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Evaluation of SuperNO$_2$VA™ mask technology in a clinical setting: A pilot study

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ABSTRACT

Background: One of the biggest challenges for anesthesia practitioners during airway management is the maintenance of adequate oxygenation and ventilation during difficult and emergency airway situations. Providing nasal ventilation during the "apneic period", defined as the time between the end of bag-mask ventilation and successful placement of an appropriate airway device, may allow for improved oxygenation throughout the process in which the airway is secured. The SuperNO$_2$VA™ mask (Revolutionary Medical Devices, USA) is a newly developed nasal mask that delivers non-invasive positive pressure nasal ventilation that is designed to provide continuous oxygenation and ventilation during anesthetic induction until the airway is secured.

Aim: The purpose of this study was to evaluate the clinical performance of the SuperNO$_2$VA™ mask for nasal oxygenation and ventilation during pre-induction, post-induction, laryngoscopy, and tracheal intubation in adult patients requiring general anesthesia.

Methods: Following IRB/ethical board approval and written informed consent, 30 adult patients, ages 18 years or older, with an ASA status I-III, who were scheduled for an elective surgery that required general anesthesia and tracheal intubation, were enrolled into this study. Patient demographic characteristics and intervening outcomes were all recorded. The SuperNO$_2$VA™'s efficacy was evaluated by the measurement and recorded values of peak airway pressures, tidal volumes, minimal oxygen saturation values (while the airway was secured), as well as, an objective assessment grading scale for mask ventilation. The time required to secure the airway, including laryngoscopy, was also recorded.

Results: The SuperNO$_2$VA™ nasal mask provided adequate oxygenation and successful ventilation in 29 of 30 patients, resulting in an overall success rate of 97% (95% confidence interval: 83%–100%). One patient was unable to be successfully ventilated by the SuperNOVA™ mask and was noted a Grade IV. The mean duration of laryngoscopy was 50.7 ± 23.2 s, with an average SpO_2 of 99.6 ± 0.8% calculated for this interval. The lowest observed SpO_2 for the 29 patients at preoxygenation, pre-induction, pre-ETT insertion, during laryngoscopy, post-intubation, and in the PACU was 95, 97, 97, 97, 98, and 94%, respectively. The average for the lowest SpO_2 during the entire airway procedure was 98.1 ± 7.0%. And the average peak airway pressure, for all 29 patients, was 17.97 ± 3.95 mmHg, with a mean tidal volume of 573.7 ± 40.7 mL.

Conclusion: This observational study demonstrated that the SuperNO$_2$VA™ mask facilitates non-invasive positive pressure ventilation while providing adequate oxygenation and ventilation during pre-induction, post-induction, laryngoscopy, and tracheal intubation in elective surgical patients. Conversely, considering the novelty of this particular study, further research is warranted to determine its usefulness in patients with known/predicted difficult airways, or even during emergent situations.

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1. Introduction

One of the biggest challenges for anesthesia practitioners during airway management is the maintenance of adequate oxygenation and ventilation when a difficult airway is encountered. Previous studies have investigated several options/techniques that may help prolong, and possibly prevent, desaturation; however, these specific techniques do not eliminate the critical apneic period, altogether [1–3]. The Difficult Airway Society (DAS) created guidelines for managing difficult airways with several techniques and tips to optimize oxygenation and ventilation prior to intubation, but there is no mention of ventilation during the period of laryngoscopy and tracheal intubation in the most recent American Society of Anesthesiologist's (ASA's) guidelines [4].

Intravenous (IV) deep sedation and the induction of general anesthesia cause respiratory compromise by fundamentally affecting the chemical, neurological, and mechanical regulation of ventilation. It is this sequence of events that induces upper airway obstruction and respiratory depression that may subsequently cause hypoventilation, atelectasis, and ultimately oxygen desaturation leading to hypoxemia [2–6]. Certain patient populations (i.e. pediatric, obese, and obstetric) are considered 'at (high) risk' for rapid desaturation after the induction of general anesthesia. Causes are due to increased oxygen consumption, reduced functional residual capacity (FRC), and/or poor oxygen reserve that hasten the development of hypoxemia [1–6].

In current clinical practice, it is common that pre-oxygenation is performed with 100% FiO_2 for approximately 3 min, and patients are instructed to breathe deeply to help establish a safe apneic period [1]. Extending the safe apneic period, or the time between the onset of apnea until end-tidal oxygen (EtO_2) percentage reaches 90% or less, increases the patient's margin of safety [1,4]. Further maneuvers are indicated in high-risk patients for optimal preoxygenation. Positive pressure ventilation and 25° ramped up positioning are recommended for obese patients [7] and may be useful in all patients. ICU patients have maximal benefit from non-invasive ventilation (NIV) [8,9], when coupled with high flow nasal cannula (HFNC) [10], while extension of safe apnea time can be granted with apneic oxygenation techniques, such as nasal oxygen during efforts securing a tube (NODESAT, usually with a nasal cannula) [1,11] or HFNC [12].

The SuperNO_2VA™ (Revolutionary Medical Devices, Inc., Tucson, AZ, USA) is a newly developed nasal mask that delivers non-invasive positive pressure ventilation through the nasal route to provide continuous oxygenation and ventilation during anesthetic induction and throughout laryngoscopy. The SuperNO_2VA™ mask was designed to create a seal, deliver gas, and generate positive pressure, allowing for continuous nasal oxygenation and ventilation during sedation, by placement over the patient's nose and connection to a gas source, so that positive pressure builds up inside the mask (Fig. 1). This pressure, therefore, helps separate the soft palate from the posterior pharygeal wall and forces oxygen to flow from the nose to the lungs.

The purpose of this study was to determine the clinical performance of SuperNO_2VA™ technology post induction, as measured by the average lowest oxygen saturation (SpO_2), peak airway pressures and tidal volumes, average end-tidal of carbon dioxide ($EtCO_2$), and average objective ventilation scale grades, as previously described by Han R., et al. [13]. SuperNO_2VA™ safety and tolerability were secondary objectives that consisted of technical performance, indicated by the incidence and nature of adverse events (AEs), serious adverse events (SAEs), unanticipated adverse device effects (UADEs) and their duration, resolution and required treatment, if any, along with the time required to secure the airway during laryngoscopy.

2. Materials and methods

After approval of the protocol by the Institutional Review Board (IRB) of the University of Texas Health Science Center at Houston (UTHealth) McGovern Medical School and the Research Committee of the Department of Anesthesiology, 30 adult patients scheduled for elective surgery at Memorial Hermann Hospital–Texas Medical Center were recruited to participate in this non-randomized, observational, prospective study. Key research personnel, such as the principal investigator, co-investigator, and/or study coordinators, obtained informed consent preoperatively. Each eligible patient was provided with a detailed explanation of the study's purpose and their role as a participant by both oral and written communications. All protected health information (PHI) was secured in an encrypted database in accordance with the Health Insurance Portability Accountability Act of 1996 (HIPAA). The study period consisted of 3 months from February through April 2016.

2.1. Patient selection

The study's cohort was comprised of individuals scheduled to undergo surgery that met the following inclusion criteria: (1) age of 18 years old or older, and (2) American Society of Anesthesiology (ASA) physical status I-III. Exclusion criteria consisted of the following: (1) any presence of an underlying neuromuscular disease, (2) use of medications known to interfere with neuromuscular transmission, (3) history of cervical spine injury or cervical pathology, (4) presence of renal or hepatic disease, and (5) inability to fit the mask. Morphometric characteristics, such as neck circumference, inter-incisor gap, thyromental distance, and sternomental distance were measured and recorded for all patients. The quality of each patient's airway was evaluated using the physical examination recommendations in the most recent American Society of Anesthesiologist's (ASA) "Practice Guidelines for Management of the Difficult Airway" [14]. Also, a review of previous airway management history was obtained, including, history of snoring, diagnosis of obstructive sleep apnea (OSA), anticipated difficult-mask-ventilation (DMV), laryngoscopy, or intubation, as well as, any history of DMV, difficult laryngoscopy or intubation, presence of facial hair, body mass index (BMI) > 30 kg/m^2, elderly (>55 years old), and/or edentulous.

2.2. Study procedure

Each patient received general anesthesia and was intubated by either direct or video laryngoscopy. In the operating room (OR), standard monitoring devices were applied, including a pulse oximeter, 3-lead electrocardiogram, and blood pressure monitoring (in which the latter may be invasive or non-invasive). Measures of blood pressure, heart rate, respiratory rate, SpO_2, and $EtCO_2$ were observed and recorded before the patient's surgical preparation, and periodically while the airway was being secured. Vital signs were recorded immediately before oxygen administration, before induction of anesthesia, before ETT insertion, during laryngoscopy, after ETT insertion, and postoperatively during the participant's recovery in the post-anesthesia care unit (PACU). Study providers included attending anesthesiologists, resident anesthesiologists, anesthesiologist assistants, and an anesthesiologist assistant student.

The SuperNO_2VA™ mask is intended to facilitate simultaneous oxygenation and ventilation through the nose, allowing the clinician to have an unobstructed view of the airway during laryngoscopy, intubation, and/or procedures requiring access to the oral cavity (Fig. 2). Only an "Adult Large" size of the SuperNO_2VA™ mask was used during the study period. This was largely due to the

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