Improving Successful Intubation on the First Attempt with the DEVICE Trial

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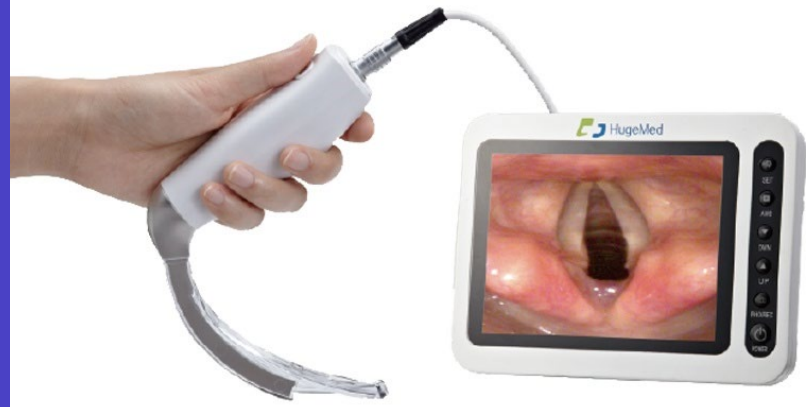
Direct Laryngoscope



Video Laryngoscope

Disclosures

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Pragmatic Critical Care Research Group

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Agenda

Translational Science Benefit Model Case Study

- Summary of Project
  - The Problem
  - Description of our Research
- Significance
- Benefits
- Lessons Learned

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Summary of Project

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The Problem

- > 1.5 million critically ill adults undergo intubation outside the operating room each year in the US.[1,2]
- Failure to intubate the trachea on the first attempt occurs 20-30% of the time AND is associated with an increased risk of complications.[3-4]
- Complications are common [3-4]
  - 8% severe hypoxemia
  - 3% cardiovascular collapse
  - 1% cardiac arrest [3-4]

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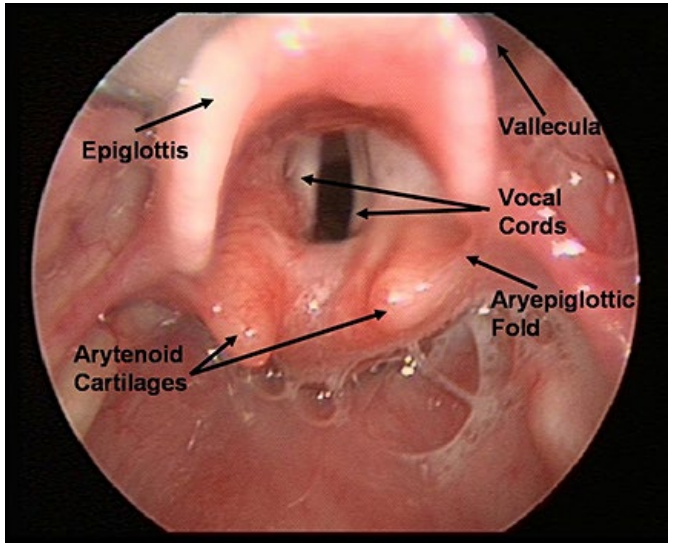
The Problem

Orotracheal Intubation

2 step-process[5]

1) Insert laryngoscope into the mouth to lift the tongue and epiglottis to expose the vocal cords

2) Pass endotracheal tube through the vocal cords and into the trachea



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The Problem

Laryngoscope – device used for step 1 → visualize the larynx to facilitate endotracheal tube passage

→ Two types of laryngoscopes are commonly used to facilitate orotracheal intubation

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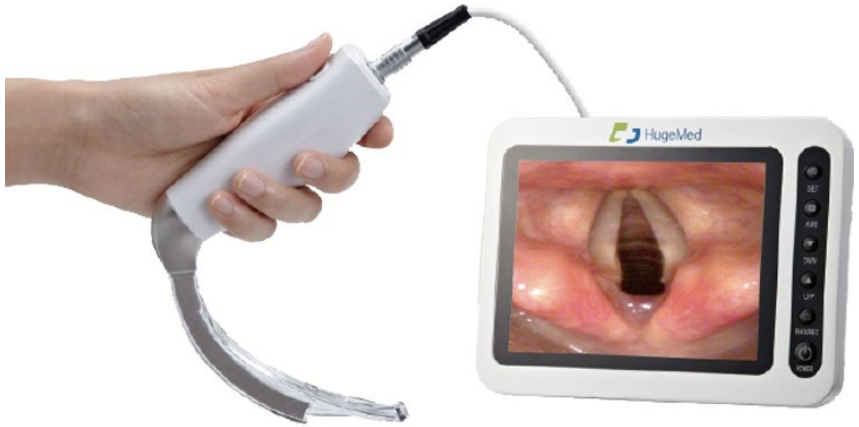

VIDEO

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The Problem

Pros and Cons of Each Laryngoscope

Direct Laryngoscope (DL)

- Standard of care for decades
- Requires skill to obtain an adequate view, particularly in anatomically difficult situations
- Easy to pass the endotracheal tube once a good view is obtained

Video Laryngoscope (VL)

- Increasingly used in U.S. EDs and ICUs
- Easier to obtain a good view even in difficult situations
- Can be harder to pass the endotracheal tube even with a good view

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The Problem

Prior Studies Comparing DL and VL

- Observational studies in US have suggested improved first pass success with VL[6]
- 3 single-center RCTs in US[7-9] and 1 multicenter RCT in France[10]
  - Improved glottic visualization with VL
  - No significant difference in first pass success between devices
- Limitations
  - Observational studies cannot control for confounding by indication
  - RCTs: under-powered, single-center, novice trainees, and performed prior to VL becoming preferred device in US EDs and ICUs.

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The Problem

Rationale for a Multicenter Randomized Trial

1. Video laryngoscope use is rapidly becoming the preferred device for intubation outside the OR, minimizing teaching and expertise with DL in non-anesthesiologists.
2. Data is inconclusive
   - Prior studies have suggested VL may be easier for operators and MIGHT be safer for patients, but RCTs have shown no difference in first past success.
3. If one device (namely VL) is superior, practice change and its associated cost is justified.

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Research Team and Partners

Protocol Team: Matthew Prekker MD, MPH; Brian Driver MD; Stacy Trent MD MPH; Matthew Semler MD

Civilian Contracting Center: Adit Ginde MD, MPH and Colorado University Center for COMBAT Research

Clinical Coordinating Center and Central IRB: Jonathan Casey MD and Vanderbilt University Medical Center

Clinical Sites and Investigators:

- Hennepin Medical Center (ED & ICU): Brian Driver MD, Matthew Prekker MD MPH, Sydney Hansen MD
- Denver Health Medical Center (ED & ICU): Stacy Trent MD MPH, Ivor Douglass MD, Tobias George NP
- University of Colorado Hospital (ED & ICU): Adit Ginde MD MPH, Daniel Resnick-Ault MD
- Vanderbilt University (ICU): Matthew Semler MD, Jonathan Casey MD, Kevin Seitz MD, Jeremy Walco MD, Christopher Hughes MD
- University of Alabama (ED & ICU): Derek Russell MD, Sheetal Gandotra MD, Micah Whitson MD, David Page MD
- University of Washington Harborview (ED & ICU): Andrew Latimer MD, Christopher Barnes MD, Steven Mitchell MD, Aaron Joffee DO
- Atrium Health Wake Forest (ED & ICU): Kevin Gibbs MD, John Gaillard MD, Jordan Goranson MD, Jessica Palakshappa MD
- Baylor Scott and White (ICU): Shekhar Ghamande MD, Heath White MD
- Oschner Health System (ICU): Derek Vonderhaar MD, Alyssa Espinera MD
- Duke University (ICU): Vijay Krishnamoorthy MD, J Herbert MD
- Beth Israel Deconess Medical Center (ED): Alon Dagan MD, Nathan Shapiro MD

***Army of Research Coordinators, Statisticians, and Senior Advisors from Executive Committee for PCCRG and US Army Institute of Surgical Research

Description of Research Project

Trial Design

Multicenter, pragmatic, parallel-group randomized trial

Population: Critically ill adults undergoing emergency tracheal intubation in ED or ICU

Intervention: Direct vs video laryngoscope

Primary Outcome: First pass success

> Definition: 1 insertion of laryngoscope + 1 insertion of endotracheal tube in the mouth

Secondary Outcome: Severe complications after induction

> Definition: severe hypoxemia (<80%), cardiovascular collapse (SBP < 65 mmHg or new/increased vasopressors), or cardiac arrest

Hypothesis: Use of a video laryngoscope will increase first pass success as compared to a direct laryngoscope

Waiver of Informed consent – central IRB review

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Description of Research Project

Randomization: 1:1 in permutated blocks, stratified by site

Allocation: Concealed prior to enrollment

Blinding: Unblinded to intervention

Sample size: 2000 patients (1000 per group)

- Assumptions: 80% first pass success with DL
- Detect a 5% absolute difference between groups

Interim analysis: preplanned at 1000 patients

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Description of Research Project

Pragmatic Trial → screening, enrollment, intervention, and data collection were embedded in routine clinical care

Eligibility → screening done by clinical team

- Inclusion criteria – (1) planned procedure is intubation with laryngoscope and (2) intubator is someone who would normally do the procedure in that unit
- Exclusion criteria – (1) pregnant, prisoner, or child, (2) too emergent to randomize, (3) clinical team thinks DL or VL is required or contraindicated (no equipoise)

Enrollment → concealed envelopes located in the unit

- Outside – reminders of inclusion/exclusion criteria
- Inside – group assignment + data collection sheet

Intervention → DL or VL on first attempt, ***all other decisions at discretion of clinical team

Data Collection → independent observe collects information during intubation (primary & secondary outcomes); intubator documents airway characteristics and other interventions after intubation (retrospect)

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Significance & Impact

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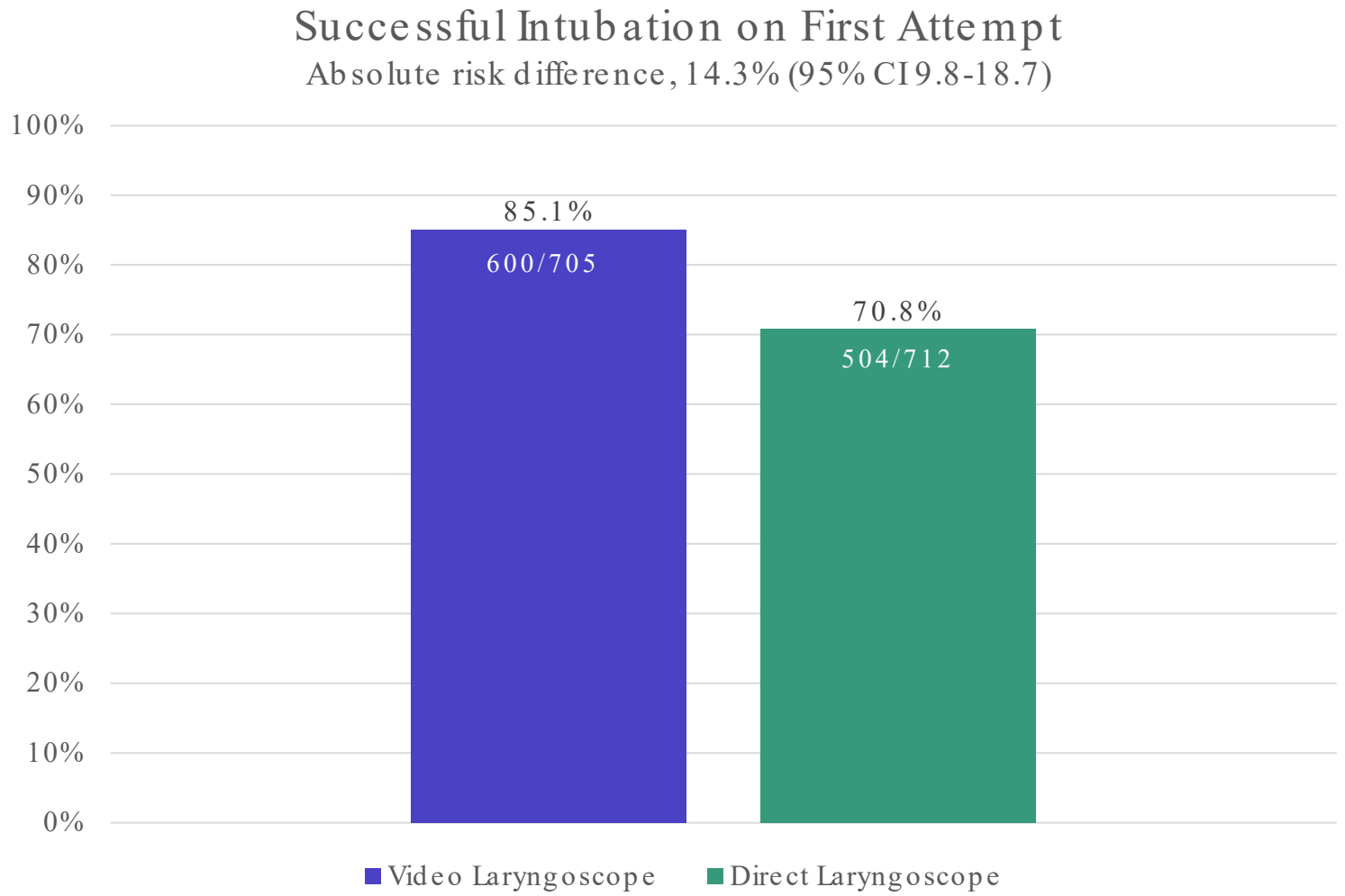
Significance[11]



❖ Trial was stopped at interim analysis (N=1417)

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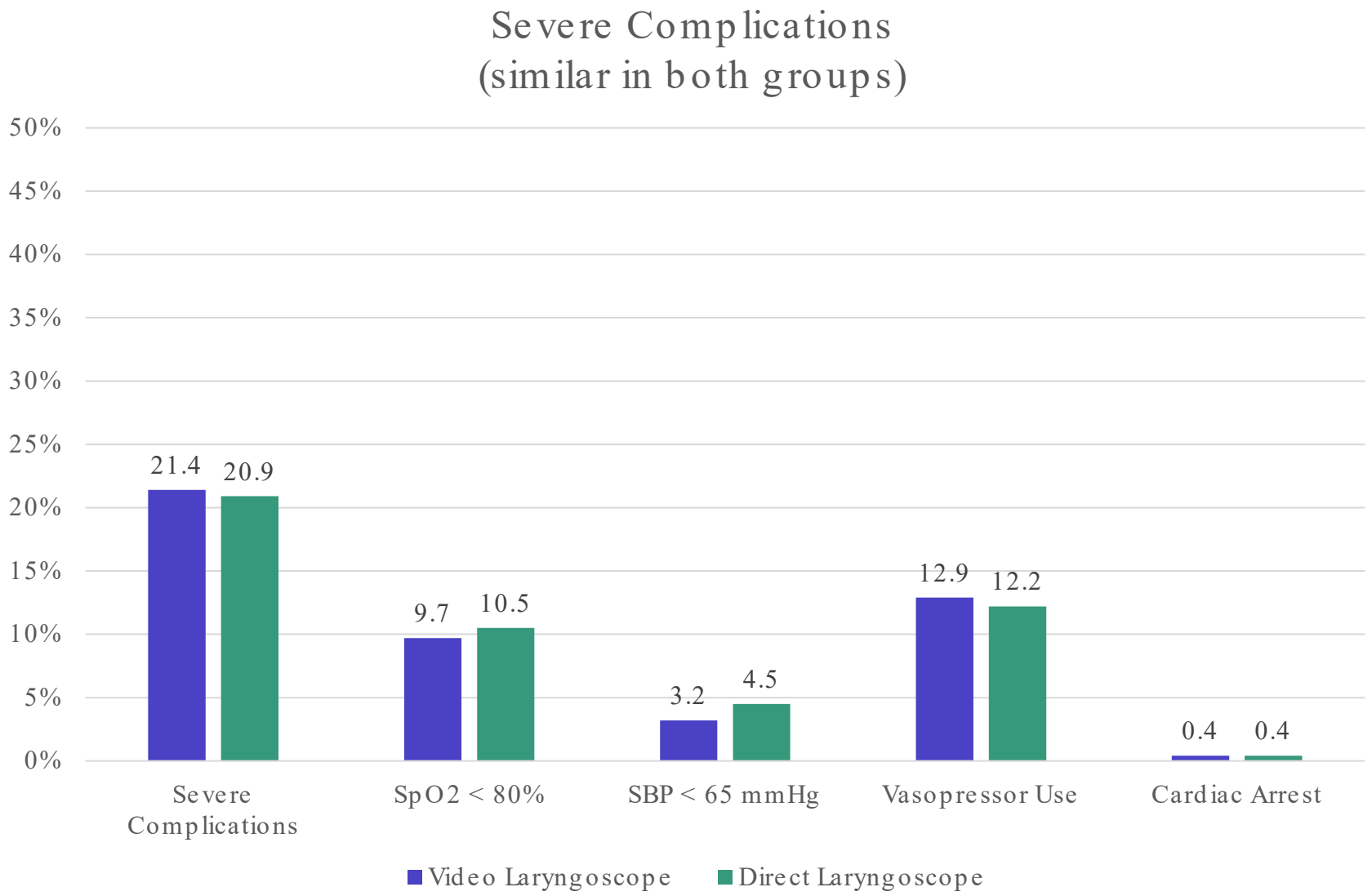
Significance[11]



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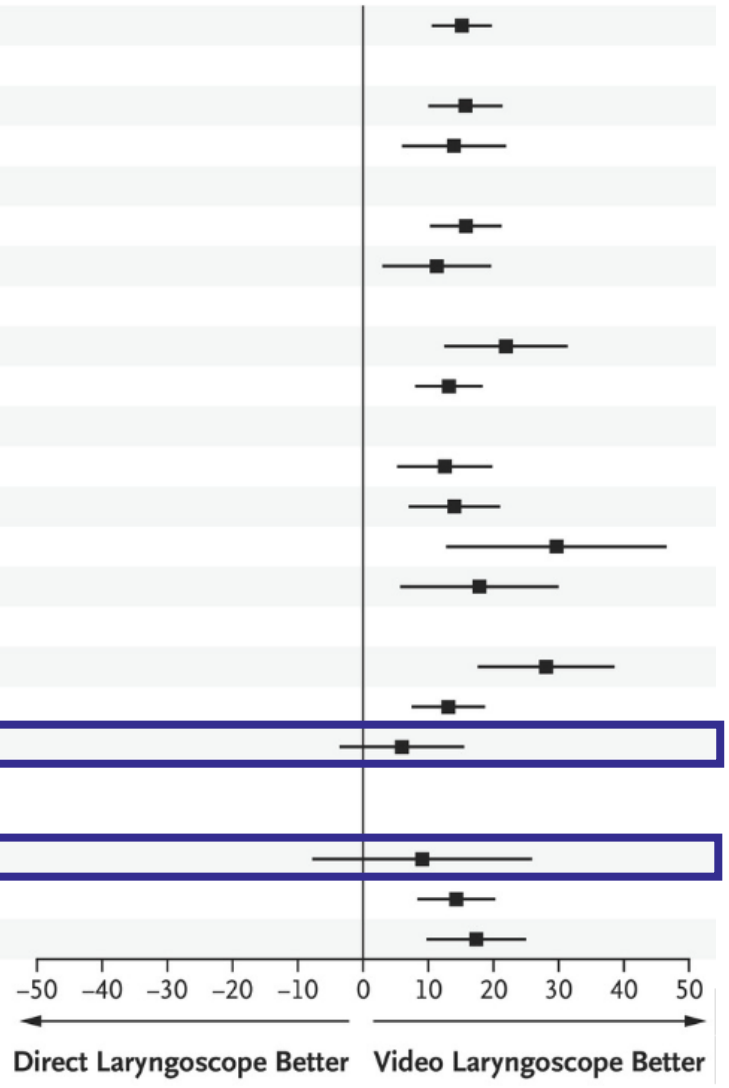
Significance[11]

Subgroup	Video Laryngoscope	Direct Laryngoscope
	no. of events/total no. (%)	
Overall	600/705 (85.1)	504/712 (70.8)
Location in hospital		
Emergency department	425/495 (85.9)	352/493 (71.4)
Intensive care unit	175/210 (83.3)	152/219 (69.4)
Body-mass index		
<30	402/468 (85.9)	343/483 (71.0)
≥30	179/217 (82.5)	155/216 (71.8)
Traumatic injury		
Yes	151/171 (88.3)	114/167 (68.3)
No	449/534 (84.1)	390/545 (71.6)
Anticipated difficulty of intubation		
Easy	206/232 (88.8)	172/223 (77.1)
Moderate	266/317 (83.9)	235/331 (71.0)
Difficult	51/67 (76.1)	30/62 (48.4)
Not reported	77/89 (86.5)	67/96 (69.8)
No. of operator's previous intubations		
<25	128/160 (80.0)	83/154 (53.9)
25–100	379/441 (85.9)	330/448 (73.7)
>100	93/104 (89.4)	91/109 (83.5)
Proportion of previous intubations performed with a video laryngoscope		
<0.25	39/44 (88.6)	27/34 (79.4)
0.25–0.75	335/398 (84.2)	303/429 (70.6)
>0.75	226/262 (86.3)	174/248 (70.2)



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Benefits

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Benefits

Demonstrated - Improved first attempt success with video laryngoscopes

Potential – May result in fewer complications during intubation due to increased first attempt success

Potential – Provides evidence to establish video laryngoscopes as the standard of care for tracheal intubation outside of the operating room.

Potential – Improved quality of care, especially in settings with less experienced operators.

Potential – Improved outcomes for patients outweigh increased cost of video laryngoscope

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Lessons Learned

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Lessons Learned

- Pragmatic Trial
- Infrastructure / Team
- Know your Weaknesses

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