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The cuff leak test to predict failure of tracheal extubation for laryngeal edema

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Abstract *Objective:* Laryngeal edema secondary to endotracheal intubation may require early re-intubation. Prior to extubation the absence of leak around an endotracheal tube may predict laryngeal edema after extubation. We evaluated the usefulness of a quantitative assessment of such a leak to identify the patients who will require early re-intubation for laryngeal edema. *Methods:* This prospective study included 76 patients with endotracheal intubation for more than 12 h. The leak, in percent, was defined as the difference between expired tidal volume measured just before extubation, in volume-controlled mode, with the cuff inflated and then deflated. The best cut-off value to predict the need for re-intubation for significant laryngeal edema was determined and the patients were divided into two groups, according to this cut-off value. *Results:* Eight of the 76 patients (11%) needed re-intubation for laryngeal edema. Patients requiring re-intubation had a smaller leak than the other patients [9 (3–18) vs 35 (13–53)%, $p<0.01$]. The best cut-off value for gas leak was 15.5%. The high leak group included 51 patients, of whom only two patients (3%) required re-intubation. The low leak group included 25 patients, among whom six patients (24%) required re-intubation ($p<0.01$). The sensitivity of this test was 75%, the specificity 72.1%, the positive predictive value 25%, the negative predictive value 96.1% and the percent of correct classification 72.4%. *Conclusions:* A gas leak around the endotracheal tube greater than 15.5% can be used as a screening test to limit the risk of re-intubation for laryngeal edema.

Keywords Cuff leak test · Laryngeal edema · Endotracheal intubation · Mechanical ventilation · Extubation failure · Stridor

Introduction

Endotracheal intubation may generate local complications, including mechanical lesions like friction, compressions between the tube and the anatomic structures [1], and also biochemical reactions at the interaction between the plastic or silicone tube material and the upper airway mucosa. Even though their incidence has decreased with the use of far more flexible polyvinyl chloride tubes generating less pressure on the anatomical structures and high volume low pressure cuffs inducing fewer mucosal lesions [1, 2, 3, 4, 5, 6], these complications remain frequent. Laryngeal edema manifests itself by respiratory distress and inspiratory whistling called "stridor". Such edema formation can develop as early as 6 h after intubation [7], so that prolonged intubation is not a prerequisite to its development [8, 9]. By decreasing the upper respiratory tract diameter, laryngeal edema increases airway resistance and, consequently, the respiratory work. When edema is present, re-intubation may be required if the patient is not able to sustain the increase in respiratory work. The development of laryngeal

edema requires close monitoring, and sometimes the application of non-invasive respiratory assistance [10], aerosolized epinephrine and perhaps corticosteroids, although the latter are controversial [8, 11]. If not rapidly recognized and adequately treated, laryngeal edema can be fatal.

There is no good method to identify patients at risk of severe laryngeal edema before extubation. Flow volume curves and their derivatives [12] can be useful to detect extra-thoracic airway stenosis, but these techniques are difficult to use in critically ill patients whose collaboration is often insufficient. Furthermore, these tests can only be used after extubation, when laryngeal edema may already be clinically evident. Fibroscopy is the gold standard for the upper airway examination, but requires at least the partial removal of the endotracheal tube [13, 14] and may be hazardous. Ideally, the test must be used for every patient just before extubation. Imaging techniques like CT scan [15] and magnetic resonance imaging (MRI) can visualize upper airway edema, but cannot be obtained routinely, and obviously have technical limitations. Echographic techniques to investigate the upper airway [16, 17] have not been thoroughly assessed in critically ill patients.

The cuff leak test was proposed as a simple tool to detect laryngeal edema. Adderley and Mullins [18] first used this test to predict successful extubation in children with croup. In this study successful extubation was likely if an air leak could be heard when the baby coughed during positive pressure ventilation with a plateau pressure of 40 cmH_2O. This test relies on the fact that the leak around the tube will be inversely proportional to the amount of edema. When the tube is in place in the trachea with the cuff inflated, no leak is observed, so that the expired tidal volume (ETV) is relatively constant. If the trachea is normal, when the cuff of the tube is deflated most of the expired gas circulates around the tube, so that the expired volume measured through the tube decreases. On the contrary, tracheal edema prevents such a leak when the cuff is deflated, so that the expired volumes through the tube with inflated (ETV BI) and deflated (ETV BD) cuff are equal. Different authors have used the cuff leak test to detect tracheal edema, using the spirometry of ventilators to measure the volume of the gas leak between the wall of the trachea and the deflated cuff [19, 20, 21, 22]. This quantitative version has the advantage of being highly reproducible and operator independent [23]. Although this method was shown to be effective at predicting extubation failure in patients with known airway obstruction [19], its predictive value was low in patients after cardiac surgery [22], so that the test may be of value only in specific populations.

We hypothesized that the cuff leak test may be used in the general population of a medico-surgical intensive care unit to identify the patients with laryngeal edema who may require early re-intubation.

Table 1 Indications for endotracheal intubation

	Indications	Number of patients
Surgical	Cardiac	27
	Vascular	6
	Trauma	4
	Neurologic	3
	Gastro-intestinal	3
	Urology/gynecology	2
	Thoracic	1
Medical	Septic shock	11
	ARDS	9
	Cardiac-respiratory arrest	3
	Cerebral hemorrhage	3
	Intoxication	2
	Cardiogenic pulmonary edema	1
	Pulmonary embolism	1
Total		76

Patients and methods

This prospective study included all adult patients (>18 years), who had been intubated for at least 12 h and who were about to be extubated after their first successful ventilator weaning trial of 30 min through a T-piece (between 8.00 h and 19.00 h, Monday to Friday), during a 3month period (Feb–April, 1999). Only one patient was investigated at a time; if several patients were simultaneously ready to be weaned, the patient was randomly selected. The study was approved by the ethics committee of the hospital and informed consent was obtained from the patients. Patients with a tracheotomy and those unable to complete a 30min T-piece trial were not considered. A total of 77 patients met the entry criteria, one of whom denied consent. The indications for endotracheal intubation are listed in Table 1. Thirty-eight patients were intubated for elective surgery (cardiac surgery n=24, vascular surgery n=6, other n=8), 8 patients for emergency surgery (trauma n=4, cardiac surgery n=3 and gastrointestinal surgery n=1) and 30 patients for a medical affection (mostly septic shock and respiratory failure).

After inclusion, the patients were briefly re-ventilated in a volume predetermined (assist-controlled) mode using the ventilators either Servo Siemens 300 or Siemens 900 (Siemens; Solna Sweden) or Evita 2 or 4 (Dräger; Lubeck, Germany), and all measurements were obtained. ETVs were measured using the cells of the ventilators. Six measurements of ETV BI and ETV BD varying by less than 30% were obtained and averaged. If necessary, up to ten measurements were obtained. The leak was calculated as follows: 100× (ETV BI–ETV BD) / ETV BI. The results of these measurements were not made available to the physician and physiotherapists in charge of the patient. The following data were also recorded: a SAPS II score at time of extubation [24], the tube size, the duration of intubation and the indication for intubation.

Arterial blood pressure, heart rate, respiratory rate and pulse oximetry were monitored before, during the measurement and after extubation. Arterial blood gas samples were obtained just before and 30 min after extubation, and repeated according to the clinical evolution. After extubation, we recorded heart rate and respiratory rate, as well as any sign of respiratory distress like supraclavicular, suprasternal and costal retractions during inspiratory breathing, contraction of the sternomastoid or other muscles, activity of vocal cords and inspiratory wheezing (stridor), suggesting an airway obstruction. Laryngeal edema was suspected in the presence of inspiratory stridor associated with any sign of respiratory

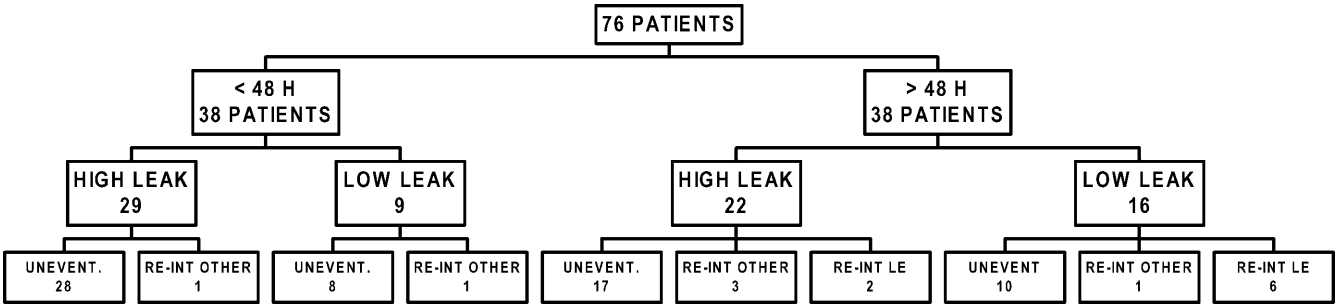

Fig. 1 Evolution of the patients after extubation. Patients were separated according to the duration of intubation and to the cuff leak. (*unevent* uneventful extubation, *re-int other* re-intubation for whatever reason excluding laryngeal edema, *re-int LE* re-intubation with laryngeal edema)

distress requiring re-intubation within 24 h of extubation, and confirmed in each case by fiberoptic examination before, or by direct view of the glottis during, re-intubation. Patients who were re-intubated for other reasons, such as stasis of pulmonary secretions or deterioration of their general state, were not considered as patients with laryngeal edema.

A receiver operating characteristic (ROC) curve was used to identify the cut-off value predicting the occurrence of laryngeal edema. The patients were then separated into two groups, above (group 1) and below (group 2) this cut-off value, and differences between the two groups were assessed using Mann-Whitney U-test or chi square analysis. A subgroup analysis was performed after excluding all the patients who were intubated in the operating room and with a duration of intubation less than 48 h. Data are presented as median (percentiles 25–75) unless stated otherwise. A p value less than 0.05 was considered as statistically significant.

Results

The variability of ETV BD was higher than ETV BI [coefficient of variation 26 (14–33) vs 5 (3–10)%, $p<0.0001$]. Accordingly, six (6–8) measurements were obtained to calculate ETV BD, while the number of measurements was always limited to six when determining ETV BI.

The 76 patients had a median age of 67 (51–76) years (Table 1). Half of the patients were ventilated for less than 48 h (Fig. 1). The median cuff leak was 33.9% (11.8–53.1), duration of intubation 2 days (1–5), tube size 8.5 (8–8.5) and SAPS II 26 (24–33.5). Eight patients (11%) required re-intubation for laryngeal edema (Table 2) within the first hours following extubation (7 within 12 h, the other one within 24 h). Six patients required re-intubation after more than 24 h for the development of pulmonary infection (2), septic shock (3) and accumulation of tracheal secretions (1) (Fig. 1). Ten patients developed stridor after extubation and 8 of these required re-intubation, 18 developed hoarseness, but none of these patients were re-intubated for laryngeal edema, and 48 patients had normal voices after extuba-

Table 2 Principal respiratory variables in patients according to the cuff leak tests

	Low leak	High leak	p value
General population			
No. of patients	25	51	
Tidal volume of the leak (ml)	50 (25–74)	249 (181–355)	<0.0001
Cuff leak (%)	9.3 (4.4–11.6)	41.1 (33.7–58.5)	<0.0001
Duration of mechanical ventilation (days)	3 (1–5)	1 (1–5)	NS
Tube size	8 (8–8.5)	8.5 (8–8.5)	NS
Tidal volume (ml/kg)	8.8 (6.9–9.3)	8.6 (7.6–9.7)	NS
PEEP level (cmH_2O)	5 (5–6)	5 (4–6)	NS
SAPS II score	28 (24–31)	26 (24–31)	NS
Patients with laryngeal edema [n (%)]	6 (24%)	2 (4%)	<0.01
After exclusion of patients following elective surgery with duration of intubation <48 h			
No. of patients	16	22	
Tidal volume of the leak (ml)	44 (24–70)	232 (130–351)	<0.0001
Cuff leak (%)	7.4 (3.1–12.3)	45.8 (34.3–62.5)	<0.0001
Duration of mechanical ventilation (days)	4 (3–6)	5 (3–9)	NS
Tube size	8 (8–8.5)	8 (8–8.5)	NS
Tidal volume (ml/kg)	8.5 (6.2–9.0)	8.0 (7.1–9.0)	NS
PEEP level (cmH_2O)	5 (5–7)	6 (5–8)	NS
SAPS II score	32 (24–44)	30 (24–41)	NS
Patients with laryngeal edema, [n (%)]	6 (38%)	2 (9%)	<0.01

Low leak is defined by a cuff leak lower than or equal to 15.5%, high leak by a leak higher than 15.5%

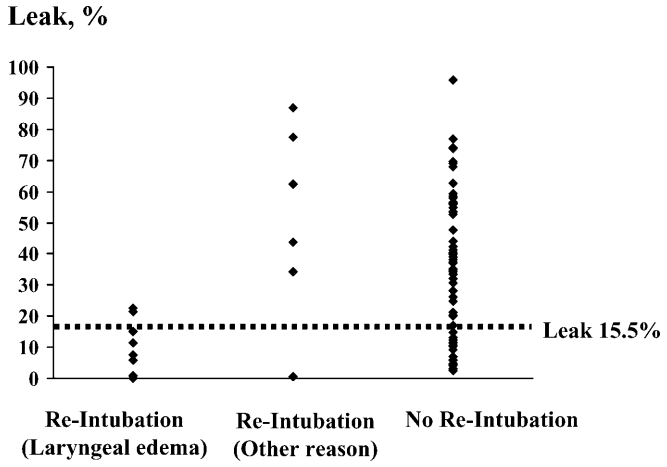

Fig. 2 Individual values of cuff leak

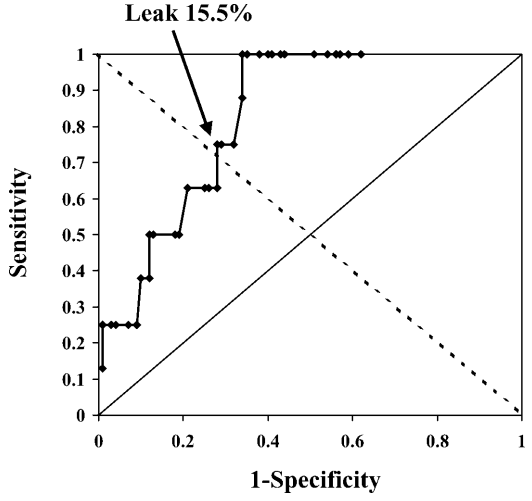

Fig. 3 Receiver operating characteristic (ROC) curve of the use of cuff leak test in the prediction of extubation failure due to laryngeal edema

tion. The cuff leak was lower in the patients with stridor than in the patients with normal voices [9.4 (0–22.6)% vs 33.5 (12.5–53.2)%, $p<0.001$] but was not different from patients with hoarseness [vs 19.9 (12.2–45.8), p=NS].

The median cuff leak in patients developing laryngeal edema was 9.4 (0–22.6)%, which was lower than in the 68 patients who did not require re-intubation for laryngeal edema [34.8 (12.8–55.3)%, $p<0.01$] (Fig. 2). The ROC curve yielded a cut-off value of 15.5% (Fig. 3), assuming an equivalent impact of false negative and false positive values. If a policy to minimize false positive (minimizing the risk of prolonged unnecessary intubation) is preferred, the cut-off value is only 1% but the sensitivity falls to 25%. If a policy to minimize false negative (minimizing the risk of extubation failure) is preferred, then the cut-off value is 23%, with a specificity of 65% and a positive predictive value for intubation of 47%. Six of the 25 patients (24%) with a cuff leak test less than 15.5%, but only 2 of the 51 patients (4%) with a cuff leak test higher than 15.5%, were re-intubated for laryngeal edema ($p<0.01$). Table 2 shows the principal respiratory variables of these patients. The indications for endotracheal intubation were multiple injuries (n=3), septic shock (n=2), intracerebral bleeding (n=2) and cardiogenic pulmonary edema (n=1). The sensitivity of this test was 75.0%, specificity 72.1%, positive predictive value 25.0% and negative predictive value 96.1%. The percent of correct classifications was 72.4%.

No patient required re-intubation for laryngeal edema in the subgroup of patients with intubation for less than 48 h, which included 35 surgical patients with elective intubation and 3 medical patients (1 patient after successful CPR and 2 patients briefly intubated for respiratory failure due to lung infection).

Discussion

The incidence of post extubation laryngeal edema observed in this cohort of patients was within the expected range in adults [5]. Esteban et al. [25, 26] reported that upper airway obstruction was responsible for 15% and 19% of all re-intubations. Epstein et al. [27] reported, in a retrospective study, that upper airway obstruction was responsible for 15% of all re-intubations, but this proportion increased to nearly 50% of early (<12 h) re-intubations. Similarly, Daley et al. [9] reported that laryngeal edema was the cause of failed extubation in 38% of cases. In all these studies, no specific investigation was performed to diagnose upper airway obstruction. The proportion of patients diagnosed with laryngeal edema varied among these series, and this may be related to the techniques used to diagnose this condition. In our study, direct laryngeal examination was performed in every extubation failure. Nevertheless, laryngeal edema may have been only one of the factors leading to re-intubation in these patients.

Several factors can increase the risk of laryngeal edema, including traumatic intubation, excessive tube size [6], excessive tube mobility due to insufficient fixation [6], patient fighting against the tube or trying to speak [6], excessive pressure in the cuff [2, 3, 4, 6], elevated insufflation pressure [6], too frequent or too aggressive tracheal aspirations [6, 7], the occurrence of infections or arterial hypotension [2, 3, 4, 6] or the presence of nasogastric tube promoting gastro-esophageal reflux [6]. Other factors, such as the duration of mechanical ventilation and female gender, have also sometimes been reported [8, 28].

We observed that a quantitative cuff leak test can be useful to exclude laryngeal edema. In particular, a nega-

tive test was useful to rule out extubation failure due to laryngeal edema. In our series, a cuff leak higher than 23% was never associated with re-intubation due to laryngeal edema. Potgieter and Hammond [13] reported that edema was likely when they were unable to hear the patient's breath around the tube during a brief obstruction maneuver. Similarly, Fisher et al. [19] reported that hearing a leak was predictive of successful extubation, although a failure to hear breaths did not preclude extubation. However, hearing the sound of breaths is very subjective. Miller and Cole [21] refined the test by measuring the difference between the inspiratory and expiratory tidal volume measured with a deflated cuff. They showed a significant predictive value of a low leak to predict the occurrence of stridor post extubation, although only a limited proportion of these patients required re-intubation.

Recently Sandhu et al. [20] further improved this test in trauma patients by comparing the expiratory tidal volumes with the cuff inflated and deflated. They concluded that a cuff leak less than 11.7% was useful for detecting patients at risk of laryngeal edema requiring re-intubation. However Engoren [22] showed that this test was not predictive in patients after cardiac surgery, who had a low incidence of re-intubation for laryngeal edema. In our series also, the cuff leak test was not useful after elective surgery and short duration (<48 h) of mechanical ventilation as none of these patients, intubated electively in an optimal environment, required re-intubation for laryngeal edema.

The positive predictive value was only 25%, implying that a patient with a cuff leak less than 15.5% still has a 75% chance of being extubated without laryngeal edema requiring re-intubation. Hence this test cannot be used to postpone extubation of the patient; however the test can help to identify patients at risk of developing complications of laryngeal edema, who may therefore require closer monitoring after extubation. Of note, after the exclusion of elective surgical patients intubated for less than 48 h, the positive predictive value of the test increased from 25% to 37.5% – indicating that this test has a greater performance in a better targeted population. Importantly the negative predictive value of this test is high, indicating that the test is particularly useful to exclude significant laryngeal edema.

Using other cut-off values did not really improve the performance of the cuff leak test. The cut-off value of 15.5% was determined assuming an equivalent impact of false negative and false positive values or, in other words, that the risk of re-intubation for laryngeal edema equals the risk of maintaining unnecessary intubation. The cuff leak test should not be used if the aim is to minimize the risk of prolonged unnecessary intubation, as the sensitivity of the test falls to 25%. Conversely, a higher cut-off value (23%) may be used if the aim is to minimize the risk of extubation failure, but then 45% of patients who could potentially be extubated will be kept intubated unnecessarily. Hence, whatever the cut-off value used, this test should be considered as an indicator of a risk for re-intubation for laryngeal edema rather than as a measurement to preclude the extubation attempt.

Several factors may limit our findings. First secretions encrusted on the outer part of the tube may influence the cuff leak volume. We tried to limit this phenomenon by gently suctioning the patients before the measurements. Second, patients may breathe around the tube when the cuff is deflated, so that the inspired tidal volume may have been minimized. This is quite unlikely, as the flow coming from the ventilator was delivered under pressure and at high flow. Finally the population we investigated was relatively small; nevertheless the incidence of laryngeal edema allowed us to draw reliable conclusions.

In summary, this quantitative cuff leak test can reliably be used to exclude the development of laryngeal edema severe enough to require subsequent re-intubation. However, the leak test may not be warranted in patients intubated for an elective operation and ventilated for less than 48 h. A small leak can help to identify patients at risk of laryngeal edema, in whom great caution should be taken after extubation, but should not preclude an extubation attempt.

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