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SMART Bag® MO Bag-Valve-Mask Resuscitator

Synchronized Manual Actuation Response Technology Resuscitator

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Summary

Bag-valve-mask ventilation is one of the most common mode used to provide ventilation during transports. It has shown to be complicated, have variable results, and make it difficult to reach consistent lung-protective ventilation in terms of tidal volume and respiratory rate. Standard bag-valve-masks deliver excessive volume, pressure or flow which may result in morbidity from lung damage, stomach insufflation, or hemodynamic and pulmonary compromise. O-Two Medical Technologies Inc. has overcome the challenges of manual ventilation by introducing the SMART Bag® MO Bag-Valve-Mask Resuscitator, a pressure-responsive, inspiratory gas flow-limiting device designed for use by all levels of health care professionals. This innovative bag-valve-mask resuscitator assists the rescuer to deliver proper respiratory frequency and tidal volume, and prevent clinical complications.

Multiple emergency medicine and critical care studies have shown that lung-protective ventilation protocols are crucial to reduce morbidity and mortality[1-5]. Manual ventilation during cardiopulmonary resuscitation (CPR) still requires lung-protective strategies. Emergency medical services (EMS) professionals rely on the bag-valve-mask (BVM) to provide life-saving positive-pressure ventilation in prehospital setting[1].

Even though BVM system is one of the most common devices used to provide ventilation during transports, it has shown that is complicated and has variable results[1,4,3,6-10]. Manual ventilation makes it difficult to reach the standards in terms of tidal volume (Vt) and respiratory rate (RR)[6,7,11] and may expose to overpressure and thoracic overinflation[4,8,12]. Ventilation rates during the on-field application of CPR by well-trained emergency personnel and respiratory therapists[4] are inconsistent and far in excess of those recommended[13].

In recent years, different strategies have been assessed to optimize manual ventilation such as altering grip technique and bag size[1,9,10]. Their goal is to reduce RR, Vt, peak pressure, and minute volume[1] when using a BVM. This would result in more consistent lung-protective ventilation avoiding excessive volume, pressure or flow which may result in morbidity from lung damage, stomach insufflation, or hemodynamic and pulmonary compromise[1,4,10,12,13].

Kroll and colleagues' study[10] aimed to determine if EMS professionals could reduce the volume delivered by adjusting the way the BVM was held. After testing 3 different grips with adult and pediatric BVM, they concluded that it is possible to alter the volume provided by the BVM by altering the grip, nevertheless the tidal volumes recorded even with the pediatric BVM were above recommended range in 2 of the 3 grips. The volumes of the pediatric BVM were overall more consistent with lung-protective ventilation volumes when compared to all 3 finger-grips of the adult BVM. However, in this study peak pressures, respiratory rate and minute volume were not recorded.

Dafilou *et al*.[9] measured and compared ventilation parameters delivered by adult and pediatric BVM to an adult mannequin. Their

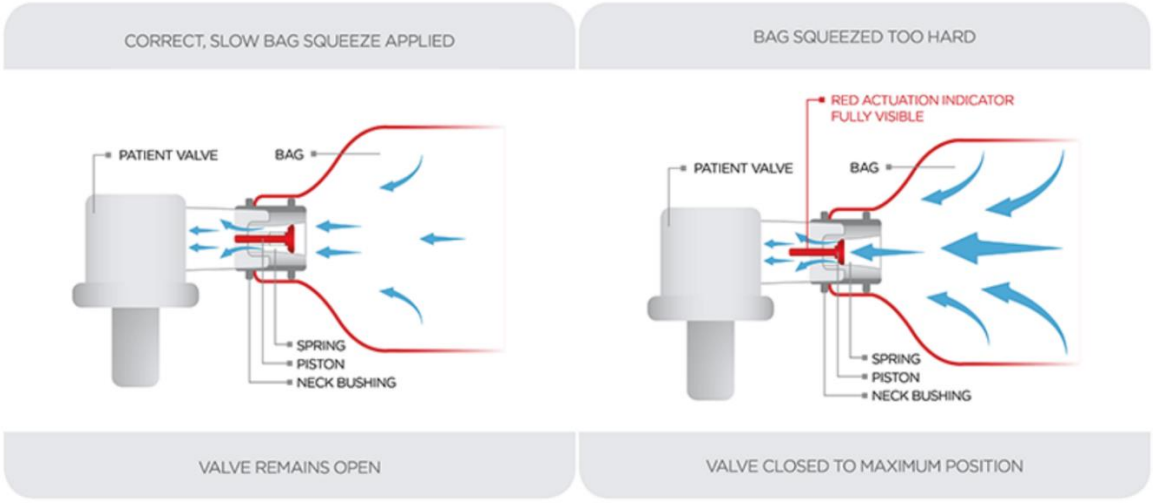

Fig. 1 SMART Bag® MO Bag-Valve-Mask Resuscitator is designed to provide lung-protective ventilation. It is a pressure-responsive, inspiratory gas flow-limiting device allowing the delivery of consistent respiratory rate and tidal volume.

findings show that pediatric BVM provided far more consistent and appropriate ventilation parameters for adult patients compared to an adult BVM, but still exceeded the upper limits of lung-protective ventilation parameters. Therefore, ventilation with adult BVM entails increased risk of pulmonary barotrauma. The authors emphasized that higher tidal volumes can contribute to lung injury.

In 2021, Culbreth and collaborators[4] examined manual ventilation performance among respiratory therapists (RT) in a simulation model. The results show that RT delivered higher tidal volumes, pressures and flow rates with a lower inspiratory time than ideal. Interestingly, the RT group with the more experience and highest confidence level (those who self-rated their confidence with the BVM the highest score: 5/5) delivered higher peak pressures and flow rates compared to their peers.

To address these issues O-Two Medical Technologies Inc. has overcome the challenges of manual ventilation by introducing the SMART Bag® MO Bag-Valve-Mask Resuscitator[14], a pressure-responsive, inspiratory gas flow-limiting device. This innovative BVM assists the rescuer to deliver proper RR and Vt and prevent the abovementioned clinical complications.

The SMART Bag® MO uses a flow-limiting balanced piston valve to limit gas flow to 40 L/min (Fig. 1). The piston provides a tactile and visual feedback to the provider when excessive "bagging" pressure is applied, causing high flow rates. In addition, the balanced valve provides feedback on lung compliance, since it will not activate when lung compliance is low. SMART Bag® MO ventilation leads 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[15,16] that are consistent with international standards[17-19].

Since early 2000s several studies[15-22] have been conducted worldwide showing that using the SMART Bag® MO during simulated ventilation provided ventilation performance that was more consistent with American Heart Association (AHA) guidelines[15,16,23]. A bench model[24] was used simulating a patient with a non-intubated airway, 20 nurses were randomized to each

ventilate a manikin using a standard single person technique for 1 min (respiratory rate, 12/min) with either a standard adult self-inflating bag, or the SMART Bag® MO. The use of the SMART Bag® MO significantly decreased inspiratory flow rate, peak inspiratory pressure, stomach inflation[24], and resulted in a significantly longer inspiratory time when compared to a BVM.

Similarly, other simulation studies[15-19,21] have shown the same results. von Goedecke *et al.*[19] tested the performance of different BVM with almost 100 emergency medicine physicians. When compared to a standard BVM, the SMART Bag® MO resulted in significantly lower mean airway pressure, respiratory rate, incidence of stomach inflation and median stomach inflation volumes, whereas lung tidal volumes were comparable (Table 1).

Wagner-Berger *et al*.[25] performed a study in 60 adult patients who underwent routine induction of anesthesia. The findings show that when compared with the standard self-inflating bag, the SMART Bag® MO resulted in significantly decreased peak airway pressure, peak inspiratory flow, and inspiratory tidal volume. Also, using the SMART Bag® MO increased participants' ability to perform BVM ventilation complied with AHA standards[22]. For all parameters, the SMART Bag® MO performed significantly better than the standard BVM.

In 2019, the EPIC (Excellence in Prehospital Injury Care) study[26] showed one more time that EMS care can dramatically improve survival. The study aimed to improve traumatic brain injury care and outcomes creating and implementing EMS TBI guidelines throughout Arizona. The statewide, multisystem, intention-to-treat controlled study consisted in different interventions to aggressively prevent and treat hypoxemia, hypotension, and hyperventilation.

The EPIC study[26] summarized an eight-year state-wide effort across Arizona where over 130 EMS agencies participated to implement a new Traumatic Brain Injury (TBI) protocol. The EMS physicians compared 15,228 TBI patients before the new protocol was activated to 6,624 post-implementation TBI patients. Over the eight years of the study, a total of 21,852 patients were evaluated. The researchers found their protocol doubled the survival rate of severe TBI patients and tripled the survival rate of the most critically ill TBI patients (those requiring intubation).

Table 1 Effects of standard adult bag-valve-mask ventilation vs. SMART Bag® MO Bag-Valve-Mask Resuscitator on ventilation parameters in a bench model of a simulated non-intubated respiratory arrest patient[19]

Variable	Standard BVM	SMART Bag® MO*	p Value
Respiratory rate, bpm	14 ± 4	13 ± 3	$p < 0.0001$
Mean airway pressure, cmH_20	16 ± 3	14 ± 2	$p < 0.0001$
Tidal volume, mL	533 ± 97	538 ± 97	NS
Incidence of gastric inflation, %	38.7	4.2	$p < 0.0001$
Median gastric inflation volume, mL	1426 [50-5882]	351 [18-1211]	$p < 0.0001$
I:E ratio	1.5 ± 0.6	1.7 ± 0.5	$p < 0.0001$

*O-Two Medical Technologies Inc., Brampton, ON
Mean ± SD; [range]; NS = Not significant; I:E = inspiratory:expiratory

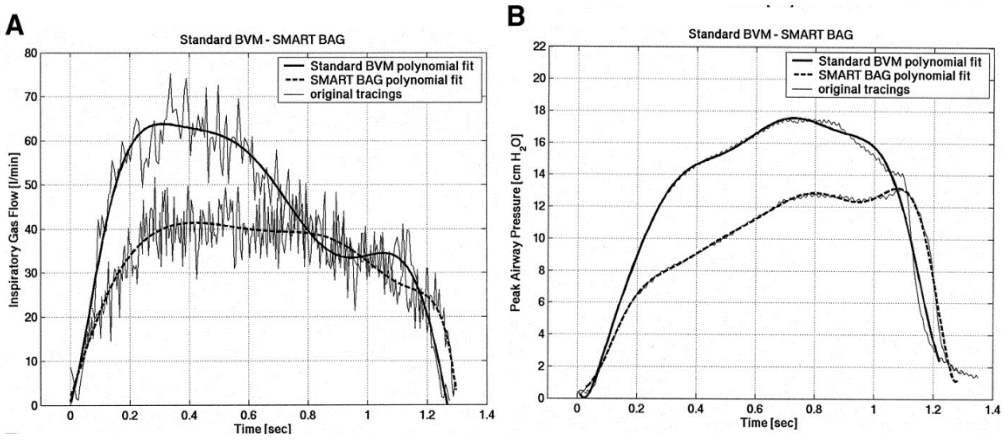

Fig. 2 Respiratory variables measured using a pulmonary monitor. **A**, Representative inspiratory flow and **B**, peak airway pressure tracings of a standard self-inflating bag and the pressure-responsive, inspiratory gas-flow-limiting SMART Bag® MO[25]

EPIC[26] airways interventions to optimize oxygenation/ventilation included the use SMART Bag® MO and its ventilation timing lights to avoid hyperventilation and help protect patients from inadvertently giving too much volume of air and too many breaths in a minute. The EPIC Study showed a lower rate of hyperventilation/ hypocapnia in intubated patients, a higher rate of BVM-only airway management, and a greater likelihood of having SpO_2 of 100%.

Since then other states, such as Maine, are looking forward to implementing Arizona's protocol using the SMART Bag® MO. As stated by Dr. Matthew Scholl[27], this protocol would result in benefits to TBI patients equivalent to those found in Arizona. SMART Bag® MO shows benefits in not only TBI patients but also patients in cardiac/respiratory arrest. Its efficacy in manual resuscitation surpasses the performance of conventional bag-valve-masks.

In conclusion, conventional bag-valve-masks deliver excessive volume, pressure or flow which may result in morbidity from lung damage, stomach insufflation, or hemodynamic and pulmonary compromise. SMART Bag® MO resuscitator has a pressure-responsive flow-limiting valve which provides ventilation performance consistent with American Heart Association and European resuscitation guidelines. By controlling the flow of air, the SMART Bag® MO can reduce hyper- and over ventilation, enhancing blood flow and gas exchange. The SMART Bag® MO is designed for use by all levels of health care professionals and has been proven in clinical studies to effectively ventilate patients in respiratory arrest, improving airway management and increasing survival rate.

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