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One-Year Outcomes of Patients Requiring Tracheostomy Placement Due to Severe Acute Respiratory Syndrome Coronavirus 2 Infection

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BACKGROUND: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes (COVID-19) have resulted in an increase in critical illness and in the prevalence of acute respiratory failure with the need for tracheostomy. The characteristics and long-term outcomes of this patient cohort are not well identified.

RESEARCH QUESTION: What are the characteristics of patients who develop the need for tracheostomy due to SARS-CoV-2 with acute respiratory distress syndrome (ARDS)? What is their 90-day and 1-year survival and are there any identifiable risk factors for mortality and ventilator dependency?

STUDY DESIGN AND METHODS: Retrospective, follow-up cohort study of adult patients with COVID-19 infection and ARDS who required tracheostomy placement in a large healthcare system.

RESULTS: One hundred sixty-four consecutive patients with SARS-CoV-2 admitted to ICUs for ARDS who required tracheostomy placement between March 2020 and March 2021 were identified. One hundred nine (66.5%) were male. Average age was 63.5 years. The most common comorbidities were obesity, hypertension, diabetes mellitus, congestive heart failure, chronic kidney disease, chronic obstructive pulmonary disease (COPD), atrial fibrillation, and asthma. The most common complications during hospitalization were delirium, secondary infections, acute kidney injury, pneumothorax, and venous thromboembolism. Ninety-day and 1-year mortality were 29.9% and 44.5%, respectively. Ninety-six patients (58.5%) were liberated from the ventilator, and 84 (51.2%) had the tracheostomy tube decannulated. Asthma, COPD, atrial fibrillation, and renal replacement therapy requirement in the ICU correlated with increased risk of ventilator dependency. Among survivors at 1 year, 71 patients (43.3%) were residing at home and 20 patients (12.2%) remained in a skilled nursing facility.

INTERPRETATION: COVID-19 has resulted in a significant burden of acute critical illness and acute respiratory failure with the need for tracheostomy. A significant percentage of patients with SARS-CoV-2 requiring tracheostomy were alive and at home 1 year after tracheostomy placement. Long-term care support, including tracheostomy, beyond 90 days appears to be beneficial in this patient population and warrants further investigation.

KEY WORDS: acute respiratory distress syndrome; COVID-19; prolonged mechanical ventilation; tracheostomy

Up to 16% of hospitalized patients with COVID-19 will require ICU admission for acute respiratory failure, septic shock, and multiple organ system failures (1–4). A significant proportion of these patients survive but require tracheostomy placement and prolonged convalescence. There are few studies published to date evaluating the outcomes of patients recovering from COVID-19 and resulting in the need for tracheostomy, with no published

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KEY POINTS

Question: Which patients with COVID-19 infection and acute respiratory distress syndrome develop the need for tracheostomy? What are the 90-day and 365-day mortality rates, and how likely are they to be liberated from the ventilator and discharged home?

Findings: The comorbidities associated with tracheostomy need are obesity and chronic heart, lung, and kidney disease. One year after tracheostomy, 55.5% were alive and 43.3% were residing at home, 58.5% were liberated from the ventilator.

Meanings: Patients who require tracheostomy are complex and suffer frequent complications during their ICU stay. Despite frequent and severe ICU complications, a significant proportion can recover and be discharged home.

studies that reported, to our knowledge, long-term outcomes beyond 90 days (5–7). Unfortunately, the short horizon of follow-up may under-represent important (and less favorable) outcomes occurring in the following months.

We sought to study the characteristics, hospital complications and 1-year outcomes of patients who required tracheostomy as a result of severe COVID-19 infection with acute respiratory distress syndrome (ARDS), within a large and integrated, regional healthcare system. The primary goal of this study was to report 1-year mortality rates in patients who required tracheostomy for ARDS due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. A secondary goal was to report the rate of liberation from mechanical ventilation and at home status 1 year after tracheostomy placement.

METHODS

Study Design

This is a retrospective, follow-up cohort study approved by the Cleveland Clinic Institutional Review Board. Informed consent was waived. All consecutive adult patients (18 yr old or older) with COVID-19 infection admitted to the ICUs of the Cleveland Clinic hospitals of northeast Ohio between March 2020 and March 2021 (13 mo), who developed ARDS (as defined by the Berlin criteria) (8) and the need for tracheostomy. Infection with COVID-19 was defined as a positive reverse transcriptase-polymerase chain reaction test confirming infection with the SARS-CoV-2 virus.

Data Collection

Data were obtained through manual chart review. Two physicians reviewed all the charts independently. We collected data on demographics, medical comorbidities on the day of admission to the ICU, and complications of the ICU stay. We then determined continued device presence, mortality and patient location by chart review at 90 and 365 days after device placement, using day of tracheostomy placement as day 0. We determined the number of days spent in an ICU for the initial COVID-19 infection, the number of days from admission to the hospital until admission to the ICU, the number of days from intubation until tracheostomy placement, mortality at 90 and 365 days, as well as the outcome of attempts to liberate the patient from mechanical ventilation and discontinue the tracheostomy.

Statistical Analysis

The continuous variables were described using the sample median and interquartile range or mean with SD, and the categorical variables were described using the number of counts with proportion. The nonparametric Mann-Whitney *U* test or two sample *t* test was applied to compare continuous variables, whereas Pearson's chi-square test or Fisher exact test was applied to compare categorical variables as appropriate. A Kaplan-Meier curve was estimated to summarize the overall survival distribution of the patient cohort. All analyses were performed by using the SAS software package (Version 9.4; SAS Institute, Cary, NC). All tests were two-tailed, and the level of statistical significance was set at *p* value of less than 0.05.

RESULTS

Patient Characteristics

During the study period, a total of 1,267 patients developed ARDS and required mechanical ventilation due to COVID infection. One hundred sixty-four of these patients went on to require tracheostomy (**Fig. 1**).

Baseline demographics and comorbidities of the patients who required tracheostomy are outlined in **Table 1**. The average age was 63.5 years, ranging from 27 to 92 years old. One hundred nine of the patients (66.5%) were male, and 102 identified as White (62.2%), while 48 identified as Black (29.3%). The average Acute Physiology and Chronic Health Evaluation III score was 65.1. The most frequent comorbidities at admission were obesity, hypertension, diabetes mellitus, chronic obstructive pulmonary disease (COPD), asthma, congestive heart failure, atrial fibrillation, and chronic kidney disease.

Patient Outcomes

The average ICU length of stay in this cohort was 24.4 days (ranging from 11 to 87 d) with 18.1 days (ranging from 6 to 31 d) of orotracheal intubation on average prior to tracheostomy placement. Of the 164 patients who underwent tracheostomy placement, 73 patients died within the first 365 days after tracheostomy placement (1-yr mortality of 44.5%), with 49 of them having died within the first 90 days (90-d mortality of 29.9%), as shown in Figures 1 and **2**. The average time from tracheostomy placement until death in the group that survived beyond 90 days was 200 days (SD, 83.3 d).

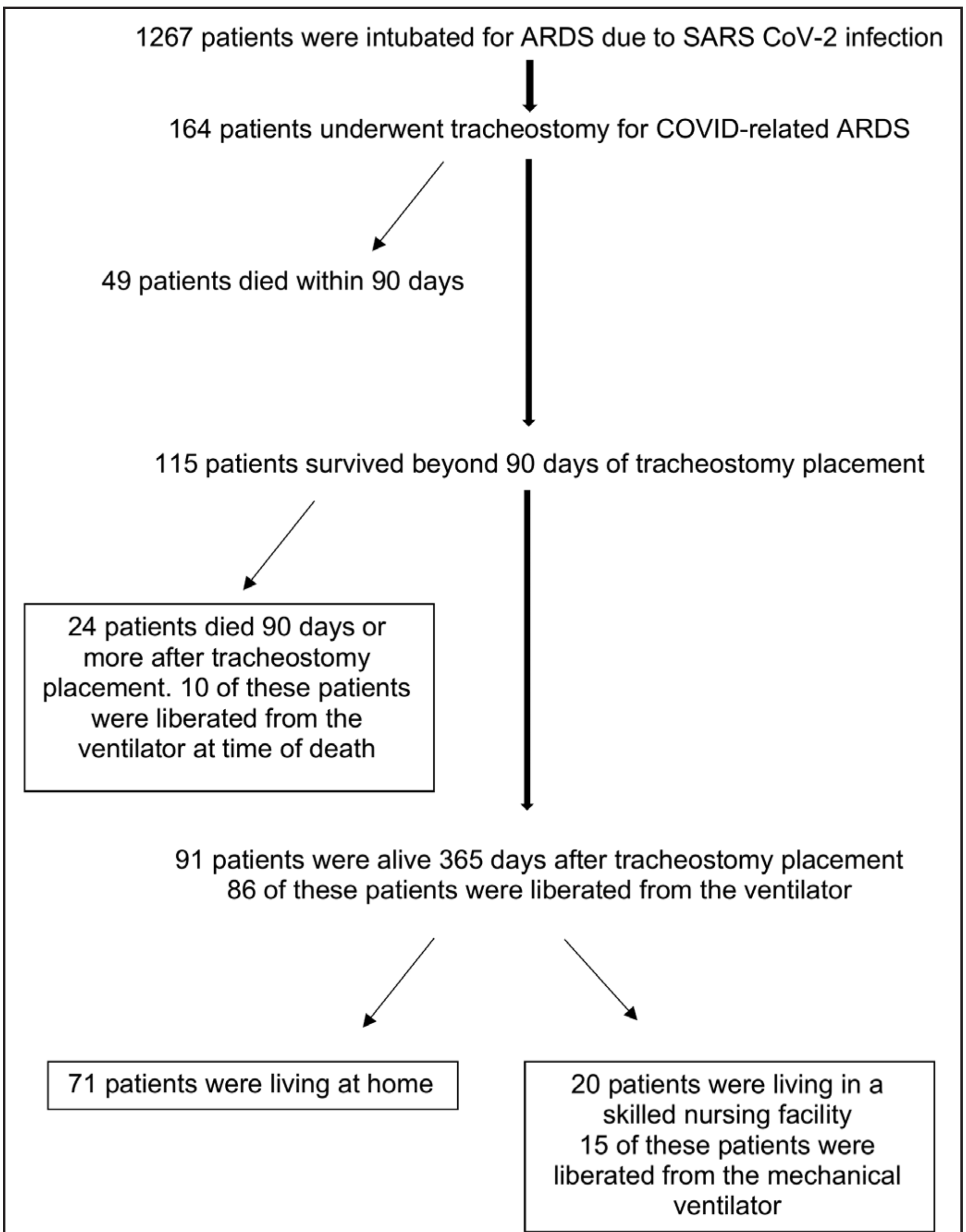

Figure 1. Schematic diagram of patient survival, liberation and residence status in first 365 days post-tracheostomy. ARDS = acute respiratory distress syndrome, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

During their ICU stays, these patients suffered frequent complications (Table 1). The most common were circulatory shock requiring more than 12 hours of IV vasoactive agents, secondary infections (both bacterial and fungal), acute kidney injury requiring renal replacement therapy (RRT), delirium, acute venous thromboembolism, and pneumothorax. When comparing the patients who died to those who survived to 365 days (**Tables 2** and **3**), we found that increased age, the presence of COPD, atrial fibrillation, and the use of RRT in the ICU correlated with increased mortality. When analyzing the

TABLE 1.
Patient Characteristics (n = 164)

Characteristic	n (%)
Age (range, SD)	63.5 (27–92, 13.24)
Male	109 (66.5)
Race	
White	102 (62.2)
Black	48 (29.3)
Other	14 (8.5)
BMI (average)	32.9
Obesity (BMI > 30)	100 (61)
Acute Physiology and Chronic Health Evaluation III	65.1
Hypertension	146 (89)
Diabetes mellitus	101 (61.6)
Chronic obstructive pulmonary disease	37 (22.6)
Congestive heart failure with a preserved ejection fraction	63 (38.4)
Congestive heart failure with a reduced ejection fraction	22 (13.4)
Atrial fibrillation	65 (39.6)
Coronary artery disease	30 (18.3)
Asthma	31 (18.9)
Chronic kidney disease (including end-stage renal disease)	93 (56.7)
Use of immune suppressive medication	19 (11.6)
Cancer (solid organ and hematological)	15 (9.1)
Shock requiring > 12 hr of vasoactive agents	157 (95.7)
Delirium	110 (67.1)
Neuromuscular blockade	110 (67.1)
Secondary bacterial infection	94 (57.3)
Prone position ventilation	82 (50)
Acute kidney injury	62 (37.8)
Venous thromboembolism	55 (33.5)
Pneumothorax	33 (20.1)
Secondary fungal infection	24 (14.6)
Extracorporeal membrane oxygenation	18 (11)

BMI = body mass index.

group of patients who died within the first 90 days as a separate subset, we found that this group also had a higher incidence of asthma (**Supplement Table**, http://links.lww.com/CCX/B228). There was no statistically significant difference between patients who survived to 365 days and nonsurvivors in therapeutics used, nadir $Pa O_2/F I O_2$ ratios in the first week after intubation and mechanical ventilatory driving pressures on the same day, the use of prone positioning during mechanical ventilation, neuromuscular blockade, or extracorporeal membrane oxygenation (Table 3).

During the study period, 96 patients (58.5% of the study population) were liberated from the ventilator. These patients were significantly younger (63 vs 69 yr old; $p < 0.001$), less likely to have asthma, atrial fibrillation, or COPD, and were less likely to have required RRT during their ICU stays (**Table 4**). Eighty-four of these patients also had the tracheostomy removed after liberation during our study period (51.2% of the study population). The most common reasons for retaining the tracheostomy tube in patients who were liberated from mechanical ventilation were prolonged encephalopathy and oropharyngeal dysphagia with aspiration risk (10 patients), chronic hypoxemic respiratory failure with underlying severe COPD (one patient), and subglottic stenosis (one patient). Of the survivors at 1 year, 71 patients were residing at home (43.3% of the study population), and 20 patients were in a skilled nursing facility (12.2% of the study population).

DISCUSSION

The few studies evaluating survivors of ARDS due to COVID who required tracheostomy placement have mostly been limited to 90-day follow-up. Capturing outcomes that occur long after hospital discharge is vital in assessing the benefit of our in-hospital interventions, especially when considering invasive procedures, like tracheostomy (8–11). Prior to the COVID-19 pandemic, patients who develop chronic critical illness (CCI) and the need for prolonged mechanical ventilation (PMV) after surviving ARDS were found to have overall poor outcomes, with estimated in-hospital mortality of 20–49%, and 1-year mortality in the 48–68% range (9–11). The rate of liberation from mechanical ventilation for unselected patients requiring PMV is also low, ranging from 30% to 53% (12–14), with the benefit mostly limited to younger patients (10). In addition, CCI patients with tracheostomies are vulnerable to increased morbidity and mortality, with 60% of patients under the age of 75 requiring at least one readmission to

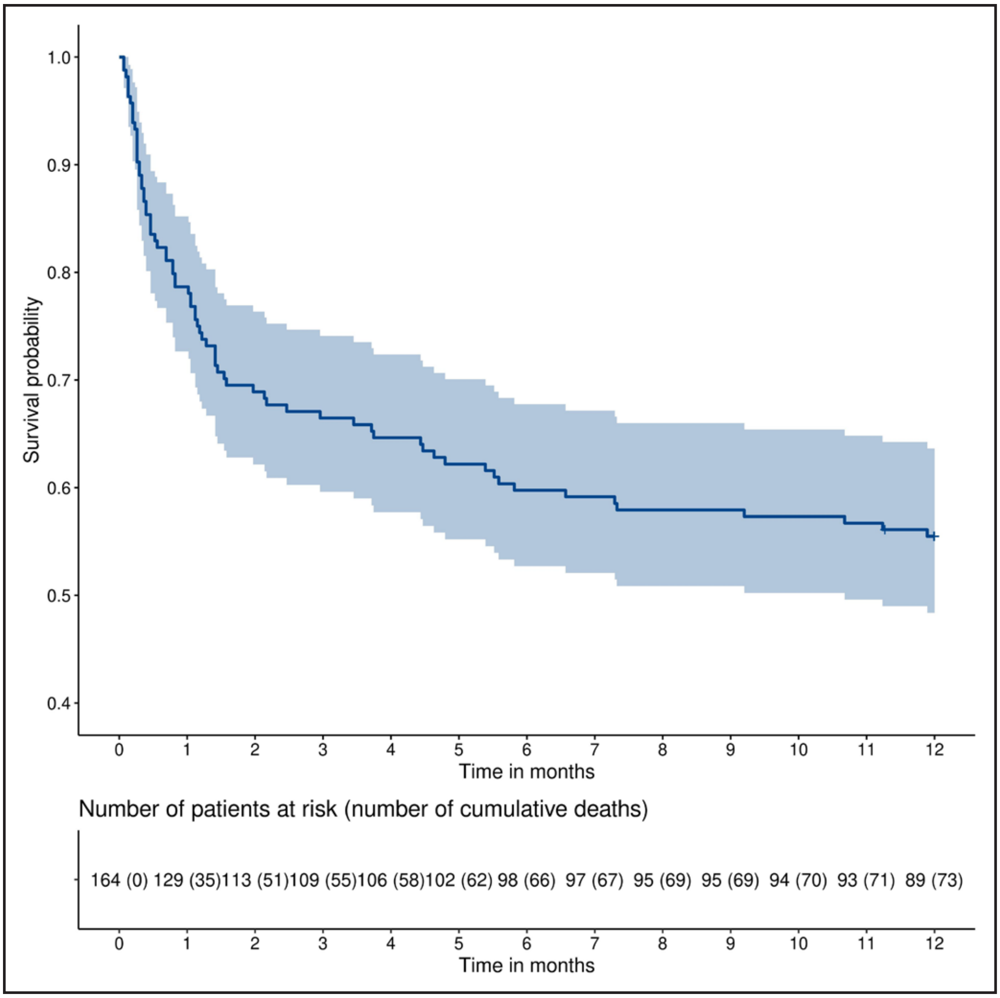

Figure 2. Kaplan-Meier survival curve post-tracheostomy placement.

the hospital within 1 year of tracheostomy placement (10). In one of the largest studies evaluating potential for recovery in patients who required long-term acute care hospital admission, median survival was found to be only 8.3 months, with a 1-year survival of 45%. Less than half of the 14,072 patients in this study were able to remain out of hospital for 60 consecutive days at any point in the first year after Long Term Acute Care Hospital admission, while more than one third (36.9%) spent the entirety of their remaining life hospitalized (15).

To address the complexity of these patients, the Cleveland Clinic Health System developed an integrated, multidisciplinary team dedicated to their care. This team consists of physicians of various specialization (pulmonologists, interventional pulmonologists, otolaryngologists, and cardiothoracic surgeons), physical and occupational therapists, and dieticians and speech-language pathology therapists. The Cleveland Clinic has also entered into a joint venture agreement with Select Medical to assist in the administration of long-term acute care hospitals in northeast Ohio and provide staffing for patients discharged from the ICU. The overarching goal of this program is to maintain continuity of these patients' care; allowing one multidisciplinary team to care for the patients across the entirety of the spectrum of their illness. This allows for minimization of interruptions and handoffs between the various clinical teams, and improves communication among the clinical staff, the patients and their families.

Our data sheds a light on some of the long-term outcomes in this group of COVID-19 patients within the context of this program, and offers some insight into both challenges and opportunities for the future. These patients had significant complications of their ICU stays, consistent with the previously described features of COVID-19 infection with ARDS, namely secondary infections, delirium, venous thromboembolism, and acute kidney injury. However, in those who survive 90 days or more beyond the acute illness and tracheostomy placement, our data indicates a high likelihood of liberation from the ventilator and of having the tracheostomy tube removed. We also demonstrated that while both 90- and 365-day survival continue to pose a challenge, those who do survive beyond 90 days have a high likelihood of residing at home 1 year after tracheostomy. These data suggests that earlier tracheostomy in those patients who are likely to survive beyond 90 days could accelerate recovery and allow for improved outcomes, as this group appears to not only survive, but also to recover enough for residence in the community. We found a significant correlation between

TABLE 2.
Demographics and Comorbidities of Survivors at 1 Year Compared With Nonsurvivors

Characteristic	Alive at 1 yr, *n* (%)	Nonsurvivors, *n* (%)	*p*
n	91	73	
Age	63	67	***0.019***[a]
Acute Physiology and Chronic Health Evaluation III	59	61	0.771
Race			
Black	23 (25.3)	25 (34.2)	0.410
White	59 (64.8)	43 (58.9)	
Other	9 (9.9)	5 (6.8)	
Male sex	61 (67)	48 (65.8)	0.995
Body mass index	32.4	30.5	0.153
Chronic obstructive pulmonary disease	12 (13.2)	25 (34.2)	***0.001***[a]
Asthma	13 (14.3)	18 (24.7)	0.137
Atrial fibrillation	17 (18.7)	48 (65.8)	***< 0.001***[a]
Hypertension	80 (87.9)	66 (90.4)	0.797
Coronary artery disease	16 (17.6)	14 (19.2)	0.953
Congestive heart failure with a preserved ejection fraction	33 (36.3)	30 (41.1)	0.638
Congestive heart failure with a reduced ejection fraction	8 (8.8)	14 (19.2)	0.087
Chronic kidney disease	25 (27.5)	10 (13.7)	0.051
End-stage renal disease	32 (35.2)	26 (35.6)	1.000
HIV/AIDS	1 (1.1)	2 (2.7)	0.847
Diabetes mellitus	58 (63.7)	43 (58.9)	0.638
Hematological malignancy	3 (3.3)	5 (6.8)	0.493
Solid organ malignancy	5 (5.5)	2 (2.7)	0.632
Transplant recipient	1 (1.1)	2 (2.7)	0.847
Immunosuppressive drugs	8 (8.8)	10 (13.7)	0.455
Immunodeficiency	5 (5.5)	3 (4.1)	0.965
Dementia	28 (30.8)	25 (34.2)	0.760
Cerebrovascular accident with residual deficit	35 (38.5)	21 (28.8)	0.256

[a]Statistically significant difference.

ventilator dependency and asthma, COPD, atrial fibrillation, and the use of RRT in the ICU.

Acute brain dysfunction (i.e., delirium) is highly prevalent in the ICU and has been shown to be especially difficult to control in patients with COVID-19 infection (16–18). The duration of mechanical ventilation, as well as the use of restraints, benzodiazepines, opioids, and vasopressors have all been shown to increase the risk of delirium in this population (19). The incidence of delirium in our patients is consistent with prior estimates in the literature, ranging from 54.9% to 84% (16–18). Our data indicates that reducing the burden of delirium in this population should be a major priority of the ICU teams. Improving the patients' ability to communicate, reducing the use of sedative and analgesic infusions, and increasing participation in physical therapy may all be facilitated by earlier placement of tracheostomy when indicated. Studies have shown that earlier tracheostomy placement is associated with a lower incidence of pneumonia (20), increased ventilator-free days (14, 21), and reduced length of ICU stay. It is also better tolerated by patients and improves their ability to communicate and participate in speech and physical therapy.

TABLE 3.
ICU Course and Complications of Survivors at 1 Year Compared With Nonsurvivors

Characteristic	Alive at 1 yr, *n* (%)	Nonsurvivors, *n* (%)	*p*
n	91	73	
Pa_{O_2}/F_{IO_2} ratio (nadir in first week after intubation)	112.63	115	0.52
Driving pressure, median (Q1–Q3)	12 (10.0–14.0)	12.0 (10.0–15.0)	
Liberation from mechanical ventilation during study period	86 (94.5)	10 (13.7)	***0.001***[a]
Renal replacement therapy in ICU	34 (37.4)	41 (56.2)	***0.025***[a]
Venous thromboembolism during ICU stay	29 (31.9)	26 (35.6)	0.735
Acute kidney injury	28 (30.8)	34 (46.6)	0.056
Secondary bacterial infection	53 (58.2)	41 (56.2)	0.914
Secondary fungal infection	15 (16.5)	9 (12.3)	0.599
Delirium	59 (64.8)	51 (69.9)	0.607
Pneumothorax	14 (15.4)	19 (26)	0.135
Remdesivir	65 (71.43)	45 (61.64)	0.19
Systemic corticosteroids	79 (86.81)	60 (82.19)	0.41
Tocilizumab	10 (10.99)	16 (21.92)	0.057
Hydroxychloroquine	9 (9.89)	9 (12.33)	0.62
Azithromycin	59 (64.84)	40 (54.79)	0.19
Prone positioning during ICU stay	47 (51.6)	35 (47.9)	0.753
Extracorporeal membrane oxygenation	11 (12.1)	7 (9.6)	0.797
Shock requiring vasoactive agents	87 (95.6)	70 (95.9)	1.000
Neuromuscular blockade	63 (69.2)	47 (64.4)	0.625

[a]Statistically significant difference.

Identifying patients with potential for long-term survival earlier in the course of their ICU stay may allow for earlier tracheostomy, with the additional benefit of minimizing duration of the infusions of sedatives and analgesics required to sustain orotracheal intubation, while accelerating recovery and rehabilitation and reducing the incidence of the numerous complications we identified.

This study has several limitations. Since it is a single-center study and retrospective in nature, it has limited generalizability. And while we believe the data on comorbidities and features of the ICU stay are helpful in predicting the ensuing development of the need for tracheostomy, the sample size is too small to develop predictive indices. Validating a predictive index that would consider comorbidities and features of the ICU stay requires a larger, prospective, and preferably multicenter study. We also do not have data on the level of functional disability these patients may continue to suffer from, and as such cannot comment on the survivors' quality of life. In addition, we could not find a comparable control group of ARDS survivors with tracheostomies from historical data in the literature, which limited our ability to evaluate COVID-19 survival specifically.

This study does, however, add valuable data to our understanding of the long-term outcomes of patients who require tracheostomy as part of the treatment for ARDS associated with COVID-19. To the best of our knowledge, this is the only study to date that has evaluated outcomes 365 days after tracheostomy placement in this group of patients. Identifying the comorbidities and ICU complications associated with ventilator dependency and mortality can also serve as a potential starting point for future prospective studies.

CONCLUSIONS

In this study of patients requiring tracheostomy after surviving ARDS due to COVID-19 infection, we

TABLE 4.
Comparison of Comorbidities and Hospital Stay by Ventilator Outcome

Characteristic	Ventilator Dependent	Liberated	*p*
	68	96	
Age	69.00 (61.75–74.00)	63.00 (52.00–68.00)	***< 0.001***[a]
Male	42 (61.8)	67 (69.8)	0.366
Body mass index	30.75 (25.90–36.55)	32.45 (27.50–37.07)	0.190
Race			0.370
White	37 (54.4)	65 (67.7)	
Black	23 (33.8)	25 (26.0)	
Other	8 (11.8)	6 (6.3)	
ICU length of stay	24.35 (16.58–30.82)	23.21 (16.71–30.61)	0.879
Asthma	19 (27.9)	12 (12.5)	***0.022***[a]
Congestive heart failure with a preserved ejection fraction	28 (41.2)	35 (36.5)	0.653
Congestive heart failure with a reduced ejection fraction	13 (19.1)	9 (9.4)	0.116
Atrial fibrillation	41 (60.3)	24 (25.0)	***< 0.001***[a]
Chronic kidney disease	31 (45.6)	62 (64.6)	0.024[a]
Chronic obstructive pulmonary disease	24 (35.3)	13 (13.5)	***0.005***[a]
Coronary artery disease	12 (17.6)	18 (18.8)	1.000
Diabetes mellitus	39 (57.4)	62 (64.6)	0.438
Malignant neoplasm	3 (4.4)	4 (4.2)	1.000
Hematological malignancy	6 (8.8)	2 (2.1)	0.108
Transplant recipient	2 (2.9)	1 (1.0)	0.762
Hypertension	60 (88.2)	86 (89.6)	0.985
Venous thromboembolism	25 (36.8)	30 (31.2)	0.569
Secondary bacterial infection	39 (57.4)	55 (57.3)	1.000
Acute kidney injury	31 (45.6)	31 (32.3)	0.117
Renal replacement therapy during ICU stay	38 (55.9)	37 (38.5)	***0.042***[a]
Secondary fungal infection	8 (11.8)	16 (16.7)	0.515
Delirium	50 (73.5)	60 (62.5)	0.330
Pneumothorax	18 (26.5)	15 (15.6)	0.131
Prone positioning	31 (45.6)	51 (53.1)	0.428
Neuromuscular blockade	41 (60.3)	69 (71.9)	0.166
Extracorporeal membrane oxygenation	7 (10.3)	11 (11.5)	1.000

[a]Statistically significant difference.

demonstrated a 55.5% 1-year survival rate, with 58.5% of the patients being liberated from mechanical ventilation, and 43.3% of the patients residing at home 1 year after tracheostomy placement. We also identified areas of potential improvement, namely the need to focus efforts on delirium prevention, infection control and identifying patients who would survive past 90 days, as they appear to have the highest potential for recovery and may benefit the most from tracheostomy.

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