A Physiological Study of Supraglottic F_{IO_2} With Three Oxygen Delivery Systems During Awake Spontaneous Breathing: Nasal Cannula, Face Mask, and Aeris Airway

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Divided or split nasal cannula and oxygen facemask are two of the most commonly used oxygen delivery systems for procedural sedation in the United States. A new device, the Aeris Airway Device (Airway Innovations), was designed to improve oxygen delivery while simultaneously providing capnography monitoring during moderate and deep sedation (Figure 1A). A detailed description of the Aeris Airway Device is provided in Supplemental Digital Content S1, https://links.lww.com/AACR/A610.

METHODS

The study was approved by the institutional review board. Written informed consent was obtained from all subjects. EQUATOR guidelines were followed. Eleven adult volunteers were studied prospectively, in a crossover study design, with each volunteer serving as their own control, to compare the inspired fraction of oxygen (F_{IO_2}) delivery at the level of the supraglottic space by the three devices (the Aeris Device, divided nasal cannula, and simple Hudson-type oxygen facemask) at clinically relevant oxygen flow rates. Exclusion criteria were: age <21 or >60 years, American Society of Anesthesiologists (ASA) physical status III or IV, lidocaine allergy, or pregnancy.

Continuous F_{IO_2} monitoring was performed with a DPM 6 clinical monitor (Mindray). The monitor's gas analyzer, which was used to measure F_{IO_2} for the study, underwent two-point calibration at room air and 100% oxygen before use on each study subject.

After topical anesthesia of the tongue, palate, and oropharynx with 2% lidocaine jelly, an appropriately sized 8, 9, or 10 cm Guedel oropharyngeal airway was gently inserted into the subject's oral cavity by an experienced anesthesia provider. The Aeris Device was then inserted into the lumen of the oropharyngeal airway. The subject was positioned supine and instructed to close their eyes and to breathe naturally while listening to soft music via headphones.

A divided nasal cannula (Braebon) was placed in the subject's nostrils, and supraglottic F_{IO_2} measured and recorded for the nasal cannula and for the Aeris Device at the end of each 2-minute period of tidal volume breathing at 2, 4, and 6 L/min of supplemental oxygen for each of the two devices. A 2-minute washout period of breathing room air was provided between each 2-minute supplemental oxygen period, before each change in oxygen flow rate. The same procedure was followed for the oxygen facemask (MFL Labs) and for the Aeris Device at 6, 8, and 10 L/min. The primary objective was to compare the F_{IO_2} delivered to the supraglottic space by the three devices. The capnography/gas sampling cannula of the Aeris Device, whose distal tip is positioned at the distal tip of the lumen of the oropharyngeal airway (Figure 1B), provided a convenient and effective method of sampling and measurement of the F_{IO_2} in the microenvironment of the supraglottic space throughout the study for all three devices (Supplemental Digital Content S3, https://links.lww.com/AACR/A610).

Statistical Analysis

A difference in F_{IO_2} of at least 0.15 between oxygen delivery systems was considered to be of clinical interest. A convenience sample of 11 subjects in a crossover design was used (exceeding five subjects used in previous physiological studies of oxygenation[1]).

For each of the three devices and at each oxygen flow rate, the mean F_{IO_2} values and standard deviations (SD) were calculated.

Two factorial repeated-measures analysis of variance (ANOVAs; Aeris versus divided nasal cannula at 2, 4, and 6 L/min; Aeris versus facemask at 6, 8, and 10 L/min) and a one-way repeated-measures ANOVA at 6 L/min were used to compare the devices, with Bonferroni- and Tukey-adjusted post-hoc contrasts.[2] The Wilcoxon signed-rank test replaced the paired *t* test where Shapiro–Wilk flagged non-normality. Detailed ANOVA results appear in Supplemental Digital Content S2, https://links.lww.com/AACR/A610.

A P <.05 was prospectively set as the criterion for statistical significance. Statistical analyses were performed using Intellectus Statistics software (Supplemental Digital Content S4, https://links.lww.com/AACR/A610).

RESULTS

The characteristics of the 11 study volunteers were as follows: eight were ASA physical status I, and three ASA

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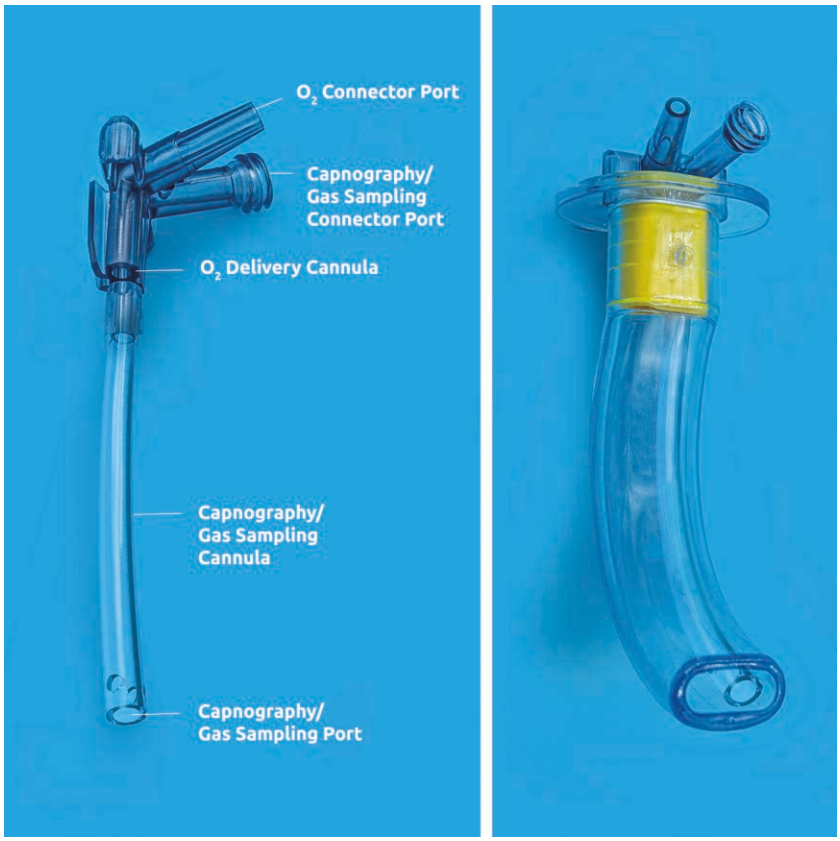

Figure 1. The Aeris Airway Device (left) and the Aeris Airway Device inserted into a Guedel oropharyngeal airway (right). Note that the distal tip of the gas sampling cannula is positioned at the distal tip of the oropharyngeal airway.

physical status II; four females and seven males; mean (SD) age 41 (15) years; height 172 (9) cm; weight 85 (16) kg; body mass index (BMI) 28 (4) kg/m^2.

The results are summarized in Figure 2 and Supplemental Digital Content S2, https://links.lww.com/AACR/A610. The Aeris Device delivered supraglottic F_{IO_2}'s 2.5 to 3.5 times greater than a divided nasal cannula, and 2 to 2.5 times greater than a facemask.

DISCUSSION

It is perhaps not surprising that the Aeris Device delivers high supraglottic O_2 concentrations since it was designed to use the naso- or oropharyngeal airway as a conduit.

Conceptually, by reducing the dead space volume needed to be filled with enriched oxygen, and by maximizing laminar rather than turbulent oxygen flow, this would result in an initial higher F_{IO_2} being delivered to the lower respiratory tract, that is, more effective oxygen delivery to the lungs, with each inspiration. By contrast, the other devices deliver oxygen to the patient's nostrils or near the patient's face, farther from the desired target of the lower respiratory tract and lungs.

The supraglottic F_{IO_2} observed with the divided nasal cannula was lower than expected based on a previous study.[3] In that study, F_{IO_2} was sampled in the oropharynx (not the supraglottic space), and no oropharyngeal airway device was in place. The oropharyngeal airway in our study may have increased mouth breathing and thus more entrainment of room air, diluting the F_{IO_2} delivered to the supraglottis by the nasal cannula. Another possible explanation is that the body of the oropharyngeal airway presents a degree of foreign body obstruction to the flow of supplemental oxygen from the nares to the supraglottis. This observation may have important implications for the clinical setting, where an oropharyngeal airway is frequently inserted to relieve soft tissue airway obstruction often encountered during moderate and deep sedation.

The functioning of the Aeris Device could be mimicked by placing a nasal cannula into the lumen of an oropharyngeal airway; however, this would be off-label, non–FDA (U.S. Food and Drug Administration)-approved use of the nasal cannula. Dislodgement could lead to hypoxia, whereas the Aeris Device is specifically designed not to dislodge.

There are several limitations to this study and to the Aeris Device in general. The advantages demonstrated to oxygenation require insertion of an oropharyngeal airway which may not be tolerated by all. Insertion of an oropharyngeal airway may be easier during sedation, but this study was performed in awake volunteers using topical anesthesia; it would need repetition in the sedated. Similarly, no conclusions can be drawn about the efficacy of the Aeris Device if used via a nasopharyngeal airway with or without sedation. Additionally, the volunteers in this test-of-concept study were healthy adults, and we do not know if these

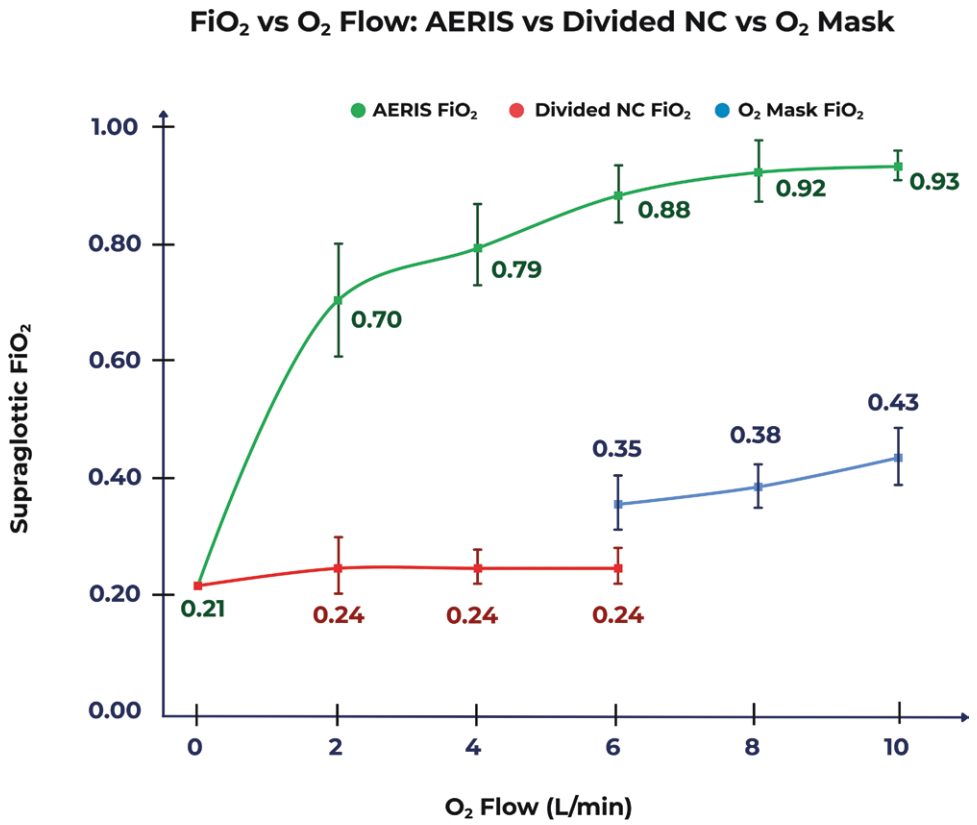

Figure 2. Composite graph comparing mean supraglottic F_{IO_2} (SD) for the Aeris device versus divided nasal cannula versus simple oxygen facemask at the oxygen flow rates tested. F_{IO_2} indicates inspired fraction of oxygen; NC, nasal cannula; SD, standard deviation.

improvements in supraglottic oxygenation will translate into reduced hypoxic episodes in the clinical setting or improved outcomes.

In summary, the results of this preclinical physiological study are encouraging with respect to the primary aim of the Aeris Device resulting in higher supraglottic oxygenation than with other conventional devices.

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