

Background and Introduction

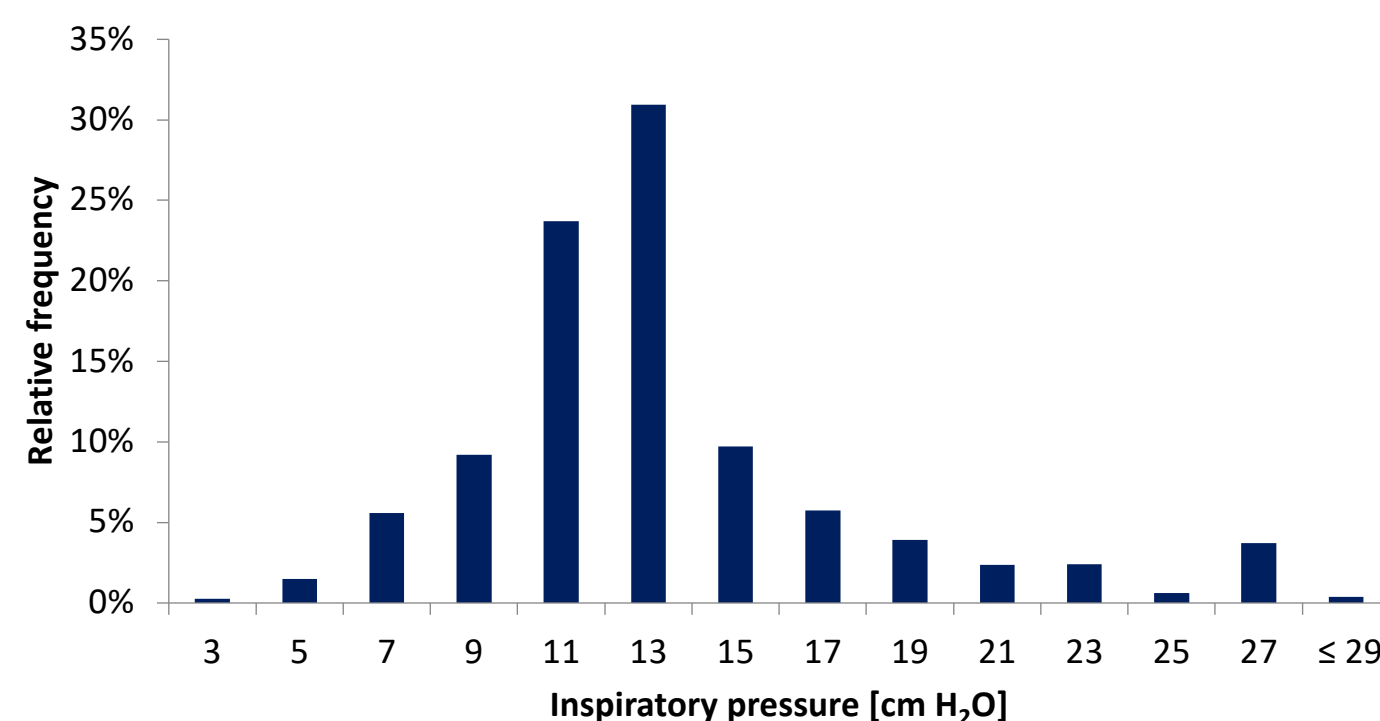
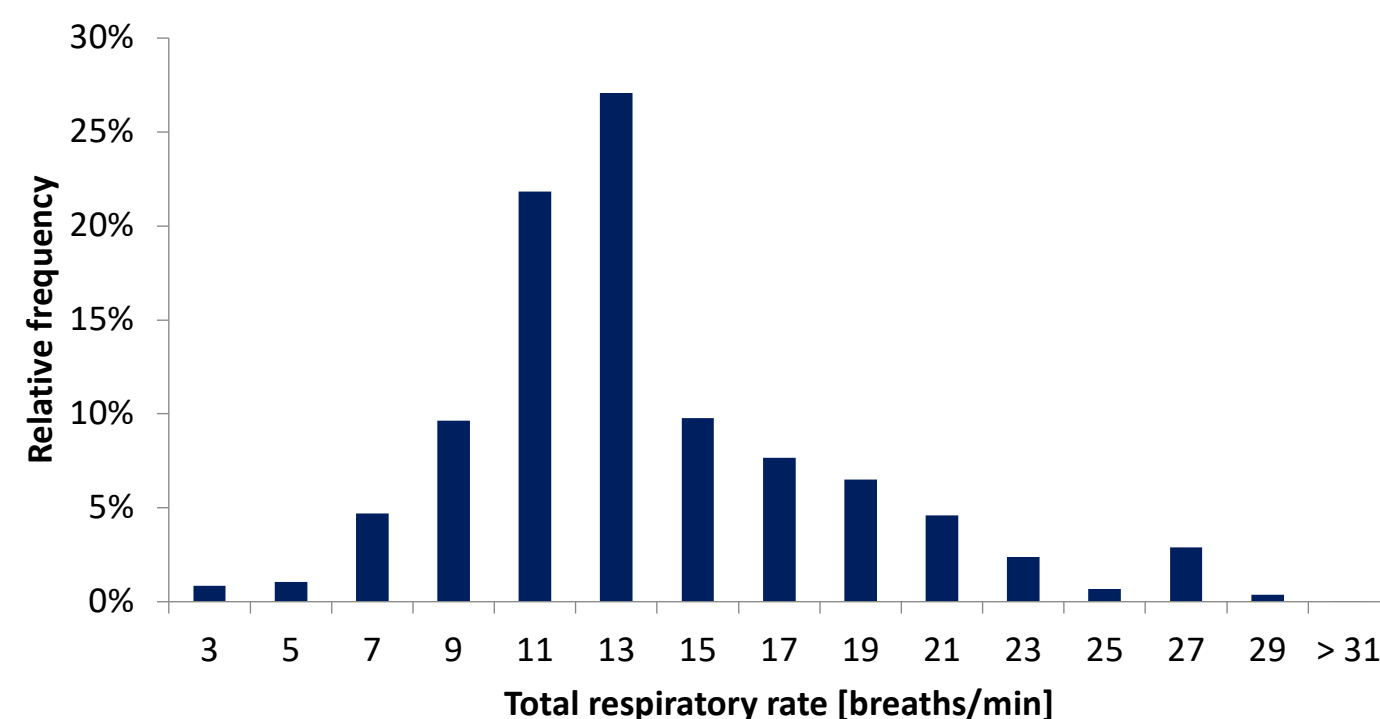
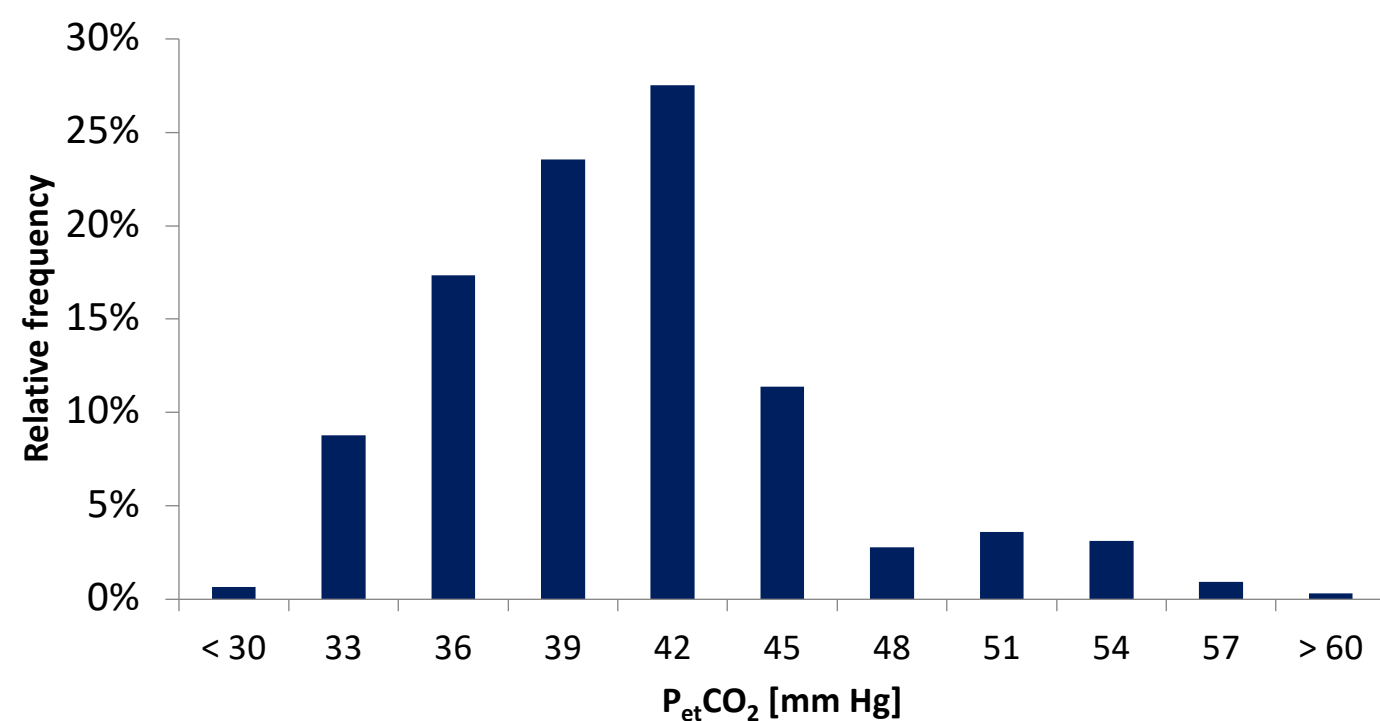
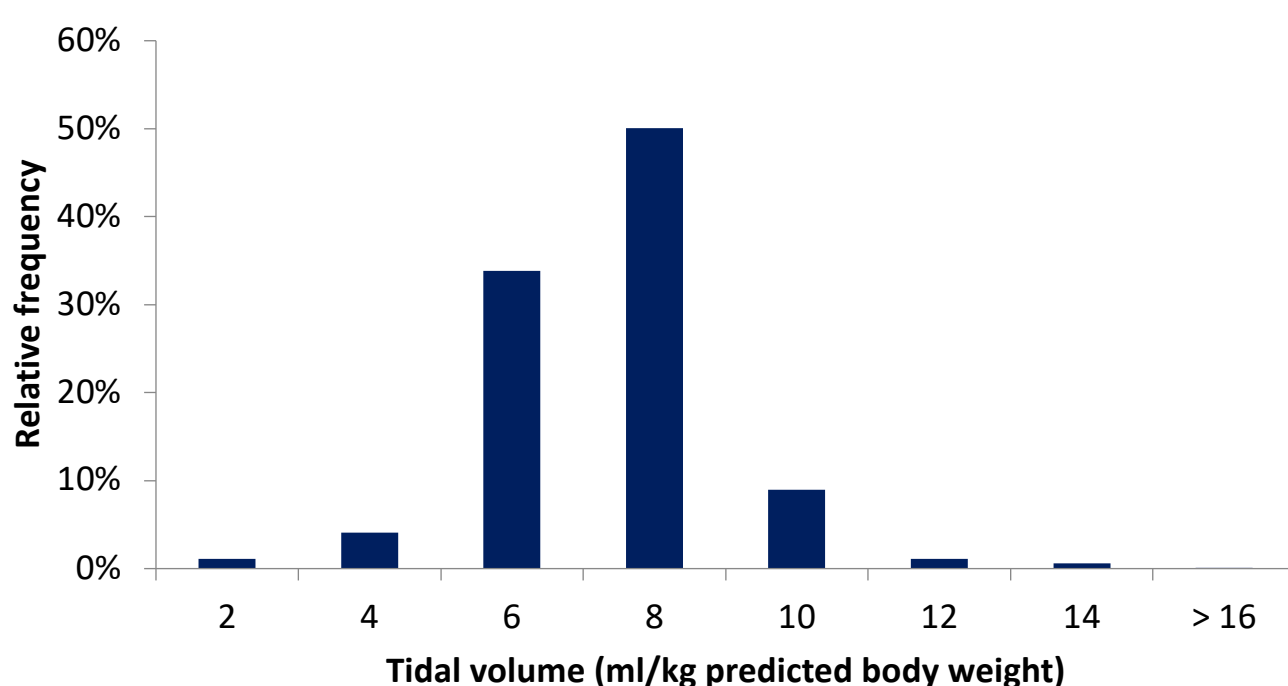
Several systems for automated control of mechanical ventilation on intensive care ventilators exist and were successfully applied in clinical studies (1-2). The goal of this study is to examine safety and efficacy of a novel system for automated control of most of the ventilator settings on an anaesthesia machine.

Materials and Methods

The novel system called Smart Ventilation Control (SVC) controls automatically the mechanical breathing frequency, inspiratory pressure, pressure support, inspiratory time and trigger sensitivity with the aim to keep a patient stable in user adoptable target zones. Patients are eligible for study inclusion when all of the following criteria are met: Classified to American Society of Anesthesiologists physical status I, II or III, scheduled for elective surgery of the upper or lower limb or for peripheral vascular surgery in general anesthesia and written consent for study participation. Primary endpoint of the study is the frequency of the following adverse events: Severe hypoventilation defined as minute volume lower than 40 ml/kg predicted body weight for longer than 5 minutes, apnea for longer than 90 seconds, Hyperventilation defined as $P_{et}CO_2$ lower than 5 mm Hg of the lower target setting for SVC for longer than 5 minutes, Hypoventilation defined as $P_{et}CO_2$ higher than 5 mm Hg of the upper target setting for the SVC for longer than 5 minutes, respiratory rate ≥ 35 breaths/minute for longer than 5 minutes, any override or stop of the automated controlled ventilation settings by the anesthesiologist in charge if the settings are clinically not acceptable.

Results and Discussion

We here report the safety analysis of the first $n=18$ included patients with a mean age \pm standard deviation of 58 ± 20 years and a mean height of 172 ± 10 cm. We plan to recruit a total of $n=100$ patients. The following adverse events were recorded: $n=3$ severe hypoventilations (low minute volume), no apnea for longer than 90 seconds, $n=2$ hyperventilations, no hypoventilation (high $P_{et}CO_2$), no respiratory rate ≥ 35 breaths/minute, no manual override.



Conclusion

This is the first clinical study of a system that automatically controls most of the ventilator settings on an anesthesia machine. Our preliminary results suggest that the novel developed system is safe.

Literature

- 1) Lellouche, F., et al. Am J Respir Crit Care Med 174:894-900 (2006)
- 2) Arnal, J. M., et al. Crit Care 17:R196 (2013)

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