Electric Blower Based Portable Emergency Ventilator

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Abstract: During CPR the victim will most likely be ventilated by a bag-valve-mask. We propose to replace the traditional bag-valve-mask with an electric blower ventilator. This handheld feedback controlled device will automatically compensate for mask leak and enable the rescuer to deliver computer controlled respiratory rates and tidal volumes. We will build a working prototype and conduct bench testing to verify that the blower delivers the desired tidal volumes, even with constantly changing leak conditions that exist when a mask that is poorly fit to a victim's face. In a volunteer study we will observe how typical rescuers use the blower ventilator so we can develop a product that can be easily and correctly used by naïve rescuers. We will conduct human trials in the operating room to demonstrate the safety and efficacy of the blower ventilator.

Introduction

The purpose of this research is to develop a replacement device for the bag valve masks by using an electric blower based portable emergency ventilator. The bag valve mask is the only form of life support for an unconscious patient before they are intubated and mechanically ventilated. The bag valve mask consists of a flexible air chamber attached to a facemask via a shutter valve. This manual form of ventilation is a difficult technique to master and requires the full attention of the person performing the ventilation. There is no indicator for the clinician signaling adequate respiratory rate or tidal volume. Clinical studies reveal that trained clinicians give on average 25-35 breaths per minute, not the 10-12 prescribed by guidelines. Hyperventilation results in decreased cardiopulmonary function, which results in decreased absolute survival. Excessive pressures during ventilation have also been shown to cause traumatic brain injury, hemorrhagic shock, gastric insufflation, and lung injury.

Figure 1: Traditional bag valve mask used to deliver rescue breaths during CPR.

Current methods of non-invasive ventilation (NIV) require strict conditions that make operating room or emergency ventilation impossible. Current NIV machines require precise and constant leak conditions in the ventilation circuit. To ensure those leak conditions the clinician must perform a time consuming fitting process of the mask to each patient. This process is not possible in an emergency situation. NIV machines also cost upwards of $20,000, which makes their large-scale implementation costly.

This research aims to overcome the limitations of current NIV machines in order to develop a replacement to the bag valve mask. This device will provide constant positive airway pressure (CPAP) to the patient while also delivering increased pressures at intervals to ventilate the patient. Most importantly, it will eliminate the need for precise mask fitting by constantly adapting to changing leak conditions, which has yet to be accomplished in NIV. It will give the clinician the ability to deliver specific pressures and tidal volumes to their patient

at regular intervals. It will provide visual feedback to the clinician assuring proper ventilation. Unlike the expensive current NIV machines, this device will be portable and powered by a rechargeable battery pack.

Significance

Sudden cardiac arrest accounts for nearly 325,000 deaths each year in the United States. About 250,000 of these deaths occur in the out-of-hospital setting.[2] An overwhelming number of these deaths are attributed to ventricular fibrillation, [4-7] which is an irregular heart rhythm that causes the heart to suddenly stop pumping blood effectively.[8] If not treated immediately, cardiac arrest leads to irreversible brain damage within 6 minutes.[9] The American Heart Association estimates that 100,000 to 200,000 lives could be saved each year if CPR were performed immediately following the cardiac arrest incident. However, only one-third of bystanders are capable of performing the CPR chest compressions and even fewer are able to deliver effective rescue breathing.[10-12]

During CPR the victim will most likely be ventilated by a bag-valve-mask like the one shown in figure 1. The bag valve mask consists of a flexible air chamber attached to a facemask via a shutter valve. When the bag is compressed it forces air through the valve and into the patient's airway. When it is released the bag refills with air and the shutter valve closes until the next compression. The bag valve method is a difficult technique to master and requires the full attention and both hands of the person performing the ventilation. [13-17]

Many novice responders have difficulty maintaining an open airway while giving breaths. Very few are properly trained to grasp the mask in a way that frees two fingers to provide the required chin-lift and the proper head-tilt to keep the airway open with one hand while squeezing the bag with the other hand. If the airway is obstructed, the rescuer, who is squeezing the bag, may mistakenly think he is delivering an adequate tidal volume when in fact, the entire tidal volume may be lost through a leak between the mask and the victim's face.

It is difficult for the person operating the bag-valve-mask to adequately ensure that the person they are ventilating is receiving the correct respiratory rate. [13-17] Clinical studies reveal that trained clinicians give on average 25-35 breaths per minute, not the 10-12 prescribed by guidelines.[18] Keeping artificial breath rates low is difficult because the high adrenaline state of the rescuer alters time perception, and the rapidly refilling bag sets up a reflex in which the rescuer is inclined to deliver breaths as soon as the bag inflates.

It is difficult for the person operating the bag-valve-mask to adequately ensure that the person they are ventilating is receiving the correct tidal volume. Excessive pressures can cause a decrease in cardiac preload, traumatic brain injury, hemorrhagic shock, gastric insufflation, and lung injury. Inadequate pressure can lead to the patient not receiving adequate oxygen delivery and carbon dioxide removal.

Methods

The electric blower shown in figure 2 has just recently become available commercially. We are the first research group to use this new technology to enable portable emergency ventilation.

Figure 2: Miniature radial blower, model U51DL-4 Micronel US, LLC.

Figure 4: Li-ion battery pack.

The Li-ion battery pack (Figure 3) is also a new enabling technology; it delivers sufficient power to turn the blower on and off at the rate required for patient ventilation for 90 minutes. Our group developed the airway flow meter that is shown connected to the blower in figure 2 and will be the first to use it to measure and feedback control the airway pressure and tidal volume delivered by the rapidly responding blower. The software algorithm developed will be unique in the way it uses the measurements of airway pressure and flow to deliver the desired tidal volumes and respiratory rates. The software algorithm will use the airway flow signal to calculate the portion of the inspired tidal volume that is lost through a mask leak and the portion that is delivered to the victim's lungs. The blower will be turned off when chest compressions are given to keep intrathorasic pressures low and to enhance preload and thus cardiac output.

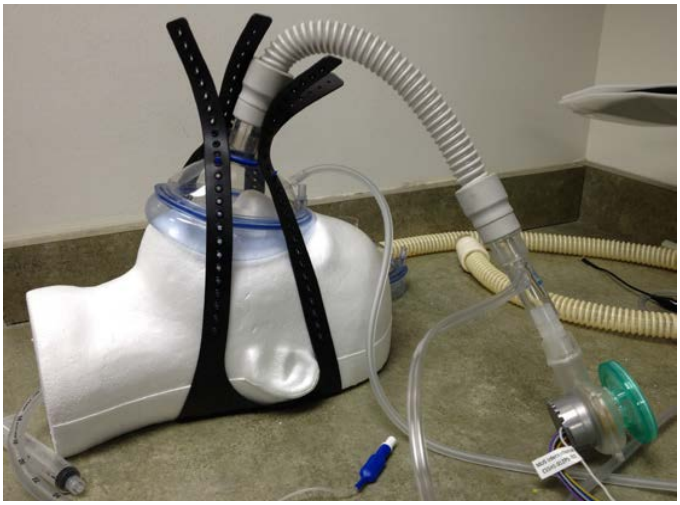

Figure 3: Prototype blower and face mask to deliver rescue breathing during CPR.

Aim 1: Build a working prototype. An Arduino mega 256 computer controller (Hagerstown, MD) will control the speed of a miniature radial blower (U51DL-4, Micronel US, Carlsbad, CA) to generate the desired pressures using the circuits in figure 5. The circuit takes the pulse-width modulated output of the Arduino board and modifies the signal to a value between 0.5-4.5V, which controls the speed of the blower.

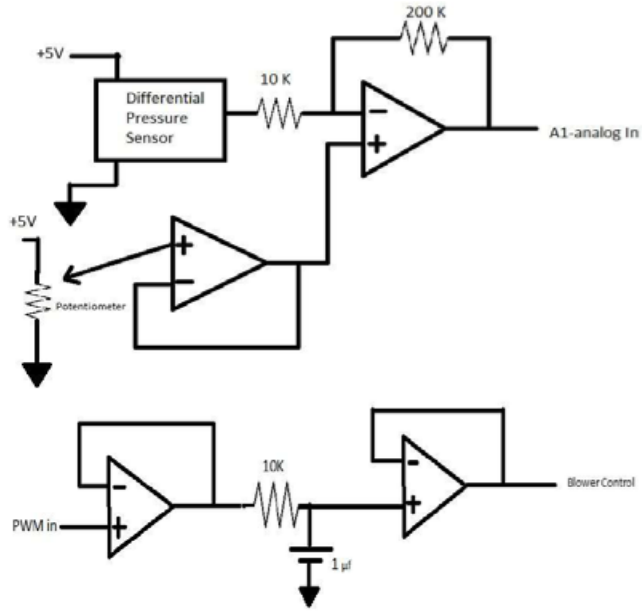

Figure 5: Circuits for feedback control of the electric blower.

Software algorithms will be written for the Arduino environment to compare the desired pressure with the actual pressure in the facemask, as measured by a pressure transducer mounted in the mask (BLVR-L01D, AllSensors, Morgan Hill, CA). Figure 5 shows the circuit diagram for the differential pressure sensor amplifier that measures the airflow delivered by the blower. The signal of the differential pressure sensor (MPXV5004DP, FreeScale Semiconductor, AustinTX) will be amplified to provide much higher resolution for the pressure drop over the fixed orifice flow meter. The signals from the pressure transducer and the flow meter will be displayed to the user via two histogram bars (column of LEDs), which rise and fall with each breath. The user will set the respiratory rate (based on age), the controller will deliver 20 cm H20 pressure during inspiration and the display will show the delivered tidal volume and airway pressure, alongside target values for each.

The flow and pressure sensors will be calibrated using a gas flow analyzer (Bio-Tek VT Plus, Winooski, VT). Figure 6 shows typical data plots of the flow and pressure calibrations. The coefficients of the best-fit linear equations will then be inserted into the Arduino code to provide accurate pressure and flow measurements.

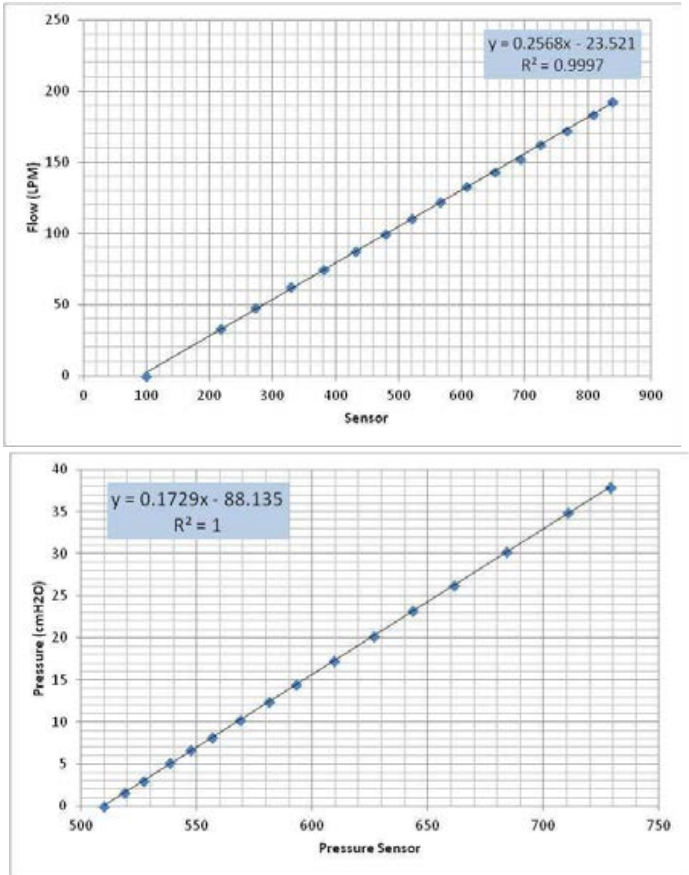

Figure 6: Calibration curves for the pressure transducer and the flow meter.

The coefficients of a proportional, integral, derivative PID controller will be tuned to optimize the blower's response time to reach the desired airway pressure in the mask. We will further tune the PID controller to optimize its response to changing mask leak conditions so that it maintains the desired pressure within the mask independent of the size of the mask leak. We will test the performance of the feedback controller by attaching the blower to a test lung (Vent AID TTL, Michigan Instruments, Grand Rapids, MI) and identifying the range of lung compliance and airway resistance over which the blower delivers the desired airway pressures, tidal volumes and respiratory rates. The results should show that the blower continues to deliver the desired ventilation, even with the changing leak conditions that exist when a mask is poorly fitted to a manikin's face.

Figure 4 shows the working prototype of the electric blower based portable emergency ventilator. It uses a miniature radial blower (model U51DL-4 from Micronel US, LLC). Figure 7 is a block diagram of the components we assembled to control the blower speed. This feedback control circuit uses the signal from a pressure sensor mounted in the mask to control the blower speed and to generate the desired pressures within the mask. The red line in figure 8 shows the desired airway pressure. The blue line shows the pressure generated by the blower and delivered to the victim, for three breaths. The feedback controller uses the signal from the flow sensor to control the blower speed to deliver the desired tidal volume.

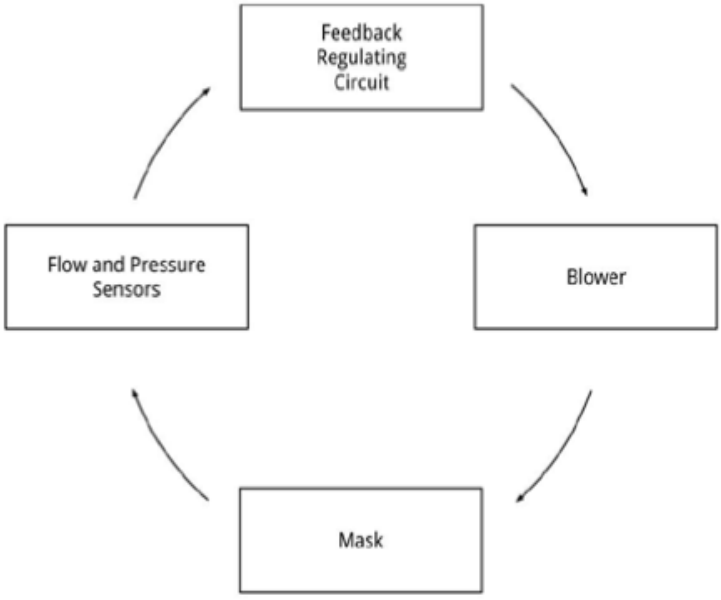

Figure 7: Block diagram of the components that make up the electric blower based portable emergency ventilator.

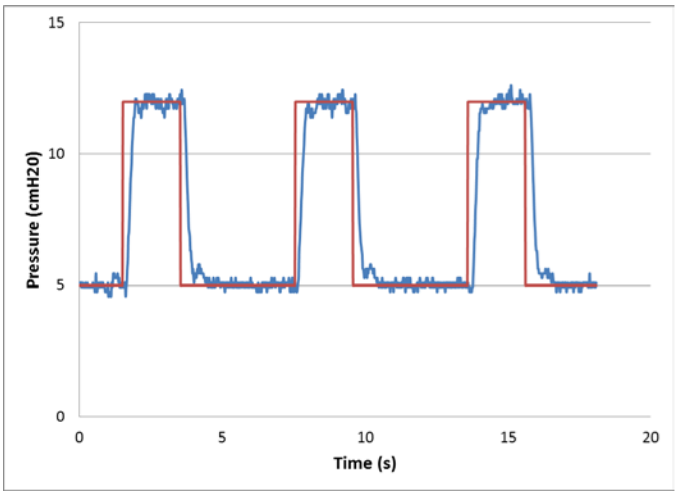

Figure 8: Demonstration of pressure control. Red line shows the desired pressure from the algorithm and the blue line shows the actual pressure within the airway.

Aim 2: Create an ergonomic and simple user interface for the prototype. Clinicians will not adopt the use of a device that is not easy to use. A comparison study of clinicians using the prototype and the bag valve mask on a test lung will be conducted. Clinician feedback will be implemented into the final design of the prototype. Also, initial equivalency will be shown between the prototype and the bag valve mask.

Aim 3: Demonstrate safety and efficacy of the device in a clinical setting. Non-invasive ventilation with leak adaptable tidal volume measurements has never been done, especially with a portable device. A clinical trial of this kind will require extensive cooperation and coordination with clinicians as well as the IRB. Through these trials, safety and efficacy will be established so that the device can be FDA approved.

Conclusion

The electric blower based portable emergency ventilator will increase the positive outcomes for patients by reducing the risk of injury that comes from bag valve mask ventilation. It will be the first portable positive pressure ventilation device to have leak adaptable tidal volume measurements. The device will reduce operator error, comply with guidelines for ventilation, and improve a clinician's ability to perform other critical tasks. The reduction of injury to the patient and the increase in convenience for the clinician will reduce the financial burden on hospitals and medical providers.

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