Expeditionary Mechanical Ventilation in Conjunction With Extracorporeal Life Support During Ground Transport

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ABSTRACT

Background: We assessed the use of an FDA-cleared transport ventilator with limited functions and settings during ground transport in a swine model of ground evacuation. We hypothesized that when used as an adjunct to extracorporeal life support (ECLS), the device would enable safe mobile ventilatory support during ground evacuation. **Methods:** Female Yorkshire swine (n = 11; mean, 52.4 ± 1.3 kg) were sedated and anesthetized and received mechanical ventilation (MV) with a standard intensive care unit (ICU) ventilator and were transitioned to the Simplified Automated Ventilator II (SAVe II; AutoMedx) during ground transport. MV served as an adjunct to ECLS in all animals. Ventilator performance was assessed in the uninjured state on day 1 and after bilateral pulmonary contusion on day 2. Data were collected pre- and post-transport on both days. **Results:** During 33 transports, the SAVe II provided similar ventilation support as the ICU ventilator. Mean total transport time was 38.8 ± 2.1 minutes. The peak inspiratory pressure (PIP) limit was the only variable to show consistent differences pre- and post-transport and between ventilators. No adverse events occurred. **Conclusion:** As an adjunctive supportive device during ground transport, the SAVe II performed adequately without failure or degradation in subject status. Further testing is warranted to elucidate the clinical limits of this device during standalone use.

KEYWORDS: *acute respiratory distress syndrome; trauma; extracorporeal life support; mechanical ventilation; expeditionary ground evacuation*

Introduction

Large-scale combat operations and multidomain operations of the future may result in both substantially higher casualty numbers and an inability to rapidly evacuate these casualties, necessitating prolonged field care in place.[1] The latter is of particular importance for combat casualty care because forward-deployed medics are in need of compact, simplified capabilities for MV to enable early interventions during critical states.[2]

To answer this need, small form-factor ventilators have been developed and fielded.[3,4] The initial versions of these devices were rudimentary, with limited capabilities that would be insufficient to support the most injured, those requiring full respiratory support. Our laboratory recently tested the next iteration of one of these ventilators—the SAVe II—as the ventilator during transport in a porcine model of polytrauma and ground evacuation. The SAVe II was assessed as an adjunctive ventilation tool in an expeditionary environment in conjunction with other mobile critical care equipment, including continuous venovenous ECLS. ECLS has been put forward by the U.S. Army Medical Research and Development Command as one of the most promising future technologies to care for the most severely injured.[5] We hypothesized that when used as an adjunct to ECLS, the SAVe II is reliable and enables safe mobile ventilatory support during ground evacuation.

Methods

This study was approved by our local Institutional Animal Care and Use Committee and was carried out in compliance with the Animal Welfare Act, the principles of the *Guide for the Care and Use of Laboratory Animals*, and all local, state, and federal guidelines for ethical use of animals. Secondary level approval was provided by the office of the Surgeon General of the Air Force.

Experimental Procedures

Details of the experimental procedures used have been previously reported.[6,7] The data reported here represent a convenience sample of the larger study. Briefly, female Yorkshire pigs (n = 11; mean, 52.4 ± 1.3 kg) were sedated and anesthetized and received arterial and venous catheters, tracheostomy, and urinary catheter placement. All animals were started on volume-control ventilation with a full-function ICU ventilator (Dräger V500; Dräger Medical) at 21% fraction of inspired oxygen (Fio_2); positive end-expiratory pressure (PEEP), 5 cm H_2O; tidal volume (V_T), 10mL/kg; and respiratory rate (RR) titrated to maintain normocarbia (arterial partial pressure of carbon dioxide [$Paco_2$], 35–45mmHg).

After baseline measurements, animals were cannulated, and continuous venovenous ECLS was initiated (Cardiohelp; Maquet, Gettinge Group) via a 23-Fr dual-lumen catheter

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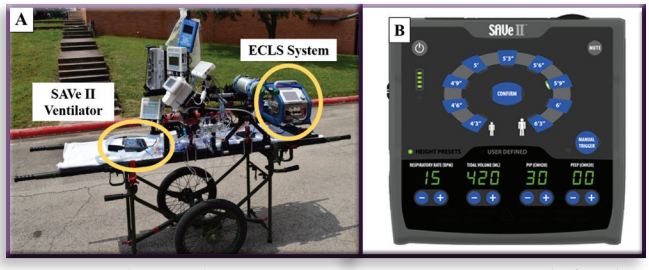
(Avalon Elite; Getinge Group) inserted into the right jugular vein.[8] Oxygen was used as the sweep gas at all times. After ECLS initiation, MV was reduced using a modified ARDS-Net protocol[9] to stepwise reduce V_T by 2mL/kg and RR by 2 breaths/minute sequentially, until minute ventilation was approximately 50% of baseline settings.

The animals were next prepared for ground transport. The SAVe II was set up according to the manufacturer's instructions and was tested for proper operation prior to use. The SAVe II settings (Fio_2, PEEP, V_T, RR) were matched to the ICU ventilator settings, and the animals were then switched from the V500 to the SAVe II. The PIP limit on the SAVe II, adjustable in increments of 5 cm H_2O only, was adjusted downward until the PIP alarm was reached, and then returned to the next highest setting (i.e., if the PIP limit alarmed when set to 25 cm H_2O, it was then set at 30 cm H_2O). Animals that were on 21% Fio_2 on the ICU ventilator were ventilated with 21% Fio_2 on the SAVe II. Animals that required supplemental oxygen received 10L/min oxygen, bled into the SAVe II circuit during transport from a size D or E cylinder (based on cylinder availability), via the designated oxygen reservoir designed for use with the SAVe II circuits. The animals were then transported, via a standard NATO litter (Model RES-7309-00; Life Support International) attached to a wheeled litter carrier (Item 9636; Brenner Metal Products) fitted with a medical equipment rail kit (Smeed Technologies), through the facility and to an adjacent building, thus simulating intra- and interhospital casualty transport (Figure 1). Our transports included approximately 50 m of hallway, a four-floor elevator ride, transition from a loading dock to ground level, and approximately 200 m of open-road ground transport between buildings before entering a building, travel in hallways for another 100 m, and loading and unloading into a hypobaric chamber, analogous to loading into and unloading from an aircraft.

FIGURE 1 *Simulation of intra- and interhospital casualty transport.*



(A) Litter with critical care equipment on practice test run before live study. Note the SAVe II at the head of the litter and the ECLS system at the foot of the litter. **(B)** User interface of the device. Image from the Quick Start guide enclosed with the device.

The animals remained on the SAVe II operating on battery power throughout transport. Data from hypobaric exposure are outside the scope of this manuscript and are reported elsewhere.[6,7] Next, we repeated all steps of the transport in the reverse order, culminating with arrival back at the origin ICU and return to ventilation via the V500, which concluded the events of day 1. Animals were maintained in the ICU overnight under continuous monitoring, remaining anesthetized and mechanically ventilated via the V500 (Figure 2). Overnight, the animals remained with ECLS circulating without sweep gas to prevent thrombus formation and limit decannulation/recannulation problems and supply use on day 2.

On day 2 of the study, the animals underwent bilateral pulmonary contusions using a modified captive bolt stunner (Model ML; Karl Schermer, Packers Engineering), followed by bilateral chest tube placement, as previously described.[6,10–12] The travel described above was repeated in the injured state, including all phases of transport to and from the chamber. At the conclusion of data collection after return to the origin ICU on day 2, the animals were humanely euthanized in accordance with our Institutional Animal Care and Use Committees–approved protocol.

Data Collection

Transport times on both days were recorded, defined as time from departure from the origin ICU to the beginning of data recording at the destination hypobaric chamber, and from the end of data recording in the chamber back to the ICU of origin. The time reported does not reflect the time of use of the transport oxygen cylinders because not every animal required supplemental oxygen during transport, and upon entry into the hypobaric chamber or origin ICU, the first step conducted was transfer from transport oxygen to the larger cylinder banks. Data on hemodynamics (i.e., heart rate and mean arterial blood pressure), MV settings, ECLS therapy, and arterial blood gas analysis were collected by manual transcription before and after all transports. Blood gas analysis was conducted via the i-STAT1 point-of-care blood gas analyzer (Abbott Point of Care). When supplemental oxygen delivery was required through the SAVe II, an oxygen delivery calculation was utilized to estimate delivered Fio_2, as previously described by our group.[7]

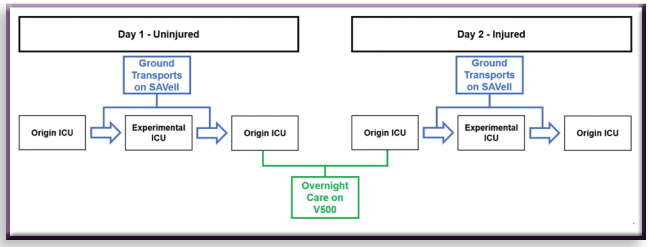
Using SAS version 9.4, a paired *t*-test or a Wilcoxon signed-rank test, depending on the distribution, was performed to evaluate the differences between each variable pre- and post-transport. Bland-Altman analysis was conducted using the variables partial pressure of oxygen:fraction of inspired oxygen (Pao_2:Fio_2; PFR)—an accepted index of lung function—as well a noninvasive PFR surrogate, the pulse oximetry saturation percentage:fraction of inspired oxygen (Spo_2:Fio_2) ratio (SFR).[7] Statistical significance was accepted at $p < .05$; data are represented as mean ± SEM (standard error of the mean).

Results

A total of 33 ground transports were completed in this study. Of the 11 animals that entered the study, all completed day 1 (uninjured control conditions) (Figure 2). Through all phases of our ground transport, no device failures were observed, and adjunctive use of a simplified ventilator did not contribute to any clinical decline in the animals. Six animals died after chest trauma before transport on day 2: two died from suspected myocardial infarction following injury, and four died from post–pulmonary-contusion cardiac contusion and unresponsiveness to vasopressors and fluids, signifying the severity of our injury model. Each surviving animal underwent transport four times: twice on day 1 in the uninjured state and twice on day 2 after polytrauma (Figure 2).

Mean total transport time was 38.8 ± 2.1 minutes. Mean transport time on day 1 was 37.5 ± 2.6 minutes (mean time out of the origin ICU, 44.9 ± 2.6 minutes; mean time returning to the origin ICU, 30.2 ± 2.9 minutes). Mean transport time in the critical state on day 2 was 41.4 ± 3.9 minutes (mean time out of the origin ICU, 47.5 ± 5.0 minutes; mean time returning to the origin ICU, 34.1 ± 4.6 minutes).

FIGURE 2 *Depiction of study timeline.*



Transports were conducted in uninjured state on day 1 and in injured state on day 2 (n = 11 animals; 33 transports total). Data were collected before and after each transport, before departure from the origin ICU (while on the V500) and upon arrival in the experimental ICU (while on the SAVe II), and then again before departure from the experimental ICU (on the SAVe II) and upon return to the origin ICU (on the V500).

Recorded values pre- and post-transport for vital sign data are shown in Table 1 and for blood gas data in Table 2; it is important to note that values for preTransport1 and preTransport3 were collected while the animal was on the V500 ICU ventilator, serving as "gold standard" measurements as standard of care therapy. The PIP limit was the only variable to show a difference pre- and post-transport (pre- vs post-transport for transport 1, 21 ± 1 vs. 28 ± 2 cm H_2O; transport 2, 29 ± 2 vs. 22 ± 1 cm H_2O; transport 3, 40 ± 3 vs. 46 ± 4 cm H_2O; transport 4, 48 ± 5 vs. 36 ± 5 cm H_2O). Additionally, increases were seen in mean arterial blood pressure after transport 1 (leaving the origin ICU) and in minute volume, end-tidal CO_2, and in PFR after transport 2 (return to the origin ICU) (Tables 1 and 2).

TABLE 1 *Collected Vital Signs Data From Pre- and Post-Ground Transports**

	Day 1				Day 2			
Vital Sign	Pre Transport 1 V500	Post Transport 1 SAVe II	Pre Transport 2 SAVe II	Post Transport 2 V500	Pre Transport 1 V500	Post Transport 1 SAVe II	Pre Transport 2 SAVe II	Post Transport 2 V500
Heart rate	115 ± 9	97 ± 11	93 ± 10	105 ± 7	128 ± 12	101 ± 16	94 ± 13	99 ± 12
ABP/M	80 ± 3	87 ± 4***	87 ± 4	83 ± 2	54 ± 3	79 ± 10	89 ± 7	91 ± 10
V_T	381 ± 19	415 ± 26	369 ± 29	391 ± 24	296 ± 33	322 ± 42	322 ± 42	308 ± 50
V_T/kg	7.3 ± 0.3	7.7 ± 0.4	6.9 ± 0.6	7.5 ± 0.5	5.4 ± 0.6	5.3 ± 0.6	5.3 ± 0.6	5.5 ± 1.2
RR	9 ± 1	10 ± 1	9 ± 1	12 ± 1	16 ± 3	12 ± 1	12 ± 1	11 ± 2
V_E	3.71 ± 0.37	4.10 ± 0.47	3.48 ± 0.54	5.00 ± 0.79	3.69 ± 0.66	3.84 ± 0.74	3.84 ± 0.74	3.59 ± 0.91
PIP**	21 ± 1	28 ± 2***	29 ± 2	22 ± 1	40 ± 3	46 ± 4***	48 ± 5	36 ± 5***
PEEP	6 ± 1	6 ± 1	6 ± 1	6 ± 1	6 ± 1	8 ± 1	8 ± 1	8 ± 1
$etCO_2$	32 ± 2	31 ± 2	28 ± 2	31 ± 3***	18 ± 3	29 ± 5	25 ± 5	26 ± 3
Blood flow	1.12 ± 0.10	1.31 ± 0.16	1.34 ± 0.15	1.30 ± 0.15	1.53 ± 0.23	2.03 ± 0.30	2.01 ± 0.29	2.00 ± 0.29
RPM	2103 ± 181	2327 ± 211	2364 ± 212	2185 ± 186	3171 ± 200	3254 ± 419	3274 ± 398	3256 ± 413
Sweep gas flow	4.9 ± 1.2	5.9 ± 1.3***	2.0 ± 0.3	1.4 ± 0.7	7.7 ± 1.3	9.0 ± 1.9	9.4 ± 1.7	8.4 ± 1.0
Spo_2%	94 ± 1	95 ± 3	97 ± 1	95 ± 1	89 ± 5	95 ± 2	98 ± 1	98 ± 1
Fio_2%	23 ± 1	49 ± 13	43 ± 8	32 ± 8	85 ± 8	78 ± 14	82 ± 11	90 ± 10
PFR	342 ± 18	388 ± 22	433 ± 30	380 ± 25***	231 ± 47	181 ± 44	252 ± 63	218 ± 43
SFR	424 ± 22	283 ± 67	309 ± 48	361 ± 39	135 ± 19	142 ± 29	131 ± 21	122 ± 24

**n* = 11 animals; 33 transports total. Data are represented as mean ± SEM.
**For SAVe II, PIP values reported are PIP limits because the SAVe II model we tested does not display measured PIP.
***Denotes significant difference between pre- and post-transport data, $p < .05$.
Heart rate, beats per minute (bpm); ABP/M, mean arterial blood pressure (mmHg); V_T, tidal volume (mL); V_T/kg, tidal volume per kilogram of bodyweight (mL); RR, respiratory rate (bpm); MV, minute ventilation (L); PIP, peak inspiratory pressure (cm H_2O); PEEP, positive end-expiratory pressure (cm H_2O); $etCO_2$, end-tidal carbon dioxide (mmHg); blood flow: extracorporeal life support (ECLS) blood flow (L/minute); RPM, ECLS pump revolutions per minute; sweep gas flow, sweep gas flow rate (L/minute); Spo_2%, pulse oximetry saturation percentage; Fio_2%: fraction of inspired oxygen percentage; PFR, ratio of Pao_2 to Fio_2; SFR, ratio of Spo_2 to Fio_2.

TABLE 2 *Collected Arterial Blood Gas Data From Pre- and Post-Ground Transport**

	Day 1				Day 2			
Blood Gas Factor	Pre Transport 1 V500	Post Transport 1 SAVe II	Pre Transport 2 SAVe II	Post Transport 2 V500	Pre Transport 1 V500	Post Transport 1 SAVe II	Pre Transport 2 SAVe II	Post Transport 2 V500
pH	7.55 ± 0.03	7.55 ± 0.04	7.55 ± 0.04	7.47 ± 0.04**	7.45 ± 0.02	7.36 ± 0.04**	7.37 ± 0.02	7.28 ± 0.08
$Paco_2$	30.0 ± 2.1	30.8 ± 3.3	26.8 ± 1.4	32.9 ± 2.7**	27.2 ± 2.5	34.1 ± 3.6	29.2 ± 2.8	39.3 ± 8.4
Pao_2	76.4 ± 3.5	204.0 ± 59.5**	179.6 ± 34.4	128.2 ± 33.0	192.3 ± 47.1	117.8 ± 11.6	185.8 ± 33.3	201.0 ± 50.6
BE	3.1 ± 0.8	3.9 ± 1.3	0.8 ± 1.8	–0.4 ± 1.3	–5.4 ± 1.7	–6.6 ± 2.0	–8.6 ± 2.3	–9.0 ± 2.3
HCO_3^-	25.6 ± 0.6	26.7 ± 1.0	24.1 ± 1.4	23.5 ± 0.9	18.6 ± 1.6	19.2 ± 1.7	17.3 ± 2.0	18.2 ± 1.6
Sao_2%	96.8 ± 0.6	98.9 ± 0.5	99.5 ± 0.21**	98.0 ± 0.5**	96.6 ± 2.1	98.0 ± 0.8	99.4 ± 0.4	98.2 ± 1.2
Lactate	2.53 ± 0.59	3.57 ± 1.11	4.23 ± 1.29**	3.16 ± 0.96**	4.56 ± 0.94	4.55 ± 1.93	5.93 ± 1.94	10.22 ± 4.22

**n* = 11 animals; 33 transports total. Data are represented as mean ± SEM.
**Denotes significant difference between pre- and post-transport data, $p < .05$.
pH, log scale of hydrogen ion concentration in blood; $Paco_2$, arterial partial pressure of carbon dioxide (mmHg); Pao_2, arterial partial pressure of oxygen (mmHg); BE, base excess (mmol/L); HCO_3^-, bicarbonate (mmol/L); Sao_2%, arterial oxyhemoglobin saturation (%); lactate, arterial lactate (mmol/L).

Discussion

In this study, we assessed the function of a simplified device as a transport ventilator during ground transport when used as an adjunct to ECLS in a large-animal model of combat-relevant trauma. The data here represent intra- and interfacility ground evacuation only; the larger experimental data set is reported elsewhere and involved clinically relevant ICU conditions, making the transports used in this study similar to human interfacility transports.[6,7]

The SAVe II was able to provide adequate ventilation for our animals during all phases of transport when used in an adjunctive mode to ECLS. This concept of adjunctive use of ventilators with various forms of ECLS was previously introduced by our group for potential applications during prolonged field care and aeromedical evacuation.[7,13] This approach can mitigate ventilator-induced lung injury and provide for lung-protective or lung-rest protocols while ECLS offloads the lung requirements for CO_2 removal and oxygenation. This concept is potentially the next phase in advancement of both aeromedical evacuation and care at or near the point of injury, where both casualty stability and optimization of care may be achieved concomitantly. Of note, the highlights of the SAVe II as tested are its light weight and cube shape rather than the functions of a fully capable ventilator; thus, any benefit of ventilator-induced lung injury reduction must be placed on the ECLS if such limited devices as the SAVe II are used.

We determined the simplified ventilator to be suitable for mobile critical care. During intra- and interfacility transport, including building, elevator, and open road, we did not incur ventilator-related complications or malfunctions. We saw sporadic significant changes in PIP, mean arterial pressure, minute ventilation, end-tidal carbon dioxide (mmHg) ($etCO_2$), and PFR, although none can be tied solely to the use of the device; rather, as in all critical care, the changes seen result from many factors. The numerical changes we saw between pre- and post-transport data were clinically insignificant. We determined adequate performance of the SAVe II as part of the critical care tool set when it is used as an adjunct to venovenous ECLS. Following injury on day 2, all animals required increased FiO_2 while in the ICU, and thus received increased FiO_2, as described above during transport.

Airway management is the second leading cause of potentially survivable injury in combat[14] and an independent mortality risk in the combat wounded,[15] and manual ventilation delivers inconsistent results.[16,17] In a targeted review of forward-deployment lessons learned, 30% of recommendations for improvement directly mention airway management skills,[18] and a recent prolonged field care clinical practice guideline highlights that although artificial ventilation is better than no ventilation, the level of training required to effectively use MV presents challenges.[19] Thus, development of small portable ventilators is a logical evolution in the care of wounded Servicemembers. Complete air superiority in recent conflicts enabled US Forces and their allies expedient, often unrestricted, air lift with a mean evacuation time of around 45 minutes—well within the "golden hour."[20] Future conflicts with near-peer adversaries possessing similar technological capabilities as the US and its allies are forecast to render rapid evacuation of combat casualties improbable.[21,22] Such realities necessitate small, lighter, and less-complex medical devices able to be deployed to the forward environment and able to be employed by non–specialty-trained medical providers.

Transport of critically ill patients represents an inherent risk, with transports potentially leading to patient complications and death.[23,24] Movement of critical patients has resulted in more than two unplanned events per transport, 46% of which were device related.[24,25] This highlights the importance of having safe and reliable equipment for all patient moves, even when those moves are conducted after care-in-place at or near the point of injury has been ongoing for days. Our study investigated these aspects, and we did not experience any unplanned events during the 33 transports we completed. We also did not identify any degradation in animal clinical status while using the SAVe II. Our findings suggest that simplified critical care equipment is a potential choice for respiratory support of casualties, specifically when used as an adjunct to ECLS, as tested in our current study.

Our transport times were, on average, less than half the minimum time on scene of the assessment done by Phillipp et al.[26] testing ECLS during transport (90 to 180 minutes[26]). The time to get a trauma patient to critical care in combat operations ranges from 35 to 50 minutes,[27,28] putting our experimental transport times in line with what has been experienced during recent armed conflicts.

The device was previously tested in swine with acute lung injury for a short duration, where it was shown to be able to provide support for 1 hour after oleic acid–induced lung injury.[29] The SAVe II does not display patient feedback, such as measured exhaled tidal volume (and thus, by extension, also does not display minute ventilation, either delivered or exhaled), airway pressures, or graphic scalars, data that are unlikely to be useful in the field by inexperienced providers but that may limit the versatility of use of the device by more highly trained personnel.

Our study found that the device provided lung-protective ventilation (V_T, 5–8mL/kg) at all times. We were able to maintain minute ventilation of approximately 50% of baseline values when the SAVe II was used as an adjunct to ECLS (data not reported; Table 1). Our day 1 animals were slightly overventilated because extracorporeal therapies, such as the ECLS used here, are not designed for application in healthy, uninjured states. After injury on day 2, we saw acid-base imbalance more reflective of typical patients with acute respiratory distress syndrome (ARDS) (Table 2). The study animals were in mild ARDS after injury (PFR < 300)[30] and had severe metabolic derangements (elevated lactate and base excess; Table 2) seen in combat casualties, again highlighting the relevance of our injury model. However, it is important to remember that our testing occurred along with ECLS. Thus, in our model, the SAVe II performed adequately, but more stringent testing is warranted to assess standalone performance of such simplified tools.

The limitations of the SAVe II presented a challenge on one occasion during this study, where the animal had low arterial CO_2 levels despite minimal sweep gas flow through the ECLS system, yet the V_T and RR could not be reduced low enough (because of limitations of the SAVe II) to match the ICU ventilator, resulting in hyperventilation of the animal. The V_T setting on the device we were provided for testing was adjustable in increments of 50mL only, which may present difficulty to

some providers requiring higher-resolution V_T adjustments to provide the best care for their patients. The lower limit of RR adjustment was 8 breaths/minute, which in our experience may not be adequate for patients who are profoundly hypocapnic or who are receiving ventilation through extracorporeal means. However, the argument may be made that at present, any patient requiring extracorporeal lung support may already be in a facility equipped with more robust ventilators, capable of more ventilation options, thus potentially rendering this particular criticism moot. For the intended market of prehospital use, this limitation may not be an issue.

The inspiratory flow of the device is variable, which is beneficial in comparison with fixed-flow devices, but it is limited to a maximum of 27L/min and is not changeable by the user. The device is designed for patients weighing >45 kg, for whom flow rates this low may be inadequate. The literature suggests that flow rates are an independent factor in patient–ventilator synchrony, and flow rates of up to 80L/min may be required.[31] Because the SAVe II is incapable of such flow, patient–ventilator synchrony may be an issue with patients who require higher flow rates, subsequently leading to increased sedation requirements.

On every transport in this study, when the stands of the wheeled litter carrier were lifted, the abrupt motion caused the High Peak Pressure alarm to sound. The motion of the litter during transport also regularly caused either High Peak Pressure, High PEEP, or Spontaneous Breath Detected alarms to sound, sometimes in combinations of two or three simultaneously. Although alarms alerting caregivers to problems delivering breaths are a requirement of all ventilator types, the sensitivity of these alarms may warrant further investigation. The alarms were sufficiently audible from a distance of up to 5 meters, although the visual alarm indicator was difficult to identify if one was not looking directly at the control panel of the device. Our team also found the ventilator circuits designed for the SAVe II to be not very durable, with several ripping apart during removal after the experiments.

The SAVe II model we tested does not provide physiologic data on the patient (e.g., exhaled V_T, PIP, plateau airway pressure). This can be troublesome to clinicians wanting to ensure that plateau pressures remain below the safe threshold of 30 cm H_2O. PIP can be realized only within a range of 5 cm H_2O, and only as a range between two limits. The manufacturer states that the display of actual measured PIP is an update that they have fielded, but it was not available on the device we tested (personal communication with Automedx, January 2017).

Our experience with the SAVe II was unique in that both healthy and injured animals were receiving at least partial lung support through ECLS. In standard clinical practice, ECLS for healthy lungs is not provided, thus rendering this data set unique and not singularly representative of standalone performance of the device. Standard practice for ECLS patients dictates rest settings on the ventilator, with 76% of centers targeting ventilation below 6mL/kg.[32] The lowest V_T available on the SAVe II provides a breath size of 4.44mL/kg when used with patients of the lowest recommended weight; larger patients will be capable of receiving lower per-kilogram tidal volumes, but at the expense of limited inspiratory flow, as discussed above.

As suggested by Macku et al.,[33] ECLS is currently underutilized in the military setting and should be further explored and implemented. It is plausible that the need for and utilization of ECLS with and without MV is slated to increase as we prepare for multidomain and large-scale combat operations with the great likelihood of high numbers of casualties with severe injury. The Special Operations Forces community is likely to benefit from considering such an approach because evacuation of surviving casualties from engagement zones will ensure higher survival rates when comprehensive life-sustaining capabilities such as ECLS are available.

Limitations

This study is limited by being a convenience sample taken from a larger study, with no designated control experiments; all animals received both SAVe II support and ECLS. We also recognize our inherent bias: we did not choose the device we tested; rather, it filled the need of our not taking our ICU ventilator between buildings repeatedly. We chose to collect data on the use of this device as a glance at a potential-use case during evacuation with primary lung support provided by ECLS, which is not what the SAVe II was designed or marketed for.

The device is indicated for short-term ventilatory support for patients weighing at least 45 kg,[34] and the listed device specifications suggest the ability to achieve up to 30 beats per minute at 800mL V_T, with combinations capped at a maximum minute ventilation of 8L per minute,[35] suggesting that the device is potentially capable of providing standalone ventilatory support for casualties with minimal to moderate respiratory insufficiency. However, it is unlikely to provide adequate support for a patient with severe ARDS who requires fine-tuned monitoring and adjustment of settings with a wider range of parameter options. Given the limitations of the allowable device settings, the SAVe II seems to be a better adjunct to ECLS than a standalone ventilator.

Conclusion

In this combat-relevant, large-animal model of respiratory failure resulting from polytrauma treated with ECLS, the SAVe II performed without failure or degradation in animal clinical conditions when used as an adjunctive supportive device to ECLS during 33 total intra- and interfacility transports. The light weight and cube shape make the SAVe II easily transported and likely more available for use by field medics, while the built-in simplicity of the device makes its employment more likely by field medics for patients with mild respiratory insufficiency. Further standalone testing of the SAVe II or similar transport ventilators is warranted and already planned in our lab.

Meeting Presentations

Portions of this work were presented at the 2017 and 2018 *Advances in the Care of Critically Ill Neonates, Children, and Adults* conferences, Snowbird, UT (March 21–25 and April 3–7, respectively), and the 2017 and 2018 *Military Health System Research Symposium*, Kissimmee, FL (August 27–30 and August 20–23, respectively).

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Author Contributions

AIB and LCC conceived of the study design. BMB, GH, DSW, JHC, KS, VK, LCC, and AIB collected and analyzed data,

BMB drafted the manuscript, GH, DSW, JWC, JHL, LCC, VGS, and AIB critically revised the manuscript.

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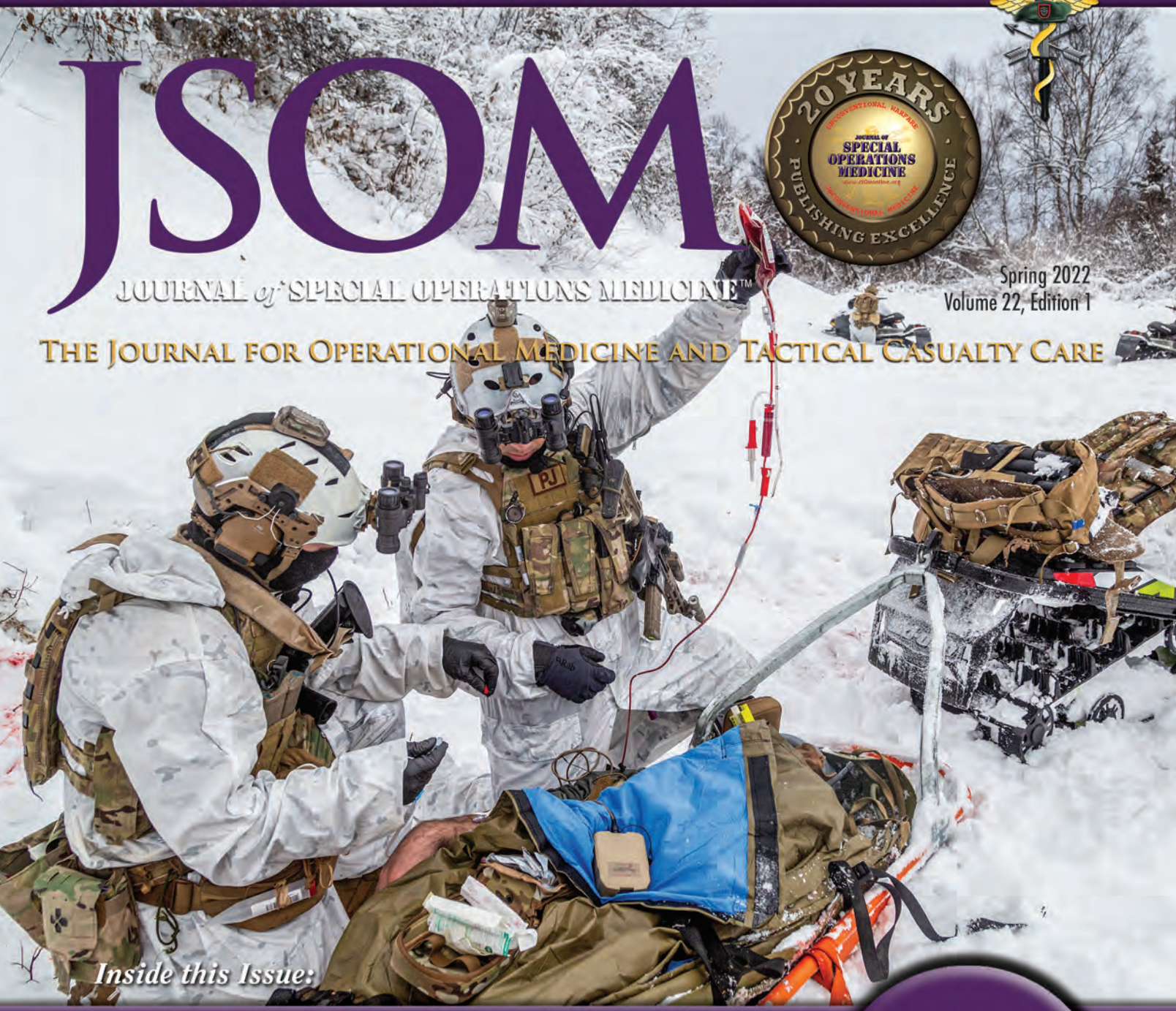

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