Evaluation of a new design of tracheal tube cuff to prevent leakage of fluid to the lungs

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Summary
A new design of tracheal tube cuff was compared with two types of high-volume, low-pressure (HVLP) cuffed tracheal tube for leakage of fluid from the subglottic space into the trachea. Spontaneous and positive-pressure ventilation were simulated using a mechanical lung, an intubated model trachea and a ventilator. Excised human tracheas were intubated and leakage past the cuff assessed. Distention of the tracheal wall was measured. HVLP cuffs leaked rapidly in the model during all modes of ventilation, and also in the excised human tracheas. This leakage occurred preferentially down longitudinal folds that occur in the HVLP cuff wall. The new design completely prevented leakage in the model during all modes of ventilation, during tracheal suctioning, and with tube movement. The new cuff also prevented leakage in the excised human tracheas. Tracheal wall distention and tracheal wall pressures were similar for all cuffs tested. (Br. J. Anaesth. 1998; 80: 796–799)

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A tracheal tube with a high-volume low-pressure (HVLP) cuff does not protect the lower airway from contamination by material leaking from the subglottis to the trachea below. Subclinical leakage of contaminated secretions around the cuff occurs in mechanically ventilated patients on the intensive care unit (ICU), causing tracheal colonization and increasing the risk of ventilator-associated pneumonia. Such leakage occurs in 100% of cases during anaesthesia, down longitudinal folds within the cuff wall. These folds generally occur in an HVLP cuff on inflation within the trachea, as the diameter of the cuff is greater than that of the trachea, and the intracuff pressure is equal to the tracheal wall pressure. Low-volume high-pressure (LVHP) cuffs provide complete protection against leakage but are unfortunately associated with high tracheal wall pressures that predispose to injury.

A new design of cuff that offers the protection against leakage provided by the LVHP cuffs, and the protection against excessive tracheal wall pressures that is provided by the HVLP cuffs, would be advantageous. Such protection against leakage could be achieved by designing the cuff so that no folds form in the cuff wall. We describe a new cuff made from latex with inflation characteristics that allow the tracheal wall pressure to remain constant.

We compared standard HVLP cuffed tracheal tubes with the new design of cuffed tube in a model and excised human tracheas, for leakage of fluid past the cuff into the trachea and for tracheal distention and pressure exerted on the model tracheal wall.

Materials and methods

NEW PRESSURE-LIMITED CUFF

Manufacture
The cuff is removed from a standard tracheal tube (Portex profile, 8 mm internal diameter). A hypoallergenic latex cuff is bonded, at stretch in line with the longitudinal axis of the tracheal tube, to the standard tracheal tube so that a new cuff is formed.

Physical characteristics of cuff (outside trachea)
As air is injected through the pilot valve, the cuff diameter increases and the intracuff pressure increases. The pressure–diameter relationship is critical to the function of the cuff. During manufacture the cuff is bonded to the tube at stretch so that the intracuff pressure stays nearly constant (forms a plateau) over the entire range of expected tracheal diameters (1.4–2.7 cm) was derived from published data of adult tracheal circumferences.

Physical characteristics of cuff (inside trachea)
When the cuff is inflated progressively inside a trachea of unknown diameter, the intracuff pressure increases quickly to its plateau while the volume continues to increase at constant pressure. The plateau
Pressure is approximately 65–70 cm H$_2$O using a cuff 4.5 cm long. Plateau pressure in this range has been consistently achieved in more than 40 pressure-limited tubes we have manufactured. During inflation the cuff wall will touch the tracheal wall, and the intracuff pressure will start to increase above the plateau pressure. The tracheal wall pressure will then increase at the same rate. The cuff inflation is limited to 30 cm H$_2$O above the plateau pressure (that is 95–100 cm H$_2$O using the 4.5 cm cuff). This provides a wall pressure of 30 cm H$_2$O at all tracheal diameters.

Figure 1  The relationship of intracuff pressure and cuff diameter for a pressure limited cuff (outside the trachea).

**VENTILATORY MODEL WITH MODEL TRACHEA**

_Lung/trachea model_

The model has been described previously and consists of an intubated model trachea ventilating a model lung (fig. 2).

**Experimental plan**

The artificial trachea was intubated in turn with full-length (32 cm), size 8 mm internal diameter tubes of three types: Portex profile, Mallinckrodt HiLo, or the new pressure-limited cuff. The intracuff pressure was set manually at 30 cm H$_2$O with a cuff inflator (Monitor control inflator, VBM, Medizintechnik) for the HVLP cuffs, and at 30 cm H$_2$O above the plateau for the new pressure-limited cuff.

The proximal tracheal tube was then connected to a Bird ventilator (6400ST volume ventilator). Three ml of water was instilled into the space above the cuff to represent the subglottic space and the trachea was observed for any leakage of the water.

**Modes evaluated**

Spontaneous ventilation was simulated by driving the model lung mechanically with the proximal tracheal tube disconnected. A tidal volume of 600 ml, a frequency of 12 breaths min$^{-1}$ and an I:E ratio of 1:2 was used. Intermittent positive pressure ventilation (IPPV) was simulated by ventilating the model lung through the trachea tube with a tidal volume of 600 ml, a frequency of 12 breaths min$^{-1}$ and an I:E ratio of 1:2. The compliance of the model lung was altered to achieve peak inflation pressures of 40 cm H$_2$O at the ventilator (10 cm H$_2$O higher than the cuff pressure).

Each ventilatory mode was tested over a 24-h period or until all of the 3 ml of water had leaked.

The effect of tracheal suctioning was also tested (using high-pressure suction from a hospital pipeline with a Clement’s adapter, which generated a maximum negative pressure of 400 mm Hg) with suction (through a 14CH catheter). The catheter was advanced to 5 cm beyond the tracheal tube tip, then withdrawn over a 6-s period under suction.

Tracheal tube movement was tested with 10 vertical 5-cm movements, and 10 rotations through 45 degree over a 5-min period.

**Cuffs tested**

A single sample of Portex profile, a Mallinckrodt HiLo and a new pressure-limited cuff were used, all
Excised human trachea

The tracheas from four human subjects within 72 h of death were dissected by a pathologist from larynx to carina (with the oesophagus left in place). The tracheas were suspended vertically and intubated with a Portex profile, 8 mm internal diameter, and then the pressure-limited cuff. The tracheas were intubated within 9 cm from the tube tip to the cords (the dark line on the Portex tube at the level of the cords).

The intracuff pressure was set at 30 cm H$_2$O manually with a cuff inflator for the HVLP cuffs, and 30 cm H$_2$O above plateau for the new pressure-limited cuff tube (95 cm H$_2$O).

The anteroposterior and lateral external diameters were measured with a caliper before and after cuff inflation, at the level of the cuff. Three ml of water were added above the cuff and observed for leakage.

WALL PRESSURE MEASUREMENT

The wall pressure was measured in two cylinders with internal diameters of 2.2 and 2.6 cm. The lateral pressure was measured by inflating the cuff within the cylinder to 130 cm H$_2$O (measured directly with a mercury column) and filling the cylinder above the cuff with water to 70 cm. The intracuff pressure was then reduced in a stepwise fashion until leakage began. When leakage had stopped, a second observer blind to the intracuff pressure used a mounted meter rule and set square to measure the height of fluid retained above the cuff.

The water column is thus used as a manometer. Hydraulic pressure exerts its effect in all directions equally. If the water column above the cuff exerts a pressure greater than the lateral pressure of the cuff on the cylinder wall, then water will leak through until the water column pressure and lateral pressure are equal.

STATISTICAL ANALYSIS

We used the Mood median test to examine differences in leakage past the cuff and linear regression analysis to examine the relationship between cuff and tracheal wall pressures. $P=0.05$ was considered significant. The statistical analysis was performed on an IBM-compatible computer using Minitab statistical software.

Results

VENTILATORY MODEL

In the model trachea both the Portex and Mallinckrodt HVLP cuffs allowed free leakage of fluid past the cuff. All 3 ml leaked past the cuff within 1 min with all ventilatory modes tested. This leakage was seen to occur along the folds in the cuff wall. There was no leakage when the new pressure-limited cuff was used during spontaneous ventilation, IPPV, tracheal suctioning and during movement of the tube in the model trachea (Chi-square = 60, df = 2, $P<0.001$). No leakage was observed with the pressure-limited cuff over the 24 tested for each ventilatory mode.

EXCISED HUMAN TRACHEA

There was no difference between the increase in tracheal wall anteroposterior or lateral external diameter between the Portex cuff and the pressure-limited cuff (2.4 mm and 1.9 mm increase respectively in anteroposterior diameter; 0.8 mm and 0.6 mm increase respectively in lateral external diameter) after inflation.

Leakage was seen with the HVLP cuff. All 3 ml of fluid leaked past the cuff within 1 min. There was no leakage observed over a 10-min period with the new pressure-limited cuff in the four tracheas studied (chi-square = 8, df = 1, $P<0.005$).

WALL PRESSURE RESULTS

The wall pressures maintained a linear relationship to intracuff pressure with a slope of 1.06 and an x axis intersection of 63.0 cm H$_2$O for the 2.2 cm diameter cylinder, and a slope of 1.15 and an x axis intersection of 65.7 cm H$_2$O for the 2.6 cm diameter cylinder (fig. 3).

Discussion

Leakage of fluid past tracheal tube cuffs has been recognized as a problem in anaesthesia with HVLP cuffs for more than 20 years. Leakage past the cuff is considered a major cause of ventilator-associated pneumonia (VAP) in the intensive care unit. In patients with previously healthy lungs ventilated in the intensive care unit, the lower respiratory tract often becomes colonized with bacteria. Several of these patients acquire VAP, which is caused by factors such as altered host defences, acquisition of pathogenic bacteria in the upper gastrointestinal and respiratory tracts, increased exposure of lung tissue to these bacteria, and impaired host clearance.

Adult intensive-care patients receiving mechanical ventilation have an incidence of VAP of 20–60% and a mortality reported at 27%. A tracheal tube that reduces or eliminates leakage from the pharynx to the lungs could have an important part to play in the reduction of VAP. A tube designed with a dorsal separate channel allowing
subglottic secretion drainage (Hi-Lo EVAC; Mallinckrodt) halved the incidence of VAP using both intermittent\(^{10}\) and continuous drainage.\(^{11}\) This method of drainage is likely to reduce but not prevent oropharyngeal secretions leaking into the lung. One would expect that complete prevention of leakage would lead to a further reduction in the incidence of VAP. Kolobow describes a “no-pressure” laryngeal seal design that uses a series of compliant gills rather than a cuff in an attempt to prevent leakage from subglottis to trachea and to minimize airway injury.\(^{12}\) This tube prevents the passage of oropharyngeal secretions to the lungs in sheep when methylene blue is placed in the oropharynx as a marker.\(^{13}\)

The slope of the wall pressure and intracuff pressure graph for the pressure-limited cuff tube is close to unity (fig. 3) and the x axis intersection is close to the plateau pressure of the cuff, that is 65–70 cm H\(_2\)O (fig. 1), indicating that in the cylinders tested tracheal wall pressure can be derived from intracuff pressure measurements. This plateau pressure varies minimally (within the range of 5 cm H\(_2\)O) over time and usage of the tube. Hence inflation of the cuff to a predetermined pressure should generate a wall pressure that is within the acceptable range.

The pressure-limited cuff tube has the advantage of being cheap and simple to manufacture from materials used commonly in anaesthetic and surgical practice, and its function in the benchtop models is excellent. The glove material is biocompatible (EN30993 Part 1). The pressure-limited cuff tube will require further validation in human studies, and a pilot study of the cuff is underway on our intensive care unit to compare the new cuff and an HVLP cuff with respect to tracheal colonization and ventilator-associated pneumonia. The present study introduces a new concept in the design of a tracheal tube cuff, in an attempt to prevent the soiling of the trachea in patients whose lungs are ventilated. For this new tube to be of use clinically, it is necessary that the cuff remains inflated above its plateau pressure at all times.

References