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TECHNICAL NOTE

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Control of tracheal cuff pressure: a pilot study using a pneumatic device

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Abstract *Objective:* To evaluate the efficacy of a simple mechanical device to maintain constant endotracheal cuff pressure (Pcuff) during mechanical ventilation (large encased inflatable cuff connected to the endotracheal cuff and receiving constant pressure from a heavy mass attached to an articulated arm). *Design and setting:* Single-center, prospective, randomized, crossover, pilot study in a medical intensive care unit. *Patients and participants:* Nine consecutive mechanically ventilated patients (age 62 ± 20 years, SAPS II score 39 ± 15). *Interventions:* Control day: Pcuff monitored and adjusted with a manometer (Hi-Lo™, Tyco Healthcare) according to current recommendations (twice a day and after each intervention on the tracheal tube); initial target Pcuff 22–28 cmH_20. Prototype day: test device connected to the endotracheal cuff; same initial target. Continuous Pcuff recording during both days. Control and prototype days in random order. *Results:* Pcuff values over 50 cmH_20 were recorded in six patients during the control day (178 ± 159 min), never during the prototype day. During the control day, Pcuff was between 30 and 50 cmH_20 for $29 \pm 25\%$ of the time, vs $0.3 \pm 0.3\%$ during the prototype day ($p < 0.01$). Pcuff was between 15 and 30 cmH_20 for $56 \pm 36\%$ of the time during the control day, vs $95 \pm 14\%$ during the prototype day ($p < 0.01$). During the control day, Pcuff was below 15 cmH_20 for $15 \pm 17\%$ of the time, vs $4.7 \pm 15\%$ during the prototype day ($p < 0.05$). *Conclusions:* The tested device successfully controlled Pcuff with minimal human resource consumption. Prospective studies are required to assess its clinical impact.

Keywords Mechanical ventilation · Tracheal intubation · Cuff pressure · Tracheal stenosis · Monitoring

Introduction

The endotracheal cuff of a tracheal tube has two main functions: (1) it ensures airtightness and therefore the efficiency of ventilatory support; (2) it protects the lower airway from the aspiration of infected oropharyngeal secretions. Insufficient cuff pressure (Pcuff) can compromise these functions, but excessive Pcuff can induce tracheal lesions [1]. Remaining between these extremes requires verification of cuff pressure several times a day. This is difficult to comply with, as illustrated by Vyas et al. [2], who showed that Pcuff was never checked in 75% of 24 intensive care units subjected to a telephone survey and that, when checked, Pcuff was above the upper limit of recommended values in two thirds of cases. Of note, French recommendations in force state that cuff pressure "should not exceed 25 to 30 cmH_20" [3], but do not mention a value below which the pressure should not sink. The present study tests the ef-

ficacy of a simple mechanical device to continuously maintain cuff pressure during mechanical ventilation with minimal human intervention.

Material and methods

Setting and inclusion criteria

The study was conducted in a 10-bed intensive care unit within the respiratory medicine department of a 2000-bed university hospital. Inclusion criteria were (1) mechanical ventilation through an endotracheal tube; (2) a reasonable likelihood of at least 48 h on mechanical ventilation; (3) age 18 years or over. The study received ethical and legal clearance from the appropriate authority (Comité Consultatif pour la Protection des Personnes se prêtant à des Recherches Biomédicales Pitié-Salpêtrière). Informed consent was obtained from the patients or their family.

Device

The Nosten® device (Leved, St-Maur, France) is a mechanical appliance that does not require power supply (Fig. 1). A sterile single-use 200-ml cylindrical cuff encased in a rigid compartment is connected to the endotracheal cuff with a plastic tubing (internal diameter 3 mm, length 2 m). 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 Pcuff. Any variation is immediately cancelled out by the disproportion between the volumes of the two cuffs.

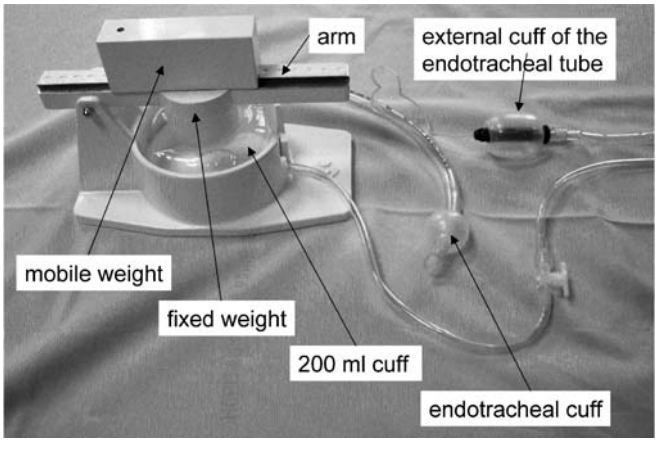

Fig. 1 Photograph of the pneumatic device, connected to the external control cuff of the endotracheal tube to ensure constant pressure within the endotracheal cuff. Moving the mobile weight along the arm modifies the pressure exerted by the fixed weight on the 200-ml external cuff

Protocol

During the control day, Pcuff was managed according to an internal procedure adapted from the French recommendations in force [3], namely a target Pcuff between 22 and 28 cmH_20 with Pcuff checks twice a day at fixed intervals and after each intervention on the endotracheal tube (manual portable manometer, Hi-Lo™, Tyco Healthcare). During the prototype day, the endotracheal cuff was connected to the continuous cuff pressure control device, the mobile weight of which was moved along the articulated arm to obtain a Pcuff between 22 and 28 cmH_20. There were no further interventions. During both days, visual inspection of the external cuff for signs of obvious deflation was part of every routine care intervention. Pcuff and airway pressure (Paw) were recorded continuously at a digitizing frequency of 100 Hz for 2 days [Validyne MP 45 linear pressure transducers (Northridge, CA, USA); 100 Hz analog-to-digital conversion (Powerlab, AD Instrument, Castle Hill, Australia); offline analysis (Chart 5®, AD Instrument, Castle Hill, Australia)]. The connection between the pressure transducer and the endotracheal cuff was identical during both days, with a three-way stopcock of which the third port was either closed or connected to the prototype.

In each patient, the control–prototype sequence was randomized. The ventilatory mode was identical during the two study days, but sedation could vary. The physicians in charge of the patients were blinded to Pcuff values.

Data management and statistical analysis

On each study day we measured the time spent with Pcuff over 50 cmH_2O, between 30 and 50 cmH_2O, between 15 and 30 cmH_2O, and below 15 cmH_2O. The data were checked for normality (Shapiro–Wilk test) and then compared using an analysis of variance followed by Fisher's post-hoc test. Differences were considered significant when the probability p of a type I error was below 0.05. Data are described as means ± standard deviations.

Results

Patients

Nine patients (five men; age 62 ± 20 years, SAPS II score 39 ± 15) were studied. The indication for ventilatory support was neurological in three cases, respiratory in five, and septic shock in one. Mechanical ventilation (assist-control in eight cases, inspiratory pressure support in one) was administered through orotracheal intubation in six cases, nasotracheal intubation in one (Hi-Contour

Table 1 Individual pressure recording data with the standard procedure (control day), and with the regulatory device (prototype day)

Patient	Control day Mean ± SD (cmH_2O)	Coefficient of variation (%)	Prototype day Mean ± SD (cmH_2O)	Coefficient of variation (%)
1	33.86 ± 10.51	31.04	19.01 ± 1.87	9.84
2	25.66 ± 11.44	44.58	21.5 ± 4.22	19.63
3[a]	21.31 ± 1.87	8.78	21.1 ± 1.10	5.21
4	20.31 ± 3.19	15.71	20.2 ± 2.12	10.50
5[a]	18.96 ± 9.82	51.79	17.9 ± 3.38	18.88
6[a]	21 ± 5.61	26.71	21.34 ± 1.08	5.06
7	12.42 ± 7.05	56.76	22.08 ± 2.72	12.32
8	26.63 ± 10.15	38.11	23.11 ± 2.65	11.47
9[a]	35.91 ± 19.88	55.36	21.4 ± 3.35	15.65
Mean ± SD		36.54 ± 17.29		12.06 ± 5.24*

* $p < 10^{-4}$
[a] Prototype during the first day and control during the second

Brandt™, Mallinckrodt, St Louis, MO, USA; internal diameter 7.5 or 8 mm), and a tracheostomy in two (Shiley, Tyco Healthcare, Pleasanton, CA, USA; internal diameter 7.5 or 8 mm). Both cuffs are high volume–low pressure, the Mallinckrodt one is balloon shaped and the Shiley one is cylindrical.

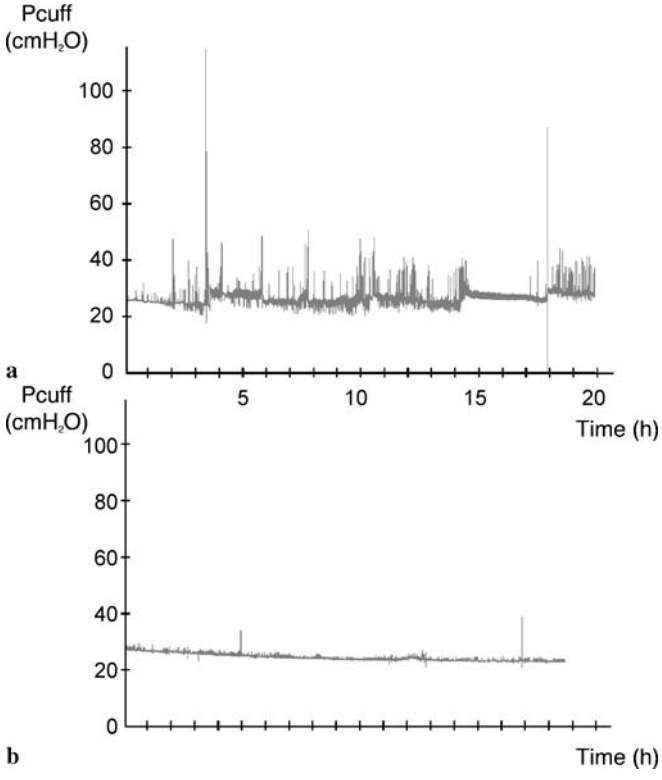

Fig. 2 Continuous recording of endotracheal cuff pressure (*Pcuff*) during volume control mechanical ventilation with intermittent manometer control (**a**, control day) and using the pneumatic device (**b**, prototype day). There was no intervention of any sort during the prototype day

Pressure measurements

No case of obvious deflation occurred during either day in any patient. Paw and Pcuff were recorded for 1333 ± 369 min during the control day and 1381 ± 207 min during the prototype day. The coefficient of variation of Pcuff was considerably lower during the prototype day than during the control day (Table 1). Pcuff values over 50 cmH_2O were recorded in six patients during the control day (178 ± 159 min), but never during the prototype day. The percentage of time with a pressure between 30 and 50 cmH_2O was 29 ± 25% during the control day and 0.3 ± 0.3% during the prototype day ($p < 0.01$). The percentage of time with a pressure between 15 and 30 cmH_2O was 56 ± 36% during the control day and 95 ± 14% during the prototype day ($p < 0.001$). The percentage of time with a pressure below 15 cmH_2O was 15 ± 17% during the control day and 4.7 ± 15% during the prototype day ($p < 0.05$). Figure 2 shows an example of the recordings during both days.

Discussion

The device tested appears to be very efficient for Pcuff regulation, with minimal human resource cost.

High pressures

A Pcuff above 30 cmH_2O reduces mucosal blood flow in the tracheal area in contact with the cuff. This contributes to long-term adverse effects [1, 4, 5]. High-volume cuffs designed to minimize pressure [6] reduce tracheal damage. However, they tend to lose their highly compliant behavior when confined within the trachea [7], and tracheal lesions persist [1, 5]. Such high-volume cuffs were used in our patients but could not prevent the occurrence of high Pcuff during the control day. The tested pneumatic control

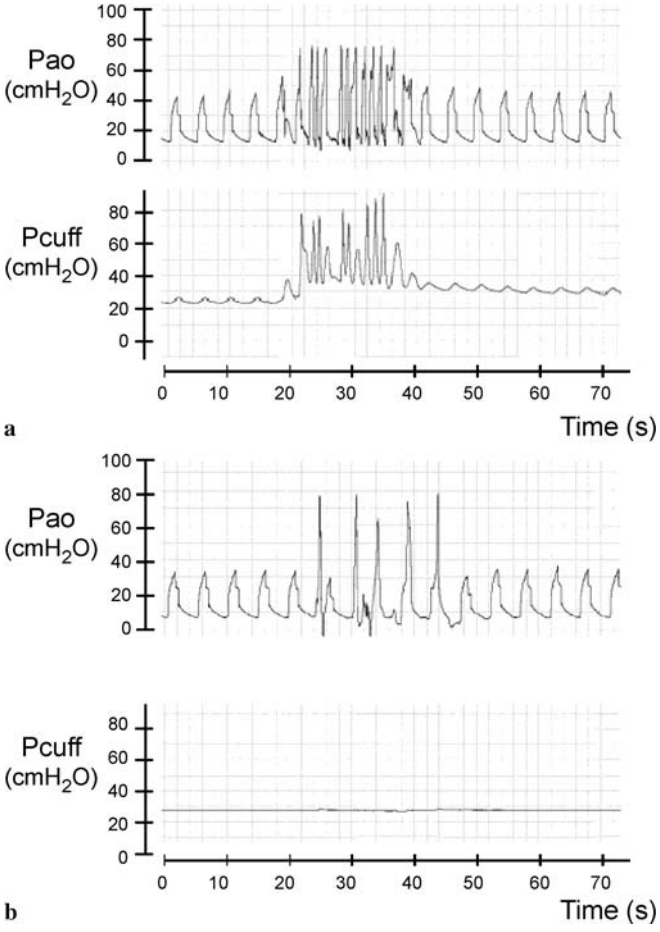

Fig. 3 Cuff pressure during coughing. **a** measurements of airway pressure (*Pao*) and pressure recorded in the endotracheal cuff (*Pcuff*) in a ventilated patient without the pneumatic device. Pcuff follows Pao during the coughing episode. **b** Same patient with the pneumatic cuff pressure control device connected to the external cuff of the endotracheal tube. Pcuff does not vary during the coughing episode despite large variations in the surrounding pressure

device appears particularly suitable for avoiding both pressure peaks and maintained high pressures. Indeed, the time spent with Pcuff > 30 cmH_2O was negligible with the device on, and cough-induced Pcuff peaks were fully dampened (Fig. 3).

Low pressures

Bronchial aspiration may occur with low Pcuff, particularly during inspiratory efforts [8]. Our results suggest that the pneumatic device is better than manual control in avoiding low Pcuff values, but the difference is less marked than it is for high Pcuff. In some cases, low average Pcuff values were recorded during the prototype day, which could be a cause of concern. The device being so efficient at controlling high pressures, this suggests that an initial target pressure close to the upper acceptable limit should perhaps be used (of note on this point, with the pressure transducer we used, minimal internal leaks are possible; this could explain the slow pressure decay visible on Fig. 2). It is difficult to determine from the literature what a safe lower limit would be for Pcuff in clinical conditions. In fact, cuff volume seems to matter more than Pcuff. Depending on the respective shapes of the trachea and of the cuff, creases and folds may form that will promote leaks independently of cuff pressure.

Comparison with available data

To control Pcuff, finger estimation, widely used in practice, is notoriously insufficient [7]. The intermittent use of a manometer seems preferable, but is seldom performed and not fully efficient [2]. In our study during the control day, very high Pcuff values were recorded, showing that measuring Pcuff is not intrinsically sufficient to achieve its control. This requires considerable educational efforts and adequate personnel availability, constraints that could theoretically be alleviated by the use of self-regulating devices. Several such devices do exist [9–12] (e.g. the Lanz® system by Mallinckrodt®, also relying on the higher cuff-system volume principle). Simple pressure controllers (e.g. Pressure-Easy™ from Respironics™) allow cuff pressure monitoring at lesser time expense. The device tested here has the advantage of being extremely simple to use. It contains no electronics and does not depend on any sort of power supply. Its ability to control rapid variations in pressure is remarkable (Fig. 3). However, this device does not provide caregivers with any means to measure Pcuff after the initial value has been set. Adding a simple pressure indicator would enhance its usefulness.

In conclusion, this small study is not sufficient to recommend widespread use of the device. However, the straightforward nature of the results seems sufficient to draw attention to this system. Further studies designed to evaluate clinical benefits should be devised.

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