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Tracheostomy is Safe in Patients with Prolonged **Intubation After Coronavirus Disease 2019** Infection



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Carma Goldstein, MD, David Deisher, DO, Elizabeth Gorman, MD, Fariha Sheikh, MD, Ziad Sifri, MD, FACS, and Nina E. Glass, MD, FACS*

Department of Surgery, Rutgers New Jersey Medical School, Newark, New Jersey

ARTICLE INFO

Article history: Received 2 November 2020 Revised 23 March 2021 Accepted 10 April 2021 Available online 27 April 2021

Keywords: Tracheostomy COVID-19 Coronavirus disease Outcomes Respiratory failure

ABSTRACT

Background: Tracheostomy improves outcomes for critically ill patients requiring prolonged mechanical ventilation. Data are limited on the use and benefit of tracheostomies for intubated, critically ill coronavirus disease 2019 (COVID-19) patients. During the surge in COVID 19 infections in metropolitan New York/New Jersey, our hospital cared for many COVID-19 patients who required prolonged intubation. This study describes the outcomes in COVID-19 patients who underwent tracheostomy.

Methods: We present a case series of patients with COVID-19 who underwent tracheostomy at a single institution. Tracheostomies were performed on patients with prolonged mechanical ventilation beyond 3 wk. Patient demographics, medical comorbidities, and ventilator settings prior to tracheostomy were reviewed. Primary outcome was in-hospital mortality. Secondary outcomes included time on mechanical ventilation, length of ICU and hospital stay, and discharge disposition.

Results: Fifteen COVID-19 patients underwent tracheostomy at an average of 31 d post intubation. Two patients (13%) died. Half of our cohort was liberated from the ventilator (8 patients, 53%), with an average time to liberation of 14 ± 6 d after tracheostomy. Among patients off mechanical ventilation, 5 (63%) had their tracheostomies removed prior to discharge. The average intensive care length of stay was 47 \pm 13 d (range 29-74 d) and the average hospital stay was 59 ± 16 d (range 34-103 d).

Conclusions: This study reports promising outcomes in COVID-19 patients with acute respiratory failure and need for prolonged ventilation who undergo tracheostomy during their hospitalization. Further research is warranted to establish appropriate indications for tracheostomy in COVID-19 and confirm outcomes.

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E-mail address: nina.glass@rutgers.edu (N.E. Glass). 0022-4804/© 2021 Elsevier Inc. All rights reserved. https://doi.org/10.1016/j.jss.2021.04.023

^{*} Corresponding author. Department of Surgery, Rutgers New Jersey Medical School, University Hospital Trauma Mezzanine, 150 Bergen Street, Newark, NJ 07103, Phone: (323) 409-7761, Fax: (323) 226-4539.

Introduction

Coronavirus disease 2019 (COVID-19), caused by a novel coronavirus, can result in severe acute respiratory failure necessitating prolonged intubation and ventilation. Although reported rates vary, one study found that 20% of COVID-19 patients presenting to the hospital required mechanical ventilation, and the mortality for these patients was 88%.¹ A Cochrane systematic review by Andriolo *et al.* suggested that early tracheostomies, defined as less than 10 d after intubation, reduces mortality in other critically ill patients.² Benefits of tracheostomy include decreased respiratory secretions and pneumonia, greater patient comfort, and faster weaning from the ventilator.²

In the COVID-19 era, the decision to perform tracheostomy must involve a careful risk benefit analysis, taking into consideration the risks of transmission to the healthcare team and a paucity of data supporting its benefit. However, patients who survive beyond the initial intubation period may benefit from tracheostomy, similar to other critically ill patients with respiratory failure. Because of viral load and risk to the healthcare team, it has been suggested that tracheostomies for COVID-19 patients be performed later in their hospital course, specifically after at least 21 d of ventilation.³⁻⁵ To our knowledge, there are no previous studies that have evaluated outcomes of COVID-19 patients who received tracheostomies after 21 d of intubation. Prior studies have focused on tracheostomies performed an average of 10-20 d post intubation and demonstrated variable mortality rates 7%-24%.6-9 Our study seeks to examine the in-hospital mortality rate and outcomes of patients with COVID-19 undergoing tracheostomy.

Methods

Study design

This is a single center, prospective observational study at University Hospital, an urban safety net hospital. We analyzed all COVID-19 patients with respiratory failure undergoing a tracheostomy from April 26, 2020 until June 26, 2020. We excluded patients under 18 y of age. Tracheostomies were only performed if patients were intubated for at least 21 d and otherwise deemed stable to undergo the procedure. This decision and scheduling of the procedure was left to the physician performing the tracheostomy. Tracheostomies were performed with full personal protective equipment. The Institutional Review Board approved this study with a waiver of consent due to its retrospective nature.

Data collection

Electronic medical records of patients were reviewed and data entered into REDCap (Research Electronic Data Capture), a secure web-based software platform.^{10,11} Data collected included patient demographic information, comorbidities, days of mechanical ventilation, ventilator settings prior to tracheostomy, operating room reports, and outcome variables.

| Table 1 – Demographics. | |
|--|-------------|
| Characteristic | Value |
| Age, median [IQR], y | 59 [54, 63] |
| Sex, No. (%) | |
| Male | 9 (60%) |
| Race/Ethnicity, No. (%) | |
| White | 0 |
| Black/African American | 8 (53%) |
| Hispanic | 6 (40%) |
| Native Hawaiian, Pacific Islander | 1 (7%) |
| Other | 0 |
| BMI, median [IQR] | 32 [25, 35] |
| Comorbidities, No. (%) | |
| Diabetes | 9 (60%) |
| Hypertension | 9 (60%) |
| Coronary artery disease | 0 (0%) |
| Asthma/Chronic obstructive pulmonary disease | 3 (20%) |
| Congestive heart failure | 2 (13%) |
| No underlying comorbidities | 4 (27%) |

Outcomes

Patients were evaluated from time of admission until discharge from the hospital. Our primary outcome was mortality. Secondary outcomes included time to liberation from mechanical ventilation, length of stay in the ICU, length of stay in the hospital, decannulation, and discharge disposition.

Statistical analysis

For this analysis of a small cohort of COVID-19 patients and tracheostomy, descriptive statistics are used. Continuous variables are expressed as means and standard deviation (SD) for normally distributed data and median and interquartile range (IQR) for non-normally distributed. Categorical variables are reported as numbers with percentages.

Results

We performed tracheostomies in fifteen COVID-19 patients who met criteria with full COVID precautions. The majority of the patients were male (9 patients, 60%) and either Black (53%) or Hispanic (40%) (Table 1). This correlates with the demographics of our hospital's COVID-19 patient population. 73% of our cohort had at least one underlying comorbidity, most commonly diabetes and/or hypertension.

The mean number of days prior to tracheostomy in our patients was 31 ± 9 d with a range of 21-48 d. Mean positive endexpiratory pressure (PEEP) prior to tracheostomy was 6, fraction of inspired oxygen (FiO2) was 49%, and P:F ratio was 231 (Table 2).

The indication for all tracheostomies was respiratory failure with need for continued mechanical ventilation. We performed tracheostomies an average of 9 d after initial consultation for tracheostomy. We delayed the procedure in 10

| Table 2 – Respiratory status prior to tracheostomy. | | |
|---|-------------------|--|
| Respiratory variables | Value | |
| Time intubated prior to tracheostomy, mean \pm SD (range) d | 31 ± 9 (21-48) | |
| COVID-19 positive prior to tracheostomy, No. (%) | 8 (53%) | |
| PEEP prior to tracheostomy, mean \pm SD | 6 ± 2 | |
| 5, No. (%) | 9 (60%) | |
| 8, No. (%) | 4 (27%) | |
| 10, No. (%) | 2 (13%) | |
| FiO2 prior to tracheostomy, mean \pm SD, % | 49 ± 8 | |
| 40, No. (%) | 6 (40%) | |
| 50, No. (%) | 5 (33%) | |
| 60, No. (%) | 4 (27%) | |
| P:F ratio prior to tracheostomy, mean \pm SD (range) | 231 ± 86 (93-395) | |

(67%) patients. Reasons for delays were goals of care discussions with families, increasing ventilatory requirements, active infections, coagulopathy, and delays in appropriate operating room availability. Tracheostomies proceeded when goals of care aligned with placement, the surgeon felt the ventilator requirements stable, cultures were negative or patient had received an appropriate course of antimicrobial therapy, and coagulopathy was improved.

Tracheostomies were performed by eight different experienced attending surgeons. The attending surgeon was assisted by another attending, a fellow, or senior resident. All but one tracheostomy was performed via an open technique. One tracheostomy was placed on the second attempt, four d after an initial attempt was aborted due to acute hypoxia in the operating room. There were no identified intraoperative complications. To reduce aerosolization, we used filters, minimized circuit connections, and ceased ventilation prior to circuit interruptions. We also minimized the number of personnel in the operating room during the procedure, specifically the junior residents. To our knowledge, there were no COVID-19 transmissions to the healthcare team.

Half of our cohort was weaned from the ventilator (8 patients, 53%), with an average time to ventilator liberation after tracheostomy of 14 \pm 6 d (range 4-24 d). Of the patients who were liberated, 5 (63%) were decannulated prior to discharge. The average intensive care length of stay was 47 \pm 13 d (range 29-74 d) and the average overall hospital length of stay was 59 \pm 16 d (range 34-103 d). The patients who were liberated from mechanical ventilation were discharged an average of 31 d after their tracheostomy and 17 d after liberation. The patients who remained on mechanical ventilation were discharge an average of 18 d after tracheostomy placement. Of note, social issues and lack of insurance delayed placement for some patients, extending their hospital stays.

Of the 15 patients who underwent a tracheostomy, two patients (13%) died, ages 60 and 62. They were both black males and had underlying medical comorbidities including hypertension and diabetes. Their ventilator settings prior to tracheostomy were slightly higher than the rest of our population. One patient was on a ventilator with a PEEP of 8 and FiO2 Table 3 – Outcomes of COVID-19 patients after tracheostomy.

| Outcome | Value |
|--|------------------|
| Mortality, No. (%) | 2 (13%) |
| Disposition of patient, No. (%) | |
| Discharged | 13 (87%) |
| Home | 1 (7%) |
| Skilled nursing facility | 4 (27%) |
| Acute rehabilitation facility | 5 (33%) |
| Long-term acute care facility | 3 (20%) |
| Died | 2 (13%) |
| Liberated from the ventilator, No. (%) | 8 (53%) |
| Decannulated prior to discharge, No. (%) | 5 (33%) |
| Time to liberation, mean \pm SD (range), d | 14 ± 6 (4-24) |
| ICU length of stay, mean \pm SD, d | 47 ± 13 |
| Hospital length of stay, mean \pm SD, d | 59 ± 16 |

of 50%, and the other patient was on a PEEP of 10 and an FiO2 of 60%. For one patient, the decision was made to institute comfort measures only and remove the ventilator. The other patient developed septic shock from a soft tissue infection, required significant vasopressor support and subsequently went into cardiac arrest and died. Neither of these deaths were directly related to the tracheostomy.

The remaining 13 patients (87%) were discharged to home, acute rehabilitation, skilled nursing facility or long-term care facility (Table 3). All five patients decannulated in the hospital presented for follow up. One of them developed tracheal stenosis and vocal cord paralysis subsequently requiring repeat tracheostomy. The other four have not required further respiratory intervention. Two patients discharged with tracheostomies presented for follow up and remained liberated from ventilation with outpatient decannulation. The other six patients discharged alive, one liberated from and five remaining on mechanical ventilation, were lost to follow up.

Discussion

This is the first study to examine outcomes of COVID-19 patients who have a later tracheostomy performed at least 21 d after initial intubation and start of mechanical ventilation. Patients with later tracheostomies are more likely to be in a recovery phase, having survived the period of early mortality. Our patients were intubated an average of 31 d prior to undergoing tracheostomy. Their overall mortality rate was 13%, in sharp contrast to the reported 88% mortality for COVID-19 patients requiring mechanical ventilation,¹ suggesting that once patients survive that initial period, tracheostomy may be an important step contributing to their survival. An appropriate comparison group would be those who survived at least 21 d and were extubated without tracheostomy. However, we had very few of those COVID-19 patients. Generally, if COVID-19 patients remained intubated past 21 d, they had failed weaning trials and were not suitable for extubation. Two patients in our cohort died and both deaths were not directly related to the tracheostomy. Compared to patients who survived to discharge, these patients were slightly older, had somewhat higher ventilator settings at time of tracheostomy, and had underlying comorbidities. Risk factors for later mortality in this cohort of patients is an area for further study.

COVID-19 is a novel disease and reported outcomes and recommendations are still emerging. To date, only a few studies have examined COVID-19 patient outcomes after tracheostomy. One early study performed tracheostomies after 14 d of intubation in COVID-19 patients and found a mortality rate of 25%, leading them to conclude that a tracheostomy should not be performed until at least 21 d of mechanical ventilation.¹² Another study that waited longer, on average 20 d, had a much lower mortality rate of 11%. They were similarly able to liberate about half of their cohort.⁶ Also, viral load appears to become undetectable around 2 wk after symptom onset,¹³ reducing risk of healthcare worker exposure during the procedure. These results led to the recommendation by some to wait until 21 d to perform tracheostomy.³⁻⁵ The largest study to date was performed by Martin-Villares et al. in Spain. This study included 1,890 patients with a median time to tracheostomy of 12 d. These patients were followed for 1 mo with a mortality of 24%.⁷ Although they were similarly successful at weaning about half their population from mechanical ventilation, they report a fairly high mortality. These prior studies as well as our own findings suggest that waiting longer (at least 21 d) before tracheostomy, when patients may be more stable and starting to recover, does not change likelihood of liberation from mechanical ventilation, may reduce risk of death, and is warranted.

Of note, prior studies had a significant portion of their study group still in the hospital at the time of study completion. We followed all patients until they were discharged from the hospital, allowing us to accurately assess the inhospital mortality rate. Given that some of our patients were discharged while still requiring mechanical ventilation, performance of a tracheostomy may facilitate discharge to a less acute care setting, freeing up ICU beds for acutely ill COVID 19 patients—especially important during a surge in patients during this pandemic.

Our study had several limitations. One limitation is the small sample size, due in part to a limited number of mechanically ventilated COVID-19 patients surviving to 21 d and being able to undergo tracheostomy. While we did not have a strict protocol for timing or method for tracheostomy, we had a standard approach and consistently took all the precautions to minimize risks to clinicians. Our demographics reflected that of our local patient population with no white non-Hispanic patients, potentially limiting generalizability to other populations. However, minority populations have been shown to have worse outcomes than white COVID-19 patients.¹⁴ This may suggest our results are even more promising on a general scale since this population usually has poorer outcomes than other populations. Lastly, our study has no control group, so we are unable to definitively conclude that a later tracheostomy is better than an earlier one or no tracheostomy. Finally, it must be said that by waiting at least 3 wk to proceed with tracheostomy, we have selected for patients who may be more likely to survive. While this may be true, the benefit of protecting the healthcare workforce during earlier periods of patients' hospitalization when they may be more infectious, outweighs whatever potential risks this may have on our outcomes.

Several topics should be investigated further to add to the evidence base and to determine formal recommendations on the timing of tracheostomy placement on COVID-19 patients. A larger scale study with a more diverse patient population is needed. In addition to demographic factors, it would be valuable to assess whether ventilator settings prior to tracheostomy are predictive of outcomes. Additionally, comparing COVID-19 patients who undergo earlier tracheostomies to those who wait 21 d would be beneficial in evaluating the direct effect timing of tracheostomy.

Overall, our results demonstrate that tracheostomy is safe for COVID-19 patients who survive to 21 d, with lower mortality than has been reported for patients who have tracheostomy performed at earlier times. In summary, this study of a small number of patients with COVID-19 and respiratory failure suggests that waiting at least 21 d after initiation of mechanical ventilation to perform tracheostomies is safe and may improve outcomes.

Authors' contributions

The literature search was performed by CG. The study design was developed by CG, DD, ZS, and NG. Data collection was completed by CG and DD. Data analysis, data interpretation, writing, and revisions were done by all authors.

Acknowledgment

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors

Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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