

The effectiveness of the perioperative use of nasal PAP ventilation using the SuperNO₂VA™ nasal PAP ventilation device/system in multiple clinical scenarios:

A collection of case studies

Introduction

Inadequate oxygenation/ventilation is the most common specific event seen in operating room claims and leads to a risk of hypoxemia which may cause more severe complications, such as brain damage or death.¹ The risk of hypoxemia also remains for patients after surgery, per a study conducted on noncardiac patients.²

This collection of case studies demonstrates the effectiveness of the SuperNO₂VA™ nasal PAP ventilation device/system when used perioperatively during various procedures to reduce the risk of hypoxemia due to upper airway obstruction. These experiences include the following results:

- Patient with possible obstructive sleep apnea underwent a 159-minute procedure for ablation of SVT with deep sedation. His SpO₂ remained 100% during the procedure with use of the SuperNO₂VA nasal PAP ventilation device. Of note, the patient suffered respiratory compromise during a previous procedure and was admitted overnight for treatment and evaluation.
- Upper endoscopies performed on a series of 6 morbidly obese, pre-bariatric surgery patients. With use of the SuperNO₂VA device, zero of the patients experienced hypoxemia and the lowest oxygen saturation recorded was 99%.
- An unanticipated difficult intubation in a morbidly obese patient with obstructive sleep apnea induced with general anesthesia for bariatric surgery. The SuperNO₂VA device was used to provide continuous nasal oxygenation during laryngoscopy. The intubation was further complicated by laryngomalacia. After numerous laryngoscopy attempts and 6.5 minutes of apnea the airway was successfully secured and the patient's oxygen saturation remained at 100% throughout the laryngoscopy attempts.
- A post-abdominal surgery patient in acute respiratory failure was placed on the SuperNO₂VA system. The patient's arterial blood gas improved and was discharged to general ward. In this case, the use of the SuperNO₂VA system prevented the need for re-intubation and therefore, all associated costs of care with intubation and mechanical ventilation.
- A patient with cervical spine surgery and sleep-disordered breathing was extubated directly to the SuperNO₂VA system. After transport to the ICU the SuperNO₂VA™ system was replaced with standard oxygen delivery and the patient experienced acute respiratory distress/insufficiency. The SuperNO₂VA system was replaced on the patient. He returned to normal respiratory parameters and was transported to CT scanner with the SuperNO₂VA™ system.

Abstracts Table of Contents

Use of Nasal CPAP with the SuperNO ₂ VA™ nasal anesthesia mask to alleviate airway obstruction during sedation for ablation of super ventricular tachycardia: A case report	3
The SuperNO ₂ VA™ decreases sedation-related hypoxemia during pre-bariatric surgery EGD in morbidly obese patients: a case series	4
Use of the SuperNO ₂ VA™ during prolonged intubation in a morbidly obese (MO) patient with unexpected difficult airway	5
Using the SuperNO ₂ VA™ device to prevent re-intubation in the PACU: A case report	6
Treating respiratory compromise in the SICU with the SuperNO ₂ VA™ following emergency anterior cervical spine surgery: a case report	7

Use of Nasal CPAP with the SuperNO₂VA™ nasal anesthesia mask to alleviate airway obstruction during sedation for ablation of super ventricular tachycardia: A case report

Presented at the International Anesthesia Research Society (IARS) Annual Meeting 2017

Laebe Lester, MD^A;
Lynette Mark, MD^A

^ADepartment of Anesthesiology & Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA;

Background: Procedural deep sedation can induce upper airway obstruction in patients, especially those with sleep-disordered breathing, like obstructive sleep apnea (OSA).³ This is likely due to the relaxant effects that anesthetic medications have on muscular tone surrounding the upper airway.⁴ Coupled with central hypoventilation, upper airway obstruction contributes substantially to respiratory compromise.

Clinical Case: Dr. Lester presents the case of a 56-year-old, thin woman with multiple comorbidities (Crohn's disease, Hypertension, Asthma) undergoing an ablation procedure for recurrent SVT. Of note, this patient experienced respiratory insufficiency during her previous visit for the same procedure, for which an extended recovery stay was necessary. She also has a history of snoring for which a sleep study was performed, but not followed up on. Given her likely history of sleep-disordered breathing and previous respiratory difficulty during her last procedure, Dr. Lester used the SuperNO₂VA nasal PAP ventilation device for respiratory support during deep sedation for SVT ablation.

The SuperNO₂VA device was placed for preoxygenation prior to the start of deep sedation. Sedation was achieved with propofol infusion and intermittent supplementation with fentanyl. Soon after the propofol infusion began, the patient experienced upper airway obstruction. The SuperNO₂VA device was tightened using the head strap to create an

air-tight seal, after which continuous positive airway pressure (CPAP) was engaged utilizing the anesthesia machine's APL-valve and the airway obstruction alleviated. Oxygen saturation remained 100% throughout the 159-minute procedure without events. Post-operatively, oxygen was weaned to room air and the patient discharged to home.

"This case illustrates that nasal positive airway pressure with the SuperNO₂VA during deep sedation can maintain airway patency to combat upper airway obstruction."

Discussion: This case illustrates that nasal positive airway pressure with the SuperNO₂VA during deep sedation can maintain airway patency to combat upper airway obstruction. Nasal CPAP is a reported treatment for atelectasis⁵ and as such, Dr. Lester hypothesizes that nasal PAP via the SuperNO₂VA device may further improve oxygenation and ventilation by maintaining lower airway patency and minimizing ventilation-perfusion mismatch.

The SuperNO₂VA™ decreases sedation-related hypoxemia during pre-bariatric surgery EGD in morbidly obese patients: a case series

Presented at the Society of Ambulatory Anesthesia (SAMBA) Annual Meeting 2017

**Cheguevara Afaneh MD FACS^B,
Steven Cataldo MD^{C*}, Rachel
Kozinn BS^D**

^BDepartment of Surgery, Weill Cornell Medical College, New York, NY; ^CVyair Medical, Mettawa, IL; ^DUniversity of Arizona College of Medicine, Phoenix, AZ

“Dr. Afaneh describes the successful use of the SuperNO₂VA nasal PAP device to effectively oxygenate and ventilate 6 obese patients undergoing pre-bariatric surgery EGD.”

Background: Prior to bariatric surgery, it is becoming routine for esophagogastroduodenoscopy (EGD) procedures to be performed to better direct the current surgical plan. Hypoxemia in these morbidly obese patients occurs in up to 42% of patients, with increased risk in those with obstructive sleep apnea.⁶⁻⁸ The SuperNO₂VA nasal PAP device delivers both oxygen and nasal positive pressure ventilation (PPV) while allowing for access to the oral cavity during EGD, combatting upper airway obstruction and hypoventilation.

Clinical Cases: Retrospectively, six consecutive patients at NY Presbyterian Weill Cornell Medical Center undergoing pre-bariatric surgery EGD under deep sedation were studied while using the SuperNO₂VA nasal PAP ventilation device connected to a Mapleson circuit. Basic demographic data and history were collected, along with data for the following sedation-related complications: hypoxemia ($SpO_2 < 90\%$ for greater than 15 seconds) number of procedure interruptions, early procedure termination, and the use of a nasal airway.

The average age and weight of the six patients were 40 years and 138 kg respectively, four of which had documented obstructive sleep apnea with home CPAP use. Zero patients experienced hypoxemia with the lowest oxygen saturation across all six patients being 99%. There were no procedural interruptions or terminations and none of the patients required a nasal airway.

Conclusion: Morbidly obese patients undergoing deep sedation for EGD are at high risk for hypoxemia. Positive pressure ventilation is effective at maintaining upper airway patency and providing ventilatory support, however, it has historically been difficult to provide PPV and maintain access to the oral cavity. Dr. Afaneh describes the successful use of the SuperNO₂VA nasal PAP device to effectively oxygenate and ventilate 6 obese patients undergoing pre-bariatric surgery EGD. Further study is necessary to fully elucidate its value in these patients and others.

Use of the SuperNO₂VA™ during prolonged intubation in a morbidly obese (MO) patient with unexpected difficult airway

Presented at Society of Airway Management (SAM) Annual Meeting 2017

Catherine Rim, M.D.^E, Jon D. Samuels, M.D.^E

^EDepartment of Anesthesiology, Weill Cornell Medical College, New York, NY

Background: Airway management for the morbidly obese patient is challenging as the risk of oxygen desaturation during laryngoscopy is increased secondary to poor functional residual capacity and increased oxygen consumption. Hypoxia is the most common cause of death during airway management, with 35% of closed claims published by the American Society of Anesthesiologists occurring in obese patients.⁹ Apneic oxygenation has been shown to improve the apnea time to desaturation but is difficult to employ in the operating room where mask ventilation precedes laryngoscopy, and typical apneic oxygenation devices disrupt proper mask seal.¹⁰

Clinical Case: Drs. Rim and Samuels at NY Presbyterian Weill Cornell Medical Center presents a 35-year-old morbidly obese male patient with obstructive sleep apnea for sleeve gastrectomy under general anesthesia. Airway exam was significant for large neck circumference and full beard. The SuperNO₂VA™ nasal PAP device was placed prior to anesthesia for preoxygenation; intravenous induction followed by successful mask ventilation was uneventful. High flow nasal oxygen was incorporated with an additional 15 L/min of oxygen flow via the supplemental oxygen port on the SuperNO₂VA device connected to the auxiliary oxygen source on the anesthesia machine using standard oxygen tubing.

Video laryngoscopy revealed laryngomalacia. The trachea was eventually intubated atraumatically with difficulty after multiple attempts and external cricoid manipulation.

“Due to its unique design, the SuperNO₂VA device does not obstruct the clinician’s access to the oral cavity during laryngoscopy and delivers high flow nasal oxygen via its supplemental oxygen port, allowing for up to 30 L/min oxygen.”

The length of apnea time was 390 seconds and the patient’s oxygen saturation remained 100% throughout the procedure without the need to re-initiate mask ventilation.

Discussion: This case illustrates the utility of the SuperNO₂VA nasal PAP ventilation device as an apneic oxygenation device during difficult endotracheal intubation. Due to its unique design, the SuperNO₂VA device does not obstruct the clinician’s access to the oral cavity during laryngoscopy and delivers high flow nasal oxygen via its supplemental oxygen port, allowing for up to 30 L/min oxygen. Dr. Samuel’s case presentation shows that high-risk patients presenting with unexpected difficult airways may be safely treated with the SuperNO₂VA nasal PAP device.

Using the SuperNO₂VA™ device to prevent re-intubation in the PACU: A case report

Steven Cataldo MD F.G*,
Michael Pedro MD F.G*

^FKings County Medical Center, Brooklyn, NY;

^GVyaire Medical, Mettawa, IL

Background: Respiratory events in the PACU occur in up to 21% of patients, and include hypoxemia, hypoventilation, and upper airway obstruction.¹¹ These events can be attributed commonly to residual neuromuscular blockade

“The SuperNO₂VA nasal PAP ventilation system allows for PPV and ventilatory support without the need for capital equipment or specialized personnel. It is immediately available for use and may improve recovery of patients at high-risk for respiratory compromise while providing significant cost savings compared to current modalities.”

and opioid-induced respiratory depression.¹² Many complications may be avoided with the use of continuous positive airway pressure (CPAP) but it is used on fewer than 20% of high-risk patients, likely secondary to poor availability of equipment and difficulty in coordinating respiratory consultants.¹³

The SuperNO₂VA nasal PAP ventilation system may allow for creating positive pressure ventilation

(PPV) non-invasively while obviating the need for capital equipment and respiratory consultants.

Clinical Case: A 59-year-old female with history of cancer, coronary artery disease and hypertension underwent a right laparoscopic hemi-colectomy under general anesthesia. The procedure was uneventful except for the need to administer naloxone (Narcan) immediately prior to extubation. She was transported to the post-anesthesia care unit (PACU) with a nasopharyngeal airway and supplemental oxygen. While in recovery, the patient became lethargic secondary to respiratory depression. Conventional CPAP was not immediately available; thus bag-mask-ventilation was initiated; initial arterial blood gas showed hypercarbia (PaCO₂ 94.6 mmHg). The SuperNO₂VA nasal PAP ventilation system was placed on the patient and used to support spontaneous ventilation. Respiratory mechanics improved and care was continued in the PACU. One hour later, repeat arterial blood gas showed PaCO₂ 51 mmHg, much improved from earlier, with mental status returning to normal. Recovery was otherwise uneventful and patient tolerated weaning from PPV and ultimate discharge from the PACU to general ward.

Discussion: Drs. Cataldo and Pedro present a case where a patient status post major abdominal surgery experienced post-operative respiratory compromise in the PACU, necessitating rescue ventilation and non-invasive ventilator support. Given the acuity of the situation, unless conventional CPAP is immediately available, support of ventilation with endotracheal intubation and mechanical ventilation is appropriate. Re-intubation and mechanical ventilation in the PACU comes at a high cost and in most institutions, requires admission to the intensive care unit. The SuperNO₂VA nasal PAP ventilation system allows for PPV and ventilatory support without the need for capital equipment or specialized personnel. It is immediately available for use and may improve recovery of patients at high-risk for respiratory compromise while providing significant cost savings compared to current modalities.

Treating respiratory compromise in the SICU with the SuperNO₂VA™ following emergency anterior cervical spine surgery: a case report

Presented at the International Anesthesia Research Society (IARS) Annual Meeting 2017

Haitham Ibrahim MD^H, Irene Osborn MD^H, Steven Cataldo MD^{I*}

^HDepartment of Anesthesiology, Montefiore Medical Center, Bronx NY; ^IVyaire Medical, Mettawa, IL

Background: Airway management and post-operative pulmonary complications (PPC) following major neck surgery is a challenge faced by most institutions. The incidence of PPCs can range between 9-44% in these patients, with associated risks for increased hospital stays and mortality.¹⁴⁻¹⁵ Avoiding post-operative mechanical ventilation remains advantageous to reduce overall hospital costs and Ventilator Associated Events (VAE). However, 2-41% of these patients experience respiratory compromise necessitating re-intubation and prolonged mechanical ventilation.¹⁶⁻¹⁷ Secondary to normal post-operative anatomic changes and surgical swelling, laryngoscopy, endotracheal intubation, and front of neck access may be difficult.

Elective post-operative continuous positive airway pressure (CPAP) has demonstrated efficacy in reducing PPCs, however, it is used on <20% of high-risk patients because of constraints in cost, availability, and clinical resources.^{13,18} The SuperNO₂VA⁻ nasal PAP ventilation system may offer a cost-efficient alternative to conventional CPAP for these patients, providing nasal positive pressure ventilation (PPV) to maintain upper airway patency and provide ventilatory support post-operatively.

Clinical Case: Drs. Ibrahim and Osborn present the case of a 42-year-old male with unknown history status post anterior cervical discectomy and fusion with corpectomy following an acute trauma. During emergence, to avoid bucking, the patient was extubated under a deep plane of anesthesia after meeting extubation criteria save for following commands. He was extubated directly to nasal PPV with the SuperNO₂VA⁻ nasal PAP ventilation system. SpO₂ remained 100%, there were no signs of upper airway obstruction, and he was transported to the SICU without events.

"This case is an example of how the SuperNO²VA nasal PAP ventilation system improved both upper airway patency and oxygenation in the setting of hypoxemic respiratory insufficiency."

Due to unfamiliarity with the SuperNO₂VA nasal PAP ventilation system, the nursing staff replaced it with a conventional nasal cannula, after which the patient experienced a partial upper airway obstruction and respiratory insufficiency. SpO₂ dropped to 90%, with an associated increase in respiratory rate and worsened upper airway obstruction. Prior to placing the SuperNO₂VA nasal PAP ventilation system back on the patient, an arterial blood gas (ABG) was drawn. After a few minutes the patient's respiratory status improved and ABG was repeated.

Arterial Blood Gas	PaO ₂	PaCO ₂	pH	SpO ₂
Oxygen nasal cannula	95 mmHg	30 mm Hg	7.52	90%
7 mins after SuperNO ₂ VA replaced on patient	315 mmHg	40 mmHg	7.43	100%

60 minutes later, the patient was transported for CT evaluation of acute stroke. The SuperNO₂VA nasal PAP ventilation system was continued throughout the transport and the SpO₂ did not drop below 100%. The CT scan was negative for stroke and after 11 hours, the patient's mental status returned to normal. PPV via the SuperNO₂VA was removed and replaced with an oxygen nasal cannula without events.

Discussion: This case is an example of how the SuperNO₂VA nasal PAP ventilation system improved both upper airway patency and oxygenation in the setting of hypoxemic respiratory insufficiency. As it delivers both positive airway pressure and oxygen from any gas source, it was employed during patient transport and during the CT procedure. As used in this case, the SuperNO₂VA nasal PAP ventilation system is a low cost, easy to use positive pressure system without the need for additional equipment.



REFERENCES

1. Bhananker S et al. Injury and Liability Associated with Monitored Anesthesia Care: A Closed Claims Analysis. *Anesthesiology* 2006; 104:228-34.
2. Zhuo S et al. Postoperative Hypoxemia Is Common and Persistent: A Prospective Blinded Observational Study. *Anesth Analg.* 2015 September; 121(3): 709-715
3. Hillman D et al. The upper airway during anaesthesia. *Br J Anaesth* 2003; 91: 31±9.
4. Mathru M et al. Magnetic Resonance Imaging of the Upper Airway. *Anesthesiology* 1996. 84:273-279.
5. Duncan R et al. Nasal Continuous Positive Airway Pressure in Atelectasis. *CHEST Journal.* October 1987. Vol. 92, Issue 4, Pgs 621-624.
6. Coté GA, Hovis RM, Ansstas MA, Waldbaum L et al. Incidence of sedation-related complications with propofol use during advanced endoscopic procedures. *Clinical Gastroenterology and Hepatology* 2010; 8: 137-42.
7. Deitch K et al. Does End Tidal CO₂ Monitoring During Emergency Department Procedural Sedation and Analgesia With Propofol Decrease the Incidence of Hypoxic Events? A Randomized, Controlled Trial. *Annals of Emergency Medicine* 2010;55(3):258-64
8. Friedrich-Rust, M et al. Capnographic monitoring of propofol-based sedation during colonoscopy. *Endoscopy* 2014;46(3): 236-244
9. Cook TM, MacDougall-Davis SR. Complications and failure of airway management. *British Journal of Anesthesia.* 2012;109(s1):i68-85.
10. Patel A and AR Nouraei. Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE): a physiological method of increasing apnoea time in patients with difficult airways. *Anaesthesia* 2015;70:323-9.
11. Sun Z et al. Postoperative Hypoxemia Is Common and Persistent: A Prospective Blinded Observational Study. *Anesth Analg.* 2015 September ; 121(3): 709-715
12. Rose DK et al. Critical Respiratory Events in Postanesthesia Care Unit: Patient, Surgical, and Aneesthetic Factors. *Anesthesiology.* 1994 August; 81:410-418.
13. Böhner H et al. Prophylactic nasal continuous positive airway pressure after major vascular surgery: results of a prospective randomized trial. *Langenbeck's Archives of Surgery* 2002; 387(1):21-6.
14. Petrar S, et al. Pulmonary complications after major head and neck surgery: A retrospective cohort study. *Laryngoscope.* 2012;122(5):1057-1061.
15. Imposti et al. Risk factors for pulmonary complications after spine surgery. 2010. Vol 1, Issue 2. pp 26-33.
16. Lee M, et al. Risk Factors for Medical Complication after Cervical Spine Surgery: a multivariate analysis of 582 patients. *Spine.* 2013; 38(3):223-8.
17. Sagi HC, et al. Spine. Airway Complications Associated With Surgery on the Anterior Cervical Spine. May 2002;27(9):949-953.
18. Lawrence VA, et al. Strategies To Reduce Postoperative Pulmonary Complications after Noncardiothoracic Surgery: Systematic Review for the American College of Physicians *Ann Intern Med.* April 2006;144:596-608.

*Dr. Cataldo and Dr. Pedro currently serve as Medical Directors for Vyairé Medical, Inc.

GLOBAL HEADQUARTERS

Vyairé Medical, Inc.
26125 North Riverwoods Blvd
Mettawa, IL 60045, USA

vyaire.com

 For U.S. distribution only

© 2018 Vyairé. Vyairé, the Vyairé Logo and SuperNO₂VA™ are trademarks of Vyairé Medical, Inc. CF/801/18/0062 (0618)