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## Post-extubation stridor in intensive care unit patients

### Risk factors evaluation and importance of the cuff-leak test

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**Abstract** *Objective:* To evaluate the incidence and identify factors associated with the occurrence of post-extubation stridor and to evaluate the performance of the cuff-leak test in detecting this complication. *Design:* Prospective, clinical investigation. *Setting:* Intensive care unit of a university hospital. *Patients:* Hundred twelve extubations were analyzed in 112 patients during a 14-month period. *Intervention:* A cuff-leak test before each extubation. *Measurements and results:* The incidence of stridor was 12%. When we chose the thresholds of 130 ml and 12% to quantify the cuff-leak volume, the sensitivity and the specificity of the test were, respectively, 85% and 95%. The patients who developed stridor had a cuff leak significantly lower than the others, expressed in absolute values ( $372 \pm 170$  vs  $59 \pm 92$  ml,  $p < 0.001$ ) or in relative

values ( $56 \pm 20$  vs  $9 \pm 13\%$ ,  $p < 0.001$ ). Stridor was associated with an elevated Simplified Acute Physiology Score (SAPS II), a medical reason for admission, a traumatic or difficult intubation, a history of self-extubation, an over-inflated balloon cuff at admission to ICU and a prolonged period of intubation. These results provide a framework with which to identify patients at risk of developing a stridor after extubation. *Conclusion:* A low cuff-leak volume ( $< 130$  ml or 12%) around the endotracheal tube prior to extubation is useful in identifying patients at risk for post-extubation stridor.

**Keywords** Post-extubation stridor · Airway obstruction · Laryngeal edema · Extubation failure · Cuff-leak test · Helium-oxygen · Unplanned extubation

## Introduction

Airway obstruction after extubation or post-extubation laryngeal dyspnea, often secondary to laryngeal edema, is one of the primary causes of respiratory distress after extubation [1]. The frequency of this complication in patients in the intensive care unit (ICU) is estimated to range between 2 and 16% [2, 3, 4]. It can be a dramatic event requiring emergency re-intubation in rather difficult circumstances. Its occurrence after extubation is poorly predictable. As the presence of an endotracheal tube (ETT) precludes direct visualization of the upper airway prior to extubation, some authors have recom-

mended the use of a cuff-leak test in an effort to screen for the occurrence of airway obstruction before extubation [5, 6, 7, 8]. This test consists in deflating the balloon cuff of the ETT in order to assess the air leak around the tube, which permits an indirect evaluation of upper airway patency. A small leak or the complete absence of one would be suspicious of an occurrence of airway obstruction, which would lead the clinician to consider preventive treatment before extubation and/or to initiate treatment after extubation as soon as possible.

Some studies in adults have evaluated the importance of the cuff-leak test to predict the occurrence of airway obstruction [5, 6, 7, 8]. The patient populations studied,

the methods and the results varied. Furthermore, few risk factors for the occurrence of an airway obstruction were studied and the results were often controversial [1, 1, 3, 4, 6]. Identifying risk factors and performing a cuff-leak test before extubation can better identify the patients who will develop airway obstruction, and it may allow optimization of therapy in order to prevent failure of extubation related to laryngeal edema.

The aims of this study were to evaluate the incidence and identify the risk factors associated with the occurrence of post-extubation airway obstruction, and to evaluate the performance of the cuff-leak test to detect this complication in an ICU population.

## Material and methods

### Patients

Over a 14-month period (1st January, 2000, to 1st March, 2001) all the patients hospitalized in our ICU who were intubated and considered likely to be extubated were included in the study. The experimental protocol was approved by the ethics committee of the French Society of Intensive Care Medicine (SRLF). The requirement for informed consent was waived because all procedures were considered to be routine clinical practice.

### Data collection

On admission to the unit and/or at the time of intubation, the following parameters were recorded: age, sex, weight, cause of hospitalization, severity of the illness evaluated by the Simplified Acute Physiology Score (SAPS II) [9], setting of intubation (operating room, pre-hospital, ICU), traumatic and/or difficult intubation ( $\geq 3$  attempts), diameter of the ETT, pressure of the balloon cuff.

In the 24 h preceding or immediately prior to extubation, the following parameters were documented: the measured and calculated values of the cuff-leak test (see below), the duration of intubation, the use of corticosteroids, the occurrence of an episode of self-extubation during the hospitalization. After the extubation, we evaluated the occurrence of a laryngeal post-extubation obstruction as evidenced by a stridor. Stridor was defined as the presence of an audible high-pitched inspiratory wheeze requiring medical intervention and usually associated with respiratory distress. We also noted the time-delay in the occurrence of the complication, the failure of extubation as defined by the need to re-intubate the patient in the 48 h following extubation with no attributable cause. All assessments for stridor, respiratory distress and need for re-intubation were made by the ICU physicians who were blinded to the measurements obtained by the respiratory therapist, according to the protocol.

### Materials

The ventilators used were either an Evita IV (Dräger) or a Servo 300 (Siemens). All the patients were ventilated with a heated humidifier (MR730 Respiratory Humidifier; Fisher & Paykel Healthcare, New Zealand) with a dual heated-wire circuit. Pressures in the balloon cuff were measured using a manual manometer (Mallinckrot Medical, St Louis, Mo). The protocol to measure the pressure of the balloon cuff in the study was the same as that used in the unit routinely [10]. This involves measuring the balloon cuff

pressure twice daily and checking that the pressure is less than 30 cmH<sub>2</sub>O without leak around the ETT. The balloon cuff pressures analyzed were those obtained on admission or immediately after intubation if this was performed in ICU.

### Cuff-leak test

The cuff-leak test is systematically preceded by a careful endotracheal and oral suctioning. The test was performed as described by Miller and Cole [6]. Briefly, the respiratory therapist places the ventilator in assist-control mode with the tidal volume (VT) set at 10–12 ml/kg. An initial measurement of inspiratory VT was achieved with the cuff inflated. Then, the cuff was deflated and after the elimination of artifacts due to cough, four to six consecutive breaths were used to compute average values for the expiratory VT. The leak was calculated as the difference between the expiratory VT with the cuff inflated and the expiratory VT with the cuff deflated.

### Statistics

The data are expressed as frequency for nominal variables and as means  $\pm$  SD for continuous variables. When patients were re-intubated during their hospital stay, only the first episode of mechanical ventilation was used in the analysis. For categorical variables, the comparisons were performed using the chi-square test or Fisher's exact test, as appropriate. For continuous variables, the comparisons were performed using the unpaired Student's *t* test or Mann-Whitney U test if the distribution of the continuous variables was not normal. Extubations performed without cuff-leak test data were not included in the analysis. The data for patients who developed stridor and those who did not were compared. Assessments of the diagnostic accuracy of a threshold cuff-leak value expressed as absolute and relative volume were measured using a receiver operating characteristic (ROC) plot that graphed the true-positive (TP) rate on the vertical axis against the false-positive (FP) rate on the horizontal axis as the value for leak volume or percentage varied [11].

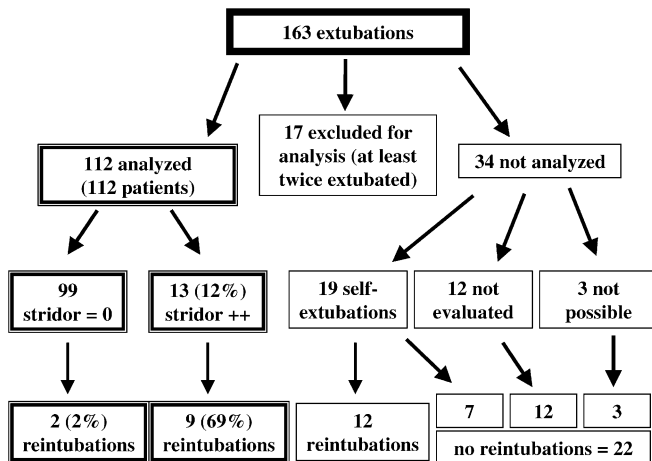
The accuracy of the test is represented as sensitivity (SE = TP/TP+FN), specificity (SP = TN/TN+FP), positive (PPV = TP/TP+FP) and negative (NPV = TN/TN+FN) predictive value where TP is a leak of less than 12% and stridor, TN (true negative) is a leak of more than 12% and no stridor, FP is a leak of less than 12% and no stridor and FN (false negative) is a leak of more than 12% and stridor. The value of 12% was the threshold cuff-leak value determined by the ROC curve (see Results). A *p* value of less than 0.05 was considered statistically significant. All statistical analysis was performed using SAS software (SAS Institute, Cary, NC).

## Results

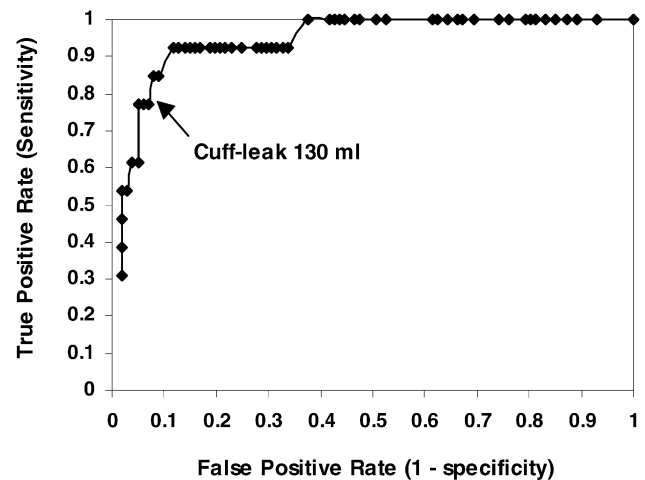
Hundred sixty-three extubations occurred during the study period. All data were obtained for only 129 extubations in 112 patients. To simplify the analysis, only the first episode of mechanical ventilation and the first extubation were used. The incidence of post-extubation stridor was 12%. The average delay for the occurrence of a complication was  $3.2 \pm 3.3$  h. A comparison of patients who did with those who did not develop stridor, according to their characteristics during the survey, is shown in Table 1. The rate of extubation failure was 10% (11/112), with a significant difference between patients who did

**Table 1** Patients characteristics (*SAPS II* Simplified Acute Physiology Score, *NS* not significant, *ETT* endotracheal tube)

	Absence of stridor	Presence of stridor	<i>p</i> value
	( <i>n</i> =99)	( <i>n</i> =13)	
Age (years)	59±13	61±19	NS
Sex (M/F)	72/27	6/7	0.050
Weight (kg)	74±16	72±15	NS
SAPS II	38±13	50±16	0.005
Indication for mechanical ventilation			
Surgical admission	81 (82%)	7 (54%)	0.029
Minor surgery	17 (20%)	0 (0%)	NS
Major surgery	24 (31%)	3 (43%)	NS
Postoperative complication	13 (16%)	4 (57%)	NS
Liver transplantation	27 (33%)	0 (0%)	0.06
Medical admission	18 (18%)	6 (46%)	0.029
Setting of intubation			
Pre-hospital + ICU	7+16= 23 (23%)	4+4=8 (62%)	0.027
Operating room	76 (77%)	5 (38%)	
Traumatic and/or difficult intubation	7/99 (7%)	7/13 (54%)	<0.001
Balloon cuff pressure (cmH <sub>2</sub> O)	40±20	83±35	<0.001
ETT diameter (mm)	7.9±0.3	7.7±0.4	NS
Duration of intubation (days)	5.5±6.3	10.9±7.0	0.001
Steroid therapy	30/99 (30%)	1/13 (8%)	0.111
Prior self-extubation	4/99 (4%)	5/13 (38%)	<0.001
Cuff leak			
Absolute value (ml)	372±170	59±92	<0.001
Percent (%)	56±20	9±13	<0.001



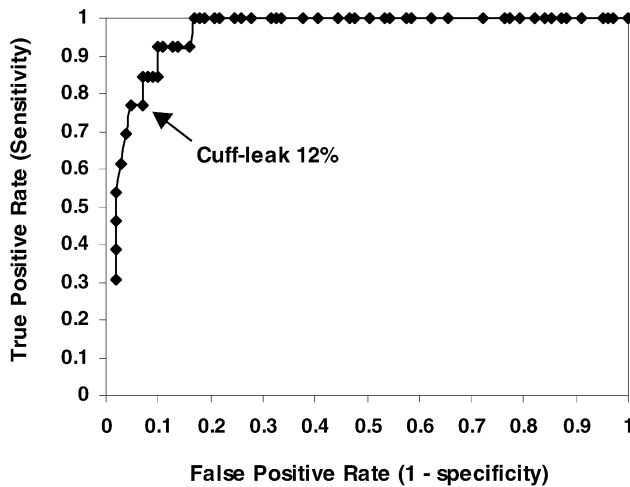
**Fig. 1** Distribution of all extubations during the study period (analyzed and not analyzed) according to stridor occurrence and need for re-intubations



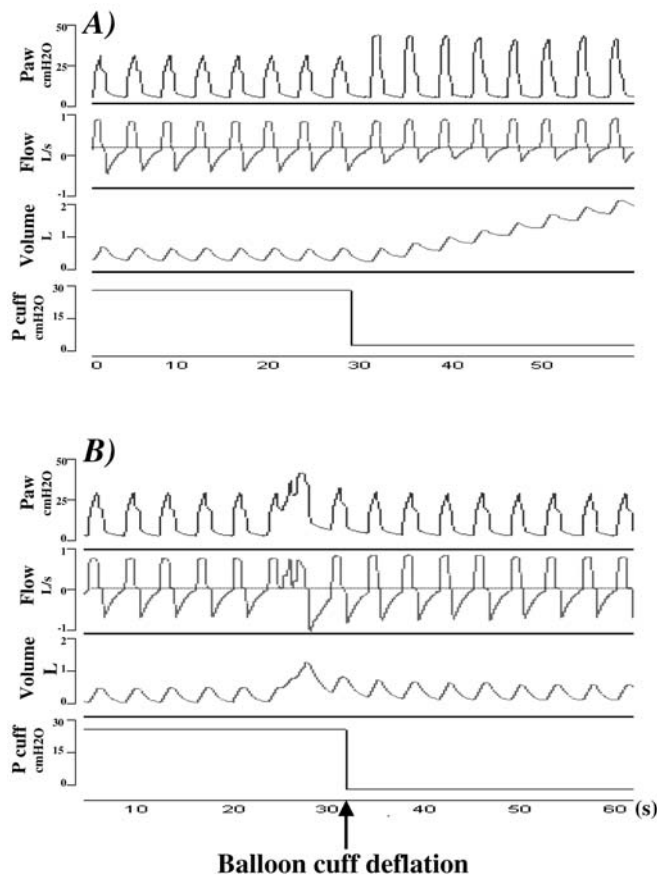
**Fig. 2** Receiver operating characteristics (ROC) plot. True positive fraction is plotted on y-axis and the true-negative fraction is plotted on x-axis. The decision threshold of 130 ml was determined by visual inspection as having a relatively high sensitivity and specificity

and those who did not develop stridor (69% vs 2%,  $p<0.001$ ). Fifty-one extubations were not included in the analysis (Fig. 1). The cuff-leak test was not performed in three patients due to excessive secretions and coughing which made it impossible to perform the test. In addition,

12 extubations could not be analyzed because they were performed in the absence of one of the respiratory therapists, most often at night in postoperative patients, and 19 were self-extubations. Among the self-extubations, 12 required re-intubation.



**Fig. 3** Receiver operating characteristics (ROC) plot. True positive fraction is plotted on y-axis and the true-negative fraction is plotted on x-axis. The decision threshold of 12% was determined by visual inspection as having a relatively high sensitivity and specificity



**Fig. 4** Representative records obtained before and after balloon cuff deflation in a patient with cuff leak (A) and in a patient with a small leak (<12%) (B)

A threshold cuff-leak volume of 130 ml and 12% of inspiratory VTs were selected by examination of the ROC plots (Figs. 2 and 3). When we chose the thresholds of 130 ml and 12% to quantify the cuff-leak volume, the sensitivity and the specificity of the test were 85% (65–99%) and 95% (91–99), respectively. The positive and negative predictive values were 69% and 98%, respectively.

Figure 4 shows the curves obtained in a patient with a cuff-leak (panel A) when the balloon cuff was deflated (negative cuff-leak test) and the curves obtained in a patient with a small leak (<12%) (panel B) when the balloon cuff was deflated (positive cuff-leak test).

## Discussion

The present study showed that a low cuff-leak volume measured before extubation permits the identification of patients with an increased risk of post-extubation stridor. This is the largest series studied in medico-surgical ICU patients. The incidence of stridor in our population was 12%, which is comparable to reports in the literature ranging from 2 to 16% [2, 3, 4].

There was a significant difference between the patients who developed a stridor post-extubation and the others in terms of severity of illness evaluated by the SAPS II index, conditions of intubation (emergency intubation in the pre-hospital setting or in the ICU in cases of laryngeal traumatism), an overly inflated balloon cuff upon admission and/or in the hours following intubation, a history of self-extubation and a prolonged duration of intubation.

### Cuff-leak test

Miller and Cole [6] evaluated the importance of the cuff-leak test from 100 extubations in 88 patients in a medical ICU population. The frequency of an episode of stridor was 6%. The value of the cuff-leak test in patients with stridor was  $180 \pm 157$  ml versus  $316 \pm 176$  ml in the control group. The positive predictive value was 80% when the threshold value of the leak was less than 110 ml. Our results are comparable with those of Miller and Cole [6] regarding the effectiveness of the cuff-leak test, but different regarding the risk factors.

Engoren [7] analyzed 531 extubations in 524 cardiac surgery patients. The study was conducted in a cardiovascular ICU after cardiac surgery. Intubations were performed by experienced nurse anesthetists or attending anesthesiologists. However, in the Engoren study, the length of intubation was less than 24 h (median 12 h), which limits comparison of the results of this study with those previously cited as well as our own because the average length of ventilation in ICU reported in these



studies ranged from 5 to 10 days. Only three of the 524 patients developed mild stridor. Two patients were treated with nebulized epinephrine and one patient was re-intubated. The result of the cuff-leak test was more than 300 ml for these three patients. Twenty patients had a cuff-leak test with a result under 110 ml and none of them developed stridor. The sensitivity of the test in this study was 0%, the specificity was 96%, the positive predictive value was 0% and the negative predictive value was 99%. The authors concluded that even if the cuff-leak test was safe and simple, it was inaccurate and could not be recommended for routine use in a cardiac surgery population. Nevertheless, in the population studied a shorter duration of intubation and the fact that intubations were performed by experienced nurses or attending anesthesiologists could explain the differences in the results they reported when compared to other studies.

More recently, Sandhu and colleagues [8] studied 114 extubations in 110 patients, most of whom suffered from multiple trauma (48% had head injuries). Fourteen patients developed stridor (12.2%). Their cuff-leak test had a mean value of 11.7%. Of these 14 patients, five were re-intubated (cuff-leak test at 11%). No patient was re-intubated when the results of the cuff-leak test were more than 11.7%. Our results were similar to Sandhu and colleagues' results [8] regarding the incidence of stridor and the effectiveness of the cuff-leak test, but diverged regarding certain factors associated with stridor when it developed (see below).

## Risk factors

### *Demographic data*

There was no significant difference between the ages and weights in our patient population compared to those reported in various other studies [2, 3, 12]. In our patient population, the severity of the illness upon admission was associated with an occurrence of stridor after extubation. This has not been reported elsewhere. This difference can be explained by the use of different indices of severity to evaluate the severity of illness in the populations studied. No other study uses the SAPS II [9]. A medical admission and a traumatic intubation were also associated with stridor after extubation. This can be explained by the fact that, in most of these cases, the patients were intubated in the pre-hospital setting or in intensive care associated with trauma as opposed to a surgical ICU population, most of whom are intubated in the operating room under conditions that are described as "optimal" (programmed intubation, experienced personnel etc.). This has never been fully reported in the literature.

### *Self-extubation*

We reported a rate of self-extubation of 8% (9/112) when we considered only the extubations analyzed. This rate was 11.7% (19/163) for all extubations, which is within the range of values reported [1]. Among the 19 patients involved, nine of the 12 re-intubated were included for analysis (Fig. 1). Five among these nine patients (56%) experienced stridor (Table 1) and all were re-intubated. Our study showed that a history of self-extubation was a factor associated with the development of post-extubation stridor. Traumatic self-extubation with a fully inflated balloon cuff can cause acute trauma to the larynx and trachea and can cause a predisposition for laryngeal edema and stridor.

### *Duration of intubation*

In our study, the patients who developed stridor had a longer duration of intubation than the others ( $5.5 \pm 6.3$  vs  $10.9 \pm 7.0$  days,  $p = 0.001$ ). This result has been reported in some studies [2, 8, 12], but not in others [6].

### *Pressures measured in the balloon cuff*

The pressure values measured upon admission to the unit and/or in the hours following intubation showed that, on average, they were systematically over-inflated in all patients. Nevertheless, the average value obtained in patients who developed stridor was significantly higher ( $40 \pm 20$  vs  $83 \pm 35$  cmH<sub>2</sub>O,  $p < 0.001$ ). This result corroborates that it is necessary to institute frequent checks of the pressure of the balloon cuffs [10]. This result can be explained by the fact that the majority of patients who developed a complication were intubated in emergency situations (23 vs 62%,  $p = 0.027$ ). Miller and Cole [6] did not find a significant difference between the two groups based on balloon-cuff pressure. Nevertheless, the values they reported were those obtained at the time of extubation and not those obtained at admission or immediately after intubation. We did not report the values obtained at the time of extubation because, after admission, the nurses monitored the pressures twice a day (see Materials and methods).

### *Limits of the study*

Our study had several limitations. Performing a laryngoscopy before extubating patients with a positive cuff-leak test would have given additional information of the presence of possible laryngeal lesions. Furthermore, it would have allowed us to verify if there is a correlation between the severity of the injury to the larynx, the result of the cuff-leak test and the outcome of the patients. In

fact, this limitation is common to all the studies on this subject. As far as we know, no study has analyzed this correlation. Kastanos and colleagues [13] studied 19 critically ill patients in whom a systematic bronchoscopy was performed. They founded laryngeal injury in 12 of the 19 patients. The authors showed that severe respiratory failure, high lateral wall pressure and respiratory infection were risk factors for injury.

The reproduction of the cuff-leak test can also be a limiting factor. In our unit, this test was systematically carried out by a respiratory therapist immediately before extubation. The procedure was standardized as described below. Moreover, in a recent study, Pettignano et al. [14] showed excellent reproducibility of the cuff-leak test by having the test performed by three different randomized operators in 30 patients. The authors stressed the need for a well standardized procedure.

### Therapeutic aspects

The two principal studies [2, 3] evaluating the use of corticosteroids in adults to prevent laryngeal edema post-extubation included all intubated patients presenting

with the usual extubation criteria. These two studies concluded that corticosteroids were not indicated in these cases, even if many clinicians had adopted this therapy. In order to answer this question properly, a study would need to be undertaken using patient populations with either a positive cuff-leak test and/or positive predictive risk factors. Identifying patients at risk of developing post-extubation stridor can allow appropriate therapy to be initiated more rapidly, such as a bronchodilator (epinephrine) inhalation and/or helium-oxygen mixture [15]. These therapies decrease airway resistance and the inspiratory effort, thereby giving time for usual therapy, such as corticosteroids, to work.

In conclusion, a positive cuff-leak test and the presence of risk factors could help to screen for a patient population at risk of developing post-extubation stridor. The occurrence of post-extubation stridor was associated with an elevated SAPS II, a medical reason for admission, traumatic or difficult intubation, a history of self-extubation, a prolonged period of intubation and an over-inflated balloon cuff at admission to ICU. Especially, a low cuff-leak volume (<130 ml or 12%) around the ETT prior to extubation seems useful in identifying patients at risk for post-extubation stridor.

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