

## Research Article

# Safety of the Use of Extracorporeal Membrane Oxygenators in Covid 19 Positive Patients with Regards to the Providers and the Institutional Environment

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## Abstract

**Background:** Respiratory failure due to the coronavirus presents a new indication for the use of Extracorporeal Membrane Oxygenation (ECMO). Recent studies have shown the ability for the coronavirus to aerosolize during plasma leakage from an oxygenator. The primary objective of this study is to determine if the gas exhaust ports of oxygenators supporting COVID positive patients are aerosolizing the coronavirus. The secondary objective is to evaluate the risk to staff caring for COVID positive patients requiring ECMO support.

**Methods:** Patient plasma, Nasopharyngeal (NP), and oxygenator samples were tested intermittently throughout the duration of ECMO support. Staff was tested prior to cannulation and 72 hours after decannulation.

**Results:** Nineteen oxygenator tests were performed on 3 patients and 5 oxygenators resulting in no positive cultures. Thirty-one staff members completed the study with tests resulting in no positive cultures.

**Conclusion:** This study found no evidence of aerosolization from the oxygenator exhaust and no staff members contracted COVID after caring for these patients.

**Keywords:** Oxygenator; Aerosolization; Covid 19

## Abbreviations

ECMO: Extracorporeal Membrane Oxygenation; NP: Nasopharyngeal; FDA: Food and Drug Administration; CSICU: Cardiac Surgery Intensive Care Unit; PPE: Personal Protective Equipment; PCR: Polymerase Chain Reaction; QRTRT: Qualitative Real-Time Reverse Transcriptase; ARDS: Acute Respiratory Distress Syndrome; ELSO: Extracorporeal Life Support Organization

## Introduction

Respiratory failure from the corona virus represents a new indication for the use of Extracorporeal Membrane Oxygenation (ECMO) as a lifesaving therapy. However, the protection and safety of providers and staff from the aerosolization of the corona virus that the present literature implies raises much concern [1]. The review of the literature presents 2 case reports of plasma leakage from the polymethyl pentene oxygenator [2,3]. Also, due to the reported evidence of virus found in respiratory droplets, blood, plasma, and

other body fluids, has been generalized to the rare plasma leakage from the polymethyl pentene oxygenator and aerosolization of the virus [1,4,5]. This is of such concern, that it has been recommended that scavenging the gas outlet ports in Covid+ cases during the public health crisis in conjunction with the Food and Drug Administration (FDA) guidance in extended use of the oxygenators be practiced [1]. This modification has suspended cannulation in any area of the institution other than a negative pressure room in the Cardiac Surgery Intensive Care Unit (CSICU) with the gas scavenging system in place.

The purpose of this study is to determine if the gas outlet ports are in fact aerosolizing the virus that will warrant continued scavenging beyond the crisis. The second objective is to evaluate risk to the providers and nursing staff that provide care to these highly labor intensive and profoundly decompensated cases that require ECMO support.

## Materials and Methods

After careful multidisciplinary consideration and adherence to a strict set of guidelines for patient selection, (Table 1), the initiation of ECMO was performed in a negative pressure room with the pump modification of a scavenging system for pump exhaust. This consisted of suction tubing from the gas outlet port of the membrane oxygenator connected to a closed suction collection canister. The equipment that was used was the Cardio help system HLS 7.0 Quadrox oxygenator (Maquet Cardiopulmonary GmbH, Rastatt, Germany). Duration of pump therapy per oxygenator was between 12 and 31 days in 3 patients and 5 oxygenators due to 2 oxygenator failures at 29, and 12 days.

The oxygenator outlet ports were swabbed frequently throughout the pump run to determine if the aging oxygenator presents a risk of aerosolization of the corona virus. The initial case oxygenator

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was swabbed daily. The subsequent oxygenators were swabbed intermittently. All oxygenators were swabbed on the day of decannulation.

Reduction of exposure to the sickest of the Covid patients to the staff was managed by monitored donning and doffing of Personal Protective Equipment (PPE), minimizing to essential activity in the room, ventilator and medication management outside the room, and visibility of the ECMO and hemodynamic monitors through a glass door. In addition, placards were posted outside the room for a constant reminder to facilitate meticulous entering and existing the room.

Two voluntary swabs of staff consisting of Providers, Perfusionists, ECMO specialist, and the Nursing staff that were directly involved in the care of the ECMO supported Covid patients were taken. The staff was observed by a room Monitor to assure appropriate donning and doffing of PPE. One swab was collected prior to exposure to the room and the second swab collected after 72 hours post decannulation.

Methodology for testing Covid swabs was by qualitative real-time reverse transcriptase Polymerase Chain Reaction (PCR).

This study (HM20019372) was submitted to the Institutional Review Board at the Virginia Commonwealth University. On 5.21.2020, this study involving the research use of human subjects was approved according to 45 CFR 46.108(b) by VCU IRB Panel A.

## Results

There were 3 patients that tested positive for Covid 19 that met criteria for ECMO therapy. There were 100 total days of pump use that 19 samples were collected from 5 oxygenators including the day of decannulation. All 19 swabs were 100% negative.

Thirty-seven staff members were swabbed at study onset and were 100% negative. Thirty-one staff members completed the second swab with 100% negativity.

All patients' plasma tested negative by PCR method. There were 2 deaths, and 1 discharge to the previous living environment. One patient converted to Covid negative on day 37. This patient tested positive for heparin induced platelet antibody, however serotonin release assay was negative. In addition, this patient has required oxygenator changes at about every 2 weeks due to clotting and increasing pressure gradient across the oxygenator (Table 2).

**Table 1:** Criteria for ECMO support in the Covid 19 patient.

Age <55
BMI <35
No Codes
<2 life supporting medications
Length of intubation <5 days.
Multidisciplinary decision making for ECMO need.

**Table 2:** Covid 19 that met criteria for ECMO therapy.

Patient	NP swab PCR	Plasma swab PCR	Oxygenator swab PCR	Outcomes	HITT SRA
1	Positive	Negative	Negative 14 days 2 Oxygenators	Discharge	-
2	Positive	Negative	Negative 29 days Negative 31 days 2 Oxygenators	Death	-
3	Positive Negative Day 37	Negative	Negative 12 days Negative 14 days	Death	±

## Discussion

In this study, 100 days of 5 oxygenators ranging from 12 days to 31 days of continuous pump runs were tested and found to be negative for the Covid virus. There were 31 providers and caregivers that completed the study and all pre and post cannulation swabs were negative. This part of the study was discontinued due to immunization of the staff and for conservation of swabs and resources.

A previous study by Martin Dres et al. [6] which concurs with this study tested 27 patients for the first 48 hours and concluded that there was no dissemination through the oxygenator membrane.

Although this is a limited study in cases, samples taken were found to be negative throughout the life of the oxygenators. There was no contamination of the environment from the gas outlet ports of the oxygenators. In addition, with the proper use of PPE, no staff members contracted the Covid virus from exposure to these patients.

## Conclusion

ECMO has provided a valuable life support for ARDS from multiple causes. Since the Covid 19 crisis, ECMO has been used successfully with about 50% survival as published by the ELSO organization. Significant concerns for protection of institutional environment and provider/caregiver safety raised the issue of aerosolization of the virus by the gas outlet ports of the aging oxygenator.

Although this is a limited study by cases, there was no contamination of the environment from the gas outlet ports throughout the life of the oxygenators. In addition, with the proper use of PPE, and meticulous adherence to reduced exposure practices, no staff members contracted the Covid virus from exposure to ECMO supported patients.

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