Association Between Reduced Cuff Leak Volume and Postextubation Stridor*

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Study objective: **Laryngotracheal injury or edema in the setting of intubation may narrow the upper airway and predispose toward postextubation stridor. The presence or absence of an audible airleak when the sealing balloon cuff of the endotracheal tube is deflated has been demonstrated to be a marker of laryngotracheal edema in high-risk patients. We hypothesized that (1) the volume of the cuff leak can be quantified in a general medical ICU population, and (2) the cuff leak volume can be correlated with likelihood of postextubation stridor.**

Methods: **Within 24 h of both the initiation and termination of mechanical ventilation, the cuff leak volume, defined as the difference between the inspiratory tidal volume and the averaged expiratory tidal volume while the cuff around the endotracheal tube was deflated, was recorded.**

Results: **In 100 consecutive intubations, the preextubation cuff leak volume was 349±163 mL [mean±SD]). Overall, 6% of extubations were accompanied by postextubation stridor. The mean cuff leak volume measured within 24 h of planned extubation was significantly lower in those who subsequently developed stridor in comparison to those who did not (180±157 mL vs 360±157 mL; p=0.012). The positive predictive value for postextubation stridor in the setting of a cuff leak less than 110 mL was 0.80, the predictive value for absence of postextubation stridor with a cuff leak volume greater than 110 mL was 0.98, and the specificity of the test was 0.99. No other demographic factors or indexes related to mechanical ventilation were significantly different between the two groups.**

Conclusion: **A reduced cuff leak volume prior to extubation identifies a population at increased risk for postextubation stridor.** ***(CHEST 1996; 110:1035-40)***

Key words: cuff leak test; extubation failure; laryngeal edema; stridor

Abbreviations: CPAP=continuous positive airway pressure; ETT=endotracheal tube; ROC=receiver operating characteristic

Respiratory complications following extubation, including stridor, carry significant morbidity and mortality, particularly when they necessitate reintubation.[1-3] Nevertheless, the predictors of inability to tolerate sustained extubation remain empiric or elusive in some patients. Despite the development of many tests of gas exchange and respiratory muscle reserve in an attempt to successfully time withdrawal of mechanical ventilation, such commonly used criteria have not been found to have high predictive value in subsequent studies.[1-4,5]

One variable influencing successful extubation is the possibility of laryngotracheal injury as a result of intubation and local trauma that can lead to narrowing of the airway because of glottic inflammation and edema and predispose to postextubation stridor and respiratory distress. Although some studies have identified this injury as an important risk factor for postextubation complications or stridor,[6-9] others have failed to corroborate such a relationship.[3,10] Part of the difficulty in defining the relationship between laryngotracheal injury and failure to tolerate extubation is that the presence of an endotracheal tube (ETT) precludes direct visualization of the upper airway prior to extubation. In the intubated patient, an indirect measure of upper airway patency is the documentation of a leak around the ETT once the usually sealing balloon cuff surrounding it has been deflated. An absent audible air leak at the time of extubation has been shown to be a predictor of postextubation stridor in pediatric trauma patients.[11] Further, the presence of an audible air leak has been shown to be a marker for the absence of significant laryngotracheal swelling and the likelihood of successful extubation in children with croup and in adult patients intubated for upper airway obstruction due to laryngeal edema.[9,12]

The present study was designed to ascertain whether the movement of gas around the ETT cuff can be quantified in a general medical ICU population. We

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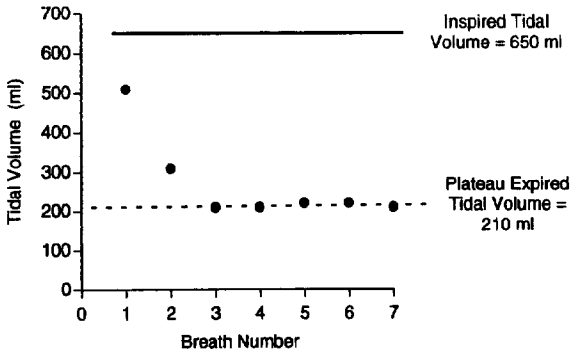

FIGURE 1. Sequential expired tidal volumes after balloon cuff deflation. Data obtained from a representative patient are shown.

also hypothesized that we could correlate the volume of the leak with the likelihood of postextubation stridor in patients who appear ready for discontinuation from mechanical ventilation.

MATERIALS AND METHODS

Patients

One hundred consecutive intubations on 88 different mechanically ventilated adult patients from December 1, 1994 through July 1, 1995 were studied. In 95 of the cases, the patients were admitted to the medical ICU at Columbia-Presbyterian Medical Center. The other five patients were admitted to the neuroscience ICU. The study was approved by the medical center's Institutional Review Board. Inclusion criteria for subjects were admission to either ICU and intubation for at least 24 h for acute respiratory failure of various causes or for airway protection. Exclusion criteria included unstable hemodynamics and profound uncorrectable hypoxemia. None of the patients were postoperative, had sustained large burns, or suffered trauma. The study protocol did not require modification of ventilator settings beyond the duration of the test or any change in the amount of sedation. All patients were intubated with a soft, high-volume, low-pressure cuffed ETT with a size 6, 7, or 8 mm internal diameter (Mallinckrodt Medical Inc; St. Louis, Mo). A ventilator (Puritan-Bennett 7200; Carlsbad, Calif) was used that utilizes a hot-film anemometer to determine mass flow. The ventilator automatically corrects for gas pressure, temperature, and humidity. The ventilator is attached to a patient only after it passes an extended self-test, which includes a check of flow sensors and leaks in the circuitry. The inspiratory tidal volume for each mandatory breath is corrected for the compliance of the tubing circuitry by adding an additional volume equal to the product of the tubing compliance and the average peak airway pressure of the four proceeding inspiratory cycles. This ensures that the patient receives the operator-selected BTPS-(body temperature and pressure, saturated) corrected tidal volume.

Protocol

Within 24 h of initiation of mechanical ventilation, the cuff leak volume was measured. Immediately prior to the test, the patient was placed on the assist control setting and any endotracheal and oral secretions were suctioned. While the cuff around the ETT was in its usual inflated position, the operator-selected inspiratory tidal volume and displayed expiratory tidal volumes were recorded and the balloon cuff pressure was measured using a manometer (Cuffmate 2; DHD; Canastota, NY). During assist control ventilation, the set inspiratory and displayed expiratory tidal volumes were always within 20 mL of each other for each subject. The balloon cuff was deflated and the expiratory tidal volume was recorded over the six subsequent respiratory cycles; the lowest three values were averaged. Six cycles were recorded because it was found that the exhaled tidal volume decreased decrementally over the first few breaths before reaching a plateau value (Fig 1). The difference between the inspiratory and averaged expiratory tidal volume was defined as the cuff leak volume. In several patients, some of the baseline data were not obtained due to unavailability of the investigators. The physicians responsible for patient care decided the mode of weaning and the timing of extubation based on their assessment of gas exchange and respiratory reserve. Each patient demonstrated an ability to tolerate at least 2 h of continuous positive airway pressure (CPAP) mode of ventilation with 5 cm H_2O pressure support on the day of extubation. Extubation usually occurred between 1 and 6 h from the final CPAP trial. The same cuff leak test was repeated within 24 h of planned extubation. Stridor was defined as the presence of an audible high-pitched inspiratory wheeze requiring medical intervention and usually was associated with respiratory distress. All assessments for stridor, respiratory distress, and need for reintubation were made by the ICU physicians who were blinded to the measurements obtained by the investigators.

Statistical Analysis

Results are presented as mean±SD. The Mann-Whitney *U* test for independent groups, Wilcoxon test for paired observations, and Fisher's Exact Test were used to compare means and groups. The technique of incremental analysis starting with a complex regression model counting many independent variables and examining the changes in log likelihood as independent variables were removed in stepwise fashion was performed using a statistical software package (Statistica-Mac, version 3.0b; Statsoft; Tulsa, Okla).[13] A two-tailed p value of less than 0.05 was considered statistically significant. Assessments of the diagnostic accuracy of a threshold cuff leak volume were measured using a receiver operating characteristic (ROC) plot that graphed the true-positive rate on the vertical axis against the false-positive rate on the horizontal axis as the value for leak volume was varied.[14]

RESULTS

One hundred intubations were conducted in 88 patients with mean age of 63±17 years. There were 42 men and 58 women. The duration of mechanical ventilation was 5.8±0.5 days. Seventeen percent (17/100) of extubations failed and required reintubation; 12 of these cases were restudied. Reasons for reintubation included respiratory fatigue (characterized by tachypnea, use of accessory respiratory muscles, and abdominal and chest wall asynchrony during respiratory efforts) (n=6), atelectasis (n=5), stridor (n=3), pulmonary edema (n=2), and apnea (n=1). In five cases, the patient withdrew the ETT tube himself or herself without supervision prior to balloon cuff deflation by the ICU staff, but after the preextubation measurements had been obtained. Three of these cases required reintubation. Characteristics of the patient groups studied are shown in Table 1.

Postextubation stridor occurred in 6% (6/100) of all extubations, in 5.2% (5/95) when the 5 cases of self-extubation were excluded, and in 20% (1/5) in the self-extubation group. There were no significant differences in duration of intubation, number of times

Table 1—*Patient Characteristics*

	Nonstridor	Stridor	All Cases	p Value*
No.	94	6	100	
Age, yr	64±17	54±19	63±17	NS
Sex, M/F	41/53	1/5	42/58	NS
Days intubated	5.8±5.2	5.8±4.3	5.8±0.5	NS
No. of times intubated	1.3±0.6	1.3±0.5	1.3±0.6	NS
ETT adjustments†	0.5±0.9	0.7±0.8	0.5±0.9	NS
Oral intubation‡ (%)	79 (84)	4 (67)	83 (83)	NS
Steroid therapy (%)	20 (21)	3 (50)	23 (23)	NS
Cuff pressure (cm H_2O)§	19±9	13±4	19±9	NS
Failed extubations (%)	14 (15)	3 (50)	17 (17)	NS
Failed self-extubations (%)	2/5 (40)	1/5 (20)	3/5 (60)	NS

*The p value compares means between nonstridor and stridor groups. NS=not significant.
†Defined as deflation of balloon cuff, movement of ETT by member of ICU staff after repositioning, and immediate reinflation of cuff.
‡Remaining cases intubated nasally.
§Measured prior to extubation.

intubated, ETT position (oral vs nasal), number of ETT adjustments during intubation, or administration of steroid therapy between those patients who experienced postextubation stridor and those who had uncomplicated extubations (Table 1).

The baseline cuff leak volume was 316±176 mL (n=72) and the preextubation cuff leak volume was 349±163 mL (n=100). These baseline and preextubation cuff leak volumes correlated weakly (r=0.27, p=0.02). For the cases in which both sets of measurements were available, the baseline inspiratory tidal volume was significantly greater than the preextubation inspiratory tidal volume (665±72 mL vs 649±75 mL; T=12; p=0.002), while the baseline cuff leak volume was smaller than the preextubation cuff leak volume, but was not significantly so (T=1076; p=0.25). The magnitude of the cuff leak volume did not correlate with peak airway pressures (r=0.012) or differences in peak airway pressures following balloon cuff deflation (r=0.17).

The cuff leak measured within 24 h of extubation was significantly lower in those patients who subsequently developed stridor in comparison to those who did not (180±157 mL vs 360±157 mL, respectively; p=0.012; Table 2). When the self-extubation attempts were excluded, the differences between the groups increased (115±96 mL vs 355±153 mL, respectively; p=0.0014; Table 2). The baseline cuff leak measured within 24 h of intubation also was significantly lower among those who later experienced postextubation stridor than those who were extubated successfully (54±76 mL vs 322±173 mL, respectively, p=0.043; Table 2). There also were no significant differences in endotracheal balloon cuff pressure, peak airway pressure, or preextubation inspiratory tidal volume between the stridor and nonstridor groups (data not shown). By logistic regression analysis, the cuff leak volume was the best predictor of the presence or absence of stridor (log likelihood=−18.3; χ^2=8.82; coefficient of slope=0.0105; standard error=0.00439). For each reduction in cuff leak volume of 100 mL, the odds ratio for the presence of stridor was 2.9 with a 95% confidence interval of 1.2 to 6.8. A model containing the additional independent variables of days of intubation, ETT size, balloon cuff pressure, and number of times intubated yielded a log likelihood of −8.5: with the exception of cuff leak volume, all coefficients had p values greater than 0.05 with odds ratio and 95% confidence intervals encompassing the value of 1.0. Stepwise elimination of these variables led to a simplified model containing only cuff leak volume as the key independent variable.[13]

A threshold cuff leak volume of 110 mL was selected by examination of the ROC plot (Fig 2).[14] The positive

Table 2—*Preextubation Cuff Leak Volume Reduction in Patients Who Developed Postextubation Stridor*

	All Cases			Planned Extubations*		
	Nonstridor	Stridor	p Value†	Nonstridor	Stridor	p Value†
Baseline cuff leak volume, mL‡	320±172 (n=69)	216±286 (n=3)	NS	322±173 (n=68)	54±76 (n=2)	0.043
Preextubation cuff leak volume, mL	360±157 (n=94)	180±157 (n=6)	0.012	355±153 (n=90)	115±96 (n=5)	0.0014

*Excludes all cases of self-extubation.
†p value compares means between nonstridor and stridor groups. NS=not significant.
‡Not obtained in all cases.

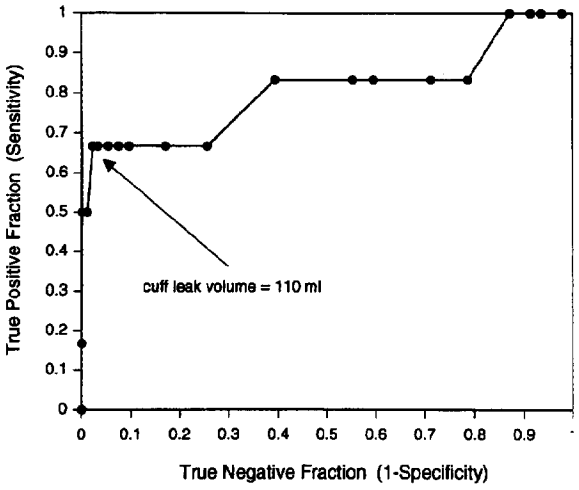

FIGURE 2. ROC plot. True-positive fraction (number of patients with stridor and cuff leak volume below a given cuff leak volume divided by total number of patients with stridor) is plotted on y axis and the true-negative fraction (1-number of patients without stridor and cuff leak volume greater than a given cuff leak volume divided by total number of patients with cuff leak volume greater than a given cuff leak volume) is plotted on the x axis. These given cuff leak volumes are in increments of 10 mL and each point on the graph refers to one such calculated cuff leak volume. The decision threshold of 110 mL was determined by visual inspection as having a relatively high sensitivity and specificity.

predictive value for postextubation stridor of a cuff leak of less than 110 mL measured within 24 h of extubation was 0.80. The calculated predictive value for absence of postextubation stridor with a volume greater than 110 mL was 0.98. The specificity of the test was 0.99. The sensitivity of the test was 0.67, but because of the low prevalence of postextubation stridor, the 95% confidence interval was 0.51 to 0.82.[15] When the five cases of self-extubation were excluded, the positive predictive value, negative predictive value, and specificity were unchanged; the sensitivity of the test increased to 0.80. The medical outcomes of those patients who experienced postextubation stridor are listed in Table 3. Three of the six patients with stridor required reintubation because the stridor was associated with respiratory failure. The three reintubations for stridor and respiratory distress added a total of 14 days of mechanical ventilation in the medical ICU. One of the three patients requiring reintubation for stridor died within 1 week of the episode of stridor with respiratory arrest.

DISCUSSION

In this study, we found that a low cuff leak volume measured within 24 h of extubation identified those patients with an increased risk of postextubation stridor. Other demographic factors (*ie*, age, duration of intubation, use of steroids) and parameters of ventilation (*ie*, times intubated, ETT adjustments, cuff pressure) did not differ significantly between those who experienced postextubation stridor and those with an uncomplicated course. These results differ from earlier reports that suggested that progressive laryngotracheal injury and risk of postextubation complications correlated with duration of intubation.[7,16]

Conventional indexes that incorporate measurements of oxygenation and respiratory mechanics such as minute ventilation, maximum inspiratory pressure generation, tidal volume, airway occlusion pressure, PaO_2/fraction of inspired oxygen ratio, and ratio of breathing frequency to tidal volume are useful tests but are not completely predictive of successful extubation.[4,5,17-20] These indexes assess a patient's ability to breathe spontaneously, but do not evaluate functional injury or stenosis of the upper airway. Local trauma to the upper airway cannot be appreciated until after the ETT is removed because the ETT blocks direct visualization of the larynx and trachea, and may stent the upper airway open while in place.[7] Even if ETTs with soft high-volume, low-pressure cuffs are used, laryngotracheal injury such as laryngeal granulomas, ulcerations or necrosis, laryngeal incompetence with consequent aspiration, and laryngeal edema occur in up to 13 to 94% of patients.[3,7,8,10] The cuff leak volume determination may be a useful index of obstruction to airflow in the upper airway, which is presumably related to injury to the airway. In this study, we are able to quantify the cuff leak volume and to establish a relation between cuff leak volume with postextubation complications.

Table 3—*Medical Characteristics of Patients With Stridor

Patient	Medical History	Indication for Intubation	Treatment for Stridor	Outcome
1	Asthma, HTN, DM, previous stridor	Asthma	Epi	Stable
2	None	Overdose	Epi	Stable
3	HTN, CVA, DM	Pneumonia	Epi, steroids	Reintub, died
4	CRI, CAD, CVA, DM	SE, pneumonia	Epi, steroids	Reintub
5†	Hodgkins disease	Pneumonia	Steroids	Reintub
6	Hypopit, hypothy, recent pneumonia	Pneumonia	Albut	Stable

*Abbreviations: HTN=hypertension; DM=diabetes mellitus; CRI=chronic renal insufficiency; CAD=coronary artery disease; CVA=cerebrovascular accident; SE=status epilepticus; epi=racemic epinephrine nebulized; albut=albuterol nebulized; hypopit=hypopituitarism; hypothy=hypothyroid; reintub=reintubated within 24 h of extubation due to stridor.

†Self-extubation.

Several potential limitations of this study need to be considered. Direct laryngoscopy was not conducted systematically in these patients at the time of extubation to provide a visual or pathologic correlate with the clinical outcomes. Recent studies that have examined weaning modes and success of weaning have not provided evidence that mode of weaning would alter rate of postextubation stridor due to laryngotracheal injury.[4,21] This study did not assess the role of particular modes of weaning on the rates of successful extubation. This might have been the case if certain weaning modes would shorten duration of mechanical ventilation. In the present study, however, the duration of mechanical ventilation did not influence the rate of development of postextubation stridor.

Another possible concern is that additional spontaneous and unmeasured patient-assisted inspiratory tidal volumes may have influenced the calculated cuff leak volume, particularly if such gas could flow through the annulus between the ETT and the airway wall when the balloon cuff was deflated. We attempted to avoid this problem by ensuring that the set inspiratory tidal volume approximated the displayed expired tidal volume prior to cuff deflation and that the set respiratory rate was equal to the observed respiratory rate. Second, we did not expect preferential gas flow around the ETT from increased intraluminal resistance due to secretions because the latter has been shown to produce only a negligible decrease in the effective diameter of the ETT during the first week of intubation.[22] Third, it might be expected that laryngotracheal edema would diminish the likelihood of inhaling unmeasured tidal volumes around a tight ETT. This would then tend to exaggerate the difference in leak volumes between the group with and without stridor.

A low baseline cuff leak volume measured following intubation correlated weakly with a low measurement prior to extubation and appeared associated with an increased incidence of postextubation stridor (Table 2). The presence of such a small number of cases of stridor herein precludes comparison of the predictive power of the two cuff leak volumes. Baseline cuff leak values may be as important as the preextubation values because they indicate that a "tight fit" between the ETT and larynx or trachea is present at the time of intubation. This factor may either predict or contribute to the later development of clinically significant laryngotracheal edema in some patients. While it may be helpful to identify cases at risk for postextubation stridor early, it is difficult from this small sample to ascertain whether the baseline test has clinical utility.

The decremental fall in expired tidal volume that occurs several breaths after deflating the balloon cuff was unexpected. One explanation is that the added effect of the compliance volume correction, which is dependent on peak airway pressures, diminishes during the first few breaths following balloon cuff deflation. This could result in a reduced delivered inspiratory tidal volume after cuff deflation and subsequent reduced expiratory tidal volume. We expect this contribution to be small. The average difference between airway pressures before and after cuff deflation was 3 cm H_2O with the maximum difference 20 cm H_2O. This would reduce the tidal volume by a maximum of 60 mL considering a tubing compliance of 3 mL/cm H_2O. Another explanation is that cuff deflation may have reduced the level of positive airway pressure at end-expiration and thereby reduced functional residual capacity. The associated reduction in lung elastic recoil may have led to a reduction in tidal volume. However, applied expiratory airway pressure was always less than 5 cm H_2O prior to extubation in the subjects studied. Alternately, this pattern may represent a change in glottic cross-sectional area which could affect the cuff leak volume.[23]

The single occurrence of postextubation stridor without a reduced cuff leak volume was in the setting of a self-extubation. In this situation, traumatic self-extubation with a fully inflated balloon cuff might have caused acute trauma to the larynx and trachea and predisposed to laryngeal edema and stridor. Direct laryngoscopy conducted immediately prior to reintubation confirmed such edema. It may be that self-extubation is an important independent risk factor for stridor but this requires a larger sample size to evaluate fully.

Our overall reintubation rate was 17%, including those patients with accidental self-extubation. The reported rates of reintubation in the literature are variable, and range from 3 to 48% depending on the patient population within the ICU, mode of weaning, and the physician's clinical judgment.[1-5,20,21] We report a rate of postextubation stridor rate of 6%, which is within the range of reported values.[3,4,7,10,16,20]

In summary, we have found that a reduced cuff leak volume measured prior to extubation is associated with an increased risk of postextubation stridor, and that a volume greater than 110 mL was associated with absence of postextubation stridor among planned, controlled extubations in a medical ICU population. The cuff leak volume was the only variable found to correlate with an increased chance of postextubation stridor with the possible exception of traumatic self-extubation. In light of the increased complication rate associated with failed extubations and the development of stridor demonstrated herein and by others, and the ease of performing this test, we suggest that it may be a useful index of clinically significant laryngotracheal narrowing. It would be of interest to investigate in future studies whether certain medical therapies (*ie,*

steroids, bronchodilators) could improve the measured cuff leak volume and influence outcome.

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