ADVANCES

Impact of a pressure-responsive flow-limiting valve on bag–valve–mask ventilation in an airway model

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ABSTRACT

Objective: Using a simulated airway model, we compared ventilation performance by emergency medical services (EMS) providers using a traditional bag–valve–mask (Easy Grip®) resuscitator to their performance when using a new device, the SMART BAG® resuscitator, which has a pressure-responsive flow-limiting valve.

Methods: We recruited EMS providers at an EMS educational forum and performed a randomized, non-blinded, prospective crossover comparison of ventilation with 2 devices on a non-intubated simulated airway model. Subjects were instructed to ventilate a Mini Ventilation Training Analyzer® as they would an 85-kg adult patient in respiratory arrest. After being randomized to order of device use, they performed ventilation for 1 minute with each device. Primary outcomes were ventilation rates and peak airway pressures. We also measured average tidal volume, gastric inflation volume, minute ventilation and inspiratory:expiratory (I:E) ratio, and compared our results to the American Heart Association standards (2005 edition).

Results: We observed statistically significant differences between the SMART BAG® and the traditional bag–valve–mask for respiratory rate (12 v. 14 breaths/min), peak airway pressure (15.6 v. 18.9 cm H_2O), gastric inflation (239.6 v. 1598.4 mL), minute ventilation (7980 v. 8775 mL), and I:E ratio (1.3 v. 1.1). Average tidal volume was similar with both devices (679.6 v. 672.2 mL).

Conclusion: The SMART BAG® provided ventilation performance that was more consistent with American Heart Association guidelines and delivered similar tidal volumes when compared with ventilation with a traditional bag–valve–mask resuscitator.

Key words: all-terrain vehicle; children; injury pattern

RÉSUMÉ

Objectif : À l'aide d'un modèle simulé de voies aériennes, nous avons comparé la performance de ventilation des fournisseurs de services médicaux d'urgence (SMU) à l'aide d'un système ballon-masque traditionnel (Easy Grip^{MD}) avec leur technique à l'aide d'un nouvel appareil, l'appareil de réanimation SMART BAG^{MD}, muni d'une valve limitant le débit répondant à la pression.

Méthodes : Nous avons recruté des fournisseurs de SMU lors d'un forum de formation sur les SMU et avons procédé à une étude comparative ouverte prospective croisée et randomisée de deux appareils sur un modèle simulé de voies aériennes. On demanda aux participants de ventiler un Mini Ventilation Training Analyzer^{MD} comme ils auraient ventilé un patient adulte en arrêt respiratoire pesant 85 kg. Après avoir été randomisés quant à l'ordre d'utilisation des appareils, les participants effectuèrent la ventilation pendant une minute à l'aide de chacun de ceux-ci. Les résultats principaux étaient le taux de ventilation et la pression maximale des voies aériennes. Nous avons

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également mesuré le volume courant moyen, le volume de distension gastrique, la ventilation minute et le rapport inspiratoire/expiratoire (I/E); nous avons comparé nos résultats avec les normes de l'American Heart Association (édition 2005).
Résultats : Nous avons observé des différences statistiquement significatives entre le SMART BAG^{MD} et le ballon-masque traditionnel quant à la fréquence respiratoire (12 v. 14 respirations/min.), la pression maximale des voies aériennes (15,6 v. 18,9 cm H_2O), la distension gastrique (239,6 v. 1598,5 mL), la ventilation minute (7980 v. 8775 mL) et le rapport I/E (1,3 v. 1,1). Les volumes courants moyens étaient similaires avec les deux appareils (679,6 v. 672,2 mL).
Conclusion : Le SMART BAG^{MD} offrait une performance de ventilation qui correspondait davantage aux lignes directrices de l'American Heart Association et fournissait des volumes courants similaires quand on le comparait avec un appareil de réanimation ballon-masque traditionnel.

Introduction

Bag–valve–mask (BVM) ventilation is an critical resuscitation skill for emergency medical providers, yet they and other health care workers have difficulty performing BVM ventilation adequately.[1–3] There have been few advances in the design and function of the BVM resuscitator since its introduction in 1955. BVM devices have many inherent performance limitations — in particular, the ability to deliver excessively high gas flows and peak airway pressures. High intrathoracic pressure impairs cardiac output,[4] and recent research[5] suggests that ventilation-related pressure rises are associated with clinically important reductions in cardiac arrest survival. In a recent animal study, Aufderheide and colleagues showed that slowing the respiratory rate from 30 to 12 breaths/min increased cardiac arrest survival from 14% to 86%.[5] During cardiac arrest, lower esophageal sphincter pressure falls to <5 cm H_2O[6] and respiratory compliance also decreases.[7] These factors increase the risk of gastric insufflation — a concern that can be mitigated by delivering lower tidal volumes and peak airway pressures.[8]

The SMART BAG (O-Two Medical Technologies Inc, Mississauga, Ont.) (SMART: synchronized manual actuation response technology) uses a pressure-responsive flow-limiting balanced piston valve (Fig. 1, next page) to limit gas flow to 40 L/min. If properly squeezed, there are no differences in performance between this valve and a standard valve. The piston provides a tactile and visual feedback to the provider when excessive pressure is applied, causing high flow rates. Previous studies using audible tone guidance have suggested that immediate feedback improves resuscitation performance.[9] In addition, the balanced valve provides feedback on lung compliance, since it will not activate when lung compliance is low. In previous studies involving nurses[8] and emergency medical services (EMS) providers,[10] SMART BAG ventilation led to lower peak airway pressures and less gastric inflation, as well as providing ventilatory rates, tidal volumes, minute ventilation, and inspiratory:expiratory (I:E) ratios that were more consistent with American Heart Association (AHA) standards. A recent pilot study showed that in-hospital providers using the SMART BAG generated adequate tidal volume with lower inspiratory flow rates and lower peak airway pressures.[11]

We hypothesized that, in a simulated airway model, EMS providers using the SMART BAG would generate ventilation parameters more consistent with the 2005 AHA guidelines[12] (Fig. 2, page 161). Our primary objectives were to evaluate the impact of the SMART BAG on respiratory rate and peak airway pressure. Our secondary objectives were to evaluate impact of the device on 1-minute tidal volume, 1-minute gastric inflation volume, minute ventilation, and I:E ratios.

Methods

Setting and subjects

This randomized, non-blinded prospective crossover trial was conducted in the exhibit hall of a large international EMS educational conference and trade show. All conference attendees received an envelope in their registration kit requesting their participation in the study. All interested and appropriately credentialled EMS providers presenting to the study booth, including first responders, emergency medical technicians (EMTs) (i.e., EMT-Basic, EMT-Intermediate, EMT-Paramedic), nurses, physicians or respiratory therapists were allowed to participate. All subjects documented their duration of EMS practice and level of certification, and all were entered in a draw for a palm pilot and digital camera.

Materials and methods

We compared the SMART BAG to the Easy Grip dispos-

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able BVM resuscitator (O-Two Medical Technologies), a traditional BVM device. Except for the flow-restricting valve on the SMART BAG, these products are identical in design and construction. In order to eliminate the variability associated with mask leak, which can range from 21%–40%,[13] we attached the BVM's 15–22-mm adaptor directly to the intake port on the Mini-Ventilation Training Analyzer (O-Two Medical Technologies).

The Mini Ventilation Training Analyzer is a device that simulates an unprotected airway. It is not a manikin and it provides no feedback to users. It has 1 input that simulates the pharynx and it has 2 outputs — one simulating the trachea and lungs, and another simulating the esophagus. The device is set with a lung compliance of 100 mL/cm H_2O and an airway resistance of 4 cm H_2O/L/s.[8] We attached a positive end-expiratory pressure valve calibrated to an opening pressure of 18 cm H_2O to the esophagus exhaust port to simulate lower esophageal sphincter pressure in the early cardiac arrest period. During ventilation, the Mini Ventilation Training Analyzer captures 1-minute trails and measures respiratory rate, average tidal volume, minute ventilation, gastric inflation volume and median I:E ratio. The analyzer prints these results at the completion of each trial. Peak airway pressures, measured using an analog manometer inserted between the "trachea" and the "lung" were manually recorded on the result sheet.

We used the uniform random number generator function of Microsoft Excel (v. 9.0.2720) to develop a randomization list for order of device use (even numbers used SMART BAG first; odd numbers used the traditional BVM first). After their order of device use was assigned, participants were given 30 seconds to familiarize themselves with each device. They then received the following instructions for both devices: "Please ventilate the ventilation analyzer as you would ventilate an 85-kg patient in respiratory arrest. This is a non-intubated model." The weight of 85 kg was chosen to represent a typical adult male patient. In addition, the following instructions were given before the use of the SMART BAG: "If the SMART BAG becomes difficult to squeeze and the red actuation indicator becomes visible, squeeze the bag less forcefully and more slowly." Each participant ventilated the Mini Ventilation Training Analyzer for 1 minute with each device. There was a 30-second break to allow the devices to be switched.

Outcomes

The primary outcome measures were 1-minute respiratory rate and peak airway pressure. Secondary outcomes included 1-minute tidal volume, minute ventilation, I:E ratio, and 1-minute gastric inflation volume (the total volume of gas delivered to the stomach during 1 minute of ventilation). Ventilations parameters achieved were compared with the American Heart Association parameters for non-intubated ventilation (Fig. 2, next page).

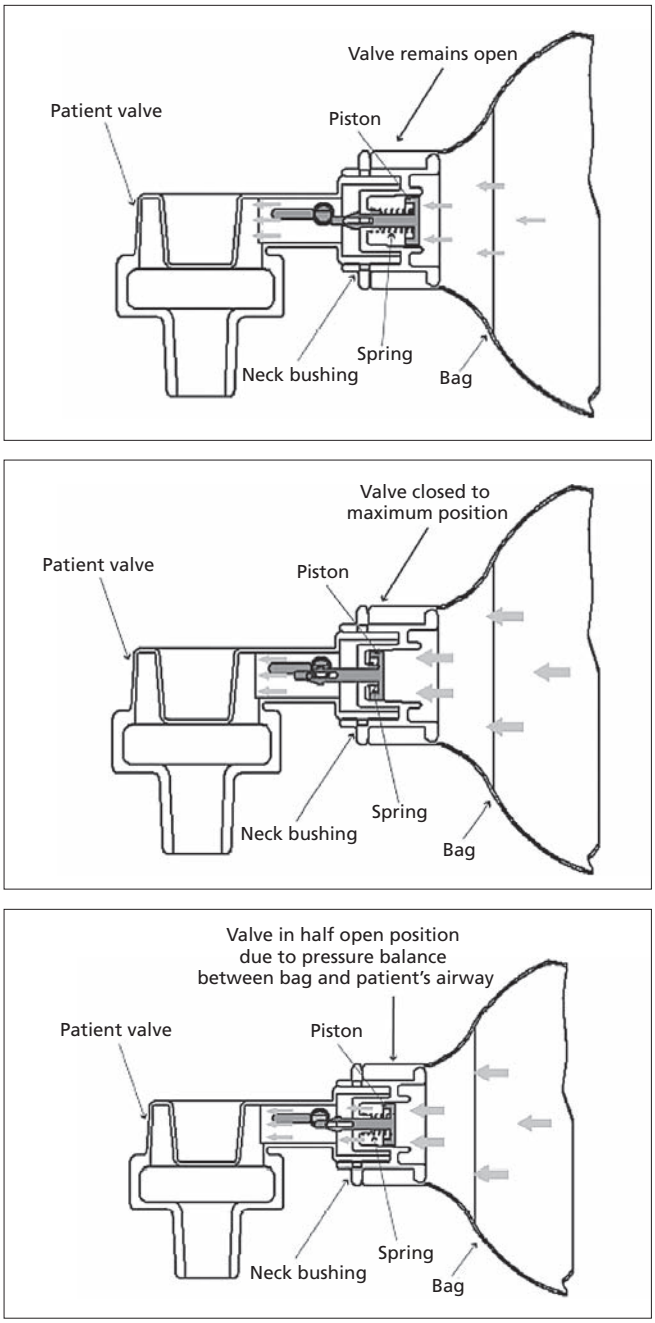

Fig. 1. The pressure-responsive flow-limiting valve
Top: Correct, slow squeeze does not result in valve activation. Middle: Too hard or rapid squeezing results in activation of the valve. Bottom: Valve is not activated with high downstream resistance (supraglotic obstruction, high airway resistance, or low lung compliance), and a harder squeeze will result in proper ventilation.

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Data analysis

Data were entered into a Microsoft® Excel 2000 spreadsheet (v. 9.0.2720) and analyzed using SAS (v. 8). Descriptive statistics including means and ranges were determined as appropriate. The significance of observed differences in the primary outcome was determined using a 2-sided paired *t* test. Based on data from a prior pilot study,10 we calculated an a priori sample size and determined that, at a 90% power level and 2-sided significance level of 5%, we required 21 participants in each study arm to detect a 10% (2 breaths/min) difference in the primary outcome (ventilatory rate). This study was approved by the Carolinas Medical Center Institutional Review Board through the standard expedited review process.

Results

A total of 153 individuals participated in the study. The completion rate was 100%, and there were no protocol violations. Mean time in practice was 12.8 years, with a range from <1 to >36 years. Table 1 describes the levels of training and mean number of years in practice for the study subjects. There were no significant performance differences based on level of certification or years in practice.

Table 2 (next page) shows that respiratory rates were 1.4 breaths/min faster and peak airway pressures were 3.32 cm H_2O higher with the traditional BVM than with the SMART BAG. Tidal volumes were not significantly different between devices; however, minute ventilation was significantly higher using the traditional device. We observed a very large absolute difference (1359 mL) in gastric inflation volumes, which was most likely associated with the lower peak airway pressures generated with the SMART BAG. Relative expiratory time was also significantly longer for the SMART BAG, probably because of the slower ventilation rates seen.

Discussion

These data suggest that a pressure-responsive flow-limiting valve like that incorporated in the SMART BAG reduces the likelihood of inappropriate hyperventilation and provides ventilation more concordant with AHA recommendations. This device was also associated with reductions in peak airway pressure, intra-thoracic pressure and gastric insufflation volume,[14] thereby improving hemodynamics and decreasing the risk of emesis and aspiration. These results are consistent with previous simulation trials in other health care provider types,[8,10,11] and it is likely that this device could minimize or eliminate excessive ventilation, a common user error associated with high peak airway pressures, gastric inflation and decreased cardiac arrest survival.[5]

Other techniques and behaviours can also decrease intrathoracic pressure and gastric inflation. The AHA suggests that small tidal volumes (6–7 mL/kg), slower ventilatory rates (10–12 breaths/min), long expiratory times (I:E of >1:2), and low peak airway pressures can diminish the risk of these complications;[12] however, avoiding hyperventilation in the high stress setting of a cardiac or respiratory arrest is challenging.[5,9] The automatic nature of the flow-re-

Table 1. Levels of training and years in practice for the 153 study participants

Certification level	No. of participants	Years in practice, mean (range)
EMT-Basic	40	8.9 (1–28)
EMT-Intermediate	20	9.7 (2–25)
EMT-Paramedic	74	14.4 (1–36)
RN	11	16.5 (1–30)
RT	1	20.0 (X–X)
Physician	3	22.0 (20–23)
Did not specify	4	18.4 (13–26)

EMT = emergency medical technician; RN = registered nurse; RT = respiratory therapist

Parameter	Value (range)	Target value	Range, mL
Tidal volume	6–7 mL/kg	552 mL	510–595
Minute ventilation	60–84 mL/kg	5525 mL	5100–5950
Respiratory rate	10–12 breaths/min	10 breaths/min	N/A
Peak airway pressure	As low as possible	As low as possible	N/A
Gastric inflation volume	0	0	N/A
Inspiratory:expiratory ratio	>1:2	>1:2	N/A

Fig. 2. Ventilation and target values and ranges for an 85-kg patient. Adapted from the 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Part 7.1.[12]

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stricting valve provides an engineered solution that appears to be effective.

Limitations

This was a non-blinded study conducted at an international trade show. Typically the most motivated EMS providers attend such shows, and this may have introduced a selection bias. In addition, provider performance using a simulated airway model may not reflect performance on an actual patient. The model's lung and gastric parameters are fixed to represent those of a healthy anesthetized adult man; hence they do not incorporate the impact of cardiac arrest on lung compliance, lower esophageal opening pressure and increasing volumes of gastric air. The airway resistance of this lung model rises exponentially at approximately 1 L tidal volume, favouring gastric ventilation. Therefore, for those individuals who provided excessively large ventilatory volumes or did not allow adequate expiratory time, pressure dynamics favouring gastric inflation occurred sooner than they might in a real patient. There is no method that adequately reproduces face-to-mask leakage, and so we eliminated the mask-to-face interface. It is possible that the leakage between the mask and the face decreases peak airway pressure and therefore gastric inflation. If this were the case, then the higher peak airway pressures and gastric inflation volumes seen with the traditional BVM would be less clinically relevant or beneficial in delivering more gas to the lungs.

While the participants were randomized to the order of use and received no feedback during their own use, the physical constraints of the testing station allowed them to observe (but not overhear) participants before them. It is possible that by observing others perform ventilations that their performance would somehow be impacted. Although the only difference in design of the SMART BAG versus a standard BVM is the presence of the flow-restricting valve, 30 seconds of practice before ventilation may have been inadequate time for familiarization. The instructions regarding the red valve stem on the SMART BAG provided user feedback and may have biased the performance of the users in favour of that device. Since a traditional BVM is the commonly used device, the short learning period (30 s) for the SMART BAG may have biased participants' performance toward the traditional BVM. Finally, we evaluated only peak airway pressure, not mean airway pressure or oxygen delivery; hence, the clinical relevance of the lower peak airway pressure in terms of oxygen delivery is not clear.

Conclusion

Non-intubated BVM ventilation is challenging, especially in the EMS environment. This simulation study suggests that the addition of pressure-responsive flow-limiting valves into traditional BVM design can reduce excessive ventilation rates and peak airway pressures in a simulated model of respiratory arrest. Further research is necessary to determine if these improvements carry over into clinical practice and, ultimately, to determine if they improve survival outcomes for victims of respiratory and/or cardiac arrest.

Competing interests: O-Two Medical Technologies Inc., manufacturer of the SMART BAG, the Easy Grip and the Mini-Ventilation Training Analyzer, provided equipment support in the form of

Table 2. Ventilation parameters for the SMART BAG and standard bag–valve–mask (BVM)

Variable	Mean, (SD) and [range]		Mean difference (95% CI)	*p* value
	SMART BAG*	Easy Grip BVM*		
Respiratory rate, beats/min	12.1, (7–24) [3.1]	13.5, (6–32) [4.8]	1.4 (0.8–1.8)	$p < 0.0001$
Peak airway pressure, cm H_2O	15.6, (8–19) [2.6]	18.9, (8–49) [5.6]	3.3 (2.5–4.2)	$p < 0.0001$
Tidal volume, mL	679.6, (320–984) [134.6]	672.2 (320–987) [120.9]	7.4 (–2.1 to 26.2)	$p = 0.9$
Gastric inflation, mL	239.6, (0–4783) [670.4]	1598.4 (0–10213) [2139.0]	1359 (1055–1663)	$p < 0.0001$
Minute ventilation, mL	7980 (4169–11524) [1629]	8775 (3590–13966) [2231]	795 (560 –1023)	$p < 0.0001$
I:E ratio, relative E time	1.3 (0.7–2.4) [0.4]	1.1 (0.4–3.1) [0.5]	0.25 (0.2–0.3)	$p < 0.0001$

*O–Two Medical Technologies Inc, Mississauga, Ont.
CI = confidence interval; I:E = inspiratory:expiratory; E = expiratory

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an equipment loan for the performance of this study. Neither of the authors was compensated in any way for this activity and neither is otherwise affiliated or holds interest in the company.

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