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# The Effect of Tracheostomy Timing in Critically Ill Patients Undergoing Mechanical Ventilation

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# Abstract :

**Background:** The ideal timing of tracheostomy in intensive care units (ICUs) for critically ill patients undergoing mechanical ventilation (MV) is still a matter of debate. The aim of this work was to determine and analyze the proper timing of tracheostomy and its impact on various clinical outcomes of adult patients in ICUs undergoing MV. **Material and Methods:** This prospective cohort observational study was carried out on 43 critically ill patients on MV in ICU patients aged  $\geq 18$  years old, both sexes, expected to be on prolonged MV. Patients were divided into two groups: Early tracheostomy (ET) group (n=20), who submitted to tracheostomy within 10 days post intubation. and late tracheostomy (LT) group (n=23), who submitted to tracheostomy between 11- and 21 days post intubation.

The correlation between the timing of tracheostomy of each group and various associated ICU clinical parameters were analyzed.

**Results:** There was a positive correlation between ventilator-associated pneumonia (VAP) and mortality (P = 0.013) which was statistically significant. There was a negative correlation between mortality and length of ICU stay (P=0.009), and duration of sedation (P=0.028) in ET **Conclusions:** ET had a notable benefit in VAP incidence, shortening the duration of the MV, lessening the sedation time, minimizing the risks of weaning failure and decreasing length of overall ICU stay, but it had no significant impact on mortality.

Keywords: Tracheostomy Timing; Critically; Mechanical Ventilation; Intensive Care Unit

# 1. Introduction:

Tracheostomy is commonly recommended for critically ill patients in Intensive Care Units (ICUs) who are on prolonged mechanical ventilation (MV). Its purpose is to facilitate the patient's weaning from the ventilator machine <sup>[1]</sup>. It has numerous advantageous effects, including reduced tracheal or laryngeal nociceptive stimuli, enhanced pulmonary mechanics, decreased need for analgesics and sedatives, enhanced communication simplified nutrition and oral hygiene <sup>[1]</sup>. Nevertheless, certain complications may arise in relation to the surgical technique employed <sup>[2]</sup>.

However, the optimal moment to execute the tracheostomy has been a subject of contention for the past twenty years. According to some international surveys, Tracheostomy should be performed seven after intubation<sup>[3]</sup>. fifteen davs to Nevertheless, there is considerable variation in the definition of early versus late tracheostomy (LT) timing across a multitude of studies. Certain reviews

specify whether the time is before or after seven days <sup>[4]</sup>, 2015 Cochrane Review <sup>[5]</sup> of randomized controlled trials (RCTs) reclassified tracheostomies performed after 10 days post-intubation as late and those performed before 10 days post-intubation as early<sup>[6]</sup>.

Additionally, certain studies proposed that early tracheostomy (ET) was more correlated with favorable outcomes compared to LT<sup>[7]</sup>, whereas other studies expressed dissent towards this conclusion <sup>[8]</sup>. However, it is crucial to tailor the tracheostomy technique to consider the patient's pathology, desired course of recovery, anticipated recovery period, risk associated with continuous endotracheal intubation, ventilator machine support, and surgical procedure complications<sup>[9]</sup>.

As a result, numerous researchers have asserted that determining the ideal time to perform a tracheostomy in intensive care unit (ICU) patients who are mechanically ventilated continues to be a clinically complex matter, characterized by substantial variations in implementation <sup>[10]</sup>.

Motivated by this quandary, the current investigation was conducted to ascertain the most opportune moment to conduct tracheostomies on critically ill patients in the ICU who are undergoing MV and to evaluate the effect this timing has on the clinical outcomes of these patients.

The purpose of this trail was to ascertain and examine the correlation among ET or LT timing and a range of concomitant outcomes.

# 2. Patients and Methods:

This prospective cohort observational study was carried out on 43 critically ill patients on MV in ICU patients aged  $\geq 18$  years old, both sexes, expected to be on prolonged MV.

An informed written consent was obtained from the patient or relatives of the patients. The study was done after approval from the Ethical Committee Tanta University Hospitals (approval code 34353/12/20).

# **Exclusion criteria**:

- Anatomical anomalies of the neck that would impair the tracheostomy procedure (e.g., absence of cervical trachea, severe tracheomalacia, and high riding innominate or thyroid internal mammary artery)
- 2. Soft tissue infection of the neck

- 3. Previous tracheostomy
- 4. Coagulation disturbances

Patients were separated to two groups: ET group (n=20), who agreed to tracheostomy within 10 days post intubation. and LT group (n=23), who agreed to tracheostomy between 11- and 21 days post intubation. Every individual was provided with sociodemographic data including sex and age, taking history from patients` relatives: medical history including cardiac disease (e.g. heart failure or ischemic heart disease), diabetes mellitus, chest disease (e.g.chronic obstructive pulmonary disease asthma), or bronchial or immunecompromise state, special habits including smoking, and medications cigarette including anticoagulants (e.g; Plavix, aspirin, warfarin, and NOACs), Clinical examination comprising the following: general examination (including respiration rate, temperature, oxygen saturation by pulse oximeter (SPO<sub>2</sub>), body weight, and heart rate), and systemic examination (including the abdomen, chest, and central nervous system). routine laboratory tests, including culture and sensitivity (sputum and blood), and radiological tests for ICU patients: Chest x-ray using portable X-Ray machine, and CT chest for all patients.

Propofol was administered intravenously to all patients in both groups, with the exception of those who presented with circulatory failure, who were sedated with midazolam. In instances where analgesia was required, fentanyl was administered concurrently with sedatives via infusion. The infusion of propofol commenced at 0.3 mg/kg/h; thereafter, the dosage was escalated by 0.1 to 0.2 mg/kg/h every two minutes until adequate sedation was achieved, with a maximum dose of 3 mg/kg/hr. Continuous infusions of 0.7 to 10 g/kg/h of Fentanyl were administered until pain was managed. Ventilation parameters for each patient were adjusted in accordance with predicted body weight and underlying pathology. The target range for SPO<sub>2</sub>, as determined by pulse-oximetry, was 88% to 92% for patients with COPD and 92% to 96% for all other patients.

The tracheostomy procedure and timing were determined in collaboration with the attending consultants and ENT consultants. Tracheostomy is performed in our ICU using two distinct techniques: surgical tracheostomy, which requires the patient to be transported to the operating room and is performed by ENT physicians; and percutaneous dilatational tracheostomy (PDT), which is performed bedside in our ICU under bronchoscopic guidance by our professional staff.

Individual consideration should be given to the surgical risks of tracheostomy, the anticipated course of recovery, and the potential for ongoing trans-laryngeal intubation when determining whether to place a tracheostomy. Tracheostomy insertion was determined by a number of factors, including the frequency of weaning failures, the expectation of prolonged MV, and the duration of the MV. **Figure 1** 



A



В



Figure 1: (A) Percutaneous tracheostomy kit, (B) ) introducing dilator along guide wire during PDT, and (C) percutaneous tracheostomy performed

addition aforementioned In to the ICU considerations. the personnel conducted round-the-clock monitoring of the patients to assess whether their medical condition warranted their removal from MV. The assessment considered every accessible resource pertaining to the timely identification and management of potential adverse events, in addition to the oversight of prescribed sedative and analgesic drug dosages. The drugs were administered through a process of continuous dripping interspersed with intervals.

Critical is the timing of MV weaning. Therefore, it is imperative to establish specific criteria that can be employed to evaluate the efficacy of the weaning trial.

In this particular segment, clinical judgment and objective indicators that aid in the decision-making process were integrated. Precise indicators would prevent unwarranted extension of MV by aiding in the timely detection of individuals

who are weanable. In addition, markers may be employed to identify physiological irregularities associated with unsuccessful weaning.

Weaning parameters encompass an assortment of indices, including but not limited to

- 1. Endurance
- 2. Respiratory muscle strength
- 3. Effort of breathing and respiratory drive
- 4. In addition to composite indices

As soon as the patient's health condition satisfies the estimated criteria for weaning, which, in accordance with our protocol, are as follows: positive end expiratory pressure (PEEP) ranging from 3 to 8 centimeters of H<sub>2</sub>O; fraction of inspired oxygen (FiO<sub>2</sub>) below 0.4 to 0.5 liters per minute; hemodynamic stability (excluding the use of vasoconstrictor agents; absence of severe cardiac arrhythmias). The participants underwent the following interventions: synchronized intermittent MV; sedation removal if the patient was able to tolerate MV without sedation; airway, pressure, and ventilation support (while maintaining 20-28 breaths per minute of spontaneous respiration); progressive reduction of positive airway pressure support; gradual decrease in PEEP; and intermittent T-piece for a trial of spontaneous breathing as the patient's condition improved.

Consequently, the cessation of MV was deemed effective provided that it persisted for a duration exceeding 72 hours. Following the completion of the weaning process and tracheostomy, the individuals were transferred to the long-term care facility while being closely monitored on a regular basis, barring any obstacles caused by concurrent medical conditions.

The weaning procedure was deemed unsuccessful when signs of acute respiratory distress were observed, including:

- An increase in positive airway pressure support demand synchronized with an increase in mandatory ventilation rate,
- As confirmed by the patient's clinical symptoms and the following parameters: heart rate > 120 beats per minute, respiratory rate > 30 mmHg, PaO<sub>2</sub> < 60 mmHg, systolic blood pressure < 90 mmHg or >180 mmHg.

# Diagnosing ventilator-associated pneumonia (VAP):

It required a comprehensive evaluation of the patient, including a computed tomography and chest X-ray, microbiological analysis of respiratory secretions, and a strong clinical suspicion. Our clinical diagnostic criteria for VAP in addition to a new and persistent (>48-hour) infiltrate on chest radiograph included two or more of the subsequent: (i) A fever that exceeds 38.3°C, (ii) Tracheobronchial secretions that are purulent, and/or (iii) Leukocytosis that surpasses  $12 \times 109/ml$ [11]

The utilization of tracheobronchial secretions to diagnose venous thromboembolism (VAP) exhibited a sensitivity of 69% and a specificity of 75%. The clinical pulmonary infection score was developed as a composite clinical metric to address the limited specificity of qualitative evaluation of endotracheal aspirates and clinical diagnosis of VAP. This score was composed of the following the semiquantitative culture of tracheal aspirate, blood leukocyte temperature, count, volume and purulence of tracheal secretions, oxygenation, and pulmonary radiography are the six variables. The range of possible scores was 12. A CPIS greater than six indicated a sensitivity of 93% and a specificity of 100% <sup>[12]</sup>.

Illness with ventilator-acquired pneumonia constituted the principal outcome. Mortality, duration of sedation, duration of MV support according to our regimen of sedation and anesthesia, duration of the weaning process trials, and overall ICU stay constituted the secondary outcomes.

#### Statistical analysis

Illness with ventilator-acquired pneumonia constituted the principal outcome. The secondary outcomes included mortality, sedation duration, MV support duration as per our sedation and anesthesia protocol, weaning process trial duration, and overall ICU stay.

# 3. Results:

In this study, 77 patients were assessed for eligibility, 21 patients did not meet the criteria and 13 patients refused to participate in the study. The remaining 87 patients were randomly allocated into two groups (ET group was 20 patients, and LT group was 23 patients). All allocated patients were followed-up and analysed statistically. **Figure 2** 



Figure 2: CONSORT flowchart of the studied patient

Complications (Localized surgical emphysema, subglottic stenosis, minor bleeding, pneumothorax, TOF, and No), VAP, and of tracheostomy were statistically significant in LT than in ET, with P value=0.020, 0.001, respectively. Weaning success was statistically significant in ET compared to LT, with P value <0.001. There were no statistically significant differences observed among groups regarding demographic characteristics (gender and age indications of intubation (including chest trauma, TBI, COPD, circulatory failure, poly-trauma (RTA), cervical spine injury, and upper airway obstruction), or tracheostomy technique (surgical, and percutaneous). **Table 1** 

		ET (n=20)	LT (n = 23)	P value	
Age (years)		$41.9 \pm 14.53$	$44.43 \pm 17.31$	0.609	
Gender	Male	14 (70%)	14 (60.87%)	0.531	
	Female	6 (30%)	9 (39.13%)		
	Chest trauma	2 (10%)	4 (17.39%)		
	TBI	3 (15%)	4 (17.39%)	0.058	
	COPD	1 (5%)	6 (26.09%)		
Indication of intubation	Circulatory failure	2 (10%)	1 (4.35%)		
	Poly-trauma (RTA)	2 (10%)	5 (21.74%)		
	Cervical spine injury	4 (20%)	3 (13.04%)		
	Upper air way obstruction	6 (30%)	0 (0%)		
Type of	Surgical	19 (95%)	21 (91.3%)	0.625	
tracheostomy	Percutaneous	1 (5%)	2 (8.7%)	0.635	
Complications	Localized surgical emphysema	2 (10%)	7 (30.43%)		
	Subglottic stenosis	0 (0%)	2 (8.70%)		
	Minor bleeding	1 (5%)	3 (13.04%)	- 0.020* -	
	Pneumothorax	1 (5%)	1 (4.35%)		
	TOF	1 (5%)	5 (21.74%)	]	
	No	15 (75%)	5 (21.74%)	]	
VAP		7 (35%)	19 (82.61%)	0.001*	
Weaning	Failed	5 (25%)	18 (78.26%)		
	Successful	15 (75%)	5 (21.74%)	<0.001*	

Table 1: Demographic data, indications of intubation, type of tracheostomy, complications post tracheostomy, VAP, and weaning of the studied groups

Data are presented as mean  $\pm$  SD or number (%). RTA: Road traffic accident, TBI: traumatic brain injury, COPD: chronic obstructive pulmonary disease TOF: trachea-esophageal fisula, VAP: ventilator-associated pneumonia. \*: significant as P value < 0.05

Upper air way obstruction was statistically significant in successful weaning than failed weaning with P value 0.016, while no significant difference was observed regarding chest trauma, TBI, COPD, circulatory failure, poly trauma, and cervical spine injury. **Table 2** 

 Table 2: Relation between weaning rates and indications of intubation of the studied groups

		Failed weaning (n=23)	Successful weaning (n=20)	P value
Indication of intubation	Chest trauma	4 (66.7%) LT=4	2 (33.3%) ET=2	0.797
	TBI	2 (28.57%) LT=2	5 (71.43%) LT=2 ET=3	0.302
	COPD	6 (85.71%) LT=5 ET=1	1 (14.29%) LT=1	0.145
	Circulatory failure	3 (100%) LT=1 ET=2	0 (0%)	0.282
	Poly trauma	5 (71.43%) LT=5	2 (28.57%) ET=2	0.531
	Cervical spine injury	3 (42.86%) LT=1 ET=2	4 (57.14%) LT=2 ET=2	0.839
	Upper air way obstruction	0 (0%)	6 (100%) ET=6	0.016*

Data are presented as number (%). TBI: traumatic brain injury, COPD: chronic obstructive pulmonary disease. \*: significant as P value < 0.05

ET had significantly shorter durations of MV and sedation than LT (P 0.001) in terms of statistical significance. Statistically, there was no difference in mortality among two groups. **Table 3** 

Table 3: Duration of MV, duration of sedation, ICU stay in days, and mortality of thestudied groups

	ET (n=20)	LT (n = 23)	P value
<b>Duration of MV</b>	$6.2\pm2.84$	$19.22 \pm 4.85$	<0.001*
Duration of sedation	$9.25 \pm 5.5$	$25.39 \pm 7.05$	<0.001*
ICU stay in days	$14.5 \pm 8.74$	$32.3 \pm 9.35$	<0.001*
Mortality	5 (25%)	10 (43.48%)	0.205

Data are presented as mean  $\pm$  SD or number (%).MV: mechanical ventilation, ICU: intensive care unit. \*: significant as P value < 0.05

A statistically significant positive correlation was observed among VAP and mortality (r = 0.544, P = 0.013). In ET, both the length of sedation (r=-0.489 and P=0.028) and the duration of ICU stay (r=-0.562 and P=0.009) were negatively correlated with mortality. There was no observed correlation between the duration of sedation, MV, VAP, ICU stay, or length of stay and mortality in the LT and early groups. **Table 4** 

	Mortality	
	R	P- value
VAP in ET group	0.544	0.013*
Duration of MV in ET group	-0.375	0.070
VAP in LT group	0.060	0.784
Duration of MV in LT group	-0.255	0.259
Length of ICU stay in ET group	-0.562	0.009*
Length of ICU stay in LT group	-0.239	0.271
Duration of sedation in ET group	-0.48961	0.028*
Duration of sedation in LT group	-0.29367	0.173

Table 4: Correlation between mortality and VAP, duration of MV, length of ICU stay, and duration of sedation in early and LT group

r: correlation coefficient, VAP: ventilator-associated pneumonia, MV: mechanical ventilation, ICU: intensive care unit. \*: significant as P value < 0.05

# **Case presentation**

# Case 1:

Age: 43 years, sex: male, indication of intubation: TBI, duration of MV before tracheostomy: 11 days (late tracheostomy), type of tracheostomy: surgical, duration of MV post tracheostomy: 12 days, duration of sedation: 23 days, weaning: failed, chest imaging: chest X-ray showing diffuse infiltrates, CPIS: 8, VAP: yes, LOS in ICU: 30 days, mortality: patient died, cause of death: severe ARDS, and moderate TBI. This is one of our cases who was MV for 11 days, surgical tracheostomy performed in day 12. The patient clinical diagnostic criteria of VAP were fever up to 40oC, leukocytic count 15,000 mm3, PF ratio 312, abundant and purulent tracheal secretions and ETAs was positive for Klebsiella. The CXR had diffuse infiltrates. With CPIS of 8. **Figure 3** 



Figure 3: (A) Patient with late tracheostomy, and (B) CXR with diffuse infiltrates

#### Case 2:

Age: 65 years Sex: female, indication of intubation: COPD, duration of MV before tracheostomy: 10 days (ET), type of tracheostomy: percutaneous duration of MV post tracheostomy: 10 days duration of sedation: 20 days, weaning: failed, chest imaging: localized infiltrates, CPIS: 9, VAP: yes, LOS in ICU: 21 days, mortality: patient died, and cause of death: ARDS, septic shock. This is one of our cases who was admitted to our ICU after a severe COPD exacerbation, patient was MV for 10 days then PDT done bed side and patient continued on MV for 10 days more. Patient failed weaning, developed VAP with positive sputum culture and chest X- ray showing bilateral localized infiltrates. CPIS was 9. Unfortunately, patient died with total LOS 21 days. **Figure 2** 



Figure 4: (A) Early PDT performed in our ICU for COPD patient, and (B) chest X ray showing localized infiltrates bilateral

# 4. Discussion:

When necessary, tracheostomy is frequently performed to facilitate long-term airway management for critically ill ICU patients on MV. Although this concept has remained unchanged, its current timing remains a subject of contention and requires further examination, as it primarily relies on the physician's prognosis concerning the necessity for prolonged MV rather than empirical evidence-based practice. <sup>[13]</sup>. Tracheostomies done within ten days of intubation were classified as early in our study, encompassing twenty patients. Tracheostomies performed between day eleven and day twenty-one were classified as late, encompassing twenty-three patients. With respect to the timing of tracheostomy, our research concurs with that of Andriolo et al., <sup>[5]</sup> and Khammas and Dawood, <sup>[1]</sup>.

There is variation among other studies with respect to the precise delineation of early and LT timing. In their study, Robba et al <sup>[14]</sup>, Early ( $\leq$  7 days upon admission) or late (> 7 days upon admission) tracheostomy was defined.

With respect to VAP as the principal outcome in our research, the LT group exhibited a significantly higher incidence of VAP in comparison to the ET group. Only seven patients out of twenty (35%) in the ET group had VAP, compared to 19 out of 23 (82.61%) in the LT group who had it. Consistent with our research, Cai et al. <sup>[15]</sup> conducted a meta-analysis of 20 studies comprising 3,305 patients in the ET group and 4,446 patients in the LT/PI group; ET was linked with a significantly reduced risk of pneumonia.

In disagreement with our study, Khammas and Dawood, <sup>[1]</sup> VAP was the most prevalent morbidity identified in this study, affecting 17 cases (25.37%), with 7 cases (23.33%) in the ET group and 10 cases (27.02%) in the LT group. Neither of these differences was statistically significant.

Weaning was considerably more successful in the ET group compared to the LT group in our trail. The rate of successful weaning was considerably greater in ET (15 patients out of 20) than in LT (5 patients out of 23). Bickenbach et al. <sup>[16]</sup>were in contrast to our findings, there was non significant difference in the duration of weaning among the groups.

In our trail, the duration of MV after tracheostomy was found to be significantly longer in the LT group as compared to the ET group. This finding was also reported in numerous other studies, including Khammas and Dawood <sup>[1]</sup> The primary finding of this research was that the ET group exhibited a significantly decreased duration of MV in comparison to the LT group.

The difference among the late group and the ET group in terms of median reduction in ventilation time by three days was not statistically significant, according to Bosel et al. <sup>[17]</sup> The ET group had a significantly shorter duration of sedation (9.25 mean days) in comparison to the LT group (25.39 mean days), which was the secondary outcome of our study.

As a secondary outcome, the duration of sedation was found to be significantly shorter in the ET group (9.25 mean days) than in the LT group (25.39 mean days) in our trail.

Consistent with our research findings regarding the length of time spent in sedation following a tracheostomy procedure. Dawood and Khammas, <sup>[1]</sup> The results of this research demonstrated a sedation time reduction in the ET group (3-8 days) that was statistically significant when compared to the LT group (7-17 days). This aligns with our research outcomes concerning the length of time patients remain sedated following tracheostomy surgery.

While Blot et al., <sup>[18]</sup> This study contradicted our findings that there was non statistically significant difference among the ET and LT groups in terms of sedationfree days.

In regard to the total length of time spent in the ICU as a secondary outcome, the ET group displayed a range of 4-37 days with an average of 14.5 days. In contrast, the LT group exhibited a range of 19-55 days with an average of 32.3 days. Statistically, the difference among the two groups was significant. Robba et al. <sup>[14]</sup>documented a result that closely resembled our own. Patients who had sustained brain injuries were included in this research. The tracheostomy was categorized as early ( $\leq 7$ days from the date of admission) or late (> 7 days from the date of admission). This study's findings indicate that ET is associated with a shorter length of ICU stav.

Combes et al. <sup>[19]</sup> discovered that the ET group had a marginally lower average number of ICU days, but non-significant differences between the groups were found. Our research identified the death of 5 out of 20 patients in the ET group and 10 out of 23 patients in the LT group as secondary outcome mortality. Although lower, mortality was not statistically significant in the ET group. In agreement with our findings, Tang et al., <sup>[20]</sup> compared early and long-term outcomes in a sample of Covid-19 intensive care unit patients. Tracheostomies performed after 14 days were associated with a higher mortality rate than those performed earlier (prior to 14 days), according to the findings.

In disagreement with our findings, Cai et al., <sup>[15]</sup> demonstrated that prolonged intubation/ET may be a more effective approach in reducing mortality among trauma patients compared to ET.Following this study, we suggested that additional research be undertaken involving a greater number of patients in order to more accurately assess potential distinctions in outcomes between early and long-term therapy for critically ill patients. Further studies on this topic are also needed to determine the of proper timing tracheostomy in ICU MV patients.

Limitations: The size of sample was comparatively modest. The research was conducted at a single facility. The duration of patient follow-up was comparatively brief.

# 5. Conclusions:

ET compared to LT was found to be coinciding with better results regarding primary outcome, VAP in MV patients in ICU. Also, ET compared to LT was found to be coinciding with better results regarding weaning successful trials and secondary outcome results including, length of ICU stays, duration of sedation, mortality and duration of MV.

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