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A DEVICE FOR IMPROVING OXYGENATION IN PATIENTS WITH ACUTE RESPIRATORY DISTRESS SYNDROME

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ABSTRACT

In this paper we present a device for improving blood oxygenation in patients with Acute Respiratory Distress Syndrome (ARDS). ARDS is caused by lung-related illness or injury, and can occur in mechanically ventilated ICU patients due to volutrauma or barotrauma. In ARDS, the lower lung is closed resulting in impaired gas exchange, and the upper lung is easily overstretched resulting in injury. The application of continuous negative abdominal pressure (CNAP) assists in opening the lower lung by pulling the diaphragm towards the abdomen. The device, consisting of a rigid arch, a compliant patient interface, and a pressure sensor module, allows for the application of CNAP to a patient suffering from ARDS.

An initial pig trial using the prototype device showed significant improvement in the ratio of oxygen in the blood to the fraction of inspired oxygen, PaO_2/FiO_2, after five minutes of -5 cmH2O pressure application. Furthermore, preliminary testing on healthy humans indicated the device was comfortable, easy to apply, and formed a consistent airtight seal. Future prototypes will focus on ease of application, rigidity, and adjustability.

INTRODUCTION

Acute Respiratory Distress Syndrome (ARDS) is an inflammatory lung condition in which gas exchange is impaired, resulting in hypoxemia. The severity of ARDS can be determined by the ratio of oxygen in the blood (PaO_2) to the fraction of inspired oxygen (FiO_2), where severe ARDS is classified as $PaO_2/FiO_2 \leq 100$ mmHg, moderate as 100 - $\leq$ 200 mmHg, and mild as 200 - $\leq$ 300 mmHg [1]. ARDS develops as a result of lung-related illness or injury; leading causes include pneumonia, aspiration, sepsis, and trauma. The syndrome is associated with a 28-day mortality rate of between 20-40% [2]. Among ICU patients, patients with ARDS are less likely to make a full recovery, with long term effects such as muscle loss, general weakness, and neuropsychiatric illness including cognitive impairment and depression [3].

Patients in the ICU are often mechanically ventilated, which can contribute to the development and/or worsening of ARDS due to the delivery of excessive volume (volutrauma) or excessive pressure (barotrauma) [1]. ARDS patients are typically nursed on their backs, resulting in the collapse of the lower lungs due to pressure from the heart and abdominal contents; in this position, the breath from the ventilator goes primarily to the upper part of the lung. However, because this 'open' lung is small, it is easily overstretched and injured. Despite recent advancements in ventilation protocols, ARDS prevalence remains high at an estimated 34 incidences per 100,000 patients in the USA [4]. Positive end-expiratory pressure (PEEP) is a common component of mechanical ventilation to prevent further alveoli collapse by maintaining positive airway pressure through the entire ventilation cycle.

To address the shortcoming of mechanical ventilation, a device was developed to deliver continuous negative abdominal pressure (CNAP) in conjunction with PEEP to minimize collapse in the lower lungs, resulting in reduced localized stretching and lung injury. Prior approaches to this by other groups have failed [5-6], likely due to inadequate containment of the abdominal wall surface, thereby incompletely applying negative pressure to the abdomen. We have previously demonstrated a proof of concept in animal studies [7] and have

shown that the approach is fundamentally different to simply increasing the degree of PEEP [8].

To the best of our knowledge, no device exists that applies negative pressure to the entirety of the abdomen. The cuirass ventilator is an existing device also used for the application of negative pressure. However, the cuirass is intended primarily for biphasic pressure ventilation, and applies pressure to both the patient's chest and abdomen, making it unsuitable for CNAP. The device presented here also intends to address a number of cuirass limitations: (1) negative pressure is applied to the front of the abdomen and chest but does not encompass the patient's circumference, (2) several cuirass sizes are required in order to fit various patients, and (3) most cuirass devices are equipped with ventilators, making them more expensive and ill-suited for continuous negative pressure. Alternately, negative pressures in the proposed device can be generated via any sufficiently powerful suction source commonly installed in hospitals.

In this paper, we present a device intended to improve oxygenation in patients with ARDS via continuous application of negative pressure to the abdomen. The design and fabrication of the device will be discussed, in addition to initial results from an animal trial.

METHODS

The design is composed of three main sub-assemblies: a rigid arch, a compliant patient interface, and a pressure sensor module (Fig. 1). The rigid arch is placed over the patient's abdomen, and provides the structural support necessary for containing the negative pressure. A tube of thin, flexible plastic sheeting is then placed around the patient and the arch structure. The plastic is tightened onto the patient, creating an enclosed chamber; air is then removed from the chamber to create negative pressure. The sensor module provides a reading of the negative pressure inside the device. The components of each sub-assembly are described below.

Rigid Arch: The rigid arch is composed of five rectangular panels of transparent polycarbonate plastic which are supported by aluminum rods and ABS braces. The five panels are oriented so that they form a supporting arch around the patient's body while lying down. These braces act as connections between the aluminum rods and plastic panels. The structure provides rigid support for the plastic sheeting as it collapses due to the induced negative pressure.

Compliant Patient Interface: The main component of the compliant patient interface system is a tube of plastic sheeting that fits around the device and is tightened onto the patient. In order to create a seal around the abdomen, the sheeting fits around the patient at two locations: at the lower end of the thorax (approximately at the xiphoid level), and at the pelvis. The plastic is fastened onto two strips of cushioning memory foam that are attached to the patient using hook-and-loop fasteners. This addresses the first and second cuirass limitations.

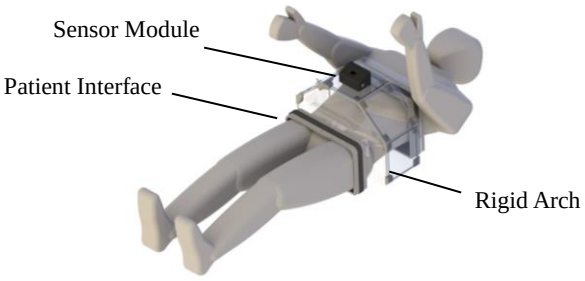

Figure 1. Diagram of CNAP device fitted on a mannequin

Pressure Sensor Module: A negative pressure sensor module was developed to monitor the pressure inside the device. A Honeywell TruStability © differential pressure sensor measures pressures in the range of +/- 12.7 cmH2O; a tube is connected to one prong of the sensor and inserted inside the chamber. Data from the sensor is received by an Arduino Uno (Rev3) and displayed on a 0.96" OLED display. An electronic buzzer is programmed to produce an alarm if the negative pressure exceeds a pre-defined amount; for initial experiments, the alarm was activated if the pressure fell below -6 cmH2O. The Arduino is powered by an external, rechargeable 4500 mAh 5 V battery pack. The sensor module is housed in a custom 3D printed case (FormLabs).

Patient Application Procedure: To fit the device to a supine patient, memory foam strips are first fitted around the patient using hook-and-loop straps, against the patient's skin, gown, or clothing at the two locations described above. The rigid arch is then placed over the patient. Next, the tube of plastic sheeting is fitted around the patient's feet and moved up into position around the arch structure. Additional hook-and-loop straps are then wrapped around the flexible plastic sheeting and fastened onto the memory foam to create an airtight seal. The plastic is then punctured in two locations: (1) to insert a plastic barb which is connected to the suction source, and (2) to insert the pressure sensor tube.

RESULTS

The CNAP method was validated in a previous study by our group [8]; however, the original device used was not suitable for clinical testing, as it was built specifically for animal trials. To validate the prototype device described in this paper, a single Yorkshire pig study was performed. Institutional approval (conforming to the Canadian Council on Animal Care) was obtained for all animal experiments. The results of this trial, which compared CNAP+PEEP to PEEP alone, showed that the device produced the same effect as described in [8]. The pig, an ARDS model [8] (surfactant depleted and high stretch ventilation), was ventilated with 100% oxygen (FiO_2=1.0). This differs from standard healthy human ventilation with room air (FiO_2=0.21).

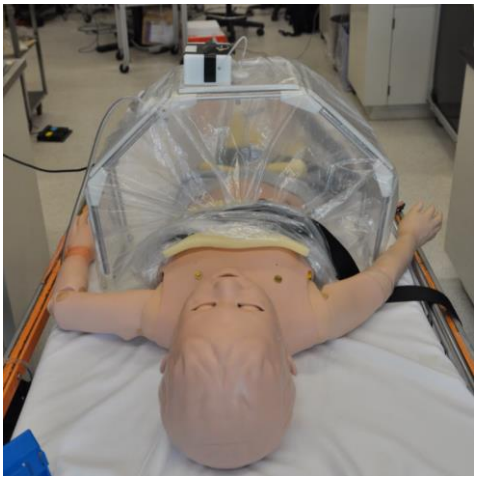

Figure 2. Continuous negative pressure mannequin testing

After five minutes of CNAP (-5 cmH_2O) application, oxygen blood gas levels in the pig increased from 125 PaO_2/FiO_2 (PEEP alone) to 438 PaO_2/FiO_2 (PEEP+CNAP), an increase by a factor of 3.5. A radiometer ABL800 Flex blood gas analyzer was used to test blood gas values.

A research ethics approved pilot study was conducted on healthy human adults which showed CNAP was able to form an airtight seal around the lower abdomen and maintain a -5 cmH_2O reading. There was no impact or changes to the CNAP structure. To ensure patient safety, the device was subjected to continuous pressure testing: -10 cmH_2O was generated inside the device, using a mannequin, for three separate eight hour tests totaling 24 hours (Fig. 2). The device showed only minor structural deflection, with no observable damage or crack formation.

INTERPRETATION

In this paper, we present a negative pressure device for improving oxygenation in patients suffering from ARDS. Although positive pressure ventilation is often required for treatment of ARDS, it can have an exacerbating effect by hyperinflating healthy regions of the lung. A negative pressure device was designed, fabricated and used in an animal study. By applying continuous negative abdominal pressure, the oxygen blood gas levels of an ARDS model pig was increased by a factor of 3.5. The prototype device also aims to improve upon the cuirass by encompassing more of the torso circumference while simultaneously fitting patients of all sizes. The device is simple in design and assembly, and is an inexpensive solution for improving oxygenation in patients suffering from ARDS. Future prototypes will consist of a 3D printed, circular arch design which is more rigid, easily collapsed for portability, and is suitable for large-scale manufacturing.

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