Continuous control of tracheal cuff pressure for the prevention of ventilator-associated pneumonia in critically ill patients: where is the evidence?

Anahita Rouzé and Saad Nseir

Purpose of review
Ventilator-associated pneumonia (VAP) is a major cause of death, morbidity and costs in ICUs. Several evidence-based clinical interventions have been increasingly described for its prevention. However, continuous control of tracheal cuff pressure \( P_{\text{cuff}} \) is rarely mentioned in the latest clinical guidelines. This review focuses on the available data about the management of \( P_{\text{cuff}} \) in the ICU, including discontinuous and continuous control, and its impact on the prevention of VAP.

Recent findings
Current discontinuous monitoring and adjustment of \( P_{\text{cuff}} \), even well performed, is inaccurate in maintaining \( P_{\text{cuff}} \) in the target range. Underinflation \( (P_{\text{cuff}} < 20 \text{ cmH}_2\text{O}) \) of tracheal cuff is an independent risk factor for VAP through microaspiration of contaminated subglottic secretions into the lower respiratory tract. Two main types of devices, electronic and pneumatic, have been developed for the continuous control of \( P_{\text{cuff}} \). Both have shown effectiveness in maintaining \( P_{\text{cuff}} \) in recommended range in ICU patients, but only the pneumatic device has provided a reduction in microaspiration and VAP incidence.

Summary
Continuous controllers of \( P_{\text{cuff}} \) represent effective, easy to use and timesaving devices in today’s busy ICU environment. However, further studies are required to determine the impact of continuous control of \( P_{\text{cuff}} \) on VAP incidence, patient outcomes, antimicrobial consumption and to compare pneumatic and electronic devices, before generalizing their use in routine practice.

Keywords
mechanical ventilation, microaspiration, tracheal cuff pressure, tracheal tube, ventilator-associated pneumonia

INTRODUCTION
Ventilator-associated pneumonia (VAP) is the most common healthcare-associated infection in patients receiving mechanical ventilation in the ICU. Its current incidence ranges from 2 to 22 episodes per 1000 ventilator-days. The mean incidence rate of VAP is 2.8 in the United States [1], 14.5 in Europe [2] and 22 episodes per 1000 ventilator-days in developing countries [3], suggesting possible improvements in VAP prevention.

VAP is associated with increased morbidity, duration of mechanical ventilation, ICU and hospital length of stay, and costs. The mortality rate attributable to VAP reaches approximately 13%, with higher mortality rates in surgical patients and those with mid-range severity scores at admission [4*]. Therefore, clinical preventive strategies have been increasingly described and implemented in ‘care bundles’ [3*,5–7], with effective reduction in VAP rates. These strategies include reduction of bacterial colonization of subglottic secretions and tracheal tube biofilm formation, prevention of aspiration and reduction of the exposure to invasive mechanical ventilation [8*]. Several preventive interventions, such as routine oral care with an antiseptic solution, head of bed elevation, or subglottic suctioning, have been recommended in clinical practice guidelines [9–12]. In most of these recommendations, maintenance of a tracheal cuff pressure \( (P_{\text{cuff}}) \) of at least 20 cmH\(_2\)O, regardless of

*Intensive Care Department, R. Salengro Hospital, CHRU and "EA 2694, Université Nord de France, Lille, France
Correspondence to Saad Nseir, Reanimation Medicale, Hôpital R. Salengro, CHRU, Boulevard du Pr Leclercq, 59037 Lille, France. Tel: +33 320444084; fax: +33 320445094; e-mail: s-nseir@chru-lille.fr
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control method or its frequency, is reported with a moderate evidence level. Furthermore, recently published VAP care bundles, including a limited number of clinical interventions, do not consider the control of $P_{\text{cuff}}$ as a key component [6,7,11]. However, recent findings with regard to the continuous control of $P_{\text{cuff}}$ might suggest highlighting the role of $P_{\text{cuff}}$ management in the prevention of VAP.

**PATHOGENESIS OF VENTILATOR-ASSOCIATED PNEUMONIA**

In order to prevent VAP, the pathophysiology of this infection should be taken into account.

**Microaspiration as a major cause for ventilator-associated pneumonia**

Microaspiration of contaminated oropharyngeal secretions and gastric contents is the first step in the development of VAP. These contaminated subglottic secretions pool above the cuff of the tracheal tube and enter into the lower respiratory tract through leakage around the cuff. In addition, a bacterial biofilm formed on the surface of the tracheal tube serves as a reservoir for airway infection. This results in bacterial colonization of the tracheobronchial tree. The balance between local and general host pulmonary defenses, and quantity and virulence of infecting microorganisms then determines whether tracheobronchitis and pneumonia will develop (Fig. 1) [8*,13].

**Risk factors for microaspiration**

Risk factors for microaspiration are related to mechanical ventilation, nasogastric tube and enteral nutrition, and the patient (see list below). However, the tracheal tube plays a central role in the occurrence of microaspiration through impossible closure of vocal cords, longitudinal folds in high-volume low-pressure (HVLP) polyvinyl chloride (PVC) cuffs and underinflation of tracheal cuff [13]. In a prospective observational study, including 83 patients under mechanical ventilation, Rello *et al.* [14] identified $P_{\text{cuff}}$ below 20 cmH$_2$O as an independent risk factor for VAP [relative risk (RR) = 4.23, 95% confidence interval (CI) 1.12–15.92] in the subgroup of patients who did not receive antibiotics. Limitations of this 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. In addition, subglottic secretion drainage was used in all study patients, which might limit the generalization of the results to all ICU patients. Risk factors for microaspiration in intubated critically ill patients are as follows [13]:

1. tracheal tube:
   - (a) impossible closure of vocal cords;
   - (b) longitudinal folds in HVLP tracheal cuff;
   - (c) underinflation of tracheal cuff ($<20$ cmH$_2$O);
2. mechanical ventilation:
   - (a) zero positive end expiratory pressure;
   - (b) low peak inspiratory pressure;
   - (c) tracheal suctioning;
3. nasogastric tube and enteral nutrition:
   - (a) gastroesophageal reflux;
   - (b) loss of anatomical integrity of lower esophageal sphincter;
   - (c) gastric distension;
4. patient-related factors:
   - (a) supine position;
   - (b) viscosity of secretions above the cuff;
   - (c) pressure above the cuff;
   - (d) tracheal diameter;
   - (e) coma, sedation;
   - (f) hyperglycemia.

**EFFICIENCY OF CURRENT DISCONTINUOUS REGULATION OF $P_{\text{cuff}}$**

Intermittent $P_{\text{cuff}}$ control using a manometer is widely used in ICUs to prevent complications related to underinflation or overinflation of the tracheal cuff. Although this method might allow reducing these complications, its accuracy in maintaining $P_{\text{cuff}}$ in normal range is not optimal.

**Current recommendations**

The main function of the tracheal tube cuff is to seal the extraluminal airway against air and fluid leakage, both to allow effective positive pressure...
mechanical ventilation and to avoid microaspiration of contaminated subglottic secretions. $P_{cuff}$ should be kept around 25 cmH$_2$O, as microaspiration occurs below 20 cmH$_2$O [14] and risk of tracheal ischemic lesions, because of impairment of tracheal mucosal blood flow, is more important above 30 cmH$_2$O [15,16]. However, no clear recommendation exists for the frequency and method of $P_{cuff}$ measurement and adjustment. Currently, intermittent monitoring of $P_{cuff}$ is routinely performed in the ICU using a manual portable manometer (Fig. 2a), allowing cuff underinflation ($P_{cuff}$ < 20 cmH$_2$O) or overinflation ($P_{cuff}$ > 30 cmH$_2$O) corrections. The 1998 French consensus conference on airway management recommends $P_{cuff}$ checking at least once a day and whenever the tracheal tube position has been modified [17]. However, surveys of airway management practices indicate that $P_{cuff}$ is usually checked every 8–12 h [18]. More frequent measurements of $P_{cuff}$ represent a workload for nurses and may result in aspiration of contaminated secretions pooled above the cuff, as each connection of the manometer to the pilot balloon is associated with transient decrease of $P_{cuff}$.

**Compliance with the current recommendations**

A telephone survey of 24 ICUs conducted in 2002 in the United Kingdom showed that $P_{cuff}$ was never checked in 75% of ICUs [19]. More recently, two European web-based surveys of VAP prevention practices in the ICU, conducted in 2008 [20] and 2012 [21], reported a compliance rate in controlling $P_{cuff}$ at least once a day, of 81 and 83%, respectively. In spite of the increasing compliance, these results highlight the important potential for improvement, especially regarding disparities among different countries [18–21].

**Accuracy of discontinuous control of $P_{cuff}$**

Recently, several studies showed that intermittent measurement and adjustment of $P_{cuff}$ was not accurate. Indeed, $P_{cuff}$ decreased over time in mechanically ventilated patients [22] and is also influenced by patient body and head position changes, body temperature, use of sedatives and neuromuscular blockers, airway pressure, tracheal suctioning and cough (Fig. 3a) [13,23,24]. These
permanent variations of $P_{\text{cuff}}$ may result in potentially harmful conditions out of the target range of 20–30 cmH$_2$O. In a pilot study assessing the feasibility of continuous measurement of $P_{\text{cuff}}$ in 10 mechanically ventilated patients, $P_{\text{cuff}}$ was recorded for a mean of 9.3 h after the initial adjustment. Only 54% of $P_{\text{cuff}}$ values were within the 20–30 cmH$_2$O range. $P_{\text{cuff}}$ was higher in 16% of measurements and lower in 30% [23]. In a prospective observational study on 101 consecutive patients requiring mechanical ventilation through a HVLP PVC-cuffed tracheal tube, $P_{\text{cuff}}$ was continuously recorded for 8 h, just after manual adjustment [24]. The analysis of 808 h of continuous recording showed that only 18% of patients did not develop cuff underinflation or overinflation. Study patients spent 75% of the recording time within the 20–30 cmH$_2$O range, 13% with cuff underinflation and 11% with cuff overinflation. In addition, no modifiable risk factor could be identified. In another prospective observational study, $P_{\text{cuff}}$ was continuously recorded for 24 h in 76 patients [26 with standard PVC, 22 with cylindrical polyurethane (CPU) and 28 with tapered polyurethane (TPU)-cuffed tracheal tubes] receiving intermittent manual control of $P_{\text{cuff}}$ every 8 h. Study patients spent a large amount of recording period with cuff underinflation or overinflation [25]. Additionally, polyurethane and cuff shape (standard, cylindrical or tapered) did not significantly influence the percentage of time spent with cuff underinflation or overinflation. However, coefficient of variation of $P_{\text{cuff}}$ was significantly higher in patients intubated with a TPU-shaped tracheal tube compared with the two other groups.

‘$P_{\text{cuff}}$ alarm’ in the ICU as a possible solution?

Sole et al. [22] performed a randomized controlled crossover study to evaluate the effect of continuous monitoring of $P_{\text{cuff}}$, combined with an alarm, in maintaining $P_{\text{cuff}}$ in the target range. Patients ($n=32$) received two 12-h periods of routine care and continuous monitoring of $P_{\text{cuff}}$. During the intervention period, when pressure fell out of the target range of 20–30 cmH$_2$O, an alarm warned...
the nurse, who adjusted $P_{\text{cuff}}$ at 22 cmH$_2$O by removing or adding air. This intervention allowed reducing the percentage of $P_{\text{cuff}}$ values out of range (11.1 versus 51.7%, $P < 0.001$) and of cuff underinflation (1.2 versus 44.3%). However, the effect of this intervention on VAP prevention is unknown. Moreover, this procedure, adding extra work for nurses and extra alarms in today’s already noisy and stressful ICU environment for patients and healthcare workers, could hardly be an effective solution for the maintenance of $P_{\text{cuff}}$ in the therapeutic range.

**NEW AVAILABLE DEVICES FOR CONTINUOUS CONTROL OF $P_{\text{cuff}}$**

In recent years, two main types of devices for continuous control of $P_{\text{cuff}}$ have been developed and evaluated based on two different regulation systems, electronic or pneumatic. As a result, several devices have been marketed for this purpose (Fig. 2), although not all have been clinically validated.

**Electronic devices**

Electronic $P_{\text{cuff}}$ controllers (e.g., Tracoe Pressure Controller, TRACOE medical GmbH, Frankfurt, Germany; Mallinckrodt electronic cuff pressure controller, VBM Medizintechnik GmbH, Sulz a.N., Germany; Fig. 2c and d) maintain a continuous $P_{\text{cuff}}$ using an automated air pump directly connected to the pilot balloon of the tracheal tube with flexible plastic tubing. A pressure sensor, requiring power supply, regulates the air pump. The use of these electronic devices simply requires to connect the pilot balloon to the device, $P_{\text{cuff}}$ is then automatically inflated to 25 cmH$_2$O, unless a different $P_{\text{cuff}}$ target is set on the device housing.

In a prospective randomized controlled trial including 80 patients, requiring 2–3 h of intubation and mechanical ventilation for surgery, effectiveness of the Tracoe pressure controller was compared with conventional manual manometer [26]. The device reliably maintained $P_{\text{cuff}}$ at the target level of 25 cmH$_2$O $\pm$ 2 cmH$_2$O, whereas increased $P_{\text{cuff}}$ up to 40 cmH$_2$O was common in the control group, because of nitrous oxide diffusion through the cuff membrane.

Another automatic $P_{\text{cuff}}$ controller, not certified or marketed, created from an aquarium air pump, was tested at the bench and in clinical practice [27]. In this pilot study performed in eight ICU patients, the device was effective in maintaining the $P_{\text{cuff}}$ target of 25 cmH$_2$O $\pm$ 2 cmH$_2$O *in vitro* and during a 24-h period of continuous recording in study patients.

**Pneumatic device**

Nosten (Leved, St-Maur, France) is an aluminum-made mechanical device, which allows continuous control of $P_{\text{cuff}}$ based on pressure equalization between two different sized cuffs (Fig. 2b). It does not require power supply. A single-use 300-ml cylindrical cuff encased in a rigid compartment is connected to the pilot balloon of the tracheal tube with plastic tubing. A weight mounted on an articulated arm constantly exerts pressure on this cuff. This pressure can be adjusted by moving another weight along the arm to modulate the corresponding force, allowing the user to obtain the desired cuff pressure.

Any variation in $P_{\text{cuff}}$ is immediately cancelled out by the disproportion between the volumes of the two cuffs, as shown in Fig. 3c during a coughing event.

Several experimental and clinical studies have demonstrated the pneumatic device’s effectiveness in deleting cuff underinflations or overinflations. In an animal study conducted in 12 piglets mechanically ventilated for 48 h, the pneumatic device provided effective continuous control of $P_{\text{cuff}}$ compared with intermittent control of $P_{\text{cuff}}$ using a manometer [28]. Percentage of time spent with underinflation or overinflation of $P_{\text{cuff}}$ was significantly lower in the intervention compared with the control group.

Duguet et al. [29] conducted a prospective randomized crossover pilot study to determine the effectiveness of the pneumatic device in ICU patients. They compared two periods of 24 h in nine mechanically ventilated patients, one with the pneumatic device and the other with routine care. Percentage of time spent with $P_{\text{cuff}}$ between 15 and 30 cm H$_2$O was significantly higher during intervention compared with the control period (96 versus 56%, $P < 0.01$). In addition, percentage of time spent with $P_{\text{cuff}}$ less than 15 cm H$_2$O was significantly lower during intervention compared with the control period (4.7 versus 15%, $P < 0.05$).

**IMPACT OF CONTINUOUS CONTROL OF $P_{\text{cuff}}$ ON VENTILATOR-ASSOCIATED PNEUMONIA INCIDENCE**

Although available devices have demonstrated their effectiveness in maintaining a constant $P_{\text{cuff}}$ in ICU patients, only a clinical benefit in reducing the incidence of VAP or tracheal ischemic lesions should result in recommending their use in routine practice. Only two prospective randomized controlled trials have studied, one for an electronic device [30] and the other for a pneumatic device [31**], the effect of continuous control of $P_{\text{cuff}}$ on incidence of VAP.
Impact of electronic device on ventilator-associated pneumonia incidence

In a prospective randomized controlled study including 142 patients without pneumonia or aspiration at ICU admission, Valencia et al. [30] assessed the effect of an electronic device for the continuous control of $P_{cuff}$ previously validated by the same authors [27], on prevention of VAP. In the control group, routine care of $P_{cuff}$ was performed using a manual manometer to check and adjust $P_{cuff}$ three times a day. Despite less frequent cuff underinflation observed in the intervention compared with the control group (0.7% of all $P_{cuff}$ determinations versus 45.3%, $P < 0.001$), no significant difference was found in the VAP rates between the two groups (15 versus 15%, $P = 0.89$). The automatic device showed no benefit as well on duration of mechanical ventilation, ICU length of stay, or ICU mortality. In this study, however, microaspiration, tracheobronchial colonization, and tracheal ischemia were not examined. Other limitations of this study included single-center design, absence of blinding and the exclusion of patients with suspected pneumonia at ICU admission.

Impact of pneumatic device on ventilator-associated pneumonia incidence

Our group performed a prospective randomized controlled trial, including 122 patients intubated with PVC-cuffed tracheal tubes, in order to determine the impact of continuous control of $P_{cuff}$ using a pneumatic device on microaspiration of gastric contents [31**]. Routine care of $P_{cuff}$ in the control group was similar to that in the study of Valencia and colleagues. As expected, the percentage of cuff underinflation determinations was significantly lower in the intervention compared with the control group (0.1 versus 19%, $P = 0.001$). The percentage of patients with abundant microaspiration (as defined by the presence of pepsin at a significant level [32] in more than 65% of tracheal aspirates) was lower in the intervention group compared with the control group (18 versus 45%, $P = 0.002$, odds ratio (OR) [95% CI] 0.25 [0.11–0.59]). With regard to secondary outcomes, mean bacterial concentration in tracheal aspirates (1.6 versus 3.1 log$_{10}$ cfu/ml, $P = 0.014$) and VAP rate (9.8 versus 26%, $P = 0.032$, OR [95% CI] 0.30 [0.11–0.84]) were significantly lower in the intervention group compared with the control group, respectively. Moreover, percentage of days in the ICU with antibiotic treatment was significantly lower in the intervention group compared with the control group (83 versus 100%, $P = 0.049$). However, the pneumatic device had no impact on the duration of mechanical ventilation, ICU length of stay and ICU mortality. In addition, no significant difference was found in tracheal ischemia score between the two groups. Several limitations of this study should also be outlined, including single-center design, absence of blinding, measurement of pepsin only during the 48 h following randomization, and the fact that VAP was not the primary outcome.

Explanations for different results on impact of continuous control of $P_{cuff}$ on ventilator-associated pneumonia prevention

Conflicting results between these two studies need further analysis (Table 1). Prima facie, other VAP preventive measures such as routine oral care with chlorhexidine or semirecumbent position were similar in the two trials. Nonetheless, differences between patient population, VAP rates in the control group and the devices used can be discussed. Actually, the percentage of surgical patients and patients suffering from chronic respiratory disorders were higher in Valencia’s study than in ours. In addition, VAP rates in the control group were lower in Valencia’s study than in ours. Finally, the device used to control $P_{cuff}$ was different in the two trials, which may suggest that the electronic device may be less efficient than the pneumatic one. $P_{cuff}$ was maintained in the target range in 98% of all determinations with the pneumatic device, compared to 79.3% with the automatic device. Further, in an in-vitro study, Weiss et al. [33] showed that electronic devices with rapid pressure correction interfere with the self-sealing mechanisms of HVLP PVC-cuffed tracheal tubes and reduce their improved sealing characteristics. These findings are corroborated by a recent prospective crossover study comparing electronic and pneumatic $P_{cuff}$ regulators in 10 mechanically ventilated patients [34], which showed that underinflation events were more common using the electronic device than the pneumatic one (in eight patients versus zero patients). This may be explained by overcompensation of any elevated $P_{cuff}$ (Fig. 3b).

Additional clinical benefits of continuous control of $P_{cuff}$

In addition to the potential benefits on preventing VAP or tracheal ischemia, continuous control of $P_{cuff}$ might result in the improvement in the well being of ICU patients. Several studies in patients requiring anesthesia for a planned surgical intervention showed a correlation between high $P_{cuff}$ and postoperative laryngotraceal complications, such as sore throat, hoarseness or blood-streaked
expectorant [35,36]. In a prospective randomized controlled trial, conducted in 90 patients undergoing thyroidectomy under general anesthesia, monitoring and adjustment of P\textsubscript{cuff} throughout the surgery significantly reduced postoperative sore throat, in comparison with the group without adjustment of P\textsubscript{cuff} [37]. This purely symptomatic effect may seem trivial in intensive care practice, but at a time when improving patient’s comfort and quality of life in ICU is a main objective in all medical teams [38], this point needs to be assessed in the future studies on continuous control of P\textsubscript{cuff}, as all devices have been shown to be effective in avoiding cuff overinflations.

### CONCLUSION

In current ICU practice, with increased workload and severity of illness, perfect management of P\textsubscript{cuff} using intermittent adjustments seems unrealistic. In addition, even well performed, discontinuous control of P\textsubscript{cuff} is inaccurate in continuously maintaining P\textsubscript{cuff} in the target range. Thus, continuous P\textsubscript{cuff} controllers could represent a suitable, easy and timesaving solution. However, cost-effectiveness of using such devices has not been evaluated yet. Furthermore, only one single-center study has shown a positive effect of the use of pneumatic device in reducing microaspiration and VAP rates. Continuous control of P\textsubscript{cuff} with a pneumatic device, obviously combined with other evidence-based preventive interventions, might therefore be beneficial in preventing VAP in ICU patients. Further studies are required to determine the impact of continuous control of P\textsubscript{cuff} on VAP incidence, ICU outcomes, antibiotic use and to compare pneumatic and electronic devices, before generalizing their use in routine practice.

### Acknowledgements

None.

### Conflicts of interest


### REFERENCES AND RECOMMENDED READING

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 000–000).

Infectious diseases


5. An interesting meta-analysis of individual patient data from randomised studies showing an attributable mortality related to VAP of 15%.


18. A recent cohort study on the incidence, risk factors and outcome of tracheal ischemic lesions in intubated critically ill patients.
