

Gel Lubrication of the Tracheal Tube Cuff Reduces Pulmonary Aspiration

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Background: Leakage of fluid occurs along the longitudinal folds within the wall of an inflated high-volume, low-pressure cuff. Theoretically, lubrication of the cuff with a water-soluble gel might prevent aspiration by plugging the channels in the cuff wall. Pulmonary aspiration during anesthesia has been linked with postoperative pneumonia and during critical illness causes ventilator-associated pneumonia.

Methods: Lubricated cuffs were compared with nonlubricated cuffs for leakage of dye placed in the subglottic space to the tracheobronchial tree in a benchtop model (n = 5) and in a prospective double-blinded randomized controlled trial of anesthetized patients (n = 36). The duration of the efficacy of the lubricant was determined in a prospective open observational study of critically ill patients with tracheostomies (n = 9). Dye was detected clinically by dye coloration of secretions during tracheal suctioning.

Results: In the benchtop model the incidence of leakage was 0% in the lubrication group and 100% in the nonlubrication group ($P < 0.01$). Dye leakage in anesthetized patients was 11% in the lubrication group and 83% in the nonlubrication group ($P < 0.0001$). In the critically ill patients with lubricated cuffed tracheostomy tubes, leakage first occurred after a median period of 48 h (range, 24–120 h).

Conclusions: Cuff lubrication with a water-soluble gel reduces pulmonary aspiration in anesthetized patients. In the critically ill patient with a tracheostomy the protective effect is lost after 24–120 h.

REGURGITATION and pulmonary aspiration are infrequently recognized during anesthesia.¹ The exact incidence of aspiration during anesthesia is unknown, but it is clear that high-volume, low-pressure (HVLP) endotracheal tube cuffs do not reliably prevent subglottic fluid from passing to the tracheobronchial tree.²⁻⁴ Postoperative pneumonia has been linked to microaspiration of pathogens originating in the gastrointestinal tract.⁵ In pediatric intensive care patients with pH probes located in the esophagus and the trachea, esophageal reflux was noted in 40% and tracheal aspiration in 20%. The tracheal aspiration occurred whether the tube was cuffed or uncuffed.⁶ Leakage of contaminated oropharyngeal secretions occurs past endotracheal tube cuffs in critically ill, mechanically ventilated patients. This is the leading cause of tracheobronchial colonization and ven-

tilator-associated pneumonia.⁷ This leakage occurs down longitudinal channels caused by folds in the cuff wall material.^{2,4} These folds always occur in an HVLP cuff inflated within a trachea because the diameter of the cuff must be greater than that of the trachea for the intracuff pressure to be equal to the tracheal wall pressure.

Seegobin *et al.*² suggested that cuff lubrication with a gel may reduce aspiration by filling and effectively damping the channels within the cuff wall. The current study compares lubricated cuffs (using a water-soluble gel) with nonlubricated cuffs in a benchtop model in anesthetized patients and in critically ill patients with tracheostomies.

Materials and Methods

Benchtop Model

Rigid Cylinder Model. A 2-cm-diameter rigid cylinder (20-ml syringe barrel, Plastipak; Becton Dickinson SA, Madrid, Spain) was intubated with lubricated and nonlubricated Portex Profile (SIMS Portex Ltd., Hythe, United Kingdom) tracheostomy tubes (8-mm ID), and the cuff was inflated to 30 cm H₂O. Dye was placed above the cuff and photographed to demonstrate the mechanism of leakage.

Static Pig Trachea Model. Nine-centimeter lengths of five pig tracheas within 24 h of slaughter were chosen to span the range for the human as calculated from a post-mortem study (1.4–2.7 cm).⁸ The tracheas were suspended vertically and sequentially intubated by one of the investigators so that the cuff center was 4 cm below the upper tracheal edge. Each trachea received a lubricated and a nonlubricated cuffed tracheal tube (8-mm ID, Portex Profile) in a random order (closed-envelope technique). The cuff pressure was set at 30 cm H₂O with a commercial cuff inflator (SIMS Portex Ltd.). This had previously been checked against a mercury column to confirm accuracy. The observer was blinded as to whether or not the cuff was lubricated. Blue dyed water (3.5 ml) was placed above the cuff. If, after 15 min, dye had leaked to the trachea, this was recorded as leak; if not, this was recorded as no leak.

Tracheal Sizes. The range of mean tracheal diameters was 1.4–2.5 cm.

Cuff Leakage with Anesthetized Patients

Ethical Considerations. After local ethical committee approval (King's Lynn and Wisbech National Health Service Trust Ethics Committee, Queen Elizabeth Hospital, King's Lynn, Norfolk, United Kingdom), informed

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consent was obtained from patients requiring orotracheal intubation as part of their anesthetic care.

Tube Modifications. The 8-mm-ID Portex Profile endotracheal tubes had a fine catheter (16-gauge epidural catheter, SIMS Portex Ltd.) glued with N-butylcyanoacrylate (Histacryl Blue; Melsungen AG, Melsungen, Germany) above the cuff to enable the instillation of dye into the subglottic space. The proximal tubes and cuff inflation ports were identical after intubation, whether or not the cuff was lubricated, thus enabling observer blinding.

Study Design. We performed a prospective, double-blinded, randomized, single-center study. A closed-envelope technique was used to allocate patients randomly to receive either lubrication of the cuff with KY gel (Johnson & Johnson, Sezanne, France) or a nonlubricated cuff.

Patients. Study patients (American Society of Anesthesiologists physical status I or II) were admitted to a day-case unit. They were between 18 and 57 yr of age, and their height varied between 153 and 188 cm. The demographic characteristics of the two groups were similar, with mean ages of 32 (SD = 10) and 31 (SD = 10) yr and heights of 168 (SD = 8.1) and 171 (SD = 7.4) cm for the lubrication and nonlubrication groups, respectively. In the lubrication group there were 11 women and 7 men, and in the nonlubrication group, 10 women and 8 men. Exclusion criteria included age less than 18 yr, pregnancy, and asthma or known food dye allergy. All patients underwent extraction of wisdom teeth.

Anesthetic Technique. All patients were treated with a standard anesthetic technique. The patients were not premedicated; a 20-gauge catheter was placed in a forearm or hand vein for drug and fluid administration. Induction of general anesthesia was performed with 2 $\mu\text{g}/\text{kg}$ fentanyl, 3–4 mg/kg propofol, and 0.1 mg/kg mivacurium to facilitate tracheal intubation with an 8-mm-ID Portex Profile cuffed endotracheal tube. Spontaneous ventilation anesthesia was maintained using isoflurane (2–4%). Continuous positive airway pressure was not used at any stage.

Randomization, lubrication, and intubation were performed by one of the investigators, and a second investigator remained blinded to this. The study group had gel applied to the cuff. Five milliliters KY gel was applied to a 7.5 \times 7.5-cm, 12-ply gauze swab (Propax, Smith and Nephew Medical Fibres, Brierfield, United Kingdom). The swab was used to coat the cuff liberally with gel. After intubation of the trachea, the cuff was inflated to 30 cm H₂O and maintained at this level with a constant-pressure inflation device (see Constant Cuff Pressure Inflator). Half a milliliter E122 blue food dye was diluted to an amount of 3.5 ml with normal saline and instilled into the subglottic space. After surgery, anesthesia was continued with the patient in a 30° head-up position. Ten minutes later, the blinded investigator performed tracheal suctioning through a 14-French catheter, using a

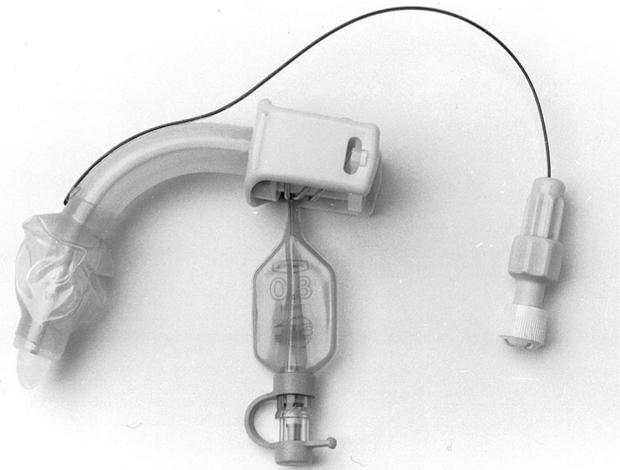


Fig. 1. Tracheostomy tube cuff modified by the addition of a subglottic catheter.

Clement adaptor capable of generating a maximum pressure of -400 mmHg. If the blue dye was noted in the catheter (viewed against a white background) by the blinded investigator, the cuff was deemed to have leaked. The subglottis and oropharynx were emptied before extubation.

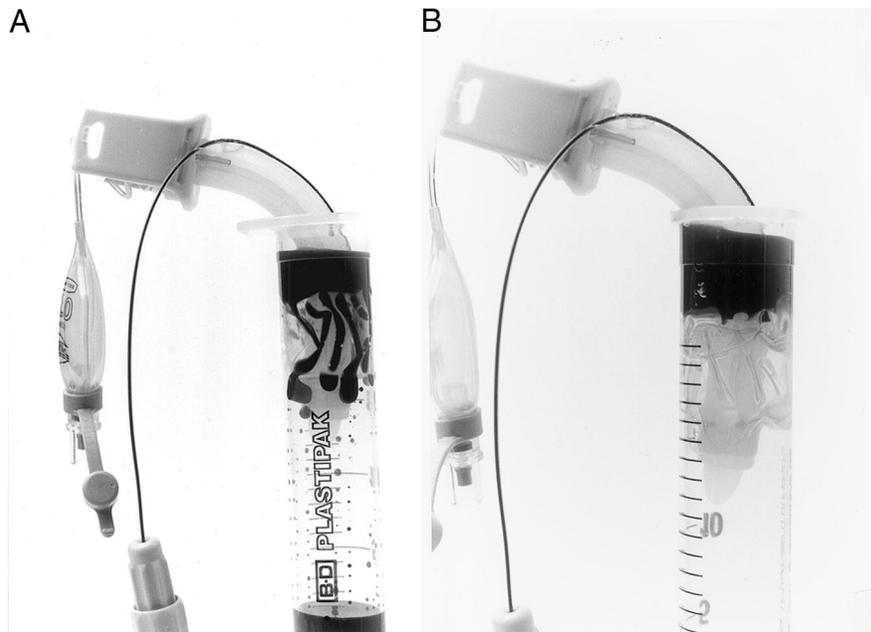
Constant Cuff Pressure Inflator. The intracuff pressure was maintained at 30 cm H₂O throughout the study period with a constant-pressure inflation device. This device consisted of a pneumatic constant-pressure generator with integral pressure gauge (PressurePAC; SIMS PneuPAC Ltd., Luton, United Kingdom) that was linked in series with a three-way tap, a one-way valve (R-Lock; Codan, Lensahn, Germany), and a length of fine-bore tubing (manometer tubing, 1.5-mm ID; Vygon, Ecouen, France) running adjacent to the ventilator tubing. This was attached to the inflation port of the cuffs. The calibration of the pressure generator gauge was verified against a mercury column. The three-way tap was used to check intracuff pressure with a second pressure gauge (Cuff inflator, SIMS Portex Ltd.).

Critically Ill Patients with Tracheostomies

Ethical Considerations. After local ethical committee approval (King's Lynn and Wisbech National Health Service Trust Ethics Committee), informed assent was obtained from the next of kin of patients requiring a percutaneous tracheostomy as part of their critical care.

Tube Modifications. The tracheostomy tubes had a fine catheter (16-gauge epidural catheter, SIMS Portex Ltd.) glued (Histacryl) above the cuff to enable the instillation of dye into the subglottic space (fig. 1).

Fig. 2. (A) Nonlubricated tracheostomy tube high-volume, low-pressure cuff inflated to 30 cm H₂O in a rigid cylinder. Leakage occurs along channels in the cuff wall. (B) Lubricated tracheostomy tube high-volume, low-pressure cuff inflated to 30 cm H₂O in a rigid cylinder. The figure shows prevention of leakage because channels in the cuff wall are blocked by the gel.



Study Design. This was a prospective open observational study. Nine critically ill patients who required a tracheostomy were recruited. All the study patients were given an 8-mm-ID Portex Profile cuffed tracheostomy tube at percutaneous tracheostomy by the Griggs technique. The cuff was lubricated with KY jelly, inflated to 30 cm H₂O (2.9 kPa) and maintained at this pressure by intermittent checks before dye instillation and every 8 h using a cuff inflator (SIMS Portex Ltd.). Half a milliliter E122 blue food dye followed by 3 ml saline was instilled daily through the catheter into the subglottic space. The nurse responsible for the patient was instructed to report dye obtained from tracheal aspirates (performed after instillation and at least every 4 h thereafter). Tracheobronchial aspiration was deemed to have occurred if dye was retrieved from the trachea.

Statistical Analysis

Power Analysis for Anesthetized Patient Study. In a previous study of intensive care unit patients with Portex Profile cuffs Young *et al.*³ showed an 87% aspiration rate, and in anesthetized patients with nonlubricated cuffs Seegobin and Van Hasselt² showed an aspiration rate of 100% of subglottic dye detected by bronchoscopy. We expected that the aspiration rate we would detect with tracheal aspirates might be approximately 85%. We thought a clinically important reduction would be a reduction of 50%. With an α value of 0.05 and a β value of 0.2, 18 patients would be required in each group.

Statistical Analysis. For the benchtop study, a 2×2 table was constructed and the data were analyzed using the Fisher exact test. For anesthetized patients, a 2×2 table was constructed and the data were analyzed using the Fisher exact test. For critically ill patients, because

this part of the study was purely observational, no statistical test was applied.

Results

Benchtop Studies

In the rigid cylinder, the nonlubricated cuff permitted leakage but the lubricated cuff did not (figs. 2A and B). All five of the nonlubricated cuffs leaked, and none of the lubricated cuffs leaked in the pig tracheal model (0 vs. 100%, $P < 0.01$).

Anesthetized Patient Study

There were 18 patients in each group. Eleven percent of the lubricated cuffs leaked, and 83% of the nonlubricated cuffs leaked ($P < 0.0001$).

Critically Ill Patients with Tracheostomies

The lubricated tracheostomy tube cuffs leaked after a median period of 48 h (range, 24–120 h).

Discussion

The prevention of aspiration in tracheally intubated anesthetized patients is important to prevent rare, clinically apparent aspirations⁴ and more commonly unrecognized aspiration.⁶ The exact incidence and morbidity of silent or unrecognized aspiration during anesthesia is unknown. Clinically apparent aspiration past adequately inflated HVLP endotracheal tube cuffs was reported as early as 1975.⁴ Seegobin and Van Hasselt² studied 30 anesthetized patients and bronchoscopically sought for leakage of dye from the subglottic space past the nonlubricated cuff to the tracheobronchial tree. Fifteen

patients had one of three different HVLP cuffs at appropriate intracuff pressures, and 15 had red rubber low-volume, high-pressure (LVHP) cuffs inflated to produce a clinically recognizable seal. Dye was seen to leak along the longitudinal folds that occurred in the walls of the HVLP cuffs resulting in a 100% aspiration rate. Furthermore, it was noted that an adequately inflated LVHP cuff prevented leakage completely (although tracheal wall pressure could not be reliably controlled). Postoperative pneumonia has been linked to microaspiration of pathogens originating in the gastrointestinal tract.⁵ The sputum of 28% of postoperative patients with nasogastric tubes became colonized with gastric pathogens, and these patients had a 40% incidence of postoperative pneumonia compared with 12% for patients without evidence of microaspiration. It is clear that both clinically apparent and more commonly unrecognized aspiration occurs in the intubated critically ill adult.

The incidence of aspiration in tracheal intubation has been found to range from 0 to 100%.⁹⁻¹¹ These diverse results can be explained by the cuff type used, the patient group studied, the mode of respiratory support, the quantity and frequency of application of the dye, the type of dye used, the method used for dye detection (*i.e.*, tracheal aspirate or bronchoscopy), the patient position, and the site of application of dye. Dye placed in oropharynx must pass the laryngeal inlet and the cuff to produce a positive test result, whereas dye in the stomach or enteral feed must be regurgitated and pass the laryngeal inlet. When dye is placed on the tongue, detected aspiration rates have varied widely (0-77%).^{9,11-16} With dye placed in the stomach no aspiration was detected,¹⁰ whereas dye placed in the subglottic space has shown aspiration rates of 31,¹⁷ 87,³ and 100%.² Notably, Petring *et al.*¹⁷ had a lower incidence of aspiration (31%), possibly because of the application of cuff lubrication with lignocaine spray (the consistency of which was not reported) before intubation. In fact, Young *et al.*³ had a 100% aspiration rate when a patient requiring excessive intracuff pressure (60 cm H₂O) for air seal was excluded. The dye test used in the current study has previously been shown to be a sensitive predictor of subglottic to tracheal fluid leakage.³ Specificity is also likely to be high because dye does not appear in the tracheal aspirates unless it has traversed the cuff. There are risks associated with dye placement. In addition to possible allergy, blue food dye contaminated with *Pseudomonas* species that was added to enteral feed has been implicated in an outbreak of ventilator-associated pneumonia in an intensive care unit.¹⁸ Maloney *et al.*¹⁹ have reported two deaths that might have been related to the addition of large quantities of blue food dye to enteral feed in critically ill patients. The authors postulated that the refractory hypotension and metabolic acidosis in these patients were caused by the inhibition of mitochondrial oxidative phosphorylation and the subsequent reduction

in oxygen consumption that is known to occur *in vitro* with this food dye. A much larger quantity of food dye is used during the coloring of enteral feed than was used in the current study.¹⁹

Gel lubrication of the endotracheal tube cuff has been used to facilitate the passage of the tube through the oropharynx²⁰ and to reduce the incidence of sore throat.²¹ There are no previous studies in the literature to demonstrate the protective effect of cuff lubrication against pulmonary aspiration, although Seegobin and Van Hasselt² suggested that cuff lubrication might have a protective effect.

In the anesthetized patient study, all patients received 8-mm-ID (HVLP) cuffed endotracheal tubes and two lubricated cuffs leaked, giving an 11% incidence of leakage. Fifteen nonlubricated cuffs leaked, giving an 83% incidence of leakage ($P < 0.0001$).

From previous work, it is known that the size of the human tracheal diameter varies from 1.4 to 2.7 cm.^{8,22-24} High-volume, low-pressure cuffs have diameters ranging from 1.5 to 2 times the diameter of the average human trachea. Thus, they necessarily develop folds in the cuff when placed in the trachea and inflated to achieve clinical seal.

It is not clear why there were two episodes of leakage with lubricated cuffs in the anesthetized patient study. These occurred in female patients. The cross-sectional tracheal shape distribution differs between the sexes,⁸ as does the tracheal diameter.²⁴ Women have a higher prevalence of elliptical and C-shaped tracheas and a smaller mean tracheal diameter than men.

We hypothesized that the two lubricated cuffs that leaked could be attributed to either the smaller tracheal diameters of these patients (causing more extensive cuff wall folding) or the persistence of lateral channels not occupied by cuff material on either side of an elliptical trachea.

There were three nonlubricated cuffs that did not leak in these patients (two women and one man). In a large trachea a good circumferential seal without any folds can occur, thus preventing dye leakage.³ However, the female tracheas would be unlikely to have diameters greater than 2.0 cm,²⁴ and it is possible that these results are false-negative results because the sensitivity of the dye detection test is unlikely to be 100%.

The precise quantity of gel on the cuff was unknown because, although 5 ml was applied, some gel remained on the swab and some dripped off the cuff. We ensured that each cuff was well lubricated.

Patients were allowed to breathe spontaneously. It is known that negative inspiratory pressure promotes leakage.²³ Patients were positioned in a 30° head-up tilt. This might facilitate fluid passage from the subglottic space to the tracheobronchial tree. Tracheal suctioning was performed through a 14CH catheter by means of an adapter capable of generating a maximal pressure of 400 mmHg,

again promoting leakage of fluid to the tracheobronchial tree. Young *et al.*²³ have shown in a benchtop study that negative tracheal inspiratory pressure, reverse Trendelenburg position, tracheal suctioning, decrease in cuff pressure, and loss of continuous positive airway pressure all promote leakage of fluid from the subglottic space into the tracheobronchial tree.

The long-term benefit of cuff lubrication might be limited in critically ill patients because we have demonstrated the loss of protection against aspiration after a median period of 48 h. Future advances in cuff technology might be important for long-term protection against aspiration. A prototype gilled tracheal tube has been evaluated in sheep and has been shown to be efficacious in the prevention of aspiration.²⁵ Subglottic secretion drainage using the Mallinckrodt Hi-Lo EVAC tube (Mallinckrodt Inc., St. Louis, MO) has been shown to reduce by half the rate of ventilator-associated pneumonia in two studies.^{26,27} At best, subglottic secretion drainage will reduce rather than eliminate aspiration.

A silicone LVHP cuff can be inflated using a novel technique (pressure-limited inflation) to provide an absolute clinical seal against leakage with control of tracheal wall pressure.²⁸ This has been shown to prevent (rather than merely reduce) leakage of dye to the trachea in critically ill patients for at least 10 days (100% leakage in control group *vs.* 0% leakage in silicone cuff group).

Thus we are able to show that cuff lubrication with KY jelly temporarily protects against aspiration of fluid from the subglottic space. This study did not investigate pneumonia rates. This would have required a much larger study, but would provide important information. Cuff lubrication is an inexpensive, highly effective way of reducing leakage past cuffed tracheal tubes for 1–5 days. We recommend consideration of the use of an inert water-soluble gel on all HVLP cuffed endotracheal tubes used in anesthesia and critical care.

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