Original Article

Oxygenated right ventricular assist device with a percutaneous dual-lumen cannula as a bridge to lung transplantation

Takashi Harano[1,2], Ernest G. Chan[1], Masashi Furukawa[1], Pedro Reck dos Santos[1], Matthew R. Morrell[3], Penny L. Sappington[4], Pablo G. Sanchez[1]

[1]Department of Cardiothoracic Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA, USA; [2]Division of Thoracic Surgery, Department of Surgery, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [3]Department of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA, USA; [4]Department of Medicine, West Virginia University, Morgantown, WV, USA

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Correspondence to: Takashi Harano, MD. Division of Thoracic Surgery, Department of Surgery, Keck School of Medicine, University of Southern California, 1510 San Pablo Street, Suite 514, Los Angeles, CA 90033, USA. Email: Takashi.Harano@med.usc.edu.

Background: Oxygenated right ventricular assist device (oxyRVAD) placement has become more streamlined with the introduction of the dual-lumen pulmonary artery cannula. Peripherally cannulated oxyRVAD may provide oxygenation support with right heart support as an alternative to venoarterial extracorporeal membrane oxygenation (ECMO) as a bridge to lung transplantation.

Methods: A single-institution, retrospective analysis was performed on patients placed on oxyRVAD with a dual-lumen pulmonary artery cannula with the intention of bridging to lung transplantation in 2019.

Results: Four patients with idiopathic pulmonary fibrosis were placed on oxyRVAD as a bridge to transplantation. Two patients were extubated and ambulated while waiting for a lung offer, and two patients required conversion to venoarteriovenous ECMO (VAV ECMO) from oxyRVAD. The median waiting time for extracorporeal life support (ECLS) was 42 h. All patients underwent double lung transplantation. Two patients stayed on oxyRVAD, and one patient was placed on venovenous ECMO (VV ECMO) after transplantation. Primary graft dysfunction score at 72 h after transplantation was grade 1 in three patients and grade 3 in one patient.

Conclusions: Peripherally cannulated oxyRVAD with percutaneous dual-lumen venous cannula could be an ambulatory bridge for lung transplantation. It is unknown whether oxyRVAD is feasible as a long-term bridge to lung transplantation.

Keywords: Oxygenated right ventricular assist device (oxyRVAD); dual-lumen pulmonary artery cannula; bridge to lung transplantation; extracorporeal membrane oxygenation (ECMO)

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Introduction

With improvements in clinical management, devices, and surgical strategies, the use of extracorporeal membrane oxygenation (ECMO) is now a widely accepted means to bridge patients to lung transplantation (1). However, the risk of complications related to ECMO, especially those related to venoarterial ECMO, is not negligible, including thromboembolic events, hemorrhagic events, and limb ischemia (2). Thus, when a patient requires ECMO bridging for lung transplantation, venovenous ECMO (VV ECMO) is preferred. Unfortunately, some clinical circumstances,

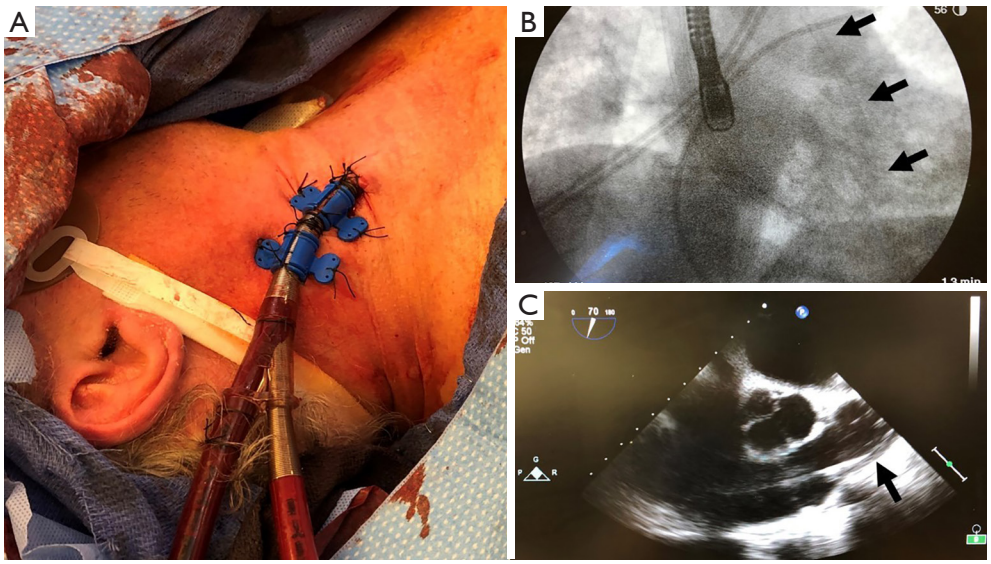

Figure 1 OxyRVAD was placed with using the dual lumen pulmonary arterial cannula under the guidance of fluoroscopy and echocardiogram. (A) The dual-lumen pulmonary arterial cannula, ProtekDuo cannula (Tandem Life, Pittsburgh, PA, USA), was placed in the right internal jugular vein. (B) The position of the cannula was confirmed with fluoroscopy (black arrow). (C) The position of the cannula was also confirmed with transesophageal echocardiogram (black arrow). OxyRVAD, oxygenated right ventricular assist device.

such as in the setting of severe pulmonary hypertension, may require the use of venoarterial ECMO because of the need for concurrent oxygenation as well as right heart support. The advent of the dual-lumen pulmonary arterial cannula, ProtekDuo cannula (Tandem Life, Pittsburgh, PA, USA), has enabled right heart support and oxygenation support with percutaneous venous cannulation alone as an oxygenated right ventricular assist device (oxyRVAD), which may prevent complications related to arterial cannulation while waiting for lung transplantation.

We hypothesized that an oxyRVAD with a dual-lumen pulmonary arterial cannula can be an alternative option to bridge the patients with end stage lung disease and pulmonary hypertension to lung transplantation. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-21-1199/rc).

Methods

Since the beginning of 2019, oxyRVAD has become an option as a bridging strategy for lung transplantation in our department. Therefore, we retrospectively analyzed all seven patients who were placed on extracorporeal life support (ECLS) with the intention of bridging to lung transplantation in 2019. All electronic patient records and relevant patient data were retrospectively reviewed.

In our department, peripheral VV ECMO was the first consideration for ECLS. During the study period, when the patients had known pulmonary artery hypertension and/or signs of right ventricular dysfunction, oxyRVAD was preferred only when they were stable enough to be brought to the operating room. Right ventricular function and estimated systolic pulmonary artery pressure were measured on echocardiogram before the patient was placed on mechanical circulatory support. When patients are hemodynamically unstable, venoarterial ECMO is emergently cannulated at the bedside. When a patient was deemed a suitable candidate for oxyRVAD, the patient was cannulated with a ProtekDuo cannula (Tandem Life, Pittsburgh, PA, USA) in the operating room under fluoroscopic and transesophageal echocardiographic guidance (*Figure 1*). After placement of the Swan-Ganz catheter from the right internal jugular vein into the pulmonary artery, a guidewire was advanced to the pulmonary artery through the Swan-Ganz catheter, and the ProtekDuo catheter was placed with its tip in the pulmonary artery using the Seldinger technique. Once proper placement was confirmed, the ProtekDuo cannula was connected to a Tandem Heart pump and an in-line oxygenator (Tandem

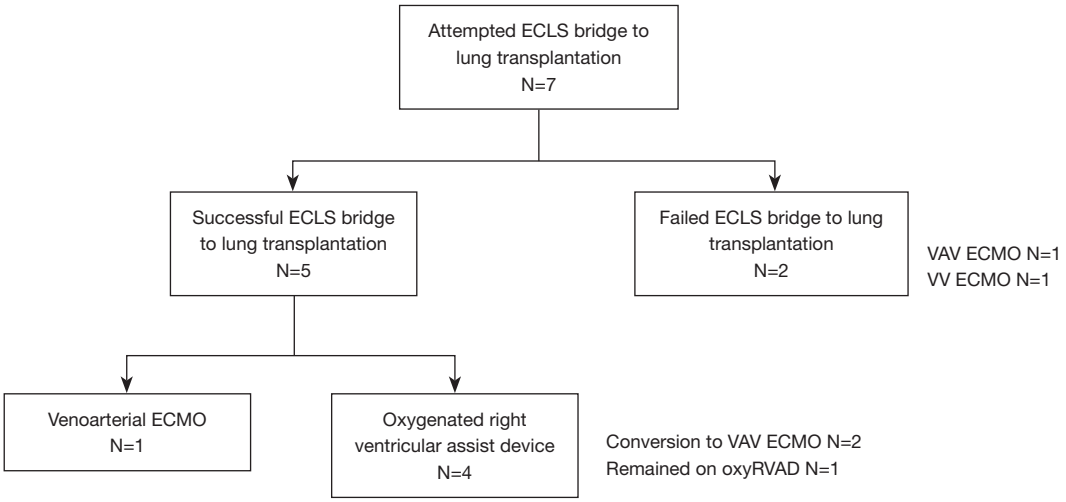

Figure 2 Out of seven patients who were placed on ECLS as a bridge to lung transplantation, five patients were successfully underwent lung transplantation. Four patients were initially placed on oxyRVAD. ECLS, extracorporeal life support; oxyRVAD, oxygenated right ventricular device; ECMO, extracorporeal membrane oxygenation; VAV ECMO, venoarteriovenous ECMO; VV ECMO, venovenous ECMO.

Life, Pittsburgh, PA, USA). A CentriMag pump (Abbott, Abbott Park, IL, USA) was also used if the patient required higher oxyRVAD flow rates. The patients were placed on anticoagulation with bivalirudin while they were on mechanical circulatory support in the intensive care unit (ICU). The target partial thromboplastin time was 61–75 s.

The primary outcomes of this study are survival to discharge and successful bridging to lung transplantation. The secondary outcomes are primary graft dysfunction at 72 h after lung transplantation and conversion rate to venoarterial ECMO or venoarteriovenous ECMO (VAV ECMO). The patient demographics and the outcomes related to ECLS and lung transplantation were collected from the electronic patient records. This study, Lung Failure and Lung Transplant Recipient Broad Chart Review, was approved by the University of Pittsburgh Internal Review Board (No. STUDY20050181), and individual consent for this retrospective analysis was waived. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Statistical analysis

Continuous variables were expressed as mean standard deviation or as median with interquartile range. Categorical variables were expressed as frequencies and percentages Comparison of patient characteristics between groups was performed using *t*-tests for parametric data or Mann-Whitney U test for nonparametric data. Frequencies were tested using Fisher's exact test. Analyses were performed in R (v.3.6.2), and $P<0.05$ was considered statistically significant.

Results

Of the seven patients who were placed on ECLS with the intention of bridging to lung transplantation, 5 patients (71.4%) successfully underwent lung transplantation (*Figure 2*). Two patients (28.6%) were withdrawn from the ECLS due to multi-organ failure. These two patients were placed on VV ECMO at bedside, and one of these two patients required ECMO configuration change to VAV ECMO 9 h after being placed on VV ECMO. Of the five patients who were successfully bridged to lung transplantation, four were initially placed on oxyRVAD with a percutaneous dual-lumen venous cannula for ECLS support. The other patient was placed on venoarterial ECMO at the bedside, as this patient was considered too hemodynamically unstable to be brought to the operating room.

The patient characteristics are shown in *Tables 1,2*. All seven patients were diagnosed with idiopathic pulmonary fibrosis. During the initial lung transplantation candidacy work-up, the mean pulmonary artery pressure was 21–40 mmHg. Before being placed on ECLS, all patients underwent echocardiography, and the estimated systolic pulmonary artery pressure was 39–74 mmHg. The estimated systolic pulmonary artery pressure was not

Table 1 Characteristics of patients that were initially placed on the oxyRVAD or non-oxyRVAD for ECLS as a bridge to lung transplantation

Characteristics	OxyRVAD (n=4)	Non-oxyRVAD (n=3)	P
Age (years)	52.5±4.04	60.7±7.80	0.165
Sex (male), n (%)	4 (100.0)	3 (100.0)	–
Diagnosis—pulmonary fibrosis, n (%)	4 (100.0)	3 (100.0)	–
O_2 requirement (L/min)	57.5±15.0	73.3±5.77	0.149
Height (cm)	181±7.68	180±5.50	0.869
Body mass index	26.9±3.93	22.2±3.50	0.161
Serum creatinine (mg/dL)	0.825±0.457	0.700±0.173	0.677
Total bilirubin (mg/dL)	0.975±0.340	0.633±0.208	0.189
Estimated systolic PA pressure (mmHg)	55.5±18.0	60.7±13.5	0.696
RV dysfunction on echocardiogram moderate-severe, n (%)	2 (50.0)	2 (66.7)	1.00
Lung allocation score	88.3±1.24	87.9±0.462	0.674
Extubation after ECLS, n (%)	3 (75.0)	2 (66.7)	1.00
Ambulation after ECLS, n (%)	2 (50.0)	1 (33.3)	1.00
ECLS configuration change, n (%)	2 (50.0)	1 (33.3)	1.00
Successful bridge to transplant, n (%)	4 (100.0)	1 (33.3)	0.143
Time on ECLS until transplant/withdrawal			
Median (hours)	42	94	0.857
Interquartile range (hours)	40.8–71.8	56.0–183	–

Pulmonary artery pressure was estimated with tricuspid regurgitation pressure gradient on echocardiogram. OxyRVAD, oxygenated right ventricular assist device; PA, pulmonary artery; RV, right ventricular; ECLS, extracorporeal life support.

significantly different between the oxyRVAD and non-oxyRVAD groups (P=0.696). Four patients (57.1%) were placed on oxyRVAD according to the department guideline of bridging strategy described in the Methods section.

The non-oxyRVAD group was older than the oxyRVAD group (60.7±7.80 *vs.* 52.5±4.04 years old) and their BMI was lower (22.2±3.50 *vs.* 26.9±3.93). They also required a higher amount of supplement oxygen than the oxyRVAD group (73.3±5.77 *vs.* 57.5±15.0). However, none of these differences was statistically significant.

Of the four patients with oxyRVAD, 3 patients (75.0%) were extubated, and 2 patients were (50.0%) ambulated for active physical therapy, out from their ICU, and then walked around the ICU with the assistance of a physical therapist (ambulatory ECMO), while waiting for lung offers. One patient required re-intubation due to hypoxia. Contrarily, out of the three patients in the non-oxyRVAD group, 2 patients (66.7%) were extubated after being placed on ECLS, 1 patient (33.3%) was ambulated for active physical therapy with the assistance of physical therapy, and the other patient had to be bedbound due to the arterial cannula in the femoral artery.

Of the 4 patients with oxyRVAD, 2 patients (50.0%) subsequently required ECLS configuration change to VAV ECMO to maintain oxygenation (Patients #2 and #4 in *Table 2*). One patient (Patient #2 in *Table 2*) had progressing hypoxia even with oxyRVAD support. Initially the pump speed was set at 7,500 rpm with Tandem Heart pump, obtaining 4.5 L/min of oxyRVAD flow. Five days after oxyRVAD initiation, the oxygenation could not be maintained by increasing the flow of the oxyRVAD. Thus, an additional arterial cannula was placed in the femoral artery, and modified VAV ECMO was initiated. Pump speed was set at 4,300 rpm with Centrimag, obtaining a VAV ECMO flow of 3.9 L/min with returning 1.8 L/min of oxygenated blood to the pulmonary artery port of the ProtekDuo cannula. Sweep of the oxygenator was 5.0 L/min. Chest radiographs of this patient is shown in *Figure 3*.

Table 2 Peri-transplant outcomes of patients who were initially placed on the oxyRVAD as a bridge to lung transplantation

Peri-transplant outcomes	Patient #1	Patient #2	Patient #3	Patient #4
Age (years)	55	59	55	41
Sex	Male	Male	Male	Male
Diagnosis	IPF	IPF	IPF	IPF
Lung allocation score	88	86.9	88.3	89.9
Extubation after oxyRVAD	Yes	Yes (reintubated)	Yes	No
Ambulatory bridge	Yes	No	Yes	No
Configuration change from oxyRVAD	No	Modified VAV ECMO	No	VAV ECMO
Wait time on ECLS (hours)	41	158	40	43
Transplant type	DLTx	DLTx	DLTx	DLTx
MCS during implant	CPB	CPB	CPB	CPB
Delayed chest closure	No	Yes	Yes	Yes
Post-transplant MCS	OxyRVAD	OxyRVAD	None	VV ECMO
PGD grade at 48 hours	1	3	1	3
PGD grade at 72 hours	1	1	1	3
Post-transplant LOS (days)	9	20	34	97

OxyRVAD, oxygenated right ventricular assist device; ECLS, extracorporeal life support; MCS, mechanical circulatory support; PGD, primary graft dysfunction; LOS, length of stay; IPF, idiopathic pulmonary fibrosis; VAV ECMO, venoarteriovenous extracorporeal membrane oxygenation; DLTx, double lung transplantation; CPB, cardiopulmonary bypass; VV ECMO, venovenous ECMO.

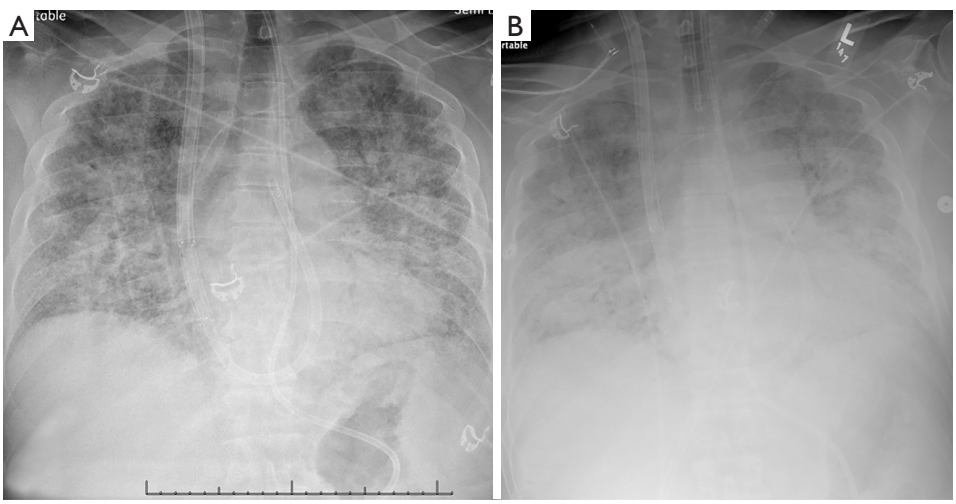

Figure 3 The patient (Patient #2 in *Table 2*) demonstrated worsening bilateral lung infiltration on chest X-ray over the 5 days after being placed on the oxyRVAD. (A) Chest X-ray immediately after being placed on the oxyRVAD with the dual-lumen pulmonary arterial cannula (Patient #2). (B) Chest X-ray 5 days after being placed on oxyRVAD. An additional arterial cannula was placed in the femoral artery, which initiated modified VAV ECMO by returning oxygenated blood to femoral artery and pulmonary artery port of the ProtekDuo cannula. OxyRVAD, oxygenated right ventricular assist device; ECMO, extracorporeal membrane oxygenation; VAV ECMO, venoarteriovenous ECMO.

Table 3 Recipient lung allocation score and donor characteristics of patients who were initially placed on oxyRVAD

Characteristics	Patient #1	Patient #2	Patient #3	Patient #4
Recipient lung allocation score	88	86.9	88.3	89.9
Donor age (years)	23	34	55	49
Donor sex	Male	Male	Male	Male
Donor death mechanism	Drug intoxication	Drug intoxication	Drug intoxication	Cardiovascular
Chest X-ray	Bilateral infiltration	Bilateral infiltration	Right-sided infiltration	Right-sided infiltration
Donor PaO_2/FiO_2 ratio	438	332	468	210

OxyRVAD, oxygenated right ventricular assist device.

There was worsening bilateral infiltration noted on chest X-ray. The other patient (Patient #4 in *Table 2*) was placed on VAV ECMO after the ProtekDuo cannula was removed. After the initiation of oxyRVAD, the patient oxygenation could not be improved with increasing flow of oxyRVAD to 5.5 L/min. With increased flow, the patient had pulmonary edema and ECLS configuration was changed to venoarterial ECMO to VAV ECMO within first 24 h.

All four patients who were initially paced on oxyRVAD underwent double lung transplantation after a waiting time on ECLS between 40 and 158 h, whereas only one patient underwent lung transplantation in non-oxyRVAD group. Donor characteristics are shown in *Table 3*. The successful bridging rate was not statistically different between two groups (P=0.143). The time on ECLS until transplant or withdrawal was also comparable the between two groups (P=0.857). All transplantations were performed on cardiopulmonary bypass. The choice of intraoperative mechanical circulatory support was based on surgeon preference. Cardiopulmonary bypass was initiated with aortic cannulation to ascending aorta, utilizing right atrium port and pulmonary artery port of ProtekDuo cannula for drainage. After implantation, one patient in oxyRVAD group and one patient in non-oxyRVAD group were decannulated from the ECLS in the operating room. Two patients were placed back on oxyRVAD. The other patient was placed on VV ECMO in the operating room after reperfusion.

Among oxyRVAD group, one patient (Patient #4 in *Table 2*) had grade 3 primary graft dysfunction at 72 h after transplantation, whereas the patient in non-oxyRVAD group did not have grade 3 primary graft dysfunction at 72 h after transplantation. The ICU length of stay was 25.8±24.0 days, and the post-transplant in-hospital length of stay was 40.0±34.1 days in oxyRVAD group. There was one case of in-hospital mortality in oxyRVAD group due to superimposed pseudomonas pneumonia with influenza virus infection on postoperative day 97. There was no significant difference in occurrence of primary graft dysfunction at 72 h after lung transplantation (P=1.00) or in-house mortalities (P=0.486) between two groups.

At the 2-year follow-up, three patients in the oxyRVAD group were alive. Whereas, the only patient discharged home in the non-oxyRVAD group died of meningitis 6 months after lung transplantation. The first lung biopsy, which was performed 2 weeks after lung transplantation, demonstrated mild to moderate acute cellular rejection in two patients in the oxyRVAD group (50.0%) and one patient in the non-oxyRVAD group (100.0%). Respiratory function test at the 2-year follow-up is shown in *Table 4*. Two patients in the oxyRVAD group were diagnosed with bronchiolitis obliterans syndrome during the follow up periods.

Discussion

The use of oxyRVAD has become more easily streamlined and accessible after the invention of the dual-lumen pulmonary artery cannula. To overcome the complications related to arterial cannulation for venoarterial ECMO bridging to lung transplantation, four patients were placed on oxyRVAD as a bridge to lung transplantation with a peripherally cannulated dual-lumen pulmonary artery cannula. Although all four patients successfully underwent lung transplantation, two patients required arterial cannulation for VAV ECMO support due to refractory hypoxemia while waiting for the lung offers.

Bridge-to-lung transplantation utilizing the dual-lumen pulmonary artery cannula (ProtekDuo cannula, Tandem Life, Pittsburgh, PA, USA) was first introduced

Table 4 Pulmonary function test at 2-year follow-up after lung transplantation

Two-year follow-up outcomes	Patient #1	Patient #2	Patient #3
Age (years)	55	59	55
Sex	Male	Male	Male
Diagnosis	IPF	IPF	IPF
Initial MCS	OxyRVAD	OxyRVAD	OxyRVAD
FVC (L)	3.11	4.65	1.28
FVC (% of predicted value)	69	94	27
FEV_1 (L)	1.83	3.09	1.18
FEV_1 (% of predicted value)	56	90	35
CLAD diagnosis	BOS	None	BOS

MCS, mechanical circulatory support; FVC, forced vital capacity; FEV_1, forced expiratory volume in the first second; CLAD, chronic lung allograft dysfunction; IPF, idiopathic pulmonary fibrosis; oxyRVAD, oxygenated right ventricular assist device; BOS, bronchiolitis obliterans syndrome.

by Drs. Diaz-Guzman and Hoopes in 2016 (3). Even though the use of the ProtekDuo cannula for right heart failure is becoming increasingly widely accepted (4,5), the use of the ProtekDuo as a bridge to lung transplantation is rarely reported in the literature (6,7). The use of the ProtekDuo cannula either in the intra-operative or post-transplant setting has been recently reported (8,9), as well as centrally cannulated oxyRVAD bridging to lung transplant (10,11). Therefore, oxyRVAD bridging to lung transplantation with the ProtekDuo cannula could be a potential bridging method for critically ill patients with end-stage lung disease preventing peripheral arterial cannulation or central cannulation. OxyRVAD bridging to lung transplantation may overcome the limitation of aggressive physical therapy during the ECLS support with peripheral arterial cannulation. In this study, two patients in the oxyRVAD group achieved ambulatory ECLS bridging to lung transplantation, whereas only one patient in the non-oxyRVAD group achieved ambulatory ECLS.

Since the implementation of the new lung allocation system in 2005, decompensating patients on the lung transplant waiting list have become a priority to receive an organ offer. This has led to a large increase in the number of lung transplant recipients who underwent lung transplantation with ECLS (1). On average, patients successfully bridged to lung transplantation with ECLS experienced a waiting time of 6–12 days (12-14). However, once the number of days on ECLS support reached 14–15 days, there was a drastic increase in the withdrawal from ECLS without transplantation (14,15). While additional data are necessary to identify why this trend exists, it is likely that patients are experiencing increased rates of post-cannulation complications associated with arterial cannulation for right heart support, which may ultimately preclude them from longer-term ECLS bridging for idiopathic pulmonary fibrosis. Thus, we started to utilize oxyRVAD as a substitute for venoarterial ECMO to prevent arterial cannulation in selected cases. In this report, the patients received lung transplantation relatively quickly (40–158 h); therefore, we could not show evidence that oxyRVAD can support patients longer term. Moreover, two patients required arterial cannulation due to refractory hypoxia. Increased pulmonary artery flow due to oxyRVAD in the setting of high pulmonary vascular resistance secondary to fibrotic disease may lead to pulmonary edema (*Figure 3B*), which would contribute to refractory hypoxia.

In this study, there was one case of grade 3 primary graft dysfunction in the oxyRVAD group, and three patients required ECLS after lung transplantation. Two patients remained on oxyRVAD and one patient was placed on VV ECMO after lung transplantation. The need for right heart support with oxyRVAD after lung transplantation is still unknown. Moreover, even though all the patients in this study underwent lung transplantation with cardiopulmonary bypass at the surgeon's discretion, it is unknown whether oxyRVAD can be an option for mechanical circulatory support during lung transplantation. The benefit of decompressing the heart during implant may outweigh the risk of cardiopulmonary bypass. However, intraoperative venoarterial ECMO would also be an option. There was

only one report describing the detail intraoperative and postoperative management with oxyRVAD. In this report, authors placed the patient on venoarterial ECMO with central aortic cannulation and ProtekDuo cannula (8). Then, the patient was placed back on oxyRVAD after implantation. It is still unknown what is the most reasonable intraoperative option for mechanical circulatory support and postoperative ECLS for the patients with ProtekDuo cannula.

There are several limitations of our study. This is a descriptive study of an observational and retrospective nature. The cases are from a single institution, and the number of cases is small. The small sample size may have underestimated the influence of significant variables in the analysis. The decision of placing oxyRVAD or ECMO could be unconsciously biased. Thus, the result of this study cannot be generalized.

In conclusion, we report four cases of oxyRVAD bridging to lung transplantation. Out of these four patients, two patients eventually required arterial cannulation for configuration change. Given the fact that the median waiting time on ECLS was 42 h, it is still unknown whether oxyRVAD can provide enough support in the longer term as a bridge to lung transplantation. However, oxyRVAD may be able to delay or prevent the need for arterial cannulation for ECMO support, which can potentially prevent the risk of devastating complications related to venoarteral ECMO, while waiting for lung transplantation.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-21-1199/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-21-1199/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-21-1199/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study, Lung Failure and Lung Transplant Recipient Broad Chart Review, was approved by the University of Pittsburgh Internal Review Board (No. STUDY20050181) and individual consent for this retrospective analysis was waived.

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