The Endotracheal Tube Cuff-Leak Test As a Predictor for Postextubation Stridor

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BACKGROUND: The endotracheal tube (ETT) cuff-leak test (CLT) has been proposed as a relatively simple, noninvasive method for detecting the presence of laryngeal edema prior to tracheal extubation. OBJECTIVE: To determine the value of the CLT for predicting postextubation stridor (PES) among medical and surgical patients, and to assess the impact of certain variables on the incidence of PES. METHODS: We conducted a prospective, observational study in the intensive care unit at Washington Hospital Center, a 907-bed acute care hospital in Washington DC, with patients who were intubated for > 24 h. As part of respiratory therapy quality assurance, patients intubated for > 24 h are evaluated daily for extubation readiness, and CLT is conducted prior to extubation. The CLT results and the postextubation outcomes were prospectively recorded for 6 months. RESULTS: Of the 462 patients studied, 20 (4.3%) developed PES that required treatment; 7 of those 20 (1.5%) required reintubation. With patients who failed the CLT, defined by an absolute leak volume ≤ 110 mL, the positive predictive value for PES was 0.12, the negative predictive value was 0.97, the sensitivity was 0.50, and the specificity was 0.84. Using different definitions for CLT failure did not improve the accuracy of CLT for predicting PES. Patients who had PES were more likely to be female (6.5% vs 2.4%, p = 0.04), to have a longer duration of translaryngeal intubation (6.5 ± 4 d vs 4.5 ± 4 d, p = 0.02), and to have a larger ratio of ETT size to laryngeal size (49.5 ± 6% vs 45.5 ± 6%, p = 0.01). CONCLUSIONS: Failing the CLT was not an accurate predictor of PES and should not be used as an indication for either delaying extubation or initiating other specific therapy. Female patients, those whose ratio of ETT size to laryngeal diameter was > 45%, and patients intubated for > 6 d were more likely to develop PES. *Key words: stridor, tracheal intubation, endotracheal tube cuff, airway obstruction, laryngeal edema, extubation failure.* [Respir Care 2005;50(12):1632–1638. © 2005 Daedalus Enterprises]

Introduction

Translaryngeal intubation is a potentially life-saving procedure for patients in respiratory distress. It allows for mechanical ventilation and protection of the airway, but it is associated with complications. Laryngeal damage, such as ulceration, edema, and mechanical dysfunction, commonly occurs.[1] Usually the associated laryngeal damage is well tolerated, hoarseness being the most common clinical manifestation. Postextubation stridor (PES) is a much less common, but feared, clinical manifestation of translaryngeal-intubation-associated laryngeal damage.

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Stridor has been reported to occur in 2–37% of patients immediately following extubation.[2–12] Treatment options for PES include nebulized racemic epinephrine, helium-oxygen mixture (heliox), and corticosteroids. Reintubation is reported in up to 10% of patients who require treatment for PES.[2–5,11] At present it is difficult to predict which patients will develop PES. The cuff-leak test (CLT) has been proposed as a relatively simple, noninvasive method for identi-

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fying patients at risk for PES. However, previous studies on the value of the CLT have been limited by small sample sizes (fewer than 110 patients)[2–5,11] and a narrow patient spectrum (pediatric, burn, or post-cardiac surgery).[7,13–14]

The primary objective of this study was to determine the value of the CLT for predicting PES in a large population of adult medical and surgical patients. A secondary objective was to determine the impact of certain variables, including the use of corticosteroids prior to extubation, duration of translaryngeal intubation, and the size of the endotracheal tube (ETT) relative to the diameter of the larynx, on the incidence of PES.

Methods

This prospective study was conducted in the medical and surgical intensive care units of Washington Hospital Center, a 907-bed acute-care hospital in Washington DC. Approval for data collection in this study as part of the respiratory therapy quality assurance program was sought and granted by the institution's review board, which waived the requirement for informed consent.

All patients who require intubation at Washington Hospital Center, either pre-operatively or in emergency situations, are evaluated by an anesthesiologist. The ETTs have low-pressure, high-volume cuffs, and cuff pressure is maintained below 24 cm H_2O. Ventilator management and discontinuance are in accordance with Washington Hospital Center's standard-of-care practices, or at the discretion of the attending physician. As part of the respiratory-therapy quality assurance program, all patients intubated for $>$ 24 h are evaluated daily for extubation readiness. With each patient, prior to endotracheal extubation, the CLT is performed by one of the staff of the respiratory therapy department, all of whom are either certified or registered respiratory therapists. Over the previous 3 years the staff have routinely performed this procedure as a part of evaluation for extubation readiness.

To perform the CLT, the patient is placed in the semi-Fowler's position, suctioned intraorally and intratracheally, and put on the assist-control ventilation mode. With the ETT cuff inflated to the minimum occlusion volume, the mechanical exhaled volume is observed and recorded. Then the therapist deflates the ETT cuff. To ensure the exclusion of erroneous values due to escaped functional residual capacity resulting from positive end-expiratory pressure, the mechanical exhaled tidal volume is observed over the next 6 respiratory cycles. The average of the 3 lowest exhaled volumes is recorded. The cuff leak is calculated as the difference between the mechanical exhaled volume with the cuff inflated and the average of the 3 lowest exhaled volumes with the cuff deflated.

Following endotracheal extubation, patients are observed for symptoms and signs of PES. For the purpose of this study, a patient was considered to have PES if respiratory distress with inspiratory grunting, whistling, or wheezing developed in the 24 h following extubation and required physician-directed medical intervention beyond humidified oxygen therapy, including nebulized racemic epinephrine, heliox therapy, noninvasive positive-pressure ventilation, or reintubation.

From the medical record we collected date of intubation; date of extubation; ETT size; intubation route; whether the patient had been intubated previously, and, if so, the reason for reintubation; the actual volume of the cuff leak and the exhaled volume with the cuff inflated; any history of either laryngeal disease or smoke inhalation; and the initial indication for intubation. We recorded whether there was corticosteroid administration prior to extubation, as well as any treatment for PES.

We calculated the absolute volume of the cuff leak and the percentage of the volume leaked relative to the exhaled volume with the cuff inflated. The ratio of the ETT size to laryngeal size was determined using the regression equation developed by Higenbottam and Payne for estimating laryngeal anterior-posterior (A-P) diameter:[15]

$$\text{A-P diameter (mm)} = (33.9 \times \text{height [m]}) - 33.7$$

In that study[15] the A-P diameter of the larynx in the area of the vocal folds had a significant correlation with cadaveric height. Each patient's height was recorded, and the A-P diameter was deduced with that regression equation. The ratio was then established by comparing the outer diameter of the ETT to the determined A-P diameter of the larynx.

Data were analyzed with commercially available software (SPSS for Windows, version 10.0, SPSS, Chicago, Illinois). All continuous variables are reported as means $\pm$ SD. Frequencies are used to describe categorical data. The unpaired *t* test was used to compare differences between patients with and without PES for continuous variables, and the chi-square test was used for categorical variables. Previous investigations[2,4] on the performance of the CLT have used receiver-operating-characteristic curves to determine threshold values for absolute cuff-leak volume and cuff-leak volume as a percent of the exhaled volume that would predict PES. Miller and Cole[4] found that $<$ 110 mL of absolute volume predicted PES. De Bast et al,[2] using an alternative approach, found that $<$ 15.5% of the exhaled volume predicted PES. In this study an absolute volume $<$ 110 mL or 15.5% of exhaled volume was considered a CLT failure, and sensitivity, specificity, positive predictive value, and negative predictive value of the CLT were calculated with those thresholds. In addition, likelihood ratios of a positive test result and a negative test result were calculated. The diagnostic accuracy of the absolute cuff-leak volume and the percent of exhaled cuff-

Table 1. Characteristics of Study Participants*

Age (mean ± SD y)	61 ± 17
Sex (M/F)	246/216
Service (medical/surgical)	212/250
Patients with history of laryngeal disease (number and %)	15 (3.2)
Patients with smoke inhalation (number and %)	5 (1.1)
Intubation route (oral/nasal)	454/8
Duration of translaryngeal intubation (mean ± SD d)	5 ± 4
Patients who received pre-extubation corticosteroids (number and %)	106 (22.9)
Ratio of ETT size to laryngeal size (mean ± SD %)	46 ± 6

*n = 462
ETT = endotracheal tube

leak volume approaches for the CLT were assessed with receiver-operating-characteristic curves.[16] These curves were visually inspected individually for ideal threshold values.

Results

The study was conducted over a 6-month period from August 1, 2002, to January 31, 2003, during which 922 patients were intubated for > 24 h. CLTs were not performed on 460 of those patients, because of death (108), self-extubation (59), tracheostomy (144), or the omission of the CLT prior to extubation (149). Seven of the 149 patients (1.5%) who did not undergo a CLT were treated for PES. A pre-extubation CLT was performed on the remaining 462 patients.

Table 1 shows the demographic and baseline characteristics of the 462 study patients. Only 15 patients had a prior history of laryngeal or oropharyngeal disease, and only 5 had a history of smoke inhalation. The majority of patients (454, 98.3%) were intubated using the traditional oral route; 8 patients were nasally intubated.

There were 82 patients who failed the CLT as defined by an absolute volume ≤ 110 mL. Ten of those patients developed PES. There were 380 patients who passed the CLT, 10 of whom developed PES. Based on those values, the positive predictive value for PES following a failed CLT was 0.12 and the negative predictive value was 0.97 (Table 2). Sensitivity and specificity for this threshold were 0.50 and 0.84, respectively.

The alternative approach (≤ 15.5% of the exhaled tidal volume) had similar performance characteristics. Of the 48 patients who failed the CLT, 7 developed PES, and of the 414 patients who passed the CLT, 13 developed PES. With this approach, the failed CLT had a positive predictive value of 0.15, a negative predictive value of 0.97, a sensitivity of 0.35, and a specificity of 0.91 (Fig. 1). Based on those performance characteristics, the likelihood ratio of a positive test (ie, the probability of a failed CLT in a patient with PES compared to the probability of a failed CLT in a patient without PES) is 3.07 for absolute volume and 3.77 for percentage of volume. The likelihood ratio of a negative test (ie, the probability of passing the CLT in a patient with PES compared to the probability of passing the CLT in a patient without PES) is 0.59 for absolute volume and 0.72 for percentage of volume. Visual inspection of the 2 receiver-operating-characteristic curves showed that they were very similar and failed to identify specific threshold values as accurate predictors of PES (see Fig. 1).

Twenty patients in this study developed PES, making the prevalence or pre-test probability of PES in the study population 4.3% (20/462). Table 3 shows the demographic data, baseline characteristics, and the immediate postextubation medical outcomes of the 20 patients who were treated for stridor. Five patients (25%) whose PES was severe required immediate reintubation. Fifteen patients received nebulized racemic epinephrine. Four of those patients required intervention in addition to the initial racemic epinephrine; 2 patients were given heliox therapy noninvasively, and 2 patients subsequently required reintubation. Reintubation due to PES occurred in 1.5% (7/462) of patients.

As a secondary analysis, Table 4 compares the demographic data and baseline characteristics of patients with and without stridor. There were no significant differences between the 2 groups in mean age ($p = 0.92$) or the hospital service in which the patient was managed ($p = 0.32$). PES occurred more often among female patients (6.5% or 14/216) than male patients (2.4% or 6/246) ($p = 0.04$). In addition, patients with PES had longer duration of translaryngeal intubation (6.5 ± 4 vs 4.5 ± 4 d, $p = 0.02$) and larger ETT/laryngeal size ratio (49.5 ± 6 vs 45.5 ± 6%, $p = 0.01$) than patients without PES. Cuff leak, expressed as either absolute volume (148 ± 143 mL vs 277 ± 149 mL, $p < 0.001$) or as percentage of tidal volume (30 ± 27% vs 55 ± 26%, $p < 0.001$), was smaller among patients with PES. Of the 106 patients who received corticosteroids prior to extubation, 5.7% (6/106) developed PES, versus 3.9% (14/356) of patients who did not receive corticosteroids ($p = 0.06$).

Based on the range for duration of translaryngeal intubation in the patients who developed PES (data not shown), 6 d was used as a threshold for determining if there was an increased risk of PES associated with duration of translaryngeal intubation. With that threshold, 7.1% (9/127) of patients intubated for ≥ 6 d developed stridor, and 3.3% (11/335) of patients intubated for ≤ 6 d developed stridor ($p = 0.02$). Based on the range for the ETT/laryngeal size ratio (data not shown), a ratio of 45% was used as a threshold.

Table 2. Incidence of Stridor Relative to Absolute Volume of Cuff Leak, and to Cuff Leak As a Percentage of Exhaled Volume

	Received Treatment for Stridor	Did Not Receive Treatment for Stridor	Characteristics
Failed cuff-leak test (< 110 mL)	10	72	PPV = 0.12
Passed cuff-leak test (> 110 mL)	10	370	NPV = 0.97
			Sensitivity = 0.50
			Specificity = 0.84
			LR (+) = 3.07
			LR (−) = 0.60
Failed cuff-leak test (< 15.5%)	7	41	PPV = 0.15
Passed cuff-leak test (> 15.5%)	13	401	NPV = 0.97
			Sensitivity = 0.35
			Specificity = 0.91
			LR (+) = 3.77
			LR (−) = 0.72

PPV = positive predictive value
NPV = negative predictive value
LR (+) = positive likelihood ratio
LR (−) = negative likelihood ratio

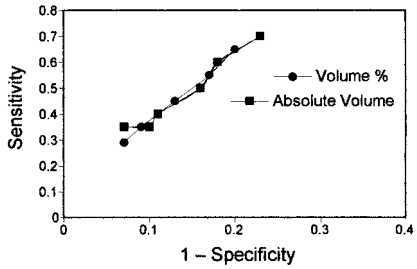

Fig. 1. Receiver-operating-characteristic curves for absolute volume of cuff leak and for cuff leak as a percentage of the exhaled tidal volume.

With that threshold, 2.4% (6/251) of patients with a ratio < 45% developed stridor, and 6.6% (14/211) of patients with a ratio > 45% developed stridor ($p = 0.01$).

Discussion

This study evaluated the performance characteristics of the CLT and the potential impact of certain variables on the incidence of PES in a large cohort of adult medical and surgical intensive-care patients. The performance characteristics of the CLT were insufficient for the test results to be used in routine treatment decisions. Specifically, the data show that failing the CLT is not a useful predictor of PES and should not delay extubation or lead to the initiation of specific prophylactic treatment. The receiver-operating-characteristic analysis showed that neither of the tested indices for cuff-leak failure, expressed as absolute volume or percent of exhaled volume performed similarly, was predictive of PES. There were significant relationships between certain variables and the probability of PES. Female sex, prolonged intubation, and a large ETT size in relation to laryngeal size were associated in this study with a higher risk of PES. Treatment with corticosteroids prior to extubation was not associated with a lower risk of PES.

PES in the adult population is reported in 2–37% of cases.[2–4,6,8,11] Such variability is the result of a lack of uniform diagnostic criteria for PES. The diagnosis of PES can be subjectively made by clinical end points, such as prolonged inspiratory phase and use of accessory muscles, or the requirement of treatment. Miller and Cole defined PES as respiratory distress associated with a high-pitched whistling that required treatment, and reported PES in 6% of cases.[4] Darmon et al reported PES in 4.2% of cases, diagnosed using clinical end points.[6] We used clinical criteria similar to those used in these studies,[4,6] and the prevalence (or pre-CLT test probability) of PES of 4.3% in our study was well within the reported adult range. Based on this pre-test probability of PES and a likelihood ratio of about 3 for a positive test, the probability of developing PES with a failed CLT would be only 12%.[17] This post-test probability of PES is too low to be relied upon for clinical decision making. It could be argued that the CLT might be more valuable in a patient population with a higher pre-test probability of PES. However, the low likelihood ratio of about 3 for a failed CLT indicates that that is not the case. Assume the case of a patient with upper-airway thermal injury and a pre-test probability of 60% for PES. A failed CLT with a likelihood ratio of about 3 would increase the post-test probability to 82%, and a

Table 3. Characteristics of the 20 Patients Treated for Stridor

Sex	Days of Intubation	Ratio of ETT Size to Laryngeal Size (%)	V_T Leak (mL)	% of V_T Leak	Prior Use of Steroids	Treatment for Stridor
M	3	47	0	0	No	Racemic epinephrine
M	4	38	0	0	No	Racemic epinephrine
F	11	51	10	2	No	Racemic epinephrine
F	12	51	10	2	No	Racemic epinephrine
F	12	46	80	14	No	Racemic epinephrine
F	2	57	100	25	Yes	Racemic epinephrine
F	8	55	120	25	Yes	Racemic epinephrine
M	5	45	149	28	Yes	Racemic epinephrine
F	3	44	283	63	No	Racemic epinephrine
M	12	58	330	73	No	Racemic epinephrine
M	9	42	430	78	No	Racemic epinephrine
F	14	61	50	17	No	Racemic epinephrine, heliox
F	5	46	136	32	Yes	Racemic epinephrine, heliox
F	3	52	10	3	Yes	Racemic epinephrine, reintubation
M	6	43	460	75	No	Racemic epinephrine, reintubation
F	8	48	50	20	No	reintubation
F	2	45	105	14	Yes	reintubation
M	5	48	120	30	No	reintubation
F	2	51	220	49	No	reintubation
F	2	62	300	60	Yes	reintubation

ETT = endotracheal tube
V_T = tidal volume

Table 4. Characteristics of Patients With and Without Stridor*

	Patients With Stridor	Patients Without Stridor	p
Number of patients	20	442	NA
Age (mean ± SD y)	62 ± 18	61 ± 17	0.92
Sex (M/F)	6/14	240/202	0.04
Service (medical/surgical)	7/13	205/237	0.32
Duration of translaryngeal intubation (mean ± SD d)	6.5 ± 4	4.5 ± 4	0.02
Ratio of ETT size to laryngeal size (mean ± SD %)	49.5 ± 6	45.5 ± 6	0.01
Cuff leak (mean ± SD mL)	148 ± 143	277 ± 149	< 0.001
Cuff leak (mean ± SD % of V_T)	30 ± 27	55 ± 26	< 0.001
Pre-extubation administration of corticosteroids (yes/no)	6/14	100/342	0.06

* n = 462
NA = Not applicable
ETT = endotracheal tube
V_T = tidal volume

passed CLT with a likelihood ratio of about 0.6 would decrease the post-test probability to 47%. The difference between the pre-test probability and the post-test probability in this case would not be great enough to substantially alter care plans.

Previous studies have utilized receiver-operating-characteristic analysis to identify thresholds for predicting PES. Using thresholds of an absolute volume of 110 mL and a percent-of-exhaled-volume of 15.5%, as predicted from earlier studies,[2,4] we found that the CLT had poor positive predictive value. Receiver-operating-characteristic analysis with our data showed that the absolute volume and the percent-of-exhaled volume provided similar information and that there was no apparent threshold for better performance characteristics. Our study was similar to others with respect to population characteristics and the standardized

manner in which the CLT was performed, but was conducted on a larger cohort of patients. We believe this to be an explanation for the contrary conclusions.

The pathogenesis of laryngeal injury and edema from translaryngeal intubation is well understood. It is probably related to abrasion of the larynx due to pressure and friction, and is laryngoscopically identified in up to 94% of patients following extubation.[1] However, it is not well understood why most patients suffer only mild hoarseness after extubation, while clinically relevant laryngeal injury, PES, occurs in only a small fraction of these patients. Laryngeal edema is postulated to be more prevalent in female patients due to subtle differences in specific anatomic features of the larynx, such as a thinner mucosa covering the cartilage of the vocal process,[6] less resistance to trauma,[6,8] and a smaller laryngeal diameter.[6,8]

The study by Darmon et al, which is the largest to date, with 700 patients, found an association between female sex and the duration of intubation and PES.[6] Similarly, in this study, the patients who were more likely to develop PES were female and had undergone prolonged translaryngeal intubation, and they had a larger ratio of ETT size to laryngeal size. These associations are consistent with the hypothesis that abrasion, friction, and pressure on the laryngeal mucosa cause laryngeal injury.

Laryngeal inflammation and edema are thought to contribute to PES. Consequently, it has been hypothesized that corticosteroids might prevent the development of laryngeal injury severe enough to cause PES. However, several double-blind randomized controlled studies have found dexamethasone[6] and hydrocortisone[8] ineffective in preventing PES. In this study we found that patients who had been receiving corticosteroids for other reasons prior to extubation were not protected from developing PES. Although the efficacy of any specific corticosteroid treatment was not assessed or controlled in this study, our results are consistent with the findings of others that corticosteroids do not reduce the risk of PES.

This study has several strengths. A large number of patients, from both medical and surgical services, who had been intubated for prolonged periods were included. The CLT was conducted in a standardized fashion that facilitated collection and comparison of quantitative data. Although, to our knowledge, no study has tested the inter-observer and intra-observer variability of the quantitative CLT in the adult population, Pettignano et al proved the CLT to be reproducible and operator-independent, using a different standardized approach.[18] Our definition of stridor was based on the need for medical intervention related to respiratory distress associated with stridor, making the definition highly relevant clinically. However, there is no standardized protocol for the treatment of PES, and inferences to the degree of PES may be ambiguous. Ideally, laryngoscopic visualization of the glottis, larynx, and subglottic area, or spirometry, would have been performed as independent corroboration of upper-airway obstruction in patients clinically recognized with PES, but it was not possible to perform these tests in a standardized and timely fashion and still provide optimal clinical care.

There may be inherent limitations, both theoretical and technical, in the CLT's ability to predict PES. When performing the CLT, laryngeal edema is assumed to be present if expiratory flow into the upper airway is nonexistent. However, turbulent flow in the upper airway is dependent upon several factors, including compliance of the lung, airway resistance, respiratory mechanics, and the degree of muscular passivity during the expiratory cycle. Neither this study nor any other has analyzed the effects of lung mechanics and properties with respect to abnormal expiratory flow in the upper airway, and their impact on the CLT. In addition, expiratory flow through the upper airway is influenced by the size relationship of the ETT to the larynx. If the ETT size is large in relation to the laryngeal size, expiratory flow into the upper airway may be hindered, even in the absence of laryngeal edema. Hence, the CLT may accurately identify decreased expiratory flow through the upper airway, but this may be due to mechanical factors other than laryngeal edema. This may explain the high false-positive rate for the CLT in this study. A majority of patients in this study who had a false positive CLT (44/72 or 61%) had an ETT/laryngeal size ratio $\geq$ 45%.

Conclusions

In summary, failure of the CLT, expressed as either the absolute volume or as a percentage of the exhaled volume, is an unreliable predictor of PES and should not be used as an indication for either delaying extubation or initiating other specific therapy. In our study the relative risk of PES was higher in patients with consistent abrasion-promoting variables, specifically: prolonged translaryngeal intubation, a ratio of ETT size to laryngeal size $\geq$ 45%, and female sex. Pre-extubation corticosteroids did not decrease the incidence of PES. Further study is needed to better understand the correlation between the abrasion-promoting variables and the development of laryngeal edema severe enough to cause PES.

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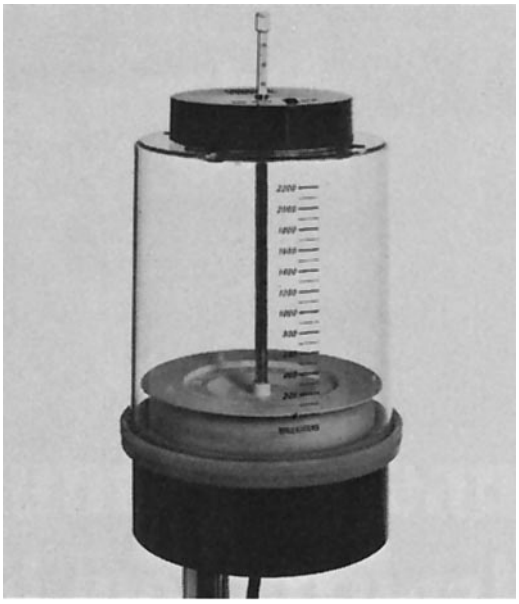

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