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# A PNEUMATIC COMPRESSION VEST FOR TRANSTHORACIC MANIPULATION OF VENTILATION-PERFUSION IN CRITICAL CARE PATIENTS WITH ACUTE RESPIRATORY DISTRESS SYNDROME CAUSED BY COVID-19

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## ABSTRACT
*Critical Care patients who experience symptoms of Acute Respiratory Distress Syndrome (ARDS) are commonly placed on mechanical ventilators to increase the oxygen being supplied to their pulmonary system. If patients' pulmonary inflammation is severe, they can experience ventilation-perfusion mismatch (V/Q mismatch) where blood flow and gas exchange are mismatched such that oxygen uptake is greatly impaired. In these cases, patients are typically rotated into a prone position to facilitate improved blood flow to segments of the lung that were not previously participating in the gas exchange process. However, proning a patient has a significant risk of complications. The low-cost vest presented in this work is designed to be used as a surrogate to patient proning while also requiring less hospital staff to operate than the proning process. The vest was preliminarily tested on 6 patients with Coronavirus disease 2019 (COVID-19) who experienced ARDS and presumptive V/Q mismatch. The results from this preliminary testing show that 5 out of 6 patients showed a significant increase in ventilation-perfusion similar to the effects of proning.*

Keywords: COVID-19, ARDS, Ventilation-perfusion Mismatch, Pneumatics, Control

## NOMENCLATURE

| | |
|---|---|
| V/Q | ventilation-perfusion |
| PaO2 | partial pressure of oxygen (arterial) |
| FiO2 | fraction of inspired oxygen |
| in | inches |
| mmHg | millimeters of mercury |
| L | liters† |

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**FIGURE 1:** THE V/Q VEST APPLIED TO A RESEARCHER. THE VEST IS SPLIT INTO 3 PIECES TO SIMPLIFY APPLICATION TO A SEDATED PATIENT: THE ANTERIOR, LEFT POSTERIOR, AND RIGHT POSTERIOR. THERE ARE ELASTIC STRAPS AND VELCRO THAT SECURE THE VEST ONTO THE PATIENT AND RESTRICT THE VEST FROM EXPANDING AWAY FROM THE PATIENT.

## 1. INTRODUCTION

A Study published in 2005 estimated that around 190,000 patients are admitted to the United States intensive care units (ICUs) every year with symptoms of acute respiratory distress syndrome (ARDS) [1-3]. With the outbreak of the human coronavirus COVID-19 disease worldwide in 2020, the number of patients admitted to ICUs with ARDS has substantially increased. The large influx of patients admitted to ICUs in 2020 has overwhelmed many countries' healthcare systems which could be contributing to an increase in mortality rates for patients with ARDS and COVID-19.

Patients who are admitted to ICUs with severe pulmonary inflammation typically are provided oxygen via cannula and in severe presentations, patients are placed on mechanical ventilators both of which help supply oxygen to the patients' lungs. However, in many presentations of ARDS, even the patients on mechanical ventilation fail to improve significantly due to inadequate change in ventilation-perfusion mismatch. Even though ample levels of oxygen are supplied to patients' lungs, the inflamed alveoli are unable to capture this oxygen as they are being bypassed. This phenomenon is called a ventilation-perfusion mismatch (V/Q mismatch) [4,5]. A V/Q mismatch potentially results when the partial pressure of oxygen in arterial blood (PaO2) decreases and the partial pressure of carbon dioxide (PaCO2) consequently rises. Normal PaO2 levels are between 80-100 mmHg and as levels fall to 50 mmHg hypoxemia occurs. However, PaO2 levels alone do not represent V/Q mismatch as the underlying mechanism and hence the P/F ratio has been introduced as a descriptor of ventilation-perfusion [6]. The P/F ratio is defined by the partial pressure of oxygen in the arterial blood divided by the fraction of inspired oxygen (FiO2).

Patients who are experiencing severe ARDS who are unresponsive to traditional mechanical ventilator maneuvers to optimize oxygenation are rotated from a supine position to a prone position. This process is called "proning." Patients who are proned are usually sedated, chemically paralyzed, on mechanical ventilation, and provided internal fluids via intravenous therapy (IV therapy). Their care is extremely labor-intensive and complex as the patients are very tenuous. As such, great caution is required in their care, and concerning proning, up to eight hospital staff are needed to safely carry out the proning process [7]. Risks include loss of the endotracheal tube (the tube that connects the patient to the ventilator), accidental removal of venous catheters, infection, pressure injury, etc. The potential for serious injury is considerable [8].

The device presented here is meant to be used as a surrogate to proning in the hope of minimizing the risk of complications while maximizing the benefits of proning. However, this device does not biomechanically replicate proning. The implications of a safer alternative to proning could be very impactful. If fewer hospital staff are needed to treat severe presentations of ARDS symptoms, hospitals could run more efficiently when dealing with an overwhelming number of patients. There also is a market gap for low-cost devices that can improve a V/Q mismatch. Currently, there are no low-cost devices on the market that are meant to improve a V/Q mismatch of patients with ARDS. As stated previously, the most common method for treating a V/Q mismatch is to prone the patient or use a very expensive and limited supply of RotoProne or ECMO systems [9, 10].

## 2. MATERIALS AND METHODS

The V/Q vest system is composed of a soft vest, with several pneumatic bladders, and an electro-pneumatic controller for regulating the internal pressure of these bladders. The prototype vest was tested on 6 patients admitted to the ARICU at Emory University Hospital with V/Q mismatches due to COVID-19. For this preliminary testing, all the bladders of the vest were controlled together rather than independently.

### 2.1 The V/Q Vest

The V/Q Vest was designed to accommodate a variety of patient sizes. The V/Q Vest can be used on patients with chest sizes ranging from 36 – 52 inches in circumference. The V/Q Vest is constructed from multiple layers of 200 denier thermoplastic polyurethane-coated nylon that creates up to eight independent airtight bladders. The polyurethane-coated nylon was cut to shape using a Universal Laser Systems PLS6.150D Laser Cutter. An annotated diagram of the V/Q Vest pieces is shown in Figure 2. The bladders are sealed using an H-306 tabletop impulse sealer from ULINE Inc. The impulse sealer melts the polyurethane layers of the fabric together forming airtight welds. Figure 3 shows an illustration of the weld created by the heat sealer.

The bladders of the vest are restricted from expanding away from the patient using elastic straps. The elastic straps are stretched around the patient to the anterior vest piece where there are secured with Velcro, constricting both the anterior and posterior bladders. This restriction is crucial since the pressure imparted on the patient is proportional to the force produced by

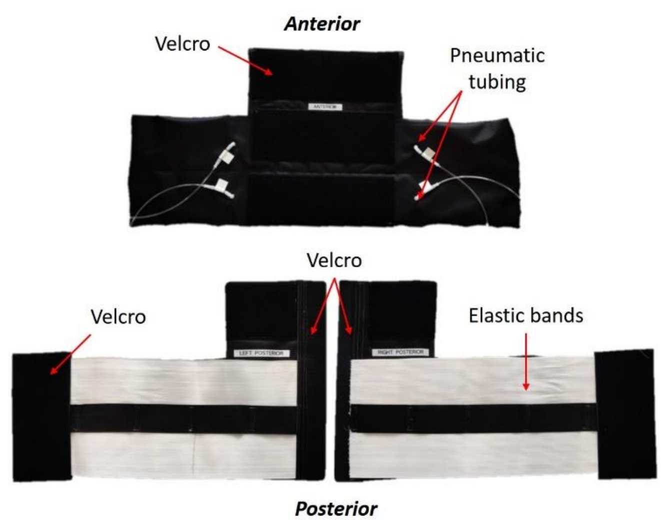


**FIGURE 2:** THE ANTERIOR AND POSTERIOR SIDES OF THE V/Q VEST. THE POSTERIOR IS SPLIT IN HALF TO SIMPLIFY THE DONNING PROCEDURE ON THE PATIENT.



 

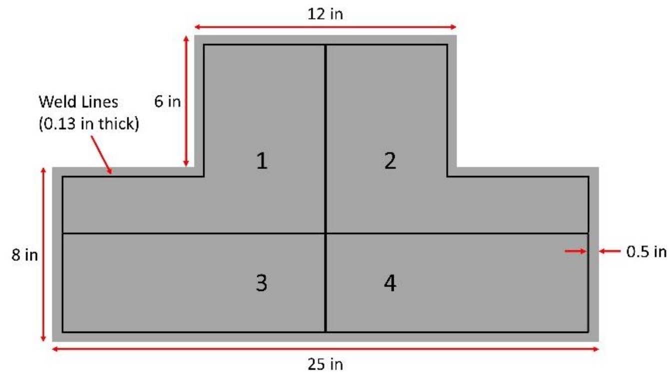


**FIGURE 3:** SHOWS THE WELD LINES CREATED BY THE IMPULSE SEALER. THE LEFT AND RIGHT SIDES OF BOTH THE ANTERIOR AND THE POSTERIOR OF THE VEST ARE CONNECTED WITH PNEUMATIC TUBING. THIS WAS DONE TO AVOID INTERIOR CORNERS THAT WEAKEN THE BLADDERS AND CAUSED THEM TO FAIL AT LOW PRESSURES.

the elastic straps when stretched. Since the material properties of the materials used to create the V/Q Vest are unknown, the exact mathematical relationship between the pressure imparted on the patient and the internal pressure of the bladder is unknown. However, a simplified relationship can be asserted through a static equilibrium analysis of the bladder.

$$P_{int}A_{int} = P_{pat}A_{pat} + 2\sigma_{mem}A_{mem} \qquad (1)$$

Since the membrane stress and the cross-sectional area of the membrane are greater than or equal to zero,

$$P_{int}A_{int} \geq P_{pat}A_{pat} \qquad (2)$$

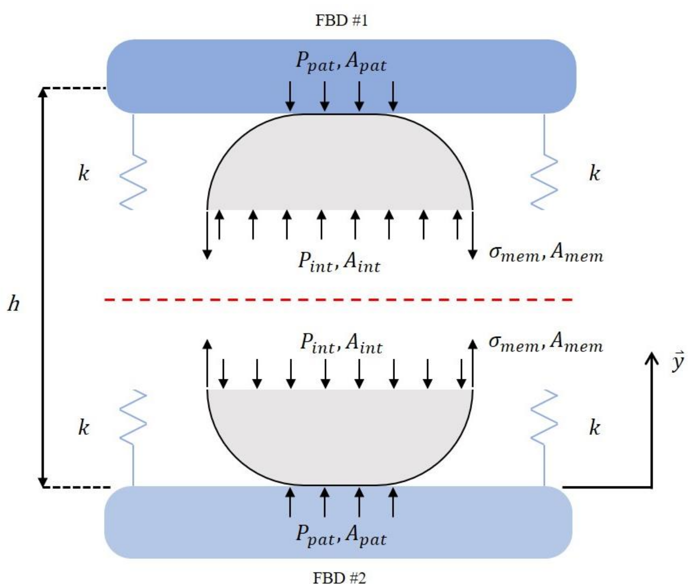


**FIGURE 4:** ILLUSTRATES THE EFFECT OF USING DIFFERENT STIFFNESSES OF ELASTIC USED TO RESTRICT THE EXPANSION OF THE BLADDERS AWAY FROM THE PATIENT. THE INTERNAL PRESSURE, $P_{int}$, REMAINS CONSTANT IN BOTH SCENARIOS AND $k_2 > k_1$. WITH HIGHER STIFFNESS ELASTIC, THE PRESSURE IMPARTED ON THE PATIENT IS INCREASED LIMITED TO THE INTERNAL PRESSURE OF THE BLADDER.

Another property of importance is that both the ratio in areas in equation 2 and the membrane stress of the bladder are functions of the stiffness of elastic used to constrict the bladders.

$$\lim_{k\to\infty} \frac{A_{pat}}{A_{int}} = 1 \;\&\; \lim_{k\to\infty} \sigma_{mem} = 0, (h = 0) \qquad (3)$$

As the stiffness increases, the ratio of pressure imparted on the patient and the internal pressure of the bladder grow closer together. With higher stiffness, the bladder walls also do not separate as much causing the membrane stress to diminish to zero. In Figure 4, the magnitude of the pressure imparted on the patient is signified by the length of the arrows.

## 2.2 The Electro-Pneumatic Controller

An electro-pneumatic controller was fabricated to autonomously regulate the internal pressure of the independent bladders that form the V/Q Vest. The controller senses and regulates the internal pressure of all the bladders at 100 Hz. The pressure of each bladder is controlled using two solenoid valves in series, one for inflation and one for deflation. A PID controller was implemented to drive the internal pressure of the bladders to a specified internal pressure set by the hospital staff. Figure 5 shows a hardware diagram of the controller.

A graphical user interface (GUI) was developed to simplify the control of the V/Q Vest for the hospital staff. The GUI allows the hospital staff to independently control each bladder and monitor the internal pressure of the V/Q Vest in real-time. Figure 6 shows a picture of the GUI developed for the hospital staff. For further safety of the patient, an emergency stop was implemented that cuts power to the controller and vents all the bladders.

## 2.3 Benchtop Evaluation

To establish the amount of pressure the V/Q Vest needs to apply to patients that experience symptoms of ARDS, 5L saline bags were placed on top of patients' chests while in the supine position. Their ventilation-perfusion was recorded for an hour. It was found that 2 bags stacked on top of each other applied enough pressure to the patient to see significant increases in ventilation-perfusion. A clinically significant increase in PaO2

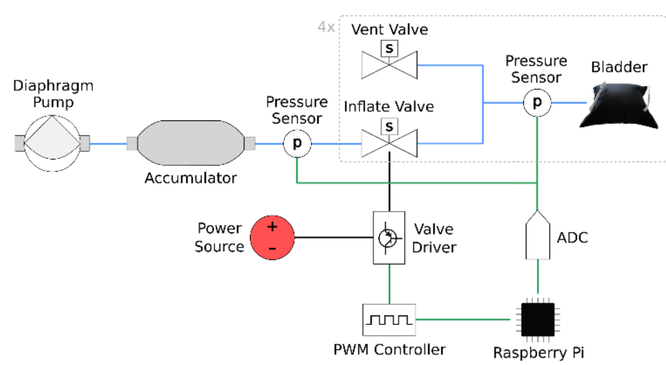


**FIGURE 5:** A CONTROL DIAGRAM FOR REGULATING THE INTERNAL PRESSURE OF THE INDEPENDENT BLADDERS THAT MAKE UP THE V/Q VEST.



 

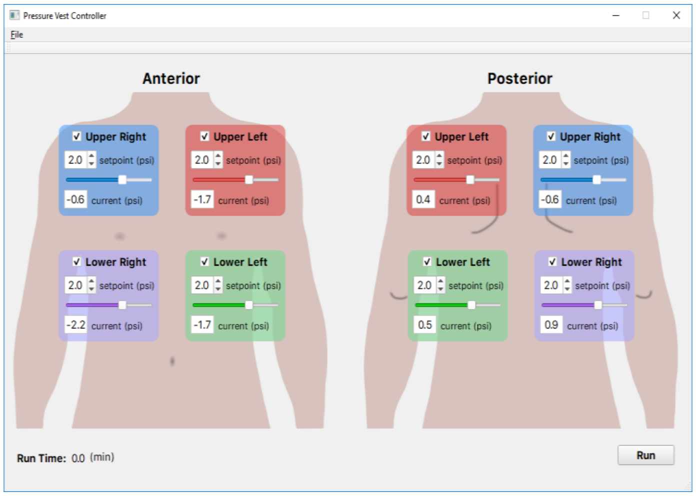

**FIGURE 6:** THE GUI DISPLAYED BY THE ELECTRO-PNEUMATIC CONTROLLER. A RASPBERRY PI 3 MODEL B IS USED FOR CONTROLLING AND DISPLAYING THE GUI.

of the P/F ratio is around 20%. The pressure imparted on the patients from the weight of the two 5L saline bags is roughly equivalent to 20 mmHg. Hence, the V/Q Vest needed to apply at least 20 mmHg of pressure to patients' thorax. Since the internal pressure of the bladders is always higher than the pressure imparted to the user, the V/Q vest was designed to withstand 100 mmHg of internal pressure as a factor of safety.

Further testing characterized the leak rate of the bladders to ensure that the controller could maintain the desired internal pressure. Three test bladders were inflated to 100 mmHg and the pressure over 2 hours was recorded to establish the leak-rate of the bladders. An exponential decay model was fit to the pressure vs time data. After many iterations of the bladders, the final bladder design presented in this work does not leak more than 1 mmHg per minute. This leak rate of these bladders is lower than the rate of inflation from the electro-pneumatic controller so the controller can still maintain the desired pressure.

### 2.4 Preliminary Clinical Trials

Both the Institutional Review Boards at Emory and Georgia Tech approved this preliminary study of the V/Q Vest on patients with ARDS. Six patients with ARDS symptoms due to COVID-19 gave informed consent or had a legally authorized representative give consent to participate in our study. All the participants were admitted to the Emory University Hospital Acute Respiratory Intensive Care Unit (ARICU). The demographic data of these participants are shown in Table 1.

The first step of the study protocol was to measure the patients' vitals while sedated in the supine position to be used as

*Table 1*

| Patient ID | Gender | Age | Weight (kg) | BMI |
|---|---|---|---|---|
| 1 | Male | 72 | 73 | 27.4 |
| 2 | Female | 48 | 154 | 38.1 |
| 3 | Male | 60 | 61 | 20.6 |
| 4 | Male | 65 | 79 | N/A |
| 5 | Male | 89 | 50 | 28.5 |
| 6 | Male | 67 | 102 | 31 |

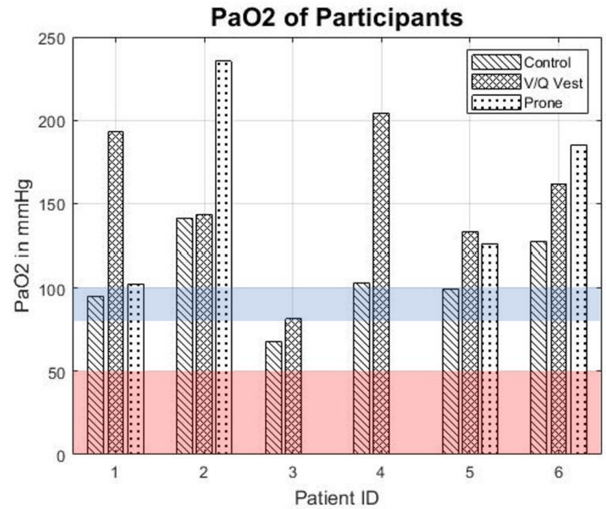

**FIGURE 7:** THE PaO2 VALUES FROM ALL THE PARTICIPANTS. PaO2 VALUES IN THE RANGE OF 80-100 MMHG (SHADED IN BLUE) ARE DEEMED NORMAL AND PaO2 LEVELS BELOW 50MMHG (SHADED IN RED) INDICATE HYPOXEMIA.

controls for the study. The V/Q Vest was then donned on the participants and all the bladders were inflated to the first internal pressure. The pressure of the V//Q Vest was inflated to varied by patient depending on their response. The participants were then given an hour for their vitals to stabilize after which their vitals were recorded again. Then the V/Q Vest was inflated to the next preset value and this process repeated. After 3 hours of increasing the V/Q Vest pressures, the vest was doffed from the participant and they were proned according to the Emory University Hospital protocol. After an hour in the prone position, their vitals were recorded concluding the study. Two participants, patient #3 and patient #4 were not able to be safely proned due to complications. For these two participants, the study concluded after the third hour of increasing pressure applied by the V/Q Vest.

## 3. RESULTS AND DISCUSSION

The stead-state PaO2 measurements from the patients during the study are shown in Figure 7. The V/Q Vest data reported in Figure 7 are the PaO2 levels that were the highest for the three pressure levels the vest was inflated to. All but one participant exhibited a remarkable increase in PaO2 levels while wearing the V/Q Vest. It is surmised that patient #2 did not see a remarkable increase in PaO2 levels from the V/Q Vest due to a high BMI. Excess tissue may disperse the pressure applied to their chest wall. This indicates a need for a new design of the V/Q Vest that can accommodate the presence of breast tissue in female and morbidly obese patients.

The shorthand expressions ΔPaO2-Vest, $OVP$ , and ΔPaO2-Prone will be introduced for further discussion. ΔPaO2-Vest signifies the greatest steady-state change in PaO2 levels from wearing the V/Q Vest compared to the control trial. ΔPaO2- $OVP$ indicates the internal pressure of the bladders on the vest that produce the greatest increase in PaO2 levels for each participant. ΔPaO2-Prone signifies the steady-state change in PaO2 levels

*Table 2*

| Patient ID | ΔPaO2-Vest (mmHg) | *OVP* (mmHg) | ΔPaO2-Prone (mmHg) |
|---|---|---|---|
| 1 | 98 | 41 | 7 |
| 2 | 2 | 21 | 95 |
| 3 | 14 | 41 | N/A |
| 4 | 101 | 72 | N/A |
| 5 | 34 | 52 | 27 |
| 6 | 35 | 52 | 58 |

**TABLE 2:** Δ*PaO2-Vest*: THE GREATEST CHANGE IN PaO2 LEVELS CAUSED BY THE V/Q VEST COMPARED TO CONRTOL. *OVP*: THE OPTIMAL VEST PRESSURE. Δ*PaO2-Prone*: THE CHANGE IN PaO2 DUE TO PRONING COMPARED TO CONTROL.

found from proning compared to the control trial. Each participant's ΔPaO2-Vest, *OVP*, and ΔPaO2-Prone values are shown in Table 2.

All participants were exhibiting symptoms of ARDS since their control P/F ratios were less than 300 while on mechanical ventilation. Normal P/F ratios are between 400-500 at sea level. The P/F ratios for all but two participants increased while wearing the V/Q Vest. For patient #5 and patient #6, proning was more effective at raising their P/F ratios than wearing the V/Q Vest. Patient #2 was morbidly obese and patient #5 had a pulmonary embolism (PE). These factors are highly suspected to have decreased the effectiveness of the V/Q Vests.

## 4. CONCLUSION

The V/Q Vest remarkably improved ventilation-perfusion mismatch and improved hypoxemia among 5 out of the 6 patients who participated in this study. Two patients had higher PaO2 levels with the V/Q Vest compared to proning. Conversely, two patients showed lower PaO2 levels with the V/Q Vest compared

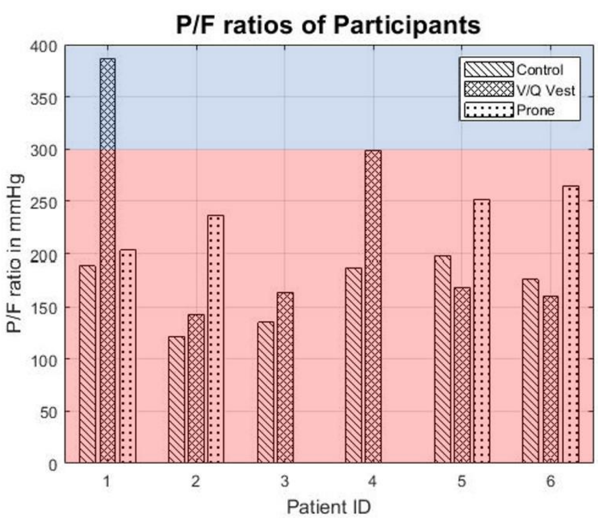


**FIGURE 8:** THE P/F RATIO (PaO2/FiO2) OF THE PATIENTS FROM THE CONTROL TRIAL AND THE BEST TRIAL WHILE WEARING THE V/Q VEST. P/F RATIOS ABOVE 300 MMHG (SHADED BLUE) ARE DEEMED NORMAL AND P/F RATIOS WHILE ON OXYGEN BELOW 300MMHG (SHADED IN RED) ARE AN INDICATION OF ARDS.

to proning. The remaining 2 patients were not able to be proned, however, the V/Q Vest was able to be used and increased these patients' PaO2 levels remarkably. More clinical testing will need to be conducted to clearly differentiate the differences in effects of the V/Q Vest and proning. One important takeaway is the fact that the V/Q Vest can help improve ventilation-perfusion for patients that cannot be safely proned which could decrease the mortality rate of ARDS.

A new vest design is to be implemented to ensure that the V/Q Vest can improve ventilation-perfusion in both male and female patients to the same degree. With the current shape of the vest, excess tissue disperses the pressure imparted on the user chest wall which caused less of an impact seen in female patients and obese patients. The next iteration of the vest controller will be integrated with the mechanical ventilation and patient monitoring systems to further automate the V/Q Vest system. This autonomy will alleviate the workload of the hospital staff needed to treat the symptoms of ARDS.

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## REFERENCES

[1] Rubenfeld, G. D., Caldwell, E., Peabody, E., Weaver, J., Martin, D. P., Neff, M., Stern, E. J., & Hudson, L. D. "Incidence and outcomes of acute lung injury," *N Engl J Med* Vol. 353 No. 16 (2005): pp. 1685-1693. https://doi.org/10.1056/NEJMoa050333

[2] Redant, S., Devriendt, J., Botta, I., Attou, R., De Bels, D., Honoré, P. M., & Pierrakos, C. "Diagnosing Acute Respiratory Distress Syndrome with the Berlin Definition: Which Technical Investigations Should be the Best to Confirm it?" *J Transl Int Med* Vol. 7 No. 1 (2019): pp: 1-2. https://doi.org/10.2478/jtim-2019-0001

[3] Bourenne, J., Carvelli, J., & Papazian, L. "Evolving definition of acute respiratory distress syndrome," *J Thorac Dis* Vol. 11. Suppl. 3 (2019): pp. S390-S393. https://doi.org/10.21037/jtd.2018.12.24

[4] Santamarina, M. G., Boisier, D., Contreras, R., Baque, M., Volpacchio, M., & Beddings, I. "COVID-19: a hypothesis regarding the ventilation-perfusion mismatch," *Crit Care* Vol. 24 No. 1 (2020): pp. 395. https://doi.org/10.1186/s13054-020-03125-9

[5] Barnat, N., Ghavam, S., Liu, Y. et al. "Reliability of a Noninvasive Measure of V/Q Mismatch for Bronchopulmonary Dysplasia," *Ann Amer Thoracic Soc* Vol. 12 No. 5 (2015): pp. 727-733. https://doi.org/10.1513/AnnalsATS.201410-462OC

[6] Rice, T., Wheeler, A., Gordon, R. et al. "Comparison of the Spo2/Fio2 Ratio and the Pao2/Fio2 Ratio in Patients with Acute Lung Injury or ARDS," *Chest* Vol. 132 No. 2 (2007): pp. 410-417. https://doi.org/10.1378/chest.07-0617

[7] Wiggermann, N., Zhou, J., & Kumpar, D. "Proning Patients With COVID-19: A Review of Equipment and Methods," *Hum Factors* Vol. 62 No. 7 (2020): pp. 1069-1076. https://doi.org/10.1177/0018720820950532

[8] Cotton, S., Zawaydeh, Q., LeBlanc, S., Husain, A., & Malhotra, A. "Proning during covid-19: Challenges and solutions," *Heart Lung* Vol. 49 No. 6 (2020): pp. 686-687. https://doi.org/10.1016/j.hrtlng.2020.08.006

[9] Slessarev, M., Cheng, J., Ondrejicka, M., Arntfield, R., & Group, C. C. W. R. "Patient self-proning with high-flow nasal cannula improves oxygenation in COVID-19 pneumonia," *Can J Anaesth* Vol 67 No. 9 (2020): pp. 1288-1290. https://doi.org/10.1007/s12630-020-01661-0

[10] Muratore, C. S., Kharasch, V., Lund, D.P. et al. "Pulomary Morbidity in 100 Survivors of Congenital Diaphragmatic Hernia monitored in Multidisciplinary Clinic," *Journal of Ped Sur* Vol. 36 No. 1 (2001): pp. 133-140. https://doi.org/10.1053/jpsu.2001.20031