Intensive Care Med (2003) 29:1849–1853
DOI 10.1007/s00134-003-1933-6

TECHNICAL NOTE

Alexander Dullenkopf
Andreas Gerber
Markus Weiss

Fluid leakage past tracheal tube cuffs: evaluation of the new Microcuff endotracheal tube

Received: 12 March 2003
Accepted: 9 July 2003
Published online: 16 August 2003

This study was supported by Microcuff GmbH, Weinheim, Germany, by providing the Microcuff tubes without charge. No financial support was obtained from the manufacturer for the study. Dr. Weiss and Dr. Gerber serve on the Medical Board of Microcuff GmbH for the development of a newly designed pediatric cuffed tracheal tube.

A. Dullenkopf (✉) · A. Gerber · M. Weiss
Department of Anesthesia,
University Children's Hospital,
Steinwiesstrasse 75, 8032 Zurich,
Switzerland
e-mail: alex.dullenkopf@kispi.unizh.ch
Tel.: +41-1-2667111
Fax: +41-1-2667994

Abstract *Objective:* This study compared the recently introduced Microcuff endotracheal tube HVLP ICU featuring an ultrathin (7-μm) polyurethane cuff membrane with endotracheal tubes from different manufacturers regarding fluid leakage past the tube cuff. *Design:* In vitro setup. *Measurements and results:* The following endotracheal tubes (ID 7.5 mm) were compared: Mallinckrodt HiLo, Microcuff HVLP ICU, Portex Profile Soft Seal, Rüsch Super Safety Clear, and Sheridan CF. A vertical PVC trachea model (ID 20 mm) was intubated, and cuffs were inflated to 10, 15, 20, 25, 30, and 60 cmH_2O. Colored water (5 ml) was added to the top of the cuff. The amount of leaked fluid past the tube cuff within 5, 10, and 60 min was recorded. Experiments were performed four times using two examples of each tube brand. Fluid leakage past tube cuffs occurred in all conventional endotracheal tubes at cuff pressures from 10 to 60 cmH_2O. In the Microcuff tube cuff pressure fluid leakage was observed within 10 min only at 10 cmH_2O. Results with the Microcuff tube were significantly better than all other tube brands at cuff pressures of 10–30 cmH_2O. *Conclusions:* Within the acceptable upper limit for tracheal cuff pressure (25–30 cmH_2O) the Microcuff endotracheal tube was the only one of the tested tubes to prevent fluid leakage in our in vitro setup. In vivo studies are required to confirm these findings.

Keywords Cuff · Tube, tracheal · Leakage · Aspiration, fluid · Sealing, high volume · Low-pressure tracheal cuff

Introduction

Cuffed endotracheal tubes are intended to seal the trachea to enhance positive pressure ventilation and prevent aspiration of fluid and pharyngeal contents into the lower trachea [1]. Sealing often requires intracuff pressure (Pc) to exceed the safety margin of about 25–30 cmH_2O, produced by compromising mucosal blood flow with higher pressures [1, 2]. Therefore high-volume, low-pressure (HVLP) cuffs were introduced. Unfortunately, these have failed to demonstrate effective prevention of leakage in vitro and in vivo [3, 4, 5, 6, 7, 8, 9, 10]. The recently introduced Microcuff HVLP ICU endotracheal tube (Microcuff, Weinheim, Germany) features an ultrathin polyurethane cuff membrane designed to prevent longitudinal folds when inflated within the trachea. The goal of the present study was to compare the efficacy of the Microcuff tube cuff in preventing fluid leakage at different cuff pressures in an in vitro setup and with that of conventional endotracheal tubes from different manufacturers.

Materials and methods

Setup

In an in vitro setup we investigated the efficacy in preventing fluid leakage past the tube cuff of five commercially available endotra-

Table 1 Commercially available cuffed tracheal tubes (ID 7.5 mm) from five different manufacturers used for in vitro evaluation for prevention of fluid leakage around the tracheal tube cuff. Data presented as provided by the manufacturers

	Tracheal tube	Reference number	Manufacturer	Outer diameter (mm)	Cuff diameter at 20 cmH_2O (mm)	Cuff material	Cuff membrane thickness (µm)
A	Mallinckrodt HiLo	109-75	Mallinckrodt Medical, Athlone, Ireland	10.2	30	Polyvinylchloride	50[a]
B	Microcuff HVLP ICU	I-HMICU-75	Microcuff GmbH, Heidelberg, Germany	10	22	Polyurethane	7
C	Portex Profile Soft Seal	100/199/075	SIMS Portex Ltd., Hythe, UK	10.3	30	Polyvinylchloride	80
D	Rüschelit Super Safety Clear	112480	Rüsch GmbH, Kernen, Germany	10	26	Polyvinylchloride	Not provided
E	Sheridan CF	5-10115	Hudson Respiratory Care, Temecula, USA	10.2	24	Polyvinylchloride	65

[a] 5 µm membrane stated in the catalog; according the local distributor 50 µm is the correct value

Table 2 Amount of fluid (ml), presented as mean (range), which passed the unprepared tracheal tube cuff within 5, 10, and 60 min at cuff pressures of 10, 15, 20, 25, 30 and 60 cmH_2O. Tests at 60 min were discontinued if more than 90% (4.5 ml) of fluid leaked past the tracheal tube cuff, and results are given as >90%

	10 cmH_2O	15 cmH_2O	20 cmH_2O	25 cmH_2O	30 cmH_2O	60 cmH_2O
Mallinckrodt HiLo						
5	4.8* (4.7–4.8)	4.7* (4.6–4.8)	4.7* (4.6–4.8)	4.8* (4.7–5.0)	3.8* (1.2–4.8)	0.5 (0–1.2)
10	4.8* (4.8–4.9)	4.9* (4.8–4.9)	4.9* (4.8–4.9)	4.9* (4.8–5.0)	4.3* (2.5–4.9)	0.9 (0–2.0)
60	>90%	>90%*	>90%*	>90%*	>90%*	3.5* (0.6–>90%)
Microcuff HVLP ICU						
5	0.3 (0–1.0)	–	–	–	–	–
10	0.6 (0–1.9)	–	–	–	–	–
60	3.9 (2.5–4.8)	0.4 (0–1.0)	–	–	–	–
Porte Profile Soft Seal						
5	4.8* (4.7–5.0)	4.8* (4.8–4.9)	4.8* (4.7–4.9)	4.9* (4.8–5.0)	4.9* (4.8–5.0)	1.2 (0–2.6)
10	4.9* (4.8–5.0)	4.9* (4.7–4.9)	4.9* (4.8–5.0)	4.9* (4.8–5.0)	4.9* (4.8–5.0)	2.2* (0.2–>90%)
60	>90%	>90%*	>90%*	>90%*	>90%*	3.8* (0.3–>90%)
Rüschelit Super Safety Clear						
5	4.9* (4.8–5.0)	4.7* (4.6–4.8)	4.1* (2.5–4.9)	3.4* (0.3–4.8)	4.3* (2.6–4.8)	1.1 (0–2.4)
10	4.9* (4.8–5.0)	4.8* (4.7–4.9)	4.6* (3.7–5.0)	3.9* (1.1–4.9)	4.7* (4.4–4.9)	2.3* (0.1–4.0)
60	>90%	>90%*	>90%*	>90%*	>90%*	2.7
Sheridan CF						
5	4.9* (4.8–5.0)	4.8* (4.7–4.8)	4.8* (4.6–4.9)	4.8* (4.7–5.0)	4.8* (4.8–4.8)	4.7* (4.4–4.9)
10	4.9* (4.8–5.0)	4.8* (4.7–4.9)	4.8* (4.7–4.9)	4.9* (4.8–5.0)	4.8* (4.8–4.9)	4.9* (4.8–4.9)
60	>90%	>90%*	>90%*	>90%*	>90%*	>90%*

* $p<0.05$, conventional tracheal tubes vs. Microcuff tracheal tube (Mann-Whitney test, Bonferroni's correction)

cheal tubes (internal diameter, ID, 7.5 mm): the Mallinckrodt HiLo (tube A), the Microcuff HVLP ICU (tube B), the Portex Profile Soft Seal (tube C), the Rüsch Super Safety Clear (tube D), and the Sheridan CF (tube E; Table 1). Fluid leakage past the cuff was evaluated using a vertical polyvinylchloride (PVC) trachea (ID 20 mm, known to be in the range of an adult trachea [11]). The artificial trachea was intubated and the cuff inflated and controlled by cuff manometer (Mallinckrodt, Athlone, Ireland). Water (5 ml) colored with methylene blue was injected over 5 s to the top of the cuff. Fluid leaking past the cuff was collected in a container below the model.

Measurements

We assessed the time to first appearance of dye in the container within 10 min and the amount collected after 5, 10, and 60 min. Assessments at 60 min were discontinued if more than 90% of fluid had leaked past the cuff. Measurements were performed in randomized order at constant (±5%) cuff pressures of 10, 15, 20, 25, 30, and 60 cmH_2O. We did not assess settings between 30 and 60 cmH_2O because in clinical use we regard 25–30 cmH_2O to be the maximum. The level of 60 cmH_2O was chosen arbitrarily to determine whether sealing was obtainable at all. In a second step

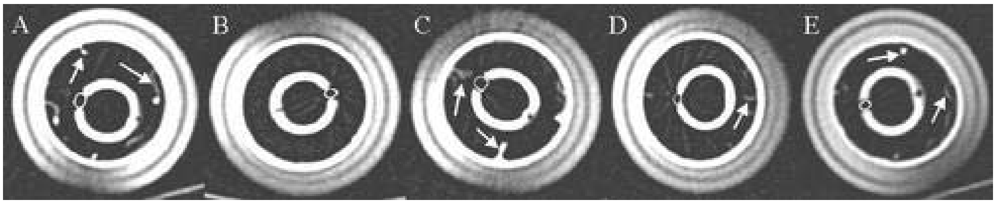

Fig. 1 Computed tomography of the tested tubes. **A** Mallinckrodt HiLo. **B** Microcuff HVLP ICU. **C** Portex Profile Soft Seal. **D** Rüsch Super Safety Clear. **E** Sheridan CF. Computed tomography (spiral CT, Picker PQ 5000, Philips, DA Best, The Netherlands) was performed after bathing the tube cuffs in contrast medium (Ultravist 300, Schering, Berlin Germany), inserting them into the horizontally placed artificial PVC trachea and inflating cuffs to a pressure of 20 cmH_2O. Scan level was set at the middle of cuffs. The high contrast circumference in these scans results from bathing the cuff in contrast medium and appears in all tubes. In contrast to the Microcuff tube, the conventional tubes show additional contrast enhancement within the cuff area due to occurring folds (*arrows*)

5- and 10- min experiments were repeated at cuff pressure of 30 cmH_2O with the cuff prepared with lubricant gel (KY, Johnson + Johnson Medical, Arlington, Va., USA). In addition, the Microcuff endotracheal tube was tested at cuff pressure of 10 cmH_2O after gel preparation.

Experiments were performed four times using two different endotracheal tubes from each manufacturer in randomized order. Tracheal tube cuffs were inflated and checked by inspection prior to each test. Between experiments the model was cleaned and dried. Measurements were performed at room temperature of 22–23°C.

Statistical analysis

The length of time to first drop of fluid into the container was recorded at each Pc level. The amount of fluid leakage after 5, 10, and 60 min from tubes A, and C–E were compared with corresponding values obtained from the Microcuff tracheal tube at each Pc level using Mann-Whitney test ($p<0.05$; Bonferroni's correction). In the same way the amount of leakage in unprepared tube cuffs was compared to lubricating gel prepared cuffs for every brand.

Computed tomography

Computed tomography (spiral-CT, Picker PQ 5000, Philips, DA Best, The Netherlands) was performed after bathing cuffs in contrast medium (Ultravist 300, Schering, Berlin, Germany), and inserting them into the horizontally placed PVC trachea. Scan level was set at the middle of cuffs.

Table 3 Amount of fluid (ml), presented as mean (range), which passed the tracheal tube cuff within 5 and 10 min at cuff pressure of 30 cmH_2O (and 10 cmH2O in the Microcuff tube cuff) with the tube cuff unprepared and prepared with lubrication gel

Cuff pressure 30 cmH_2O	Unprepared cuff	Gel
Mallinckrodt HiLo		
5	3.8 (1.2–4.8)*	0.6 (0–1.6)
10	4.3 (2.5–4.9)*	1.4 (0–3.2)
Microcuff HVLP		
5	0	0
10	0	0
Portex Profile Soft Seal		
5	4.9 (4.8–5.0)*	0.03 (0–0.1)**
10	4.9 (4.8–5.0)*	0.03 (0–0.1)**
Rüschelit Super Safety Clear		
5	4.3 (2.6–4.8)*	0.3 (0–0.7)**
10	4.7 (4.4–4.9)*	0.6 (0–2.0)**
Sheridan CF		
5	4.8 (4.8–4.8)*	4.5 (4.0–4.9)*
10	4.8 (4.8–4.9)*	4.8 (4.6–4.9)*
Cuff pressure 10 cmH_2O		
Microcuff HVLP		
5	0.3 (0–1.0)	0
10	0.6 (0–1.9)	0

* $p<0.05$, Mallinckrodt HiLo, Portex Profile Soft Seal, Rüschelit Super Safety Clear, and Sheridan CF vs. Microcuff, ** $p<0.05$, prepared vs. unprepared cuffs (Mann-Whitney test, Bonferroni's correction)

Results

There were considerable differences in tracheal sealing between the different tube brands. With unprepared cuffs fluid leakage occurred in all conventional tracheal tubes (A, C–E) at cuff pressures up to 60 cmH_2O, but in the Microcuff tube fluid leakage was observed only at Pc of 10 and 15 cmH_2O. Onset of leakage was within seconds with all conventional tubes at Pc level 10–20 cmH_2O, and within 1 min for all conventional tubes but one at cuff pressure up to 30 cmH_2O. No leakage was observed with the Microcuff tube within 10 min at cuff pressures of 15–60 cmH_2O. The amount of leakage after 5, 10, and 60 min for Pc of 15, 20, 25, and 30 cmH_2O was significantly higher with the conventional tubes than with the Microcuff tube (Table 2). At cuff pressures of 60 cmH_2O the observed difference to tubes A, C, and D was not statistically significant. Preparation of cuffs with lubricating gel resulted in improved sealing, but did not abolish leaking, at 30 cmH_2O cuff pressure with all conventional tubes except tube E. The observed improvement was statistically significant with tubes C and D. Gel preparation abolished leaking at 10 cmH_2O cuff pressure with the Microcuff tube (Table 3). Folds are clearly visible on CT of cuffs inflated in our trachea model to 20 cmH_2O (Fig. 1). The contrast circumference in these scans results from bathing the cuff in contrast medium.

Discussion

This study compared the ability of the recently introduced Microcuff HVLP ICU endotracheal tube cuff to prevent fluid leakage past the cuff and with that of four commonly used cuffed endotracheal tubes. The main finding in our in vitro setup was that the Microcuff tube was the only one of the tested tubes effectively to prevent fluid leakage within a range of cuff pressure accepted to be clinically safe.

Sealing of endotracheal tubes is required to prevent aspiration of fluid or particular matter into the lower trachea, which results in morbidity in intensive care patients and also occurs during anesthesia [1, 12]. Furthermore, air-proof sealing improves reliability of positive pressure ventilation, capnography, and assessment of end-tidal concentration of inhalation anesthetics [13]. Endotracheal tube cuffs tend to seal the trachea more tightly if inflated to higher pressure [3, 7, 8]. Cuff pressure exerts its effects on the tracheal mucosa. This is known to compromise tracheal blood flow, leading to injuries such as erosion, ulceration, tracheal stenosis, and tracheomalacia [2, 14]. The acceptable limit for cuff pressure is believed to be about 25–30 cmH_2O [1], a value much lower than that reported in usual practice [15].

HVLP cuffs were therefore introduced and have now become standard. Based on the principle of cuff diameter at 20 cmH_2O, corresponding to about 150% of tracheal diameter, these seal the trachea not primarily by pressure but by filling out the lumen. However, HVLP cuffs did not reliably prevent leakage in in vitro [3, 4, 6, 7, 8, 10] or in vivo [5, 9, 10, 11] studies. Leakage in HVLP cuffs occurs principally down longitudinal folds which form in the cuff membrane when inflated in the trachea [6, 7]. These folds are clearly visible on CT of cuffs inflated in our trachea model to 20 cmH_2O (Fig. 1). In contrast to the Microcuff tubes, the conventional tubes show contrast enhancement in the cuff area due to occurring folds. This unpredictable fold formation may be the reason for the high standard deviations in our results, indicating considerable unreliability and variability in the sealing characteristics despite stable laboratory conditions.

The Microcuff tube features a special cuff design consisting of an ultrathin (7 µm) polyurethane membrane, in contrast to conventional cuff membranes of about 50 µm thickness. Structure and design prevent fold formation when the cuff is inflated within the trachea. The Microcuff tube's results may have the following implications. First, fluid leakage and microaspirations into the lower trachea may be prevented more efficiently within a reasonable limit for cuff pressure. Second, the improved sealing characteristics of the ultrathin polyurethane membrane offers an interesting way to design effective but shorter HVLP cuffs, a critical issue when cuffed tracheal tubes are used in children [13].

Different authors have reported leakage of fluid in HVLP cuffs. In general the rate of leakage has been in the range of milliliters per second [7, 8]. Oikkonen and Aromaa [8] found no fluid leakage with the Mallinckrodt HiLo tube at a cuff pressure of 40 cmH_2O in an in vitro setup with the trachea model positioned at 45° to the horizontal and the study period limited to 5 min. The Portex Soft Seal was found to be more resistant to fluid leakage than other tubes in a setup with ventilation of a test lung, but leakage was in the range of 2–10 ml in 5 min with all tubes [3]. Preparing the endotracheal tube cuffs with lubricating gel significantly improved the sealing performance of most tubes in our study. This has also been reported previously [10] but is not established in clinical practice.

Several limitations to our study must be considered. First, we used a vertical in vitro setup. Sealing characteristics of tracheal tubes may be more advantageous when assessed at body temperature in a human trachea and the patient in supine position. In addition, pharyngeal contents and saliva may be more viscous than water, resulting in less leakage in vivo. Gel preparation can be rated as imitation of in vivo conditions, in which tracheal mucosal layer and mucus may improve sealing characteristics of tracheal cuffs. Second, we did not assess the effects of ventilation on the sealing performance of tracheal tube cuffs. It is possible that different experimental designs would have created more even comparisons.

In conclusion, our in vitro experiments show the recently introduced Microcuff tube cuff to be the only one of the tested HVLP endotracheal tube cuffs that effectively prevents fluid leakage around the tracheal tube when cuff pressure was set to 30 cmH_2O or less. Clinical studies including different tube sizes are needed to confirm these preliminary results.

Acknowledgements We thank Mrs. Stephanie Müller, RNA, Department of Radiology, University Children's Hospital Zurich, for her most helpful assistance in performing CT of the investigated tracheal tube cuffs.

References

1. Latto P (1997) The cuff. In: Latto IP, Vaughan RS (ed) Difficulties in tracheal intubation. Saunders, Philadelphia, pp 51–78
2. Seegobin RD, van Hasselt GL (1984) Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs. BMJ 288:965–968
3. Asai T, Shingu K (2001) Leakage of fluid around high-volume, low-pressure cuffs. Anaesthesia 56:38–42

4. Young PJ, Blunt MC (1999) Improving the shape and compliance characteristics of a high-volume, low-pressure cuff improves tracheal seal. Br J Anaesth 83:887–889
5. Young PJ, Basson C, Hamilton D, Ridley SA (1999) Prevention of tracheal aspiration using the pressure-limited tracheal tube cuff. Anaesthesia 54:559–563
6. Young PJ, Ridley SA, Downward G (1998) Evaluation of a new design of tracheal tube cuff to prevent leakage of fluid to the lungs. Br J Anaesth 80:796–799
7. Young PJ, Rollinson M, Downward G, Henderson S (1997) Leakage of fluid past the tracheal tube cuff in a benchtop model. Br J Anaesth 78:557–562
8. Oikkonen M, Aromaa U (1997) Leakage of fluid around low-pressure tracheal tube cuffs. Anaesthesia 52:567–569
9. Reali-Forster C, Kolobow T, Giacomini M, Hayashi T, Horiba K, Ferrans V (1996) New ultrathin-walled endotracheal tube with a novel laryngeal seal design: long-term evaluation in sheep. Anesthesiology 84:162–172
10. Blunt MC, Young PJ, Patil A, Haddock A (2001) Gel lubrication of the tracheal tube cuff reduces pulmonary aspiration. Anesthesiology 95:377–381
11. Metha S, Myat HM (1984) The cross sectional shape and circumference of the human trachea. Ann R Coll Surg Engl 66:356–358
12. Inglis TJJ, Sproat LJ, Sherrat MJ, Hawkey PM, Gibson JS, Shah MV (1992) Gastroduodenal dysfunction as a cause of gastric bacterial overgrowth in patients undergoing mechanical ventilation of the lungs. Br J Anaesth 68:499–502
13. Ho AM, Aun CS, Karmakar MK (2002) The margin of safety associated with the use of cuffed paediatric tracheal tubes. Anaesthesia 57:173–175
14. James I (2001) Cuffed tubes in children. Paediatr Anaesth 11:259–263
15. Satishkumar S, Young P (2002) Tracheal cuff pressure–a survey of clinical practice. Br J Anaesth 88:456