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A Comparison of Ventilation Rates Between a Standard Bag-Valve-Mask and a New Design in a Prehospital Setting During Training Simulations

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Introduction

Excessive ventilation of sick and injured patients is associated with increased morbidity and mortality.1–5 The current standard of practice is the use of a traditional bag-valve-mask (BVM) to provide ventilation to critically ill and/or injured persons. Current BVM devices do not have a method to control ventilation rate and this may contribute to excessive ventilation rates, which have been implicated in iatrogenically induced morbidity and mortality. Excessive ventilation with BVM devices can occur among well-trained healthcare professionals and is not limited to unusual circumstances or the undertrained. The minute ventilation provided to patients is the product of the ventilation rate and tidal volume (TV) delivered, both of which are controlled by the operator of the device. Because excessive ventilation depends on the individual healthcare provider, changes in the equipment that address rate, TV, or both could decrease or eliminate this error. Therefore, it has been recommended that a means to remove the human error component in the use of the BVM device be further developed. Combat Medical Systems® (CMS; http://www.combatmedical systems.com) is developing a new BVM device that limits the rate of ventilation by controlling the amount of time for the bag to inflate. This device uses a spring to inflate over 5–6 seconds and is designed to prevent excessive ventilation. It is also designed to be completely compressed, with the intent of reducing variability in TVs. This device has the potential to address many of the current shortcomings of the traditional BVM. Physiology Significantly increased intrathoracic pressure resulting from positive pressure ventilation decreases venous return to the heart by compressing the low-pressure veins, and subsequently decreases cardiac output, systolic blood pressure, and coronary perfusion pressure. With higher ventilation rates, the increased thoracic pressure is present for a longer time and decreases the ability of the cardiovascular system to deliver oxygen via the blood to tissue and organs. This is particularly problematic in hypotensive patients. Hyperventilation occurs when carbon dioxide is cleared from the body through ventilation at a rate greater than it is produced. It results in hypocarbia and induces respiratory alkalosis. Both of these factors cause hemoglobin, the oxygen-binding portion of blood, to bind more tightly to oxygen, increasing the likelihood of poor gas exchange. Hypocarbia also has a direct effect on blood vessels, leading to cerebral vasoconstriction and inadequate oxygen delivery to the brain, which can be especially detrimental in patients who have suffered a traumatic brain injury (TBI) Military Relevance Excessive ventilation of patients with both significant hemorrhage and/or TBI is associated with worse outcomes when compared with accepted recommendations for proper ventilation rates. These two conditions have obvious significance for the military, given the high incidence of both types of injuries in combat casualties due to the frequent occurrence of blast injuries and penetrating trauma. In austere environments commonly encountered by Medics, it is even more difficult to monitor for hyperventilation because they likely will not have the monitoring equipment to do so. If effective, the new device could result in changes to the established medical equipment sets of military units and integration of the device into standard medical training. Ultimately, this type of device could lead to reductions of iatrogenically induced morbidity and mortality by decreasing or eliminating the incidence of hyperventilation in the early treatment of combat casualties. Our hypothesis was that the new device would decrease excessive rates of ventilation compared with a traditional device when used by Army Medics in a classroom and a prehospital/ field environment.

Study Design and Methods

Setting and Subjects

This study was conducted at the Brigade Combat Team Trauma Training (BCT3) course located at Camp Bullis, Texas. BCT3 is a 5-day course required for Army Medics within 180 days of deployment to a combat theater of operations. This course was chosen because Medics come from around the country, providing a more diverse sample population, and it includes simulated combat training scenarios in field conditions to more closely simulate real-world performance. Subjects were U.S. Army Medics attending BCT3 who volunteered to participate in the study. There were no additional exclusion criteria.

Study Design

Our study used a prospective, observational, semirandomized, cross-over design that was integrated into the 5-day structure of the BCT3 course.

Materials

The standard BVM device used in this study was a Cyclone® Pocket BVM distributed by North American Rescue (http:// www.narescue.com). This device was being used at BCT3 at the time of this study and was not chosen by the investigators. The Cyclone Pocket BVM is typical of traditional BVMs. The study device is a prototype (Figure 1) under development by CMS and has not been approved by the U.S. Food and Drug Administration. In addition to the BVM devices, two types of training manikins were used. A Training Resuscitation Manikin consisting of a head, neck, and lungs was used in the classroom portion of BCT3 for airway training. A Rescue Randy® training manikin was used during the combat casualty simulations in the field.

Methods

The first portion of the study was integrated into the surgical airway skill station, during which one Medic secured the airway in the manikin and a second Medic delivered breaths with a BVM device. This station consisted of five manikins, each with the standard and study devices located next to it. Two to three Medics were assigned to each manikin at a time. Each group received a review of the procedure before performing the skill. After this, the principal investigator gave a demonstration of the study device. Ventilation rates were not addressed in this training. Volunteers participating in the study were then identified. Participants were assigned a letter-number designator (e.g., A1), with the letter indicating which class the participant was in (A = first class, B = second class, and so on) and the numbers assigned consecutively. Participants then each took turns practicing with the study device and then continued with the training scenario. The assigned numbers were used to randomly assign the participants to device order, with odd numbers using the study device first and even numbers using the standard device first. The first Medic in each group performed the surgical airway and the second Medic delivered breaths with either the standard BVM or study device. The investigators timed each iteration with an iPhone stopwatch beginning with the first breath given. The number of breaths given and the total duration of assisted ventilation were recorded. The Medic delivered breaths with the first device until the airway was secured or a minimum of 1 minute had elapsed. The Medic was then asked to switch devices and again time was measured starting with the first breath delivered. Total duration of assisted ventilation and number of breaths given were then recorded for the second device. All data were collected on standardized forms. The second portion of the study was integrated into the simulated combat training. During this portion of the course, small groups of Medics carrying all their equipment were given a mission to respond to a simulated event. They then moved on foot through a course roughly 600–800m long, treating and evacuating casualties (Figures 2 and 3). This is the culminating event of BCT3 and is designed to be both physically demanding and stressful to the Medics. Groups consisted of three to four Medics, including one senior Medic per group. All study participants had their study identification marked on their helmet so the investigators could identify them. Each group responded to their scenario individually and the investigators could not influence which study participants were assigned to particular scenarios. In addition, not all scenarios required an airway or breathing intervention. Finally, the senior Medic in each group directed the care provided by the junior Medics and when the need to provide an airway or breathing intervention arose, it was the junior Medics who performed these tasks. When a simulated casualty required assisted ventilation, measurements were recorded in similar fashion to the first portion of the study. For these scenarios each Medic carried a standard device in their aid bag. The study devices were carried by the investigators and handed to the Medics as required. Medics assigned odd numbers used the study device first and those assigned even numbers used the standard device first. Total duration of assisted ventilation and number of breaths given were recorded for each device.

Outcome Measures and Data Analysis

Descriptive data, ventilation rates per device, and ventilation rate percentage by groups were collected. The independent variables were device and device order. The dependent variable was ventilation rate in BPM. A two-factor analysis of variance (ANOVA; device, order) was calculated for both the classroom and field training portions. A Wilcoxon signed-rank test on BPM by device in the classroom and the field was done based on three groups: low, rate <10 BPM; correct, rate = 10–12 BPM; and high, rate >12 BPM.

Sample-Size Determination

We used SPSS Sample Power, version 2.0 to estimate the sample size needed for a power of 80% with a level of confidence of 95%.

Initial analysis was done with a mean ± standard deviation (SD) respiratory rate of 13 ± 3 BPM and a clinically significant difference of 6 BPM, which is equivalent to an effect size of 2.0 SDs. With these assumptions, a sample size of five per group would give the test a power of 79.1% and a sample size of six per group would give the test a power of 87.6%. Due to concern about generalizability with such a small number of subjects, the analysis was instead performed on the basis of effect size. With 64 subjects per device, the investigators would be able to detect an effect size of 0.5 SD; with 26 subjects per device, an effect size of 0.8 SD would be detectable.

Results

A total of 89 Medics were enrolled in the study and completed the classroom portion. A subset of 36 Medics were evaluated in the field. Descriptive statistics are listed in Table 1. Mean ventilation rates were analyzed with a two-factor ANOVA on BPM by device and order, with repeated measures on device in the classroom and in the field. There was a small but statistically significant difference ($p < .001$) in overall ventilation rate between devices in the classroom, representing a difference of 1.3 BPM. There was no difference in overall ventilation rate in the field between devices ($p > .05$). Order of devices had no effect on the results in the classroom or the field ($p > .05$). There was also no difference in the total duration of assisted ventilation between devices in the classroom or in the field ($p > .05$). Statistically significant differences were seen in both the classroom ($p < .001$; Figure 4) and in the field ($p < .044$; Figure 5) using the Wilcoxon signed-rank test to evaluate ventilation rates for each device by group.

Discussion

Although the differences in overall mean BPM between devices was negligible, there were apparent differences when the rates were broken down by groups. Risk of hyperventilation was eliminated in the classroom portion of the study, with a maximum recorded ventilation rate of 12.54 BPM. However, this came with increased rates of underventilation. In the field, ventilation rates increased in general, which was expected, but the trends remained the same, with an increased percentage of subjects exceeding the recommended rate with the standard device and an increased percentage falling below the recommended rate with the study device.

Ventilation rates in this study were lower than expected for both devices, but particularly so for the standard devices. Previous studies reporting ventilation rates include that of Aufderheid et al.1 in 2004, who reported a rate of 30 ± 3.2 BPM with Paramedics in a prehospital setting, and Milander et al.6 in 1995, who reported a rate of 37 ± 13 BPM with respiratory therapists responding to in hospital cardiopulmonary resuscitation. The large difference in values between these studies, which were performed in real clinical settings, and our study illustrate the limitations of using a training environment to predict real-world performance. It is likely that the nature of our training environment did not provide the same stress response seen in actual resuscitation scenarios. It is also worth noting that in terms of clinical significance, studies have shown worsening hemodynamics with increasing ventilation rates, particularly at rates ≥20 BPM.1,2 Although uncommon, rates ≥20 BPM were seen in this study with the standard device only, whereas the highest recorded rate with the study device was <15 BPM. On the other hand, both devices had a significant percentage of participants ventilating below the recommended rate, with both devices having lowest recorded rates slightly greater than 6 BPM. In one study,2 improved hemodynamics in a porcine hemorrhage model were seen with a ventilation rate of 6 BPM compared with rates of 12, 20, and 30 BPM, with preservation of oxygenation and only mild acidosis. This suggests that mildly underventilating is unlikely to be as detrimental as overventilating, and may actually be beneficial in some circumstances. However, Davis et al.7 found worse outcomes with both hyper- and hypoventilation. No current guidelines recommend ventilation rates <8 BPM and more research is needed in this area.

Limitations and Areas of Further Study

There are several limitations to this study. It is questionable whether the training environment reflects real-world performance. Despite our attempt to conduct this study with the most accurate combat simulations by using BCT3, it is likely that only a prospective, randomized, study involving real scenarios would be able to answer the question of which device is superior when used early in a prehospital setting. A significant limitation of this study came from integrating our protocol into the BCT3 training. We were limited to short periods of ventilation because of training requirements of the course, which included moving Medics to different stations and evaluating multiple aspects of casualty management. It is possible that there would be different rates seen over time with both devices when used for longer durations, and this should be considered in future studies.

A potential confounding variable in this study is that BVM devices designed for single use were used repeatedly in our study. This likely had a significant effect on the CMS devices because we only had five prototypes and they rely on a spring to inflate. We were informed by the manufacturer during the study that they had observed "spring fatigue" resulting in slower inflation rates with increased use. A related issue that was not accounted for in our study was variability in rate between the study devices themselves. It was observed that some of the devices took longer to inflate than others. However, no data were collected regarding the individual devices' performance, so it is difficult to say whether this impacted results. Future studies should limit repeated use if possible and test each device or track data by device to identify variances between like devices.
Finally, limited training and exposure to the new device may have affected results as well. Different techniques were observed involving use of the CMS device. Some Medics were observed forcibly opening the device rather than allowing the spring to open it, which would increase the ventilation rate. Medics were also observed using the red-green indicator on the spine of the device not only for when to give a breath (when it turns green), as it is intended, but also to stop giving a breath (when it turned red), which it is not intended for. This would increase ventilation rate because the bag is only being partially compressed instead of fully compressed, as designed. With more exposure and training, these incorrect techniques may be avoided.
An additional area of study would be a comparison of TVs as the other half of the minute-volume equation. We chose to focus on rate in this study because we believed this to be the more significant variable, but clarifying the differences in TVs, if any, would be useful in comparing these devices.

Conclusion

The study device was clearly shown to decrease the incidence of ventilation rates exceeding the recommended rate of 10–12 BPM in the classroom and the field environments. The clinical significance of this finding is difficult to determine based on the results of this study because ventilation rates, in general, were low and there were only two instances of ventilation rates ≥20 BPM, although both of these occurred with the standard device in the field, which is the area of concern. The new device has been shown to be at least partially effective and merits further research and development.

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