Simple Ventilation Device for Procedural Sedation, Difficult Intubation in the OR, and Transport

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Abstract: The American Society of Anesthesiology Task Force on Sedation and Analgesia found drug-induced respiratory depression and airway obstruction to be the primary cause of morbidity associated with sedation and analgesia. Similarly, if a patient in the operating room is anesthetized to be intubated, but the intubation is difficult, the patient requires immediate respiratory support until a more intensive intubation attempt can be made, to prevent severe morbidity. The typical approach in these cases is to temporarily ventilate the affected patient by hand, using a face mask and a bag that is periodically squeezed to deliver breaths. This requires skill, both hands, and completely involves one clinician who is not able to assist elsewhere. Intensive Care Unit ventilators are an option for ventilating patients with a mask in hospital settings, but they are bulky, expensive, and complicated, and require specially trained personnel.

Our innovative device provides continuous positive airway pressure which helps prevent the airway from obstructing due to soft tissue collapse. It also monitors tidal volume, respiratory rate, and airway resistance. If a respiratory complication is detected, it increases respiratory support to provide a breath to the patient and warns the clinician. In effect, it reduces respiratory complications and replaces the need for manually bag-ventilating the patient. The tested algorithms create reliable and continual respiratory support and monitoring even in the presence of large or varying leaks around the patient's face mask. Using a modern blower motor and a strategy to minimize power consumption, our ventilator is small (about 8X6X2 inches), operates without compressed gas, and can run on batteries for up to 8 hours at a time if needed. An early prototype of the technology has shown very good performance in preliminary bench testing on a manikin.

Introduction

The American Society of Anesthesiology Task Force on Sedation and Analgesia found drug-induced respiratory depression and airway obstruction to be the primary cause of morbidity associated with sedation and analgesia[1]. Mechanical ventilation is commonly used when a person is incapable of adequate spontaneous breathing. Such situations include emergencies, transport, and sedated or anesthetized patients between intubation attempts in clinics and hospitals. In most cases, when respiratory support is indicated but intubation is not possible or not deemed necessary, clinicians use a self-inflating manual ventilator or bag-valve-mask (BVM). It is often the only form of life support for an unconscious patient before they are intubated and placed on a ventilator. This manual ventilation is a difficult technique to master and requires the full attention of the person performing the ventilation[2], creating the need for additional staff to assist in vital patient care. Further, there is no indicator that lets the clinician know whether their patient is adequately ventilated, which can lead to considerable patient risk and even death.

Non-invasive ventilation (NIV) is the administration of ventilatory support without an invasive artificial airway such as an endotracheal tube. Continuous positive airway pressure (CPAP) is a form of NIV that can be used to hold the airway open during procedural sedation, following sedation, and during monitored anesthesia care (MAC) when patients are sedated but are not intubated. Low cost disposable CPAP devices use high flow oxygen to generate CPAP but they do not work well when the mask leak is changing nor do they provide monitoring of airway pressure or tidal volume. We have developed a prototype portable electric blower-based mask ventilator system (EBMV) that provides ventilation and CPAP with integrated reliable ventilation monitoring and alarms. This new device effectively combines the portability and simplicity of the BVM with the high tech monitoring and patient support of NIV.

The crucial feature of our system is automatic leak compensation that accounts for changing air leaks around the mask. Leak adaptation allows the EBMV to deliver consistent and safe CPAP pressures to the patient as well as quick and accurate ventilation monitoring. The system operates in two main modes: monitoring and automatic mode. Monitoring mode provides CPAP to a spontaneously breathing patient and displays ventilatory statistics. If no breaths are detected for a specified amount of time the system shifts into automatic mode. Auto mode raises and lowers the pressure at the mask in order to deliver fresh gas to the lungs (pressure support breaths). During both modes of ventilation the EBMV utilizes an integrated flow sensor and the leak adaptation algorithm to accurately calculate the volume of inspired air (tidal volume) as well as respiration rate (RR). The EBMV reports these values to the clinician in a simple display,

allowing them to adjust the care of the patient to ensure they are adequately ventilated.

During manual ventilation using a BVM, the clinician's full attention is needed to hold the mask in place and to give breaths. One hand is needed to hold the mask tightly to the patients face with the thumb and index finger to prevent leak while also holding the airway open with the smaller digits to allow breathing during airway collapse. The other hand is used to carefully squeeze the bag to ensure adequate tidal volume while being careful not to over-pressurize the lungs and cause harm. Because this task requires the full attention of the person giving ventilation, a second clinician is needed to perform additional patient care tasks such as administering medications and providing other care. Preliminary test data show that the EBVM allows ventilation using just a single hand or using a simple disposable elastomeric strap (H-strap).

The EBMV is likely to increase the positive outcomes for patients by reducing the risk of barotrauma or hypoventilation from BVM ventilation. It will be the first portable positive pressure ventilation device to have leak adaptable ventilation monitoring. The device is expected to 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.

Significance

Respiratory Depression. Most agents used to induce and maintain general anesthesia also drastically affect the drive of the patient to breathe. Breathing is controlled both behaviorally as well as chemically and anesthesia alters both [4,5]. Anesthesia can also cause respiratory depression by sedative-induced airway collapse. This is when the muscles surrounding the airway are relaxed to the point that they can no longer support the tissue surrounding the airway. There is not an accepted standard for the definition of respiratory depression but it is commonly described as a combination of apneic events and/or oxygen desaturation [6-12]. The most common metric that defines respiratory depression is a breath rate below 8-10 breaths/minute and/or and oxygen desaturation of less than 80%-90% SpO_2 [7]. Other methods of diagnosing respiratory depression attempt to count the number of apnea/hypopnea events in a given unit of time. There is some variation in the definition of apnea but it is most commonly defined as the complete cessation or reduction by 50% of airflow into the lungs. Much of the research that has been aimed at apnea focuses on sleep apnea but the principles translate over to opioid induced respiratory depression [13,14]. Respiratory depression, if not properly addressed, is a serious and life threatening problem that accompanies anesthesia in most cases [9].

Respiratory depression is also common during procedural sedation where sedatives and analgesics are administered to facilitate a procedure without inducing general anesthesia. Millions of procedural sedations are performed each year in the U.S. during colonoscopies and other procedures. Sedation agents have been shown to cause respiratory depression. The literature reports clinically significant respiratory complications in up to 6% of procedures with sedation.[15-17] In a preliminary study, we observed 26 sedated patients undergoing a colonoscopy with an average of 2.69 apneic events (>10 seconds with no gas flow) per patient. The EBMV will address this problem by providing respiratory support and monitoring during procedural sedation. It can easily be extended later to a variety of other applications and situations, in which respiratory depression is an issue.

Ventilation Methods. The EBMV provides the portability of bag-valve-masks (BVM) and the sophisticated ventilation support and monitoring of high-end and expensive non-invasive ventilators (NIV). It utilizes the benefits of these devices while avoiding their shortcomings:

Bag-Valve Mask Ventilation. During emergency patient ventilation, the victim will most likely be ventilated by a bag-valve-mask (BVM) like the one shown in **Figure 1**. The BVM is used to ventilate patients during transport, between intubation attempts and at other critical times when the patient is incapable of adequate spontaneous ventilation [18]. The BVM 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 [19].

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

The bag valve method is a difficult technique to master and requires the full attention and both hands of the person performing the ventilation [20,21]. In the operating room (shown in **Figure 2**), manual ventilation may be performed by squeezing the bag of the anesthesia machine while holding the mask to the patient in a similar manner as when using a BVM. Many novice clinicians have

Figure 2 – Manual ventilation using BVM built into anesthesia machine.

difficulty maintaining an open airway while giving breaths. One hand is needed to grasp the mask tightly to the patients face to prevent leak while using two fingers to provide the required chin-lift and the proper head-tilt to keep the airway open. The other hand is used to carefully squeeze the bag to ensure adequate tidal volume while being careful not to over-pressurize the lungs and cause barotrauma. If the airway is obstructed, the clinician, who is squeezing the bag, may mistakenly think there is an adequate tidal volume being delivered when in fact, the entire tidal volume may be lost through a leak between the mask and the patient's face[2]. Because this task requires the full attention of the person giving ventilation, a second clinician is needed to perform additional patient care tasks such as administering medications and providing other care.

It is difficult for the person operating the BVM to be sure that the patient they are ventilating is receiving the correct respiratory rate. Clinical studies in emergency situations reveal that trained clinicians give on average 25-35 breaths per minute (bpm), not the 10-12 bpm prescribed by guidelines. Keeping artificial breath rates low is difficult because the high adrenaline state of the situation alters time perception and the rapidly refilling bag sets up a reflex in which the clinician is inclined to deliver breaths as soon as the bag inflates[2]. Successful BVM is classified as approximately 8-10 mL/kg tidal volume and an upper limit pressure of 20-25 cmH_2O [22].

It is also difficult for the person operating the BVM to ensure that the person they are ventilating is receiving the correct tidal volume. Excessive pressures from too high tidal volumes can cause a decrease in cardiac preload, traumatic brain injury, hemorrhagic shock, gastric insufflation[23-25], and lung injury. Inadequate pressure can lead to the patient not receiving adequate oxygen delivery and carbon dioxide removal. [25]

Difficult or impossible mask ventilation is defined as inadequate gas flow, unstable ventilation, or requiring of an additional provider. The incidence rate of difficult or impossible mask ventilation is reported as 1.4% [26,27]. The factors that contribute to difficult mask ventilation are mostly physiological and patient specific. There are multiple references calling for additional BVM training to medical staff in order to raise consistency and avoid complications[28-32].

Endotracheal Intubation. The most common form of airway management in an OR setting is endotracheal intubation (ETI). When a patient is undergoing general anesthesia he/she will most likely be placed on a mechanical ventilator via endotracheal intubation. The time between when the patient loses consciousness and the ability to support their airway and the time that he/she is successfully intubated is critical and depends on the ease of the intubation procedure. There are multiple problems that can occur during this process that can result in injury to the patient. The probability of airway injury and infection increases drastically with each failed attempt to intubate[33]. Injury is common in the following areas: cervical spine, nasal mucosa/septum, dental trauma, lips, tongue, laryngeal trauma, and airway perforation[34]. When ETI fails multiple times the patient is subjected to extended periods of time without oxygen. In difficult intubations the esophagus can be mistaken for the airway, which is referred to as esophageal intubation. When this occurs the patient is at risk of regurgitation and aspiration of stomach contents as well as other contaminants that result in airway infections. Multiple studies have shown that the longer the endotracheal tube is in place, the greater the chance the patient will develop an airway infection[35].

In the operating room intubation fails 0.035% of the time[36], and up to 1% of the time in emergency situations. 17% of the respiratory-related injury is caused by difficult intubation and 28% of all deaths associated with anesthesia are due to the inability to mask ventilate or intubate[37]. Difficult intubation accounts for about 1-4% of cases. Obesity and poor mouth opening are the main causes of difficult intubations.

Airway support. When a patient is overweight, there is extra soft tissue surrounding the airway that may cause it to collapse and obstruct when the patient is under sedation. 30% of adults 20 years and older in the U.S. are obese and it is estimated that there are 300 million obese people worldwide and another 750 million are overweight [37]. In many sedated patients the patient's spontaneous respiration is adequate if the airway is supported so that inspiratory flow is unobstructed by soft tissue around the airway. The clinician can support the airway manually using a chin lift, jaw thrust, or by inserting an artificial airway if sedation is sufficiently deep. An alternative method of supporting the airway is to use CPAP which uses elevated air pressure inside the airway to hold the airway open against sagging soft tissues so that the patient can breathe. In CPAP, a mask is placed on the face and air flows constantly into the mask out of a leak port in the mask so that the airway is slightly pressurized at all times. Obstructive Sleep Apnea patients are often prescribed home-use CPAP machines in order to prevent their soft

tissues obstructing their airways during sleep. [6,9,12,13] CPAP can be given using simple constant flow generators such as the Boussignac device or using feedback controlled systems that maintain set airway pressure regardless of mask tightness and leak. These feedback controlled systems are generally large, expensive, and complex (e.g., V60 noninvasive ventilator, Philips-Respironics, Carlsbad, CA). The EBMV provides the benefits of the larger system in a small (approximately 8X6") battery operated package.

Non-Invasive Ventilation. CPAP is a form of non-invasive ventilation (NIV), which is a technique that is growing rapidly in popularity for mask ventilation support primarily in intensive care units (ICU). NIV avoids placing any devices inside of the patient's airway but instead supports a compromised airway with a pneumatic splint of air pressure. Compared with endotracheal intubation, NIV reduces the length of ICU and hospital stay, morbidity, and mortality in patients with acute and chronic respiratory failure[38]. Current noninvasive ventilators are physically large and expensive. To facilitate patient monitoring and accurate breath triggering, they require a precise fitting of the mask to each patient using a complex headgear that cannot be stretched. This tight seal to the patient's face allows the machine to accurately calculate the tidal volume delivered to the patient since the leak conditions are stable and can be well characterized. While these large devices would function during an emergency situation, they are too large to accommodate a patient in transport and too expensive to have readily available in every setting where ventilation is needed. A typical noninvasive ventilator includes features such as complex breath triggering and high levels of pressure support capability that are needed to treat ICU patients suffering from respiratory disease, but are not needed for typical ventilation or simple airway support.

The BVM can be thought of as a manual form of NIV without the benefit of ventilation feedback to the operator or airway support for the compromised airway. The EBMV brings the benefits of NIV to OR, sedation, and emergency situations in a form factor that mimics that of a BVM in portability and simplicity of use.

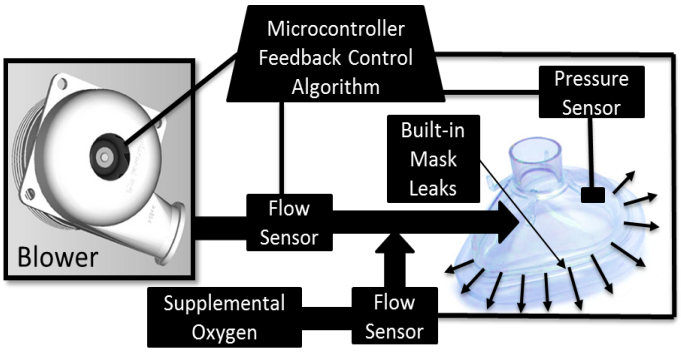

Figure 3: Schematic diagram of the proposed device.

Methods

The EBMV is a non-invasive ventilator which has been optimized to meet the needs of procedural sedation airway support and ventilation. The breath delivery, monitoring algorithms, flow generator and sensors have been modified and simplified to meet the conditions that are unique to clinics and operating rooms.

The resulting system provides:

- Ability to deliver pressure support ventilation up to 25 cm H2O without the need for compressed gas from the wall or tanks with automatic mask leak compensation.
- Integrated monitoring of the patient's breathing and inspired oxygen. Tidal volume calculation and breath rate measurement using a poorly fitted mask that is held in place with variable force (hand or disposable elastomeric strap) during the breath.
- Leak compensated continuous positive airway pressure (CPAP) up to 25 cm H2O to support a collapsed airway
- Long battery life (> 8 hours on a single charge) in a package weighing less than 3 lbs.

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

The electric blower shown in **Figure 4** has just recently become available commercially. The electric blower based portable ventilator offers a wide range of benefits over the current standard of care. The device endeavors to replace the bag-valve mask devices as well as combine them with non-invasive ventilator technology in a portable, reliable, and easy to use device.

Pressure Control: The system uses a high performance miniature radial blower (model U51DL-4 from Micronel US, LLC) shown in **Figure 3** to generate precise flows and pressures under microprocessor control. A pressure sensor (BLVR-L01D, AllSensors, Morgan Hill, CA)

measures mask pressure and the system software controls the speed of the blower to provide precise mask pressure regardless of mask leak. The system ventilates the patient by periodically raising the mask pressure so that gas is forced into the patient's lungs. The volume of each breath is determined by the amount of pressure support, and the patient's lung (and chest wall) compliance. In a typical patient with compliance of 50 ml/cm H_2O, pressure support of 10 cm H_2O will result in a 500 ml breath. The prototype system can deliver pressure support breaths of up to 25 cm H_2O.

Major hazards of manual mask ventilation include barotrauma (pressure damage of the lungs) and esophageal ventilation where gas is forced into the stomach rather than the lungs. In the EBMV, mask pressure is precisely controlled so that it will not exceeds the opening pressure of the esophageal sphincter (20-25 cm H_2O) to avoid forcing gas into the stomach rather than into the lungs.

Integrated Monitoring: The EBMV incorporates a differential pressure (MPXV5004DP, FreeScale Semiconductor, Austin TX) type flow sensor which continuously measures the flow from the blower and supplemental oxygen going to the patient. Using the known flow and mask pressure signals, the software is able to characterize the amount of leak at each pressure level for each breath. After the leak flow has been compensated for, the EBMV calculates the flow of gas into and out of the patient for each breath. Continuous monitoring of the delivered breath gives the user information about effective ventilation and provides alarms for airway obstruction and other causes of inadequate ventilation. The system also monitors mask pressure and alarms if the leak is so large that a minimum mask pressure cannot be maintained. We have modified the monitoring algorithms typically found in a non-invasive ventilator so that measurements can be made even when the position of the mask relative to the face is not constant. For instance, when the mask is held in place by hand or using an elastomeric H-strap that is typically used in anesthesia and emergency care, the mask moves slightly off the face when mask pressure is raised. Non-invasive ventilators designed for ICU use cannot make accurate measurements in this condition and typically give alarm messages when the mask leak is unstable. We are able to relax the mask position requirements of the algorithm, making it more robust and reliable. In addition, the EBMV measures the flow of supplemental oxygen that is added into the breathing circuit and, combined with the blower flow signal, calculates the inspired oxygen fraction (FiO_2) that is being delivered to the patient on each breath. The clinician is then able to adjust the flow of oxygen according to the needs of the patient.

Leak compensated, monitored CPAP. The EBMV utilizes CPAP to support the airway of a patient who is under anesthesia and is at risk for airway collapse. By holding the mask pressure at a fixed constant level under feedback control, the system maintains airway support. The system is automatically leak compensating so that the mask can either be held in place manually by the clinician or can be secured using a common disposable elastomeric H-strap (**Figure 6**). Leak compensation is what sets the EBMV apart from current NIV devices. NIV typically requires an extensive and precise mask fitting in order to minimize mask leak and ensure the ventilator can correctly report the breath information. The EBMV automatically adapts to leak conditions and gives the clinician accurate stats regardless of a poor mask fit or excessive leak. Because the system monitors respiratory rate and tidal volume during CPAP, the clinician is aware of slowed respiratory rate caused by opioid medication and/or of upper airway obstruction.

Auto Mode: (Figure 5)

- CPAP to maintain open airway
- Easy one-finger chin-lift
- BiPAP breath delivery – bi-level positive airway pressure
- Easily adjusted pressure levels
- Instant tidal volume measurement
- Set respiration rate as high as 20 breaths/min
- Clinician can manually trigger breaths with physical control

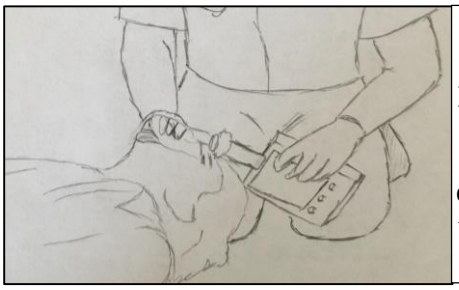

Figure 5 – Illustration of prototype concept being used in Auto-Mode to deliver ventilation to an unconscious patient.

Monitor Mode: (Figure 6)

- Set level of CPAP
- Monitors patient's breathing
  - Respiration rate
  - Tidal volume
  - FiO_2
- Smart monitor mode

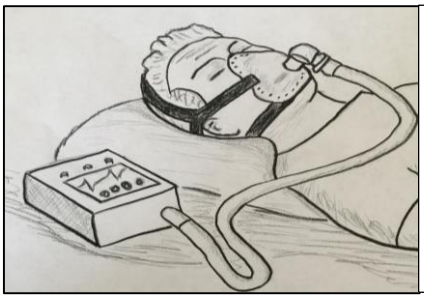

Figure 6 – Illustration of prototype concept being used in Monitor-Mode on a breathing patient.

Portability. In order to adequately replace the BVM devices for use during transport, the device must be portable. The EBMV is portable and lightweight at approx. 1.4 kg and occupies a volume similar to a BVM (about 1.5 L or 96 in^3). It is powered by a rechargeable battery that provides ventilation and monitoring for an excess of 8 hours. The battery powers the electric blower to be able to deliver pressures up to 25 cmH_2O, which exceeds what is physiologically necessary.

Auto On/Off. The combination of pressure and flow sensors automatically detects when the mask is placed on the face of the patient and begins ventilation support. Likewise, when the mask is not in use the blower automatically shuts down to conserve battery power and reduce noise.

Preliminary Feasibility Data

Evaluation of Monitor Mode

CPAP through a patient mask can be used to hold the airway open during procedural sedation, in the recovery room, and during other monitored anesthesia care when patients are sedated but are not intubated. Low cost disposable CPAP devices use high flow oxygen to generate CPAP but do not compensate well for changing mask leak nor do they provide monitoring pressure level or patient breathing. The EBMV includes integrated patient monitoring that measures airway pressure, breath rate, and spontaneous tidal volume in the presence of mask leak while maintaining CPAP. We used a bench simulation to evaluate the accuracy of the patient monitoring capability integrated into the prototype system.

Methods: The EBMV was connected to a manikin head via a modified air cushion mask that was held in place using a common elastomeric strap (H-strap). The trachea of the manikin head was connected to one side of a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA) and the other side of the test lung was mechanically ventilated and the two sides of the test lung were mechanically coupled so that spontaneous breathing was simulated in the side connected to the manikin. CPAP was delivered by the test system and respiratory rates and tidal volumes as measured by the CPAP system and the gas flow analyzer were compared. The EBMV measures supplemental oxygen flow and calculates FiO_2 from the ratio of flow from its compressor to supplemental oxygen flow. Data was collected over a range of CPAP settings (4, 6, 8 cm H_2O), respiratory rates (6, 8, 10, 15, 20 breaths/min), supplemental oxygen flows (1, 2, 3, 4, 5 L/min), and tidal volumes (200 and 500 ml).

Results: The average difference between measured and actual respiration rate was 0.093 ± 0.024 (mean ± one standard deviation) breaths per minute. The average difference between FiO_2 measured in the test lung and FiO_2 calculated by the system was near zero and was too small evaluate using a clinical monitor (CapnoMAC Ultima, Datex, Helsinki Finland). The plot (**Figure 7**) shows average error in tidal volume measurement when 200 ml breaths were simulated was 2.93 ± 6.83 ml and was -7.4 ± 7.55 ml when 500 ml breaths were simulated.

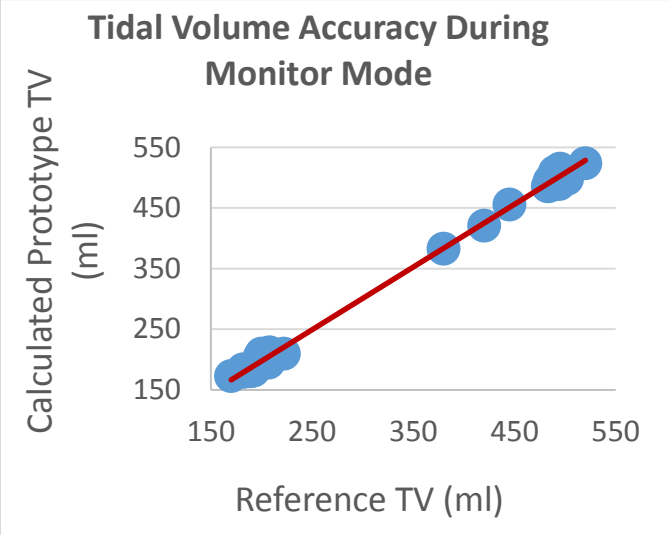

Figure 7: Tidal volume calculated by the prototype system versus the reference tidal volume as measured by the gas flow analyzer during spontaneous ventilation.

Evaluation of Auto Mode

The self-inflating manual ventilator or BVM is used to ventilate patients during transport, between intubation attempts, and at other critical times when the patient is incapable of adequate spontaneous ventilation. The EBMV automatically compensates for mask leak and delivers CPAP to hold the airway open during obstructive apnea and delivers mandatory pressure support breaths to ventilate during opioid induced central apnea. However, if the lungs are stiff (low compliance) the set level of pressure support may not induce large enough tidal volumes for adequate ventilation. The EBMV has an integrated flow sensor and algorithms that measure patient tidal volume even in the presence of mask leak and inform the user of the possible need to use more pressure support. The EBMV also measures the flow of supplemental oxygen and calculates the resulting inspired oxygen fraction (FiO_2). We evaluated the accuracy of the integrated tidal volume measurement and FiO_2 calculation in the EBMV using a bench simulation. The EBMV measures the total (patient plus leak) flow leaving the ventilator and uses a compensation algorithm to determine the portion of gas that enters the patient.

Methods: The prototype system was connected to a manikin head via an air cushion mask that was modified to include an intentional leak. The mask was held in place using a head strap. The trachea of the manikin head was connected to a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA) that directly measured tidal volume, respiratory rate and airway

pressure. These direct measurements were compared against measurements made by the portable ventilator that was connected distal to the patient through the modified mask. Various levels of simulated lung compliance and pressure support were tested. The system was tested over a range of simulated lung compliance (0.10, .030, 0.50 L/cm H_2O), CPAP (2, 4, 6, 8 cm H_2O) and respiratory rate settings (6, 8, 10, 15, 20 breaths/min).

Results: The plot (**Figure 8**) shows the tidal volume calculated by the EBMV versus the reference tidal volume as measured by the gas flow analyzer. The average difference in the tidal volume measurement was -4.77 ± 7.02 (mean ± one standard deviation) ml. The average difference and standard deviation was consistent over all levels of CPAP that were tested.

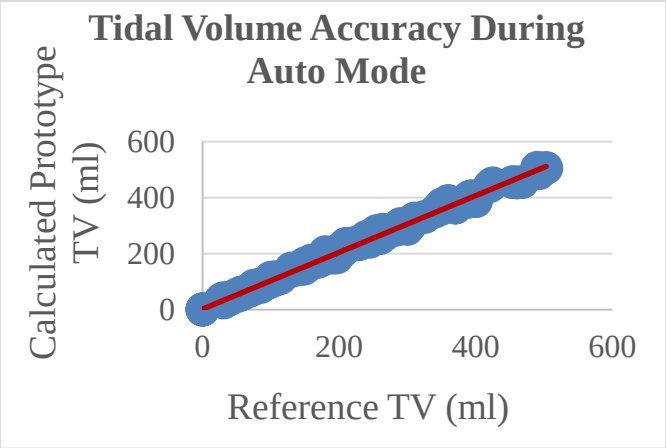

Figure 8 - Tidal volume calculated by the prototype system versus the reference tidal volume as measured by the gas flow analyzer.

Evaluation of Single-Handed Mask Ventilation

During manual emergency patient ventilation using a BVM the clinician's full attention is needed to hold the mask in place and to give breaths. One hand is needed to hold the mask tightly to the patients face to prevent leak while also holding the airway open to allow breathing during airway collapse. The other hand is used to carefully squeeze the bag to ensure adequate tidal volume while being careful not to over-pressure the lungs and cause harm. Because this task requires the full attention of the person giving ventilation, a second clinician is needed to perform additional patient care tasks such as administer medications and provide other care. The EBMV uses pressure controlled high gas flow to compensate for mask leak and generates CPAP to hold the airway open. Mandatory breaths are given by increasing the feedback-controlled mask pressure during inspiration which forces gas into the lungs even where there is mask leak. The mask can be held on the patient manually using a single hand or can be held in place using a simple elastomeric strap (H-strap). We compared the ability of volunteers to deliver breaths in a bench simulation using a conventional BVM and both hands and using the test system with a single hand.

Methods: The EBMV was connected to a manikin head via an air cushion mask that was modified to include intentional mask leak. The trachea of the manikin head was connected to a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA). The gas flow analyzer directly measured the volumes entering and leaving the test lung. Eight volunteers were asked to deliver 500 ml tidal volumes at six breaths per minute. The same volunteers were then asked to use the prototype system by holding the modified mask on the manikin face using their non-dominant hand while performing a distracting task on their smart-phones with the other hand. The resulting delivered tidal volumes, breathe rates and airway pressures were recorded using the gas flow analyzer. If the mask leak was too high to deliver the full volume, the system alerted the user to apply more pressure to the mask and reduce the leak. The accuracy of the delivered ventilation was measured by the gas flow.

Results: The average delivered tidal volumes ranged from 207 to 723 ml using manual ventilation and from 420 to 524 ml using the EBMV. The average peak inspiratory pressure ranged from 6 to 16.93 cm H_2O with a single breath maximum of 19.3 cm H_2O using manual mask ventilation and from 13.95 to 14.13 with a single breath max of 14.3 cm H_2O using the prototype system. The prototype system maintained CPAP at 4 cm H_2O throughout the test.

Conclusion

The portable mask ventilator system could help maintain adequate ventilation by maintaining positive airway pressure to hold the airway open in overly sedated patients and those susceptible to sleep apnea. Patient monitoring capability in this system is useful for selecting CPAP levels and ensuring adequate patient ventilation during sedation. The system includes a battery powered blower to generate a high gas flow under feedback control to maintain a fixed pressure even when mask leak is high. Our system uses an integrated flow sensor along with a leak-compensation algorithm to accurately measure breathing rate, tidal volume, airway pressure, and inspired oxygen (FiO_2). The system will also alert the clinician of sudden changes in airway resistance. If apnea is detected the system can automatically engage in BPAP (Bi-level positive airway pressure), which will ventilate the patient during central apnea. This allows the patient to receive automatic mask ventilation until respiratory drive is restored.

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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