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TITLE
Treatment of Acute Respiratory Distress Syndrome from COVID-19 with Extracorporeal Membrane Oxygenation in Obstetric Patients

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Condensation: Treatment of acute respiratory distress syndrome from COVID-19 with extracorporeal membrane oxygenation as a rescue option for obstetric patients.

Short Title: Treatment of ARDS from COVID-19 with ECMO in Obstetric Patients

AJOG at a Glance:

A. The study was conducted to examine outcomes of pregnant and postpartum patients who are placed on ECMO for severe ARDS from COVID-19.
B. ECMO appears to be a reasonable option for critically ill obstetric patients that were otherwise unlikely to survive.
C. While there have been studies describing use of ECMO in obstetric patients, little information exists on the outcomes of ECMO for severe ARDS from COVID-19 in this patient population.

Keywords:

ARDS
COVID-19
COVID vaccination
ECMO
Postpartum
Pregnancy

ABSTRACT:

Background: Extracorporeal membrane oxygenation therapy (ECMO) has been used as a rescue therapy for patients with severe acute respiratory distress syndrome (ARDS) from COVID-19 who have failed conventional ventilatory strategies. Little is known about the outcome of pregnant and postpartum patients on ECMO.

Objectives: Describe the medical and surgical outcomes of pregnant and postpartum patients who were placed on ECMO therapy for severe ARDS from COVID-19.

Study Design: A case series reviewing pregnant or post-partum patients with laboratory confirmed COVID-19 who were placed on ECMO was conducted within the Baylor Scott & White Healthcare system. Demographics, medical, and surgical outcomes were collected and reviewed.

Results: Between March 2020 and October 2021, 5 pregnant and 5 postpartum women were supported with veno-venous ECMO. Median age was 30 (IQR 26-33.5) years and median BMI was 36.6 (IQR 29.5-42.0) kg/m^2. There was a median of 4.5 (IQR 1.5-6.8) days from admission

to any hospital to intubation and 9 (IQR 7-13) days to ECMO cannulation. One patient had an ischemic stroke, one patient had presumed hemorrhagic stroke, and nine patients developed bleeding while on ECMO. Of the five pregnant women, two patients had intrauterine fetal demise and three underwent delivery for maternal hemodynamic instability. The five postpartum women were initiated on ECMO a median of 10 (IQR 3-11) days after delivery. The median length of time on ECMO was 22 (IQR 11-31) days. At the time of the study there were two inpatient mortalities, six patients who survived to discharge to from the ECMO hospital, and two patients still admitted.

Conclusions: There is limited information regarding the use of ECMO for COVID-19 ARDS in obstetric patients. This case series describes use of ECMO and survival in pregnant and post-partum patients with COVID-19.

INTRODUCTION

Coronavirus SARS-CoV-2, the causative agent of COVID-19, has made a staggering impact worldwide to public health. While studies continue to elucidate and explore the pathophysiology of COVID-19, it has become apparent that severe forms of this disease can cause devastating and lasting insult [1-3]. Severe presentations include acute respiratory distress syndrome (ARDS) and multisystem organ failure [4]. Several studies have described the use of extracorporeal membrane oxygenation (ECMO) for patients with severe ARDS from COVID-19 that have failed conventional mechanical ventilatory strategies [5-11]. Limited reports have described successful implementation of ECMO during pregnancy for other indications [12,13]. Initial enthusiasm for ECMO as an option for obstetrical patients stemmed from encouraging observational reports during the Influenza (H1N1) epidemic in 2009 [14], but as the public health threat of COVID-19 continues to burgeon, information regarding the applicability of ECMO as a rescue therapy in obstetric patients affected by this pandemic remains scarce. We

present a case series of pregnant and postpartum patients who were placed on ECMO for severe ARDS from COVID-19.

METHODS

We describe a case series of all patients from March 2020 to October 2021 who were pregnant or up to 6 weeks postpartum and initiated on ECMO support for refractory ARDS from COVID-19 within a single healthcare system. There were 2 hospitals acting as ECMO referral centers within this system that contributed to this study. All patients had laboratory-confirmed SARS-CoV-2 infection and obstetric consultation and evaluation during their hospital admission. Patients were managed by multidisciplinary teams including medical and surgical intensivists, cardiothoracic surgeons, maternal fetal medicine, ECMO specialists, infectious disease specialists, nephrologists, and other consultants as needed. The clinical indications for ECMO, ECMO settings, and ECMO weaning strategies were guided by a system wide ECMO protocol established by the Baylor Scott & White ECMO Governance Council [8]. All patients were therapeutically anticoagulated with heparin intravenous infusion target of anti-Xa assay target of 0.2-0.4. Heparin was held for ongoing major blood loss requiring frequent transfusions with blood products [8]. It was also held for 24 hours in the case of non-fatal central nervous system bleeding and non-urgent cesarean delivery. The study was approved by the Baylor Scott & White institutional review board (#014-179).

Demographics, comorbidities, and maternal and fetal outcomes were retrospectively reviewed. Pre-ECMO initiation information was collected including length of time to from symptom onset and hospital admission to intubation and initiation of ECMO, the partial pressure of oxygen to fraction of inspired oxygen (P/F) ratio, and whether patients were intubated,

paralyzed, prone, had undergone cardiopulmonary resuscitation (CPR), or required vasopressor support. The P/F ratio characterized the severity of ARDS according to the Berlin criteria [15]. Outcomes after ECMO evaluated were incidence of tracheostomy and length of time to tracheostomy, chest tube placement, new renal replacement therapy (RRT), intensive care unit (ICU) length of stay at any facility, length of stay at the ECMO facility, length of ECMO, maternal and fetal/neonatal survival. In hospital complications including cerebrovascular accident (CVA) and bleeding were examined. Bleeding was defined as acute blood loss anemia requiring blood transfusion. Descriptive statistics are presented as median with interquartile range (IQR) and categorical variables as proportions unless otherwise specified.

RESULTS

Patients

From March 2020 to October 2021, 5 pregnant and 5 postpartum women were hospitalized and placed on ECMO support within a single healthcare system for ARDS from COVID-19. The median age of these women was 30 (IQR 26-33.5) years and median body-mass index (BMI) was 36.6 (IQR 29.5-42.0) kg/m^2. There were no active smokers. COVID treatment therapies and patients' inflammatory markers are detailed in **Table 1**. Nine of ten (90%) women in this study were confirmed to be unvaccinated against COVID-19, the last woman had an unknown vaccination status. All women were diagnosed with COVID-19 and cannulated on ECMO after vaccination became widely available in the state of Texas. Prior to being initiated on ECMO, 6 of 10 patients were (60%) were paralyzed, 1 of 10 (10%) had undergone CPR, 2 of 10 (20%) were on vasopressor support, and 3 of 10 (30%) were prone. The median P/F ratio was

60.5 (IQR 58.5-64.3). There was a median of 4.5 (IQR 1.5-6.8) days from admission to any hospital to intubation, and 9 (IQR 7-13) days to ECMO cannulation.

Maternal Characteristics

Among the five pregnant women, the gestational age at ECMO initiation was 20 weeks and 1 day, 22 weeks and 3 days, 12 weeks and 6 days, 23 weeks and 1 day, and 27 weeks, respectively. Two pregnant patients (40%) had intrauterine fetal demises within one week of ECMO cannulation. One was induced and delivered vaginally at 20 weeks and 1 day after confirmation of intrauterine fetal demise and the other had an incomplete abortion requiring dilatation and curettage at 13 weeks and 5 days. Two pregnant patients (40%) delivered periviable infants via operative delivery-one of which was performed on day 8 of ECMO for maternal hemodynamic instability, and the other shortly after ECMO cannulation due to persistent fetal decelerations refractory to positional adjustment. Both patients had multidisciplinary counseling with maternal fetal medicine and neonatology prior to intubation. One elected for no resuscitation prior to 24 weeks, the other elected full intervention, however her neonate expired shortly after delivery. The last patient underwent non-urgent cesarean delivery due to concern for maternal disseminated intravascular coagulation versus evolving hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome at 28 weeks 5 days. Her infant survived. Among the 5 postpartum women in our series, initiation of ECMO occurred at 2 to 20 days after delivery. All deliveries (100%) were via cesarean and preterm due to maternal instability. All infants of women who were cannulated postpartum are currently still alive. Ultimately, all infants delivered at a viable gestational age survived regardless of pregnant or postpartum status at time of cannulation. Two of the 8 patients (25%) who underwent

operative delivery had wound complications. One patient had a wound infection and the other developed an incisional hematoma. The obstetric history of these patients is detailed in **Table 2**.

Outcomes on ECMO

All patients were initiated on veno-venous (VV) ECMO. Initial cannulation sites of six patients (60%) were bifemoral, two patients (20%) had right femoral and left subclavian cannulation sites, and two patients (20%) had an echocardiogram guided right internal jugular dual lumen cannulation. All patients were fully anticoagulated with unfractionated heparin. Nine of ten (90%) patients had a tracheostomy performed and the median time from intubation to tracheostomy was 13 (IQR 8-16) days. The patient who did not receive a tracheostomy expired within two weeks of arrival to the ECMO center. There were four patients (40%) that required chest tube placement while on ECMO, and two patients (20%) that required initiation of RRT. Complications during hospitalization included one patient who developed ischemic stroke, one patient who had a presumed hemorrhagic stroke after acute neurological change in the setting of anticoagulation, and nine patients (90%) who had bleeding requiring transfusion of blood products. Of the 9 patients who had bleeding, three patients (33.3%) had acute blood loss anemia from thrombocytopenia, and two patients developed rectus sheath hematomas. The remaining sources of bleeding were: one from chest tube site, three from the tracheostomy site, and three from ongoing vaginal bleeding. The total median length of time on ECMO was 22 (IQR 11-31) days. There were two patients who required recannulation after initial decannulation for respiratory decline. The length of stay was a median of 28 days (IQR 17.5-46.3) in ICU care, and 31.5 (IQR 16.5-49) days at the ECMO facility. At the time of this study, there were two inpatient mortalities (25%, 2 of 8 either discharged or deceased patients), five patients who had been discharged to either a returning hospital, long term assisted care (LTAC) facility, skilled nursing

facility (SNF) or rehabilitation center, and one patient discharged home (75%, 6 of 8). Two patients are still admitted (20%, 2 of 10). These outcomes are detailed in **Table 3**.

COMMENT

Principal Findings

The existing literature regarding use of ECMO for COVID-19 ARDS in pregnant or postpartum women is scarce. Our case series describes ten patients in this category within a single healthcare system. All patients underwent VV ECMO and were cannulated according to Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome (EOLIA) criteria [16]. Seven patients have been successfully decannulated and six discharged from the ECMO facility, two patients deceased after withdrawal of care, and one patient is currently on ECMO. Comparable studies are limited mostly to case reports [17-20]. Only one other case series of more than two obstetric patients with COVID-19 managed with ECMO has been previously reported. Barrentes el al described 9 pregnant patients on ECMO with COVID-19 ARDS across multiple centers with survival of 7 patients to discharge, 2 hospitalized patients, and only one newborn death [21]. Five women in their study were cannulated postpartum, two at delivery, and two during pregnancy. Of note, all patients in their series had operative deliveries. This is consistent with the trajectory of care seen in our study. Besides the pregnant women who had intrauterine demises, the remainder of patients required operative delivery due to maternal clinical instability. Initial cannulation sites are most commonly bifemoral due to the ability to perform them emergently and safely relative to other cannulation sites. Important considerations of this strategy specific to pregnant patients include injury to the iliac vessels and inferior vena cava during cannulation, as well as the mass effect of the uterus on these structures [22]. Such

was the case of one patient in our series with a previable pregnancy, who ultimately required a resuscitative hysterotomy after ECMO cannulation due to hypotension and poor ECMO flows refractory to any positional or medical correction. Ultimately, the decision was made to preserve survival of the mother.

All newborns who were delivered beyond 24 weeks either pre- or post-ECMO cannulation survived. Our study extends and reinforces the findings of case reports and case series of successful ECMO use in pregnant or postpartum patients which demonstrate favorable survival of neonates who are viable at the time of cannulation [17-21]. In our case series, the only surviving infant from a patient placed on ECMO support during pregnancy was cannulated at a viable gestational age.

The time to intubation from admission was about 5 days, with 9 days to initiation of ECMO. This is similar to other reports of non-pregnant COVID-19 patients placed on ECMO [8]. Furthermore, all patients in our series who have survived have received tracheostomies. Our practice agrees with other groups describing non-pregnant COVID-19 patients who advocate for early planning of tracheostomy after ECMO cannulation with the goal of decreasing sedation requirements and improving pulmonary toilet [10,23]. More than half the patients in this series have been successfully decannulated from ECMO after respiratory recovery, and although the length of stay at the ECMO facility is variable, almost all patients were discharged back to their transferring hospital or to an assisted facility for ongoing ventilatory weaning and rehabilitation. This highlights the magnitude of debilitation and length of recovery patients face should they survive the initial acute phase of severe COVID-19 ARDS.

Research Implications

Although this study describes outcomes of ECMO in obstetric patients while hospitalized, further studies involving a larger cohort of patients should be pursued. Furthermore, there is a lack of knowledge regarding long term outcomes of these women and their surviving newborns. Of note, all women in our study with known vaccination status were not vaccinated against COVID-19. Early data shows increased morbidity and mortality associated with COVID-19 infection in pregnancy [24,25]. With the growing body of evidence supporting the safety of COVID-19 vaccination in pregnancy [26,27], it is essential that healthcare professionals address hesitancy and create awareness of vaccine safety in this population.

Strengths and Limitations

As this study is a case series, the ability to generalize based on the data is limited by the small size of cohort. However, this study presents the outcomes of these ten women from a unique demographic of patients affected by the COVID-19 pandemic for which we have limited understanding of the outcomes and treatment options for severe disease. Additionally, detailed follow up of the surviving neonates is scarce, therefore, the long-term survival and outcomes of these patients is unknown.

Conclusions

Although our series is limited, 6 of the 10 women who were critically ill from COVID-19 ARDS have survived to discharge with ECMO therapy. As ECMO is a resource intensive therapy, further studies with larger sample size and long term follow up are needed to navigate how to identify obstetric patients that would best benefit from ECMO therapy.

GLOSSARY:

ARDS (acute respiratory distress syndrome)

ECMO (extracorporeal membrane oxygenation)

H1N1 (Influenza A virus subtype H1N1)

P/F (partial pressure of oxygen to fraction of inspired oxygen ratio)

CPR (cardiopulmonary resuscitation)

RRT (renal replacement therapy)

ICU (intensive care unit)

CVA (cerebrovascular accident)

IQR (interquartile range)

BMI (body-mass index)

VV (veno-venous)

Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome (EOLIA)

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Table 1. Patient demographics and characteristics

	Pregnancy					Postpartum				
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
Age	29	35	31	32	34	22	29	35	25	22
Race	White	White	Black	Black	Hispanic	Black	White	White	Hispanic	Hispanic
BMI	32.2	43.1	36.7	45.4	26.45	42.8	38.4	34.8	27.04	28.62
Gestational age at ECMO initiation	12w6d	20w1d	23w1d	22w3d	27w0d	n/a	n/a	n/a	n/a	n/a
Number of days postpartum at ECMO initiation	n/a	n/a	n/a	n/a	n/a	2	3	10	11	20
Comorbidities										
HTN	No	No	No	No	No	Yes	No	No	No	No
Gestional HTN	No	No	No	No	No	No	No	No	No	No
Pre-eclampsia	No	No	No	No	No	Yes	No	No	No	No
HELPP	No	No	No	No	Yes	No	No	No	No	No
HLD	No	No	No	No	No	No	No	No	No	No

DM	No	No	No	No	No	No	Yes	No	No	No
Gestional Diabetes	No	No	No	No	No	No	No	No	No	No
COPD	No	No	No	No	No	No	No	No	No	No
Active Smoking	No	No	No	No	No	No	No	No	No	No
Received COVID vaccination	No	n/a	No	No	No	No	No	No	No	No
Fibrinogen	n/a	80	357	232	543	214	131	n/a	553	573
Ferritin	654	593	349	49	66	125	88	2778	1363	106
LDH	667	>4000	585	416	487	433	214	334	n/a	398
Lactic Acid	1.7	14.8	2.9	2	1.1	0.9	2.5	0.8	1.4	1.5
Procalcitonin	1.1	0.2	0.1	0.1	0.2	0.1	0.1	0.2	1.0	0.3
Time from symptoms onset to intubation (d)	15	10	7	19	14	21	13	7	8	11
Time from admission to intubation (d)	7	3	0	17	9	5	6	1	13	21
Time from symptom onset to ECLS (d)	15	10	10	19	14	23	26	19	17	31
Time from admission to ECLS (d)	7	3	3	17	9	7	9	13	13	21
Paralyzed	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
Proned	No	Yes	Yes	No	No	No	No	No	No	Yes
CPR	No	Yes	No	No	No	No	No	No	No	No
Intubate	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

d										
Vasopressors	No	Yes	No	No	No	No	No	No	Yes	No
PF ratio prior to cannulation	60	62	75	58	65	79	56	60	43	61
Covid treatment therapy received	remdesivir, dexamethasone, rocephin	remdesivir, dexamethasone	remdesivir, tocilizumab, dexamethasone	remdesivir, rocephin, methylprednisolone	remdesivir, dexamethasone, ceftriaxone	remdesivir, tocilizumab, rocephin, dexamethasone	remdesivir, tocilizumab, cefepime, linezolid, dexamethasone	vancomycin, cefepime, methylprednisolone	dexamethasone, tocilizumab, azithromycin, cefepime	remdesivir, dexamethasone, azithromycin, ceftriaxone
ECMO type	VV	VV	VV	VV	VV	VV	VV	VV	VV	VV
Cannulation sites	right internal jugular	bifemoral	bifemoral	left subclavian, right femoral	bifemoral	bifemoral	left subclavian, right femoral	bifemoral	bifemoral	bifemoral

n/a (not available); BMI (body mass index); y (years); w (weeks); d (days); ECMO (extracorporeal membrane oxygenation); CRP (C-reactive protein), LDH (lactate dehydrogenase); HTN (hypertension); HELLP (hemolysis, elevated liver enzymes, low platelet count); (HLD (hyperlipidemia); DM (diabetes mellitus); COPD (chronic obstructive pulmonary disease); CPR (cardiopulmonary resuscitation); P/F ratio (PaO2/FiO2)

Table 2. Obstetric Events

	Pregnancy					Postpartum				
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
Gravida Para	2/1	1/0	2/1	4/3	4/3	n/a	3/3	n/a	4/3	4/4
Gestational age at delivery	13w5d	20w1d	23w1d	23w5d	28w0d	26w0d	28w0d	30w0d	30w0d	35w5d
Delivery method	spontaneous abortion	spontaneous abortion	resuscitative hysterotomy	resuscitative hysterotomy	resuscitative hysterotomy	resuscitative hysterotomy	resuscitative hysterotomy	C-section	C-section	resuscitative hysterotomy
Estimated blood loss during operative delivery (mL)	n/a	n/a	500	500	1200	n/a	n/a	n/a	n/a	n/a
Wound Complications	n/a	n/a	No	Yes	No	Yes	No	No	No	No
Intrauterine fetal demise	Yes	Yes	No	No	No	No	No	No	No	No
Infant death	-	-	Yes	Yes	No	No	No	No	No	No

n/a (not available); w (weeks); d (days); D&C (dilation and curettage); ICU (intensive care unit). Bold line represents viable gestational age. All newborns of patients who were of viable gestational age at delivery survived.

Table 3. ECMO Outcomes

	Pregnancy					Postpartum				
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
Tracheostomy	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Time from intubation to tracheostomy (days)	3	n/a	10	16	8	13	7	14	17	21
Concurrent interventions										
Chest tube	No	Yes	No	Yes	No	No	No	Yes	Yes	No
RRT	Yes	Yes	No	No	No	No	No	No	No	No
Complications										
Bleeding	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
CVA	Yes	Yes	No	No	No	No	No	No	No	No
Length of ECLS (days)	11	16	n/a	37	28	5	6	43	22	n/a
In hospital mortality	Yes	Yes	n/a	No	No	No	No	No	No	n/a
ICU LOS	16	18	n/a	44	53	22	7	59	34	n/a
ECMO center LOS	17	15	n/a	45	61	20	7	78	43	n/a
Discharge disposition	deceased	deceased	n/a	LTAC	IPR	LTAC	Other hospital	SNF	Home	n/a

n/a (not available); RRT (renal replacement therapy); ECMO (extracorporeal membrane oxygenation); CVA (cerebrovascular accident); ICU (intensive care unit); LOS (length of stay); VV (venovenous); LTAC (long term assisted care facility); IPR (inpatient rehabilitation)