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A Prospective randomised study on impact of early tracheostomy on withdrawal of mechanical ventilation in severe head injury patients- A comparison with late tracheostomy

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Abstract: *Trauma is currently one of the most important causes of morbidity and mortality in the age group between 15 to 35 years. Head injury patients constitute a major bulk of trauma patients admitted in intensive care settings. Patients with impaired consciousness may require mechanical ventilation to protect their airway, treatment of intracranial hypertension and ventilatory support to treat pulmonary complications. Prolonged intubation with mechanical ventilation is associated with increased hospital mortality and impaired post ICU discharge health related quality of life. tracheostomy provides an early airway protection and serves to decrease the need for prolonged mechanical ventilatory support, facilitates pulmonary toilet and oral hygiene and has been shown to reduce the incidence of ventilator associated pneumonia. This study was undertaken in severe head injury patients to assess the impact of early tracheostomy on the duration of mechanical ventilation, length of stay (LOS) in intensive care unit (ICU), incidence of ventilator - associated pneumonia (VAP) & outcome in ICU and compare it with late tracheostomy. This prospective randomized study included 100 patients with severe head injury having GCS<8 admitted to SICU for mechanical ventilation. Patients were sedated and paralyzed for first 48 hours. After 48 hours, patients with a GCS score <8 were to undergo randomly either early tracheostomy (within 5 days of initiation of mechanical ventilation) or late tracheostomy (after 5 days). Total duration of mechanical ventilation in early tracheostomy group (group I) varied between 3 to 19 days with a mean of 7.9$\pm$2.9 days while in the tracheostomy (group I) it ranged between 8-25 days with a mean of 11.5 $\pm$ 2.9 days . Thus total duration of mechanical ventilation in early tracheostomy was significantly shorter (p=0.000).The length of stay (LOS) in ICU in early tracheostomy group was shorter as compared to late tracheostomy group and this difference was statistically significant (p=0.000). we conclude that early tracheostomy benefits the severely injured patient who requires more than 7 days of mechanical ventilation, decreased duration of mechanical ventilation and intensive care unit days and can have long term implications on cost containment, especially in our scenario where ICU facilities are scarce.*

Keywords*: early tracheostomy, head injury, intensive care, length of stay, VAP.*

I. Introduction

Trauma is currently one of the most important causes of morbidity and mortality in the age group between 15 to 35 years**[1,2].** Many trauma patients require intubation and mechanical ventilation for several reasons, including relief of upper airway obstruction secondary to severe facial or laryngeal trauma, airway access in patients with cervical spine injury, management of retained airway secretions, maintenance of patent airway and airway access for prolonged mechanical ventilation. **[3].**

Head injury patients constitute a major bulk of trauma patients admitted in intensive care settings. An important factor contributing to high mortality in patients with severe head injury is cerebral hypoxia **[4]**. During the early phase after acute brain injury, patients with impaired consciousness may require mechanical ventilation to protect their airway, treatment of intracranial hypertension and ventilatory support to treat pulmonary complications. After the acute phase, and once satisfactory weaning parameters have been achieved, the patients' impaired level of consciousness and inability to protect their airway represent strong reasons why extubation should be delayed **[5].** These patients might benefit from continued intubation through prevention of aspiration and because of their limited ability to clear secretions, but it has been shown that prolonged intubation in traumatic brain injury patients is associated with high incidence of pneumonia **[6].** The incidence of ventilator associated pneumonia (VAP) is related directly to the duration of mechanical ventilation **[7]** - a complication that carries significant morbidity & mortality **[8,9,10]**. In addition, prolonged endotracheal intubation is associated with trauma to larynx, trachea, and patient discomfort in addition to requirement of

systemic sedatives [11,12,13,14,15,16,17,18,19,20,21,22,]. Local complications including subglottic stenosis are more likely if tracheal intubation is continued for more than two weeks [23]. Pena et al [24] found that 86% of all patients with subglottic stenosis had a history of tracheal intubation with a mean duration of ventilatory support of 17 days. Ely and coworkers**[25**] demonstrated that prolonged intubation with mechanical ventilation is associated with increased hospital mortality and impaired post ICU discharge health related quality of life**[26]**Tracheostomy has been thus found to play an integral role in the management of such patients.

Firstly tracheostomy provides an early airway protection and serves to decrease the need for prolonged mechanical ventilatory support. Secondly severe head injury patients require a prolonged time for recovery and airway reflexes are rarely optimal [**27].** The tracheostomy tube facilitates pulmonary toilet and oral hygiene and has been shown to reduce the incidence of ventilator associated pneumonia. In a developing country like ours, where intensive care facilities are scarce and catering to a whole population, these critical patients have to be managed in high dependency units often with inadequately trained nursing staff and equipment to monitor them. **[4].** Increased demand, coupled with a lack of availability of critical resources, has resulted in placing the more stable patients outside of traditional ICUs. Airway security and safety are paramount in the non–ICU environment, where personnel skilled in airway management and intubation may not be immediately available. The belief that a tracheostomy is safer than translaryngeal airway has led to earlier tracheostomy and early placement of these patients on acute medical floors **[28].**

The standard of care has varied considerably over the years and the current trend seems to be early tracheostomy in severe head injury patients as it would be effective to reduce the duration of mechanical ventilation **[29]**.The association between duration of intubation and risks of laryngotracheal injury is an important consideration in the timing of tracheostomy. The transition from "low volume, high pressure" to "high volume, low pressure" cuffs for tracheostomy tubes allowed tracheal tubes to be kept in place longer because significantly less damage to the trachea was seen with the use of "high volume, low pressure" cuffs **[30]**. Against this background, a randomized prospective study was undertaken in severe head injury patients to assess the impact of early tracheostomy on the duration of mechanical ventilation, length of stay (LOS) in intensive care unit (ICU), incidence of ventilator - associated pneumonia (VAP) & outcome in ICU and compare it with late tracheostomy.

II. Material Methods

This prospective randomized study included 100 patients with severe head injury having GCS<8 admitted to SICU for mechanical ventilation .The patients were managed as per ATLS protocol and mechanically ventilated before a decision to perform tracheostomy was taken. Patients were sedated and paralysed for first 48 hours. After 48 hours ,patients would be weaned off sedation and reassessd. Those who continued to have a GCS score <8 for more than 48 hours and requiring prolonged ventilation were to undergo randomly either early tracheostomy (within 5 days of initiation of mechanical ventilation) or late tracheostomy (after 5 days). Randomisation was done on the basis of hospital MRD numbers. Patients with odd MRD nos were assigned to early tracheostomy group while patients with even MRD nos were assigned to late tracheostomy group.None of the patients included in the study were given an extubation trial. Those patients who were shifted back to ICU from high dependency unit for restarting of mechanical ventilation were also excluded from the study.

Age And Sex Eligibility And Inclusion Criteria were: 18years and above, GCS<8 upon admission to SICU, traumatic brain injury or severe head injury defined as penetrating or blunt injury including SAH, EDH, brain contusion ,DAI, Patients projected to need ventilatory support for≥ 7 days.,
Mechanically ventilated by endotracheal intubation

Exclusion Criteria: Age <18years,Patients projected to need ventilation for less than 7 days. Anatomical deformity of neck, including thyromegaly and cervical tumours.,Previous tracheostomy,-COPD or pre existing comorbid state, uncontrolled coagulopathy, evidence of platelet count <50,000. Clinical evidence of ongoing infection at the site of tracheostomy. Pregnancy, Mechanical ventilation with a positive end-expiratory pressure (PEEP) greater than 12cm H_2OPatients who have undergone cricothyroidotomy. Cricoid cartilage, trachea, or sternal notch not palpable with neck in position Immunosuppressed or immunodepressed patients:leukocytes <1000/ul-neutrophils <500/ul-AIDS-Long term steroid treatment (daily dose >0.5 mg/kg for more than 30 days.);Patients already enrolled in other trials.

According to Hospital MRD nos ,patients were randomly stratified into two groups:

Neurosurgical resident performed tracheostomy by standardized open technique using high volume, low pressure ,cuffed tracheostomy tube. Meanwhile patients were weaned off tracheostomy gradually. Patients were discharged from ICU only after they were off from mechanical ventilation for at least 24 hours.

The number of days from initiation of mechanical ventilation to tracheostomy ,from admission in SICU to tracheostomy ,from tracheostomy to discharge from SICU, duration of mechanical ventilation, length of stay in ICU was calculated. All these durations were calculated as number of calendar days with date of admission in SICU being considered as day 0. All ICU mortality rates were documented. All data was collected and comparison between two groups for continuous variables was expressed as Means ± standard deviation of mean and were analysed using standard statistical tests and inferences were drawn accordingly.

III. Aims And Objectives Of The Study

Primary Objective:-to compare duration of mechanical ventilation between early and late tracheostomy groups.

Secondary Objectives:-To compare length of stay in intensive care unit (LOS in ICU), to compare incidence of mortality in each group during intensive care unit (ICU) stay.

Observations And Results:-The aim of this prospective, randomized study was to determine the impact of early tracheostomy on the duration of mechanical ventilation, ICU length of stay and ICU outcomes in head injury patients.

Data was obtained from a prospective ICU database containing information on all head injury patients who received tracheostomy over a three year period: Demographics; Simplified Acute Physiology Score (SAPS)II, Glasgow Coma Scale(GCS)Score, Type of Injuries (head injury and other co injuries),Operative Interventions, mechanical ventilation duration, ICU length of stay and ICU outcomes.. Group I /Early Tracheostomy Group and Group II /Late Tracheostomy Group. Following parameters were recorded and evaluated statistically using chi-square:Age,Weight,Sex, Glasgow Coma Score Scale, Simplified Acute Physiology Score II, Duration of Mechanical Ventilation in ICU, Length of Stay in ICU, Mortality/Outcome in ICU, Surgical Interventions(operated or not operated) Following Observations were made:-

Table 3: Tracheostomy and Ventilation Parameters in the Studied Subjects

Duration (day)	Early			Late			p value
	mean ± SD	Median	n	mean ± SD	Median	n	
Day of Tracheostomy	3.5 ± 1.1 (1, 5)	3	50	7.9 ± 1.1 (6, 10)	8	50	0.000
Duration from tracheostomy to withdrawal of ventilation	4.2 ± 2.7 (1, 15)	3	46	3.6 ± 2.6 (1, 15)	3	48	0.287
Total duration of mechanical Ventilation	7.7 ± 3.0 (3, 19)	7	46	11.5 ± 2.9 (8, 25)	11	48	0.000
Length of stay in ICU	8.7 ± 3.1 (3, 20)	8	46	12.6 ± 2.9 (9, 26)	12	48	0.000

In early tracheostomy group,the average day of tracheostomy was 3.5 days (3.5 ± 1.1) while in late tracheostomy,the mean day of tracheostomy was found out to be 7.9days(7.9 ± 1.1). p value for mean day of tracheostomy was found to be statistically significant(p=0.000).

In the early tracheostomy group duration from tracheostomy to withdrawal of ventilation varied from 1 to 15 days with a mean of 4.2 ± 2.7 days. In late tracheostomy group duration from tracheostomy to withdrawal of mechanical ventilation also ranged between 1-15 days with a mean of 3.6 ± 2.6 days. There duration from tracheostomy to withdrawal of mechanical ventilation in both the groups was not statistically significant(p =0.287)

Total duration of mechanical ventilation in early tracheostomy group (Group I) varied between 3-19days with a mean of 7.7 ± 3.0 days. In late tracheostomy group (Group II) total duration of mechanical ventilation varied between 8-25 days the duration of mechanical ventilation in early tracheostomy group was shorter and statistically significant(p =0.000) .

The length of stay in ICU in early tracheostomy group varied between 3-20 days with an average length of stay of 8.7 ± 3.1 days. In late tracheostomy group, the length of stay in ICU varied between 9-26 days with an average length of stay of 12.6 ± 2.9 days. This difference was statistically significant (p = 0.000).

Table 4 : Glasgow Coma Scale Score in Studied Subjects						
	GCS Score	Early		Late		p value
		N	%	n	%	
Day of Admission in SICU	3	8	16.0	4	8.2	0.404 (NS)
	4	10	20.0	8	16.3	
	5	9	18.0	12	24.5	
	6	12	24.0	14	28.6	
	7	11	22.0	11	22.4	
	Median	5		6		
Day of Tracheostomy	3	6	12.8	3	6.5	0.026 (Sig)
	4	7	14.9	4	8.7	
	5	13	27.7	7	15.2	
	6	10	21.3	14	30.4	
	7	8	17.0	13	28.3	
	8	3	6.4	5	10.9	
	Median	5		6		
Day of Discharge from SICU	4	1	2.2			0.583 (NS)
	5	4	8.9	1	2.2	
	6	9	20.0	9	20.0	
	7	12	26.7	17	37.8	
	8	15	33.3	13	28.9	
	9	3	6.7	4	8.9	
	10			1	2.2	
	11	1	2.2			
	Median	7		7		

GCS scores analysed on day zero (Day of Admission in SICU) revealed no statistically significant differences between early & late tracheostomy group
(p =0.404).However GCS scores analysed on the day of tracheostomy revealed a statistically significant difference(p =0.026) between the two groups. Again the analysis of GCS scores on the day of discharge from SICU revealed statistically insignificant differences(p = 0.583).

Table 4 : Glasgow Coma Scale Score in Studied Subjects						
	GCS Score	Early		Late		p value
		N	%	n	%	
Day of Admission in SICU	3	8	16.0	4	8.2	0.404
	4	10	20.0	8	16.3	
	5	9	18.0	12	24.5	
	6	12	24.0	14	28.6	
	7	11	22.0	11	22.4	
	Median	5		6		
Day of Tracheostomy	3	6	12.8	3	6.5	0.026
	4	7	14.9	4	8.7	
	5	13	27.7	7	15.2	
	6	10	21.3	14	30.4	
	7	8	17.0	13	28.3	
	8	3	6.4	5	10.9	
	Median	5		6		
Day of Discharge from SICU	4	1	2.2			0.583
	5	4	8.9	1	2.2	
	6	9	20.0	9	20.0	
	7	12	26.7	17	37.8	
	8	15	33.3	13	28.9	
	9	3	6.7	4	8.9	
	10			1	2.2	
	11	1	2.2			
	Median	7		7		
Intra Group Variance	a-b	0.685 (NS)		0.001 (Sig)		
	ac	0.000 (Sig)		0.000 (Sig)		
	bc	0.000 (Sig)		0.000 (Sig)		
	Overall	0.000 (Sig)		0.000 (Sig)		

ab: Comparison between GCS on Day of Admission in SICU (a) with Day of Tracheostomy(b)
ac: Comparison between GCS on Day of Admission in SICU(a) with Day of Discharge from SICU(c)
bc: Comparison between GCS on Day of Tracheostomy(b) *with Day of Discharge from SICU(c)*

Table 5 : Simplified Acute Physiology Score (SAPS) II in Studied Subjects						
SAPS II		Early		Late		p value
		n	%	N	%	
Day of Admission in SICU	< 50	43	87.8	41	85.4	0.737 (NS)
	> 50	6	12.2	7	14.6	
Day of Tracheostomy	< 50	32	69.6	35	74.5	0.600 (NS)
	> 50	14	30.4	12	25.5	
Day of Discharge from SICU	< 50	45	100.0	44	100.0	1.000 (NS)
	> 50	0	0.0	0	0.0	
Intra Group Variance	Ab	0.005		0.083		
	Ac	0.157		0.025		
	Bc	0.000		0.002		
	Overall	0.000 (Sig)		0.003 (Sig)		

Analysis of SAPS II scores on day of admission in SICU revealed no statistically significant difference (p = 0.737) between the two groups.

Table 6 : Outcome in the Studied Subjects					
Outcome	Early		Late		p value
	n	%	N	%	
Survived	46	92	47	94	0.697 (NS)
Died	4	8	3	6	

In the early tracheostomy group mortality was 8% while in late tracheostomy mortality was 6%.Overall differences in mortality between the two groups were statistically insignificant(p = 0.697).

Table 9 : Operative statistics done in the Studied Subjects					
Operated	Early		Late		p value
	n	%	N	%	
Yes	14	28	14	28	1.000 (NS)
No	36	72	36	72	

In early tracheostomy group, 28% (n=14) of the patients were operated while in late Tracheostomy group, again 28% (n=14) of patients were operated.surgical interventions were carried out in patients with acute extradural haematoma(EDH),subdural haematoma(SDH),large contusions etc

Table 10 : Comparison of Final Outcome in Operated and Non-Operated Patients						
Outcome			Early	Late	Total	p value
Operated	Survived	n	10	11	21	0.663 (NS)
		%	71.4	78.6	75.0	
	Died	n	4	3	7	
		%	28.6	21.4	25.0	
Non-Operated	Survived	n	35	35	70	1.000 (NS)
		%	97.2	97.2	97.2	
	Died	n	1	1	2	
		%	2.8	2.8	2.8	

Statistical analysis of the final outcome between operated and non operated patients in the two groups revealed an insignificant difference.in the early tracheostomy group,14 patients were operated(28%).among the operated patients,28.6%(n=4) died while in late tracheostomy group same no of patients were operated but mortality was 21%(n=3).overall difference was not statistically significant.(p=0.663)
In the non operated group,mortality was 2.8% (n=1) in both groups, .overall difference between the two groups was statistically insignificant(p=1.000)

Prolonged Length of stay (>14 days) in ICU of the Studied Subjects			
Group	n	%	p value
Early	3	6	0.112 (NS)
Late	8	16	

A comparison of prolonged ICU stay in two groups showed that 6% of patients in early tracheostomy had a prolonged ICU stay while in late tracheostomy group 16% of the patients had a prolonged ICU stay. the difference was statistically insignificant.(p=0.112)

Cause of Death in the Studied Subjects					
Cause of Death	Early		Late		p value
	n	%	n	%	
Cardiovascular Instability	2	40.0	1	25.0	0.308 (NS)
CT documented severe brain edema	2	40.0	0	0.0	
Sepsis	1	20.0	2	50.0	
ARDS	0	0.0	1	25.0	
Total	5	10.0	4	8.0	

In early tracheostomy group,cardiovascular instability and severe brain edema were major causes of death(40%) while in late tracheostomy group sepsis was the major cause of mortality.(50%)

Table 10 : Comparison of Final Outcome in Operated and Non-Operated Patients						
Outcome			Early	Late	Total	p value
Operated	Survived	n	10	11	21	0.663 (NS)
		%	71.4	78.6	75.0	
	Died	n	4	3	7	
		%	28.6	21.4	25.0	
Non-Operated	Survived	n	35	35	70	1.000 (NS)
		%	97.2	97.2	97.2	
	Died	n	1	1	2	
		%	2.8	2.8	2.8	

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CT documented severe brain edema	2	40.0	0	0.0	
Sepsis	1	20.0	2	50.0	
ARDS	0	0.0	1	25.0	
Total	5	10.0	4	8.0	

In early tracheostomy group,cardiovascular instability and severe brain edema were major causes of death(40%) while in late tracheostomy group sepsis was the major cause of mortality.(50

IV. Discussion

AGE: The average age of patients in early tracheostomy or group I was 39.4±12.1 years with a range of 18 to 64 years whereas in late tracheostomy or group II it was 38.8±9.5, with a range of 18 to 62 years (table 1). Statistically no significant variation in the age of the patients was observed between the two groups (p=0.77). **GENDER** In both early and late tracheostomy groups, the incidence of head injury was higher in male gender (90% in early tracheostomy and 88% in late tracheostomy.) Overall genderwise distribution in the

two groups was comparable and statistically insignificant (p=0.750). **WEIGHT** The weight of patients in Early tracheostomy or Group I ranged between 35 to 78kg with a mean of 64.2 ± 5.4 whereas in late tracheostomy or Group II, the weight of patients ranged between 51-76 kg with a mean of 65.6 ± 5.4. So average weight of the patients in both the groups was comparable and the discrepancy in the average weights between the two groups was statistically insignificant (0.179). Thus the two groups matched and were comparable in their demographic characteristics of age, gender and weight.

Diagnosis: Brain Contusion was the commonest brain injury in both the groups (72% in early tracheostomy and 66% in late tracheostomy groups). There was no statistically significant variation in the diagnosis of head injury between the two groups.

Operative Statistics And Outcomes: In the early tracheostomy group, 28% (n=14) of the patients were operated while in the late tracheostomy group, again 28% (n=14) of patients were operated. Surgical interventions were carried out in patients with acute extradural haematoma (EDH), subdural haematoma (SDH), large contusions etc.

Statistical analysis of the final outcome between operated and non operated patients in the two groups revealed an insignificant difference. In the early tracheostomy group, 14 patients were operated (28%). Among the operated patients, 28.6% (n=4) died while in late tracheostomy group, same no of patients were operated but mortality was 21% (n=3). Overall difference in mortalitity was not statistically significant (p=0.663).

In the non operated group, mortality was 2.8% (n=1) in both groups. Overall differences in mortality between the two groups were statistically insignificant (p=1.000). Our results corroborate with those of Rodriguez et al 1990[**15].**

Glasgow Coma Scale (Gcs) Score : Our rationale for choosing GCS score < 8 as an inclusion criteria is that low GCS score is an important criteria that aids in the identification of patients who are unlikely to be extubated and thus may require prolonged mechanical ventilatory support. Namen and coworkers **[31]** also found that a GCS score below 8 was associated with an increased likelihood of extubation failure in neurosurgical patients. Also Lanza et al **[32]**in their retrospective review of head injury patients found that likelihood of tracheostomy is significantly greater in patients with GCS score ≤7. In our study, GCS score was recorded on daily basis but for statistical analysis GCS scores on the day of admission in SICU, day of tracheostomy and day of discharge from SICU were considered. Statistical analysis of GCS on these three days failed to reveal any statistically significant difference between the two groups. At the same time intragroup comparisons were significant within both the groups, thus indicating that GCS scores improved with time in both the groups. Median scores of GCS on the day of discharge from SICU was 7 in both the groups while on day of tracheostomy it was 5 in early tracheostomy group and 6 in late tracheostomy group.

These results are in conformity with the findings of Rodriguez et al **[15]**. However, Arabi et al **[33]** in their study of tracheostomy in intensive care trauma patients found that patients with early tracheostomy had lower GCS scores, reflecting the common practice of performing tracheostomies earlier in patients with lower GCS while delaying tracheostomy in patients with higher GCS in case extubation becomes possible.

Similarly, Ahmed N and coworkers **[34]** study on severe traumatic brain injury patients revealed that GCS scores were comparable between early (≤7 days) and late tracheostomy (≥7 days) groups.

Simplified Acute Physiology Score (Saps) Ii

SAPS II scoring consists of 17 variables, with specific points assigned to each variable. It includes 12 physiological variables (Heart Rate, Systolic blood pressure, Body Temperature, PaO_2/FiO_2 ratio, Serum Urea or Serum Urea Nitrogen level, WBC Count, Serum Potassium Level, Serum Sodium Level, Serum Bicarbonate Level, Serum Biluribin Level, Glasgow Coma Scale), age, type of admission (Scheduled surgical, unscheduled surgical or medical) and three underlying disease variables (acquired immunodeficiency, metastatic cancer and haematological malignancy) **[9]**.

Analysis of SAPS II scores on these three days revealed no statistical significant difference between the two groups. These findings are in conformity with the findings of Arabi et al **[33]** and Rodriguez et al **[15]**. However Moller et al **[35]** found that APACHEII scores were significantly higher in late tracheostomy group.

Ventilator - Associated Pneumonia (Vap)

The presumed etiology of VAP is aspiration of oral secretions into larynx and then past the tracheal cuff, into the lungs. In our study, the incidence of ventilator associated pneumonia (VAP) was slightly higher in late tracheostomy (24%) group as compared to early tracheostomy (20%) group, although the difference was not statistically significant (0.233).

Similar to Rodriguez et al[**15],** Sugerman et al [**36**], Dunham et al**[3],** Bouderka et al [**27**],Saffle et al [**37]** failed to demonstrate any significant relationship between VAP and early tracheostomy. But studies by Nseir et al **[38]** VAP. Moller et al **[35]** Lesnik et al **[11]** and Kluger et al **[16]** c and Lesnik et al **[1992]** found that the incidence of nosocomial pneumonia was higher in the late trachesostomy group.

Tracheostomy Complications :

Complication rates of tracheostomy were low in both the groups. In early as well as late tracheostomy groups 6% of patients developed complications related to tracheostomy. Main complications related to tracheostomy were surgical emphysema, pneumothorax, displacement of tracheal tube etc. No death in either of the groups was attributable to tracheostomy.

Mortality Statistics And Causes :

In our study, mortality was 8% in early tracheostomy group and 6% in late tracheostomy group Overall differences in mortality between the two groups were statistically insignificant (p = 0.697). In the early tracheostomy group, cardiovascular instability and severe brain were edema were major causes of death (40%) while in Late Tracheostomy group, sepsis accounted for the majority of deaths (50%).

The low mortality rates in our study could be explained in the light of the fact that these results reflect mortality in SICU only. No follow up was done after patient was shifted from SICU to high dependency units.so mortality rates in our study excluded hospital mortality rates. Other reason for low mortality could be that only patients with isolated head injuries were considered, those with multiple coexisting injuries or polytrauma were excluded from the study. Also patients with co-morbid diseases like COPD, hypertension, diabetes mellitus (DM), cardiac disease, renal insufficiency, hepatic disease etc were excluded from the study.

These results are in conformity with the findings of Rodriguez et al **[15],** Arabi et al **[33]** Ahmed N et al **[34]** &Sugerman et al **[36].**

Duration Of Mechanical Ventilation And Length Of Stay (Los) In Surgical Intensive Care Unit (Sicu)

In the early tracheostomy group, the average day of tracheostomy was 3.7 days (3.7±0.8) while in late tracheostomy group, the mean day of tracheostomy was found out to be 7.9days (7.9 ± 1.3) which was found to be statistically significant (p=0.000).

In the early tracheostomy group duration from tracheostomy to withdrawal of ventilation varied from 1 to 15 days with a mean of 4.2±2.7 days. In the late tracheostomy group, duration from tracheostomy to withdrawal of mechanical ventilation also ranged between 1-15 days with a mean of 3.6±2.6 days. Although duration from tracheostomy to withdrawal of mechanical ventilation was slightly shorter in the late tracheostomy group (mean 3.6$\pm$2.6 days) as compared to early tracheostomy group (mean 4.2$\pm$2.7 days), but this difference was not statistically significant (p =0.287).

Total duration of mechanical ventilation in early tracheostomy group (Group I) varied between 3-19days with a mean of 7.9 ± 2.9 days. In late tracheostomy group (Group II), total duration of mechanical ventilation varied between 8-25 days with a mean of 11.5±2.9 days. The total duration of mechanical ventilation in early tracheostomy group was shorter and statistically significant (p =0.000)

The length of stay in SICU in early tracheostomy group varied between 4-20 days with an average length of stay of 8.9 ± 2.9 days. In late tracheostomy group, the length of stay in ICU varied between 9-26 days with an average length of stay of 12.5 ± 3.0 days. Again, this difference was statistically significant (p = 0.000). Our study results are in congruence with the studies by Arabi[**33]**, Rodriguez[**15**]and Pasini's[**38]**. but not in conformity with Barquist**[39**] and Sugerman's[**36]** studies.

Most of the prospective studies with the exception of Barquist[**39]** and Surgerman**[36]** agreed with our results that early tracheostomy significantly reduced the duration of mechanical ventilation as well as ICU LOS without affecting overall mortality. Similar results were reached by a number of retrospective studies.

Results in the medical intensive care unit (MICU) population mirror those in trauma patient population as is proved by the results of Brook et al[40] Rumbak et al [29] and Chin Lin – Hsu et al [41] in their respective studies. Prospective studies of Bouderka[27] and Chintamani[4] involved comparison between tracheostomised and non tracheostomised trauma patients.

Meta - analyses by Griffith et al [42] and Maziak et al [43] revealed conflicting results. Maziak et al [43] in his systematic review of timing of tracheostomy, analysed five studies, [Rodriguez (15), Lesnik (11), Blot (44), Dunham (3), El-Naggar (45)], three of which were done on trauma patients [Rodriguez(15), Lesnik,(11), Dunham(3)]. The investigators concluded that there was insufficient evidence to support that early tracheostomy could result in shorter mechanical ventilation or lower airway injury in critically ill patients. But there are many limitations in this systematic review, including the mixed population of patients (trauma and non trauma) and two studies being retrospective chart reviews in addition to significant limitation of randomized controlled trials

On the other hand, Griffith et al [42] in their systematic review and meta-analysis of five studies (Bouderka(27), Rodriguez(15), Rumbak(29), Saffle,(37), Dunham(3)]found out that early tracheostomy significantly reduced the duration of artificial ventilation and length of stay in intensive care unit. Early tracheostomy however did not significantly alter mortality or risk of pneumonia. Griffith's conclusions are in conformity with the results of our study.

Comparing our study with other studies of Meta-analysis reveals following findings (see the Table):

1. **Study Population:-** In our study homogenous patient population was studied i.e patients with isolated head injury only were considered for the study. Whereas studies of Rodriguez**[15],,** Lesnik**[11**] etc study included a heterogenous group i:e multiple trauma patients were included. Other studies like Rumbak's**[29**], Saffle's**,[37]** Blot's**[44]** etc. studied tracheostomy in non trauma patients. In Bouderka's**[27**] study, however, early tracheostomy was compared with prolonged translaryngeal intubation.
2. **Randomisation method:**-Like Rodriguez[**15**] and Dunhams[**3**] study, our study also utilized a quasi-randomisation method whereas Rumbak[**29]** and Saffle[**37]** utilized a true randomization method.
3. **Duration of Artificial Ventilation:-** Except Dunham's**[3**] study, rest all the studies including ours showed that duration of artificial ventilation was significantly lower in early tracheostomy group. Our study also showed the same result. In Dunhams**[3**] study, mean duration of mechanical ventilation was not specified.
4. **Risk of Ventilator associated pneumonia:**- Most of the studies [Rodriguez **(15),** Blot **(44)**] showed that the risk of acquiring pneumonia was unchanged by the timing of tracheostomy Lesnik's**[11]** study, however, showed that incidence of pneumonia was significantly lower in early tracheostomy group. In our study too, incidence of VAP in early tracheostomy group was not statistically significant from that in late tracheostomy group i:e timing of tracheostomy did not alter the incidence of VAP
5. **Length Of Stay (LOS) in Intensive Care Unit (ICU):-**Rodriguez**[15]** and Rumbak's**[29]** study showed that LOS in the critical care unit was significantly lower in early tracheostomy group . Our study also proved the same.
6. **Tracheostomy Complications:-**In both our and Rodriguez's**[15**] study, complication rates of tracheostomy were low in both early and late tracheostomy groups (4% in Rodriguz study and 6% in our study.)
7. **Mortality:-** all the studies including ours proved that mortality rates were not altered by the timing of tracheostomy..

Data point	**Rodriguez**	**Lesnik**	**Blot**	**Dunham**	**El-Nagger**	**Our study**
Randomization method	Yes	None	None	Yes	yes	Yes
Population	adult (n=106)	adult (n=111)	adult (n=53)	adult (n=74)	Adult (n=52)	Adult) (n=100)
Early tracheostomy defined	(n=51) ≤ 7days	(n=32) ≤4 days	(n=20) 2 days	(n=34) 3-4 days	(n=26) 3 days	(n=50) ≤5 days
Late tracheostomy defined	(n=55) ≥8 days	(n=69) >4 day	(n=33-12) ≥7 days	(n=40-12) ≥14 days	(n=26-?) >10-11 days as needed	(n=50) >5 days
Long term follow up	Hospital stay	ICU only	Hospital stay	4-12 months	ICU only	ICU only
Length of ventilation						
Early	12±1	6±3.4	23.8±21.1	N\A	N\A	7.9±2.9
Late	32±3	20.6±12.2	13.3±12.2	N\A	N\A	11.5±2.9
Length of ICU stayed						
Early	16±1	N\A	28.2±24.2	N\A	N\A	8.9±2.9
Late	37±4	N\A	18.8±17.8	N\A	N\A	12.5±3.0
Hospital Stay						
Early	34±4	N\A	30.5±25.9	N\A	N\A	N\A
Late	51±4	N\A	22.6±20.8	N\A	N\	N\A

					A	
Complications from tracheostomy						
Early	4%	Yes	5%	N\A	N\A	6%
Late	4%	Yes	N\A	N\A	N\A	6%
Death from tracheostomy						
Early	0%	0%	N\A	N\A	N\A	0%
Late	0%	0%	N\A	N\A	N\A	0%
Incidence of Pneumonia						
Early	78%	19%	10%	N\A	N\A	20%
Late	96%	59%	9%	N\A	N\A	24%
Incidence of tracheal stenosis						
Early	2%	N\A	N\A	17.6%	N\A	N\A
Late	2%	N\A	N\A	12.5%	N\A	N\A
Long term complications	N\A	N\A	N\A	N\A	N\A	N\A

Although our study supports early tracheostomy because of the potential benefits of shorter duration of mechanical ventilation and shorter stay in the intensive care unit, yet premature or ill advised placement of a tracheostomy tube may not represent an appropriate balance of risk. To avoid this problem, attempts should be made to develop the criteria that can predict the probability of patients requiring prolonged mechanical ventilation and thus allowing better selection of patients likely to benefit from early tracheostomy. However, till date no validated specific or sensitive test or scoring system is available that predicts the need for prolonged ventilation in critical care population, so the selection of patients for tracheostomy remains a subjective decision.

V. Limitations

Strengths of our study include its prospective design, homogenous cohort etc. but at the same time our study had its share of limitations too which can be summed up as:

1. Our study was conducted from a single centre i.e surgical intensive care unit (SICU) of Sheri Kashmir Institute of Medical Sciences (SKIMS) hospital. Ideally a large multicentric, randomized, controlled trial is needed to corroborate our findings.
2. Secondly our study period was limited to ICU only. No hospital follow up and post discharge follow up of patients was done. Even patients who were shifted back to SICU from high dependency unit for restarting of mechanical ventilation were excluded from the study.
3. GCS was taken as the primary criteria for taking a decision on tracheostomy. Although SAPS II scores were also taken into consideration, but GCS<8 was the prime deciding factor for performance of tracheostomy. Thus we may have created a bias in selecting patients for tracheostomy. Other factors like injury severity score (ISS), emergency room trauma score (ERTS), Acute injury score (AIS) etc which are important positive predictors of tracheostomy should have been taken into consideration before taking up patients for tracheostomy.
4. Quasi-randomisation method based on hospital MRD (Medical Records Department) Numbers was employed in our study. The ideal would have been a true randomization method.
5. Only early and immediate complications of tracheostomy were noted Late complications or long term sequlae of tracheostomy were not examined in our study.

VI. Summary

This prospective, randomized study entitled "Impact of Early Tracheostomy on Withdrawl of Mechanical Ventilation in Severe Head Injury Patients - A Comparison with Late Tracheostomy" was conducted in the department of Anesthesiology and Critical Care, SKIMS, Srinagar from 2006 to 2009. The study included 100 patients with severe head injury having GCS<8 admitted to surgical intensive care unit for mechanical ventilation. The patients were managed as per ATLS protocol and mechanically ventilated before a decision to perform tracheostomy was taken. Patients would be sedated and paralysed for first 48 hrs. After 48 hours , patients would be weaned off sedation and reassesed ,those patients who continued to have a GCS score <8 for more than 48 hours and requiring prolonged ventilation were to undergo randomly either early tracheostomy (within 5 days) or late tracheostomy (more than 5 days). Randomisation was done on the basis of hospital MRD (medical records department) numbers. Those patients with odd MRD numbers were assigned to early tracheostomy group (within 5 days) while those with even MRD numbers were assigned to late

tracheostomy group (after 5 days). Tracheostomy was performed by a neurosurgical resident with a standardized (open) technique.

Early tracheostomy was defined as the one performed within five days of initiation of mechanical ventilation and late tracheostomy as the one performed beyond five days of initiation of mechanical ventilation.

Observations were made from :-

Early Tracheostomy / Group I

Late Tracheostomy / Group II

Following parameters were recorded and evaluated statistically using standard statistical tests.

1) Age
2) Sex
3) Weight
4) Glasgow Coma Score (GCS) Scale
5) Simplified Acute Physiology Score II (SAPS II)
6) Total duration of Mechanical Ventilation in ICU
7) Length of Stay in ICU
8) Incidence of ventilator associated pneumonia(VAP)
9) Surgical Interventions
10) Mortality/Outcome in ICU

Following observations were made.

1. There was no statistically significant difference ($p>0.05$) between early and late tracheostomy groups in respect of demographic characteristics such as age, gender, and weight.
2. Glasgow Coma Scale (GCS) and SAPS II scores were comparable in both the groups & revealed a statistically insignificant difference ($p>0.05$)
3. Although incidence of VAP was higher (24%) in late tracheostomy group compared to early tracheostomy group (20%) but the difference was not statistically significant ($p=0.233$)
4. Total duration of mechanical ventilation in early tracheostomy group (group I) varied between 3 to 19 days with a mean of 7.9 ± 2.9 days while in the tracheostomy (group II) it ranged between 8-25 days with a mean of 11.5 ± 2.9 days . Thus total duration of mechanical ventilation in early tracheostomy was significantly shorter ($p=0.000$).
5. The length of stay (LOS) in ICU in early tracheostomy group was shorter as compared to late tracheostomy group and this difference was statistically significant ($p=0.000$). The length of stay in ICU in early tracheostomy (group I) varied between 4-20 days with an average length of stay of 8.9 ± 2.9 days while in late tracheostomy (group II), length of stay in ICU veried between 9-26 days with an average length of stay of 12.5 ± 3.0 days.

In early tracheostomy group, 6% of patients had prolonged length of stay (>14 days) in SICU while in late tracheostomy group, 16% of patients had prolonged length of stay in SICU. Overall difference was statistically insignificant.

6. Mortality rates in the two groups were not affected by the timing of tracheostomy. In the early tracheostomy group, mortality was 8% while in late tracheostomy group, mortality was 6%. Overall difference in mortality between the two groups were statistically insignificant ($p= 0.697$). Cardiovascular instability & severe brain edema were the major causes of death in early tracheostomy group and in late tracheostomy group, sepsis was the major cause of mortality.
7. Timing of the tracheostomy did not affect the operative outcomes in the two groups. In early tracheostomy group, 28.6% of the operated patients died while in late tracheostomy group, mortality was 21% in operated patients. Overall difference in mortality was insignificant ($p=1.000$).
8. Morbidity rates of tracheostomy were low in both groups. In early as well as late group, 6% of patients had complications related to tracheostomy. Main complications related to tracheostomy were surgical emphysema, pneumothorax, displacement of tracheal tube. No death in either of the groups was attributable to tracheostomy.

VII. Conclusions

Our study involving a homogenous patient population admitted to a surgical critical care setting after severe head trauma revealed several important findings:-

1. Early tracheostomy benefits the severly injured patient who requires more than 7 days of mechanical ventilation.
2. Early tracheostomy in patients with isolated severe head injury decreases duration of mechanical ventilation and intensive care unit days. Thus early tracheostomy may allow for earlier discharge from ICU.

3. By reducing the length of ICU stay, early tracheostomy can have long term implications on cost containment, especially in our scenario where ICU facilities are scarce.
4. Timing of tracheostomy did not alter the incidence of the ventilator- associated Pneumonia (VAP).
5. Tracheostomy is a safe procedure and the morbidity rates of tracheostomy are low. It can be performed with no deaths as a result of the procedure.
6. Early tracheostomy has not been found to provide a survival benefit for its recipients. So effect of early tracheostomy on mortality remains to be seen.
7. Operative outcomes are not affected by timing of tracheostomy.
8. Large and more scientifically rigrous, prospective randomised studies need to be undertaken before we can answer the critical question, "tracheostomy in whom and when?" In addition, predictors of prolonged ventilatory support in trauma need to be validated in large studies. Such predictors are likely to help in selecting patients who will benefit from early tracheostomy. By adopting a standardized method for selecting patients who will require early tracheostomy, prolonged ICU and hospital stay will be avoided and this will be certainly helpful in better resource utilization.

Heffner [2003] said it best when he observed that "tracheostomy is a complex medical decision that defies simple solutions". Over 90 years ago, Jackson [1921] stated that we all preach doing it (tracheostomy); but almost always do it late.

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