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Maximizing Oxygen Delivery Across Deployed Devices

Background: Maintaining oxygen (O$_2$) supplies for mechanically ventilated military transport patients is crucial. A portable oxygen concentrator (POC) can provide an endless supply of O$_2$. Evidence suggests that 3 L/min of O$_2$ could manage 2/3 of the mechanically ventilated military aeromedical transport patients. Methods: We evaluated two each of the AutoMedx SAve II, Hamilton T1, Zoll 731, and Ventec VOCSN portable ventilators paired with 1 and 2 Caire SAROS POCs at ground level and simulated altitudes. Ventilator parameters and FiO$_2$ were continuously measured. Each ventilator was attached to a test lung. POC output was bled-in to each ventilator via the mechanism provided with each device. Results: FiO$_2$ varied between ventilator models. Differences in FiO$_2$ between ventilators at a majority (98.5%) of testing conditions was statistically significant (p < 0.05) but not all were clinically important. The Zoll 731 delivered the highest and most consistent FiO$_2$ over all ventilator/POC settings and altitudes. Differences in FiO$_2$ at a given ventilator/POC setting from ground level through 22,000 ft were not clinically important (<5%) with this device. Conclusions: Oxygen delivery utilizing POCs is dependent upon multiple factors including ventilator operating characteristics, ventilator settings, altitude, and the use of pulsed dose or continuous flow O$_2$.
# TABLE OF CONTENTS

1.0 BACKGROUND ................................................................................................................ 1

2.0 METHODS ......................................................................................................................... 1

3.0 STATISTICAL ANALYSIS .............................................................................................. 3

4.0 RESULTS ........................................................................................................................... 3

5.0 DISCUSSION .................................................................................................................... 6

6.0 CONCLUSIONS ................................................................................................................ 8

7.0 REFERENCES ................................................................................................................... 9

LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS .................................................... 12
1.0 BACKGROUND

Transportation of the critically ill or injured war fighter requires the coordinated care and judicious use of resources. Availability of oxygen (O₂) supplies for the mechanically ventilated patient is crucial. Size and weight of cylinders makes transport difficult and presents an increased risk of fire. A proposed solution is to use a portable oxygen concentrator (POC) to supply oxygen for mechanical ventilation. A POC would allow for continuous output of O₂, provided power is available. Previous efforts have identified that as little as 3 Liters/minute (L/min) of O₂ could manage as much as 68 percent (%) of U.S. Air Force Critical Care Air Transport Team (CCATT) patients¹. Current missions have moved to a battlespace that has limited resources and the implementation of POCs has proven beneficial with the use of a single device. Combining multiple POCs has not been described in the literature under those environmental conditions. The intent of this study was to determine the capability of multiple POCs to support mechanical ventilation in austere environments and evaluate the potential benefit of possibly reducing the reliance on compressed/liquid O₂, while maintaining the same standard of care. This study was reviewed by the University of Cincinnati Institutional Review Board and the Air Force Research Laboratory, Human Resources Protection Office and was classified as a Non-Human Use research activity.

2.0 METHODS

We evaluated 2 each of 3 ventilator models currently deployed for field use by the Department of Defense (DoD): Zoll 731 (Zoll Medical, Chelmsford, MA), Hamilton T1 (Hamilton Medical, Reno, NV), SAVe II, AutoMedx LLC, Addison, TX), and 2 of a newly developed portable ventilators (VOCSN, Ventec Life Systems, Bothell, WA). The VOCSN offers 4 adult circuit configurations: Active, passive, valveless, and mouthpiece circuits. We use the active circuit with integrated O₂ tube for the evaluation. Each ventilator was paired with 1 and 2 POCs (Model 3000, Sequal SAROS, Caire Inc, Ball Ground, GA) also currently deployed by the Department of Defense, at ground level and simulated
altitudes of 8,000 feet (ft), 16,000 ft, and 22,000 ft in a man-rated altitude chamber (Wright Patterson AFB, OH). See table 1 for testing conditions.

Table 1. Testing matrix used for the evaluation

<table>
<thead>
<tr>
<th>Respiratory Rate (bpm)</th>
<th>Tidal Volume (mL)</th>
<th>Inspiratory Time (sec)</th>
<th>PEEP (cm H₂O)</th>
<th>Lung Compliance (cm H₂O/L/sec)</th>
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<td>0.75</td>
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</table>

Table 1. Testing matrix used for the evaluation. Each condition was tested using both 1 and 2 POCs or pulsed dose equivalent (VOCSN using internal concentrator).

Testing was done twice with each ventilator at each testing condition. The maximum continuous flow output of each POC is 3 L/min producing a reported Free Inspired Oxygen (FiO₂) of 93 ± 3%. This flow rate was used for all tests. The Ventec VOCSN has the capability of utilizing an internal O₂ concentrator that employs pulsed dose technology, which was also evaluated. Output from the POC(s) was bled-in to each ventilator via the mechanism provided with each device. The 731 was kitted with a 3-liter reservoir bag that attaches to the ventilator air intake port which allows mixing of bled-in oxygen with entrained room air. Similarly, the SAVe II utilizes an expandable large bore tubing on the air intake port containing an adapter that also allows mixing of bled-in oxygen with entrained room air. The remaining ventilators provided a connection for simple oxygen tubing directly into the device. High pressure gas supply was not necessary for ventilator operation as each was powered by either an internal compressor or blower. Each ventilator was attached to a single chamber Training Test Lung (TTL), (Michigan Instruments, Grand Rapids, MI). A Fleisch pneumotach model 4700 with data acquisition via SmartLab Data Acquisition system (Hans Rudolph, Shawnee, KS) was placed between the ventilator circuit and the TTL to measure delivered ventilator parameters. A fast response O₂ analyzer (O2CAP, Oxigraf Inc, Sunnyvale, CA) was placed in the provided port on the TTL to measure FiO₂ within the simulated lung. Appropriate dead space to simulate the airway anatomy of a 68-kilogram (kg) man was
added between the ventilator circuit and TTL for pulsed dose O₂ delivery with the VOCSN. Each ventilator/concentrator combination was allowed to stabilize for 1-2 minutes or until FiO₂ was stable at each setting. Breath to breath ventilator output and FiO₂ were continuously measured and recorded at ground level and each altitude for later analysis.

3.0 STATISTICAL ANALYSIS

The comparisons of FiO₂ were analyzed utilizing the one-way analysis of variance (ANOVA), with a significance level of 0.05. Each combination of tidal volume (Vₚ) (250, 450, and 700 milliliters (mL)), lung compliance (Cₚ) (20 and 80 mL/centimeter of water (cm H₂O)) and POC (1 and 2) compared altitude groups (Sea level, 8000, 16,000 and 22,000 ft) for each device combination. Positive End Expiratory Pressure (PEEP) settings (5 & 20 cm H₂O) and POC combinations compared each altitude level separately and each ventilator was compared by altitude combinations. All comparisons were adjusted by Tukey–Kramer multiple comparison tests for post hoc analysis. All analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC)

4.0 RESULTS

Delivered FiO₂ varied between ventilators when paired with both 1 & 2 POCs and among the same ventilator model at various altitudes. A total of 522 comparisons were completed and 514 (98.5%) were highly statistically significant (p ≤ 0.01), although many of those can be attributed to a large number of samples and low standard deviations. The 731 consistently delivered the highest FiO₂ at all ventilator/POC combinations at ground level and all altitudes. Figures 1-3 show the delivered FiO₂ at each Vₚ setting respectively with 1 & 2 POCs, PEEP of 5 & 20 cm H₂O at ground level and all altitudes. The SAVe II paired with 1 POC delivered FiO₂ comparable to the 731 at the 250 mL setting using 5 cm H₂O PEEP, but FiO₂ was considerably lower than the 731 with the 250 mL Vₚ/2 POC setting. Due to the limited performance capabilities, this device was unable to perform the remainder of the testing protocol. The T1 failed to operate appropriately at 16,000 and 22,00 ft altitude at selected
settings due to delivered $V_T$s > 10% of set $V_T$ or error messages “Pressure limitation” and/or “Performance limited by high altitude” which resulted in $V_T$ alterations. One VOCSN ventilator’s internal concentrator failed at 22,000 ft therefore FiO2 with that ventilator model at that altitude was analyzed with data from 1 device. The VOCSN using the integrated internal concentrator delivered the lowest FiO2 in 34 of 48 (71%) ventilator/POC/altitude settings.

Figure 1. Delivered FiO2 at ground level and altitude at the 250 mL $V_T$ setting using 5 & 10 cm H2O PEEP and 1 & 2 POCs

Figure 1. Delivered FiO2 at ground level and altitude at the 250 mL $V_T$ setting using 5 & 10 cm H2O PEEP and 1 & 2 POCs
Figure 2. Delivered FiO2 at ground level and altitude at the 450 mL Vt setting using 5 & 10 cm H2O PEEP and 1 & 2 POCs

*Device failure

Figure 2. Delivered FiO2 at ground level and altitude at the 450 mL Vt setting using 5 & 10 cm H2O PEEP and 1 & 2 POCs
5.0 DISCUSSION

The results of this study showed that the FiO₂ delivered when utilizing POCs to provide O₂ during mechanical ventilation varies widely depending on the ventilator and the altitude at which the devices are used. A search of the literature revealed several bench studies evaluating POCs alone at ground level, at altitude, and paired with portable ventilators at ground level. To our knowledge there was only 1 bench study similar to ours pairing 1 & 2 POCs (SAROS) with a single compressor-driven portable ventilator performed at altitudes of 1,200 and 6,500 ft. The results of the study showed that the POC(s) could deliver an FiO₂ of 90% provided the minute ventilation did not exceed the liter flow of the POC. Additionally, the delivered FiO₂ was slightly higher at 1,200 ft altitude as compared to 6,500 ft and the difference increased with increased minute ventilation. These findings are in contrast to our prior work with POCs at altitude suggesting that mean FiO₂ increased with increased altitude during bolus O₂ delivery, although not paired with a portable ventilator.

Figure 3. Delivered FiO₂ at ground level and altitude at the 700 mL Vₜ setting using 5 & 10 cm H₂O PEEP and 1 & 2 POCs

*Device failure
As with the previously detailed work, minute ventilation affected delivered FiO₂ in our study. Minute ventilation in our testing conditions range was 7.5 – 14 L/min. Our study results showed that the highest FiO₂ was consistently delivered with the 731 at all test conditions and with the SAVe II at 2 test conditions. Limited minute ventilation (maximum 8 L/min) and PEEP (maximum 10 cm H₂O) capabilities prevented testing the SAVe II at all test conditions. Ventilator performance characteristics and O₂ bleed-in mechanisms result in varied FiO₂ delivery. Both of the ventilators utilize a compressor to deliver breaths, provide no bias flow and have large reservoirs attached to the air inlet. The 731 uses a 3L reservoir bag and the SAVe II uses 72-inch corrugated tubing as a reservoir, both attached directly to the respective ventilator’s air inlet. This method of reservoir use has been shown to provide the highest delivered FiO₂ when using continuous flow O₂. The combination of no bias flow and maximized reservoir use results in the highest delivered FiO₂ as shown in our study. The T1 and VOCSN both utilize a blower to generate gas flow and bias flow to facilitate patient breath triggering. The T1 generates a bias flow of 3 L/min. The VOCSN generates a minimum bias flow of 5 L/min and automatically adjusts to flow trigger + 2 L/min to a maximum of 10 L/min. Flow triggering for the VOCSN testing was set at 2 L/min, consequently bias flow was 5 L/min. O₂ is bled directly into a designated port on each device. The internal reservoir in the devices is presumably much smaller than the reservoirs utilized by the 731 and SAVe II. Although these devices likely allow easier patient triggering, the lack of a large reservoir and continuous bias flow wasting the bled-in O₂ resulted in a lower FiO₂.

The VOCSN was also tested utilizing the integrated O₂ concentrator to generate O₂. The device utilizes pulsed dose technology to deliver the reported equivalent of 0.5 – 6 L/min continuous flow oxygen or up to 40% FiO₂. To be comparable to the SAROS POC, 3 and 6 L/min equivalent pulsed dose settings were used for the evaluation. Bolus doses of oxygen are delivered near the patient connector via an integrated O₂ tube that is optional with the active circuit was used for testing. The O₂ bolus is injected at the beginning of the ventilator delivered breath and is not subject to dilution by bias flow which results in a greater percentage of O₂ reaching the TTL. Our previous work in a porcine model demonstrated...
that injecting the O₂ bolus just before or as close to the beginning of the breath as possible produced the highest oxygenation by maximizing bolus O₂ efficiency.\textsuperscript{14} It has been shown that the pulsed dose equivalent to continuous flow O₂ produced a lower FiO₂ in a bench model although the differences may not be clinically important.\textsuperscript{3,4}

6.0 CONCLUSIONS

Oxygen delivery utilizing POCs is dependent upon multiple factors including ventilator operating characteristics, ventilator settings, altitude, and the use of pulsed dose or continuous flow O₂. In this study, the Zoll 731 consistently delivered the highest FiO₂ at all testing conditions likely due to the lack of bias flow and a larger reservoir. Careful patient selection and realizing device capabilities/limitations is paramount to providing safe mechanical ventilation using the POC method of O₂ delivery.
7.0 REFERENCES


16. Gustafson JD, Yang S, Blakeman TC, Dorlac WC, Branson R. Pulsed dosed delivery of

Distribution Statement A: Approved for public release. AFRL-2021-3272, cleared 27 September 2021


## LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

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<th>Symbol</th>
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