Percutaneous Dilational Tracheostomy for Coronavirus Disease 2019 Patients Requiring Mechanical Ventilation*

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OBJECTIVES: To assess the impact of percutaneous dilational tracheostomy in coronavirus disease 2019 patients requiring mechanical ventilation and the risk for healthcare providers.

DESIGN: Prospective cohort study; patients were enrolled between March 11, and April 29, 2020. The date of final follow-up was July 30, 2020. We used a propensity score matching approach to compare outcomes. Study outcomes were formulated before data collection and analysis.

SETTING: Critical care units at two large metropolitan hospitals in New York City.

PATIENTS: Five-hundred forty-one patients with confirmed severe coronavirus disease 2019 respiratory failure requiring mechanical ventilation.

INTERVENTIONS: Bedside percutaneous dilational tracheostomy with modified visualization and ventilation.

MEASUREMENTS AND MAIN RESULTS: Required time for discontinuation off mechanical ventilation, total length of hospitalization, and overall patient survival. Of the 541 patients, 394 patients were eligible for a tracheostomy. One-hundred sixteen were early percutaneous dilational tracheostomies with median time of 9 days after initiation of mechanical ventilation (interquartile range, 7–12 d), whereas 89 were late percutaneous dilational tracheostomies with a median time of 19 days after initiation of mechanical ventilation (interquartile range, 16–24 d). Compared with patients with no tracheostomy, patients with an early percutaneous dilational tracheostomy had a higher probability of discontinuation from mechanical ventilation (absolute difference, 30%; $p < 0.001$; hazard ratio for successful discontinuation, 2.8; 95% CI, 1.34–5.84; $p = 0.006$) and a lower mortality (absolute difference, 34%, $p < 0.001$; hazard ratio for death, 0.11; 95% CI, 0.06–0.22; $p < 0.001$). Compared with patients with late percutaneous dilational tracheostomy, patients with early percutaneous dilational tracheostomy had higher discontinuation rates from mechanical ventilation (absolute difference 7%; $p < 0.35$; hazard ratio for successful discontinuation, 1.53; 95% CI, 1.01–2.3; $p = 0.04$) and had a shorter median duration of mechanical ventilation in survivors (absolute difference, −15 d; $p < 0.001$). None of the healthcare providers who performed all the percutaneous dilational tracheostomies procedures had clinical symptoms or any positive laboratory test for severe acute respiratory syndrome coronavirus 2 infection.

CONCLUSIONS: In coronavirus disease 2019 patients on mechanical ventilation, an early modified percutaneous dilational tracheostomy was safe for patients and healthcare providers and associated with improved clinical outcomes.

***See also p. 1194.**

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KEY WORDS: adult respiratory distress syndrome; coronavirus disease 2019; mechanical ventilation; percutaneous dilational tracheostomy; viral pneumonia

Earlier reports of coronavirus disease 2019 (COVID-19) patients on mechanical ventilation described high patient mortality (41–71%) and need for prolonged mechanical ventilation (MV) with 50% of the patients requiring more than 2 weeks of MV (1–8). Percutaneous dilational tracheostomy (PDT) was considered an attractive intervention to potentially reduce the length of hospitalization, time on a ventilator, and mortality (9, 10). However, due to these early reports suggesting high patient mortality and high risk for possible severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission to healthcare workers during the tracheostomy procedure, most published guidelines did not recommend performing early PDTs (**Table 1S** in the Supplementary Appendix, http://links.lww.com/CCM/G303) (11–17).

Here, we report outcomes in 394 patients on MV eligible for tracheostomy during the start of the COVID-19 pandemic in New York City. We used a propensity score matching approach to compare outcomes in patients who received an early PDT with those who never had a tracheostomy or underwent a late PDT. The aim of this study was to evaluate for each group if there was a difference in the primary outcomes of time for discontinuation off MV, length of hospitalization, and overall patient survival.

METHODS

Patients

We included all adult patients 18 years old or older, admitted to the ICUs at two New York University (NYU) Langone Health Hospitals with a nasal swab confirmed diagnosis of SARS-CoV-2 infection by reverse transcriptase polymerase chain reaction (RT-PCR) assay and requiring MV. **Figure 1** depicts the study design and the patient flow. The definition of early versus late PDT was based on consensus statement recommendations of avoiding early tracheostomies (defined as < 14 d) in patients with COVID-19 disease (11–17). We report the patient characteristics and outcomes for the three study groups: patients who underwent early PDT, patients who had no tracheostomy, and patients who underwent late PDT. We obtained approval from the Office of Science and Research Institutional Review Board at the NYU School for Medicine (approval number i20-00475) to collect and analyze all data.

Patient Selection and Exclusion

The decision to recommend a tracheostomy or to keep the patient orally intubated was made by the primary critical care team. Patients were considered for PDT if they had no significant extrapulmonary organ dysfunction (except for acute renal failure on dialysis), required only low dose of vasopressors (< 0.05 μg/kg/min of norepinephrine or equivalent), and had no active bleeding secondary to severe coagulopathy. Patients requiring extracorporeal membrane oxygenation (ECMO) support were scheduled for an early PDT within 24 hours of starting ECMO support; patients requiring prone positioning more often had a late PDT. The selected patients met the following requirements on MV: positive end-expiratory pressure (PEEP) less than 12 cm H_2O, FIO_2 0.6, respiratory rate less than 30 breaths per minute, and $PaCO_2$ less than 60 mm Hg. For all of these patients, there were many decisions about medical treatments, use of the available antivirals, interleukin-6 inhibitors, convalescent plasma, steroids, anticoagulation, ECMO, and tracheostomy among others that were made by the critical care teams in charge of the daily management of these critically ill patients. In every patient for whom we received a consult for a PDT, we did our own evaluation to determine the risk and benefits of a potential PDT. Because we recognize that patients were certainly selected for PDT, we applied the propensity score matching algorithm to address this selection bias.

PDT Procedures

All procedures were performed at the bedside in negative pressure rooms. Personnel entering the patient's room for the procedure wore standard full personal protective equipment per institutional policies (N95 mask, standard surgical mask, face shield, plastic gown, and gloves). The PDT was modified to minimize the risk of aerosolization during the procedure and to improve visualization of the subglottic space (18). This modified PDT procedure differs from the conventional PDT in that the bronchoscope was placed anterior to

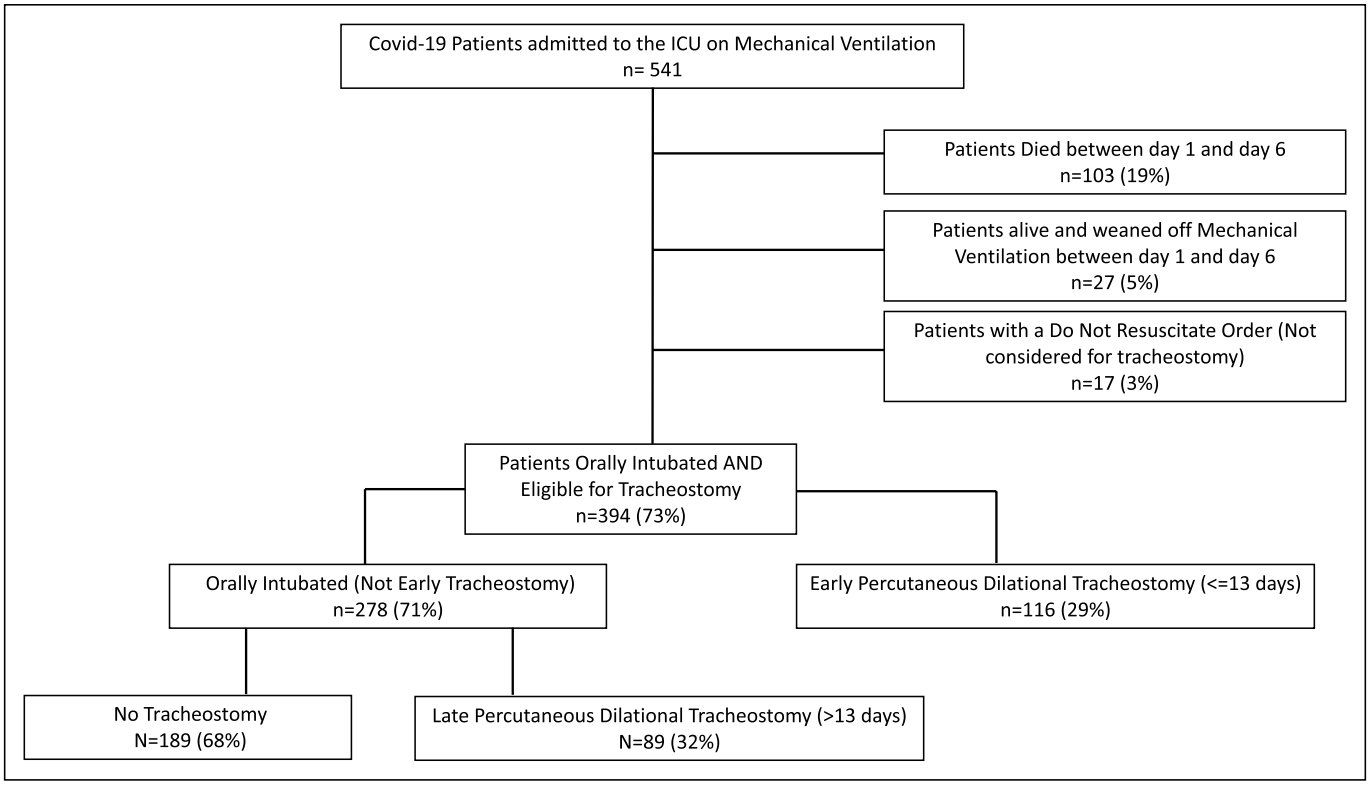

Figure 1. Study design and patient flow diagram.

the endotracheal tube (ETT), the ETT was advanced to the distal trachea, and the cuff was kept inflated; the patient was ventilated during most of the procedure apart from the few seconds required to initially advance and later remove the ETT. The accompanying **Supplemental Video** (http://links.lww.com/CCM/G304) shows the PDT modifications to the procedure. Surgical tracheostomy was done at the bedside with standard surgical technique by otolaryngological surgeons in patients in whom a PDT was not feasible.

The risk of particle aerosolization and SARS-CoV-2 transmission to healthcare providers performing PDTs was evaluated by measuring particulate matter generated during 15 modified PDT procedures with a real-time light-scattering laser photometer (DustTrak DRXII; TSI, INC., Shoreview, MN) that provides real-time aerosol mass and size measurements of the respirable particles. The device was placed in the area of the highest potential exposure to aerosolized particles (next to the patient's head and neck). We obtained a baseline measurement for a minimum of 4 minutes followed by measurements during the entire PDT procedure. Positive control measurements were obtained in patients with tracheostomy tubes off MV (tracheostomy collar mask). All team members performing the procedures were evaluated for COVID-19 symptoms at the initiation of the study and daily during the entire study and tested 12 weeks later with a SARS-CoV-2 RT-PCR test and immunoglobulin G (IgG) antibodies.

Outcome Measures

All patients were followed during the entire hospitalization, and survivors and or family members were contacted within 1–2 months after discharge to confirm survival status. The primary outcomes were discontinuation from MV, length of hospitalization, and overall survival. All complications during the PDTs and the follow-up period were reported.

Statistical Analysis

The primary outcomes were chosen before the investigators had access to the study database. Continuous variables are summarized using mean, SD, median, and interquartile range; categorical variables are summarized using frequencies. Variables were compared between groups using *t* tests, Wilcoxon rank-sum test, chi-square tests, or Fisher exact test, as appropriate. To

address confounding via selection of patients for PDT and other sources of bias that may arise from the use of observational data, we estimated a propensity score for receipt of PDT using logistic regression. We matched patients who did and did not receive tracheostomy in a 1:1 ratio using a nearest-neighbor matching strategy; we separately matched the early PDT and no tracheostomy groups, and the early and late PDT groups; clinical variables, medications, and procedures included in the propensity score estimation algorithm are shown

TABLE 1.

Patient Characteristics, Interventions and Laboratory Results in Patients with Early Percutaneous Dilational Tracheostomy, Late Percutaneous Dilational Tracheostomy, and No Tracheostomy

Variables	Early PDT ($n = 116$)	Late PDT ($n = 89$)	p[c]	No Tracheostomy ($n = 189$)	p[d]
Demographics and medical history					
Median age (interquartile range), yr	59 (46–67)	64 (55–70)	**0.01**	67 (59–73)	**< 0.001**
Female sex, *n* (%)	23 (20)	26 (29)		61 (32)	**0.03**
Median body mass index[a]					
< 30, *n* (%)	78 (67)	61 (69)		90 (48)	
≥ 30, *n* (%)	38 (33)	28 (31)		99 (52)	**0.001**
Active or previous smoker, *n* (%)	29 (25)	19 (21)		54 (29)	
Mechanical ventilation and oxygenation values					
Median plateau pressure (interquartile range), cm H_2O	25 (22–29)	27 (24–32)	**0.008**	27 (22–32)	**0.04**
Median positive end-expiratory pressure (interquartile range), cm H_2O	12 (10–15)	12 (10–15)		12 (10–15)	
Median Pao_2/Fio_2 ratio (interquartile range)	123 (81–188)	90 (67–154)	**0.003**	92 (71–138)	**0.001**
Multilobar consolidations with diffuse distribution, *n* (%)	82 (71)	70 (79)		137 (73)	
Adult respiratory distress syndrome criteria by the Berlin definition, *n* (%)	78 (67)	69 (78)		132 (70)	
Interventions received while on mechanical ventilation, *n* (%)					
Prone positioning[b]	72 (62)	64 (72)		146 (77)	
Extra corporeal membrane oxygenation	36 (31)	4 (4)	**< 0.001**	5 (3)	**< 0.001**
Dialysis	26 (22)	25 (28)		68 (36)	**0.02**

PDT = percutaneous dilational tracheostomy.

[a]The body mass index is the weight in kilograms divided by the square of the height in meters.

[b]Defined as prone positioning > 2 times over 2 or more days.

[c]*p* for comparison of early PDT group to late PDT group using Wilcoxon rank-sum test for continuous variables and χ^2 for categorical variables.

[d]*p* for comparison of early PDT group to no PDT group using Wilcoxon rank-sum test for continuous variables and χ^2 for categorical variables.

Percentages may not total 100 because of rounding. *p* values not shown in the table were nonsignificant. Boldface values are statistically significant.

in **Figures 2S–4S** in the Supplementary Appendix, http://links.lww.com/CCM/G303). Before and after creating the matched sets, we evaluated differences in time to discontinuation from MV, length of hospitalization, and overall survival comparing patients with an early PDT to those with no tracheostomy and those with early versus late PDT. Patient survival time and time to discontinuation from MV were estimated with the Kaplan-Meier method; adjusted probabilities were compared between groups via a Cox proportional hazards model and competing risk model. All of the variables used in the propensity score matched, Cox proportional hazards, logistic regression, and competing risk models were measured on all patients, except for body mass index (BMI), PEEP, Pao_2/Fio_2 ratio, Pco_2, and chest radiology for which 99% of the data were available. The D-dimer, ferritin, C-reactive protein, and lymphocyte counts were available for 88–95% of the patients. Statistical analyses were performed using R software Version 3.6.3 and R studio Version 1.3.959 (Lucent Technologies, New Providence, NJ). Two-sided *p* values with a significance level of 0.05 were used to assess statistical significance.

RESULTS

Patient Characteristics and Outcomes

Between March 11, and April 29, 2020, 541 patients infected with SARS-CoV-2 requiring MV were admitted to the ICUs at two NYU Langone Health (NYULH) Hospitals in Manhattan (298 patients) and Long Island (243 patients). Of the 394 patients on MV who were eligible for a PDT, 205 patients (52%) underwent a PDT procedure (Fig. 1). Of the 205 tracheostomies, 116 (57%) were early tracheostomies with median time of 9 days (interquartile range, 7–12 d), whereas 89 (43%) were late tracheostomies with a median time of 19 days (interquartile range, 16–24 d). **Table 1** and **Table 2s** in the Supplementary Appendix (http://links.lww.com/CCM/G303) show the clinical characteristics of patients with early, late, or no tracheostomy. Most of the clinical characteristics of the patients were similar, with the exception that the early PDT patients were younger (59 vs 64 yr; $p < 0.001$), and had a lower weight (BMI < 30; 67% vs 69%). Nine of the PDTs were performed in patients with a BMI between 40 and 50.

TABLE 2.

Outcomes in Propensity Score–Matched Patients With Coronavirus Disease 2019 According to Treatment With Early Percutaneous Dilational Tracheostomy Versus No Tracheostomy and Early Versus Late Percutaneous Dilational Tracheostomy

	Propensity Score–Matched Patients					
Outcomes	Early PDT (*n* = 76)	No Tracheostomy (*n* = 76)	*p*[a]	Early PDT (*n* = 89)	Late PDT (*n* = 89)	*p*[b]
Survival, *n* (%)	55 (72)	21 (28)	< 0.001	68 (76)	66 (74)	0.86
Discontinuation of MV, *n* (%)	51 (67)	21 (28)	< 0.001	61 (69)	54 (61)	0.35
Total days of MV, d, median (IQR)						
Survivors	26 (19–45)	13 (9–22)	< 0.001	25 (19–48)	40 (27–56)	< 0.001
Nonsurvivors	23 (17–26)	14 (10–19)	< 0.001	23 (17–26)	30 (24–36)	0.007
Total days in the hospital, d, median (IQR)						
Survivors	47 (37–59)	34 (20–45)	0.001	42 (35–58)	50 (41–60)	0.05
Nonsurvivors	28 (22–34)	19 (15–25)	0.001	28 (22–34)	35 (31–56)	0.002

IQR = interquartile range, MV = mechanical ventilation, PDT = percutaneous dilational tracheostomy.

[a]*p* for comparison of early PDT group to no tracheostomy group using Wilcoxon Rank-sum test for continuous variables and χ^2 for categorical variables.

[b]*p* for comparison of early PDT group to late PDT group using Wilcoxon rank-sum test for continuous variables and χ^2 for categorical variables.

TABLE 3.

Multivariate Analysis Comparing Mortality and Discontinuation From Mechanical Ventilation Outcomes in Propensity Score–Matched Patients (Cox Proportional Analysis)

	Mortality						Discontinuation From Mechanical Ventilation					
	Early PDT and No Tracheostomy ($n = 152$)			Early and Late PDT ($n = 178$)			Early PDT and No Tracheostomy ($n = 152$)			Early and Late PDT ($n = 178$)		
Variables	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*
Demographics, medical history, and severity of the respiratory failure												
Age (for every 10 yr change in age)	1.27	0.95–1.7	0.11	1.03	0.71–1.48	0.89	0.72	0.57–0.9	**0.004**	0.89	0.761.04	0.14
Body mass index < 30[a]	3.01	1.65–5.45	**< 0.001**	1.79	0.87–3.69	0.14	1.01	0.56–1.80	0.98	1.51	0.98–2.3	0.06
Active or previous smoker	0.85	0.44–1.65	0.64	1.75	0.71–4.32	0.22	0.81	0.37–1.77	0.6	1.01	0.59–1.74	0.97
Cardiac disease	0.62	0.33–1.18	0.146	1.62	0.69–3.81	0.27	1.3	0.68–2.49	0.43	1.04	0.67–1.61	0.87
Diabetes	1.07	0.55–2.09	0.83	0.61	2.83–1.30	0.2	0.64	0.32–1.31	0.22	1.02	0.66–1.59	0.92
Adult respiratory distress syndrome criteria by the Berlin definition	1.14	0.58–2.15	0.75	0.91	0.39–2.12	0.83	1.47	0.76–2.87	0.25	1.1	0.68–1.8	0.69
Laboratories												
WBC count (>12.10 × 3/uL)	1.65	0.91–2.97	0.09	1.87	0.87–4.04	0.11	0.59	0.35–1.03	0.06	0.47	0.31–0.71	**< 0.001**
Lymphocyte count (≤ 5%)	1.21	0.69–2.16	0.5	3.08	1.3–7.01	**0.008**	0.33	0.17–0.62	**0.001**	0.29	0.18–0.48	**< 0.001**
Ferritin (> 1,500 ng/mL)	1.91	1.07–3.4	**0.03**	1.54	0.74–3.23	0.25	1.18	0.66–2.14	0.58	0.95	0.63–1.45	0.82
C-reactive protein (> 100 mg/L)	1.04	0.59–1.83	0.89	1.28	0.55–1.91	0.74	0.56	0.27–1.18	0.13	0.56	0.340.91	**0.02**
D-dimer (> 2,500 ng/mL)	0.78	0.46–1.50	0.46	0.88	0.40–1.91	0.74	0.90	0.45–1.84	0.78	1.26	0.79–2.03	0.33
Medications												
Deep sedation and paralysis[b]	0.91	0.47–1.73	0.77	0.55	0.24–1.25	0.15	0.76	0.43–1.36	0.36	0.73	0.47–1.15	0.17
High dose of IV steroids[c]	1.63	0.85–3.14	0.14	1.38	0.60–3.16	0.45	0.51	0.28–0.94	0.03	0.56	0.38–0.85	**0.006**
Anticoagulation[d]	0.57	0.2–1.16	0.12	0.99	0.35–2.77	0.98	1.05	0.55–1.98	0.89	0.98	0.55–1.74	0.95
Tocilizumab	0.96	0.5–1.84	0.9	0.96	0.37–2.49	0.93	0.84	0.42–1.66	0.61	0.78	0.45–1.38	0.95

(*Continued*)

TABLE 3. (*Continued*).

Multivariate Analysis Comparing Mortality and Discontinuation From Mechanical Ventilation Outcomes in Propensity Score–Matched Patients (Cox Proportional Analysis)

	Mortality						Discontinuation From Mechanical Ventilation					
	Early PDT and No Tracheostomy ($n = 152$)			Early and Late PDT ($n = 178$)			Early PDT and No Tracheostomy ($n = 152$)			Early and Late PDT ($n = 178$)		
Variables	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*	Hazard Ratio	95% CI	*p*
Interventions												
Dialysis	1.0	0.52–1.92	1	0.77	0.35–1.68	0.51	0.66	0.26–1.65	0.37	0.83	0.48–1.45	0.52
Prone positioning[e]	0.88	0.46–1.66	0.69	0.71	0.31–1.65	0.43	0.82	0.38–1.77	0.62	1.02	0.6–1.71	0.96
Extracorporeal membrane oxygenation	0.48	0.14–1.64	0.24	0.09	0.01–0.94	**0.04**	0.41	0.17–1.31	0.15	0.31	0.12–0.82	**0.02**
Early PDT	0.11	0.06–0.22	**< 0.001**	2.4	1.13–5.1	**0.02**	2.8	1.34–5.84	0.006	1.53	1.01–2.3	**0.04**

PDT = percutaneous dilational tracheostomy.

[a]The body mass index is the weight in kilograms divided by the square of the height in meters.

[b]Defined as multiple sedatives and a paralytic infusion or paralytic boluses over 2 or more days.

[c]Defined as a dose of IV steroids over 1–2 mg per Kg over 3 or more consecutive days.

[d]Full dose anticoagulation with therapeutic anti-Xa level > 0.3 IU/mL and/or partial thromboplastin time > 45 s.

[e]Defined as prone positioning > 2 times over 2 or more days.

Survival and discontinuation from mechanical ventilation analysis with a cox proportional hazard model.

Boldface values are statistically significant.

The modified PDT procedure with visualization anterior to the ETT was completed successfully in 195 patients (95%); surgical tracheostomy was planned before PDT in 10 patients (5%), three patients who were morbidly obese, two with history of previous tracheal stenosis, and five because of lack of personnel availability. The most common complication was transient hypoxemia at the end of the procedure while confirming position of the tracheostomy tube and obtaining lower airway samples. Moderate-to-severe bleeding was documented in 12 patients (5%), starting between 1.5 and 5 days post procedure. No deaths were attributed to the PDT procedure. Most of the patients required prolonged MV with a median duration from the PDT procedure to discontinuation of MV of 19 days (interquartile range, 13–28 d). Among 136 patients who successfully discontinued MV, 131 (97%) were decannulated, with a median of 4 days (interquartile range, 3 to 8 d) after the last day on MV. Six patients (3%) died, and 14 patients (7%) discontinued MV within 5 days of the PDT procedure.

There was no increase in aerosolization of respirable particle matter during the PDT procedure when compared with the baseline measurements that were obtained before starting the procedure. Also, the distribution of aerosol particles for the modified PDT was significantly lower than in the tracheostomy mask collar setting, confirming that the PDT with this modified technique was not a high-risk procedure for aerosolization of viral particles (**Table 3s**, in the Supplementary Appendix, http://links.lww.com/CCM/G303 and **Fig. 1s** in the Supplementary Appendix, http://links.lww.com/CCM/G303). After 205 bedside tracheostomies during a 12-week period, none of the healthcare providers or clinical team who performed all the PDT procedures had clinical symptoms or any positive laboratory test for SARS-CoV-2 infection by RT-PCR or SARS-CoV-2–specific IgG antibodies.

PDT Outcomes

Early PDT Versus No Tracheostomy. Compared with patients with no tracheostomy (**Tables 2** and **3**), propensity score–matched patients with an early PDT had a longer median duration of MV in survivors (absolute difference, +13 d; $p < 0.001$) and nonsurvivors

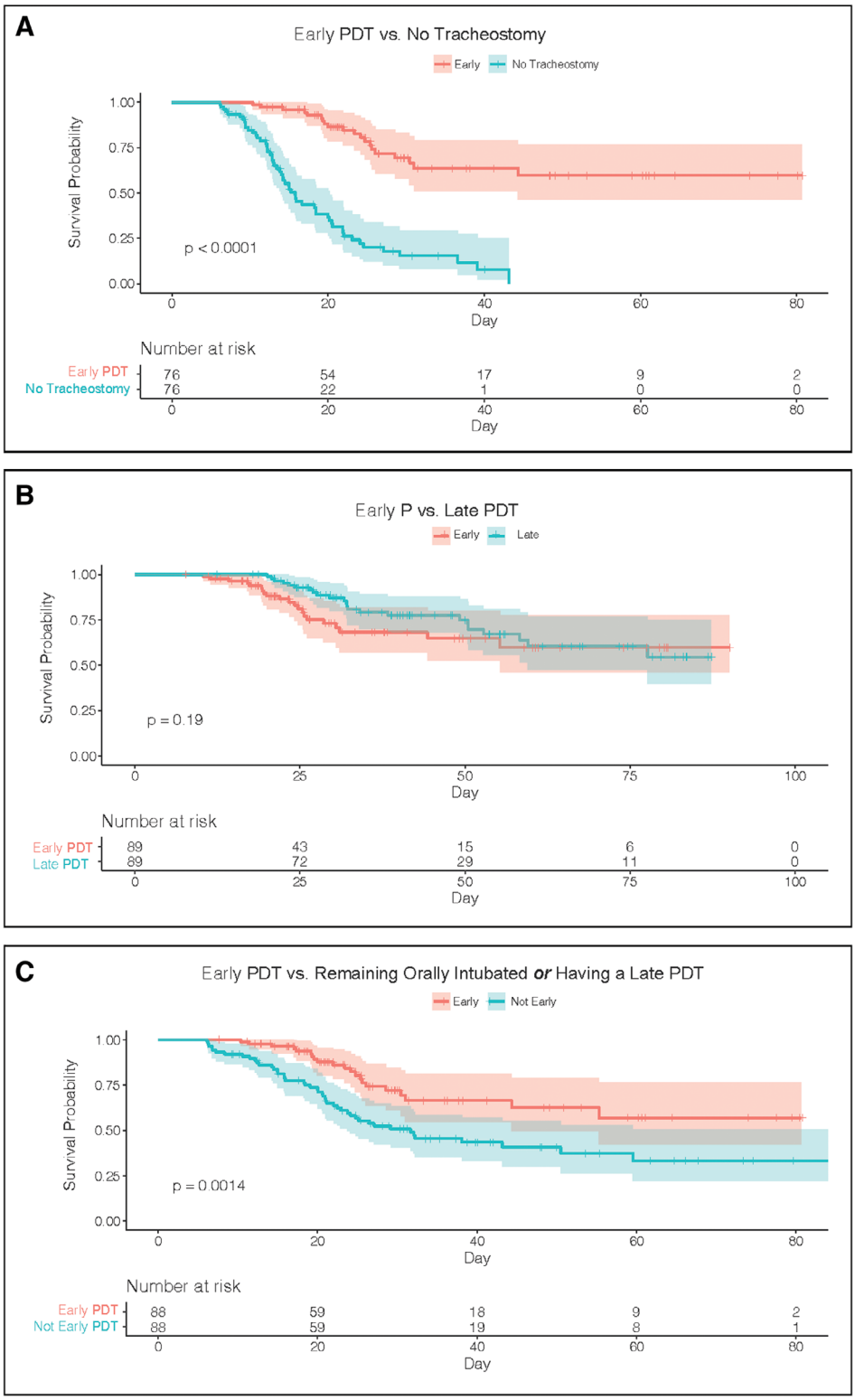

Figure 2. Kaplan-Meir survival estimates of survival for propensity score–matched patients. **A**, Shows Kaplan-Meier estimate for survival for patients with early percutaneous dilational tracheostomy (PDT) (≤ 13 d from initiation of mechanical ventilation, *red*), and patients who did not have a tracheostomy (*green*). **B**, Shows Kaplan-Meier estimate for survival for patients with early PDT (≤ 13 d from initiation of mechanical ventilation, *red*) and patients with late PDT (> 13 d, *green*). **C**, Shows Kaplan-Meier estimate for survival for patients with early PDT (*red*) and patients without early PDT (not early tracheostomy) who either remained orally intubated or who received a late PDT (> 13 d after initiation of mechanical ventilation) (*blue*).

(absolute difference, +9 d; $p < 0.001$), higher probability of discontinuation from MV (absolute difference, 30%; $p < 0.001$; hazard ratio for successful discontinuation, 2.8; 95% CI, 1.34–5.84; $p = 0.006$), and a lower mortality (absolute difference, 34%, $p < 0.001$; hazard ratio for death, 0.11; 95% CI, 0.06–0.22; $p < 0.001$). **Figure 2** shows the Kaplan-Meier survival estimates in propensity score–matched patients.

Early PDT Versus Late PDT Patients. Compared with patients with late PDT (Tables 2 and 3), propensity score–matched patients with an early PDT had higher discontinuation rates from MV (absolute difference, 7%; $p < 0.35$; hazard ratio for successful discontinuation, 1.53; 95% CI, 1.01–2.3; $p = 0.04$) and no difference in mortality. Early PDT patients had a shorter median duration of MV in survivors (absolute difference, –15 d; $p < 0.001$) and nonsurvivors (absolute difference, –7 d; $p < 0.001$). Figure 2 shows the Kaplan-Meier survival estimates in propensity score–matched patients.

DISCUSSION

In this study, we report outcomes in 394 patients on MV during the start of the COVID-19 pandemic at two large metropolitan hospitals in New York City. Among the 205 patients who had a PDT, this procedure was associated with clinical benefit as measured by

overall survival and discontinuation time from MV. Given our use of a modified PDT technique to improve safety, the risk of SARS-CoV-19 infection to healthcare workers performing these procedures was low.

Our decision to perform PDTs early during hospitalization was based on evidence from systematic reviews showing benefits in patients with anticipated prolonged MV (9, 10). The potential to decrease the days on MV was an important factor in this decision as we anticipated a very high need for mechanical ventilators and ICU beds. However, there were concerns about performing early tracheostomies based on recommendations from multiple medical organizations cautioning about the medical futility and high risk of SARS-CoV-2 transmission for healthcare providers (11–16). The use of our modified PDT technique showed low risk of aerosolization of respirable particles and SARS-CoV-2 infection during the procedure (Table 3s, in the Supplementary Appendix, http://links.lww.com/CCM/G303 and Fig. 1s, in the Supplementary Appendix, http://links.lww.com/CCM/G303). It is plausible that, from the positive SARS-CoV-2 test at admission to the PDT procedure, there was already a lower rate of active viral replication that reduced the risk of infection to healthcare providers more than anticipated (19).

The comparison of patients with an early or late PDT versus the no tracheostomy patients has major limitations associated with unmeasured variables in the no tracheostomy group; some patients improved and discontinued MV early, whereas other patients had anticipated high mortality, so that a tracheostomy was not recommended. In our propensity score–matched analysis, early PDT was associated with improved primary outcomes when compared with patients with no tracheostomy with higher discontinuation from MV and overall survival. The duration of MV was shorter in survivors and nonsurvivors with no tracheostomy, suggesting that our selection criteria for an early PDT excluded patients when there was a high probability of death or discontinuation from MV in the early days of the hospitalization. Similarly, compared with late PDT, early PDT was associated with faster discontinuation from MV. However, overall survival and overall discontinuation rates were similar between patients who had early PDT and those who had late PDT. This was clinically expected, as late PDT was commonly performed in patients with an anticipated high probability of survival and prolonged discontinuation from MV. An additional potential problem in interpreting the comparison between early and late PDT is immortal time bias, in which patients were only eligible for a late PDT by virtue of surviving for at least 14 days.

Our findings should be interpreted in the context the realities of clinical research during the surge of the COVID-19 pandemic in New York City. Randomization of medical and especially surgical interventions during this pandemic was extremely challenging (20, 21) and was deemed infeasible for this intervention. The primary critical care teams determined the potential for extubation and survival for each patient with or without the use of tracheostomy, counseled families remotely about the procedure, and then consulted the PDT team. The lack of randomization and resulting selection of patients on whom to perform tracheostomies raises the possibility of confounding in the subsequent comparison of those who did and did not receive tracheostomy. We have tried to substantially address this limitation through the use of a propensity score–matched population of patients with SARS-CoV-2–induced respiratory failure.

CONCLUSIONS

Patients with COVID-19 who survive the early days of MV experience severe and prolonged respiratory failure. An early modified PDT was safe for patients and healthcare providers and associated with improved clinical outcomes.

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