Original Article

Tracheostomy for COVID-19 respiratory failure: timing, ventilatory characteristics, and outcomes

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Background: Whereas data from the pre-pandemic era have demonstrated that tracheostomy can accelerate liberation from the ventilator, reduce need for sedation, and facilitate rehabilitation, concerns for healthcare worker safety have led to disagreement on tracheostomy placement in COVID-19 patients. Data on COVID-19 patients undergoing tracheostomy may inform best practices. Thus, we report a retrospective institutional cohort experience with tracheostomy in ventilated patients with COVID-19, examining associations between time to tracheostomy and duration of mechanical ventilation in relation to patient characteristics, clinical course, and survival.

Methods: Clinical data were extracted for all COVID-19 tracheostomies performed at a quaternary referral center from April-July 2020. Outcomes studied included mortality, adverse events, duration of mechanical ventilation, and time to decannulation.

Results: Among 64 COVID-19 tracheostomies (13% of COVID-19 hospitalizations), patients were 64% male and 42% African American, with a median age of 54 (range, 20–89). Median time to tracheostomy was 22 (range, 7–60) days and median duration of mechanical ventilation was 39.4 (range, 20–113) days. Earlier tracheostomy was associated with shortened mechanical ventilation (R^2=0.4, P<0.01). Median decannulation time was 35.3 (range, 7–79) days. There was 19% mortality and adverse events in 45%, mostly from bleeding in therapeutically anticoagulated patients.

Conclusions: Tracheostomy was associated with swifter liberation from the ventilator and acceptable safety for physicians in this series of critically ill COVID-19 patients. Patient mortality was not increased relative to historical data on acute respiratory distress syndrome (ARDS). Future studies are required to establish conclusions of causality regarding tracheostomy timing with mechanical ventilation, complications, or mortality in COVID-19 patients.

Keywords: Tracheostomy; COVID-19; severe acute respiratory syndrome; coronavirus 2; mechanical ventilation

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Introduction

Patients hospitalized for COVID-19 illness may develop acute respiratory distress syndrome (ARDS) requiring prolonged invasive mechanical ventilation that amid surges may overwhelm intensive care resources (1,2). Since tracheostomy may accelerate ventilator weaning, guidance documents have recommended that decisions regarding timing of tracheostomy should consider institutional demand for ventilators (3); and that allocation decisions should consider ethical tenets, scarce critical care resources (4,5), and survivorship (6). Amid emphasis on possibly unique considerations of COVID-19 and corresponding paradigms for management (7), data are accruing that many acute manifestations and outcomes of severe COVID-19 parallel those of ARDS arising from other pathogens (8,9). Such evidence is prompting a reappraisal of the appropriateness of significantly delaying tracheostomy in patients with COVID-19 (10,11).

While the optimal timing of tracheostomy has long been debated (12-14), the controversy assumed new prominence amid the COVID-19 pandemic (1,15). Balancing the theoretical benefits of earlier tracheostomy and critical care resources versus the potential risks of viral transmission during the aerosolizing tracheostomy procedure (16) have challenged prior commonly accepted practices. Reports of high mortality in mechanically ventilated patients may have resulted in reluctance to perform tracheostomy in patients believed to have a relatively poor prognosis, as seen in New York City (17), the United Kingdom (15), and China (18). Subsequent studies have reported lower mortality in mechanically ventilated patients (19,20). Early data of tracheostomy in COVID-19 patients from Europe demonstrate variability in practice but overall low tracheostomy-related morbidity (21,22). Further outcomes data are required for tracheostomy in COVID-19 patients, including rates of and time to decannulation and successful liberation from mechanical ventilation. Herein, we contribute a description of an additional large single institution cohort of COVID-19 patients from the United States who underwent tracheostomy.

We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/jtd-21-10).

Methods

Institutional guidelines for placement of tracheostomy were developed in March 2020 (see https://cdn.amegroups.cn/static/public/jtd-21-10-1.pdf in the supplemental digital content). Tracheostomy was considered for patients with COVID-19 who remained ventilator dependent at 3-week post-intubation. Earlier tracheostomy was gradually allowed based on multidisciplinary discussion of risks and benefits. Tracheostomy was performed via an open or percutaneous approach at bedside, except in cases of concurrently needed operation, history of laryngotracheal stenosis, or high-risk cases based on proceduralist recommendation. Further details on institutional guidelines, tracheostomy technique, personal protective equipment, and infectivity mitigation procedures can be found on the supplemental digital content (see Supplemental Methods).

Clinical data were collected from Michigan Medicine and collaborative medical institutions for overall number of COVID-19 infections, intubations, and tracheostomies performed at Michigan Medicine from April through July 2020. Clinical variables examined included demographics; dates for admission, intensive care, intubation, tracheostomy procedure, subsequent tracheostomy management, and hospital discharge; laboratory studies; duration of mechanical ventilation (liberation defined as no further requirement for positive pressure ventilation for any part of the day); respiratory support requirements prior to and post-tracheostomy; Sequential Organ Failure Assessment (SOFA) scores (23) prior to tracheostomy; Charlson Comorbidity Index (24) value during the admission; tracheostomy-related adverse events; and discharge disposition. Tracheostomy-related adverse events included bleeding, defined as: (I) requiring hemostatic agent, (II) cessation of anticoagulation, (III) blood product transfusion, or (IV) operative management; mucous plugging requiring more than suctioning for clearance; pneumothorax caused or worsened by tracheostomy placement or subsequent management; and desaturation during tracheostomy, defined as SpO_2 <90% for >5 minutes during or up to 60 minutes following the procedure. Study data were collected and managed using REDCap (25) electronic data capture tools hosted at the University of Michigan. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the University of Michigan (HUM00185123), and individual consent for this retrospective analysis was waived. This study received a determination of exempt status by the Institutional Review Board.

Statistical analysis

All statistical tests were performed in R (version 4.0.2),

Table 1 Cohort demographics

Characteristic	Value
Age, median [range]	54 [20–89]
Sex, n [%]	
Male	41 [64]
Female	23 [36]
Race/ethnicity, n [%]	
African American	27 [42]
Caucasian	26 [41]
Asian	2 [3]
Other/unknown	9 [14]
Body mass index, median [range]	33 [20–57]
VV-ECMO requirement, n [%]	
During hospitalization	13 [20]
During tracheostomy	11 [11]
Sequential Organ Failure Assessment at time of tracheostomy, median [range]	9 [4–14]
Charlson Comorbidity Index, median [range]	3 [0–12]
Comorbidities noted during admission, n [%]	
Diabetes	40 [63]
Renal disease	32 [50]
Chronic pulmonary disease	21 [33]
Congestive heart failure	17 [27]
Cerebrovascular disease	12 [19]

VV-ECMO, veno-venous extracorporeal membrane oxygenation (n=11).

and plots were created with R package ggplot2 (version 3.3.2). Fishers exact testing and two-tailed *t*-tests were used to compare categorical and continuous variables respectively. For comparison of adverse events by pre-procedural respiratory support requirements, samples were dichotomized with a cutoff of PEEP >10 representing a high respiratory support requirement. In hospital mortality was also compared by dichotomized groups of high admission D-dimer level (cutoff of >4) and SOFA score (cutoff of >6), as suggested by Volo *et al.* (26). Time-to-event analyses were performed using the Kaplan-Meier method, with censoring by length of follow-up and death. Linear regression was performed to compare time to tracheostomy from intubation with length of mechanical ventilation, with outliers (SD >2) removed (n=2). Statistical significance was defined as P value <0.05.

Results

Patient cohort and tracheostomy placement

Between April 1 and July 31, 2020, there were 490 patients hospitalized at Michigan Medicine with laboratory-confirmed COVID-19 infection. Of these patients, 146 (30%) were intubated, and 113 (23%) died. A total of 64 patients underwent tracheostomy (13% of hospitalized COVID-19 patients), performed by one of 12 attending proceduralists representing interventional pulmonology, acute care surgery, otolaryngology-head and neck surgery, neurosurgical intensivists, and thoracic surgery. None of the physicians who participated in a tracheostomy procedure - proceduralists, physicians performing bronchoscopy, or anesthesiologists - were diagnosed with COVID-19 within one month of the procedure. Demographics of the tracheostomy cohort are detailed in *Table 1*.

Tracheostomy was performed at a median of 22 days (range, 7–60) after the start of mechanical ventilation. There was no significant difference (P=0.36) between the time to tracheostomy in patients who had the tracheostomy placed while on ECMO (median 21, range, 16–32) and the remainder of the cohort (median 22, range, 7–60). As PEEP and FiO_2 requirements may reflect lung rest settings when a patient is on ECMO, PEEP and FiO_2 requirements were only examined for non-ECMO patients. The average (range) PEEP and FiO_2 requirements in the 24 hours prior to tracheostomy were 10 [5–16] and 0.55 [0.30–0.82]. One day after tracheostomy, the average (range) PEEP and FiO_2 requirements were 9.6 [5–16] and 0.47 [0.30–1.00].

The vast majority of patients (n=60, 94%) had their tracheostomy placed bedside. There were 38 tracheostomy procedures (59%) performed percutaneously, and 26 (41%) performed via open technique. All tracheostomy operations during the study period were planned elective procedures, with timing and technique of placement determined by the patient's multidisciplinary care team with guidance from institutional protocols (see https://cdn.amegroups.cn/static/public/jtd-21-10-1.pdf in the supplemental digital content).

Duration of mechanical ventilation and time to decannulation

Median follow-up time for the cohort was 94 days. Duration

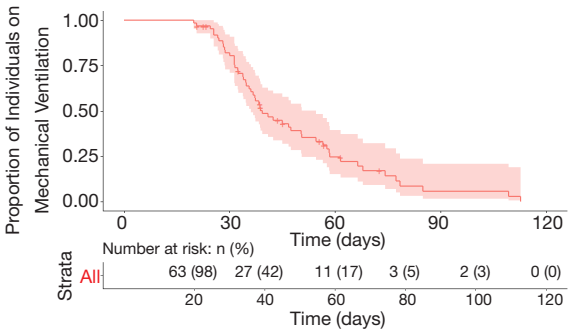

Figure 1 Time-to-event analysis for liberation from mechanical ventilation.

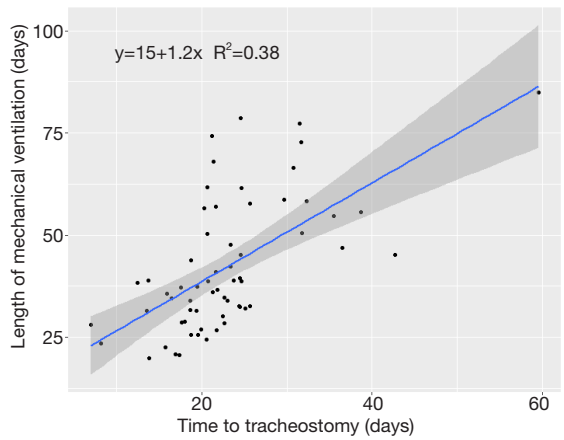

Figure 2 Linear regression model of time to tracheostomy with length of mechanical ventilation as the criterion. R^2=0.378** [95% CI: 0.19, 0.52]. ** indicates P<0.01.

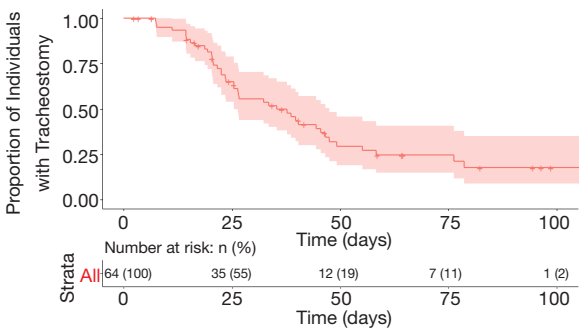

Figure 3 Time-to-event analysis for tracheostomy decannulation.

of mechanical ventilation ranged from 20–113 days, with a censored median liberation from mechanical ventilation time of 39.4 days (*Figure 1*). There was no statistically significant difference in duration of mechanical ventilation between patients with tracheostomy placement on ECMO (median 50 days, range, 30–109 days) and the remainder of the cohort (median 37 days, range, 20–113 days) (P=0.13) (see Figure S1 in the supplemental digital content). A shorter time to tracheostomy was associated with a significantly decreased overall duration of mechanical ventilation (R^2=0.4, P<0.01, *Figure 2*). By this analysis, each additional day to tracheostomy was associated with an incremental addition of 1.2 days to liberation from the ventilator.

Tracheostomy capping was documented in 38 patients at a median of 23 days after tracheostomy (range, 6–61 days). A total of 41 patients were decannulated during the study period, with a censored median decannulation time of 35.3 days (range, 7–79 days) (*Figure 3*). Of the 12 remaining patients alive with a tracheostomy in place, two had not yet been weaned from mechanical ventilation and were still admitted to Michigan Medicine, five patients were still admitted to a hospital but had been weaned off mechanical ventilation, four had been discharged to long-term care facilities, and one was discharged home. There was a trend of earlier decannulation with percutaneous tracheostomy as compared to an open technique (P=0.08) (see Figure S2 in the supplemental digital content); no other clinical variables showed trends toward earlier time to decannulation. Similarly, there was no difference between patients with tracheostomy placement on ECMO and the remainder of the cohort in terms of time to decannulation (P=0.32) (see Figure S3 in the supplemental digital content).

Morbidity and mortality

During the study period, a total of 12 patients in the cohort (19%) died. All patients who died had a tracheostomy in place except for a patient who experienced a cardiac arrest 4 weeks after tracheostomy decannulation. No deaths in the cohort were attributed to the tracheostomy. Two patients died within 5 days of the procedure, with both cases attributed to underlying disease. One of these patients developed septic shock attributed to his pneumonia two days following tracheostomy placement. The other patient developed acute myocardial dysfunction four days after tracheostomy. No association between in hospital mortality and admission D-dimer level (P=0.75) and SOFA score (P=0.19) was identified on univariate testing.

The overall rate of patients experiencing an adverse event was 45% (*Table 2*). The breakdown of adverse events was 20 patients who had one event, 7 patients with two events, and

Table 2 Tabulated complications in the cohort

Complication	All patients (n=64)		Patients with tracheostomy placed on VV-ECMO (n=11)	
	Number of patients	Percentage (%)	Number of patients	Percentage (%)
Bleeding[†]	21	33	8	73
Local hemostatic agent and pressure only	2	10	0	0
Systemic anticoagulation held	18	86	5	63
Transfusion given for degree of tracheal bleeding	6	29	3	38
Operative hemorrhage control	1	5	0	0
Mucous plug[‡]	7	11	1	9
Pneumothorax[§]	2	3	0	0
Accidental decannulation	3	5	0	0
Desaturation during tracheostomy[¶]	2	3	0	0
False passage	2	2	0	0
Vocal fold paresis	2	3	0	0

VV-ECMO, veno-venous extracorporeal membrane oxygenation (n=11). [†], bleeding requiring intervention as further listed in the table above. Of the patients experiencing a bleeding complication, 8 patients (38%) were on extracorporeal membrane oxygenation during and following their tracheostomy placement; [‡], documented mucous plugging event of tracheostomy requiring more than suctioning for plug clearance. Each case was reviewed by a second physician and determined to not be associated with the tracheostomy procedure itself, i.e., presented in a delayed fashion, and due to underlying tenacious secretions notable in most COVID-19 patients; [§], pneumothorax caused by or worsened by tracheostomy placement or management; [¶], desaturation during tracheostomy, i.e., SpO_2 <90% for >5 minutes during or up to 60 minutes following the tracheostomy.

2 patients with three events. Bleeding was the most common adverse event in the overall cohort (n=21, 33%). Bleeding was significantly more common (P=0.003) in patients who had a tracheostomy placed on ECMO (n=8, 73%) versus the remainder of the cohort (n=13, 25%). The majority of patients were on therapeutic anticoagulation (n=51, 80%) or prophylactic anticoagulation (n=12, 19%); all patients with tracheostomy-related bleeding complications were on therapeutic anticoagulation. No significant differences in complication rates were identified between patients who had a high (>10) versus low (≤10) pre-tracheostomy PEEP requirement.

Discussion

In this series, tracheostomy was safely performed in the setting of COVID-19 infection despite high pre-procedural respiratory support requirements. We found that longer time to tracheostomy was associated with increased length of mechanical ventilation. To our knowledge, this study is one of the larger well-characterized institutional case series on tracheostomy in COVID-19 patients, and one of the few to include ECMO patients. Herein, we provide a detailed description of the rates of, and time to, liberation from mechanical ventilation and subsequent decannulation.

Comparison to other cohorts

Benito *et al.* recently published a systematic review of tracheostomy for COVID-19, which demonstrates increasing but scattered data on this subject (27). The review includes four studies of comparable size, all of which had a significant percentage of patients still on mechanical ventilation (range, 24–52%) (21,22,28,29). The percentage of these cohorts still on the ventilator mirrors two more recent publications (30,31). In contrast, due to the longer duration of follow-up in the current study, 97% of our patients had either been liberated from mechanical ventilation or died. Rovira *et al.* were able to also follow their United Kingdom cohort for a similar duration of time (32); importantly, our study differs in that our cohort includes ECMO patients. Finally, Avilés-Jurado *et al.*

published a smaller well-characterized cohort from Spain that also followed patients longer (33); in contrast to their study, our study applies a time-to-event analysis to duration of mechanical ventilation, rather than defining an early/late tracheostomy cutoff.

Duration of mechanical ventilation and time to tracheostomy

We found a median duration of mechanical ventilation of 39.4 days, which is longer than other cohorts (32,33). Importantly, however, our study includes a significant number of patients on ECMO, which reflects underlying disease severity and often is associated with prolonged mechanical ventilation (34). While there was no statistically significant difference between duration of ventilation in our ECMO and non-ECMO cohorts, it is likely that our number of patients with tracheostomy placed on ECMO was too small to detect a difference. Furthermore, as a quaternary referral center, a large number of our patients were transferred from other hospitals; ventilator days at these other institutions were factored into our calculations.

The 64 tracheostomy procedures in this cohort represented 13% of intubated COVID-19 patients at our institution during the study period, as compared to published tracheostomy rates of 10–46% (1,26,35). A recent multinational survey revealed an average time to tracheostomy of 14 days in COVID-19 patients (1), with other institutional case series reporting a median of 9–24 days (21,22,26,29,30,35-37). Our median time to tracheostomy of 22 days was at the later end of the spectrum, in keeping with our institutional recommendations (see https://cdn.amegroups.cn/static/public/jtd-21-10-1.pdf in the supplemental digital content) and early national guidelines (38).

Outside of the COVID-19 pandemic, a meta-analysis found that early tracheostomy (<10 days) was associated with decreased duration of intensive care (39). We found an association between shorter time to tracheostomy and decreased duration of mechanical ventilation (*Figure 2*), in keeping with the results of the pre-pandemic TracMan trial (40). In our study, each additional day to tracheostomy was associated with an incremental addition of 1.2 days to liberation from the ventilator. Even a small decrease in need for mechanical ventilation or intensive care per patient could be meaningful during a pandemic with limited critical care resources (4). This must be balanced with increased consumption of personal protective equipment and testing supplies, as well as increased healthcare worker exposure during the procedure itself (41).

Tracheostomy-associated morbidity and mortality

The mortality of 19% in this series compares favorably to historical data showing a mortality rate closer to 40% in patients with pre-COVID-19 ARDS (42,43), as well as mortality rates for COVID-19 patients admitted to intensive care (25–54%) and other COVID-19 tracheostomy cohorts (21,26,27). Furthermore, no deaths in our case series were directly attributable to tracheostomy placement.

While the mortality rate of our cohort was low, our adverse event rate of 45% was higher than previous publications (21,22). Most notably, a third required intervention for tracheal bleeding (*Table 2*). The majority of these (86% of patients with bleeding) met the definition of bleeding because of the need to hold therapeutic anticoagulation. As the thrombotic nature of COVID-19 has been further elucidated (44), practice has shifted toward therapeutic anticoagulation for the critically ill (45). Our series likely represents a later phase of the pandemic than previous reports and thus had a higher rate of therapeutically anticoagulated patients (80%). Additionally, a large portion of our cohort (20%) required full anticoagulation for ECMO, which notably has a reported 40% historical rate of requiring blood product transfusion in the first 48 hours after tracheostomy (34).

Selection of patients for tracheostomy

Some groups have advocated for prioritizing tracheostomy for patients based on pre-tracheostomy disease severity (26). A multivariate analysis of mortality in COVID-19 tracheostomy patients in a retrospective cohort of 23 patients demonstrated association of both SOFA score >6 and D-dimer level >4 with a higher risk of death, and thus the authors recommended delaying or not pursuing tracheostomy in these patients (26). In our cohort, no association between these scores and in hospital mortality was identified. All-cause mortality is certainly multifactorial and will require data from the multicenter studies for further delineation in COVID-19 tracheostomy patients.

Given the high pre-procedural respiratory support requirements in our cohort, we also examined whether complications would be more likely in patients with a PEEP >10. Higher mechanical support requirements reflect poor lung compliance, which contributes to the known high baseline incidence of perioperative pulmonary

complications in COVID-19 patients (46). Additionally, higher respiratory support requirements may be a marker for poorer prognosis. We found that tracheostomy could be safely performed in patients despite high respiratory support requirements in our case series. Furthermore, we observed no association of complications with pre-tracheostomy high respiratory support parameters.

Limitations

This study has several limitations inherent in single-institution retrospective case series. The design precludes any inferences of causality regarding timing of tracheostomy and endpoints, such as duration of mechanical ventilation, complications, or mortality. While the association of earlier tracheostomy with shorter duration of mechanical ventilation is consistent with the results of the TracMan trial (40), selection bias is likely. For example, delays in tracheostomy may be necessary in sicker patients requiring a higher level of ventilator support or a function of transfers from outside institutions. Secondly, as a large referral hospital with ECMO services, our experience may not be generalizable to other clinical settings. Additionally, long-term outcomes for these patients, including full decannulation rates, delayed laryngotracheal complications of intubation or tracheostomy, and final mortality statistics cannot be described in this early report. Despite these limitations, this institutional experience is among the first to provide longer-term detailed data on rates of liberation from mechanical ventilation and subsequent decannulation of COVID-19 patients who undergo tracheostomy at different time points.

Conclusions

In conclusion, we find that tracheostomy can be safely performed in COVID-19 patients, including those on ECMO, and may be associated with decreased duration of mechanical ventilation.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the University of Michigan (HUM00185123), and individual consent for this retrospective analysis was waived.

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