ORIGINAL ARTICLE

Outcome of Patients on Prolonged V-V ECMO at a Tertiary Care Center in India

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Abstract

Introduction: Extracorporeal membrane oxygenation (ECMO) is a life-support system that provides cardiopulmonary support. With recent advances, the duration of ECMO has increased but data on the outcomes of prolonged V-V ECMO are limited and inconsistent.

Materials and methods: It is a retrospective observational study done at a tertiary care center in Kolkata to study the outcome of patients receiving prolonged V-V ECMO defined as >14 days.

Observation: A total of 22 patients received prolonged ECMO support. Fifteen patients (68.2%) had severe coronavirus disease-2019 (COVID-19). The mean duration of invasive mechanical ventilation (IMV) before ECMO was 5 days. Baseline PaO_2/FiO_2 (p/f) ratio was 82 and Murray score was 3.5. The mean duration of ECMO support was 27.18 days (SD: 11.59). Five patients (22.7%) had minor bleeding and one patient had oxygenator failure. Survival at hospital discharge was seven patients (31.8%).

Conclusion: Duration of ECMO support alone should not represent a basis for decision making to decide futility or continuation of ECMO support. Prolonged ECMO in acute respiratory distress syndrome (ARDS) has minor complications and can lead to recovery in almost one-third of the patients.

Keywords: Coronavirus disease-2019, Extracorporeal membrane oxygenation.

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Highlights

We present the data of 22 patients with acute respiratory distress syndrome (ARDS) who received prolonged V-V extracorporeal membrane oxygenation (ECMO) support (>14 days). Mean duration was 27.18 days with survival at hospital discharge being 31.8%. There was no difference in duration of ECMO support between survivors and non-survivors.

Introduction

Extracorporeal membrane oxygenation is an advanced form of life-support system used in patients with severe respiratory or cardiac failure. Extracorporeal membrane oxygenation was first successfully used in the early 1970s and since then more than one lakh adults have been treated with it.[1] The two major types of ECMO include the veno-arterial (V-A) ECMO used in cases of cardiac failure and the more commonly employed veno-venous (V-V) ECMO used to treat respiratory failure. Large-scaled trials have shown that the use of V-V ECMO in patients with severe ARDS reduces the 60-day mortality [34 vs 47%, relative risk (RR) 0.73].[2] The Extracorporeal Life Support Organization (ELSO) guidelines currently recommend the use of V-V ECMO in patients with severe ARDS [PaO_2/FiO_2 (p/f) ratio < 80], or pH < 7.25 and pCO_2 >60 with respiratory rate (RR) 35 per minute, who are not improving with conventional ventilation strategies.[3] While in the past, the use of V-V ECMO was associated with high complication rates and poor outcomes, technical advances, better equipment and increasing expertise has led to increased ECMO use over the years with a large subgroup of patients being on prolonged ECMO support. Prolonged ECMO support has been variably defined as >14, 21, or 28 days in different studies with data regarding the outcome of these patients being inconsistent and limited.

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Materials and Methods

A retrospective observational study was conducted in a single tertiary care center in Kolkata to study the outcome of patients receiving prolonged ECMO support.

All patients aged more than 18 years who received prolonged V-V ECMO support defined as >14 days irrespective of underlying etiology were included. Patients for whom data regarding outcome were not available were excluded from the study.

Data were collected retrospectively for demographic details, comorbidities, admitting diagnosis, baseline characteristics including p/f ratio, Murray score, positive end expiratory pressure (PEEP), and duration of invasive mechanical ventilation (IMV) at time of ECMO initiation, type of ECMO support, initial ventilation

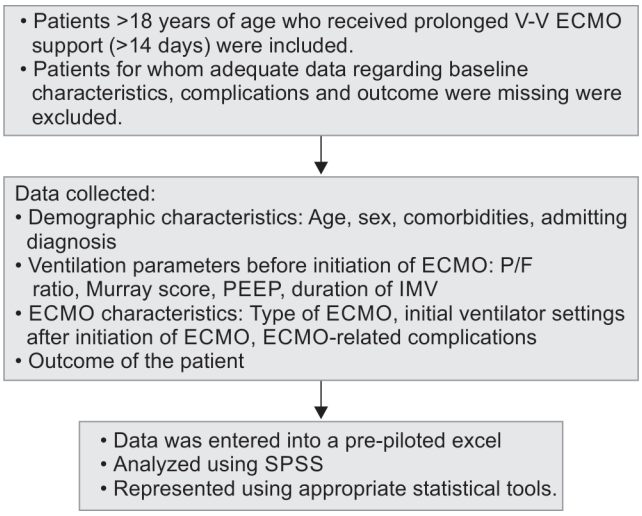

Fig. 1: Workflow

parameters on ECMO, ECMO-related complications including patient- and machine-related, duration of ECMO support, and final outcome. All the data were entered in a pre-piloted Excel sheet and was analyzed using SPSS. Continuous data were represented by mean and standard deviation. Discontinuous data were reported as median with interquartile range. In between group comparisons between ECMO survivors and non-survivors were done using Chi-square test for proportions and the Wilcoxon rank sum test for means. The workflow is represented in Figure 1.

ARDS was defined and graded as per the 2012 Berlin definition. Various studies have defined prolonged ECMO differently (>14 days, >21 or 28 days) with no globally accepted standard definition. We used a cut-off of >14 days to define prolonged ECMO and further subdivided them into those who received ECMO for 14–28 days or >28 days.

Results

A total of 22 patients were recruited during the study period. Nineteen patients (86%) were male. The mean age of the patients was 53.9 years. Five patients (22.7%) had diabetes mellitus, six (27.3%) patients had hypertension, and two patients (9.1%) had chronic kidney disease (not on hemodialysis). The admitting diagnosis for all the patients was ARDS. Etiology was COVID-19 in 15 patients (68.2%), H1N1 in two patients (9%), and pneumonia with unclear etiology in five patients (22.8%; Table 1).

Seventeen patients (77.27%) had severe ARDS and five patients (22.73%) had moderate ARDS. The mean p/f ratio was 82 (SD: 20.01). The mean Murray score was 3.5 (SD: 0.35). Four patients were on ionotropic support at the time of initiation of ECMO with mean duration of IMV prior to ECMO being five days. All the patients were put on V-V ECMO. The drainage cannula was put in the right femoral vein and the return cannula in right internal jugular vein for all the patients. Post initiation of ECMO, 10 patients were put on pressure assist controlled ventilation (45%) and 12 patients on volume assist controlled ventilation (55%). The mean PEEP set was eight and Fio_2 40%. Proning post initiation of ECMO was done for five patients (22.7%; Table 1).

The mean duration of ECMO was 27.18 days (SD: 11.59 days). The longest duration of ECMO support was 51 days. Eight patients (36.36%) received ECMO for >28 days and 14 patients (63.64%) received ECMO for 14–28 days. Twenty patients (90.1%) underwent tracheostomy in view of prolonged mechanical ventilation (Table 2).

Table 1: Baseline characteristics

Number of patients	*22*
Male	19 (86%)
Age	53.9 (SD: 11.6)
Comorbidities	
Diabetes mellitus	5 (22.7%)
Hypertension	6 (27.3%)
Chronic kidney disease	2 (9.1%)
Chronic liver disease	0
Admitting diagnosis	
COVID-19 ARDS	15 (68.2%)
H1N1 ARDS	2 (9%)
Pneumonia	5 (22.8%)
Baseline characteristics	
Murray score	3.5 (SD: 0.35)
P/F ratio	82 (SD: 20.01)
Ionotropic support	4 (18%)
Duration of IMV (days)	5 (SD: 1.66)
ECMO settings	
Type of ECMO (V-V)	22 (100%)
Mode of ventilation post initiation of ECMO	
PCV	10 (45%)
VCV	12 (55%)
PEEP	8 (6–12)
Proning	5 (22.7%)

Table 2: Patient outcomes

Duration of ECMO (days)	*27.18 (SD: 11.59)*
Outcome	
Alive	7 (31.8%)
Death	15 (68.2%)
Tracheostomy	20 (90.1%)
Machine complications	
Oxygenator failure	1 (4.5%)
Membrane rupture	0
Limb ischemia	1 (4.5%)
Patient complications	
Bleeding	5 (22.7%)
AKI	3 (13.6%)
Hemodialysis	2 (9.1%)
Stroke	0
Thrombosis	0
Infection	2 (9.1%)
Pneumothorax	2 (9.1%)
Transaminitis	2 (9.1%)
Shock	2 (9.1%)

Table 3: Comparison between survivors and non-survivors

	Survivor group (n = 7)	*Non-survivor group (n = 15)*	
Age	44 years (SD: 8.1)	58.53 (SD: 10.18)	$p = 0.005$
Male	5 (71.43%)	14 (93.33%)	$p = 0.16$
Admitting diagnosis			$p = 0.72$
COVID-19	4	11	
Influenza	1	1	
Pneumonia (unclear etiology)	2	3	
Murray score	3.53 (SD: 0.39)	3.46 (SD: 0.34)	$p = 0.72$
P/F ratio	77 (SD: 20.33)	87.07 (SD: 23.05)	$p = 0.42$
Duration of IMV prior to ECMO initiation (days)	4.28 (SD: 1.12)	5.33 (SD: 1.79)	$p = 0.23$
Duration of ECMO support	24.71 (SD: 6.94)	28.33 (SD: 13.29)	*P = 0.88*
ECMO-related complications			
Oxygenator failure	1	–	
Limb ischemia	1	–	
Patient-related complications			
Bleeding	2	3	
CRBSI	–	2	
Pneumothorax	1	1	
Transaminitis	–	2	

Seven patients (31.8%) were successfully weaned off ECMO and discharged from the hospital. Fifteen patients (68.2%) died while on ECMO support. Out of the seven patients who recovered, four had severe COVID-19, one had H1N1 pneumonia, and two had pneumonia. The mean age of the survivor group was less compared with non-survivors with no difference in the admitting diagnosis, ventilation parameters, or duration of ECMO support (Table 3).

Machine-related complications in the form of oxygenator failure and limb ischemia were seen in one patient each. Both of these patients recovered and were discharged. There were no incidences of chattering or membrane rupture.

Patient-related complications were infrequent with the most common complication being minor bleeding seen in five patients, all of which were managed conservatively. Three patients had acute kidney injury and two of them needed hemodialysis. Two patients developed pneumothorax for which tube drainage was done, one each in the survivor and non-survivor group. None of these patients had prior underlying structural lung disease. Transaminitis was seen in two patients and another two patients had new onset shock post ECMO initiation. Catheter-related blood stream infection occurred in two patients. None of the patients developed any episodes of thrombosis or stroke (Table 2).

Discussion

Extracorporeal membrane oxygenation is a type of life-support system that provides cardiopulmonary support. The process involves removing blood from the body, circulating it through a mechanical pump outside the body, and then reintroducing it back into the circulation. Hemoglobin is fully oxygenated, and carbon dioxide is removed while the blood is outside the body. Oxygenation is regulated by the flow rate, while CO_2 elimination can be adjusted by modifying the rate of counter current gas flow through the oxygenator.[4]

Extracorporeal membrane oxygenation is used for three types of indications: respiratory support, cardiac support, or a combination of the two. Indications for cardiac support include refractory low cardiac output and hypotension despite adequate intravascular volume, high-dose inotropic agents, and an intra-aortic balloon pump. In the case of acute respiratory failure, both V-V ECMO and V-A ECMO can be used as a rescue therapy to support life while awaiting improvement of the underlying disease. Extracorporeal membrane oxygenation is also used to provide oxygenation and CO_2 removal during lung recovery or as a bridge to transplant in cases of end-stage lung disease.[5] However, ECMO has several complications, which can be related to the underlying pathology or the ECMO condition itself (surgical insertion, circuit tubing, anticoagulation, etc.). As a general rule, ECMO inserted for pulmonary support has fewer complications than ECMO inserted for cardiogenic support. These complications increase morbidity and mortality rates significantly.[4]

The duration of ECMO support has increased due to advancements in biocompatible materials, miniaturization of the ECMO system, and a better understanding of ECMO support. Prolonged ECMO has been defined variably in different studies with some defining it as >14 days, few >21 days, and remaining as >28 days. However, data on prolonged VV ECMO support are limited, and outcomes are inconsistent.

A study done by Na et al.[6] retrospectively analyzed all patients who received ECMO support in South Korea. A total of 487 patients were included (V-V ECMO in 425 and V-A ECMO in 46), with the median duration of ECMO being 8 days (4–20). Seventy-six patients (15.6%) received support for >28 days and were defined as the long-term group. The age, sex, and baseline severity of respiratory failure were similar among the two groups; however, the proportion of patients with pre-existing interstitial lung disease was higher in the long-term group. Although the mortality increased from 56.7% in

the first week to 73.5% in the fourth week, there was no difference in mortality between the short-term and long-term group (60.8% vs 69.7 %, $p = 0.14$).[6] Posluszny et al. evaluated the data on all adults who received prolonged ECMO support (>14 days) in between 1989 and 2013 from the extracorporeal life-support organization multi-institutional registry. A total of 974 patients (V-V ECMO in 774 and V-A ECMO in 96) with a mean age of 40.2 years were included. Median duration of support was 21 days (14–208). There was an increase in the prevalence of prolonged ECMO support over the years with 72% of all cases reported from 2008 onwards. Survival at discharge was 45.4%. Although the survival rates were lower as compared with previous reported short ECMO group, increasing ECMO duration did not alter the survival fraction. Multi-variate regression analysis showed that the survival of these patients improved over the years. Prolonged ECMO support patients from 2007 to 2013 had a lower risk of death (OR 0.65, $p = 0.01$).[7]

Rabie et al. did a single center retrospective study in Saudi Arabia in which they compared the outcomes of patients receiving V-V ECMO support for greater or less than 21 days (prolonged ECMO and short ECMO, respectively). A total of 37 patients with 13 patients (35.1%) in the prolonged ECMO arm were included. The most common primary diagnosis was H1N1 ARDS in 35.1% patients (46.2% in prolonged ECMO group) followed by trauma ARDS (21.6%) and MERS-CoV (18.9%). Survival at hospital discharge was 78.4%. There was no difference between the short and prolonged ECMO groups (83.3% vs 69.2%, $p = 0.32$). All the patients in the prolonged ECMO group underwent tracheostomy.[8] A retrospective study on 39 patients receiving ECMO support (V-V ECMO in 38 and V-A ECMO in one patient) for ARDS in Indian ICU's showed mean age of 44.6 years, median duration of ECMO support 9.4 days and survival at hospital discharge being 38.5%.[9] We present the findings of 22 patients who received prolonged ECMO support (>14 days). As the study included patients between 2020 and 2022, most of the patients had severe COVID-19 with two patients of H1N1 ARDS. The mean age was 53.9 years and at least half the patients had some underlying co-morbidity in the form of diabetes mellitus, hypertension, or chronic kidney disease. Almost one-third of the patients were alive at hospital discharge which was lower when compared to Posluszny et al. (31.8% vs 45.4%) and could be related to the higher mean age of our patients (53.9 vs 40.2 years), a factor that has consistently been shown to impact survival.[7]

Kakar et al. reported the outcomes of 12 patients who received prolonged V-V ECMO support for COVID-19 in the UAE. Median duration of ECMO use was 28 days (IQR: 13.5–50) with survival at hospital discharge being 50%.[10]

Rabie et al. reported a higher rate of patient-related complications in the prolonged ECMO group. Five patients (38%) had bleeding, six patients (46%) had acute kidney injury requiring hemodialysis, three patients (23%) developed thrombosis, 2 patients (15%) had stroke, and 8 patients (62%) had a pneumothorax.[8] Posluszny et al. reported the outcome of 4361 patients who received prolonged ECMO between 2009 and 2018. The hospital survival was 51.3% which was higher compared with the last cohort from 1989 to 2013. In their cohort around 14% patients developed gastrointestinal bleeding, A total of 17% patients had pneumothorax, almost one fifth had stroke and limb ischemia was seen in 0.1% of patients.[11] In our study population, minor bleeding was seen in five patients (22.7%). There were no events of thrombosis or stroke that could be due to the use of therapeutic anticoagulation in most of the patients in view of severe COVID-19. Only around one-tenth of the patients developed pneumothorax. The lower incidence could be due to the use of lower PEEP post ECMO in our patients. Also, around half of our patients were put on pressure assist control ventilation post ECMO, which reduces the risk of barotrauma.

In the study by Rabie et al., ECMO-related complications were frequent. All patients on prolonged ECMO support required membrane lung exchange, one patient had membrane rupture, and three patients had chattering. There was no episode of limb ischemia in the prolonged ECMO group.[8] Posluszny et al. reported oxygenator failure in 18% of their patients. Membrane or tubing rupture was seen in 0.2% of patients. In our study, oxygenator failure warranting replacement was seen in one patient and another patient had limb ischemia which was managed conservatively.

There is also an increased risk of infections in patients on ECMO support. These include catheter-related blood stream infections and ventilator-associated pneumonia. A study done by Lee et al. reported the incidence of catheter-related blood stream infection to be 20 episodes per 1000 ECMO days. Approximately 20.3 and 5.4% of patients developed bacteremia and candidemia, respectively. The median number of days of BSI development was 11 days for candidemia and 8 days for bacteremia. Total ECMO duration was associated with increased risk of bacteremia [odds ratio (OR) 1.03, $p = 0.007$] and candidemia (OR 1.035, $p = 0.01$).[12] In our study two patients met the criteria for CRBSI both of whom died due to their underlying illness. The duration of ECMO support at development of infection was 14 and 17 days.

Numerous studies have tried to look at factors predicting outcomes of patients requiring prolonged ECMO. Posluszny et al. showed that young age was significantly associated with survival. Decreased time to ECMO initiation post intubation also improved survival. Occurrence of ECMO complications like gastrointestinal hemorrhage, neurologic complications, and CPR was associated with increased mortality.[11]

Yaqoob et al. compared the clinically important outcomes in recipients of ECMO for COVID-19 to those with ARDS of other etiologies.[13] Survival to hospital discharge was not different between the two groups (33% vs 50%, $p = 0.255$). However, the proportion of patients who received ECMO support >30 days was higher in the COVID-19 ARDS group (69% vs 17%, $p = 0.001$). Another study done by Blazoski et al. showed that median duration of ECMO support in COVID-19 patients was 21.4 days with survival being 68%.[14] A consistent pattern that has emerged from studies done in COVID-19 is delayed lung recovery. In our study, there was no difference in average duration of ECMO support between survivors and non-survivors (24.7 vs 28.3 days).

European ECMO centers' perceptions on managing prolonged extracorporeal life support indicate that 16% of the participating centers regarded treatment as futile after a specific time point. This varied from 2 to 90 days, with a median of 12 days. However, relying solely on the duration of ECMO support cannot predict hospital survival as it is affected by irreversible lung injury. Nevertheless, continuing ECMO support can be beneficial in enhancing lung regeneration in patients with a slow healing rate and no fibrosis evident on computed tomography. In cases where the native lung is unlikely to recover, and a patient is awake with no contraindications, a quick evaluation for lung transplantation should be carried

out since the duration of ECMO support while awaiting lung transplantation affects morbidity and mortality.

Ethical concerns can arise with prolonged ECMO runs, as committing to them can tie up limited and expensive resources for a single patient with an uncertain chance of recovery. Additionally, it can be challenging to make decisions about withdrawing ECMO support from an awake patient with minimal chances of recovery. Unfortunately, there is little information to guide such decisions, and future studies should address the best ways to handle these situations.

Our study adds to the existing literature on outcomes of patients on prolonged ECMO support, suggesting that delayed lung recovery is possible and that duration of ECMO alone should not be taken as a prognostic factor to decide futility of further care.

Conclusion

This is a retrospective observational study done at a tertiary care center at Kolkata which aimed to study to outcome of patients who received prolonged V-V ECMO support. We presented the data of 22 patients who received prolonged V-V ECMO support defined as greater than 14 days. Fifteen patients had severe COVID-19, two patients had H1N1 influenza, and five patients had pneumonia of unclear etiology. Baseline p/f ratio was 82 and median duration of IMV before ECMO initiation was 5 days. All patients received V-V ECMO support. Median duration was 23.5 days. Seven patients (31.8%) were discharged alive from the hospital. Minor bleeding was seen in five patients (22.7%). Oxygenator failure was seen in one patient (4.5%). Previous studies have shown that mortality does not vary significantly between patients receiving short or prolonged ECMO. Our study though having the limitations of a small sample size with majority of patients having COVID-19 ARDS, adds to existing literature showing that prolonged ECMO support can lead to recovery.

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