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The Impact of Tracheostomy Timing (Early and Late) on Severe Head Injury Patients Toward Clinical Outcomes

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ABSTRACT

Introduction: Severe head injury (SHI) patients require a specific treatment plan and nursing care to achieve an optimal clinical outcome. Patients with SHI may require a more extended period of hospitalisation for complex neuro-medical and neurosurgical management. Tracheostomy may be performed on head injury patients with protracted breathing problems. Early tracheostomy (ET) may improve the clinical outcomes of late tracheostomy.

Objective: This study aims to determine the impact of ET on a patient's clinical outcomes before being discharged.

Methods: This retrospective cohort study involves 45 SHI patients with tracheostomy in two Neuro-Centre hospitals in Klang Valley. The clinical outcome was observed before the participants were discharged, including the participant's GCS upon discharge, length of stay (LOS) in the ICU and hospital, the incidence of VAP, duration of mechanical ventilation dependency, and decannulation rate.

Results: Crude analysis performed in this study showed that there is a significant association between tracheostomy classification (early and late) toward participant length of stay in the ICU with a p-value of <0.001, LOS in the hospital (p=0.002) and duration on the mechanical ventilation use (p<0.001) with no association with the GCS upon discharge (p=0.057), the incidence of VAP (p=0.374), and decannulation rate (p=0.081). Multivariate logistic regression analysis showed that the association between these variables remained significant for the LOS in the hospital (p=0.035) and duration of mechanical ventilation used (p=0.005).

Conclusion: The initiation of ET contributes to a favourable clinical outcome regarding the duration of mechanical ventilation, and length of hospital stay for patients with a SHI. Future study to evaluate other outcomes, such as cognitive function and quality of life from the initiation of ET, is recommended to explore its benefit for the patient with a SHI.

Keywords: Tracheostomy; Severe head injury patients; Clinical outcome

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INTRODUCTION

Head injury is a medical condition described when an individual suffered an injury or trauma to the scalp, skull or brain. The damage could result from a blow to the head or penetrating trauma, which follows with an episode of alteration in the individual's level of consciousness (1). The intensity of the head injuries will be evaluated, and patients will be categorised as having mild, moderate or severe head injuries. Establishing an airway is regarded as the most crucial intervention to sustain adequate oxygenation for a patient with a severe head injury (2). They are among those who typically require mechanical ventilation support to prevent hypoxemia or hypercapnia, which may result in secondary insult or further brain damage.

Severe head injuries are one of the common reasons leading to ICU admission following the commencement of mechanical ventilation support (3). Due to cerebral protection, a patient with a severe TBI who underwent craniotomy or craniectomy was required to have mechanical ventilation support while being fully sedated. This method of neuroprotection or neuro-resuscitation is defined as a therapy to prevent the onset of ischaemia (4). However, for the patients who are likely to have difficulty weaning off from the mechanical ventilation support or who require re-intubation, the question arises as to whether they should be preserved with mechanical ventilation support via oral intubation of endotracheal tube (ETT) or whether they should undergo early cannulation of tracheostomy. The decision of whether to proceed or not to proceed with tracheostomy will depend on the attending physician or neurosurgeon in charge of the patients (5-7). The decision to proceed with a tracheostomy should be individualised for each case with the consideration of mortality risk, expected duration of mechanical ventilator dependency, and neurological prognosis (5).

Severe head injury patients accompanied by neurological issues require higher tidal volume and lower positive end-expiratory pressure (PEEP) levels compared to non-neurological patients (8). These patients also may require longer mechanical ventilation duration since the faster extubation process is difficult to be performed. In addition, it was recorded that 45% incidence of re-intubation reported within 24 to 72 hours post-extubation (9). In order to overcome the problem of prolonged mechanical ventilation support via ETT, the patient is usually planned for a tracheostomy procedure to assist in the weaning process from the ventilator support. The initiation of tracheostomy was indicated to assist in the weaning of the mechanical ventilation process and facilitate tracheobronchial hygiene. However, if the decision for initiation of tracheostomy is deferred, the process of weaning will still be affected. A delay in the decision for a tracheostomy was significantly associated with failure in the weaning process (10). Thus, the idea of ET needs to come into the discussion.

ET is believed to offer a significant positive impact on the prognosis of the patient. From the aspect of the patient's recovery, ET will help to shorten the duration of ICU stay and duration of the mechanical ventilation support (11-12), a significantly reduced time for administration of antibiotics for treatment of pneumonia (13), reduced mortality rate (14), and improve patient neurological and functional outcome (9). However, information on the positive impact of ET on head injury patients is limited, especially in the Malaysian setting. Malaysian neurosurgical CPG in 2015 discussed early management of head injury in adults without further discussion on the practice of the tracheostomy approach as the alternative method (2).

The timing of tracheostomy for head injury patients with mechanical ventilator support is inconclusive. The decision of the tracheostomy plan also differs from one healthcare facility to another due to multiple considerations such as cost, family dilemma, and neurological outcome. There is no specific guideline provided on the issue of prolonging invasive ventilation and tracheostomy. The practice of timing and execution of tracheostomy is different from one healthcare facility to another as the benefit and implication of ET is inconclusive in Malaysia. The evidenced-based data and comprehensive information on the issue on hand are limited. Therefore, it is crucial to conduct studies to explore the advantages of ET among severe head injury patients not only during the treatment process in the hospital but

also during the recovery phase after they have been discharged. Therefore, this study aims to determine the impact of ET on a patient's clinical outcomes. We hypothesized, there is a significant positive impact of early initiation of tracheostomy on the clinical outcomes for patients with severe head injury.

METHODS

Study design & setting

A retrospective cohort study design approach was chosen for this study. A group of severe head injury patients who underwent cannulation of tracheostomy were engaged consisting of 45 participants, presenting at the two Neuro-Centre hospitals in Klang Valley from January 2021 to December 2021. The sequential sampling method was chosen for the participant recruitment process in this study. The participant's detail pertaining to their clinical data, laboratory result, and daily progress was retrieved and recorded according to the study checklist via access from the Health Information Department of both centres.

Data collection & analysis

The participant's record was identified through a thorough screening process extracted from the in-patient records of the ICU admission book, the Patient Information System, and the patient case note from the Health Information Department of both hospitals for the patients admitted from January 2021 to December 2021. The collected data consists of information about the participant's independent variables of socio-demographics as per the prepared checklist. Throughout this phase, several tools were reviewed to guide the data collection including the. GCS chart, SOFA score, and SAPS II score.

Ethical considerations

This study obtained approval from Kulliyyah of the Nursing Postgraduate and Research Committee, International Islamic University Malaysia, the Ministry of Health Malaysia Medical Review & Ethics Committee (MREC), and the University Malaya Medical Centre Ethic Committee. The data were strictly used for this study and academic research only. The confidentiality of the information acquired is in accordance with the Personal Data Protective Act (PDPA).

RESULTS

Sociodemographic characteristics

The sociodemographic characteristics of the patients recruited in this study are presented in **Table 1**. 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 the age of 50 years old and above. The majority were male patients (71%, n=32) with most of them is 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), 13 of them were still single (28.9%), and the other four participants were widowers (8.9%). The participants were categorised a severe head injury when the GCS is less than 9/15 upon admission. In this study, the average (median (IQR)) of GCS upon admission was 3.00 (3.00).

Table 1: Sociodemographic data and GCS score upon admission

Variables	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	25.4
India		9	20.0
Others		0	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)

Patient's tracheostomy status

In this study, 46.7% of the participants had undergone ET and more than half (53.3%) of the participants had undergone LT (**Table 2**). The average day the participants underwent the tracheostomy procedure was at day 10 (SD±9.66), ranging between day 2 and day 52.

Table 2: Classification of patients' tracheostomy status (n = 45)

Variables	Mean (SD)	Frequency (n)	Percentage (%)
Day of tracheostomy procedure	0.11 ± 9.663		
Tracheostomy classification (days)			
Early tracheostomy (< 7 days)		21	46.7
Late tracheostomy (≥ 7 days)		24	53.3

Participants clinical outcomes

The median (IQR range) of the LOS in the ICU was 9.76 (9.00) days ranging from 3 to 19 days for the ET group whereby the median (IQR) LOS in the ICU for the LT group was 27.75 (15.00) days ranging between 9 to 140 days. Consequently, for the LOS in the hospital, the ET group 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 ranging from 18 to 148 days. As the dependency on mechanical ventilation (MV) also plays a significant role in the LOS of the participants in the ICU, the duration of MV dependency also was considered. The ET group median (IQR) was 7.14 (7.00) days extending from three to 12 days while the median (IQR) for the LT group was 19.13 (14.50) days with a scale of nine to 69 days. Before being discharged 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 scored 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 six to 13, whereby the LT group means (SD) was 9.71 (1.55). The median (SD) of the SAPS II score for the ET group was 43.24 (9.77) and for the LT group was 39.63 (10.11) (Table 3).

Table 3: The participants' in-hospital clinical outcome between ET and LT (n=45)

Variables	Early tracheostomy (*n*=21)	Late tracheostomy (*n* = 24)
	Mean (SD)	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

Incidence of Pneumoniae and Tracheostomy Decannulation

Given the incidence of pneumonia, 27 participants were diagnosed with pneumonia during their hospitalisation whereby 11 participants were from the ET group (52.4%) and 16 participants (66.7%) from the LT group (**Table 4**). The most prevalent microorganism that affected the participants during their history of pneumonia was Klebsiella pneumonia, which appeared in five participants from the ET group and eight from the LT group. Acinetobacter baumannii is the most common microorganism (N=9) found in the participants followed by Pseudomonas aeruginosa (N=50), Proteus mirabilis, Staphylococcus aureus (N=2), and Enterobacter cloacae (N=1). The details distribution of the microorganisms found among the participant with pneumonia incidence is shown in **Figure 1**. Another aspect that was observed was the successful decannulation of tracheostomy among all participants. All of them were discharged home with tracheostomy in situ. However, the data of them being decannulated at any point within the 6-month post-discharge

was recorded. Among 21 participants from the ET group, eight of them have successfully done the decannulation of tracheostomy (38.1%) compared to the LT group, which recorded only three out of 24 participants (12.5%) as shown in **Table 5**.

Table 4: Incidence of pneumonia among the participants.

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

Figure 1: Micro-organisms identified among the participants affected with pneumonia.

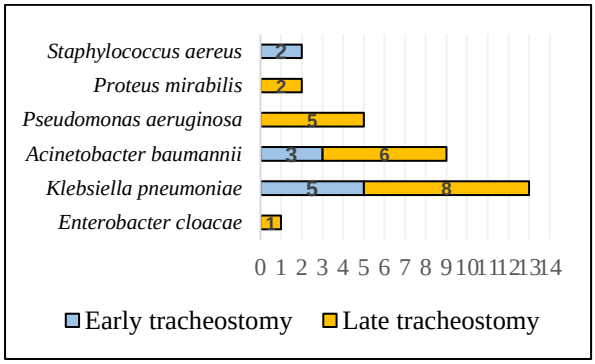

Table 5: Decannulation of tracheostomy among the participants.

Variables	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

Tracheostomy Classification (Early vs Late) and Clinical Outcomes.

Table 6 illustrates the association between tracheostomy classification (early and late) and the clinical outcomes. The clinical outcomes include their SOFA score, SAPS II score, LOS in the ICU, LOS in the hospital, duration of mechanical ventilation support, GCS score upon discharge, incidence of pneumonia, and decannulation of the tracheostomy. The analysis showed a significant association between tracheostomy classification and LOS in the ICU (p=<0.001), LOS in the hospital (p=0.002), and duration on the mechanical ventilation (p=<0.001). However, the SOFA score and SAPS II score, which were used to assess and predict ICU mortality based on laboratory results and clinical data, showed 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 showed no association with the tracheostomy classification despite all variables descriptively recording a better outcome in the ET group compared to the LT group.

Association of Tracheostomy Classification Toward the Clinical Outcomes

Table 7 shows the association of tracheostomy classification towards the clinical outcomes of severe head injury patients by adjusting the age, gender, race, marital status, and GCS upon admission. The multivariate analysis revealed the LOS in the hospital and the duration of mechanical ventilation support remained associated with the LT after adjusting for age, gender, race, marital status, and GCS upon admission (p-value = 0.035; 0.005). The analysis revealed that the patient who had undergone LT were more likely to have a longer duration of mechanical ventilation support than those who had ET (OR=39.68; p=0.005).

Table 6: Association between ET/LT and clinical outcomes

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

[a] = mean rank, ^ = Independent t test, * = Mann Whitney test, [#] = Pearson Chi Square test, **bold** = highly significant p value < 0.05

Table 7: Association of Late Tracheostomy towards the Clinical Outcomes

Clinical outcomes	Regression coefficient (B)	Standard error	Wald	Adjusted odd 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	1.577	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	-0.597	1.363	0.191	0.551	0.038 – 7.970	0.662
No (reference)						
Yes						
Decannulation	0.204	1.424	0.021	1.226	0.075 – 19.999	0.886
No (reference)						
Yes						

Adjusted for age, gender, race, marital status, and GCS upon admission, **bold** = p value < 0.05

DISCUSSION

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 a few of the previous study (14,15,18). In this study, the tracheostomy rate was slightly higher in the LT group (N=24) compared to the ET group (N=21). The initiation of tracheostomy was delayed due to several reasons including the primary caregiver's or immediate family member's reluctance to consent to the procedure, the inconsistency 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 a family conference, the patient's unstable condition which rendered them temporarily unfit for the procedure, financial constraints, and others (5, 17, 20-21). This finding, however, is consistent with the

previous research that recorded a significantly higher participant in the LT group compared to the ET group (6-7, 9, 14-22). Previous studies have reported that the delayed decision to proceed with ET was due to the patient's unstable condition, old age, poor expected outcome, and financial constraints (5, 17, 19-21, 23). All these factors need to be meticulously evaluated before the procedure is decided to be initiated. The tracheostomy approach will be delayed day by day if all of these factors remained contraindicated for it to be carried on.

Length of stay in the ICU and hospital

In this study, the LT 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) which was similar with the previous study (10). However, other studies do report a significant association between tracheostomy classification and LOS in ICU with a p-value of 0.001 which involved larger sample size and longer duration for data collection (17, 20, 23). 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. The patients requiring an ICU bed would spend an additional 1.5 days in the hospital for each day they had been nursed in ICU (28). This finding was consistent with previous studies on severe head injury patients (17, 20, 25, 27). After they have been tracheostomised, the onset of the weaning process from the ventilator will occur (30). As their tracheostomy was delayed, the weaning-off process will also be delayed. 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 (30-32).

Duration of the mechanical ventilation support

This study also recorded a significant association between tracheostomy classification with the duration of mechanical ventilator support (p-value=0.005). However, although it was shown to be significant, the 95% confidence interval was huge, between 3.347 - 95.56, potentially due to the sample size issue (N=45). Therefore, the result needs to be interpreted cautiously. Similarly, patients who had undergone LT were more likely to have a longer LOS in the hospital than those who had an ET (OR=5.737; 95% CI (1.126 – 29.229)). From the last decade, the study on ET among severe head injury patients always discussed its association with a shorter duration of mechanical ventilation support as their core argument in which majority of the studies have proven its significant association (6-7, 14, 17, 19-20, 22, 26). The main reason for initiating tracheostomy is to assist in the weaning process for those with prolonged mechanical ventilation support (18). 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 dependency. Thus, it was clear that the ET should emphasised one of its main benefits, which is promoting a shorter duration of mechanical ventilation usage.

Incidence of pneumoniae and decannulation rate

Previous studies reported a significant association between ET and the incidents of pneumonia in their studies by addressing pneumonia in general without specifically categorising its type (16-17). On the other hand, other studies had specifically addressed VAP as the measured variable in their studies whereby they recorded a significant association with ET (7, 9, 19-20). From this present study, even though the LT group recorded a more significant number of samples affected with pneumonia compared to the ET group, the analysis shows no significant association

between tracheostomy classification and the incidence of pneumonia (p=0.662). As for the success of tracheostomy decannulation among the participants, the ET group recorded a higher rate of decannulation (38.1%) compared to the LT group (12.5%). However, the crude analysis showed no significant association between these two variables (p=0.886). On the contrary, previous studies recognise a significant association between decannulation rate and ET (p-value=0.003; 0.021) (21, 28). However, those studies focused on head injury patients with poor SAH and stroke patients instead of severe head injury patients with tracheostomy (21, 28).

Limitation and recommendation

This study comes with several limitations. First, the sample size included in this study was small because of a significant decrease in hospital admission due to the Malaysian endorsement of the Movement Control Order (MCO) due to the COVID-19 pandemic. During this period, road traffic accidents, which usually contribute to severe head injury incidents, were greatly reduced. Second, the duration of the data included was only limited to a year duration (January 2021 to December 2021), and the data collection process was halted at some point due to MCO. Even after it had been lifted, the strict standard precautions applied in the whole country had limited the researchers to physically accessing the participant's medical records at the selected facilities. Thus, it contributed to a small sample size which limit the generalisation of the results to other setting. Future study is recommended to have a larger sample size within multiple setting, with additional outcome to be measured such as the mortality rate, the incidence of nosocomial infection, in-hospital rehabilitation compliance, and others.

CONCLUSION

The initiation of ET contributes to a favourable clinical outcome in terms of mechanical ventilation duration and length of hospital stay for patients with severe head injuries. However, the association between tracheostomy categorisation and ICU LOS, incidence of pneumonia, decannulation rate, and GCS at discharge was not statistically significant in this study. A larger sample size and a longer period of data collection are required to determine a convincing significant association between tracheostomy classification and clinical outcomes related to it.

CONFLICT OF INTEREST

The authors declare that no conflicts of interest exist.

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AUTHOR CONTRIBUTIONS

MFM: involved in drafting the manuscript, data collection, analysed the data, support with literature content.
SML: involved in analysed the data, finalising and editing the manuscript, support with literature content.
LWL: involved in finalising and editing the manuscript, support with literature content.
MSA: involved in reviewing the manuscript and providing expert advice.

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