Automatic regulation of the endotracheal tube cuff pressure with a portable elastomeric device. A randomized controlled study

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Research

Keywords: Cuff pressure, Underinflation, Intubation, Intratracheal [MeSH] Manometer, Pneumonia, Aspiration [MeSH], Smart Cuffmanager

Posted Date: January 21st, 2020

DOI: <https://doi.org/10.21203/rs.2.20957/v1>

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Abstract

Background

Endotracheal tube cuff underinflation contributes to microaspiration of contaminated oropharyngeal content, source of pneumonia. Overinflation exposes to airway damage. Intermittent manual adjustment of the cuff pressure (P_{cuff}) may delay the detection of under- or overinflation. Devices for automated continuous adjustment of P_{cuff} are promising but some are inconvenient, expensive or even harmful. This prospective randomized controlled study tested whether the Tracoe Smart Cuff Manager TM reduced the rate of patients undergoing ≥ 1 episode of underinflation ($P_{\text{cuff}} < 20 \text{ cmH}_2\text{O}$), as compared with routine manual P_{cuff} adjustment. Secondary endpoints included comparisons of the rate of patients with ≥ 1 overinflation episode ($P_{\text{cuff}} > 30 \text{ cmH}_2\text{O}$), of the incidence of under- and overinflation episodes and of their magnitude. Methods Patients likely to receive invasive mechanical ventilation for > 48 hours because of acute brain injury were randomly allocated to receive, during 48 hours, automated P_{cuff} adjustment (combined with manual adjustment) or manual adjustment alone. In each group, P_{cuff} was measured with a dedicated manual manometer, at least every 8 hours.

Results

Sixty patients were analyzed (28 patients with automated and 32 with manual P_{cuff} adjustment) for 506 measurements of P_{cuff} (237 and 269, respectively). As compared with manual adjustment, automated adjustment of P_{cuff} was associated with 1) a lower rate of patients with ≥ 1 episode of underinflation (63% and 18%, respectively, $p < 0.001$), 2) a lower incidence of underinflation episodes (15% vs. 2%; $p < 0.001$), 3) a lower rate of manual adjustments (77% vs. 56%; $p < 0.001$) and 4) manual adjustments of lower magnitude (5.9 ± 4.5 vs. $3.6 \pm 4.7 \text{ cmH}_2\text{O}$; $p < 0.001$). For overinflation, there was no significant between-groups differences ($p > 0.99$).

Conclusions

The adjunction of a continuous P_{cuff} control with the Tracoe Smart Cuff Manager TM to routine manual intermittent adjustment reduced both the incidence of P_{cuff} underinflation episodes and their magnitude without provoking overinflation.

Background

Keeping the endotracheal tube cuff pressure (P_{cuff}) between 20 and 30 $\text{cm H}_2\text{O}$ [1] is part of nurse routine care of critically ill patients requiring mechanical ventilation [2, 3]. On the one hand, cuff underinflation exposes to the microaspiration of contaminated oropharyngeal content, an important contributor to ventilator-associated pneumonia [2]. On the other hand, cuff overinflation promotes airway (mucosa or cartilage) damage [4]. However, routine intermittent P_{cuff} monitoring and adjustment via a manual manometer may not avoid underinflation or overinflation episodes between measurements. Hence, less than one fifth of patients have a correct P_{cuff} during the 8 hours between two manual adjustments [5].

Besides cuff leakage, changes in the airway tone or in patient's position can alter P_{cuff} between intermittent adjustments [6]. Episodes of under- or overinflation are therefore often overlooked or detected [5]

To achieve a correct P_{cuff} over 24 hours a day, devices for continuous monitoring of P_{cuff} have been developed and marketed. Encouraging findings were reported with these devices (blurry, provide a result) [7]. Yet, the amount of data is still too limited to recommend their use [7]. Moreover, these devices are bulky, inconvenient, expensive, and/or need electrical power supply. In addition, some devices may be ineffective and even potentially harmful since not only do they fail in preventing tracheal cuff underinflation as well as they provoke overinflation [8]. For all these reasons, the use of automated P_{cuff} regulation is still not widespread [9]. A simple elastomeric device, already on the market, may overcome these issues: the Tracoe Smart Cuff Manager™ (Tracoe medical GmbH, Nieder-Olm, Germany). Whether it is effective in keeping P_{cuff} within the correct range is unknown since no published study assessed this device.

The primary objective of this prospective randomized controlled study was to evaluate whether the adjunction, to routine care, of automatic adjustment of P_{cuff} with the Tracoe Smart Cuff Manager™ reduced the rate of patients undergoing at least one episode of tracheal cuff underinflation ($P_{\text{cuff}} < 20 \text{ cm H}_2\text{O}$), as compared with intermittent manual P_{cuff} adjustments. As secondary endpoints, we compared, between the two strategies, the rate of patients with ≥ 1 overinflation episode ($P_{\text{cuff}} > 30 \text{ cm H}_2\text{O}$), the incidence of under- and overinflation episodes and their magnitude. The incidence of early respiratory infections, ventilator free days, ICU length of stay and mortality was also examined.

Methods

Patients

This prospective randomized controlled study was performed in two ICUs of Nantes University Hospital (16 and 20 beds). Adult patients admitted to the ICU with acute brain injury were included within the first 48 hours of their ICU stay if they were likely to require mechanical ventilation for at least 48 additional hours through orotracheal tube with a low pressure-high volume cuff.

Patients were not included or were excluded if they had a nasotracheal tube or tracheostomy, if there was a change in the upper airway management within the 48 hours following the inclusion (extubation, change in the tracheal tube or tracheostomy). Pregnancy and safeguarding regimen were also non-inclusion criteria.

Patients were randomly assigned to receive either solely intermittent manual P_{cuff} adjustments or their combination with Tracoe Smart Cuff Manager™-driven automated adjustments (a group subsequently referred to as automated P_{cuff} adjustment). Randomization was performed using a 1:1 computer-generated random assignment list.

P_{cuff} monitoring and adjustment

In both groups, intermittent P_{cuff} measurements and adjustments were performed with a dedicated manual manometer (Endotest®, Rusch™Teleflex ®, Wayne, USA), every 8 hours [11] and immediately before and after intra-hospital transfer [12].

The use of the Tracoe Smart Cuff Manager™ is detailed in Fig. 1. Briefly, this elastomeric device includes a blue inner balloon. This balloon can either receive air from the tracheal cuff (if the latter is overinflated) or inflate the tracheal cuff (if underinflated). This keeps P_{cuff} within the 20–30 cm H₂O range.

Immediately after randomization, the Tracoe Smart Cuff Manager™ was connected to the P_{cuff} control port of the endotracheal tube via a three way stopcock in order to avoid repeated disconnections of the device when manometer measurements of P_{cuff} are performed. Indeed, for a more direct measurement of P_{cuff} in this study, we chose to measure P_{cuff} upstream of the Tracoe Smart Cuff Manager™ rather than using the dedicated air inlet of the device.

The Tracoe Smart Cuff Manager™ was kept connected 24 hours a day, even during patient transfer (to the imaging facility for instance), for at least 48 hours (the observation period). Its maintenance after the 48th hour was left to the discretion of caregivers.

Study endpoints

The primary objective was to evaluate whether the Tracoe Smart Cuff Manager™ reduced the rate of patients undergoing at least one episode of tracheal cuff underinflation (P_{cuff} <20 cm H₂O), as compared with intermittent P_{cuff} adjustments only.

As secondary endpoints, comparisons between the two groups were as follow: the rate of patients undergoing at least one episode of tracheal cuff overinflation (P_{cuff} >30 cm H₂O), the incidence of under- and overinflation episodes, the rate of P_{cuff} adjustments and their magnitude. Ventilator free days, ICU length of stay and mortality and incidence of early respiratory infections were also compared. The latter was defined as the prescription, by the attending physician, of antimicrobial therapy for pneumonia or tracheobronchitis, over at least a 7-day period beginning 48 hours after the randomization. Indeed, an infection occurring within the first 48 hours is likely to be related to aspiration of upper airway content prior to the inclusion rather than to failure of the allocated strategy for P_{cuff} control. Patients with ongoing antimicrobial therapy for respiratory infection at the beginning of this 7-day period were excluded from this analysis. After careful review of the medical charts, cases of early respiratory infections were adjudicated by a physician blind to the randomization.

Sample size calculation

A previous study reported that, with no device for automated P_{cuff} control, 55% of patients experienced at least one episode of underinflation within a 48-hour observation period [7]. To detect a Tracoe Smart Cuff

Manager™-induced decrease, from 55 to 20%, in the proportion of patients experiencing at least one episode of underinflation, 56 patients were required (two groups of 28), with two-sided tests, an alpha risk of 0.05 and a power of 80%. A 5% margin yielded a total of 60 patients.

Statistical tests

Intention-to-treat analyses were performed. Normally and non-normally distributed quantitative parameters were expressed as mean $\pm$ SD or median [interquartile range], respectively. Their comparisons relied on Student's t-test or Mann-Whitney U test, respectively. Qualitative parameters were expressed in count (%) and compared with Fisher's exact test. The Epi info™ version 7.2.2.6 (CDC, Atlanta, GA, USA, 2011) and the RStudio version 1.2.1335 (R Foundation for Statistical Computing, Vienna, Austria) softwares were used. A $p < 0.05$ was considered significant.

Results

From March 2018 to July 2019, 65 patients were included. Informed consent could not be obtained in 5 patients. Therefore, 60 patients were analyzed: 28 were allocated to the adjunction of automated P_{cuff} adjustment, 32 to routine manual adjustments only (Fig. 2).

Overall, 506 measurements of P_{cuff} were performed: 237 and 269 in patients with automated and with manual adjustments, respectively (mean of 8.5 ± 3.5 and 8.4 ± 2.4 measurements per patient).

Most patients' characteristics were similar in the 2 groups except for a few of them, including some airway pressures which were higher in patients with manual P_{cuff} adjustment (Tables 1 and 2). Prone position was not performed in any of the included patients during the observation period.

Table 1
Patients characteristics at ICU admission

	Total (n = 60)	Automated P_{cuff} adjustment (n = 28)	Manual P_{cuff} adjustment (n = 32)	p
Age (years)	55 [42–64]	57 [44–66]	52 [42–60]	0.24
Female gender (n [%])	25 (42%)	10 (36%)	15 (47%)	0.44
Height (cm)	170 [162–175]	168 [162–180]	170 [163–174]	0.79
Weight (kg)	69 [59–80]	70 [61–77]	68 [58–81]	0.86
BMI	23.4 [21.6–26.7]	22.9 [19.8–24.8]	24.0 [22.5–28.0]	0.14
SAPS II	47 [34–60]	49 [39–43]	43 [32–58]	0.53
SOFA score				
admission	8 [5–9]	8 [6–9]	7 [5–10]	0.75
inclusion	9 [7–10]	9 [6–9]	9 [7–11]	0.15
Reason for ICU admission (n [%])				
SAH	26 (43%)	12 (43%)	14 (44%)	> 0.99
ICH	10 (17%)	5 (18%)	5 (16%)	> 0.99
Post-operative admission after elective surgery	9 (15%)	4 (14%)	5 (16%)	> 0.99
TBI	6 (10%)	2 (7%)	4 (13%)	0.67
Stroke	5 (8%)	2 (7%)	3 (9%)	> 0.99
Other	4 (7%)	3 (11%)	1 (3%)	0.33
Comorbidities (n [%])				

Legend: BMI: body mass index; SAPS II: simplified acute physiology score; SOFA: sequential organ failure assessment; ICU: intensive care unit; SAH: subarachnoid hemorrhage; ICH: intra-cerebral hematoma; TBI: traumatic brain injury. *Profile™ Soft-Seal® Cuff, Portex, Smith Medical, MN, USA.

	Total (n = 60)	Automated P_{cuff} adjustment (n = 28)	Manual P_{cuff} adjustment (n = 32)	p
Hypertension	17 (28%)	5 (18%)	12 (38%)	0.15
Immunocompromised	1 (2%)	1 (4%)	0	0.47
Diabetes mellitus	3 (5%)	2 (7%)	1 (3%)	0.59
Antimicrobial therapy started within 48 h after tracheal intubation (n [%])	15 (25%)	5 (18%)	10 (31%)	0.37
Endotracheal tube model (n [%]) Profile™ Soft-Seal® Cuff* Other	37 (62%) 22 (38%)	19 (68%) 9 (32%)	18 (56%) 14 (44%)	0.43
Intra-hospital transport during the 48 hour observation period (n [%])				
1	44 (77%)	18 (64%)	26 (81%)	0.02
2	16 (27%)	6 (21%)	10 (31%)	0.55
3	6 (10%)	4 (14%)	2 (6%)	0.40
4	2 (3%)	1 (4%)	1 (3%)	1
MV duration (days)	14 [7– 23]	17 [8–28]	13 [7–20]	0.45
Ventilator Free Days	4 [0–8]	5 [0–7]	3 [0–10]	0.96
Length of stay (days)	20 [11– 34]	25 [11–35]	17 [11–28]	0.39
ICU Mortality (n [%])	22 (37%)	10 (36%)	12 (38%)	0.99
Legend: BMI: body mass index; SAPS II: simplified acute physiology score; SOFA: sequential organ failure assessment; ICU: intensive care unit; SAH: subarachnoid hemorrhage; ICH: intra-cerebral hematoma; TBI: traumatic brain injury. *Profile™ Soft-Seal® Cuff, Portex, Smith Medical, MN, USA.				

Table 2

Clinical data collected, at each P_{cuff} manual determination, during the 48 hour observation period.

	Automated adjustment of P_{cuff}	Manual Adjustment of P_{cuff}	p
Assisted Controlled Ventilation	179/246 (73%)	225/277 (81%)	0.02
Peak Pressure (cm H ₂ O)	27.4 ± 5.9	28.3 ± 7.8	0.18
Plateau Pressure (cm H ₂ O)	13.6 ± 5.6	15.4 ± 5.8	0.002
Pressure Support Ventilation	67/246 (27%)	52/277 (19%)	0.02
Pressure support (cm H ₂ O)	12.0 ± 4.1	13.4 ± 3.3	0.052
Enteral Feeding	150/246 (62%)	200/277 (72%)	0.01
Vomiting since the previous P_{cuff} determination	5/246 (2%)	8/277 (3%)	0.59
Head of bed elevation, degrees	29 ± 3 (n = 246)	29 ± 5 (n = 277)	0.97
PEEP	5.5 ± 1.6	5.6 ± 1.4	0.46
RASS	-5 [-5, -4]	-5 [-5, -5]	0.08
Infusion of, n (%)			
Propofol	21/28 (75%)	24/32 (75%)	> 0.99
Midazolam	16/28 (57%)	24/32 (75%)	0.18
Sufentanil	23/28 (82%)	28/32 (87%)	0.72
Sodium thiopental	4/28 (14%)	6/32 (19%)	0.74
Neuromuscular blocking agent	6 (21%)	12 (38%)	0.26
Legend: P_{cuff} : tracheal cuff pressure; PEEP: positive end-expiratory pressure; RASS: Richmond agitation sedation scale.			

Primary endpoint

The rate of patients with at least 1 underinflation episode within the 48 hour observation period was significantly lower with automated P_{cuff} adjustment than with manual P_{cuff} adjustment only 5/28 (17.9% [95%CI 7.4–36.0]) vs. 20/32 (62.5% [95%CI 45.2–77.1]); p = 0.006)(Fig. 3).

Secondary endpoints

The rate of patients with at least 1 overinflation episode was similar ($p > 0.99$) in the 2 groups: 3/28 (10.7% [95%CI 2.9–28.0]) vs. 4/32 (12.5% [95%CI 4.4–28.7]) with automated P_{cuff} adjustment and with manual P_{cuff} adjustment only, respectively.

Incidence of under- and overinflation episodes. During the 48-hour observation period, mean P_{cuff} was higher with the automated P_{cuff} adjustment (25.3 ± 5.0 vs. 22.9 ± 4.3 cm H₂O; $p < 0.001$). The incidence of underinflation episodes was significantly lower in the automated P_{cuff} adjustment (237 measurements) than in the manual adjustment group (269 measurements): 2.1% [95%CI 0.3–3.9] vs. 14.9% [95%CI 10.3–19.4]; $p < 0.001$ (Fig. 4). The incidence of overinflation episodes was similar in the two groups: 1.7% [95%CI 0.5–4.4] vs. 1.9% [95%CI 0.7–4.4], $p > 0.99$ (Fig. 4).

The rate of P_{cuff} adjustments performed -after P_{cuff} measurement was lower with the automated P_{cuff} adjustment: 55.7% [95%CI 49.4–61.8] vs. 76.6% [95%CI 71.1–81.3]; $p < 0.001$. In addition, these adjustments were of lower magnitude in patients with automated P_{cuff} adjustment (3.6 ± 4.7 vs. 5.9 ± 4.5 cm H₂O; $p < 0.001$).

Other outcomes. In each group, 8 early respiratory infections occurred in 8 patients yielding an incidence of 29% and 25% in the automated and the manual P_{cuff} adjustment group, respectively ($p = 0.78$). No significant difference was found between the two groups with regard to the following outcomes at the ICU discharge: duration of mechanical ventilation, ventilator free days, length of ICU stay, and ICU mortality (Table 1).

Discussion

The main finding of this randomized controlled study coordinated by nurses of two surgical ICUs of the University Hospital of Nantes is that implementing an automated adjustment of P_{cuff} by the Tracoe Smart Cuff Manager™ in combination with intermittent manual adjustments was more effective to regulate P_{cuff} than a strategy with manual adjustments alone. Indeed, automated adjustment of P_{cuff} markedly decreased the rate of patients experiencing at least one underinflation episode and the incidence of detected episodes of underinflation. Importantly, the automated P_{cuff} adjustment strategy was not associated with a higher incidence of detected episodes of tracheal cuff overinflation.

Interestingly, despite the randomization, airway pressures were or tended to be higher in patients allocated to undergo manual P_{cuff} adjustments solely (Table 2). Since airway pressure is transmitted to P_{cuff} [13], this imbalance could have reduced the incidence of underinflation episodes among patients with manual P_{cuff} adjustments solely. In other words, assuming strictly identical airway pressure between the two groups, the protective effect of the Tracoe Smart Cuff Manager™ against underinflation episodes could have been even more prominent.

To avoid both microaspirations and tracheal damage, achieving a 24-hour balance between under- and overinflation of the tracheal cuff is desirable. The issue is not new. Indeed, from the 1970s, some

modified endotracheal tubes were released onto the market for this purpose. One of these tubes housed a valve connected to a larger balloon than the standard pilot balloon. This regulating valve aimed at maintaining P_{cuff} close to 30 cm H₂O [14]. This so-called Lanz system is the forerunner of the Tracoe Smart Cuff Manager™. One advantage of the latter relies on its ability to be connected to the standard port of most tracheal tube models (contrary to the Lanz system which is natively-embedded into one model of tracheal tube). To the best of our knowledge, no published study evaluated the Tracoe Smart Cuff Manager™. Overall, devices automatically regulating P_{cuff} were surprisingly poorly assessed. Indeed, besides some very preliminary reports of “home-made” devices [15], a dozen studies evaluated whether an automated device connected to the endotracheal tube effectively maintains P_{cuff} within an acceptable range (7,8,15,18–24). All these previous studies were single-center studies. They were uncontrolled [22], not randomized [17], of limited size (18 patients or less)[8, 16, 20, 22], experimental [13, 21] and/or tested non-commercialized devices [19, 22]. Although several very different devices have been tested, most of these studies have concluded that maintenance of P_{cuff} within the acceptable range was better achieved with an automated rather than an intermittent manual control of P_{cuff} , especially via the reduction of underinflation episodes. In their hallmark study, Nseir et al. went even further by demonstrating that implementing an automated P_{cuff} control reduced both the tracheal level of pepsin (suggesting a reduction of gastric content microaspiration) and the rate of ventilator-associated pneumonia [7]. Importantly, the reduction in the rate of underinflation episodes must not be at the expense of a potentially harmful increase in the rate of overinflation episodes. Unfortunately, one device [8] and possibly another one [19] were associated with a higher rate of P_{cuff} episodes above 30 cmH₂O than routine care. Other drawbacks applying to some devices are worth mentioning: they are bulky and/or inconvenient (which encourages their disconnection before patient transport, a procedure at-risk of aspiration of oropharyngeal content), relatively expensive, need electric [16] or gas [23] supply. This may explain the lack of wide clinical use of automated P_{cuff} control. The Tracoe Smart Cuff Manager™ may overcome all these issues.

Limitations of the study

First, inherently to the nature of the tested intervention, caregivers could not be blinded to the randomization arm.

Second, the study was focused on the specific population of brain injured patients, and we mostly used one model of endotracheal tube. However, this population is of interest in the field of prevention of respiratory infections since it is prone to develop such infections because, among other reasons, prolonged median duration of mechanical ventilation [24, 25]. We therefore believe that focusing on this specific population should be seen as strength rather than limitation of this study. Therefore, relative caution should be exercised before extrapolating our findings to other settings or populations or even to other airway access devices. Furthermore, this population is also particularly prone to be deeply sedated (Table 1). Since the absence of sedation is independently associated with increased risk for cuff

underinflation [5], one can hypothesize that the adjunction of the Tracoe Smart Cuff Manager™ to routine care in less sedated patients would have been associated with an even more marked reduction in the incidence of underinflation episodes than that herein reported. This hypothesis remains to be tested.

Third, P_{cuff} measurements were not collected continuously. Therefore, undetected episodes of under- or overinflation may have been overlooked. This would have impacted our conclusions if these undetected episodes of incorrect P_{cuff} were significantly more frequent in the automated adjustment group than in the manual adjustment group, i.e., an imbalance totally opposite to that observed for detected events. This hypothesis is therefore highly unlikely.

Fourth, in patients with automated P_{cuff} adjustment but not in patients from routine care group, we used a three-way stopcock. Of note, direct connection of the manometer to the endotracheal tube may be source of air leakage [27]. The use of the three-way stopcock may have limited the air leakage by connecting the manometer before opening the dedicated outlet. Therefore, some patients may have benefitted more from the use of the three-way stopcock than from the use of the Tracoe Smart Cuff Manager™. We chose to add the three-way stopcock to the Tracoe Smart Cuff Manager™ in order to avoid its disconnection (and therefore its necessary re-inflation) each time a manometer is connected, i.e., several times a day. This allowed direct P_{cuff} measurements, i.e., upstream of the Tracoe Smart Cuff Manager™ rather than using the dedicated inlet of the device (Fig. 1). Of note, the manufacturer proposes the direct connection of the Tracoe Smart Cuff Manager™ to the tracheal tube with no three-way stopcock, intermittent manometer P_{cuff} measurements being then performed via the dedicated inlet. Interestingly, with this latter approach, manometer connection-induced possible air leakage would slightly deflate the inner balloon of the device but, importantly, not the tracheal cuff. Therefore, when using the Tracoe Smart Cuff Manager™ with a three-way stopcock or not, manometer connection-induced deflation of the tracheal cuff is theoretically reduced. We believe this is a strength of the device. In the present study, using a three-way stopcock in both groups would have been helpful to delineate the specific contribution of the Tracoe Smart Cuff Manager™ and the three-way stopcock to our findings. However, adding a three-way stopcock to the endotracheal tube when no device for automated adjustment is connected is not recommended [24, 25] and is therefore neither wide current practice nor part of our routine care.

Fifth, in this study, manual adjustments were not guided by strict specific rules except correcting a P_{cuff} value outside the recommended range of 20–30 cmH₂O. Indeed, the decision of manual adjustment and its magnitude tightly depends on previous measurements and adjustments in a given patient. Hence, several manual adjustments have consisted in modifying a P_{cuff} value already within this recommended range (from 21 to 27 cmH₂O for instance) in a possibly unduly manner. This may explain the somewhat high incidence of manual adjustments in both groups (56% in the Tracoe Smart Cuff Manager™ group vs. 77% in the routine care group, $p < 0.001$). Since the Tracoe Smart Cuff Manager™ is able to inflate or deflate the tracheal cuff, these manual adjustments could have been unnecessary in patients equipped with this device. Indeed, less than 4% of P_{cuff} measurements lied outside the recommended range in this group.

Last, our study was not designed to assess whether the Tracoe Smart Cuff Manager™ reduces the incidence of ventilator-associated respiratory infections and therefore the ventilator free days, ICU length of stay or even mortality. Indeed, the Tracoe Smart Cuff Manager™ was not kept in place throughout the duration of invasive ventilation but only 48 hours in most patients, i.e., just the duration of the study observation period for its primary endpoint. The present study demonstrates that the Tracoe Smart Cuff Manager™ reduced the incidence of cuff underinflation. Whether this encouraging finding would translate into a reduction in ventilator-associated respiratory infections is not straightforward and deserves a dedicated study [19]. Indeed, a too rapid P_{cuff} correction by the automated device may interfere with the self-sealing mechanism of the cuff and may reduce its sealing characteristics, therefore exposing to microaspirations [28]. Interestingly, the Tracoe Smart Cuff Manager™ houses a valve aiming at slowing down the reaction time before P_{cuff} correction but its effectiveness has to be specifically assessed. Moreover, prevention of ventilator-associated respiratory infections is multifaceted and demonstrating a reduction in their incidence by acting on only one facet (reduction of underinflation episodes) may require a large study size. An ongoing multicenter study testing another pneumatic device may provide further insight on this relevant topic [29].

Conclusion

By showing that an approach including the Tracoe Smart Cuff Manager™ allowed a better control of P_{cuff} into the recommended range of 20–30 cm H₂O as compared with routine care, this study paved the way for a large study specifically addressing whether this device (as part of a multifaceted preventive strategy) is effective in the prevention of ventilator-associated pneumonia.

Abbreviation

BMI: body mass index

CDC: control disease center

ETT: Endotracheal tube

ICH: intra-cerebral hematoma

ICU: intensive care unit

MV: mechanical ventilation

P_{cuff} : endotracheal tube cuff pressure

SAPS II: simplified acute physiology score

SAH: subarachnoid hemorrhage

SD: standard deviation

SOFA: sequential organ failure assessment

TBI: traumatic brain injury

Declarations

Ethics approval and consent to participate

A national ethics committee (Comité de Protection des Personnes, CPP 2017/62) approved the study design. Written and oral informed consent was obtained from each patient or to his next of kin if the patient was not able to consent.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

Jérôme Dauvergne has no conflict of interest in connection with the work submitted. In addition, JD received, during the past 5 years, travel fees from HALYARD (once in 2016).

Anne-Laure Geffray has no conflict of interest in connection with the work submitted.

Bertrand Rozec has no conflict of interest in connection with the work submitted. In addition, BR received, during the past 5 years, lecture fees from Fisher&Paykel, Baxter, LFB, Aspen, research grants from Baxter and consulting fees from LFB, Astra Zeneca.

Karim Asehnoune received fees from Fisher Paykel, LFB, Fresenius, Edwards (outside the submitted work).

Karim Lakhal has no conflict of interest in connection with the work submitted. In addition, KL received, during the past 3 years, lecture fees from MEDTRONIC (once, in 2017), congress registration fees from SANOFI AVENTIS (once in 2018), travel fees from MSD France (once, in 2017), NOVEX PHARMA (once, in 2016), GILEAD SCIENCES (twice, 2016 and 2017), PFIZER (once, in 2019).

Funding

This study was fully funded by TRACOE Medical GmbH, prior to its conduction. The Tracoe Smart Cuff Manager™ was also provided by TRACOE Medical GmbH. This company has not interfered in the design, conduct and data analysis of the study. None of the investigators has any direct conflict of interest with the company. The financial relationship only involved the institutional research department.

Authors' contributions

Conception and design: JED, KL.

Collection of data: JED, ALG.

Statistical analysis: JED, KL.

Drafting and revision of the manuscript: JED, KL, BR, KA

Acknowledgements

We are grateful to Mrs. Laurence Pacaud and Mrs. Sylvie Le Guillou, research nurses, and Mrs. Emmanuelle Cartron, nurse research coordinator, for their important contribution to this work. We are indebted to the Critical Care nurses and all the medical staff of our department of Anaesthesia and Critical Care Medicine.

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Figures

Figure 2

The Tracoe Smart Cuff Manager™ Legend: This figure displays the Tracoe Smart Cuff Manager™ and our routine care manual manometer, the latter being only intermittently connected to the former. The Tracoe Smart Cuff Manager™ houses a blue inner balloon protected by a rigid transparent sphere. This blue balloon keeps the tracheal cuff pressure (Pcuff) within the 20-30 cm H₂O range. Indeed, if Pcuff is high, air is transferred from the tracheal cuff to the blue inner balloon and vice-versa if Pcuff is low. Beforehand, the blue balloon is inflated, via the air inlet (arrow), by a healthcare provider using a syringe to a volume representing $\frac{1}{2}$ to $\frac{3}{4}$ of the volume of the transparent rigid sphere (this represents the injection of about 60 mL of air). When the quick visual inspection (for example, at each healthcare provider visit) indicates that the volume of the blue balloon has decreased (< half the volume of the transparent sphere), the blue balloon has to be reinflated. The Tracoe Smart Cuff Manager™ also houses a valve which aims at slowing down the reaction time in order to respect the tracheal cuff intrinsic sealing properties [28]. Thus, in this study, we chose to measure Pcuff upstream of the Tracoe Smart Cuff Manager™ rather than using the dedicated air inlet of the device (arrow). Hence, for this study, the Tracoe Smart Cuff Manager™

was connected to the Pcuff control port of the endotracheal tube via a three way stopcock in order to avoid repeated disconnections of the device when manometer measurements of Pcuff are performed.

Figure 4

Study flow chart Legend: MV: mechanical ventilation; ICU: intensive care unit; ETT: Endotracheal tube; Pcuff: endotracheal tube cuff pressure. Eligible patients were patients admitted to the ICU for acute brain injury and invasive mechanical ventilation.

At least 1 detected episode of underinflation

($P_{\text{cuff}} < 20 \text{ cm H}_2\text{O}$)

$p < 0.001$

Figure 6

Impact of the P_{cuff} adjustment technique on the occurrence of at least one underinflation episode.

Legend: P_{cuff} : cuff pressure. An underinflation episode corresponds to $P_{\text{cuff}} < 20 \text{ cm H}_2\text{O}$.

Under- and overinflation episodes

Figure 8

Incidence of under- and overinflation episodes with respect to the P_{cuff} adjustment strategy. Legend: P_{cuff} : cuff pressure. An underinflation episode corresponds to $P_{cuff} < 20 \text{ cm H}_2\text{O}$, overinflation episode corresponds to $P_{cuff} > 30 \text{ cm H}_2\text{O}$. *: $p < 0.001$ for the comparison of underinflation episodes between the two groups.