Abstract

**Background:** Preoxygenation before anesthetic induction is a widely accepted maneuver to increase oxygen reserves and delay desaturation during apnea. There is limited data regarding the use of the NuMask® in the perioperative setting, and no data as to its efficacy in achieving maximal preoxygenation. We hypothesize that the NuMask® may be a useful alternative to the face mask in achieving maximal preoxygenation.

**Methods:** After IRB approval, the NuMask® was compared with the classic face mask with respect to achieving maximal pre-oxygenation in 30 healthy volunteers using tidal volume breathing. All volunteers were tested for three periods of 5 minutes intervals and the following parameters were recorded every 30 seconds: inspired, and end-tidal oxygen concentration and end-tidal carbon dioxide concentration.

**Results:** The mean ETO₂ of ≥90% was achieved with both masks at 3.5 minutes (SD = 1.62 and 1.98 for facemask and NuMask® respectively) and thereafter the ETO₂ remained above 90%. There were no statistical differences noted in FiO₂ and ETO₂ between the face mask and the NuMask® in the same time periods. ETCO₂ values were also not statistically different between the two masks.

**Conclusions:** The study showed that the NuMask® is as effective as the classic face mask in achieving maximal pre-oxygenation during tidal volume breathing.

Introduction

Preoxygenation before anesthetic induction and tracheal intubation is a widely accepted maneuver intended to increase oxygen reserves, and thereby delay the onset of arterial oxyhemoglobin desaturation during apnea. In healthy adults breathing air, oxygen desaturation to 90% can occur in 1-2 min, whereas, with adequate preoxygenation it can be delayed up to 8 min during apnea. Preoxygenation is particularly important when manual ventilation is undesirable, if difficulty with ventilation or tracheal intubation is anticipated and in patients with oxygen transport limitations.
In 2003, the American Society of Anesthesiologists task force on the Management of the Difficult Airway, recommended “face mask preoxygenation before initiating management of the difficult airway” in their updated practice guidelines. In 2015, Difficult Airway Society intubation guidelines working group in United Kingdom, developed specific guidelines for management of unanticipated difficult intubation in adults. The guidelines include the statement that all patients should be preoxygenated before the induction of general anesthesia.

Typically in the operating room, preoxygenation is carried out with an oxygen flow of ≥7 l/min delivered from a semiclosed circle absorber anesthetic system via face mask. The most common reason for the failure to achieve a fraction of inspired oxygen (FiO₂) close to 100% is a leak under the face mask due to the inability to obtain a tight seal. This may result from an improperly inflated cushion on the rim of the mask, improper mask size (too small or too large), presence of a large beard, sunken cheeks, presence of nasogastric tube or abnormal facial anatomy.

The shortcomings of various face masks and the problems associated with their use during difficult mask ventilation (DMV) has led to the development of newer airway devices. The NuMask® is an intraoral mask, which became available for anesthetic induction in 2006. It is marketed to be positioned behind the lips and in front of the gum line (similar to a snorkel mouth piece) and thus providing a different anatomical seal in comparison to the commonly used face mask.

There is limited data regarding the use of the NuMask® in the perioperative setting, and no data as to its efficacy in achieving maximal preoxygenation. We hypothesized that the NuMask® may be a useful alternative to the face mask in achieving maximal preoxygenation. This study compared the efficacy of preoxygenation using both the NuMask® and the face mask during tidal volume breathing (TVB).

**Methods**

After Advocate Healthcare IRB approval and registration with clinicaltrials.gov (NCT01865851), the efficacy of preoxygenation with the NuMask® was compared to the classic face mask in 30 consented, healthy volunteers. The study group mainly consisted of anesthesia residents and attendings. After being informed of the different steps in the study, the volunteers were given time to familiarize themselves with both the NuMask® (NuMask Inc, Woodland hills, CA) (Fig. 1A-B) and the classic face mask (Vital Signs adult mask with adjustable air cushion). The study was conducted in the supine position using a single anesthesia machine (Apollo® Dräger Medical Ag & Co, Germany). The following parameters were measured every 30 seconds: fraction of inspired oxygen (FiO₂), end-tidal oxygen (ETO₂), and end-tidal carbon dioxide (ETCO₂).

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![Fig. 1A](Numask® airway device)

![Fig. 1B](NuMask® attached to anesthesia circuit)

![Fig. 1C](Demonstration of preoxygenation technique with NuMask®)
Each volunteer was tested for three separate, five minutes intervals using 100% oxygen at a fresh gas flow (FGF) of 7 l/min. Volunteers acted as their own controls by undergoing preoxygenation with both types of masks. When using the NuMask®, a nose clip was placed to guarantee that each volunteer was breathing only through the mouth. The volunteers were also given the option of closing their nostrils with their fingers (Fig. 1C). They were allowed to breathe room air for 5 minutes between each test period. After the study, each volunteer completed a three-item questionnaire: 1. which mask was more comfortable, 2. which mask would they prefer to be used on themselves if they were patients, and 3. which mask would they prefer to use on their own patients.

The volunteers were assigned into two groups using computer generated randomization numbers. Each volunteer in the first group was preoxygenated for five minutes in the following order: 1) face mask; 2) room-air break; 3) NuMask®; 4) room-air break; 5) face mask. Each subject in the second group was preoxygenated for five minutes in the following order: 1) NuMask®; 2) room-air break; 3) face mask; 4) room-air break; 5) NuMask®.

The sample size estimate for this study (n = 30) was determined to detect a difference in preoxygenation at α = 0.05 and power = 0.90. Statistical analysis was performed using SPSS software (IBM SPSS Statistics 18, Chicago, IL). Student T-test was used to compare the two groups with respect to age, height, weight, FiO2, ETO2 and ETCO2. A p value less than 0.05 was considered to be statistically significant.

**Results**

The mean age, height and weight of the volunteers were 36.9 ± 9.5 years, 170 ± 8cm, and 70 ± 8 kg respectively. All volunteers completed the study protocol. After one minute of preoxygenation, ETO2 rose to 76% with both masks (SD = 8.81 and 6.50 for facemask and NuMask® respectively). The mean ETO2 of ≥ 90% was achieved with both masks at 3.5 minutes (SD = 1.62 and 1.98 for facemask and NuMask® respectively) and thereafter the ETO2 remained above 90%. There were no statistical differences noted in FiO2 and ETO2 between the face mask and the NuMask® in the same time periods (Fig. 2A-B). ETCO2 values were also not statistically different between the masks. Sixteen (53.3%) of the volunteers reported that the NuMask® was more comfortable than the face mask whereas fourteen (46.6%) reported the opposite. All volunteers stated that both masks were acceptable during preoxygenation. Twenty one (70%) of the volunteers stated that they would prefer the use of NuMask® for preoxygenation on themselves and on their patients, whereas, nine (30%) of the volunteers would still prefer the use of the face mask.

![Fig. 2A](image1)

**ETO2 in volunteers preoxygenated with facemask (blue) and NuMask® (red).**

![Fig. 2B](image2)

**FI02 in volunteers preoxygenated with facemask (blue) and NuMask® (red). No significant differences between groups**
**Discussion**

The current study demonstrated that the NuMask® is as effective as the classic face mask in achieving maximal preoxygenation in healthy volunteers. With the use of either mask, an \( \text{ETO}_2 \) of 90% or higher was achieved in 3.5 minutes (SD = 1.62 and 1.98 for facemask and NuMask® respectively). In half the volunteers, preoxygenation with the NuMask® was repeated and in the other half, preoxygenation was repeated with the face mask. The reason for repeating the cycle was to assess whether a true difference existed between the two preoxygenation methods and we found no differences. We used a FGF flow of 7 l/min because, previous studies have shown that FGF of 7 l/min using semiclosed circle absorber system results in minimal nitrogen rebreathing\(^{10}\). Consistent with other investigations, we used \( \text{ETO}_2 \) of 90% as the endpoint in defining maximal preoxygenation\(^8\). Anesthesia attendings and residents were chosen for the study because of their availability, and also because they are in a better position to evaluate the use of both masks.

The presence of a leak under the face mask can lead to decreased \( \text{FiO}_2 \) and ineffective preoxygenation. The fact that both masks in our study were found to be effective in achieving maximal preoxygenation implies that with the use of either mask, the leak was prevented. This is not surprising since our volunteers had normal facial anatomy and the masks were used properly. In the general population, the incidence of DMV is about 5%\(^{11}\), whereas the incidence of impossible mask ventilation has been estimated to be 0.15%\(^{12}\). In both groups, the presence of a beard has been found to be an independent risk factor. It is conceivable that patients who are at high risk for developing leak under the face mask would benefit from the use of the NuMask® because, it provides a different anatomical seal. Furthermore, in some patients, the NuMask® may have the advantage of attenuating the feeling of discomfort, anxiety and claustrophobia that may occur with the use of a standard face mask, since the NuMask® occupies only the mouth, leaving the rest of the face free. In conclusion, the current study found that the NuMask® is as effective as the classic face mask in achieving maximal preoxygenation during TVB.

**Acknowledgements**

The authors would like to thank the volunteers, without whom this study could not have been possible.
References

BRIDION—For **optimal neuromuscular blockade management** and improved recovery

**Predictable and complete reversal**

- 98% of BRIDION patients recovered to a TOF ratio of 0.9 from reappearance of T₁ within 5 minutes²
- 97% of BRIDION patients recovered to a TOF ratio of 0.9 from 1 to 2 PTCs within 5 minutes³

**Rapid reversal**

- BRIDION rapidly reversed patients from reappearance of T₁ in 1.4 minutes²
- BRIDION rapidly reversed patients from 1 to 2 PTCs in 2.7 minutes³

BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. In children and adolescents (aged 2-17 years), BRIDION is only recommended for routine reversal of moderate rocuronium-induced neuromuscular blockade.

Important safety information

BRIDION is not recommended in patients with severe renal impairment. Studies in patients with hepatic impairment have not been conducted and, therefore, patients with severe hepatic impairment should be treated with great caution. Caution should be exercised when administering BRIDION to pregnant women as clinical data on exposed pregnancies are available.

BRIDION has not been investigated in patients receiving rousium or vecuronium in the intensive care unit (ICU) setting.

Neuromuscular blockade is required within 24 hours of BRIDION administration, a nondepolarizing neuromuscular blocking agent should be used instead of rocuronium or vecuronium. The most commonly reported adverse reactions were dyspnea (acute or late onset) and anesthetic complications (movement, coughing, straining, or sucking on the endotracheal tube). In patients treated with BRIDION, a few cases of awareness were reported. The relation to BRIDION was uncertain. In a few individuals, allergic-like reactions (e.g., flushing, erythematous rash) following BRIDION were reported. Contraindications should be prepared for the possibility of allergic reactions and take the necessary precautions. In a trial of patients with a history of pulmonary complications, bronchospasm was reported in 2 patients and a causal relationship could not be fully excluded.

Volunteer studies have demonstrated a slight (11.7%) to moderate (23.2%) increase in partial thromboplastin time (PTT) with BRIDION; however, clinical studies have demonstrated no clinically relevant effect on postoperative bleeding complications with BRIDION alone or in combination with anticoagulants. As BRIDION has demonstrated an in vitro pharmacodynamic interaction with anticoagulants, caution should be exercised. In patients on anticoagulants for a pre-existing or concomitant condition, this pharmacodynamic interaction is not clinically relevant for patients receiving routine postoperative prophylactic anticoagulation. Although formal interaction studies have not been conducted, no drug interactions were observed in clinical trials. Preclinical data suggest that clinically significant drug interactions are unlikely with the possible exception of terfenadine, fusidic acid, and hormonal contraceptives.

² train-of-four
³ second twitch

REFERENCES:
1. BRIDION Summary of Product Characteristics (SPC).

Please see summary of product characteristics for full prescribing information.

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