


The ProtekDuo for percutaneous V-P and V-VP ECMO in patients with COVID-19 ARDS

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Abstract

Objective: The ProtekDuo with oxygenator mimics veno-venous (V-V) extracorporeal membrane oxygenation (ECMO) in veno-pulmonary (V-P) configuration. We have recently developed a new configuration by utilizing a 25 Fr multistage femoral venous drainage cannula and by returning oxygenated blood through both lumina of the double lumen ProtekDuo cannula (V-VP configuration), thereby creating partial right ventricular bypass and oxygenated blood flow of up to seven LPM. We investigated our experience with V-P and V-VP ECMO in patients suffering from COVID-19 acute respiratory distress syndrome (ARDS).

Methods: Single center, retrospective observational study.

Results: Of nine patients, one was initiated on V-A, two on V-P, and six on V-V ECMO. All patients were reconfigured to V-P and five patients in addition had V-VP ECMO configuration. All patients had at least one and up to three circuit exchanges. Patients were on ECMO support between 20 and 122 (55 ± 29) days, were in ICU between 46 and 161 (78 ± 40) days with a total hospital length of stay between 35 and 171 (82 ± 42) days. Six of nine (67%) patients could successfully be weaned off ECMO, survived, and were discharged.

Conclusion: The ProtekDuo cannula in V-P configuration provides ECMO blood flow while reducing RV flow, wall-stress and dilatation, as well as oxygen consumption. The V-VP configuration is useful to provide high blood flows of up to seven LPM of oxygenated blood, and partial RV support without over-circulating the pulmonary vascular bed. Our results show that V-P and V-VP ECMO configurations are feasible, have good outcome and are without complications.

Keywords

ECLS, extracorporeal life support, extracorporeal membrane oxygenation, right ventricular assist device, veno-pulmonary, veno-venopulmonary

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Introduction

The coronavirus disease of 2019 (COVID-19) may lead to acute respiratory failure with development of acute respiratory distress syndrome (ARDS). In this patient demographic, the use of mechanical ventilation and escalation to extracorporeal membrane oxygenation (ECMO), an intervention which can reduce mortality in severe cases of ARDS, is often required.^{1–3} Several different cannulas are available to facilitate ECMO support. The ProtekDuo was initially designed as right ventricular assist device (RVAD) cannula supplied in conjunction with the TandemHeart pump (LivaNova PLC, London, UK), and is percutaneously

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inserted through the right internal jugular vein. The inflow (drainage) into the pump is from the right atrium (RA) and the outflow (return) in the main pulmonary artery (PA). This may also be connected to an ECMO circuit with oxygenator, instead of the pump. Therefore, with the flow into the PA, the right ventricle (RV) can be bypassed, and the oxygenated blood flow used as veno-pulmonary (V-P) ECMO support.⁴ To date, literature concerning the ProtekDuo, particularly in the setting of patients with ARDS secondary to COVID-19 infection, is very limited. Over the last 2 years we have been proactive in managing this patient cohort and have frequently adjusted the circuit configuration dependent upon oxygen requirements or right heart failure. We have also described a new method utilizing the ProtekDuo cannula as double lumen return cannula after placing a 25 Fr femoral drainage cannula (Veno-Venopulmonary (V-VP) ECMO configuration).^{5,6} It was thought that these frequent adjustments were beneficial to our patients and, in view of this, the authors wished to review and share the knowledge gained from this experience. The data reported has been collected from our single center retrospective review of the ProtekDuo used in V-P and V-VP ECMO configuration in patients suffering from COVID-19 ARDS.

Materials and methods

The review of the ProtekDuo was undertaken as a single center, retrospective, observational study in the setting of COVID-19 ARDS. After Institutional Review Board (IRB # 18-005) approval was obtained, the institutional ECMO database was screened for adult patients in the time period between April 1, 2020 and March 31, 2022.

The ECMO circuit utilized consisted of either the Cardiohelp System (Getinge) with a non-modified HLS Set Advanced 7.0, or the CentriMag (Abbott) pump with Maquet Quadrox oxygenator and custom Terumo x-coated circuit. Anticoagulation at this institution includes bolus administration of 50–100 units/kg of unfractionated heparin at the time of ECMO cannulation, followed by heparin infusion to maintain an aPTT of 30–60 s (correlating to an anti-factor Xa level of 0.2–0.5 IU/mL). The circuitry was kept simple without pigtailed, bridge, or other connectors all of which are not heparin coated and may promote coagulative effects. The requirement therefore for anticoagulation in these patients is minimal from the circuit perspective, with the requirement for anticoagulation dependent on individual patient factors. The ProtekDuo is not heparin coated and therefore presents a higher risk factor for clot formation. In this study setting, it is sufficient to run aPTT levels between 40 and 60 s. In COVID-19 patients this was kept at around 50–60 s to introduce another layer of safety. In addition, two ultrasonic flow probes were utilized for both arms of the circuit to ensure at least 2 L of blood flow through each lumen of the ProtekDuo cannula. With approximately 150 ECMO runs per year, the authors have

gained adequate experience with anticoagulation regimens based on our circuit. Bearing institutional differences on circuitry in mind, it is recommended that each provider should adjust the anticoagulation strategy to their specific protocols.

The transition from dual site V-V ECMO (femoral vein to right internal jugular vein) to ProtekDuo (usually inserted in the right internal jugular vein) was performed either by placing another cannula in the contralateral femoral vein for “femoro-femoral” or in the left internal jugular vein for “femoro-jugular” configuration, to allow adequate time on ECMO for ProtekDuo cannula insertion.

In the absence of a cannula previously inserted in the right internal jugular vein (RIJV), a 8 Fr introducer sheath was placed into the RIJV and an Arrow balloon wedge/pressure catheter was inserted through the sheath into the right PA. Following this, a Lunderquist Extra-Stiff (Cook, Bloomington, USA) or Amplatz Super Stiff (Boston Scientific, Marlborough, MA, USA) exchange guidewire (both 0.035” × 260 cm) was inserted through the Arrow catheter, which was removed while keeping the wire in the PA position. Serial dilators were used to achieve the desired level of dilation and the ProtekDuo cannula was pushed over the wire under fluoroscopy into its position in the main PA. After V-P or V-VP ECMO was then initiated on a separate circuit, the other cannulas were removed.

We tolerated a low threshold of SpO₂ in V-V ECMO patients and transfused to keep Hgb at least >10 grams per deciliter (g/dL). The V-VP configuration was invented by Dr. Maybauer when a patient dropped SpO₂ far below 80%. After we experienced great success with the novel method, patients on ProtekDuo were converted from V-P to V-VP once they dropped SpO₂ below 80% on maximum flow. The additional V cannula was removed once we could wean FiO₂ on V-VP ECMO down to 50% and the SpO₂ was still >90%.

Institutionally, a consortium of intensivists manage this ECMO service and perform all percutaneous cannulations, including ProtekDuo cannulation which has a relatively short learning curve in the hands of experienced ECMO providers. The ProtekDuo may be inserted by surgeons, cardiac anesthesiologists, intensivists, or cardiologists, depending on institutional requirements.

Data was reviewed for patients’ demographics, present illness, and comorbidities, ECMO cannulation, settings and duration, and complications, as well as ICU and hospital length of stay.

Descriptive statistical analyses were performed for continuous variables using the median. Categorical variables were expressed as number (%).

Results

Table 1 displays individual patient’s demographics, comorbidities, and pre-ECMO laboratory as well as arterial blood gas values.

Table 1. Demographics and characteristics of COVID 19 patients prior to ECMO.

Patient	1	2	3	4	5	6	7	8	9	All patients (n=9)
Age (years)	20	49	30	45	33	37	47	29	26	35.1 ± 10.1
Sex (F/M)	M	M	F	M	M	M	M	F	M	M=7 (78%) White=4 (44%) Hispanic=3 (33%) Others=2 (22%)
Race	Hispanic	Caucasian	Native Hawaiian	Hispanic	Unknown	Caucasian	Caucasian	Hispanic	Caucasian	
BMI (kg/m ²)	44.73	32.58	43.97	29.89	37.54	33.79	31.52	34.65	27.46	35.1 ± 6
DM	N	Y	N	N	N	N	N	Y	N	2 (22%)
DLP	N	Y	N	Y	N	N	N	N	N	4 (22%)
HTN	N	Y	N	Y	N	N	N	N	N	2 (22%)
Asthma	Y	N	N	N	N	N	Y	N	Y	3 (22%)
Obesity	Y	Y	Y	N	Y	Y	Y	Y	N	7 (78%)
AKI	N	N	N	Y	Y	N	N	N	Y	3 (33%)
CRRT	N	N	N	N	N	N	N	N	Y	1 (11%)
PRE WBC (×10 ³ /μL)	11.3	-	20.2	8.1	18.7	29.1	9.5	11.6	22.3	16.3 ± 8.8
PRE Platelet (×10 ³ /μL)	70	-	165	174	102	134	64	121	140	121.3 ± 55.4
PRE creatinine (mg/dL)	0.73	-	1.01	0.68	1.58	0.64	0.46	0.4	2.01	0.9 ± 0.6
PRE BUN (mg/dL)	24	-	35	12	68	53	15	6	40	31.6 ± 22.7
PRE LA (mg/dL)	0.57	-	0.98	0.68	1.99	1.13	0.66	0.67	0.74	0.3 ± 0.4
PRE pH	7.31	-	7.33	7.38	7.31	7.4	7.39	7.45	7.32	7.4 ± 2.5
PRE CO ₂ (mmHg)	62	-	55	69	48	49	59	49	37	53.5 ± 20.1
PRE P/F ratio	48	-	50	54	111	69	50	72	49	62.9 ± 29.1
PRE HCO ₃	32	-	29	41	24	31	36	34	19	30.7 ± 12.1
PRE O ₂ Sat (%)	79	-	79	85	98	95	84	95	81	87.5 ± 29.9
PRE SOFA	12	-	11	12	9	9	5	11	13	10.3 ± 4.2

ECMO: extracorporeal membrane oxygenation; V-P: veno-pulmonary; BMI: body mass index; DM: diabetes mellitus; DLP: dyslipidemia; HTN: hypertension; AKI: acute kidney injury; CRRT: continuous renal replacement therapy; WBC: white blood cells; AST: aspartate aminotransferase; ALT: alanine aminotransferase; BUN: blood urea nitrogen; LA: lactic acid; SOFA: sequential organ failure assessment. The data are presented as number (%) or mean ± SD.

Table 2. ECMO configuration and days on support.

ECMO										
Patient	1	2	3	4	5	6	7	8	9	All Patients (n=9)
ECMO configuration (days)	V-P (15) → V-VP (29)	V-P (29)	V-V (35) → V-VP (5) → V-P (25)	V-V (7) → VV-V (16) → V-VP (3) → V-P (9) → V-VP (17)	V-A (8) → V-V (39) → V-P (6) → V-V (6)	V-V (39) → V-VP (7)	V-V (15) → VV-P (13) → V-A/V-P (94)	V-V (40) → V-P (24)	V-V (12) → V-P (7) → V-VP (13) → V-P (19)	Mean ECMO support 55 ± 29 days
	Total=44	Total=29	Total=65	Total=52	Total=20	Total=46	Total=122	Total=64	Total=51	

ECMO: extracorporeal membrane oxygenation; V-P: veno-pulmonary; V-VP: veno-veno pulmonary; V-V: veno-venous; VV-V: venovenovenous; V-A: veno-arterial.

The → indicates the change of configuration to the one after the →.

Table 3. Outcomes of COVID 19 patients on ProtekDuo in the peri-ECMO period.

ECMO											
Patient	1	2	3	4	5	6	7	8	9	All patients (n=9)	
Days from intubation to ECMO implantation	1	1	2	1	5	6	1	6	1	2.7 ± 2.3 days	
Circuit exchange	1	1	2	3	2	1	3	2	3	One exchange = 3 (33%) Two exchanges = 3 (33%) Three exchanges = 3 (33%)	
Repositioning (Y/N)	N	N	N	Y	N	N	N	Y	Y	3 (33%)	
GIB	Y	N	N	N	N	N	N	N	Y	2 (22%)	
Off anticoagulation >24 h	Y	Y	Y	Y	Y	Y	N	Y	Y	8 (88%)	
Total days in ICU	49	35	65	75	161	46	122	73	74	78 ± 40 days	
Total hospital days	51	35	65	81	171	46	122	81	88	82 ± 42 days	
Weaned (Y/N)	Y	Y	N	Y	Y	N	N	Y	Y	6 (67%)	
Survived to discharge	Y	Y	N	Y	Y	N	N	Y	Y	6 (67%)	

GIB: gastrointestinal bleeding; ICU: intensive care unit.

Nine patients with ProtekDuo were identified, seven male and two female patients were between 20 and 49 (35.1 ± 10.1) years old with BMIs in the range of 27.46–44.73 (35.1 ± 6). Of this patient group, none were vaccinated, and obesity was the most common comorbidity in 78% of cases. All patients had liver function tests (AST, ALT, and total bilirubin) within normal limits before ECMO. Three patients had acute kidney injury (AKI) during ECMO; in two patients increased creatinine was measured before ECMO and one patient required renal replacement therapy. SOFA scores ranged between 5 and 13.

ECMO configurations, days on each configuration and the total days on ECMO support are displayed in Table 2.

Specific data on time from endotracheal intubation to ECMO cannulation, ICU, and hospital length of stay, as well as survival rate and complications, are presented in Table 3.

Two patients had ECMO initiated in V-P configuration, one had V-A and six had V-V as dual site cannulation with femoral drainage and right internal jugular return. For one patient, oxygenation and right heart function were

sufficient for the patient to remain on V-P for the entire time of the ECMO run. One patient received V-A ECMO for combined ARDS and left ventricular failure secondary to cardiomyopathy and later developed biventricular failure and required additional V-P ECMO. The other seven patients were closely monitored and proactively reconfigured as needed for either worsening, or improvement of oxygenation and/or right heart function. In one patient it was necessary to reconfigure four times however, the patient did survive the ECMO run. All patients had at least one and up to three circuit exchanges, with the patient who was 122 days on ECMO requiring three. These patients already had a tracheostomy at the late stage when they were reconfigured to V-VP for worsening hypoxia, therefore no changes on the airway were made during the V-VP runs. Mobilization was usually commenced when they were downgraded to V-P ECMO. All patients were resident in the ICU between 46 and 161 days with a total hospital stay of between 35 and 171 days. Six of nine (67%) patients were weaned off ECMO and could successfully be discharged from the hospital.

Discussion

At the beginning of the COVID-19 pandemic, our group elected to transition from mostly single- to dual-site configuration. The majority of patients were cannulated for drainage from the femoral vein position with a 25 Fr multistage cannula and return to the RIJV position with a 23 Fr gun tip cannula. The rationale was to reduce exposure to staff, including fluoroscopy technicians, and time required for cannulation, as well as improve the ability to retrieve patients from outside hospitals after performing cannulation at the bedside, without the need to utilize the cardiac catheterization laboratory. The use of two large bore cannulas also allowed for high blood flow of about seven LPM offering high levels of oxygenated blood to the patients. A certain amount of recirculating blood depending on cannula position did however require consideration. In the authors' experience, ECMO runs for COVID-19 had a duration of approximately double to triple the time of that experienced pre-pandemic, with more patients suffering from RV failure secondary to pulmonary hypertension from ARDS.

In the setting of ARDS, hypoxemia and hypercarbia increases pulmonary vascular resistance. This pathophysiology worsened during COVID-19 by the occurrence of clinical and subclinical pulmonary emboli leading to further increased pulmonary vascular resistance, RV dilation and decrease in RV systolic function, which led to increased inotropic or vasopressor requirements, as well as to acute kidney injury or liver injury. RV failure occurs secondary to two distinct processes, direct RV systolic failure and increase in RV afterload. Impaired RV physiology occurs in up to 20% of patients with ARDS and is a major determinant of mortality.^{7,8} The group of Lorusso et al. had previously shown that pulmonary artery cannulation enhances extracorporeal membrane oxygenation management in acute cardiac failure.⁹ Therefore, it was necessary to reconsider and use the ProtekDuo RVAD plus oxygenator to provide oxygenated blood to the patient as well as RV off-loading by bypassing the RV. The ProtekDuo is a multi-purpose cannula that has been used and described in several different settings, such as for RVAD,¹⁰ LVAD,^{11,12} BiVAD (ECPELLA 2.0),^{12,13} ECMO, or cardiopulmonary bypass (CPB)^{14,15} support. Default is the V-P configuration with blood drainage from the RA and blood return into the PA. An average blood flow of 4.5 LPM may be achieved.⁴

The V-P ECMO configuration represents the default ProtekDuo position. Adding an oxygenator to the circuit mimics combined RVAD and V-V ECMO support. Cain et al.¹⁶ described this configuration solely for respiratory ECMO support. The authors compared patients either undergoing V-P ECMO (18 patients) or invasive mechanical ventilation (IMV, 21 patients) without ECMO support. The in-hospital (52.4% vs 11.1%, $p=0.008$) and 30-day mortality (42.9% vs 5.6%, $p=0.011$) was significantly

lower in the V-P ECMO group. In addition, the incidence of AKI in the V-P ECMO group was significantly lower ($p<0.001$). The authors did not observe any complications associated with the RVAD. It was concluded that RVAD/ECMO displayed no secondary end-organ injury and higher in-hospital and 30-day survival compared to the IMV group. In severe COVID-19 ARDS, it was surmised that RVAD/ECMO should take priority over other configurations. We observed that only one patient out of nine required renal replacement therapy. However, our data is somewhat different since only two patients were initially started on the ProtekDuo. In our study the cannula was usually inserted later in the course of the disease when problems like RV failure or poor oxygenation had occurred. Therefore, our survival rate of 67% is lower than the one observed by Cain et al.¹⁶ however, considering our outcome is still better than in their control group after the ECMO course was complicated, speaks for the use of this device. The group of Tatoes et al.^{17,18} underscored these results with their retrospective study of 40 patients on V-P ECMO with early extubation. In this case, the authors showed outcomes with a 73% discharge rate, and a low mortality of 15%. These study results are similar to our outcome with 67% survival and discharge rate.

Oh et al.¹⁹ bridged a patient, who required V-V ECMO, to lung transplantation, using the ProtekDuo with oxygenator. In addition, also Patel et al.²⁰ bridged a patient to lung transplantation. This patient was initially started on dual site V-V ECMO, and subsequently changed to a 27 Fr Medtronic Crescent double lumen cannula after 2 weeks on support to facilitate mobilization, but later developed severe RV failure for which the ProtekDuo was placed demonstrating significant improvement in renal and hepatic as well as RV function.

Unfortunately, RVADs are not free from complications, including pulmonary edema and hemorrhage.^{21,22} In addition, in case of LV diastolic failure, mitral stenosis or pulmonary venous occlusive disease, the LV systolic function may drop below RVAD flows.

To protect the RV using an RVAD, while simultaneously protecting the pulmonary circulation from over-circulation, the authors used partial flow to the PA by using the V-VP ECMO strategy. Our group has recently developed this new configuration by placing a large-bore multistage femoral drainage cannula (25 Fr) solely for venous drainage, directing blood toward the CentriMag pump. After the pump, the tubing was spliced with a 3/8" Y-connector and arterialized blood was returned to the patient through both lumina of the ProtekDuo with combined flow of up to seven LPM.⁵ Given the length and diameter of the distal cannula, the flow distribution, as measured with ultrasonic flow probes, approximately averages 60% of blood flow through the proximal opening of the cannula in the RA, and approximately 40% of blood flow through the distal end in the PA.⁶ With this

partial decrease of RV preload by 40%, and partial decompression of the RV, these patients could be well managed. This study differs from those of Cain and Mustafa since the ProtekDuo was not used as an initial device, but after occurrence of either hypoxia secondary to inadequate ECMO flow relative to cardiac output or RV failure many weeks into the course of ECMO intervention. This may also explain why our outcome is not as dramatic as in the studies described above however, using our modified V-VP approach was beneficial in stabilizing these patients and bridging most of them to recovery. It should be considered that the ProtekDuo cannula is not heparin coated, thereby anticoagulation with either heparin or direct thrombin inhibitors is recommended.²³ In addition, it was ensured that blood flow through the distal end of the ProtekDuo never was below two LPM to prevent clot formation.

A limitation of this study is the retrospective analysis and the fact that it was not possible to record detailed hourly or daily blood flows to exactly determine potential percental changes over time. This study has shown that the use of V-VP ECMO is feasible and useful and without complications in our nine patients of which five had V-VP configuration at some point during the ECMO runs.

Conclusion

The ProtekDuo may be used when RVAD, LVAD, BiVAD, ECMO, or CPB support is indicated, as well as for bridge to heart and lung transplantation. In patients suffering from COVID-19 ARDS it is particularly advantageous in providing adequate ECMO blood flows while reducing RV flow, wall-stress and dilatation, as well as oxygen consumption. The V-VP configuration is useful to provide higher blood flows of up to seven LPM with good oxygenation combined with partial RV support without over-circulating the pulmonary vascular bed. However, future prospective trials would be of benefit to delineate flow and oxygenation capacity for each configuration, as well as the risk for pulmonary hemorrhage. Furthermore, effects on acute kidney and liver injury should be explored. The present evidence is promising and necessitates future investigations of this multipurpose canula. Subsequent studies on this configuration should also outline the exact range of blood flows for the distal and proximal end of the cannula.

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