

Rapid pressure compensation by automated cuff pressure controllers worsens sealing in tracheal tubes

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Background. Cyclic redistribution of air within the cuff during respiratory pressure changes creates a self-sealing mechanism which allows tracheal sealing, despite tracheal airway pressure being above baseline cuff inflation pressure. The aim of the present study was to investigate the effect of continuous automated cuff pressure regulation on tracheal sealing during cyclic respiratory pressure changes.

Methods. *In vitro* tracheal sealing was studied in four different high volume–low pressure (HVLP) tracheal tube cuffs size internal diameter 8.0 and 5.0 mm in combination with a conventional pressure manometer and two different automated pressure controllers (VBM Cuff Controller; Cuff Pressure Control Tracoe™). Experiments were performed at 10, 15, 20, and 25 cm H₂O cuff pressure during intermittent positive pressure ventilation with peak inspiratory pressures of 20 and 25 cm H₂O. Air leakage was assessed spirometrically. Experiments were performed four times with each tube brand and size with two exemplars of each of the three cuff pressure controllers.

Results. Owing to immediate cuff pressure correction, tracheal sealing at cuff pressure below inspiratory pressure was reduced in most of the tracheal tube cuffs, except in those with reduced sealing characteristics when using the Pressure Control Tracoe™ compared with the conventional pressure manometer and the VBM Cuff Controller. Tracheal sealing with the Pressure Control Tracoe™ comparable with the other two devices was only achieved at cuff pressures of 20 and 25 cm H₂O.

Conclusions. Automated cuff pressure controllers with rapid pressure correction interfere with the self-sealing mechanism of high sealing HVLP tube cuffs and reduce their improved sealing characteristics.

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High volume–low pressure (HVLP) tube cuffs seal the trachea at baseline cuff pressures lower than peak airway pressure by the so-called self-sealing mechanism.^{1,2} Tracheal airway pressure thereby produces a retrograde compression in the distal part of the cuff and moves air within the cuff proximally towards the upper end. This results in tracheal sealing.^{3,4} The cyclic redistribution of air within the cuff creates a self-sealing mechanism, which allows tracheal occlusion by the cuff, despite an increase in distal tracheal airway pressure above baseline cuff inflation pressure.

In the past, several cuff pressure regulators have been introduced in clinical practice in order to limit cuff

pressures and to maintain cuff pressure by continuously inflating and deflating.^{5–12} This study aimed to investigate the effect of continuous cuff pressure regulation by two different modern automated cuff pressure controllers on tracheal self-sealing in different HVLP tracheal tube cuffs.

[†]*Declaration of interest.* The tracheal tubes and the cuff regulators studied were ordered from local distributors. No financial support was obtained from the manufacturers for the present study. No agreements or financial benefits arise from these co-operations. There are no financial or non-financial competing interests in the accomplishment of this study.

Methods

In an *in vitro* laboratory model, we investigated the sealing quality of HVLP tracheal tube cuffs in combination with a manual cuff pressure controller (Cuff pressure manometer, Microcuff GmbH, Weinheim, Germany) and two automated cuff pressure controllers (VBM Cuff Controller, VBM Medizintechnik GmbH, Sulz a.N., Germany, and Cuff Pressure Control, Tracoe™, TRACOE medical GmbH, Frankfurt, Germany) (Fig. 1). All devices tested were new and represented the latest version from each manufacturer. Before measurements, the devices were tested and calibrated if necessary according to the manufacturers' instructions for use.

A mechanical lung (Testlung, Carbamed, Zurich, Switzerland—Compliance 22 ml cm H₂O⁻¹) connected to a model trachea made from clear, rigid polyvinylchloride (PVC) [20 mm, respectively, 12 mm internal diameter (ID)] was used to simulate changes in inspiratory pressures. ID 8.0 and 5.0 mm tracheal tubes with a HVLP cuff from different manufacturers were used (Table 1). The deflated, unlubricated tracheal tube cuffs were completely inserted into the model trachea and connected to the ventilator. The cuff inflation line was connected to one of the three cuff pressure controller devices tested. Inspiratory and expiratory

tidal volumes were measured with a spirometer (Spirometer, AS5 Monitor, Datex Ohmeda, Helsinki, Finland) interposed between the ventilator and the tracheal tube. Pressure-controlled ventilation was provided by an anaesthesia respirator (ADU, Datex Ohmeda). Respirator settings were: fresh gas flow (air) 6 litre min⁻¹; PEEP 5 cm H₂O; ventilatory frequency 10 bpm; *I:E* ratio 1:2; inspiratory pressure 15 and 20 cm H₂O [peak inspiratory pressure (PIP) 20 and 25 cm H₂O]. With the ventilator bellows completely filled with air, experiments were started using cuff pressures of 10, 15, 20, and 25 cm H₂O, respectively.

Minimal and maximal cuff pressures, as indicated by the corresponding device, and inspiratory and expiratory volumes were measured. Ratio of expiratory to inspiratory tidal volumes (VtE/VtI ratio) was calculated.

Experiments were performed four times using four new tracheal tubes with two exemplars of each of the three cuff pressure controllers at room temperature of 20–22°C.

Measured VtE/VtI ratios and maximal and minimal cuff pressures were compared using two-tailed Student's *t*-test within the two identical devices, the two different PIP levels, and the tube sizes from the same manufacturer. Similarly, data were compared between the conventional cuff pressure manometer and the VBM and the Tracoe™

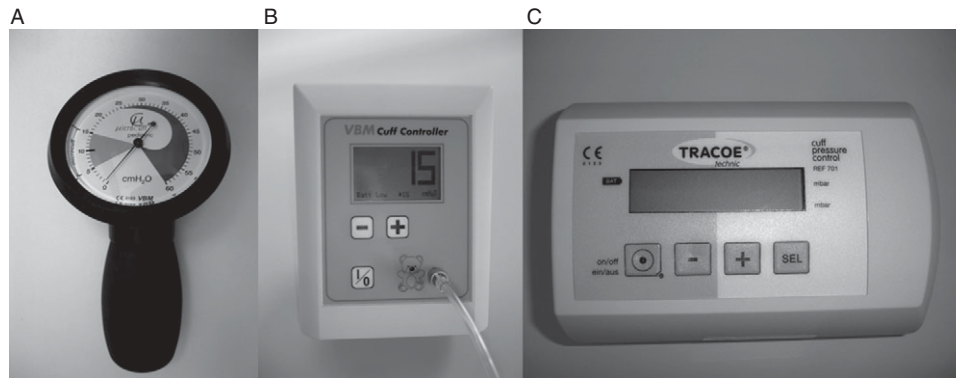


Fig 1 Cuff pressure controllers tested: (A) Cuff Pressure Manometer, Microcuff GmbH, Weinheim, Germany; (B) VBM Pressure Controller, VBM Medizintechnik GmbH, Sulz a.N., Germany; (C) Tracoe™ Pressure Controller, TRACOE medical GmbH, Frankfurt, Germany.

Table 1 Investigated tracheal tubes with HVLP cuffs with ID of 8.0 and 5.0 mm. PU, polyurethane; PVC, polyvinyl chloride

Manufacturer	ID (mm)	Tracheal tube series	Reference no.	Outer cuff diameter (mm)	Cuff length (mm)	Cuff material
Kimberly Clark, Zaventem, Belgium	8.0	Microcuff Tracheal Tube	35216	26	50	PU
	5.0	Microcuff Paediatric Tracheal Tube	35115	14	15	PU
Mallinckrodt, Athlone, Ireland	8.0	Hi-Lo™ Tracheal Tube, Murphy, Oral/Nasal	109–80	33	40	PVC
	5.0	Hi-Lo™ Tracheal Tube, Murphy, Oral/Nasal,	109–50	20	25	PVC
SIMS Portex Ltd, Hythe, Kent, UK	8.0	Tracheal Tube—Profile Soft Seal Cuff, Murphy, Oral/Nasal	100/199/080	30	35	PVC
	5.0	Tracheal Tube—Profile Soft Seal Cuff, Murphy, Oral/Nasal	100/199/050	17	22	PVC
Rüsch GmbH, Kernen, Germany	8.0	Rüschelit Super Safety Clear, Murphy, Nasal/Oral	112482	25	40	PVC
	5.0	Rüschelit Super Safety Clear, Murphy, Nasal/Oral	112482	13	25	PVC

pressure controllers and between the Microcuff tracheal tube and the three other tracheal tube brands for each size. Data are presented as mean (SD).

Results

A total of 1526 measurements were made. There were no statistically significant differences between two similar pressure control devices or between experiments performed with 20 and 25 cm H₂O PIP, except that maximum cuff pressures recorded with the cuff pressure manometer were higher in some of the ID 8.0 mm tracheal tubes. With the conventional cuff pressure, manometer sufficient tracheal sealing (<5% air leakage; approximately ≤20 ml per tidal volume) at all cuff pressures and both PIPs tested was only obtained in the Microcuff tracheal tubes ID 8.0 and 5.0 mm. In the other three tracheal tube brands, tracheal sealing was significantly reduced, whereas two out of three ID 5.0 mm tube cuffs demonstrated significantly better values than their corresponding ID 8.0 mm sizes (Table 2).

Tracheal sealing obtained with the VBM pressure controller was similar to that obtained with the cuff pressure manometer at all cuff pressure levels in most of the tubes; however, tracheal sealing was reduced with the Tracoe™ Pressure Controller. This was seen in most of the tracheal tubes tested (Table 2, Figs 2 and 3) except in the Portex tracheal tubes, demonstrating the lowest sealing qualities of all tubes. The Tracoe™ Pressure Controller achieved tracheal sealing comparable with that of the cuff pressure manometer only at cuff pressures of 20 and 25 cm H₂O (Figs 2 and 3). The VBM Pressure Controller achieved even better sealing than the cuff manometer in two high quality sealing tube cuffs. However, this device showed a similarly poor performance to the Tracoe™ Pressure Controller in the 5.0 mm Portex tracheal tubes (Table 2).

Cyclic cuff pressure changes noted from the devices corresponded well to baseline cuff pressures and set PIPs in the conventional cuff manometer and the VBM device (Supplementary material, Tables 1 and 2). In all tracheal

tubes tested, the Tracoe™ pressure controller demonstrated minimal cuff pressures significantly lower than the set cuff pressure. Similarly, maximal cuff pressures recorded with the Tracoe™ pressure controller were significantly lower than the other two devices but only in the ID 8.0 sized tracheal tubes. Notably, cuff pressure regulation with the Tracoe™ pressure controller was accompanied by continuous audible deflating and inflating noises, particularly at cuff inflation pressure of 10–20 cm H₂O.

Discussion

Maintaining an appropriate cuff pressure in mechanically ventilated patients is important in order to avoid cuff hyperinflation as a consequence of manual cuff inflation or nitrous oxide diffusion and to guarantee constant proper sealing of the trachea. Automated cuff pressure controllers have been introduced to overcome these risks and to keep the cuff constantly inflated. The main finding of our study clearly demonstrates that a rapid compensating pressure controller worsens tracheal sealing in HVLP tube cuffs with improved sealing qualities, but not in those with reduced sealing characteristics, independent from tube size and tube brand.

Inadequate sealing leading to leakage of contaminated secretions pooled above the tracheal tube cuff and then to ventilator-associated pneumonia (VAP) is of increasing interest.^{13 14} The routine management of cuff inflation in the intensive care unit consists of a periodic manual check of cuff pressure. Connection/disconnection of a conventional cuff manometer to/from the cuff inflation line and manipulation (increasing/reducing) of the cuff pressure leads to pressure drops.¹⁵ In addition, sudden changes in tracheal diameter or gas diffusion across the cuff membrane down the pressure gradient prevent an unchanged cuff pressure and an equal cuff expansion. In contrast to periodically adjusting the cuff pressure in ventilated intensive care patients, automated cuff controllers provide a more constant cuff pressure.¹⁶ To date only one study was

Table 2 Summarized air leakage, minimum and maximum cuff pressures measured for the three cuff pressure controllers and for the ID 8.0 and 5.0 mm tracheal tubes. Data are the mean values obtained from all measurements (cuff pressures of 10, 15, 20, and 25 cm H₂O and PIPs of 20 and 25 cmH₂O). Cuff pressure controllers compared with cuff pressure manometer: *****P*<0.0001, ****P*<0.001, ***P*<0.01, **P*<0.05. Tracheal tube sizes ID 5.0 mm compared with ID 8.0 mm: ++++*P*<0.0001, +++*P*<0.001, ++*P*<0.01, +*P*<0.05. Tracheal tube brands compared with similar sized Microcuff tracheal tubes: #####*P*<0.0001, ###*P*<0.001, ##*P*<0.01, #*P*<0.05. PIPs 20 vs 25 cm H₂O: †††*P*<0.001, †*P*<0.05

Tracheal tubes		Leakage (%)			Minimal cuff pressure (cm H ₂ O)			Maximal cuff pressure (cm H ₂ O)		
Tracheal tube size (ID)	Tracheal tube brand	Cuff Pressure Manometer	VBM Pressure Controller	Tracoe™ Pressure Controller	Cuff Pressure Manometer	VBM Pressure Controller	Tracoe™ Pressure Controller	Cuff Pressure Manometer	VBM Pressure Controller	Tracoe™ Pressure Controller
8.0 mm	Microcuff	99.4	99.4	89.8****	17.5	17.5	13.1***	24.1 ^{†††}	24.5	19.2****
	Mallinckrodt	68.3#####	68.8#####	56.1***#####	17.5	17.5	11.3****	23.5 [†]	24.9	20.1****
	Portex	53.2#####	57.9#####	53.0#####	17.5	17.5	12.8****##	21.8	22.3	20.1*
	Ruesch	93.0#####	96.3***#####	78.4****##	17.5	17.5	10.5****#	24.4 [†]	24.8	21.4****#
5.0 mm	Microcuff	98.7	99.7*	90.1***	17.5	17.5	11.9****	21.2 ⁺	23.5	20.9
	Mallinckrodt	85.9++++#####	87.7++++#####	76.7***++++#####	17.5	17.5	11.5****	20.7 ⁺⁺⁺	22.6	21.3
	Portex	67.8++++#####	59.6*#####	62.1 ⁺⁺ #####	17.5	17.5	15.0***+##	18.7 ⁺⁺⁺ ##	19.6 ⁺⁺ ##	18.6 [#]
	Ruesch	77.9++++#####	75.2++++#####	75.5###	17.5	17.5	11.4****	20.2 ⁺⁺⁺⁺	22.0	20.8

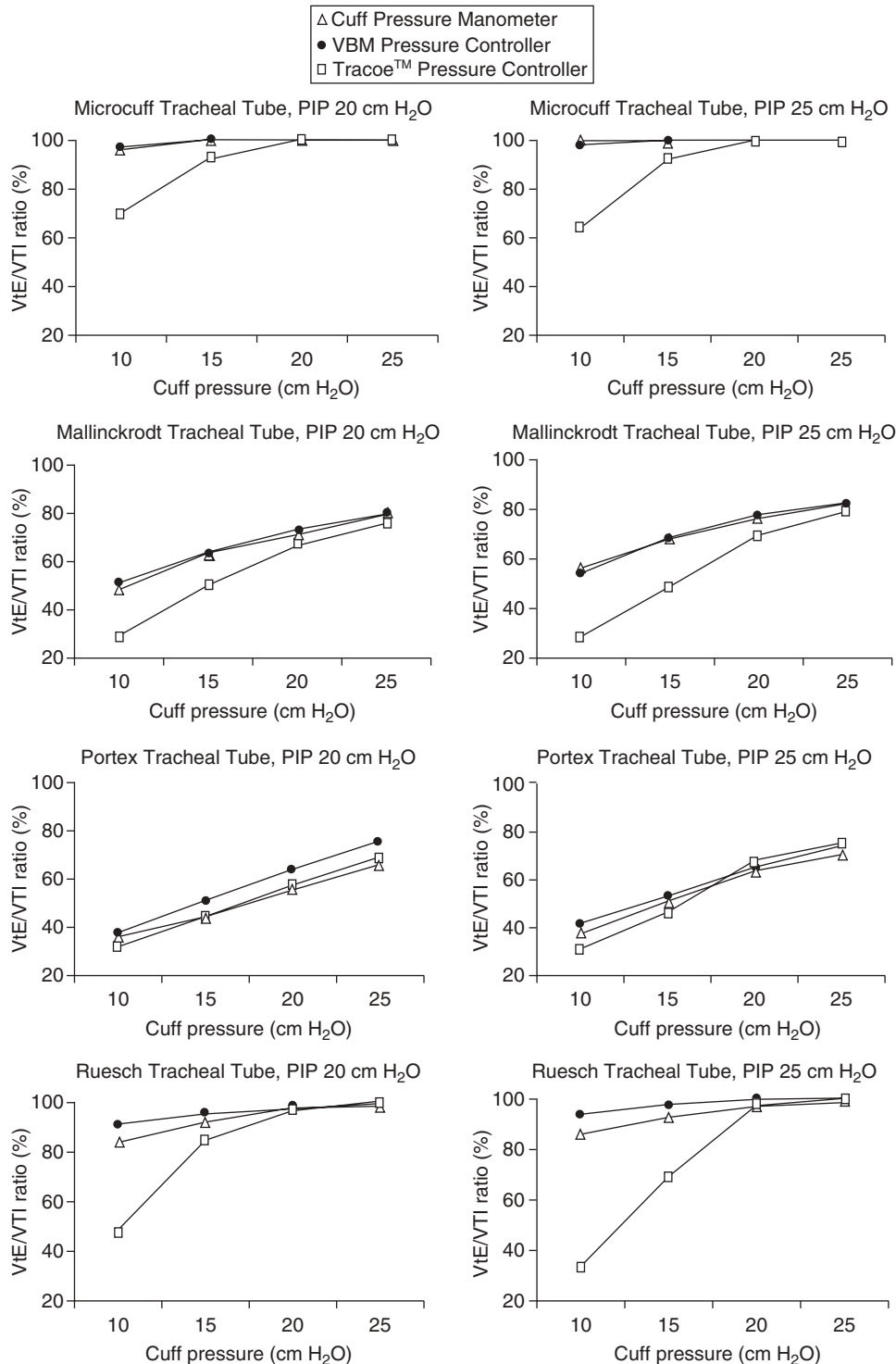


Fig 2 Mean ratio (%) of expiratory to inspiratory tidal volumes recorded with each of the three cuff pressure controllers and each of the four different ID 8.0 mm tracheal tube brands tested at cuff pressures of 10, 15, 20, and 25 cm H₂O and at peak inflation pressure of 20 and 25 cm H₂O ($n=16$ measurements per device, tracheal tube brand, cuff pressure and inspiratory peak pressure).

able to demonstrate that intermittent cuff pressures of <20 cm H₂O are a risk factor for VAP.¹⁵

As demonstrated by our results, sealing characteristics between tube brands tested differed considerably (Table 2) which is consistent with earlier published investigations.^{2,17} As shown by Young and colleagues,¹⁸ the reduced sealing

characteristics of some of these tubes are caused by the formation of folds and channels within the cuff, when they are inflated in the tracheal lumen. Therefore, beside oropharyngeal contamination, head-of-the-bed elevation, subglottic continuous suctioning of secretions, and continuous cuff pressure control, in the past 10 yr tracheal tube cuffs with

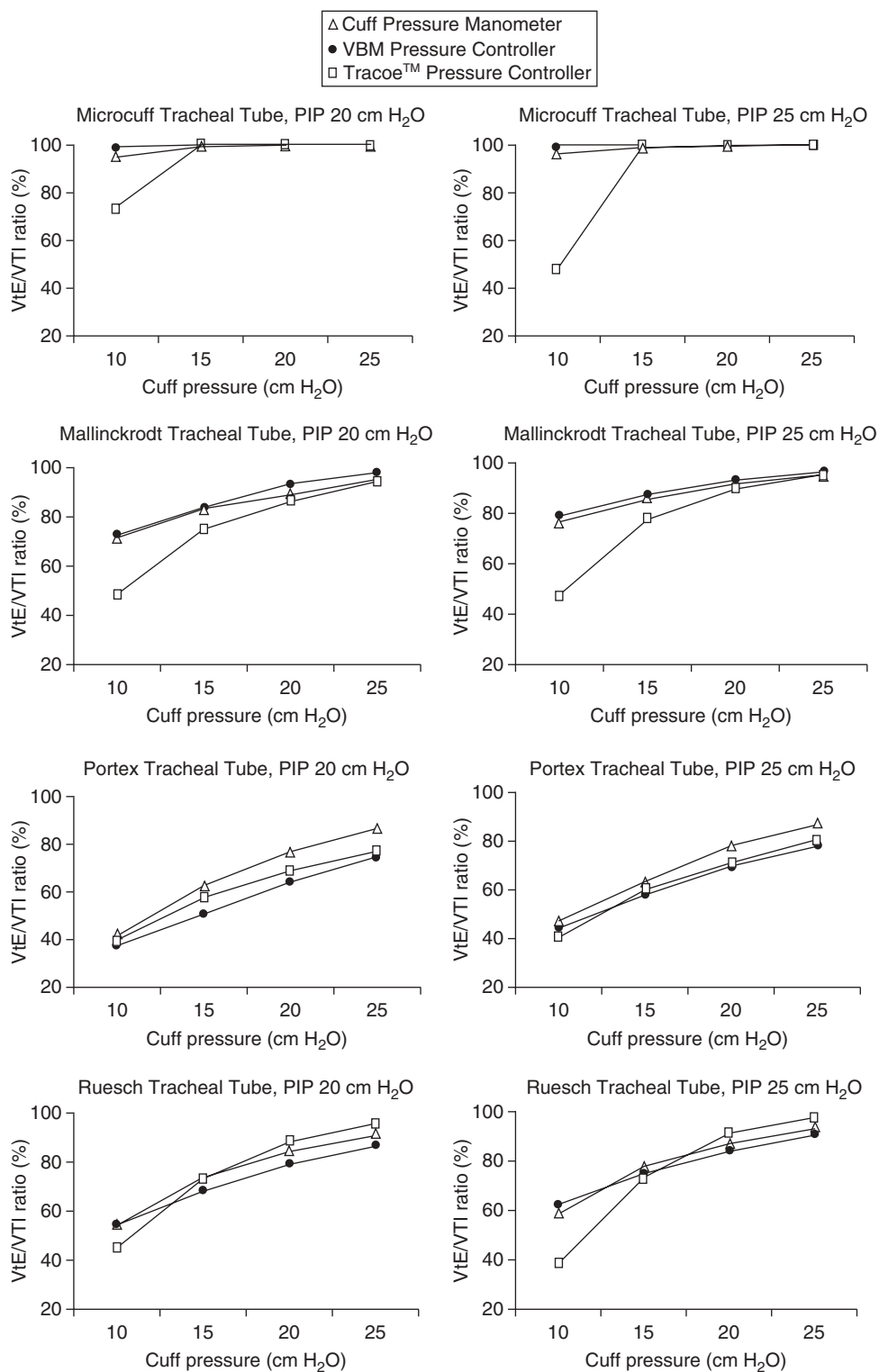


Fig 3 Mean ratio (%) of expiratory to inspiratory tidal volumes recorded with each of the three cuff pressure controllers and each of the four different ID 5.0 mm tracheal tube brands tested at cuff pressures of 10, 15, 20, and 25 cm H₂O and at peak inflation pressure of 20 and 25 cm H₂O ($n=16$ measurements per device, tracheal tube brand, cuff pressure and inspiratory peak pressure).

improved sealing characteristics, avoiding longitudinal channels and folds, have been developed in order to reduce VAP.^{17 19–22} In particular, the new ultrathin polyurethane cuffs not only reduce micro-aspiration,^{21 22} but also allow

tracheal sealing at cuff pressure much lower than inspiratory pressure by their self-inflating mechanism^{2–4} as confirmed by our investigation. Lower cuff pressures are very desirable in long-term ventilated patients in order to prevent cuff

pressure-related injury to the trachea, including tracheomalacia and tracheal dilatation. However, to date, there are no data, whether the cyclic decompression—associated with the self-inflation mechanism of high volume low pressure tracheal tube cuffs—has itself an impact on tracheal sealing, respectively on micro-aspiration of subglottic pooled secretions past the tube cuff.

On the basis of our *in vitro* findings, automatic cuff pressure regulators may interfere with the self-sealing mechanism of HVLP tube cuffs, as long as the set cuff pressures are lower than PIPs. This can be explained by the rapid compensations or even overcompensation (lower than set cuff pressure) of any elevated cuff pressures, such as in the Tracoe™ device. The implication of our findings is that in automated cuff pressure controllers, the cuff pressure set should be similar to PIP to avoid cyclic up- and down-regulation by these devices. An ideally designed automated cuff pressure controller should immediately stabilize any acute cuff pressure drops (sudden widening of the trachea before coughing) or chronic fall in cuff pressure (out diffusion of air from the cuff), whereas elevated cuff pressures by respiratory pressures or coughing should be corrected only by slow decompression.

However, two limitations of this study have to be mentioned. First, the *in vitro* testing of tracheal tube cuffs was performed in circular tracheas, which are different from the human d-shaped trachea and may affect tracheal sealing. Secondly, we did not lubricate the cuffs, mimicking the wet mucosal layer, in order not to eliminate small differences, which may become important over a longer time, since sealing by tracheal mucous is not a constant factor.

In conclusion, automated cuff pressure controllers with rapid correction of cuff pressure increases reduce the improved sealing characteristics of HLVP tube cuffs at cuff pressures lower than airway pressures. Development of pressure controllers with rapid correction of cuff pressure drops and delayed release of increased pressures is needed. Until then, cuff pressure should be set closely to PIP when using automated cuff pressure controllers.

Supplementary material

Supplementary material is available at *British Journal of Anaesthesia* online.

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