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The Comparison Between the Early Tracheostomy and Orotracheal Intubation in COVID-19 Patients Required Mechanical Ventilation

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Abstract

Background: Supportive respiratory care and airway management are very important in treating COVID-19 patients with respiratory failure. There are two techniques for supporting patients with respiratory failure.

Objectives: The current study aims to evaluate the efficacy and quality of patient care with early tracheostomy in intensive care unit (ICU) and compare mortality, hospital stay, and outcome between intubation and early tracheostomy.

Methods: This study is conducted on total patients with confirmed COVID-19 in the ICU centers of a tertiary hospital. At the beginning of the study, all patients were intubated and connected to a mechanical ventilator. Within three days, the intensivists randomly performed bedside percutaneous dilational tracheostomy (PDT) for half of the patients. Early tracheostomy was defined as conducting tracheostomy within three days from intubation.

Results: The total number of 36 patients was included in the study and categorized into two groups, including 18 patients in the early tracheostomy and 18 in orotracheal intubation. Half of the patients (50%) in the tracheostomy group were recovered from COVID-19 respiratory failure and discharged from ICU and hospital. All patients in the intubation group were expired. The length of staying alive in ICU in patients with an early tracheostomy was 26.47 ± 3.79 compared with 7.58 ± 2.36 days in intubated patients.

Conclusion: The early tracheostomy compared with orotracheal intubation in respiratory failure patients with COVID-19 can significantly decrease mortality. However, airway management with an early tracheostomy increases the hospitalization stay and can increase recovery. So, conducting the early tracheostomy is recommended in this study.

Keywords: COVID-19, Intubation, Tracheostomy, Respiration

1. Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a new virus, and the information about the treatment is limited. In addition, the results of many antiviral efficacies are controversial. Today, the best-known treatment of COVID-19 is supportive care and airway management.[1]

Noninvasive ventilation may help avoid endotracheal intubation and invasive mechanical ventilation.[2-4] Noninvasive ventilation does not change the natural disease course for patients with viral infections complicated by pneumonia.[5] Some researchers do not recommend noninvasive ventilation until the patient has viral clearance.[6]

The experience of our intensivists and the different epidemiologic studies represent the high mortality rate in COVID-19 patients who required mechanical ventilation. In a Chinese study, of 22 COVID-19 patients required mechanical ventilation and were managed by orotracheal intubation, 19 (86%) patients expired.[7] Also, in Zhou and colleagues' study, 31 of 32 (97%) COVID-19 patients required mechanical ventilation eventually expired.[8] The mortality rate of orotracheal intubated patients is dramatically high, and our expert specialists trend toward noninvasive ventilation.

There are many methods for invasive airway management, including orotracheal intubation, early and late tracheostomy. The early tracheostomy is a tracheostomy performed within 3 days from intubation and is recommended in many studies to decrease mortality and hospitalization stay.[9] However, at present, it is unknown whether the early tracheostomy decreases the mortality rate of critically ill patients with COVID-19.

2. Objectives

The current study aims to present the mortality rate of all COVID-19 patients who required mechanical ventilation admitted in the intensive care unit (ICU) sections of a tertiary hospital with early tracheostomy airway management and comparing with orotracheal intubation.

3. Methods

This study is a randomized, single-blinded clinical trial with two groups. The clinical trial study subjects comprised all critically ill patients diagnosed with COVID-19 using polymerase chain reaction (PCR) methods and the radiologic studies admitted to the ICU centers of Baqiyatallah hospital, Tehran, Iran, in March 2020.

The sample size was calculated with the formula for means for two-tailed comparisons. First, we selected 32 patients willing to participate in the study. Then, considering the formula ($\alpha = 0.05$, $\beta = 0.2$, and also regarding effect size = 1); The sample size was 18 patients in each group.

This study was done based on block randomization. We used 4 sized blocks for randomization of participants, including 6 possibilities. In order to reach the expected sample size, we randomly chose possibilities, and based on listed possibilities; Participants were allocated in A and B groups.

Figure 1 shows the method of participant allocation. In this trial, eighteen subjects were selected randomly in the intubation group and eighteen in the tracheostomy group.

At the beginning of the study, all patients were intubated and connected to a mechanical ventilator. Then, the intensivists randomly performed bedside percutaneous dilational tracheostomy (PDT) for half of the patients within 3 days.

The patients were treated with supportive care and wide-spectrum antibiotics for secondary bacterial infections. The criteria for mechanical ventilation were considered as PaO2/FiO2 lower than 300, apnea, hypopnea, and abnormal blood gases with pH lower than 7.25.[10,11] The mechanical ventilators of all patients are set on a certain model. Airway pressure release ventilation (APRV) is a suitable model to recruit and improve oxygenation in ARDS patients. APRV is an applied continuous positive airway pressure that releases the applied pressure at a set timed interval. This mode can improve oxygenation while maintaining acceptable peak airway pressure. The modality consisted of a high-pressure (Phigh) and low-pressure (Plow) and 25 and 10 cmH_2O, respectively. The recruitment and oxygenation mostly occur during the inspiratory phase or P_{high} at a set time interval or T_{high} and releasing airway pressure during P_{low} by at a set time interval or T_{low}. The T_{high} and T_{low} were set as 4 and 2 seconds, respectively. The FiO_2 was 100%. Also, ventilator sets' high and low-pressure support were 5 and 10 cmH_2O.[12-14]

Data analyzed using SPSS software version 18 (SPSS Inc. Chicago, IL, USA) with $P < 0.05$ considered statistical significance. The variables were compared using paired samples and an independent *t* test.

4. Results

Supportive care and airway management are important to point in the treatment of COVID-19 patients. Half of the patients (50%) in the tracheostomy group were recovered

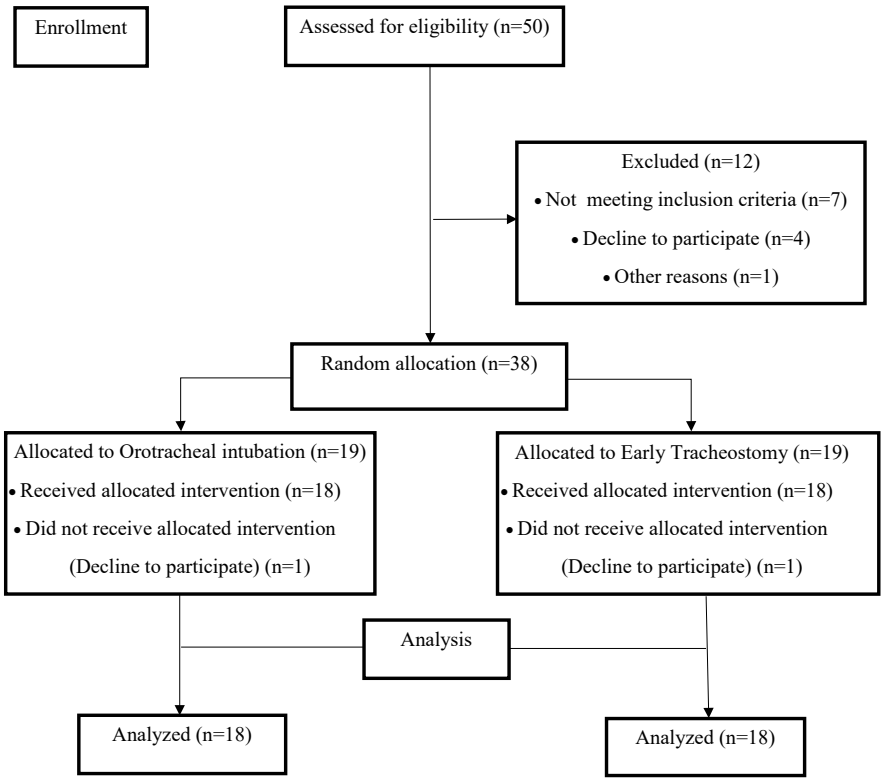

Figure 1: The Study Flowchart of Participant Allocation.

from COVID-19 respiratory failure and discharged from ICU and hospital. All patients in the intubation group were expired. Before and after intubation, the blood oxygen saturation was 51.57 ± 11.27 and 89.32 ± 7.67, respectively. Also, in the other group, the saturation before and after the intervention was 86.47 ± 3.67 and 93.06 ± 3.32. The length of staying alive in ICU in patients with an early tracheostomy was 26.47 ± 3.79 compared with 7.58 ± 2.36 days in intubated patients (Table 1).

The days free of mechanical ventilation with Pressure support ventilation (PSV) mode were 8-10 days in the early tracheostomy group and nearly zero in intubated patients. Therefore, the need for sedation with Benzodiazepines (BZD) or opioid in the early tracheostomy group was very low, whereas we cannot manage patients without sedation in the intubation group.

5. Discussion

The early tracheostomy in ventilated patients is a safe technique and reduces sedation. Also, the suction of respiratory and tracheal secretions is more feasible in tracheostomy. These advantages can decrease the bacterial superinfection incidence rate in the patients.[15]

The study showed that early tracheostomy could significantly decrease the mortality rate with longer hospitalization and ventilator need. Also, the early tracheostomy can increase blood oxygen saturation significantly in intubated patients. Indeed, the radiologic study of the patients in the early tracheostomy group showed the resolution of opacities and abnormalities during hospitalization.

These results are similar to another study that compared early tracheostomy and orotracheal intubation in neurocritical care patients who were needed for mechanical ventilation and showed that the early tracheostomy decreases mortality in ICU.[9]

There is a significant difference between the two groups in duration. The intubated patients were significantly lower under mechanical ventilators. Therefore, it may have justified expiring all of the patients in the intubation group. Also, the patients‘ total hospitalization time shows similar results, and length of stay (LOS) in the intubation group is significantly lower than in the early tracheostomy group.

The recovery of patients in the early tracheostomy group can increase hospitalization time and require mechanical ventilation. However, if the recovered patients were excluded from analysis, the results did not change, and the patients with early tracheostomy airway management were significantly longer under ventilator ($P = 0.001$). There is also a significantly longer time of LOS in expired patients with early tracheostomy comparing patients with intubation ($P = 0.032$). So, the results show that the early tracheostomy may increase hospitalization stay and increase the need for mechanical ventilation significantly.

These results are different from Rodriguez et al study. This study was conducted on critically ill surgical patients, and the LOS, ICU stay, and under ventilator days were significantly shorter in the early tracheostomy group. However, the LOS, ICU stay, and ventilator stay was not significantly different in another study.[16]

In another study conducted on patients with a severe head injury requiring a mechanical ventilator, the mechanical ventilator days decrease significantly in early tracheostomy. However, the LOS was similar in early tracheostomy compared with prolonged intubation [17].

Another similar study conducted on burn patients showed no differences in ventilator support, LOS, the incidence of pneumonia, or survival between two methods of early tracheostomy and orotracheal intubation.[18] However, all different studies were performed in a different setting, and the current study results were different from the other studies.

The orotracheal intubation increased aspiration pneumonia and superinfections of normal flora in the lungs. Also, this technique may increase the incidence rate of tracheal strictures. However, the tracheostomy may facilitate the exhaustion of respiratory secretions. Also, the suction of respiratory and tracheal secretions is more feasible in tracheostomy. These advantages can decrease the bacterial superinfection incidence rate in the patients. Also, the early tracheostomy in ventilated patients is a safe and feasible technique that may reduce sedation need.[8,9]

The information about infection with COVID-19 is limited now, and future studies with bigger sample sizes are necessary. Although the airway management with an early tracheostomy may increase the hospitalization stay, the need for mechanical ventilation can increase the chance of patients for recovery. So, early tracheostomy is recommended in this study. However, due to this study‘s limitations (i.e., small sample size, lack of blinding, different nurses and care), further study is needed to confirm our preliminary results. Focusing on the different methods of ventilation is also necessary for future studies.

6. Conclusion

The early tracheostomy can decrease mortality compared with orotracheal intubation in respiratory failure patients with COVID-19. However, airway management with an

Table 1. Comparison of Blood Oxygen Saturation and Length of Stay Alive in ICU Between Intubation and Tracheostomy Group

Variable	Intubation			Tracheostomy		
	Pre	Post	*P* Value	Pre	Post	*P* Value
Blood oxygen saturation	51.57 ± 11.27	89.32 ± 7.67	<0.001*	86.47 ± 3.67	93.06 ± 3.32	0.01*
Length of stay alive in ICU	7.58 ± 2.36			26.47 ± 3.79		<0.001**

* Paired *t* test; ** Independent *t* test.

Research Highlights

What Is Already Known?

Noninvasive ventilation may help avoid endotracheal intubation and invasive mechanical ventilation. The experience of our Intensivists and the different epidemiologic studies represent the high mortality rate in COVID-19 patients who required mechanical ventilation. There are many methods for invasive airway management, including orotracheal intubation, early and late tracheostomy. However, at present, it is unknown whether the early tracheostomy decreases the mortality rate of critically ill patients with COVID-19.

What Does This Study Add?

The early tracheostomy can decrease mortality compared with orotracheal intubation in respiratory failure patients with COVID-19. However, airway management with an early tracheostomy may increase the hospitalization stay and under mechanical ventilator stay and increase the chance for recovery.

early tracheostomy may increase the hospitalization stay and under mechanical ventilator stay and increase the chance for recovery. So, the early tracheostomy in required mechanical ventilator COVID-19 patients is recommended in this study. However, more similar studies with higher sample sizes are also necessary.

Authors' Contributions

MM, HG, MB, AB, and EK developed the study concept, performed testing and data collection. SS, MR, and HG performed data analysis and interpretation. All authors contributed to the study design and approved the final version of the manuscript for submission

Conflict of Interest Disclosures

The authors declare that they have no conflicts of interest.

Ethical Approval

The study protocol was approved by the national ethics committee (IR.BMSU.REC.1399.055) and registered at the Iranian registry of clinical trials (Approval code: IRCT20180129038542N1).

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