# HEMOLUNG RAS

Use of ECCO<sub>2</sub>R with the Hemolung RAS in the Treatment of Severe Hypercaphic Respiratory Failure Caused by SARS-CoV-2 Acute Lung Injury

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This report describes the case of a 57-year-old male with COVID-19 who was transferred to our facility for consideration of treatment with ECMO. The patient was maintaining acceptable levels of oxygenation but was severely hypercapnic with a  $PaCO_2$  of 188 mmHg refractory to ventilation adjustments. Instead of ECMO, the patient was treated with extracorporeal  $CO_2$  removal (ECCO<sub>2</sub>R) via percutaneous insertion of a 15.5 French central venous catheter and low blood flows of only 500 mL/min. The patient was anticoagulated with argatroban during therapy to achieve standard anticoagulation levels for extracorporeal life support. The Hemolung device provided rapid and safe reduction in  $PaCO_2$  and normalization of pH within a short time and with a comparatively small catheter and performed without complications.

### Introduction

The COVID-19 pandemic has brought about an urgent need for effective treatment of the critically ill while conserving vital resources such as ICU beds and ventilators. The search for effective treatment is underway worldwide. The COVID-19 ARDS, as it has been labeled, clearly does not fit the standard ARDS definitions or characteristics. Patients with COVID-19 demonstrate relatively high lung compliance, suggesting well-preserved lung gas volume, in sharp contrast to what is traditionally seen in severe ARDS. The clinical hallmarks of ARDS, according to the Berlin Criteria. are hypoxemia and bilateral radiographic opacities associated with increased venous admixture, increased physiological dead space, and decreased lung compliance. The morphological hallmark of ARDS in the acute phase is diffuse alveolar damage [1].

Treatment of acute lung injury associated with severe COVID-19 is an ongoing challenge with little consensus on how best to ventilate this patient population. Extracorporeal membrane oxygenation (ECMO) has been used as a rescue therapy in those with severe hypoxic respiratory failure for whom inhaled nitric oxide, prone positioning and pushing of mean airway pressures have failed [2].

Hypercapnic respiratory failure has not been widely described, but we report the case of a patient with COVID-19 Lung Injury who developed severe hypercapnia despite ventilation adjustments, while oxygenation was able to be maintained within acceptable levels. This patient was successfully treated with low flow extracorporeal carbon dioxide removal (ECCO<sub>2</sub>R) until CO<sub>2</sub> ventilation could be safely managed with mechanical ventilation.



### **Case Report**

A 57-year-old male with prior medical history of hypertension initially presented to a local hospital with shortness of breath and fever, then was eventually intubated for hypoxic respiratory failure with chest x-ray findings of atypical pneumonia. He was also placed in prone position. He completed treatment for 5 days with Plaquenil and azithromycin.

On the sixth day, the patient developed severe hypercapnia in spite of numerous ventilator adjustments. He was subsequently transferred to Ochsner/LSU Academic Medical Center for consideration of ECMO. Upon arrival to the COVID-19 ICU, the patient remained in prone position. The initial arterial blood gas measure returned with pH=6.98, PCO<sub>2</sub>=188 mmHg,  $PO_2=93.4$  mmHg, and  $HCO_3=28$ mEq/L. Because of the acceptable oxygen level, the patient was considered for treatment with an extracorporeal carbon dioxide removal (ECCO<sub>2</sub>R) device instead of ECMO. In contrast to ECMO, ECCO<sub>2</sub>R can be administered with lower extracorporeal flows and a smaller central venous catheter. An investigational device called the Hemolung Respiratory Assist System was utilized to provide ECCO<sub>2</sub>R therapy in accordance with FDA Emergency Use guidelines after receiving approval from our IRB device manufacturer and the (ALung Technologies, Pittsburgh, PA, USA).

The patient was rolled on to supine position to briefly insert the Hemolung 15.5 French Catheter via the right internal jugular vein into the superior vena cava under ultrasound. The patient was returned to prone position after which the primed Hemolung circuit was connected to the catheter and blood pump turned on. The centrifugal pump speed was set to 1300 rpms achieving an extracorporeal blood flow of 420 mL/min. The initial sweep gas flow using room air was 1 L/min and shortly after was raised to 2.5 L/min. Under these settings, the rate of  $CO_2$  removal measured and displayed by the Hemolung system was 58 ml/min. The patient was anticoagulated with argatroban per our institutional protocol for extracorporeal life support (ECLS). The sweep was then increased to 3.0 L/min and blood flow to 500 mL/min which increased the  $CO_2$  removal to a range of 80-110 mL/min. Maximum sweep gas flow with this ECCO<sub>2</sub>R system is 10 L/min, but higher levels of CO<sub>2</sub> removal were not required.

**Figure 1** shows the progression of  $ECCO_2R$  therapy during the first 48 hours of therapy where the  $CO_2$  removal rate is controlled by the set sweep gas flow and blood flow is controlled by the set pump speed. Independently of sweep gas flow, the  $CO_2$  removal rate is also directly proportional to the patient's  $PCO_2$ . **Figure 2** includes graphs of  $PaCO_2$  and pH during the first 48 hours of therapy.

#### Figure 1



Hemolung system data showing set sweep gas flow and corresponding  $CO_2$  removal rate (top) and set motor speed and corresponding blood flow (bottom) for first 48 hours of therapy.





Arterial measures of  $PCO_2$ , pH, and bicarbonate during the first 48 hours of  $ECCO_2R$  therapy.

 $PaCO_2$  fell from 123 mmHg just before starting  $ECCO_2R$  to 88 mmHg after just one hour and settled to the range of 45-50 mmHg during the second day. Correspondingly, pH was also increased from 7.189 just before therapy to normal range. As  $PCO_2$  fell, the  $CO_2$ removal rate also dropped and stabilized.

The ventilator during this time remained unchanged except for some advancement in mean airway pressure and  $FiO_2$  adjustments. During this timeframe, the patient's ventilator settings were PEEP of 20 cmH<sub>2</sub>O, rate of 15, and minute ventilation (MV) of 2.9 liters. The respiratory rate was adjusted without significant change in MV. After the 48-hour mark of being on the Hemolung with essentially the same ventilator settings (except of  $FiO_2$  adjustments due to changes in oxygen requirements), the MV began to improve with a rise at the 72-hour mark of up to 8.4 liters. After 96-hours, there was again a decline in minute volume felt to be secondary to positive fluid balance.

The patient was placed on an aggressive CRRT prescription with an ultrafiltrate rate of 100 cc/hour net fluid removal. Five days after initiation of ECCO<sub>2</sub>R, the minute volume rose to 10-11 L/min and remained stable. The sweep gas on the Hemolung was weaned to zero to trial cessation of ECCO<sub>2</sub>R support (while blood flow was continued). The arterial blood gas showed the patient was able to maintain a PaCO<sub>2</sub> of 45-55 mmHg with an acceptable pH. The patient was maintained on the Hemolung with no sweep for an additional 24 hours. At that point, the ABG revealed a pH = 7.317, PaCO<sub>2</sub> = 48 mmHg, HCO<sub>3</sub> = 22 mEq/L, and Sat = 95%. The Hemolung was then disconnected and the catheter removed without incident.

The total duration of ECCO<sub>2</sub>R therapy with the Hemolung was 6 days. We experienced no complications with either the Hemolung system or the catheter. No circuit components required replacement during this time. We did observe that after 4 hours of the patient being placed on the Hemolung, the level of plasma-free hemoglobin was measured to be 200 mg/dL. However, there were no changes in circuit dynamic, no visibile thrombosis and no change in urine color. This prompted an immediate repeat level which was normal. Because nothing was changed from the level reported at 200 to the repeat of 40, the level of 200 was felt to be lab error which was confirmed with subsequent daily measurements which never rose above 60 mg/dL. No additional clinical manifestations of hemolysis were observed.

In addition to  $ECCO_2R$  therapy and proning, the patient also received therapeutic plasma exchange (1500 mL fresh frozen plasma) and 500 mL of convalescent serum. The patient was successfully weaned from mechanical ventilation after 39 days of support with the help of  $ECCO_2R$ .

### Conclusion

The extracorporeal  $CO_2$  removal capabilities of the Hemolung enabled delivery of lung protective ventilation, significant correction of  $PaCO_2$  and normalization of pH without the complexities associated with ECMO. We found no issues with the circuit or the catheter designed for the Hemolung. Without this additional tool in the arsenal of treatment options for the unpredictable presentation of COVID-19, this patient would likely not have survived.

#### **References:**

[1] Phua J, Stewart TE, Ferguson ND. Acute respiratory distress syndrome 40 years later: time to revisit its definition. Crit Care Med. 2008;36(10):2912-292118766113.

[2] Ramanathan K Antognini D, Combes A et al.Planning and provision of ECMO services for severe ARDS during the COVID-19 pandemic and other outbreaks of emerging infectious diseases. Lancet Respir Med. 2020; (published online March 20.)

#### About the Hemolung RAS\*

The Hemolung RAS from ALung Technologies provides Respiratory Dialysis<sup>®</sup>, a simple, minimally-invasive form of extracorporeal carbon dioxide removal (ECCO<sub>2</sub>R). The system utilizes patented technology to provide highly efficient CO<sub>2</sub> removal at dialysis-like blood flow rates which are achieved through a single 15.5 Fr venous catheter.

For more information, on the use of the Hemolung RAS for COVID-19, refer to the following websites:

In the United States: www.alung.com/covid-19/covid-19-us

In the United Kingdom and Ireland: www.alung.com/covid-19/covid-19-uk

- \* The Hemolung RAS has not been FDA cleared or approved;
- \* The Hemolung RAS has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for patients with COVID-19;
- \* FDA authorization for emergency use in patients with COVID-19 is only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Hemolung RAS under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner;
- \* The Hemolung RAS has CE Marking and is cleared for use in the EU and UK in accordance with the Instructions for Use (IFU).



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