ATEMPT TO INCREASE SAFETY MEASURES IN EMERGENCY MECHANICAL VENTILATOR SHARING DURING THE COVID-19 PANDEMIC

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Abstract: This project was developed in the context of the COVID-19 pandemic, during which the shortage of mechanical ventilators was pointed in several countries. Desperate measures included sharing a single mechanical ventilator between multiple patients. That non-recommended approach brings several problems and risks and, nonetheless, is eventually used. The idea is to enable the possibility of supervising effectiveness of the flow delivered to each patient, which is one of the biggest challenges in this setting. The developed device would identify whether a patient is not minimally attended to by this ventilation setting and alarm the medical team, should they be momentarily using such sharing configuration.

Introduction

The average adult mechanical ventilator is usually able to supply more than 2000ml per cycle. The guidelines devised at the International Pulmonologist's Consensus on Covid-19 recommended ventilating patients at maximum pressure of 30 cmH_2O, with 4 to 6 ml/kg, [6,7], which is between 300ml and 600ml for most adult patients, for each ventilatory cycle. Therefore, the same ventilator could be able to meet the needs of up to four patients, as in the arrangement proposed by Neyman et al. [1]

However, unequal characteristics of resistance and compliance of each patient and circuit (influenced by the disease progression, previous health conditions of the patient, age, weight, reactions or movements, among others) would cause a problem of dynamically controlling the gas flow to be received by each patient.

A standard ventilator can respond to system variations in real time, controlling the flow, volume and pressure it sends to the patient. Yet, in a group of patients sharing the same device, the distribution of the total volume among more than one patient would prevent the ventilator from receiving feedback on variations of a specific patient. This would endanger all patients, who would receive inadequate volume, either insufficient or excessive.

Related Works

Neyman et al. [1] proposed and simulated the adaptation of a single ventilator for four patients and concluded that the volumes delivered by the equipment would be able to sustain up to four 70 kg patients. Paladino et al. [2] extended the study by experimenting it with four adult sheep. However, stated that further studies would be necessary to conclude about patients with different lung compliances, and potential cross-contamination.

Branson and Rubinson have repeatedly argued against the technique. [3,4] The main concerns raised were the impossibility of detecting changes in a single patient, and the alterations in tidal volume distribution caused by changes in compliance.

On another study, [5] Branson and Rubinson simulated lungs of variable compliances and concluded that the tidal volume could not be controlled for each subject and the disparity was proportional to the variability in compliance.

Cavanilles et al. [12] used a single ventilator with a modified circuit to individually ventilate the lungs of a patient. The system allowed control of tidal volume to each lung by altering resistance in the circuit and separate exhalation valves for differential positive end-expiratory pressure. Separation of the exhaled gas would also limit the possibility of cross-infection.

Recent studies have also been trying to create safer arrangements. Solis-Lemus et al. [9] and Raredon et. al. [10] have simulated circuits with variable resistances and one-way valves to enable control of tidal volume delivered to each individual patient, for the case of different compliances.

A joint statement released by the Anesthesia Patient Safety Foundation in March 2020 [8] strongly discourages this procedure, unless in grave temporary emergency, in absence of alternative reliable options.

Another reason against the procedure is an ethical concern, of risking life-threatening treatment failure for all patients, when a ventilator might be able to save one of them individually.

As stated by the International Pulmonologist's Consensus on Covid-19 [6,7], the high risk of running into shortage of ventilators during the pandemic may lead to the consideration of innovations such as introducing a t-piece into the inspiratory and expiratory limbs of the ventilators to connect more than one patient to one ventilator. Although not recommended, such adaptation may become necessary.

Proposal

We propose a supervising device, low-cost and easily reproducible, to allow minimal safety in emergency sharing of a mechanical ventilator between multiple patients. In two existing scenarios, a ventilator may control flow based on either pressure or volume. We assume the pressure-controlled system would be the most adequate for the event of sharing.

We were also able to devise a solution for the volume-controlled system. However, the complexity of the solution involved the inclusion of valves to shut the necessary tubes. The speed and precision requirements for the valves and sensors in this case resulted in the choice of a simplified model, limited to the pressure-controlled option. Future works may be done toward the volume-controlled scenario.

Assuming the ventilator to be in the pressure control mode, the prescribed pressure will be maintained for all patients simultaneously by the control system of the mechanical ventilator. It is paramount, however, to ensure all patients receive the necessary volume of air.

In this project, this will be done by monitoring each flow, and triggering an alarm, in case one or more patients do not achieve his targeted volume. This may be caused by an isolated, temporary condition, or by a relevant one, e.g., faster progression of the disease. Each case should be evaluated by a doctor, who will be responsible for deciding whether the patient or patients should be removed from the current group and transferred to a different or even separate ventilator.

Methods

Each patient connected to a non-individual ventilator should be monitored by a device, consisting of a measuring system, a microcontroller, buttons and a display for efficient configuration and visualization, and an alarm.

The measuring system is built of a variable orifice meter (VOM) and a differential pressure sensor. The operating principle of a VOM is to generate a pressure drop between the upstream and downstream sides of a variable orifice plate, which is placed inline the pipeline where gas is flowing. As flow increases and becomes progressively turbulent, the hinged flap which comprises the orifice plate opens, mechanically lowering the resistance caused to the flow, and therefore resulting in a linear pressure drop, in response to gas flow. [14,16] These kinds of flowmeters require a secondary device (a differential pressure sensor) to perform the measurement of the resulting pressure differential, which will be done by an Mp3v5010dp differential pressure transducer. It works on a 0-10 kPa pressure range, with a sensibility of approximately 27mV/cmH_2O, and a dynamic response time of 1 millisecond. [17]

Figure 1: Variable Orifice Meter

The measuring system calibration was performed at the Brazilian National Institute of Metrology, Quality and Technology (INMETRO). A stable, fully developed air flow was delivered to the circuit, controlled by a fine control needle valve. The calibration was made by direct comparison between the output of the meter under test and the flow in a traceable calibrated thermal mass flowmeter (model Aalborg GFM37).

The following calibration curve was obtained, from which we generated a first order polynomial equation, using linear regression.

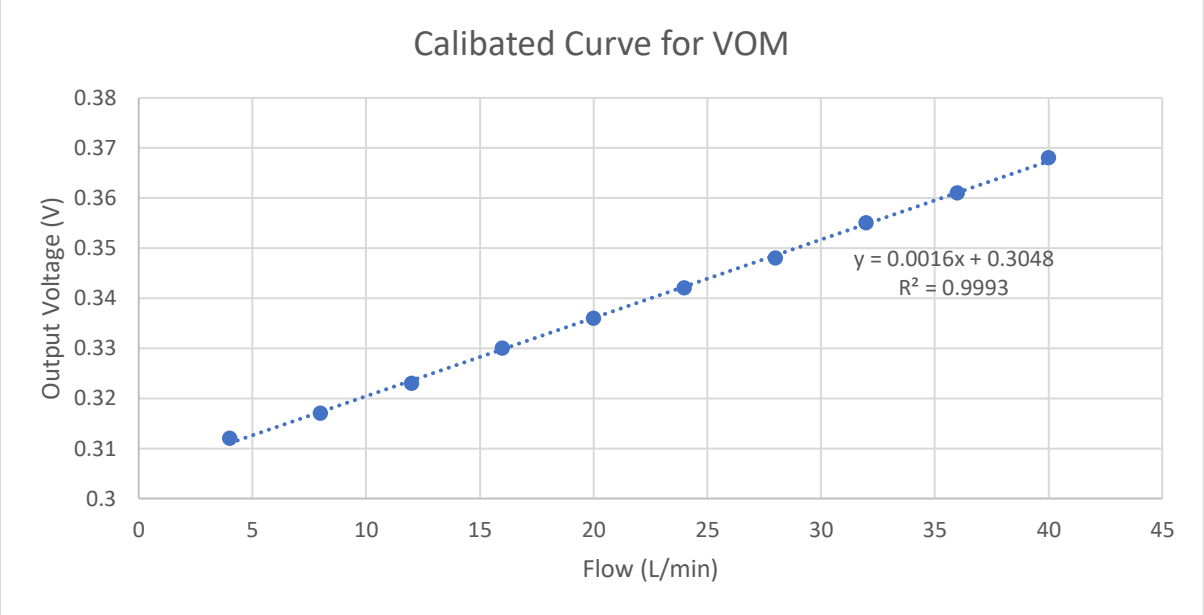

Figure 2: Calibrated curve for VOM and Mp3v5010dp sensor

A 16-bit Analogical to Digital converter, ADS1115, was used in order to obtain better discrimination threshold. The resulting sensitivity was 0.32552 (ml/s)/bit. A voltage regulator was used to reduce noise in the power supply, especially for the analogical part of the circuit.

The control of the device is done by a Nodemcu. It was chosen for its faster processor, when compared to similar devices, such as Arduinos. The alarm is both sonorous and visual, to facilitate identification of the patient in question.

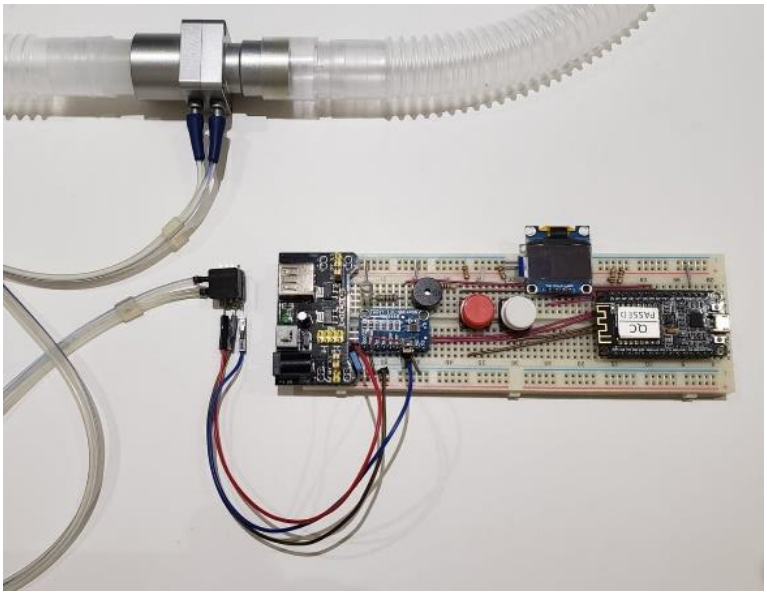

Figure 3: Assembled circuit

The developed software obtains the instant flow by applying the calibrated function to the sensor's output voltage. The flow is then integrated in time to obtain the tidal volume received by the patient, in each inspiratory cycle. A moving average filter was used for noise reduction. A peak detection algorithm was studied and tuned to determine the beginning and end of each inspiratory cycle. When inspiration ends, the system compares the volume to a target tidal volume, set by the medical team. The alarm is triggered when the volume received in a given the cycle is lower than the targeted one.

Results shown in figure 4 were obtained in a simulation where the developed device was connected to the inspiratory branch of a mechanical ventilator in pressure-controlled mode, and a bag performed the role of a simulated lung. The curves shown are the calculated flow, and the integrated volume in each inspiratory cycle.

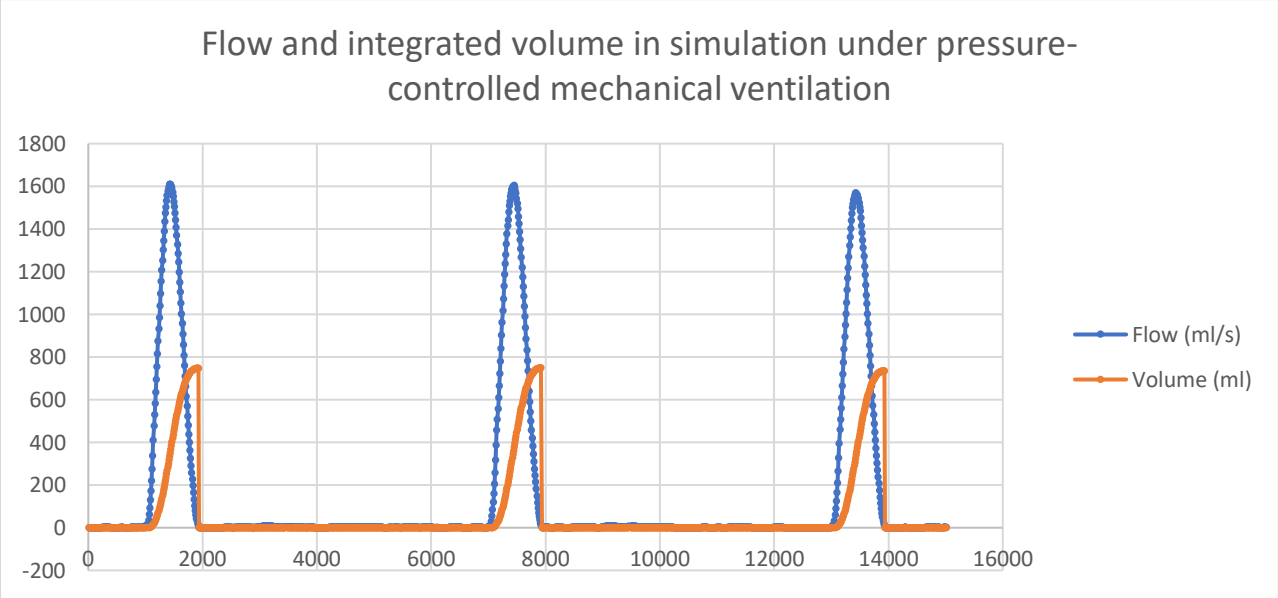

Figure 4: Flow and integrated volume in simulation under pressure-controlled mechanical ventilation

Limitations

- The system does not yet provide for the possibility of spontaneous ventilation or triggered by the patient's respiratory effort. It is exclusively a solution for mechanically controlled ventilation.
- The respiratory rate and driving pressure must be the same for all patients.
- All safety systems for possible cases of excess pressure or leaks are dependent on the mechanical ventilator's own existing control system.
- Aiming to minimize episodes of inadequate ventilation and the need to switch patients to other ventilators, it would be more efficient to group patients with similar characteristics.
- In order to reduce differences in resistance to the inspiratory flow, those circuits must have the same length and diameter. We suggest an arrangement of the beds in an H, centralizing the ventilator, while allowing circulation of health professionals and space optimization.
- All patients should be under the same Positive End Expiratory Pressure (PEEP). It is possible, if desired, to set up an expiratory circuit that provides different PEEP values for each patient. In

this case, however, an inspiratory valve is needed for each patient, in order to avoid reverse flow in the inspiratory limb.

- The use of the proposed equipment is not recommended in every-day situations, due to the risk of cross-contamination. In this scenario, we assume the patients in question are all being treated for the same infection.

Conclusions

Simulations have shown the proposed device was able to perform accurate measurement of the tidal volume delivered under a pressure-controlled mechanical ventilation. While the adaptation of mechanical ventilators has been debated and discouraged, a monitoring and alarming system would increase patient safety, should it happen in an absolute emergency.

Future works

- Data may also be sent to a central computer, where a dashboard could be implemented for monitoring several patients' ventilation. This would allow for other comparisons, e.g. volume and flow over a longer timeline. Nodemcu already contains an ESP8266 Wi-Fi module, which would facilitate implementation of the wireless network communication.
- The circuit should ideally be printed on a Printed Circuit Board and encapsulated.

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