Clinical White Paper

Enhancing Airway Management with the Epic Airway®

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Abstract

Multiple intubation attempts in emergency airway management are associated with increased risks of injury, adverse events, delayed time to securing the airway and death. These challenges highlight the need for innovative solutions that improve first-pass intubation success while minimizing complications. This white paper discusses the clinical implications of repeated intubation attempts, evaluates current alternatives such as supraglottic airways (SGA), and introduces the Epic Airway, a novel solution designed to streamline airway management and improve patient outcomes.

Introduction

Prehospital intubations by paramedics provide airway support during emergencies until hospital care is available. However, infrequent intubation practice often leads to skill decline and higher failure rates¹. Emergencies involving airway obstructions or heavy aspirations further increase difficulty, impacting larynx visibility as measured by the Cormack-Lehane grade. Studies show a 30% first-pass success rate for the most obstructed view (grade 4) and an average of 70% across all grades². Success rates also vary by provider type, with ambulance nurses achieving 48%³ and helicopter emergency personnel 75% first-pass success rates⁴.

Additionally, multiple intubation attempts extend the duration between paramedic arrival and successful endotracheal tube (ETT) placement. This delay may have severe, life-threatening consequences, particularly in critical conditions such as cardiac arrest, where expedited intubation is correlated with improved survival outcomes.

Challenges in Airway Management

- 1. **Injury Risks**: Repeated intubation attempts increase the likelihood of patient injuries.
- 2. Adverse Events: Complications rates increase >10X, compounding the complexity of emergency care. (see Table 1)
- 3. **Time Delay**: Prolonged intubation time delays patient care.

Intubation is associated with risks such as airway damage, vocal cord injury, and dental trauma. Increased attempts to access the trachea heighten these risks and are also linked

Table 1. Complications by Intubation Attempts ⁶			
Complication	2 or fewer	>2	
	Attempts	Attempts*	
Hypoxemia	10.5%	70.0%	
Sever hypoxemia	1.9%	28.0%	
Esophageal intubation	4.8%	51.4%	
Regurgitation	1.9%	22.0%	
Aspiration	0.8%	13.0%	
Bradycardia	1.6%	18.5%	
Cardiac arrest	0.7%	11.0%	
* All categories P<0.001 when comparing 2 or fewer attempts to >2 attempts.			

to complications like vomiting, hypotension, and cardiac arrest.^{5,6} These adverse events add complexity to prehospital and clinical workflows, as providers must manage both the complications and the underlying condition requiring airway intervention.

Additionally, multiple intubation attempts prolong the time from paramedic arrival to endotracheal tube (ETT) placement, which can be critical for patient outcomes⁷. For example, quicker intubation in cardiac

arrest patients is associated with higher survival rates⁸, and delays reduce time available for treating the primary condition.

Given these challenges, non-physician responders may opt for laryngeal masks, which have fewer complications⁹ and a first-pass success rate of 98%¹⁰. However, laryngeal masks are less effective at securing the airway compared to ETTs, which remain the gold standard.¹¹ Despite this, prehospital intubation attempts have decreased by 30%¹², often leading to initial placement of a laryngeal mask. Transitioning from a laryngeal mask to an ETT requires temporarily disconnecting the patient from ventilation, resulting in little to no oxygen delivery during the switch.

The Epic Airway: A Novel Solution

To address these challenges, Epic Airway Systems, Inc. has developed the Epic Airway, a device that combines the simplicity of SGA insertion with the airway security of an ETT. Key features include:

- 1. **Ease of Use**: The Epic Airway is a supraglottic airway with the same easy insertion technique as current SGAs, eliminating the need for visualization tools.
- 2. **Improved First-Pass Success**: Designed to increase the likelihood of successful intubation on the first attempt, reducing injury and adverse event rates.
- 3. **Continuous Oxygenation**: Unlike current alternatives, the Epic Airway eliminates the need for device switching, ensuring uninterrupted oxygen delivery and reduced respiratory and cardiac stress.
- 4. **Enhanced Airway Security**: The device provides the same level of airway protection as an ETT, supporting optimal ventilation and reducing the risk of aspiration.

Paramedic Study Results

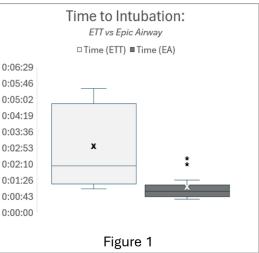
To evaluate the efficacy of the Epic Airway, a focused study was conducted comparing its performance to a standard ETT. Fourteen paramedics, all certified in intubation, participated in the study. Each paramedic performed intubations using both the Epic Airway and a standard ETT on an anatomically accurate difficult airway manikin. Participants received only high-level instructions on the use of the Epic Airway and were not afforded any practice before their attempts. The key findings were as follows:

Intubation Time: The time to intubate was defined as the time between picking up the first opened device package(s), inclusive of necessary support devices (ex: laryngoscope, stylet, lubricant, etc.) and the confirmation of placement via successful lung inflation.

Trial results are characterized by (see figure 1):

	ETT	Epic Airway (EA)
Sample (n):	14	14
Mean:	0:02:55	0:01:06
StdDev:	0:01:45	0:00:32
Median:	0:02:05	0:00:57
Min:	0:01:03	0:00:36
Max:	0:05:32	0:02:23

Two observations within the data are worth noting: 1) one participant was unable to successfully intubate with the ETT after three attempts and, 2) within the EA data, two samples

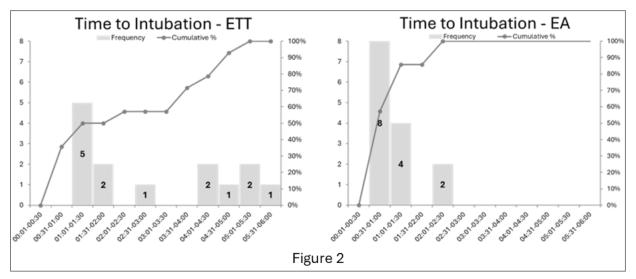


were deemed statistical outliers (denoted by "*" in Figure 1), likely due to the lack of familiarity with the EA. If excluded, the resulting mean for the EA was 0:55.

Statistical comparison of ETT and EA data via hypothesis testing was challenged by the non-normal distribution of the ETT intubation data set. Characterized by a bi-modal distribution, the first ETT population centered at 00:01:28 while the second ETT population centered at 00:04:55 (see Figure 2).

Although unverifiable, early ETT intubation participants were observed offering recommendations to queued participants, likely leading to artificial learning within the study. This is supported by the fact that (5) of the (6) attempts comprising the second population were also (5) of the first (6) participants in the study.

In effort to support hypothesis testing methods sensitive to non-normal data distributions, the higher ETT population (six data points ranging from 00:04:01 to 00:06:00) was conservatively pared from the data. The resulting two test populations were shown to represent similar variances, supported by a p-value of 0.413 when conducting a "Two-Sample F-Test for Variances"; while they were shown to not represent similar means, supported by a p-value of 0.003 when conducting a "2-Sample T-Test Assuming Equal Variances".

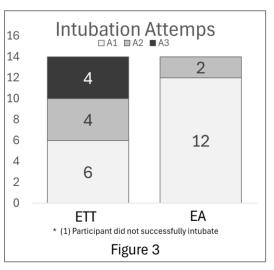


First-Attempt Success Rate: Successful intubation was confirmed by the first visualization of lung inflation. All but one participant (in the ETT population) achieved successful intubation (See figure 3). For the purposes of this study the one participant that did not successfully intubate was included in the A3 population.

The Epic Airway achieved a first-attempt success rate of 86%, significantly higher than the 46% observed with the standard ETT.

Applying the Chi Square hypothesis test using parameters of Chi Square (X^2)=11.78 and Degrees of Freedom (dF)=2 results in a p-value=0.003, we can confidently state that the use of the Epic Airway drives higher "First-Attempt" intubation successes.

These results underscore the clinical advantages of the Epic Airway, particularly in scenarios requiring rapid and reliable airway management. The shorter intubation time and higher firstpass success rate highlight its ease of use, even with minimal instruction, making it a valuable tool for emergency responders. This study was uncontrolled and supports the need for further



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studies in more controlled situations (training, randomization, and blinding to the hypothesis and ideally by the observers too).

Clinical Implications

The Epic Airway represents a paradigm shift in emergency airway management by addressing the limitations of existing tools, skills and experience. It enables non-physician responders and clinicians to achieve faster, safer, and more reliable airway management without compromising patient safety.

By reducing the time and risks associated with multiple intubation attempts, the Epic Airway improves workflow efficiency and enhances patient outcomes. Its innovative design bridges the gap between the simplicity of SGAs and the security of ETTs, offering a comprehensive solution for prehospital and clinical settings.

Conclusion

The Epic Airway is a groundbreaking device that redefines the standard of care in airway management. By combining ease of insertion afforded by a Supraglottic Airway with the robust security of an ETT, it minimizes complications, streamlines workflows, and optimizes patient outcomes. As emergency medicine continues to evolve, the Epic Airway stands out as a critical tool for improving the success and safety of intubation practices.

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