Continuous control of tracheal cuff pressure and ventilator-associated pneumonia

Régulation continue de la pression du ballonnet trachéal et pneumonie acquise sous ventilation mécanique

S. Nseir · E. Jaillette

Abstract Intubation is performed in a large proportion of critically ill patients. Underinflation (< 20 cmH$_2$O) and over-inflation (> 30 cmH$_2$O) of tracheal cuff were identified as risk factors for microaspiration and tracheal ischemic lesions, respectively. Maintaining cuff pressure (P$_{cuff}$) around 25 cmH$_2$O is recommended to prevent these complications. Periodic adjustment of P$_{cuff}$ using a manual manometer might be helpful in preventing severe tracheal ischemic lesions. However, despite manual control of P$_{cuff}$, patients spend a large amount of time with underinflation of P$_{cuff}$. Two randomized controlled studies evaluated the impact of continuous control of P$_{cuff}$ on microaspiration of gastric contents and ventilation-acquired pneumonia (VAP) incidence. The first study using an electronic device failed to demonstrate any impact of continuous control of P$_{cuff}$ on VAP rate (15% in the two groups). However, the second one found the pneumatic device to be associated with significantly reduced microaspiration of gastric contents, tracheobronchial colonization, and VAP rate (9.8% vs. 26.2%, p = 0.032, odds ratio [95% confidence interval] 0.30 [0.11-0.84]). Different devices and different patient characteristics might explain the different results found in these studies. Further randomized controlled multicenter trials are needed to determine the impact of continuous control of P$_{cuff}$ on VAP incidence, and to compare the different available devices.

Keywords Pneumonia · Cuff pressure · Tracheal tube · Microaspiration · Mechanical ventilation

Résumé L'intubation est réalisée chez un pourcentage important de patients hospitalisés en réanimation. Les sous-pressions (< 20 cmH$_2$O) et surpressions (> 30 cmH$_2$O) du ballonnet trachéal ont été identifiées comme facteurs de risque de micro-inhalation et d'ischémie trachéale, respectivement. Le maintien de la pression du ballonnet (P$_{bal}$) autour de 25 cmH$_2$O est recommandé pour prévenir ces complications en réalisant un ajustement périodique de la P$_{bal}$ avec un manomètre manuel. Cependant, en dépit de ce contrôle, les patients passent un pourcentage important du temps avec une sous-pression du ballonnet trachéal. Deux études ont évalué les effets de la régulation continue de la P$_{bal}$ sur la survenue de micro-inhalations et de pneumonie acquise sous ventilation mécanique (PAVM). La première qui a utilisé un appareil électronique pour le contrôle continu de la P$_{bal}$ n'a pas retrouvé de bénéfice de l'utilisation de ce type d'appareil en termes d'incidence de la PAVM (15 % dans les deux groupes). La seconde a démontré que la régulation continue de la P$_{bal}$ par un appareil pneumatique permettait de réduire significativement l'incidence des micro-inhalations du liquide gastrique, de la colonisation trachéobronchique et des PAVM (9,8 vs 26,2 %, p = 0,032, odds ratio [intervalle de confiance à 95 %] : 0,30 [0,11–0,84]). Plusieurs différences entre ces études pourraient expliquer les résultats discordants : appareil électronique versus pneumatique, pourcentages des patients chirurgicaux et des patients présentant une PAVM dans le groupe témoin différents entre les deux études. D'autres études randomisées contrôlées multicentriques sont nécessaires afin de déterminer l'impact de la régulation continue de la P$_{bal}$ sur l'incidence des PAVM et de comparer les différents appareils disponibles.

Mots clés Pneumonie · Pression du ballonnet · Sonde trachéale · Micro-inhalation · Ventilation mécanique

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Introduction

Despite the increasing use of noninvasive mechanical ventilation and high-flow nasal oxygen to treat acute respiratory

failure, intubation is still performed in a large proportion of critically ill patients. Complications related to this procedure could be classified into immediate and long-term. Long-term complications are caused by inappropriate cuff pressure (P_{cuff}), and include microaspiration, and tracheal ischemic lesions [1]. Microaspiration of contaminated oropharyngeal secretions and gastric contents is the main route of entry for bacteria into the lower respiratory tract. Colonization of the lower respiratory tract could progress into ventilator-associated pneumonia (VAP) when local or general defense mechanisms are altered in the intubated critically ill patients [2]. This infection is still common in the intensive care unit (ICU) and is associated with high morbidity and mortality, especially in patients with comorbidities [3].

Prevention of microaspiration is a key issue in preventing VAP. Several recent studies evaluated different individual methods to prevent microaspiration and VAP. Others evaluated bundles aiming to prevent VAP, using several preventive measures. In order to prevent microaspiration and VAP, all risk factors should be taken into account since this infection is multifactorial with important interaction between risk factors [4]. The aim of this review is to discuss recent findings on the relationship between continuous control of P_{cuff} and VAP occurrence.

Control of tracheal cuff pressure in the ICU

The low compliance of nurses and physicians with current recommendations and the inefficiency of manometer in controlling P_{cuff} might explain the absence of efficient control of P_{cuff} in critically ill patients.

Based on national and international recommendations, P_{cuff} should be kept between 20 and 30 cmH$_2$O [5,6]. Several surveys and audits showed that unfortunately not all ICU physicians and nurses are following these recommendations. A recent multicenter French study aimed to determine the incidence and type of medical errors in 70 ICUs during a 2-week period. Thus, 1369 patients were included, and 1992 medical errors were detected in 26% of them. Error in administering insulin was the most frequent medical error (31% of all medical errors), followed by overinflation of tracheal cuff (13%). A recent survey was performed in a large number of physicians and nurses in European ICUs in order to evaluate current practices in VAP prevention [7]. Eighty-one percent of all responders declared performing regular check of P_{cuff} in their ICU. This percentage was lower among French nurses and doctors who responded to this survey (72%).

A recent randomized controlled study performed in a large number of patients scheduled for elective surgery found proper control of P_{cuff} using a manometer to be associated with significantly reduced clinical complications,

such as cough, sore throat, hoarseness, and blood-streaked expectorant, related to cuff overinflation compared with no measurement of P_{cuff} [8]. However, to our knowledge, no study has evaluated the impact of discontinuous control of P_{cuff} using a manometer on incidence of complications related to underinflation or overinflation of tracheal cuff in ICU patients.

Our group performed a prospective observational study to determine the incidence of underinflation and overinflation of P_{cuff} in 101 critically ill patients intubated with a PVC-cuffed tracheal tube [9]. P_{cuff} was adjusted (25 cmH$_2$O) by nurses thrice a day, and was continuously recorded during 8 h (between two adjustments). Only 18% of study patients spent 100% of recording time with normal (20–30 cmH$_2$O) P_{cuff}. Fifty-four percent of study patients developed cuff underinflation, 73% developed cuff overinflation, and 44% developed both. Thirty-three percent of study patients developed underinflation or overinflation for >30 minutes.

In another prospective observational study [10], we aimed to determine the impact of polyurethane and cuff shape on variations of P_{cuff}. Cuff pressure was continuously recorded for 24 h in 76 intubated patients, including 26 with PVC, 22 with cylindrical polyurethane (CPU), and 28 with tapered polyurethane (TPU)-cuffed tracheal tubes. P_{cuff} was manually adjusted every 8 h by nurses, and was maintained around 25 cmH$_2$O. No significant difference was found in the percentage of time spent with underinflation (mean ± SD, 26 ± 22, 28 ± 12, $30 \pm 13\%$ in PVC, CPU, and TPU groups; respectively) and overinflation (median [IQR], 7 [2–14], 6 [3–14], 11% [5–20]) between the three groups. However, a significant difference was found in the coefficient of variation of P_{cuff} (mean ± SD, 82 ± 48, 92 ± 47, 135 ± 67, $p = 0.002$). Taken together, these results suggest that discontinuous control of P_{cuff} using a manometer is ineffective in patients intubated with PVC- or PU-cuffed tracheal tubes.

Reltionship between underinflation of tracheal cuff and VAP

Surprisingly, no experimental or clinical study has evaluated the impact of underinflation of tracheal cuff on microaspiration of oropharyngeal secretions or gastric content. To our knowledge, only one study has evaluated the relationship between underinflation of tracheal cuff and the occurrence of VAP [11]. Eighty-three patients were included in that prospective observational study aiming to determine risk factors for VAP in patients receiving mechanical ventilation through a tracheal tube allowing subglottic secretion drainage. Whereas incidence of VAP was significantly higher in patients with underinflation of tracheal cuff compared with those without underinflation of tracheal cuff (39% vs. 18%, $p = 0.03$), underinflation of tracheal cuff was not

independently associated with VAP. In addition, no significant difference was found in P_{cuff} between patients with VAP and those without VAP (23 ± 3.2 vs. 21.8 ± 3.1 cmH$_2$O). However, in the subgroup of patients who did not receive antibiotics, underinflation of tracheal cuff was independently associated with VAP occurrence (relative risk (95% confidence interval) 4.2 (1.12-15.9)). Limitations of that study included the use of clinical criteria to diagnose VAP, and the fact that only VAP episodes diagnosed during the first 8 days of mechanical ventilation were taken into account.

Devices for continuous control of cuff pressure

Currently available devices allowing continuous control of P_{cuff} could be classified into pneumatic and electronic. The pneumatic device was first validated by Duguet et al. [12] in a prospective randomized study performed in 9 patients. P_{cuff} was continuously recorded for 48 hours, including 24 h with routine control of P_{cuff} using a manometer, and 24 h of continuous control using the pneumatic device. The authors found the pneumatic device to be associated with a significantly reduced variation of P_{cuff}. These results were confirmed by another randomized controlled animal study including 12 piglets (six with routine control of P_{cuff}, and six with continuous control of P_{cuff}) [13]. Duration of time spent with overinflation or underinflation of P_{cuff} was significantly lower in animals which received continuous control of P_{cuff} compared with those which received routine care of P_{cuff}. In these studies, patients and animals were intubated with PVC-cuffed tracheal tubes. Our group conducted a randomized controlled study in 64 patients intubated and mechanically ventilated for >48 h in order to determine the efficiency of the pneumatic device in controlling P_{cuff} in patients intubated with PU-cuffed tracheal tubes. The pneumatic device was efficient in controlling P_{cuff}, since the percentage of patients with underinflation or overinflation of P_{cuff} and percentage of time spent with underinflation and overinflation of P_{cuff} was significantly reduced during the 24h period of continuous control of P_{cuff} compared with the 24 h of routine care of P_{cuff} [14].

Farré et al. [15] designed an electronic device using a simple aquarium pump. This device was evaluated in eight critically ill patients and was proven to be efficient in continuously controlling P_{cuff}. However, to our knowledge, this device is not commercially available. Several other electronic devices designed to continuously control cuff pressure are currently available in the market. However, few data is available in critically ill patients on the efficiency of these devices in the continuous control of P_{cuff}.

Weiss et al. [16] performed an *in vitro* study aiming to evaluate the efficiency of different electronic devices in continuously controlling P_{cuff}. Tracheal sealing was studied in four different high-volume low-pressure tracheal tubes, including three PVC-cuffed and one PU-cuffed. All experiments were repeated using two different sizes of tracheal tubes (5 and 8 mm). Two different electronic pressure controllers were compared with a conventional manometer. Experiments were performed at different P_{cuff} (10, 15, 20, and 25 cmH$_2$O) during intermittent positive pressure ventilation with peak inspiratory pressure at 20 and 25 cmH$_2$O. Air leakage was assessed spirometrically. Tracheal sealing obtained with the VBM device was similar to that obtained with the manometer. However, tracheal sealing was reduced with the Tracoe^{TM} device. The VBM device achieved better sealing than the manometer in two high-quality sealing tube cuffs. However, this device showed a similarly poor performance to the Tracoe^{TM} device in other small-sized (5 mm) tracheal tubes. The authors concluded that these electronic devices reduce the sealing characteristics of high-volume low-pressure tube cuffs by rapid correction of P_{cuff} increases.

A recent randomized cross-over study compared the efficiency of an electronic device to that of a pneumatic one in 10 critically ill patients. P_{cuff} was continuously recorded for 9 h (3 h with routine care of P_{cuff}, 3 hours with continuous control of P_{cuff} using an electronic device (Tracoe^{TM}), and 3 hours of continuous control of P_{cuff} using a pneumatic device). The authors found underinflation of P_{cuff} to be more frequent using the electronic device compared with the pneumatic device (8% vs. 0%, respectively), and attributed this result to the over compensation of any elevated P_{cuff} [17].

Could continuous control of cuff pressure reduce microaspiration and VAP incidence?

Only two randomized controlled single-center studies evaluated the impact of continuous control of P_{cuff} on microaspiration of gastric content or VAP incidence. Valencia et al. [18] performed the first study in 142 critically ill patients without pneumonia or aspiration at ICU admission. Patients received continuous control of P_{cuff} using an electronic artisanal device previously validated by the same authors (intervention group, n = 73) or routine care of P_{cuff} (control group, n = 69). Patient characteristics that might influence VAP occurrence were similar at ICU admission, at randomization, and during ICU stay. Whereas underinflation of tracheal cuff was significantly less frequently observed in intervention compared with control group (45.3% vs. 0.7%, p < 0.001), no significant difference was found in the incidence of microbiologically confirmed VAP between the two groups (15% in the two groups). Similarly, no significant difference was found in the incidence of suspected VAP (22% vs. 29%), distribution of early and late-onset VAP, causative microorganisms, and ICU (27% vs. 23%) or hospital (41% vs. 33%) mortality. Limitations of this study included the

single-center design, the absence of blinding, the absence of evaluation of microaspiration and colonization, and the exclusion of patients with suspected pneumonia at ICU admission.

The authors suggested that the negative result of their study might be explained by the fact that all patients were placed in semirecumbent position, arguing that the microaspiration of gastric contents is the primary route of entry for bacteria into the lower respiratory tract. Several studies performed during the early eighties using radioactive markers (^{99}Tc) outlined the importance of the gastropulmonary route in the pathogenesis of VAP [19–23]. However, other studies did not find the same results, and suggested that microaspiration of contaminated oropharyngeal secretions also played an important role in the entry of bacteria into the lower respiratory tract [24–26]. Garrouste-Orgeas et al. [26] evaluated the impact of oropharyngeal or gastric content colonization on the subsequent occurrence of VAP using genomic DNA analysis. The authors found that an identical strain was isolated from oropharyngeal (83%) or gastric content (22%) and bronchial samples in the majority of patients with VAP, suggesting that both oropharynx and stomach are important sources for bacteria infecting the lung. Although semirecumbent position is recommended in mechanically ventilated ICU patients, this recommendation is based on only one positive randomized controlled study [27]. In addition, another large randomized controlled multicenter study using continuous measurement of head-of-bed position demonstrated that semirecumbent position is very difficult to obtain in ICU patients, and failed to show any beneficial effect of this position on VAP incidence [28].

Our group performed a randomized controlled study to determine the impact of continuous control of P_{cuff} on microaspiration of gastric contents [29]. The impact of this intervention on tracheobronchial colonization, VAP incidence, and tracheal ischemic lesions were secondary objectives of that study. Patients requiring mechanical ventilation through a PVC-cuffed tracheal tube for > 48 h were eligible, and were randomly allocated to continuous control of P_{cuff} using a pneumatic device (intervention group, n = 61) or routine care of P_{cuff} (control group, n = 61). Target P_{cuff} was 25 cmH$_2$O in the two groups.

Pepsin was quantitatively measured in all tracheal aspirates during the 48 h following randomization. A patient was considered as having abundant microaspiration when >65% of tracheal aspirates were pepsin positive (>200 ng/mL). Quantitative tracheal aspirate was performed at intubation and thrice a week. Patients remained in a semirecumbent position in bed. No significant difference was found in patient characteristics between the two groups. The pneumatic device was efficient in controlling P_{cuff}, as demonstrated by the higher percentage of P_{cuff} measurement between 20 and 30 cmH$_2$O during the 48 h following randomization in the

intervention group compared with the control group (98 ± 13 vs. 74 ± 26, p < 0.001). Pepsin was measured in 1205 tracheal aspirates. Percentage of patients with abundant microaspiration (18% vs. 46%, p = 0.002, odds ratio [95% confidence interval] 0.25 0.11-0.59]), bacterial concentration in tracheal aspirates (mean ± SD, 1.6 ± 2.4 vs. 3.1 ± 3.7 log$_{10}$ cfu/ml, p = 0.014), and VAP rate (9.8% vs. 26.2%, p = 0.032, 0.30 [0.11-0.84]) were significantly lower in the intervention group compared with the control group. Further, percentage of days in the ICU with antimicrobials was significantly lower in the intervention group compared with the control group (median [IR] 83 [56, 100] vs. 100 [75, 100], p = 0.049). However, no significant difference was found in tracheal ischemia score (4.5 [1–6] vs. 4.5 [1-7], p = 0.9) between the two groups. Several limitations of this study should also be outlined, including the single-center design, the absence of blinding, the fact that pepsin was only measured during the 48 h following randomization, and the important proportion of study patients who had pneumonia at ICU admission.

Several differences between our study and that of Valencia et al. might explain the different results with regards to VAP prevention. Although VAP incidence was the primary outcome in Valencia's study, it was a secondary outcome in ours. Patient population was also different between the two studies, with more surgical patients (28% vs. 0%) and patients with respiratory disorders (38% vs. 27%) in Valencia's study than in ours. In addition, the rate of microbiologically confirmed VAP was lower in Valencia's study compared with ours (15% vs. 26%). However, the most important difference between these studies is probably the different device used to control P_{cuff}. Although Valencia et al. used an electronic device, we used a pneumatic device to continuously control P_{cuff}. As discussed previously, the pneumatic device is probably more efficient in controlling P_{cuff}. Further, the percentage of P_{cuff} determinations in the normal range (20–30 cmH$_2$O) was lower in Valencia's study compared with ours (79% vs. 98%).

Continuous control of P_{cuff} is not widely used in the ICU. Several factors might explain the limited use of these devices. First, only two randomized controlled single-center studies are available on the impact of continuous control of P_{cuff} on VAP. Second, the results of these studies are not concordant. Finally, the cost-effectiveness of using such devices was not evaluated.

Future studies

Further multicenter randomized large studies are needed to determine the impact of continuous control of P_{cuff} on VAP occurrence. In addition, other studies should also compare the efficiency of pneumatic and electronic devices in controlling P_{cuff}. The impact of continuous control of P_{cuff} on

microaspiration and VAP should be assessed in patients intubated with PU-cuffed tracheal tubes, and in those intubated with tracheal tubes allowing subglottic drainage.

Conclusion

Underinflation of tracheal cuff is common in intubated critically ill patients receiving periodic routine care with a manometer. Several devices aiming at controlling P_{cuff} are currently available. Two recent randomized controlled studies using different devices for P_{cuff} control found different results on the relationship between continuous control of P_{cuff} and VAP incidence.

Conflict of interest: Dr Saad Nseir is reader for Covidien.

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