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# Impact of Monitoring Endotracheal Cuff Pressure on **Endoscopic Laryngo-Tracheal Injury: A Randomized Pilot Study**

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## Authors' contributions

This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

## Article Information

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# **ABSTRACT**

Aims: Underinflation (<20 cmH2O) and overinflation (>30 cmH2O) of tracheal cuff are independent factors of microaspiration and tracheal ischemic lesions respectively. The aim of this study was to evaluate the impact of discontinuous monitoring of endotracheal cuff pressure on the incidence of endoscopic laryngotracheal injury and to analyze factors associated with the development of these

Study Design: Prospective and randomized study.

Place and Duration of Study: Medical Intensive care unit at Taher Sfar Hospital in Mahdia, between December 2010 and April 2012.

Methodology: All patients admitted to our intensive care unit (ICU) and requiring invasive mechanical ventilation for more than 48 hours were randomly assigned to have or not a discontinuous cuff pressure monitoring. The primary outcome was the incidence of endoscopic laryngotracheal injury during ICU stay. Secondary outcomes were the incidence of endoscopic laryngotracheal injury at day-90, ventilator-associated pneumonia, the length of stay, the duration of mechanical ventilation and mortality.

**Results:** Ninety-five patients (49 in the monitored group and 46 in the control group) aged  $59 \pm 20$  years, were included in the study. The incidence of endoscopic laryngotracheal injury was 42% with no significant difference between study groups. The proportion of patients with tracheal granulation was significantly lower in the monitored group: 4% vs 24% (p= 0.0049). Secondary outcomes were similar between the two groups. ICU admission for intoxication was the only independent factor associated with the occurrence of endoscopic laryngotracheal injury (OR 6.779, CI 95% (1.121- 41,008); p= 0.037).

**Conclusions:** Discontinuous monitoring of cuff pressure did not reduce the overall incidence of endoscopic laryngotracheal injury but only the incidence of tracheal granuloma. These results recommend the routine survey of cuff pressure in ICU.

Keywords: Endotracheal cuff pressure; laryngotracheal injury; mechanical ventilation; critical care; intoxication.

#### 1. INTRODUCTION

Endotracheal intubation is a frequent procedure in Emergency Department and Intensive Care Unit. It is often performed without any complications [1], and appears to be well tolerated for several days [2-6]. Nevertheless, laryngeal and tracheal complications occur in 15 to 20% of cases [7,8] caused by the movements of the tube and the endotracheal tube cuff [9]. Endotracheal tube cuff is used to avoid air leakage and to prevent aspiration of pharyngeal and larvngeal secretions and regurgitated gastroesophageal contents. However, endotracheal tube cuff pressure is transmitted to the tracheal wall and a cuff pressure greater than 30 cm H<sub>2</sub>O [10-12] may cause ischemia of mucosal vessels followed by alterations such as ciliary loss [13], ulceration [14], bleeding [15], tracheal stenosis [16] and tracheoesophageal fistula [17]. Other complications such as micro-aspiration oropharyngeal secretions and nosocomial pulmonary infections [18] are associated with insufficient cuff inflation. Consequently, cuff pressure (Pcuff) should be kept between 20 and 30 cm H<sub>2</sub>O to avoid complications related to underinflation and overinflation [19]. objective of this study was to evaluate the impact of monitoring P<sub>cuff</sub> on the incidence of endoscopic laryngotracheal injury in ICU patients and to determine associated factors with development of these lesions.

# 2. MATERIALS AND METHODS

Patients were recruited from a 10-bed intensive care unit at Taher Sfar Teaching Hospital in Mahdia-Tunisia between December 2010 and April 2012. The study protocol was approved by

the hospital ethics committee. All patients or their relatives gave written informed consent before enrolment in the study.

Eligible patients were all adults (aged ≥ 18 years) expected to require more than 48 hours of invasive mechanical ventilation through an endotracheal tube and with no history of prior laryngeal pathology. Exclusion criteria were non-consenting patients; intubated patients transferred from other intensive care unit, patients with tracheostomy, and patients who died before endoscopic exploration.

# 2.1 Protocol

Eligible patients were randomly allocated in a 1:1 ratio to the monitored group or the control group. In the control group, after tracheal intubation, the endotracheal cuff was inflated with air through a 10 ml syringe. The adequacy of cuff inflation was determined by palpation of the pilot balloon. No measure of cuff pressure was done at any time during the study.

In the monitored group, cuff pressure was measured by the nursing staff using a manual manometer (Rusch endo test, Teleflex, Le Faget, France) connected to the distal edge of the pilot balloon four times a day and maintained at 25 cmH<sub>2</sub>O. All patients were intubated with high volume/low pressure cuff tracheal tube (Covidien Mallinckrodt, USA) and explored by a laryngotracheal endoscopy 24 to 48 hours after extubation and three months later.

## 2.2 Data Collection

We recorded the demographic characteristics of patients, the Simplified Acute Physiology Score II

(SAPSII), diagnosis at admission (acute respiratory failure, shock, coma, intoxication, other), reason for mechanical ventilation (exacerbation of chronic respiratory disorder, congestive heart failure, sepsis, difficulties at intubation defined as more than two attempts before successful intubation of the trachea [20], internal diameter of the cuffed tube, early complications of intubation (bleeding, hypotension, and failure bradycardia, intubation), the values of cuff pressure for the monitored group, administration of corticosteroid therapy, the occurrence of an auto-extubation or a reintubation and the laryngotracheal endoscopic abnormalities (laryngeal edema, granulations, stenosis) found 24 to 48 hours after the extubation and at day-90.

# 2.3 Study Outcomes

The primary endpoint of the study was the incidence of endoscopic laryngotracheal injury observed after extubation. The secondary endpoints were the incidence of endoscopic laryngotracheal injury at day-90, the incidence of ventilator-associated pneumonia, ICU length of stay, duration of mechanical ventilation and mortality.

# 2.4 Statistical Analysis

Statistical analyses were performed using SPSS 18 (IBM SPSS Inc., Chicago, IL). Qualitative or categorical variables were compared with chisquare or Fisher's exact tests, when appropriate. Quantitative continuous variables compared using the unpaired Student's t-test or the Mann-Whitney nonparametric test, when appropriate. For all tests, a p value less than 0.05 was deemed significant. Multiple logistic regression analysis was performed to determine independent factors associated the endoscopic laryngotracheal injury. We included in the model of the multivariate analysis variables associated with post-extubation lesions with a p value less than 0.2 in the univariate analysis.

## 3. RESULTS

During the study period 200 mechanically ventilated patients were considered for eligibility. Among them 95 met the inclusion criteria and were randomized, 49 were included in the monitored group, and 46 in the control group. The main reasons for non-inclusion were consent refusal (17 patients), and the non-realization of endoscopy (48 patients: 18 tracheostomy and 30 death) (Fig. 1).

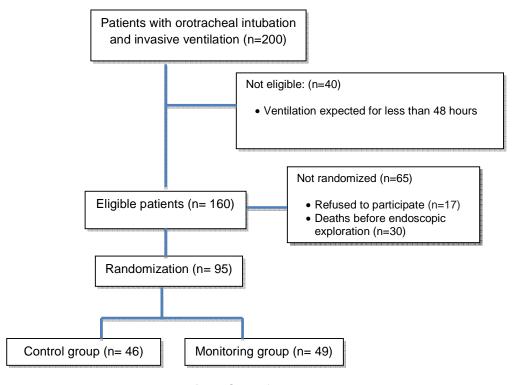


Fig. 1. Study flow chart

Table 1 shows the baseline characteristics of the study population. There were no significant differences between the groups (Table 1).

Half of the patients (50%) in the monitored group had cuff overinflation.

The incidence of endoscopic laryngotracheal injury was 42%. Twenty patients (40.8%) in the monitored group and 20 patients (43.4%) in the control group had at least one endoscopic tracheal lesion (odds ratio: 0.896; 95% CI, 0.396 to 2.025; p=0.793). However, the incidence of tracheal granulation was significantly higher in the control group: 4% vs 24% (odds ratio: 0.135; 95%CI, 0.028 to 0.650; p= 0.004). A laryngeal

edema was observed in 18 patients (36.7%) in the monitored group and in 9 patients (19.5%) in the control group (odds ratio: 2.38; 95%CI, 0.94 to 6.06; p=0.063)

(Table 2) In both groups, symptomatic patients with endoscopic laryngotracheal injury were treated with systemic corticosteroids after endoscopic results.

Secondary outcomes were similar in both groups. Indeed, the incidence of ventilator associated pneumonia (VAP) in monitored group and in the control group were 20% and 28.5% respectively (p=0.261). All patients with at least one episode of underinflation of tracheal cuff in

Table 1. Baseline characteristics of all patients

Characteristics	All patients (n: 95)	Monitored group: (n: 49)	Control group (n=46)	р
Age (years)	59±20	60±20	58±20	0.642
Sex ratio (M/F)	1.96	1.88	2.06	0.83
Chronic disease at ICU admission; n (%)				
Diabetes mellitus	26(27.4)	13(26.5)	13(28)	0.85
Hypertension	33(37.7)	13(26.5)	20(43)	0.083
Heart failure	3(3.2)	2(4)	1(2)	0.595
COPD	41(44)	22(45)	20(41)	0.724
History of mechanical ventilation; n (%)	21(22)	11(22)	10(22)	0.934
SAPS II	44±170	43.7±18	44±18	0.928
Diagnosis at admission; n (%)				
Acute respiratory failure	48(50.5)	23 (51)	25 (54)	0.686
Shock	16(16.8)	10(20)	6 (13)	0.337
Coma	7(7.4)	4 (8)	3(6.5)	0.759
Intoxication	13(13,7)	7(14)	6(13) <sup>´</sup>	0.860
Other	11(11.6)	5(10)	6 (13)	0.807
Causes of mechanical ventilation; n (%)	,	,	,	
Acute exacerbation of COPD	42(44)	24(49)	18(39)	0.334
Congestive heart failure	7( <del>?</del> )	3(6)	4(9) ´	0.631
Sepsis	10(10.5)	5(10)	5(11)	0.915
Coma	24(25) <sup>′</sup>	11(22)	13(28)	0.514
Other	12(13)	6(12) <sup>′</sup>	6(13) <sup>′</sup>	0.051
Easy intubation; n (%)	84(88.4)	43 (88)	41(89)	0.834
Size of endotracheal tube; n (%)	,	(	,	
6- 6.5	2(2.2)	1(2)	1(2)	0.963
7	15(15.8)	10(20)	5(11)	0.202
7.5	39(41.1)	20(41)	19(41)	0.961
8	39(41.1)	18(37)	21(46)	0.377
Early complications of intubation; n(%)	( /	-(/	( /	2.2.7
Hypotension	61(64.2)	30(61)	31(67)	0.531
Bleeding	4(4.2)	2(4)	2(4)	0.655
Bradycardia	4(4.2)	2(4)	2(4)	0.655
Second intubation; n (%)	11(11.5)	6(12.2)	5(10.2)	0.911
Self-extubation; n (%)	5(5)	3(6)	2(4)	0.681

the monitored group (cuff pressure < 20 cm H<sub>2</sub>O) developed VAP. The incidence of post extubation stridor, the number of patients who needed tracheostomy to facilitate weaning mechanical ventilation, the duration mechanical ventilation, the length of stay in intensive care unit, and the mortality were comparable between the two groups. At day-90 endoscopic control showed that tracheal lesions observed after extubation persisted in two patients in each group (one granulation and one tracheal stenosis in each group) (Table 2).

In univariate analysis, the comparison between patients with and without endoscopic laryngotracheal injury showed no significant differences between groups at baseline except for the history of mechanical ventilation (12.5 vs 29%) in the abnormal endoscopic group and the normal endoscopic group respectively (p=0.05), and the rate of patients admitted to the ICU for intoxication (25% vs 5.4%, p=0.014) (Table 3).

The logistic regression analysis showed that the only factor associated with endoscopic laryngotracheal injury was ICU admission for intoxication (OR: 6.779 Cl 95% (1.121- 41. 008); p= 0.037) (Table 4).

# 4. DISCUSSION

This study showed that discontinuous monitoring of endotracheal cuff pressure did not reduce the incidence of endoscopic laryngotracheal injury. The post hoc analysis showed a significant reduction in the rate of granuloma. We found no difference between the two groups regarding the following parameters: incidence of laryngeal edema, VAP, length of stay, endoscopic

laryngotracheal injury at day-90 and mortality. ICU admission for intoxication was the only factor associated with the occurrence of endoscopic laryngotracheal injury.

In our study the incidence of laryngotracheal injury following orotracheal intubation was 42%. This incidence seems similar to the incidence reported by Chung et al. [16]. For Francois et al. the incidence was 12% [12]. Other studies reported an incidence of laryngeal edema between 4.2 to 11% [12-15]. The difference observed in the rate of laryngotracheal injury could be explained by the difference in the methodology adopted whether it is a prospective or a retrospective study, the inclusion criteria, the duration of the patients' follow up and the diagnostic methods. In our study, corticosteroids were not systematically administered before extubation and 64% of our patients experienced a hypotensive episode after intubation, which could alter larvngotracheal mucosal perfusion predisposing to laryngotracheal injury.

We did not found a difference in the main outcome between the monitored and the control group, and half of the affected patients were not symptomatic. The incidence of granuloma observed in our study was 13.6%. This incidence is comparable to that reported in the literature [17-19]. Cuff pressure monitoring could reduce significantly the incidence of granuloma by 19%. Several reasons might explain this finding. First, while large volume cuffs may achieve clinical seal at low cuff pressure, inflation beyond this point with small increments of air easily generates excessive cuff pressure and thus lateral wall pressure which cannot be

Table 2. Main outcome variables

Variable	All patients (N: 95)	Monitoring group: N: 49	Control group N=46	р
Endoscopic laryngotracheal injury; n (%)	40(42)	20(40.8)	20(43.4)	0.793
Laryngeal edema	27 (28.4)	18(36.7)	9(19.5)	0.063
Granulation	13(13.6)	2(4)	11(23.9)	0.004
Postextubation stridor; n (%)	19(20)	10(20)	9(19.5)	0.091
Ventilator-Associated Pneumonia; n (%)	24(25)	10(20)	14(28.5)	0.261
Tracheostomy; n (%)	7 (7.3)	3(6.1)	4 (8.6)	0.930
Duration of mechanical ventilation (days)	11±9	12±12	11±9	0.494
Length of stay in ICU (days)	15±13	14±13	16±13	0.602
Endoscopic laryngotracheal injury at day-90	4 (4.2)	2 (4)	2 (4.3)	0.65
Granulation	1(1)	1(2)	1(2.1)	0.5
stenosis	2(2)	1(2)	1(2.1)	0.5
Mortality; n (%)	18 (18.9)	9 (18.36)	9 (19.5)	0.882

ICU: Intensive Care Unit

detected by a simple palpation of the pilot balloon. It is an important factor for tracheal injury by affecting tracheal capillary blood flow. Capillary perfusion pressure normally ranges between 22 and 32 mmHg. While some damage to tracheal mucosa due to the contact between cuff material and tracheal wall is inevitable, the depth of such erosions should be minimized by monitoring and avoiding excessive lateral wall pressure. There is an evidence of obstruction to

mucosal blood flow at a lateral wall pressure above 30 cm H2O (22 mmHg) with total occlusion of flow to the mucosa over the tracheal rings and posterior tracheal wall at a lateral wall pressure of 50 cm H2O (37 mmHg) [20]. On the other hand, even at low pressures, some injuries of tracheal epithelium are evident. Four hours of inflation may affect ciliary appearance and function for 3 days [21].

Table 3. Univariate analysis of factors associated with endoscopic lesions

Characteristics	Abnormal endoscopic (n: 40)	Normal endoscopic (n=55)	р
Age (years)	55±21	62±19	0.1
Sex; n (%)			
Men	24(60)	39(71)	0.267
Chronic disease at ICU admission; n (%)			
Diabetes mellitus	13(32.5)	13(23.6)	0.339
Hypertension	11(27.5)	20(40)	0.206
Heart failure	2(5)	1(1.8)	0.381
COPD	16(40)	19(45.4)	0.596
History of mechanical ventilation; n (%)	5(12.5)	16(29)	0.05
SAPS II	44±17	44±18	0.92
Diagnosis at admission; n (%)			
Acute respiratory failure	17 (42.5)	31 (56.3)	0.18
Shock	7(17.5)	9 (16.3)	0.88
Coma	2 (5)	5(9)	0.45
Intoxication	10(25)	3(5.4)	0.014
Causes of mechanical ventilation; n (%)			
Acute exacerbation of COPD	20(50)	22(40)	0.72
Congestive heart failure	3(7.5)	4(7.2)	0.84
Sepsis	4(10)	6(10.9)	0.59
Decrease of consciousness	9(22.5)	15(27.2)	0.72
Easy intubation; n(%)	34 (85)	50(91)	0.37
Size of endotracheal tube; n (%)	,	, ,	
≤7	10(25)	7(12.7)	0.12
7.5	16(40)	23(41.8)	0.85
8	14(35)	25(45.4)	0.30
Second intubation; n (%)	4(10)	7(12.7)	0.66
Monitored groups; n (%)	20(50)	20(36.3)	0.79
Self-extubation; n (%)	2(6)	3(4)	0.94
Tracheostomy; n (%)	2(5)	5(9)	0.721
Duration of mechanical ventilation (d)	9.95±9.68	10.01±9.78	0.97
Duration of mechanical ventilation >5 days; n (%)	25(62.5)	35(63)	0.91
Length of stay in ICU (days)	15.2±11.6	14.6±13.7	0.821
Mortality; n (%)	6(15)	12(22%)	0.402

COPD: Chronic obstructive pulmonary disease; ICU: Intensive Care Unit

Table 4. Multivariate analysis of independent factors associated with endoscopic lesions

	Crude OR (95% CI)	р
Age	0.348 (0.060 - 2.013)	0.238
Hypertension	0.637(0.242 - 1.676)	0.361
History of mechanical ventilation	0.393 (0.124 - 1.251)	0.114
Intoxication	6.779 (1.121 – 41.008)	0.037
Size of endotracheal tube ≥ 7	1.852(0.581 - 5.909)	0.98

OR: Odds Ratio

Second, cuff pressure can induce ischemia, mucosa ulcerations and expose the cartilages through local inflammatory and infectious phenomenon; these damages will be followed by a progressive deterioration of the tracheal cartilages. Controlled cuff pressure can decrease these lesions.

We showed that monitoring cuff pressure has not decreased the incidence of laryngeal edema. Laryngeal or tracheal edema occur in almost all patients intubated for 4 days or more [11,22,23] and it result from the consecutive inflammatory response in contact with the endotracheal tube or its cuff. These lesions are relatively harmless. Our negative results can be explained by the presence of other risk factors for acute laryngeal injury in the monitored group: being a female [24-26], duration of mechanical ventilation [24-27], size of endotracheal tube [27], presence of a naso-gastric tube [28] and infection. Another explanation of these negative results is that the control group might be considered as partially monitored, because the palpation of the pilot balloon is currently used as monitoring tool of the cuff pressure and was evaluated as effective by some studies [29,30], but necessitate to be performed by an experienced team.

The duration of mechanical ventilation in our patients was long (mean 10±9 days) and 75% of patients were intubated with an endotracheal tube ≥ 7.5 mm. Probably the most potent force causing laryngeal injury was the pressure exerted by the tube. The tube is a round structure fitted into a pentagonal structure of the larynx, which is constituted by the membranous and cartilaginous vocal cords and the cricoid. The external diameter of the endotracheal tube stretches the normal glottic width by 6-8 mm [27], resulting in substantial pressure at the tangential interface between the tube and the mucosa. This pressure is in the range of hundreds of millimeters of mercury, even with a relatively small endotracheal tube [31].

The endoscopic laryngo-tracheal injury at day-90 was similar in the two groups. The frequency of stenosis reported in historical studies is ranging between 10% and 21% [19,32-34] which is largely superior to that found in our study (2%). For a better understanding of the effects of cuff pressure monitoring on the incidence of stenosis we need to include more patients.

The relationship between underinflation of tracheal cuff and VAP was poorly studied. Rello et al. [8] observed a significantly higher incidence of VAP in patients with underinflation of the tracheal cuff compared with those without underinflation of the tracheal cuff (39% vs 18%, p=0.03). In the study of Valencia et al. [35] no significant difference was found in the incidence of microbiologically confirmed VAP between patients with continuous control of cuff pressure using an electronic artisanal device and patients with routine care. The negative result of this study might be explained by the fact that all patients were placed in semi recumbent position, the use of clinical criteria to diagnose VAP and the inclusion of VAP episodes diagnosed only during the first 8 days of invasive mechanical ventilation.

In a randomized controlled study, Nseir et al[36] observed that the incidence of VAP in the group with continuous control of cuff pressure using a pneumatic device was significantly lower, compared with the group with routine care of cuff pressure (18% vs 46%, p=0.002). The most important difference between our study and Nseir's was the use of a pneumatic device to continuously control cuff pressure. pneumatic device was associated with a significantly reduced variation of cuff pressure compared with control of cuff pressure using manometer [37].

In our study the only independent factor associated with endoscopic injury was the admission for intoxication. The mechanism of induced laryngotracheal injury by intoxication is

unknown. The possible explanation is that in our ICU, chloralose was the leading cause of poisoning characterized by hypertonic coma and myoclonus resistant to sedation. These two factors can induce movements of endotracheal tube in intubated patients. The movements of the tube with abrasion of the mucosa and pressure necrosis are two possible major mechanisms that can cause laryngeal injury [38]. Radiographic examination shows that the endotracheal tube can move 3.8 cm (mean distance) when the head is moved from flexion to extension [38]. Since even the simple act of inspiration causes appreciable cephalic-caudal laryngeal movement many times a minute [39], significant abrasion could occur.

Several limitations of our study should be outlined, including the single center design, the absence of blinding, the number of patients included and the device used to control cuff pressure. In our study cuff pressure was measured by a manual manometer connected to the distal edge of the pilot balloon. This method is simple, and no specific training is necessary. The continuous control of cuff pressure with pneumatic or electronic device has been proven to be more efficient. However, this device is not widely available in the ICU.

## 5. CONCLUSION

Endoscopic laryngotracheal injury was found in almost the half of the subjects in this study. Cuff pressure monitoring did not reduce laryngotracheal injury but reduced the incidence of granuloma. Intoxication was an independent factor associated with laryngotracheal injury.

## **CONSENT**

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

# **ETHICAL APPROVAL**

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

# **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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