

# Emergency Tracheal Intubation: Complications Associated with Repeated Laryngoscopic Attempts

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Repeated conventional tracheal intubation attempts may contribute to patient morbidity. Critically-ill patients ( $n = 2833$ ) suffering from cardiovascular, pulmonary, metabolic, neurologic, or trauma-related deterioration were entered into an emergency intubation quality improvement database. This practice analysis was evaluated for airway and hemodynamic-related complications based on a set of defined variables that were correlated to the number of attempts required to successfully intubate the trachea outside the operating room. There was a significant increase in the rate of airway-related complications as the number of laryngoscopic attempts increased ( $\leq 2$  versus  $> 2$  attempts): hypoxemia (11.8% versus 70%), regurgitation of gastric

contents (1.9% versus 22%), aspiration of gastric contents (0.8% versus 13%) bradycardia (1.6% versus 21%), and cardiac arrest (0.7% versus 11%;  $P < 0.001$ ). Although predictable, this analysis provides data that confirm the number of laryngoscopic attempts is associated with the incidence of airway and hemodynamic adverse events. These data support the recommendation of the ASA Task Force on the Management of the Difficult Airway to limit laryngoscopic attempts to three in lieu of the considerable patient injury that may occur.

(Anesth Analg 2004;99:607-13)

**E**mergency airway management can be fraught with complications related to hemodynamic alterations and difficulty with oxygenation and ventilation (1,2). Esophageal intubation, pneumothorax, and pulmonary aspiration, as well as other major complications, were reported by Schwartz et al. (1) to occur relatively frequently during emergency tracheal intubation outside of the operating room (OR). However, the severity and frequency of complications were not correlated with the number of intubation attempts. Another anesthesia-based study of emergency intubation reported that 1 in 10 airway encounters required 3 or more intubation attempts and suggested that multiple attempts were associated with an increased incidence of hypoxemia, regurgitation, and esophageal intubation (2). Our emergency department (ED) colleagues have published many studies, but none has quantified an association of increasing complications with repetitive laryngoscopic attempts (3-8). The ASA Task Force on the Management of the Difficult Airway

has made a recommendation, based on the consultant's consensus opinion, that an alternative method should be pursued to secure the airway when difficulty with intubation is encountered (9,10). As difficulty arises with securing the airway and the number of laryngoscopic attempts increases, the occurrence of hypoxemia, esophageal intubation, regurgitation, airway trauma, and cardiac arrest should be more common (11-15). Despite the consequences of repetitive conventional intubation attempts, there is little published evidence directly supporting the ASA's recommendation to limit conventional intubation attempts to three (multiple) with subsequent use of accessory airway devices or alternative techniques (tracheal tube introducer [bougie], laryngeal mask airway (Laryngeal Mask Company, Henley-on-Thames, UK), Combitube<sup>®</sup>, [Kendall-Sheridan, Argyle, NY] fiberoptic bronchoscopy, and cricothyrotomy/tracheotomy). This quality improvement database was analyzed: (a) to determine the incidence of airway and hemodynamic complications during emergency tracheal intubation outside the OR based on a predetermined set of defined criteria and (b) to determine if there is any relationship between the number of conventional intubation attempts and the incidence of complications.

Accepted for publication February 3, 2004.

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DOI: 10.1213/01.ANE.0000122825.04923.15

## Methods

The study was conducted over a 119-mo period (September 1990 to July 2000) at Hartford Hospital, a tertiary care, level 1 trauma center in central Connecticut. Patients aged 16 yr or older who required emergent tracheal intubation using conventional laryngoscopy outside of the OR for clinical deterioration from cardiac, pulmonary, traumatic, septic, metabolic, or neurologic insults were studied as part of the department's continuing quality improvement program. This study was approved by the IRB; however, informed consent was waived based on the emergency nature of the patient intervention. Airway management cases for those patients in cardiac arrest (upon arrival of the anesthesia personnel) were excluded from the database.

Hartford Hospital has 24-h in-house airway management coverage that is staffed by at least a CA-1 level resident (minimum of 6 mo of training) and an attending anesthesiologist covering all hospital areas except the ED. This area was served by the anesthesia airway team on an emergent or urgent consultative basis. The evolution of the anesthesia team varied over time: attending staff presence throughout the patient evaluation and the intubation procedure was approximately 70% from 1990–1993 and was ubiquitous after this period (100% between 1993–2000). The respiratory therapy team with nursing staff assistance supported the patient with bag-valve-mask oxygen supplementation before the arrival of the anesthesia personnel. Clinical judgment to determine the approach to airway management (topical anesthesia, sedatives, opiates, and neuromuscular blocking drugs [NMBD]) were individualized based on the patient's airway status, comorbidities, and the primary diagnosis prompting the need for intubation. Ventilation with 100% oxygen before and between prolonged intubation attempts (>30 s) was standard practice. Endotracheal tube verifying devices (disposable CO<sub>2</sub>, esophageal detector device, or battery-operated capnogram) were available during and after 1995.

After intubation, the personnel performing the tracheal intubation completed a questionnaire that outlined the patient's demographics, procedural details, hemodynamic alterations, airway related mishaps, and other miscellaneous complications. Demographics included the patient's age, sex, medical history, and primary diagnosis requiring tracheal intubation. Procedural data included patient location, route of intubation, level of training, number of attempts, medications administered for patient preparation, pre- and postintubation hemodynamic data, and complications. The author reviewed each case within 48 h after submission of the questionnaire and discarded incomplete questionnaires ( $n = 476$ ). Cross-referencing with

the department's billing records was performed to determine the number of missed cases.

Complication variables were defined in 1990, as outlined in Table 1, on the basis of the department of anesthesiology's quality improvement data collection so to allow categorization of complications and remained unchanged during the study period. To clarify specific conditions present in critically ill patients (hypotension and hypoxemia): if hypotension was present preintubation (systolic blood pressure <90 mm Hg with mean arterial blood pressure <60 mm Hg), then any further reduction postintubation was categorized as hypotension. Likewise, if vasoactive medications were supporting hemodynamics before the airway intervention, then any increase in their requirements after intubation was categorized as hypotension. If the baseline SpO<sub>2</sub> after administration of oxygen or reoxygenation was >90%, then any reduction less than 90% was categorized as hypoxemia. Likewise, if the SpO<sub>2</sub> could not be increased to >90% with breathing 100% oxygen, then a 5% point reduction in SpO<sub>2</sub> from the baseline administration of oxygen maximum was categorized as hypoxemia. A laryngoscopic attempt was considered as the placing of the blade within the oropharynx with an attempt to pass the endotracheal tube.

The cases completed with conventional laryngoscopy and intubation were analyzed by the number of intubation attempts and the incidence of complications. The number of interventions with accessory airway devices and advanced alternative rescue techniques were excluded from this analysis.

All statistical analyses were performed with SPSS version 11.5 (SPSS Inc, Chicago, IL). Categorical data were analyzed using  $\chi^2$  tests and, where appropriate, Fisher's exact probability tests. Logistic regression models were constructed and odds ratios with 95% confidence intervals (95% CI) were calculated to evaluate airway-related and hemodynamic complications. Statistically significant differences and outcomes were determined as a  $P$  value <0.05.

## Results

A total of 2833 conventional laryngoscopy-intubation questionnaires were completed from a pool of 3720 (476 incomplete questionnaires and 411 cases involving accessory airway devices). Based on billing record sampling, approximately 22% of patients did not have a questionnaire completed. Moreover, patients requiring endotracheal intubation did not have a billing record submitted in 20% of the cases based on a sampling audit (1992, 24%; 1997, 12%; and 2000, 3%). Hence, the exact numerator is unknown, but it was estimated that the database captured approximately 60% of the procedures. The patients ranged in age

**Table 1.** Complication Variable Definitions

Bradycardia	HR <40 if >20% decrease from baseline
Tachycardia	HR >100 if >20% increase from baseline
Hypotension	SBP <90 mm Hg (MAP <60 mm Hg) if >20% decrease from baseline
Hypertension	SBP >160 if >20% increase from baseline
Hypoxemia	Spo <sub>2</sub> <90% during intubation attempt (profound <70%)
Regurgitation	gastric contents which required suction removal during laryngoscopy in a previously clear airway
Aspiration	visualization of newly regurgitated gastric contents below glottis or suction removal of contents via the ETT
Cardiac arrest	asystole, bradycardia, or dysrhythmia w/nonmeasurable MAP & CPR during or after w/in intubation (5 min).

HR = heart rate; SBP = systolic blood pressure; MAP = mean arterial blood pressure; Spo<sub>2</sub> = pulse oximetry saturation; CPR = cardiopulmonary resuscitation; ETT = endotracheal tube.

**Table 2.** Hospital Location and Complication Risk Ratio Compared to Other Areas

Hospital location	% patients	Complications	P-value, risk ratio (95% CI)
Surgical ICU (32 beds)	27	bradycardia	<0.04, 1.5 (1.1-2.2)
Medical ICU (16 beds)	21	regurgitation	<0.004, 1.9 (1.2-2.9)
Floor	16	aspiration	<0.002, 3 (1.6-5.7)
Neurosurgical/trauma ICU (10 beds)	12	hypoxemia	<0.03, 0.6 (.43-93)
Emergency department	10	hypoxemia	<0.001, 1.7 (1.7-2.2)
Coronary ICU (12 beds)	9		
Radiology/cardiac catheterization/PACU	5		

ICU = intensive care unit; PACU = postanesthesia care unit.

**Table 3.** Primary Disease Leading to Intubation and Intubation Attempts

Primary disease category	% patients	2 or fewer attempts (%)	>2 attempts (%)
All groups combined		90	10
Cardiac (CHF, MI, arrhythmia)	28	93.2	6.8
Pulmonary (pneumonia, aspiration, COPD, secretions)	24	89.8	10.2
Sepsis-SIRS (pulmonary, abdominal, misc.)	16	93.7	6.7
Neurosurgical/neurological (CVA, seizure, trauma)	14	86.9	13.1*
Trauma	12	87.8	13.9*
Metabolic (DKA, renal or liver failure, OD)	4	90.2	9.8
GI bleeding	2	85.9	14.1*

MI = myocardial infarction; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; Misc. = miscellaneous; CVA = cerebral vascular event; DKA = diabetic ketoacidosis; GI = gastrointestinal; SIRS = systemic inflammatory response syndrome; OD = over dose.

\* P < 0.03 when compared with sepsis and cardiac groups.

**Table 4.** Methods of Patient Preparation

Medication	% patients
Topical local anesthetic or nothing	17
Thiopental (0.5-5 mg/kg, 75-500 mg)	10
Midazolam (0.02-0.12 mg/kg, 1-9 mg)	27
Midazolam & morphine (0.02-0.07 mg/kg of each, 2-5 mg each)	6
Morphine (0.04-0.1 mg/kg, 2-8 mg) or fentanyl (50-150 µg)	7
Etomidate (0.04-0.25 mg/kg, 4-24 mg)	27
Propofol (0.5-1.9 mg/kg, 40-240 mg)	4
Diazepam (0.05-0.12 mg/kg, 5-10 mg), methohexital (0.3-1.2 mg/kg, 30-130 mg)	2
Muscle relaxant	
depolarizer-succinylcholine (81% of total use)	20
nondepolarizer-vecuronium, rocuronium (19% of total use)	

from 16 to 98 yr old (mean, 68.71 yr; median, 67 ± 17.5 yr), with a sex distribution of 62:38 men:women. The location of the airway procedure is listed in Table 2.

The immediate availability of advanced airway equipment was nearly nonexistent before 1995, and thereafter, portable airway bags were made available with

**Table 5.** Complications by Intubation Attempts

Complication	2 or fewer attempts (90%)	>2 attempts (10%)*	Relative risk for >2 attempts	95% CI for risk ratio
Hypoxemia	10.5%	70%	9X	4.20 – 15.92
Severe hypoxemia	1.9%	28%	14X	7.36 – 24.34
Esophageal intubation	4.8%	51.4%	6X	3.71 – 8.72
Regurgitation	1.9%	22%	7X	2.82 – 10.14
Aspiration	0.8%	13%	4X	1.89 – 7.18
Bradycardia	1.6%	18.5%	4X	1.71 – 6.74
Cardiac arrest	0.7%	11%	7X	2.39 – 9.87

\* All categories  $P < 0.001$  when comparing 2 or fewer attempts to >2 attempts.

an assortment of devices as suggested by the ASA Guidelines (laryngeal mask airway, Combitube<sup>®</sup>, bougie stylet, hand-held jet apparatus, and a percutaneous cricothyrotomy kit). The airway bag had to be transported to the intubation location by anesthesia personnel. A difficult airway cart was deployed in the year 2000 to all intensive care unit (ICU) locations, radiology, cardiac catheterization suite, and various floor locations.

The indications for emergency airway management were multifactorial in nature, yet the patients were categorized in general groups based on the primary system contributing to the need for airway support (Table 3). Cardiac disease (acute myocardial infarction, congestive heart failure, tamponade, and dysrhythmia), primary pulmonary issues (chronic obstructive pulmonary disease, pulmonary aspiration, secretions, and respiratory failure), neurosurgical/neurological disease (cerebral vascular accident, intracerebral bleed, and seizure), trauma-related injury (orthopedic, thoracic, and abdominal and neuro-trauma), and sepsis were major categories. Upper gastrointestinal bleeding and metabolic derangements (hepatic, renal failure, etc.) were less common categories.

The majority of patients undergoing emergency tracheal intubation received relatively small doses of sedative-hypnotics for sedation-only preparation, as compared with elective anesthesia induction doses customary in the OR. Topical anesthesia to the oral airway alone, or no medications at all, accounted for 17% of the cases. Parenteral medication included midazolam, morphine, midazolam combined with morphine, thiopental, etomidate, propofol, diazepam, and methohexital. NMBDs were used in 20% of the cases, consisting of succinylcholine (81%) or a nondepolarizing drug (rocuronium or vecuronium, 19%) (Table 4).

Overall, more than two thirds (68%) of the intubations were successful on the first attempt, and 1 in 10 cases required three or more intubation attempts (10%; Table 3). More specifically, the attending staff, as a group, had a 9.0% rate of three or more attempts, CA-1 residents had 14.5%, CA-2 residents had 10.4%, and CA-3 residents had 9.0%. The staff attending was credited with the intubation after taking over for the

resident in 19% of cases. Discounting these cases, attending-only cases had a rate of 6.3% (3 or more attempts;  $P < 0.05$  when compared with the resident groups). More than 99% of the intubations were completed orally versus only a small number of nasal approaches ( $n = 26$ ).

Based on the complication variables, the incidence of hypoxemia, overall, was 17.7%, and one third of these cases represented severe hypoxemia ( $\text{SpO}_2 < 70\%$ ). The incidence categorized by intubation attempts varied significantly; endotracheal intubation requiring 2 or fewer attempts was 10.5% versus 70% for more than 2 attempts (Fig. 1 and Table 5). More specifically, the rate for 1 attempt was 4.8%, 2 attempts was 33.1%, 3 attempts was 62%, and 4 or more attempts was 85% ( $P < 0.001$ ). In their respective intubation categories, severe hypoxemia was distributed disproportionately in those requiring more than 2 attempts (28% of total patients and 40% of the total hypoxemic patients) versus 2 or fewer attempts (1.9% of total patients and 18% of the total hypoxemic patients). Those suffering a single episode of esophageal intubation (EI) had a 51% chance of hypoxemia. Independently, EI increased the risk of hypoxemia nearly 11-fold (95% CI, 7.7–13.2). Furthermore, patients who experienced 2 or more esophageal intubations had a significant rate of hypoxemia (85% overall; 2 EI, 76%; 3 EI, 96%; and 4 EI, 100%).

The overall rate of EI in the database was 9.7%. The incidence of EI in the 2 or fewer attempts group was <5% (zero for 1 attempt and 19.8% for 2 attempts) in comparison to more than 2 attempts with an overall incidence of 51.4% (3 attempts, 48.9%; 4 or more attempts, 55.1%) (Fig. 1 and Table 4). The relative risk ratio of suffering an EI was 6-fold more in those who had more than 2 attempts. Moreover, the risks of a single EI was considerably less in comparison to those suffering multiple EI (2 or more EI) because each of the airway and hemodynamic complications escalated (hypoxemia, 58% versus 88.3%; regurgitation, 21.8% versus 35%; aspiration, 10% versus 15.6%; bradycardia, 13.4% versus 45%; and cardiac arrest, 4% versus 20%).

The risk of regurgitation, with or without aspiration, was considerably higher than what anesthesia

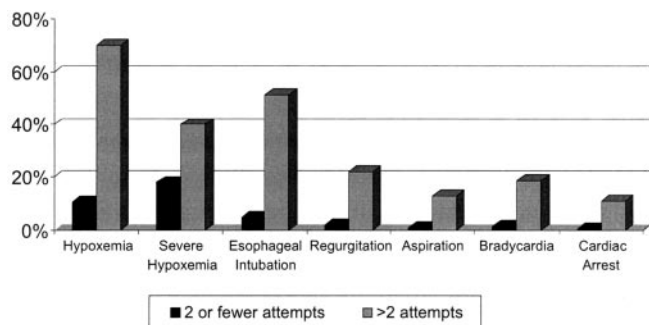


Figure 1. Graphic display of complications by intubation attempts.

practitioners are typically accustomed to in the elective situation in the OR. The incidence was very small (1.9%) for those who had their airway secured on 2 or fewer attempts (1 attempt, 1.1%; 2 attempts, 5.2%) and increased 10-fold when 3 or more attempts were required (Table 5 and Fig. 1). Aspiration of gastric contents was minimal for 1 attempt (0.3%) and 2.3% for those requiring 2 attempts. EI independently increased the relative risk of regurgitation (9.6-fold; 95% CI, 6.5–14.2) and aspiration (8-fold; 95% CI, 4.7–15.1) considerably.

There was a significant relationship between the various airway-related complications as the number of laryngoscopic attempts accumulated. Often, one complication creates others, most often in patients requiring 3 or more intubation attempts. For example, those who experienced EI had a significant risk of developing hypoxemia (60%). Likewise, 9 of 10 patients who regurgitated developed hypoxemia (91%). Aspirating gastric contents overwhelmingly lead to hypoxemia (95%), of which 30% experienced profound desaturation less than  $\text{SpO}_2 < 70\%$ .

The location of the intubation took place in several areas of the hospital, as outlined in Table 2. Logistic-regression analysis confirms that the location within the hospital had no statistical bearing on the number of intubation attempts (1 to 2 attempts versus more than 2 attempts and 3 attempts versus 4 or more attempts, individually). However, several airway and hemodynamic complications were significantly influenced by the location of the airway procedure. Patients intubated on the floor had a 3-fold increased risk (95% CI, 1.6–5.7;  $P < 0.002$ ) of suffering aspiration compared with other areas. The medical ICU location had an increased risk of regurgitation (2 $\times$ ), hypoxemia was nearly twice as likely in the ED, and there was a 40% reduction in risk of hypoxemia in the neuro-trauma ICU locale when compared with other locations (Table 2). In evaluation of the primary reason for intubation, upper gastrointestinal bleed patients (14.1%), trauma (13.9%), and neurologic-based intubations (13.1%) had a statistically increased need for 3 or more intubation attempts compared with the sepsis

and cardiac groups ( $P < 0.03$ ) but not when compared with the overall group (10%).

The incidence of tachycardia, hypotension, and hypertension showed no statistically significant differences with an increasing number of laryngoscopic attempts. However, the incidence of a bradycardic response, most often associated with a marked reduction in the  $\text{SpO}_2$ , was relatively uncommon (1.6%) in those who were successfully intubated with 1 (1.3%) or 2 attempts (2.6%) but burgeoned to 18.5% when 3 or more attempts were required. As an independent variable, those suffering EI had a substantially increased risk of bradycardia (12-fold; 95% CI, 8.2–13.3). Nearly 90% of the bradycardia cases had associated severe hypoxemia ( $\text{SpO}_2 < 70\%$ ), and one half of the bradycardic episodes culminated in cardiac arrest requiring cardiopulmonary resuscitation. The risk of cardiac arrest similarly increased as the number of intubation attempts increased. The overall risk was minimal (0.7%) with 1 or 2 attempts versus 11% for more than 2 attempts (a weighted average of 10% among those requiring 3 attempts and 12.5% requiring 4 or more attempts).

## Discussion

A detailed analysis of intraoperative mishaps has shown that respiratory-based complications during airway management, i.e., oxygenation and ventilation difficulties, account for nearly one third of all anesthetic deaths (11–14). Conversely, the hemodynamic alterations and airway-related complications anesthesiologists face when providing emergency airway management outside of the OR are numerous and often cause significant patient morbidity and potentially mortality. Schwartz et al. (1) reported in a prospective review of emergency intubation outside the OR (and emergency department) that the incidences of aspiration, esophageal intubation, postintubation pneumothorax, and difficult intubation but did not report on the relationship between repetitive intubation attempts and complications. Conversely, however, the more common hemodynamic alterations associated with emergency airway management, such as intubation-related hypotension, hypotension, and tachycardia, and airway-related complications, such as hypoxemia, esophageal intubation, and regurgitation, have not received their warranted consideration in the anesthesia literature. The difficult intubation requiring 3 or more attempts, although relatively uncommon in the elective clinical situation, is reported to represent nearly 10% of the patients that require emergency airway management outside the OR and that airway-related and hemodynamic-related complications are relatively common in this clinical setting (2).

The ASA Task Force on the Management of the Difficult Airway has put forth the recommendation,

based on consensus opinion of their expert consultants and not evidence-based medical data, to limit conventional intubation attempts to three to reduce airway trauma, swelling, and patient injury (9,10). However, to this end, there has been little clinical information offered to support, contest, or refute this airway management viewpoint. Moreover, the extent of penetration of the Guidelines into clinical practice in the OR as well as the remote location under emergency circumstances remains unreported.

This practice analysis provides evidence that the rate of hypoxemia, esophageal intubation, regurgitation, aspiration, bradycardia, and cardiac arrest accelerated beyond two intubation attempts. These findings lend support to the recommendation of limiting intubation attempts to three conventional attempts, albeit for emergency airway management services provided in the remote location, because of the impressive increase in airway-related and hemodynamic critical events. The considerable increase of complications between two and three attempts may warrant further refinement of the recommendation of limiting attempts to three, and perhaps emphasize that alternative airway techniques and the use of accessory devices may better serve the patient if considered even earlier in the process of securing the airway. However, this data review does not provide any evidence that aborting conventional laryngoscopy and intubation after three attempts in lieu of an accessory airway device or alternative airway rescue technique, will provide any patient benefit or improve the level of patient safety. Intuitively, incorporation of such a device or technique may decrease the incidence of complications, but the design of this practice review does not address this important airway management issue.

Several factors that the Guidelines have attempted to address but may still hamper the intubator's ability to secure the airway may include the pursuit of conventional laryngoscopy on a repetitive basis at the exclusion of other methods by the individual, multiple personnel attempting intubation by conventional methods in a repetitive fashion, the relative lack of confidence, cognitive skills, or lack of experience with advanced rescue techniques, and the lack of immediate accessibility to advanced airway equipment. Based on the findings of this practice analysis, laryngoscopy on a repetitive basis, using three or more attempts as a reference basis, is beleaguered by patient morbidity and possible life-threatening critical events. Although the question regarding the value of pursuing the use of an advanced technique after three attempts was not addressed, the evidence suggesting the potential for a marked increase in airway-related and hemodynamic critical events when more than two attempts are required should encourage one to more timely pursue incorporation of the ASA recommendation of non-emergency and emergency pathway rescue options.

The limitations of this database include the reliance on personnel to accurately complete the questionnaire for submission to the database and may have benefited by a sampling of questionnaires by an independent, neutral observer rated to validate the accuracy of the self-report system. Furthermore, consideration should be given to the stressful, emergent, and dire circumstances in which the airway procedures were performed and the subsequent potential to underestimate and therefore underreport the number of intubation attempts or complications. Although the author reviewed each questionnaire and made every attempt to confirm the documented data with the physician, nurses, and support staff, a major concern with any spontaneous reporting system is underreporting of adverse events and the subsequent effect on the true numerator and the denominator of actual cases. Sanborn et al. (16) and others (17-19) have suggested that voluntary reporting of undesirable anesthesia clinical events is strikingly infrequent. A portion of the questionnaires that were excluded because of illegibility or incomplete documentation and a number of patient encounters that failed to generate a submitted questionnaire are additional limitations of this reporting vehicle.

The primary focus of the ASA Guidelines is the management of the difficult airway encountered during administration of anesthesia and tracheal intubation. The ASA, however, acknowledges that some aspects of the Guidelines may be relevant in other clinical contexts (9,10). This data review provides substantial evidence that the incidence of airway and hemodynamic complications distinctly increase beyond two laryngoscopic attempts during emergency airway management in the remote location. Therefore, adapting the recommendation put forth by the ASA Guidelines on the Management of the Difficult Airway to limit intubation attempts to three seems warranted in emergency airway management outside the confines of the OR. This database did not investigate the clinical utility of accessory airway devices or advanced rescue techniques nor any improvement in the degree of safety we may offer to our patients when conventional methods prove difficult or unsuccessful.

This practice analysis and its findings prompt anesthesia personnel to rethink their approach to the elective and emergency management of the airway for the promotion of patient safety. The development of a secondary or backup airway management approach combined with the timely incorporation of rescue options in airway management strategy, although not proven, may be prudent toward improving the delivery of airway care for our patients. Moreover, this information has vast implications for the education and training of our anesthesia and nonanesthesia colleagues who are responsible for airway management outside the OR under the demands of an urgent or

emergent situation and should serve as a motivation for rethinking his or her approach to airway management in the promotion of patient safety.

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David O'Sullivan, Senior Scientist, Department of Research Administration, Hartford Hospital and Jonathan Clive, PhD, Department of Biostatistical Consultation, University of CT School of Medicine provided statistical analysis.

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