Physiologic Closed-Loop Control of Mechanical Ventilation in a Porcine Model of Lung Injury and Hemorrhage

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INTRODUCTION

Mechanical ventilation (MV) is a fundamental therapy for patients with acute respiratory failure, including those following acute illness, trauma, and acute respiratory distress syndrome (ARDS). Conventional MV is clinician managed and requires manual adjustments of ventilator settings to maintain acid base balance and oxygenation. Evidence for physiologic closed loop control (PCLC) performance in complex, multi-injury models is sparce. We evaluated the Hamilton S1 ventilator with Intellivent-ASV PCLC software in a porcine model of hemorrhage, lung injury, and combined hemorrhage/lung injury.

METHODS

This study compared clinician managed standard-of-care (SOC) MV (n=15) with PCLC MV (n=15) in three porcine injury models: controlled hemorrhage (HEM) alone, lung injury alone, and lung injury with HEM. Primary endpoints were the percentage of time spent within predefined physiologic targets of oxygenation (SpO_2 92-96%), tidal volume (4–10 mL/kg), Plateau pressure (≤ 30 cm H_2O), driving pressure (< 15 cm H_2O cm H2O), and end-tidal CO_2 (35–45 mm Hg) during the 3-hour post-intervention ventilation period.

Research was conducted in accordance with an approved animal use protocol at an AAALAC International-accredited facility, in full compliance with all applicable federal statutes and regulations governing the use of animals in research including the Animal Welfare Act. The study adhered to the principles outlined in the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 2011 edition).

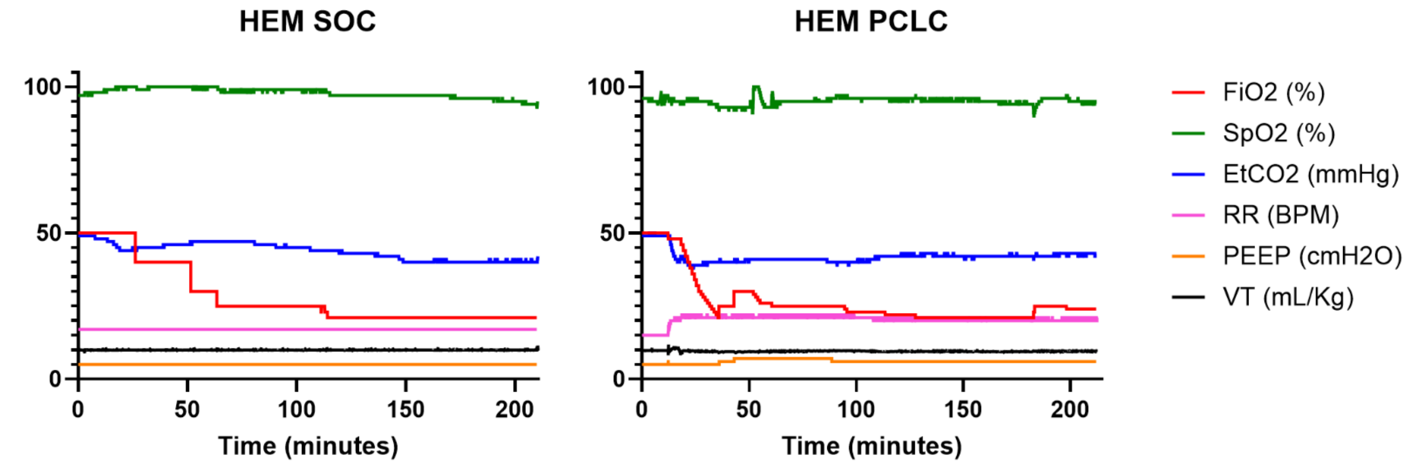

Figure 1: Waveform data of a representative animal from the HEM injury model group.

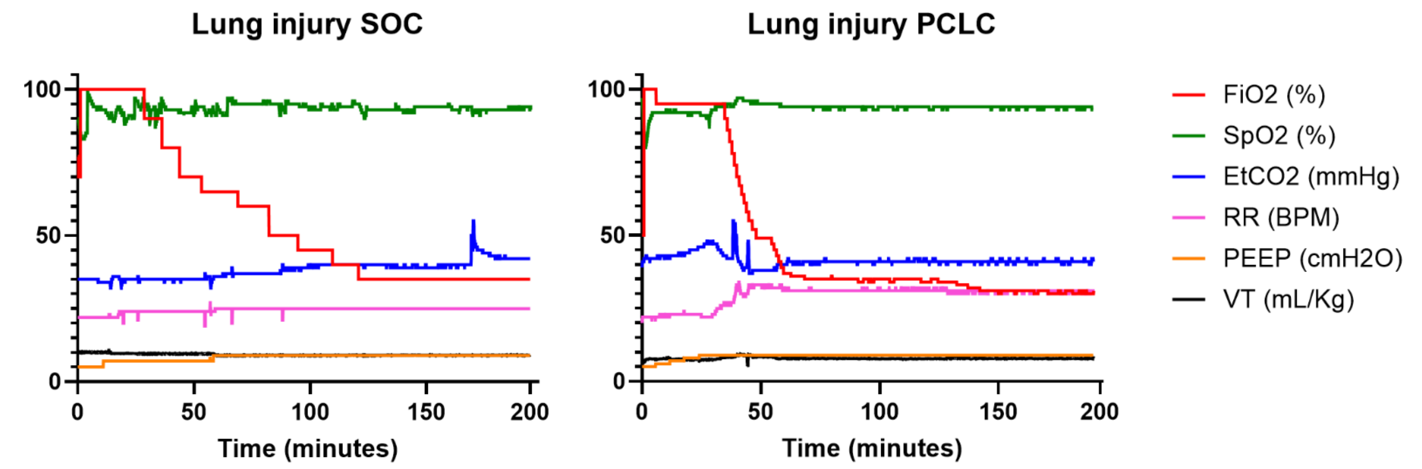

Figure 2: Waveform data of a representative animal from the lung injury model group.

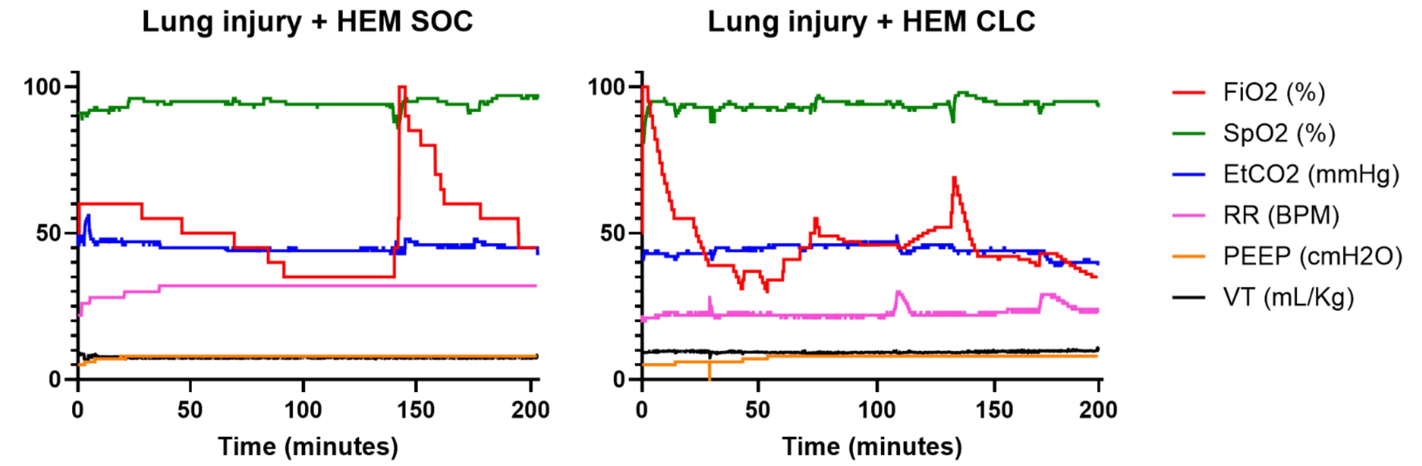

Figure 3: Waveform data of a representative animal from the lung injury + HEM injury model group.

RESULTS

PCLC animals spent a higher percentage of time within targeted SpO_2 range compared with SOC (76% ± 7% vs 70% ± 12% of time) across all injury models, but differences were not statistically significant (p=0.52). Mean SpO_2 for all study animals was 95% ± 2%. In the hemorrhage group, mean V_T (mL/kg) was lower in the PCLC group (9.1 ± 0.3 vs 10.1 ± 0.5) (p=0.01), while the remaining parameters within lung injury alone and hemorrhage with lung injury were otherwise equivalent ($p > 0.05$). Across all cohorts and study time points, arterial pH and $PaCO_2$ were not significantly different ($p > 0.05$). Figures 1-3 show waveform data with one representative animal from each of the study groups (as noted).

CONCLUSION

The Hamilton Intellivent-ASV PCLC ventilator was not inferior to or was superior to SOC mechanical ventilation management with respect to clinical performance parameters. Across all cohorts, regardless of injury type, PCLC maintained target SpO_2 more often than SOC, with differences most notable in the hemorrhage alone and hemorrhage with lung injury cohorts. Although not approved for human use in the US, PCLC MV was at least safe as clinician managed MV in this multi-injury porcine model.

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