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Comparison of Oxygen Delivery (FIO_2): the New AERIS Airway™ Device for Sedation vs. Divided Nasal Cannula vs. Oxygen Face Mask

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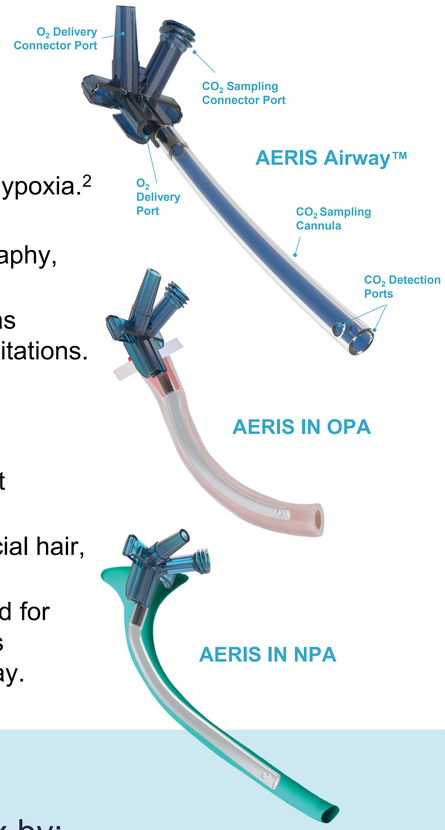
INTRODUCTION

- Tens of millions of procedures are performed under I.V. sedation annually in the United States.
- Recent study (N = 6,000 patients): Hypoxia (O_2 Saturation < 90% for > 2 min) occurred in almost 30% of sedation cases.[1]
- Majority of malpractice lawsuits in non-operating room anesthetics are due to hypoxia.[2]
- Hypoxia can have catastrophic consequences.[2]
- 2018 ASA Guidelines for Sedation recommend supplemental oxygen, capnography, and pulse oximetry for all procedures utilizing moderate or deep sedation.[3]
- Most of the currently available O_2 delivery systems are based on nasal cannulas or O_2 face masks (or off-label uses thereof). These devices have significant limitations.
- Divided nasal cannulas (which deliver O_2 via only one prong) have become popular, despite a scarcity of data on their actual FIO_2 delivery.
- Limitations of nasal cannulas: mouth breathing, congestion, allergic rhinitis, turbinate hypertrophy, polyps, deviated septum causing obstruction or turbulent flow → decreased FIO_2.
- Limitations of O_2 face masks: require high O_2 flow rates, poor mask fit (e.g., facial hair, etc.) → dilution by room air → decreased FIO_2.
- A new device, the AERIS Airway™ Device for Sedation, is designed/engineered for improved oxygen delivery and capnography monitoring during sedation. Inserts securely into any existing adult nasopharyngeal or Guedel oropharyngeal airway.



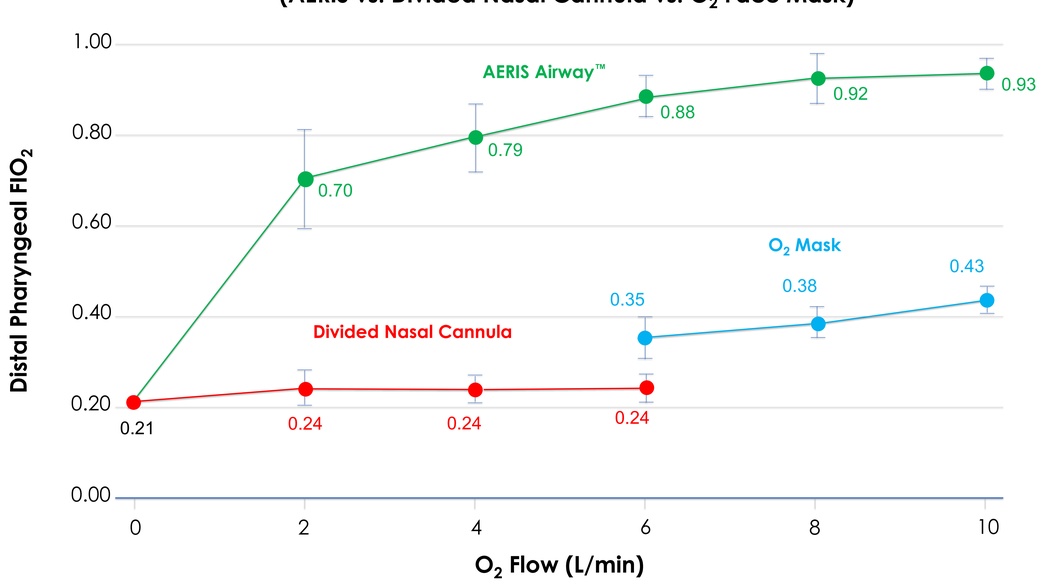
PRIMARY OBJECTIVE

To measure and compare FIO_2 delivery to the distal pharynx by: the **AERIS Airway™ vs. divided nasal cannula vs. simple O_2 face mask**.

METHOD

- IRB-approved, prospective, crossover study
- N = 11, healthy (ASA PS 1 and 2), adult volunteers, age 21-60 years
- Guedel oropharyngeal airway inserted after topical anesthesia of the oral cavity with 2% lidocaine jelly
- AERIS Airway™ Device for Sedation inserted via the Guedel oropharyngeal airway
- FIO_2 measured via distal CO_2/gas sampling port of the AERIS Airway™ using the gas analyzer from a Mindray DPM 6 clinical monitor
- Phase 1: AERIS vs. divided nasal cannula at 2, 4, and 6 L/min O_2 flow rates
- Phase 2: AERIS vs. O_2 face mask at 6, 8, and 10 L/min O_2 flow rates

RESULTS



CONCLUSIONS

- The AERIS Airway™ Device for Sedation delivered markedly higher distal pharyngeal FIO_2's than divided nasal cannula and simple O_2 face mask at clinically relevant O_2 flow rates (2, 4, 6, 8, and 10 L/min).
- These differences in delivered FIO_2 were highly statistically significant.
- Divided nasal cannula delivered lower-than-expected FIO_2's with a Guedel oropharyngeal airway in place.
- The AERIS Airway™ Device for Sedation represents an improved and efficient new oxygen delivery system for moderate and deep sedation.

REFERENCES

(1) VanShaik EP, et al: Hypoxemia During Procedural Sedation, Can J Anesth 2021
(2) Woodward ZG, et al: Safety of non-operating room anesthesia: a closed claims update, Anesthesiol Clin 2017
(3) Practice guidelines for moderate procedural sedation and analgesia 2018: A report by the American Society of Anesthesiologists Task Force, Anesthesiology 2018