# Tracheostomy Practices and Outcomes in Patients With COVID-19 Supported by Extracorporeal Membrane Oxygenation: An Analysis of the Extracorporeal Life Support Organization Registry

**OBJECTIVES:** The use of extracorporeal membrane oxygenation (ECMO) in patients with COVID-19 has been supported by major healthcare organizations, yet the role of specific management strategies during ECMO requires further study. We sought to characterize tracheostomy practices, complications, and outcomes in ECMO-supported patients with acute respiratory failure related to COVID-19.

DESIGN: Retrospective cohort study.

**SETTING:** ECMO centers contributing to the Extracorporeal Life Support Organization Registry.

**PATIENTS:** Patients 16 years or older receiving venovenous ECMO for respiratory support for: 1) COVID-19 in 2020 and 2021 (through October 2021) and 2) pre-COVID-19 viral pneumonia in 2019.

## INTERVENTIONS: None.

**MEASUREMENTS AND MAIN RESULTS:** We identified 7,047 patients who received ECMO support for acute respiratory failure related to COVID-19. A total of 32% of patients were recorded as having a tracheostomy procedure during ECMO, and 51% had a tracheostomy at some point during hospitalization. The frequency of tracheostomy was similar in pre-COVID-19 viral pneumonia, but tracheostomies were performed 3 days earlier compared with patients with COVID-19 (median 6.7 d [interquartile range [IQR], 3.0–12.0 d] vs 10.0 d [IQR, 5.0–16.5 d]; p < 0.001). More patients were mobilized with pre-COVID-19 viral pneumonia, but receipt of a tracheostomy during ECMO was associated with increased mobilization in both cohorts. More bleeding complications occurred in patients who received a tracheostomy, with 9% of patients with COVID-19 who received a tracheostomy reported as having surgical site bleeding.

**CONCLUSIONS:** Tracheostomies are performed in COVID-19 patients receiving ECMO at rates similar to practices in pre-COVID-19 viral pneumonia, although later during the course of ECMO. Receipt of a tracheostomy was associated with increased patient mobilization. Overall mortality was similar between those who did and did not receive a tracheostomy.

**KEY WORDS:** acute respiratory distress syndrome; critical care outcomes; extracorporeal membrane oxygenation; respiratory insufficiency; severe acute respiratory syndrome coronavirus 2; tracheostomy

ulticenter studies and major health organizations support the use of extracorporeal membrane oxygenation (ECMO) for COVID-19related acute hypoxemic respiratory failure (1–5), but the optimal clinical management strategies during ECMO remain largely unstudied (6). Joseph G. Kohne, MD, MSc<sup>1,2</sup> Graeme MacLaren, MBBS, MSc<sup>3</sup> Leigh Cagino, MD<sup>4</sup> Philip S. Boonstra, PhD<sup>5</sup> Daniel Brodie, MD<sup>6,7</sup> Ryan P. Barbaro, MD, MSc<sup>1,2</sup>

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In patients with prolonged mechanical ventilation, a tracheostomy is often considered. Placement of a tracheostomy has been associated with reduced sedation, increased rehabilitation, improved communication, and better clinical outcomes in select patients (7-11). Placement of a tracheostomy in a patient supported by ECMO incurs the additional risk of bleeding related to anticoagulation and ECMO-associated coagulopathy (12, 13). A recent analysis of four large-volume ECMO centers demonstrated that tracheostomies are commonly performed in patients supported by ECMO for severe acute respiratory distress syndrome from 2009 to 2017 (14). However, one in four patients who received a tracheostomy in this cohort had local bleeding, and placement of a tracheostomy was not associated with increased wakefulness or reduced sedation or analgesia. In the COVID-19 pandemic, there are additional potential risks to the healthcare team (virus aerosolization with airway manipulation) that may influence tracheostomy placement and timing (15). Given these unknown factors, we sought to describe how ECMO centers approach the placement and timing of a tracheostomy in patients supported by ECMO during the COVID-19 pandemic. Having detailed knowledge of current practices can enable future identification of optimal management strategies.

In this study, we used detailed clinical data within the Extracorporeal Life Support Organization (ELSO) Registry, the largest international ECMO Registry, to characterize tracheostomy practices within ELSO centers caring for patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on venovenous (VV) ECMO. We compared these practices with patients in the ELSO Registry supported on ECMO for pre-COVID-19 viral pneumonia.

# MATERIALS AND METHODS

# **Data Source and Population**

The ELSO Registry contains clinical and outcome data collected by trained data managers with error and validity checks and full-record validation to ensure completeness. This cohort study of anonymized data from the ELSO Registry was determined to be exempt from human subjects review by the University of Michigan Institutional Review Board (HUM00187382).

Patients in the ELSO Registry 16 years old or older with an initial support type of VV ECMO for

**Clinical Investigations** 

respiratory support in 2019-2021 were eligible (16). We queried the ELSO Registry from January 2020 to October 2021, for patients with COVID-19 defined as the confirmed presence of SARS-CoV-2 on laboratory testing. We also included a comparator cohort of patients diagnosed with viral disease in 2019, defined as pre-COVID-19 viral pneumonia. This cohort was identified by extracting all records with an International Classification of Diseases, 10th Edition, and Related Health Problems code indicating viral disease (J09-J12.9: influenza, other viral pneumonia, excluding J12.81: Pneumonia due to SARS-associated coronavirus [Supplemental Table 1, http://links. lww.com/CCM/H128]) among patients receiving VV ECMO for respiratory support in 2019. To evaluate temporal differences in practices during the pandemic, we identified whether ECMO support was initiated between January 1, 2020, and June 1, 2020, or after June 1, 2020, for patients with COVID-19.

## Exposure

Data managers recorded whether patients had a tracheostomy prior to ECMO cannulation. The ELSO Registry only requires reporting procedure codes if a procedure was related to ECMO, so procedure timing was only available for those who received a tracheostomy on ECMO. Procedure codes were extracted for Current Procedural Terminology (CPT) codes for tracheostomy procedures (31600, 31601, 31603, 31605, and 31610). When CPT codes were present, we recorded the procedure time from ECMO initiation in hours. If no procedure code was available, we report whether the patient was recorded as having a tracheostomy at registry completion. No timing of tracheostomy was available if a procedure code was not available.

# Outcomes

Our primary outcomes were survival to hospital discharge and duration of ECMO support. We also reported the proportion of patients who were mobilized to a level of "sitting in bed, exercises in bed" or higher as reported to the ELSO Registry. If a patient had multiple ECMO runs reported, we report data from the first run. We reported cumulative occurrence of relevant complications and the rate of complication occurrence per 1,000 ECMO hours. Complications

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were reported as defined and reported by ELSO (17). Surgical site bleeding is defined as requiring packed RBC transfusion greater than or equal to 3 units in 24 hours or surgical intervention. It is not connected to any specific procedure. Mechanical complications are defined as oxygenator failure, pump failure, raceway rupture, tubing rupture, circuit change, cannula problems, heat exchanger malfunction, clots, and air emboli. Neurologic complications are defined by brain death, seizures, diffuse ischemia, infarct, intraparenchymal/extraparenchymal/intraventricular hemorrhage, or neurosurgical intervention. We also report the discharge location as home, long-term acute care or rehabilitation center, or other (unknown, hospice, and another hospital).

# **Statistical Analysis**

Descriptive statistics were provided as median and interquartile ranges (IQRs) for continuous variables and as count and percent for categorical variables. To test whether COVID-19 center volume is associated with tracheostomy performance, we fit a hierarchical logistic regression model with the outcome of receiving a tracheostomy during ECMO. We modeled ELSO center as a random effect. Covariates determined a priori included patient age and duration of ECMO support. To describe center-level variation, we report the predicted probability of a model patient (age 50 yr with a 30-d ECMO duration) to receive a tracheostomy by ECMO center. Complication rates were compared using occurrence rate differences. Analyses were completed in Stata Statistical Software, release 16 (StataCorp, College Station, TX) and R (R Core Team: R: A Language and Environment for Statistical Computing; R Foundation for Statistical Computing, Vienna, Austria) (18).

# RESULTS

# **Patient Characteristics**

We identified 7,047 patients who were supported with VV ECMO for respiratory failure due to COVID-19 from January 2020 to October 2021. We identified 729 patients with pre-COVID-19 viral pneumonia from January 1, 2019, to December 31, 2019, who received VV ECMO for respiratory support (**Table 1**). Median patient age was 49 years in pre-COVID-19

viral disease (IQR, 39-58 yr) and 49 years in COVID-19 (IQR, 40-57). The median body mass index was 32 kg/m<sup>2</sup> in pre-COVID-19 viral pneumonia (IQR,  $27-38 \text{ kg/m}^2$ ) and  $33 \text{ kg/m}^2$  in COVID-19 (IQR, 28-38). Compared with pre-COVID-19 viral pneumonia, patients with COVID-19 were more likely to be Black or Hispanic (Table 1). Differences also existed in patient sex and ICU type (Table 1). The median duration of ECMO support in pre-COVID-19 viral pneumonia was 11.8 days (IQR, 6.8-20.0 d) and 18.0 days (IQR, 9.6-31.9 d) in patients with COVID-19. Hospital mortality in the pre-COVID-19 viral pneumonia cohort was lower than in the COVID-19 cohort (32% vs 51%; p < 0.001); however, the percentage of survivors discharged to home were similar (31% vs 28%; *p* = 0.27).

# **Tracheostomy Practices**

Of the 729 patients identified with pre-COVID-19 viral pneumonia, 205 (28%) received a tracheostomy during ECMO support. Similarly, of the 7,047 patients identified with COVID-19, 2,259 (32%) received a tracheostomy during ECMO support. Patient characteristics were largely similar between those that did and did not receive a tracheostomy during ECMO (**Table 2**).

Of 382 centers reporting caring for a patient receiving ECMO for COVID-19, 66% (251/382) reported performing at least one tracheostomy during ECMO, compared with 47% (93/198) of centers reporting a patient with pre-COVID-19 viral pneumonia. Median COVID-19 case volume per center was 11 patients (IQR, 3-24 patients). After adjusting for patient age and duration of ECMO support, center COVID-19 volume was not associated with receiving a tracheostomy during ECMO (odds ratio per patient increase in volume 1.005; 95% CI, 0.995-1.015). There was variation in tracheostomy rates by center. As an interpretative example, for a 50-year-old patient with a 30-day duration of ECMO support, the median predicted probability of tracheostomy across centers was 0.27, the IQR was (0.13–0.51), and the 5th and 95th percentiles were (0.03–0.71).

During the ECMO hospitalization, 45% (332/729) of all ECMO-supported patients with pre-COVID-19 viral pneumonia received a tracheostomy [including seven patients [1%] with a preexisting tracheostomy), as did 51% of patients (3,597/7,047) with COVID-19

# TABLE 1.

# Characteristics of Patients on Extracorporeal Membrane Oxygenation With Pre-COVID-19 Viral Pneumonia and COVID-19 in 2020/2021

Characteristics	Pre-COVID-19 Viral Pneumonia ( <i>n</i> = 729)	COVID-19 ( <i>n</i> = 7,047)
Age (yr), median (IQR)	49 (39–58)	49 (40–57)
Body mass index (kg/m²), median (IQR)	32 (27–38)	33 (28–38)
Sex, n (%)		
Male	452 (62)	5,005 (71)
Female	277 (38)	2,041 (29)
Race/ethnicity, n (%)		
Black	49 (7)	774 (11)
White (non-Hispanic)	425 (58)	2,876 (41)
Asian	92 (13)	657 (9)
Middle Eastern or North African	24 (3)	254 (4)
Other	16 (2)	130 (2)
Unknown	22 (3)	264 (4)
Multiple	24 (3)	300 (4)
Hispanic	69 (9)	1,668 (24)
Number of comorbidities, <i>n</i> (%) <sup>a</sup>		
None	432 (59)	4,333 (61)
1	162 (22)	1,353 (19)
2	63 (9)	681 (10)
> 2	72 (10)	680 (10)
ICU category, n (%)		
Adult cardiac ICU	311 (43)	2,660 (38)
Adult medicine ICU	94 (13)	2,190 (31)
Adult surgical ICU	59 (8)	392 (6)
Extracorporeal Life Support Organization ICU	44 (6)	339 (5)
Mixed ICU	177 (24)	1,092 (15)
Other/unknown	44 (6)	374 (5)
Any tracheostomy, n (%) <sup>b</sup>	332 (46)	3,597 (51)
Preexisting tracheostomy	7 (1)	68 (1)
Tracheostomy during ECMO	205 (28)	2,259 (32)
$\geq$ 10 d from cannulation	69 (9)	1,114 (16)
< 10 d from cannulation	136 (19)	1,145 (16)
Duration of ventilation prior to ECMO (d), median (IQR)	2 (1-4)	3 (1–6)

ECMO = extracorporeal membrane oxygenation, IQR = interquartile range.

<sup>a</sup>Comorbidities as determined by Elixhauser Comorbidity Index.

<sup>b</sup>Any tracheostomy includes preexisting tracheostomy, a tracheostomy on ECMO, or a tracheostomy during the hospitalization at unknown time.

(including 68 [1%] patients with a preexisting tracheostomy]. Among survivors to hospital discharge or transfer, 50% of patients (250/497) with pre-COVID-19 viral pneumonia received a tracheostomy, whereas 60% patients (2,091/3,482) with COVID-19 received a tracheostomy.

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# TABLE 2.

Patient and ICU Characteristics of Patients that Did or Did Not Receive a Tracheostomy on Extracorporeal Membrane Oxygenation for Pre-COVID-19 Viral Pneumonia and COVID-19

	Pre-COVID-19 Vir	al Pneumonia		COVID-19			
Clinical Outcomes	Did Not Receive Tracheostomy on ECMO $(n = 524)$	Tracheostomy on ECMO ( <i>n</i> = 205)	pª	Did Not Receive Tracheostomy on ECMO ( $n = 4,788$ )	Tracheostomy on ECMO (n = 2,259)	pª	
Age (yr), median (IQR)	49 (39–59)	48 (40–58)	0.87	49 (40–57)	49 (40–57)	0.03	
Body mass index (kg/m²), median (IQR)	32 (27–39)	32 (27–37)	0.77	33 (28–38)	32 (28–38)	0.006	
Sex, n (%)							
Male	317 (60)	135 (66)	0.18	3,368 (70)	1,637 (72)	0.06	
Female	207 (40)	70 (34)		1,420 (30)	621 (27)		
Race/ethnicity, n (%)							
Black	37 (7)	12 (6)	0.36	542 (11)	232 (10)	0.28	
White (non-Hispanic)	305 (58)	120 (59)		1,977 (41)	899 (40)		
Asian	71 (14)	21 (10)		437 (9)	220 (10)		
Middle Eastern or North African	16 (3)	8 (4)		166 (3)	88 (4)		
Other	11 (2)	5 (2)		93 (2)	37 (2)		
Unknown	18 (3)	4 (2)		192 (4)	72 (3)		
Multiple	18 (3)	6 (3)		197 (4)	103 (5)		
Hispanic	41 (8)	28 (14)		1,101 (23)	567 (25)		
Extracorporeal Life Support	Organization chapter	r, n (%)					
Asia-Pacific	67 (13)	10 (5)	0.002	57 (1)	12 (1)	<0.001	
European	140 (27)	40 (20)		1,037 (22)	448 (20)		
Latin American	10 (2)	6 (3)		247 (5)	161 (7)		
North American	279 (53)	133 (65)		3,188 (67)	1,454 (64)		
South and West Asian	28 (5)	16 (8)		259 (5)	184 (8)		
Number of comorbidities, n	(%) <sup>b</sup>						
None	320 (61)	112 (55)	0.09	3,038 (63)	1,295 (57)	< 0.001	
1	110 (21)	52 (25)		840 (18)	513 (23)		
2	49 (9)	14 (7)		450 (9)	231 (10)		
> 2	45 (9)	27 (13)		460 (10)	220 (10)		
ICU category, n (%)							
Adult cardiac ICU	224 (43)	87 (42)	0.38	1,736 (36)	924 (41)	< 0.001	
Adult medicine ICU	65 (12)	29 (14)		1,589 (33)	601 (27)		
Adult surgical ICU	45 (9)	14 (7)		248 (5)	144 (6)		
Extracorporeal life support ICU	26 (5)	18 (9)		162 (3)	177 (8)		
Mixed ICU	130 (25)	47 (23)		743 (16)	349 (15)		
Other/unknown	34 (6)	10 (5)		310 (6)	64 (3)		

ECMO = extracorporeal membrane oxygenation, IQR = interquartile range.

<sup>a</sup>*p* value determined by Wilcoxon rank-sum for continuous variables, and Pearson chi-square for categorical variables. <sup>b</sup>Comorbidities as determined by Elixhauser Comorbidity Index (Elixhauser Comorbidity software refined for ICD-10-CM Healthcare Cost and Utilization Project [HCUP]. 2021. Agency for Healthcare Research and Quality, Rockville, MD; http://www.hcup-us.ahrq.gov/ toolssoftware/comorbidityicd10/comorbidity\_icd10.jsp).

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# **TABLE 3.**Clinical Outcomes of Those That Did or Did Not Receive a Tracheostomy on ExtracorporealMembrane Oxygenation

	Pre-COVID-19 Viral Pneumonia			COVID-19		
Clinical Outcomes	Did Not Receive Tracheostomy on ECMO ( <i>n</i> = 524)	Tracheostomy on ECMO ( <i>n</i> = 205)	pª	Did Not Receive Tracheostomy on ECMO ( <i>n</i> = 4,788)	Tracheostomy on ECMO ( <i>n</i> = 2,259)	pª
Hospital mortality, n (%)	172 (33)	60 (29)	0.35	2,437 (51)	1,128 (50)	0.45
Mobilized on ECMO, n (%)	114 (22)	89 (43)	< 0.001	856 (18)	819 (36)	< 0.001
ECMO duration in survivors (d), median (IQR)	9.0 (6.0–14.7)	17.1 (10.7–23.5)	< 0.001	12.3 (7.4–22.5)	27.9 (17.3–43.0)	< 0.001
Length of stay in survivors, median (IQR)	25 (16–36)	36 (27–51)	< 0.001	36 (23–55)	52 (36–70)	< 0.001
Surgical site bleeding						
Total run, <i>n</i> (%)	11 (2)	14 (7)	0.002	147 (3)	208 (9)	< 0.001
Pre-tracheostomy, n (%)	-	0 (0)		-	32 (1)	
Rate/1,000 hr	0.07	0.17	0.02	0.07	0.13	< 0.001
Pulmonary hemorrhage						
Total run, <i>n</i> (%)	9 (2)	9 (4)		153 (3)	115 (5)	< 0.001
Pretracheostomy, n (%)	-	0 (0)		-	36 (2)	
Rate/1,000 hr	0.07	0.08	0.8	0.07	0.08	0.8
Neurologic complication						
Total run, <i>n</i> (%)	25 (5)	4 (2)	0.08	478 (10)	200 (9)	0.13
Pretracheostomy, n (%)	-	3 (1)		-	63 (3)	
Rate/1,000 hr	0.2	0.05	< 0.001	0.25	0.12	< 0.001
Mechanical complication						
Total run, <i>n</i> (%)	121 (23)	85 (41)	< 0.001	1,322 (28)	1,037 (46)	< 0.001
Pretracheostomy, n (%)	-	39 (19)		-	491 (22)	
Rate/1,000 hr	1.19	1.37	0.17	1	1.09	0.005
Discharge location of survi	vors, <i>n</i> (%)					
Home	116 (22)	36 (18)	0.09	734 (15)	247 (11)	< 0.001
Long-term acute care or rehab	102 (20)	55 (27)		956 (20)	531 (24)	
Other (hospice, another hospital, and unknown)	134 (26)	54 (26)		661 (14)	353 (16)	

ECMO = extracorporeal membrane oxygenation.

<sup>a</sup>*p* determined by Wilcoxon rank-sum for continuous variables, Pearson chi-square for categorical variables, and occurrence rate difference for rates.

# **Outcomes After Tracheostomy**

Clinical outcomes among those that did and did not receive a tracheostomy during ECMO are presented in **Table 3**. Hospital mortality among the ECMO-supported patients was 32% (232/729) for patients with

pre-COVID-19 viral pneumonia and 51% (3,565/7, 047) in patients with COVID-19. Of those who received a tracheostomy during ECMO, hospital mortality was 29% (60/205) in patients with pre-COVID-19 viral pneumonia and 50% (1,128/2,259) in patients with

COVID-19. The median duration of ECMO support after tracheostomy was 10.8 days in patients with pre-COVID-19 viral pneumonia (IQR, 5.1–19.1) and 16.8 days in patients with COVID-19 (IQR, 7.8–30.0). In the COVID-19 cohort, fewer patients were discharged to home following an ECMO tracheostomy than those who did not receive a tracheostomy on ECMO (11% vs 15%, among survivors: 22% vs 31%; p < 0.001).

Among all patients, mobilization to a level of sitting in bed or higher was achieved in 28% (203/729) of patients with pre-COVID-19 viral pneumonia and 24% (1,675/7,047) of patients with COVID-19 (p = 0.01). Of patients who received a tracheostomy during ECMO, 43% (89/205) and 36% (819/2,259) of patients with pre-COVID-19 viral pneumonia and COVID-19 were mobilized to a level of sitting in bed or higher, respectively. The proportion of patients with COVID-19 who were mobilized on ECMO was higher among those who received a tracheostomy than those that did not (36% vs 18%; *p* < 0.001). Compared with before June 1, 2020, more patients later in the pandemic achieved mobilization among all patients (26% vs 17%; p < 0.001) and among those that received a tracheostomy (39% vs 22%; p < 0.001). Clinical characteristics and outcomes of the cohorts of patients who did and did not achieve mobilization on ECMO are presented in Supplemental Table 2 (http://links.lww.com/CCM/H129).

# **Complications Reported**

Of patients with COVID-19 who did not receive a tracheostomy during ECMO support, 147/4,788 (3%) experienced surgical site bleeding, compared with 208/2,259 (9%) of those who received a tracheostomy during ECMO (p < 0.001). When normalized per 1,000 ECMO hours, those who had received a tracheostomy more frequently had surgical site bleeding (0.13 events/1,000 hr vs 0.07 events/1,000 hr; p < 0.001). The proportion of patients with neurologic complications was similar between those that did and did not receive a tracheostomy (9% vs 10% respectively; p = 0.13). More patients in the tracheostomy cohort experienced mechanical complications over the course of ECMO support (46% vs 28%; p < 0.001 and 1.09 events/1,000 hr vs 1.00 events/1,000 hr; p = 0.005).

# **Timing of Tracheostomy**

Of those with a tracheostomy placed during ECMO, the median time to the procedure was 6.7 days (IQR,

3.0–12.0 d) of ECMO support in pre-COVID-19 viral pneumonia and 10.0 days (IQR, 5.0–16.5 d) in patients with COVID-19. The proportion of patients receiving a tracheostomy earlier in the pandemic was lower—before June 1, 2020, 24% (362/1,534) of patients with COVID-19 received a tracheostomy during ECMO with a median time of 11.0 days (IQR, 5.3–17.3 d) (p < 0.001). After June 1, 34% (1,897/5,513) of patients with COVID-19 received a tracheostomy during ECMO with a median time of 9.8 days (IQR, 5.0–16.0 d) (p value for Kruskal-Wallis test for tracheostomy timing = 0.04).

Patients who received a tracheostomy before 10 days of ECMO support were similar in age and comorbidities, but were mechanically ventilated longer before ECMO cannulation (median 4 vs 3 d; p < 0.001) (**Table 4**). Hospital mortality and mobilization rates were similar to those receiving a tracheostomy before and on or after 10 days of ECMO support. The receipt of a tracheostomy on or after 10 days was associated with a longer ECMO run than those that received a tracheostomy before 10 days (median, 34 vs 24 d; p < 0.001).

# DISCUSSION

In this analysis of the ELSO Registry, over half of the 7,047 COVID-19 patients supported by VV-ECMO received a tracheostomy during their index hospitalization, with 32% of patients receiving a tracheostomy during ECMO. When comparing patients with COVID-19 relative to pre-COVID-19 viral pneumonia patients, we found that tracheostomies on ECMO were performed at similar rates, but patients with COVID-19 received a tracheostomy later in their ECMO support. Tracheostomy placement during ECMO was not associated with a difference in mortality but was associated with patient mobilization and the complication of surgical site bleeding.

ECMO centers approached placement of tracheostomy in patients receiving ECMO similarly for pre-COVID-19 viral pneumonia and respiratory failure secondary to COVID-19, with 28% of patients receiving a tracheostomy during ECMO in pre-COVID-19 viral pneumonia compared with 32% of patients with COVID-19. Mortality in the COVID-19 cohort was higher than those with pre-COVID-19 viral pneumonia (51% vs 32%), although single-center studies have shown similar outcomes for patients with

# TABLE 4.

Patient Characteristics and Clinical Outcomes of Patients With COVID-19 Who Received a Tracheostomy Before 10 d of Extracorporeal Membrane Oxygenation Support and Those That Received a Tracheostomy on or After 10 d of Extracorporeal Membrane Oxygenation Support

Characteristics	Tracheostomy Before 10 d ( <i>n</i> = 1,145)	Tracheostomy on or After 10 d ( $n = 1,114$ )	P <sup>a</sup>
Age (yr), median (IQR)	49 (40–57)	48 (40–57)	0.71
Body mass index (kg/m²), median (IQR)	32 (28–37)	32 (28–38)	0.12
Sex, n (%)			
Male	843 (74)	794 (71)	0.27
Female	301 (26)	320 (29)	
Duration of ventilation before ECMO (d), median (IQR)	4 (1-7)	3 (1–6)	< 0.001
Comorbidities, n (%) <sup>b</sup>			
None	646 (56)	649 (58)	0.05
1	286 (25)	227 (20)	
2	109 (10)	122 (11)	
$\geq$ 3	104 (9)	116 (10)	
ECMO days, median (IQR)	24 (14–37)	34 (25–48)	< 0.001
Mobilized on ECMO, n (%)	434 (38)	385 (35)	0.1
Hospital mortality, n (%)	551 (48)	577 (52)	0.08

ECMO = extracorporeal membrane oxygenation, IQR = interquartile range.

<sup>a</sup>p value determined by Wilcoxon rank-sum for continuous variables and Pearson chi-square for categorical variables.

<sup>b</sup>Comorbidities as determined by Elixhauser Comorbidity Index.

influenza and SARS-CoV-2 supported on VV-ECMO (19). At the level of the ECMO center, COVID-19 patient volume was not shown to be a significant factor in whether a tracheostomy was performed. The key difference was in the timing of tracheostomy: the median tracheostomy was performed 3 days earlier in patients with pre-COVID-19 viral pneumonia than COVID-19, potentially reflecting concerns for nosocomial transmission during an aerosol-generating procedure (15).

The most significant concern with performing a tracheostomy or any surgical procedure during ECMO is clinically significant bleeding. Among COVID-19 patients who received a tracheostomy during ECMO, 9% were identified as having surgical site bleeding after the tracheostomy. Importantly, patients needed to require greater than or equal to 3 units or surgical intervention to be recorded as a bleeding complication, and clinically significant airway bleeding may not meet this threshold. We were unable to determine if this bleeding was at the tracheostomy site, as other procedures may have been performed in these patients, and bleeding is not coded to the surgical site in the ELSO Registry. The frequency of bleeding complicating tracheostomy placement with ECMO has ranged from 1.7% to 40% in case series (12, 20, 21). In the International ECMO Network (ECMONet) study, 25% of patients who received a tracheostomy had local bleeding (14). This study and our analysis suggest that although some patients will have bleeding complications, this procedure may be done safely in the majority of patients. It is worth noting that the rate of mechanical complications per 1,000 ECMO hours was slightly higher in those that received a tracheostomy, which could be associated with changes in perioperative anticoagulation. Future work should identify best practices in the management of anticoagulation surrounding surgical procedures and surgical techniques to minimize bleeding.

Although the indication for tracheostomy placement and factors influencing clinician decision-making surrounding tracheostomy was not a focus of this study, the clinical outcomes reported here have potentially important implications. Receiving a tracheostomy during

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ECMO support was associated with a greater proportion of patients achieving a level of mobilization of sitting and exercising in bed or higher in both cohorts. The potential benefits of a tracheostomy during ECMO may include improved patient comfort, facilitating a more awake state and improved rehabilitation (22). In the comparator cohort of pre-COVID-19 viral pneumonia, 28% of patients were mobilized (43% among those who received a tracheostomy on ECMO) compared with 24% (36% among those who received a tracheostomy on ECMO) of patients with COVID-19. This difference may be explained by resource and personnel limitations during the pandemic and isolation restrictions that preclude patient mobilization that was able to be achieved in 2019. This is also supported by the lower mobilization rates seen earlier in the pandemic. It is also worth noting that patients who did not receive a tracheostomy on ECMO were more frequently discharged to home. The functional status and quality of life among survivors should be assessed in future studies of interventions to facilitate rehabilitation during ECMO.

The optimal time to place a tracheostomy in a patient with COVID-19 on VV-ECMO is unknown. A Cochrane systematic review suggests that among patients with respiratory failure and expected prolonged ventilation, placement of a tracheostomy before 10 days has a lower risk of mortality (7). In a single-center study, DiChiacchio et al (9) reported a lower duration of ECMO support and reduced ECMO costs in patients who received an early (within 7 d of ECMO initiation) versus late tracheostomy in patients on VV-ECMO for respiratory failure. In the ECMONet cohort, tracheostomies performed after ECMO support had fewer bleeding complications, and patients achieved a more wakeful state with reduced analgesia/ sedation than tracheostomies performed on ECMO (14). During the COVID-19 pandemic, tracheostomy timing guidance has been variable-there was an early suggestion to delay tracheostomy for at least 10 days and up to 21 days from initiation of mechanical ventilation due to concerns of virus aerosolization increasing the risk to healthcare workers and initial reports of poor prognosis in those receiving mechanical ventilation (15, 23, 24). However, there are also case series demonstrating that early tracheostomy in patients with COVID-19 was associated with improved survival (11). In our study, fewer patients with COVID-19 received a tracheostomy before 10 days than patients

with pre-COVID-19 viral pneumonia (16% vs 19%). Of those who received a tracheostomy on ECMO, hospital mortality and mobilization rates were similar whether the tracheostomy was performed before or after 10 days of ECMO support.

This study has several limitations. First, our retrospective use of registry data provides detailed information about tracheostomy practices but should not be inferred as causal relationships between tracheostomy practices and outcomes. It was not possible in this study to determine whether a patient is "at-risk" for a tracheostomy (e.g., in those patient expected to recover quickly or is moribund, the risks associated with tracheostomy placement on ECMO are unlikely to be incurred because tracheostomy is less likely to be performed). Second, because ELSO centers are asked to report procedures performed during ECMO but not after discontinuation of ECMO support, we are unable to determine the timing of tracheostomy for those patients who are documented as having a tracheostomy during the hospitalization but do not have an associated procedure reported. Therefore, it is likely that we are underreporting the number of tracheostomies performed in these ECMO cohorts. Third, we included only patients supported by venovenous ECMO support since they compose the vast majority of patients supported by ECMO for COVID-19, but these results may not necessarily be applicable to patients with other ECMO configurations. This international cohort also represents patients voluntarily reported to the ELSO Registry, and it is unknown what proportion of patients with COVID-19 receiving ECMO support this cohort represents. Finally, there are important outcomes to assess in tracheostomy decision-making (e.g., liberation from mechanical ventilation, delirium rates, and functional recovery) that are not contained within the ELSO Registry and worthy of future investigation.

# CONCLUSION

Overall, tracheostomies were performed in patients with COVID-19 reported to the ELSO Registry prior to April 2021 at rates similar to practices in pre-COVID-19 viral pneumonia, although at a median 3 days later in the ECMO run. Center COVID-19 patient volume was not associated with the performance of tracheostomies on ECMO support. The occurrence of surgical site bleeding in patients who received a tracheostomy on ECMO support was lower than described in other cohorts. More patients who received a tracheostomy were mobilized, but overall mortality was similar between those who did and did not receive a tracheostomy.

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