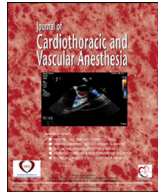




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Original Article

Bleeding Hazard of Percutaneous Tracheostomy in COVID-19 Patients Supported With Venovenous Extracorporeal Membrane Oxygenation: A Case Series

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Objectives: Tracheostomy usually is performed to aid weaning from mechanical ventilation and facilitate rehabilitation and secretion clearance. Little is known about the safety of percutaneous tracheostomy in patients with severe COVID-19 supported on venovenous extracorporeal membrane oxygenation (VV-ECMO). This study aimed to investigate the bleeding risk of bedside percutaneous tracheostomy in patients with COVID-19 infection supported with VV-ECMO.

Design: A Retrospective review of electronic data for routine care of patients on ECMO.

Setting: Tertiary, university-affiliated national ECMO center.

Participants: Patients with COVID-19 who underwent percutaneous tracheostomy while on VV-ECMO support.

Interventions: No intervention was conducted during this study.

Measurements and Main Results: Electronic medical records of 16 confirmed patients with COVID-19 who underwent percutaneous tracheostomy while on VV-ECMO support, including patient demographics, severity of illness, clinical variables, procedural complications, and outcomes, were compared with 16 non-COVID-19 patients. The SPSS statistical software was used for statistical analysis. The demographic data were compared using the chi-square test, and normality assumption was tested using the Shapiro-Wilk test. The indications for tracheostomy in all the patients were prolonged mechanical ventilation and sedation management. None of the patients suffered a life-threatening procedural complication within 48 hours. Moderate-to-severe bleeding was similar in both groups. There was no difference in 30- and 90-days mortality between both groups. As per routine screening results, none of the staff involved contracted COVID-19 infection.

Conclusions: In this case series, percutaneous tracheostomy during VV-ECMO in patients with COVID-19 appeared to be safe and did not pose additional risks to patients or healthcare workers.

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Key Words: COVID-19; extracorporeal membrane oxygenation; ECMO; percutaneous tracheostomy; bleeding; safety

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SEVERE ACUTE RESPIRATORY DISTRESS syndrome is an indication for venovenous extracorporeal membrane oxygenation (VV-ECMO) in patients with COVID-19 pneumonia.¹ Percutaneous dilatational tracheostomy (PDT) is performed typically for prolonged mechanical ventilation and to facilitate sedation and secretion management. Other suggested advantages of tracheostomy include patient comfort, rehabilitation and mobilization, less risk of sinusitis, and better oral hygiene.^{2,3}

Patients undergoing PDT on VV-ECMO are at higher risk of bleeding due to several reasons. Critical illness coagulopathy, extracorporeal circuit, platelet dysfunction, and use of anticoagulation are contributing factors.⁴⁻⁶ Procedural and nonprocedural bleeding are common in patients supported with ECMO, and are associated with more morbidity and mortality. In this patient group, the severity of bleeding may not correlate to the intervention or procedure,⁷ and periprocedural bleeding has been reported as high as 40%.⁸ There is a wide variation in the incidences of bleeding, transfusion requirements, and anticoagulation management among studies, as well as complications including circuit dysfunction and trauma.⁹⁻¹⁴

COVID-19 is associated with deregulated inflammatory, immune, and hematologic responses, which add more complexity to hematologic management.¹⁵ SARS-CoV-2 is highly contagious and can spread via aerosol, contact, and droplet. This poses significant risk to healthcare workers, particular during airway interventions like intubations and tracheostomy.¹⁶

The aim of the present study was to investigate the safety of PDT in patients with severe COVID-19 pneumonia supported with VV-ECMO during the first peak of the pandemic at a single national respiratory failure/ECMO center.

Methods

This was a single-center retrospective review of collected electronic data for routine care of patients on ECMO at a tertiary, university-affiliated national ECMO center. The inclusion criteria were patients who were >18 years of age who underwent PDT while on VV-ECMO. The exclusion criteria were patients <18 years of age, pregnant, and those who were on venoarterial ECMO (VA-ECMO).

All eligible patients with COVID-19 between March 1, 2020 and January 1, 2021 were identified. A similar number of patients without COVID-19 were identified as the control group in the immediate prepandemic period between April 23, 2017 and February 28, 2020.

The study was approved by the institutional research board. Given the anonymity and retrospective nature of data, need for informed consent was waived. The study was registered in the Protocol Registration and Results System.

At the study institution, PDT is the standard practice unless there is a major contraindication (eg, grossly distorted anatomy, inability to identify surface landmarks, aberrant vascular anomalies on neck ultrasound examination, or major bleeding risks), which would require a surgical approach.

VV-ECMO Management

All patients underwent ultrasound-guided percutaneous cannulation of either bifemoral or internal jugular-femoral configuration. The patients were placed on a centrifugal pump system, Heart-Lung Support (Getinge, Rastatt, Germany) or Xenios (Fresenius Medical Care, Heilbronn, Germany). All ECMO circuit components were heparin-coated. At the authors' center, the anticoagulation on VV-ECMO is composed of full heparinization guided by an activated partial thromboplastin time (aPTT) of 45–70 seconds unless contraindicated or a different target is indicated.

As per the authors' service protocol, the anticoagulation was held for 4 hours before any invasive procedure, including PDT. The periprocedure coagulation profile targeted an aPTT <45 seconds, an international normalized ratio <1.5, a platelet count >50 × 10⁹ cells/L, and a fibrinogen >2 g/L. The hemoglobin was maintained at >7 g/L. The study institution does not routinely administer antifibrinolytics during procedures.

Percutaneous Dilatational Tracheostomy

The PDT is performed in the patient's room in the intensive care unit (ICU). Preprocedural ultrasound examination of the neck is performed in all patients. Standard patient positioning, preparation, monitoring, and sedation were established. A procedural checklist was followed in all cases. The standard tracheostomy insertion kit is TRACOE twist size 7 or 8 (TRACOE Medical GmbH, BVMed, Nieder-Olm, Germany). Procedural details are available in supplementary electronic material attached.

Data Collection

Data were extracted from the electronic medical record into the case record form and then entered onto the study datasheet (Cerner Electronic, Kansas City, MO). The following patient data were collected: age, sex, height, weight, significant comorbidities, the severity of illness, calculated by acute physiology and chronic health evaluation-II and sequential organ failure assessment (SOFA) score on the day of admission and day of PDT, and VV-ECMO variables.

Routine hematologic, coagulation, and inflammatory markers and type and quantity of blood product transfusion were collected on the day of and up to 48 hours post-PDT. The authors searched for major bleeding up to 5 days postprocedure. The ICU variables included days of intubation and ECMO support before and after PDT. The outcome variables included duration and outcome of ECMO, and ICU stay. The other outcomes included 30- and 90-day post-PDT survival. Feasibility of PDT in this cohort was investigated by the frequency of surgical referral in patients presenting any contraindication for a PDT.

The safety of PDT was tested by the frequency and severity of complications within 48 hours of the procedure. The following complications were investigated: periprocedural death, cardiac arrest, tracheal stoma infection leading to sepsis,

pneumothorax necessitating intervention, tracheal or bronchial injury, ECMO membrane change, and COVID-19 transmission to those performing the procedure. Akin to published literature,¹⁵⁻¹⁸ bleeding was categorized into the following:

Minor: Minimal external or endotracheal bleeding with minimal or no drop in hemoglobin and no surgical intervention.
Moderate: Obvious external or endotracheal bleed, or a drop in hemoglobin of <1 g/dL or transfusion of 1 unit of red blood cells.
Severe bleeding: A drop of ≥ 2 g in hemoglobin/dL, and/or transfusion of ≥ 2 red cell packs or other blood products, disseminated intravascular coagulopathy or the need for surgical intervention.

For medical personnel safety, the authors' department policy was to conduct bimonthly serology tests for COVID-19 for all clinical ICU staff. Lateral flow immunoassay was performed to check for IgM and IgG antibodies. In addition, the staff was asked to report sick leave or sickness after the procedure.

Statistical Analysis

Descriptive statistics were used to summarize the continuous data, with mean and SD for the normally-distributed data; for non-normally distributed, the data median and IQR were reported. For the dichotomous data, absolute number and percentage were reported. The demographic data were compared using the chi-square test or independent sample Student t-test, as appropriate. The outcome measures were distributed normally and allowed for parametric analysis. Normality assumption was tested using a Shapiro-Wilk test. Although the data were not normally distributed, the nonparametric equivalent Mann-Whitney U-test was used. The Fisher exact test was used instead of chi-square test when the cell values were <5 subjects for categorical data. The SPSS (Chicago, IL) statistical software was used for statistical analysis. A p value of < 0.05 was considered significant. To estimate the association, the authors have calculated the odds ratio (OR) and 95% CI for the outcome measures using RevMan 5.4 (Cochrane, London, UK).

Results

Out of 34 confirmed COVID-19 adult patients placed on ECMO from March 1, 2020 to December 31, 2020, 17 patients underwent tracheostomy (n = 17/34, 50%). Only 1 patient underwent surgical tracheostomy due to extensive cervical vascular structures, and was excluded from the analysis.

In this case control study, a group of 16 patients with COVID-19 were matched to a group of 16 patients without COVID-19. Both groups underwent PDT while on VV-ECMO. Detailed presentation of baseline clinical characteristics and demographics are presented in Table 1. The ICU clinical variables, severity of illness, and ECMO variables are presented in Table 2. Group comparisons of hematologic, coagulation, and inflammatory markers are presented in Table 3. Table 4 presents blood product requirements and

Table 1
Demographics and Comorbidities of the Study Cohort

	COVID-19 (n = 16) Mean \pm SD	Non-COVID-19 (n = 16) Mean \pm SD	p Value
Age, y	50 \pm 10	39 \pm 14	0.15
Male	16 (100%)	14 (88%)	0.144
Weight, Kg	74 \pm 12	69 \pm 14	0.238
Height, cm	168 \pm 7	162 \pm 8	0.019
Body mass index	26.35 \pm 5.12	26.27 \pm 4.64	0.960
Comorbidities			
Hypertension*	3 (19%)	3 (19%)	1.00
Diabetes*	3 (19%)	4 (25%)	0.669
CAD*	2 (13%)	1 (6%)	0.544

NOTE. Data are presented as frequency (%) or mean and standard deviation. Abbreviations: CAD, coronary artery disease.

* Percentages of patients within each subcategory are shown in in parenthesis.

anticoagulation management in both groups. All complications are reported in Table 5. Prediction of postprocedural transfusion, circuit change, and major bleeding, using univariate and multivariate logistic analysis, is detailed in Figure 1. None of the medical personnel involved in PDT tested positive or reported for sick leave ≤ 2 weeks after the procedure.

Demographics and Baseline Characteristics

Both groups were similar in demographics and comorbidities (Table 1).

Regarding the severity of illness, both groups had similar acute physiology and chronic health evaluation-II and SOFA scores on the day of admission to the ICU. However, the SOFA score on the day of procedure was significantly higher in the COVID-19 group (p = 0.026). This was demonstrated by a higher number of patients on vasopressors on the day of the procedure (56% v 19%; p = 0.028).

Six out of the 16 COVID-19 patients (37.5%) tested positive by polymerase chain reaction (PCR) on the day of PDT. The remaining patients had a mean of 13 days (SD = 12.2) from their last COVID-positive PCR to the day of PDT. The PDT was done at an average of 22 days (SD = 6.17) after ECMO initiation for this COVID-19 patient group. In comparison to the non-COVID-19 cohort, patients with COVID-19 had a more prolonged duration of intubation, more days on ECMO before PDT, and longer ECMO runs. However, none of these was statistically significant. Detailed representation of patient clinical characteristics is shown in Table 2.

Hematologic, Inflammatory, and Coagulation Parameters

The variables demonstrated in Table 3 were collected and analyzed on the day of the procedure and the following day. There were no statistical differences between cohorts except for a slightly higher aPTT on the day of the procedure. Of note, white blood cell counts were significantly higher in patients without COVID-19 and without any reported incidence of stomal infection.

Table 2
COVID-19 and Non–COVID-19 Patient Clinical Characteristic

	COVID-19 (n = 16) Mean ± SD	Non–COVID-19 (n = 16) Mean ± SD	p Value
Ventilation parameters			
F _I O ₂	38.5 ± 8.94	29.81 ± 10.22	0.016*
PaO ₂	70.31 ± 20.47	80.13 ± 26.12	0.246
PaO ₂ /F _I O ₂	194.81 ± 94.19	274.34 ± 120.62	0.046
PaCO ₂	48.69 ± 9.45	48.38 ± 8.79	0.923
Ph	7.38 ± 0.05	7.38 ± 0.05	0.96
Lactate	0.91 ± 0.49	1.32 ± 0.53	0.030*
Tidal volume (mL/kg)	2.08 ± 1.21	3.76 ± 2.57	0.025
Mode of ventilation			
Pressure assist/control (% of patients within subcategory)	10 (63)	14 (88)	0.102
Volume assist/control (% of patients within subcategory)	6 (38)	2 (13)	
Hemodynamic status			
Patients on vasopressors	9 (56)	3 (19)	0.028
Patients on inotropes	0 (0)	1 (6)	0.31
Systolic arterial blood pressure	113.25 ± 13.78	124 ± 16.14	0.052
Diastolic arterial blood pressure	59.38 ± 9.58	67.94 ± 13.52	.048*
Mean arterial blood pressure	77.5 ± 11.38	85.58 ± 11.92	0.059
Heart rate (beats/min)	88.13 ± 13.25	90.13 ± 16.07	0.704
Severity of illness			
APACHEII	26.13 ± 5.032	23.75 ± 8.307	0.336
SOFA on admission	11.63 ± 1.544	10.25 ± 4.45	0.252
SOFA on day of PDT	9.5 ± 4.211	6.13 ± 3.964	0.026*
ECMO Variables			
ECMO to PDT, d	22.13 ± 6.17	17.75 ± 8.25	0.1
ECMO pump flow, L/min	4.09 ± 0.56	3.83 ± 0.45	0.162
Sweep gas flow, L/min	4.75 ± 1.73	3.69 ± 1.83	0.104
Transmembrane pressure, mmHg	39 ± 18.07	24.06 ± 7.37	0.005*
Post-oxygenator PaO ₂	381.5 ± 78.08	305 ± 139.01	0.065
Days until decannulation	56.31 ± 26.67	48 ± 29.28	0.408

Abbreviations: APACHEII, acute physiology and chronic health evaluation II; ECMO, extracorporeal membrane oxygenation; PaO₂/F_IO₂, ratio of partial pressure of oxygen in arterial to the fractional inspired oxygen; PDT, percutaneous dilatational tracheostomy; SOFA, sequential organ failure assessment.

* Statistical significance. p value is calculated using t test or nonparametric Mann-Whitney U test. The p value for statistical significance was set at p < 0.05.

Table 3
Detailed Patient Group Comparison of Hematologic and Coagulation Parameters, 24 Hours Pre- and Post-PDT

	COVID-19 (n = 16) Mean ± SD	Non–COVID-19 (n = 16) Mean ± SD	p Value
Hemoglobin 24 h pre-PDT, g/dL	8.76 ± 0.61	8.99 ± 0.84	0.367
Hemoglobin 24 h post-PDT, g/dL	8.82 ± 0.53	9.05 ± 0.77	0.33
Platelets 24 h pre-PDT, x10 ⁹ /L	122.06 ± 66.01	144.94 ± 73.24	0.361
Platelets 24 h post-PDT, x10 ⁹ /L	127.75 ± 70.17	151.31 ± 66.11	0.336
INR 24 h pre-PDT	1.11 ± 0.1	1.15 ± 0.18	0.392
INR 24 h post-PDT	1.14 ± 0.15	1.11 ± 0.11	0.586
APTT 24 h pre-PDT	38.14 ± 9.02	36.72 ± 10.3	0.68
APTT 24 h post-PDT	37.86 ± 7.18	31.06 ± 5.57	0.006*
Fibrinogen 24 h pre-PDT, g/L	3.2 ± 1.4	3.78 ± 1.63	0.301
Fibrinogen 24 h post-PDT, g/L	3.16 ± 1.3	3.79 ± 1.96	0.294
D-Dimers 24 h pre-PDT, u/dL	20.26 ± 20.75	17.17 ± 20.28	0.678
D-Dimers 24 h post-PDT, u/dL	24.84 ± 24.53	18.19 ± 15.57	0.378
WCC 24 h pre-PDT, x10 ⁹	11.83 ± 3.73	12.45 ± 5.21	0.699
WCC 24 h post-PDT, x10 ⁹	11.1 ± 4.04	14.51 ± 4.43	0.030*
CRP 24 h pre-PDT, mg/L	115.48 ± 85.88	70.86 ± 58.96	0.113
CRP 24 h post-PDT, mg/L	127.73 ± 110.28	100.18 ± 107.72	0.488
Procalcitonin 24 h pre-PDT, µg/L	1.55 ± 1.64	4.7 ± 7.72	0.135
Procalcitonin 24 h post-PDT, µg/L	1.61 ± 1.67	6.2 ± 17.6	0.323

Abbreviations: APTT, activated partial thromboplastin time; CRP, c-reactive protein; INR, international normalized ratio; PDT, percutaneous dilatational tracheostomy; WCC, white blood cell count.

* Statistical significance. p value is calculated using t test, or nonparametric Mann-Whitney U-test. The p value for statistical significance was set at p < 0.05.

The transfusion requirements were similar in both groups. More detailed description of transfusion requirements is provided in Table 4. Most patients were on continuous infusion of heparin, which was on hold for a mean of 11.43 hours (SD 8.4 v 10.42, SD 8, respectively, p = 0.75; Table 4).

Complications

None-to-mild bleeding was observed in the majority, and moderate or severe procedural bleeding was uncommon. No surgical intervention was indicated. The ECMO membrane change within 48 hours due to ECMO circuit dysfunction

Table 4
Blood Product Transfusion Patients Received Within 48 Hours of PDT

Blood Product Transfused	COVID-19 (n = 16)		Non–COVID-19 n = 16)		p Value
	Number of patients received a transfusion (%) [*]	Number of patients received a transfusion (%) [*]	Number of patients received a transfusion (%) [*]	Number of patients received a transfusion (%) [*]	
Packed red blood cells					
0 Units	3 (19)	5 (31)			0.598
1 Unit	5 (31)	3 (19)			
2 Units	5 (31)	4 (25)			
3 Units	2 (13)	1 (6)			
4 Units	0	1			
Fresh frozen plasma					
0 Units	16 (100)	15 (100)			0.31
6 Units	0 (0)	1 (6)			
Platelets[†]					
0	12 (75)	11 (69)			0.665
1 Adult dose	2 (13)	3 (19)			
2 Adult doses	1 (6)	2 (13)			
4 Adult doses	1 (6)	0 (0)			
Cryoprecipitate[‡]					
0	14 (88)	16 (100)			0.344
1	1 (6)	0 (0)			
4	1 (6)	0 (0)			
Anticoagulant administration	14 (88)	12 (75)			0.365
Anticoagulant hold, h	11.43	10.42			0.757

Abbreviations: PDT, percutaneous dilatational tracheostomy.
^{*} Percentage of patients within subcategory.
[†] Platelet units shown represent adult dose, 1 adult dose = 6 platelet units.
[‡] Cryoprecipitate is transfused in pools of 10 units (1= 10 units, 4 = 40 units).

occurred in 2 patients with COVID-19 and 3 patients without. There was no difference between groups in 30- and 90-day survival rate (Table 5). There were no statistically significant differences between groups with respect to bleeding, circuit change, or survival, as demonstrated by OR and 95% CI (Fig 1).

Bronchoscopy was used less often (n = 11/16) in the COVID-19 group. Twenty-five percent of the patients in the COVID-19 group (n = 4/16) had a positive COVID-19 PCR test on the day of tracheostomy. Routine screening confirmed none of the staff involved in the procedure tested positive for the virus within 2 weeks post-PDT. The authors did not observe any death, cardiac arrest, stoma infection, and pneumothorax or airway injury directly associated with PDT.

Table 5
Representation of Complications and Survival Rate

	COVID-19 (n = 16) Number (%) [*]	Non–COVID-19 (n = 16) Number (%) [*]	p Value
Bleeding, overall			
Mild	12 (75)	12 (75)	0.766
Moderate	3 (19)	2 (13)	
Severe	1 (6)	2 (13)	
ECMO circuit change	2 (13)	3 (19)	0.626
30-day survival rate	11 (69)	13 (81)	0.414
90-day survival rate	8 (50)	9 (56)	0.723

Abbreviations: ECMO, extracorporeal membrane oxygenation.
^{*} % of patients within subcategory. The p value for statistical significance was set at p < 0.05.

Discussion

In this case series, severe COVID-19 infection did not increase the bleeding hazard or transfusion requirements in patients who underwent PDT while on VV-ECMO. There were no differences in the incidence or severity of complications between the patients with COVID-19 and those without, even though the patients with COVID-19 were older, had a higher SOFA score, and were more likely to be on vasopressor infusion on the day of the procedure. No major procedural complications or mortality were observed in either group. This was in keeping with previous reports.^{8,10}

In either groups, minimal or no bleeding was observed in 75% of the patients. Minor bleeding typically is noted by nursing staff and describes oozing of tracheostomy dressing or blood-tinged tracheal secretions on suction. Only 4 patients (25%) in each group, accounting for a total of 8 of 32 (25%) of the whole cohort, developed moderate or severe bleeding, but none exhibited life-threatening PDT-related hemorrhage. The largest multicenter study to date reported local bleeding in 25% of patients.⁹ Schmidt et al. called into question the need to routinely perform tracheostomy while patients are still on VV-ECMO, and called for an individualized approach and case-by-case decision to tracheostomy in this patient group.⁹ Table 6 below represents a summary of the bleeding complications and anticoagulation protocols reported in the literature.

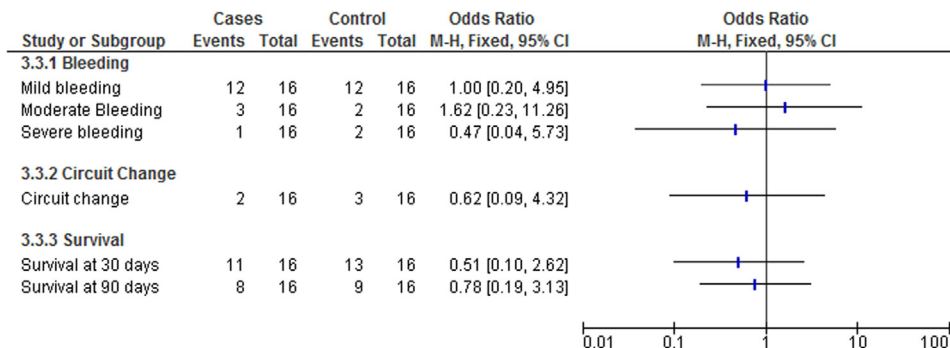


Figure 1. Odds ratio for circuit change, major bleeding and survival rate representation values

Table 6
Summary of Reported Bleeding and Anticoagulation Protocols Associated With PDT in ECMO Patients

Study Details	Study Design	Sample Size	Study Duration	Reported Bleeding	Anticoagulation Management Strategies
Braune et al. ⁸	Multicenter retrospective study	118	6 y	2 patients (1.7%) developed procedure-related major bleeding. One patient required surgical intervention while the other bleeding stopped spontaneously. Minor bleeding reported in 37 patients (31.4%).	Heparin was held 1 h before tracheostomy and recommenced immediately after without any recorded increase in the incidence of bleeding.
Kruit et al. ¹⁰	Single center retrospective study	50	10 y	Total of 20 patients experienced bleeding. Sixteen patients (32%) experienced minor bleeding, and 4 patients (8%) experienced significant bleeding requiring transfusion, surgical intervention, or frequent packing.	Individualized heparin protocols according to clinicians' decision. It was mentioned that heparin was stopped >4 h in 8 of the 20 patients (40%) who experienced bleeding. The majority had heparin restarted <4 h after PDT.
Dimopoulos et al. ¹²	Single center retrospective study	65	6 y	Major bleeding requiring blood transfusion or intervention was reported in 7 patients (11%), and minor bleeding was reported in 16 patients (25%).	Individualized heparin protocols according to clinicians' decision. There was no association between duration of heparin cessation before PDT and major complications
Salna et al. ¹¹	Single center retrospective study	127 total sample size. 110/127 had PDT and 17/127 had surgical approach.	8 y	This study primarily focused on PRBC transfusion requirements and survival outcomes. It did not provide detailed information about the bleeding complication; however, it was mentioned in the text that 13 patients had bleeding from their tracheostomy sites that required transfusion.	Heparin was held 1 h before procedure initiation and resumed almost immediately postprocedure. There was no association between the followed anticoagulation protocol and postprocedural bleeding.
Valchanov et al. ¹⁴	Single center case series	38	8 wk	The study reported no transfusion of blood products for tracheostomy bleeding and 2/38 patients needed additional skin sutures to stop skin bleeding.	The study institution protocol is to stop heparin infusions routinely 2 to 4 h before tracheostomy. However, anticoagulation was not discontinued in 15/38 patients, without any bleeding complications recorded.
Schmidt et al. ⁹	Multicenter retrospective study	353	9 y	Only 4 patients (1%) developed local major bleeding requiring transfusion, and minor local bleeding was reported in 87 patients (25%).	Heparin was stopped for 4 h preprocedure and restarted at a lowered dose approximately 2 h postprocedure.

Abbreviations: ECMO, extracorporeal membrane oxygenation; PDT, percutaneous dilatational tracheostomy; PRBC, packed red blood cells.

It is recognized that critical illness, ECMO circuit, and COVID-19 can induce unpredicted effects on coagulation, bleeding tendency, platelet function, and fibrinolysis.^{4-6,17} Limited evidence of safety of PDT on ECMO has been published, and even fewer have reported on PDT in COVID-19 patients on VV-ECMO. A handful of retrospective reports investigated the safety of PDT on ECMO patients.⁸⁻¹⁴

Braune et al. investigated PDT safety in a variety of extracorporeal configurations. They reported major bleeding in 1.7% (2/118 patients) and minor bleeding in 37 out of 118 patients. A PDT was performed in 87 of the 118 patients, and the majority of these patients (68/87) were on VV-ECMO. They also reported a median platelet count of $126 \times 10^9/L$, and a median international normalized ratio of 1.1 before tracheostomy.⁸

In a retrospective review of 50 cases of PDT on VV-ECMO over a 10-year period, Kruit et al. reported 40% incidence of bleeding (8% described as significant and requiring surgical intervention and 32% as minor bleeds). Interestingly, anticoagulation management before PDT was not protocolized, and holding anticoagulant for >4 hours did not reduce bleeding compared to a 4-hour hold.¹⁰

Salna et al. reported on 127 tracheostomies, of which 110 were done percutaneously. Most of their patients (99/127) were supported with VV-ECMO. A significant number, 55 patients of the 127 (43%), received blood transfusion within 48 hours postprocedure. However, tracheostomy site bleeding was observed in only 13 patients, indicating transfusion for nonprocedural related bleeding.¹¹

Dimopoulos et al. reported on PDT in 65 patients on VV-ECMO. Twenty-nine out of 65 patients (45%) developed at least 1 complication, of whom 10 from the 29 patients (15%) sustained at least 1 major complication. Significant bleeding, which required transfusion or intervention, was observed in 11% of patients.¹²

On the contrary, data from another single center report did not demonstrate increased major procedural complications nor bleeding with tracheostomy on ECMO. The transfusion requirements did not increase after tracheostomy. However, the number of patients was only 31 over a 5.5-year period.¹³

Valchanov et al. reported no major complications in a series of 38 patients with COVID-19 supported with ECMO. The pursestring suture was required in 2 patients to stop skin bleeding, and none of the patients required blood transfusion for tracheostomy bleeding.¹⁴

None of the authors' patients sustained mechanical procedural complications such as pneumothorax, air leaks, or loss of the airway.

As per the authors' results, no staff tested positive nor reported sickness ≤ 2 weeks post-PDT, suggesting that PDT in patients with COVID-19 may not carry added risk to the staff involved in the procedure provided appropriate personal protective equipment (PPE) precautions are applied. Two recent reports suggested PDT is safe for both patients with COVID-19 and medical personnel undertaking the procedure, albeit with modification to minimize the exposure and with strict adherence to institutional infection prevention and control policy and PPE precautions.^{18,19}

Using PPE reduced the risk of transmitting COVID-19 infection to healthcare staff involved in performing procedures in critical care environments.^{20,21}

This study had several methodologic limitations. First, these were the results of a single, although high-volume, ECMO center, and, therefore, may not be generalizable. Second, the retrospective nature has inherited reporting bias. The true incidence of clinically relevant bleeding may be underestimated due to some potential overlap of mild and moderate bleeding. Small sample size did not allow for multivariate logistic analysis to find association between periprocedural variables and complications. There was also no significant difference between the patients with COVID-19 and the control group, the patients without COVID-19, which did not allow for the

attribution of risk factors to complications, such as bleeding or ECMO dysfunction requiring circuit change. In addition, the novelty of COVID-19, medical personnel apprehension, and scarcity of data might have influenced the performance of practitioners.

Conclusions

In conclusion, the authors' limited data demonstrated that PDT in patients with COVID-19 infection and on VV-ECMO support is feasible and associated with low risk of bleeding. The risk of bleeding is similar to those without COVID-19. There was no report of mechanical complications or death. The risk of transmission of COVID-19 to staff can be minimized by appropriate timing, dedicated procedure team, and strict adherence to PPE protocols.

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Conflict of Interest

None.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1053/j.jvca.2022.09.084](https://doi.org/10.1053/j.jvca.2022.09.084).

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