterion (QIC)=50.03, Corrected Quasi-Likelihood Under Independence Model Criterion (QICC)=48.81
Adjusted for time follow up (3- discharge, 3-month, 6-month), age, gender, race, marital status, length of stay (LOS) in hospital, length of stay (LOS) in Intensive Care Unit (ICU), mechanical ventilation duration, Glasgow Coma Scale (GCS) score, Sequential Organ Failure Assessment (SOFA) score, Simplified Acute Physiology II (SAPS II) score, Quality of Life After Brain Injury (QoLIBRI)

4.5 SUMMARY

The present study showed that the proportion of late tracheostomy (n=24; 53.3%) was slightly higher compared to the early tracheostomy (n=21; 46.7%) among all participants (n=45). Most were male (71.1%), and more than half were Malay (55.6%). Twenty-eight were married; the others were single and widowed (n=13; 4). Descriptively, the early tracheostomy group recorded a shorter stay in the ICU, hospitalization, and fewer days on mechanical ventilation support, lower SOFA and SAPS II scores than the late tracheostomy group. The GCS upon discharge was almost similar between those two groups. The incidence proportion of pneumonia was higher for the late tracheostomy group (66.7%) compared to early tracheostomy group (52.4%). The early tracheostomy group recorded a higher decannulation rate (n=8) than late tracheostomy group (n=3). Given their functional outcome, none of the participants acquired a 'good recovery' during the discharge period, and only one participant gained a good recovery for three-months post-discharge. Subsequently, 15 participants were in a good recovery, showing that the early tracheostomy group was more prominent, with 13 participants achieving that. The QoLIBRI score, intended to measure the participant's health-related quality of life, noted 75% of participants in the late tracheostomy group remained in an ‘impaired’ state at the period of 6 months post-discharge. Instead, three participants from the early tracheostomy group managed to obtain a score 'above normal', with the majority of them (38.1%) in a normal score category. The level of motivation measured by the MoT-Q scores also positively impacts those participants from the early tracheostomy group. Severe head injury patients in the late tracheostomy group only recorded an average score of 6.96 to 11.38 during all three follow-up periods compared to the early tracheostomy group ranging from 16.57 to 22.86. The univariate analysis between tracheostomy classification and clinical outcomes shows a significant association with LOS in ICU, LOS in the hospital and duration on mechanical ventilation support (p=<0.001; 0.002; <0.001). The longitudinal analysis did not show a significant association between tracheostomy classification and LOS in ICU (p=0.944). However, it shows a consistent significant association with LOS in the hospital (OR=5.737; p=0.035; 95% CI (1.126 – 29.229)) and duration on mechanical ventilation support (OR=39.68; p=0.005; 95% CI (3.347 - 95.56)). Next, the longitudinal analysis showed that tracheostomy classification (early and late) had a significant association between the participant's functional outcomes

(RR=1.189; 95% CI (1.10-1.28); p=<0.001) and motivation toward rehabilitation (RR=1.470; 95% CI (1.074-2.011); p=0.016). Nevertheless, the analysis did not show a significant association between tracheostomy classification and quality of life (RR=0.470; 95% CI (0.19-1.16); p=0.102).

CHAPTER FIVE

DISCUSSION

5.0 INTRODUCTION

Regardless of the patient's age, personal background, or medical history, severe head injuries have claimed numerous lives over the years. Everyone is susceptible to developing this condition following a life-threatening event, such as a fall, a road traffic accident, assault, or any trauma that results in severe head injury. Their clinical outcomes, functional outcomes, quality of life, and motivation toward rehabilitation are the aspects that should be evaluated regularly as part of the evaluation of any interventions, procedures or approaches delivered to the patients. The initiation of an early or late tracheostomy is one of the procedures that should be evaluated for its efficacy and to determine if it will improve the patient's outcomes. This chapter will discuss further the findings presented in the previous chapter by addressing all research objectives posed in this study. This chapter is divided into four sections. The first section will discuss the participants' sociodemographic characteristics and tracheostomy classification (early and late). The next section will discuss significant findings about the participant's clinical outcomes. The third section will delve into greater detail about the study's significant findings on functional outcome, quality of life, and rehabilitation motivation, which are also the study's primary objectives. Lastly, the study's findings concerning its theoretical framework will be briefly discussed. The finding discussed in all sections will be compared to existing research on the effects of early and late tracheostomy in individuals with serious head injuries.

5.1 PROPORTION OF EARLY AND LATE TRACHEOSTOMY

This study found that among the forty-five participants involved, those with a late tracheostomy (n=24) were slightly higher than those with an early tracheostomy (n=21). This finding indicated that early tracheostomy has not yet been implemented on all

severe head injury patients, which may be attributed to some factors, and that severe head injury patients are highly likely to experience delayed or late tracheostomy. This finding was consistent with the previous research, which recorded higher participants in the late tracheostomy group compared to the early tracheostomy (Pinheiro et al., 2010; Wang et al., 2011; Alali et al., 2013; Huang et al., 2013; Jeon et al., 2014; Gessler et al., 2015; Siddique et al., 2016; Khalili et al., 2017; Shihabashi et al., 2017; Qureshi et al., 2018; Alsherbini et al., 2018; and Robba et al., 2020). The initiation of tracheostomy was delayed due to several causes. Based on the information taken from the participant's progress notes, the reasons include immediate family member's disinclination to consent to the procedure, the inconsistency in reaching a final decision among the family members regarding whether to proceed or not to proceed with the procedure, the lengthy period spent waiting for the participant's family members to gather for a family conference, the patient's unstable condition due to old age or multiple comorbid conditions – which rendered them temporarily unfit for the procedure, and financial constraints. Tai et al., (2019) reported that the main reason for the delayed initiation of tracheostomy was family members' hesitation in consenting to the procedure and the physician's decision to opt for the tracheostomy approach. A recent study by Sindi, (2022) found that late or delayed tracheostomies due to a concern for other morbidity and unstable condition, hectic operation theatre schedule and refusal of the family members. If none of these concerns were resolved, the tracheostomy procedure would be delayed day after day, which could result in several unfavourable outcomes for the patients.

5.2 SOCIODEMOGRAPHIC CHARACTERISTICS AND TRACHEOSTOMY CLASSIFICATION (EARLY AND LATE)

This study recorded a total of 45 severe head injury patients with tracheostomy. Even though the sample size was small, the number was comparable to some previous studies. Qureshi et al. (2018) included 48 TBI patients in a facility in Islamabad, Pakistan. Some studies, such as Pinheiro et al. (2010) with 28 participants and Huang et al. (2013) with 38 participants, even used a smaller sample size. In Malaysia, a previous study conducted by Sim et al., (2011) only listed 35 TBI patients from their study at Sarawak General Hospital, whereby a study by Ludin et al., (2019) managed to conclude a cohort

of 33 TBI patients in two healthcare facilities sited in the country's east coast region. A meta-analysis by Arulsamy et al., (2020) also mentioned that in the last decade, most studies involving moderate to severe head injury patients in Malaysia were conducted with a sample size ranging from 25 to 38. Even though this study was limited to severe head injury patients with the initiation of tracheostomy, 45 participants were successfully recruited, which was greater than the previous studies involving head injury patients in Malaysia.

In this study, from the 105 severe head injury patients with tracheostomy admitted to the ICU of both hospitals, 32.4% passed away (n=34) during hospitalisation, and the other 10.5% (n=11) were dead less than six months after they were discharged. This finding was comparable to the previous report by Ling et al., (2017), which documented that head injury patients in ICU had a mortality rate of more than 20% each year from 2012 until 2017. Even if the patient had survived their hospitalization and was successfully discharged, their survival rate was low in the long run, contributing to death less than six months post-discharge, especially among the adult population (Purcell et al., 2020). McMillan et al. (2011) and Ventura et al. (2010) also reported that individuals who experienced head injury incidents, specifically TBI, had a reduced life expectancy even after overcoming hospital mortality. The cause of death post-discharge for TBI patients includes respiratory issue, circulatory problems, neoplasms, external factor such as self-harm, drug toxicity, subsequent event such as falls and other existing comorbidities (McMillan et al., 2011; Ventura et al., 2010).

Most participants (71.1%) were male, while only 28.9% were female. This finding was similar to the majority of the past studies involving head injury patients with tracheostomy within the last decade (Robba et al., 2020; Rosyidi et al., 2018; Shibahashi et al., 2017; Khalili et al., 2017; Siddique et al., 2016; Huang et al., 2013; and Alali et al., 2013). This finding reflected the epidemiological fact that males are around 40% more likely than females in the general community to suffer from TBI (Faul & Coronado, 2015). Furthermore, previous studies had avowed that most motorcycle riders were male with the main cause of head injury was due to MVA, which contribute to a higher prevalence of head injury cases compared to female (Ludin et al., 2019; Sandhaug et al., 2015; Sim et al., 2011; and Klemenc-Ketis et al., 2011).

The finding demonstrated that most participants were married, and the majority of them were 30 years old and above (n=39; 86.7%). Both findings were related to one another. As reported in Marriage and Divorce Statistics Malaysia 2021, the median age of Malaysian getting married was 26 to 28. Therefore, since most participants were adults over 30 years old, most of them had already married. The participant's marital status had been included in this study as one of the sociodemographic characteristics as this variable had been underrepresented in previous research. According to Hammond et al. (2021), until ten years post-injury, TBI patients could maintain a healthy marriage while receiving regular inpatient rehabilitation. Hence, this study finding can give an idea of whether participants' marital status might affect their functional outcomes, quality of life, and motivation toward rehabilitation after being discharged.

This study did not find any significant association between sociodemographic characteristics and clinical outcomes regarding the timing of tracheostomy (early and late). As mentioned by McShane et al., (2022) and Scales & Ferguson (2010), the tracheostomy intervention will be performed after it has been consented to by the family members and proposed based on the patient's condition and physician/surgeon in charge judgement. Although a previous study by Tamir et al., (2018) had documented that a patient's age is significantly associated with tracheostomy timing, as the elderly are more likely to have a late or delayed tracheostomy, the present study has shown that a patient's age does not significantly associate with the tracheostomy timing. The decision on when to proceed for tracheostomy was not listed the patient's age as the main criteria. As long as there are no contraindications for the patients to undergo tracheostomy and the procedure is consented to by the immediate family members, the patients will be tracheostomised despite their age. This condition was parallel to the finding by Gillis et al., (2020) which mentioned no differences in the time of the tracheostomy to be initiated based on the patient's age.

5.3 CLINICAL OUTCOMES AND TRACHEOSTOMY CLASSIFICATION

The patient's duration on mechanical ventilation support and length of stay in the ICU were among the prominent clinical outcomes discussed in previous studies (Wang et al., 2012; Alali et al., 2013; Jeon et al., 2014; Siddique et al., 2016; and Shihabashi et al., 2017). This is because, in recent years, the indication of early tracheostomy has

become a concern to shorten the dependency on mechanical ventilation and subsequently reduce the ICU stay (Deng et al., 2021). The present study found that duration of mechanical ventilation support and length of stay in the hospital were significantly associated with the tracheostomy classification (early and late), whereby the length of stay in ICU was found otherwise.

5.3.1 Length of Stay in ICU and Hospital

According to a meta-analysis conducted by Marra et al. (2021), early tracheostomy is significantly associated with a shorter ICU stay. In this study, the late tracheostomy group spent an average of 28 days in the intensive care unit (ICU), 2.8 times longer than the early tracheostomy group (10 days). Even though the univariate analysis revealed a significant association between tracheostomy classification and ICU LOS (p=<0.001), the multivariate analysis showed no significant association between these variables (p=0.944). Similarly, a study by Gessler et al. (2015) found no significant association between tracheostomy classification (early and late) and LOS in ICU, although most recent research indicated the opposite. On the other hand, Rizk et al. (2011), Alali et al. (2013), and Robba et al. (2020) report a significant association between tracheostomy classification and LOS in ICU with a p-value of 0.001. Compared to the past studies by Rizk et al. (2011), Alali et al. (2013) and Robba et al. (2020), which involved larger sample size and longer duration for data collection, this present study was not able to address a significant association similar to those past studies which may be due to small sample sizes and shorter data collection period.

The collinearity of two variables existed between the participant's LOS in ICU and LOS in hospital. As the longer the patient requires ICU treatment, the more likely their LOS in the hospital will also be longer. Hunter et al., (2014) mentioned that patients requiring an ICU bed would spend an additional 1.5 days in the hospital for each day they had been nursed in ICU. Therefore, the patients with a late tracheostomy will have more extended hospitalization as they have longer ICU stays and mechanical ventilation support. This study's multivariate analysis shows a significant association with tracheostomy classification with a p-value of 0.035. This finding was consistent with previous studies on severe head injury patients (Alali et al., 2013; Baron et al., 2016; Khalili et al., 2017; Shibahashi et al., 2017; Qureshi et al., 2018 and Robba et al.,

2020). After they have been tracheostomised, the onset of the weaning process from the ventilator will occur (Lim et al., 2015). As their tracheostomy was delayed, the weaning-off process will also be delayed. Sanabria et al. (2013) added that if the decision for tracheostomy were postponed for more than 8 days, the success of weaning off mechanical ventilation would be poor. The period of hospitalisation could also be extended if the patient develops additional complications such as acute respiratory failure, renal failure, sepsis, aspiration pneumonia, deep vein thrombosis, poor GCS and others (Omar et al., 2017; Bohmer et al., 2017; and Ingraham et al., 2010).

5.3.2 Duration on Mechanical Ventilation Support

Within the last decade, the study on tracheostomy classification (early and late) among head injury patients always discussed its association with a shorter duration of mechanical ventilation support as their core argument; and the majority of the studies have proven its significant association between early tracheostomy and shorter duration on mechanical ventilation support (Alali et al., 2014; Alsherbini et al., 2019; Gessler et al., 2015; Qureshi et al., 2018; Shibahashi et al., 2017; Siddiqui et al., 2015; and Jeon et al., 2014). In this study, the early tracheostomy group had recorded an average of 7 days on mechanical ventilator support compared to the late tracheostomy group with an average of 19 days. In addition, the statistical analysis shows a significant association between late tracheostomy and the longer mechanical ventilator support duration (p-value=0.005). Despite being proven significant, the 95% confidence interval was enormous, ranging from 3.347 to 95.56, possibly because of the problem with the sample size (n=45). Therefore, the result needs to be interpreted cautiously. However, as mentioned by Machin et al. (2013), the width of the confidence interval will be larger in a small sample size study, and it can be narrowed down by increasing the sample size.

As mentioned in the previous chapter, the main reason for initiating tracheostomy is to assist in the weaning process for those with prolonged mechanical ventilation support (Meng et al., 2012; & Huang et al., 2013). The initiation of tracheostomy could be early or late. However, this recent study added a shred of consistent evidence which suggests that late tracheostomy, on the other hand, was more likely to have a longer duration of mechanical ventilation support. Thus, it was clear

that the early tracheostomy should have been emphasized with one of its main benefits - promoting a shorter duration of mechanical ventilation usage.

5.3.3 Incidence of Pneumonia and Decannulation Rate

In this present study, although the late tracheostomy group had a more proportion of participants affected with pneumonia than the early tracheostomy group, the analysis shows no significant association between tracheostomy classification and the incidence of pneumonia (p=0.662). Sixty percent of the participants had been diagnosed with pneumonia in this study. This statistic was almost identical to the 60.6% incidence of VAP reported by Esnault et al., (2017). However, the incidence proportion of pneumonia in this present study was not specifically addressed to the VAP but was the general incidence of pneumonia instead. Thus, pneumonia occurs at any point of hospitalization period of the participants compared to the VAP, that only occurs in ICU. The type of pneumonia also was not properly classified, as during the data collection process, the entry in the patient's clinical notes was inconsistent in addressing the type of pneumonia. Therefore, the incidence of pneumonia recorded in this study is addressed as general pneumonia rather than specifically described as VAP or other hospital-associated pneumonia groups such as viral pneumonia, bacterial pneumonia, fungal pneumonia, parasitic pneumonia, or idiopathic interstitial pneumonia (Peterson, 2020). This present study may suggest that the timing of tracheostomy, whether early or late, does not significantly influence the risk for pneumonia incidence as good quality of nursing care and tracheostomy care may prevent the incidence of pneumonia to occurs although the initiation of the tracheostomy early or late. As Boltey et al. (2017) mentioned, providing excellent oral hygiene care and the coordination of subglottic suctioning may reduce the risk of pneumonia. The suctioning procedure also must be sterile at all times for tracheostomy patients to prevent hospital-acquired pneumonia (Stacy, 2020).

As for the success of tracheostomy decannulation among the participants, the early tracheostomy group records a higher rate of decannulation compared to the late tracheostomy group in this present study. However, the analysis shows no significant association between these two variables (p=0.886). On the contrary, the previous study by Gessler et al., (2015) and Schneider et al., (2017) recognizes a significant association

between decannulation rate and early tracheostomy (p-value=0.003; 0.021). However, those studies had focused explicitly on head injury patients with poor SAH and stroke whereas the present recent study was particularly subjected to severe head injury patients with the initiation of tracheostomy. In this study, only 24.4% of participants (n=11) had been decannulated within six (6) months post-discharge, and the others remained intact with a tracheostomy. Conversely, the previous study by Jenkins et al., (2020) recorded a higher rate of successful decannulation of tracheostomy (74.7%) among severe TBI patients (n=59).

5.4 FUNCTIONAL OUTCOMES OF THE PARTICIPANTS

The participant's level of functional outcome was determined using the GOSE instrument. According to Wilson et al., (1997), the recommended time for GOSE assessment should be three-month and six-month post-discharge. In this study, the GOSE scores were measured at the discharge period as a baseline and were reassessed at three-months and six-months post-discharge. Even though some studies had assessed GOSE in TBI patients at 6 months and 12 months post-discharge (Corral et al., 2007; Soberg et al., 2013), several recent studies (McCrea et al., 2021; Ludin et al., 2019; and Weber et al., 2016) had assessed GOSE at three-months and six-months post-discharge with promising results.

From the cohort of 45 participants engaged in this study, only one participant in the early tracheostomy group had accomplished a good recovery three-months post-discharge. Eventually, a remarkable improvement was noted at six-months post-discharge as fifteen of them achieved good recovery. This study's findings were comparable to those published by McCrea et al., (2021), Ludin et al., (2019) and Weber et al., (2016), which indicate that GOSE scores improved significantly from three to six-months after discharge. Wilkins et al. (2018) also mentioned that severe TBI patients significantly improved their functional outcome status from the three-month post-discharge until 24 months post-discharge. Their study recorded that 43% of the severe TBI patients included in the study had progressed from unfavourable to favourable outcomes from the period of three-month to six-month post-discharge. Vendantam et al. (2018) added that approaching the period of six-month post-discharge, severe head TBI patients will significantly acquire favourable functional outcomes if

the patients can follow commands during the period two weeks post-injury. Even though the past literature had proven that it is beneficial to evaluate the severe head injury and severe TBI patient's functional outcomes over three months and six months post-discharge, this present study, however, had added another value. The present study observed the improvement of the participant's functional outcomes with addition in determining the impact of tracheostomy classification (early and late) on the participant's functional outcomes, which is measured by the GOSE score.

5.4.1 Sociodemographic Characteristics and Functional Outcomes

Only the participant's age significantly correlates with the functional outcome (p=0.047) among all sociodemographic factors in this study. This finding supported the previous study by Kim et al., (2011), Hassani et al., (2018), Kowalski et al., (2021), and Mazlan et al., (2021), which indicated that patients with younger age contribute to higher functional outcomes' status compared to the elderly. In order to achieve a better functional outcome especially following the incident of severe head injury, the patient should have a proper and continuous rehabilitation regime (Al-Hassani et al., 2018). Throughout the recovery process, other complications that might be due to the incident of recent head injury or other existing medical comorbidities will slow down the recovery process (Ganesh et al., 2013; Whyte et al., 2013). Given that younger patients will have fewer comorbid disorders, their recovery toward a better functional outcome will be much faster than those of much older individuals (Chan et al., 2017). The meta-analysis done by Laic et al., (2021) also reported that older age is one of the risk factors that lead to poor functional outcomes for the patients following the TBI incident and the unfavourable functional outcomes worsening over time as time passed. Albrecht et al., (2015) mentioned that the incidence of TBI among the elderly would increase the risk of depression among the patients, eventually affecting their recovery toward a functional outcome.

5.4.2 Clinical Outcomes and Functional Outcomes

This study also analysed the association between clinical outcomes and functional outcomes among the participants. The univariate analyses showed that LOS in ICU and

duration on mechanical ventilation support were significantly associated with the participant's functional outcomes (p-value=0.005; 0.004) six-months post-discharge. This study's findings are congruent with those of a recent study conducted on TBI patients by Ludin et al. (2019), which recorded a significant association between LOS in the ICU and duration of mechanical ventilation with the patient's functional outcomes using the same GOSE instrument (p-value=0.049; 0.048). Given the association between LOS in ICU and functional outcome, a past study by Wiegers et al., (2021) recorded a similar finding whereby shorter ICU stay may improve the patient's functional outcome (p=<0.005). From a different angle of different TBI population, a previous study by Dhanda et al., (2022) among pediatric TBI patients had reckoned that longer duration in ICU, specifically NICU were the main predictor for a poor functional outcome. Like other past studies, this present study concludes that more extended ICU stay, and mechanical ventilation support affected the severe head injury patient's functional outcome.

Given the other clinical outcomes in this study, none of them were proven statistically significant with the participant's functional outcomes. This finding might be due to the limited sample size, that may fail to reach statistically significant association between these variables, similar to past research such as the previous study by Kesinger et al., (2015), which concluded that hospital-acquired pneumonia among TBI patients was a significant independent predictor of lower GOSE score (poor functional outcomes). On the other hand, Esnault et al., (2017) discovered that the incidence of pneumonia, specifically the early onset of VAP, was an independent predictor linked to unfavourable neurologic functional outcomes among TBI patients. Both studies included a longer time frame of data collection and a larger population to acquire more reliable and convincing results.

5.4.3 Tracheostomy Classification (Early and Late) and Functional Outcomes

The tracheostomy classification was separated into two groups (early and late) based on the chosen cut-off times of 7 days. Initially, the univariate analysis shows that there is no association noted between tracheostomy classification and functional outcome among the participants at the period of 3 months post-discharge (p=0.467). However, the analysis performed six-months post-discharge shows a significant association with

the p-value of <0.001. The longitudinal analysis of GEE shows a consistent significant association between tracheostomy classification and functional outcomes (RR=1.189; 95% CI (1.10-1.28); p=<0.001). The early tracheostomy was significant to in obtaining good recovery measured by GOSE. The data revealed that patients with early tracheostomy were 18.9% more likely to recover well than those with a late tracheostomy.

This study's finding reflected the previous study by Robba et al., (2020), which reported that late tracheostomy was significant in poor GOSE scores. On the other hand, the other study by Rizk et al., (2011) also documented that early tracheostomy significantly improves the patient's functional status using the Functional Independence Measure (FIM) score. Another study by Khalili et al., (2017) described that early tracheostomy does promote a favorable outcome based on the GOSE scores even though it was not statistically significant. The study on the effect of early and late tracheostomy on the patient's functional outcomes was somewhat limited with inconsistent findings (Rizk et al., 2011; Khalili et al., 2017; Schneider et al., 2017; & Robba et al., 2020). Thus, the finding from this present study could provide additional evidence that early tracheostomy does promote a better functional outcome among severe head injury patients.

5.5 HEALTH RELATED QUALITY OF LIFE OF THE PARTICIPANTS MEASURED BY QoLIBRI

One of the significant challenges for severe head injury survivors is acquiring a good quality of life, including social relationships, emotion, physical ability, self-independent, and cognitive function. The head injury that may affect their physical ability for an extended period ultimately as well as their emotion and life satisfaction (Romanov et al., 2021; & Juengst et al., 2015). Thus, it is crucial for the community, including family members and healthcare practitioners, to ensure the severe head injury patients' emotional status and quality-of-life satisfaction in relation to ensure that other interventions, such as rehabilitation programs, will be more efficient. In this study, the QoLIBRI score of all participants was less than 60 points during the discharge period, which indicated as 'Impaired'. After six-months post-discharge, sixteen participants (34.78%) from both groups (early and late tracheostomy) reached 'normal' or 'above

normal' scores. The participant's mean score also gradually improved from 15.33 during the discharge period to 52.64 for 6 months post-discharge. This finding was quite similar to the previous study by Ludin et al. (2019) among 33 severe TBI patients with a mean score of 53.09 during the six-month post-discharge period. The improvement in the participant's subjective perspective on their quality of life, based on the QoLIBRI score, manifests their acceptance and adaptation to the certain limitation they had to endure following the head injury incident. As Machamer et al. (2013) mentioned, most patients, including those with severe functional limitations, became aware of their impairment six months post-discharge and could rate their satisfaction accordingly.

Nevertheless, this study added another piece of information: comparing the mean QoLIBRI of the severe head injury patients according to their tracheostomy classification (early and late). After the participants were separated based on their tracheostomy classification, it shows that those from the early tracheostomy group obtained a higher mean QoLIBRI score of 64.51 compared to late tracheostomy group with the mean score of 42.26. The univariate analysis between sociodemographic data, clinical outcomes and tracheostomy classification (early and late) toward the participant's quality of life was performed alongside their functional outcomes and rehabilitation motivation. However, since the specific objectives of this recent study focused on determining the impact of early tracheostomy, this variable was not assessed as it is beyond the scopes of this present study.

5.5.1 Sociodemographic Characteristics and Quality of Life

The analysis revealed that none of the variables listed in the clinical outcomes was significantly associated with the participant’s quality of life during the three and six-months post-discharge. On the other hand, the univariate analysis performed between sociodemographic characteristics and quality of life recorded significant finding: the participant’s age at the 6 months post-discharge (p=0.028) even though it was initially not significant at the period of 3 months post-discharge (p=0.159). The significant association between age and health-related quality of life was demonstrated in the previous study by Siponkoski et al., (2013), which explained that younger patients expressed satisfaction with their cognitive function.

As mentioned earlier (kindly refer to sub-section 5.4.1), younger patients were related to better functional outcomes' recovery. This condition will affect the patient's health-related quality of life as they become more determined to get better and achieve a good recovery; to return to their normal activity daily living (ADLs) life. As mentioned by von Steinbuchel et al., (2010), the QoLIBRI score had a significant association with the GOSE score to evaluate functional outcomes. Thus, as the younger patients had higher GOSE scores, it is highly likely that their QoLIBRI score will also be higher compared to elderly patients. However, a recent study by Krenz et al., (2023) had proven otherwise, whereby younger patients under the age of 24 years old had poor QoLIBRI scores, which indicate an impaired quality of life compared to the older age. In that study, despite having other comorbidity compared to the younger ones, the elderly patients had greater satisfaction with their health-related quality of life compared to the younger patients who rated poor QoLIBRI scores over the fact that their inability to perform everyday activities and lost their significant roles in the community. Even though past literature had suggested a different finding on the patient's age (younger or older) toward a better health-related quality of life, this study supported the hypothesis that the age of the severe head injury patients does influence their health-related quality of life.

5.5.2 Tracheostomy Classification (Early and Late) and Quality of Life

In this study, all participants, regardless of their tracheostomy classification, had obtained a QoLIBRI score of less than 60, categorizing them as 'Impaired'. Even though after 3 months, only five participants reached 'Normal' scoring (n=1) and 'Borderline' scoring (n=4). After 6 months post-discharge, some improvement on the QoLIBRI score can be seen whereby almost half of them (n=21; 46.7%) of the participants obtained 'Borderline' to 'Above normal' scoring. The 'plateau' phase within 6 months following a head injury incident on the patient's quality of life was also reported in past studies by Machamer et al., (2013) and Ludin et al., (2019). Oeyen et al., (2010) mentioned that improving health-related quality of life for the patients discharged from the ICU would occur three to 12 months post-discharge. In addition, compared to other diseases or disabilities, TBI patients claimed to have a poor quality of life due to dissatisfaction with their cognitive function and physical abilities (Harfmann et al.,

2020). Thus, they may require a longer time to get back on their feet with a better physical ability and eventually rate a higher quality of life after a more extended period of discharge from the hospital.

In this present study, more than half of the participants (n=24; 53.5%) reported in the 'Impaired' category even after 6 months post-discharge. This finding was consistent with the review by Sukraeny et al., (2014), which mentioned that the majority of the previous studies among head injury patients recorded a low quality of life score. However, they did mention that even though the majority of the study reported a lower score of quality of life, the comparison of the finding from one study to another was quite difficult to be done because each study was conducted differently in term of study method, conceptualisation to approach the quality of life, and different tool or instrument to measure the health-related quality of life. Descriptively, this study added another information that shows the late tracheostomy group had a higher number of patients with 'Impaired' QoLIBRI score (n=18; 75%) compared to the early tracheostomy group (n=6; 28.6%). Instead, the early tracheostomy group had eleven participants (52.4%) with a 'Normal' and 'Above normal' score compared to the late tracheostomy group, which had none of them an 'Above normal' score and only five participants (20.1%) in 'Normal' score category.

5.6 PARTICIPANT'S LEVEL OF MOTIVATION TOWARD REHABILITATION MEASURED BY THE MoT-Q

In this present study, early tracheostomy participants recorded higher MoT-Q scores compared to the late tracheostomy group. They had achieved an average score of 22.86 during the six months post-discharge, ranging from -5 to 42. On the other hand, during the same assessment period, the late tracheostomy group had only obtained an average score of 6.96, with a minimum score as low as -16 and a maximum score of 37. Even though the average scores were still far from the maximum score of 62, it was expected, given that all of them were bedridden with a very poor functional status during the discharge period. As Ruet et al. (2019) mentioned, the recovery phase for neurological impairment, such as physical movement and cognitive function experienced by the patients, may take weeks or years. Therefore, the rehabilitation program's success depends on the patient's overall health, range of motion, muscle strength, bladder and

bowel function, functional abilities, social and learning capabilities and motivation to participate in the rehabilitation program (Portugal, 2021).

Head injury survivors require a routine of rehabilitation to assist them in achieving the best possible functional outcomes they could have. However, as the degree of neurological impairment might vary from one patient to another, the goal of the rehabilitation program also could differ based on their current state (Ruet et al., 2019). Further assessment at the period of one-year post-discharge could be helpful to keep track of their level of motivation, which helps in the effectiveness of the rehabilitation program. This continuous assessment is crucial to assist the healthcare provider, especially the physiotherapist, identify the patient's motivation level to modify their routine exercise in partnership with the patients to improve patient engagement and motivation (Teo et al., 2022).

Decades ago, in the scope of rehabilitation issues among patients with a head injury, past studies were conducted to assess their engagement in the rehabilitation programs and the prevalence of poor participation during rehabilitation therapy (Lequerica et al., 2009; & Lenze et al., 2004). However, studies assessing head injury patients' motivation toward rehabilitation were rather scarce. This present study added new information on the level of motivation toward rehabilitation among patients with a severe head injury, particularly involving the comparison between early and late tracheostomy. Compared to previous studies, the level of motivation toward rehabilitation was mainly conducted among stroke patients (Rapolieni et al., 2018; Palmcrantz et al., 2021; Yoshida et al.., 2021; Oyake et al., 2020).

5.6.1 Sociodemographic Characteristics and MoT-Q Scores

Participants' age was the only sociodemographic characteristic significantly associated with the motivation toward rehabilitation based on the MoT-Q scores. The analysis indicates a significant association at all three evaluation periods – discharge, 3 months post-discharge, and 6 months post-discharge (p-value = 0.001; <0.001 and 0.017). Corresponding to this finding, past study by Rapoliene et al., (2018) also discovered that elderly patients were less motivated than their younger counterparts. This finding was corroborated by a previous study by Palmcrantz et al. (2012), which stated that younger patients who received more care and rehabilitation activities had a higher

motivation level for rehabilitation programs than elderly patients. This is because older patients have comorbid diseases that hinder their capacity and participation in more intense rehabilitation programs. However, both studies utilised different questionnaires which are Map Young persons with Strokes (MYS) questionnaire and Multidimensional Health Locus of Control (MHLC) scale and the populations were among the patients with strokes. Similar to the MoT-Q scores, the MYS and MHLC instruments were used to evaluate the participants' motivational status toward the rehabilitation program.

5.6.2 Clinical Outcomes and MoT-Q Scores

The participant's LOS in ICU, LOS in the hospital, and duration on mechanical ventilation support were significantly associated with MoT-Q scores (p-value=0.004; 0.037; 0.004) at the period of 6 months post-discharge. The decannulation of tracheostomy had a significant association with MoT-Q scores during the discharge period (p=0.028), but it was not significant at the later stage of MoT-Q evaluation (3 months and 6 months post-discharge; p=0.083; 0.082). This recent study analysed the association between clinical outcomes and MoT-Q scores, however, to compare the findings with previous studies was quite challenging because the past studies discussing the association between these two variables was not found in the literature search. A previous study by Boosman et al., (2016) further validated the use of MoT-Q scores by evaluating the total score and all sub-scores of the MoT-Q among the in-patient and out-patient of ABI. On the other hand, another study by Kusec et al., (2017) also assessed motivation among in-patients and out-patients of ABI using the MoT-Q scores.

A study by Randiambelonoro et al., (2020) reported that most patients were bored during their hospitalisation, which reflected their poor motivation to comply with the rehabilitation program. Although the study does not explicitly focus on head injury patients, it has showed that a more extended period of hospital stay may reduce patient's motivation toward the rehabilitation process, especially among elderly patients. Nevertheless, this study reveals that the LOS of the ICU, LOS of the hospital, and mechanical ventilation duration affect the rehabilitation motivation among the participants measured by the MoT-Q scores.

5.6.3 Tracheostomy Classification (Early and Late) and Rehabilitation Motivation

The univariate analysis shows a significant association between rehabilitation motivation based on MoT-Q mean score and severe head injury patients 6 months post-discharge (p=0.001). The longitudinal analysis shows that the significant association between these two variables remains significant (RR=1.470; 95% CI (1.074-2.011); p=0.016). A past study by Whiting et al., (2020) documented a different finding on the head injury patient's MoT-Q score, which declined after repeated assessments over three different periods. However, the study by Whiting et al., (2020) determined the impact of acceptance and commitment therapy (ACT) compared to this present study that discusses the impact of the tracheostomy classification approach. Yoshida et al., (2021) also utilise the MoT-Q score to evaluate stroke patients' motivation levels in their study. However, the instrument was used to identify factors influencing the stroke patient's motivation level toward rehabilitation rather than to determine the impact of any intervention.

This present study added new information regarding the factors associated with severe head injury patients' motivation toward rehabilitation, which showed that the status of tracheostomy classification (early and late) was associated with rehabilitation motivation. It is suggested that early tracheostomy increased the MoT-Q scores by 47% compared to those with a late tracheostomy. Freeman (2017) mentioned that initiating tracheostomy will help head injury patients' mobilisation and engagement in rehabilitation. Early tracheostomy will help the patients to start their rehabilitation program sooner (Sutt et al., 2020). When patients engage early in physical therapy or rehabilitation, their functional outcomes will improve sooner (Konigs et al., 2018). Thus, their motivation toward the rehabilitation process will be better as they can feel that their condition has improved over time from the effect of their commitment to the rehabilitation program.

5.7 STUDY FINDING AND FRAMEWORK

5.7.1 Findings Related to The Theoretical Framework

This study adapted the International Classification of Functioning, Disability and Health (ICF) as the theoretical framework underpinning the study. The ICF consists of the interaction of all its components: health condition, body function and structures, activities, participation, and environmental and personal factors. According to Braden et al., (2012) and Stalnacke, (2007), head injury survivors are significant toward poor health status and life satisfaction. The physical disability and impairment of body structure and functions will significantly impact the head injury survivors and their family members, eventually affecting the society around them (Forslund et al., 2013; Graves et al., 2013). The introduction of ICF facilitated the measurement of outcomes, health-related quality of life, and the effect of specific interventions and improving the quality of the treatment for individuals with head injuries (Sykes, 2006; Cieza et al., 2018; Laxe et al., 2014). Several studies in the past also measured head injury 'participation' as an outcome toward independent living skills, social relations, and occupation (Simpson et al., 2011; and Whiteneck et al., 2011).

Figure 5.1 demonstrates the implementation of the ICF framework based on the finding of this study. Severe head injury is the focus of the health condition experienced by the participants in this study. The disability of the participant's body function and structures resulting from the effect of severe head injury will reflect their functional outcomes, quality of life and clinical outcomes. This disability may include the inability of the patients to perform their ADL due to physical and movement problems, cognitive and behavioural disturbances, inability to concentrate and visual or auditory problems (Ruet et al., 2019). As all of the components interact with each other's, the disability they suffered may be affecting their 'activity', which includes the rehabilitation process. On the other hand, to achieve the best functional outcomes, head injury survivors require a good level of motivation in their 'participation' in the rehabilitation program.

Referring to the components of the ICF, the tracheostomy classification is regarded as one of the Environmental Factors that play a significant role in affecting the Body Functions and Structures components (functional outcomes, health-related quality of life and clinical outcomes) of the patients with a severe head injury. 'Environmental factors' are the factors that either facilitate or become a barrier to the individual

functioning status (Escorpizo et al., 2010; & Sykes, 2006). This study found that implementing the early tracheostomy facilitates the participant's body functions. The longitudinal analysis showed a significant association between early and late tracheostomy toward the participant's functional outcomes and clinical outcomes (duration of mechanical ventilation support and LOS in hospital). Even though the longitudinal analysis shows no significant association between tracheostomy classification (early and late) and health-related quality of life, the crude analysis initially showed a significant association between these two variables. The tracheostomy classification also significantly correlates with participants' motivation toward the rehabilitation program.

The 'activity' component refers to the individual carrying out a task or chores, whereas the 'participation' component refers to their engagement in any situation of their daily life (Arvidsson et al., 2015). The finding of this study connected the interaction between the participant's 'participation' (level of motivation) toward the 'activity' component (rehabilitation) in acquiring their best 'Body Functions and Structures', which is the functional outcomes and health-related quality of life. In addition, the sociodemographic characteristics of the participant's age are labelled as the other contextual factor which is 'Personal factors'. Even though, this finding proved that none of the sociodemographic characteristics listed were significantly associated with the tracheostomy classification, the univariate analysis shows a significant association with all functional outcomes, clinical outcomes and rehabilitation motivation.

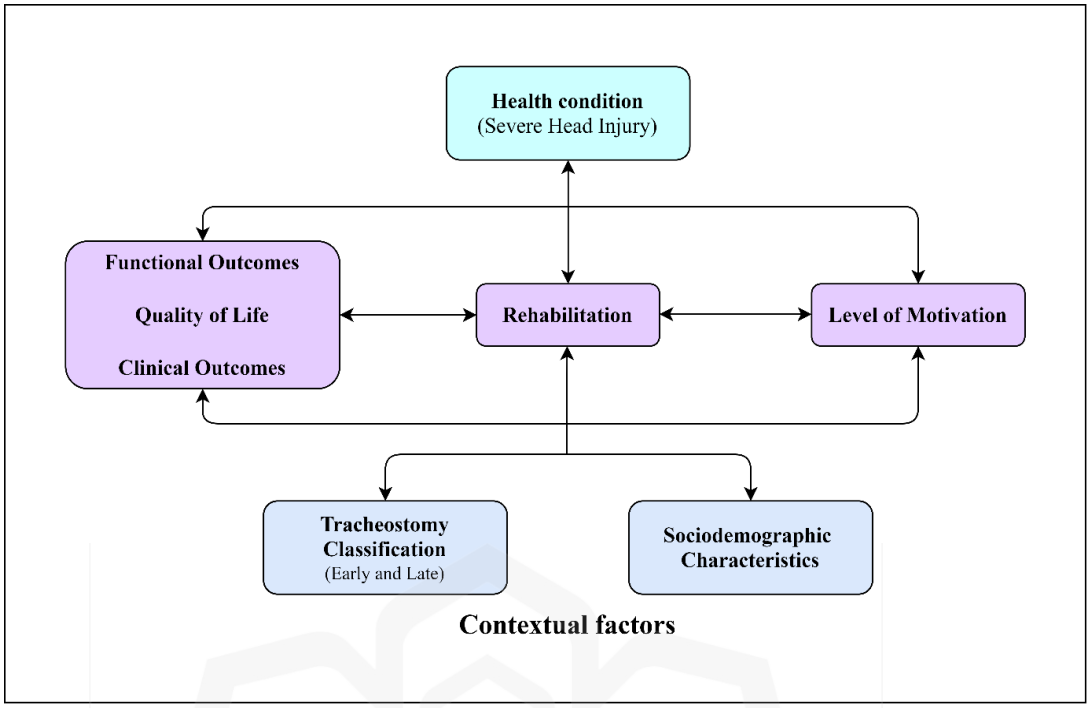


Figure 5.1: Illustration of the study finding related to the ICF components.

5.7.2 New Framework Identified

The previous chapter explained the conceptual framework that will guide this study's direction to achieve its objectives. Based on the finding and the adaptation of the ICF theoretical framework, this study has been able to construct its framework and discuss the association of several components and their interaction toward the implementation of early or late tracheostomy among severe head injury patients. This study found that all sociodemographic characteristics include does not play a role that influences the initiation of tracheostomy classification – either early or late tracheostomy. However, the researcher would suggest that sociodemographic characteristics, will contribute to or influence the patient's clinical outcomes, functional outcomes, quality of life, and motivation toward rehabilitation with the additional of possible cofounding factors such as financial status, existing comorbidities, level of education, family involvement and others. As mentioned by Taylor et al., (2010) and Yeates et al., (2012) the head injury patient's socioeconomic status and family involvement will influence their recovery following head injury incident.

Figure 5.2 portrays the interaction between all components discussed in this study. Even though the longitudinal analysis of this study shows no significant association between tracheostomy classification and health-related quality of life, the other components may have the ability to influence each other. Their functional outcomes will improve accordingly as they are motivated to perform rehabilitation activities. Furthermore, as their functional outcome gets better, their quality of life will also improve as they can feel that their present condition is better compared to the initial period following the head injury incident. This study did not determine the association among all dependent variables (clinical outcomes, functional outcomes, quality of life and rehabilitation motivation). However, it has been proved that the quality of life significantly influences the patient's functional outcome and rehabilitation motivation (Ludin et al., 2020; Wilson et al., 2017; von Steinbuchel et al., 2017; Lee & Won, 2022). On the other hand, rehabilitation motivation also does significantly associate with higher functional outcomes and quality of life (Wang et al., 2014: Oyake et al., 2020; Manzoor et al., 2020). In addition, Yoshida et al., (2021) also emphasised that rehabilitation motivation is a prognosticator for the patient's functional outcome.

The LOS in the hospital and duration of mechanical ventilator support are the finding of the clinical outcomes in this study that had a significant association with the tracheostomy classification. In addition, the univariate analysis also shows that ICU LOS is associated with participants' functional outcomes and rehabilitation motivation. Prolonged ICU stay and hospitalization influence the deterioration of the patient's functional outcomes and quality of life (van Vliet et al., 2017; Carenzo et al., 2021). Thus, this new framework suggested that the patient's clinical outcomes, functional outcomes, health-related quality of life and motivation toward rehabilitation are listed as the components that will affect each other. The tracheostomy classification, which is suggested to be done earlier, may influence all other components derived from this framework.

This framework applies to patients with severe head injury or requiring a tracheostomy approach. Even though they had been tracheostomised, their chance of having a better life should not be marginalised. The patient care shall not just be delivered to fulfill their need, but the main objective for the patients with severe head injury is to obtain the best possible recovery they could have. As these three criteria are

suggested to influence each other in this framework, the caregiver and professional healthcare provider should regularly assess their functional outcome, quality of life, and motivation toward the rehabilitation program. A poor functional recovery maybe results from their poor motivation toward rehabilitation programs, which eventually affects their quality of life satisfaction. Thus, if all of these three components are given attention simultaneously as a part of continuous care, the chance of having a better prognosis for them is higher.

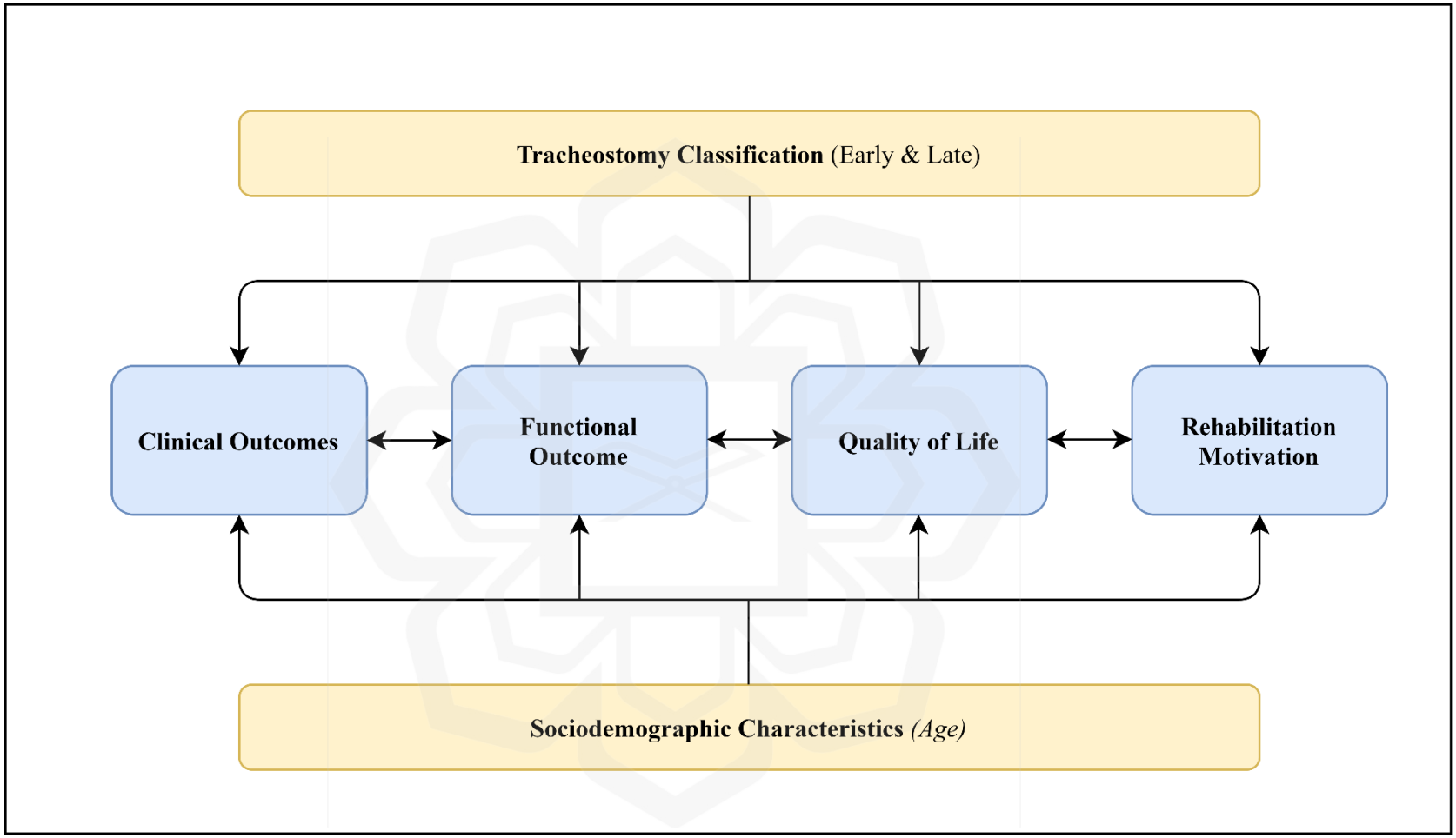


Figure 5.2: The Study Conceptual Framework

CHAPTER SIX

CONCLUSION

6.1 INTRODUCTION

The association between tracheostomy classification (early and late) and functional outcomes, health-related quality of life, and rehabilitation motivation has been discussed in the previous chapter. In this chapter, the conclusion of the overall study is presented. In addition, the study's limitations identified by the researcher were explained, and the actions taken to mitigate their influence were described. Finally, this chapter will also elaborate on the recommendation from the researcher, which focuses on improving nursing education, further research, nursing care, and practice toward head injury patients are anticipated.

6.2 LIMITATION

The study limitations discovered by the researcher throughout the study process will influence the study outcomes and conclusions (Ross & Zaidi, 2019). Drotar, (2008) mentioned that the revelation of the study's limitation is also considered a component of scientific investigation. This current study also had its own set of limitations. The first limitation encountered in this study since the preliminary data collection phase was a small sample size. Even though this study was conducted among two tertiary hospitals in Klang Valley, it recorded the highest census of ICU admission in the country according to the report by Ling et al., (2017); acquiring a larger sample size was quite challenging. Thus, it had limited the generalisations of the study finding.

The researcher attempted to minimise the chance of getting a lesser sample size by reviewing every patient admitted to the ICU of both hospitals based on the admission record. Still, the number of head injury patients that fulfilled the inclusion and exclusion

criteria for the study was less than the expected sample size. Even the preliminary review recognised 105 severe head injury patients reviewed; the chance to acquire a larger sample size was more difficult as 32% of them died during hospitalisation (n=34). This number was apart from the other patients that refused to be involved or were missing, which made the more significant sample size recruitment difficult. Furthermore, the data collection occurred during the COVID-19 pandemic, which mandated the whole nation under a national Movement Control Order (MCO) policy. During this period, the incidence of motor vehicle accidents (MVAs), which typically contributed to severe head injury, decreased by 26.3% in 2020 compared to the previous year and further declined to 11.5% in 2021 (Environment Statistics, 2023). Thus, the number of severe head injury cases, particularly those with tracheostomy initiation, was also greatly reduced.

The COVID-19 pandemic globally impacted all sectors and individuals, majorly on physical contact and social relation. The researcher acknowledges and appreciates the assistance and cooperation given by the hospital in facilitating ethical approval for the data collection. However, the prohibition against crossing the state border due to the MCO's endorsement caused a delay in the preliminary data collection process. Furthermore, after the MCO was lifted, the researcher and the participants' engagement via physical meeting was still restricted due to COVID-19 standard precautions. The researcher tried to circumvent this limitation with a few alternatives for the data collection, including using technology devices such as telephone conversations, video calls and virtual meetings. However, this approach limits the interaction and good rapport between the researcher and participants. Furthermore, there is a propensity for some participants to leave a virtual meeting session due to personal factors or environmental factors such as poor internet connection and technological device issues. In addition, the participants of this study consist of severe head injury survivors with some neurological disability; thus, some of them will easily get bored during the session, and the session must be repeated multiple times until the questionnaire is completed.

This study focused on the impact of early and late tracheostomy among severe head injury patients on their functional outcomes, quality of life and rehabilitation motivation, whereby the other confounding factors that might influence their recovery process were not exclusively discussed. During the stipulated time for the follow-up

assessment, the other factors that may influence the patient's recovery process, such as the duration of the head injury incident prior to the ICU admission, history of readmission to the hospital due to any health issues after they had been initially discharged, participant's existing comorbidities and others were not being addressed and discussed accordingly. These factors were not identified due to the time limitation to gather thorough health status records of all participants pre and post-hospitalisation. However, the clinical data, such as the participant's GCS upon admission and prior discharge; and the SOFA and SAPS II score to predict the mortality risk, were included to identify its association with the other outcomes measured.

In addition, both study settings had different data management and storage. For example, one study set still uses paper-based documentation, while the other has moved to an electronic system, which is much easier to use. Thus, the consistency of the data retrieval between these two settings was different.

6.3 STRENGTH

In Malaysia, the study on the impact of tracheostomy timing (early and late) among severe head injury patients was limited. This study added new information on the association between tracheostomy timing and multiple variables, which is not just limited to clinical outcomes but also includes functional outcomes, quality of life and rehabilitation motivation. The longitudinal analysis used in this study allowed the present study to determine the association between variables at three different periods (discharge, three months and six months post-discharge) on each participant. It had been mentioned earlier that one of this study's limitations was the inability to engage with participants physically due to the COVID-19 pandemic standard precaution. However, these circumstances also brought an opportunity to the researchers and future studies on how to utilise the use of current technology in the data collection process, which offers some advantages such as the ability to connect with distance participants, time conserve as the engagement with the participant which can be done multiple time virtually according to the participant's preferred time, and provide a better engagement between researcher and participants who are reluctant to meet with other parties in person. This present study also offered a new framework on the impact of tracheostomy timing among severe head injury patients to be explored and discussed further in future studies.

The patient's outcomes which consist of their functional outcome, quality of life and rehabilitation motivation, were described to have an influence on each other in improving the patient's recovery and prognosis.

6.4 IMPLICATIONS AND RECOMMENDATIONS

Nursing research significantly affects present and future nursing practices delivered by contemporary nursing education. It is a significant move in relevant to the "Sustainable Development Goals (SDG) 3 of Good Health and Well-being" developed by the United Nations (Department of Statistics, 2018; Tingen et al., 2009). One of the primary purposes of nursing research is to provide factual evidence to rationalize nursing care and practice and guide us in delivering exceptional nursing care (Altman, 2020). With that being said, this present study was essential as a piece of work that provides additional important information for the healthcare sector to improve the quality and standard of nursing alongside the other professions.

6.4.1 Nursing Care and Practice

Often, survivors of head injuries will be scheduled for a follow-up appointment to evaluate their recovery. Particularly, those with a moderate and severe head injury, the follow-up visit may include repeated blood tests, imaging tests, and rehabilitation referrals to evaluate and improve their current health conditions (Stippler et al., 2012; Wade et al., 1997). This present study recommends that each head injury survivor have their functional outcomes, quality of life and rehabilitation motivation status to be regularly assessed; to track their progress over time. The assessment shall be initiated by the nurses during their hospitalisation as a baseline, which is later evaluated regularly during their follow-up by the nurses in clinics and the physician in charge. From the assessment, the nurses may identify head injury survivors with a greater tendency to default their follow-up visit or be least interested in the rehabilitation process. Early detection will assist healthcare professionals in preventing a growing number of defaulters among head injury survivors. For those with poor motivation toward rehabilitation programs, a personalised and interesting intervention plan can be

established to encourage their participation in rehabilitation. This effort will improve their interest in the recovery journey, improving their functional outcomes and quality of life. The patient functional outcome, quality of life and rehabilitation motivation should be regularly assessed starting the day they are discharged and during each follow-up or home visit to ensure that all head injury survivors are on the right track toward a better recovery.

The researcher also emphasises the importance of the highest quality nursing care for severe head injury patients. As a part of a vulnerable group of patients, all severe head injury patients in the vegetative state depend on the health professionals taking care of them. Therefore, nurses must always practice the greatest quality of nursing care to promote faster recovery and prevent the risk of infection that will jeopardize the recovery process. Even though the finding of this study does not reveal any significant association with any of the study's variables, the fact that 60% of the participants (n=27) had experienced pneumonia during their hospitalization is something that we should be concerned about and addressed carefully. Kim et al., (2022) mentioned that the incidence of hospital-acquired pneumonia (HAP) associated with various risk factors includes the patient's sociodemographic status, underlying comorbidities, and hospital environment. Therefore, even though the risk of pneumonia among hospitalised patients is always there, the healthcare practitioners especially the nurses still play a major role in preventing this situation. Providing oral care and suction according to protocol, good teamwork among team members, the strict practice of hand hygiene, and efficient chest physiotherapy are nurses' efforts that will help in preventing HAP (Boltey et al., 2015).

Severe head injury survivors may require a long period for physical movement and cognitive recovery (Fleminger & Ponsford, 2005; Ruet et al., 2019). While rehabilitation could take several years, thorough follow-up evaluation and treatment escalation is critical for the head injury survivors. During the data collection, the researcher noticed that some head injury survivors could not comply with the scheduled follow-up, not just due to the MCO but because they have limited access to a proper transportation arrangement and manpower to bring their loved ones for follow-up visits. Some participants mentioned that they could not afford a good private rehabilitation service from a trained physiotherapist and only depends on the rehabilitation scheduled by the hospital, which is quite limited. The scope of home visits by healthcare

professionals in Malaysia has evolved from maternal child health to the elderly, children, and those with special needs (Domiciliary Health Care Services at Primary Care, 2021). Alongside this, present study would recommend that a special mobility team consisting of nurses, medical assistants and physiotherapists could plan periodically home visit for them as a part of the public health nursing care for those with special needs, in this case, head injury survivors. Home visits enable the healthcare professionals, including nurses, to evaluate the head injury survivor's condition and their environmental status, which may or may not assist them in their recovery journey. Through a comprehensive assessment and health education, the head injury survivor might have a better chance of recovery (Hart et al., 2018; Demir et al., 2018).

This study implemented various tools of assessment used on the head patients: GCS, SOFA score, SAPS II score, GOSE, QoLIBRI and MoT-Q. The list mentioned is just a few instruments from many more that have been validated and used worldwide. However, these assessments are only meaningful if used with a clear justification and rationale. The nurses practising the use of several sets of instruments on the patient at the hospital should understand how to perform the assessment and determine the needs and indications of that assessment for that particular patient. Nurses also must be able to identify the critical condition from the assessment done and highlight it to other healthcare professionals, such as the physician and the surgeon, to plan the best treatment for the patient.

Continuous nursing education (CNE) sessions are often held to provide new knowledge, updates, and reminders regarding nursing care and practice. It should be taken seriously, and the nurses should not attend merely to satisfy their key performance indicator or job obligations; rather, they should have a clear vision and good *niyah* (attention) to improve themselves to serve their patients. It was the first hadith narrated in Sahih Bukhari of the Revelation topic (Khan, 1997).

> *"The reward of deeds depends upon the intentions, and every person will receive their reward according to what they have intended…"*
> (Sahih Bukhari, 1:1)

As narrated in the above *hadith*, it is all back to the individual's intention for any action they perform to have any form of reward in return. Improving the nursing workforce by cultivating knowledge and competent skills was not meant to a single

individual but could benefit the healthcare professions and the community. All nurses should be advocate to set their main objectives on the right track to serve the '*Ummah* and community for the greater benefit of our nation. With good intentions good motivations and positive impacts to everyone, especially the patients in the healthcare setting. Poor nursing care and practices would impede the effectiveness of any attempt to enhance patient outcomes. For example, the use of medical devices on the head injury patients, such as ripple mattresses to prevent the incidence of pressure injury, mechanical ventilation for cerebral protection and airway protection, sequential compressive devices in prevention of the incidence of DVT, use of PPE to minimize the risk of infection and others will not have a good effect if the nurses themselves did not provide a high quality of nursing care to the patients.

6.4.2 Nursing Research

The findings of this study offer a few significant results and additional information, despite the small sample size. The present study highly suggests that future studies should have a larger sample size and multicentred. Extending the study population will provide better knowledge and interpretation of the impacts of early and late tracheostomy among severe head injury patients in Malaysia. It is also recommended that a longer period be allotted to the study to assist the researcher in gathering larger sample size and advanced analyses can be performed.

Other possible co-founding demographic factors should also be added in future research to identify their impact on the initiation of early and late tracheostomy, such as the head injury survivors' financial status, level of education, types of head injury and pre-existing comorbidities. Various demographic factors that act as the independent variables will provide a robust and valuable finding to the study. This study was able to identify the participant's quality of life and level of motivation toward rehabilitation. More than half of the participants recorded an 'Impaired' quality of life (53.3%; n=24) and MoT-Q score as low as -16 (compared to the maximum score of 62) even after 6 months post-discharge. It would be more meaningful if future research would have an interview session for them to identify the reason for this situation. Some patients may lack access to proper rehabilitation facilities and support groups, leading to

demotivation and dissatisfaction. Other environmental factors influencing their quality of life and rehabilitation motivation will ultimately affect their functional outcomes.

A different angle of research on the issue of early and late tracheostomy impact on severe head injury should be done from the perspective of the registered nurses and the family members. Although, as described in the ICF framework, environmental factors also affect the recovery progress of severe head injury patients. The support system of the healthcare professionals and family members will directly involve as a part of the environmental factors in this context (Sykes, 2006; Gerring & Wade, 2012). Therefore, any challenges, evaluations and recommendations from their perspectives were crucial in assisting the patient's recovery process. In addition, future studies on spiritual care should be added as they might boost the patients' motivation level, which may improve their perception of the quality of life.

Herer, (2018) mentioned that many patients with tracheostomy would be transferred to intermediate-care facilities or nursing homes before returning to their homes. This facility's quality of nursing care should be evaluated regularly to rectify the advantages they could offer to head injury patients with tracheostomy. A further study evaluating the nursing care at a nursing home is recommended to ensure that the patient's recovery will be much better compared to at home, thus, indirectly promoting the admission to the nursing home for some time before the patients return to their home with a better condition.

6.4.3 Nursing Education

Nursing education is a long, never-ending journey for the individual who embarks on their journey in nursing life and profession. Success in any profession results from an excellent, comprehensive, high-quality education. It is the same criteria required by our nursing students who will graduate and kick off their journey as young graduate novice nurses. To uphold this vision, all nursing students should be educated with adequate knowledge and skills to serve the community from their first day of college. Nurses must have the skills and knowledge to deliver nursing care to patients. However, they must be able to provide an effective health education session to the patients and their family members. Pueyo-Garrigues et al. (2022) reported that nurses could perform

diligent skills in nursing care, but their knowledge to provide health education needed to be improved. It shows that nursing education should be improvised gradually to ensure that the graduated nurses will be among those with decent skills and knowledge in practice and health education. In the end, it is one of the roles and responsibilities of nurses to provide health education for their patients as a part of the service to the patients (Tomey, 2009).

Toney-Butler and Unison-Pace, (2022) emphasised that nursing assessment is the first step of the nursing process which entails systematic and continuous data collection. Therefore, the nursing assessment is a fundamental aspect that will be taught to all student nurses to guide them in developing patient care plans. The researcher recommends that, in addition to understanding the anatomy and pathophysiology of the disease and constructing an efficient nursing process to be delivered to the patients, the nursing students must also be equipped with the ability to assess and evaluate the patient's functional outcomes and health-related quality of life to identify the long-term effects of their nursing intervention delivered to the patients. The assessment of GOSE, QoLIBRI and MoT-Q used in this study should be exposed to them early to improve their understanding of the patient's status of functional outcome, quality of life and motivation toward the rehabilitation process following head injury. As mentioned earlier, the ICF framework suggested that different individuals with different disabilities may require a different approach to help them meet the best functional status they could have (Arvidsson et al., 2015; Laxe et al., 2015). By acquiring the ability to perform a proper assessment of the patients, it will help the students to evaluate and differentiate the needs of the head injury survivors and, eventually, construct the best and most effective nursing care, which might differ from one patient to another according to their need. The need to learn about these additional assessments (GOSE, QoLIBRI and MoT-Q), in addition to the existing basic neuro assessment such as cranial nerve assessment, GCS, pupillary reactivity assessment, and motor power, was not limited only to the nursing students. As knowledge and information evolve daily, registered nurses may also learn and sharpen their assessment skills by mastering all the instruments mentioned to be practised during their service, perhaps via the continuous nursing education (CNE) sessions regularly organised by each hospital in Malaysia or nursing education seminars or conferences.

Ministry of Health Malaysia has offered various post-basic courses in all aspects of clinical nursing ranging from six months to one-year programs for over 25 years (The Status of Nursing in Malaysia, 2010). One of the post-basic courses offered related to treating patients with a severe head injury is the Advanced Diploma in Neuroscience Care. One of its sub-courses is Neuroscience Nursing, offered to eligible experienced nurses. This is a suitable platform to train nurses enrolled in the course to provide comprehensive nursing care to head injury patients with an accurate assessment, interventions, and evaluation. Once they have completed their training, they can champion that topic to become the trainer and centre of reference for the other nurses in their respective hospitals.

Wasfie et al., (2020) and Brito et al. (2019) reported that up to 26 % to 35% of TBI-discharged patients required at least one hospital readmission which may happen within 6 months post-discharge home. Gardner et al., (2018) added that over half of home-discharged patients would be readmitted to the hospital (46.7%) compared to those from rehabilitation centres (21.7%), nursing homes (21.9%) and intermediate care facilities with only 2.5%. This indicates that providing the patient's family members and/or caregivers with comprehensive health education or take-home advice is crucial. Healthcare practitioners, especially nurses, must provide that essential and comprehensive health education to them prior to discharge to reduce the likelihood of this hospital readmission incidence. When the nurses are acquainted with the patient's condition and well-versed in the patient's nursing care needs, they will likely be able to educate the patient's family members clearly and concisely.

This present study showed that the tracheostomy classification is significantly associated with functional outcomes and rehabilitation motivation. However, this approach might not offer any advantages to the patients if the patients and their family members were not provided with a proper health education related to the patient’s condition. Comprehensive health education on the head injury symptoms, standard recovery course and rehabilitation plan will improve the likeliness of better functional outcomes and rehabilitation success (hart et al., 2018; Demir et al., 2018). The present study would recommend that the delivery of health education or take-home advice to the patients and their relatives should be supplemented with supporting documents in the form of a hardcopy booklet or eBook link for virtual access based on the patient's preference and level of comfort. This documentation will assist them in recalling the health education given earlier by the nurses or other healthcare professionals to take

care of themselves or their loved ones, which reduces the possibility of health deterioration of the patients that contribute to hospital readmission.

Since the Public Health Nurse program began in the early 1960s, the Nursing curriculum in Malaysia has evolved significantly toward the 21st-century era (The Status of Nursing in Malaysia, 2010). Today's diversity in nursing education allows all nurses to improve themselves at different levels. In addition to learning basic nursing skills and knowledge in diploma and undergraduate programs, registered nurses can advanced their expertise in post-basic and postgraduate courses. As their degree of education level increases, they are expected to acquire more specific and critical skills and knowledge. For instance, if undergraduate and diploma students are taught about basic neuro assessment such as GCS and motor power to assess their patient's consciousness level and physical ability, at post-basic and postgraduate levels, they should be able to perform other critical and comprehensive assessments, such as GOSE, Brain Injury Functional Outcome Measure (BI-FOM), Functional Independence Measure (FIM) and others.

6.5 CONCLUSION

This study discovered the prevalence of early and late tracheostomy among severe head injury patients in the selected population. The impact of early tracheostomy was significantly associated with the participant's functional outcomes and motivation toward rehabilitation. Even though the multivariate analysis does not prove the significant association between tracheostomy classification (early and late) the health-related quality of life, the descriptive data does capture lesser participants with an 'Impaired' state in the early tracheostomy group compared to the late tracheostomy group in both 3 months and 6 months post-discharge. Early and late tracheostomies are also significantly associated with hospital LOS and duration of mechanical ventilation. The patient that required a longer stay in the hospital and prolonged use of mechanical ventilation, which was majorly recorded in the late tracheostomy group, may have their functional outcomes, quality of life, and rehabilitation motivation affected.

Further discussion on each study finding has been described. This study concludes that the tracheostomy classification (early and late) does bring a different

impact on their functional outcomes, quality of life and rehabilitation motivation of the severe head injury patients.This study focused on interpreting patients' functional outcomes, quality of life and rehabilitation motivation up until 6 months post-discharge. Further assessment up until one-year post-discharge or more should be carried out to identify the effect of early and late tracheostomy in the long run.

Even though this study focuses on the impact of early tracheostomy and functional outcomes, quality of life and rehabilitation motivation, multiple crude (univariate) analyses also were performed among the other variables in this study as the data collected were available. Participants' age does not influence the initiation of early and late tracheostomy, but it has recorded a significant association with the GOSE score, QoLIBRI score, and MoT-Q score of the participants. This study also shows that LOS in ICU was associated with the GOSE and MoT-Q scores as their ICU stay is shorter and rehabilitation is started earlier; they may be kept motivated on the rehabilitation program as their functional outcome improves. The tracheostomy classification (early and late) might not affect the incidence of pneumonia among the participants. However, the fact that 60% (n=27) of the participants had been diagnosed with it was a worrying figure that should be further investigated on its factors and preventive measure plan.

Even though the sample size was rather small compared to the initial targeted sample size, the finding of this study would be beneficial to add to the body of knowledge in head injury research area. For instance, the finding on the participant's MoT-Q score could be an important additional knowledge as a prevalence in measuring the rehabilitation motivation among patients with a severe head injury. In addition, it could be a starting point to other possibilities for future research to explore more on the topic. Therefore, it is hoped that the finding of this study, together with its list of limitations and recommendations, could positively impact the national healthcare system and benefit all severe head injury patients in Malaysia.

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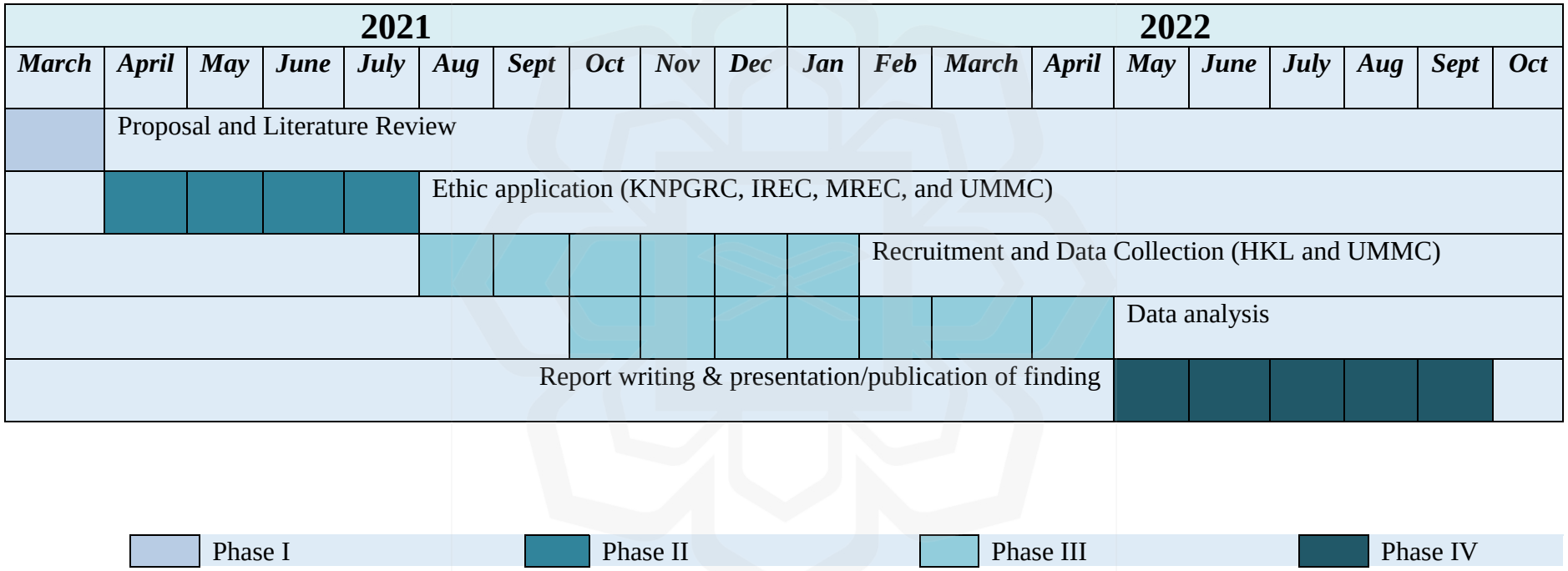
Zeger, S., and Liang, K. Y. (1986). Longitudinal Data Analysis for Discrete and Continuous Outcomes". Biometrics .Vol. 42. (1). 121-130

APPENDIX I: ***Gantt Chart***



APPENDIX II: ***Patient Information Sheet & Informed Consent (English/Malay)***

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects)

1. **Title of study**: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients.

2. **Name of investigator and institution:** Muhammad Farhan Bin Mahmud – International Islamic University Malaysia (IIUM)

3. **Name of sponsor**: No external funding. Self-sponsored.

4. **Introduction:**
   This information sheet will explain briefly about the study in a detail manner. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Kindly ask the researcher if anything is unclear or if you would like to get more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form at the last page of this sheet. You will be notified if new information relevant to consent is available.

   Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical treatment or health benefits to which you are otherwise entitled.

   This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the study?**
   The purpose of this study is to understand the impact of early tracheostomy toward the functional outcome, quality of life and rehabilitation compliance among severe head injury patients after they had been discharged from the hospital. The outcomes that will be evaluated includes the aspect of independent living and social rehabilitation, health-related quality of life, and the motivation of the participants toward rehabilitation program will be done after the incident of head injury. This research is necessary to determine the understanding of early initiation of tracheostomy among patients with severe head injury to improve patient prognosis and positive outcome.

   This research will be conducted for duration of 12 months from 01/09/2021 until 30/08/2022. The expected number of participants are 129 individuals.

6. What is the method and investigational process of this study?

Investigator will access your medical records for the following information including your daily assessment data during your hospitalization, laboratory result and neurological assessment record as a baseline data prior the interview session. You will be interviewed by the investigator. Prior the interview session, the investigator will explain each sections of the questionnaire to the participants and caregiver. If the participants which are the patient were unable to respond due to the post-vegetative stage condition, explanation and written instruction will be given to the responsible caregiver.

During the interview session, the participants will be asked by the investigator according to the question asked in the questionnaire prepared. This set of questionnaire contains three (3) sections which will enquire about the functional outcome, quality of life and rehabilitation compliance topics. The investigator will record each answer given by the participant or caregiver accordingly.

7. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the investigator honestly and the session will take about 30 to 40 minutes of your time. The participation of the respondent will be terminated if there is any chance of health and safety issue arise between both parties (researcher and respondent); or due to any instruction by the Malaysian government that prohibit for the data collection to take place.

8. What are the potential risks and side effects of being in this study?

Participation to this study will not affect your treatment, and the risk is minimal. You are free to decline to answer any of the questions that you feel uncomfortable with.

9. What are the benefits of being in this study?

There may or may not be any benefits to you. Information obtained from this study will help to improve the quality of medical, surgical and nursing management of patients with severe head injury in future. However, each participant will not be informed of the study findings.

If you are interested to get information regarding the finding of the research, you may contact the research secretariat.

10. Who is funding the research?

This study is self-sponsored by the researcher and does not receive any source of external funding. You will not be paid for participating in this study and there is no expenses or fee required to be paid by the respondents throughout this study.

11. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. All the information obtained will be stored in a locked cabinet which only investigator have access to and will be transferred into a computer that is password protected. Then, data in the computer will be copied to CDs and the data in the computer will be erased. CDs and any related

documents will be kept for a minimum of five years after the completion of the study. The CDs and data will be destroyed after that period of storage. Respondents will not be allowed to view their personal study data, as the data will be consolidated into a database. Respondents can write to the investigators to request access to study findings.

When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Only members of this study team, qualified monitors and auditors, and governmental or regulatory authorities including MREC may inspect the study data and private information of the subjects, where appropriate and necessary. No identifiable information will be transmitted to other parties.

12. Who should I call if I have questions?

If you have any questions about the study or you want information about this study, please contact the investigator, Muhammad Farhan Bin Mahmud at telephone number 013 315 6974.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407/8205/8888/8100.

INFORMED CONSENT FORM

Title of Study: Understanding The Impact of Early Tracheostomy Among Severe Head Injury Patients

By signing below, I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary, and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at the moment. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. *(*delete which is not applicable)*

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness:

Signature: I/C number:

Name: Date:

RISALAH MAKLUMAT PESERTA DAN BORANG PERSETUJUAN / KEIZINAN

PESERTA

(untuk subjek dewasa)

1. **Tajuk penyelidikan:** Mengenalpasti Kesan Awal Trakeostomi Awal Dalam Kalangan Pesakit Kecederaan Kepala Yang Teruk.

2. **Nama Institusi dan nama penyelidik:** Muhammad Farhan Bin Mahmud – Universiti Islam Antarabangsa Malaysia (UIAM).

3. **Nama penaja:** Tidak menerima penajaan/dana dari pihak luar. Tajaan sendiri.

4. **Pengenalan:**
   Risalah informasi ini menjelaskan hal-hal berkenaan penyelidikan tersebut dengan lebih mendalam dan terperinci. Adalah amat penting untuk anda memahami tujuan penyelidikan ini dijalankan termasuk perkara yang akan terlibat di dalam penyelidikan ini. Sila luangkan masa secukupnya untuk membaca dan mempertimbangkan dengan teliti setiap penerangan yang diberikan sebelum anda membuat keputusan untuk bersetuju menyertai penyelidikan ini. Jika anda mempunyai sebarang kemusykilan ataupun memerlukan maklumat lanjut yang ingin anda tahu, anda boleh mengajukan pertanyaan anda dengan mana-mana kakitangan yang terlibat dalam penyelidikan ini. Setelah anda berpuas hati dan memahami sepenuhnya tentang penyelidikan ini, serta anda berminat untuk turut serta, anda dikehendaki menandatangani Borang Persetujuan atau Keizinan Peserta, pada muka surat akhir risalah ini. Anda akan dimaklumkan sekiranya terdapat maklumat dan perincian baru yang berkati dengan borang persetujuan ini.

   Penyertaan anda dalam penyelidikan ini adalah secara sukarela. Anda tidak perlu menyertai penyelidikan ini jika anda tidak mahu. Anda berhak untuk tidak menjawab mana-mana soalan yang diajukan. Anda juga boleh menarik diri daripada penyelidikan ini pada bila-bila masa sahaja. Jika anda menarik diri, segala maklumat yang telah diperolehi sebelum anda menarik diri masih boleh digunakan dalam penyelidikan ini. Jika anda tidak mahu menyertai ataupun menarik diri dari penyelidikan ini, tindakan anda tidak akan menjejaskan segala hak kesihatan dan rawatan perubatan yang selayaknya anda terima.

   Penyelidikan ini telah mendapat kelulusan Jawatankuasa Etika dan Penyelidikan Perubatan, Kementerian Kesihatan Malaysia.

5. **Apakah tujuan penyelidikan ini dilakukan?**
   Tujuan penyelidikan ini adalah untuk memahami kesan daripada kaedah trakeostomi awal terhadap perkembangan fungsi anggota tubuh badan, kualiti hidup dan kepatuhan rawatan

rehabilitasi dalam kalangan pesakit yang mengalami kecederaan kepala yang teruk setelah mereka dibenarkan discaj daripada hospital. Kesan-kesan yang akan dinilai adalah termasuk aspek kebergantungan hidup dan rehabilitasi sosial, kualiti hidup yang berkait dengan kesihatan dan motivasi peserta terhadap program rehabilitasi pasca kecederaan kepala yang mereka alami.

Penyelidikan ini diperlukan untuk mengenalpasti kesan rawatan trakeostomi awal terhadap pesakit yang mengalami kecederaan kepala yang teruk untuk membantu meningkatkan prognosis dan kesan positif terhadap pesakit.

Penyelidikan ini akan berjalan dalam tempoh 12 bulan bermula dari 01/09/2021 sehingga 30/08/2022. Jumlah penglibatan peserta yang dijangka akan terlibat adalah seramai 129 individu.

6. Apakah kaedah dan proses penyiasatan yang dilakukan dalam kajian ini?

Penyelidik akan mengakses data perubatan anda yang mengandungi penilaian kesihatan harian semasa tempoh anda menerima rawatan di hospital, rekod keputusan makmal dan rekod penilaian neurologikal sebagai panduan sebelum sesi temuduga dijalankan. Anda akan ditemuduga oleh penyelidik. Sebelum sesi temuduga dimulakan, penyelidik akan menerangkan setiap bahagian borang soal selidik kepada peserta dan penjaga yang bertanggungjawab. Jika peserta terlibat merupakan individu yang tidak mampu untuk menjawab soal selidik berikutan daripada keadaan pasca vegetatif, penerangan lengkap dan bertulis akan diberikan kepada penjaga yang bertanggungjawab bagi pihak peserta.

Ketika sesi temuduga dijalankan, peserta kajian akan diajukan soalan-soalan mengikut kandungan soal selidik yang telah disediakan oeleh penhhyelidik. Borang soal selidik ini mengandungi tiga (3) bahagian iaitu soal selidik data perkembangan fungsi anggota tubuh badan, kualiti hidup dan kepatuhan terhadap rawatan rehabilitasi

7. Apakah tanggungjawab saya sewaktu menyertai penyelidikan ini?

Adalah penting untuk anda menjawab semua soalan soal selidik seperti yang dikemukakan oleh penyelidik dengan jujur dan sesi temuduga ini hanyalah mengambil masa selama 30 ke 40 minit masa berharga anda. Penyertaan respondenakan ditamatkan sekiranya terdapat kemungkinan isu yang berkait dengan masalah kesihtan dan keselamatan timbul terhadap mana-mana pihak (responden dan penyelidik); atau kerana arahan oleh kerajaan Malaysia yang tidak membenarkan proses pengumpulan data untuk dilakukan.

8. Apakah risiko dan kesan-kesan sampingan menyertai penyelidikan ini?

Risiko untuk penyertaan penyelidikan ini yang adalah minima dan tidak akan menjejaskan hak kesihatan dan hak rawatan yang anda perlukan. Anda juga bebas memilih untuk tidak menjawab mana-mana soalan yang membuatkan anda berasa tidak selesa.

9. Apakah manfaat bagi saya jika saya menyertai kajian ini?

Penyelidikan ini mungkin akan mendatangkan manfaat kepada anda atau sebaliknya. Segala hasil maklumat yang diperolehi daripada penyelidikan ini diharapkan akan dapat membantu meningkatkan kualiti rawatan perubatan, pembedahan dan pengurusan penjagaan kejururawatan dalam kalangan pesakit yang mengalami kecederaan kepala yang teruk di masa hadapan. Walaubagaimanapun, setiap peserta tidak akan dimaklumkan tentang keputusan hasil kajian.

Jika anda berminat untuk mendapatkan informasi berkenaan keputusuan kajian ini, anda boleh mengajukan permohonan anda kepada Jawatankuasa penyelidikan.

10. Siapakah yang membiayai penyelidikan ini?

Kajian ini tidak menerima penajaan/dana dari pihak lua dan ditanggung sepenuhnya oleh penyelidik. Anda tidak akan dibayar untuk menyertai kajian ini dan tiada sebarang bayaran ataupun yuran yang akan dikenakan terhadap anda sepanjang proses kajian ini.

11. Adakah maklumat saya akan dirahsiakan?

Semua maklumat anda yang diperolehi dalam kajian ini akan disimpan dan ditangani secara rahsia, sesuai dengan undang-undang dan/atau peraturan. Semua maklumat yang diperolehi akan disimpan di kabinet terkunci yang hanya dapat diakses oleh penyelidik dan akan dipindahkan ke data komputer yang dilindungi dengan kata. Kemudian, data di komputer akan disalin ke CD dan data di dalam komputer akan dihapuskan. CD dan sebarang dokumen yang berkaitan akan disimpan sekurang-kurang selama lima (5) tahum setelah penyelidikan tamat. CD dan data akan dimusnahkan selepas tempoh simpanan tersebut tamat. Responden tidak akan dibenarkan melihat data kajian peribadi mereka, kerana data tersebut akan digabungkan dalam pangkalan data. Pihak responden boleh melakukan permohonan bertulis kepada penyelidik untuk meminta akses tentang hasil kajian.

Semasa menerbitkan atau membentangkan hasil kajian, identiti anda tidak akan didedahkan tanpa persetujuan anda. Hanya anggota pasukan kajian ini, juruaudit berkelayakan, dan pihak berkuasa kerajaan termasuk MREC sahaja yang dapat memeriksa data kajian dan maklumat peribadi subjek, jika sesuai dan perlu. Tidak ada maklumat yang dapat dikenal pasti akan dihantat kepada pihak lain.

12. Siapakah yang perlu saya hubungi sekiranya saya mempunyai sebarang pertanyaan?

Anda boleh menghubungi penyelidik Muhammad Farhan Bin Mahmud pada nombor telefon 013-315 6974 sekiranya anda mempunyai sebarang pertanyaan mengenai penyelidikan ini dan anda mahukan maklumat tentang penyelidikan ini.

Jika anda mempunyai sebarang pertanyaan berkaitan dengan hak-hak anda sebagai pesakit dalam penyelidikan ini, sila hubungi: Setiausaha, Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia, melalui talian telefon 03-3362 8407/8205/8888

BORANG PERSETUJUAN/KEIZINAN PESERTA

Tajuk penyelidikan: Mengenalpasti Kesan Awal Trakeostomi Awal Dalam Kalangan Pesakit Kecederaan Kepala Yang Teruk.

Dengan menandatangani di bawah, saya mengesahkan bahawa:

- Saya telah diberi maklumat tentang penyelidikan di atas secara lisan dan bertulis dan saya telah membaca dan memahami segala maklumat yang diberikan dalam risalah ini.
- Saya telah diberikan masa yang secukupnya untuk mempertimbangkan penyertaan saya dalam penyelidikan ini dan telah diberi peluang untuk bertanyakan soalan dan semua persoalan saya telah dijawab dengan sempurna dan memuaskan.
- Saya juga faham bahawa penyertaan saya adalah secara sukarela dan pada bila-bila masa saya bebas menarik diri daripada penyelidikan ini tanpa harus memberi sebarang alasan dan ianya sama sekali tidak akan menjejaskan saya pada masa akan datang. Saya tidak mengambil bahagian dalam mana-mana penyelidikan lain pada masa ini. Saya juga memahami tentang risiko dan manfaat penyelidikan ini dan saya secara sukarela memberi persetujuan untuk menyertai penyelidikan ini di bawah syarat-syarat yang telah dinyatakan di atas.
- Saya faham saya harus mematuhi nasihat dan arahan yang berkaitan dengan penyertaan saya dalam penyelidikan ini daripada penyelidik.
- Saya faham bahawa kakitangan penyelidikan, pemantau dan juruaudit terlatih, pihak penaja dan pihak berkuasa kerajaan atau undang-undang, mempunyai akses langsung dan boleh menyemak laporan perubatan saya bagi memastikan penyelidikan ini dijalankan dengan betul dan data direkodkan dengan betul. Segala maklumat dan data peribadi akan dianggap sebagai SULIT.
- Saya akan menerima satu salinan 'Risalah Maklumat Pesakit dan Borang Persetujuan atau Keizinan Pesakit' yang telah lengkap dengan tarikh dan tandatangan untuk dibawa pulang ke rumah.
- Saya **bersetuju/ tidak bersetuju*** untuk doktor yang merawat keluarga saya diberitahu tentang penyertaan saya dalam penyelidikan ini. *(*Potong mana yang tidak berkenaan)*

Subjek:

Tandatangan: Nombor K/P:

Nama: Tarikh:

Penyelidik yang mengendalikan proses menandatangani boring keizinan:

Tandatangan: Nombor K/P:

Nama: Tarikh:

Saksi tidak-berpihak/adil:

Tandatangan: Nombor K/P:

Nama: Tarikh:

UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: A multicentre study

Version No: 1

Version Date: 27 December 2021

Dear Sir/Madam,

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

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1. What is the purpose of this study?

Patients with severe head injury are often requiring a procedure called tracheostomy (a surgical puncture made to windpipe that allow air entry to lung) as necessary treatment.

We aim to study the extent of tracheostomy affect patient outcomes that includes independent living, social life, health-related quality of life, and motivation toward the recovery program.

2. Why is this study important?

Your participation will enable us to gather information that will help to improve the nursing care and management of patients with severe head injury in future.

3. What type of study is this?

This is non-experimental study.

4. What is the procedure that is being tested? (If applicable)

Not applicable.

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)
Not applicable.

6. Why have I been invited to participate in this study?
You have been invited to participate in this study because the fulfilment of the inclusion criteria as below:

a. *Adults aged 18 years old and above.*
b. *Had history of severe brain injury*
c. *Had tracheotomy to allow use of breathing machine called ventilator.*
d. *Understand English and Bahasa.*

7. Who should not participate in the study?
We do NOT include participates if he or she:

a. *Had not been admitted to ICU.*
b. *Had experienced cardiac arrest (loss of conscious, unable to breath and heart stop beating) during admission to hospital.*
c. *Had history of lung and breathing problem before admission.*
d. *Had several trauma injuries and backbone injury area at neck.*
e. *Passed away after 72 hours admitted to the hospital.*

8. Can I refuse to take part in the study?
*It is entirely **voluntary**. Whether you participate or not, all the services you received at this hospital will continue and nothing will change.*

9. What will happen to me if I take part?
- *We will access your medical records on your hospitalization progress and laboratory result.*
- *From the medical record, we obtain information to contact you by phone and to explain the study.*
- *Upon your consent, we will arrange an online video call to interview you using questionnaires. The online conversation will not be recorded.*
- *There are 3 sets of questionnaires taking around 30 minutes to complete.*
- *We will pose questions to the caregivers if participants unable to answer due to poor condition.*

10. How long will I be involved in this study?
It will take only one to two separate sessions of 30 to 40 minutes of your time depending on your recovery progress.

11. What are the possible disadvantages and risks?
No foreseeable disadvantages and risks from interviewing participants using questionnaires.

12. What are the possible benefits to me?

There is no immediate benefit for you. If you are interested to get information regarding the finding of the research, you may contact the research secretariat.

13. Who will have access to my medical records and research data?
Only the researcher team members have access to data and record.

14. Will my records/data be kept confidential?
All questionnaires and research files reports are using code.

Your corresponding data is kept in one separate logbook. All records and data are kept in locked cabinet. All data in computer files is password protected. All data will be destroyed after 5 years of study completion (paper will be shredded and datafile will be deleted and removed from trash bin).

15. What will happen to any samples I give? (If applicable)
Not applicable.

16. What will happen if I don't want to carry on with the study?
You may stop taking part in the study at any time. Your treatment will be provided to you as per usual care.

Please notify the researchers of your decision as soon as possible. We may ask you the reason for recording purposes.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)
Not applicable

18. What happens when the research study stops? (If applicable)
Not applicable because this study is not an experimental study.

19. What will happen to the results of the research study?
The results of this study will be share through research reports, journal articles, conference papers and public presentations with other healthcare professionals. All the materials will NOT contain identity of research participants.

20. Will I receive compensation for participating in this study?
There is no monetary compensation to participants in this study.

21. Who funds this study?
This study is funded by the Fundamental Research Grant Scheme (FRGS), Ministry of Higher education (FRGS/1/2021/skk06/UIAM/02/6)

22. Who should I contact if I have additional questions/problems during the course of the study?

Name of investigator 1: Dr Lee Wan Ling
Affiliation: Senior Lecturer
Telephone number (Mobile number): 016-668 6648
Name of investigator 2: Dr. Salizar Mohamed Ludin
Affiliation: Assoc. Prof.
Telephone number (Mobile number): 019-222 9942
Name of investigator 3: Muhammad Farhan Mahmud
Affiliation: Mr/Encik

Telephone number (Mobile number): 013-315 6974
Name of investigator 4: Mohd Irsyad Mahd Nor
Affiliation: Mr/Encik
Telephone number (Mobile number): 019-456 7796

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251

UNIVERSITY OF MALAYA MEDICAL CENTRE

RISALAH MAKLUMAT PESERTA

Tajuk Kajian: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: A multicentre study

Versi : 1

Tarikh Versi : 27 Disember2021

Encik/Puan/Cik,

Kami ingin menjemput anda untuk mengambil bahagian di dalam projek kajian kami. Sebelum anda membuat keputusan untuk turut serta, anda hendaklah memahami mengapa kajian ini dilakukan dan perkara yang akan terlibat. Sila luangkan masa untuk membaca maklumat yang disertakan dengan teliti; jika anda mahu, anda boleh berbincang tentang kajian ini dengan pihak lain.

Sila ajukan sebarang persoalan kepada kami jika anda menginginkan maklumat yang lebih lanjut. Sila luangkan masa untuk membuat keeputusan sama ada anda ingin turut serta dalam kajian ini atau tidak.

Kajian ini telah mendapat kelulusan daripada Medical Research and Ethics Committee,

Penyelidikan ini telah mendapat kelulusan Jawatankuasa Etika dan Penyelidikan Perubatan, Kementerian Kesihatan Malaysia.

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1. **Apakah tujuan kajian ini dilakukan?**

   Pesakit yang megalami kecederaan kepala yang teruk pada kebiasaannya perlu melalui prosedur trakeostomi (kadah pembedahan yang membuka laluan di bahagian leher untuk tujuan laluan masuk udara ke bahagian paru-paru) sebagai salah satu langkah perubatan yang diperlukan.

   Kami ingin mengkaji tahap keberkesanan prosedur trakeostomi ini terhadap pesakit yang merangkumi aktiviti kehidupan seharian, kehidupan sosial, kualiti hidup berkaitan dengan kesihatan dan tahap motivasi dalam program pemulihan.

2. **Mengapa kajian ini penting untuk dijalankan?**

   Penglibatan anda di dalam kajian ini akan membantu kami mengumpul maklumat penting bagi membantu meningkatkan perawatan kejururawatan dan pengurusan pesakit kecederaan kepala yang teruk di masa hadapan.

3. **Apakah jenis kajian ini?**

Ini adalah kajian berbentuk bukan eksperimen.

4. Apakah bentuk prosedur yang bakal diuji? (Jika berkaitan)
Tidak berkaitan.

5. Adakah produk di dalam kajian ini mengandungi bahan sensitive terhadap sesuatu budaya; Contoh: daging lembu atau khinzir? (Jika berkenaan)
Tidak berkaitan.

6. Mengapa saya dijemput untuk menyertai kajian ini?
Anda dijemput kerana anda didapati memenuhi kriteria seperti berikut:

e. Orang dewasa yang berumur 18 tahun dan ke atas.
f. Mempunyai sejarah mengalami kecederaan kepala/otak yang teruk.
g. Pernah menjalani prosedur trakeostomi untuk disambungkan kepada mesin bantuan pernafasan yang dipanggil ventilator.
h. Memahami Bahasa Inggeris atau Bahasa Melayu

7. Siapa yang tidak boleh menyertai kajian ini?
Kami TIDAK akan mengambi kiral penyertaan kepada mereka yang:

f. Tidak dimasukkan ke Pusat Rawatan Rapi (ICU).
g. Pernah mengalami kejadian serangan jantung (yang mengakibatkan hilang kesedaran, tidak mampu bernafas dan degupan jantung terhenti) ketika kemasukan ke hospital.
h. Mempunyai sejarah masalah pernafasan dan paru-paru sebelum kemasukan ke hospital.
i. Mempunyai beberapa kecederaan, dan kecederaan tulang belakang di bahagian leher.
j. Meninggal dunia selepas 72 jam kemasukan ke hospital.

8. Bolehkah saya menolak untuk menyertai kajian ini?
*Ia adalah secara **sukarela.** Sama ada anda menyertai kajian ini atau tidak, semua perkhidmatan yang anda terima di hospital ini akan diteruskan dan tiada sebarang perubahan akan berlaku.*

9. Apakah yang akan berlaku terhadap saya jika saya menyertai kajian ini?

- *Kami akan mengakses rekod perubatan anda yang berkaitan dengan perkembangan rawatan anda di hospital termasuk keputusan-keputusan ujian makmal.*
- *Daripada rekod perubatan anda, kami akan memperolehi maklumat untuk menghubungi anda melalui telefon bertujuan menjelaskan tentang kajian ini.*
- *Selepas mendapatkan persetujuan anda, kami akan mengaturkan perbualan video atas talian untuk menemuual anda menggunakan borang soal selidik. Perbualan tersebut tidak akan dirakam.*
- *Terdapat tiga set borang soal selidik yang mengambil masa sekitar 30 minit untuk dilengkapkan.*

- *Kami akan mengemukakan soalan kepada pihak penjaga sekiranya peserta kajian tidak dapat menjawab kerana keadaan mereka yang tidak mengizinkan.*

10. Berapa lama saya akan terlibat dalam kajian ini?
Ia akan mengambil hanya satu hingga dua sesi berasingan selama 30 ke 40 minit masa anda bergantung kepada tahap kepulihan anda.

11. Apakah kelemahan dan risiko yang mungkin berlaku?
Tiada kelemahan dan risiko yang tidak terjangka boleh berlaku daripada menemu bual peserta menggunakan soal selidik.

12. Apakah faedah yang mungkin saya dapatkan?
Tiada faedah secara langsung kepada anda. Sekiranya anda berminat untuk mendapatkan maklumat berhubung dapatan kajian, anda boleh menghubungi urusetia penyelidikan.

13. Siapakah yang akan mempunyai akses kepada rekod perubatan dan data penyelidikan saya?
Hanya ahli pasukan penyelidik mempunyai akses kepada data dan rekod.

14. Adakah rekod/data saya akan dirahsiakan?
Semua laporan soal selidik dan fail penyelidikan disimpan menggunakan kod khas. Data anda yang sepadan disimpan di dalam satu buku log yang berasingan. Semnua rekod dan data disimpan dalam kabinet yang berkunci. Semua data didalm perisian computer dilindungi dengan kekunci kata laluan. Semua data akan dimusnahkan selepas 5 tahun kajian selesai (dokumen kertas akan dihancurkan dan data di dalam komputer akan diapdamkan secara kekal).

15. Apakah yang akan berlaku kepada mana-mana sampel yang saya berikan?(Jika berkenaan)
Tidak berkenaan.

16. Apakah yang akan berlaku jika saya tidak mahu meneruskan kajian?
Anda boleh berhenti mengambil bahagian dalam kajian ini pada bila-bila masa. Rawatan yang anda terima akan diberikan seperti biasa.

Sila maklumkan kepada penyelidik tentang keputusan anda secepat yang mungkin. Kami mungkin akan bertanyakan alasan anda untuk tujuan catatan.

17. Bagaimana jika terdapatnya maklumat baharu yang berkaitan tentang prosedur/ubat/intervensi? (Jika berkenaan)
Tidak berkaitan

18. Apakah yang akan berlaku jika kajian ini berhenti? (Jika berkenaan).
Tidak berkenaan kerana kajian ini bukan berbentuk kajian eksperimen.

19. Apakah yang akan berlaku kepada hasil kajian penyelidikan?
Hasil kajian ini akan diterbitkan melalui laporan penyelidikan, risalah jurnal, persidangan dan pembentangan awam bersama-sama ahli kesihatan profesional yang lain. Semua bahan yang dinyatakan TIDAK akan mengandungi identity peserta kajian.

20. Adakah saya akan menerima pampasandengan menyertai kajian ini?

Tiada wang pampasan yang diberikan kepada peserta dalam kajian ini.

21. Siapakah yang membiayai kajian ini?

Kajian ini dibiayai oleh skim Fundamental Research Grant Scheme (FRGS), Kementerian Pengajian Tinggi Malaysia (FRGS/1/2021/skk06/UIAM/02/6)

22. Siapakah yang perlu saya hubungi jika saya mempunyai soalan/masalah tambahan semasa proses kajian?

Nama penyelidik 1: Dr Lee Wan Ling
Gelaran: Pensyarah
Nombor telefon: 016-668 6648
Nama penyelidik 2: Dr. Salizar Mohamed Ludin
Gelaran: Prof. Madya
Nombor telefon: 019-222 9942
Nama penyelidik 3: Muhammad Farhan Mahmud
Gelaran: Encik
Nombor telefon: 013-315 6974
Nama penyelidik 4: Mohd Irsyad Mahd Nor
Gelaran: Encik
Nombor telefon: 019-456 7796

23. Siapakah yang boleh saya hubungi jika saya tidak berpuas hati dengan cara kajian ini dilaksanakan?

Jawatankuasa Etika Penyelidikan Perubatan
Pusat Perubatan Universiti Malaya
Nombor telefon: 03-7949 3209/2251

KEIZINAN OLEH WARIS YANG BERTANGGUNGJAWAB UNTUK PENYELIDIKAN KLINIKAL

Sila letakkan Nombor Versi dan Tarikh Versi untuk dokumen ini:

Nombor Versi: **1**
Tarikh Versi: **27 Disember 2021**

Saya,……..…….. Kad Pengenalan ……..……
(Nama Waris yang bertanggungjawab)

beralamat……..……
(Alamat)

dengan ini bersetuju supaya saudara saya……..…… menyertai
(Nama Pesakit)

dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

TajukPenyelidikan: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: a Multicentre study

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh **Encik Muhammad Farhan Bin Mahmud** mengikut terjemahan ……
(Nama & Jawatan Penterjemah)

yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat……

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan metodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Saya mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini. Saya merelakan/mengizinkan saudara saya menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik balik penyertaan saudara saya dalam penyelidikan klinikal ini pada bila-bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat. Sekiranya saudara saya kembali berupaya untuk memberi keizinan, beliau mempunyai hak untuk terus menyertai kajian ini atau memilih untuk menarik diri.

Tarikh: …… Pertalian dengan Pesakit ……..…… Tandatangan/Cap Jari Waris yang bertanggungjawab ……

DI HADAPAN

Nama ……..…..)
)
No. K/P……..…….)
)
Jawatan……..……..…….)

Tandatangan ……..…..
(Saksi untuk Tandatangan Waris yang Bertanggungjawab)

Saya sahkan bahawa saya telah menerangkan kepada waris yang bertanggungjawab sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ……..…… Tandatangan ……..
(Doktor yang merawat)

KEIZINAN OLEH WARIS PESAKIT UNTUK PENYELIDIKAN KLINIKAL	No. Pend. Nama Jantina Umur Unit		**BK-MIS-1117-E02**

CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH

Please create Version No. and Version Date for this document:

Version No.: **1**
Version Date: **27 December 2021**

I, …….. Identity Card No……..
(Name)
of ……
(Address)

hereby agree that my relative ……I.C. No……
(Name)
participate in the clinical research (clinical study/questionnaire study/drug trial) specified below:-

Title of Study: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: a Multicentre study.

The nature and purpose of which has been explained to me by Mr. Muhammad Farhan Bin Mahmud ,

and interpreted by ……
(Name & Designation of Interpreter)

to the best of his/her ability in …… language/dialect.

I have been informed of the nature of this clinical research in terms of procedure, possible adverse effec and complications (as per patient information sheet). I understand the possible advantages an disadvantages of participating in this research. I voluntarily give my consent for my relative to participa in this research specified above.

I understand that I can withdraw my relative from this clinical research at any time without assigning ar reason whatsoever and in such situation, my relative shall not be denied the benefits of usual treatment b the attending doctors. Should my relative regains his/her ability to consent, he/she will have the right t remain in this research or may choose to withdraw.

Date: …… Relationship to Patient …… Signature or Thumbprint ……

IN THE PRESENCE OF

Name ……)
)
Identity Card No. ……)
)
Designation ……)

Signature ……
(Witness)

I confirm that I have explained to the patient's relative the nature and purpose of the above-mentioned clinical research.

Date …… Signature ……
(Attending Doctor)

CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH	R.N. Name Sex Age Unit		**BK-MIS-1117-E**

KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL

Sila letakkan Nombor Versi dan Tarikh Versi untuk dokumen ini:

Nombor Versi: **1**
Tarikh Versi: **27 Disember 2021**

Saya,…….. No. Kad Pengenalan ……
(Nama Pesakit)

beralamat……
(Alamat)

dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian sc selidik/percubaan ubat-ubatan) disebut berikut:

TajukPenyelidikan: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: a Multicentre study.

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Encik Muhammad Farhan Bin Mahmu

mengikut terjemahan ……
(Nama & Jawatan Penterjemah)

yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Baha / loghat……

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan methodologi, risiko d komplikasi (mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkir kebaikan dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyer penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik diri dari penyelidikan klinikal ini pada bila-bila masa tar memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan d doktor yang merawat.

Tarikh: …….. Tandatangan/Cap Jari ……
(Pesakit)

DI HADAPAN

Nama ……)
)
No. K/P……) ……
) *(Saksi untuk Tandatangan Pesakit)*
Jawatan ……)

Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klini tersebut di atas.

Tarikh: …….. Tandatangan ……
(Doktor yang merawat)

KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL	No. Pend. Nama Jantina Umur Unit		BK-MIS-1117-

CONSENT BY PATIENT FOR CLINICAL RESEARCH

Please create Version No. and Version Date for this document:

Version No.: **1**
Version Date: **27.12.2021**

I, ……Identity Card No.……
(Name of Patient)
of ……
(Address)
hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients from patients and nurses perspective: a Multicentre study.

the nature and purpose of which has been explained to me by Mr Muhammad Farhan Bin Mahmud ,

and interpreted by ……
(Name & Designation of Interpreter)

to the best of his/her ability in …… language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: …… Signature or Thumbprint ……
(Patient)

IN THE PRESENCE OF

Name ……)
)
Identity Card No. ……)
)
Designation ……) ……
(Witness for Signature of Patient)

I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.

Date …… Signature ……
(Attending Doctor)

CONSENT BY PATIENT FOR CLINICAL RESEARCH	R.N. Name Sex Age Unit		

APPENDIX III: ***Data Collection Form***

Sample No : ☐

DATA COLLECTION FORM

(for adult participants)

Title of study: Determining the Impact of Early Tracheostomy Among Severe Head Injury Patients.

Part I: Demographic Data

1) Age ☐

2) Gender

Male ☐

Female ☐

3) GCS on admission ☐

4) Location of head injury

Frontal ☐

Parietal ☐

Temporal ☐

Occipital ☐

5) Timing of tracheostomy (number of days after intubation) ☐

6)

Part II: Clinical Outcome (In-Hospital)

1) Length of stay in ICU ☐ days Remarks: _____

2) Length of stay in hospital ☐ days Remarks: _____

3) Duration on mechanical ventilation ☐ days Remarks: _____

4) Incidence of pneumonia ☐ Type of microorganism (for the pneumonia): _____

5) Final GCS upon discharge ☐ SOFA Score ☐

SAPS II Score ☐

6) Mortality

Yes ☐

No ☐

Other information:

7) Decannulation (N/A if not yet decannulate)

Yes ☐

No ☐

APPENDIX IV: ***Research Questionnaire***

Research Title:

DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS

Part I: Post Discharge Structured Interview GOSE.

Instruction: Please tick (√) with the response that is most applicable.

Respondent :

( ) Patient ( ) Relative/caregiver only ( ) Patient with caregiver

---

Consciousness:

1. Is the head-injured person able to obey simple commands or say any words?
   ( ) Yes ( ) No (VS)

   Note: *Anyone who shows ability to obey even simple commands or utter any word or communicate specifically in any other way is no longer considered to be in the vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff. Confirmation of VS requires full assessment as in the Royal College of Physician Guidelines*

Independence at home:

2a. Is the assistance of another person at home essential every day for some activities of daily living?

( ) Yes ( ) No (VS)

If NO, go to Question 3.

Note: *For a 'No' answer they should be able to look after themselves at home for 24 hours if necessary, though they need not actually look after themselves. Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers, and handling minor domestic crises. The person should be able to carry out activities without needing prompting or reminding and should be capable of being left alone overnight.*

2b. Do they need frequent help of someone to be around at home most of the time?

( ) Yes (Lower SD) ( ) No (Upper SD)

Note: *For a 'No' answer they should be able to look after themselves at home for up to 8 hours during the day if necessary, though they need not actually look after themselves*

2c. Was the patient independent at home before the injury?

( ) Yes ( ) No

Independence outside home:

3a. Are they able to shop without assistance?

( ) Yes ( ) No (Upper SD)

Note: *This includes being able to plan what to buy, take care of money themselves, and behave appropriately in public. They need not normally shop, but must be able to do so*

3b. Were they able to shop without assistance before?

( ) Yes ( ) No (Upper SD)

4a. Are they able to travel locally without assistance?

( ) Yes ( ) No (Upper SD)

Note: *They may drive or use public transport to get around. Ability to use a taxi is sufficient, provided the person can phone for it themselves and instruct the driver.*

4b. Were they able to travel locally without assistance before the injury?

( ) Yes ( ) No

Work:

5a. Are they currently able to work (or look after others at home) to their previous capacity?

( ) Yes ( ) No

If YES, go to Question 6

5b. How restricted are they?
a. Reduced work capacity?
b. Able to work only in a sheltered workshop or non-competitive job or currently unable to
work?

( ) a. (Upper MD) ( ) b. (Lower MD)

5c. Does the level of restriction represent a change in respect to the pre-trauma situation?

( ) Yes ( ) No

Social and Leisure activities :

6a. Are they able to resume regular social and leisure activities outside home

( ) Yes ( ) No

If YES, go to Question 7

Note: *They need not have resumed all their previous leisure activities, but should not be prevented by physical or mental impairment. If they have stopped the majority of activities because of loss of interest or motivation then this is also considered a disability*

6b. What is the extent of restriction on their social and leisure activities?

a. Participate a bit less: at least half as often as before injury ( ) Lower GR
b. Participate much less: less than half as often ( ) Upper MD
c. Unable to participate: rarely, if ever, take part. ( ) Lower MD

6c. Does the extent of restriction in regular social and leisure activities outside home represent a change in respect or pre-trauma?

( ) Yes ( ) No

Family and friendship:

7a. Has there been family or friendship disruption due to psychological problems?

( ) Yes ( ) No

If YES, go to Question 8

Note: *Other typical problems reported after head injury: headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.*

7b. What has been the extent of disruption or strain?

a. Occasional – less than weekly ( ) Lower GR
b. Frequesnt – once a week or more, but not tolerable ( ) Upper MD
c. Constatnt – daily and intolerable ( ) Lower MD

7c. Does the level of disruption or strain represent a change in respect to pre-trauma situation?

( ) Yes ( ) No

Note: *If there were some problems before injury, but these have become markedly worse since injury then answer 'No' for this question*

Return to normal life:

8a. Are there any other current problems relating to the injury which affect daily life?

( ) Yes (Lower GR) ( ) No (Upper GR)

Note: *Other typical problems reported after head injury: headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.*

9. What is the most important factor in outcome?
   a. Effects of head injury ( )
   b. Effects of illness or injury to another part of the body ( )
   c. A mixture of these ( )

Part II: Quality of Life After Brain Injury (QoLIBIRI)

Section A

In the first section of the questionnaire, we would like to know **how satisfied** you are with different aspects of your life since your brain injury.

Please tick (√) with the response that is most applicable.

1	Not at all
2	Slightly
3	Moderately
4	Quite
5	Very

a. These questions are about your thinking abilities now (including last week).

	Item	1	2	3	4	5
1.	How satisfied are you with your ability to concentrate, for example when reading or keeping track of conversation?					
2.	How satisfied are you with your ability to express yourself and understand others in a conversation?					
3.	How satisfied are you with your ability to remember everyday things, for example where you have put things?					
4.	How satisfied are you with your ability to plan and work out solutions to everyday practical problems, for example what to do when you lose your keys?					
5.	How satisfied are you with your ability to make decisions?					
6.	How satisfied are you with your ability to find your way around?					
7.	How satisfied are you with your speed of thinking?					

b. These questions are about your emotions and view of yourself now

	Item	1	2	3	4	5
1.	How satisfied are you with your level of energy?					
2.	How satisfied are you with your level of motivation to do things?					
3.	How satisfied are you with your self-esteem, how valuable you feel?					
4.	How satisfied are you with the way you look?					
5.	How satisfied are you with what you have achieved since your brain injury?					
6.	How satisfied are you with the way you perceive yourself?					
7.	How satisfied are you with the way you see your future?					

c. These questions are about your independence and how you function in daily life.

	Item	1	2	3	4	5
1.	How satisfied are you with the extent of your independence from others?					
2.	How satisfied are you with your ability to get out and about?					
3.	How satisfied are you with your ability to carry out domestic activities, for example cooking or repairing things?					
4.	How satisfied are you with your ability to run your personal finances?					
5.	How satisfied are you with your participation in work and education?					
6.	How satisfied are you with your participation in social and leisure activities, for example sports, hobbies, parties?					
7.	How satisfied are you with the extent to which you are in charge of your own life?					

d. These questions are about your social relationships now

	Item	1	2	3	4	5
1.	How satisfied are you with your ability to feel affection towards others, for example your partner, family, and friends?					
2.	How satisfied are you with your relationship with members of your family?					
3.	How satisfied are you with your relationships with your friends?					
4.	How satisfied are you with your relationship with a partner or with not having partner?					
5.	How satisfied are you with your sex life?					
6.	How satisfied are you with the attitude of other people towards you?					

Section B

In the second part we would like to know how bothered you feel by different problems . For each question please choose theanswer which is closest to how you feel now (inc luding the
past week).

e. These questions are about how bothered you are by your feelings now.

	Item	1	2	3	4	5
1.	*How bothered are you by feeling lonely, even when you are with other people?*					
2.	*How bothered are you by feeling bored?*					
3.	*How bothered are you by feeling anxious?*					
4.	*How bothered are you by feeling sad or depressed?*					
5.	*How bothered are you by feeling angry or aggressive?*					

f. These questions are about how bothered you are by physical problems no w

	Item	1	2	3	4	5

1.	How bothered are you by slowness and/or clumsiness of movement?					
2.	How bothered are you by effects of any other injuries you sustained at the same time as your brain injury?					
3.	How bothered are you by pain, including headache?					
4.	How bothered are you by problem with seeing or hearing?					
5.	Overall, how bothered are you by the effect of your brain injury?					

Part III: Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MoT-Q)

Instruction: Please tick (√) with the response that is most applicable.

1	Strongly Disagree
2	Disagree Somewhat
3	Undecided
4	Agree Somewhat
5	Strongly Agree

	Item	**1**	**2**	**3**	**4**	**5**
1.	If it was recommended, I would see a rehabilitation therapist.					
2.	Given a choice I would spend more time in therapy.					
3.	Rehabilitation will probably help me.					
4.	Rehabilitation is very useful.					
5.	At first, I had some problems, but I'm fine now.					
6.	I'm better now than I ever was.					
7.	Rehabilitation therapists can't help me with my problems.					
8.	Rehabilitation has nothing to do with my needs.					
9.	I have always had the problems I'm having now.					
10.	I have some problems, but I'm doing fine.					
11.	Rehabilitation therapists would probably treat me like a child.					
12.	I'm very excited about getting treatment as soon as possible.					

13.	There is nothing wrong with me.					
14.	I'll be the same if I get treatment or not.					
15.	Therapists would have me do things that are irrelevant.					
16.	The head injury had minimal effect on my abilities.					
17.	Rehabilitation is useful, but I don't think I need it.					
18.	I rely on doctors to help me with my problems.					
19.	I don't have any problems worth mentioning.					
20.	I would ask my therapists to do extra therapy tasks.					
21.	I always follow medical orders because I think they will help me.					
22.	Doctors know what I need, and I will do what they say.					
23.	I would do what a therapist tells me even if it doesn't make sense.					
24.	I'm very interested in rehabilitation, but it's not for me.					
25.	I don't have time for rehab.					
26.	Its fine to see a rehabilitation therapist.					
27.	My problems are my own business.					
28.	I don't like people prying too deeply.					
29.	Therapists would waste my time.					
30.	Going through rehabilitation will help me get (or keep) a job.					
31.	Doctors shouldn't say I have problems without knowing how I was before my journey.					

End of question.
Thank you very much.

APPENDIX V : Permission to Use MoT-Q

Gmail **Muhammad Farhan <farhanmahmud90@gmail.com>**

FW: Permission to use the MoT-Q instrument
1 message

Chervinsky, Alexander <Alexander.Chervinsky@nyulangone.org> Thu, Aug 26, 2021 at 8:17 PM
To: "farhanmahmud90@gmail.com" <farhanmahmud90@gmail.com>

Hi MUHAMMAD FARHAN BIN MAHMUD,

Yes, please feel free to use the instrument and let me know about the results.

Best regards,

Alexander B. Chervinsky, Ph.D., ABPP

Board Certified in Clinical Neuropsychology

Clinical Professor

Department of Neurology

New York University School of Medicine

NYU Langone Hospital – Brooklyn

Department of Neurology

150 55th Street

Brooklyn, NY 11220

tel 718-630-6267

fax 718-630-6329

NYU Langone Brooklyn Medical Arts Pavilion

8714 5th Avenue

Brooklyn, NY 11209

tel 718-630-8600

fax 718-630-8615

alexander.chervinsky@nyulangone.org

From: Alexander Chervinsky <achervin@chervinskyneuropsych.com>
Sent: Tuesday, August 24, 2021 10:17 PM
To: Chervinsky, Alexander <Alexander.Chervinsky@nyulangone.org>
Subject: FW: Permission to use the MoT-Q instrument

[EXTERNAL]

Alexander B. Chervinsky, Ph.D., ABPP

Board Certified in Clinical Neuropsychology

From: Muhammad Farhan [mailto:farhanmahmud90@gmail.com]
Sent: Tuesday, August 24, 2021 10:52 AM
To: achervin@chervinskyneuropsych.com
Subject: Permission to use the MoT-Q instrument

Dear Dr. Alexander B. Chervinsky,

Regarding the above matter, I, Muhammad Farhan Bin Mahmud a postgraduate student at International Islamic University Malaysia (IIUM) would like to request your permission to use the Motivation for Traumatic Brain Injury rehabilitation Questionnaire (MoT-Q) instrument in my research.

For your information, currently, I am proposing a study as a part of the requirement for my Masters in Nursing Science with the title of "DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG HEAD INJURY PATIENTS" in Kuala Lumpur, Malaysia. One of the instruments that will be included in this research is MoT-Q to assess the participant's level of motivation and compliance to the rehabilitation process.

I am looking forward to your feedback about this matter.

Regards,

MUHAMMAD FARHAN BIN MAHMUD
Post-graduate student,
Master in Nursing Science,
International Islamic University Malaysia (IIUM).

APPENDIX VI: Permission to Use GOSE

Gmail **Muhammad Farhan <farhanmahmud90@gmail.com>**

RE: Requesting Permission to Use GOSE Instrument

1 message

Lindsay Wilson <l.wilson@stir.ac.uk> Fri, Feb 12, 2021 at 6:50 PM
To: Muhammad Farhan <farhanmahmud90@gmail.com>

Dear Muhammad,

I confirm that I am happy for you to use the GOSE in your research, and you may copy it freely for this purpose.

I wish you success.

Best wishes

Lindsay

Professor Lindsay Wilson

Division of Psychology

School of Natural Sciences

University of Stirling

Stirling FK9 4LA

UK

Tel: +44 1786467658

Fax: +44 1786467641

From: Muhammad Farhan <farhanmahmud90@gmail.com>
Sent: 10 February 2021 06:07
To: Lindsay Wilson <l.wilson@stir.ac.uk>
Subject: Requesting Permission to Use GOSE Instrument

Dear Prof. Lindsay Wilson,

Regarding the above matter, I, Muhammad Farhan Bin Mahmud a postgraduate student at International Islamic University Malaysia (IIUM) would like to request your permission to use the GOSE instrument in my research.

For your information, currently, I am proposing a study as a part of the requirement for my Masters in Nursing Science with the title of "THE OUTCOME OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY SURVIVORS" in Kuala Lumpur, Malaysia. One of the instruments that will be included in this research is GOSE.

I am looking forward to your feedback about this matter.

Regards,

MUHAMMAD FARHAN BIN MAHMUD
Post-graduate student,
master in Nursing Science,
International Islamic University Malaysia (IIUM).

2 attachments

GOSE.pdf
142K

Gosguide.PDF
41K

APPENDIX VII: Permission to Use QoLIBRI

Gmail **Muhammad Farhan <farhanmahmud90@gmail.com>**

Re: Request Permission To Use The Motivation Quality of Life After Brain Injury (QoLIBRI) Instrument

1 message

Steinbüchel-Rheinwall, Nicole <nvsteinbuechel@med.uni-goettingen.de> Tue, Mar 23, 2021 at 4:05 PM
To: Muhammad Farhan <farhanmahmud90@gmail.com>
Cc: "Covic, Amra" <amra.covic@med.uni-goettingen.de>

Than goof luck! BW NvS

> Am 23.03.2021 um 08:55 schrieb Muhammad Farhan <farhanmahmud90@gmail.com>:
>
> Dear Prof,
>
> I will use the English version for the study.
>
> Thank you.
>
> Regards,
>
> MUHAMMAD FARHAN BIN MAHMUD
> Post-graduate student,
> Master in Nursing Science,
> International Islamic University Malaysia (IIUM).
>
> On Tue, Mar 23, 2021 at 3:27 PM Steinbüchel-Rheinwall, Nicole <nvsteinbuechel@med.uni-goettingen.de> wrote:
>> Dear Mr. Mahmud,
>>
>> In which language would you use it?
>>
>> With best regards
>>
>> NvSteinbüchel
>>
>> Am 23.03.2021 um 07:44 schrieb Muhammad Farhan <farhanmahmud90@gmail.com>:
>>
>> Dear Prof. Nicole von Steinbuchel,
>>
>> Regarding the above matter, I, Muhammad Farhan Bin Mahmud a postgraduate student at International Islamic University Malaysia (IIUM) would like to request your permission to use the Motivation Quality of Life After Brain Injury (QoLIBRI) instrument in my research.
>>
>> For your information, currently, I am proposing a study as a part of the requirement for my Masters in Nursing Science with the title of "UNDERSTAND THE IMPACT OF EARLY TRACHEOSTOMY AMONG HEAD INJURY PATIENTS" in Kuala Lumpur, Malaysia. One of the instruments that will be included in this research is MoT-Q to assess the participant's level of motivation and compliance to the rehabilitation process.
>>
>> I am looking forward to your feedback about this matter.

Regards,

MUHAMMAD FARHAN BIN MAHMUD
Post-graduate student,
Master in Nursing Science,
International Islamic University Malaysia (IIUM).

<image001.png>

Prof. Dr. Nicole von Steinbüchel
Head of Institute
Professor of Medical Psychology and Medical Sociology

University Medical Center Göttingen
Georg-August-University
Institute of Medical Psychology and Medical Sociology
Waldweg 37
37073 Göttingen
Germany

Phone +49 / (0)551 / 39-8197
Fax +49 / (0)551 / 39-8194
Cell +49 / (0)15112049316

UNIVERSITÄTSMEDIZIN GÖTTINGEN : UMG

Prof. Dr. Nicole von Steinbüchel
Head of Institute
Professor of Medical Psychology and Medical Sociology

University Medical Center Göttingen
Georg-August-University
Institute of Medical Psychology and Medical Sociology
Waldweg 37
37073 Göttingen
Germany

Phone +49 / (0)551 / 39-8197
Fax +49 / (0)551 / 39-8194
Cell +49 / (0)15112049316

APPENDIX VIII: ***Supervisor's Appointment***

الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
Garden of Knowledge and Virtue

LEADING THE WAY
KHALIFAH · AMANAH · IQRA' · RAHMATAN LIL-'ALAMIN

SUSTAINABILITY INSTITUTION OF THE YEAR

Our Ref : IIUM/313/G/DDPGR/13/11/2
Date : 28th September 2020

Assoc. Prof. Dr. Salizar Mohamed Ludin
Department of Critical Care Nursing
Kulliyyah of Nursing

Dear Assoc. Prof. Dr.,

APPOINTMENT AS SUPERVISOR

May this letter reach you in the best of health.

The Kulliyyah would like to congratulate you on your appointment as the Supervisor for the student as below:

Name	:	Muhammad Farhan bin Mahmud
Matric No.	:	G2019421
Program	:	Master in Nursing Science
Kulliyyah	:	Kulliyyah of Nursing
Approved Thesis Title	:	Determining The Impact Of Early Tracheostomy Among Severe Head Injury Patients

Effective Date of Appointment : 28th September 2020

You are kindly requested to abide by the IIUM Code of Supervision.

Your contribution towards the successful supervision of our postgraduate student is highly appreciated.

Thank you.

Yours sincerely,

ASST. PROF. DR. LEE SIEW PIEN
Deputy Dean (Postgraduate & Research)
Kulliyyah of Nursing

c.c : Prof. Dato' Dr. Mohamed Saufi bin Awang
Kulliyyah of Medicine
Co-Supervisor

Muhammad Farhan bin Mahmud
G2019421

KULLIYYAH OF NURSING (KON)
International Islamic University Malaysia, Jalan Sultan Ahmad Shah, Bandar Indera Mahkota, 25200 Kuantan, Pahang Darul Makmur
(Company No: 101067-P)

Tel: +609 570 7300 Email: nursingadmin@iium.edu.my
www.iium.edu.my/kulliyyah/kon

APPENDIX IX: ***Letter of Ethical Approval – Kulliyyah of Nursing Postgraduate Research Committee (KNPGRC)***

الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
(Company No. 101067-P)
Garden of Knowledge and Virtue

KULLIYYAH OF NURSING

Our Reference : IIUM/313/14/3/1
Date : 21st April 2021 / 9 Ramadan 1442H

Muhammad Farhan bin Mahmud
G2019421
Postgraduate Student
Master in Nursing Science
Kulliyyah of Nursing IIUM

Dear Br. Muhammad Farhan,

APPROVAL OF RESEARCH PROPOSAL
- MASTER IN NURSING SCIENCE

May this letter find you in the best of health.

With reference to the above matter, kindly be informed that your research proposal title "*Determining The Impact Of Early Tracheostomy Among Severe Head Injury Patients*" has been approved by the Kulliyyah of Nursing Postgraduate and Research Committee (KNPGRC) No. 3/2021 dated 21st. April 2021.

Kindly proceed with necessary action accordingly.

Thank you.

ASSOC. PROF. DR. SALIZAR MOHAMED LUDIN
Dean
Kulliyyah of Nursing

cc : Deputy Dean (Postgraduate & Research)
Kulliyyah of Nursing

: *Filing/ Student file*

CERTIFIED TO ISO 9001:2015
CERT. NO. QMS 01195

Office Address: Kulliyyah of Nursing, International Islamic University Malaysia, Jalan Sultan Ahmad Shah, Bandar Indera Mahkota, 25200 Kuantan, Pahang
Tel: +609-570 7300 | **E-mail:** nursingadmin@iium.edu.my | **Website:** http://www.iium.edu.my/kulliyyah/kon

APPENDIX X: Letter of Notification – *IIUM Research Committee (IREC)*

Gmail

Muhammad Farhan <farhanmahmud90@gmail.com>

NOTIFICATION ON IREC APPROVAL OF OTHER ETHICS COMMITTEE - IREC 2021-245

1 message

Reference of IIUM Research Ethics Committee (IREC) . <irec@iium.edu.my> Thu, Aug 19, 2021 at 8:00 AM
To: Muhammad Farhan <farhanmahmud90@gmail.com>

Assalamualaikum wrt.

Dear Bro. Muhammad Farhan Bin Mahmud

ID No : IREC 2021-245
Title of Project: Determining The Impact Of Early Tracheostomy Among Severe Head Injury Patients
Principal Investigator: Bro. Muhammad Farhan Bin Mahmud
Study Site: 1. Hospital Kuala Lumpur (HKL)
2. University Malaya Medical Centre (UMMC)
Duration of Study: 01 Sep 2021 - 30 Jul 2022

NOTIFICATION ON IREC APPROVAL OF OTHER ETHICS COMMITTEE

We are glad to inform you that your ethics application has been approved by the IREC committee.
The **Notification Letter (without signature)** with the attached notification email may be used by the applicant to submit to the study site.

Please note the notification letter with signature will be issued once the MCO is lifted.

PROF. DR. NASSER MUHAMMAD AMJAD
Chairman
IIUM Research Ethics Committee (IREC)

IIUM Research Ethics Committee (IREC)
Research Management Center (RMC), Kuantan Campus
Level 1, Administrative Building (OCD)
International Islamic University of Malaysia
Jalan Sultan Haji Ahmad Shah, Indera Mahkota
25200 Kuantan, Pahang

Tel No.: 09 - 570 4733 (Bro. Mohd A'imullah)
Tel No.: 09 - 570 4227 (Sis. Azaidatul)
Website: http://www.iium.edu.my/centre/irec

Note:-
Please note that effective from April 2016 any communication will be via email. IREC will not issue original letter to minimize paper consumption.

PDF.pdf
128K

Our Ref. : IIUM/504/14/11/2/IREC 2021-245
Date : 18 Aug 2021

Bro. Muhammad Farhan Bin Mahmud (Principal Investigator)
No. 32, Lorong Seri Mahkota Damai 2, Taman Perdana
25150 Kuantan Pahang

Dear Bro.

NOTIFICATION ON ETHICAL APPROVAL FROM OTHER ETHICS COMMITTEE

The IIUM Research Ethics Committee (IREC) has received the below mentioned application for notification on ethical approval from other Ethics Committee (EC). The following research project has been submitted for notification and record purposes:

ID No	:	IREC 2021-245
Project Title	:	Determining The Impact Of Early Tracheostomy Among Severe Head Injury Patients
Study Site	:	1. Hospital Kuala Lumpur (HKL) 2. University Malaya Medical Centre (UMMC)
Ethics Committee	:	Medical Research & Ethics Committee (MREC)
Co-Investigator	:	Assoc. Prof. Dr. Salizar Bte Mohamed Ludin

Upon review of the application and approval letter from MREC, the IREC acknowledged the notification and recommended the commencement of archiving procedures. The Investigator is required to notify IREC of any approval of continuing review from the aforementioned ethics committee.

Thank you.

Kind Regards,

PROF. DR. NASSER MUHAMMAD AMJAD
Chairman
IIUM Research Ethics Committee (IREC)

Copy : *File - IREC 2021-245*

APPENDIX XI: Letter of Ethical Approval – *Medical Research Ethical Committee (MREC) and National Medical Research Register (NMRR)*

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(*MEDICAL RESEARCH & ETHICS COMMITTEE*)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Kompleks Institut Kesihatan Negara (NIH)
No.1, Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam, Selangor. Tel.: +(6)03-33628888/ 33628205

Ref. : KKM/NIHSEC/P21-1241(12)
Date : **3-August-2021**

MUHAMMAD FARHAN BIN MAHMUD
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA (IIUM) - KUANTAN CAMPUS

Dear Dato'/ Dr/ Sir/ Madam,

LETTER OF ETHICAL APPROVAL:

NMRR-21-971-59620 (IIR)
DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS

This letter is made in reference to the matter above.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator/ Hospital Director and all relevant heads of departments /units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations including the Access to the Biological and Benefit Sharing Act 2017.

3. The investigators and sites involved in this study are:

Hospital Kuala Lumpur
Muhammad Farhan Bin Mahmud (Principal / Coordinating Investigator)

University Malaya Medical Centre (UMMC)
Muhammad Farhan Bin Mahmud (Principal / Coordinating Investigator)

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Cover letter to MREC (Version 3, dated 02-08-2021)
2. Declaration of Conflict of Interest (COI) (Version 1, dated 23-05-2021)
3. Protocol (Version 4, dated 02-08-2021)
4. English: Patient Information Sheet/ Informed Consent Form (Version 4, dated 02-08-2021)
5. Malay: Patient Information Sheet/ Informed Consent Form (Version 4, dated 02-08-2021)
6. Questionnaire (Version 3, dated 02-08-2021)
7. Data Collection Form (Version 3, dated 25-06-2021)
8. Follow-up Review Report (Version 1, dated 02-08-2021)
9. IA-HOD-IA and CV of:
    - Muhammad Farhan Bin Mahmud

…/2-

Ref : KKM/NIHSEC/P21-1241(12)

5. Please note that the approval is valid until **02-August-2022**.The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry (NMRR) website.

i. **Continuing Review Form** has to be submitted to MREC within 2 months (60 days) prior to the expiry of ethical approval.
ii. **Study Final Report** upon study completion to the MREC.
iii. Ethical approval is required in the case of **amendments/ changes** to the **study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
iv. **Applicable for Clinical interventional Studies only:** Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.

6. There will be **129 subjects/ patients/ respondents** targeted to be enrolled in this study within Malaysia.

7. Please take note that the reference number of this letter must be stated in all future correspondence related to this study to facilitate the administrative processes.

Project Sites:
HOSPITAL KUALA LUMPUR
UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

Date of Approval : **03-August-2021**

DR. HJH SALINA BINTI ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
(MMC No: 27117)

c.c:

HRRC Hospital Kuala Lumpur

CM\MREC_Share\Approval 2020\Expedited by Primary Reviewer\August 2021\59620

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(*Medical Research & Ethics Committee*)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Kompleks Institut Kesihatan Negara
Blok A, No 1, Jalan Setia Murni U13/52,
Seksyen U13, Bandar Setia Alam,
40170 Shah Alam, Selangor.
Tel: 03-3362 8888/8205

Ruj.Kami:KKM/NIHSEC/ P21-1241
Tarikh: 07-July-2022

ENCIK/MR. MUHAMMAD FARHAN BIN MAHMUD
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA (IIUM) - KUANTAN CAMPUS

Dato'/ Tuan/ Puan,

Annual Ethical Renewal for 2022

NMRR-21-971-59620 (IIR)
Protocol No :
DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS

With reference to the 'Continuing Review Form' submitted 01-July-2022, we are pleased to inform that the conduct of the above study has been granted approval (via Expedited Review by Chairperson) for a year by the Medical Research & Ethics Comittee, Ministry of Health Malaysia. Please note that the approval is valid until 02-August-2023. To renew the approval, a completed 'Continuing Review Form' has to be submitted to MREC **within 2 months** before the expiry of the approval.

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to The International Council for Harmonization of Technical Requirement for Pharmaceutical for Human Use (ICH) dan Malaysia Guidelines for Good Clinical Practice.

Effective date: 03-August-2022 Until 02-August-2023

Comments (if any): NIL

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Yours sincerely,

(DR HJH SALINA ABDUL AZIZ)
Chairman
Medical Research & Ethics Committee
Ministry of Health Malaysia

APPENDIX XII: *Agreement for Undertaking Research at Hospital Kuala Lumpur NMRR-21-971-59620 (IIR) HKL HCRC AK 02 01*

PUSAT PENYELIDIKAN KLINIKAL HOSPITAL KUALA LUMPUR
TINGKAT 3, BANGUNAN PENTADBIRAN & KEWANGAN
HOSPITAL KUALA LUMPUR
TEL 03 26155555 EXT. 6262

EMAIL: crc.hkl@moh.gov.my

AGREEMENT FOR UNDERTAKING RESEARCH AT HOSPITAL KUALA LUMPUR

Persetujuan Penggunaan Kemudahan Hospital Kuala Lumpur Untuk Menjalankan Penyelidikan

CRC Research Registration No *No. pendaftaran penyelidikan CRC*	CRCHKL-2021-08-193
Research Title *Tajuk penyelidikan*	DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS
NMRR Research ID *No. Penyelidikan NMRR*	NMRR-21-971-59620 (IIR)
Protocol ID (ISR only) *No Protokol (ISR sahaja)*	
Type of Research *Jenis penyelidikan*	IIR- Observational Study
Study Sponsor (*If Relevant*) *Penaja penyelidikan (sekiranya berkenaan)*	
Principle Investigator's Name *Nama penyelidik utama*	Muhammad Farhan Bin Mahmud
PI's Department (HKL only) *Jabatan penyelidik utama (HKL sahaja)*	
PI's Institution (*if non HKL*) *Institusi penyelidik utama (bukan HKL)*	(Faculty) of Nursing, International Islamic University Malaysia (IIUM)
PI Contact No *No. telefon penyelidik utama*	013-315 6974
PI email *Email penyelidik utama*	farhanmahmud90@gmail.com
HKL PI at Site/Co-I/Supervisor Name *Nama Penyelidik Utama di HKL*	Siti Azleen
Department *Jabatan*	Neurosurgery
Contact No *No. telefon*	012-3275357
Email *Emel*	siti.azleen@gmail.com
Good Clinical Practice (GCP) Certificate *Sijil Good Clinical Practice (GCP)*	Not Applicable
GCP Refresher *GCP Refresher*	Not Applicable
Research Site *Tempat penyelidikan*	HKL
HKL Requirement Prior to Data Collection **MREC Approval** *(Kelulusan JEPP)*	APPROVED (As attached)
MREC Approval Date *Tarikh Kelulusan JEPP*	3/8/2021
Site Consent (AK 02-02) *(Persetujuan Pengarah HKL)*	PENDING (To submit prior to data collection)
Registered by *Didaftar oleh*	PT Siti Nur Salshabila binti Mohd Kamal
Date *Tarikh*	1/10/2021

By signing the agreement:
Dengan menandatangani persetujuan ini:

√ I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility for this project at this site.
Saya mengaku maklumat di dalam borang ini adalah benar dan tepat sepanjang pengetahuan saya dan saya bertanggungjawab penuh untuk projek ini.

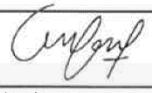
√ I certify that I and all members of the research team have the appropriate qualifications, training, experience and facilities to conduct the research set out in the proposal attached and to deal with any emergencies and contingencies related to the research that may arise.
Saya mengaku bahawa saya dan semua ahli pasukan penyelidikan mempunyai kelayakan yang sesuai, latihan, pengalaman dan kemudahan untuk menjalankan penyelidikan yang dinyatakan dalam permohonan yang disertakan dan untuk menangani sebarang kecemasan yang mungkin timbul diluar jangkaan yang berkaitan dengan penyelidikan.

√ I undertake to conduct this research project in accordance with the protocols and procedures as approved by the Medical Research Ethics Committee (MREC) and the ethical and research arrangements of the organisation(s) involved.
Saya berjanji untuk menjalankan projek penyelidikan ini mengikut protokol dan prosedur yang diluluskan oleh Jawatankuasa Etika Penyelidikan Perubatan (JEPP) dan etika penyelidikan dengan organisasi yang terlibat.

√ I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am the Principal Investigator including any monitoring/reporting requirements. I will discontinue the research if the authorising authority withdraws the authorisation at the site where I am the Principal Investigator.
Saya akan mematuhi syarat-syarat kelulusan yang ditetapkan oleh pihak berkuasa yang membenarkan di tempat di mana saya, selaku Penyelidik Utama termasuk apa-apa keperluan pemantauan / pelaporan. Saya tidak akan meneruskan penyelidikan jika pihak berkuasa yang memberi kuasa menarik balik kebenaran.

√ I will inform the HKL departmental Research Coordinator, and CRC HKL in the event of study completion/closure.
Saya akan maklumkan pada koordinator penyelidikan jabatan HKL dan CRC HKL apabila penyelidikan saya telah tamat/ditutup.

√ I declare that if my research requires a Research Agreement, I have read, understood and will adhere to it.
Saya mengakui bahawa sekiranya penyelidikan saya memerlukan Perjanjian Penyelidikan, saya telah membaca, memahami dan akan mematuhinya.

Name of Principal Investigator/ Principal Investigator at Site *Nama Penyelidik Utama/ Penyelidik Utama Setempat*	**MUHAMMAD FARHAN BIN MAHMUD**
Signature and Official Stamp *Tandatangan dan Cop Rasmi*	
Date *Tarikh*	**01/10/2021**

APPENDIX XIII: ***Head of Department(s) & Director of Hospital Kuala Lumpur Agreement NMRR-21-971-59620 (IIR) HKL HCRC AK 02 01***

HKL/HCRC/AK-02-02

CLINICAL RESEARCH CENTRE HOSPITAL KUALA LUMPUR
TINGKAT 3, BANGUNAN PENTADBIRAN & KEWANGAN
HOSPITAL KUALA LUMPUR
TEL 03 26155555 EXT. 6262 Email: crc.hkl@moh.gov.my

Borang *Head of Department & Director of Hospital Kuala Lumpur Agreement*

Strictly for use within Hospital Kuala Lumpur ONLY

Principal Investigator/Site PI ***Penyelidik Utama/Penyelidik setempat***	Muhammad Farhan Bin Mahmud
Research Title ***Tajuk Penyelidikan***	DETERMINING THE IMPACT OF EARLY TRACHEOSTOMY AMONG SEVERE HEAD INJURY PATIENTS
NMRR Registration No. ***No. Pendaftaran NMRR***	NMRR-21-971-59620 (IIR)
CRC Registration No. ***No. Pendaftaran CRC***	CRCHKL-2021-08-193

DR NIK NUR ELIZA MOHAMED
MBChB (EDINBURGH) (UMC NO: 50117)
MEDICAL OFFICER ID 52
CLINICAL RESEARCH CENTRE
HOSPITAL KUALA LUMPUR

HEAD OF DEPARTMENT AGREEMENT
PERSETUJUAN KETUA JABATAN

1. I certify that I have read the project details in this research project application named above.
   Saya mengesahkan bahawa saya telah membaca butiran projek penyelidikan yang dinamakan di atas.
2. I certify that I am aware of this research project and the resource implications for this Department and site.
   Saya mengaku bahawa saya faham projek penyelidikan ini dan implikasi sumber bagi Jabatan ini dan dipusat ini
3. I certify that the research is appropriate to be conducted within this Department and at this site.
   Saya mengaku bahawa penyelidikan adalah sesuai untuk dijalankan di Jabatan ini dan dipusat ini
4. I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'In kind' contribution.
   Saya mengesahkan bahawa terdapat kemudahan dan sumber yang sesuai dan mencukupi untuk projek penyelidikan yang akan dijalankan di Jabatan. Ini adalah untuk 'kos sebenar' dan 'dalam jenis' sumbangan.
5. My signature indicates that I support this research project being carried out using such resources.
   Tandatangan saya menunjukkan bahawa saya menyokong projek penyelidikan ini dijalankan dengan menggunakan sumber-sumber tersebut.

Department *Jabatan*	**Name of Head of Department** *Nama Ketua Jabatan*	**Signature and official stamp** *Tandatangan dan Cop Rasmi*	**Date** *Tarikh*
NEUROSURGERY	DR. AZMI BIN ALIAS	DR. AZMI BIN ALIAS NO. MMC 01481 MBBS (UM) M.Surg (UKM) FRCS (Ireland) FAMM Fellow in Minimal Invasive Neurosurgery (Mainz, Germany) Ketua Jabatan Dan Pakar Perunding Kanan Jabatan Neurosurgeri Hospital Kuala Lumpur	09-09-2021
Medical Record	Cik Elisabeth Angang	ELISABETH ANGANG KETUA JABATAN REKOD PERUBATAN HOSPITAL KUALA LUMPUR	5/10/2021

No. Keluaran : 01 Pindaan : 01 Tarikh Kuatkuasa : 1 Jun 2020

DIRECTOR OF HOSPITAL KUALA LUMPUR AGREEMENT
PERSETUJUAN PENGARAH HOSPITAL KUALA LUMPUR

My signature indicates that I :
Tandatangan saya menunjukkan bahawa saya :

☑ Authorise this research project to commence in Hospital Kuala Lumpur on the condition that all the scientific and ethical aspects of the Medical Research Ethics Committee approved protocol are met.
Memberi kebenaran projek penyelidikan ini bermula di Hospital Kuala Lumpur dengan syarat semua aspek saintifik dan etika protokol yang telah diluluskan oleh Jawatankuasa Penyelidikan Etika Perubatan KKM, dipenuhi oleh penyelidik.

☐ Do not authorise this research project to commence in Hospital Kuala Lumpur.
Tidak memberi kebenaran projek penyelidikan ini dijalankan di Hospital Kuala Lumpur.

Name of Hospital Director *Nama Pengarah Hospital*	
Signature and official stamp *Tandatangan dan Cop Rasmi*	DR. FAIROZ AZLIM BIN MUSLIM MMC : 43115 TIMBALAN PENGARAH (PEMBEDAHAN) b.p PENGARAH HOSPITAL KUALA LUMPUR
Date *Tarikh*	11TH OCTOBER 2021

(FOR CRC HKL OFFICE USE)
(UNTUK KEGUNAAN PEJABAT CRC HKL)

The Investigator named above has provided to CRC HKL before the commencement of his/her research, proof of:
Penyelidik di atas telah mengemukakan kepada CRC HKL sebelum penyelidikan beliau dimulakan, bukti:

☑ **Head of Department(s) Agreement**
Persetujuan Ketua Jabatan

☑ **Director of Hospital Kuala Lumpur's Agreement**
Persetujuan Pengarah Hospital Kuala Lumpur

☑ **MREC approval**
Kelulusan JEPP

Verified by:
Disemak oleh:

Date & CRC stamp:

PUSAT PENYELIDIKAN KLINIK KL HOSPITAL
11 OCT 2021
HKL

DR NIK NUR ELIZA MOHAMED
MBChB (EDINBURGH) (MMC NO: 50117)
MEDICAL OFFICER UD 52
CLINICAL RESEARCH CENTRE
HOSPITAL KUALA LUMPUR

APPENDIX XIV: ***University Malaya Medical Centre Medical Research Ethics Committee UMMC-MREC) Online Ethical Approval***

UNIVERSITY OF MALAYA MEDICAL CENTRE

MEDICAL RESEARCH ETHICS COMMITTEE
(Formerly known as Medical Ethics Committee)
UNIVERSITY OF MALAYA MEDICAL CENTER

ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE : 03-79493209/2251 FAXIMILE : 03-79492030

NAME OF ETHICS COMMITTEE/IRB Medical Research Ethics Committee, University Malaya Medical Center	**MRECID.NO**: 202211-10879
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	
PROTOCOL NO(if applicable) :	
TITLE: Determining Impact of Early Tracheostomy Among Severe Head Injury Patients (Patients' and Nurses' Perspectives)	
PRINCIPAL INVESTIGATOR : Dr Lee Wan Ling	**SPONSOR** -

The following item [✓] have been received and reviewed in connection with the above study to conducted by the above investigator.

[✓]	Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 01-01-2022
[✓]	Study Protocol	Ver.No : 1	Ver.Date : 27-12-2022
[✓]	Patient Information Sheet	Ver.No : 1	Ver.Date : 27-12-2021
[✓]	Consent Form	Ver.No : 1	Ver.Date : 27-12-2021
[✓]	Questionnaire	Ver.No :	Ver.Date :
[✓]	Investigator's CV / GCP (Dr Lee Wan Ling,Salizar Bt. Mohamed Ludin, Muhammad Farhan Bin Mahmud , MUHAMMAD IRSYAD BIN MAHD NOR,)	Ver.No :	Ver.Date :
[ ]	Insurance certificate	Ver.No :	Ver.Date :
[✓]	Other Attachments		

and the decision is [✓]

[ ] Approved
[✓] Expedited approved
[ ] Rejected(reasons specified below or in accompanying letter)

Comments:

Questionaire-based study. Ethical issues addressed.

Investigator are required to:

1) *follow instructions, guidelines and requirements of the Medical Research Ethics Committee.*
2) *report any protocol deviations/violations to Medical Research Ethics Committee.*
3) *provide annual and closure report to the Medical Research Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.*
6) *ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.*
7) *note that he/she can appeal to the Chairman of Medical Research Ethics Committee for studies that are rejected.*
8) *note that Medical Research Ethics Committee may audit the approved study.*
9) *ensure that the study does not take precedence over the safety of subjects.*

2/15/22, 6:20 PM Untitled Document

Date of expedited approval : 04-02-2022
Approval By : LOOI LAI MENG (Chairman,MREC)

This is a computer generated letter. No signature required.

APPENDIX XV: ***University Malaya Medical Centre Medical Research Ethics Committee UMMC-MREC) Official Ethical Approval***

PUSAT PERUBATAN
UNIVERSITI
MALAYA

Ruj. Kami : PPUM/RDI/400/09/001/34

27 Sya'ban1443H
30 Mac 2022

Dr. Lee Wan Ling
Jabatan Sains Kejururawatan
Fakulti Perubatan
Universiti Malaya

Puan,

Kebenaran Untuk Menjalankan Penyelidikan Di Pusat Perubatan Universiti Malaya

Dengan hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa permohonan untuk menjalankan penyelidikan seperti dibawah adalah diluluskan dengan syarat perlu mendapatkan kebenaran dari Jabatan Maklumat Pesakit bagi mengakses eMR. Pihak penyelidik juga diingatkan untuk mematuhi syarat bahawa data hanya boleh diakses daripada jangka masa yang dimohon serta sebarang penerbitan perlulah menghantar *'softcopy'* kepada pihak Jabatan Penyelidikan, Pembangunan dan Inovasi.

3. Maklumat penyelidikan adalah seperti berikut :

Nama Penyelidik	:	Seperti Di Lampiran A
Tajuk Penyelidikan	:	*Determining The Impact of Early Tracheostomy Among Severe Head Injury Patients (Patient's and Nurses' Perspectives)*
Tarikh Penyelidikan	:	15/3/2022 – 31/3/2023

4. Dengan kebenaran ini diharap dapat menjalankan penyelidikan dengan penuh integriti dan dapat menghasilkan penyelidikan yang berkualiti dan berimpak tinggi.

Sekian, terima kasih.

"PENERAJU PENGAJARAN PERUBATAN"
"WAWASAN KEMAKMURAN BERSAMA 2030"
"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

PROFESOR DR. NAZIRAH BINTI HASNAN
Pengarah
Pusat Perubatan Universiti Malaya

PUSAT PERUBATAN UNIVERSITI MALAYA
(University Malaya Medical Centre)
LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
☎+603-79494422 (Hunting Line) : 🖷 03-7956 2253
www.ummc.edu.my :ummc@ummc.edu.my

The Leader In Medical Education
'Peneraju Pengajaran Perubatan'

APPENDIX XVI: ***University Malaya Medical Centre – Research Module Certificate***

APPENDIX XVII: *Acceptance for Oral/Poster Presentation*

MUHAMMAD FARHAN BIN MAHMUD . <farhanmahmud@iium.edu.my>

Abstract for SeSICNiMPH Oral Presentation

1 message

MUHAMMAD FARHAN BIN MAHMUD . <farhanmahmud@iium.edu.my> Sun, Sep 12, 2021 at 2:37 PM
To: roza.marlinda@gmail.com
Cc: "SALIZAR BT. MOHAMED LUDIN" <msalizar@iium.edu.my>, SANISAH BINTI SAIDI Sanisah <sanisahsaidi@iium.edu.my>

السلام عليكم ورحمة الله وبركاته

Dear Dr./Sir/Madam/Brother/Sister,

May this e-mail reach you in the best of health and *Iman* by the grace of *Allah SWT*.

Kindly find the attachment of **Abstract** for the paper entitled ***"A Review of the Impact of Early Tracheostomy Among Head Injury Patients"*** in conjunction with **The 2nd Syedza Saintika International Conference (SeSICNiMPH)** for your perusal.

Looking forward to the event. Thank you very much.

Best regards, والسلام

MUHAMMAD FARHAN BIN MAHMUD
Postgraduate Student
Master in Nursing Science

Kulliyyah of Nursing
International Islamic University Malaysia
Jalan Sultan Ahmad Shah Bandar Indera Mahkota
25200 Kuantan, Pahang, Malaysia.

t: +6013 315 6974
e: farhanmahmud@iium.edu.my
w: www.iium.edu.my/kulliyyah/kon

LEADING THE WAY
KHALĪFAH • AMĀNAH • IQRA' • RAHMATAN LIL-ĀLAMĪN

Abstract - Muhammad Farhan Bin Mahmud.pdf
137K

Date : 15th September 2021 *(8 Safar 1443 Hijrah)*

Stikes Syedza Saintika
Jl. Prof. Dr. Hamka No.228,
Air Tawar Tim.,
Kec. Padang Utara,
Kota Padang,
Sumatera Barat 25132
INDONESIA

Dear Sir/Madam, السلام عليكم ورحمة الله وبركاته

THE 2nd SYEDZA SAINTIKA INTERNATIONAL CONFERENCE ON NURSING, MIDWIFERY, MEDICAL LABORATORY TECHNOLOGY, PUBLIC HEALTH, AND HEALTH INFORMATION MANAGEMENT (SeSICNiMPH)

May this letter find you in the good health and Iman by Allah *Subhanahu Wata'ala*.

This is to inform the committee members that the following presenters are given free seats for the above conference:

1. Selamat Yasin
2. Ayuni Asma' Baharuddin
3. Hamidah Othman
4. W Solihatul Hafidzah W Mohd Annuar
5. Muhammad Farhan Mahmud
6. Junainah Azmi

Your kind cooperation in this matter is highly appreciated.

Thank you, والسلام

DR. MUHAMMAD KAMIL CHE HASAN
Dean
Kulliyyah of Nursing
International Islamic University Malaysia

CERTIFICATE

OF APRECIATION

STIKes Syedza Saintika

THIS CERTIFICATE IS PROUDLY PRESENTED TO

MUHAMMAD FARHAN BIN MAHMUD

AS ORAL PRESENTER

2nd Syedza Saintika International Conference On Nursing, Midwifery, Public Health, Medical Laboratory Technology, Health Informotion Management (SeSICNiMPH)

Building Community Resilience : Overcoming Immunity Issues Towards COVID-19 Pandemic

That was held online at Zoom Programme on
Thursday, 23 September 2021, 08.00-16.30 Wib Indonesia

Accteditation Of IBI (3 SKP :7333/SKP-IBI/IX/2021)
Accreditation Of PPNI (2 SKP : 1061/DPP.PPNI/SK/K.S/VIII/2021)
Accreditation Of IAKMI (6 SKP : 039/SKP/IAKMI-SB/VII/2021)

Speakers :

1. Dr. dr. Andani Eka Putra, M.Sc
2. Prof. Dr. Salizar Bt. Mohamed Ludin
3. Prof. Dr. Sakinah Binti Harith
4. Dr. Sari Andajani
5. Guldane Damla KAYA, Ph.D (C)
6. Dr. (C). Annita, M.Biomed

Chairman of STIKes Syedza Saintika

Drs. H. Hasrinal, Amd. Kep, MM

Committee President

Ns. Helena Patricia,M.Kep

IIUM INTERNATIONAL CONFERENCE OF NURSING 2023 IICoN

LEADING THE WAY KHALIFAH · AMANAH · IQRA' · RAHMATAN LIL 'ALAMIN LEADING THE WORLD

AN INTERNATIONAL AWARD-WINNING INSTITUTION FOR SUSTAINABILITY

SULTAN AHMAD SHAH MEDICAL CENTRE @IIUM

ACCEPTANCE LETTER

Dear Muhammad Farhan Mahmud,

We are pleased to inform you that your paper entitled, "The Impact of Early Tracheostomy Toward the Functional Outcome of Severe Head Injury Patients", has been accepted for ORAL PRESENTATION at the 3rd IIUM International Conference of Nursing 2023 with the theme of "Future global Direction in Nursing and Midwifery For Sustainable Healthcare Workforce, being held from July 12-13, 2023 in Kuantan, Pahang, Malaysia.

As the presenting author, you must be registered and have your registration fees paid in full by (Monday, June 25, 2023).

Once you have registered for the conference, you must make your own hotel reservations and other travel arrangements. The hotel reservation and other information are provided on this web https://conference.iium.edu.my/3inc/.

Congratulations on being selected to present your paper at the conference. If you have any enquiry or concern, please do not hesitate to contact the conference scientific committee at iiumicon2023@gmail.com/ iiumicon@iium.edu.my. We look forward to welcoming you to Kuantan, Pahang, Malaysia and to the 3rd IIUM International Conference of Nursing 2023.

Sincerely,

Assoc. Prof. Dr. Mohd. Said Nurumal
Head
Scientific committee
3rd IIUM International Conference of Nursing 2023.

IIUM INTERNATIONAL CONFERENCE OF NURSING 2023
IICoN

LEADING THE WAY
LEADING THE WORLD
AN INTERNATIONAL AWARD-WINNING INSTITUTION FOR SUSTAINABILITY

SULTAN AHMAD SHAH
MEDICAL CENTRE @IIUM

KULLIYYAH OF NURSING,
INTERNATIONAL ISLAMIC UNIVERSITY OF MALAYSIA

CERTIFICATE
OF APPRECIATION

This hereby awarded to

Muhammad Farhan Mahmud

In recognition as

BEST PRESENTER

3rd IIUM INTERNATIONAL CONFERENCE OF NURSING 2023 (IICON)

12th - 13th JULY 2023
24 - 26 ZULHIJJAH 1444H
SWISS-BELHOTEL KUANTAN, MALAYSIA

Assoc. Prof. Dr. Sanisah Saidi
Chairman
IICoN 2023

Assoc. Prof. Dr. Muhammad Kamil Che Hasan
Dean,
Kulliyyah of Nursing

APPENDIX XVIII: *Successful Publication*

ATLANTIS PRESS

Advances in Health Sciences Research, volume 39

Proceedings of the 2nd Syedza Saintika International Conference on Nursing, Midwifery, Medical Laboratory Technology, Public Health, and Health Information Management (SeSICNiMPH 2021)

A Review of the Impact of Early Tracheostomy Among Head Injury Patients

Salizar Mohamed Ludin[1,*] Muhammad Farhan Mahmud[2]

[1,2] *Kulliyyah of Nursing, IIUM*

[*] *Corresponding author: msalizar@iium.edu.my*

ABSTRACT

Individual suffers from a head injury required a specific plan of treatment and nursing care to achieve the best outcome they could have. The initiation of tracheostomy is one of the interventions that may be executed on head injury patients especially for those with prolonged respiratory issue. Early tracheostomy (ET) is believed to offer a significant positive impact compared to late tracheostomy (LT). The objectives of this literature search are to determine past studies regarding the evaluation of the tracheostomy approach among head injury patients and identifying the gaps of knowledge on the initiation of tracheostomy and head injury patients. The information and past research on the topic of tracheostomy and head injury were identified according to the systematic review PRISMA approach from multiple online databases which are PubMed, Science Direct, Springer Link, and ProQuest. Recent articles from the last decade of 2010-2020 had been identified to explore the practice and outcome of tracheostomy among head injury patients. There are 17 studies were included which discussed the impact of the tracheostomy approach and 15 of the studies in which a total of 6, 705 patients were really focused on the comparison between ET (n=3189) and LT (n=3516) among head injury patients. The definition of ET was varied between the studies, but it is within the range of fewer than 7 days for ET. ET had reported significant findings in reducing the duration of mechanical ventilation, reduce the duration of ICU stay, better functional outcome, and faster decannulation rate. On the other hand, most of the past studies had shown that ET was not significant in reducing the mortality rate of the patients. The initiation of ET does contribute a good outcome for the head injury patients in terms of the duration of mechanical ventilation and ICU stay. However, the association between ET with overall hospitalization duration, the incident of pneumonia, and the mortality rate are still inconclusive. The review also shows that ET contributes to a better functional outcome.

Keywords: *Early Tracheostomy, Head Injury Patients*

1. INTRODUCTION

Head injury is a medical condition described when the individual had suffered an injury or trauma to the scalp, skull, or brain. The injury could be blunt or penetrating trauma to the head which is accompanied by an episode of alteration in that person's level of consciousness [1]. Patients who experienced head injury are one of the cases that usually needed the support of mechanical ventilation (MV) to prevent the condition of hypoxemia or hypercapnia that may lead to secondary insult or further damage to the brain. In case of severe head injury, the establishment of an airway and oxygen therapy via MV is deemed to be the most important intervention to maintain adequate oxygenation for the patient [2]. However, for those head injury patients who are likely to have difficulty in weaning off MV support or requires re-intubation, the issue arises whether these patients should be preserved with MV support via oral intubation of endotracheal tube (ETT) or to proceed with early cannulation of tracheostomy instead.

The term tracheostomy is subjected to the technique of anterior opening into the trachea via the incision at the neck area to create an artificial surgical airway. This procedure creates an air passage to help the individual breathing effort in case the upper airway is obstructed or impaired [3, 4]. The main reason for a tracheostomy to be initiated is due to prolong episodes of mechanical ventilation, when the weaning off the ventilator is difficult to be done which is quite common in case of head injury especially in the patient with severe traumatic brain injury (TBI) or a massive haemorrhagic stroke [5-7].

The idea of early cannulation of tracheostomy is believed to offer benefits and positive outcomes for the patient with a head injury. Nevertheless, the indication of whether to perform ET or on the later stage is still uncertain. Thus,

APPENDIX XIX: ***Submission for Publication***

MUHAMMAD FARHAN BIN MAHMUD . <farhanmahmud@iium.edu.my>

[IJCS] Submission Acknowledgement

1 message

Editor via <journal_press@iium.edu.my> Thu, May 18, 2023 at 1:08 AM
Reply-To: Editor <ijcs@iium.edu.my>
To: MUHAMMAD FARHAN MAHMUD <farhanmahmud@iium.edu.my>

MUHAMMAD FARHAN MAHMUD:

Thank you for submitting the manuscript, "The Impact of Tracheostomy Timing (Early and Late) on Severe Head Injury Patients Toward Clinical Outcomes" to INTERNATIONAL JOURNAL OF CARE SCHOLARS. With the online journal management system that we are using, you will be able to track its progress through the editorial process by logging in to the journal web site:

Submission URL: https://journals.iium.edu.my/ijcs/index.php/ijcs/authorDashboard/submission/305
Username: farhanmahmud

If you have any questions, please contact me. Thank you for considering this journal as a venue for your work.

Editor

INTERNATIONAL JOURNAL OF CARE SCHOLARS