Utility of the Sotair^{TM} Device in Manual Ventilation of Different Lung Compliances

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Abstract

Background: During positive pressure ventilation, peak inspiratory pressure (PIP) and Tidal Volume (TV) must be kept at optimal levels to achieve appropriate ventilation without causing complications, such as trauma to the lung parenchyma or stomach insufflation. Manual ventilation using a Bag-valve-mask (BVM) results in highly variable TVs and PIPs that could increase the risk of volutrauma and barotrauma. It is unknown whether pathologic changes in lung compliance alter the TV and PIP during manual ventilation.

Methods: This study used a lung simulator and volunteer medical students, medics and nurses to assess whether the pressure and flow limiting Sotair™ device resulted in more appropriate TVs and PIPs during manual ventilation compared to BVM only, using a mechanical ventilator as the standard. The secondary aim was to determine whether decreased lung compliance, which simulates the physiology of lungs with Acute Respiratory Distress Syndrome (ARDS), affected the conclusion.

Results: We found that the Sotair™ device helped maintain PIP and TV closer to mechanical ventilator baseline levels than BVM only ventilation across lung compliance settings. The Sotair™ device also helped providers maintain PIP levels below the threshold of pressures known to cause gastric insufflation and barotrauma.

Conclusions: This data indicates that manual ventilation using the Sotair™ device is a safer option than unmitigated BVM only ventilation in both normal and decreased lung compliance conditions.

Introduction

Effective respiratory ventilation is achieved by moving the right amount of air in and out of the lungs while keeping the pressures in the airways at a safe level. Tidal volume (TV) is the volume of air that goes into the lungs during each respiratory cycle and is critical for maintaining adequate gas exchange.[1] With positive pressure ventilation, inspiratory pressure must also be kept at optimal levels to achieve appropriate ventilation without introducing trauma to the lungs. Pulmonary pathologies can alter respiratory mechanics and, depending on the severity, can modify the way clinicians need to deliver manual or mechanical ventilation. For instance, changes in pulmonary compliance occur in Acute Respiratory Distress Syndrome (ARDS) and may alter the inspiratory pressure necessary to deliver adequate tidal volume.[2] Pulmonary compliance (C) is the ease at which the lungs can be stretched, which is formally defined as the ratio of the change in volume (ΔV) due to change in pressure (ΔP) following the equation $C = \Delta V/\Delta P$.[3] Less compliant lungs require higher pressures to reach the same tidal volume compared to more compliant lungs.

Manual ventilation using a Bag-valve-mask (BVM) results in highly variable tidal volumes and peak inspiratory pressures.[4,5,6] Safely overcoming decreases in lung compliance to maintain adequate tidal volumes without using high peak pressures is a challenge for manual ventilation. The Safe Inspiratory

Pressure (Sotair™) Device attaches in-line with the manual resuscitator bag and was designed to decrease the risk of complications due to improper bag-valve-mask ventilation techniques.[7] The aim of this study was to compare manual ventilation using BVM against BVM with the Sotair™ device at altered levels of pulmonary compliance, using tidal volume and peak inspiratory pressure as the main outcome measures of safe ventilation.

Methods

This study was approved through the University of Tennessee Healthcare System Institutional Review Board. To assess physical output characteristics of manual ventilation and efficacy of a barotrauma mitigation device, 24 medical student, nurse, and medic volunteers manually ventilated a lung manikin while observing chest rise. Prior to participating, participants completed a questionnaire regarding their previous experience with manual ventilation.

The participants were told that the manikin represented an average American adult male (5’10”, 200 pounds, ideal body weight 73 kg); they were informed that the manual resuscitator bag was 1.5 liters and that the proper TV for this ideal body weight was X-Y mL. Participants performed manual ventilation under both normal and decreased lung compliance conditions that simulated adult respiratory distress syndrome (ARDS); participants did this both with and without the Sotair™ device; participants were blinded to lung compliance but it was not possible to blind them to the Sotair™ device. The manikin consisted of a AMBU® SPUR II® (AMBU, Denmark) BVM, Endotracheal tube, SmartLung 2000 2L test lung (IMT Analytics, Switzerland) and a 5300 series gas flow meter (TSI, USA).

Volunteers participated in a total of four, 15-minute ventilation sessions. In order to attenuate any learning or order biases, participants were randomly assigned to each lung compliance condition and whether to begin with or without the Sotair™ device. A total of 24 hours of data was recorded with a 10 millisecond sample rate. A metronome application on a tablet that gave audio and visual prompting was provided to ensure a consistent respiratory rate (12 breaths per minute). A Puritan Bennett 980 (Medtronic, Ireland) and a ReVel® Portable Critical Care transport Ventilator (Carefusion, USA) were each evaluated for comparison to manual ventilation with identical testing equipment as above. Ventilators were set to volume control and programmed to provide a peak end expiratory pressure (PEEP) of 5 cm H_2O with an inspiratory time of 1 second and TV of 500 ml. Total ventilation time for each testing case was limited to 5-10 minutes as both ventilators provided highly consistent ventilator pressure and volume recordings with negligible variability.

PIP and TV means and standard deviations were calculated for each scenario by provider. An independent sample t-test was utilized to evaluate each participant, randomized group, and the overall effect of the Sotair™ device. Mixed linear regression models were used to compare the Sotair versus no Sotair conditions, as well as normal versus decreased compliance, with TV and PIP as the dependent variables, matched by the provider.

Results

Of the 24 participants that completed the study, 13 were female and 11 were male, with an average age of 28.5 years. 13 of participants were medical students while other healthcare workers made up the remaining 11. All participants were BLS certified; however, only 54% indicated that they had used a BVM in a live scenario.

As seen in Figure 1, PIP and TV with the Sotair™ device (Green dots) more closely resembles mechanical ventilator baseline data (blue lines - each representing PIP delivered by one of the two mechanical ventilators tested) than bag only ventilation (Red dots). Under both normal and decreased compliance conditions, manual ventilation with the Sotair™ device delivered PIP closer to ventilator baseline ranges (indicated by the blue lines on Figure 1) ($p=0.01$) . Under the normal and decreased compliance conditions, clinicians delivered more breaths within ventilator baseline TV ranges using the Sotair™ device compared to bag only breath delivery ($p=0.001$). Of note, in Figure 1 there were two blue lines representing the PIP for the two ventilators and only one for TV; this is because the ventilators were set to volume control and did demonstrate variability in PIP to get to the same TV.

As seen in Figure 2, the distribution of number of breaths delivered within a given PIP or TV range shifts to the left with the Sotair™ device (green bars) as compared to Bag only Ventilation (blue bars) across both compliance settings. More breaths were delivered within ventilator base line TV ranges (pink box) and below thresholds for gastric insufflation, 22 cm H_2O, and Barrotrauma, 40 cm H_2O, (orange and red lines respectively) when using Sotair™ device.[8,9]

Discussion

Under normal conditions the Sotair™ device helped providers maintain PIP and TV in ranges closer to the mechanical ventilators. The same outcome was true for PIP and TV in the decreased compliance setting.

This is the first report of manual ventilation we are aware of that demonstrates an increase in PIP with decreased lung compliance. This increase in PIP could be expected as the decrease in pulmonary compliance requires higher pressures in order to deliver the same TV to the lungs. As was seen in Figure 2, the decrease in lung compliance resulted in a shift of breaths past reported thresholds for gastric insufflation. Although the Sotair™ device did not prevent PIP from going above the reported threshold for gastric insufflation (22 cm H_2O), in the decreased compliance groups it did help providers to maintain levels below those that induce barotrauma (40 cm H_2O).

Interestingly, the decreased compliance setting resulted in an increase in PIP but a decrease in TV. This may indicate that while the participants may have been squeezing the bag harder, they were less likely to compress the bag to the same volume as in the normal compliance setting. TVs were also lower using the Sotair™ device in both compliance settings (see Figure 2), suggesting that volunteers were less likely to overinflate the lungs when using the device. Despite the Sotair™ device resulting in more appropriate

TVs, the majority of PIP was still above the threshold for gastric insufflation in abnormal compliance states. It is unclear whether the necessary trade-off of increased PIP to attain adequate TV is better for patient outcomes; assessment of such a tradeoff would require a study that is likely ethically unattainable.

Conclusion

Manual ventilation is not an optimally safe practice due to individual provider variability in pressure and volume delivery. However, it remains the standard of care in instances where mechanical ventilators aren't immediately available, such as during patient transport, in developing countries, and in times when mass casualty disasters cause resource scarcity. The COVID-19 pandemic has further exposed the need for a pressure mitigating device to make the common practice of manual BVM ventilation safer and more viable, as manual ventilation is the likely alternative to mechanical ventilation in the scenario that our mechanical resources become depleted. The Sotair™ device helped providers in both compliance groups to maintain PIP in a safer range, making clinicians less likely to induce barotrauma or gastric insufflation during breath delivery. This is critically important to patient outcomes as barotrauma and aspiration are associated with increased mortality.[10,11] The Sotair™ device also facilitated delivery of lower TV throughout, which has been associated with decreased mortality rates in Acute Respiratory Distress Syndrome (ARDS) patients.[12]

Declarations

Ethics approval and consent to participate:

Not applicable

Consent for publication:

Not applicable

Availability of data and material:

Datasets available upon request. Please contact author for data request.

Competing interests:

This study has no conflicts of interest to report.

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Authors' contributions:

Randy S. Carpenter, BA: Assisted with study design, managed data collection, assisted with statistical analysis, assisted with manuscript preparation.

Mark F. Brady, MD: Conceived of project, study design, managed data collection, assisted with statistical analysis, assisted with manuscript preparation.

J. Richard Walker, III, MD: Assisted with study design and manuscript preparation.

Samantha A. Ni, MD: Assisted with study design and data collection.

Shane Young, MD: Assisted with study design and data collection.

Ethan D. Monhollon, MD: Assisted with study design and data collection.

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Not applicable

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Table

Table 1.

Demographics of participants (n=24)

Gender	Male - 11/24 (46%) Female - 13/24 (54%)
Average age	28.5 yrs.
Training Completed	BLS- 24/24 (100%) BLS + ACLS - 14/24 (58%) BLS + ACLS + PALS - 9/24 (3.8%)
Previous experience with the Manual Resuscitator (BVM)	Yes - 13/24 (54%) No - 11/24 (46%)
Role	Medical Student - 13/24 (54%) Nurse - (25%) Paramedic - 3/24 (13%) Resident - 2/24 (8%)

Figures

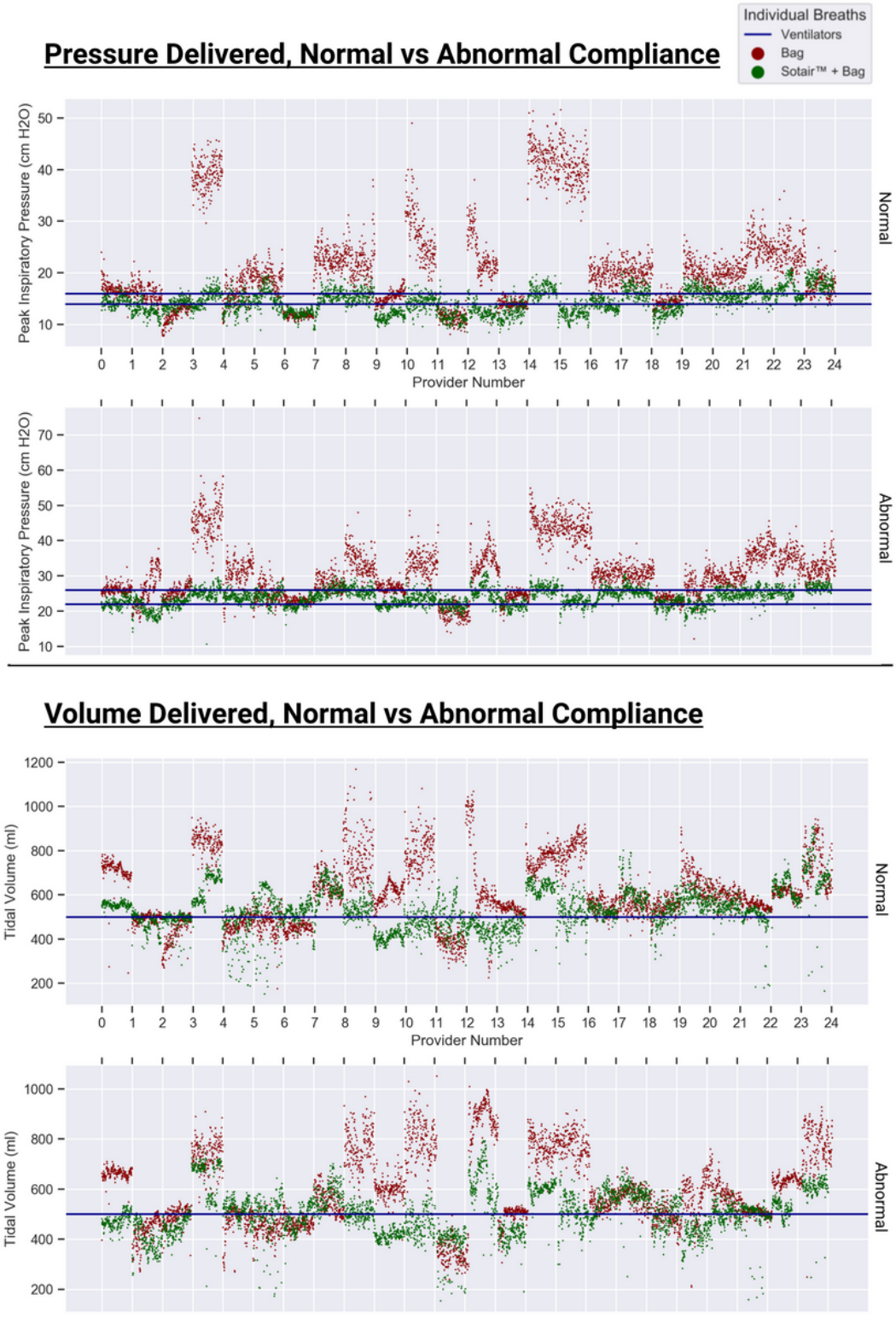

Figure 1

Peak Inspiratory Pressure (PIP) and Tidal Volume (TV) delivered at normal and decreased lung compliance conditions, both with and without the SotairTM device. Each dot represents an individual breath delivered. PIP and TV with the SotairTM device (Green dots) more closely resembles mechanical ventilator baseline data (blue lines) than bag only ventilation (Red dots).

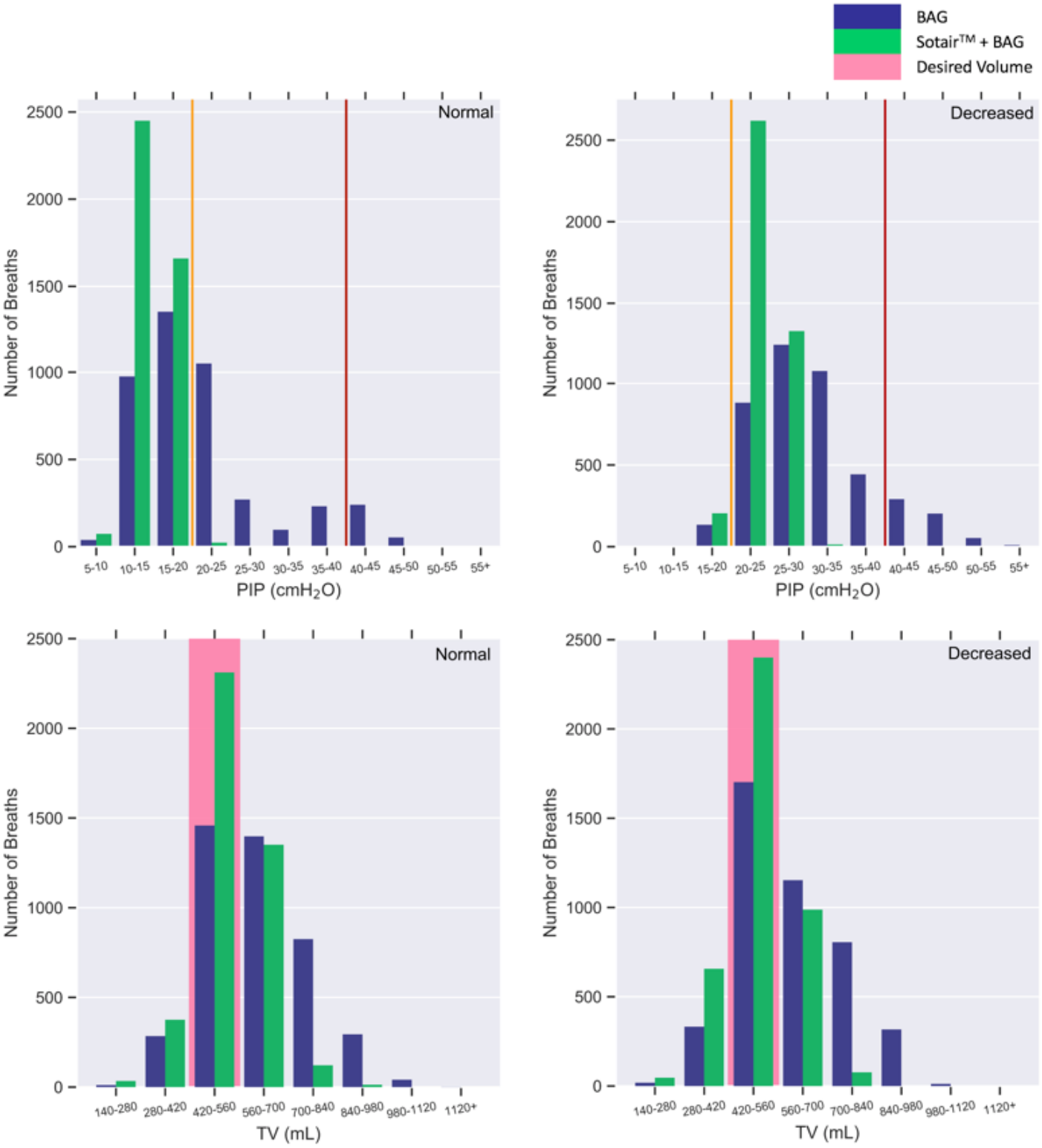

Figure 2

Bar graphs of number of breaths delivered with and without the SotairTM device, at normal and decreased lung compliances.