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Background: Acute respiratory distress syndrome (ARDS) due to coronavirus 2019 (COVID-19) can result in severe disease requiring mechanical ventilatory support. A subset of these patients, however, demonstrate refractory hypoxemia/hypercarbia requiring veno-venous extracorporeal membrane oxygenation (V-V ECMO) as adjunctive therapy. The primary goal of V-V ECMO is a "bridge" to recovery of native lung function; however, patients may progress to irreversible pulmonary damage requiring lung transplantation.

Material/Methods: We conducted a retrospective review of patients with refractory COVID-19 ARDS/pulmonary fibrosis that required a V-V ECMO bridge to lung transplantation at our institution from May 2021 to December 2022. Data for analysis included patient demographics, pre/post-transplantation course, and 1-year outcomes.

Results: Nine patients (6 male, 3 female) with an average age of 44.6±12.1 years required V-V ECMO support for COVID-19 and subsequently underwent lung transplantation. The median number of ECMO days was 57 (IQR 53-78). At listing, these patients had a median lung allocation score (LAS) of 91.86 (IQR 89.05-92.13). The median hospital length-of-stay was 89 days (IQR 54-144) with the longest hospital stay at 255 days. All patients were discharged home and survived to 1-year post-transplant.

Conclusions: Our case series shows that patients with COVID-19 ARDS/pulmonary fibrosis had no meaningful difference in overall survival compared to our institution's overall 1-year lung transplant survival rate. Our results suggest that with careful selection and care, long-term lung transplantation outcomes can be equivalent for those requiring a bridge to transplantation with V-V ECMO support despite the severity of illness in the peri-transplant period.

Keywords: **COVID-19 • Extracorporeal Membrane Oxygenation • Transplantation**

Abbreviations: **ARDS** – acute respiratory distress syndrome; **CLAD** – chronic lung allograft dysfunction; **COVID-19** – coronavirus disease 2019; **ECLS** – extracorporeal life support; **ISHLT** – International Society for Heart and Lung Transplantation; **PGD** – primary graft dysfunction; **V-V ECMO** – veno-venous extracorporeal membrane oxygenation

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Introduction

To date, the severe acute respiratory syndrome coronavirus-2 (SARS-COV-2) global pandemic has resulted in 650 million cases and 6.5 million deaths worldwide. Symptoms can range from a mild, limited, upper-respiratory illness to severe respiratory failure. Patients with coronavirus 2019 (COVID-19)-induced acute respiratory distress syndrome (ARDS) that require mechanical ventilation have a mortality rate of approximately 30% [1]. If mechanical ventilation alone is insufficient to support these patients, they can be considered for veno-venous extracorporeal membrane oxygenation (V-V ECMO) as a rescue therapy for refractory hypoxemia and/or hypercarbia [2-4]. Mortality in this setting is approximately 50% internationally [5-7] compared to those unable to obtain this treatment due to resource limitations (survival rate 10-20%) [8,9]. Despite its survival benefits, V-V ECMO support is associated with numerous complications, including bleeding/coagulopathy, as well as an increased risk of intracranial hemorrhage specifically in patients with COVID-19 [10]. Additionally, it only provides support to the patient, bridging to native pulmonary recovery or, if medical therapy fails, to lung transplantation [11,12].

Since the beginning of the pandemic, 261 lung transplants have been performed for COVID-19 ARDS/pulmonary fibrosis, [13] but there are limited data on the longer-term outcomes of patients transplanted in this setting. We describe the pre-transplant considerations for patients at our center with COVID-19 ARDS/pulmonary fibrosis who required V-V ECMO support as a bridge to lung transplantation, as well as the 1-year post-transplant outcomes for this cohort. Given the ongoing importance of COVID-19, it is important to consider the factors that determine transplant candidacy in these patients, as well as the associated longer-term complications and outcomes. This knowledge will allow us to successfully care for these patients in the present as well as during potential future respiratory-related pandemics.

Material and Methods

Study Cohort

Between May 2021 and July 2022, all patients with COVID-19 ARDS/pulmonary fibrosis who required V-V ECMO support for refractory hypoxemia that subsequently underwent lung transplantation at our center were identified. This study was approved by the Institutional Review Board (IRB) at the University of California San Diego (IRB# 190181X). Requirement to obtain consent for the retrospective analysis of these cases was waived by the IRB.

COVID-19 Treatment and V-V ECMO Support

Patients received standard-of-care treatment for COVID-19 according to Centers for Disease Control guidelines. At the time of this study, this therapy mainly included dexamethasone and remdesivir. All patients were cared for by a multidisciplinary medical team that included pulmonary and critical care physicians, infectious disease physicians, and surgeons. Patient candidacy for V-V ECMO support was based on standard criteria by ELSO, a local county-wide ECMO consortium and the criteria established for severe ARDS in the EOLIA trial [2,3,6,14]. Briefly, patients were candidates for ECMO if their PaO_2/FiO_2 ratio was <100 despite optimization of ventilator settings and adjunctive therapies. In addition, patients with poor compliance, barotrauma, and respiratory acidosis (P_aCO_2 >60 with a pH <7.2) despite elevated respiratory rates were also considered candidates.

Patients that required lung transplantation for COVID-19 ARDS had significant and profound gas exchange abnormalities, which resulted in almost complete dependence on high V-V ECMO blood flows. Furthermore, these high ECMO blood flows needed to be unimpeded during physical therapy to ensure adequate SpO2 (goal >80 during physical therapy). Standard cannulation consisted of a right femoral vein 25-French drainage cannula and a 21-French right internal jugular vein return cannula. If circuit drainage insufficiency consistently prevented adequate physical therapy, the circuit was modified to include 2 drainage cannulas (25-French and 21-French, 1 in each femoral vein). All patients were placed on systemic anticoagulation (goal anti-Xa levels 0.11 to 0.3). Standard phlebotomy was performed with pediatric/small-volume blood tubes and transfusions were minimized to prevent development of allo-sensitization.

Assessment of Lung Transplant Candidacy

All patients placed on V-V ECMO for severe COVID-19-related ARDS had the initial primary goal of utilization of extracorporeal life support (ECLS) as a support to native pulmonary recovery. Referral to the lung transplantation team was made after 6 weeks and/or when there were clinical data that demonstrated lack of sufficient recovery, including inability to wean V-V ECMO or mechanical ventilation, poor pulmonary compliance, and lack of improvement on imaging studies [15]. The team evaluated and assessed each patient for candidacy according to the established International Society for Heart and Lung Transplantation (ISHLT) guidelines [16]. In conjunction with these criteria, our center required specific parameters to assess suitability of candidate selection. Individuals were required to be <60 years old, have a body mass index ≤32 kg/m^2, have 2 negative SARS-COV-2 polymerase chain reaction tests by tracheal aspirate or bronchoalveolar lavage, and

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demonstrate adequate rehabilitation potential with the ability to walk ≥150 feet. Patients were excluded from consideration if they had multi-organ dysfunction, evidence of active or multi-drug-resistant infection, acute encephalopathy that precluded participation with physical therapy, or recent/active malignancy [17,18].

Data Collection

For the 9 cases in this series, we collated information related to patient demographics and pre-COVID-19/ARDS characteristics and pre-transplantation information, including clinical features, treatment and management, V-V ECMO considerations, and medical course), and post-transplantation outcomes, including primary graft dysfunction, episodes of acute cellular/antibody-mediated rejection, and early chronic lung allograft dysfunction (CLAD).

Results

Between May 2021 and December 2022, 91 patients required V-V ECMO support for severe ARDS related to COVID-19 at our center. Nine of these patients underwent bilateral sequential cadaveric lung transplantation. No patients with severe ARDS from COVID-19 who had undergone lung transplantation at our center at the time of data collection were excluded from the analysis.

The 9 recipients (6 male, 3 female) had an average age (±SD) of 44.6±12.1 years, BMI 27.4±3.8 kg/m^2, and required V-V ECMO for a median of 57 days (IQR 53-78), with the longest ECMO course prior to transplant at 221 days (**Table 1**). V-V ECMO was initiated on a median hospital day 16 (IQR 11-78). During ECMO, 4 (44%) patients required a second drainage cannula due to recurrent drainage insufficiency and hypoxemia. One patient required limb amputation, while 7 (87.5%) had significant hemorrhage requiring >3 units of packed red blood cells. There was an average of 2.1±1.2 infections while on ECMO (**Table 1**). One patient was successfully weaned from V-V ECMO support 11 days prior to transplantation, 7 patients (77.7%) were decannulated immediately at the conclusion of the transplant operation, and 1 patient was decannulated on post-operative day 4. No other mechanical circulatory support devices were required for any patients during their hospitalization. Baseline characterizes and outcomes for patients with COVID-19 on V-V ECMO but who did not receive a lung transplantation can also be found in **Table 1**.

The median lung allocation score at the time of listing was 91.86 (IQR 89.0-92.1). Six (66.7%) of the patients received standard induction therapy (basiliximab 20 mg intra-operatively and on post-operative day 4). One patient required peri-operative desensitization with anti-thymocyte globulin and plasma exchange per prior published protocol due to calculated panel reactive antibody (cPRA) of 97% [17]. No patients had primary graft dysfunction (PGD) Grade 3 at 72 hours post-transplant; 1 had PGD Grade 2, and 3 had PGD Grade 1. In the immediate post-transplant period, patients were started on standard immunosuppressive therapy (prednisone, tacrolimus, and mycophenolate mofetil). The median ICU length-of-stay for the hospitalization was 76 days (IQR 45-141) and hospital length-of-stay was 89 days (IQR 54-144); all patients were discharged home without supplemental oxygen therapy. In the first post-transplant year, 3 (33.3%) patients had biopsy-proven acute cellular rejection. Three (33.3%) patients developed *de novo* donor-specific antibodies but only 1 patient was treated for acute antibody-mediated rejection. All patients survived the first post-transplant year, but 2 patients (22.2%) had lung function decline at a time point consistent with chronic lung allograft dysfunction (CLAD) (**Table 2**).

Discussion

We report our single-center experience of treatment of patients with severe COVID-19 ARDS/pulmonary fibrosis requiring V-V ECMO support as a bridge to lung transplantation. During the study period, 88 patients with severe COVID-19 ARDS required V-V ECMO support; 9 underwent transplantation as definitive therapy for progressive and irreversible lung damage (ie, pulmonary fibrosis). Despite the high morbidity and complexity of these patients as candidates, all were discharged without supplemental oxygen therapy and survived to 1-year post-transplant.

The initial goal of the utilization of V-V ECMO at our center was as a "bridge" to native lung recovery. Prone positioning and minimization of driving pressure on mechanical ventilation were utilized to minimize ventilator-induced lung injury and promote recovery [19]. For all patients with COVID-19 ARDS (including those that did not undergo transplant), the median number of ECMO days was 39 (IQR 22-59). However, prior studies have indicated that lung recovery in this population can be difficult to predict and can occur over weeks to months [7], a finding that was demonstrated in our center's population as well.

If the multidisciplinary team determined that pulmonary recovery was unlikely, the focus of care shifted to minimization of sedation, neuromuscular blockade, analgesic medications, and systemic corticosteroid therapy, combined with intensive physical therapy to reduce the occurrence of critical illness polyneuropathy/myopathy and deconditioning [18]. Hoetzenecker et al described the use of "awake" ECMO as a bridge to transplant for 71 patients, where the median duration of support prior

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Table 1. Demographics and characteristics of patients with COVID-19 on V-V ECMO who received and did not receive lung transplantation. Data are n (%), median (IQR), n, or n/n (%) unless stated otherwise.

	Patients with COVID-19 ARDS with lung transplantation	Patients with COVID-19 ARDS without lung transplantation
	n=9	n=82
Sex		
Female	3 (33%)	17 (21)
Male	6 (66%)	65 (79)
Age (years)	48 (36-55)	47 (38-54)
Body mass index (kg/m^2)	28.8 (23.1-30.3)	31.8 (28.7-34.7)
Blood group		
A	2 (22%)	–
B	1 (11%)	–
O	6 (66%)	–
AB	0 (0%)	–
Race		
White	7 (77%)	67 (81)
Black	0 (0%)	2 (2)
Asian	2 (22%)	6 (7)
Native Pacific islander	0	2 (2)
More than 1 race	0	4 (5)
Hispanic ethnicity	5 (56)	60 (73)
Vaccination status		
Unvaccinated	8 (89%)	65 (79)
Vaccinated	1 (11%)	4 (5)
Unknown	0	13 (16)
Treatment for COVID-19		
Corticosteroids	9 (100%)	71 (87)
Tocilizumab	2 (22%)	14 (17)
Remdesivir	5 (56%)	62 (76)
Baricitinib	2 (22%)	8 (10)
Immunoglobulins	0 (0%)	1 (1)
SOFA Score at ICU admission	8.0 (6.0-8.0)	8 (5.0-9.0)
APACHE II Score at ICU admission	23.0 (15.0-29.0)	–
ECLS		
V-V ECMO (single dual-lumen cannula)	3 (33)	3 (4)
V-V ECMO (2 cannulae)	6 (66)	78 (95)
Second drainage cannula	4 (44)	4 (5)
Length of support (days)	57 (53-78)	25 (14-44)

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Table 1 continued. Demographics and characteristics of patients with COVID-19 on V-V ECMO who received and did not receive lung transplantation. Data are n (%), median (IQR), n, or n/n (%) unless stated otherwise.

	Patients with COVID-19 ARDS with lung transplantation	Patients with COVID-19 ARDS without lung transplantation
	n=9	n=82
ECLS Complications		
Air entrapment	2 (22)	0 (0)
Hemorrhage (>3 units pRBC)	8 (89)	24 (29)
Venous thromboembolism	4 (44)	14 (17)
Cerebrovascular accident	1 (11)	15 (18)
Seizure	1 (11)	2 (2)
Cardiac arrest	5 (55)	8 (10)
Limb amputation	1 (11)	3 (4)
Renal replacement therapy	1 (11)	26 (32)
Bacterial infection	8 (89)	–
Fungal infection	3 (33)	–
Survival to hospital discharge	9 (100)	36 (44)

SOFA – sequential related organ failure assessment; APACHE – acute physiology and chronic health evaluation; ECLS – extracorporeal life support; V-V ECMO – veno-venous extracorporeal membrane oxygenation; pRBC – packed red blood cells.

to transplant was 10 days (range, 0-98 days); 63 patients survived to undergo transplantation [20]. In contrast to this study, our duration of support was significantly longer, with a median of 57 days (IQR 53-78). Indeed, we felt that this increased duration of support was required as it allowed for the continual assessment for native pulmonary recovery, as well as allowing patients to participate in and maximize their physical conditioning prior to transplantation. We would allow for 4-6 weeks prior to assessment for candidacy; however, it should be noted that the "ideal" time to work-up a patient for transplant is controversial and not well-defined.

Mental and physical conditioning have been well-established as important factors to consider regarding transplant candidacy and post-transplant outcomes [16,21,22]. To optimize these factors, patients underwent early tracheostomy placement (within 1 week of V-V ECMO cannulation) to allow for minimization of sedative/analgesic medications. Concerning physical conditioning required for lung transplantation, it has been reported that candidates who are able to walk 1200-1400 feet had a survival advantage following lung transplantation [23]. At our center, our standard requirement for walking for patients not requiring ECMO is at least 300 feet. However, for patients on ECMO, we deviated from this by decreasing the walking goal to at least 150 feet, given the difficulties associated with walking in these patients. Regardless of ECMO circuit configuration (fem-fem, fem-IJ, fem/fem-IJ, or single-site dual-lumen cannulas), we were able to get all our patients walking. Despite the ambulation modification, our outcomes suggest that walking feet is a sufficient measure of physical conditioning for these patients on ECMO requiring lung transplantation.

Overall, reports of patients who require prolonged mechanical ventilation and ECLS for ARDS as a bridge to transplantation are increasing; these patients are critically ill with high LAS scores and subsequent risk of post-transplant complications (eg, primary graft dysfunction, hospital length-of-stay, long-term mortality) [13,24]. Harano et al described 63 patients with non-COVID ARDS listed for lung transplantation; 39 were transplanted (28 of which required V-V ECMO support), but 24 were also delisted due to clinical worsening/death. Notably, there was no significant difference in survival between those that required V-V ECMO support versus those that did not [25]. Specific to COVID-19 ARDS, Bharat et al reported the first 12 patients globally to undergo lung transplantation as definitive therapy; 11 required ECLS (median 49 days), all of whom survived to 30 days post-transplant [26]. Kurihara et al subsequently reported their experience with 17 patients that required ECMO support prior to transplant; post-transplant, most patients had any grade PGD at 72 hours after transplant, as well as increased number ventilator days and hospital length-of-stay [27]. Our cohort echoes these findings; 4 (57.1%) of patients had any

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Table 2. Peri-transplant characteristics and post-transplant events. Data are n (%), median (IQR), n, or n/n (%) unless stated otherwise.

	Transplanted patients with COVID-19 ARDS	
Lung Allocation Score	91.86	(89.0-92.1
Time on waitlist (days)	21	(7-43)
Type of transplant		
Single	0	(0%)
Bilateral	9	(100%)
Surgery time (skin to skin) (min)	485	(433-532)
Ischemic time (min)		
Right lung	209	(181-229)
Left lung	279	(250-346)
Intraoperative blood products (# units)		
pRBC	2	(1-6)
FFP	1	(0-2)
Cryoprecipitate	2	(0-2)
Platelets	0	(0-2)
Induction therapy		
Standard	6	(66%)
Non-standard	2	(22%)
Desensitization	1	(11%)
PGD at 72 hours		
PGD 0	5	(56%)
PGD 1	3	(33%)
PGD 2	1	(11%)
PGD 3	0	
Length of mechanical ventilation after transplant (days)	8	(6-15)
Total length of ICU stay (days)	76	(45-141)
Length of hospital stay (days)	89	(54-144)
Need for supplemental oxygen at discharge	0	(0%)
Any ISHLT Grade rejection within 1 year	3	(33%)
Airway dehiscence within 30 days of transplant	0	(0%)
CLAD (1-year)	2	(22%)
Survival (1-year)	9	(100%)

pRBC – packed red blood cells; FFP – fresh frozen plasma; PGD – primary graft dysfunction; ICU – Intensive Care Unit; ISHLT – International Society for Heart and Lung Transplantation; CLAD – chronic lung allograft dysfunction.

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grade PGD at 72 hours with a median of 8 (IQR 6-15) ventilator-days after transplant and similar prolonged hospital length-of-stay. However, our study is the first to report post-transplant outcomes >60 days, which is another important aspect to contemplate when considering these patients as potential transplant candidates. Within our cohort, 3 patients had biopsy-proven acute cellular rejection in the first year and 1 was treated for acute antibody-mediated rejection, comparable to the general post-lung transplant population; all patients survived to the first post-transplant year [28].

There are several limitations to our study. As a single-center case series, our outcomes are not necessarily applicable to all lung transplant centers. We had a small sample size with no direct comparison cohort. In addition, the relationship between care and length of V-V ECMO and physical conditioning outcomes are not necessarily causative. Despite the longer time on ECLS and lower pre-transplant walking distance, however, we demonstrate excellent one-year outcomes for this cohort. Nonetheless, we do not have any long-term (3- and 5-year post-transplant) data in this population that can demonstrate decreased survival and/or early onset of chronic lung allograft dysfunction.

Conclusions

V-V ECMO as a bridge to transplantation for severe COVID-19 ARDS/pulmonary fibrosis can result in good 1-year outcomes for these patients. A specific focus on physical rehabilitation, as well as minimization of ECLS-associated complications, may be potential reason(s) for our favorable outcomes. Thus, we hope our experience can help guide clinicians in the support of patients that have severe non-resolving ARDS requiring ECLS and that may require lung transplantation as definitive therapy. Given that these patients have significant peri-transplant morbidity, lung transplant programs will need to individually assess if they have the resources to support these potential recipients in the short and long term.

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