New Alternatives for Acute Respiratory Therapy

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Acute respiratory failure is not uncommon and can occur from a variety of causes to people of all ages. Chronic obstructive pulmonary disease (COPD) and acute respiratory distress syndrome (ARDS) are just two of many reasons why a patient may experience respiratory failure and require invasive mechanical ventilation (IMV). Approximately 13.7 million people in the United States are living with COPD, and ARDS averages approximately 160,000 cases per year. While IMV has proven to be an indispensable therapy for persons undergoing such incidents, an increased understanding of further lung injury that can in fact be caused by the ventilator has led to a shift in the paradigms for providing respiratory support. A new device offers a minimally invasive option for respiratory support that may allow patients to either avoid IMV or mitigate its injurious side effects.

Impact of Mechanical Ventilation

The side effects of IMV are broad and varied. Barotrauma, oxygen toxicity and hemodynamic compromise are examples of actual damage to the lungs that can result from IMV and which are associated with higher morbidity and mortality. These complications, as well as weakened diaphragm muscles due to lack of use, may also increase patient dependency on the ventilator, making it hard for the patient to wean. Intubation with an endotracheal tube is another significant drawback of IMV. Sedation and analgesics, with all their attending risks, are needed to alleviate the pain and discomfort of intubation. In addition, patients are unable to feed themselves, speak or engage in any helpful physical therapy, thereby diminishing quality of life.

When to Remove CO$_2$

IMV aims to provide adequate oxygenation and carbon dioxide CO$_2$ removal while allowing the respiratory muscles to heal. However, under certain conditions of respiratory failure, the primary obstacle to adequate respiratory support is CO$_2$ removal, rather than oxygenation. This is primarily true in COPD patients who are experiencing an acute exacerbation. If CO$_2$ removal can be assisted by less invasive measures, IMV can be avoided. For COPD patients, non-invasive ventilation with a mask is often able to achieve this goal, but for many, non-invasive ventilation is inadequate or intolerable.

ARDS can occur in patients of any age and can result from many causes, most often pneumonia, sepsis, or from shock due to severe injury and blood loss. Any of these situations presents a perfect Catch 22 scenario. ARDS patients will not survive without IMV, but traditional methods providing respiratory support with IMV have been shown to actually increase mortality. Reducing the volume of air that a ventilator forces into the lungs was found to ameliorate the damage caused by IMV, but this form of lung-protective ventilation can only be achieved at the expense of inadequate CO$_2$ removal, often resulting in dangerously high levels of CO$_2$ in the blood. ARDS patients can benefit from CO$_2$ removal as a means of facilitating IMV settings which are gentler on the lungs.

Pitfalls with ECMO

Extracorporeal Membrane Oxygenation (ECMO) is the final option for respiratory life support in patients with ARDS, when all other methods are failing, including IMV. ECMO is a device that removes deoxygenated blood
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from the body, oxygenates it, and returns it to circulation. To meet the full oxygenation demands of the body requires a highly invasive procedure associated with risks that only warrant its use in patients not likely to survive mechanical ventilation. Interestingly, there is not a complete ECMO device approved by the US FDA. A very specialized team of experts must compile separate components — a pump, an oxygenator and a heat exchanger — and coordinate their use in an off-label manner. The procedure is considered highly invasive because it requires the insertion of two large catheters, and high levels of blood flow (3-6 liters per minute) to be pumped through the ECMO circuit.

An Extracorporeal Alternative

The Hemolung Respiratory Assist System (ALung Technologies, Inc., Pittsburgh, PA) is a newcomer to the field that potentially addresses both the issue of CO$_2$ removal as well as the highly invasive nature of traditional IMV and ECMO. Using techniques similar to renal dialysis, the Hemolung RAS provides extracorporeal CO$_2$ removal (ECCO$_2$R) in an effective and minimally invasive way. The Hemolung RAS uses an approach like ECMO, but with substantially lower blood flows (less than half a liter per minute) and only a single, much smaller catheter. Unlike ECMO, there is only one component in the circuit, and it is operated from a single, user-friendly control unit, making it the only fully integrated system on the market.

The single circuit component of the Hemolung RAS is a cartridge, about the size and shape of a one quart can of paint, that contains both gas exchange membranes and a centrifugal pump. The unique design of this cartridge is based on a hollow, spinning, cylindrical core which both pumps the blood and creates enhanced mixing of blood flow near the membranes to maximize the efficiency of CO$_2$ removal. The Hemolung RAS is the only gas exchange device to employ active mixing.

The increased efficiency achieved with active mixing allows for a reduced membrane surface area necessary to achieve effective levels of CO$_2$ removal without requiring dangerously high blood flows.

The gas exchange membranes are hollow fibers which are arranged in a cylindrical bundle around the spinning core. The fibers are manifolded such that oxygen gas can be drawn through the fiber lumens with a vacuum pump. When blood flowing through the cartridge passes around the hollow fibers, CO$_2$ diffuses from the blood, across the membrane wall, and into the oxygen flowing through the fiber lumens. Oxygen also diffuses in the opposite direction into the blood, but at a lower rate than CO$_2$.

The Hemolung uses a 15.5 Fr dual-lumen catheter to access the venous circulation, which is inserted either through the femoral vein or the right jugular vein. Blood is drawn into the outer lumen of the catheter through the annular region around the inner lumen. After passing through the cartridge, decarbonated blood is returned via the circular inner lumen. The catheter employs wire reinforcements, enabling thinner walls and higher flow rates.
than standard hemodialysis catheters. The integrated Hemolung controller operates the cartridge pump, drives sweep gas through the membranes, continuously measures CO\textsubscript{2} removal and provides safety monitoring.

The Hemolung RAS is the only device specifically designed for CO\textsubscript{2} removal, a key differentiation among extracorporeal therapy techniques. It is possible to achieve clinically meaningful levels of CO\textsubscript{2} removal at much lower blood flows than are necessary for meaningful oxygenation. The Hemolung RAS removes CO\textsubscript{2} at a rate of 50 to 100 mL/min, using a blood flow rate of 350 to 500 mL/min. The active mixing technology enhances gas exchange 150% over passive diffusion devices, and the entire system is battery operated, allowing the patient to ambulate.

The Future
The regulatory process in the US requires large, pivotal clinical trials, which are currently in the works. In the meantime, the device has been approved for use in the European Union, Canada, and in Australia on a limited basis. Its use in these countries is influencing the paradigm of care for patients with hypercapnic respiratory failure. There is a need for devices that are minimally invasive, that can be used earlier in the treatment paradigm, and that can be made available to a greater percentage of the population. The Hemolung RAS appears to offer all of these benefits.

About the Author
This article is written by Dr. Laura Lund, Director of Scientific Affairs at ALung Technologies, in response to Medgadget’s invitation to explain the nature of the company’s Hemolung CO\textsubscript{2} removal technology and how it can benefit patients.

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About the Hemolung RAS
The Hemolung RAS from ALung Technologies provides Respiratory Dialysis\textsuperscript{®}, a simple, minimally-invasive form of extracorporeal carbon dioxide removal (ECCO\textsubscript{2}R). The system utilizes patented technology to provide highly efficient CO\textsubscript{2} removal at dialysis-like blood flow rates which are achieved through a single 15.5 Fr venous catheter. For more information, please visit http://www.alung.com.
