The Menegazzi Scientific Sessions: Resarch Abstracts for the 2025 National Association of EMS Annual Meeting

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

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Background

- Manual ventilation using a bag-valve apparatus can be a life-saving prehospital maneuver
- During prehospital resuscitation, overly forceful ventilations can lead to excessive peak inspiratory pressures (PIP), and either excessive or inadequate delivered tidal volumes (TV)
- Inappropriate PIPs can exacerbate lung injury, and inadequate TVs can lead to hypoxemia, hypocapnia, and/or hypercapnia
- "EMS clinicians should use available techniques and adjuncts to achieve optimal mask seal, improve airway patency, optimize delivery of the correct rate, tidal volume, and pressure during manual ventilation, and allow continual assessment of manual ventilation effectiveness" – 2022 NAEMSP Position Statement

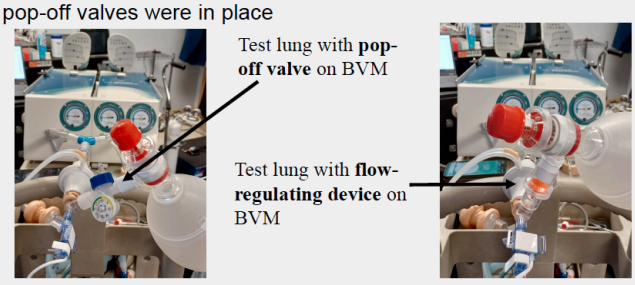
Methods

- Using a two-lung mechanical test lung, six ventilators delivered 50 ventilations per condition, at a rate of 12 BPM

Table 1. Experimental Parameters

Simulated State	Lung Compliance	Upper Resistance	Lower Resistance
Healthy	0.05	Rp 5	None
Obstructive	0.05	Rp 10	Rp 50
Restrictive	0.02	Rp 5	Rp 20

- 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



Objective and Hypothesis

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.

Conclusions:

- The flow regulating device maintained positive inspiratory pressures in all conditions, while delivering safe tidal volumes
- The tidal volume delivered by a flow regulating safety device was invariant across healthy, restrictive and obstructive conditions
- Pop-off valves inconsidently released at the set pressures, often leading to higher than anticipated inspiratory pressures
- The flow regulating valve decreased intra-person heterogeneity in delivered peak inspiratory pressure, but not delivered tidal volume

Acknowledgements:

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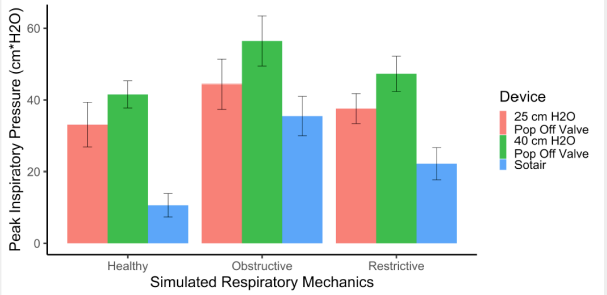
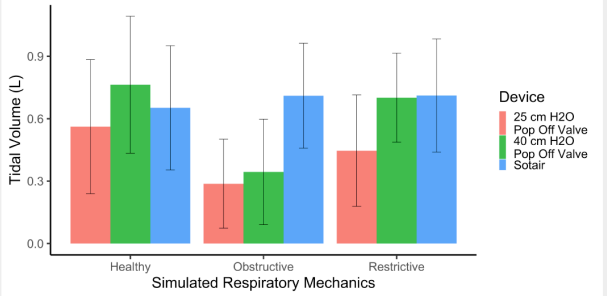
Figure 1. Peak Inspiratory Pressures with Pop-Off and Flow-Regulating Valves Across Varying Lung Mechanics



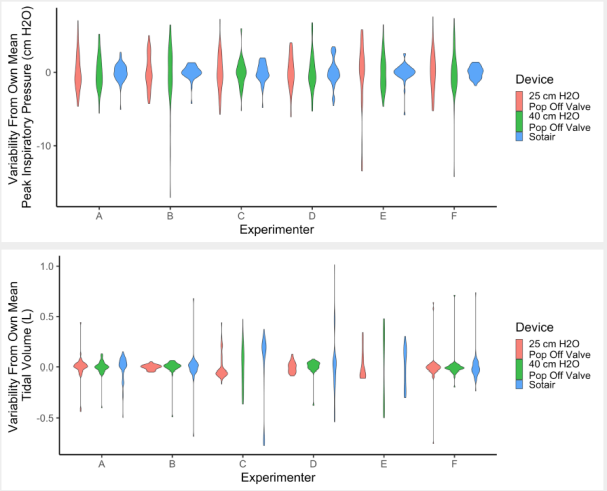
- Peak Inspiratory Pressure (PIP) is lower in the flow-regulating Sotair device than the 25- and 40- pop off valves across all lung conditions (healthy: 10.6 vs. 33.1 vs. 41.6 cm H2O, $p < 0.001$; obstructive: 35.5 vs. 44.4 vs. 56.5 cm H2O, $p < 0.001$; restrictive: 22.2 vs. 37.6 vs. 47.3 cm H2O, $p < 0.001$)

Figure 2. Tidal Volumes with Pop-Off and Flow-Regulating Valves Across Varying Lung Mechanics



- Tidal Volume (VT) is relatively preserved with the flow-regulating Sotair device across all three simulated lung conditions (0.652 L healthy vs. 0.710 L obstructive vs. 0.711 L restrictive)

Figure 3. Intra-Individual Heterogeneity in Peak Inspiratory Pressure and Tidal Volume With Pop-Off and Flow-Regulating Devices



ABSTRACT 142. A Comparison Between Manual Ventilation with a Flow Control Valve Versus a Mechanical Transport Ventilator

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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.

Objective

- We compared 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 (TV) compared to the transport ventilator.

Methods

- We used a dual-lung mechanical test lung (Michigan Instruments) with settings designed to simulate three general lung conditions. See Table 1 and Fig 1

Table 1. Experimental Parameters

Simulated State	Lung Compliance	Upper Resistance	Lower Resistance
Healthy	0.05	Rp 5	None
Obstructive	0.05	Rp 10	Rp 50
Restrictive	0.02	Rp 5	Rp 20

- Fifty breaths were delivered at 12 breaths/minute (BPM) for each lung condition manually and mechanically
- Manual ventilations were performed by six volunteers using a self-inflating resuscitation bag (Spur II, Ambu, Inc) with the FCV (Sotair, SafeBVM) in line
- Mechanical ventilations were performed by a T1 transport ventilator (Hamilton Medical)

Acknowledgements: This project was supported by funding from the National Science Foundation.

Methods (continued)

- The mechanical ventilator was operated in volume-targeted mode with the following parameters:
  - Rate: 12 BPM
  - Volume: 750mL
  - Peak Pressure Alarm: 35 cmH_2O
- The FCV was designed to limit inspiratory flow to 55 liters per minute prior to activation (on/off)
- Airway pressure was measured continuously using a valved line pressure transducer (Utah Medical)
- Airway flow was measured with a differential pressure flowhead and spirometry unit
- Ventilation variables were captured using an analog-to-digital signal acquisition unit (PowerLab 16/35, ADInstruments) and its associated software control system, LabChartPro (Version 8).
- Tidal volume (TV) was calculated via cyclic integration of the airway flow signal; peak inspiratory pressure (PIP) was calculated by peak analysis of the airway pressure signal
- Mean TV and PIP were calculated for each simulated state and compared between FCV and mechanical ventilator

Figure 1. Experimental Apparatus

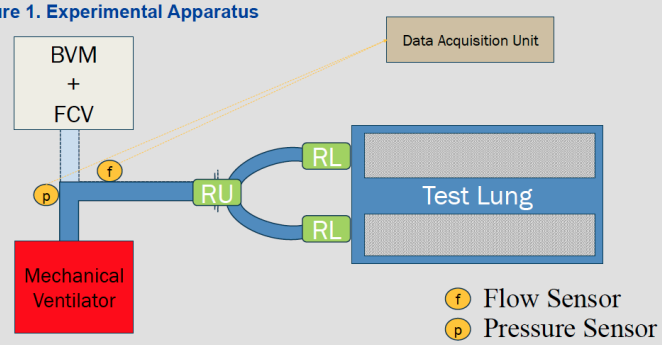
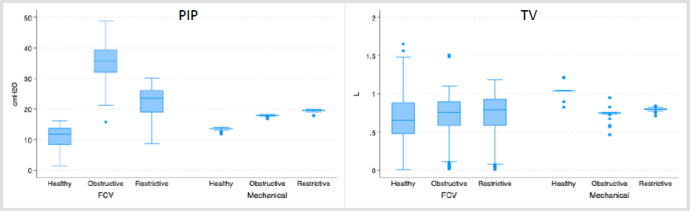
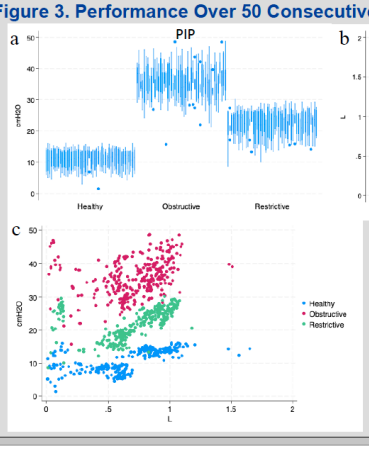


Figure 2. PIP and TV versus Simulated State and Ventilation Mechanism



Within each ventilation mechanism, overall mean PIP and TV differed between states ($p > 0.001$). The pattern of PIP and TV relative to ventilation mechanism differed, showing an apparent different relative response to Healthy and Obstructive states. Low-end TV contribution resulted from the mechanism of the FCV, which nearly instantly shuts off flow entirely for a manual ventilation that exceeds 55 LPM.

Figure 3. Performance Over 50 Consecutive Ventilation Events (Manual Only)



Aggregate volunteer variability was largely consistent across simulated health states in manual ventilations for both PIP and TV (3a-3b).

TV trends demonstrate the impact of FCV shut-off when flow exceeded 50LPM (note zeroing).

Notably, volunteers exhibited innate variability in ventilation performance that resulted in P-V clusters (3c).

Results:

- A total of 1,050 ventilations were performed (900 manual + FCV, 150 mechanical)
- Aggregate PIP and TV results by simulated state and ventilation modality are shown in Fig 2. Within-state variability was markedly higher in manual ventilations
- Within-modality PIP and TV demonstrated different aggregate patterns across states
- Volunteer performance showed a high level of variability across the 50 ventilation cycles without an obvious temporal trend (Fig. 3)

Conclusion

We observed that the FCV produced PIPs and TVs were similar to that of the mechanical ventilator, although operator variability strongly influences performance