Early Versus Late Tracheostomy in Mechanically Ventilated COVID-19 Patients: A Comparative Study

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Received: 01 Sep. 2022; Accepted: 24 May 2023

Abstract- The decision to perform tracheostomy during the COVID-19 pandemic has been based mainly on practical and empirical standards. Also, the amount of scientific evidence to determine the exact timing of tracheostomy in patients with severe COVID-19 on mechanical ventilation is not significant. We conducted a retrospective cohort study on mechanically ventilated COVID-19 patients from April 25, 2021 to January 25, 2022 in intensive care units of Imam Khomeini Hospital Complex, Tehran, Iran. The 30-day survival of patients was calculated and compared between patients under tracheostomy and those without tracheostomy. A number of 135 COVID-19 cases (75 patients in the intubated group and 60 patients in the tracheostomy group) were included in this study. The mean age of the population was 53.6±12.4. The overall mortality rate was 101 (74.8%). The 30-day mortality rate was significantly higher in the intubated group (90.6%) than in the tracheostomy group (55%) ($P< 0.001$). The mortality rate was 60% in the early (≤ 7 days) tracheostomy group and 50% in the late (>7 days) group. This difference was not statistically significant ($P> 0.05$). Tracheostomy is a preferred method in airway management of severe COVID-19 patients under mechanical ventilation; however, early tracheostomy during the first week of intubation may not be superior to late tracheostomy in decreasing the mortality rate.

Acta Med Iran 2023;61(6):323-328.

Keywords: Coronavirus disease 2019 (COVID-19); Late tracheostomy; Early tracheostomy; Airway management

Introduction

Over the past few decades, emerging new strains of coronaviruses has caused severe respiratory diseases (1-4). In December 2019, the first pneumonia patients with an unknown origin were detected in Wuhan, Hubei, China (5). The causative agent was identified as a novel betacoronavirus, currently named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which shares phylogenetic similarity with SARS-CoV (6,7). The World Health Organization (WHO) named the new disease COVID-19 and declared it a public health emergency (8).

The most common clinical symptoms of COVID-19 include fever, myalgia, weakness, and dry cough. However, the respiratory symptoms can progress and develop into pneumonia in some cases (9,10). In most severe clinical forms, the respiratory failure associated with COVID-19 may meet the definition of acute respiratory distress syndrome (ARDS) (11,12).

Among patients with COVID-19 admitted to hospitals, the need for invasive mechanical ventilation ranges widely from 2.3% to 33.1% (13-15). Determining the exact time for starting mechanical ventilation in ICU patients with Covid-19 and respiratory failure can be highly challenging (16). Moreover, long-time mechanical

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ventilation is usually associated with endotracheal intubation and weaning complications. Therefore, a tracheostomy can be recommended as an alternative method in patients under mechanical ventilation (17,18).

However, tracheostomy is not always beneficial for patients with respiratory diseases, including COVID-19 because tracheostomized patients can develop serious complications for several months after discharge (19). Careful considerations should therefore be taken by a multidisciplinary team during decision-making for tracheostomy (17). The decision to perform a tracheostomy on COVID-19 patients has been based mainly on practical and empirical standards, and the scientific evidence to help decision-making, especially in terms of the exact timing of tracheostomy is not sufficient (17,20).

As the point of advantages and disadvantages of tracheostomy, we compared the 30-day survival of COVID-19 patients under invasive mechanical ventilation with and without tracheostomy in this study. We also compared the survival of patients under early tracheostomy with those under late tracheostomy.

Materials and Methods

A retrospective cohort study was conducted on mechanically ventilated COVID-19 patients in intensive care units of Imam Khomeini Hospital Complex, Tehran, Iran, from April 25, 2021 to January 25, 2022. The Delta variant (B.1.617.2) of SARS-CoV-2 was reported to be dominant in Iran during that time. Patients included in the study had the following criteria:

1) aged 18–75 years

2) SARS-CoV2 RT-PCR test positive from nasopharyngeal swab or respiratory secretions

3) diagnosed with respiratory failure caused by COVID-19 as the reason for mechanical respiratory support

4) being under mechanical ventilation for more than 48 hours

5) undergone the tracheostomy performed by percutaneous dilatational tracheostomy (PDT) technique.

Exclusion criteria included patients with incomplete information files, patients who underwent emergency tracheostomy, or pregnant women.

Demographic data, vital signs, percentage of lung involvement, and clinical scores including the Glasgow Coma Scale (GCS), Acute Physiology and Chronic Health Evaluation (APACH-II) score, and Sequential Organ Failure Assessment (SOFA) score were collected from the patients' files upon admission to the ICU.

The 30-day survival of patients was first calculated and then compared between patients under tracheostomy and those without tracheostomy. The overall average survival time was also calculated for total patients and for each group. Patients with early tracheostomy (PDT was performed ≤7 days of intubation) were further compared against those with late tracheostomy (PDT was performed >7 days of intubation) (Figure 1).

The study was approved by the ethics committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1400.140).

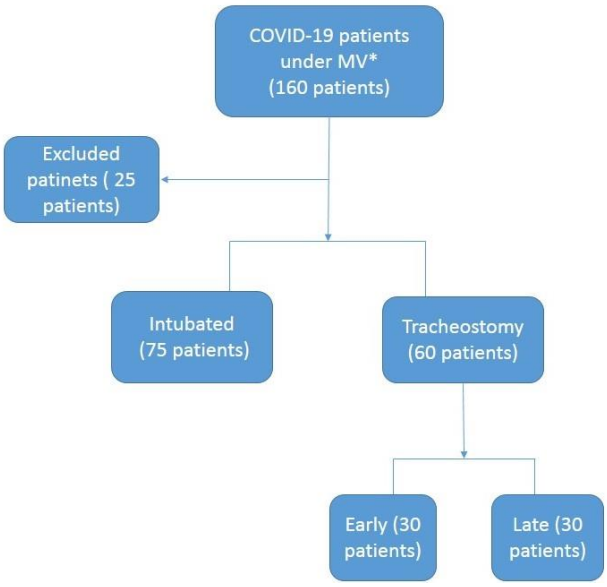

Figure 1. flowchart of the study enrollment, *Mechanical Ventilation

Statistical analysis

The SPSS software version 22 was used to analyze the data. The Kaplan-Meier method was used to analyze the 30-day survival of patients. The t-test (Mann-Whitney test if necessary) and chi-square test (Fisher's exact test if necessary) were used to compare quantitative variables between the two groups. An Alpha error level of less than 5% was considered significant.

Results

Out of 160 COVID-19 cases with the history of mechanical ventilation initially evaluated, a total of 135 patients were eligible for inclusion (75 patients in the intubated group, 60 patients in the tracheostomy group). The mean age of the population was 53.6 ±12.4, and 52.6% of the patients were male (Table 1). The most common comorbidities were hypertension and diabetes mellitus. There were no differences between the two groups in any comorbidities ($P > 0.05$). Similarly, there were no significant differences in vital signs and clinical scores of patients in the first two days of admission and in the percentage of pulmonary involvement ($P > 0.05$).

The overall mortality rate was 101 (74.8%). The 30-day mortality rate was significantly higher in intubated patients (90.6%) than in tracheostomy patients (55%) ($P< 0.001$). The survival analysis of patients in ICU showed that the overall survival was 29 days on average (median=18 days). In the group of intubated patients, the average survival was 15 days (median=12), while in the group of tracheostomized patients, the average survival was 44 days (median=34), indicating that tracheostomized patients had a significantly longer survival time (length of stay in ICU) than intubated patients ($P < 0.001$) (Figure 2).

Table 1. Comorbidity and mortality comparison between intubated and tracheostomized patients

	Intubated patients N=75	Tracheostomized patients N=60	*P*
Hypertension	35 (46.6%)	26 (43.3%)	0.48
Diabetes	39 (55.7%)	28 (46.6%)	0.33
Ischemic heart disease	8 (10.6%)	13 (21.6%)	0.08
Asthma, COPD	9 (12%)	3 (5%)	0.15
Chronic kidney disease	8 (10.6%)	2 (3.3%)	0.17
Hypothyroidism	0	1 (1.6%)	0.99
CVA	0	2 (3.2%)	0.97
Epilepsy	0	1 (1.6%)	0.99
Mortality	68 (90.6%)	33 (55%)	<0.001*

Abbreviations: COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident
* Statistically significant

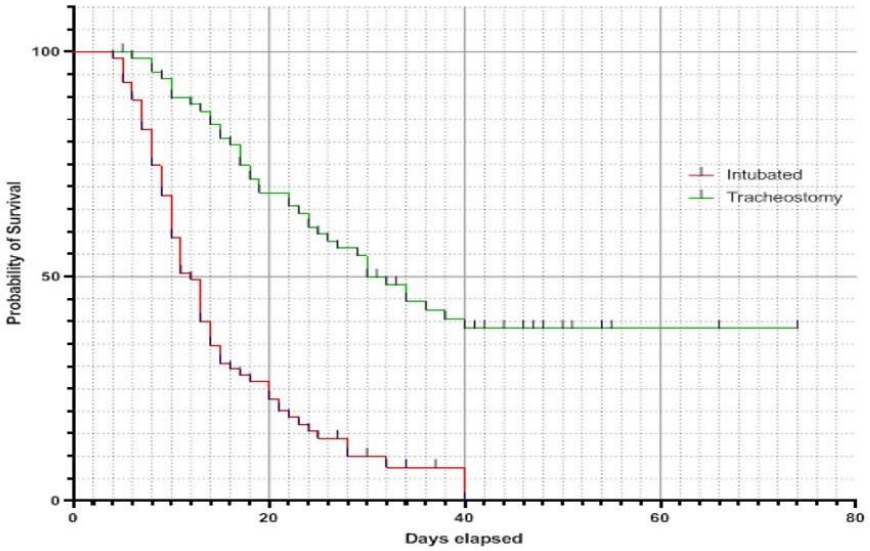

Figure 2. The 30-day survival analysis of intubated and tracheostomized patients, $P< 0.001$

Analysis of the survival in tracheostomy patients showed no significant difference (P>0.05) in the mean survival between early tracheostomy patients (41 days) and late tracheostomy patients (44 days). The overall mortality rate in tracheostomy patients was reported to be 55%. No statistically significant (P > 0.05) difference was seen between the early tracheostomy group (18/30-60%) and the late tracheostomy group (15/30-50%).

Discussion

This study confirms the lifesaving value of the tracheostomy method in critical COVID-19 patients under mechanical ventilation. Being safe for both COVID-19 patients and healthcare workers (21), tracheostomy is one of the oldest respiratory tract surgical procedure (22). The PDT procedure over a guide wire was first described in 1985, and it is increasingly performed in intensive care units (23).

The need for tracheostomy and its timing is a controversial issue, particularly in COVID-19 patients. Our results showed that tracheostomized COVID-19 patients had a significantly longer survival time than intubated patients. In several studies, Intubated COVID-19 patients, showed poor prognosis, and some were extubated (14,24-26). On the other hand, Post-extubation complications such as laryngeal edema and stridor in these patients, lead to the need for re-intubation immediately (20,21). Critical COVID-19 patients who were under intubation for an average of five days, had a short survival time of five days or less (27,28). Tracheostomy can reduce the Post-extubation complications, facilitate weaning from mechanical ventilation, decrease the length of ICU stay, and increase the availability of ICU beds during the pandemic (17). However, a longer ICU stay in the tracheostomized patients was seen in our study as the result of longer survival time in these patients, and the death of COVID-19 patients was probably associated with less access to the ICU beds.

Emergency tracheostomy may be performed in airway or threatened obstruction, laryngeal edema, or failed extubation due to weakness, weak cough, and profuse secretions for non-COVID-19 and COVID-19 patients (17,20). Patients who underwent the emergency tracheostomy due to obstructive reasons were excluded from our study.

Time of tracheostomy in COVID-19 patients varies from 3 to 21 days in different studies, although most protocols have recommended 14 days from the time of intubation to perform tracheostomy (29). In non-Covid-19 mechanically ventilated patients, early tracheostomy (usually within 7 days of intubation) is often recommended for its reducing effects on extubation complications, mechanical ventilation duration, the length of ICU stay, the chance of subglottic stenosis, and the mortality rate (30-34). In COVID-19 patients, early tracheostomy is less encouraged due to safety concerns for healthcare providers. Although strong scientific evidence does not seem to support this hypothesis (21,35,36), some protocols advocate delaying tracheostomy until the negative COVID-19 PCR test (29). However, the use of appropriate personal protective equipment (PPE) is critical to prevent the spread of viral aerosols (37,38). In our study, 30 people underwent early tracheostomy during the first week from intubation and in accordance with tracheostomy instructions before the COVID-19 pandemic. All healthcare providers were obliged to use PPE, including standard precautions, N95 mask, gowns, and face shield during the procedure. Due to these infection control concerns, most protocols recommend tracheostomy after the second week in COVID 19 patients despite the existence of abundant evidence in pre-COVID 19 area to support early tracheostomy within the first week of intubation (29,31,39,40).

Considering the variation in the definition of early tracheostomy, different studies have evaluated different timing of tracheostomy. In a multicenter retrospective study on COVID-19 patients undergoing elective tracheostomy in China, early tracheostomy (≤14 days) was associated with a higher mortality rate, despite improved clinical conditions of patients (SOFA and APACHE II scores) (41). In another prospective cohort study, early tracheostomy (≤10 days) was associated with a shorter duration of mechanical ventilation and decreased hospital stay but no significant difference in the mortality rate (42). Similarly, in our comparative study, early tracheostomy (≤7 days) was not significantly associated with longer 30-day survival and overall survival time in COVID-19 patients. Further prospective studies on more samples are required to increase the reliability of our results.

In conclusion, tracheostomy is a preferred method in airway management of severe COVID-19 patients under mechanical ventilation; however, tracheostomy within the first week of intubation may not be associated with an increased chance of survival.

Acknowledgments

The authors would like to thank Mrs. Fariba Zamani for language editing of this paper. They also thank all ICU staff at Imam Khomeini Hospital Complex for their efforts during the COVID-19 pandemic.

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