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Outcome of Early Tracheotomy in Comparison to Prolonged Endotracheal Intubation in Severe Traumatic Brain Injury Critically Ill Patients

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ABSTRACT

Background: In patients with severe traumatic brain injury, the goal of this study is to determine whether or not early tracheostomy on day 5 lowers mechanical ventilation time, intensive care unit (ICU) stay, incidence of pneumonia, and death compared to extended intubation. Our study aimed to determine the effects of early tracheostomy on mechanical ventilation time, intensive care unit (ICU) stay, and nosocomial pneumonia.

Patients and methods: All patients who satisfied the following selection criteria were prospectively included in the study: Patients with isolated traumatic brain injury with scores of 8 or below on the first and fifth days of the Glasgow Coma Scale were randomly assigned to one of two groups: Total time of mechanical ventilation, ICU duration of stay, incidence of pneumonia, days of mechanical ventilation after nosocomial pneumonia, and mortality were compared between the early tracheostomy (T group, n = 400) and extended endotracheal (I group, n = 400) groups.

Results: ICU length of stay was 17.13 (SD 1.93) days in early tracheostomy versus 48.94 (SD 6.08) in the prolonged intubation group, in terms of a p-value that is highly significant (P<0.001). Also, mortality was statistically highly significant in comparison between both groups with only three patients in the early tracheostomy group versus thirty eight patients in the prolonged intubation group.

Conclusion: Early tracheostomy in severe traumatic brain injury carries a great beneficial outcome regarding total number of days requiring mechanical ventilation and post-nosocomial pneumonia days requiring mechanical ventilation, incidence of pneumonia, complications either clinical or endoscopic and mortality when compared to prolonged intubation patients.

Keywords: Early tracheostomy, Prolonged intubation, Traumatic brain injury.

INTRODUCTION

Tracheostomy is a common procedure in the intensive care unit. Because of the risk of significant oropharyngeal and laryngeal damage, prolonged translaryngeal intubation is not suggested [(1-7)].

Despite the longevity of the tracheostomy procedure, the current body of evidence is insufficient to characterize the impact of early tracheostomy on mechanical ventilation and intensive care unit (ICU) length of stay [(2-7)].

Many advantages come with tracheostomies for patients on mechanical ventilation, including better nursing care, more comfort, more safety, the ability to speak, assistance with oral nourishment, and early weaning from the ventilator [(8-9)].

Nosocomial pneumonia especially ventilator associated pneumonia was reported in some studies to occur more with tracheostomy [(10-12)].

This recommendation was given by the American consensus conference on artificial airways in 1989, and the same conclusion was reached by the European consensus in 1998: tracheostomy is the preferred option when an artificial airway is needed for duration of more than 21 days [(13-14)].

Our study's aim is to learn how early tracheostomy affects the time a patient spends on mechanical ventilation and in ICU, nosocomial pneumonia, other complications from intra-cranial hypertension, acute respiratory distress syndrome (ARDS), sinusitis, cardiac dysfunction, bleeding, sepsis, occurrence of granuloma, fibrosis and finally mortality when compared specifically, in individuals with isolated severe traumatic brain damage who require extended intubation.

PATIENTS AND METHODS

After receiving clearance from the Helwan University School of Medicine's Ethical Review Committee, this randomized controlled clinical trial was conducted from January 2020 to May 2022.

Participants were patients who fulfilled the following criteria:

- Traumatic brain injury (Glasgow Coma Score [GCS] 8 or lower at admission) that occurred in isolation.
- If these conditions were satisfied on the fifth day of hospitalization, patients were randomly assigned to get a tracheostomy (T) or continue with extended endotracheal intubation (I).
- GCS $\leq$8 on fifth day without any sedation.
- CT scan shows brain contusion.
- Patients in the T group (early tracheostomy group) had tracheostomies on days 5 or 6 after admission by a critical care physician using the conventional procedure in the intensive care unit and low pressure tracheostomy tube cuffs.

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- We compared patient demographics, APACHE II scores at admission, and outcomes such as time of mechanical ventilation, rate of nosocomial pneumonia, and length of stay in the intensive care unit, other clinical complications which may occur like intra cranial hypertension, sinusitis, ARDS, cardiac dysfunction also the endoscopic complications like granuloma formation fibrosis, bleeding, sepsis and also the mortality between both groups, the early tracheostomy and prolonged endotracheal intubation group.

Diagnosis of nosocomial pneumonia was depending on Centers for Disease Control and Prevention (CDC) criteria [15].

Ethical consent:

The study was sanctioned by the Academic and Ethical Committee of Helwan University. All participants agreed to participate in the study after signing an informed written permission form. All procedures involving human subjects in this study have been performed in conformity with the principles outlined in the World Medical Association's Declaration of Helsinki on the conduct of scientific research involving human subjects.

Statistical analysis:

Data collected and encoded using Microsoft Excel software. Data were then imported into Statistical Package for Social Sciences (SPSS version 20.0) software for analysis. The Shapiro-Wilk test was used to check if the data followed a normal distribution. Frequencies and relative percentages were used to illustrate the qualitative data. To determine the significance of a difference between two or more sets of qualitative variables, a Chi-square test (2) is often used. Mean and standard deviation (SD) were used to summarize quantitative data. A t-test for comparing normally distributed samples was performed to assess if two groups of data were statistically different (parametric data). Statistical significance was considered at p-value $\leq$0.05.

RESULTS

Between January 2020 and May 2022, 800 patients with severe traumatic brain damage were randomly assigned to either the early tracheostomy group (n=400) or the protracted intubation group (n=400). There was no statistically significant difference between the groups in terms of age, sex, or APACHE II score (**Table 1**).

Table (1): Demographic characteristics of the studied patients in both groups.

Variable	Early tracheostomy	Prolonged intubation	T test		
	Mean ± SD	Mean ± SD	T value	P-value	Sig.
Age	48.38 ± 9.15	47.93± 8.71	0.713	0.476	NS
Sex Male Female	209 (52.25%) 191 (47.75%)	221 (55.25% 179 (44.755)	0.72	0.395	NS
APACHE II Score	7.16 ± 1.39	7.14 ± 1.4	0.203	0.839	NS

NS: Not significant.

It shows that the early tracheostomy group had a shorter mean time for mechanical ventilation 12 (SD 1.34) versus 45.45 (SD 11.05) in the prolonged intubation group given an extremely high statistical significance p-value <0.001. Also the days of mechanical ventilation was shorter in the early tracheostomy group when compared to the prolonged intubation group 6.67 (SD 1.38) versus 33.54 (SD 3.72) respectively with given an extremely high statistical significance p-value <0.001 (**Table 2**).

Table (2): Mechanical ventilation duration of the studied patients in both groups.

Variable	Early tracheostomy	Prolonged intubation	T-test		
	Mean ± SD	Mean ± SD	T value	P-value	Sig.
Days of MV	12 ± 1.34	45.45 ± 11.05	-109.006	<0.001	HS
Days of MV after nosocomial pneumonia	6.67 ± 1.38	33.54 ± 3.72	-163.126	<0.00l	HS

HS: Highly significant.

Data demonstrates a statistically significant difference between the rates of nosocomial pneumonia in the early tracheostomy group (25 cases) and the extended intubation group (140 cases) p-value <0.001, from the cases which had nosocomial pneumonia 22 case was due to gram negative early tracheostomy group had bacilli whereas the prolonged intubation group had 116 cases, and due to gram positive cocci was 3 cases versus 24 case in the early tracheostomy group and prolonged intubation group, respectively with a highly significant statistical difference, Also it shows the clinical complications from sinusitis, sepsis, intra-cranial hypertension, ARDS and cardiac dysfunction which was in the privilege of the early tracheostomy group with given an extremely high statistical significance (P-value <0.001) (**Table 3**).

Table (3): Incidence of nosocomial pneumonia and other clinical complications of the studied patients in both groups.

Variable		Early tracheostomy	Prolonged intubation	T-test		
		N (%)	N (%)	X^2	P-value	Sig.
Nosocomial pneumonia incidence	No	375(93.75%)	260 (65%)	100.98	<0.001	HS
	Yes	25 (6.25%)	140 (35%)			
Gram negative bacilli	No	378 (49.55)	284 (71%)	134.72	<0.001	HS
	Yes	22 (5.5%)	116 (29%)			
Gram positive Cocci	No	397 (99.25%	376 (94%)	50.18	<0.00l	HS
	Yes	3 (0.75%)	24 (6%)			
Sinusitis	No	390 (97.5%)	309 (77.25%)	74.35	<0.00	HS
	Yes	10 (2.5%)	91 (22.75%)			
Sepsis Intra-infra-cranial	No	380 (95%)	288 (72%)	76.790	<0.00	HS
	Yes	20 (5%)	112 (28%)			
Hypertension	No	397 (99.25%)	347 (86.75%)	48	<0.00	HS
	Yes	3 (0.75%)	53 (13.25%)			
ARDS	No	395 (98.75%)	316 (79%)	78.9	<0.00	HS
	Yes	5 (1.25%)	84 (21%)			
Cardiac dysfunction	No	398 (99.5%)	338 (84.8%)	61.14	<0.00	HS
	Yes	2 (0.5%)	62 (15.5%)			

HS: Highly significant.

When compared to the prolonged-intubation group, the early tracheostomy group demonstrates a statistically significant reduction in the incidence of local complications such granuloma development and fibrosis. with p-value <0.001 with only significant statistical difference as regard the bleeding which is less in the early tracheostomy group p-value 0.042 (**Table 4**).

Table (4): Local endoscopic complications of the studied patients in both groups.

Variable		Early tracheostomy	Prolonged intubation	T-test		
		N (%)	N (%)	X^2	P-value	Sig.
Granuloma	No	342 (85.5%)	288 (72%	21.78	<0.001	H.S.
	Yes	58 (14.5%)	112 (21.78			
Fibrosis	No	376 (94%)	192 (48%)	205.54	<0.001	H.S.
	Yes	24 (6%)	208 (52%)			
Bleeding	No	385 (96.25%)	372 (93%)	4.15	0.042	S.
	Yes	15 (3.75%)	28 (7%)			

S: Significant. HS: Highly significant.

Statistically, the early tracheostomy group fared better than the protracted intubation group in terms of ICU length of stay and death (p <0.001) (**Table 5**).

Table (5): ICU length of stay and mortality of the studied patients in both groups.

Variable	Early tracheostomy	Prolonged intubation	T-test	
	N (%)	N (%)	P-value	Sig.
ICU length of stay	17.13 $\pm$ 1.93	48.94 $\pm$ 6.08	<0.001	HS
Mortality	3	38	<0.001	HS

HS: Highly significant.

DISCUSSION

There are few studies strictly recommend early tracheostomy in head injury patients, although it is frequently recommended in expected patients not to recover in near future after traumatic brain injury. Optimal time of tracheostomy in mechanically ventilated patients has little agreement [16-18]. If mechanical breathing is projected to be necessary for more than 21 days, a tracheostomy was suggested by a 1989 consensus conference [4].

They spawned a slew of inquiries, the most pressing of which being, "Is it worth it to get a tracheostomy?" Exactly what time, if so. Just a few of research have even attempted to find answers to these issues [8-9, 19-22].

Radriguez *et al.* [8] stated that shorter periods of mechanical breathing, ICU stays, and overall hospital stays are associated with improved outcomes, but he did not express or address the consequences of extended intubation as opposed to early tracheostomy.

Also other like **Dunham *et al.*** [19]**,** didn't find any difference as regard important clinical outcomes, they also found that significant laryngotracheal injury occurred at the same rate whether the tracheostomy was performed early or late.

El Naggard and colleagues [20]**,** reached to the conclusion that late tracheostomy groups had a greater rate of extubation and a lower rate of airway lesions.

One hundred and one adult patients were reviewed by **Lensik and colleagues** [8] **and Blot and colleagues** [21] admitted to ICU after head injuries thirty two patients had tracheostomy within the first four days and sixty nine patients underwent tracheostomy after four days, Early tracheostomy patients required mechanical ventilation for an average of 6 days, whereas those in the late tracheostomy group needed it for an average of 20.6 days ($p < 0.001$). This also matches with our result which we reached that days of mechanical ventilation in our study in early tracheostomy group was 12 (SD 1.34) days versus 45.45 (SD 11.05) days in prolonged intubation group with a highly significant statistical difference between both groups (P-value <0.001).

Early tracheostomy within 48 hours was compared to late tracheostomy after seven days by **Blot *et al.*** [21] although our study found no statistically significant difference in the occurrence of nosocomial pneumonia, ICU deaths, or hospitalizations for 53 neutropenic patients, we did discover that the early tracheostomy group stayed in the hospital and required mechanical ventilation for more days.

Those aforementioned studies all suffer from the same problem: they were conducted on quite similar populations [18-20], retrospective study not prospective [9,20] no randomization [9,18], poor randomization, if any was used [8,18,19]. They also contrast tracheostomy performed at different times, but not with extended endotracheal intubation [8,9,17-21]. Certain conditions, such as a consistent sample size and a unified approach to weaning, have to be met for this to be possible.

To avoid any methodological bias, we sought out a population that was similar in pathology and severity, and we required that the population we selected be ventilated for an extended period of time. This allowed us to avoid performing tracheostomies when they were not clinically indicated. The patients who met these criteria were those who had sustained an isolated severe traumatic brain injury.

Patients with severe traumatic brain injury who required mechanical ventilation had an alarmingly high risk of unsuccessful extubation and subsequent tracheostomies.

Airway protection is the main issue after the first week in this group of patients as they became not in need for mechanical ventilatory support after the first week unless their course complicated by nosocomial pneumonia like ventilator associated pneumonia.

Early termination of mechanical ventilation can be aided by early tracheostomy and so decrease the ICU and hospital length of stay in this patient category.

Knowing that these patients were unlikely to be extubated this come at the time of intubation by two clinical features, GCS is less than 8, brain stem deficit and computed tomography finding of cerebral contusion.

Depending on the previous condition, our patients were chosen according to the previous inclusion criteria.

Patients having GCS of 8 or above were not included at the outset of the trial for probable extubation since this number was deemed too high to reliably predict a successful outcome from tracheostomy.

Pulmonary causes of mechanically ventilated patients secondary to a neurological disease is the corner stone in deciding the time for tracheostomy from the daily practice in the ICU [3, 23].

Patients with severe traumatic brain injury who were included in our study required intubation for airway protection primarily and did not require mechanical ventilation support unless they developed nosocomial pneumonia; therefore, early tracheostomy is a good option to decrease, the need for prolonged mechanical ventilation support in patients presented with severe traumatic brain injury requiring a long term for recovery where airway protection will be necessary [24, 25].

In our study nosocomial pneumonia in early tracheostomy was obviously less than that occurred in the prolonged intubation group and there was a highly significant statistical difference between the two groups; many studies had emphasized on these results that early tracheostomy was associated with less incidence of nosocomial pneumonia [9,21,26], other studies stated that tracheostomy in general increases the incidence of pneumonia.

Although there was no difference in the likelihood of laryngotracheal damage between intubation times of 0-6 days and 7-13 days, patients with closed severe traumatic brain injury who were intubated for longer than fourteen days were at risk of developing severe tracheal problems., this was reported by **Nowak *et al.*** [30].

Frequency rate of laryngotracheal stenosis in three hundred and fifteen patients with severe neurological insult, (Severe head injury and tetraplegia) was not dependent on the duration of intubation; this was stated by **Richard *et al.*** [31].

This was on the contrary of our study findings that prolonged intubation carried a considerable and highly significant statistical difference as regard the clinical and endoscopic complications, when compared to the early tracheostomy; also mortality in our study was much less in early tracheostomy group, together with all stated clinical complications from intra-cranial hypertension, sepsis, ARDS, and cardiovascular dysfunction this carries a highly significant statically difference when compared to the prolonged intubation group.

Based on experience from many other studies, tracheostomy must be done before the time of laryngotracheal injury expected to occur especially in patients with severe neurological insult [29-31].

Kollef *et al.* [32] concluded that patients with respiratory failure who had tracheostomy early had a better prognosis than those who did not, Despite the heterogeneity of the research population (all types of ICU patients with varying pathologies were included), our findings indicating the early tracheostomy group experienced fewer respiratory issues than the protracted intubation group are consistent with these findings.

In conclusion, in patients with severe traumatic brain injury, early tracheostomy reduced the number of days of required mechanical ventilation, the length of ICU time needed when pneumonia developed, and the overall number of ICU days. Also, clinical complications like intra-cranial hypertension, sinusitis, sepsis, bleeding, ARDS and cardiac dysfunction were less frequent. At the same time early tracheostomy decreased local endoscopic complications like fibrosis, and granuloma formation, together with the overall mortality when compared to prolonged intubation.

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