

Improving the shape and compliance characteristics of a high-volume, low-pressure cuff improves tracheal seal

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A prototype design of a compliant latex, high-volume, low-pressure cuffed tracheal tube cuff (CHVLP) was compared with the Mallinckrodt Hi-Lo, Sheridan preformed and Portex Profile high-volume, low-pressure (HVLP) cuffed tracheal tubes for leakage of dye placed above the cuff in a benchtop mechanical ventilation model and in five isolated pig tracheas. There was no leakage in the ventilation model or in the pig tracheas with the prototype CHVLP. There was rapid leakage in the ventilation model and in all the pig tracheas for the Mallinckrodt Hi-Lo, the Sheridan preformed and the Portex Profile cuffs. This benchtop study suggests that improved HVLP cuff compliance characteristics may be beneficial in the prevention of leakage of fluid to the lungs known to occur with HVLP cuffs.

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Subclinical leakage of oropharyngeal secretions past tracheal cuffs to the lungs in patients undergoing mechanical ventilation in the intensive care unit (ICU) is a leading cause of tracheal colonization and ventilator-associated pneumonia.¹

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.^{2–3} This leakage occurs down longitudinal folds within the cuff wall.^{3–4} These folds occur in a HVLP cuff on inflation within the trachea, as the diameter of the cuff must be greater than that of the trachea for the intracuff pressure to be equal to tracheal wall pressure.

We manufactured a prototype of a HVLP cuff with a smooth tapering shape of compliant latex, in an attempt to eliminate the folds circumferentially for a portion of the cuff. In this study, we have compared the prototype HVLP cuff with three standard HVLP cuffed tracheal tubes for leakage of dye past the cuff in a benchtop model of mechanical ventilation and in isolated pig tracheas with dimensions across the human tracheal range.

Methods

Manufacture of compliant HVLP cuffed tube

A mould was made from a steel bar and polished to produce a smooth surface (Department of Medical Physics, Christchurch Hospital, New Zealand). The maximum

dimension in the middle was 2.3 cm and this tapered to a minimum of 1.1 cm at each end (Fig. 1). These values were chosen as an estimate to span the human tracheal range expected for an 8-mm internal diameter (id) tracheal tube.⁵ The mould was dipped in natural latex (Batavian Rubber Company, New Zealand), producing a prototype cuff suitable for *in vitro* testing. The cuff produced was 5 cm long and approximately 0.2 mm thick (Micrometer screw gauge). The cuff was bonded using tissue glue (Histacryl, Braun) to a size 8 Portex Profile tube with the cuff removed and tested for strength in a mechanical ventilation model described previously⁴ for a 24-h period. No problems were encountered.

Pig trachea static model

Five pig tracheas (9 cm in length) were obtained within 24 h of slaughter and were chosen to span the range for the human trachea for which a size 8 mm id tube would be used. The range for human tracheal diameter calculated from a postmortem study⁵ was 1.4–2.7 cm and the mean diameter of a female trachea was 1.84 cm. We felt that it would be reasonable to take 1.4–2.2 cm as an estimate for tracheal size appropriate for a size 8 mm id tube (i.e. smaller adults are often intubated with an 8-mm id tube and large adults with a size 9 mm id tube). A 2.0-cm diameter rigid cylinder (20-ml syringe barrel, Plastipak) was also used.

The cylinder and all tracheas were suspended vertically and intubated sequentially by one of the investigators, so that

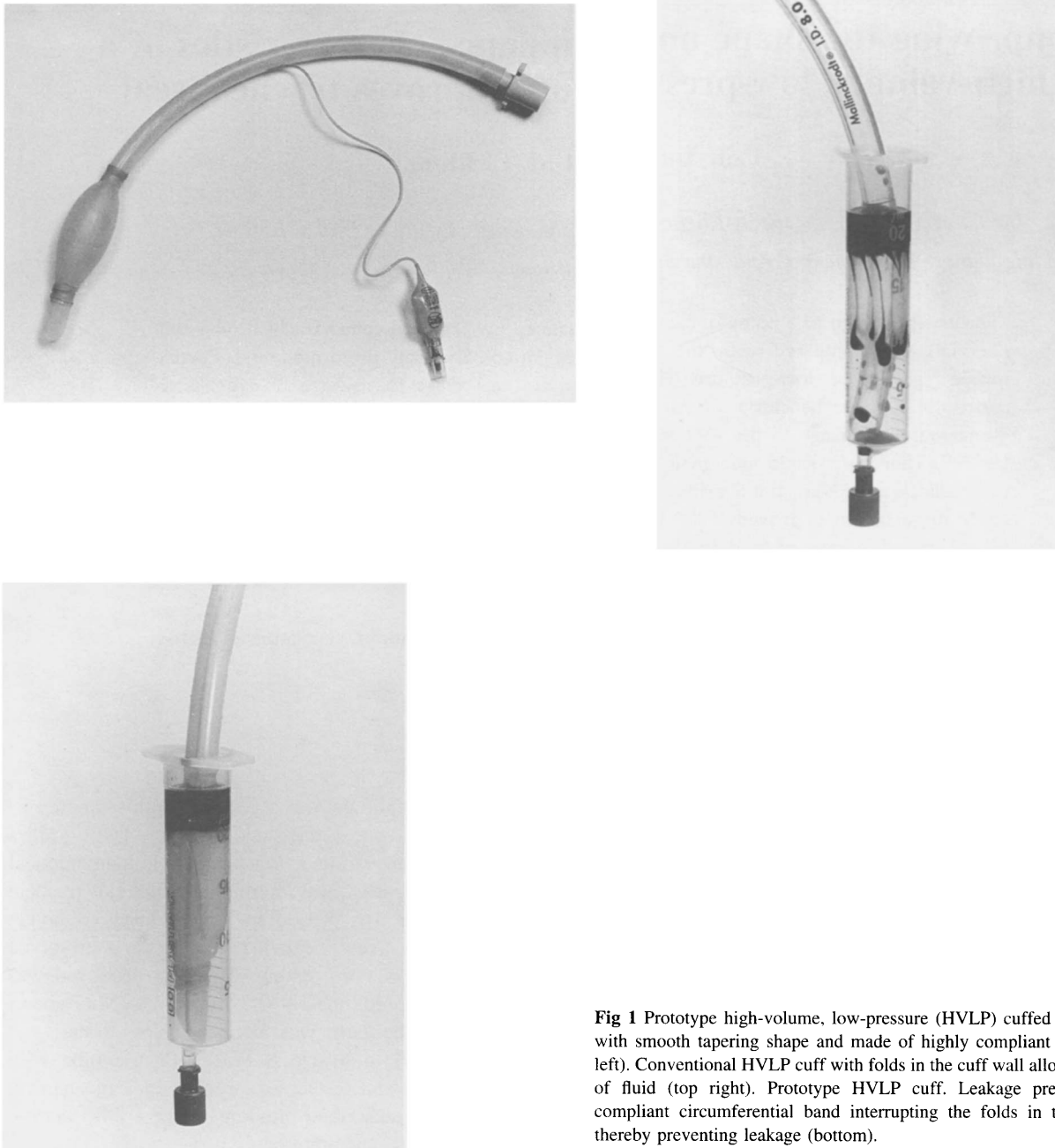


Fig 1 Prototype high-volume, low-pressure (HVLP) cuffed tracheal tube with smooth tapering shape and made of highly compliant material (top left). Conventional HVLP cuff with folds in the cuff wall allowing leakage of fluid (top right). Prototype HVLP cuff. Leakage prevented by a compliant circumferential band interrupting the folds in the cuff wall thereby preventing leakage (bottom).

the cuff centre was 4 cm below the upper tracheal edge, in a random order (closed envelope technique). Cuff pressure was set at 30 cm H₂O with a commercial cuff inflator (Portex, UK). The cuff inflator had been checked against a mercury column to confirm accuracy. The tube was hidden so that the observer was blinded to the tube type used. Blue-dyed water 3.5 ml was placed above the cuff and a stopwatch started. This volume was chosen as the intubated subglottic space had been measured at 3.6 ± 2 ml⁶ and this results in a 1.5–2.5 cm H₂O head of pressure above the upper edge of the cuff, depending on tracheal diameter. The observer stopped the watch when dye was first observed to drip from the trachea. After 15 min, if no dye had leaked, this was recorded as no leak.

Lung–trachea dynamic model

The patient model consisted of a model lung described previously⁴ (Fig. 2) but modified so that instead of a silicone trachea, a 9-cm section of pig trachea (anteroposterior diameter 1.6 cm, lateral diameter 1.85 cm measured with a calliper) was used. The pig trachea was secured by inserting the tubing 2 cm into the lower end of the tracheal lumen and binding it tightly with circumferential elastic bands. The trachea lay at 60° to the horizontal.

The trachea was intubated in random order and the centre of the cuff lay 3.5 cm below the upper end of the tracheal segment. The proximal tracheal tube was connected to a Nuffield Penlon ventilator and a Bain breathing system. The ventilator inspiratory time was set at 2 s and expiratory

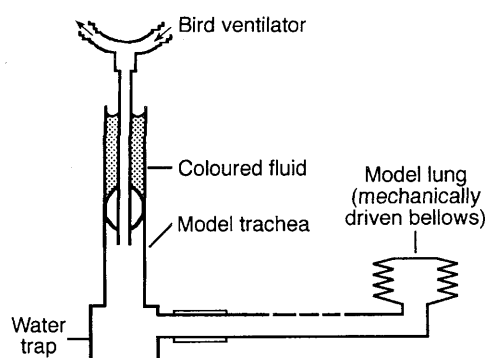


Fig 2 Mechanical ventilation model.

Table 1 Time to leak (s) for the tracheal tube cuffs

Cuff type	Rigid cylinder	Pig trachea (mean (range))	Ventilation model
Portex Profile	3	38 (12–75)	15
Mallinckrodt Hi-Lo	4	15 (12–29)	19
Sheridan preformed	4	17 (15–32)	16
Prototype CHVLP	No leak	No leak	No leak

time at 4 s. Inspiratory flow rate was set at 0.375 litre s⁻¹ and the compliance of the lung was adjusted to cause a peak inspiratory pressure of 20 cm H₂O.

Blue-dyed water 3.5 ml was instilled above the cuff by one investigator and an observer blinded to the tube type observed the lower trachea for leakage for 15 min.

Conventional HVLP tubes

A size 8-mm id Portex Profile, Mallinckrodt Hi-Lo and Sheridan preformed tubes were used as control tubes.

Results

The five tracheas in the static model had a mean lateral diameter of 1.62 (range 1.4–1.85) cm and an anteroposterior diameter of 1.65 (1.5–1.9) cm.

There was no leakage in the ventilation model, the rigid cylinder or in the pig tracheas with the prototype CHVLP group. There was rapid leakage in the ventilation model, the rigid cylinder and in all of the pig tracheas for the Mallinckrodt Hi-Lo, the Sheridan preformed and the Portex Profile cuffs (Table 1). This difference was statistically significant ($P < 0.05$, Fisher's exact test).

Discussion

Leakage past the tracheal tube cuff is now regarded as a major cause of ventilator-associated pneumonia in the intensive care unit.¹ Acquisition of ventilator-associated pneumonia involves several factors including altered host defences, colonization with pathogenic bacteria in the upper gastrointestinal and respiratory tracts, increased exposure of lung tissue to these bacteria and impaired host clearance.⁷

Adult intensive care patients undergoing mechanical ventilation have an incidence of ventilator-associated pneumonia of 20–60% and an attributable mortality reported at 27%.⁸ A tube that eliminates leakage from the pharynx to the lungs could have an important role in improving the safety of mechanical ventilation. We studied one size of tracheal tube (size 8 mm id) to demonstrate the principle of the protective effect against leakage afforded by the combination of improved cuff compliance and shape. We tested the tube in pig tracheas of diameters that spanned the range expected in the patient population in which this tube would be used commonly. It is not clear from this study if a single larger diameter tapering compliant cuff would be suitable for preventing aspiration at the higher and lower range of tracheal diameters or if different diameter cuffs will be required for size 9 and size 7 mm id tubes. Our prototype cuff was made of natural latex which is clearly unsuitable for *in vivo* use. Consideration of the use of hypoallergenic latex or preferably a compliant synthetic material of low allergenicity and toxicity, such as silicone, may be appropriate for clinical use.

Our study showed that the CHVLP tracheal tube cuff effectively prevented leakage of subglottic fluid to the lungs in the isolated pig trachea. Tracheal and tracheostomy tube manufacturers should reconsider the shape and compliance characteristics of cuffs to limit or prevent aspiration that is causative in the development of ventilator-associated pneumonia.

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