COMPARING OUTCOMES OF EARLY AND LATE TRACHEOSTOMY IN SEVERE TRAUMATIC BRAIN INJURY PATIENT

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DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SURGERY (NEUROSURGERY)

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Here I would also like to express my deepest appreciation to my thesis advisor Dr Noor Azman bin Abdul Rahman, Head Dpeartment of Neurosurgery Department Hospital Sultanah Aminah Johor Bharu, Malaysia and Professor Zamzuri Idirs, Head Deparmtent of Neurosurgery, School of Medical Sciences, University Science Malaysia and Dr Mazin Bt Noordin Consultant radiologist in department of Radiology Hospital Sultanah Aminah Johor Bahru, Johor.

Their office were always open whenever I ran into a trouble spot or had a question about my research. They consistently allowed this paper to be my own work, but steered me in the right the path whenever I needed it.

To Dr Noor Azman bin Abdul Rahman, Head of Neurosurgery Department, HSAJB, in providing me with the opportunity to practice and learn neurosurgery in this esteemed center, I would like to express my highest appreciation. Not forgetting the wonderful ideas and suggestions from Dr Sharon Casilda Theophilus, Dr Ashraf Sharifuddin, and Dr Risdhawati Hassan consultant and specialist in Neurosurgery Department,HSAJB. Special thanks to Dr

Zhafran Bin Mohammad Razif and Dr Nabilah Bt Khalim for data collection as well as to dedicated staff in the Clinical Research Center (CRC) HSAJB, Ms Prema in helping me with the statistical analysis for this thesis.

Last but not least, my personal gratitude towards all other specialists, respected colleagues and neurosurgical HSAJB department staffs, for the relentless support and cooperation in helping me to complete this dissertation. This accomplishment would not have been possible without them. Thank you.

Muhammad Ihfaz Bin Ismail

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LIST OF ABBREVIATIONS

	Abbreviation	Descritption
1	ETG	Early trachesotomy group
2	GCS	Glassgow coma scale
3	LTG	Late tracheostomy group
4	NHDU	Neurosurgery High Dependency Unit
5	AIS	Abbreviated Injury Score
6	ISS	Injury Severity Score
7	HSAJB	Hospital Sultanah Aminah Johor Bharu
8	SD	Standard deviation
9	n	Total number
10	VAP	Ventilator associated pneumonia
11	CT	Computed Tomography
12	TBI	Traumatic Brain Injury

ABSTRAK

Latar belakang: Pesakit yang mengalami kecederaan kepala yang serius, dijangkakan akan mengambil masa yang lama untuk sedarkan diri, maka mereka terpaksa bergantung kepada mesin "ventilator" untuk bantuan pernafasan. Oleh yang demikian, sudah menjadi kemestian bagi pesakit yang mengalami kecederaan kepala yang serius untuk melalui prosedur pembedahan pada salur trakea untuk memendekkan tempoh kebergantugan pada mesin ventilator dan memudahkan kerja-kerja penjagaan jururawat. Disebabkan kebimbangan timbul berkenaan prosedur pembedahan pada salur trakea pada peringkat yang lebih awal, jadi ia adalah patut diberi perhatian sewajarnya.

Metadologi: Kajian ini dilakukan untut membandingkan keputusan diantara pembedahan peringakt awal atau peringkat lewat di salur trakea bagi pesakit yang mengalami kecederaan kepala yang serius. Kajian ini hanya melibatkan pesakit yang mengalami kecederaan kepala yang serius dan telah menerima rawatan rapi di ward NHDU, Hopsital Sultanah Aminah, Johor Bharu dan yang telah melalui pembedahan pada salur trakea. Berdasarkan kajian ini terdapat tiga hasil penemuan yang sangat penting; iaitu masa kebergantungan pada mesin ventilator

,masa keberadaan dalam ward NHDU dan kadar jangkitan kuman paru-paru yang berkaitan mesin ventilator.

***Keputusan**:* Daripda 155 pesakit ,72 (46.5%) adalah daripda kumpulan awal pembedahan dan 83(53.5%) adalah daripada kumpulan yang lewat membuat pembedahan pada salur trakea. Bangsa Melayu adalah penyumbang terbesar iaitu sebanyak 95(61.3%) dari keseluruhan pesakit. Purata hari pesakit bergantuung kepasa mesin ventilar adalah 2.65 (1.57) hari bagi kumpulan awal dan 5.63(2.35) bagi kumpulan lewat. Kemudian, purata hari bagi pesakit berada dalam ward NHDU adalah 4.75(1.98) bagi kumpulan awal dan 9.77 (2.70) bagi kumpulan lewat. Berdasarkan independent t-test , pembedahan peringkat hari dan purata hari bagi pesakit berada dalam ward NHDU adalah 7.44 hari. Daripada 155 pesakit ,136 (87.2%) tidak menghidapi jankitan kuman paru-paru berkaitan mesin ventilator (VAP) dan 19 (12.3%) menghidapi VAP. Berdasarkan independent t-test pembedahan awal pada saluran trakea menunjukkan hasil yang ketara dalam memendekkan keberadaan dalam ward NHDU (p<0.004) dan memendekkan masa kebergantungan kepapda mesin ventilator (p<0.001). Selain itu Pearson chi-square test telah menunjukkan hasil yang ketara, iaitu pembedahan awal pada saluran trakea boleh mengurangkan kadar jangkitan kuman paru-paru yang berkaitan dengan mesin ventilator (p = 0.004).

Kesimpulan : Dalam dapatan kajian ini, prosedur pembedahan pada salur trakea pada peringakt awal menunjukkan hasil ketara didalam memendekkan masa kebergantugan kepada mesin ventilator, memendekkan masa keberadaan dalam ward NHDU and mengurangkan kadar jankitan kuman berkaitan mesin ventilator (VAP).

ABSTRACT

Background: Patients with severe traumatic brain injury were expected to have poor GCS recovery and prolonged intubation. Therefore, early tracheostomy procedure was indicated for all severe traumatic brain injury . In view of growing concern regarding the safety and outcome of early tracheostomy on these patients, it was deemed valid and needed to be addressed.

Method: This study was conducted to compare the outcomes of early and late tracheostomy in severe traumatic brain injury. This study had recruited only severe TBI patient who were admitted to Neurosurgery High Dependency Unit, Hospital Sultanah Aminah, and among them who had underwent tracheostomy.There were three main outcomes noted; duration on ventilaton, length of NHDU stay and rate of ventilator associated pneumonia

Results: Out of 155 patient, 72 (46.5%) were in early tracheostomy group and 83 (53.5%) were in late tracheostomy group. Malay ethnicity contributed 95 (61.3%) participants,composed a majority of the study participants. The mean duration on ventilator use was 2.65(1.57) for ETG and 5.63(2.35) for LTG. While, mean NHDU stay was 4.75(1.98) for ETG and 9.77(2.70) for LTG. Upon independent t-test, early duration of tracheostomy had

shown significant outcome in reducing length of NHDU stay, (p<0.004) and had shortened duration on mechanical ventilator (p<0.001). Then, from ETG, 69(95.8%) participants had no VAP, and 3(4.2%) had VAP, while for LTG 67(80.7%) had no VAP and 16(19.3%) had VAP. Upon Pearson chi-square test, an association was found between the early tracheostomy in reducing the rate of VAP (p= 0.004).

Conclusion: In this study it was found that early tracheostomy was significant in shortening the duration on ventilator, reducing the length of NHDU stay and reducing the rate of ventilator associated pneumonia.

Keywords: Severe traumatic brain injury , Neurosurgical High dependency unit (NHDU), GCS, Tracheostomy, Ventilator associated pneumonia (VAP).

1. INTRODUCTION & LITERATURE REVIEW

Traumatic brain injury is common in Malaysia, either isolated or associated with multiple trauma. The causes of traumatic head injury vary from road traffic accident, assaults to work related head injury.

Hospital Sultanah Aminah is located at the southern part of Malaysia. This hospital is the tertiary referral centre for neurosurgical cases. It is equipped with Neurosurgery High dependency unit with 10 beds and 8 mechanical ventilators. There is a high turnover of patient needing neurosurgical care. This NHDU ward caters for emergency as well as elective cases, including brain and spine cases.

Tracheostomy is a simple procedure for the purpose of securing the airway. It can be done by neurosurgery resident and otolaryngology resident. Tracheostomy has lot of advantages over translaryngeal endotracheal intubation such as; to reduce laryngeal ulceration, to reduce respiratory resistance and to make easier for nursing care; to facilitate airway suctioning ,mouth care and patient mobility. [1, 2]

Patients with severe traumatic brain injury would need artificial or mechanical ventilation support to maintain airway to prevent secondary brain insult. Severe traumatic brain injury patients are expected to have poor GCS recovery and prolonged intubation. Therefore tracheostomy is a must for all severe traumatic brain injury patient.

Gurkin et al[2] concluded that the indicators for tracheostomy in trauma patients are; GCS <8, Injury severity score >25 and need for ventilator support for longer than 7 days.

Shamim et al[3] summarized the predictors for early tracheostomy in traumatic brain injury depend on severe traumatic brain injury ,abnormal pupil response, delay in emergency department arrival exceeding 1.5 hours, demographic data and comorbidity of patients.

The timing of early tracheostomy is still a controversial issue. There is no uniformity in the literature about the definition of "early" tracheostomy. In the 1980s a tracheostomy was considered "early" if it was performed before 21 days of translaryngeal intubation. The timing of tracheostomy had changed over the last several years, and now many suggest tracheostomy within 2–10 days.

The definition of "early tracheostomy" corresponds to that proposed by the otorhinolarygologists, who had always suggested tracheostomy within several days in order to prevent laryngeal injury from even these short periods of intubation.[4] According to Durbin et al[4], early tracheostomy is defined as within 3–5 days of translaryngeal intubation.

Four retrospective studies and one prospective analysis had suggested that pneumonia rate, mechanical ventilator support, ICU days and hospital days are less with early tracheostomy.

Shibahashi et al[5,] suggested for the performance of tracheostomy within 72 h of severe TBI to decrease the duration of mechanical ventilation and length of stay in ICU.

Lesnik et al[6] performed early tracheotomy (<4 days) in multitrauma patients with significant reduction in ventilator days and pneumonia rates. All of the patient undergoing early tracheostomy were liberated from the ventilator by Day-7.[6] According to D'Amelio et al there was a reduction in ventilator dependant, ICU and hospital days for head-injured patient undergoing tracheostomy to less than 7 days[7].

Rizk et al[8], demonstrated an early tracheostomy (hospital days one through seven) when performed on patient with reasonable chance of survival, resulting in a better overall clinical outcome, shorter length of stay and higher likelihood of functional independence. Simillar result were achieved in a prospective study of trauma patient by Rodrigeuz et al[9] which revealed that an early tracheostomy will result in an early weaning off from ventilator, reducing ICU length of stay and reducing rate of pneumonia and reducing overall treatment cost.[9]

However there was still controversy over the outcomes of early tracheostomy and safety of tracheostomy in severe traumatic brain injury. According to Stoccheti et al[10], tracheostomy can cause hypoventilation, hypercarbia, hypoxemia and arterial hypertension during the procedure but concluded that translaryngeal tracheostomy is safe for the majority of the patient. However the risk of ICP rising must be taken into consideration and appropriate monitoring must include ICP so that advantage of early intervention would not outweighed by the danger of intracranial decompensation.

This study was conducted to compare the outcome of early and late tracheostomy on duration on mechanical ventilator, length of stay in NHDU from date of tracheostomy done and to compare incidence of ventilator associated pneumonia.

The ventilator associated pneumonia defined as a pneumonia acquired when patients were on mechanical ventilation for more than 48 hours on the date of event, with day of ventilator placement being day one.[11] The criteria for the diagnosis of ventilator acquired pneumonia is based on radiological evidence and clinical sign.

Hence,it is helpful that this study would pose as a guideline for early tracheostomy in severe traumatic brain injury cases where and when prolonged intubation would be expected.

2. STUDY PROTOCOL

(The full proposal as submitted for ethics committee)

COMPARING OUTCOMES OF EARLY AND LATE TRACHEOSTOMY IN SEVERE TRAUMATIC BRAIN INJURY PATIENT

Protocol number and date: Tracheostomy 002, 25th October 2017.

Name and Institution of Principal investigator:

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Hospital Sultanah Aminah Johor Bahru, Johor

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Hospital Sultanah Aminah Johor Bahru, Johor

Name and address of Sponsor:

This study is self-funded by;
Department of Neurosurgery,
Hospital Sultanah Aminah Johor Bahru, Johor.
There is no conflict of interest from study team.

Study site:

Hospital Sultanah Aminah Johor Bahru, Johor

List of Abbreviations

NSU	Neurosurgical Unit
GSU	General Surgical Unit
GOS	Glasgow Outcome Scale
GCS	Glasgow Coma Scale
HSA	Hospital Sultanah Aminah

Research Synopsis

Study title	Outcomes of early and late tracheostomy in severe traumatic brain injury
Study Population	The study population comprised of severe traumatic brain injury patients referred to Neurosurgery Department Hospital Sultanah Aminah Johor Bahru from 1st Jan 2016 to 30th Sep 2017.
Study Design	This is a retrospective cross-sectional study. Patient were selected retrospectively into 2 group; early and late tracheostomy group. Severe head injury patients who underwent tracheostomy procedure were selected. Early tracheostomy define as Day-3 or earlier. Late tracheostomy define as Day-4 and later.

General Objective	To determine the outcomes of early and late tracheostomy in patients with severe traumatic brain injury
Specific Objectives	1) To compare duration on ventilator 2) To compare length of NHDU stay 3) To compare rate of ventilator associated pneumonia
Study endpoints/outcomes	1. Duration on ventilator use 2. Length of stay in NHDU 3. Rate of ventilator associated pneumonia
Sample Size	150 (Refer to the sample size calculation as described in Study protocol)
Study Duration	1st June 2017 to 31st January 2018

1. Background and Significance

Traumatic brain injury is common in Malaysia, and it is found either isolated or associated with polytrauma. The causes of traumatic head injury varies from road traffic accident, assaults to work related head injury.

Hospital Sultanah Aminah is located at the southern tip of peninsular Malaysia. This hospital is the referral centre for the southern part of the country .It is equipped with High dependency unit with 10 beds and 8 mechanical ventilators. There is a high turnover of patient needing neurosurgical care. This NHDU caters for emergency as well as elective cases, including brain and spine cases.

Tracheostomy is a simple procedure conducted for the purpose of securing the airway. It can be done by neurosurgery resident and otolaryngology resident. Tracheostomy has lot of advantages over translaryngeal endotracheal intubation such as; to reduce laryngeal ulceration, to reduce respiratory resistance and to make easier for nursing care; to facilitate airway suctioning ,mouth care and patient mobility [1,2]

Patients with severe traumatic brain injury would need artificial or mechanical ventilation support to maintain airway to prevent secondary brain insult. Severe traumatic brain injury patient is expected to have poor GCS recovery and prolonged intubation. Therefore tracheostomy is a must for all severe traumatic brain injury patient.

Shamim et al, summarized the predictors for early tracheostomy in traumatic brain injury depend on severe traumatic brain injury ,abnormal pupil response, delay in emergency department arrival exceeding 1.5 hours, demographic data and comorbidity of patients[3]

Gurkin et al, concluded indicators for tracheostomy in trauma patients are; GCS <8, Injury severity score >25 and need for ventilator support for longer than 7 days.[2]

The timing of early tracheostomy is still a controversial issue. There is no uniformity in the literature about the definition of "early" tracheostomy. In the 1980s a tracheostomy was considered "early" if it was performed before 21 days of translaryngeal intubation. The timing of tracheostomy had changed over the last several years, and now many suggest tracheostomy within 2–10 days. This definition of "early" corresponds to that proposed by the otorhinolarygologists, who had always suggested tracheostomy within several days in order to prevent laryngeal injury from even these short periods of intubation [4]. According to Durbin et al, early tracheostomy is defined as within 3–5 days of translaryngeal intubation.[4]

Four retrospective studies and one prospective analysis had suggested that pneumonia rate, mechanical ventilator support, ICU days and hospital days are less with early trachesotomy.

Shibahashi et al, suggested for the performance of tracheostomy within 72 h of severe TBI may decreases the duration of mechanical ventilation and length of stay in ICU. [5] Lesnik et al performed early tracheotomy (<4 days) in multitrauma patients with significant reduction in ventilator days and pneumonia rates.[6]

All patients undergoing early tracheostomy were liberated from the ventilator by Day-7.[6] According to D'Amelio et al there was a reduction in ventilator, ICU and hospital days for head-injured patient undergoing tracheostomy to less than 7 days.[7] Rizk et al, demonstrated early tracheostomy (hospital days one through seven) when performed on patients with reasonable chance of survival, resulting in a better overall clinical outcome, shorter length of stay and higher likelihood of functional

independence.[8] Simillar result were achieved in a prospective study of trauma patient by Rodrigeuz et al which revealed that, an early tracheostomy will result in an early weaning off from ventilator, reducing ICU length of stay and reducing rate of pneumonia and reducing overall treatment cost.[9]

However there was still controversy over the outcome of tracheostomy in traumatic brain injury. According to Stoccheti et al, tracheostomy can cause hypoventilation, hypercarbia, hypoxemia and arterial hypertension during the procedure but concluded that translaryngeal tracheostomy is safe for the majority of the patient. However the risk of ICP rising must be taken into consideration and appropriate monitoring must include ICP so that advantage of early intervention would not outweighed by the danger of intracranial decompensation.[10]

This study was conducted to compare the outcomes of early and late tracheostomy on duration of use of mechanical ventilator, length of stay in NHDU from the day of tracheostomy was conducted and to compare incidence of ventilator associated pneumonia.

The ventilator associated pneumonia defined as a pneumonia acquired when patients were on mechanical ventilation for more than 48 on the date of event, with day of ventilator placement being day one.[11]

Criteria for the diagnosis based on: 1) Radiographic evidence for two or more serial chest radiograph with at least one of the following; a) new or progressive and persistent infiltrate, b)consolidation, c) cavitation. In patient without underlying pulmonary or cardiac disease, example respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable. 2) Clinical signs; at least one of

the following; a) fever (38 degree celcius) with no other recognized cause, b) Leucopenia(<4000 WBC) or leukocytosis (>12000 WBC), c) For adult >70 years old, altered mental status with no other recognized cause and 3) At least 2 of the following; a) New onset of purulent sputum or change in character of sputum, b) New onset or worsening of cough, or dyspnea, or tachypnea, c) Rales or bronchial breath sounds, d)Worsening of gas exchange (eg;O2 desaturations (eg;PaO2;FiO2 ratio <240), e) increased oxygen requirement, or increased ventilator demand. [11]

Hence, it is helpful that this study would pose a guideline for early tracheostomy in patients with severe traumatic brain injury where and when prolonged intubation would be expected.

2. Objective

General Objective

- To compare the outcomes of early and late tracheostomy in patients with severe traumatic brain injury.

Specific Objective

1) To compare the duration on mechanical ventilator in early and late tracheostomy for severe traumatic brain injury
2) To compare the length of stay in NHDU in early and late tracheostomy for severe traumatic brain injury
3) To compare the rate of ventilator acquired pneumonia in early and late tracheostomy for severe traumatic brain injury

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3.Methodology

3.1 Study Type and Design

This is a retrospective cross-sectional study on patient with severe traumatic brain injuries. Patients were selected and devided retrospectively into 2 group; early and late tracheostomy group. Severe head injury patients who underwent tracheostomy procedure were selected. Early tracheostomy was defined as Day-3 or earlier while late tracheostomy defined as Day-4 or later. Baseline demographic and presenting characteristics, including injury type and pre-existing conditions were recorded. The chest radiograph were interpreted by radiologist without knowing of whether patients were either in the early or late tracheostomy group. Clinical status at the presentation in the form of GCS and Injury Severity Score (ISS) were documented. ISS is an anatomical scoring system that provide an overall score for patient with multiple injuries. In this study each injuries is assigned an Abbreviated Injury Scale (AIS) score and was allocated to one of six body regions (Head, Face, Chest, Abdomen, Extremities (Including pelvis) and External.

Injury Severity	**Abbreviated Injury Score**
Minor injury	1
Moderate injury	2

Severe but not life-threatening	3
Potentially life-threatening but survival likely	4
Critical with uncertain survival	5
Unsurvivable injury (maximal possible)	6

Only the highest AIS score in each body region was used. The three most severely injured body regions have their score squared and added together to produce the ISS score. The patients who were recruited in this study would proceed to follow-up until were discharged from the NHDU ,prior to leaving the hospital. Information on the patients; duration on mechanical ventilator, length of NHDU stay and incidence of VAP while staying in NHDU were recorded

3.2 Study Population

The study population includes all severe traumatic brain injury patients, referred to Neurosurgery Department Hospital Sultanah Aminah Johor Bahru. The duration of data collected was from 1st January 2016 to 30th September 2017

3.3 Inclusion Criteria

1) Patients with severe traumatic brain injury patient with an Abbreviated Injury Scale (AIS) ≥4

2) Patients who had underwent tracheostomy procedure during stay

3) Patients admitted into Neurosurgery High Dependency Unit only

4) Patients with clear history of trauma

5) Patients between the age of > 18 to <65 years old

3.4 Exclusion Criteria

1) Patients with severe chest injury with an Abbreviated Injury Scale (AIS) ≥ 4,eg Flail chest

2) Patients with severe cervical injury with an AIS ≥4, eg Unstable cervical fracture.

3.5Sample Size

The duration of data collection was from 1st January 2016 to 30th September 2017. All participants who had fulfilled both inclusion and exclusion criteria during that period were recruited. The standard deviation of ICU stay and duration of use of mechanical ventilators were based on clinical article by Muhammad Shahzad et al. It was estimated that from about 110 sample size, including 10% dropout, had derived a value of standard deviation of 3.21 days for ICU stay, a difference of 2 days between early and late tracheostomy. This resulted in the significance level of 0.05 and power of study of 80%. On the duration of mechanical ventilators, an estimated sample size of about 60, including 10% dropout, had produced a standard deviation of 2.4 days. This gave a difference of 2 days between early and late tracheostomy, with a significance level of 0.05 and power of study of 80%. Then, the rate of pneumonia was based on Rodrigeuz et al. The estimated sample size including 10% dropout was 150, while the proportion pneumonia in early tracheostomy, P_0 was 0.76, while the proportion of pneumonia in late tracheostomy, P_1 was 0.98 with a significance level of 0.05 and power of study of 80%. All these

calculations had utilised a software of Power and sample size program version 3.05, while the sample size was estimated in accordance to the rate of pneumonia since it was the largest sample size.

3.6 Study Duration and Timeline

Projected start date: 1st June 2017

Projected end date: 31st January 2018

Stage 1: Preparation of study documents and submission for ethical review – four months (1st June – 30th September 2017)

Stage 2: Data collection and analysis – three months (1st October 2017 – 31st December 2017)

Stage 3: Presentation and publication – one month (1st January 2018 until 31st January 2018)

3.7 Study Visits and Procedures

All data collected for the study were recorded in the case report form, as attached in the Appendix. No specimens will be collected from the patients participating in this study. The data collected for the study were solely used for this study and not for any future research.

3.8 Statistical Analysis Plan

The data analysis was done through the SPSS version 22. Descriptively, all categorical data were expressed in proportions and percentages while continuous data expressed in mean (standard deviation) or median (interquartile range), whichever appropriate. Analytically, for categorical data, Chi-square was used while for continuous data, Student's t-test was used. A set p-value of <0.05 was considered of statistical significance.

3.9 Risk and benefit to study participants

This study does not present any direct benefit to the participants. However it had provided researcher with better understanding the outcomes of early and late tracheostomy in patients with severe traumatic brain injuries

3.10 Risk Benefit Assessment

Findings from this study had given some indications on how to improve the management of traumatic brain injury through an early tracheostomy

3.11 Ethics of Study

The study was conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. It had been granted an ethical approval from Medical Research Ethics Committee (MREC), and had been r

egistered in the National Medical Research Register (NMRR)

3.12 Informed Consent Process

Informed consent was not required in this retrospective study

3.13 Privacy and Confidentiality

To maintain confidentiality, all names of participants were kept on a password-protected database and were linked only with a study specific code for this research. No personal information or identifiers were collected or maintained in this study.

All identified data were keyed-in into a password-protected computer. Upon completion of study, data in the computer were copied into CDs, prior to their deletion in the computer. CDs and any other hardcopy data were stored in a secured office of the investigators and were maintained for a minimum of seven years after the completion of the study. The CDs and data would be destructed after that period of storage.

However, these information and can be made accessible to fellow investigators, and relevant governmental or regulatory bodies. Participants can also request access to their individual study findings on request. Furthermore, all these information or data collected for this study will not be used for future research unless additional relevant approvals are sought.

3.14 Conflict of Interest

The investigators hereby declare that they have no conflict of interest.

3.15 Publication Policy

No personal information shall be disclosed and participants would not be identified when the findings of the survey were to be published.

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3. ETHICAL APPROVAL

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To

ihfazrose5919@gmail.com

11/3/2017

Dear Dr Muhammad Ihfaz Bin Ismail (corresponding person) and Principal / Coordinating Investigator,

Research Title : OUTCOME OF EARLY TRACHEOSTOMY AND LATE TRACHEOSTOMY IN TRAUMATIC BRAIN INJURY

Submission No: S5

Revision No : R0

The Ministry of Health Medical Research Ethics Committee (MREC) has made the following decision on the above mentioned research protocol

Approved, with expedited review by MREC Chairperson/ Deputy Chairperson/ Secretary

Thank you

With warm regards,

MREC Secretariat

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]

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JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
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Dr Muhammad Ihfaz Bin Ismail
Hospital Sultanah Aminah

YBhg. Dato' / Tuan / Puan,

SURAT KELULUSAN ETIKA : NMRR-16-2815-32317 (IIR)
OUTCOME OF EARLY TRACHEOSTOMY AND LATE TRACHEOSTOMY IN TRAUMATIC BRAIN INJURY

Lokasi Kajian:
HOSPITAL SULTANAH AMINAH

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) tiada halangan, dari segi etika, ke atas pelaksanaan kajian tersebut. JEPP mengambil maklum bahawa kajian tersebut hanya melibatkan pengumpulan data melalui:

i. Rekod perubatan

3. Segala rekod dan data subjek adalah **SULIT** dan hanya digunakan untuk tujuan kajian ini dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi.

4. Kebenaran daripada Pegawai Kesihatan Daerah / Pengarah Hospital dan Ketua-Ketua Jabatan atau pegawai yang bertanggungjawab disetiap lokasi kajian di mana kajian akan dijalankan mesti diperolehi sebelum kajian dijalankan. YBhg. Dato' / Tuan / Puan perlu akur dan mematuhi keputusan tersebut. Sila rujuk kepada garis panduan Institut Kesihatan Negara mengenai penyelidikan di Institusi dan fasiliti Kementerian Kesihatan Malaysia (Pindaan 01/2015) serta lampiran *Appendix 5* untuk templet surat memohon kebenaran tersebut.

5. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **01-November-2018**. YBhg. Dato'/ Tuan/ Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web Jawatakuasa Etika & Penyelidikan Perubatan (JEPP) (http://www.nih.gov.my/mrec).

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i. ***Continuing Review Form*** selewat-lewatnya dalam tempoh 1 bulan (30 hari) sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.

ii. ***Study Final Report*** pada penghujung kajian.

iii. Mendapat kelulusan etika sekiranya terdapat pindaan keatas sebarang dokumen kajian/ lokasi kajian/ penyelidik.

6. Sila ambil maklum bahawa sebarang urusan surat-menyurat berkaitan dengan penyelidikan ini haruslah dinyatakan nombor rujukan surat ini untuk melicinkan urusan yang berkaitan.

Sekian terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah

(DR SALINA ABDUL AZIZ)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
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Hz/Approval2017/MRECshare

COMPARING THE OUTCOMES OF EARLY AND LATE TRACHEOSTOMY IN PATIENT WITH SEVERE TRAUMATIC BRAIN INJURY

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4.2 Abstract

ABSTRACT

Background: Patients with severe traumatic brain injury were expected to have poor GCS recovery and prolonged intubation. Therefore, early tracheostomy procedure was indicated for all severe traumatic brain injury . In view of growing concern regarding the safety and outcome of early tracheostomy on these patients, it was deemed valid and needed to be addressed.

Method: This study was conducted to compare the outcomes of early and late tracheostomy in severe traumatic brain injury. This study had recruited only severe TBI patient who were admitted to Neurosurgery High Dependency Unit, Hospital Sultanah Aminah, and among them who had underwent tracheostomy.There were three main outcomes noted; duration on ventilaton, length of NHDU stay and rate of ventilator associated pneumonia

Results: Out of 155 patient, 72 (46.5%) were in early tracheostomy group and 83 (53.5%) were in late tracheostomy group. Malay ethnicity contributed 95 (61.3%) participants,composed a majority of the study participants. The mean duration on ventilator use was 2.65(1.57) for ETG and 5.63(2.35) for LTG. While, mean NHDU stay was 4.75(1.98) for ETG and 9.77(2.70) for LTG. Upon independent t-test, early duration of tracheostomy had shown significant outcome in reducing length of NHDU stay, (p<0.004) and had shortened duration on mechanical ventilator (p<0.001). Then, from ETG, 69(95.8%) participants had no VAP, and 3(4.2%) had VAP, while for LTG 67(80.7%) had no VAP and 16(19.3%) had VAP. Upon Pearson chi-square test, an