

https://doi.org/10.5090/jcs.22.117 pISSN: 2765-1606 eISSN: 2765-1614 J Chest Surg. 2023;56(2):128-135



# Percutaneous Dilatational Tracheostomy in Patients with COVID-19 Supported by Extracorporeal Membrane Oxygenation

JeongA Son, M.D., Seungji Hyun, M.D., Woo Sik Yu, M.D., Joonho Jung, M.D., Seokjin Haam, M.D., Ph.D.

Department of Thoracic and Cardiovascular Surgery, Ajou University School of Medicine, Suwon, Korea

#### **ARTICLE INFO**

Received October 17, 2022 Revised November 10, 2022 Accepted November 23, 2022

### Corresponding author

Woo Sik Yu Tel 82-31-219-4214 Fax 82-31-219-5215 E-mail yws081011@aumc.ac.kr ORCID https://orcid.org/0000-0002-5100-9131

<sup>1</sup>This article was presented at the session of the 54th Annual Meeting of the Korean Society for Thoracic & Cardiovascular Surgery (KTCVS), Pyeongchang, Korea, November, 3–5, 2022. **Background:** Pneumonia caused by severe acute respiratory syndrome coronavirus 2 can cause acute respiratory distress syndrome, often requiring prolonged mechanical ventilation and eventually tracheostomy. Both procedures occur in isolation units where personal protective equipment is needed. Additionally, the high bleeding risk in patients with extracorporeal membrane oxygenation (ECMO) places a great strain on surgeons. We investigated the clinical characteristics and outcomes of percutaneous dilatational tracheostomy (PDT) in patients with coronavirus disease 2019 (COVID-19) supported by ECMO, and compared the outcomes of patients with and without ECMO.

**Methods:** This retrospective, single-center, observational study included patients with severe COVID-19 who underwent elective PDT (n=29) from April 1, 2020, to October 31, 2021. The patients were divided into ECMO and non-ECMO groups. Data were collected from electronic medical records at Ajou University Hospital in Suwon, Korea.

**Results:** Twenty-nine COVID-19 patients underwent PDT (24 men [82.8%] and 5 women [17.2%]; median age, 61 years; range, 26–87 years; interquartile range, 54–71 years). The mean procedure time was 17±10.07 minutes. No clinically or statistically significant difference in procedure time was noted between the ECMO and non-ECMO groups (16.35±7.34 vs. 18.25±13.32, p=0.661). Overall, 12 patients (41.4%) had minor complications; 10 had mild subdermal bleeding from the skin incision, which was resolved with local gauze packing, and 2 (6.9%) had dislodgement. No healthcare provider infection was reported. **Conclusion:** Our PDT approach is safe for patients and healthcare providers. With bronchoscopy assistance, PDT can be performed quickly and easily even in isolation units and with acceptable risk, regardless of the hypo-coagulable condition of patients on ECMO.

**Keywords:** Tracheostomy, COVID-19, Mechanical ventilation, SARS-CoV-2, Extracorporeal membrane oxygenation

## Introduction

Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which first emerged in Wuhan, China, in November 2019 [1]. The first confirmed case in Korea was diagnosed on January 20, 2020; since then, Korea has experienced an abrupt and explosive outbreak of COVID-19 [2]. Consequently, COVID-19 was designated as a class I infectious disease in the Republic of Korea from January 20, 2020, to April 24, 2022. According to the Korea Disease Control and Prevention Agency, COVID-19 was confirmed in 16,929,564 patients during this period, with an incidence rate of 32,785 per 100,000 population. The number of severe and critical cases during this period was 22,137 and the case mortality was 0.14%, with 23,045 deaths [3]. COVID-19 can present with various clinical phenotypes, ranging from asymptomatic to severe cases. In severe cases, COVID-19 can lead to acute respiratory distress syndrome (ARDS), which often requires prolonged mechanical ventilation and extracorporeal membrane oxygenation (ECMO). The Korean health authorities designated 782 beds from 75 hospitals for critically ill patients suffering from COVID-19 disease to cope with these circumstances [4]. As a designated hospital for COVID-19 patients, our facility had to care for critically ill patients.

Copyright © 2023, The Korean Society for Thoracic and Cardiovascular Surgery

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/

Tracheostomy is considered for patients requiring prolonged mechanical ventilation because of its advantages, including decreased work of breathing, improved ventilator synchrony, enhancement of secretion clearance, and patient comfort [5,6]. Several tracheostomy techniques exist (percutaneous and surgical); however, traditionally, tracheostomy has been performed in the operating room using standard surgical principles [7,8]. In 1985, Ciaglia et al. [9] described an alternative method in which tracheostomy was performed percutaneously using the Seldinger approach. Compared with a surgical tracheostomy, percutaneous dilatational tracheostomy (PDT) is a relatively easy procedure that can be performed at the patient's bedside with a limited number of healthcare workers. PDT can also minimize the potential risks associated with transporting critically ill patients, and the inconvenience and expense of scheduling and utilizing operating room facilities. In contrast, surgical tracheostomy requires greater technical skill and longer operative time, with an associated higher complication rate [8,10]. PDT, which can mitigate the bleeding risk, is more attractive than the surgical approach, considering that patients supported by ECMO have a higher bleeding tendency.

This retrospective observational descriptive study evaluated the outcomes and techniques used to perform PDT in patients with COVID-19-related respiratory failure. In addition, this study also compared the outcomes of PDT between two groups (ECMO and non-ECMO).

### Methods

### Patients

This retrospective observational study included patients with respiratory failure due to COVID-19 who underwent elective PDT at Ajou University in Korea between April 1, 2020, and October 31, 2021. The patients were divided into ECMO and non-ECMO groups. The ECMO group included patients who were on ECMO at the time of procedure. If a patient had been on ECMO at any point during the study period, but was not on ECMO at the time of the procedure, he or she was excluded from the ECMO group and included in the non-ECMO group. The non-ECMO group comprised patients who were not on ECMO when tracheostomy was performed. Polymerase chain reaction tests were used to diagnose COVID-19 in all patients.

This study was approved by the Ajou University Institutional Review Board (IRB no., AJOUIRB-MBD-2022-282). The informed consents were not obtained because of the

# Percutaneous dilatational tracheostomy procedure

The procedure was executed alternately by 2 surgeons using standard personal protective equipment (PPE) to minimize aerosol generation from high-risk procedures. The PPE included N95 masks, double gloves, disposable protective uniforms, shoe covers, and powered air-purifying respirator devices (PAPR) (Fig. 1). Ciaglia Blue Rhino Percutaneous Tracheostomy Introducer Set (Cook Critical Care Inc., Bloomington, IN, USA) was used in all PDT cases in this study.

The procedure was carried out at the patient's bedside inside an isolated room with negative pressure and high-efficiency particulate air filtration system. The patient was sedated with an adequate dose of a neuromuscular blocking drug to prevent aerosol-generating coughing. Then, the patient was positioned close to the surgeon and placed in a supine position with the neck extended and the head stabilized. Chlorhexidine solution was applied to the anterior side of the neck, and sterile drapes were placed. The sternal notch and inferior border of the cricoid cartilage were recognized, and a bronchoscope was then inserted into the endotracheal tube. The pulmonologist checked and cleaned the airway using the bronchoscope before the incision. After administering local anesthesia with 2% lidocaine, a 1-cm transverse incision was made at about 2 cm above the suprasternal notch. Next, the subcutaneous tissues were dissected until the tracheal cartilage was recognized using the tip of a mosquito forceps, and the anterior tracheal wall was placed in the bronchoscope's view. The tracheostomy site was localized between the first and second tracheal rings by pressing the anterior tracheal wall. The trachea



Fig. 1. Personal protective equipment.

was punctured with the needle included in the Ciaglia tracheostomy set (Fig. 2A). The bevel of the needle was angled slightly caudally. Its location was confirmed via bronchoscopy. The guidewire was then fed through a needle (Fig. 2B). The needle was removed, and dilation was performed with dilators placed through the guidewire, creating an opening through which the tracheostomy tube was placed (Fig. 2C–F). The guidewire was then removed, and the cuff was inflated with air. After this, a bronchoscopy assistant disconnected the endotracheal tube from the ventilator and connected the tracheostomy tube to the ventilator. The bronchoscope was then inserted into the tracheostomy tube to confirm its position, and check for bleeding. Finally, the dressing was applied with Y-gauze and a tracheostomy collar. If necessary, the skin was sutured.

### Data collection

Data were retrospectively collected by reviewing the electronic medical records at Ajou University Hospital in Suwon, Korea. The following variables were reviewed: demographics, body mass index (BMI), Charlson comorbidity index (CCI), length of intubation, intraoperative complications, perioperative complications, ECMO type and settings before and during the procedure, ECMO weaning, laboratory findings, ventilator settings, weaning from the mechanical ventilator, seal off, perioperative complications, 30-day all-cause mortality, all-cause mortality without weaning mechanical ventilation, all-cause mortality without weaning from ECMO, and discharged survivors. The CCI uses administrative data to create a single score that sums the adjusted risk of mortality due to comorbidities and the age of patients receiving medical care [11]. Perioperative complications were defined as follows: (1) major complications were either life-threatening or required surgical intervention under general anesthesia and (2) minor complications required bedside procedures, such as bleeding controlled with simple sutures or a compression dressing.

### Statistical analysis

Categorical data were presented as numbers (percentage), and the Fisher exact, chi-square, and Wilcoxon rank sum tests were used to compare the demographic characteristics, and outcomes between the ECMO and non-ECMO groups. Continuous variables were presented as either means with the standard deviation or medians with the interquartile range (IQR) and compared using the Student t-test or the Mann-Whitney U test. Survival was measured from the date of tracheostomy to the date of all-cause death, plotted with Kaplan-Meier curves, and compared using the log-rank test. A swimmer plot was used to describe the time to outcome. A p-value <0.05 was required to reach statistical significance. Statistical analyses were done using IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA) and R ver. 3.2.3 (R Development Core Team, Vienna, Austria).

## Results

### Cohort demographic characteristics

During the study period, 30 patients underwent tracheostomy. One patient was excluded from this study due to



**Fig. 2.** (A–F) Percutaneous dilatational tracheostomy procedure.

undergoing surgical tracheostomy during the operation for a deep neck infection and mediastinitis. The patients were divided into 2 groups. The non-ECMO group comprised 12 patients who were not on ECMO when the tracheostomy was performed. There were 19 patients on ECMO during the study period. However, 2 of these 19 patients were excluded from the ECMO group and included in the non-EC-MO group, because 1 had already been weaned from ECMO when undergoing PDT, and the other underwent tracheostomy just before ECMO was applied. PDT was performed on 29 patients, including 24 men (82.76%) and 5 women (17.24%), with a mean age of 60.86±14.63 years. The mean BMI was 26.28±4.94 kg/m<sup>2</sup>. The demographic characteristics and laboratory findings of the study population are presented in Table 1.

Patients underwent PDT at a median of 28 days (IQR, 19–32 days) from COVID-19 diagnosis. The patients were intubated for a median of 18.00 days (IQR, 12.00–20.00 days) before tracheostomy, which was not significantly different between the ECMO and non-ECMO groups (17.00 days [IQR, 13.00–19.00 days] versus 18.00 days [IQR, 11.75–22.00 days], p=0.477). Among the 29 patients, 17

#### Table 1. Cohort demographic characteristics

(58.62%) were supported with ECMO during the tracheostomy procedure. The median duration of the ECMO run before tracheostomy was 14.00 days (IQR, 12.00–15.00 days).

The mechanical ventilation settings before the procedure are listed in Table 1. The ventilator positive end-expiratory pressure values were lower in the ECMO group than in the non-ECMO group ( $5.29\pm1.16$  cmH<sub>2</sub>O versus  $8.42\pm3.20$  cm-H<sub>2</sub>O, p=0.007). In addition, the respiratory rates were lower in the ECMO group than in the non-ECMO group ( $10.47\pm1.55$  breaths/min versus  $21.00\pm4.33$  breaths/min, p<0.001). The tidal volume was also statistically significantly lower in the ECMO group than in the non-ECMO group ( $259.41\pm55.17$  mL versus  $345.86\pm116.6$  mL, p=0.031).

# Outcomes of percutaneous dilatational tracheostomy

The mean procedure time was  $17.14\pm10.07$  minutes. There was no clinically or statistically significant difference in procedure time between the ECMO and non-EC-MO groups:  $16.35\pm7.34$  in the ECMO group versus  $18.25\pm$ 

Characteristic         Total (n=29)         ECMO (n=17)         Non-ECMO (n=12)         p-value           Age (yr)         60.86±14.63         56.12±10.61         67.58±17.23         0.035           Sex         0.622           Male         24 (82.76)         15 (88.24)         9 (75.00)           Female         5 (17.24)         2 (11.76)         3 (25.00)           BMI (kg/m²)         26.3±4.9         27.0±5.6         25.2±3.9         0.351           Underweight (BMI <18.5)         0         0         0         0           Normal (18.5≤ BMI <25.0)         13 (44.8)         8 (42.11)         5 (41.67)         5           Overweight (25≤ BMI <30.0)         10 (34.48)         5 (29.41)         5 (41.67)         -           Obese (BM ≥30.0)         6 (20.69)         4 (23.53)         2 (16.67)         -           Days of intubation to tracheostomy         18.00 (12.00–20.00)         17.00 (13.00–19.00)         18.00 (11.75–22.00)         0.477           Days of ECMO to tracheostomy         18.00 (12.00–20.00)         17.00 (13.00–19.00)         18.00 (11.75–22.00)         0.477           Days of intubation to tracheostomy         18.00 (12.00–20.00)         17.00 (13.00–19.00)         18.00 (11.75–22.00)         0.477           Days of ECMO to					
Age (yr)         60.86±14.63         56.12±10.61         67.58±17.23         0.035           Sex         0.622           Male         24 (82.76)         15 (88.24)         9 (75.00)           Female         5 (17.24)         2 (11.76)         3 (25.00)           BMI (kg/m²)         26.3±4.9         27.0±5.6         25.2±3.9         0.351           Underweight (BMI <18.5)         0         0         0         0           Normal (18.5≤ BMI <25.0)         13 (44.8)         8 (42.11)         5 (41.67)         5 (41.67)           Overweight (25≤ BMI <30.0)         10 (34.48)         5 (29.41)         5 (41.67)         5 (41.67)           Obese (BMI ≥30.0)         6 (20.69)         4 (23.53)         2 (16.67)         -           Days of intubation to tracheostomy         18.00 (12.00-20.00)         17.00 (13.00-19.00)         18.00 (11.75-22.00)         0.477           Days of ECMO to tracheostomy         18.00 (12.00-15.00)         -         -         -         CCI score         4.00±2.65         3.65±2.62         4.50±2.71         0.402           Lab findings         -         -         -         -         -         -         -         -         -         -         -         -         -         - <th>Characteristic</th> <th>Total (n=29)</th> <th>ECMO (n=17)</th> <th>Non-ECMO (n=12)</th> <th>p-value</th>	Characteristic	Total (n=29)	ECMO (n=17)	Non-ECMO (n=12)	p-value
Sex         0.622           Male         24 (82.76)         15 (88.24)         9 (75.00)           Female         5 (17.24)         2 (11.76)         3 (25.00)           BMI (kg/m <sup>3</sup> )         26.3±4.9         27.0±5.6         25.2±3.9         0.351           Underweight (BMI <18.5)	Age (yr)	60.86±14.63	56.12±10.61	67.58±17.23	0.035
Male24 (82.76)15 (88.24)9 (75.00)Female5 (17.24)2 (11.76)3 (25.00)BMI (kg/m²)26.3 $\pm$ 4.927.0 $\pm$ 5.625.2 $\pm$ 3.90.351Underweight (BMI <18.5)0000Normal (18.5< BMI <25.0)13 (44.8)8 (42.11)5 (41.67)Overweight (25< BMI <30.0)10 (34.48)5 (29.41)5 (41.67)Obese (BMI $\geq$ 30.0)6 (20.69)4 (23.53)2 (16.67)Days of intubation to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.472Days of ECMO to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy18.00 (12.00–20.00)18.00 (13.00–19.00)18.00 (11.75–22.00)0.472Days of tracheostomy18.00 (12.00–20.00)10.63±4.1011.110±5.8200.076 </td <td>Sex</td> <td></td> <td></td> <td></td> <td>0.622</td>	Sex				0.622
Female $5 (17.24)$ $2 (11.76)$ $3 (25.00)$ BMI (kg/m²) $26.3\pm 4.9$ $27.0\pm 5.6$ $25.2\pm 3.9$ $0.351$ Underweight (BMI <18.5)	Male	24 (82.76)	15 (88.24)	9 (75.00)	
BMI (kg/m²)         26.3±4.9         27.0±5.6         25.2±3.9         0.351           Underweight (BMI <18.5)	Female	5 (17.24)	2 (11.76)	3 (25.00)	
$\begin{array}{l lllllllllllllllllllllllllllllllllll$	BMI (kg/m <sup>2</sup> )	26.3±4.9	27.0±5.6	25.2±3.9	0.351
Normal (18.5< BMI <25.0)13 (44.8)8 (42.11)5 (41.67)Overweight (25< BMI <30.0)	Underweight (BMI <18.5)	0	0	0	
Overweight (25 < BMI < 30.0)10 (34.48)5 (29.41)5 (41.67)Obese (BMI $\geq$ 30.0)6 (20.69)4 (23.53)2 (16.67)Days of intubation to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy14.00 (12.00–15.00)CCI score4.00 $\pm$ 2.653.65 $\pm$ 2.624.50 $\pm$ 2.710.402Lab findingsWhite blood cell (/µL)10,830 $\pm$ 4,80010,630 $\pm$ 4,11011,110 $\pm$ 5,8200.796Platelet (/µL)10.08 $\pm$ 1.2610.43 $\pm$ 1.179.59 $\pm$ 1.260.076Platelet (/µL)172,200 $\pm$ 81,294142.530 $\pm$ 67,080214,160 $\pm$ 83,6400.016Prothrombin time (INR)1.62 $\pm$ 0.622.00 $\pm$ 0.561.10 $\pm$ 0.08<0.001	Normal (18.5≤ BMI <25.0)	13 (44.8)	8 (42.11)	5 (41.67)	
Obese (BMI $\geq$ 30.0)6 (20.69)4 (23.53)2 (16.67)Days of intubation to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy14.00 (12.00–15.00)CCI score4.00 $\pm$ 2.653.65 $\pm$ 2.624.50 $\pm$ 2.710.402Lab findingsWhite blood cell (/µL)10,830 $\pm$ 4,80010,630 $\pm$ 4,11011,110 $\pm$ 5,8200.796Hemoglobin (g/dL)10.08 $\pm$ 1.2610.43 $\pm$ 1.179.59 $\pm$ 1.260.076Platelet (/µL)172,200 $\pm$ 81,294142.530 $\pm$ 67,080214,160 $\pm$ 83,6400.016Prothrombin time (INR)1.62 $\pm$ 0.622.00 $\pm$ 0.561.10 $\pm$ 0.08<0.001	Overweight (25≤ BMI <30.0)	10 (34.48)	5 (29.41)	5 (41.67)	
Days of intubation to tracheostomy18.00 (12.00–20.00)17.00 (13.00–19.00)18.00 (11.75–22.00)0.477Days of ECMO to tracheostomy4.00±2.653.65±2.624.50±2.710.402CCI score4.00±2.653.65±2.624.50±2.710.402Lab findings10,830±4,80010,630±4,11011,110±5,8200.796Memoglobin (g/dL)10.08±1.2610.43±1.179.59±1.260.076Platelet (/µL)172,200±81,294142.530±67,080214,160±83,6400.016Prothrombin time (INR)1.62±0.622.00±0.561.10±0.08<0.001	Obese (BMI ≥30.0)	6 (20.69)	4 (23.53)	2 (16.67)	
Days of ECMO to tracheostomy14.00 (12.00–15.00)-CCI score4.00±2.653.65±2.624.50±2.710.402Lab findings10,830±4,80010,630±4,11011,110±5,8200.796White blood cell (/μL)10.08±1.2610.43±1.179.59±1.260.076Platelet (/μL)172,200±81,294142.530±67,080214,160±83,6400.016Prothrombin time (INR)1.62±0.622.00±0.561.10±0.08<0.001	Days of intubation to tracheostomy	18.00 (12.00-20.00)	17.00 (13.00-19.00)	18.00 (11.75-22.00)	0.477
CCI score         4.00±2.65         3.65±2.62         4.50±2.71         0.402           Lab findings         White blood cell (/μL)         10,830±4,800         10,630±4,110         11,110±5,820         0.796           Hemoglobin (g/dL)         10.08±1.26         10.43±1.17         9.59±1.26         0.076           Platelet (/μL)         172,200±81,294         142.530±67,080         214,160±83,640         0.016           Prothrombin time (INR)         1.62±0.62         2.00±0.56         1.10±0.08         <0.001	Days of ECMO to tracheostomy		14.00 (12.00-15.00)		-
Lab findings           White blood cell (/µL)         10,830±4,800         10,630±4,110         11,110±5,820         0.796           Hemoglobin (g/dL)         10.08±1.26         10.43±1.17         9.59±1.26         0.076           Platelet (/µL)         172,200±81,294         142.530±67,080         214,160±83,640         0.016           Prothrombin time (INR)         1.62±0.62         2.00±0.56         1.10±0.08         <0.001	CCI score	4.00±2.65	$3.65 \pm 2.62$	4.50±2.71	0.402
White blood cell ( $\mu$ L)10,830±4,80010,630±4,11011,110±5,8200.796Hemoglobin (g/dL)10.08±1.2610.43±1.179.59±1.260.076Platelet ( $\mu$ L)172,200±81,294142.530±67,080214,160±83,6400.016Prothrombin time (INR)1.62±0.622.00±0.561.10±0.08<0.001	Lab findings				
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	White blood cell (/µL)	10,830±4,800	10,630±4,110	11,110±5,820	0.796
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Hemoglobin (g/dL)	10.08±1.26	10.43±1.17	9.59±1.26	0.076
Prothrombin time (INR)         1.62±0.62         2.00±0.56         1.10±0.08         <0.001           aPTT (sec)         67.31±26.92         87.00±14.71         39.42±9.03         <0.001	Platelet (/µL)	172,200±81,294	142.530±67,080	214,160±83,640	0.016
aPTT (sec)67.31±26.9287.00±14.7139.42±9.03<0.001Ventilator settingsPEEP (cmH2O)6.59±2.695.29±1.168.42±3.200.007Respiratory rate (breaths/min)14.83±6.0510.47±1.5521.00±4.33<0.001	Prothrombin time (INR)	1.62±0.62	2.00±0.56	1.10±0.08	< 0.001
Ventilator settings         PEEP (cmH2O)         6.59±2.69         5.29±1.16         8.42±3.20         0.007           Respiratory rate (breaths/min)         14.83±6.05         10.47±1.55         21.00±4.33         <0.001	aPTT (sec)	67.31±26.92	87.00±14.71	39.42±9.03	< 0.001
PEEP (cmH <sub>2</sub> O)         6.59±2.69         5.29±1.16         8.42±3.20         0.007           Respiratory rate (breaths/min)         14.83±6.05         10.47±1.55         21.00±4.33         <0.001	Ventilator settings				
Respiratory rate (breaths/min)         14.83±6.05         10.47±1.55         21.00±4.33         <0.001           FiO2 (mm Hg)         0.47±0.16         0.41±0.09         0.55±0.21         0.052	PEEP (cmH <sub>2</sub> O)	6.59±2.69	5.29±1.16	8.42±3.20	0.007
FiO2 (mm Hg)0.47±0.160.41±0.090.55±0.210.052	Respiratory rate (breaths/min)	14.83±6.05	10.47±1.55	21.00±4.33	< 0.001
	FiO <sub>2</sub> (mm Hg)	0.47±0.16	0.41±0.09	0.55±0.21	0.052
Tidal volume (mL)295.18±94.67259.41±55.17345.86±116.60.031	Tidal volume (mL)	295.18±94.67	259.41±55.17	345.86±116.6	0.031
Plateau pressure (cmH <sub>2</sub> O)         28.00±7.70         28.18±7.72         27.75±8.01         0.886	Plateau pressure (cmH <sub>2</sub> O)	28.00±7.70	28.18±7.72	27.75±8.01	0.886

Values are presented as mean±standard deviation, number (%), or median (interquartile range).

ECMO, extracorporeal membrane oxygenation; BMI, body mass index; CCI, Charlson comorbidity index; INR, international normalized ratio; aPTT, activated partial thromboplastin time; PEEP, positive end-expiratory pressure; FiO<sub>2</sub>, fraction of inspired oxygen.

13.32 in the non-ECMO group (p=0.661).

No major complications were observed during the procedures. However, 12 patients (41.4%) had minor complications; 10 patients (34.5%) had mild subdermal bleeding resulting from the skin incision, which was resolved with local gauze packing. Additionally, 2 cases (6.9%) of dislodgement occurred due to postural change and were resolved with re-insertion of the tracheostomy tube at the bedside. Although no major complications were found, there were 10 (58.8%) minor bleeding complications in the ECMO group; in contrast, no bleeding complications were seen in the non-ECMO group. None of the patients required reoperation for bleeding.

Of the 29 patients who underwent PDT, 2 underwent lung transplantation, and 13 patients (44.8%) were discharged home or to a health care center. Furthermore, 13 patients (44.8%) died within 30 days of tracheostomy. The patients' clinical courses are shown in Fig. 3. After PDT, the median time to ECMO weaning was 14.50 days (IQR, 5.75-35.75 days). There was no significant difference in mortality without weaning from the mechanical ventilator between the ECMO and non-ECMO groups (9 [52.9%] versus 7 [58.3%], p=0.792). Fig. 4 shows the absence of a significant difference in the 6-month survival probability between the ECMO and non-ECMO groups (p=0.48). The clinical outcomes among patients who did and did not undergo tracheostomy during ECMO are presented in Table 2.

### Discussion

This retrospective observational study included 29 patients with COVID-19 who underwent percutaneous tracheostomy and observed the clinical characteristics and outcomes of the procedures. The study also compared the outcomes between patients with and without ECMO.

PDT was first introduced in 1957 [9] and became popular after a commercially available kit was released in 1985 [12]. This technique involves blunt dilatation to open the pretracheal tissue to pass the tracheostomy tube. While full dissection of the pretracheal tissues and insertion of the tracheostomy tube into the trachea under direct vision is necessary for surgical tracheostomy, PDT requires only limited dissection, results in less tissue damage, and lowers the risk of bleeding and wound infection. Al-Ansari et al. [12] reported that surgical tracheostomy should be considered first in cases of goiter, obesity, pneumomediastinum,



**Fig. 4.** Kaplan-Meier analysis shows no significant difference in the 6-month survival probability between the extracorporeal membrane oxygenation (ECMO) and non-ECMO groups (p=0.48).



Fig. 3. (A, B) Swimmer plot showing the patients' clinical courses. ECMO, extracorporeal membrane oxygenation; COVID-19, coronavirus disease 2019.

Characteristic	Total (n=29)	ECMO (n=17)	No-ECMO (n=12)	p-value
Procedure time (min)	17.14±10.07	16.35±7.34	18.25±13.32	0.661
Complication	12 (41.4)	10 (58.8)	2 (16.7)	0.053
Major	0			
Minor	12 (41.4)	10 (58.8)	2 (16.7)	
Bleeding	10 (34.5)	10 (58.8)	0	0.001
Dislodgement	2 (6.9)	0	2 (16.7)	0.163
Death within 30 days	13 (44.8)	6 (35.3)	7 (58.3)	0.213
Death without weaning from MV	16 (55.2)	9 (52.9)	7 (58.3)	0.792
ECMO weaning	-	8 (47.06)	-	-
Tracheostomy to ECMO weaning (day)		14.50 (5.75-35.75)		
Tracheostomy to MV weaning (day)	22 (15.00-27.00)	23.50 (18.00-56.75)	22.0 (13.0-26.0)	-
Discharged survivors	13 (44.8)	8 (47.06)	5 (41.67)	1.000

Values are presented as mean±standard deviation, number (%), or median (interquartile range).

ECMO, extracorporeal membrane oxygenation; MV, mechanical ventilator.

difficult anatomy, coagulopathy, and hemodynamic, or respiratory instability. However, in this study, none of the patients required reoperation for bleeding, although a large proportion of them received anticoagulation therapy. PDT can be executed safely with a bronchoscope, in obese patients and patients with prolonged prothrombin time/activated partial thromboplastin time.

PDT was carried out at the bedside to reduce the risks that might have arisen during patient transfer. Using the modified Seldinger technique, which involves the use of a bronchoscope, the exposure of healthcare providers to aerosols during the procedure could be minimized. As recommended in previous studies, healthcare providers wore PAPR, N95 masks, double gloves, disposable protective uniforms, and shoe covers to protect themselves [13,14]. Although this equipment and an isolated environment interfere with the procedure, PDT requires only limited pretracheal tissue dissection, allowing the procedure to be done quickly and safely.

ARDS has been reported to develop in 15% to 30% of patients with COVID-19, significantly increasing mortality [15]. Based on the initial Extracorporeal Life Support Organization guidance document and interim guidelines by the World Health Organization, patients with refractory hypoxemia despite lung-protective ventilation were supported by ECMO [16,17]. Evidence from 2 randomized controlled studies, post hoc Bayesian analysis, and meta-analyses also support the benefit of ECMO in combination with ultra-lung-protective ventilation in patients with very severe ARDS [18,19]. Based on their findings, if patients in the present study still had refractory hypoxemia or hypercapnia, ECMO was applied (n=19, 65.52%). Seventeen patients were on veno-venous ECMO, and 2 were veno-arterial ECMO for cardio-circulatory compromise.

Early in the pandemic, observational studies suggested that SARS-CoV-2 was associated with thromboembolic diseases [20]. Although results of prospective randomized studies have not yet been reported, anticoagulation therapy using low-molecular-weight heparin (LMWH) has been widely accepted as a standard therapy for COVID-19 patients [21]. At our center, a prophylactic dose of LMWH was considered in all patients requiring hospital admission for COVID-19 without contraindications such as active bleeding and platelet count  $<25\times10^{9}$ /L. Among the 29 tracheostomized patients, 26 (89.66%) were anticoagulated and 3 were not. Patients without ECMO were anticoagulated with LMWH. The dosage of LMWH was determined by a doctor from the infectious disease department depending on their severity. However, patients on ECMO were anticoagulated with argatroban (Novastan; Mitsubishi Tanabe Pharma Corp., Osaka, Japan).

Previous studies have reported that bleeding was the most frequent complication associated with ECMO support in critically ill patients [22]. Schmidt et al. [23] found that local bleeding within 24 hours of tracheostomy was 4 times more frequent during ECMO (25% versus 7%, p<0.01). In our study, all bleeding complications were observed in the ECMO group, which is comparable to the results of Schmidt et al. [23]. Even though there were 10 cases of bleeding complications, all were resolved with simple gauze packing. Despite the high proportion of therapeutic anticoagulation, there were no major complications requiring reoperation for bleeding. In the present study, the potential risks of PDT, such as tracheal laceration, tracheoesophageal fistula, and paratracheal insertion, were avoided using a bronchoscope.

According to our findings, the patients who underwent tracheostomy were predominantly men (82.8%). This result is similar to those of previous studies that reported higher disease severity and poor prognosis in men [24-27]. A meta-analysis of 59 studies comprising 36,470 patients showed that male patients experienced more severe disease than female patients (risk ratio, 1.18; 95% confidence interval, 1.10–1.27) [24]. According to Lisco et al. [28], 17 $\beta$ -estradiol could exert protective effects in female patients. Furthermore, Li et al. [29] also observed that although only slightly more than half (50.9%) of all patients were male, and male patients accounted for a significantly higher proportion of severe cases (56.9% versus 45.2%, p=0.006). Chao et al. [26] reported that 53 patients undergoing tracheostomy were predominantly male (n=33 patients, 62%).

Two cases of dislodgement, which were easily resolved with re-insertion of the tracheostomy tube at the bedside, were reported in the non-ECMO group. The reasons for dislodgement, observed only in the non-ECMO group, are as follows. First, the patients were in an isolated room, and they could not be monitored continuously. Secondly, unlike the patients with ECMO, the patients in the non-EC-MO group were not administered neuromuscular blocking drugs.

### Limitations

First, this study used retrospective observational data, with poor control over exposure factors, covariates, and possible confounders. Second, due to the cohort being from a single center, its small sample size over a short period could have caused type II error in the analyses. Although further studies are needed to elucidate the safety of this procedure in patients with highly contagious respiratory disease and the outcomes comparing 2 groups (ECMO versus non-ECMO), our findings justify the use of PDT in patients with highly contagious respiratory disease under a hypocoagulable condition.

### Conclusion

The PDT approach applied in this study is safe for patients, and healthcare providers. With bronchoscopic assistance, PDT can be performed quickly and easily, even in isolation units where PPE is needed. This study also found that despite the hypo-coagulable state of patients with ECMO and in patients with highly contagious diseases, such as COVID-19, PDT can be safely performed within acceptable risks.

## Article information

### ORCID

JeongA Son: https://orcid.org/0000-0002-0736-1226 Seungji Hyun: https://orcid.org/0000-0002-2578-3510 Woo Sik Yu: https://orcid.org/0000-0002-5100-9131 Joonho Jung: https://orcid.org/0000-0002-1078-8116 Seokjin Haam: https://orcid.org/0000-0002-0403-2216

### Author contributions

Conceptualization: WSY. Data curation: JAS, S Hyun, JJ, WSY, S Haam. Formal analysis: JAS, WSY. Methodology: JAS, WSY. Project administration: WSY. Visualization: JAS, WSY. Writing-original draft: JAS, WSY. Writing-review & editing: JAS, WSY, S Hyun, JJ, S Haam. Final approval of the manuscript: JAS, WSY, S Hyun, JJ, S Haam.

### Conflict of interest

No potential conflict of interest relevant to this article was reported.

### Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-forprofit sectors.

## References

- Ziehr DR, Alladina J, Petri CR, et al. Respiratory pathophysiology of mechanically ventilated patients with COVID-19: a cohort study. Am J Respir Crit Care Med 2020;201:1560-4. https://doi.org/10.1164/rccm.202004-1163LE
- Kim JY, Choe PG, Oh Y, et al. The first case of 2019 novel coronavirus pneumonia imported into Korea from Wuhan, China: implication for infection prevention and control measures. J Korean Med Sci 2020;35:e61. https://doi.org/10.3346/jkms.2020.35.e61
- Ahn S, Jang J, Park SY, et al. Outbreak report of COVID-19 during designation of class 1 infectious disease in the Republic of Korea (January 20, 2020 and April 24, 2022). Public Health Wkly Rep 2022;15:1759-72.
- Korea Disease Control and Prevention Agency. A study on the COVID-19 beds status of measures for urgent securing of beds. Cheongju: Korea Disease Control and Prevention Agency; 2021.
- Heyd CP, Desiato VM, Nguyen SA, et al. Tracheostomy protocols during COVID-19 pandemic. Head Neck 2020;42:1297-302. https://

doi.org/10.1002/hed.26192

- Zhang X, Huang Q, Niu X, et al. Safe and effective management of tracheostomy in COVID-19 patients. Head Neck 2020;42:1374-81. https://doi.org/10.1002/hed.26261
- 7. Wood DE. Tracheostomy. Chest Surg Clin N Am 1996;6:749-64.
- Freeman BD, Isabella K, Lin N, Buchman TG. A meta-analysis of prospective trials comparing percutaneous and surgical tracheostomy in critically ill patients. Chest 2000;118:1412-8. https://doi.org/10. 1378/chest.118.5.1412
- Ciaglia P, Firsching R, Syniec C. Elective percutaneous dilatational tracheostomy: a new simple bedside procedure; preliminary report. Chest 1985;87:715-9. https://doi.org/10.1378/chest.87.6.715
- Heikkinen M, Aarnio P, Hannukainen J. Percutaneous dilational tracheostomy or conventional surgical tracheostomy? Crit Care Med 2000;28:1399-402. https://doi.org/10.1097/00003246-200005000-00023
- Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40:373-83. https://doi.org/ 10.1016/0021-9681(87)90171-8
- Al-Ansari MA, Hijazi MH. Clinical review: percutaneous dilatational tracheostomy. Crit Care 2006;10:202. https://doi.org/10.1186/cc3900
- 13. Respiratory Care Committee of Chinese Thoracic Society. Expert consensus on preventing nosocomial transmission during respiratory care for critically ill patients infected by 2019 novel coronavirus pneumonia. Zhonghua Jie He He Hu Xi Za Zhi 2020;17:E020. https://doi.org/10.3760/cma.j.issn.1001-0939.2020.0020
- Radhakrishnan S, Perumbally HA, Surya S, Ponneth MS. Guidelines for surgical tracheostomy and tracheostomy tube change during the COVID-19 pandemic: a review article. Indian J Otolaryngol Head Neck Surg 2020;72:398-401. https://doi.org/10.1007/s12070-020-01893-y
- Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet 2020;395:1054-62. https://doi.org/10.1016/ S0140-6736(20)30566-3
- World Health Organization. Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected: interim guidance, 13 March 2020. Geneva: World Health Organization; 2020.
- Bartlett RH, Ogino MT, Brodie D, et al. Initial ELSO guidance document: ECMO for COVID-19 patients with severe cardiopulmonary failure. ASAIO J 2020;66:472-4. https://doi.org/10.1097/MAT.000000000001173
- 18. Abrams D, Schmidt M, Pham T, et al. Mechanical ventilation for

acute respiratory distress syndrome during extracorporeal life support: research and practice. Am J Respir Crit Care Med 2020;201: 514-25. https://doi.org/10.1164/rccm.201907-1283CI

- Goligher EC, Tomlinson G, Hajage D, et al. Extracorporeal membrane oxygenation for severe acute respiratory distress syndrome and posterior probability of mortality benefit in a post hoc Bayesian analysis of a randomized clinical trial. JAMA 2018;320:2251-9. https:// doi.org/10.1001/jama.2018.14276
- Paranjpe I, Fuster V, Lala A, et al. Association of treatment dose anticoagulation with in-hospital survival among hospitalized patients with COVID-19. J Am Coll Cardiol 2020;76:122-4. https://doi.org/ 10.1016/j.jacc.2020.05.001
- Thachil J, Tang N, Gando S, et al. ISTH interim guidance on recognition and management of coagulopathy in COVID-19. J Thromb Haemost 2020;18:1023-6. https://doi.org/10.1111/jth.14810
- Aubron C, DePuydt J, Belon F, et al. Predictive factors of bleeding events in adults undergoing extracorporeal membrane oxygenation. Ann Intensive Care 2016;6:97. https://doi.org/10.1186/s13613-016-0196-7
- Schmidt M, Fisser C, Martucci G, et al. Tracheostomy management in patients with severe acute respiratory distress syndrome receiving extracorporeal membrane oxygenation: an International Multicenter Retrospective Study. Crit Care 2021;25:238. https://doi.org/10.1186/ s13054-021-03649-8
- 24. Pijls BG, Jolani S, Atherley A, et al. Demographic risk factors for COVID-19 infection, severity, ICU admission and death: a meta-analysis of 59 studies. BMJ Open 2021;11:e044640. https://doi. org/10.1136/bmjopen-2020-044640
- Papadopoulos V, Li L, Samplaski M. Why does COVID-19 kill more elderly men than women? Is there a role for testosterone? Andrology 2021;9:65-72. https://doi.org/10.1111/andr.12868
- Chao TN, Harbison SP, Braslow BM, et al. Outcomes after tracheostomy in COVID-19 patients. Ann Surg 2020;272:e181-6. https://doi. org/10.1097/SLA.000000000004166
- Bertini P, Guarracino F, Falcone M, et al. ECMO in COVID-19 patients: a systematic review and meta-analysis. J Cardiothorac Vasc Anesth 2022;36(8 Pt A):2700-6. https://doi.org/10.1053/j.jvca.2021. 11.006
- Lisco G, De Tullio A, Stragapede A, et al. COVID-19 and the endocrine system: a comprehensive review on the theme. J Clin Med 2021;10:2920. https://doi.org/10.3390/jcm10132920
- Li X, Xu S, Yu M, et al. Risk factors for severity and mortality in adult COVID-19 inpatients in Wuhan. J Allergy Clin Immunol 2020; 146:110-8. https://doi.org/10.1016/j.jaci.2020.04.006