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Tracheostomy while on Extracorporeal Membrane Oxygenation: A Comparison of Percutaneous and Open Procedures

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Abstract: Although the ideal timing of tracheostomy for critically ill patients is controversial, transitioning from an endotracheal tube can be beneficial. Concerns arise for patients under extracorporeal membrane oxygenation (ECMO) support. Studies have described percutaneous and open tracheostomy approaches for critically ill patients but, to our knowledge, have not compared the two specifically in ECMO patients. This study analyzed safety and aimed to identify if there was a difference in major bleeding or other tracheostomy-associated complications. A single-center retrospective cohort study of all patients who received tracheostomy while on ECMO from July 2013 to May 2019 was completed. The primary endpoint was a significant difference in the incidence of a major bleeding adverse event at 48 hours. Secondary endpoints included differences in the incidence of complications (e.g., procedure-related mortality, ECMO decannulation, tracheal/esophageal injury, and pneumothorax/pneumomediastinum) and survival to discharge. A secondary analysis separated the groups further by comparing those with bleeding events and those without. The study included 27 ECMO patients: 16 (59%) in the percutaneous arm and 11 in the open arm. The median number of ECMO days before tracheostomy was 10 vs. 13, respectively. There were no statistically significant differences between the two groups for major bleeding events (percutaneous 44% vs. open 27%, $p = .45$), procedure-related mortality, or procedure-related complications. Both percutaneous and open tracheostomies in patients on ECMO require a multidisciplinary approach to minimize adverse effects. Major bleeding does occur, but there was no statistically significant correlation between bleeding events and the type of the tracheostomy approach. Thus, both open and percutaneous tracheostomy approaches have a favorable safety profile. **Keywords:** extracorporeal membrane oxygenation, open tracheostomy, percutaneous tracheostomy, complications, bleeding. *J Extra Corpor Technol. 2020;52:266–71*

The timing of tracheostomies for critically ill patients remains controversial; however, a transition from an endotracheal tube has beneficial implications for the overall care of patients in the intensive care units (ICUs). Prolonged endotracheal intubation may increase the use of sedation, length of ICU days, and occurrence of ventilator-associated pneumonia, whereas early tracheostomy can decrease them (1,2). Special concerns arise for patients receiving extracorporeal membrane oxygenation (ECMO) support who need a tracheostomy (3). This subgroup of patients faces perioperative challenges: hemodynamic and respiratory compromise, a systemic inflammatory response, multi-organ dysfunction, and hypo- and hypercoagulable states. Although tracheostomy placement can facilitate sedation and ventilatory weaning, bleeding is a common complication in patients on ECMO support (4).

Numerous studies have described both tracheostomy approaches (open and percutaneous) separately (5–7). To

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our knowledge, the percutaneous approach has not been directly compared with the surgical approach in the ECMO population. This study aimed to evaluate safety and identify any differences in major bleeding or other tracheostomy-associated complications associated with the different approaches in our ECMO patient population.

MATERIALS AND METHODS

This single-center retrospective cohort study was approved by the local institutional review board (HSC-MS-18-0709). The electronic medical records of our institution were screened for all patients who were placed on ECMO support from July 1, 2013, to May 31, 2019. This list was then further screened for patients who underwent a tracheostomy while on ECMO support. Any patient who received a tracheostomy before ECMO support or after removal of ECMO support was excluded.

Data collection included patient demographics, medical history, type (open or percutaneous) and timing of tracheostomy, type and timing of ECMO support, adverse events (major bleeding [defined as need for reoperation or transfusion], tracheal or esophageal injury, pneumothorax, or pneumomediastinum), ventilation data, anticoagulation and renal therapies, laboratory values (pre-tracheostomy), length of stay, and mortality. The primary endpoint was a difference in the incidence of major tracheostomy/airway bleeding that required surgical intervention or transfusion of red blood cells (RBC) within the first 48 hours after tracheostomy. Secondary endpoints included ability to wean to a tracheostomy collar, survival to discharge, and a difference in the incidence of other adverse events, including tracheal or esophageal injury, pneumothorax or pneumomediastinum, cannula dislodgment, pump thrombosis, or intraprocedural mortality. A difference in the ability to wean to a tracheostomy collar before discharge and a statistically significant difference in survival to discharge rates also served additional outcomes.

Patient Care Protocols

Patients on ECMO support at our institution can receive veno-venous (VV), veno-arterial (VA), or hybrid configurations. All patients are managed with protective lung ventilatory settings. Plateau pressures are maintained $\leq$30 cm H_2O. The ECMO runs are performed with CardioHelp consoles (Maquet Cardiovascular, Wayne, NJ) or Stöckert SCP systems (LivaNova, Inc., Arvado, CO). The ECMO runs are performed with the CardioHelp System (Getinge, Wayne, NJ) or Stöckert SCP systems (LivaNova, Inc.). Depending on the ECMO circuitry, either of the following was used: 1) Cardiohelp HLS Advanced 7.0 Bioline-coated kits (Maquet Cardiovascular) or 2) the stand-alone Getinge Quadrox-i Adult Bioline-coated oxygenator (Getinge) in correspondence with Medtronic Balance Biosurface tubing packs (Medtronic, Minneapolis, MN) and the LivaNova Revolution Ph.I.S.I.O. centrifugal blood pump (LivaNova).

Intravenous heparin is primarily used for anticoagulation. Bivalirudin is reserved for patients with suspected or confirmed heparin-induced thrombocytopenia or patients who are in a hypercoagulable state. The use of heparin and/or bilvalirudin is at the discretion of the hemopathology team. Anticoagulation is titrated to a target an activated partial thromboplastin time of 40–60 seconds while on VV ECMO and 60–80 seconds while on VA ECMO, unless there is concomitant bleeding tendency.

Patients are deemed "ready for tracheostomy" based on a multidisciplinary decision by pulmonary/critical care intensivists, cardiothoracic surgeons, and cardiologists. Open tracheostomies are performed in the operating room by a cardiothoracic surgeon with the assistance of cardiovascular anesthesiologists and a perfusionist, whereas percutaneous tracheostomies are performed at the bedside in the ICU by a cardiothoracic surgeon and/or interventional pulmonologist with a bronchoscopy technician and a bedside nurse. A kit (Ciaglia Blue Rhino G2®, Cook Medical, Bloomington, IN) was used for all bedside percutaneous tracheostomies.

Data were gathered into REDCap database, and statistical analysis was completed with Microsoft Office 365 Excel (Microsoft Corp., Redmond, WA). Demographic data are presented as frequency and proportions for categorical variables and median and interquartile range (IQR) for continuous variables. Categorical variables were compared using a chi-square test or Fisher's exact test for equal proportion. Dichotomous variables are presented as percentages and compared using Fisher's exact test. $p < .05$ is considered statistically significant, with the use of two-sided tests.

RESULTS

A total of 614 patients underwent ECMO support during the study time frame. Of those 614 patients, a cohort of 27 ECMO patients underwent a tracheostomy while on ECMO support. Sixteen patients (59%) underwent a percutaneous tracheostomy, and 11 patients (41%) underwent an open tracheostomy. Patient demographics and other pre-tracheostomy data were similar between groups and are summarized in Table 1. For all patients, the median age was 39 (IQR: 28–55) years and the median body mass index was 30.0 (IQR: 24.3–36.5) kg/m^2. The predominant ECMO configuration was VV for both groups: 12 (75%) in the percutaneous group and seven (64%) in the open group. The top two reasons for ECMO support were other acute respiratory diagnoses (30%) and trauma/burn (22%). The median number of mechanical ventilator days before tracheostomy was 18 (IQR: 11–25), and the median number of ECMO-support days before tracheostomy was

Table 1. Patient population data before the tracheostomy procedure.

	All Patients	Percutaneous	Open	*p*-Value
n	27 (100%)	16 (59%)	11 (41%)	
Age (years)	39 (28–55)	48 (36–59)	30 (26–52)	.30
Body mass index (kg/m^2)	30.0 (24.3–36.5)	31.3 (25.2–38.3)	25.1 (22.7–34.9)	.17
ECMO configuration				
VV	19 (70%)	12 (75%)	7 (64%)	.68
VA	6 (22%)	4 (25%)	2 (18%)	1.00
Other	2 (7%)	0 (0%)	2 (18%)	.16
Reason for ECMO				
Other acute respiratory diagnosis	8 (30%)	5 (31%)	3 (27%)	1.00
Trauma/burn	6 (22%)	2 (13%)	4 (36%)	.19
Postcardiotomy shock	3 (11%)	2 (13%)	1 (9%)	1.00
Aspiration pneumonitis	3 (11%)	2 (13%)	1 (9%)	1.00
Viral pneumonia	3 (11%)	2 (13%)	1 (9%)	1.00
Cardiac arrest	2 (7%)	1 (6%)	1 (9%)	1.00
Decompensated cardiomyopathy	1 (4%)	1 (6%)	0 (0%)	1.00
Bacterial pneumonia	1 (4%)	1 (6%)	0 (0%)	1.00
Mechanical ventilation support (days)	18 (11–25)	18 (14–21)	14 (9–30)	.47
ECMO support (days)	10 (8–19)	10 (8–18)	13 (8–25)	.20
Anticoagulation				
Heparin	22 (81%)	12 (75%)	10 (91%)	.62
Bivalirudin	5 (19%)	4 (25%)	1 (9%)	.62
On renal replacement therapy	13 (48%)	9 (56%)	4 (36%)	.44

All data are presented as frequency (%) or median (IQR).

10 (IQR: 8–19). Every patient was anticoagulated with either continuous heparin (81%) or bivalirudin (19%) intravenous infusion.

During and 48 hours after the procedure, the team monitored delta pressure and the presence of fibrin in the originator. Significant changes were not noted, and no thrombus formation at any location was found in any case. Of note, there were neither tracheostomy site infections nor ECMO cannula site infection during the ECMO run in our cohort of patients. Outcome data are presented in Table 2. Major bleeding was noted in seven patients (44%) in the percutaneous group vs. three patients (27%) in the open group, which was not significantly different ($p = .45$) when compared via Fisher's exact test. Other than a dislodgement of an ECMO cannula in one open surgical approach patient, there were no major tracheostomy-related complications (tracheal/esophageal injury, pneumothorax/pneumomediastinum, or intraprocedural mortality). More than half of the patients were able to tolerate a tracheostomy collar before discharge in both groups (56% for the percutaneous group vs. 82% for the open group).

When bleeding cases were separated out for each group (Table 3), the duration of holding and restarting heparin or bivalirudin did not correlate with the tracheostomy approach. When groups were divided by incidence of bleeding, no statistical relationship was found (median heparin hold time pre-tracheostomy of 5.0 [IQR: 5–7] hours in the percutaneous bleeding group vs. 10.0 [IQR: 8–16] hours in the bleeding open group). As seen, the patients who suffered major bleeding events did have longer holds of anticoagulants before and after tracheostomy. The preoperative blood urea nitrogen level, total bilirubin level, platelet count, international normalized ratio, and activated partial thromboplastin time were not associated with major bleeding. In total, 20 patients (74%) survived to ECMO decannulation and to hospital discharge, with no

Table 2. Outcome data comparisons via Fisher's exact test.

	Percutaneous	Open	*p*-Value
n	16 (59%)	11 (41%)	
Primary endpoint			
Major bleeding event	7 (44%)	3 (27%)	.45
Secondary endpoint			
Tracheal/esophageal injury	0 (0%)	0 (0%)	1.00
Pneumothorax/pneumomediastinum	0 (0%)	0 (0%)	1.00
ECMO complication	0 (0%)	1 (9%)	.40
Intraprocedural mortality	0 (0%)	0 (0%)	1.00
On tracheostomy collar before discharge	9 (56%)	9 (82%)	.23
Survived to discharge	11 (69%)	9 (82%)	.66

Table 3. Secondary analysis of patient population data before the tracheostomy procedure.

		Percutaneous Tracheostomy		Open Tracheostomy		
	All Patients	No Bleeding	Bleeding	No Bleeding	Bleeding	*p*-Value
n	27	9 (56%)	7 (44%)	8 (73%)	3 (27%)	
Age (years)	39 (28–55)	39 (37–48)	51 (42–60)	35 (27–51)	28 (26–50)	.27
Body mass index (kg/m^2)	30.0 (24.3–36.5)	25.3 (24.1–32.6)	34.7 (31.4–43)	24.8 (22.8–36.4)	30.4 (26.4–32)	.09
ECMO configuration						
VV	19 (70%)	8 (67%)	4 (33%)	6 (86%)	1 (14%)	.60
VA	6 (22%)	1 (25%)	3 (75%)	1 (50%)	1 (50%)	1.00
Other	2 (7%)	0 (0%)	0 (0%)	1 (50%)	1 (50%)	1.00
Mechanical ventilation support (days)	18 (11–25)	16 (10–19)	21 (18–25)	22 (12–35)	2 (2–14)	.13
ECMO support before tracheostomy (days)	10 (8–19)	10 (7–10)	19 (10–22)	14 (10–34)	2 (2–11)	.15
Ventilation therapy before tracheostomy						
Ph	7.44 (7.42–7.45)	7.44 (7.43–7.45)	7.45 (7.43–7.45)	7.43 (7.41–7.44)	7.49 (7.45–7.51)	.22
Partial pressure of carbon dioxide	48 (44–52)	48 (45–52)	48 (45–51)	50 (44–54)	43 (40–46)	.12
PaO_2	65 (56–97)	58 (56–62)	81 (53–127)	83 (61–106)	89 (74–98)	.39
FiO_2	60 (50–75)	60 (56–93)	60 (53–60)	60 (48–78)	40 (40–70)	.50
Positive end-expiratory pressure	8 (5–12)	8 (5–12)	8 (5–12)	9 (7–11)	10 (9–11)	.18
PaO_2/FiO_2 ratio	110 (74–197)	94 (74–107)	134 (85–245)	139 (101–221)	223 (141–244)	.41
Anticoagulation						
Heparin	22 (81%)	7 (58%)	5 (42%)	7 (70%)	3 (30%)	–
Withheld before tracheostomy (hours)	3.5 (2–5.8)	2.0 (2–4)	5.0 (5–7)	1.0 (.5–3.5)	10.0 (8–16)	.13
Withheld after tracheostomy (hours)	6.0 (5–8.5)	6.0 (4–6)	7.0 (5–10)	6.0 (5.5–7)	17.0 (11.5–21)	.18
Bivalirudin	5 (19%)	2 (50%)	2 (50%)	1 (100%)	0 (0%)	
Withheld before tracheostomy (hours)	7.0 (6–10)	5.5 (5.3–5.8)	15.0 (12.5–17.5)	7.0 (7–7)	– (0–0)	
Withheld after tracheostomy (hours)	8.0 (5–9)	7.0 (6–8)	41.0 (24.5–57.5)	3.0 (3–3)	– (0–0)	
On renal replacement therapy	13 (48%)	3 (33%)	6 (67%)	3 (75%)	1 (25%)	.27
Received desmopressin	3 (11%)	0 (0%)	0 (0%)	1 (13%)	2 (67%)	
Pre-Tracheostomy Laboratory Values						
Blood urea nitrogen	30 (22–39)	38 (27–41)	30 (26–31)	31 (21–40)	21 (19–27)	.25
Total bilirubin	1.3 (.7–4.1)	1.3 (.4–1.6)	1.9 (.8–3.7)	.9 (.7–3)	4.8 (2.8–6.2)	.37
Platelet count	121 (86–177)	156 (89–182)	117 (68–133)	148 (113–245)	115 (74–143)	.34
International normalized ratio	1.26 (1.14–1.34)	1.27 (1.22–1.33)	1.26 (1.19–1.32)	1.14 (1.1–1.17)	1.57 (1.44–1.62)	.27
Partial thromboplastin time	53.1 (40.6–66.3)	64.6 (48.8–68.2)	40.7 (38.2–55.7)	56.4 (49.3–67.5)	37.9 (35.6–45.5)	.26
Transfusions Post-Tracheostomy						
pRBC within 24 hours	1.5 (1.0–2.0)	–	1.5 (1.0–2.0)	–	5.0 (3.0–7.0)	.27
pRBC within 24–48 hours	1.0 (1.0–1.3)		1.0 (1.0–1.5)		1.0 (1.0–1.0)	
Platelets within 24 hours	.0 (.0–.0)		.0 (.0–.0)		.0 (.0–.0)	
Platelets within 24–48 hours	1.0 (1.0–1.0)		1.0 (1.0–1.0)		.0 (.0–.0)	
FFP within 24 hours	3.0 (2.5–3.5)		4.0 (.0–4.0)		2.0 (.5–2.0)	
FFP within 24–48 hours	2.0 (2.0–2.0)		2.0 (2.0–2.0)		.0 (.0–.0)	
Survived to discharge	20 (74%)	5 (56%)	6 (86%)	7 (88%)	2 (67%)	.20

FFP, fresh frozen plasma; pRBC, packed RBCs; PaO_2, partial pressure of oxygen; FiO_2, the fraction of inspired oxygen; P/F ratio, PaO2/FiO2 ratio. All data are presented as frequency (%) or median (IQR). *p*-value comparison is Fisher's exact test comparison of the patients who experienced bleeding events.

differences found between groups even when separated by incidence of bleeding.

DISCUSSION

Our patients had a median of 10 days of ECMO support before tracheostomy. Although not statistically significant, the duration of holding anticoagulation before tracheostomy did not correlate with major bleeding in either groups. Curiously, patients who experienced bleeding had longer holds of anticoagulants than those who did not. We noticed a wide range of holding anticoagulation times; this was explained by operator, equipment, or operating room availability in the setting of a busy service with a combination of critical patients including thoracic organ transplantation and emergent cases. In general, the institutional protocol is to hold anticoagulation for 4 hours before and after surgical procedures. The use of renal replacement therapy or any specific pre-tracheostomy laboratory value

that we examined was not associated with an increased risk for major bleeding. Furthermore, tracheostomy-related major bleeding did not have a statistical correlation with the survival to discharge rate.

Overall, the range of reported complications between percutaneous and open tracheostomies has been variable, with more studies revealing the safety of the percutaneous approach (5,8,9). In the largest study to date, Salna et al. (8) recently reported their experience. Both VV ECMO (78%) and VA ECMO (22%) were used to support 127 tracheostomy patients; the rate of transfusion was 43% within 48 hours after tracheostomy, with a median transfusion of two units (IQR: 1–3), and no procedural mortality was reported (8). In a large German study, Braune et al. (5) studied the safety of percutaneous dilational tracheostomy in 118 critically ill patients on an extracorporeal lung-assist device requiring anticoagulation. A median platelet count of 126×10^9/L, and a median international normalized ratio of 1:1 was noted before tracheostomy; 1.7% of patients experienced procedure-related major bleeding (5). They concluded that percutaneous dilational tracheostomy performed by experienced operators with careful optimization of the coagulation state is relatively safe and not contraindicated for this patient group (5). In another single-center retrospective study, bleeding complications were identified in 50 percutaneous tracheostomies undergoing VV ECMO support over a 10-year period (9). Bleeding was observed in 40% of the cases, with 32% characterized as minor and 8% characterized as significant (necessitating surgical control) (9). These safety data are similar to the data and conclusions from our study.

Our institution has long-standing experience with tracheostomy after mechanical ventricular assist device implantation (10), which served as a platform for performing tracheostomy procedures in these critically ill patients. Improvement in the ECMO pump, circuits, and oxygenators has also decreased the amount of heparin anticoagulation and blood products needed for ECMO patients (3). Overall, we performed five more percutaneous tracheostomy procedures in the ICU compared with open tracheostomies in the operating room. This is because of the multidisciplinary approach to percutaneous tracheostomies at the bedside used at our center. An interventional pulmonary team along with the ability to mobilize ICU resources to do bedside procedures with minimal disruption to the operating room schedule allows for more access to this approach. An open tracheostomy is chosen when we believe there is an anatomic constraint, such as a very short neck, an inability to extend the neck, previous tracheostomy, or central neck surgery, among others.

Another important limitation for open tracheostomy is the transport of critically ill patients from the ICU to the operating room and then back to the ICU. This is resource- and personnel-intensive, as it requires a cardiovascular anesthesiologist, a perfusionist, and circulatory support staff who will ensure the stability and intactness of the ECMO cannula, as well as stable hemodynamics and gas exchange during transport. Cannula dislodgement is a real hazard for ECMO patients requiring tracheostomy, regardless of the approach. In our open tracheostomy group, the only dislodgement occurred while transferring off the operating bed. However, the cannula was clamped, and there were no sequelae after the patient was discharged home. In the percutaneous tracheostomy group, dislodgement is also a risk if the cannula is positioned in the neck because of the manipulation required and procedure proximity.

In the percutaneous group, major bleeding was noted in 44% of cases, which is higher, although not statistically significant, than the open procedure group (27%). The authors acknowledge that this may be a trend, and caution should always be used when opting for a percutaneous approach. Like other retrospective studies, this one does have limitations, including that of being a single center and observational with a small case cohort (11). However, this baseline information is needed to properly execute and power future randomized, larger studies. There appears to be a lower risk of bleeding with open tracheostomy than with the percutaneous approach, but the difference was not statistically significant possibly because of our small sample size. Larger studies are needed to understand the safety differences in ECMO populations. Importantly, as ECMO is an evolving field, it is important to share this knowledge, as clinicians continue to decide between open and percutaneous approaches in this high-risk population.

We had one adverse event in our open approach group, which draws attention to the need to secure cannulas and monitor the procedure to avoid the risk of dislodgement during neck manipulation. Selection bias is also a factor. Patients with a shorter neck, previous tracheostomy, morbid obesity, an inability to hyperextend the neck, or previous neck surgery were selected for an open tracheostomy, which might have affected the safety profile of the percutaneous tracheostomy patients to have a lower risk profile.

In conclusion, our study suggests that the tracheostomy procedure, regardless of the approach, can be considered in patients on ECMO support. This is the first study to directly compare the two approaches, and these initial data indicate that both approaches have a similar safety profile. There was no statistical difference in major bleeding, procedure-related mortality, or complications (e.g., tracheostomy false track, loss of airway, or tracheal/esophageal injury). In accordance with previously published data, both open and percutaneous tracheostomy approaches have a favorable safety profile. This study found no statistically significant difference in the incidence of post-procedure bleeding. We believe that ECMO support should not be a contraindication for either open or percutaneous tracheostomy, and the application of either techniques should be determined based

on patient characteristics, physician expertise, and a multidisciplinary discussion. Furthermore, larger prospective studies should be performed to confirm our findings.

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