Validation of SuperNO$_2$VA® Et Nasal Performance CO_2 Measurement and Pressure Test

INTRODUCTION

Moderate and deep sedation has long been associated with high rates of respiratory complications such as hypoxemia and hypoventilation.[1-3] These complications have been shown to be caused by inadequate monitoring and sedation medications which result in upper airway obstruction and central respiratory depression.[1-3] In an attempt to mitigate respiratory complications, the measurement of exhaled carbon dioxide has recently become accepted as an improvement over pulse oximetry for the monitoring of ventilation.[4] In addition, the American Society of Anesthesiologists (ASA) has endorsed end-tidal capnography ($EtCO_2$) as a standard of care for moderate and deep procedural sedation.[5] A key reason for capnography being adopted is because it measures ventilation by capturing the concentration of exhaled carbon dioxide in a process known as end tidal CO_2 while pulse oximetry measures only oxygenation. Another reason why pulse oximetry is not the preferred method for monitoring ventilation is because of its inability to detect hypoventilation or apnea.[6] This is especially true in patients undergoing procedural sedation receiving supplemental oxygen.[6-7]

Although capnography has been shown to effectively detect hypoventilation and apnea much faster than pulse oximetry, accurate and consistent measurements of the $EtCO_2$ during minimally invasive procedures under deep sedation have historically been challenging.[8]

One reason for this is because it is open to air, causing atmospheric gases to be entrained and sampled.[9] A second reason is due to patients receiving supplemental oxygen, which at flows > 5 LPM "wash-out" or dilute the sample of exhaled carbon dioxide resulting in either a falsely low reading or no reading at all.[10]

Recent prospective randomized controlled trials (RCTs) reported up to 54% of all patients experience severe hypoxemia secondary to sedation-related upper airway obstruction (UAO) and respiratory depression.[11] Although passive oxygenating devices have the ability to provide higher concentrations of oxygen, they are incapable of generating positive pressure to maintain airway patency. Continuous Positive Airway Pressure (CPAP) has been shown to relieve upper airway obstruction by creating a pneumatic stent.[12] However, its utility is limited by the fact that the machines are very large and expensive, and the high flows required to maintain pressure also dilute the $EtCO_2$ sample.[13-14] Another promising therapy is the SuperNO$_2$VA®, which is a completely sealed nasal positive airway pressure (PAP) device that provides positive pressure to maintain upper airway patency without the use of capital equipment. A recent RCT comparing the SuperNO$_2$VA vs nasal cannula with capnography during deep sedation showed a significantly higher Minute Ventilation and reduction in the incidence of severe hypoxemia in the SuperNO$_2$VA group compared to the nasal cannula with capnography.[15] However, a disadvantage is its inability to capture $EtCO_2$, especially when the patient exhales from their mouth resulting in false apnea alarms.

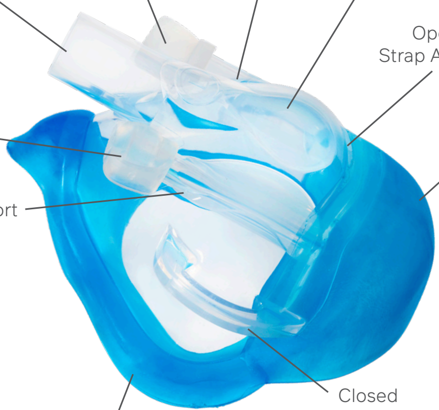

Figure 1: SuperNO$_2$VA Et Nasal Mask features a $EtCO_2$ Hood and $EtCO_2$ nasal sampling port

The SuperNO$_2$VA Et (figure 1) is a novel completely sealed nasal positive airway pressure (PAP) device designed to capture $EtCO_2$ exhaled from either the patient's mouth or nose and provide positive pressure to maintain upper airway patency. Combining capnography with positive pressure may prove to be a methodology to further improve outcomes in deep sedation as opposed to passive oxygenation techniques with capnography.

The objectives of this study are to validate that the SuperNO$_2$VA Et can capture $EtCO_2$ exhaled from the nose and the mouth, provide ≤ 20 cm H_2O of positive pressure, quantify leak rates, and summarize the performance testing of the SuperNO$_2$VA Et compared to predicate devices.

METHODS

A simulated patient setup was utilized to compare the accuracy of CO_2 measurements within the SuperNO$_2$VA® Et and predicate device (Smart CapnoLine Plus Adult/Intermediate CO_2, “Oral-Nasal Set”). Specifically, the Device Under Test (DUT) was placed on a face surrogate and a ventilator (Harvard Apparatus Model 613) simulated breathing while flow controllers set O_2 flow rate and CO_2 concentration. Eight combinations of Input CO_2 (1 ± 0.25%; 5 ± 0.5%), breath rate and tidal volume (12 BPM/500 mL; 20 BPM/300 mL), and O_2 flow rates (1;5 LPM) were tested. A CO_2 monitor (Ohmeda 5250) recorded 16s of data and trials were repeated three times for each condition. Absolute and relative errors between CO_2 Max (i.e., maximum CO_2 over 16s trial) and Input CO_2 were quantified for each DUT: Absolute Error=CO_2 Max¬DUT–InputCO_2; Relative Error=(CO_2 MaxDUT–InputCO_2)/InputCO_2*100%. CO_2 Max errors were compared to the ISO80601-2-55:2018 accuracy specification (± 0.43%vol + 8% of gas level). Unpaired t-tests were used to compare CO_2 Max errors between the two devices for tests with Input CO_2 of 1% and 5%. Leak rate and ability to hold a positive pressure were also tested for three SuperNO$_2$VA Et and Full Face Anesthesia Mask (Ventlab VR5100) samples. The DUT was placed on a surrogate face and sealed with 10 lb of force. Leak rate was determined as the minimum O_2 flow rate to maintain 20 cm H_2O.

RESULTS

The SuperNO$_2$VA Et had lower CO_2 Max error than the Oral-Nasal Set for all eight conditions (Figure 2). For 1% Input CO_2, CO_2 Max errors were -0.12 ± 0.03%vol (-12.2 ± 3.3%, mean ± SD) for the Oral-Nasal Set compared to -0.01 ± 0.02%vol (-1.3 ± 2.2%) for the SuperNO$_2$VA Et (p=0.0005). For 5% Input CO_2, the Oral-Nasal Set dramatically underestimated CO_2 (error = -0.93 ± 0.16%vol (-18.6 ± 3.2%)) while the SuperNO$_2$VA Et had error of -0.08±0.06%vol (-1.5 ± 1.2%) (p<0.0001). At 5% InputCO_2, eight out of 12 trials for the Oral-Nasal Set were outside the ISO error bound while all SuperNO$_2$VA Et trials were within this bound.

Both the SuperNO$_2$VA Et and anesthesia mask successfully held a pressure of 20 cm H_2O for the 5-min trials. The SuperNO$_2$VA Et had a leak rate of 2.0 LPM for all three samples while the anesthesia mask had a mean leak rate of 2.7 (range: 2.5-3.0 LPM) (table 1).

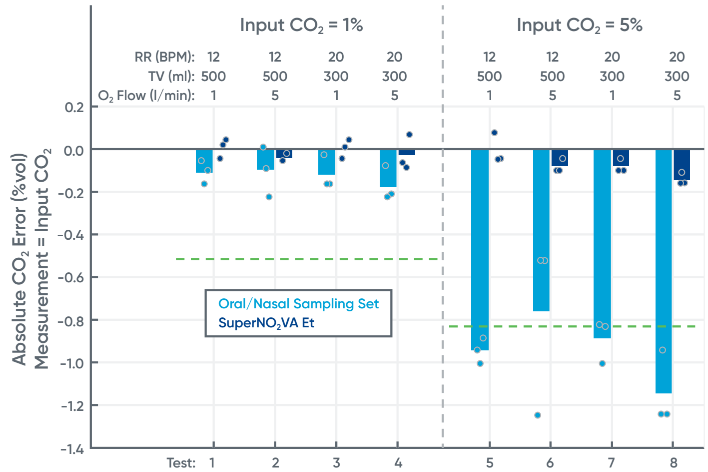

Figure 2: CO_2 Max Error (in % vol) for the eight performance tests for Oral-Nasal Set (orange) and SuperNO$_2$VA Et (blue) Horizontal green dashed line corresponds to the ISO 80601-2-55:2018 error limit (0.51% and 0.83% for 1% and 5% input CO_2 respectively). Filled circles are individual trials and bars represent mean error across the three trials for each test.

CONCLUSIONS

The testing described in this report show that measurements of CO_2 within the SuperNO$_2$VA Et mask are accurate over a range of respiratory rates, tidal volumes, O_2 flows, and CO_2 concentrations and are within the error bounds specified by the International Organization for Standardization. Measurements of CO_2 from within the SuperNO$_2$VA Et were significantly more accurate than measurements taken within the predicate device, an oral-nasal sampling set. Furthermore, the SuperNO$_2$VA Et can maintain a positive pressure of 20 cm H_2O within the mask with a low leak rate of 2.0 LPM.

SuperNO$_2$VA Et is differentiated from other methods of airway management as it can combat upper airway obstruction without sacrificing end tidal measurements. Additionally, it can provide positive pressure to force the airways open, maintaining airway patency. This may help prevent patients from becoming hypoxemic and improve overall outcomes in this patient population.

FLOW LEAK RATE (LPM)

SAMPLE NUMBER	FULL FACE ANESTHESIA MASK	SUPERNO$_2$VA ET
1	3.0	2.0
2	2.5	2.0
3	2.5	2.0
Average	**2.7**	**2.0**

Table 1: Flow leak rate results for Full Face Anesthesia Mask and SuperNO$_2$VA Et.

1. *Yilmaz M, Aydin A, Karasu Z, Et al. Risk factors associated with changes in oxygenation and pulse rate during colonoscopy. Turk J Gastroenterol 2002;13(4):203-8. [PMID: 16378306]*
2. *Qadeer MA, Lopez AR, Dumot JA, Et al. Risk factors for hypoxemia during ambulatory gastrointestinal endoscopy in ASA I-II patients. Dig Dis Sci 2009;54:1035-40. [PMID: 19003534 DOI: 10.1007/s10620-008-0452-2]*
3. *Qadeer MA, Lopez AR, Dumot JA, Et al. Hypoxemia during moderate sedation for gastrointestinal endoscopy: causes and associations. Digestion 2011;84:37-45. [PMID: 21304242 DOI: 10.1159/000321621]*
4. *Lam, Thach, Et al. “Continuous pulse oximetry and capnography monitoring for postoperative respiratory depression and adverse events: a systematic review and meta-analysis.” Anesthesia & Analgesia 125.6 (2017): 2019-2029*
5. *Weaver, Joel. “The latest ASA mandate: CO_2 monitoring for moderate and deep sedation.” Anesthesia progress 58.3 (2011): 111.*
6. *Burton, John H., Et al. “Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices?.” Academic Emergency Medicine 13.5 (2006): 500-504.*
7. *Arakawa H, Kaise M, Sumiyama K, Et al. Does pulse oximetry accurately monitor a patient’s ventilation during sedated endoscopy under oxygen supplementation. Singapore Med J 2013;54(4):212-5. [PMID: 23624448 DOI: 10.11622/smedj.2013075]*
8. *Frasca, D., Et al. “Comparison of acoustic and impedance methods with mask capnometry to assess respiration rate in obese patients recovering from general Anesthesia.” Anesthesia 70.1 (2015): 26-31.*
9. *Morimoto, Keiko, Et al. “Respiratory rate is an inadequate parameter of ventilation in non-intubated sedation.” Odontology 107.2 (2019): 219-222.*
10. *Teng, Wei-Nung, Et al. “Oral capnography is more effective than nasal capnography during sedative upper gastrointestinal endoscopy.” Journal of clinical monitoring and computing 32.2 (2018): 321-326.*
11. *Mehta, PP Et al. Capnographic monitoring in routine EGD and colonoscopy with moderate sedation: a prospective, randomized, controlled trial. The American journal of Gastroenterology 2016;111(3):395-404.*
12. *Mathru, Mali Et al. Magnetic Resonance Imaging of the Upper Airway Effects of Propofol Anesthesia and Nasal Continuous Positive Airway Pressure in Humans. The Journal of the American Society of Anesthesiologists 1996;84(2):273-79*
13. *Chung F, Nagappa M, Singh M, Et al. CPAP in the perioperative setting: evidence of support. Chest 2016;149(2):586-97.*
14. *Schonhofer, B. and S. Sortor-Leger, Equipment needs for noninvasive mechanical ventilation. Eur Respir J, 2002. 20(4): p. 1029-36.*
15. *Zeping Xu. Comparison of oxygenation and ventilation in patients undergoing colonoscopy during anesthesia using the SuperNO$_2$VA nasal PAP ventilation device vs. routine care: A prospective randomized trial.*

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