Simulation and education

An evaluation of bag-valve-mask ventilation using an ergonomically designed facemask among novice users: A simulation-based pilot study

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Purpose: We sought to compare the ability of novice operators to provide artificial ventilation using a standard facemask and a new ergonomically designed facemask. Whether or not proper technique was used was also assessed.

Methods: Thirty-two allied-health students used both masks in random crossover fashion to ventilate an airway trainer. Breaths were delivered by a mechanical ventilator and exhaled tidal volume was recorded for each of 12 breaths for each participant for each mask. The effect of each mask during ventilation over time was assessed using repeated-measures ANOVA. Assessment of mask technique among participants and association between mask type and hand repositioning were analyzed using the Wilcoxon-Rank Sum Test and McNemar’s paired proportions test, respectively.

Results: The tidal volume achieved when participants used the ergonomic mask was higher than when participants used the standard mask by the fourth breath (361 ± 104 mL vs. 264 ± 163 mL; Bonferroni adjusted p-value = 0.040) and increased over time. The repeated-measures ANOVA showed that the ergonomic mask consistently resulted in higher tidal volumes than the standard mask regardless of rescuer’s gender. Over time the standard mask resulted in a linear decrease in tidal volume of ~10 mL/breath (estimated difference in decay of 10 mL/breath versus the ergonomic mask; p < 0.001).

Conclusion: Novice airway operators were better able to provide facemask ventilation using an ergonomically designed mask than with a traditional facemask. We conclude that better hand position facilitating improved mask seal and less operator fatigue account for our findings.

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1. Introduction

Providing adequate oxygenation and ventilation for an apnoeic patient is the primary goal of rescuer-provided artificial ventilation. Traditionally, this has been performed using a self-inflating resuscitation circuit interfaced with a facemask, generically referred to as bag-valve-mask (BVM). Generation of an effective seal between the mask and the patient’s face in order to establish and maintain upper airway patency is needed for effective BVM ventilation.

Efficacy of BVM ventilation is dependent on the interaction between operator-dependent variables such as experience,1–3 hand size,4 gender,5 and patient-dependent variables including obesity, facial hair, lack of teeth, age, limited cervical spine motion, and facial anatomic features impeding a mask seal.6–8 In addition, situation-dependent variables including mask ergonomics, environmental familiarity, and the presence or absence of distractions will also influence the effectiveness of artificial ventilation with a BVM.9 Given the number of variables at play in stressful and unfamiliar environments surrounded by distractions, it is not surprising that rescuers with limited airway management experience are unable to provide adequate BVM ventilation.10

The ErgoMask™ (EM, King Systems, Noblesville, IN) is a new facemask designed to ergonomically fit the clinician’s hand. It is available as a left-handed device only (Fig. 1). This design may enable better contact between the operator’s hand and the mask, avoid hand fatigue, and allow for better control of the facemask resulting in a better mask seal. In addition, an ergonomic hand position may be more effective in maintaining patient positioning maneuvers such as the head-tilt/chin-lift that facilitate upper airway patency.11 We hypothesized that an ergonomic face-
mask would promote better technique among novice operators with limited or little experience providing BVM ventilation. We also hypothesized that using an ergonomically designed facemask would promote more effective ventilation. The purpose of this study was two-fold. First, we sought to compare the ability of novice operators to provide artificial ventilation using both a standard facemask (SM) and the EM and second, to compare the operator’s ability to use adequate technique for each mask.

2. Methods

Participants were 32 allied-health students with minimal airway management training. The convenience sample included 6 emergency medical technician students (EMT), 9 paramedic students, and 17 respiratory therapy students enrolled at a Midwest technical college. Twelve (37.5%) of the subjects were men and 20 (62.5%) were women. The mean age for all participants was 28 years old. All participants had taken the American Heart Association Basic Life Support course at least once as a prerequisite to their current training program. This curriculum provides specific training on rescue breathing with a BVM. Additional basic training in rescue breathing and BVM ventilation technique is included as part of the EMT, paramedic and respiratory therapy curricula at the technical college. Instructional staff from the college’s Respiratory Therapy and Paramedic programs collected all data. Primary investigators were not involved in data collection. The ethics committee of Western Technical College (La Crosse, Wisconsin) and the Health Sciences Institutional Review Board at the University of Wisconsin-Madison approved the study.

Prior to data collection, a brief tutorial was provided to each participant about the proper use of the SM and the EM. For the SM, participants were instructed to use the “E-C” technique as prescribed by the American Heart Association guidelines for emergency cardiac care in which the thumb and forefinger form a “C” shape over the mask and exert downward pressure on the mask while the third, fourth, and fifth fingers (forming an E) are positioned along the jaw to maintain the jaw thrust. For the EM, participants were instructed in its use per manufacturer recommendations (Fig. 2). The SM used for all procedures was a single-use medium size adult mask (Clear Comfort® Air-Cushion FaceMask, Teleflex Medical, Research Triangle Park, NC) with the o-ring removed. One SM and EM were reused for all study procedures. Each participant performed all study procedures using both SM and EM in a random, crossover fashion.

A single left-handed technique was used with both masks. Participants were asked to perform basic airway maneuvers, including opening the airway and properly placing the facemask on a Laerdal® Airway Management Trainer (Laerdal Medical Corporation, Wappingers Falls, NY). After obtaining a mask seal, breaths were delivered using a Pulmonetics LTV® 1200 volume-cycled ventilator (CareFusion, San Diego, CA) set to deliver a tidal volume of 500 mL, 12 times per minute, at an inspiratory-to-expiratory ratio of 1:4 (cycle-length 5 s). In order to simulate actual BVM ventilation, participants squeezed a breathing bag with their free hand in time with each ventilator-delivered breath. The experimental setup is shown in (Fig. 3). The exhaled tidal volume was recorded for each of 12 breaths by the ventilator for each participant using both the SM and the EM. During performance of each study procedure, two non-blinded expert observers evaluated participants on airway positioning, hand technique, quality of mask seal, and maintenance of mask seal over time using a one through six Likert-style scale with one representing the poorest possible technique and six the best possible technique. Repositioning of the airway and/or the mask during the data collection period was also recorded. The study protocol only sought to evaluate the effectiveness of ventilation by simulating artificial or rescue breathing using a BVM and two different types of facemasks. This study did not attempt to address effectiveness of ventilation during cardio-pulmonary resuscitation (CPR) or any component related to circulation.
The effect of each mask during ventilation over time was assessed using repeated-measures ANOVA (RM-ANOVA) with the exhaled tidal volume set as the response variable. Mask type, number of breaths, gender, age, and the presence of two-way interactions with mask type were examined as possible dependent variables. Normal distribution was assumed and parametric testing was used when assumptions of the RM-ANOVA were met. Bonferroni’s post-test was performed to adjust p-values when the RM-ANOVA model stated that tidal volume was statistically different based on breath time and mask type with p-values < 0.05. Assessment of proper technique with each mask among participants was analyzed using the Wilcoxon-Rank Sum Test and McNemar’s paired proportions test, respectively. Expert scores were averaged as the final score in each category for the operator. Data is presented as mean ± SD or median [IQR] unless otherwise noted. Statistical significance was defined as a p-value < 0.05.

### 3. Results

Differences in exhaled tidal volume were examined at each of the 12 breaths and compared by mask type. Results are summarized in (Table 1). By the fourth breath, the tidal volume achieved when participants used the EM was higher than that with the SM (361 ± 104 mL vs. 264 ± 163 mL; Bonferroni adjusted p-value = 0.040). This difference increased over time such that by the end of the study period, participants using the EM achieved, on average, a tidal volume of 154 mL greater per breath than with the SM. The RM-ANOVA showed a significant interaction between mask type and number of breaths (i.e. over time). Additionally, mask type, time, gender, the interaction of mask type and time, and the interaction of mask type and gender were all associated with tidal volume. The final model showed that use of the EM by study participants consistently yielded higher tidal volume than the SM regardless of gender and that over time, tidal volume remained constant (decay = −0.13 mL/breath, p = 0.921). However, use of the SM resulted in a linear decrease in tidal volume of −10 mL/breath (estimated difference in decay of 10 mL/breath; p < 0.001). This was independent of the participant’s gender. Lastly, the model showed a difference between the first breath tidal volume by mask type among females (277 mL for the Standard and 351 mL for the EM, p = 0.001), but no difference between males (409 mL for the Standard and 399 mL for the EM, p = 0.568). The fitted RM-ANOVA model with estimated regression lines for mask type and gender is presented in (Fig. 4).

There was reasonable agreement between the two experts grading operator technique in all areas (interclass correlation coefficient > 0.5). No differences were found between masks in facilitating airway positioning prior to ventilation (EM: 6 [6–6], Standard: 6 [5.5–6], p = 0.175). Participants were more likely to use proper hand technique when they were using the SM (5.8 [4.9–6]) and appeared to have difficulty using the demonstrated technique for the EM (5.0 [4.0–5.5], p = 0.002). However, generation and maintenance of an effective mask seal were judged as better when participants used the EM (6 [5.5–6] and 6 [5.5–6]) compared to the SM (4.5 [3.5–5.6] and 4.5 [3.5–6], p < 0.001 and p = 0.001, respectively).

### 4. Discussion

Failure to provide effective ventilation can be associated with negative patient outcomes including hypoventilation, hypercarbia, hypoxia and acidosis. Historically, effective use of the BVM has been challenging even among skilled clinicians. Teaching effective BVM skills to clinicians who will act as first responders in and

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**Table 1**

<table>
<thead>
<tr>
<th>Breath*</th>
<th>Standard Mask</th>
<th>ErgoMask</th>
<th>Difference</th>
<th>p-Value(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>330 (125)</td>
<td>377 (99)</td>
<td>47 (133)</td>
<td>0.682</td>
</tr>
<tr>
<td>2</td>
<td>317 (136)</td>
<td>369 (104)</td>
<td>52 (145)</td>
<td>0.594</td>
</tr>
<tr>
<td>3</td>
<td>304 (142)</td>
<td>364 (106)</td>
<td>60 (150)</td>
<td>0.369</td>
</tr>
<tr>
<td>4</td>
<td>264 (163)</td>
<td>361 (124)</td>
<td>97 (172)</td>
<td>0.040</td>
</tr>
<tr>
<td>5</td>
<td>261 (155)</td>
<td>372 (114)</td>
<td>111 (171)</td>
<td>0.011</td>
</tr>
<tr>
<td>6</td>
<td>260 (161)</td>
<td>370 (106)</td>
<td>110 (183)</td>
<td>0.023</td>
</tr>
<tr>
<td>7</td>
<td>257 (152)</td>
<td>363 (122)</td>
<td>106 (194)</td>
<td>0.049</td>
</tr>
<tr>
<td>8</td>
<td>244 (166)</td>
<td>370 (118)</td>
<td>126 (181)</td>
<td>0.005</td>
</tr>
<tr>
<td>9</td>
<td>234 (170)</td>
<td>368 (108)</td>
<td>134 (193)</td>
<td>0.005</td>
</tr>
<tr>
<td>10</td>
<td>218 (164)</td>
<td>365 (114)</td>
<td>147 (197)</td>
<td>0.003</td>
</tr>
<tr>
<td>11</td>
<td>223 (168)</td>
<td>370 (114)</td>
<td>147 (173)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12</td>
<td>216 (170)</td>
<td>370 (119)</td>
<td>154 (195)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total</td>
<td>261 (159)</td>
<td>368 (111)</td>
<td>107 (176)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* Breaths were taken successively every 5 s.

b Paired t-tests and are Bonferroni adjusted for 12 comparisons.
out of the hospital remains an important and relevant aspect for successful resuscitation. It is not feasible to provide all first responders, whether they are EMTs, nurses, physicians or others with advanced airway management skills. It is widely accepted that effective BVM ventilation is more likely to occur when two rescuers are using the BVM, one rescuer using both hands to maintain mask seal and the other rescuer squeezing the bag. However, this is not always possible or even feasible during initial emergency response and as such; the one rescuer/single hand EC technique continues to be taught as part of the American Heart Association Basic Life Support for Healthcare Providers course. In the United States, the American Heart Association Basic Life Support for Healthcare Providers curriculum is the practice standard for first responder training for those practicing in both the hospital and out of hospital settings. Thus, devices that improve clinical performance in this group of practitioners are of particular relevance.

In our simulation-based pilot study, novice airway managers were more able to provide effective facemask ventilation using an ergonomically designed device, the EM, than with a SM as indicated by higher average tidal volume per breath over time. Additionally, ventilation provided using the EM was constant over the study period, whereas effectiveness of ventilation decayed over time when subjects provided facemask ventilation via the SM. A prior study using a Resusci-Annie mannequin reported that >50% of the emergency medical technicians tested were not capable of ventilating to the minimum emergency cardiac care standard using a single left-handed technique with a tear-drop shaped, clear plastic, soft air-cushion mask. Our study supports these findings and extends observations attributing difficult or ineffective BVM ventilation and adequate mask seal to a single-handed mask sealing technique and provides a potential effective alternative to the “four hand/two person skill.”

Matico hypothesized that the design of the traditional facemask itself has been a contributing factor associated with ineffective BVM ventilation among novice clinicians. The single handed “E-C” technique traditionally used with a standard facemask often tilts the facemask to the left allowing air to leak under the right side of the mask. Our findings suggest that creation and maintenance of an adequate mask seal are improved by using an ergonomically designed facemask. Despite demonstrations of proper mask technique for each mask tested, participants were more likely to use proper technique when using the SM. Because all of the participants had some exposure to the SM and the E-C technique through their current program of study, this finding is likely related to prior experience and familiarity with the SM. Still, mask seal and its maintenance over time were better with the EM than with the SM.

Our study has limitations. It is simulation-based and may have limited generalizability to actual clinical scenarios. Our methodology, however, is consistent with previous studies that have attempted to evaluate novice airway managers. Although our study design employed a mechanical ventilator to deliver the breaths provided during ventilation, we believe the process and procedure of providing traditional BVM ventilation was accurately simulated. We used an inspiratory-to-expiratory ratio set on the ventilator (1:4) to simulate the type of flow rate that might be seen in practice when a breathing bag is squeezed by a person performing actual BVM, but acknowledge that higher gas flow rates may have highlighted any leaks in the system. This could have biased the results in favor of the EM. However, given that the mean effect size on tidal volumes with the EM was 36–71%, it is doubtful that our results were substantially altered by inspiratory flow rate alone. We believe that our method of evaluation adequately controlled for the subjects’ ability to squeeze the self-inflating breathing bag and reduced variability between subjects in delivered tidal volumes. Our intent was to study the participant’s ability to generate and maintain a mask seal, not to assess tidal volume generated by squeezing the self-inflating breathing bag. Further, the randomized crossover design of our study controlled for any variables that may have been related to hand size that could have confounded the ability of subjects to generate and maintain a mask seal using either mask. While improved performance using the EM was independent of gender, men were able to provide higher baseline tidal volumes than women with both masks. Because we did not include hand size, digital spread, flexibility, and hand dominance as recorded variables, the observed differences between genders may be related to these unmeasured variables.

In a previous study Koga and Kawamoto found that it was more difficult for female anesthesia residents to provide an effective mask seal early in their training as compared to their male counterparts and that gender was shown to be an independent risk factor for difficult mask ventilation. Our data is consistent with the gender findings shown by Koga and Kawamoto, but we also found that females were able to maintain consistent tidal volumes when using the EM and hypothesize that the use of the EM might be particularly beneficial to female rescuers in their attempts to provide BVM ventilation in actual patients.

We acknowledge the use of novices in all evaluations is a limitation. Novices were chosen, as they resemble in skill level many first responders. However, use of novices in our study likely exaggerated differences in performance between SM and EM. Thus, our findings may not be valid in and should not be extrapolated to more experienced operators.

5. Conclusions

Novice airway managers were able to more effectively ventilate with a facemask during this simulation-based investigation by using an ergonomically designed device than they were with a traditional SM. Future studies using the ErgoMask™ should involve anaesthetized patients undergoing actual BVM ventilation by both novice and more experienced operators. Our finding related to constant performance over time when participants used the EM may be of particular interest and warrants study for durations greater than the 1 min period included in our simulation.

Conflict of interest statement

None.

References

