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Early ventilator liberation and decreased sedation needs after tracheostomy in patients with COVID-19 infection

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ABSTRACT

Background Since the outset of the coronavirus disease 2019 (COVID-19) pandemic, published tracheostomy guidelines have generally recommended deferral of the procedure beyond the initial weeks of intubation given high mortality as well as concerns about transmission of the infection to providers. It is unclear whether tracheostomy in patients with COVID-19 infection facilitates ventilator weaning, and long-term outcomes are not yet reported in the literature.

Methods This is a retrospective study of tracheostomy outcomes in patients with COVID-19 infection at a single-center academic tertiary referral intensive care unit. Patients underwent percutaneous tracheostomy at the bedside; the procedure was performed with limited staffing to reduce risk of disease transmission.

Results Between March 1 and June 30, 2020, a total of 206 patients with COVID-19 infection required mechanical ventilation and 26 underwent tracheostomy at a mean of 25±5 days after initial intubation. Overall, 81% of tracheostomy patients were liberated from the ventilator at a mean of 9±6 days postprocedure, and 54% were decannulated prior to hospital discharge at a mean of 21±10 days postprocedure. Sedation and pain medication requirements decreased significantly in the week after the procedure. In-hospital mortality was 15%. Among tracheostomy survivors, 68% were discharged to a facility.

Discussion The management of patients with COVID-19 related respiratory failure can be challenging due to prolonged ventilator dependency. In our initial experience, outcomes post-tracheostomy in this population are encouraging, with short time to liberation from the ventilator, a high rate of decannulation prior to hospital discharge, and similar mortality to tracheostomy performed for other indications. Barriers to weaning ventilation in this cohort may be high sedation needs and ventilator dyssynchrony.

Level of evidence Level V—Therapeutic/care management.

INTRODUCTION

The current cumulative coronavirus disease 2019 (COVID-19) hospitalization rate in the USA is 98.4 per 100,000, with the highest rates in people aged 65 years and older.[1] Up to 20% of these patients require hospitalization.[2 3] Early experience in China found that 5% of patients require intensive care unit (ICU) admission.[3 4] If admitted to the ICU, 35% to 88% of patients require mechanical ventilation (MV) with an associated mortality of 25% to 88%.[2 3 5–8]

Patients with COVID-19-induced respiratory failure frequently require extended MV beyond 2 to 3 weeks.[9 10] Early guidelines recommended deferring tracheostomy in these patients beyond the first weeks of MV due to high early patient mortality and potential risks to proceduralists.[11–14] Consistent with reports from other centers, we observed that many intubated patients with COVID-19 infection require unusually high doses of sedation, increasing the risk of delirium, an independent predictor of longer lengths of stay, higher mortality, greater cost of care, and acquired dementia in ICU survivors.[15–19] Increased sedation requirements may contribute to failure to liberate patients with COVID-19 infection from ventilator support successfully.

Published series of tracheostomy in patients with COVID-19 infection now suggest that with appropriate precautions, it is safe for both patients and healthcare workers.[20–24] Nevertheless, the benefit of tracheostomy for these patients is unclear. We sought to report the primary outcomes of MV weaning and liberation after tracheostomy in critically ill patients with COVID-19 infection. Secondary outcomes include in-hospital mortality, sedation and analgesia requirements, and need for long-term care.

METHODS

We identified all patients with COVID-19 infection undergoing tracheostomy at an urban tertiary academic medical center from March 1, 2020 to June 30, 2020, during the first wave of COVID-19 infections in Colorado. This study was approved by the Colorado Multi-Institutional Review Board (COMIRB #20–0947) with a waiver for patient consent.

Tracheostomy was generally performed after at least 21 days of intubation, a timeframe which was selected in mid-April of 2020 to balance healthcare provider safety/exposure with the ability to facilitate ventilator weaning and limit sedative usage. Repeat COVID-19 testing was performed on tracheal aspirate and nasopharyngeal swabbing prior to tracheostomy. However, positive results did not preclude performing the procedure. All initial procedures were done at bedside in negative pressure ICU rooms.

Prior to tracheostomy, the ICU team performed a 15 to 20 second respiratory hold to ensure no significant derecruitment or prolonged desaturation, to demonstrate adequate reserves to allow a respiratory hold during the procedure. This permitted a period without ventilation while both the endotracheal tube and tracheostomy tube cuffs were deflated, thereby minimizing aerosol exposure. Guidelines for ventilator settings were left to attending surgeon discretion, generally accepted as fraction of inspired oxygen (FiO_2) ≤60% and a positive end-expiratory pressure ≤10. Personal protective equipment (PPE) for those in the room consisted of gown, gloves, and either a powered air-purifying respirator or a half-face respirator and face shield.

All tracheostomies in this series were performed percutaneously, although the technique was at surgeon discretion. The tracheostomy protocol (for further details, see online supplemental digital content) was agreed on by the trauma and acute care surgeons and distributed to the entire multidisciplinary team of pulmonary, anesthesia, and surgical critical care intensivists who were caring for patients with COVID-19 infection. If applicable, therapeutic anticoagulation was held both before (2 to 4 hours for heparin/bivalirudin and 12 to 24 hours for enoxaparin) and after (2 to 4 hours) tracheostomy.

Patient data abstracted from the electronic medical record were stored securely in REDCap. Average daily doses of intravenous infusion sedatives and analgesics (hydromorphone, ketamine, propofol, midazolam, and dexmedetomidine) were calculated for each patient for the day preceding tracheostomy, day of tracheostomy (postoperative day (POD) 0), and each of the 7 days after tracheostomy (POD1 to POD7). We used total volume infused to calculate the average rate of the infusion during the 24 hours for each patient. For oral opioids (oxycodone or methadone), equianalgesic doses were calculated using morphine milligram equivalents (MMEs).[25] For opioid infusions (hydromorphone), the volume infused was used to calculate an oral equivalent dose, with a ratio of 2.5 to 1 for intravenous to oral conversion, and this was again converted to MMEs.[26] Daily morning assessments using the Richmond Agitation and Sedation Scale (RASS) and the Critical Care Pain Observation Tool (CPOT) were recorded, and patients were considered to be adequately sedated with a RASS ≤1 and CPOT of 0.

We used the R Program for Statistical Computing V.4.0.0 for statistical analyses.[27] Except where otherwise noted, values are expressed as mean±SD. Comparisons of proportions were made using a χ^2 test, or where appropriate, a Fisher's exact test. For comparisons between doses of medications, a repeated-measures analysis of variance was calculated to analyze if doses differed across the timeframe studied (day prior to tracheostomy up until POD7). We excluded patients who were not on a given medication at any point during this timeframe. To compare daily doses to baseline doses, mixed-effect modeling was used to analyze whether the average dose on any given day differed from the average dose the day prior to tracheostomy.

RESULTS

During the study period, 919 patients with COVID-19 were treated at our institution: of the 300 treated in the ICU, 206 were intubated and required MV (figure 1). We identified a total of 26 patients undergoing tracheostomy at an average of 25±5 days (range 15 to 38 days) after initial intubation. Only one patient underwent tracheostomy earlier than the recommended 21 days of MV per our policy. Patients were predominately male (n=21, 81%), averaged 55±12 years of age (range 27 to 78), and were Hispanic/Latino (n=13, 50%), Black (n=5, 19%), White/Caucasian (n=6, 23%), or Other (n=2, 8%); further characteristics are given in table 1.

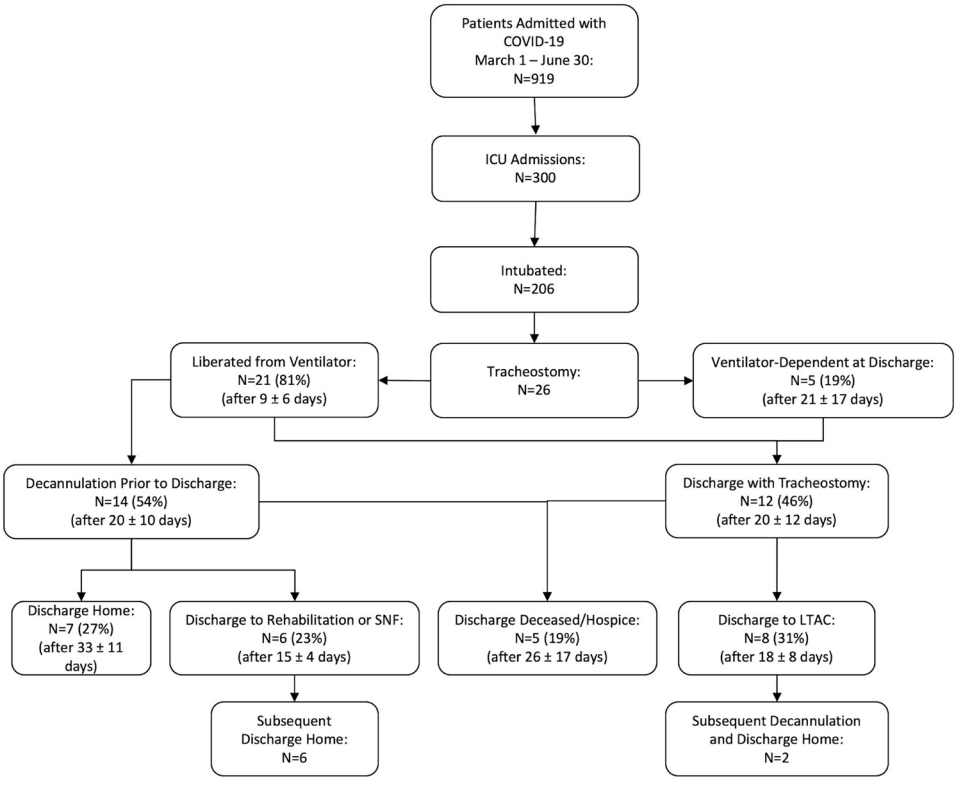

Figure 1 Flow diagram of patients included in the study, outcomes, and discharge disposition. Average time from the tracheostomy procedure to each outcome is reported. COVID-19, coronavirus disease 2019; ICU, intensive care unit; LTAC, long-term acute care; SNF, skilled nursing facility.

Table 1 Characteristics of the population as well as comparison of patients who were or were not ventilator-dependent at 15 days post-tracheostomy

	All patients (n=26)	Ventilator dependence at 15 days (n=9)	No ventilator dependence at 15 days (n=17)	P value
Age in years (mean±SD)	55±12	55±11	55±13	0.96
Male sex, n (%)	21 (81%)	5 (56%)	16 (94%)	0.06
Obesity (BMI >30), n (%)	8 (31%)	3 (33%)	5 (29%)	1.00
At least one major medical comorbidity, n (%)	20 (77%)	8 (89%)	12 (71%)	0.57
Diabetes, n (%)	12 (46%)	4 (44%)	8 (47%)	1.00
Hypertension, n (%)	11 (42%)	4 (44%)	6 (35%)	0.97
ECMO prior to tracheostomy, n (%)	8 (31%)	3 (33%)	5 (29%)	1.00
CRRT prior to or at time of tracheostomy, n (%)	11 (42%)	4 (44%)	7 (41%)	1.00
History of failed extubation/reintubation, n (%)	13 (50%)	2 (22%)	11 (65%)	0.10
Days of MV before tracheostomy (mean±SD)	24±5	24±6	25±5	0.43
FiO_2 >40% at time of tracheostomy, n (%)	8 (31%)	5 (56%)	3 (18%)	0.12
PEEP >8 cm H_20 at time of tracheostomy, n (%)	4 (15%)	2 (22%)	2 (12%)	0.90
PaO_2 to FiO_2 ratio <200, n (%)	9 (35%)	4 (44%)	5 (29%)	0.74
Impaired neurologic status with GCS<8, n (%)	7 (27%)	6 (67%)	1 (6%)	<0.01

BMI, body mass index; CRRT, continuous renal replacement therapy; ECMO, extracorporeal membrane oxygenation; FiO_2, fraction of inspired oxygen; GCS, Glasgow Coma Scale; MV, mechanical ventilation; PEEP, positive end-expiratory pressure.

All procedures were completed in an ICU designated for the care of patients who were COVID-19 positive, with no intraoperative complications. Five patients were COVID-19 negative before the procedure (19%). The duration of the procedure was 36±16 minutes (range 11 to 86 minutes).

Most patients were therapeutically anticoagulated prior to tracheostomy (n=20, 77%), either with a heparin/bivalirudin continuous infusion (n=12) or subcutaneous enoxaparin (n=8). Two patients had minor bleeding postoperatively managed with topical absorbable hemostatic agents and/or holding anticoagulation.

There were no surgical site infections. Five patients had accidental dislodgment of the tracheostomy tube: two patients had adequate respiratory status and remained decannulated, two patients required tracheostomy tube replacement at the bedside, and one tracheostomy tube was replaced in the operating room due to difficult airway concerns. Two additional patients had tracheostomy tube cuff malfunctions requiring orotracheal reintubation due to an inability to adequately ventilate. One patient was able to undergo redo tracheostomy in the operating room 1 week after reintubation. The other patient had relapsing adult respiratory distress syndrome and was subsequently on high ventilator settings prohibiting redo tracheostomy; the decision was ultimately made to pursue comfort measures. This death was not deemed to be a complication of the tracheostomy procedure itself.

Most patients (n=22, 85%) were on at least one intravenous infusion for pain or sedation management 24 hours prior to tracheostomy, including hydromorphone, ketamine, midazolam, propofol, and dexmedetomidine; patients were on an average of two such infusions (range 0 to 4). After tracheostomy, use of intravenous infusions for pain/sedation management fell steadily during the first postoperative week with the number of patients requiring >2 infusions decreasing also (figure 2A). Concurrently, a significant number of patients were actively weaning from the ventilator (partial support meaning some time with spontaneous modes of ventilation) or were fully liberated (figure 2B). Furthermore, average doses of all intravenous sedation medications decreased during the week after tracheostomy (figure 3A–C). The average daily dose of intravenous opioid infusions was significantly less on POD2 to POD7 as compared with the day prior to tracheostomy, without a corresponding increase in the daily consumption of oral MMEs (figure 3D,E). During the day preceding tracheostomy, the proportion of

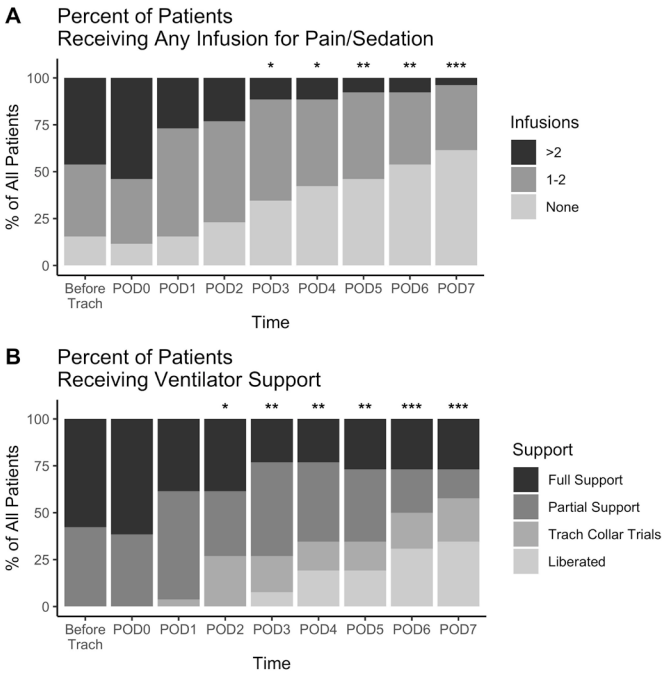

Figure 2 (A) Percentage of patients on multiple intravenous infusions for sedation, single intravenous infusion, or no intravenous infusions during the 24-hour period prior to tracheostomy, day of tracheostomy (POD0), and first 7 days after tracheostomy (POD1 to POD7). (B) Corresponding proportion of patients on different degrees of ventilator support across the same timeframe. Stars denote significant change in distribution across groups as compared with distribution at baseline according to Fisher's exact test (*p<0.05, **p<0.01, ***p<0.001). POD, postoperative day.

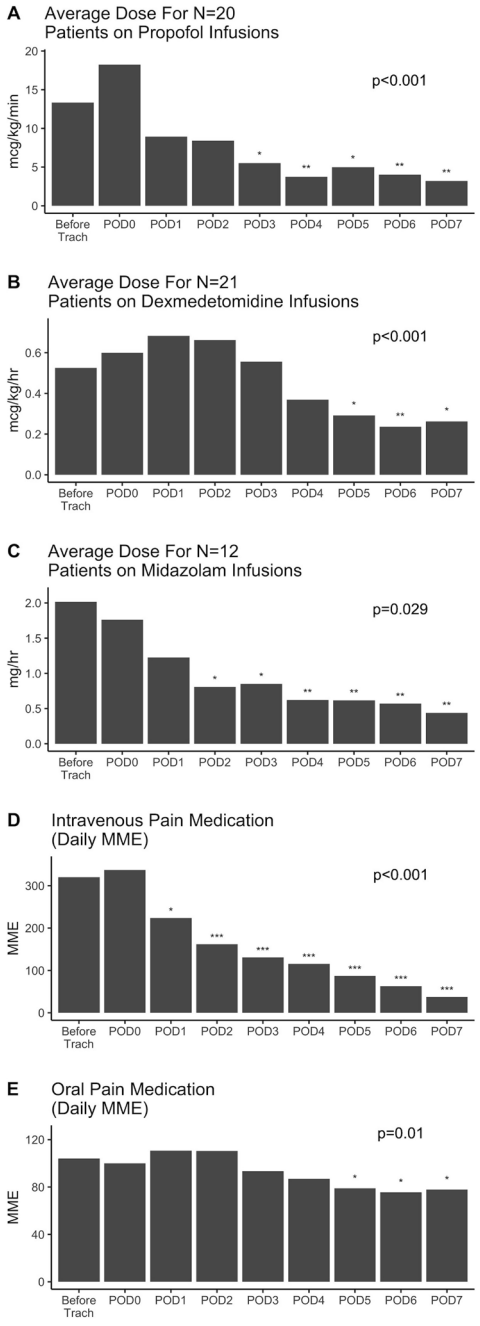

Figure 3 Average rates of intravenous sedation agents: (A) propofol (mg/kg/minute), (B) dexmedetomidine (mcg/kg/hour), and (C) midazolam (mg/hour) during the 24-hour period prior to tracheostomy, day of tracheostomy (POD0) and first 7 days after tracheostomy (POD1 to POD7). Also displayed are average daily cumulative doses of opioid medications given (D) via intravenous infusion or injection and (E) orally. Results of repeated-measures ANOVA across entire timeframe are displayed in top right corner of each figure. Stars denote significant decrease from baseline (day prior to tracheostomy) according to mixed-effects modeling (*p<0.05, **p<0.01, ***p<0.001). ANOVA, analysis of variance; MME, milligram morphine equivalent; POD, postoperative day.

patients with a RASS>1 was 4% (1/26) and the proportion with CPOT >0 was 23% (6/26). These proportions did not change significantly during the postoperative period, ranging from 0% to 15% and 12% to 27%, respectively, on each of the 7 days after tracheostomy.

Patients were followed until the most recent encounter documented in the medical record as of July 14, 2020, for an average of 49±23 days (range 7 to 89 days) after tracheostomy. Overall, 21 patients (81%) liberated from the ventilator after an average of 9±6 days (range 2 to 25 days) after tracheostomy. Three patients remained on full ventilator support, and two patients remained on intermittent ventilatory support at the time of discharge or death. Eighteen patients had their tracheostomy tube downsized before discharge (69%), and 14 patients (42%) were decannulated prior to discharge at an average of 20±10 days (range 8 to 43 days) after tracheostomy. Of the decannulated patients, seven were discharged home, five were discharged to an acute rehabilitation facility, one was discharged to a skilled nursing facility (SNF), and one died prior to discharge. Six patients were on room air at the time of discharge. Two additional patients were known to have been decannulated after discharge for a total of 16 patients (62%) decannulated at the time of most recent follow-up, with the majority living at home (15/16, 94%). Eight patients discharged to a long-term acute care (LTAC) facility with six (6/8, 75%) already liberated from the ventilator prior to discharge. The average time from tracheostomy to discharge was 23±12 days and total hospital stay was 49±13 days.

Four patients died (15%) and one patient was discharged to a facility-based hospice program (4%). The mean time to death or hospice discharge after tracheostomy was 24±17 days (range 7 to 49 days). Four patients were transitioned to comfort measures: two after devastating neurologic complications and two because of failure to wean from the ventilator. One patient suffered a cardiac arrest of unknown cause 1 week after decannulation.

Looking at outcomes at 15 days post-tracheostomy, 7 patients (27%) had been decannulated, 10 (38%) were off the ventilator with a tracheostomy in place, 2 (8%) were on intermittent ventilator support, 2(8%) were on partial ventilator support, 3 (12%) were on full ventilator support, and 2 (8%) died while still ventilated. Comparing patients fully liberated from the ventilator to those who were not/had died, we found these groups were similar in age, rates of obesity and other comorbidities, history of extracorporeal membrane oxygenation (ECMO) or continuous renal replacement therapy (CRRT), and time to tracheostomy. Patients with impaired neurologic status at the time of tracheostomy were less likely to be liberated from the ventilator (p=0.01) (table 1).

DISCUSSION

The management of patients with COVID-19 related respiratory failure can be challenging due to prolonged ventilator dependency, often lasting more than 3 weeks. In this study, we found that 81% of patients who underwent a tracheostomy for prolonged respiratory failure in the setting of COVID-19 infection were liberated from the ventilator, and 54% were decannulated before discharge from the hospital, with average time to decannulation of 21±10 days.

Our study provides the most information to date on long-term disposition after tracheostomy in patients with COVID-19 infection, with the longest follow-up time currently reported in the literature (49±23 days after tracheostomy) and with all patients included patients discharged at the time of follow-up (table 2). We observed that most patients in our cohort were discharged alive (n=22), often to an LTAC (n=8, 36%) SNF (n=1, 5%) or acute rehabilitation facility (n=5, 23%). Due to difficulties with discharging patients with COVID-19 infection during the pandemic as well as insurance issues, some patients who might have otherwise discharged to a facility were hospitalized until

Table 2 Comparison of current study results to other published series in the literature

	Turri-Zanoni *et al*[20]	Zhang *et al*[21]	Broderick *et al*[22]	Angel *et al*[23]	Chao *et al*[29]	Floyd *et al*[24]	Current study
Study period	2/24–3/15	1/23–4/6	–	3/10–4/15	–	4/1–4/30	3/1–6/30
Study location	Varese, Italy	Wuhan, China	Manchester, UK	New York, USA	Philadelphia, USA	New York, USA	Denver/Aurora, USA
Number of patients	32	11	10	98	53	38	26
Time from intubation to tracheostomy in days (mean±SD or (range))	15 (9–21)	17 (6–36)	17±5	11±5	20±7	24 (20–28)	25±5
Percutaneous	10 (31%)	6 (55%)	0	98 (100%)*	19 (55%)	0	26 (100%)
Complications							
Bleeding	0	0	0	5 (5%)	1 (2%)	4 (11%)	2 (8%)
Wound infection	0	2 (18%)	0	–	1 (2%)	0	0
Follow-up after tracheostomy in days (mean±SD or (range)))	21 (8–37)	–	14±7	11±6	–	–	49±23
Ventilator support at discharge or follow-up, n (%)							
Full support	–	–	1 (10%)	40 (41%)	–	–	3 (12%)
Partial support	–	–	2 (20%)	19 (19%)	–	–	2 (8%)
No ventilatory support	–	9 (82%)	7 (70%)	32 (33%)	30 (57%)	21 (55%)	21 (81%)
Time to liberation from ventilator (mean±SD or (range))	–	7 (2–19)	–	–	12±7	10	9±6
Tracheostomy status, n (%)							
Downsized	–	–	–	19 (19%)	14 (26%)	7 (18%)	18 (73%)
Decannulated	1 (3%)	–	6 (60%)	8 (8%)	7 (13%)		16 (65%)
Time to decannulation (mean±SD)	–	–	10±4		17±5	14	20±10
Disposition							
Deceased	5 (16%)	0	0	7 (7%)	6 (11%)	2 (5%)	4 (15%)
ICU	–	–	4 (40%)	76 (78%)	–	–	0
Non-critical care	–	–	4 (40%)	11 (11%)	–	–	0
Discharged	–	–	2 (20%)	4 (4%)	16 (30%)	–	22 (85%)

*Majority performed using a "novel" percutaneous dilation technique.
ICU, intensive care unit.

they could safely be discharged home, which is reflected in the long time to hospital discharge after tracheostomy (23±12 days). At the time of the most recent follow-up, a total of 15 patients were living at home.

Early in the pandemic, guidelines were published with regard to tracheostomy for COVID-19 related respiratory failure, generally recommending deferral of tracheostomy beyond the initial weeks of MV.[11–14] Early series from China and Italy showed high mortality with COVID-19 disease requiring ICU care, suggesting limited benefit to tracheostomy.[3 8] Additionally, early surgical society recommendations emphasized presumed high risk of provider exposure during tracheostomy.[14 28] From personal correspondence, we were aware that multiple surgical groups in the USA in April of 2020 were not considering tracheostomy in patients with COVID-19 infection given these concerns of limited benefit to patients coupled with potential provider risk. Reports now suggest that the operation can be performed safely in patients with COVID-19 infection with regard to viral transmission, with several case series reporting no evidence of transmission to proceduralists.[20–24 29] Furthermore, a study by Cummings *et al* found that survivors of MV for COVID-19 had a median duration of MV of 27 days (compared with 10 days in non-survivors),[9] suggesting that those who survive MV for COVID-19 are not necessarily just those who extubate early. Thus, tracheostomy should be a clinical consideration for COVID-19 patients when appropriate PPE is available.

Overall, four patients (15%) died prior to discharge with an additional patient discharged to hospice (4%), a mortality rate slightly higher than that quoted in other recent studies of tracheostomy for COVID-19, which have ranged from 0% to 16%.[20–23 29] This likely reflects our longer follow-up time, as time to death/hospice discharge after tracheostomy was 24±17 days. Our in-hospital mortality is consistent with the overall post-tracheostomy death rate of 20% in the USA, even though patients with severe COVID-19 infection have high rates of multiorgan failure.[30] No patient died of complications specifically related to tracheostomy; only two patients were transitioned to comfort care because of worsening respiratory status after tracheostomy. Complications after tracheostomy were similar to those reported in other small cohorts of patients with COVID-19 infection. Although 8% of patients experienced minor bleeding managed without surgical intervention, this may reflect the large portion of patients in the study on therapeutic anticoagulation at the time of the procedure (77%). Further research is needed to analyze if the risks of holding anticoagulation for a longer period of time after tracheostomy in patients with COVID-19 infection outweigh the benefits.

Compared with other studies published to date,[20–24 29] we were relatively conservative regarding tracheostomy timing, with nearly all procedures performed after 21 days after initial intubation, and mean duration of MV of 25±5 days preprocedure. All procedures were performed at bedside in the ICU without

intraoperative complications. Other authors have reported and advocated for tracheostomy at an earlier timepoint, as soon as 1 week after intubation. Emerging evidence would suggest that patients are no longer infectious to others within 10 days of the time of diagnosis and symptoms. Earlier tracheostomy in patients with COVID-19 infection could have the benefit of decreasing ICU length of stay and conserving resources when hospital systems are overwhelmed. However, a downside may be an increase in unnecessary procedures—tracheostomy may be performed in patients who would otherwise be able to quickly wean off the ventilator without intervention, or conversely, in patients who may not survive illness. In our cohort, among patients who were intubated for at least 1 week, a majority were able to extubate prior to 21 days or died before that time point.

Comparing patients who were liberated from the ventilator at 15 days post-tracheostomy to those who were not, we found no significant differences in age, comorbidities, history of ECMO/CRRT, or duration of MV before tracheostomy between these groups, suggesting that survival to at least 21 days postintubation may be a useful indicator when considering tracheostomy benefit. We found that neurologically impaired patients who underwent tracheostomy were more likely to be ventilator-dependent at 15 days after tracheostomy, suggesting a cohort where tracheostomy may be of less benefit. Additional larger studies will be necessary to analyze indications and optimal timing for tracheostomy in patients with COVID-19 infection.

This study is the first to examine changes in pain and sedation management after tracheostomy in patients with COVID-19 infection. We analyzed that the average daily quantity of intravenous opioids (hydromorphone) used substantially decreased on postoperative days 2 to 7 as compared with preoperative baseline, without any significant change in oral opioids (oxycodone and methadone). Similarly, both the number of patients requiring any form of an intravenous infusion for sedation and the average doses of sedation used decreased significantly after tracheostomy. This finding is particularly important given reports of high sedation needs among patients with COVID-19 infection.[17] Hospital-wide shortages of intravenous infusions require adaptability from standard and preferred approaches to pain and sedation management. Thus, tracheostomy may be beneficial in decreasing the use of these strained resources. Additionally, the short time to wean from the ventilator and to decannulation for many patients indicates that high levels of sedation prior to tracheostomy, and not the degree of lung parenchymal disease itself, may be a limiting factor in weaning patients with COVID-19 infection from the ventilator.

This study is limited by its small sample size, retrospective nature, and lack of a comparator group. Because of our policy, nearly all patients who were intubated at least 21 days and on appropriate ventilator settings underwent tracheostomy at around this time point. Indeed, of the 180 patients who were intubated for COVID-19 and did not receive a tracheostomy during the timeframe considered, only nine patients remained alive and intubated at 25 days of MV, which was the average time to tracheostomy in our cohort; of these, one patient went on to extubate without receiving a tracheostomy and eight were never felt to be stable for the procedure and died while intubated. This fact limits our ability to comment on the benefits of earlier tracheostomy and also makes it impossible to consider a matched comparator group within our patient population. Consideration for tracheostomy was based on consultation by a mixed group of pulmonary, anesthesia, and surgical critical care faculty, with potential selection bias. Additionally, it is unclear whether the decreased need for intravenous pain and sedation medication after tracheostomy is because of a decreased need or increased willingness on the part of intensivists to wean these agents with a more secure airway. Finally, although no symptomatic COVID-19 infections were reported among procedural members, our institution was not testing asymptomatic providers.

In conclusion, we find that tracheostomy in patients with prolonged COVID-19 related respiratory failure is a useful adjunct to facilitate ventilator weaning. Most patients are quickly liberated from the ventilator after tracheostomy, many are decannulated prior to discharge, and mortality is comparable to published studies of tracheostomy in other populations. Tracheostomy appears to facilitate weaning from sedation; the short duration of MV after tracheostomy suggests that sedation requirements and ventilator dyssynchrony may be primary barriers to weaning these patients from the ventilator. Further study is needed to determine the optimal timing of tracheostomy in these patients.

Contributors HC had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis, including and especially any adverse effects. HC, FLW, RCM, TV, SU, and JPI contributed substantial to the study conception and design. HC, FLW, RCM, TV, SU, SEJ, ELB, WF, CGV, and JPI contributed substantially to data analysis and interpretation and the writing of the article.

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