Original Article

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TANAFFOS

Beneficial Outcomes of Early Tracheostomy in Patients Requiring Prolonged Mechanical Ventilation

Danial Samiei Nasr [1], Batoul Khoundabi [2], Golara Monshizadeh Azar [3], Majid Malekmohammad [4], Hamidreza Jamaati [1], Seyed Mohammadreza Hashemian [1]

[1] Chronic Respiratory Disease Research Center (CRDRC), National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran, [2] Iran Helal Institute of Applied-Science and Technology, Research Center For Health Management in Mass Gathering, Red Crescent Society of the Islamic Republic of Iran, Tehran, Iran, [3] Shahid Beheshti University of Medical Sciences, Tehran, Iran, [4] Lung Transplantation Research Center, NRITLD, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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Correspondence to: Hashemian SMR
Address: Chronic Respiratory Disease Research Center (CRDRC), NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Email address: iran.criticalcare@yahoo.com

Background: Considering that tracheostomy is being done for huge amount of critically ill patients, the ideal time for this procedure is still controversial among different intensive care units (ICU).

Materials and Methods: 70 intubated patients were included in our study which was sorted into two subgroups: half of our patients received an early tracheostomy (ET) within 1-10 days post intubation and the rest received late tracheostomy (LT) within 11-21 days after getting intubated.

Results: 61.9% of the study population was male and the mean age was of 54 + 10.5 years. ET group mean Mechanical Ventilation (MV) duration was 8.11±4.9 days and was 16.3 ± 6.01 in the LT group ($p<0.05$) with a mean sedation duration of 6.1 ± 4.4 vs. 12.0 ± 6.5 (ET vs. LT) ($p<0.05$). Mean time of weaning process from ventilator was 2.7 ±2.3 for ET group and 5.5 ± 5.0 for LT group ($p<0.05$). The Mean ICU stay was 18.8 ± 2.2 in the ET group, and 22.1 ± 4.1 in the LT group (p: 0.98) at the same time. Length of stay at hospital for two group of patients did not show a meaningful difference (p= 0.279).

Conclusion: Early tracheostomy decreases duration of mechanical ventilation and sedation use and more rapid weaning process in those patients who will require mechanical ventilation. Our findings revealed that tracheostomy timing has no significant impact on rate of hospital mortality and LOS at ICU and hospital.

Key words: Mechanical ventilation; Outcome; Tracheostomy

INTRODUCTION

Tracheostomy is among the most common procedures performed in critically ill patients requiring prolonged mechanical ventilation for acute respiratory failure and for airway issues, it is shown to be a safe bedside procedure in trained hands (1, 2).

Weaning process might be facilitated due to major contributory factors that tracheostomy can induce such as dead space mitigations, decreased airway resistance on the account of greater secretion clearance, mobility augmentation and less aspiration probability. Though most studies are in fact supporting the idea of reduced airway resistance and smaller dead space post tracheostomy, a broad consensus that whether these reductions can thoroughly explains the clinical observations of accelerated weaning after tracheostomy has not been attained (3, 4).

Some guidelines have mentioned that does patients which have been mechanically ventilated for more than 21 days should undergo the tracheostomy procedure (5).

There has been much discussion revolving around the optimal time for tracheostomy. Early and late tracheostomy timing has different definitions in studies have been done until now. Some define the set points as 7 days (6), but other studies such as a Review published in 2015 claims that tracheostomies performed before 10 days post intubation were the early ones, and does that were performed after 10 days were a LT (7, 8). The aim of this study is to focus on the major beneficial features of early tracheostomy (ET) in critically ill patients who require prolong ventilation.

MATERIALS AND METHODS

Study population

This study is a retrospective (case-control) study of critically ill patients in intensive care unit of Masih Daneshvari hospital whom had the indications for tracheostomy and underwent this bedside procedure. Briefly all patients in intensive care unit receiving tracheostomy where evaluated in order to assess the impact of early tracheostomy on the patient outcomes.

Of the 110 patients, those aged 17-75 years who underwent a tracheostomy procedure in Masih Daneshvari hospital ICU until March 2019, 70 patents were randomly selected and were sorted into two subgroups: half of our patients received an early tracheostomy (ET) within 1-10 days post intubation and the rest received late tracheostomy (LT) within 11-21 days after getting intubated.

This random selection was achieved by employment of random block technique. After exclusion of patients with an absolute or a relative contraindications to percutaneous tracheostomy such as coagulopathy (thrombocytes<60,000 μL, prothrombin time>40 s, international normalized ratio>1.4), having previous tracheostomy scar, severe infection at the puncture site or burn injury, those performed emergently or a cervical spinal injury that had not been internally fixed and those patients meeting one of the following criteria: anatomic variants or deformities of the larynx and trachea; a preexisting tracheostomy; pre-existing pneumonia; estimated to die within the next 24 h; a planned permanent tracheostomy (after laryngectomy); more than 3 days of ventilation before entry into the study and whom sufficient medical records could not be obtained from, 70 patients which representatively signed the informed consent were included in this study.

Measurements

Trained investigators collected data according to the study protocol. APACHE II is a severity of disease classification system that's was measured post tracheostomy in order to evaluate patients conditions. APACHE II uses a point score based upon initial values of 12 routine physiologic measurements, body temperature (degree C), mean arterial pressure (mmHg), heart rate, respiratory rate, PaO2, arterial PH or HCO3, serum potassium (mEq/L), serum creatinine, hematocrit,

WBC count (10^3/gl), Glasgow coma score (3-15), age (years) (Table 1) (9).

Table 1. APACHE score classification

APACHE II Score	Hospital mortality (%)	
	Non-Operative	Post-Operative
0-4	4	1
5-9	6	3
10-14	12	6
15-19	22	11
20-24	40	29
25-29	51	37
30-34	71	71
>35	82	87

Data from Knaus et al.(9) APACHE: Acute Physiology and Chronic Health Evaluation

The SAPS II, based on a large international sample of patients, provides an estimate of the risk of death without having to specify a primary diagnosis includes: physiology variables, body temperature (degree C or F), systolic blood pressure (mmHg), heart rate (bpm), PaO2 (mmHg)/FiO2 (%) if mechanical ventilation or CPAP, urine output (L/24h), serum Urea (g/L) or BUN (mg/dl), bilirubin (mg/dl), HCO3 (mEq/L), serum potassium (mEq/L), serum sodium (mEq/L), WBC count (cells/mm^3), Glasgow coma score (3-15), age (years), type of admission (scheduled surgical, medical, unscheduled surgical), chronic diseases (none, metastatic cancer hematologic malignancy, AIDS) (Figure 1) (10).

Procedures

There are several techniques for tracheostomy such as surgical tracheostomy (ST), percutaneous dilated tracheostomy (PDT) and modified mini-surgical PDT (msPDT).The procedure which patients underwent in this study was the modified mini surgical technique (msPDT). Former studies demonstrated that the mean value of procedural time was significantly lower in the msPDT. Paratracheal insertion, intraprocedural hypoxemia, and bleeding were also significantly lower in the msPDT(11).

All procedures were completed through a single surgical team at Masih Daneshvari hospital ICU. Data analysis demonstrated that. Other complications were not significantly different between msPDT and ST patients.

Definitions

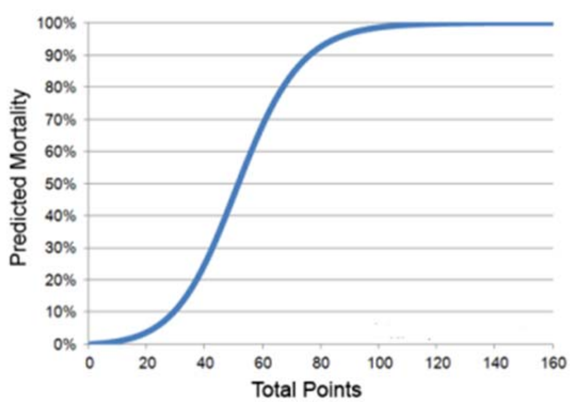
"VAP: Ventilator-associated pneumonia (VAP) is defined as pneumonia that occurs 48-72 hours or thereafter following endotracheal intubation, characterized by the presence of a new or progressive infiltrate, signs of systemic infection (fever, altered white blood cell count), changes in sputum characteristics, and detection of a causative agent as well as minor bleeding"(12).

Statistics

The data were analyzed using the statistical package IBM SPSS version 22.0 and descriptive statistics (Statistical Package for the Social Sciences, Chicago, IL). The categorical variables are expressed as proportions and frequencies. The continuous variables are summarized as means. The data variation is quantified using standard deviation. To explore the independent nature of some variables and the time length of the procedure, chi-square and *t* tests were used for independent samples, categorical, and continuous variables, respectively. *P* values less than 0.05 were considered significant.

Random block

Block randomization was used for achieving equal sample sizes in each group. For example, in ET/LT comparison, the process involved recruiting participants in short blocks and ensuring that half of the participants within each block were allocated to the "ET" group and the other half to the "LT" group. However, in each block, the order of patients was random, we considered size 4 blocks. If ET/LT is represented by E/L methods, there would be 6 different ways in which 4 patients can be split evenly between 2 methods: EELL, ELEL, ELLE, LEEL, LELE, and LLEE. Selecting the numbers' sequence "52516464635246233" via random permutation table, 40 patients were allocated to methods equally in this order: LELE, ELEL, LELE, EELL, LLEE, LEEL, LLEE, LEEL,LLEE, ELLE, LELE, ELEL, LEEL, LLEE, ELEL, ELLE, ELLE and EL. The last one is used according to a size 2 blocks.



Mortality	SAPS II Score
10%	29 pts
25%	40 pts
50%	52 pts
75%	64 pts
90%	77 pts

Figure 1. SAPS II score and mortality

RESULTS

In this retrospective case control study, of the initial 110 subjects, 70 individual with no absolute or a relative contraindications were included. The mean age was (LT 55.0±11.0, ET 53.1±10.1) years (rang 17-75) and the majority of our patients were male (62.55%).

Patients were divided regarding time of tracheostomy: ET (50%) and LT (50%). Two scoring systems, APACHE II and SAPS II were used in order to assess patient's condition pre-tracheostomy in ICU. The APACHE II score in ET and LT group was respectively 21.7 ± 2.0, 19.6 ± 1.7 which did not shows a significant difference and SAPS II score was 42.5 ± 2.0 in ET vs. 39.2±2.6 in LT group which also indicates a similar condition in two groups of patients pre-tracheostomy (Table 2).

Table 2. Basic characteristics and post tracheostomy outcomes in of study population

Items	Groups		p-value
	LT	ET	
Sex(male)	61.9%	63.2%	0.730
Age	55.0±11.0	53.1±10.1	0.301
APACHE II	19.6 ± 1.7	21.7 ± 2.0	0.200
SAPS II	39.2±2.6	42.5 ± 2.0	0.310
VAP	11.6%	13.2%	0.150

SAPS II : The Simplified Acute Physiology Score (SAPS) II estimates the probability of mortality for ICU patients, APACHE II : a disease severity scoring system which estimates ICU mortality , VAP : Ventilation Associated Pneumonia , COPD: chronic obstructive pulmonary disease

*Significant in 0.005 level

MV duration

Tracheostomy was performed 2.8 days (interquartile range (IQR) [2.2–3.6]) after intubation in the ET group.
In the LT group, patients were tracheostomized after8.1 days (IQR [6.1–10.6]). By MV duration assessment in in ICU a great difference was observed in period of time MV was needed between two group of patients (ET: 8.11 ± 4.9, LT: 16.3 ± 6.01) (Table 3).

Sedation requirement in two groups

With 12.0 ± 6.5 days sedation duration was significantly decreased in the ET group compared with the LT group (6.1 ± 4.4 days) (Table 3).

Facilitation in weaning process from ventilator

This bridging process from MV to extubation is called weaning in which mechanical ventilation is gradually withdrawn and the patient resumes spontaneous breathing. Analysis revealed great amount of reduction in days required for weaning process in ET patients suggesting that an early tracheostomy can successfully facilitate the patients weaning from ventilator.

Table 3. Comparison two groups by studied variables

Items	Mean ± SD Or n(%)		P-Value
	LT	ET	
LOS in ICU (days)	22.1 ± 4.1	18.8 ± 2.2	0.098
MV duration (days)	16.3 ± 6.01	8.11 ± 4.9	0.002
Sedation duration (days)	12.0 ± 6.5	6.1 ± 4.4	0.001
Weaning process duration (days)	5.5 ± 5.0	2.7 ± 2.3	0.025
Hospital mortality	9%	5%	0.196
Hospital LOS (days)	105 ± 7.8	99.3 ± 19.0	0.279

Length of stay in both ICU and hospital and mortality rate

Hospital and ICU length of stay was approximately the same in both group and did not show a meaningful difference. LOS in ICU for ET and LT group was 18.8 ± 2.2 vs. 22.1 ± 4.1. As for the hospital LOS (P=0.279), there was no significant difference in patients LOS at hospital, the ET (99.3 ± 19.0) and the LT group (105±7.8).

Analysis of data did not reveal a difference in mortality between ET and LT (P: 0.196) (Table 3).

DISCUSSION

Our findings demonstrated that ET has major advantage over LT in critically ill patients who were predicted to need prolonged ventilation. The MV duration is significantly reduced in the early group and the sedation duration was approximately 100% less in ET comparing to LT. More rapid weaning from ventilation was performed when the patients underwent ET.

Patients who were randomized to the delayed tracheotomy group had a mortality rate of 9% post-tracheostomy, which is enormously lower than we expected according to the APACHE II score for this group. This was the same in early group and we had a 5% hospital mortality. This is in keeping with other studies where overall hospital mortality didn't seem to be influenced by tracheostomy timing (6, 21, 26). Recently, the focus of studies that comparing early and late tracheostomy has shifted to assessment of the procedure value. There is growing body of evidence confirming our finding regarding time of ventilation which as mentioned earlier shorter duration of ventilation is required in patients receiving an ET (24, 25, 27). There also has been recent studies that showing great facilitation in weaning process from ventilator in patients undergoing early tracheostomy (14, 18).

In contrast to our study results considerable amount of publication (19, 20, 23, 26) have claimed that ET can effectively reduce the duration of stay at hospital and ICU.

An earlier meta-analysis by Griffiths et al conclude that overall the length of stay in the critical unit was

significantly lower in the early tracheostomy group (28).

But according to our analysis the LOS at both ICU and hospital was not significantly reduced in ET group comparing to LT group but on the other hand these two timing for tracheostomy have shown different results regarding MV duration, sedation requirement and the period of time needed for weaning process from the medical ventilator, where all these items were reduced in ET group.

There was 4% decline in hospital mortality in early group comparing to delayed tracheostomy. In our study, with a limited number of patients, this does not lead to a significant difference in patients' mortality. Also other study limitations we can point out is that all patients where at a single ICU center and the fact that the study was not a blind study. Therefore, decision on timing of the tracheostomy was based on the physical condition of patients and doctors opinions.

CONCLUSION

Our results reinforce the findings of previous studies showing that ET decreases the ventilator time and sedation use. Furthermore we could conclude that an ET can lead to a more rapid weaning process in those patients who will require mechanical ventilation. At the same time our findings revealed that tracheostomy timing has no significant impact on rate of hospital mortality and LOS at ICU and hospital.

Last but not least is that more randomized studies should be carried out so as to determine those patients who will benefit the most from tracheostomy.

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