TITLE

Electric Blower Based Ventilator Used During Procedural Sedation

NCT NUMBER

NCT02621463

DOCUMENT DATE

September 30, 2015 (date of the most recent approval of the IRB application from which the Study Protocol was extracted)

STUDY PROTOCOL (extracted from IRB_00074281, approved on Sep 30, 2015)

All study procedures will be performed in adult patients following informed consent at the endoscopy suite of the University of Utah Health Sciences Center in Salt Lake City, Utah. A ventilation mask will be placed on the patient's face and connected to the V60 ventilator. Supplemental oxygen will be delivered by the V60 ventilator through the mask; the concentration of oxygen delivered will be left to the clinician's discretion. A modified mask with multiple small leaks will be used with a standard elastomeric H-strap to secure it to the patient's face.

The endoscopy suite nurse and technicians will attach all clinically necessary standard sensors and connect them to the patient and monitoring system. Height, weight, and neck circumference will be measured and recorded digitally on an encrypted laptop. In addition to the standard of care monitors, we will collect data from additional non-invasive modalities and save the data to a laptop using custom software for later analysis. Respiratory Inductance Plethysmography bands (Q-RIP, Braebon, Kanata, Canada) (also called chest bands) will be placed to monitor the patients' tidal volumes. The chest bands will be calibrated using data from a tight fitting mask connected to a flow sensor collected for approximately 1-3 minutes at the end of the case. The concentration of oxygen delivered will be left to the clinician's discretion and will be recorded to a data sheet.

Pressure and flow sensors included in the V60 ventilator will be used to monitor the patients' tidal volumes and respiratory rate during the procedure. The data that will be collected and recorded on the laptop will include: RIP data, mask pressure, flow, and breath rate. An additional flow sensor connected to an NM3 (LoFlo/NM3, Philips Medical) will placed in line with the V60 ventilator. The additional flow sensor is an approved medical device for measuring flow in patients receiving respiratory support and will have no effect on the functionality of the V60 ventilator or its ability to provide patient support and monitoring. It simply collects additional data that will be used to demonstrate the accuracy of our prototype system's algorithm.

The ventilator mask will be placed on the patient's face according to their comfort using an elastomeric H-strap. CPAP of 8 cm H2O will be the starting setting for the V60 ventilator. The clinician will determine the concentration of oxygen that shall be delivered to the patient. The V60 ventilator is capable of providing concentrations between 21% - 100% of oxygen. Unless otherwise directed by the clinician, the V60's default setting of 40% will be used.

The clinical procedure and administration of sedation medication other than the ventilatory support and monitoring will follow the clinical routine used for colonoscopies. The attending staff will be instructed to not alter medication doses or any other standard of care just because of the study or use of the ventilator. An anesthesiologist will be immediately available for consult and assistance during all patient treatment.

STATISTICAL ANALYSIS

All statistical analysis was performed using Excel (Microsoft, 2013) and R version 3.3.1 (2016-06-21). Demographic data were analyzed using the Welch two sample t-test to show demographic uniformity across both populations. p values for the primary and secondary outcome variables were calculated using

Mann–Whitney test due to nonparametric data and the uneven sample sizes between the intervention group and the control group. SpO2 data were averaged over 15 data points (15 s) to eliminate artifacts in the data due to movement and disconnection of the sensor from the patient. Area-under-curve (AUC) analysis integrated the difference between the SpO2 data and the 90% threshold every second. A sample size of 29 patients was calculated to have a 90% power to detect a 9% difference in means of the percent time of the procedure that the patient experienced apnea. We expected to show that the use of CPAP during procedural sedation would reduce apneic time from these procedures and yield an average of less than 2% of the procedure time in an apneic state.

(extracted from: Fogarty M, Orr JA, Sakata D, Brewer L, Johnson K, Fang JC, Kuck K. A comparison of ventilation with a non-invasive ventilator versus standard O2 with a nasal cannula for colonoscopy with moderate sedation using propofol. J Clin Monit Comput. 2020 Dec;34(6):1215-1221)