# Percutaneous and Open Tracheostomy in Patients with COVID-19

Comparison and Outcomes of an Institutional Series in New York City

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**Objective:** The aim of this study was to report the safety, efficacy, and early results of tracheostomy in patients with COVID-19 and determine whether differences exist between percutaneous and open methods.

**Summary Background Data:** Prolonged respiratory failure is common in symptomatic patients with COVID-19, the disease process caused by infection with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Tracheostomy, although posing potential risk to the operative team and other healthcare workers, may be beneficial for safe weaning of sedation and ventilator support. However, short- and long-term outcomes remain largely unknown.

**Methods:** A prospectively collected database of patients with COVID-19 undergoing tracheostomy at a major medical center in New York City between April 4 and April 30, 2020 was reviewed. The primary endpoint was need for continued mechanical ventilation. Secondary outcomes included complication rates, sedation weaning, and need for intensive care unit (ICU) level of care. Patient characteristics, perioperative conditions, and outcomes between percutaneous and open groups were analyzed.

**Results:** During the study period, 67 consecutive patients underwent tracheostomy, including 48 males and 19 females with a median age of 66 years [interquartile range (IQR) 52–72]. Two surgeons alternated techniques, with 35 tracheostomies performed percutaneously and 32 via an open approach. The median time from intubation to tracheostomy was 23 days (IQR 20–26).

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Copyright © 2020 Wolters Kluwer Health, Inc. All rights reserved. ISSN: 0003-4932/20/27303-0403 DOI: 10.1097/SLA.000000000004428 At a median follow-up of 26 days, 52 patients (78%) no longer required mechanical ventilation and 58 patients (87%) were off continuous sedation. Five patients (7.5%) died of systemic causes. There were 11 total complications (16%) in 10 patients, most of which involved minor bleeding. There were no significant differences in outcomes between percutaneous and open methods.

**Conclusions:** Tracheostomy under apneic conditions by either percutaneous or open technique can be safely performed in patients with respiratory failure due to COVID-19. Tracheostomy facilitated weaning from continuous intravenous sedation and mechanical ventilation. Continued follow-up of these patients to ascertain long-term outcome data is ongoing.

Keywords: COVID-19, open tracheostomy, percutaneous tracheostomy, tracheostomy, tracheostomy outcomes

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As of May 24, 2020, there have been >4.7 million cases and >315,000 deaths worldwide from COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2). The United States has seen >1.6 million cases and >95,000 deaths thus far.<sup>1</sup> New York was an early epicenter of the pandemic; to date, it has accounted for approximately 23% of cases and 30% of deaths domestically.<sup>2</sup> Symptomatic patients with COVID-19 can rapidly develop acute respiratory distress syndrome (ARDS) and superimposed pneumonia requiring invasive mechanical ventilation. Intensive care unit (ICU) admissions have ranged from 12% to  $26\%^{3-6}$  and rates of intubation can be as high as 20% to 33% for severe cases.<sup>7,8</sup> As a result, mounting numbers of patients in need of prolonged mechanical ventilation are now commonplace, and securing an adequate supply of ventilators to serve this population has been one of the many challenges faced by healthcare institutions across the world.<sup>9</sup>

In nonpandemic times, tracheostomy is generally recommended for stable patients who have had prolonged intubation with an endotracheal tube (ETT). Prolonged intubation can be associated with laryngotracheal stenosis, ventilator-associated pneumonia, and longer length of stay.<sup>10–12</sup> A tracheostomy typically allows the patient to require less sedation, which may subsequently hasten ventilator weaning.<sup>13–15</sup> Despite these potential benefits, there is no consensus from the critical care literature that tracheostomy confers a significant survival advantage.<sup>14,16,17</sup>

Tracheostomy can be performed by either an open or percutaneous method. Randomized trials have shown only minor differences between techniques, but some early guidelines favored one approach over another for patients with COVID-19.<sup>11,18–20</sup> Irrespective of the method chosen, in the current pandemic there is significant uncertainty regarding patient selection and timing of tracheostomy.<sup>10,18,19,21</sup> Similarly, during the 2003 outbreak of severe acute respiratory syndrome (SARS), the high prevalence of mechanically ventilated patients prompted a discussion on the safety and utility of tracheostomy.<sup>22</sup> Still, only 23 cases of tracheostomy among 5 institutions were

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reported in the setting of that epidemic.<sup>23,24</sup> We now find ourselves in a pandemic during which data are urgently needed, particularly given the long duration of sedation and mechanical ventilation required for large numbers of patients with respiratory failure, as well as the potential shortage of ICU beds and ventilators.<sup>11,25</sup>

Tracheostomy has the potential to facilitate ventilator weaning and free up resources<sup>26,27</sup>; however, the outcomes of tracheostomy in patients with COVID-19 have not been extensively reported. The objective of this study is thus to report our institution's experience with tracheostomy in patients with COVID-19, with a focus on percutaneous versus open methods. We hypothesized that there would be no significant differences between the 2 methods in this patient population.

# **METHODS**

An institutional protocol for tracheostomy was established. Patients with respiratory failure from COVID-19 were considered for tracheostomy after two to three weeks of intubation. Patients had to tolerate a period of apnea following pre-oxygenation for approximately 90 seconds without desaturations below 90% SpO<sub>2</sub> or hemodynamic change. Given the apneic tolerance required, the protocol initially recommended that the fraction of inspired oxygen (FiO<sub>2</sub>) be no greater than 50% and positive end-expiratory pressure no greater than 10.

All consecutive adult patients with COVID-19 who underwent tracheostomy by 2 attending surgeons at our institution during April 2020 were included. Patients had at least 2 weeks of postoperative time available for analysis. Percutaneous and open tracheostomies were performed in a sequential, alternating pattern by a thoracic surgeon and an otolaryngologist, respectively. The 2 surgeons alternated patients and assisted each other on the majority of cases. Personal protective equipment (PPE) was worn by all providers according to hospital policy for aerosol-generating procedures (AGPs). The minimum number of required personnel were present. The anesthesia team ensured complete paralysis and adequate sedation for the entirety of the procedure. The tracheotomy was performed under apneic conditions to minimize viral aerosolization as described in other published protocols.<sup>21,28</sup> Only nonfenestrated, cuffed tracheostomy tubes were used (#6 or #8 Shiley<sup>TM</sup> DCT). Procedures were performed in traditional and nontraditional ICUs as well as former operating rooms converted to ICUs.

All patients had a documented diagnosis of COVID-19 confirmed by reverse transcription polymerase chain reaction (RT-PCR). A prospective database included demographics, medical comorbidities, COVID-19 laboratory results, intubation history, ventilator requirements, perioperative medications, and postoperative outcomes. Anticoagulation regimens were grouped into prophylactic and therapeutic based on institutional protocol. Doses in between these 2 groups were categorized as intermediate. It was our clinical practice to hold the morning dose of anticoagulation. The electronic medical record was queried for patients in the database (Eclipsys Allscripts Enterprise, Allscripts Healthcare Solutions, Inc., Chicago, IL).

The primary outcome was defined a priori as need for mechanical ventilation. Secondary outcomes included time to wean off sedation, need for ICU level of care, and complication rates between percutaneous and open tracheostomy. Tracheostomy collar tolerance for >24 hours was used to determine the time to wean off all ventilatory and positive pressure support. Sedation weaning was defined as the time at which the patient no longer required any intravenous sedating drip medications for >24 hours. Oral and intravenous medications not delivered by continuous drip were not considered for this endpoint.

Complications were divided into major, intermediate, and minor categories. Major was defined as any significant procedural problem occurring during the tracheostomy or any complication requiring an unplanned return to the operating room. Intermediate included any complication requiring a bronchoscopy or antibiotic treatment. Minor was defined as requiring basic bedside intervention (eg, local packing for bleeding).

Fisher exact,  $\chi^2$ , and Wilcoxon rank sum tests were utilized to compare the percutaneous and open tracheostomy groups on demographic variables, clinical characteristics, and outcomes. Time to outcome events was estimated using the Kaplan-Meier method and medians were compared using the log-rank test. Hypothesis tests were 2-sided and statistical significance was evaluated at the 0.05 alpha level. Analyses were performed in R Core Team (Survival and Tidyverse, version 3.5.3, 2019, Vienna, Austria). This study was approved by the Weill Cornell Medicine Institutional Review Board.

#### RESULTS

From April 4, 2020 to April 30, 2020 there were a total of 144 patients with COVID-19 who were intubated and dependent on mechanical ventilation for >14 days at our institution. Tracheostomy was performed in 67 (47%) of those patients during that time period, including 35 percutaneous (52%) and 32 open (48%) tracheostomies. There were 19 females (28%) and 48 males (72%). The median age was 66 years (range 32–87, IQR 52–72).

Seventeen patients (25%) had at least 1 failed extubation before tracheostomy. The median time from first intubation to tracheostomy was 23 days (range 13–37, IQR 20–26) and the median time from admission to tracheostomy was 24 days (range 14–42, IQR 21–28). Twenty patients (30%) were overweight and 29 patients (43%) were obese. Patient characteristics are shown in Table S1 (Supplemental File, http://links.lww.com/SLA/C551). Of patients undergoing percutaneous versus open tracheostomy, there were no significant differences.

Perioperative conditions are shown in Table S2 (Supplemental File, http://links.lww.com/SLA/C551). Thirty tracheostomies (45%) were performed in converted operating room-to-ICU environments, 11 (16%) were performed in traditional ICUs, and 26 (39%) were performed in other nontraditional ICUs. There were no significant differences in the proportion of each procedure location between those undergoing percutaneous and open tracheostomy (P = 0.7). The median procedure time was 15.5 minutes (range 5–25, IQR 12–20) for percutaneous tracheostomy and 16 minutes (range 5–41, IQR 13–20) for open tracheostomy. This difference was neither clinically nor statistically significant (P = 0.6).

The majority of patients (63%) were on intermediate-dose or therapeutic anticoagulation perioperatively. Patients undergoing percutaneous tracheostomy had a higher frequency of FiO<sub>2</sub>  $\leq$ 40% (*P* = 0.035). The remaining perioperative conditions did not differ between those undergoing percutaneous and open tracheostomy.

Complication and mortality rates are shown in Table 1. There were 11 total complications (16%) in 10 patients related to the tracheostomy. Complication rates did not differ significantly between the percutaneous and open tracheostomy groups. There was 1 major procedure-related complication in a percutaneous tracheostomy requiring conversion to an open procedure after loss of the airway. There were 5 intermediate-level complications including 1 patient with ETT dislodgement at the start of a percutaneous tracheostomy who required reintubation before tracheostomy. There were 5 (7.5%) minor bleeding complications, 2 of which were in percutaneous tracheostomies and the remaining 3 in open tracheostomies (P = 0.7). No patients required reoperation for bleeding despite the high proportion on therapeutic anticoagulation. There were 2 (3%) surgical site wounds requiring antibiotic treatment, both of which occurred in open tracheostomies (P = 0.2).

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# TABLE 1. Complications

Complication, Intervention Category <sup>*</sup> (Minor/Intermediate/Major)	Total, No. (%)	Percutaneous No. (%)	<b>Open</b> <b>No.</b> (%)	$P^{\dagger}$
Surgical site wound or infection, intermediate	2 (3)	0 (0)	2 (6.3)	0.2
Bronchoscopy for noninfectious airway concern or bleeding, intermediate	2 (3)	1 (2.9)	1 (3.1)	>0.9
Procedure-related, intermediate	1 (1.5)	1 (2.9)	0 (0)	>0.9
Procedure-related, major <sup>‡</sup>	1 (1.5)	1 (2.8)	0 (0)	>0.9
Death within 30 days	5 (7.5)	4 (11)	1 (3.1)	0.4

\*Statistics presented: number (%).

†Statistical tests performed: Fisher exact test.

‡For the procedure-related, major complication, the denominator was 36 for the percutaneous and 31 for the open group to account for the patient who ultimately had a percutaneous tracheostomy converted to an open tracheostomy. For the remaining complications, this patient is considered with the open tracheostomy group.

The median follow-up was 26 days (IQR 19-30) and did not differ between those undergoing percutaneous and open tracheostomy (P = 0.6). At the time of review, 52 patients (78%) no longer required mechanical ventilation [n = 28 (80%)] for percutaneous and n = 24 (75%) for open tracheostomy, P = 0.2]. Patients tolerating tracheostomy collar at the time of review required a median of 13 days to reach this outcome (range 2-28). When censored for patients who died or remained on mechanical ventilation at the time of review, the median time was 15 days (95% CI 13-19) and did not differ between those who underwent percutaneous and open tracheostomy [14 days (95% CI 12-20) vs 16 days (95% CI 11-21), respectively, P = 0.9]. The proportions of patients tolerating tracheostomy collar alone by postoperative days 3, 7, and 14 are depicted in Figure 1. At the time of review, 25 patients (37%) had been decannulated at a median postoperative time of 25 days (range 17-36). Again, when censored for patients who did not reach this outcome the median time to decannulation was 29 days and did not differ between groups (P = 0.67).

At the time of review, 58 patients (87%) no longer required continuous intravenous sedation. The median time from tracheostomy to cessation of sedative drips for >24 hours was 5 days (range 1–24). When censored for patients who died or remained on sedation at the time of review, the median time was 7 days (95% CI 5–10) and did not differ between groups (P = 0.73).

At the time of review, 54 patients (81%) had been transferred out of the ICU to floor or stepdown beds at a median postoperative time of 10 days (range 2–29). When censored for patients unable to reach this outcome, the median time was 12 days (95% CI 10–15) and did not differ between groups (P = 0.35). Twenty-two patients (33%) were discharged home or to a rehabilitation center at a median of 22 days postoperatively (range 14–38). Time to outcomes by patient is shown in Figure 2. Five patients (7.5%) died from progressive multiorgan failure during the follow-up period. Of the 77 patients with COVID-19 during this time period who were dependent upon mechanical ventilation for >14 days and who were not determined to be acceptable for tracheostomy, the mortality rate was 49% (n = 38).

# DISCUSSION

## **Patient Characteristics and Outcomes**

Most patients in our cohort were males in their sixth decade with medical comorbidities, most commonly diabetes and hypertension. An overwhelming majority were classified as overweight or obese, with less than one-third of patients in the normal-weight category. These findings are consistent with other reports of comorbidities in patients with COVID-19.<sup>7,29,30</sup>

Despite reports of high mortality rates in patients with COVID-19 requiring mechanical ventilation, a large proportion of patients in our cohort were successfully weaned off continuous sedation and ventilator support. Weaning from sedation and mechanical ventilation enables patients to transfer out of ICUs, thereby freeing hospital resources. In addition, 37% of our patients were decannulated at a median of approximately 1 month postoperatively. In a series of 32 patients with COVID-19 undergoing percutaneous and open tracheostomy in Italy, only 1 patient was decannulated during the study period.<sup>28</sup> Another series of 98 patients with COVID-19 undergoing percutaneous tracheostomy reported a decannulation rate of 8%.<sup>19</sup> Although these are notably less than our results, our median time to decannulation was 4 to 14 days past the follow-up periods of those studies. This likely accounts for these differences and highlights the importance of tracking long-term outcomes for these patients.

Approximately 81% of patients were transferred to stepdown or floor beds where they were able to work with physical and occupational therapists as well as speech and language pathologists on voicing and swallowing. Our mortality rate was <8% and we had no procedure-related mortalities. This is in contrast to some studies in the nonpandemic literature reporting much higher mortality rates from 22% to 25% at 1 month and 46% at 1 year following tracheostomy.<sup>31,32</sup> Although long-term outcomes of our study population are still unknown, our results at this time point are promising.

#### Timing of Tracheostomy

In our cohort, the duration of intubation before tracheostomy was approximately 3 weeks. In critical illness outside of a pandemic, early tracheostomy before intubation day 10 may reduce the incidence of some but not all of the risks associated with prolonged ETT intubation.<sup>33–36</sup> At the start of the outbreak, the mortality rate of intubated patients with COVID-19 was estimated to be >50% by some reports.<sup>6,29,37</sup> Other estimates place mortality in the range of 14% to 25%; however, many patients in these series remain intubated and therefore the final percentages remain unknown.<sup>7,8,38</sup> Given the high mortality rate, lack of consistent benefit, and concern for viral exposure in AGPs, current recommendations are to consider tracheostomy no sooner than 2 to 3 weeks following intubation, and preferably once COVID-19 testing is negative.<sup>10,18</sup> Our comparatively low mortality rate may be partially attributed to selection bias, as many patients with a more guarded prognosis likely died before reaching the consideration time for tracheostomy. It was our practice to only perform tracheostomy on patients with a reasonable expectation of recovery, which was determined though a multidisciplinary effort with input from pulmonary critical care medicine, anesthesia, and surgery teams. All patients were on minimal ventilator settings and were able to tolerate apneic conditions during airway entry. However, in carefully selected patients with prolonged intubation, the mortality rate following tracheostomy appears to be low, at least at this time point of analysis. The relatively prolonged time to

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Postoperative Day

FIGURE 1. Rate of tracheostomy collar tolerance for >24 hours on POD3, POD7, and POD14 for total, percutaneous, and open tracheostomy.

weaning from mechanical ventilation, at approximately 2 weeks postoperatively, speaks to the profound deconditioning and depressed mental status of patients after several weeks of sedation, intermittent paralysis, and ventilator support. This may also reflect sequela not yet appreciated of prolonged COVID-19 infection. Arguably, early tracheostomy may have facilitated more rapid weaning<sup>15,35</sup>, although the potential for this must be weighed against the infectious risk to the healthcare teams<sup>39–41</sup> and the potentially higher rate of secondary complications or progression of disease in patients who undergo tracheostomy earlier in their course.<sup>19</sup>

#### Percutaneous Versus Open Technique

The discussion of percutaneous versus open tracheostomy in mechanically ventilated patients is one that is well-documented in the critical care literature.<sup>42,43</sup> The rate of postoperative bleeding has been shown in some studies to be higher with open tracheostomy compared to percutaneous tracheostomy.<sup>16,44</sup> In a randomized trial of 139 critically ill patients, Antonelli et al found a significantly higher rate of major postoperative bleeding in the open tracheostomy group compared with the percutaneous tracheostomy group. The difference in minor bleeding was not significant, however, which is similar to our findings.<sup>16</sup> Large meta-analyses have also reported higher rates of bleeding and stomal infections from open tracheostomy compared

to percutaneous.<sup>42,44</sup> This is in contrast to our study in which there were no significant differences in complication rates between the 2 methods, and no patient required more than bedside interventions to control bleeding despite having a large proportion of patients on high-dose anticoagulation.

Other studies have shown quicker operative times with a percutaneous technique compared to an open technique.<sup>16,44,45</sup> There was no difference between the 2 methods at our institution, which may have been driven in part by the use of a dedicated surgical team to perform all of the tracheostomies in this study. Furthermore, only 2 attending surgeons were involved, each serving as the primary surgeon for a particular technique. This likely improved the efficiency for both methods, as everyone was well-familiarized with the set-up, donning and doffing of PPE, and procedural steps required.

#### Safety of Tracheostomy

Adhering to our institutional protocols for AGPs, we have been able to perform both open and percutaneous tracheostomies safely thus far in our cohort of patients. Other authors have suggested the use of plastic drapes and other barriers between the surgical site and surgeon.<sup>46–49</sup> Modifications such as these were not used in our study. PPE included use of a head covering, face shield, N95 respirator mask, impermeable surgical gown, neck covering, and

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FIGURE 2. Swimmer plot showing timeline to outcomes by patient.

double gloves. Importantly, all patients were given sedating and paralytic agents to prevent movement and further aerosolization of viral particles and only providers essential to the procedure were inside the room. Many but not all rooms were negative-pressure. Although outside the scope of this article, to date neither of the 2 surgeons performing these procedures have become symptomatic and both have had negative RT-PCR and antibody tests for COVID-19 following the study period.

The influx of patients in New York City during this study's time period created a substantial need for new and increased ICU capacity. The majority of our hospital system during this time was repurposed into functioning ICU spaces to care for overwhelming numbers of patients with COVID-19.<sup>50</sup> Many patients were transferred to converted ICUs within former operating room spaces to perform their tracheostomies, but a significant proportion were performed in areas previously considered to be recovery room, floor, or stepdown units. Despite this challenge, with a dedicated team of surgeons, anesthesiologists, respiratory therapists, and nurses, we were able to safely and efficiently conduct this procedure in multiple units throughout the hospital.

### Limitations

There are several limitations to discuss. Patient selection for tracheostomy necessitated inherent selection bias. Our low mortality rate may be attributed to the choice to perform tracheostomy on

patients who had reasonable expectation of recovery at the time when tracheostomy was considered. In this prospective study, there was also no formal randomization to the percutaneous and open tracheostomy groups. However, the 2 lead surgeons performed the vast majority of these procedures together and alternated between open and percutaneous techniques in essentially a randomized fashion. Data on surgical times and intraoperative details were limited and hand-charted by different members of the anesthesia team, all from outside of the patient's room. In addition, particularly in the early stages of this pandemic, recommendations for anticoagulation were constantly in flux. Prophylactic and therapeutic categories were made based on our institution's current anticoagulation protocol, which may differ from that of other institutions. Lastly, this is an ongoing study of outcomes and the senior authors are still performing tracheostomies in this patient population. In this analysis, only patients who underwent tracheostomy in April were included to allow sufficient postoperative time for reporting of outcomes. Nevertheless, many patients in our series remain hospitalized and their outcomes are subject to change. Furthermore, it is possible that our small sample size failed to identify differences between open and percutaneous tracheostomy that may be illuminated with a larger cohort. Future study on the sequelae of prolonged ventilator dependence, particularly tracheal or glottic stenosis, is also planned. It remains critical to report long-term data as we accrue more experience caring for patients with COVID-19.

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# CONCLUSIONS

This represents one of the largest series of tracheostomy in patients with COVID-19 and the first to compare open versus percutaneous techniques. Our outcomes to date are encouraging, and a high proportion of our patients were able to be weaned from continuous sedation and mechanical ventilation. Percutaneous and open tracheostomy were both safely performed under apneic technique with equivalent outcomes. Continued follow-up of these patients is critical to ascertain long-term outcome data.

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