Ethical dilemmas in COVID-19 patients awaiting lung transplantation on extracorporeal membrane oxygenation

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Abstract

Background: Extracorporeal membrane oxygenation (ECMO) may serve as a bridge to successful lung transplantation (LT) in selected patients with coronavirus disease 19 (COVID-19) pneumonia. Compliance with the recognized LT criteria however, may be impossible to be met in this particular and extremely challenging group of patients. This situation creates huge moral and ethical dilemmas. To indicate this, we decided to explore this difficult topic and present how non-compliance to the recognized LT criteria enabled us to perform three successful and life-saving LT procedures in COVID-19 patients.

Methods: Data of all consecutive patients on ECMO support as rescue treatment for COVID-19 pneumonia, awaiting LT at SCHD between October 1, 2020 and May 31, 2021 were reviewed.

Results: 18 patients on ECMO entered the list for LT at SCHD (mean age: 40.5 ± 5.6 years, range 28–48 years). Mean duration of ECMO was 29.6 ± 15.5 days (range 6–71 days). 11 patients died: either during LT (n = 3), post-LT (n = 1), or on ECMO awaiting LT (n = 7). The overall mortality rate in this group was 61.1%. Survivors (n=7) were either successfully transplanted (n = 3) or weaned from ECMO (n = 4). In the medical literature, there are several enthusiastic case reports describing successful LTs, however there might be a significant publication bias in this area, as failed procedures probably remain largely under-reported. There are no data to indicate the right time for LT in post-COVID-19 patients. Experts in this field require minimum recovery period of 4 weeks to exclude native lung recovery, active participation in physical rehabilitation and the possibility of providing informed consent to proceed with LT. All these conditions were impossible to be met in our patients awaiting LT on ECMO support.

Conclusions: Traditional lung transplantation criteria are difficult to be applied in COVID-19
patients requiring ECMO support due to medical and ethical reasons. Performing LT without prior consent of patients violates the ethical principles of solid organ transplants, but may be life-saving in some patients.

Introduction

Patients with severe coronavirus 19 disease (COVID-19) associated acute respiratory distress syndrome (ARDS) may develop irreversible lung damage and pulmonary fibrosis [1–3]. Lung transplantation (LT) is currently recognized a last-resort, life-saving treatment option for highly selective patients with irreversible COVID-associated respiratory failure [1, 2, 4]. There are several obvious concerns limiting the use of LT in this group [5, 6].

Patients who undergo extracorporeal membrane oxygenation (ECMO) for COVID-19 are trapped in the most difficult situation. Rescue ECMO for COVID-19 is usually performed in very young patients without significant comorbidities [7]. In many cases, weaning these patients from ECMO is not possible due to the development of irreversible lung fibrosis, with a progressive (and later complete) loss of tidal volumes and lung compliance [4, 6]. This results in a severe intra-pulmonary shunt and difficulties in providing adequate oxygenation, despite maximal ECMO support. These patients are added to the urgent transplant list; at this point, a dramatic race against time begins.

The Silesian Centre for Heart Diseases in Zabrze (SCHD) is currently running the most active lung transplant program in Poland, performing an average of 30–35 LTs per year. The COVID-19 pandemic generated a sudden and tremendous number of candidates for LT. Following the first successful lung transplant performed in a patient with COVID-19 early on during the pandemic [8], our center has become a referral site for dozens of patients with irreversible lung damage resulting from COVID-19 infection. An analysis of all 119 consecutive patients with COVID-19 referred to our center for LT has already been published by Urlik at al.[9]. The aim of the present study was to perform a subgroup analysis of our patients awaiting LT on ECMO support and present ethical and moral dilemmas associated with the process of treatment in this particular group of patients.

Material and Methods

In this retrospective, single-center study, we analyzed the data of all consecutive patients with COVID-19 awaiting LT on ECMO between October 1, 2020, and May 31, 2021. Due to the retrospective and anonymous nature of the research, the Ethical Committee of the Medical University of Silesia in Katowice waived the need for patient consent to participate in this study.

The data of interest included: circumstances surrounding admission to the intensive care unit (ICU), and the implementation of ECMO, demographic data, comorbidities, clinical status upon ICU admission, clinical status on ECMO implantation, as well as other procedure- and treatment-related variables.
Patients were treated at various locations. To be included in this study, patients had to have a SARS-CoV-2 infection, confirmed by real-time reverse transcriptase-polymerase chain reaction (RT-PCR) analysis from nasal and pharyngeal swabs or lower respiratory tract aspirates and to remain both on ECMO and on a waiting list for LT, for at least 24 hours, between October 1, 2020, and May 31, 2021.

Criteria for LT were as follows: reduction of tidal volume to less than 100 ml despite lung-sparing ventilation, failure to recruit, images on chest ultrasound and CT scan indicating completely airless lung tissue, no comorbidities, no complications during current therapy confirmed by CT scans, age less than 50 years and BMI less than 30 kg/m\(^2\), no information from the family about the recipient’s reported opposition to organ transplantation, conversation with the family with a presentation of the consequences of lung transplantation: the need to take medications and support that the patient will need after transplantation.

During ECMO, protective mechanical ventilation was applied based on the ELSO Coronavirus Disease 2019 Interim Guidelines [10]. This was supported by conventional critical care, including early enteral nutrition, sedation with neuromuscular blockade (if needed), and prone positioning, if appropriate [11, 12].

Descriptive analyses were performed using the IBCO Software Inc., (2017) and Statistica, version 13 (http://statistica.io) software packages.

**Results**

During the analyzed timeframe, 20 patients on ECMO support entered the LT list at SCHD. In this group, two patients were still on ECMO support at the end of the observation period; therefore, the analysis was performed in 18 patients only. The mean age of patients in the analyzed group was 40.5 +/- 5.6 years (range 28–48 years). There were only four female patients (22%) in this group. The mean body mass index (BMI) was 27.4 +/- 3.9 kg/m\(^2\) (range 17.3–33.9 kg/m\(^2\)). Three patients were classified as obese (BMI > 30 kg/m\(^2\)).

Patients were either awaiting LT on ECMO in SCHD (n = 8), in the other centers (n = 5), or initially in the other centers and later in SCHD (n = 5). The latter subgroup (patients who underwent ECMO treatment at two different locations) were transferred to SCCS on ECMO support to await qualification for lung transplantation on-site.

In the analyzed group, 15 patients (83%) were transferred to ECMO centers from other facilities. The condition of five patients (28%) was too severe for safe transport; therefore, they had to be transferred to ECMO centers on extracorporeal life support.

The mean duration of hospital stay before ICU admission was 10.2 +/- 8.1 days (range 0–33 days). The mean duration of mechanical ventilation before the initiation of ECMO was 8.1 +/- 11.5 days (range 0 – 46 days).
The vast majority of analyzed patients had no comorbidities before the onset of COVID-19 infection. Three patients had arterial hypertension and one patient had bipolar disorder. Two female patients without comorbidities developed severe COVID-associated ARDS during late pregnancy and underwent emergency caesarean section in a period directly preceding ICU admission.

All patients were intubated, heavily sedated, and mechanically ventilated. The mean ICU stay before the implementation of ECMO was 7.5 +/- 11.9 days (range 0–23 days); however in 7 patients (39%) ECMO was implemented directly after ICU admission as an emergency. Veno-venous peripheral ECMO technique was used in all subjects.

One patient underwent tracheostomy already before the initiation of ECMO, while the next seven patients underwent tracheostomy while on ECMO support. Three patients were temporarily extubated on extracorporeal support. During ECMO treatment, nine patients developed hemorrhagic complications, six patients required renal replacement therapy, and one patient suffered from cerebral bleeding and was further certified brain dead. Most patients (83%) developed concomitant bacterial infections requiring broad-spectrum antibiotics during ECMO therapy.

The mean duration of ECMO support was 27.2 +/- 16.1 days (range 6–71 days). Overall, 11 patients died: either during LT (n = 3), post-LT (n = 1) and on ECMO awaiting LT (n = 7); therefore, the mortality rate in this group was 61.1%. Survivors (n = 7) were either successfully transplanted (n = 3), or successfully weaned from ECMO (n = 4).

In a group of seven patients who died on ECMO awaiting LT, severe progressive loss of tidal volume was observed over the course of illness. In an extreme form, tidal volumes dropped below 50 ml and mechanical ventilation was not possible (with the presence of non-obstructed bronchial tree in a bronchoscopy). No recruitment was feasible, and severe hypoxemia was observed in these patients despite maximal ECMO support. Patients in this group died either due to multi-organ failure (n = 6), or brain death that followed the intracranial hemorrhage (n = 1).

Among patients who died during LT (n = 3), the procedure itself proved to be extremely difficult due to tissue fragility, upward displacement of the diaphragm, and severe clotting impairment resulting from previous transfusions of various blood products on long-term ECMO support. All three patients died in the operating room due to unmanageable bleeding. Another patient died in the late postoperative period post-LT due to the severe hepatic insufficiency.

In a subgroup of patients who successfully underwent LT (n = 3), ECMO support was stopped immediately once the surgical procedure was completed. These three patients were:

1. a 45-year-old male who previously underwent ten days of ECMO and remained extubated on ECMO support,
2. a 32-year-old male who previously underwent nine days of ECMO support,
3. a 38-year-old female who previously underwent 36 days of ECMO support.
The subgroup of patients who initially qualified for LT and were successfully weaned from ECMO started to improve rapidly at some stage. However, it must be noted that none of these patients had previously developed ARDS characterized by extremely low tidal volumes.

The data of the total patient sample are summarized in Table 1.

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Outcome</th>
<th>LT</th>
<th>ECMO run (days)</th>
<th>Extremely low TV</th>
<th>Cause of death</th>
<th>Comments</th>
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<tr>
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<td>death</td>
<td>yes</td>
<td>47</td>
<td>yes</td>
<td>*MOF</td>
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</tr>
<tr>
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<td>bleeding</td>
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<tr>
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<tr>
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<tr>
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</table>

*MOF – multiorgan failure
A typical lung CT scan, with radiological features of irreversible lung injury and a lung ultrasound, is presented in Fig. 1a and 1b, respectively.

A macroscopic image of the post-COVID lungs explanted during the procedure is shown in Fig. 2a while a comparison of the explanted lung to the donor lung is shown in Fig. 2b.

**Discussion**

In our single-center study, we aimed to describe a particularly challenging group of patients on ECMO support listed for LT at our institution. The results of our study may be disappointing, since in a group of 18 patients awaiting LT on ECMO, only three patients were successfully transplanted. Some patients however, initially entered the transplant list, were later successfully weaned from ECMO, recovered, and survived to hospital discharge, therefore the final crude hospital mortality rate in this group was 61%.

What lessons have we learned so far from treating these patients?

COVID-19 can result in severe, irreversible lung injury. In these cases, LT may represent the only viable therapeutic option, albeit in a highly selective group of patients [2]. The management of patients with post-COVID ARDS-related fibrosis is particularly challenging, since there are no data to indicate the right time for LT [2, 6]. Experts in this field generally recommend that very restrictive criteria be applied to select patients eligible for LT [2, 4, 6]. Although arbitrary, a minimum 4-week recovery period after LT has been suggested, unless life-threatening complications that cannot be managed without LT occur at an earlier stage [2, 4, 5]. Several reputable LT centers decided not to open their programs to patients during the early phases of COVID-19 infection [2]. By the end of April, 2021, only around 100 LTs for patients with COVID-19 had been performed both in the United States and Europe [2].

Interestingly, an analysis of the available literature in this field creates a slightly different impression. There are several enthusiastic case reports describing successful LTs [13–15], a view which is supported by recent reviews [16, 17]. Only one multicenter case series on this subject, collected across four different countries, has been published so far [4].

It is possible that there is a significant publication bias in this area, as failed procedures probably remain largely under-reported [5].

Finding the right donor for these patients can be very difficult, for several reasons. First, there was a significant collapse in terms of available organs around the world during the COVID-19 pandemic [18, 19] and Poland was no exception in this regard [9, 19, 20]. Second, due to the upward shift of the diaphragm in patients with COVID-19, there is rapidly progressive fibrosis and a loss of tidal volumes, which makes it extremely difficult to find suitable donors for LT [2, 10, 21]. In these particular cases, only short stature donors (or older pediatric donors) may be considered, as downsizing of donor lungs is technically very demanding [21]. Third, choosing the right recipient is very challenging. There are many "safer" and more
typical candidates on the transplant list, with much more favorable risk-benefit ratio, for whom LT is associated with a much greater chance of success [6].

King et al.[2], mentioned in their excellent review that the COVID-19 pandemic generated emotionally involving and intellectually challenging situations, with patients frequently being unable to meet the traditional criteria for an acceptable LT recipient, but having no other path forward towards recovery [2, 16]. We fully agree with this statement. The issue of how to treat these patients creates a huge moral dilemma, both for the ICU staff and patients’ relatives. In some cases, LT often becomes the only remaining, albeit extremely risky, therapeutic option [7].

Apart from that, clinicians may experience enormous pressure from patients’ relatives. The families of patients on prolonged ECMO support due to COVID-19 are usually fully aware of the hopeless situation that their family members is in, and any mention of the possibility of LT raises unjustified hopes. We observed many patients with a severe progressive loss of tidal volumes, with mechanical ventilation being practically impossible. The explanted lungs in our study demonstrated histological changes typically seen in patients with idiopathic lung fibrosis, including collagen deposition and honeycombing [22]. Moreover, this fatal scenario was sometimes observed quite early in the course of the disease, even when these patients were still COVID-positive in lower respiratory tract aspirates. Interestingly, this issue has not been described so far in the medical literature.

Some of our results are also quite difficult to explain. One of our successfully transplanted patients had a combined time of mechanical ventilation and ECMO of only 14 days. According to expert opinions, LT should take place no earlier than after 4 weeks of ECMO support. A similar situation was also identified among patients who died during LT procedure: two of them had a combined duration of mechanical ventilation and ECMO support of only 16 and 19 days, respectively.

Does it mean that we should always wait a few weeks until the patient may be considered for LT? We express serious doubts about that. In view of the abovementioned difficulties with the donation pool during a pandemic [18, 19], the appearance of a suitable organ for such patients is sometimes an opportunity that may not repeat itself. Regardless of this, patients with COVID-19 undergoing prolonged ECMO therapy later develop complications that significantly reduce their chances of entering the active transplant list [5]. Moreover, COVID-19 infection could directly promote lung fibrosis by triggering several mechanisms starting from the very early stage of the illness [23]. Although the possible mechanisms involved are uncertain, a wound repair response with predominance of pro-fibrotic pathways may be implicated, while mechanical stress associated with invasive ventilation may also play a contributory role [22–24]. Seven patients who died awaiting LT on ECMO (Table I) had the longer combined duration of mechanical ventilation and ECMO support (range 26–56 days). Therefore, we feel that the window of opportunity for these patients may sometimes appear much earlier than suggested by experts.

Our material was clearly overly heterogeneous, and the sample size too small, to perform any statistical comparisons. However, looking at the data in Table I, it may be seen that the survivors were slightly
younger, and there were no obese patients in this group.

Two separate phenotypes of patients with COVID-19 who are referred for LT might be identified: patients in the acute phase of COVID-associated ARDS, and patients with post-COVID chronic respiratory insufficiency [2]. We would like to underline, that in our group of patients awaiting transplant on ECMO support, we did not have a single patient with post-COVID chronic respiratory insufficiency.

The experts suggest that all efforts should be made to wake patients up before transplantation to obtain consent for the procedure, provide education, assess interest, and engage them in active rehabilitation. A minimum recovery period of 4 weeks has been suggested [2]. Other experts go even further and propose a minimum recovery period of 8 weeks to exclude native lung recovery, active participation in physical rehabilitation, the possibility of providing informed consent and minimal acute comorbidity – on a top of an entire list of other obvious conditions that usually could be met [6].

These conditions were entirely unrealistic when applied to our patients. Only three patients in our sample could be extubated and actively participate in physical rehabilitation. So maybe our LT program for patients with COVID-19 was based on fundamentally wrong assumptions?

Two specific stories of our patients provide an answer to this difficult question. Of the three cases where LT was a full success, two would normally have had no chance of being placed on the transplant list at all.

The first example is a 32-year-old male patient (Table I) who was transplanted after only 9 days of ECMO treatment because of the rapid loss of tidal volume and the unexpected availability of suitable donor lungs. If we had not decided to perform LT at this point, this patient would most probably have shared the fatal trajectory of all other patients who died due to multi-organ failure on prolonged ECMO support. This patient was discharged home and remains in a very good condition in a 5-month follow-up period.

Another example is a 38-year-old female patient (Table I) who developed severe COVID-19 symptoms during the 30th week of her pregnancy, and therefore underwent an urgent caesarean section. The patient gave birth to a healthy child; however, during the post-partum period, developed a severe form of CARS, and was urgently transferred to our center where ECMO support was implemented. A rapid loss of tidal volumes was observed, and a lung CT scan revealed no obvious radiological features of irreversible lung injury (Fig. 1). The patient entered an urgent LT list; however, due to an extreme upward shift of the diaphragm, it took a very long time to find a suitable donor. Ultimately, this was achieved after 39 days on ECMO, when the patient already required renal replacement therapy for a long time and had obvious acute comorbidities. Throughout this time, the patient was deeply sedated and required muscle relaxants most of the time due to the extremely unstable operation of the ECMO system, so there was no way of obtaining informed consent from the patient for the LT. Severe critical illness polyneuropathy was observed during the post-operative period, therefore the total duration of ICU stay was 81 days, and the hospitalization time exceeded 4 months. Ultimately, the patient was also discharged home, and remained in a very good condition when observed after a 5 month follow-up period.
It must be underlined that our study had significant limitations. Retrospective studies are always prone to bias, and our data were collected during the most difficult period of the COVID-19 pandemic. Since some of the patients were awaiting LT at the other centers, we did not have direct access to all patient data. Also, we did not have access to all the follow-up data of those patients, who had been successfully weaned from ECMO, and then discharged from the ICU. All these limitations, however, should be considered in the context of the pandemic situation - the data were collected when Poland was struggling with the second and third waves of the COVID-19 pandemic.

Conclusions

During the second and third waves of the COVID pandemic, a significant number of patients with irreversible lung damage were awaiting lung transplantation with ECMO support. The need to meet the requirement of 28 days for ECMO support before lung transplantation, recommended by the LT guidelines, results in irreversible multiorgan failure making transplantation impossible or affecting post-transplant survival. Performing LT without prior consent of patients violates the ethical principles of solid organ transplants, but may be life-saving in some patients. This may create profound moral and clinical dilemmas for the clinicians treating these patients.

Abbreviations

**ECMO** - Extracorporeal Membrane Oxygenation  
**LT** - Lung transplantation  
**COVID-19** - Coronavirus disease 2019  
**SCHD** - Silesian Center for Heart Diseases in Zabrze  
**ARDS** - Acute respiratory distress syndrome  
**SARS-CoV-2 infection** - Severe acute respiratory syndrome coronavirus 2  
**RT-PCR** - Real-time reverse transcriptase-polymerase chain reaction  
**BMI** - Body Mass Index  
**ICU** - Intensive care unit

Declarations

1. Ethics approval and consent to participate

We confirm that all procedures utilised in this study were conducted following the principles of the Helsinki Declaration. Ethical clearance and approval letters were secured from The Bioethical Committee
of the Medical University of Silesia in Katowice (PCN/CBN/0022/KB/248/21).

The Bioethical Committee of the Medical University of Silesia after obtaining full information regarding this study, due to the retrospective and anonymous nature of the research, waiver of the need the obligation to obtain informed consent from the participants. During the data collection, the issue of confidentiality and privacy was assured by maintaining the anonymity of participants.

2. Consent for publication

Not applicable

3. Availability of data and materials

Data are available from the corresponding author upon reasonable request.

4. Competing interests

The authors declare no competing interests.

5. Funding

None of the authors has a financial relationship with a commercial entity, that has an interest in the subject of the presented manuscript, or other conflicts of interest to disclosure.

6. Authors' contributions

E.T, P.P., PK, conceived the study design, M.U, M.O., M.W-P, S.S. assisted with data acquisition M.W-P, PC oversaw statistical analyses. All authors assisted with data interpretation, manuscript revisions, and final manuscript review.

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**References**


Figures

Figure 1

a. Lung CT scan with radiological features of irreversible lung injury.

b. Lung ultrasound with radiological features of irreversible lung injury.
Figure 2

a. A macroscopic image of the post-COVID lungs explanted during lung transplantation.

b. Comparison of the explanted lung to the donor lung during lung transplantation