Clinical Investigation

Cuff leak test and laryngeal survey for predicting post-extubation stridor

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ABSTRACT

Background and Aims: Evidence for the predictive value of the cuff leak test (CLT) for post-extubation stridor (PES) is conflicting. We evaluated the association and accuracy of CLT alone or combined with other laryngeal parameters with PES. **Methods:** Fifty-one mechanically ventilated adult patients in a medical-surgical intensive care unit were tested prior to extubation using; CLT, laryngeal ultrasound and indirect laryngoscopy. Biometric, laryngeal and endotracheal tube (ETT) parameters were recorded. **Results:** PES incidence was 4%. CLT demonstrated 'no leak' in 20% of patients. Laryngeal oedema was present in 10% of the patients on indirect laryngoscopy, and 71% of the patients had a Grades 1-3 indirect laryngoscopic view. Mean air column width on laryngeal ultrasound was 0.66 ± 0.15 cm (cuff deflated), mean ratio of ETT to laryngeal diameter was 0.48 ± 0.07, and the calculated CLT and laryngeal survey composite was 0.86 ± 1.25 (range 0–5). CLT and the CLT and Laryngeal survey composite measure were not associated with or predict PES. Age, sex, peri-extubation steroid use, intubation duration and body mass index were not associated with PES. **Conclusion:** Even including ultrasonographic and indirect laryngoscopic examination of the airway, no single aspect of the CLT or combination with laryngeal parameters accurately predicts PES.

Key words: Post-extubation stridor, risk predictors, laryngeal edema

INTRODUCTION

Endotracheal intubation is the gold standard for airway management in critically ill patients in many hospital settings. It may, however, be associated with life-threatening complications. Injury to the larynx is common, but clinically unimportant in most patients.[1] The incidence of post-extubation stridor (PES) varies widely from 2% to 37% as has the necessity for re-intubation should it occur.[2-4] Since extubation is such a frequent event, there has been considerable interest in predicting the development of PES. Risk factors that have been identified include: Duration of intubation, female sex, a larger (≥45%) ratio of endotracheal tube (ETT) to laryngeal size, upper airway trauma, burns, or surgery and a high body mass index (BMI).[5]

The most studied predictor of PES is the cuff leak test (CLT). This test was originally described by Adderley and Mullins in children with croup, where the ability of the child to cough when the cuff of the ETT was deflated predicted successful extubation.[6] Multiple refinements of the CLT have since been proposed, with conflicting conclusions. These refinements have included measurement of the leak volume, measurement of the leak air column width by ultrasonography and direct laryngoscopy.[7] The evidence regarding the utility of the CLT for predicting PES is mixed particularly since its sensitivity and specificity for PES is highly variable.[8] Studies with varying designs and patient population have reported an increased sensitivity though lower specificity of the CLT for predicting PES[2] and a recent systematic review by Ochoa *et al*. concluded that a positive leak

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was associated with an increased risk for upper airway obstruction.[9] A recent study by Shin *et al*. reports the non-utility of the CLT in their patient samples.[10] Interest in the accuracy of the CLT has focused mostly on the utility of the quantitative CLT, though many clinical settings still commonly utilize the qualitative test. Additionally since laryngeal oedema is recognized as a risk factor for PES, it is reasonable to posit that the predictive accuracy of the CLT may be improved with co-consideration of laryngeal parameters. No study that we know to date has examined the predictive value of the CLT in combination with laryngeal parameters for PES prediction. The primary objective of this study was to evaluate the association and accuracy of the CLT alone or in combination with laryngeal parameters including ultrasonography and laryngoscopy for predicting PES. We also secondarily examined the association of other clinical risk factors and endotracheal intubation parameters with PES.

METHODS

This prospective study was performed in the medical and surgical intensive care units of a tertiary care hospital between January 1, 2007 and March 31, 2007. Patients were eligible if they were 18 years or older, mechanically ventilated for more than 24 h, and deemed ready for extubation by their primary physicians. Patients were included only once in the study. The only exclusion criteria were failure of the primary team to extubate the patient after data were collected. This study was approved by the medical centre's Institutional Review Board.

A weaning trial appropriate to the diagnosis and duration of intubation was performed on each patient (5 min to 2 h) and then an order for extubation was given by the medical or surgical primary team. At that time the investigators then performed a qualitative CLT, laryngeal ultrasound, indirect laryngoscopy, and a determination of BMI, estimated laryngeal anterior-posterior (AP) diameter and ETT size to laryngeal size ratio on each patient. All patients were intubated with soft pressure high volume ETT (Mallinckrodt® Endotracheal Tube), cuff pressures were monitored every 8 h with a goal of 20–24 cm H_2O. All patients were evaluated on mechanical ventilation settings of pressure support of 8 cm H_2O or less, or spontaneous mode with 100% tube compensation (Puritan® Bennett 840™).

The qualitative CLT was performed by one of the investigating physicians. The patient was placed in a semi-Fowler position, suctioned intra-orally and intratracheally, and the ETT balloon deflated. The ventilator tubing was disconnected from the ETT and the opening occluded with the thumb while listening for airway sounds during inspiration and expiration. If no sounds were audible, then the neck was auscultated with a stethoscope. The CLT was graded as follows: A 'significant leak' was defined as clearly audible airway sounds to the naked ear, 'minimal leak' as airway sounds only heard with a stethoscope, and 'no leak' as no audible airflow with and without a stethoscope. The test was done during inspiration and exhalation.

Ultrasound (General Electric Logiq 400 Pro®) examination of the larynx through the cricothyroid membrane with measurement of the air column width during inflation and deflation of the ETT balloon was performed on all patients in the fashion described by Ding *et al*.[7]

Indirect laryngoscopy (Olympus ENF Type P4) was also performed using a paediatric fibreoptic laryngoscope. This was placed through the mouth or nose, and the glottis and supraglottic structures were then visualized. The presence of oedema was noted as positive or negative, and a grading system of the indirect laryngeal view seen was utilized [Figure 1].

Body mass index was calculated using the patient's height and weight. Estimated laryngeal AP diameter was calculated using the method of Higenbottam and Payne, and ETT to laryngeal size ratio was then calculated by comparing the outer diameter of the ETT tube to the AP laryngeal diameter. In addition to the CLT, we evaluated the association of endotracheal intubation parameters, indirect laryngoscopy, intubation duration, steroid use, presence of a pre-existing respiratory condition, BMI and demographic characteristics of participants (age and

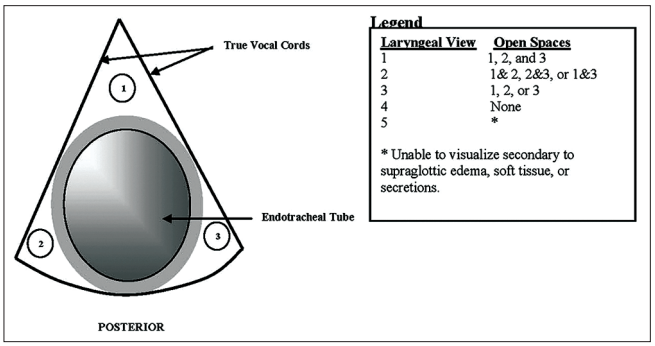

Figure 1: Indirect laryngoscopic view of the endotracheal tube at vocal cords. Areas 1, 2 and 3 in the figure

gender) on PES incidence. We calculated a composite risk measure 'CLT and laryngeal survey composite' using two CLT and three laryngeal survey parameters reported in some studies to be associated with PES. These included: (a) Grades 4–5 laryngeal view on indirect laryngoscopy, (b) CLT with no air leak on inspiration, (c) CLT with no air leak on expiration, (d) ETT external diameter/laryngeal AP diameter ≥ 0.54 and (e) air column width during cuff deflation of ≤ 0.45 cm. Each of these parameters received a score of 1 for a total possible score of 5.

The results of all of the above tests were not made available to the primary physicians. After the study tests were completed, the patient was extubated as ordered. The patient was then observed for the next 24 h for signs of PES. PES was defined as respiratory distress occurring within 24 h of extubation characterized by inspiratory sounds of whistling, wheezing, or grunting, and a physician-directed medical intervention aside from humidified oxygen, including nebulized racemic epinephrine, heliox therapy, non-invasive positive-pressure ventilation, or reintubation of the trachea.

The relationship between the CLT, laryngeal parameters and PES was examined in several ways. First, the frequency and distribution of patient characteristics, predictive parameters and PES were determined. Frequencies and distributions were used for categorical measures while means and standard deviations (SDs) were used for continuous measures. Next, the association between patient characteristics and predictive parameters was then explored using Fishers exact test for categorical variables and analysis of variance (ANOVA) with exact tests for continuous measures. The exact test was selected because of the expected small and non-parametric distribution of the study outcome variable (PES). Finally, using non-parametric assumptions, we determined the accuracy of predictor measures for PES using the area under the receiver operating characteristic (AUC) analysis. Accuracy was determined if the AUC was >0.5 and statistically significant ($P < 0.05$). All statistical analyses were conducted using Statistical Package for the Social Sciences, IBM version 16.0.

RESULTS

Fifty-one patients were enrolled during the study period. No eligible patients required exclusion from this study. Two patients had pre-existing laryngeal pathology/surgery, but neither developed PES. Patient characteristics are presented in Table 1. The sample was predominantly male (59%), aged 55 years and above (49%), of normal weight (45% with BMI < 25), mostly medical patients (69%), and most did not have a pre-existing respiratory condition on admission (71%). The mean and SD's for the air column width deflated was 0.66 ± 0.15 cm, air column width inflated was 0.74 ± 0.17 cm with a mean difference of 0.08 ± 0.67 cm. The mean and SD for the external ETT diameter was 11.38 ± 0.67 mm

Table 1: Distribution of study variables (*n*=51)

Variables	Percentage or mean±SD (frequency)
Sex	
Male	59 (30)
Age (years)	
<45	26 (13)
45-54	26 (13)
>55	49 (25)
BMI	
Normal (<25)	45 (23)
Overweight (25-30)	28 (14)
Obese (>30)	28 (14)
Pre-existing respiratory condition	
No	69 (35)
Yes	31 (16)
ETT size (in mm)	
Internal diameter	7.68±0.43 (51)
External diameter	11.38±0.67 (51)
Calculated laryngeal AP diameter (in mm)	1.09±3.14 (51)
ETT external diameter/laryngeal AP diameter	0.48±0.07 (51)
Peri-extubation steroid use (within 24 h)	25 (13)
Intubation duration (d)	3.84±3.44 (51)
Oedema on laryngoscopy	10 (5)
Indirect laryngoscopy	
Normal (grades 1-3)	71 (36)
Grade 4	26 (13)
Grade 5 (oedema)	3.9 (2)
Air column width by laryngeal ultrasound (in cm)	
Inflated	0.74±0.17 (51)
Deflated	0.66±0.15 (51)
Air column width (difference in cm)	0.08±0.67 (51)
CLT (inspiration)	
No leak	20 (10)
Minimal leak	22 (11)
Significant leak	59 (30)
CLT (expiration)	
No leak	12 (6)
Minimal leak	12 (6)
Significant leak	77 (39)
CLT and laryngeal survey composite	0.86±1.25 (51)
PES	4 (2)

SD – Standard deviation; BMI – Body mass index; AP – Anterior-posterior; ETT – Endotracheal tube; CLT – Cuff leak test; PES – Post-extubation stridor

and the calculated external ETT diameter to laryngeal AP diameters was 0.48 ± 0.07. The mean and SD of the duration of endotracheal intubation was 3.84 ± 3.44 days. Only 25.5% (13) patients had steroids administered within 24 h of extubation. Laryngeal oedema was present in 10% patients on indirect laryngoscopy. Indirect laryngoscopic view was Grades 1–3 (normal) for 36 patients (71%), Grade 4 (no visible space between ETT and glottis) for 13 patients (26%) and Grade 5 (oedema) for 2 patients (4%). The CLT showed a 'significant leak' during inspiration in 30 patients (59%), 'minimal leak' in 22% patients and 'no leak' in 20% patients. During expiration there was a 'significant leak' in 39 patients (77%), 'minimal leak' in 6 patients (12%) and 'no leak' in 6 patients (12%). PES occurred in 2 (4%) of the sample. The mean for the calculated CLT and laryngeal survey composite was 0.86 ± 1.25 (score of 0–5).

In Table 2, we present the results of the Fishers exact test analysis and ANOVA for the association between sample characteristics, other predictive parameters and incidence of PES. Patient characteristics like age, gender, BMI, primary pre-existing respiratory condition, care type (medical or surgical) were all not significantly associated with the incidence of PES. In addition, ETT diameter (internal and external) and even the ratio of ETT external diameter to laryngeal AP diameter were not significantly associated with PES. CLT (inspiration and expiration) was not associated with PES ($P = 0.40$ and 0.42, respectively). The CLT and laryngeal survey composite was also not associated with PES ($P = 0.68$). Finally, progressively less leak was associated with larger ratios of ETT/laryngeal diameter ratios.

The CLT (inspiration and expiration) did not demonstrate any statistically significant accuracy for PES prediction in the study sample: CLT inspiration AUC = 0.40 (95% confidence interval [CI]: 0.07–0.87 and $P = 0.63$) and CLT expiration AUC = 0.39 (95% CI: 0.01–0.78 and $P = 0.61$). In addition, laryngeal AP diameter, intubation duration and oedema on indirect laryngoscopy demonstrated higher though not statistically significant predictive accuracy (0.69, 0.60 and 0.71, respectively) compared to other tested parameters [Table 3]. Finally, the combination of CLT and laryngeal parameters (CLT and laryngeal survey composite) also demonstrated no accuracy for PES prediction; AUC 0.47 (95% CI: 0.14–0.81 and $P = 0.91$).

Two patients developed PES (one male, one female). Intubation duration was 3 and 4 d, respectively. Neither patient had received steroids. The male patient (age 27) had significant air leak on CLT during inspiration and expiration. His laryngeal air column width with the balloon deflated was 0.58 cm with indirect laryngeal view Grade 2, a BMI of 21.4, and an ETT outside diameter to laryngeal diameter ratio of 0.44. The female patient (age 51) had no leak on inspiration and a minimal leak on expiration on the CLT. She had a laryngeal air column width of 0.72 cm, an indirect laryngeal Grade 3 view, a BMI of 30.6, and an ETT to laryngeal diameter of 0.45. Both patients developed stridor immediately after extubation. Both failed racemic epinephrine and required re-intubation. The overall distribution of planned versus emergency versus unknown (performed in the emergency room) intubations was 18%, 16% and 68%, respectively. No association between planned versus emergency versus unknown and PES incidence was observed on analysis ($P = 0.11$).

DISCUSSION

Extubation of intensive care unit (ICU) patients is potentially a high-risk procedure associated with multiple complications including difficult post-extubation ventilation and difficult re-intubation especially in patients where the details of the original intubation are not available. Predicting the likelihood of developing PES is, therefore, critically important.[11,12]

This study is an important evaluation of the CLT and its refinements as a predictor of PES. The low observed incidence of PES in the study sample was consistent with similar previously reported studies.[13,14] The findings of this study regarding the clinical utility of the qualitative CLT for PES are important because we examined the CLT and refinements of the test that incorporate laryngeal survey parameters. This study contributes to the limited and conflicting evidence regarding both the association and predictive accuracy of the CLT, in addition to the clinical utility of co-considering laryngeal parameters in making decisions about the risk of PES. This study also adds to the previously reported literature in smaller studies suggesting that the qualitative CLT had little clinical utility,[3,15] and contrasts with the original report on CLT by Adderley and Mullins of its utility.[6] The observation of poor predictive accuracy suggest that the qualitative CLT is a poor clinical prognosticator of PES or re-intubation risk even when refined with the addition of laryngeal survey parameters and should be used with caution as a parameter for clinical decisions in this regard.

Table 2: Association between PES and predictor measures (*n*=51)

Variable	PES		No PES		Significant
	Percentage or mean±SD (*n*)	95% CI	Percentage or mean±SD (*n*)	95% CI	
Sex					
Male	3 (1)	N/A	97 (29)	N/A	0.66
Female	5 (1)		95 (20)		
Age (years)					
<45	8 (1)	N/A	92 (12)	N/A	0.26
45-54	8 (1)		92 (12)		
>55	0 (0)		100 (25)		
BMI					
Normal (<25)	4 (1)	N/A	96 (22)	N/A	1.00
Overweight (25-30)	0 (0)		100 (0)		
Obese (>30)	7 (1)		93 (13)		
Pre-existing respiratory condition					
No	3 (1)	N/A	97 (35)	N/A	0.51
Yes	7 (1)		93 (14)		
Care type					
Medical	0 (0)	N/A	100 (35)	N/A	0.09
Surgical	13 (2)		87 (14)		
ETT size (in mm)					
Internal diameter	7.75±0.35 (2)	4.57-10.93	7.67±0.44 (49)	7.55-7.80	0.81
External diameter	11.50±0.42 (2)	7.69-15.31	11.38±0.68 (49)	11.18-11.58	0.81
Calculated laryngeal AP diameter (in mm)	25.71±0.42 (2)	14.77-36.65	24.02±3.18 (49)	23.11-24.93	0.46
ETT external diameter/laryngeal AP diameter	0.45±0.05 (2)	0.41-0.49	0.48±0.07 (49)	0.46-0.50	0.49
Peri-extubation steroid use					
No	5 (2)	N/A	95 (36)	N/A	1.00
Yes	0 (0)		100 (13)		
Intubation duration (d)	3.50±0.71 (2)	−2.85-9.85	3.86±3.51 (49)	2.85-4.86	0.89
Oedema on laryngoscopy					
No	2 (1)	N/A	98 (45)	N/A	0.19
Yes	20 (1)		80 (4)		
Indirect laryngoscopy					
Normal (grades 1-3)	6 (2)	N/A	94 (34)	N/A	1.00
Grade 4	0 (0)		100 (13)		
Grade 5 (edema)	0 (0)		100 (2)		
Air column width by laryngeal ultrasound (in cm)					
Inflated	0.69±0.12 (2)	−0.40-1.77	0.74±0.17 (49)	0.69-0.79	0.66
Deflated	0.65±0.09 (2)	−0.24-1.54	0.66±0.15 (49)	0.62-0.75	0.92
Air column width (difference in cm)	0.04±0.02 (2)	−0.16-0.23	0.08±0.07 (49)	0.06-0.10	0.36
CLT (inspiration)					
No leak	10 (1)	N/A	90 (9)	N/A	0.40
Minimal leak	0 (0)		100 (11)		
Significant leak	3 (1)		97 (29)		
CLT (expiration)					
No leak	0 (0)	N/A	100 (6)	N/A	0.42
Minimal leak	17 (1)		83 (5)		
Significant leak	3 (1)		97 (38)		
CLT and laryngeal survey composite	0.50±0.71 (2)	−5.85-6.85	0.88±1.27	0.51-1.24	0.68

*Analysis conducted under non-parametric assumption; Significant for fisher's exact test (fisher, R. A. (1922). "On the interpretation of χ^2 from contingency tables, and the calculation of *P*". Journal of the royal Statistical society 85 (1): 87-94.) and ANOVA (Speed, T. P. (1987). What is an analysis of variance? (with discussion). *Ann. Statist.* 15 885-941.); N/A: 95% CI value not applicable. PES – Post-extubation stridor; CI – Confidence interval; SD – Standard deviation; BMI – Body mass index; AP – Anterior-posterior; ETT – Endotracheal tube; CLT – Cuff leak test; ANOVA – Analysis of variance

In addition, our study corroborates the poor accuracy of previously reported independent parameters associated with an increased likelihood of PES including duration of intubation, steroid use, gender, BMI and the ratio of ETT to laryngeal diameter.[5,16-20] The findings in this study that laryngeal oedema was also not associated with an increased risk for PES is similar to a previous report by Colice *et al*.[21] that though

Table 3: Accuracy of PES risk prediction measures using AUC (*n*=51)

Variable	AUC	95% CI	Significant
BMI	0.61	0.19-1.03	0.61
Pre-existing respiratory condition	0.55	0.07-1.02	0.83
ETT size			
ETT internal diameter mm	0.55	0.19-0.90	0.83
ETT external diameter in mm	0.55	0.19-0.90	0.83
Calculated laryngeal AP diameter (in mm)	0.69	0.53-0.85	0.37
ETT external diameter/laryngeal AP diameter	0.32	0.19-0.45	0.38
Peri-extubation steroid use (within 24 h)	0.37	0.05-0.68	0.53
Intubation duration (day)	0.60	0.45-0.76	0.63
Oedema on laryngoscopy	0.71	0.27-1.15	0.32
Indirect laryngoscopy (Grade 5 edema)	0.35	0.05-0.65	0.47
Air column width by laryngeal ultrasound (in cm)			
Inflated	0.42	0.09-0.75	0.70
Deflated	0.51	0.15-0.86	0.98
Air column width (difference in cm)	0.25	0.09-0.41	0.23
CLT			
Significant leak on inspiration	0.40	−0.07-0.87	0.63
Significant leak on expiration	0.39	0.01-0.78	0.61
CLT and laryngeal survey composite	0.47	0.14-0.81	0.91

PES – Post-extubation stridor; ROC – Receiver operating characteristic; AUC – Area under the ROC curve; CI – Confidence interval; ETT – Endotracheal tube; CLT – Cuff leak test; BMI – Body mass index; AP – Anterior-posterior

laryngeal ulceration and oedema are very common in intubated patients, their presence is not associated with significant clinical events post-extubation. As might be expected, the larger the ETT and the smaller the trachea, (as determined by the ETT/AP diameter ratio) the less likely there was to be a cuff leak. Though not statistically significant for predicting PES incidence, Kriner *et al*.[19] reported that a majority of patients (61%) who had a false positive CLT (failed the CLT but did not develop PES) had an ETT/laryngeal size ratio >0.45 cm in their study. Overall, none of the parameters we examined was strongly associated with or accurately predicted PES.

Because PES cannot easily be predicted, physicians should be prepared to deal with this complication during any anticipated ICU extubation. A senior physician with experience in advanced airway management should be available, a difficult airway kit with advanced devices for airway placement should be at the bedside during extubation, and in patients with a high potential for complications, consideration should be given to the use of an airway exchange catheter or pre-treatment with steroids at least 12 h prior to extubation. Routine use of an extubation algorithm as described by Wittekamp *et al*. and Francon *et al*. may be beneficial.[11,12]

The findings of this study are subjected to certain limitations. The small sample size and the low PES rate, though similar to many published studies, may underestimate the true association of PES with the examined parameters. We, however, utilized appropriate statistical techniques to mitigate the potential for such error.

CONCLUSION

Post-extubation stridor, a sign of severe laryngeal narrowing, may herald the need for re-intubation. The CLT and multiple subsequent refinements have been used to predict this complication. This study demonstrates that even combining multiple techniques for evaluating airway patency including ultrasonographic and indirect laryngoscopic examination, no single aspect of the CLT or combination with laryngeal parameters accurately predicts PES.

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