Sotair® Literature

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Original research

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).

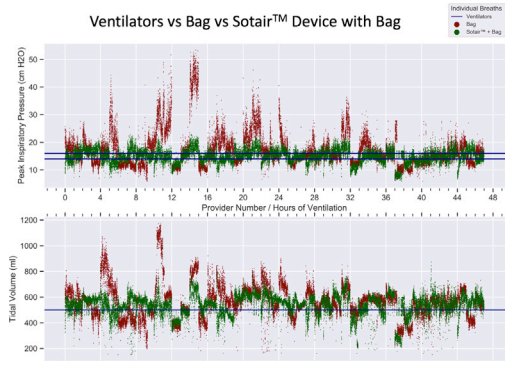

Figure 1 Results with different methods of ventilation. Peak inspiratory pressure and tidal volume versus provider number/hours of ventilation while ventilating the SmartLung 2000 Lung Simulator (IMT Analytics, Switzerland) using a SPUR II resuscitator bag (Ambu, USA) and endotracheal tube mimicking 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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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This protocol was approved by the University of Tennessee Health Science Center Institutional Review Board.

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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Prehospital Emergency Care

The Menegazzi Scientific Sessions: Research Abstracts for the 2024 National Association of EMS Physicians Annual Meeting

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

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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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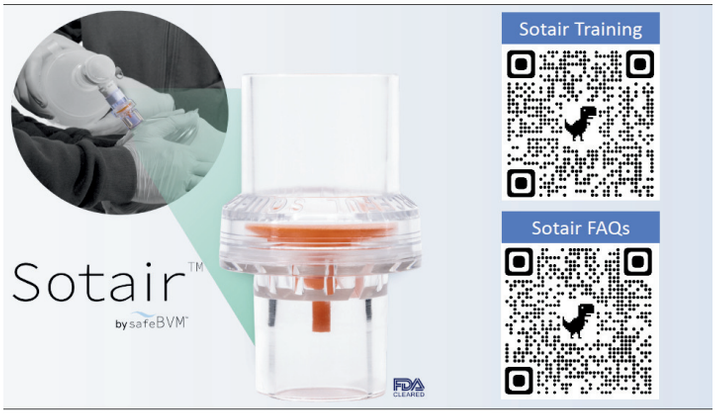
BROWN EM

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

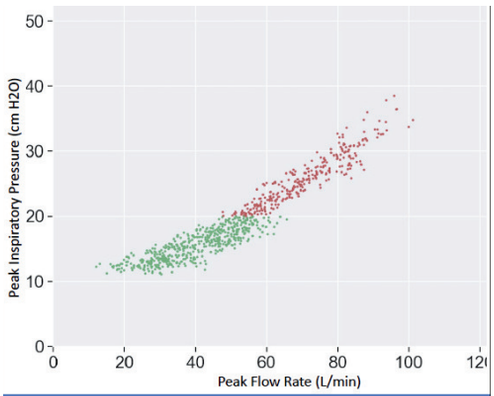
- Expand upon video and printed educational interventions for Sotair™ in order to improve performance with the device
- Create and validate the utility of video and printed materials for proper use of Sotair™

Methods

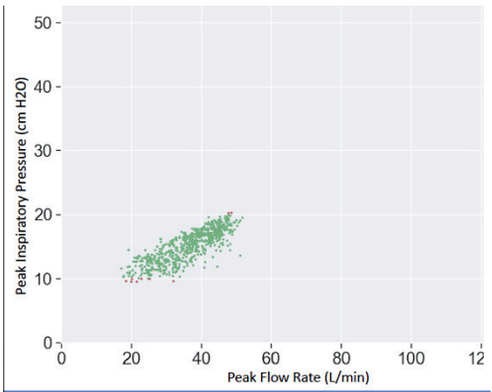
- Recruitment of EMS providers (n=32)
- Record each individual manually ventilating a simulated adult male lung for 2 minutes
- Apply educational intervention, attach Sotair™ and repeat
- Primary outcome: peak pressure; Secondary outcomes: volume, flow, rise time, and inspiratory/expiratory ratio

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™

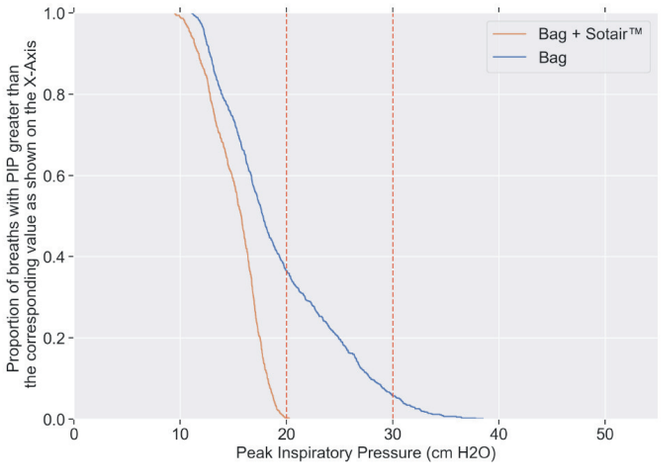


Figure 3. Proportion of delivered breaths with PIP greater than X-axis value for standard BVM and BVM+Sotair™

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

RESPIRATORY CARE

Manual Bag Valve Mask Ventilation Performance With Safety Device Among Second Year Respiratory Therapy Students: A Non-Inferiority Trial Design Study

Rachel Culbreth, Kyle Brandenberger, Robert Brent Murray, Yu Wei Hou, Ying Jung Wu and Douglas S Gardenhire

Respiratory Care October 2023, 68 (Suppl 10) 3950170;

Abstract

Background: Resuscitator bags are common in acute care settings; however, poor technique is a well-documented problem which occurs irrespective of a provider's qualifications or experience. A safety device has been created (Sotair) to improve the quality of air delivery via resuscitation bags by preventing harmful effects of manual ventilation. This study seeks to determine the differences in airflow measurements between the Sotair device via bag-valve mask and the mechanical ventilator using a non-inferiority trial design.

Methods: Respiratory therapy students were recruited from an Advanced Cardiovascular Life Support class at a southern urban university. Participants conducted a 2-minute trial of ventilating a test lung alongside a metronome of 12 breaths per minute for two-min utilizing an abnormal compliance and normal compliance lung settings. Ventilation characteristics were obtained by a TSI flow meter (Laois, Ireland). Participants completed a brief survey after the ventilation exercises to assess age, race/ethnicity, sex, education, experience with BVM (scale: 0-10) and confidence with BVM (scale: 0-10). A control group was implemented using three total mechanical ventilation trials for 2 min using a test lung with abnormal compliance and normal compliance settings. Mean differences were compared between Sotair and the control group using independent samples T-tests. Statistical significance was set at $P < .05$. All analyses were conducted in R 3.6.2. The university Institutional Review Board approved this study.

Results: A total of 41 respiratory therapy students participated in the ventilation exercises. Among the participants, 70.7% were female, and the majority were undergraduate students (75.6%). The mean experience level using the bag-valve mask was 6.71 (SD = 1.72), and the mean confidence level using the BVM was 8.02 (SD = 1.27). No differences were found in peak pressures between the mechanical ventilation trials and the Sotair device trials for the abnormal lung setting ($P = .12$) and the normal lung setting ($P = .24$). For the abnormal lung setting, no differences were found for tidal volume between Sotair and the mechanical ventilation trials (412.20 mL vs. 388.89 mL, respectively).

Conclusions: There were no differences found between the manual ventilation with the Sotair device and the mechanical ventilation trials with regards to peak pressure for both normal and abnormal lung settings. Sotair ventilated at similar safety thresholds as the mechanical ventilator.

June 20th, 2019,
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Comparative study on a fresh cadaver for quantifying gastric insufflation during manual ventilation with commonly used airway devices and the Sotair Device, a safe pressure device by SafeBVM Corp.

Background

There are approximately 13.1 million Bag Valve Masks (BVMs) used annually in the United States (1). Poor manual ventilation technique with the BVM is a well-documented problem that occurs irrespective of a provider's qualifications and/or experience. Currently, there are no limitations or restrictions on how hard or fast a provider might squeeze a BVM. Increased force and frequency of a bag squeeze results in a rapid increase in airway pressure. When the airway pressure exceeds the lower esophageal sphincter opening pressure, air is inadvertently forced into the patient's stomach (gastric insufflation) and results in two sets of complications (2). As the stomach expands with air, the diaphragm is pushed upwards, decreasing space for the lungs to expand, reducing compliance, and increasing air diverted to the stomach. This causes an increasingly cyclic worsening of the patient's condition. Additionally, as the stomach expands with air, blood flow is diverted to the stomach, decreasing oxygenation to the body. Secondly, gastric insufflation causes the patient to vomit and increases the chance of aspiration of stomach contents into the lungs leading to complications like chemical pneumonitis, aspiration pneumonia, acute lung injury, and ARDS.

Literature reports that up to 71% of the time while using a BVM, patients exhibit gastric insufflation (3). Oxygen delivery to the lungs decreases by 65% following gastric insufflation (4). The incidence of regurgitation of stomach contents during CPR during cardiac arrest is 20-29% in the out-of-hospital setting and 12% in-hospital (5). One-third of all treated out-of-hospital cardiac arrest patients exhibit vomiting. A quarter of these instances occur under EMS care while using a BVM (6). The costs of major complications due to the adverse effects of poor manual ventilation are estimated to range from $28,000 to $140,000 per patient (7-15).

There are a few commonly used prehospital airway devices that address the problem of gastric insufflation with the resuscitator bag. These include the endotracheal (ET) tube and supraglottic airway (SGA) devices such as the Laryngeal Mask Airway (LMA), King LT, and iGel SGA. These devices have documented safety and efficacy, and are currently the standard of practice in airway management and cardiopulmonary resuscitation. However, they are invasive options, primarily used as an alternative to the mask in the BVM assembly, and they are usually restricted to advanced level providers. The pop-off valve and the disposable manometer are the only accessories for the BVM on the market that are used to regulate inspiratory pressure. However, neither intuitively addresses gastric insufflation.

SafeBVM Corp. is developing the universally compatible Sotair Device to prevent gastric insufflation during manual ventilation with the BVM. In regular use, the device snugly fits between the bag and the mask (Figure 1). It ensures that every time a provider squeezes the resuscitation bag, the pressure and flow of air delivered to the patient is safe and optimal. If the provider squeezes the bag too hard or too fast, generating a pressure beyond the safe pressure threshold, the Sotair Device blocks flow, controls pressure, and generates tension within the resuscitation bag. This tension that is felt in the provider's palm(s) is a pressure generated recoil signifying an improper squeeze. This haptic feedback functions as a training mechanism and assists the provider in modifying ventilation technique to deliver air at safe inspiratory pressures. The resulting breaths have increased inspiratory time and slower rise time, thus creating greater compliance with the current AHA recommendations (16). The device standardizes ventilation technique, enabling providers to manually ventilate at an optimal level, irrespective of their training or qualifications. The safe pressure threshold for blocking flow and pressure is dynamic and is a function of characteristics of the airway system and lung compliance of the individual being ventilated. This white paper explores applications for the Sotair Device device based on results obtained from the comparative studies with the Ambu® SPUR® II and the Ambu® Aura40™ Straight Reusable Laryngeal Mask.

Methods

The study was conducted at the University of Arkansas for Medical Sciences- East Campus in collaboration with the Regional One Health and Paragon Medical Education Group. The principal investigator was Joe Holley, MD, FACEP, FAEMS, Emergency Medical Services (EMS) Medical Director for the State of Tennessee. Other investigators include Haris Shekhani, MD, MBID, and Prathamesh Prabhudesi, MD, MBID. A fresh, non-embalmed, cadaver with an open chest wall was used for this study. The cadaver was set up in anatomical position for providing ventilation. Before initiating the cadaver studies, the Sotair Device along with the associated benchtop instruments was calibrated on the IMT Analytics SmartLung 2000 2L. The lungs were adequately ventilated using a BVM to ensure proper lung. Following this, a Continuous Positive Airway Pressure (CPAP) device with a mask was used to ventilate the cadaver and test for physiologic functionality. The pyloric sphincter was secured closed using a surgical thread to prevent air from escaping into the small intestine. Utilizing a nasogastric (NG) tube and suction, the stomach was emptied. Then, a 60 ml syringe and an NG tube were used to gradually distend the stomach and obtain 600 ml of gastric insufflation as a benchmark. A surgical ligature was used to encircle the largest diameter of the distended stomach to obtain a correlation between stomach distension and the length of ligature. Later, the stomach was again emptied using an NG tube and suction, with the ligature still in place at the former location to obtain ligature length on an empty stomach. Subsequent tests to quantify the amount of gastric insufflation involved measurement of the length of the ligature around the same point on the stomach.

A 2nd-year Emergency Medicine resident physician was asked to manually ventilate the patient under normal conditions in accordance with the AHA recommendations for 5 minutes (16). Dr. Holley selected and inserted the appropriate LMA and ensured no air leakage with the device and a tight mask seal. TSI Mass Flow Meter 5310-1 was connected to the mouth of the bag to record the pressure, flow, and volume of air being delivered with each breath. Gastric insufflation was recorded while the cadaver was being manually ventilated in the following scenarios: While using the 1) BVM alone, 2) resuscitation bag with LMA device, and 3) BVM with the Sotair Device.
While using the LMA (2nd test), the provider delivered air at safe pressures for fear of gastric insufflation which occurred during the 1st test with the BVM alone. So the investigators intervened and asked the user to deliberately ventilate forcefully to reach higher inspiratory pressures, simulating improper ventilation technique. For subsequent tests with the Sotair Device, the user was asked to forcefully ventilate at high pressures from the very beginning (3rd test) with frequent reminders at 30-second intervals. This was done to test the safety feature, gauge haptic feedback, and mechanism for modification of ventilation technique, which is activated only during poor manual ventilation.

Results
The results of the study are displayed in Table 1. The graphs (Figure 2A-4C) obtained from the TSI Mass Flow Meter 5310-1 are displayed in the appendix. They depict the performance of the user with regards to the frequency, inspiratory pressure, flow-rate, and pressure-flow curves during manual ventilation. The test with the BVM alone resulted in extremely high volumes of gastric insufflation (805 ml) within the first 60 seconds of manual ventilation at an average tidal volume of 551 ml. The test was stopped to prevent damage to the anatomy of the cadaver. The LMA with the resuscitation bag did not show air entry into the stomach (test 2). Investigator intervention for test 2 can be observed at the 195-second mark on Figures 3A and 3B. Similarly in test 3, the Sotair Device, when used with the BVM resulted in no air entry into the stomach. As per the provider's testimony, the flow blocking mechanism and haptic feedback prevented the user from squeezing the bag with high force that was requested for delivering high-pressure breaths (test 3). All of the aforementioned scenarios had an average tidal volume in accordance with the AHA recommendations (16).

Table 1. Device comparison in relationship to the amount of gastric insufflation over time.

Airway device	Amount of Gastric insufflation	Average Tidal Volume Delivered Per Squeeze	Manual Ventilation Time
BVM Alone	805 ml	551 ml	60 sec
LMA+Bag Valve	0 ml	610 ml	5 min
SIP + BVM	0 ml	565 ml	5 min

Discussion
Several authors have published on the prevalence of inadvertent high-pressure ventilation in the EMS and ED domain, the resulting gastric insufflation and subsequent complications. During the induction of general anesthesia, gastric insufflation and aspiration while providing face mask ventilation (FMV) are one of the most dreaded complications before, during, and after surgery. It can lead to significant morbidity, mortality, and increased hospital stay (17). It has been reported that the risk of gastric insufflation and its potential complications are significantly reduced while giving pressure-controlled FMV, compared with manual or volume-controlled FMV (18). Thus, it is vital that inspiratory pressure is continuously maintained below the safety threshold.

Bouvet et al. reported that during pressure-controlled FMV a peak airway pressure of 15 cm H2O resulted in an incidence of gastric insufflation of 35% according to real-time ultrasonography while providing the highest probability of acceptable FMV during induction of anesthesia with remifentanil and propofol in nonobese and noncurarized patients (18). A study by Qian X et al. determined via ultrasonographic that an inspiratory pressure of 12 cm H2O is sufficient to provide adequate ventilation with a lower occurrence of gastric insufflation during induction of general anesthesia in paralyzed children ages 2-4 (17). Also, impaired respiratory function, presence of obstructive or restrictive diseases, changes in lung compliance, or neck position can affect the optimal inspiratory pressure needed to ventilate the patient adequately.

SafeBVM Corp. is building the Sotair Device while taking into account the variability in safe inspiratory pressure requirements. The safety threshold at which the valve functions is personalized and automatically adjusted with respect to the pressure gradients in the airway tract of the patient. This personalization is possible because the safety threshold is relative. For instance, if a patient has low lung compliance, the valve will control pressure and block flow at a higher inspiratory pressure threshold, while giving instantaneous haptic feedback to the provider during a sudden high-pressure squeeze of the bag. The feedback guides providers to modify technique accordingly and provide breaths at safe inspiratory pressure consistently.

SGA devices like LMA and LT and the ET tube have been in use for more than two decades to prevent gastric insufflation. They are invasive solutions. A study using a fibrotic investigation of LMA position in adults, conducted by Latorre et al., reported a 40% incidence of LMA malpositioning to be associated with gastric air insufflation at airway pressures above 20 cm H2O in adults (19). Weiler et al. also reported that the LMA is not better at preventing airway transmission to the esophagus than a conventional face mask (2). LMA first attempt insertion success rates for inexperienced ward nurse operators serving as first responders were 76%, with an overall success of 84–94% (20). In the fast-paced EMS and Emergency Department environment, providers strive to perform their duties quickly and efficiently. One study reports that the Insertion of an LMA required a mean of 39 seconds (with a mean of 1 attempt/patient success) compared with 206 seconds for an ET tube (2.2 attempts/patient success) (20). An experienced provider can successfully insert an LMA in 98% of patients within 20 seconds (20). The Sotair Device is noninvasive and functional 100% of the time with < 5 seconds required for installation.

Contraindications for the LMA include poor lung compliance, airway pressure more than 20 cm of H2O, mouth opening less than 1.5 cm, and a non-fasting patient (21). The Sotair Device device addresses some of the concerns with the use of LMA and carries the potential to make the LMA/SGA safer. In patients with reduced lung compliance, when the Sotair Device is added as an accessory to the LMA, the safety threshold of the device automatically sets at a marginally higher threshold. Thus, enabling the provider to both deliver air at pressures that are high enough to adequately ventilate the patient and reduce the incidence and volume of air entry into the stomach. In patients with significantly obstructed airways or in drowning victims, where extremely high airway pressure is needed to ventilate patients, the Sotair Device is contraindicated and should not be used. We hypothesize that providers will be able to identify conditions that require extremely high inspiratory pressure, based on patient history and tactile feedback from the resuscitation bag, and refrain from using the add-on accessory.

Previous studies have determined that when using the traditional auscultation method, the inspiratory pressure threshold for gastric insufflation during face mask ventilation is 20 cm H2O in adult patients and 15 cm H2O in children (17, 18, 22). Recently, two studies reported that ultrasonography could detect air in the stomach more precisely when compared with stethoscope auscultation during FMV (18, 22). Ultrasonic measurement of the cross-sectional antral area is believed to be a quantitative approach to determine gastric insufflation. Brimacombe et al. reported that auscultation for detecting air entering the stomach through a gastric tube had 91% sensitivity and 79% specificity (23), whereas Brun et al. reported in eight patients that ultrasonographic detection of gastric insufflation had both sensitivity and specificity equal to 100% (18). The manual measurement of stomach expansion in a fresh cadaver with an open chest cavity, as depicted in the current study, mimics other gold-standard approaches frequently used in the field of medicine. The results of the cadaver study, thus serve as a benchmark for further evaluation of the Sotair Device in live patients using ultrasonography. Further clinical studies focused on quantification of gastric insufflation with ultrasonography will help support claims with the Sotair Device and its potential role in clinical practice.

Additional research is needed to support the adoption of the Sotair Device device. More extensive, multi-cadaver studies with blinded EMTs, paramedics, and other providers are necessary to reinforce the usability, application, and value of the invention. The use of fresh cadavers without a chest cavity can be debated based on the assumption that an absence of chest cavity and cellular changes after death can alter lung compliance. The study has intrinsic biases because the user was aware that their performance was being recorded and the primary attribute being measured was inspiratory pressure. Usability research on patterns of manual ventilation with the Sotair Device and the training requirements for new users ventilation technique adjustment needs to be further studied. The add-on accessory nature makes the Sotair Device risk-averse, thus minimizing concerns about safety, but requires more research as well.

Conclusion

Based on this comparative study, the Sotair Device produced similar results as the LMA in preventing gastric insufflation on the fresh cadaver. The device carries the potential to add significant value to the current standard of practice by assisting providers to manually ventilate patients at safe pressures, thus minimizing the risk of gastric insufflation and subsequent complications. There are avenues for integrating the device as a bundle with the BVM as well as an add-on safety accessory to the LMA.
There is potential, in some scenarios, to use the Sotair Device as a substitute to the LMA. Further research is required to examine the benefits, value, and potential applications of the Sotair Device in the EMS, ER, and Anesthesiology domain.

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Appendix images available on request: Please contact info@safebvm.com