Proof-of-Concept Leak Pressure Validation of the SupraVent™ Dual-Lumen Supraglottic Intubating and Ventilating Device

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Abstract

The Ventubation System™ is a revolutionary airway management system comprised of the SupraVent™ supraglottic ventilating and intubating device and the IntroGard™ endotracheal tube (ETT) introducer. The SupraVent is unique, with three physically independent lumens: 1) one dedicated to ventilation and oxygenation, 2) a second dedicated exclusively to ETT passage, and 3) a third for orogastric tube passage. The intubating lumen incorporates two design elements that distinguish it from traditional intubating supraglottic airways (SGAs): 1) a distal one-way valve that prevents retrograde flow of ventilation gases during positive-pressure ventilation, and 2) a longitudinal anterior split running the length of the intubating channel, that permits the device to be peeled away from the ETT after successful intubation. Whether these two added features create a leak path that compromises the laryngeal seal and proper positioning was unknown prior to this trial. To address this, we conducted a cadaveric bench study comparing the SupraVent head-to-head against a second-generation SGA with a non-inflatable cuff, and an intubating laryngeal mask airway (LMA), in three non-embalmed human cadavers using a standard anesthesia-machine leak protocol. The SupraVent achieved airway leak pressures of 20–26 cmH_2O across the three specimens. In every cadaver, the SupraVent matched the cuffed LMA within 1–3 cmH_2O, in addition to the published clinical range of the non-inflatable cuff SGA.[2] These data support the conclusion that the SupraVent's valve-and-slit architecture does not meaningfully degrade the laryngeal seal, and that the device is functionally equivalent to existing cuffed and non-inflatable cuff SGAs when compared within and across different anatomic specimens.

Introduction

Clinical problem

Existing intubating SGAs (e.g., LMA™ Fastrach™, Air-Q®, AuraGain™, and similar) use a single common lumen that serves as the conduit for both positive-pressure ventilation and the passage of an ETT. The direct consequence is that ventilation must be interrupted during endotracheal intubation. In difficult airways and critically ill patients, this interruption is critically consequential and correlates with poor outcomes in a time-dependent manner.[4]

1.2 The SupraVent design

The SupraVent SGA separates these two functions into independent conduits:

1. A primary ventilation conduit, terminating in a laryngeal seal and mask analogous in function to existing SGA designs.
2. An independent intubating conduit running parallel to the ventilation lumen and exiting at the laryngeal aperture, through which an ETT can be advanced under continuous ventilation through the primary lumen.

1.3 Reference benchmarks

Published clinical leak pressures for second-generation SGAs cluster between 20 and 28 cmH_2O.[2, 6] Representative values from large network meta-analyses and head-to-head randomized controlled trials include the i-gel® at 25–28 cmH_2O, LMA® Supreme™ at 23–27 cmH_2O, LMA™ Proseal™ at 24–28 cmH_2O, and LMA Fastrach generally in the high teens to low twenties (Note: the LMA Fastrach was designed primarily as an intubating conduit).[2]

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2. Methods

2.1 Specimens

Three unembalmed human cadavers (designated A, B and C) were used. All three were acquired through the University of Minnesota's tissue donation program and were females between the ages of 75-82 years. Their heights ranged from 5'4''to 5'6'' and weight from 105-170 lbs. Cadavers were visually inspected for normal head and neck anatomy, and their medical history reviewed to make sure no medical conditions or surgeries were present that would affect neck and head extension and flexion.

2.2 Devices tested

- A non-inflatable thermoplastic-elastomer non-inflatable cuff second-generation SGA (i-gel; Intersurgical)
- A reusable inflatable-cuff intubating LMA (Fastrach; Teleflex)
- The SupraVent supraglottic ventilating and intubating device (Gardner Medical)

Equivalent device sizes were used for comparison.

2.3 Insertion and positioning

Each device was inserted by a single anesthesiologist using the manufacturer's recommended technique. Cuffed devices were inflated to the manufacturer-recommended intracuff pressure (≈60 cmH_2O). Proper positioning was confirmed by fluoroscopy in addition to flexible bronchoscopy.

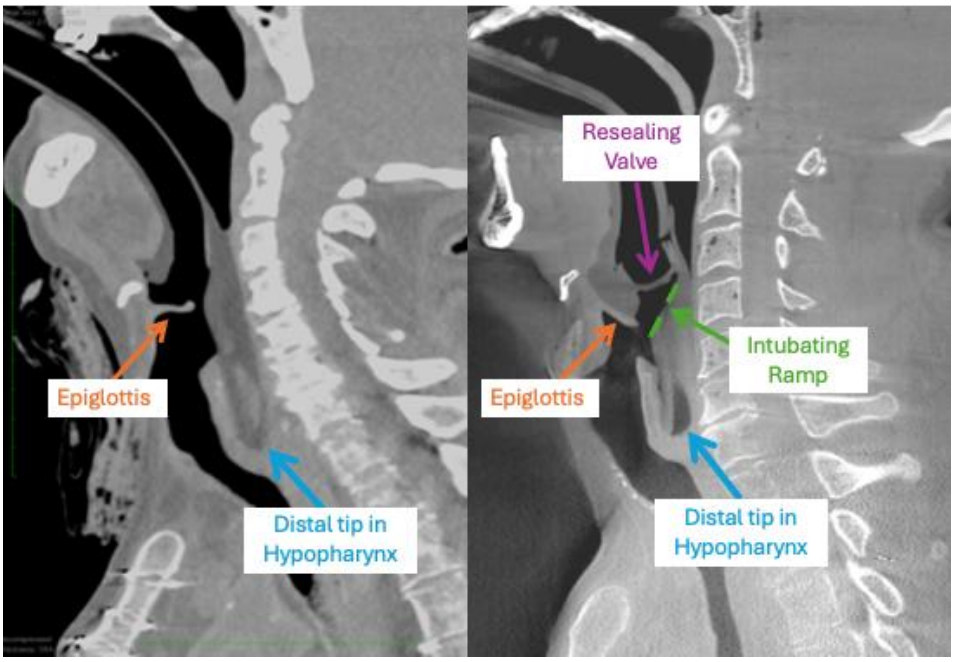

Figure 1 (above): Two computerized tomography sagittal cross-sections representing proper placement of the non-inflatable cuff SGA (left) and the SupraVent (right). Both devices sit well within the hypopharynx as intended. Note the SupraVent's unique intubating ramp and its relative alignment with the trachea and epiglottis. This ramp is intended to guide the ETT centrally and anteriorly for easy passage through the vocal cords. Proximal to the ramp is the patented split-valve that prevents retrograde airflow during ventilation. The valve is designed to reseal after multiple intubation attempts, and the device can be removed, repositioned and replaced without any detriment to its full functionality.

2.4 Leak pressure measurement

Oropharyngeal leak pressure was measured using the standard anesthesia-machine technique described by Keller et al[3] with the adjustable pressure-limiting (APL) valve closed and a fresh gas flow of 3 L/min. Airway pressure was allowed to rise until an audible leak was detected at the mouth or neck. The plateau pressure at the moment of first audible leak was recorded as the leak pressure for that trial. Three replicate measurements per device for each cadaver were taken in total.

2.5 Analysis

Mean and standard deviation were calculated for each device within each cadaver. Given the proof-of-concept design and small specimen number (n=3), no inferential statistics were performed and equivalence claims are descriptive rather than statistically powered.

3. Results

Mean leak pressures by cadaver and device, read from the study figure, are summarized below.

Cadaver	Non-inflatable Cuff SGA	Inflatable Cuff LMA	SupraVent SGA
A	24.7 (± 3.5)	17.0 (± 3.0)	20.0 (± 3.0)
B	44.7 (± 6.3)	26.3 (± 3.0)	26.7 (± 6.7)
C	22.6 (± 12.9)	22.4 (± 3.0)	23.4 (± 3.0)

Table 1 (above): Descriptive statistics for each device and cadaver tested in triplicate. Pressure was measured in all three dynamically per protocol and is noted in cmH_2O with standard deviation in parentheses.

The SupraVent matched or modestly exceeded the cuffed LMA in all three cadavers (A: 20 vs. 17; B: 27 vs. 26; C: 23 vs. 22). Mean SupraVent leak pressure was within 1-3 cmH_2O of the inflatable cuffed comparator across the full dataset, which is the most directly relevant within-class comparison.

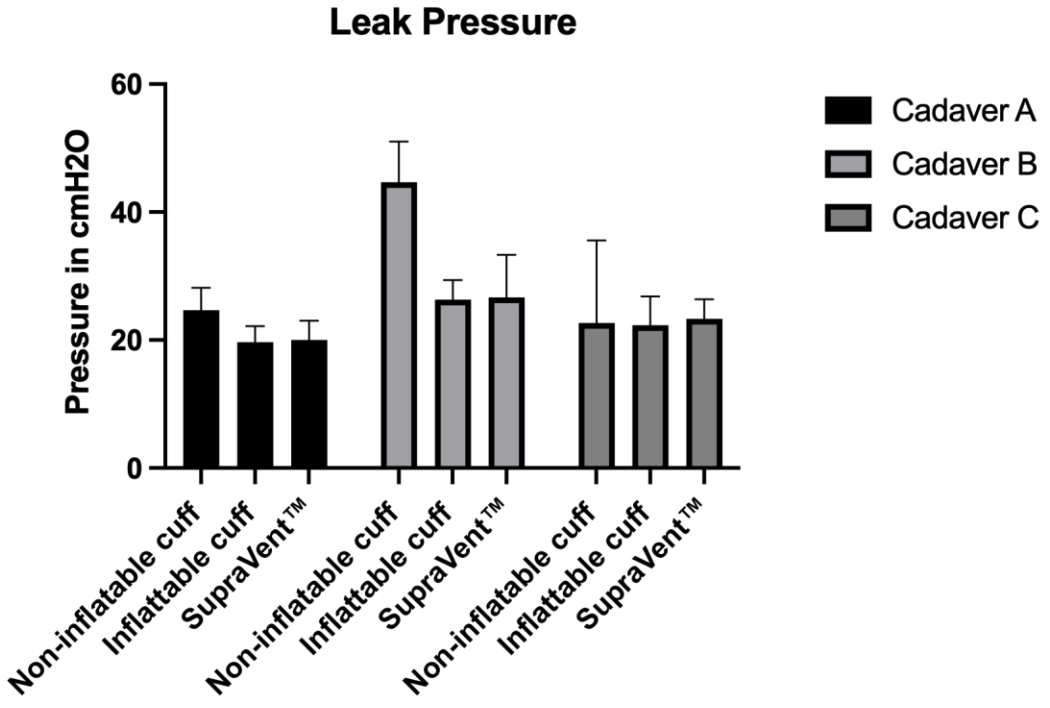

Figure 1 (above): Mean leak pressure compared across device type, within cadavers. The above graph represents mean leak pressures in cmH_2O with error bars reflecting standard deviations.

The new device fell within the non-inflatable cuff SGA performance range in two of three cadavers (A and C). In Cadaver B, the non-inflatable cuff SGA produced an outlier value of 45 cmH_2O — well above its published clinical mean of 25–28 cmH_2O.[2,] We attribute this to specimen-specific anatomy producing an unusually tight cuff fit. Notably, in this same cadaver, both the inflatable cuff LMA and the SupraVent clustered tightly around 26 cmH_2O, indicating that the SupraVent was performing in line with the inflatable cuff SGA benchmark even when the non-inflatable cuff device happened to perform exceptionally.

In Cadaver C, all three devices produced essentially identical leak pressures (22–23 cmH_2O). When three structurally different devices yield indistinguishable seals in the same anatomy, our interpretation is that the limiting factor in that specimen was anatomic rather than device-specific, which supports rather than undermines the claim that the three devices are functionally equivalent in routine-anatomy use.

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4. Discussion

The primary technical risk addressed by this study was whether the SupraVent's two unique and patented design features — the distal one-way valve in the intubating lumen, and the anterior longitudinal slit — would create a leak path that reduced the quality of the laryngeal seal and mask.

The SupraVent's leak pressures in all three cadavers fell within the published clinical range for second-generation SGAs. No specimen showed a SupraVent leak pressure markedly below either benchmark device. The data are consistent with the valve sealing competently against ventilation pressure and the longitudinal slit remaining closed under physiologic ventilation pressures.

Two related observations support the equivalence claim. First, the absolute mean SupraVent leak pressure (23 cmH_2O) sits squarely inside the 20–28 cmH_2O envelope reported across multiple meta-analyses of second-generation SGAs in routine clinical use.[2] Second, and more importantly, the within-cadaver pattern (SupraVent mirroring the inflatable cuff SGA performance within 1–3 cmH_2O in every specimen) is more informative than the absolute means because it controls for anatomic variability between cadavers. The fact that the SupraVent tracks a known and market-established device closely suggests the limiting factor for its seal is the device-anatomy interface that governs all SGAs, not an additional leak path through the proprietary valve or slit.

Limitations

This is a small proof-of-concept study and we want to be explicit about what it does and does not establish.

Cadaveric tissue mechanics differ from living tissue: post-mortem specimens have lower compliance, no muscle tone, no swallowing or peristalsis, and altered mucosal hydration. Absolute leak pressures measured in cadavers therefore may not translate directly to living

patients. However, this limitation applies equally to all three devices tested in parallel, so the within-cadaver comparisons remain interpretable even if absolute values do not.

Three specimens cannot characterize the full range of anatomic variation, particularly difficult-airway phenotypes (e.g., Mallampati III/IV, retrognathia, restricted neck mobility), pediatric sizes, or high body mass index patients. No inferential statistics are reported, and none should be inferred; the equivalence framing at this stage is descriptive.

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References

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