Sotair®
LITERATURE 11.14.25

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A comparative trial of a novel flow limiting device attached to a manual ventilation bag versus a manual ventilation bag alone during forceful breaths in patients undergoing non-emergent surgery with general anesthesia: A prospective crossover randomized controlled trial.

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INTRODUCTION

- Poor manual ventilation often results in excessive tidal volumes and high airway pressures, independent of provider experience, increasing the risk of gastric insufflation and aspiration.
- In 2022, the FDA approved a novel flow-limiting device (Sotair®,SafeBVM Corp.) designed to restrict flow rates >55 L/min, thereby mitigating excessive airway pressures and reducing gastric insufflation risk

OBJECTIVE

- This study aimed to compare peak airway pressures and tidal volumes during forceful manual ventilation with and without the use of the Sotair® flow-limiting device in patients undergoing general anesthesia for non-emergent surgical procedures.

METHOD

- Randomized, two-group crossover superiority trial involving adult ASA I–III patients undergoing non-emergent surgery with general anesthesia.
- Following endotracheal intubation, patients received forceful manual ventilations (every 30 seconds for 3 minutes) both with and without the Sotair® flow-limiting device, in randomized order.
- Ventilations were considered forceful if they triggered the APL (pop-off) valve, which was set at 35 cm H2O.
- **Primary Endpoint:** Mean peak inspiratory pressure (PIP) from five forceful breaths per condition
- **Hypothesis:** Use of the flow-limiting device would reduce mean PIP by an estimated 7.5 ± 7.5 cm H2O compared to manual ventilation alone
- **Statistical Analysis:** Generalized mixed effects modelling

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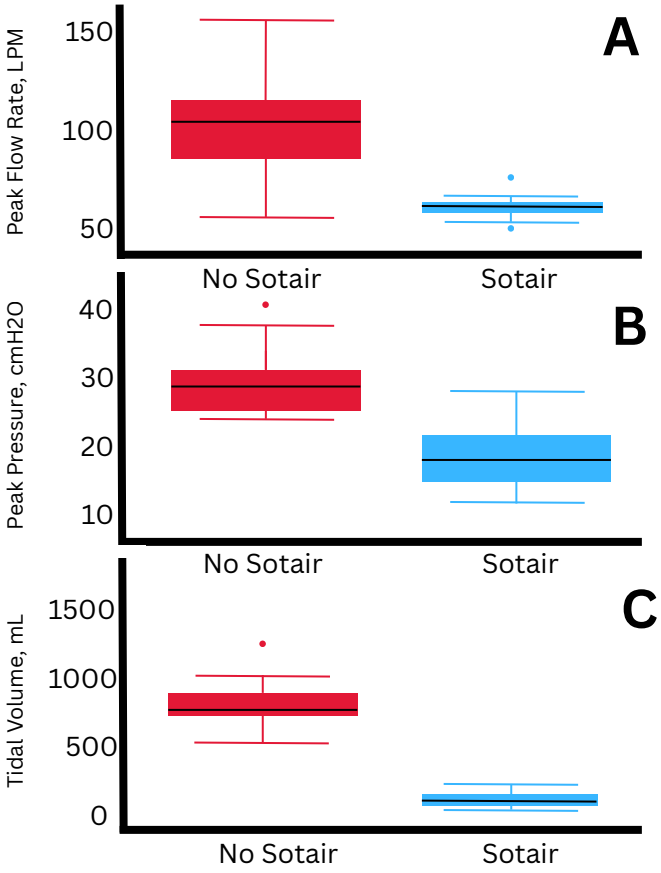
RESULTS

Patient Characteristics

A total of 30 patients were enrolled:
• Sex: 12 male (40%) vs. 18 female (60%)
• Age:47.9+/-13.8 years
• BM/: 28.9 +/- 5.3 kg/m2

All 150 Forceful Breaths successfully Blocked by flow limiting device



The figures (A-C) show ventilator parameters with and without the flow-limiting valve (Sotair) during "forceful" ventilations. These ventilation events were designed to test the impact of flow limitation on overventilation as measured via a Sensirion SFM3300-D disposable airflow sensor. By design, a flexible diaphragm in the Sotair completely obstructs airflow through the airway circuit when 55LPM is exceeded. Panel A shows that Peak Airway Flow, the instantaneous maximum in the airway flow waveform, was vastly lower in the flow-limited group, and in practice reflects a transient spike above the design limit of 55LPM. Panel B demonstrates the range of pressures under flow limitation was markedly lower as well. Panel C highlights the consequence of complete flow-gating: a potential overventilation event becomes a non-ventilation. Mean peak presure, tidal volume and peak flow rate differed between groups p (<0.001).

CONCLUSION

- Evidence that adding the novel flow limiting device to a manual ventilation bag offers advantages over standard manual ventilation.
- Device effectively reduces peak pressures and excessive tidal volumes during forceful breaths that may be delivered inadvertently during high stress situations

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Feasibility of manual ventilation replacing mechanical ventilation

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ABSTRACT

Background During the COVID-19 pandemic it is anticipated that there will be a shortage of mechanical ventilators available for patients in critical condition. This has sparked many discussions about rationing resources and withholding care; however, an alternative may be to implement manual ventilation in these situations instead. Manual ventilation and a safety device were assessed for efficacy of extended use, such as may be required during this pandemic.

Methods To evaluate physical output characteristics of extended manual ventilation and efficacy of a barotrauma mitigation device, 47 medical students, nurses and medics completed two 1-hour manual ventilation sessions using the SmartLung 2000 Lung Simulator and 5300 Series Mass Flow Meter with a SPUR II resuscitator bag and endotracheal tube, mimicking a healthy adult with normal lung physiology, both with and without the Sotair device. Providers were randomised to complete their initial session either with or without the Sotair device.

Findings Collected data show wide variability in tidal volume and peak pressure in unmitigated manual breaths despite prior training and independent exploration of the resuscitation equipment prior to testing. The mean (±SD) tidal volume with bag only was 563.9±128.8 mL and with the safety device 536.1±80.9 mL ($p<0.0001$). The mean peak inspiratory pressure with bag only was 17.2±6.3 cm H_2O and with the safety device 14.9±2.4 cm H_2O ($p<0.0001$).

Interpretation While extended manual ventilation cannot replace mechanical ventilation, it is feasible with a safety device, which may reduce barotrauma, underventilation and overventilation. These results also demonstrate that withholding care and rationing resources may not be necessary.

Summary box

What are the new findings?

- This study shows the parameters for mechanical ventilation and shows the variability that may result from it. It also shows the benefit of using a safety accessory, as that improved these parameters and reduced the risk of barotrauma, underventilation and overventilation. The authors conclude that this shows manual ventilation may be used in the absence of mechanical ventilation, but that certain measures should be in place to reduce the risk of harm to the patient.

How might it impact on healthcare in the future?

- This information is particularly relevant to the medical community at this time, as we may be facing a mechanical ventilator shortage due to the influx of patients needing to be ventilated as a result of the COVID-19 pandemic. This offers another alternative for practitioners that does not require them to ration resources.

INTRODUCTION

Anticipated mechanical ventilator shortages during the novel coronavirus pandemic have sparked debate and speculation about rationing and withholding care,[1–4] but there is another option that needs to be explored for this and other disaster scenarios: manual ventilation. While not optimal due to the manpower needed and the variability in pressures and volumes compared with a mechanical ventilator, manual ventilation by squeezing a resuscitator bag connected to an endotracheal tube has been acknowledged as an option when no mechanical ventilation exists.[5 6]

Prior experience with extended manual ventilation has shown that it is labour intensive, tiring and increases the risk of exposure to operators.[7] Despite the challenges, extended manual ventilation has been successful for up to several months during a polio epidemic and for hours to days in other disaster situations.[8–12] Additionally, manual ventilation provides similar gas exchange compared with mechanical ventilation in the patient transport setting.[13–15] However, it risks potential overventilation and barotrauma, especially from inexperienced or overconfident operators. In spite of demonstrated past and potential future need for extended manual ventilation, there is a lack of data regarding the viability and ventilation parameters of long-term manual ventilation.[13–16] In order to mitigate the risk of improper ventilation, a safety device was developed to provide feedback through limitation in inspiratory pressure provided via compression of the resuscitation bag in order to modify the provider's technique and obtain optimal airflow.[17]

METHODS

The Sotair device (safeBVM Corp., USA) is a single use, disposable accessory to the manual resuscitator that can be used for in-hospital, emergency and transport care. The Sotair device comprises a flow-limiting valve that limits the inspiratory flow, enabling providers to ventilate at approximately 40 L/min. The Sotair device can be disabled by removing the device, thereby returning the manual resuscitator to its conventional operation.

To evaluate physical output characteristics of extended manual ventilation and efficacy of a barotrauma mitigation device, 47 medical students, nurses and medics completed two 1-hour manual ventilation sessions using the SmartLung 2000 Lung Simulator (IMT Analytics, Switzerland) and TSI 5300 Series Mass Flow Meter (TSI, USA) with a SPUR II resuscitator bag (Ambu, USA) and endotracheal tube, mimicking a healthy adult male (ideal body weight 73 kg and tidal volume (TV) 6–8 mL/kg) with normal lung physiology (resistance 5 mbar/L/s; compliance 50 mL/mbar), both with and without the Sotair device. Providers were randomised to complete their initial session either with or without the Sotair device. Before each session, providers were given 15 minutes to read the instructions for use included with the AMBU Spur II and the SafeBVM. Providers were allowed to practise with the devices, but no feedback was provided. All providers were crossed over for the second 1-hour session for a total of 94 hours of data recorded with a 10 ms sample rate using the 5300 Series Flo-Sight Software and recording equipment (TSI, USA).[18] A metronome application on a tablet provided a consistent respiratory rate (12 breaths/min). A Puritan Bennett 980 (Medtronic, Ireland) and a ReVel Portable Critical Care transport Ventilator (Carefusion, USA) were each evaluated for comparison with manual ventilation with identical testing equipment as above. Each ventilator was programmed to provide a peak end expiratory pressure of 5 cm H_2O, inspiratory time of 1 s and TV 500 mL. Total ventilation time for each testing case was limited to 5–10 min as both ventilators provided highly consistent ventilator pressure and volume recordings with negligible variability.

Providers were asked a series of questions regarding their experience with manual ventilation. Pressure and volume curves were recorded and evaluated for peak inspiratory pressure (PIP) and TV, respectively. PIP and TV were then analysed by mean and SD for each testing case for each provider. An independent samples t-test was used to evaluate each participant, randomised group and overall effect of the Sotair device. A mixed linear regression model was used to compare the Sotair device versus bag data which were matched by provider. The role session sequence was also assessed.

Patient and public involvement

Volunteers were solicited via listservs, social media groups and word of mouth for medical students at the University of Tennessee Health Science Center in Memphis, Tennessee, USA, and by word of mouth among nurses and medics who work in the emergency department at Methodist University Hospital in Memphis, Tennessee. No incentives were given to participants. All participants gave informed consent to participate in the study.

RESULTS

There were 48 volunteer providers enrolled in this study. Due to not being present for the second arm of the study, one provider was excluded (n=47). The mean age for this study was 26.0 years of age. Out of the entire cohort, 85.1% consisted of medical students attending the University of Tennessee Health Science Center Medical School and the other 14.9% of volunteer providers consisted of emergency medical services personnel and in-hospital nurses. Forty-nine per cent were women and 51% were men. Only 21.2% of the providers had ever manually ventilated a real patient prior to this study. Basic Life Support (BLS) certification only was completed by 89.3% of the cohort, while BLS, Advanced Life Support and Pediatric Advanced Life Support certification had been completed by 10.6% of the volunteers (table 1).

No participants needed to stop ventilation during either session. There was wide variability in TV and peak pressure in unmitigated manual breaths despite prior training and independent exploration of the resuscitation equipment prior to testing (figure 1). The mean (±SD) TV with bag only was 563.9±128.8 mL and with the safety device 536.1±80.9 mL. The instruction was to use a TV of 6–8 mL/kg for a 73 kg ideal body weight patient; 44.3% of bag only breaths were within the goal TV range and 61.4% of breaths

Table 1 Demographic information (n=47)	
Age	26.0 mean value
Sex	Female: 49% Male: 51%
Profession	
Medical students	40/47 (85.1%)
EMS provider	5/47 (10.6%)
In-hospital nurses	2/47 (4.3%)
Previously manually ventilated real patient	10/47 (21.2%)
BLS certified	42/47 (89.3%)
BLS, ACLS and PALS certified	5/47 (10.6%)

ACLS, Advanced Life Support; BLS, Basic Life Support; EMS, emergency medical services; PALS, Pediatric Advanced Life Support.

with the safety device were within this range. The mean PIP with bag only was 17.2±6.3 cm H_2O and with the safety device 14.9±2.4 cm H_2O. Peak pressures ($p<0.0001$) and TVs ($p<0.0001$) were significantly improved with the device (which is currently pending emergency Food and Drug Administration approval).

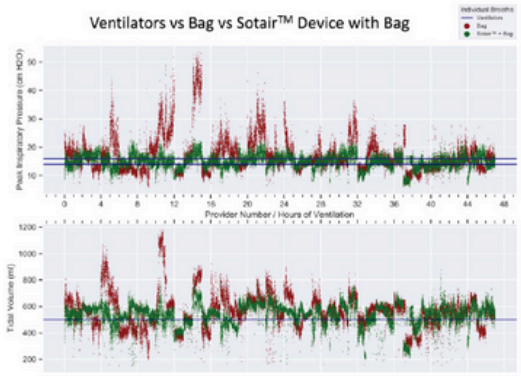

Figure 1 Results with different methods of ventilation. Peak inspiratory pressure and tidal volume versus provider number/hours of ventilation while ventilating the SmartLung 2000 Lung Simulator (IMT Analytics, Switzerland) using a SPUR II resuscitator bag (Ambu, USA) and endotracheal tube mimicking a healthy adult man (ideal body weight 73 kg and tidal volume 6–8 mL/kg) with normal lung physiology (resistance 5 mbar/L/s; compliance 50 mL/mbar). The provider number/hours of ventilation represent an individual provider and the recorded data over the hour-long ventilation session for each of the bag only and bag+Sotair protocols. Provider number/hours of ventilation 1–25 represent individuals initially ventilating with the bag only then crossed over to bag+Sotair device. Provider number/hours of ventilation 26–47 represent individuals who started with the bag+Sotair device then crossed over to bag only. The two ventilators provided peak pressures of 14±0.1 cm H_2O for the Puritan Bennett 980 ventilator (Medtronic, Ireland) and 15.5±0.2 cm H_2O fort the ReVel Portable Critical Care transport Ventilator (Carefusion, California) at settings of PEEP of 5 cm H_2O, inspiratory time of 1 s, and tidal volume of 500 mL. Blue lines rather than plotted points represent ventilator outputs as the ventilators were recorded for 5–10 min in each case and found to have highly repeatable results with negligible variation. PEEP, peak end expiratory pressure.

Group-level analysis among all participants, bag first cohort, and Sotair first cohort demonstrated statistical significance between bag only and bag+Sotair device ventilation sessions for both TV and PIP. Further analysis by independent samples t-test was conducted to compare TV and PIP for bag only and Sotair device use in initial versus follow-up sessions. There was a significant difference in TV for bag only use in initial sessions (589.1±151.4 mL) versus bag only use in follow-up sessions (535.3±88.5 mL); ($t(29\,344)=40.2$, $p<0.001$). There was a significant difference in PIP for bag only use in initial sessions (18.8±7.6 cm H_2O) versus bag only use in follow-up sessions (15.5±3.7 cm H_2O); ($t(26\,662)=51.6$, $p<0.001$). There was a significant difference in TV for bag+Sotair use in initial sessions (530.8±87.8 mL) versus bag+Sotair use in follow-up sessions (540.8±74.0 mL); ($t(30\,944)=11.2$, $p<0.001$). There was a significant difference in PIP for bag+Sotair use in initial sessions (14.6±2.5 cm H_2O) versus bag+Sotair use in follow-up sessions (15.2±2.2 cm H_2O); ($t(31\,875)=24.7$, $p<0.001$).

CONCLUSION

Extended manual ventilation is not an optimal replacement for mechanical ventilation due to the extreme variability in output parameters, especially for unmitigated breaths. However, if needed due to a lack of mechanical ventilation equipment, it is feasible, and we have described baseline parameters in providers who might reasonably be asked to do it. The Sotair device appears to prevent high peak pressures and overventilation, which are associated with increased mortality secondary to barotrauma.[16] The Sotair device also appears to improve underventilation. Manual ventilation with the Sotair device could reduce iatrogenic injury and improve oxygenation while temporising critically ill patients awaiting mechanical ventilation. A learning effect was observed, with those who performed their first session with the device having lower mean TV and PIP as well as SDs for both. This might suggest an additional application to using the device in training scenarios in addition to real-world application.

These data highlight a possible solution to improve patient outcomes when mechanical ventilation is not available due to the shortage that healthcare providers may face due to COVID-19 and in acute settings where mechanical ventilation is not possible. Emanuel *et al*, in their article addressing allocation of resources,[1] speak to the ethical values of 'maximising benefits, treating equally, promoting and rewarding instrumental value, and giving priority to the worst off.' We believe the principle of non-abandonment[19] should be added and note that the Institute of Medicine and others have developed crisis standards of care plans and guidance.[20] Ethical decisions regarding care should not be made

by individual physicians without clear guidance, but instead by policies put in place prior to the need arising, for as Thompson *et al*[21] note, 'Even if the utilitarian maximisation of benefit is thought to be ethically sound, how to implement a system based on this criterion is not ethically straightforward, and requires ethical reflection about what counts as good stewardship, and about the moral obligation to demonstrate transparency, accountability, fairness and trustworthiness in the allocation of scarce resources.' These policies should take into account things such as the principles set out in response to the SARS pandemic in Toronto which included ideas such as duty to care, equity, proportionality and protection of the public from harm, and stewardship in order to reduce morbidity, mortality and social disruption. In addition, being transparent and open about the decision-making process and incorporating ethics into this process can increase the ability to form trust and solidarity, which are critical and often in short supply during a pandemic.[21] However, a recent survey showed that in March of 2020 fewer than half of the respondents' hospitals had policies regarding ventilator rationing, and of those that did there was large variance in what was taken into consideration when making these decisions, highlighting the need for clear and consistent guidelines.[22]

Manual ventilation is the standard of care in many places outside the USA when there are not enough ventilators, as we have seen first-hand.[5] It is a needed measure during any resuscitation inside and outside the hospital. The Sotair device appears to reduce barotrauma, underventilation and overventilation with a small device to prevent these complications from a common procedure. As such we should look to manual ventilation as a viable option before we begin to think about withholding care and rationing resources, especially until ethically sound guidelines are fully assessed, approved and in place.

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Contributors MFB conceived the project and study design, managed data collection, assisted with statistical analysis and assisted with manuscript preparation. NKW assisted with manuscript preparation. RW assisted with study design and manuscript preparation. JEH assisted with study design and manuscript preparation. SAN assisted with study design and data collection. SY assisted with study design and data collection. EDM assisted with data collection and manuscript preparation. RSC assisted with study design and data collection. JWT assisted with data review and manuscript preparation.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article. Deidentified participant data are available upon request. Please contact Dr Mark Brady for permissions for reuse.

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RESPIRATORY CARE

ORIGINAL RESEARCH

Manual Ventilation Performance With Safety Device in Normal Versus Decreased Lung Compliance: A Single-Center Simulation Study

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Abstract

Background: Resuscitator bags are commonly utilized in acute care settings; however, poor performance occurs irrespective of a provider's qualifications or experience. A new flow-limiting device (Sotair by SafeBVM, Boston, Massachusetts) limits inspiratory flow during manual ventilation, thus minimizing peak inspiratory pressures. This study examined the differences in flow, pressure, and tidal volume (V_T) during ventilation with a manual resuscitator connected to the flow-limiting device versus a mechanical ventilator.

Methods: Second-year respiratory therapy students were recruited from an advanced cardiovascular life support class. Participants conducted a 2-min trial of manually ventilating a test lung utilizing normal and decreased compliance settings with the flow-limiting device connected to an endotracheal tube. Demographic data on participants' age were collected. The control group consisted of a mechanical ventilator providing ventilation with the same test lung and compliance settings. Mean differences were compared between the manual ventilation and control group.

Results: A total of 41 respiratory therapy students (71% female, 76% undergraduate) participated. The mean experience level using the bag-valve-mask was 6.71, and the mean confidence level was 8.02; the scale was 0–10 with high numbers indicating greater experience or confidence. A small but statistically significant difference was found in mean peak pressures between manual ventilation with the flow-limiting device (15 cm H_2O) and the mechanical ventilator (13 cm H_2O) for the normal lung setting (P = .008) but not for the decreased compliance lung setting (23 cm H_2O vs 23 cm H_2O with the ventilator). There was a significant difference in mean V_T between manual ventilation (412 mL) and the mechanical ventilator (460 mL) in the decreased compliance lung setting (P = .003) but not the normal compliance setting (452 mL vs 474 mL with the ventilator).

Conclusions: Although there were some statistically significant differences between the 2 groups, these differences were not clinically important. Participants adequately manually ventilated with V_T similar to a mechanical ventilator.

Keywords: manual ventilation, mechanical ventilation, ventilation-associated lung injury, ARDS, flow-regulating device

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Introduction

A manual bag-valve-mask (BVM) is the primary initial method of ventilating patients who have respiratory failure (eg, cardiac arrest, etc) and during the initial delivery of general anesthesia.[1–3] Whereas the BVM is an effective method, epidemiological studies have demonstrated that difficult mask ventilation occurs in about 1.4% of subjects undergoing general anesthesia.[3] The occurrence is even higher in emergency department settings, ranging from 4–11%.[4,5] In addition, the use of the BVM can lead to insufflation of the stomach with increased risk of aspiration, increased intra-abdominal pressure, hemodynamic instability caused by decreased venous return, and increased risk of ventilator-induced lung injury.[1,6–8] To minimize these risks, health care providers should be trained in proper technique, use an appropriately sized mask, and be mindful of the volume and pressure delivered.[3,9]

Despite extensive education of providers, manual ventilation is still a difficult skill to master.[1] Even with feedback methods such as capnography or pulse oximetry, BVM ventilation relies on provider skill. In contrast, mechanical ventilation is machine controlled, providing precise control of critical parameters. However, ongoing research has even called into question the superiority of mechanical ventilation over BVM ventilation during resuscitations.[10–12]

Continuous monitoring and prompt adjustments can help mitigate complications and enhance the effectiveness of ventilation. There have been no devices that have consistently been shown to enhance the quality of manual ventilation.[1,3,13] To address this issue, a safety device (Sotair) was developed by SafeBVM (Boston, Massachusetts). This flow-limiting device fits in line between the bag and the patient. During manual ventilation, if inspiratory flow exceeds 55 L/min, the device completely stops flow to the patient until the provider releases the pressure on the bag. By limiting flow, it minimizes peak airway pressure to mitigate the potential adverse effects associated with manual ventilation.

The goal of this study was to assess and compare air flow, pressure, and tidal volume (V_T) between manual ventilation using the flow-limiting device and mechanical ventilation even though a mask was not used. The study aimed to ascertain whether the performance of the flow-limited resuscitator was comparable to a mechanical ventilator with regard to ensuring controlled air flow during simulated resuscitation.

Methods

This prospective, manikin-based randomized study was conducted by the Department of Respiratory Therapy at Georgia State University and approved by the institutional review board. Written informed consent was obtained from all participants.

QUICK LOOK

Current knowledge

Manual ventilation is an important resuscitative intervention when mechanical ventilation is not available. However, it is operator dependent, and associated risks include air trapping during rapid ventilation, hemodynamic compromise, and pulmonary barotrauma.

What this paper contributes to our knowledge

Using a flow-limited resuscitator at clinically similar thresholds compared to a mechanical ventilator was similar with regard to peak inspiratory pressures and tidal volumes (V_T). Respiratory therapy students were able to effectively do so with a manikin at both normal compliance and low compliance (to simulate ARDS conditions). The measured peak inspiratory pressures and V_T were within, or close to, target clinical ranges.

A convenience sample was recruited from an advanced cardiovascular life support (ACLS) class for second-year respiratory therapy students at Georgia State University. Exclusion criteria included previous use of the Sotair device and unwillingness to participate. All students had basic life support certification and were going through ACLS for the first time. A total of 45 individuals were considered for this study, but 4 were excluded because they were faculty members and possessed a degree of training above the remaining participants.

Participants were informed that the manikin (Ambu SPUR II, Ambu, Ballerup, Denmark), BVM, endotracheal tube, and SmartLung 2000 2-L test lung (IMT Analytics, Buchs, Switzerland) represented an average 70 kg adult male, that the resuscitator bag volume was 1.5 L, that the target V_T was 500 mL, and that the target breathing frequency was 12 breaths/min. A metronome gave audio and visual prompting at a rate of 12/min; and air flow, pressure, and volume were measured using a TSI 5300 series gas flow meter (TSI, Shoreview, Minnesota). Inspiratory time was measured as the start of inspiratory flow to the start of expiratory flow.

Participants performed 2 min of manual ventilation using the flow-limiting device connected to the test lung set to a normal resistance of 5.1 cm H_2O/L/s and 2 compliance (compliance of the respiratory system [C_{RS}]) settings—normal respiratory compliance (C_{RS} = 73.5 mL/cm H_2O at V_T = 1,000 mL) or decreased compliance (C_{RS} = 24.5 mL/cm H_2O at V_T = 1,000 mL). The decreased lung compliance setting corresponds to a patient with ARDS. Participants were blinded to C_{RS} of the manikin and were randomized to start on the normal or low-compliance setting using a random number generator.

Table 1. Characteristics of respiratory therapy student participants

	Participants n = 41
Sex	
Male	12 (29)
Female	29 (71)
Race/ethnicity	
White/white	5 (12)
Black/African American	14 (34)
Hispanic/non-white	8 (20)
Asian	11 (27)
Other/multiracial	3 (7)
Education	
Undergraduate student	31 (76)
Graduate student	10 (24)
BVM experience, range 0–10	7 (2)
BVM confidence, range 0–10	8 (1)
Age, y	24.4 (3.9)

Data are presented as *n* (%) or mean (SD).
BVM, bag-valve-mask.

The control group was obtained using a mechanical ventilator (LTV 1200, Vyaire Medical, Mettawa, Illinois). There were 3 trials of 90 s for both the normal and decreased compliance settings. The ventilator was set to volume control, 21% O_2, V_T 500 mL, PEEP 5, frequency 12 breaths/min, and 1 s inspiratory time. The TSI 5300 series gas flow meter was used to measure flow, pressure, and volume.

After the exercise, participants completed a survey that included questions about age, race/ethnicity, sex, education, participant self-assessment of experience with BVM (quantified on a Likert scale of 0–10), and participant self-assessment of confidence with BVM (quantified on a Likert scale of 0–10); 0 indicated no experience or confidence, and 10 indicated very confident or experienced. Differences in minute ventilation and peak pressures were compared between the flow-limited resuscitator and the control group using 2-tailed independent samples *t* tests. Differences in ventilation between normal and low-compliance lung settings for each individual were analyzed using a 2-tailed paired sample *t* test. $P < .05$ was used to identify statistical significance.

Results

Table 1 provides demographic characteristics of the 41 participants; 71% were female, and the majority were undergraduate students (76%). The mean prior experience level using a BVM was 6.71 (SD = 1.7), and the mean confidence level using the BVM was 8.02 (SD = 1.3).

Data on the measured and calculated ventilatory variables under the normal and decreased lung compliance conditions are presented in Table 2 and analyzed using independent samples *t* test. There was a statistically significant difference between the manual ventilation group and the control group with regard to mean peak inspiratory pressures (14.6 cm H_2O vs 13.4 cm H_2O, respectively, $P = .008$) in the normal lung compliance setting. There was also a statistically significant difference with respect to V_T in the decreased compliance lung setting (412.2 mL vs 460.0 mL, $P = .003$).

Paired sample *t* tests were also conducted to evaluate how participants ventilated normal compliance lungs versus low-compliance ones. There were statistically significant differences in mean peak inspiratory pressure in the normal (14.6 cm H_2O) versus low-compliance setting (23.0 cm H_2O) ($P < .001$). There was also a statistically significant difference in mean V_T in the normal compliance (451.8 mL) versus the low compliance (412.2 mL) ($P < .001$) (Table 3).

Discussion

Improving the way patients are manually ventilated is important as mechanical ventilators are not always available, especially in out-of-hospital settings or austere environments. Manual ventilation can be associated with a number of risks including air trapping, gastric insufflation, hemodynamic compromise, and ventilation-induced lung injury. As practice patterns and training significantly

Table 2. Manual ventilation measurements with the sotair device compared to the mechanical ventilator for the normal and decreased lung compliance setting

	Manual ventilation with sotair device n = 41	*Mechanical ventilation* n = 3	P
Normal lung compliance settings			
Peak inspiratory pressure, cm H_2O	14.6 (2.6)	13.4 (0.04)	.008
V_T, mL	451.8 (99.1)	473.6 (1.1)	.17
Peak flow, L/min	40.9 (5.5)	39.5 (0.3)	.10
Inspiratory time, s	1.0 (0.2)	1.0 (< 0.1)	.77
Decreased lung compliance settings			
Peak inspiratory pressure, cm H_2O	23.0 (3.2)	23.4 (< 0.01)	.50
Tidal volume, mL	412.2 (96.4)	460.0 (1.0)	.003
Peak flow, L/min	39.9 (5.7)	39.5 (0.05)	.68
Inspiratory time, s	1.0 (0.2)	1.0 (< 0.01)	.38

Data are presented as mean (SD).
V_T, tidal volume.

Table 3. Comparison of subject performance in the normal lung compliance versus decreased lung compliance settings using the sotair device

	Normal lung compliance n = *41*	*Decreased lung compliance* n = *41*	P
Peak inspiratory pressure, cm H_2O	15 (3)	23 (3)	< .001
V_T, mL	452 (99)	412 (96)	< .001
Peak flow, L/min	41 (6)	40 (6)	.10
Inspiratory time, s	1 (0)	1 (0)	.08

Data are presented as mean (SD).
V_T, tidal volume.

vary among operators, effectively, and safely, ventilating patients becomes of utmost importance.

Our study demonstrates that operators were able to adequately ventilate the manikin under both normal lung compliance and low lung compliance with ventilatory variables that are close to being within target ranges.[14] Under both circumstances, the peak pressure and V_T were similar to those obtained with the mechanical ventilator, albeit with some small but statistically significant differences. Participants ventilated at a lower V_T than the ventilator for the decreased compliance lung setting but still maintained V_T within 5% of the ARDS recommendations of 6–8 mL/kg (corresponding to 420–560 mL). Peak flow and inspiratory time were not significantly different between the participants and controls in both groups. In addition, we found that using the flow-limiting device participants were able to effectively adapt to the decreased lung compliance. Participants effectively adjusted their peak pressures and yet still ventilated with adequate V_T.

The study sample consisted of respiratory therapy students, which may decrease external validity because these participants represent a segment of the population that undergoes specific training. As such, respiratory students may more skillfully ventilate patients compared to other providers who receive less training. In addition, this study was conducted in a simulated environment, which may not be representative of real-life scenarios. Another limitation of our study is that we relied on lung models based on the average-sized 70 kg human, and thus these results may not generalize to pediatrics. Lastly, as this study was conducted at a single institution, future studies are warranted to confirm that these findings are generalizable.

Conclusions

Our study suggests that manual ventilation with the flow-limiting device may deliver short-term ventilation with variables (pressure and volume) similar to a mechanical ventilator under normal and decreased C_{RS} settings. Manual ventilation is often used under conditions when mechanical ventilation is not feasible, such as in out-of-hospital resuscitation or in resource-limited settings or austere environments. Optimizing manual ventilation is an important goal.

Author Disclosure Statement

Data were submitted as an abstract and accepted by RESPIRATORY CARE, 2023;68(10).

Dr Slutsky discloses a relationship with SafeBVM. The remaining authors have disclosed no conflicts of interest.

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Bag Valve Mask Ventilation in Tactical Combat Casualty Care: Flow Limitation is a Viable Alternative to Volume Limitation with 1000mL Resuscitator

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1 Alpert Medical School of Brown University, Providence, RI 2 Li Ka Shing Knowledge Institute, St. Michael's Hospital, Unity Health Toronto; University of Toronto, CA 3 SafeBVM, Boston, MA

Introduction

- Optimal ventilation is a challenge in Tactical Combat Casualty Care (TCCC), particularly in casualties with traumatic brain injury (TBI), hemorrhagic shock, or those requiring prolonged field care.
- Based on pre-hospital data, a single hypoxic or hypotensive episode in TBI patients is associated with a doubling of mortality, and hyperventilation was independently associated with a 2-5.9 times increase in mortality.
- References: Spaite DW, Bobrow BJ, Keim SM, et al. Association of statewide implementation of the prehospital

Capability Description

- The Sotair® device (FDA 510K-K212905) limits peak flow to 55 liters per minute (LPM) and attaches to any manual resuscitation bag.
- Flow above 55 LPM causes haptic, auditory and visual feedback, acting as a "forcing function" stopping providers from delivering forceful breaths that could result in gastric insufflation and overventilation.

Technical Approach

- High peak inspiratory pressures (PiP) can cause gastric insufflation (PiP>22 cm H_2O) leading to aspiration. They can also cause leaks in supraglottic airways due to challenges with seal pressure.
- Hypoxia (SpO2<90), hypoventilation, and hyperventilation (outside of EtCO2 32-38 mmHg goal) worsen outcomes. TCCC 2024 guidelines recommend using smaller resuscitator BVMs (~1000 ml) i.e. a volume-limiting approach to mitigate risk of over-ventilation.
- However, recent research suggests that this strategy may fail to deliver adequate ventilation and even reduce survival rates.
- A flow-limiting valve in the circuit can also address over-ventilation. Data from manikin studies support that this approach is effective.
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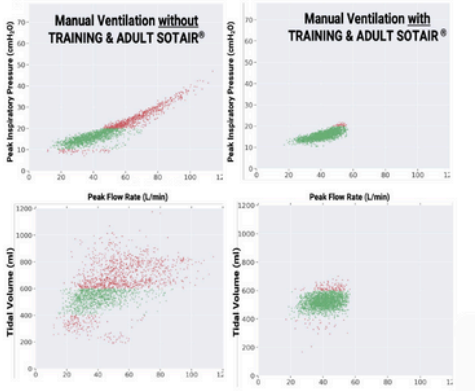
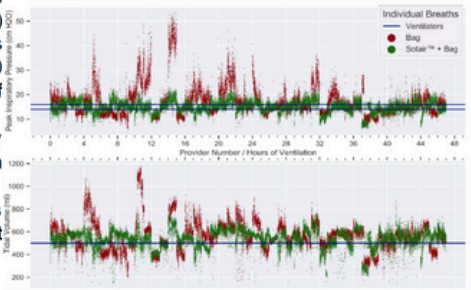


Results

- We previously demonstrated that the flow limiting device minimizes peak pressures and limits excessive tidal volumes over 1 hour of manual ventilation.
- Reference: Brady MF, Weber NK, Walker, III R, et alFeasibility of manual ventilation replacing mechanical ventilationBMJ Innovations 2021;7:297-301.



Applicability to Medical Roles of Care

- For Role 1, 2 and 3 scenarios involving the use of manual resuscitator bags, a flow-limiting device (Sotair) can be deployed, since data suggest that this helps prevent over-ventilation while reducing the risk of under-ventilation.
- This approach avoids the need to switch to a 1000 ml BVM, which has been associated with worse outcomes.

Impact to the Warfighter/Significance

- Flow limitation is an immediately available alternative solution to TCCC guidelines. The Sotair can very easily be attached to existing BVM kits. There is the potential to improve manual ventilation during the chain of survival.

e reference: Kumar, P; Holley, J; Justice, J; Slutsky, A; Brady, M. "Manual lation Performance in First Responders using a Flow-Rate Limiting Device ir)" poster presentation at national American Academy of Emergency ine (AAEM25) annual conference, 2025

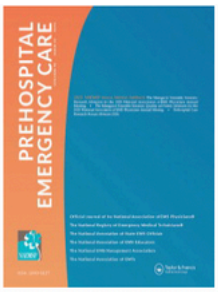
Developmental Status of Technology

- TRL8, commercially available and being used at 100+ Fire and EMS Departments nationwide. There are pending studies assessing the utility of the flow-limiting device in the out-of-hospital setting.

This is a training evolution and not an actual casualty

Disclaimer

Disclaimer:The U.S. Army Medical Research Acquisition Activity, 808 Schreider Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This work was supported by The Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense, in the amount of $4,536,252 through the Peer Reviewed Medical Research Program under Award Number HT9425-23-1-0316. Opinions, interpretations, conclusions, and recommendations are those of the author(s) and are not necessarily endorsed by The Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense. PP is the CEO of SafeBVM. AS serves as the part time Chief Scientific Officer for SafeBVM.



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Prehospital Emergency Care

Forghani, R, Lane, N, Gumucio, JA, Menegazzi, J, Salcido, D. Relative Efficacy of a Flow-Regulating Safety Device versus Pop-off Valves during Simulation of Healthy and Disease-State Lungs. (2025) The Menegazzi Scientific Sessions: Research Abstracts for the 2025 National Association of EMS Physicians Annual Meeting, Prehospital Emergency Care, 29:sup-S113, S39-S40, DOI: 10.1080/10903127.2024.2425372 To link to this article: https://doi.org/10.1080/10903127.2024.2425372

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81. Relative Efficacy of a Flow-Regulating Safety Device versus Pop-off Valves during Simulation of Healthy and Disease-State Lungs

Rameen Forghani, Nina Lane, Nabeeha Farhan, Antonio Gumicio, James Menegazzi, David Salcido
University of Pittsburgh

Background: Manual ventilation using a bag-valve apparatus can be a life-saving maneuver. During prehospital resuscitation, overly forceful ventilations can lead to excessive peak inspiratory pressures (PIP), and either excessive or inadequate delivered tidal volumes (TV). Pop-off valves have the potential to limit these untoward effects, as does a flow-regulating safety device.
Objectives: We sought to compare the relative efficacy of a flow-regulating safety device, to pop-off valves set at 25 and 40 cmH2O, under conditions simulating healthy lungs and obstructive and restrictive lung disease. We hypothesized that the flow-regulating safety device would provide superior PIP and TV compared to the pop-off valves.
Methods: Using a two-lung mechanical test lung, six ventilators delivered 50 ventilations per condition, at a rate of 12 BPM. Test lung settings were as follows: Healthy lungs- compliance, 0.05, upper airway resistance (UAR) Rp5, lower airway resistance (LAR) 0.0; Obstructive disease- compliance 0.05, UAR Rp10, LAR Rp50; Restrictive disease- compliance 0.02, UAR Rp5, LAR Rp20. Manual ventilations were delivered with the 25 cmH2O, the 40 cmH2O pop-off valves, or the flow-regulating safety device. PIP and TV were recorded continuously. Ventilators were instructed to deliver forceful breaths when the pop-off valves were in place.
Results: We analyzed 2,801 ventilations. Under healthy lung conditions, the mean (SD) PIPs were: 33.1(6.2) 25 cmH2O valve; 41.6(3.8) 40 cmH2O valve; 10.6(3.3) flow-regulating device. The mean (SD) TVs were: 561mL (322) 25 cmH2O valve; 762 (329), 40 cmH2O valve; 654 (298) flow-regulating device. Under obstructive lung conditions, the mean (SD) PIPs were: 44.4 (7.0) 25 cmH2O valve; 56.5 (7.0) 40 cmH2O valve; 35.5 (5.5) flow-regulating device. The mean (SD) TVs were: 288mL (213) 25 cmH2O valve; 344 (254), 40 cmH2O valve; 710 (252) flow-regulating device. Under restrictive lung conditions, the mean (SD) PIPs were: 37.6 (4.2) 25 cmH2O valve; 47.3 (4.9) 40 cmH2O valve; 22.2 (4.5) flow- regulating device. The mean (SD) TVs were: 446mL (268) 25 cmH2O valve; 701 (214), 40 cmH2O valve; 711 (272) flow-regulating device.
Conclusions: The flow-regulating device maintained safe PIPs under all three conditions, while delivering adequate TVs. Pop-off valves did not always release at the designed pressures.

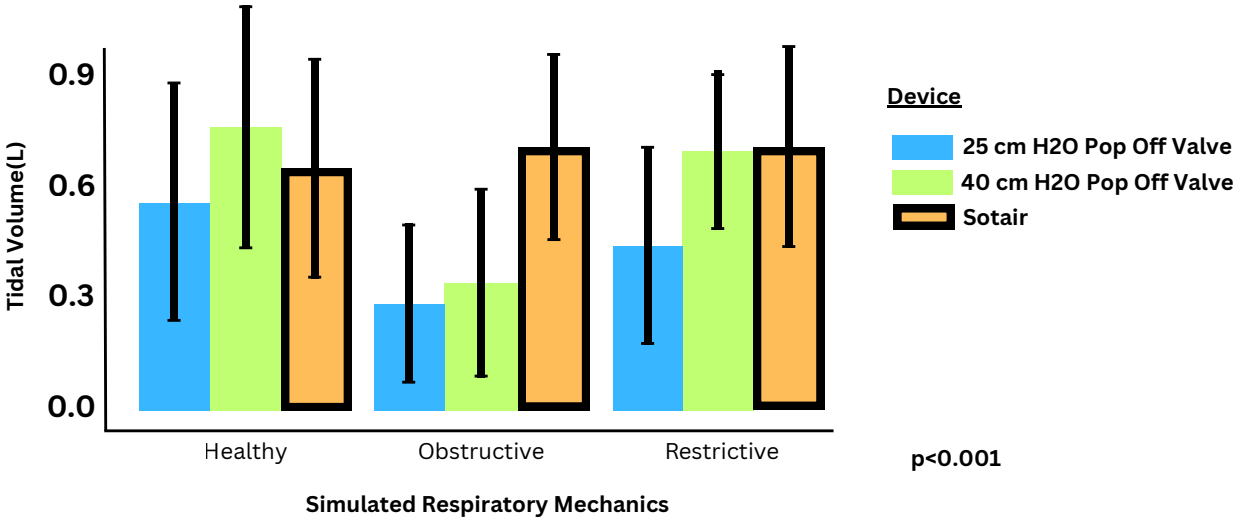
Conclusions:

Pop-off valves inconsistently released at the set pressures, often leading to higher than anticipated inspiratory pressures

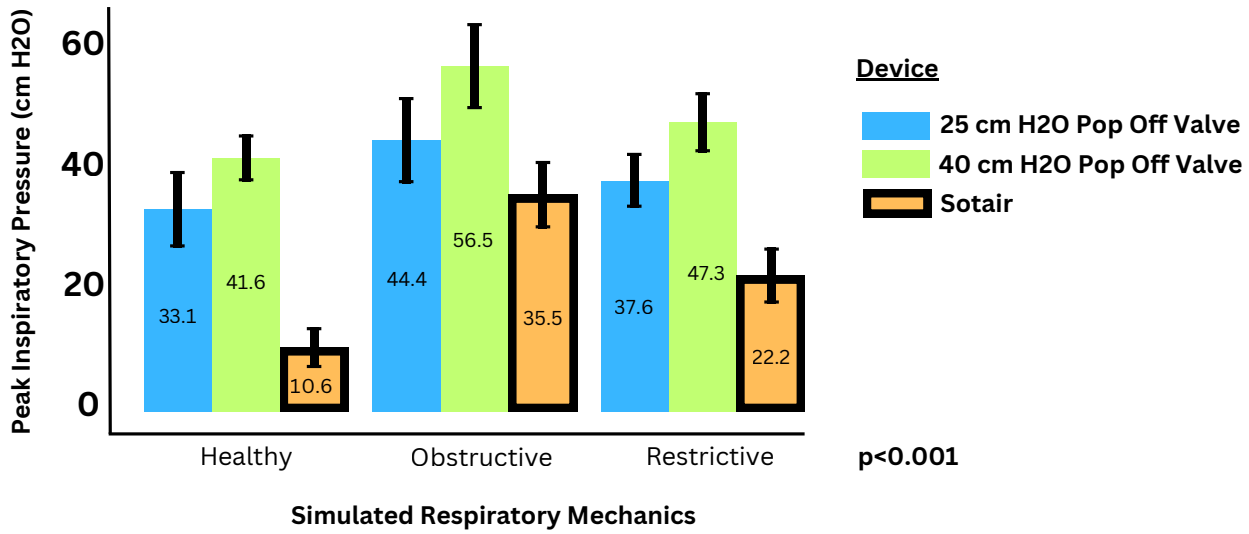
The tidal volumes delivered by a flow regulating safety device was invariant across healthy, restrictive, and obstructive conditions

With the flow regulating device, the tidal volumes were maintained at lower peak inspiratory pressures in all conditions

Tidal Volume with Pop-off and Flow-Regulating Valves Across Varying Lung Mechanics

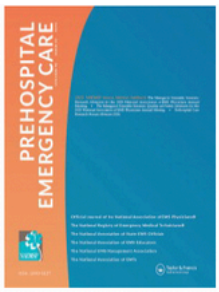


Peak Inspiratory Pressures with Pop-Off and Flow-Regulating Valves Across Varying Lung Mechanics



Forghani, R, Lane, N, Gumucio, JA, Menegazzi, J, Salcido, D. Relative Efficacy of a Flow-Regulating Safety Device versus Pop-off Valves during Simulation of Healthy and Disease-State Lungs. (2025) The Menegazzi Scientific Sessions: Research Abstracts for the 2025 National Association of EMS Physicians Annual Meeting, Prehospital Emergency Care, 29:sup-S113, S39-S40, DOI: 10.1080/10903127.2024.2425372 To link to this article: https://doi.org/10.1080/10903127.2024.2425372

Disclosure: This research was funded by the National Science Foundation and conducted independently by the authors. The authors have no financial interest in SafeBVM, Corp.



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Salcido, DD, Forghani, R, Lane, N, Gumucio, JA, Menegazzi, JJ. A Comparison between Manual Ventilation with a Flow Control Valve versus a Mechanical Transport Ventilator. Prehospital Emergency Care, S67-S68. (2025) The Menegazzi Scientific Sessions: Research Abstracts for the 2025 National Association of EMS Physicians Annual Meeting, Prehospital Emergency Care, 29:sup1, S1-S113, S67-S68DOI: 10.1080/10903127.2024.2425372 To link to this article: https://doi.org/10.1080/10903127.2024.2425372

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142. A Comparison between Manual Ventilation with a Flow Control Valve versus a Mechanical Transport Ventilator

David D. Salcido, Rameen Forghani, Nina Lane, Nabeeha Farhan, Jorge Gumucio, James J. Menegazzi
University of Pittsburgh School of Medicine

Background: Initial respiratory support in the prehospital environment often utilizes a bag-valve-mask or bag-valve tube airway configuration. Manual ventilation is often discontinued when mechanical ventilators become available. While a mainstay of out-of-hospital care, manual ventilation can be fraught with risks of excessive inspiratory pressures and hyperventilation or hypoventilation due to inappropriate delivered volumes. A commercially available flow control valve (FCV) may mitigate these undesirable clinical effects.
Objectives: We examined the pressure and flow characteristics of manually performed ventilations using an FCV, to a commercially available transport ventilator. We hypothesized that the use of the FCV would provide similar peak inspiratory pressures (PIP) and tidal volumes (Vt) compared to the transport ventilator.
Methods: We used a dual-lung mechanical test lung with settings designed to simulate three conditions: healthy lungs; lungs with obstructive disease (e.g., asthma, COPD); and lungs with restrictive lung disease (e.g., idiopathic pulmonary fibrosis, sarcoidosis, obesity). The three conditions varied in compliance, upper airway resistance, and lower airway resistance. Manual ventilations were performed by six ventilators with a self-inflating resuscitation bag with the FCV in line. Ventilations were maintained at a rate of 12 BPM and 50 breaths were given under each of the three conditions. The transport ventilator settings were: rate 12 BPM; volume 750mL; peak pressure alarm 35 cmH2O.
Results: We analyzed 1,050 ventilations (900 manual and 150 mechanical). Values are reported as means and standard deviations (SD). Healthy lung conditions: manual ventilations and FCV, the PIP was 10.6 (3.3) cmH2O, and the Vt was 654 (298) mL; the mechanical ventilator PIP was 13.6 (0.3) cmH2O and the Vt was 1,037 (54) mL. Obstructive lung disease conditions: the PIP was 35.5 (5.5) cmH2O with the FCV and the Vt was 710 (252) mL; the mechanical ventilator PIP was 17 (0.2) and the Vt was 747 (65) mL. Restrictive lung disease conditions: the FCV PIP was 22.2 (4.5) and the Vt was 711 (272); the mechanical ventilator PIP was 19.6 (0.3) and the Vt was 801 (23) mL.
Conclusions: We observed that the FCV produced PIPs and Vts that were similar to that of the mechanical ventilator.

EMS World Expo's International Scientific Symposium in partnership with UCLA's Prehospital Care Research Forum

Abstract Presented September 2024- EMSWORLD EXPO, Las Vegas

Manual Ventilation Performance in First Responders using a Flow-Rate Limiting Device (Sotair)

Authors: Prasanna Kumar, Joseph E Holley, Joshua M Justice, Arthur S. Slutsky, Mark F Brady

Introduction: Manual ventilation with a resuscitator bag is a basic and essential skill for first responders, but performance is highly variable. Sotair is a flow-rate limiting valve designed to prevent peak flow from exceeding 55 LPM, thus minimizing peak pressures and tidal volumes. A limited market release of the Sotair flow-rate limiting valve took place in Tennessee.

Methods: 217 providers from the city fire departments of Collierville, Bartlett, and Germantown in Tennessee participated. Providers performed 60 seconds of ventilation with a manual resuscitator bag on a simulated lung. After a brief educational intervention demonstrating how to use the Sotair flow-rate limiting device, providers again performed 60 seconds of manual ventilation on the simulated lung using the Sotair attached to the manual bag. Peak inspiratory pressures, tidal volumes, and respiratory rates were compared before and after the educational intervention.

Results: The mean peak inspiratory pressure was lower with Sotair (15.70 cm H2O +/- 1.50) compared to the bag alone (17.57 cm H2O +/- 5.06) $p < 0.01$ [Image]. The mean tidal volume was also significantly lower with Sotair (525 mL +/- 31) than the bag alone (594 mL +/- 141) $p < 0.01$. Mean respiratory rate with Sotair was slightly higher (11.54 breaths per minute +/- 3.36) compared to bag alone (10.89 breaths per minute +/- 4.91) $p= 0.011$.

Conclusion: Use of the Sotair flow-rate limiting device after a brief educational intervention significantly improved ventilation parameters with manual ventilation by minimizing interprovider variability.

Peak Pressures and Tidal Volumes Delivered by 217 Providers

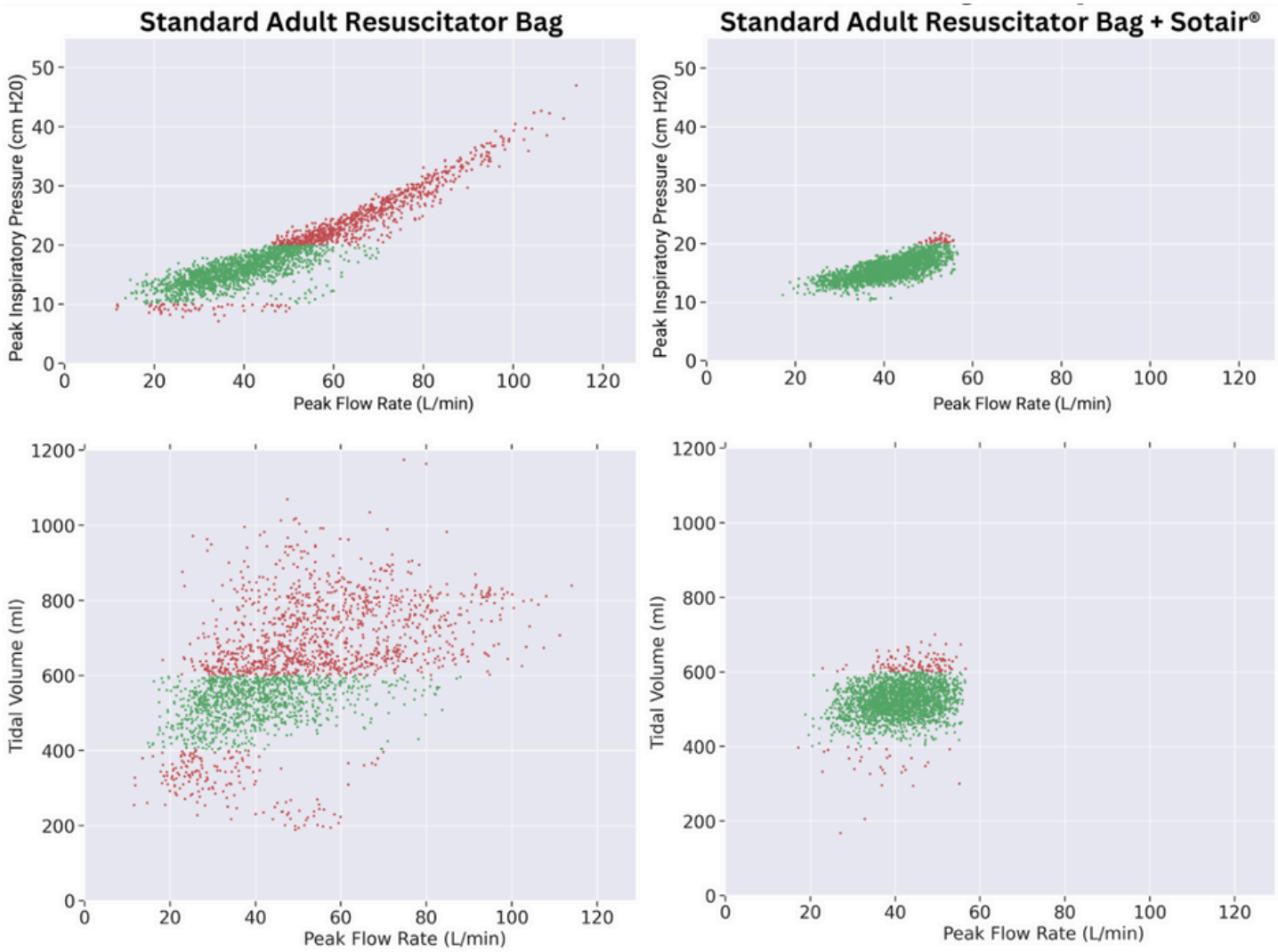
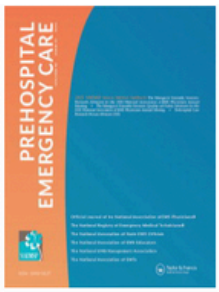


Figure 1: Peak pressures and tidal volumes delivered by participants with a resuscitator bag versus a resuscitator bag with the Sotair device. The green color indicates values within safe manual ventilation parameters (10 to 20 cmH20 peak inspiratory pressure and 400 to 600 mL tidal volumes) whereas the red color indicates values outside this range.



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Efficacy of a Ventilatory Safety Accessory for Use with Manual Ventilations during Simulated Prolonged Transport: A Porcine Experimental Study

David D. Salcido, Jorge A. Gumucio, Kyung Woon Jeung, Holly Stewart, Haris Shekhani, Arthur Slutsky, Prathamesh Prabhudesai, Advika Ventrapragada, Nina Lane, Dylan Defilippi, James J. Menegazzi

University of Pittsburgh, SafeBVM Corp.

Background: During prehospital care, those in need of respiratory support are most commonly ventilated manually by EMS clinicians. This often results in excessive peak inspiratory pressures (PIP) and excessive inspiratory flow rates (IFR), both of which can be detrimental. Objectives: We sought to determine the effects of an FDA-cleared ventilatory accessory on PIP and IFR during simulated prolonged transport using porcine models of both bag-valve-mask (BVM) and endotracheally intubated (ETI) patients needing positive pressure ventilation.

Methods: We used 14 mixed-breed domestic swine of both sexes, weighing 25–30 kgs. Animals were sedated, anesthetized, and instrumented with central arterial and venous micromanometer pressure transducers. Animals were randomly assigned to one of four groups: BVM with active device or BVM with sham device; ETI with active or ETI with sham. Seven ventilators who were trained at least to the EMT level manually ventilated the animals for 30min. Ventilations were delivered at a rate of 12/minute during all conditions. Ventilators were given visual (airway pressure tracing, ETCO2) and verbal feedback, and were instructed to intentionally give a “forceful” breath on every sixth inspiration. Abdominal and thoracic x-rays, and necropsies were obtained, and lung injury scores (LIS) calculated. The primary outcome variables were PIP and Vt. Secondary outcomes were LIS, and findings at necropsy.

Results: There were 4,922 manual ventilations analyzed (2,706 with the active device and 2,216 with the sham) with 866 forceful ventilations (407 active device, 459 sham). PIP values during regular ventilations did not differ during BVM (active device vs. sham) or ETI conditions (active device vs. with sham). During forceful ventilations the PIP with the active device (31.2 cmH2O, 95%CI 29.9–32.4) differed from that of the sham device (72.8 cmH2, 95% CI 70.8-74.7) with $p<0.0001$. The IFRs also did not differ across conditions during regular ventilations. During forceful ventilations, the IFR with the active device (20.7L/min, 95% CI 19.1–22.4) differed from that of the sham (62.4L/ min, 95% CI 55.8–69.1) with $p<0.0001$.

Conclusions: The safety accessory functioned as designed and prevented excessive PIP and IFR during both prolonged BVM and ETI ventilation, even during intentionally forceful experimental ventilations.

Development and validation of an educational intervention to improve performance with a new manual ventilation device (Sotair™)

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Introduction

- Improper bag-valve mask (BVM) technique can lead to stomach insufflation and complications, including aspiration and lung barotrauma
- Sotair™, (SafeBVM Corp., Massachusetts) can improve BVM delivery. Developing educational interventions for the proper use of Sotair™ is necessary to improve performance and optimize outcomes

Objectives

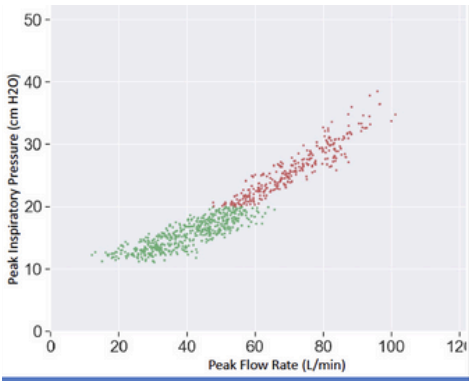
- Expand upon video and printed educational interventions for Sotair™ in order to improve performance with the device
- Create and validate the utility of video and printed materials for proper use of Sotair™

Methods

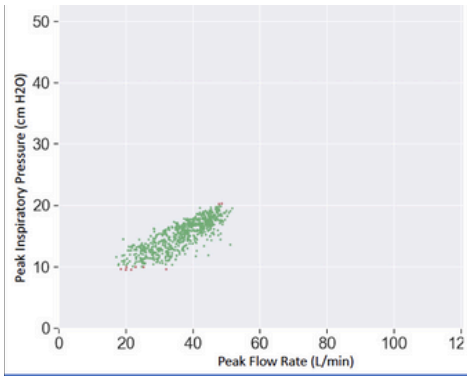
- Recruitment of EMS providers (n=32)
- Record each individual manually ventilating a simulated adult male lung for 2 minutes
- Apply educational intervention, attach Sotair™ and repeat
- Primary outcome: peak pressure; Secondary outcomes: volume, flow, rise time, and inspiratory/expiratory ratio

Results

- Significantly lower PIPs by an average of 4.06 cmH_2O (19.32 ± 5.80 across 791 breaths vs 15.26 ± 2.44 across 686 breaths; T-value 17.06; $p < 0.0001$). Minute ventilation was also lower by 1238.06cc (7550.47 vs 6312.41)
- 36.54% of breaths delivered by BVM crossed the 20 cmH_2O threshold for gastric insufflation compared to 0.25% of breaths delivered with the Sotair™



Figures 1 . Ventilation with standard BVM



Figures 2. Ventilation with BVM+Sotair™

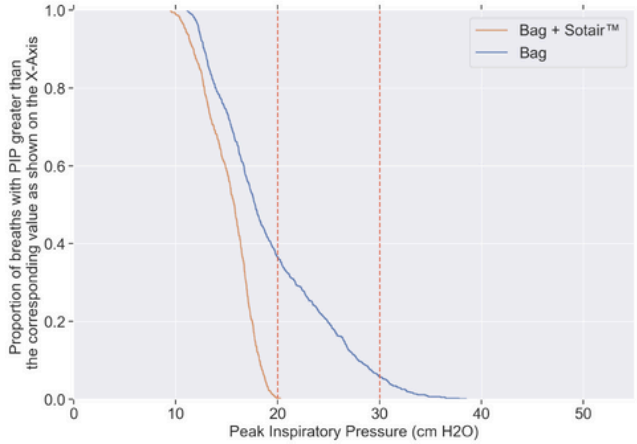


Figure 3. Proportion of delivered breaths with PIP greater than X-axis value for standard BVM and BVM+Sotair™

Conclusions

- Our data demonstrates the effectiveness of implementing a brief educational intervention that leads to safer delivery of breaths using the Sotair™ feedback about the educational materials was 65.6% positive and 34.4% neutral

UNDERVENTILATION WITH A SMALL ADULT BAG (1,000 ML): PERSISTENT GAPS DESPITE REAL-TIME FLOW-GUIDED TRAINING

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Resuscitation Science Symposium (ReSS) Nov 8-9 2025

Background

- Manual ventilation is a critical but highly variable skill in prehospital and hospital settings.
- Concerns over over-ventilation have led some EMS systems to adopt smaller BVMs.
- Risk: smaller bags may underventilate adult patients.

Research Question

- Can a small adult bag (1,000 mL) deliver adequate tidal volume for a average adult male?
- Can performance improve after a brief training intervention using:
  - Real-time flow and volume feedback (SotairIQ)
  - A flow-limiting device (Sotair, 55 LPM cap) to encourage appropriate squeeze without over-ventilation.

Methods

- Participants: 55 first responders, Johnson County, KS.
- Task: 60 seconds of manual ventilation on simulated healthy adult (target Vt: 420–570 mL).
- Device: VENTLAB AirFlow 1,000 mL small adult bag.
- Measurements: Tidal volume (Vt), peak flow, respiratory rate (RR) — recorded via SotairIQ Training Platform (SafeBVM, Boston).
- Intervention: 2-minute video + 1-minute hands-on training with Sotair valve (flow control at ~55 LPM) (SafeBVM, Boston). Repeat ventilation task with Sotair inline.

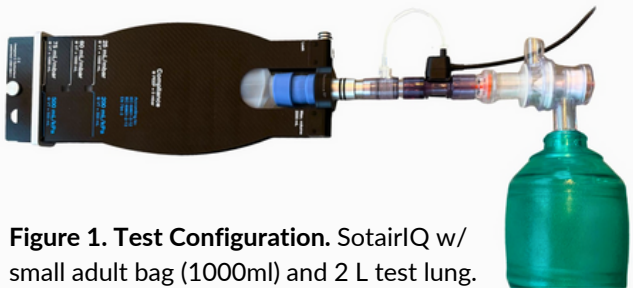

Figure 1. Test Configuration. SotairIQ w/ small adult bag (1000ml) and 2 L test lung.

Image 1. Training on the flow control valve (Sotair)
(Participating Depts: Olathe FD, Johnson County Fire District #1(JCFD#1), Johnson County Medical Action (MedAct), Leawood FD, Northwest Consolidated Fire Distrct #1 (NWCFD#1), Shawnee FD)

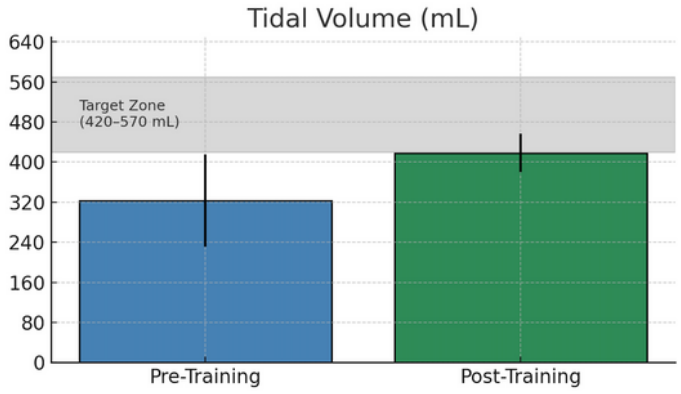

Figure 2. Volume Delivered Before and After Training. Despite improvements, mean tidal volume struggled to consistently reach the target zone after training. Ventilating with Sotair had less variability in performance.

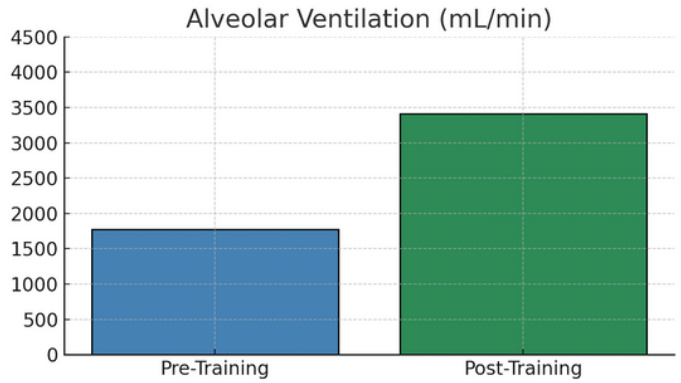

Figure 3. Alveolar Ventilation Before and After Training. Alveolar Ventilation Doubled after Training and Sotair implementation.

Results

- Mean peak flow rates and Vt were higher after training (44.5+5.2 vs 28.3+12 LPM; $p<0.05$; 418+38.6 vs 323.2+92.2 ml; $p<0.05$).
- Before training, 87.8% of breaths were <420 mL compared to 51.5% post-training ($p<0.05$).
- Baseline respiratory rate was 9.73+2.49, compared to 11.8+4.36 after training; $p<0.05$.
- Estimated alveolar ventilation (assuming a dead space of 150 ml) increased from 1776.7 to 3409.7 ml/minute after training ($p<.0.05$).

Conclusion

- Small adult bags deliver suboptimal tidal volumes for average adult males.
- Training + flow-limiting device improved alveolar ventilation significantly.
- However: many breaths remained below target volumes post-training.
- Findings suggest that small bags may be inadequate for routine adult ventilation, but performance can be partially improved through targeted flow controlled training.