The Dangers of Bag Valve Devices

a report by

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Utilizing a bag valve device to ventilate has been the standard of care in the pre-hospital environment for the last 50 years. However, because a bag valve device requires constant and steady manual pumping by the operator, it does not guarantee consistent air delivery. As a result, bag valve device resuscitation has been linked to a high incidence of hyperventilation, which adversely affects cardiac arrest patients, patients with traumatic brain injury, and patients in shock. Bag valve devices have also been linked to gastric insufflation. A new device that mitigates the potential for injury, reduces operator error, complies with guidelines, and improves the medical responder's ability to perform other critical tasks is urgently needed.

Ventilating a patient using a bag valve device requires significant concentration and skill in stressful situations. With every squeeze of the bag, the rescuer is selecting the respiratory rate and tidal volume. This can be extremely difficult for even the most highly trained professional: "Keeping artificial ventilation rates low is difficult because the high-adrenaline state of the rescuer alters time perception, and the rapidly refilling bag–ventilation systems set up a reflex in which rescuers are inclined to deliver breaths as soon as the bag inflates."[1]

Cardiac Arrest

A clinical study observing ventilation rates in cardiac arrest patients found that emergency medical services (EMS) rescuers who were trained to follow the American Heart Association (AHA) guidelines were delivering on average 37±4 breaths per minute, not the 10–12 breaths per minute prescribed by the guidelines. Even after the rescuers were re-trained to deliver 12 breaths per minute, they were observed delivering an average of 22±3 breaths per minute.[2]

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To test the impact of hyperventilation, the same study investigated a swine model with ventilation delivered at either 12 or 30 breaths per minute. Six out of seven animals in the group that received 12 breaths per minute survived, while only one of seven that were hyperventilated survived: a 70% reduction in absolute survival. Hyperventilation results in high intrathoracic pressure during the decompression phase of cardiopulmonary resuscitation (CPR), which decreases cardiac pre-load[3] and cardiac output[4] and impedes right ventricular function. Increased tidal volume is also known to adversely affect cardiac output.[5] The authors of the study believe that "the elevated mean intrathoracic pressures caused by excessive ventilation inhibited venous blood flow back to the right heart, as there was insufficient time to allow for the development of negative intrathoracic pressure between compressions." Reduced pre-load results in lower stroke volume and, ultimately, decreased cardiac output

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A separate study evaluating the respiration rates provided by critical-care trained physicians with more than 10 years of acute care experience, most of whom were basic life support (BLS) and advanced life support (ALS) instructors, demonstrated that the respiration target rate was achieved only 18% of the time for CPR patients even when performed in a hospital setting.[6] These physicians on average delivered 33% more ventilations than the guidelines prescribed. These two studies highlight the difference in performance in a classroom and during actual cardiac arrest even among well-trained professionals and professionals who have been re-trained.

Traumatic Brain Injury

There are 1.6 million head injuries in the US every year,[7] costing the American people an estimated $100 billion annually.[8] Sustaining a significant head injury as the result of trauma doubles the mortality rate, and two-thirds of survivors suffer permanent disability. Treatment options in the pre-hospital environment are limited.[9] However, it is important that the rescuer does not cause further injury by unduly elevating intracranial pressure (ICP) during positive-pressure ventilation. Positive-pressure ventilation increases intrathoracic pressure and ICP.[10] Hyperventilating a patient or delivering excessive tidal volumes could be disastrous, as elevated ICP is a leading cause of secondary brain injury.

Hemorrhagic Shock

"Even after moderate levels of hemorrhage in animals, positive-pressure ventilation with normal or higher respiratory rates can impair hemodynamics."[131] Some investigators have now begun to question "the notion that severity of injury is the lone factor leading to worse outcomes and, in turn, have raised the issue that overzealous ventilation may also be a contributory factor."[12] Excessive ventilation raises the mean intrathoracic pressure, which impedes venous return and decreases pre-load, stroke volume, and, consequently, cardiac output.[10] During shock, the body's natural response is to recruit blood volume to the vital organs. Increased intrathoracic pressure associated with excessive positive-pressure ventilation impedes this process.

Gastric Insufflation

Gastric insufflation is a major concern when ventilating through an unprotected airway. A study measuring the differences between a bag valve device and a transport ventilator used with a mask found that "almost 10 times the amount of air was insufflated into the simulated stomach per breath when the subjects used a bag valve device."[13] Aggressive bagging allows air to enter the patient's stomach by creating airway pressures that exceed the pressure of the lower esophageal sphincter.[14] Once air enters the stomach, it begins an adverse cycle in which it becomes more likely that air will continue to be pumped into the stomach, causing further stomach insufflation, reduced pulmonary compliance, and decreased lung ventilation.[15] Gastric inflation can lead to regurgitation and aspiration.

The Hidden Cost of Bag Valve Devices

In addition to the many safety concerns of bag valve devices, bagging completely incapacitates a medical responder from addressing other injuries, performing compressions, attending to other patients, or transporting the patient. Sending additional responders to the scene to address the possible need for respiratory support is not a cost-effective or realistic use of man-power. In mass casualty situations where responders have to triage the critically wounded, patients who need to be bagged are likely to be left to die. Equipment that mitigates the potential for injury, reduces operator error, complies with guidelines, and improves a medical responder's ability to perform other critical tasks is therefore critically needed.

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The Merger of Ventilatory Capability

The majority of the EMS market relies on either bag valve devices or pneumatic ventilators. Although bag valve devices are simple instruments, skill and vigilance are essential, and even then consistent air delivery is not assured. Many of the pneumatic ventilators in use by EMS departments do not provide sensing capabilities or safety alarms. The devices that do provide these features are often overly sophisticated and expensive for pre-hospital use. EMS providers usually rely on 50 psi tanks that are secured in the ambulance. Consequently, the patient is usually bagged from point of injury to the ambulance and then again when transported from the ambulance to the emergency department.[1]

AutoMedx has developed an efficient, safe, and cost-effective alternative to bag valve devices and pneumatic ventilators that provides the safety, ease of use, and level of respiratory support required in the pre-hospital environment. The Simplified Automated Ventilator (SAVe) provides the ideal adjunct between bag valve devices and expensive transport ventilators. It is a hybrid of both ends of the market. Like many of the high-end models, it is compressor-driven and has an array of sensing capabilities and safety alarms. However, it is easier to use, more compact, and less expensive than most low-end pneumatically driven models. The SAVe delivers an AHA-compliant tidal volume (600ml) at a fixed rate of 10 breaths per minute. The device can be used with either a mask or an airway. In a BLS setting, the device can be quickly set up en route or on the scene with a mask so that ventilations can be given immediately. The flow rate (16 liters per minute) and tidal volume are designed to minimize gastric inflation.

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Simplified Automated Ventilator

SAVe was originally designed for Special Forces medics for use at point of injury until the patient could be evacuated. It is rugged and highly portable, and contains a number of alarms and safety features not found in similarly priced devices. The SAVe delivers a single tidal volume and respiratory rate, which removes any guesswork and reduces operator error. It is a set-flow, time-cycled, pressure-limited (38cmH2O) device. It is intended to be used with a mask in a pre-hospital setting until a more secure airway is available.

The ventilator is completely self-contained, weighs only 3lb, and does not require a compressed gas source for power. Low-pressure supplemental oxygen can be used if desired. The SAVe utilizes a rechargeable battery-driven pump to deliver ambient air for 5.5 hours on a single battery charge. It may be recharged from a standard AC outlet. It is ideally suited for situations where the size, weight, portability, and extreme ease of use are a consideration. SAVe's small footprint (6.5x6.25x2.5 inches; 3.1lb) enables easy storage in a medical bag or on an ambulance. Field medics, mass casualty incident coordinators, and EMS professionals will find the device well suited to their needs. ■

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