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SuperNO₂VA™ nasal PAP ventilation system Playbook

There are six steps to successfully converting a customer to our SuperNO₂VA™ nasal PAP ventilation system.

- Understanding Customer Areas of Care
- Addressing Decision Maker Needs
- Understanding Product & Competition
- Product Demonstration
- Marketing Collateral
- Clinical Evaluation

vyaire™ MEDICAL

Understanding Customer Areas of Care

To be successful, approval is required from several key departments before the product is presented to a Value Analysis Committee (VAC). We have included some information about various departments in order to reinforce the problems associated with respiratory compromise.

ACUTE CARE & TRAUMA SURGERY | BARIATRIC & GI SURGERY | CARDIAC SURGERY | COLORECTAL SURGERY

HEPATO-PANCREATO-BILIARY AND GASTROINTESTINAL | STAND ALONE SURGERY CENTERS/ ENDO CENTERS

SURGICAL ONCOLOGY | THORACIC SURGERY | VASCULAR SURGERY | NEURO-SURGERY

ACUTE CARE & TRAUMA SURGERY

Injury is one of the leading causes of death and accounts for significant disability, regardless of race, gender or economic status. When seconds count, the specialized care offered in this department can mean the difference between life and death.

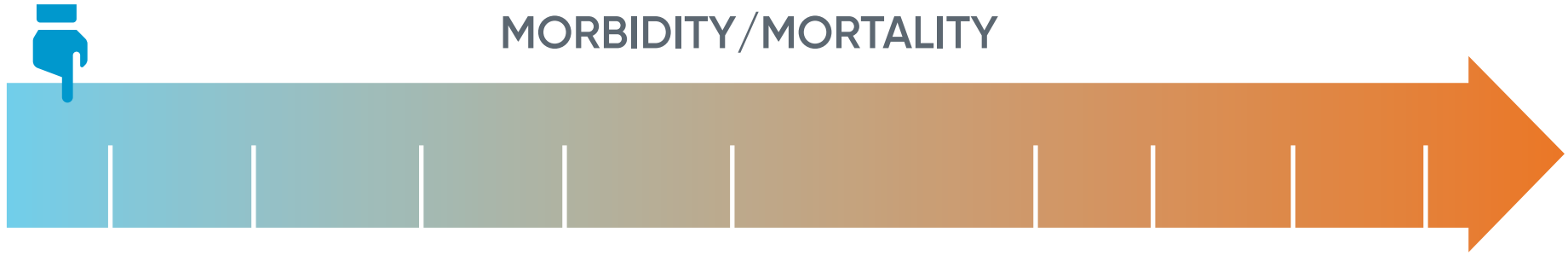
INSIDER TIP:

Identify a champion — usually an anesthesiologist, ideally department head

Addressing Decision Maker Needs

Most anesthesiologists are likely aware of the issues around Respiratory Compromise.

Hypoventilation and upper airway obstruction are the two mechanisms that result in a life-threatening complication known as Respiratory Compromise (RC). Respiratory Compromise is a continuum of respiratory complications that consists of minor complications such as oxygen desaturation to life-threatening complications such as respiratory failure.



It is important to know what the incidence is of each individual complication. For high-risk patients, which is defined as a patient with either morbid obesity, obstructive sleep apnea, heart failure, or lung failure, the incidence of respiratory compromise following general anesthesia is:

Respiratory Complications	Incidence
Hypoxemia	25-40%
Atelectasis	20%
Pneumonia	2.4%
Respiratory insufficiency	6.5%
Respiratory failure	5.1%

Addressing Decision Maker Needs

SuperNO₂VA has been shown to decrease the incident of hypoxemia by relieving airway obstruction and increasing oxygenation.

Hypoxemia is a step in the continuum of respiratory compromise. Reducing the incidents of hypoxemia will reduce the incidents of other respiratory complications that come after it.

Understanding Product & Competition

SuperNO₂VA offers more clinical features translating to considerable benefits over any other method of oxygen delivery and ventilation for use in intubation and sedation situations.

Competitive advantage	Nasal cannula	High Flow nasal cannula	Anesthesia mask	Nasal CPAP	SuperNO₂VA™
Oral access	●	●	○	●	●
Passive oxygenation	●	●	●	●	●
High flow O_2	○	●	○	○	●
Rescue ventilation/RC	○	○	●	○	●
Additional capital equipment	Not required	●	Not required	●	Not required

THRIVE and HFNC versus SuperNO₂VA™ System*

HFNC Ineffective in the setting of:

- Upper Airway Obstruction
- Obesity (BMI > 30)
- Hypoxemia/ Desaturation

*For the international market

SuperNO₂VA™:

Preventative – stents open the airway to maintain apneic ventilation

Therapeutic – by manipulating the head or occluding the oral cavity oxygen can be driven with PEEP into the lungs, creating ventilation preventing CO_2 accumulation

Rescue – if required complete ventilation can be done via the SuperNO₂VA

SuperNO₂VA™:

Clinically Superior • Lower cost per patient
No additional equipment

Understanding Product & Competition

Either the customer is already aware of the issue of respiratory compromise and is using their own solution or you've convinced them SuperNO2VA is worth trialing. The key to success here is understand what the other options are and how **SuperNO2VA** is superior to what they are already using.

Clinical Solutions for Respiratory Compromise:

Passive Oxygenation Devices

A passive oxygenating device is any device that provides a continuous flow of oxygen. Oxygen delivery here depends on the patient breathing spontaneously. These devices are not capable of producing positive pressure and delivering ventilatory support. Examples of oxygen devices are the nasal cannula, supplemental oxygen mask and the POM mask.

Understanding Product & Competition

Respiratory compromise is a result of both sedation-induced upper airway obstruction and central hypoventilation.

High flow nasal cannula

It is an open system oxygenation device that can provide up to 60L/min of oxygen to the patient via nasal cannula. Despite being an open system, at such high flows it is able to provide a mild continuous positive airway pressure (CPAP) between 2-5cmH_2O. In contrast, because of the extremely high flows, it cannot measure EtCO_2 as the CO_2 is washed out (ie: diluted). It cannot provide pressures high enough to reliably relieve upper airway obstruction or perform positive pressure ventilation.

Non-invasive ventilation (NIV) Devices

The lungs must be actively ventilated using positive pressure. The goal is to inflate the lungs and allow for deflation, whereby gas exchange will allow for the delivery of oxygen to the blood and the removal of carbon dioxide. A ventilation device is any device that creates a closed-sealed system, which allows positive pressure to be generated within the airway, stent open an obstruction and actively inflate the lungs. Examples of ventilation devices are the **SuperNO₂VA**, an anesthesia mask, and a CPAP mask.

Product Demonstration

There are several methods to explain how **SuperNO₂VA** is used.

1. Use the video below to explain how **SuperNO₂VA** works.
2. Help facilitate peer-to-peer conversation by enrolling the customer in DocMatters/**SuperNO₂VA** community.
    - This is a clinician-led community of users and potential users or **SuperNO₂VA**, that can discuss or ask questions related directly to **SuperNO₂VA**
    - To sign up go to: [www.docmatter.com/SuperNO₂VA](www.docmatter.com/SuperNO2VA)

WATCH ONLINE [Click image above to watch at www.vyaire.com](www.vyaire.com)

Product Demonstration

The goal of any demonstration is to advance to the next stage of the sales process.

- Product demonstrations should be concise.
- They should focus only on the key customer need you are trying to meet.
- The primary area of focus for the demonstration is creating a tight seal.

The best person to demonstrate on is yourself.

NOTE: Practice at home before you do this.

Product Demonstration

Setting up the SuperNO₂VA nasal PAP ventilation system

1. Slide the head strap around your head. Hold the mask in your dominant hand. Use the other hand to run the strap around your head and hook into the cleat on the other side.
2. Place the **SuperNO₂VA** mask over your nose and ensure the lower seal is between the upper lip and nose.
3. Demonstrate the flat spot on the mask, just at your nose, which the clinician can use to push down.

NOTE: To ensure an air-tight seal, apply firm downward pressure to the mask and use the head strap to secure in place. When adjusting the strap, pull perpendicular (straight away from your face rather than off to the side).

Show a few trouble shooting maneuvers: manual mouth closure, slight head flexion and sub-mental pressure.

4. Completely close APL valve on the hyperinflation bag and firmly attach it to the **SuperNO₂VA** device. [Remember to place your hand or finger on the oxygen flowmeter port.]
5. The reservoir bag should completely fill within 4–5 breaths. [Take deep breaths through your mouth and breath out through your nose.]

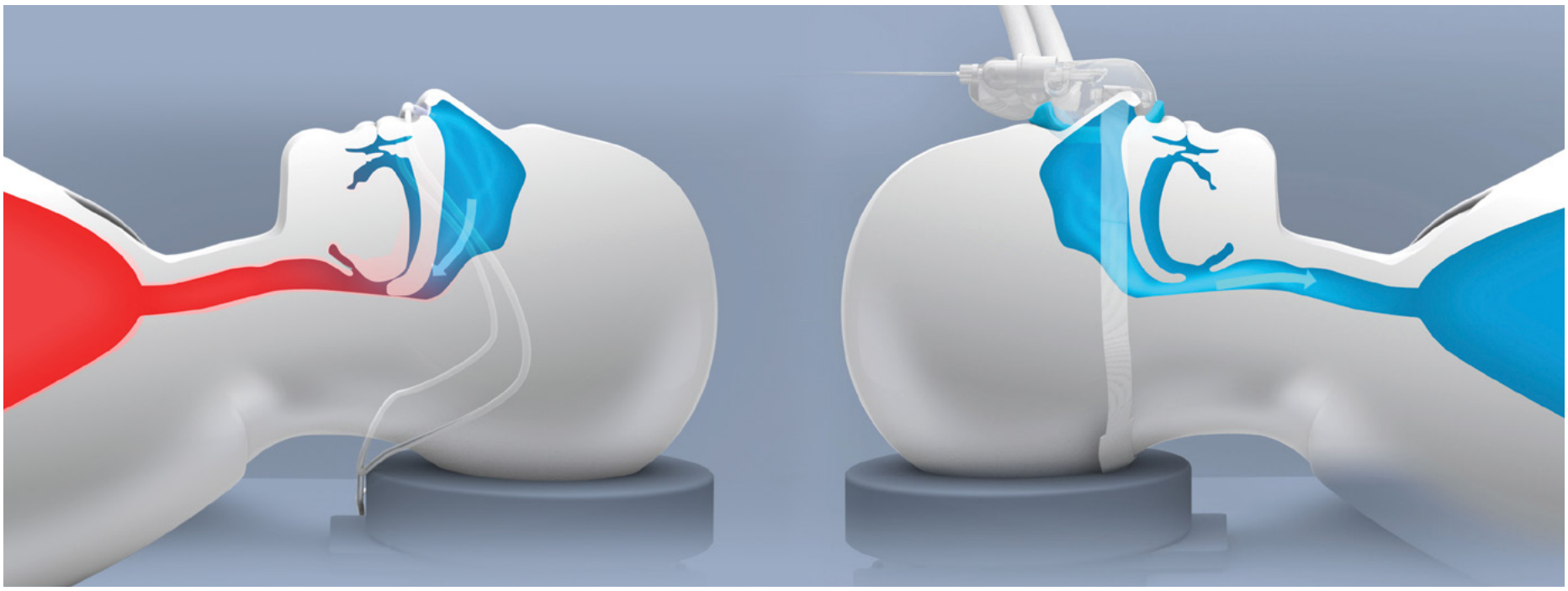
Visualize reservoir bag completely inflating and staying inflated to confirm positive pressure is being delivered. Once the bag is inflated it is possible to augment ventilation (squeeze the bag).

Discuss connect hyperinflation bag's oxygen tubing to the oxygen flowmeter/regulator. Turn on the oxygen tank's flow to 10 LPM.

Marketing Collateral

SuperNO₂VA device was designed by two anesthesiologist to reduce the incidence of hypoxemia.

SuperNO₂VA uses nasal positive airway pressure to pre-oxygenate, relieve upper airway obstruction due to decreased level of consciousness, maintain ventilation, rescue ventilate, ease access for intra-oral procedures, and be used peri-operatively.



Download International Version

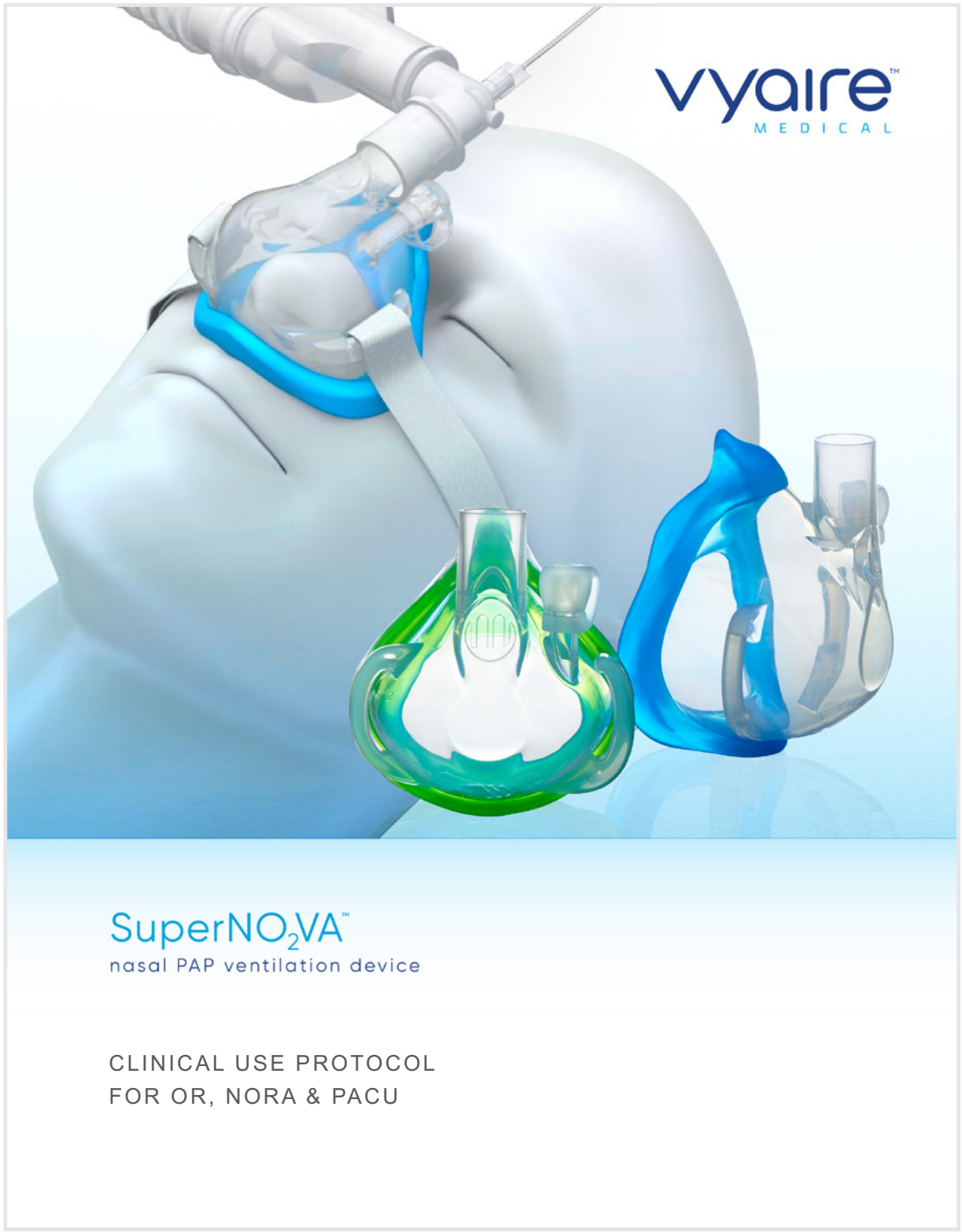
Download US Version

Marketing Collateral

SuperNO₂VA clinical protocol is authored by Vyaire Medical Affairs to offer guidelines for the use of the **SuperNO₂VA nasal PAP ventilation device** in the operating room (OR), non-operating room anesthesia care areas (NORA), and the post-anesthesia care unit (PACU).

This protocol is intended to be used as an example for the perioperative use of nasal positive airway pressure that includes the **SuperNO₂VA nasal PAP ventilation device**.

SuperNO₂VA nasal PAP ventilation device is intended for short term use (<24 hours) on adult patients (>30 kg).



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Marketing Collateral

Check out our publications!

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Nasal Ventilation Is More Effective than Combined Oral–Nasal Ventilation during Induction of General Anesthesia in Adult Subjects

Yafen Liang, M.D., William R. Kimball, M.D., Ph.D.,† Robert M. Kacmarek, Ph.D.,‡ Warren M. Zapol, M.D.,§ Yandong Jiang, M.D., Ph.D.†*

Background: **The authors hypothesized that nasal mask ventilation may be more effective than combined oral–nasal mask ventilation during induction of general anesthesia. They tested this hypothesis by comparing the volume of carbon dioxide removed per breath with nasal *versus* combined oral–nasal mask ventilation in nonparalyzed, apneic, adult subjects during induction of general anesthesia.**

Methods: **Fifteen adult subjects receiving general anesthesia were ventilated first with a combined oral–nasal mask and then with only a nasal mask. The patient's head was maintained in a neutral position, without head extension or lower jaw thrust. Respiratory parameters were recorded simultaneously from both the nasal and oral masks regardless of ventilation approach.**

Results: **The volume of carbon dioxide removed per breath during nasal mask ventilation (median, 5.0 ml; interquartile range, 3.4–8.8 ml) was significantly larger than that during combined oral–nasal mask ventilation (median, 0.0 ml; interquartile range, 0.0–0.4 ml; $P = 0.001$); even the peak inspiratory airway pressure during nasal ventilation (16.7 ± 2.7 cm H_2O) was lower than that during combined oral–nasal ventilation (24.5 ± 4.7 cm H_2O; $P = 0.002$). The expiratory tidal volume during nasal ventilation (259.8 ± 134.2 ml) was also larger than that during combined oral–nasal ventilation (98.9 ± 103.4 ml; $P = 0.003$).**

Conclusions: **Nasal mask ventilation was more effective than combined oral–nasal mask ventilation in apneic, nonparalyzed, adult subjects during induction of general anesthesia. The authors suggest that nasal mask ventilation, rather than full facemask ventilation, be considered during induction of anesthesia.**

MASK ventilation is an essential component of airway management either as the primary technique during general anesthesia or only during the induction period. In each scenario, upper airway obstruction (UAO) is frequently encountered.[1] To overcome UAO, an oral or nasal airway device is frequently inserted. However, even when these devices are used, difficult mask ventilation (DMV) still occurs in 1.4–7.8% of patients.[2–4] Occasionally, although the patient can be ventilated with a full facemask, very high airway pressure is required. Such high pressure may lead to gastric insufflation through the partially obstructed upper airway and may precipitate vomiting and subsequent aspiration.[5] Therefore, the ability to successfully ventilate patients with low airway pressure using a bag–mask system is essential for the practice of anesthesia.

The exact pathogenesis of DMV is not fully understood, but UAO plays an essential role, because risk factors related to DMV include older age, obesity, a history of snoring, and a history of sleep apnea.[2–4] It has been recognized that mechanisms of UAO during sleep and anesthesia share similarities.[6] The reduction in upper airway muscle tone and the effect of gravity on the tongue and soft palate in the supine position are key factors causing upper airway collapse during both sleep and general anesthesia.[6,7] Nasal continuous positive airway pressure (CPAP) is used to successfully treat obstructive sleep apnea,[8] and studies using magnetic resonance imaging have shown that nasal CPAP decreases anesthesia-induced upper airway narrowing in both adults and infants.[9,10] Therefore, we hypothesized that nasal mask ventilation might provide a more effective ventilation than combined oral–nasal mask ventilation during induction of general anesthesia. We tested this hypothesis by comparing the volume of carbon dioxide removed per breath with nasal *versus* combined oral–nasal mask ventilation in nonparalyzed, apneic, adult subjects during induction of general anesthesia.

Materials and Methods

The study was approved by the Massachusetts General Hospital Human Research Committee, Boston, Massachusetts, and written informed consent was obtained from all study subjects.

Patients

A total of 17 subjects older than 18 yr were recruited from the inpatient main operating rooms of the Massachusetts General Hospital. All recruited subjects required general anesthesia and had a preoperative physical status of I or II as defined by the American Society of Anesthesiologists. In addition, we ensured that all subjects, while awake, were able to breathe through both their nose and mouth without using accessory respira-

* Fellow, † Assistant Professor, ‡ Professor, § Professor and Chairman.

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Francesca Dimou. Nasal positive pressure with the SuperNO2VA device decreases sedation-related hypoxemia during pre-bariatric surgery EGD. Surgical Endoscopy 2019.

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ORIGINAL ARTICLE

Comparison of a simplified nasal continuous positive airways pressure device with nasal cannula in obese patients undergoing colonoscopy during deep sedation

A randomised clinical trial

Yiping Bai*, Zeping Xu*, Meera Chandrashekar, Paul J. St Jacques, Yafen Liang, Yandong Jiang and Koffi Kla

BACKGROUND Continuous positive airways pressure (CPAP) with a CPAP machine and mask has been shown to be more effective at minimising hypoxaemia than other devices under deep sedation. However, the efficacy of a new and simple CPAP device for spontaneously breathing obese patients during colonoscopy is unknown.

OBJECTIVE We hypothesised that oxygenation and ventilation in obese patients under deep sedation during colonoscopy using CPAP via a new nasal mask (SuperNO2VA) would be better than routine care with oxygen supplementation via a nasal cannula.

DESIGN Randomised study.

SETTING Single-centre, June 2017 to October 2017.

PATIENTS A total of 174 patients were enrolled and randomly assigned to Mask group or Control group. Thirty-eight patients were excluded and data from 136 patients underwent final analysis.

INTERVENTION Patients in the Mask group were provided with nasal CPAP (10 cmH_2O) at an oxygen flow rate of 15 l min^{-1}. In the Control group, patients were given oxygen via a nasal cannula at a flow rate of 5 l min^{-1}.

MAIN OUTCOME MEASURES The primary outcome was elapsed time from anaesthesia induction to the first airway intervention.

RESULTS The elapsed time from anaesthesia induction to the first airway intervention was 19 ± 10 min in the Mask group (n=63) vs. 10 ± 12 min in the Control group (n=73, $P < 0.001$). In all, 87.5% (56/64) of patients achieved the target CPAP value. More patients in the Control group (63%) received airway intervention than in the Mask group (22%) ($P < 0.001$). Hypoxaemia (pulse oximeter oxygen saturation, $SpO_2 < 90\%$) occurred more frequently in the Control group (22%) than in the Mask group (5%) ($P = 0.004$). Minute ventilation$_{Postinduction}$/minute ventilation$_{Baseline}$ and minute ventilation$_{Procedure\text{-}end}$/minute ventilation$_{Baseline}$ was lower in the Control group than in the Mask group ($P = 0.007$ and 0.001, respectively).

CONCLUSION Application of a nasal mask at a target CPAP of 10 cmH_2O improves ventilation and decreases the frequency and severity of hypoxaemia.

TRIAL REGISTRATION NCT03139448, registered at ClinicalTrials.gov.

Published online 15 July 2019

Introduction

Colonoscopy as a routine screening procedure has been incorporated and frequently utilised within the healthcare system.[1–3] Sedation with spontaneous breathing via a natural airway is commonly used during gastrointestinal endoscopic procedures.[4] However, hypoxaemia and/or hypercapnia frequently occur during colonoscopy

* Yiping Bai and Zeping Xu contributed equally to the article.

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Zeping Xu. Comparison of oxygenation and ventilation in patients undergoing colonoscopy during anesthesia using the SuperNO2VA™ nasal PAP ventilation device vs. routine care: A prospective randomized trial. European Journal of Anaesthesiology 2019.

Marketing Collateral

Annual cost of respiratory compromise is a concern for all hospitals. Respiratory Compromise can run a hospital as much as $10M USD per year. For specific departments like GI or orthopedic surgery the cost can be approximately $1.6M USD. Review the **SuperNO2VA** Value Tool with each hospital to show a customized cost analysis of how much **SuperNO2VA** can decrease respiratory compromising events.

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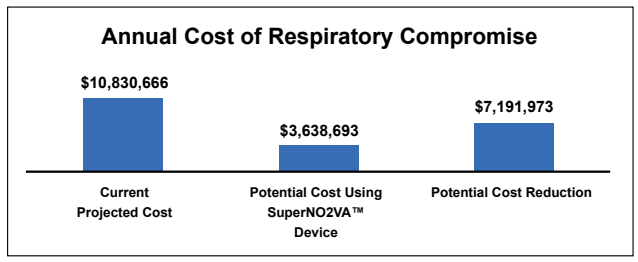
VALUE ANALYSIS TOOL

Rev 2.3 • November 2017

SuperNO2VA™
Airway Management Platform

Facility Name:
Address:
Name of Contact:
Title:
Email Address:
Phone:
Vyaire Representative:
Other Notes:



Description of Complication	*Current Cost (per Incident)*
PPC3: Respiratory Failure (without Ventilation)[1]	***$7,109***
PPC4: Respiratory Failure (with Ventilation)[1]	***$27,134***
PPC5: Pneumonia and Other Lung Infections[1]	***$16,901***
PPC6: Other Pulmonary Complications[1]	***$11,566***
Actelectasis	***$396***
[1] Citations to Cost Study Data is provided on the Incidence and Citations[1] Tab	

Print Value Analysis Tool Output to PDF

Vyaire Components	
Cost of Vyaire SuperNO2VA™ Device (per procedure)	$25
***Potential % reduction in RC events[2]**	*67.3%*
*[1] Citations to Cost Study Data is provided on the Incidence and Citations[1] Tab**	
**Numbers are based on results of nasal oxygenation studies generally; the studies did ot use the SuperNOVA mask specifically.*	

Type of Procedure	*Volume (per Year)*	**Source of Data**	*Additional Comments*
All Procedures (Inpatient + Outpatient)	***26,000***	US News & World Report 2016 Annual Hospital Rankings	
MAC/Deep Sedation Procedures (47% of All Procedures[2])	***12,220***		
[2] Frequency of MAC/Deep Sedation as a % of Total Procedures per Nayman Study (2011)			
Med/High Risk for PPC (30%)	***3666***		

Marketing Collateral

SuperNO₂VA has a range of clinical papers and resources to help explain the benefits of **SuperNO₂VA** to potential customers.

All materials WILL BE AVAILABLE on internal libraries.

International click here

US: salesforce.com, when you search files: **SuperNO₂VA**

Internal Next Steps:

- Coordinate meetings with champion
- Have purchasing provide an estimate on annual units
- Prepare samples for a trial

Clinical Evaluation

Steps to Setting Up an Evaluation:

The key to success in this step is organizing a successful evaluation. A successful evaluation starts with having the right products available. You need to understand if the customer will be using the **SuperNO2VA** system or mask and how many of each are needed. 80% of patients require a medium **SuperNO2VA** mask (SNM-20).

INSIDER TIP:

Include Et sampling options with samples

Clinical Evaluation

Additional sedation products:

When you talk to the customer you want to understand what monitors they have for gas sampling and what accessories they using to sample.

INSIDER TIP:

Include Et sampling options with samples

SuperNO2VA Accessories			
Material #	**Material Description**	**UOM**	**Items/UOM**
VYAIRE ADAPTER/SAMPLE LINE OPTION			
73385-HEL	Vital Signs™ Straight T-Adapter, with Female Luer Lock Connector, Disposable	10	PAK
73319-HEL	Vital Signs™ Anesthesia Gas Sampling Line, Disposable, 3m/10ft	10	PAK
5600T	Vital Signs™ Luer Capped T	20	CASE
56401	Vital Signs™ Gas sampling interface	20	CASE
Capnoflex			
2013068-001	Adult/Pediatric Airway Adapter for Capnoflex Module	10	BOX
Oridien			
XS04620	FilterLine Set-Adult-Pedatirc CO_2 Sampling Line (7ft) and Airway adapter	25	BOX
10579	FilterLine Set-Adult-Pedatirc CO_2 Sampling Line (7ft) and Airway adapter	100	BOX

Clinical Evaluation

Prior to Evaluation

1. Look for champion that are looking at **SuperNO₂VA** as a solution
2. Ask what a successful evaluation looks like
3. Determine length of the evaluation
4. Determine what clinical education resources are needed and for how long
    - Complete the **Pre-Evaluation Questionnaire** before scheduling clinical resources*
    - Make sure the product has arrived at the facility and they are ready for the trial
5. Determine number of cases needed for evaluation
6. Try to schedule the evaluation on days during sedation procedures

* Approved for US distribution only.

INSIDER TIP:

There is a learning curve (takes 3-4 cases to become familiar)

Clinical Evaluation

During an Evaluation

1. According to hospital policy when entering the OR use hospital provided scrubs
2. Get in touch with your champion/ anesthesiologist for daily schedule
3. Meet with your anesthesiologists and/or CRNAs that are assigned to use **SuperNO2VA** that day
4. Additional training may be needed for anesthesiologists/ CRNAs
5. Be prepared to answer trouble shooting during the procedures
    - Have a copy of clinical protocol trouble shooting section*
6. Complete evaluations forms after each use
7. After each day recap with your champion

*Approved for US distribution only

Clinical Evaluation

Post Evaluation

1. Gain a thorough understanding of total steps in the value analysis process, what constitutes success
2. Follow-up with your champion and anyone in the decision-making process to discuss compiled evaluation forms and feedback

Clinical Evaluation

Now that customers are aware of **SuperNO₂VA** and how it reduced the risk of hypoxemia and you have conducted a successful trial, it's time to help the customer convert to **SuperNO₂VA** as quickly as possible.

INSIDER TIP:

Do not forget the Anesthesia Techs

Prior to Implementation

1. Get your champion on board
2. Gain permission from the Chief/ Medical Director to train
   - Clinicians will feel more comfortable to use/request a new device if Chief approves
3. Ask what a successful implementation looks like
4. Determine what clinical education resources are needed and for how long
5. Is a protocol being created around the change in practice? [**SuperNO₂VA** Clinical Protocol)
6. Schedule training
7. Schedule dinner lecture before start of training
   - Coordinate with marketing for scheduling a speaker
8. Make sure the part numbers are set up at the facility and that they know how to reorder
   - 80% medium mask/ 20% large mask
9. Make sure the appropriate product has arrived
10. Acquire list of anesthesia providers and clinical leadership in ancillary areas
11. Notify other anesthesia areas to let them know the implementation is taking place

Clinical Evaluation

During an Implementation

1. Coordinate training with the Chair of Anesthesia or Chief Certified Registered Nurse Anesthetists
    - Identify patients/procedures that will require change of practice
2. Coordinate hospital specific goals/change of practice with Regional clinical specialists
3. Communicate prior to implementation:
    - Protocol change to staff
    - Training videos
    - Clinical papers
4. Hang Troubleshooting poster

    International Download

    US Download
5. Define goal of working 1:1 with 75% of staff
    - Or until staff can train themselves
6. Work in GI lab &/or OR to train anesthesiologist that cycle through

INSIDER TIP:

Remember to look for pull through opportunities for other sedation products

Clinical Evaluation

After an Implementation

1. Coordinate with supply chain that the **SuperNO₂VA** is stocked and readily accessible
   - Use our hang cards

   International Download

   US Download
2. Understand how they prefer to capture $EtCO_2$ and coordinate stocking efforts
3. Utilize sign-in sheet for all trainees

INSIDER TIP:

Once a champion is earned, ask for referrals to their other facilities. Typically an anesthesia group might cover a handful of locations.

4. Summarize data and deliver to champion or Chief
   - Success stories
   - # of team members trained
   - # and type procedures observed
   - # of each type of mask used
   - Questions and how they were addressed
   - Common objections and/or trouble shooting along with patient outcomes
5. Identify anesthesia providers not trained

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