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The effect of gel lubrication on cuff leakage of double lumen tubes during thoracic surgery*

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Summary

High-volume, low-pressure tracheal cuffs of disposable double lumen tubes may offer limited protection to the dependent lung if fluid leaks through folds in the inflated cuffs. This study was undertaken to determine the incidence of fluid leakage past the tracheal cuff and whether gel lubrication reduces the incidence. Fifty-five patients were randomly assigned to receive a double lumen tube with or without gel lubrication. The dependent lung was intubated. With the patient in the lateral position, methylthionium chloride was administered above the tracheal cuff via a pre-attached catheter. Fibreoptic bronchoscopy was performed to determine if dye had passed the tracheal cuff. Three patients were excluded. Dye leakage was seen in 12/27 and 3/25 patients in the unlubricated and lubricated group, respectively ($p = 0.014$). Gel lubrication significantly reduces fluid leakage past the tracheal cuff of a double lumen tube and should be considered for all thoracic surgical patients requiring one-lung ventilation.

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Post-thoracotomy pulmonary complications are the major cause of morbidity and mortality in patients undergoing lung resection [1] but their aetiology is not well understood. Intra-operative lung contamination may contribute to the development of pulmonary complications. For patients undergoing thoracotomy in the lateral position, the inflated tracheal cuff of a double lumen tube (DLT) is often the last barrier to lung contamination by oropharyngeal material, including refluxed gastric acid. Gastro-oesophageal reflux is relatively common during thoracotomy in the lateral position and the trachea proximal to the tracheal cuff of the DLT becomes contaminated with gastric acid in 8% of patients [2].

Although gross contamination of the lungs with gastric contents is prevented by an adequately inflated tracheal cuff, modern high-volume, low-pressure (HVLP) cuffs may not completely protect the lungs from contamination [3, 4]. Fluid leakage may occur along folds in adequately inflated HVLP cuffs [5]. It has been shown that the application of aqueous gel to the tracheal cuff of a single lumen tracheal tube reduces fluid leakage [6]. The incidence of fluid leakage past the tracheal cuffs of modern DLTs is not known. Design differences between double and single lumen tubes make it difficult to extrapolate data from studies of single lumen tubes to double lumen tubes. Unlike single lumen tubes, the main body of DLTs are not usually round in cross-section. The outer diameter of DLTs are usually much larger, relative to the trachea, than that of single lumen tubes. The outer diameter of the main body of a 41 FG left Mallinckrodt®, Broncho-Cath (Mallinckrodt®, Athlone, Ireland) double lumen tube is 14–15 mm. The tracheal cuff of a DLT is usually considerably longer than the tracheal cuff of a single lumen tube. We therefore conducted this randomised, double blind study in patients undergoing surgery in the lateral position to determine the incidence of dye leakage past the tracheal cuff of DLTs (Mallinckrodt®, Broncho-Cath) and the effect of gel lubrication of the tracheal cuff on this incidence.

Methods

After local research ethics committee approval, written informed consent was obtained from 55 adult patients

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scheduled to undergo elective surgery in the lateral position, requiring one-lung ventilation. Patients were excluded from the study if they were pregnant or lactating, allergic to methylthioninium chloride, glucose-6-phosphate dehydrogenase deficient or had severe renal impairment.

A standardised anaesthetic technique was used. Patients were premedicated with oral diazepam 10 mg and ranitidine 150 mg approximately 2 h before surgery. On arrival in the anaesthetic room, a 14-gauge IV cannula, a 20-gauge radial arterial cannula and, for those patients scheduled to undergo thoracotomy, a mid-thoracic epidural were inserted under local anaesthesia.

After pre-oxygenation, general anaesthesia was induced with fentanyl 1.5 $\mu g.kg^{-1}$ and propofol 2–3 $mg.kg^{-1}$. Atracurium 0.6 $mg.kg^{-1}$ was used to facilitate the placement of a modified DLT (Mallinckrodt®, Broncho-Cath). The DLT was modified by the attachment of an epidural catheter to the outer surface of the dependent side just above the tracheal cuff. Patients were randomly allocated to one of two groups by a shuffled, sealed envelope technique. Patients assigned to one group had their trachea intubated with a DLT, the tracheal cuff of which had been lubricated with 5 g of water-soluble jelly (Aquagel®, Adams Healthcare, Leeds, UK) applied from a swab. Patients assigned to the other group received a DLT without tracheal cuff lubrication. The dependent lung was intubated with a size 39 or 41 FG DLT for men and a size 35 or 37 FG DLT for women. Correct DLT placement was confirmed by fibreoptic bronchoscopy. The tracheal cuffs were inflated with the minimal volume of air required to prevent audible air leak during positive pressure ventilation by an individual blinded to the patient's group. The trachea cuff pressure at this volume was recorded with a cuff pressure manometer.

Anaesthesia was maintained with isoflurane in an oxygen air mixture. Patients undergoing thoracoscopy received intravenous fentanyl; patients undergoing thoracotomy received an epidural infusion of 5 $\mu g.ml^{-1}$ fentanyl in 0.1% bupivacaine. After patients had been placed in the lateral position, a bridge, positioned at the level of the xiphoid process, was elevated. Immediately prior to commencement of the study, the absence of an audible air leak during inspiration was confirmed and the correct position of the DLT was re-confirmed by fibreoptic bronchoscopy. Five millilitres of a 0.2% solution of methylthioninium chloride was then instilled above the tracheal cuff using the pre-attached epidural catheter. Fibreoptic bronchoscopy was performed 10, 30 and 60 min after dye placement by an observer who was blind to whether the tracheal cuff had been lubricated or not. Leakage of the cuff was recorded if dye was visible in the trachea or bronchus distal to the tracheal cuff. Before extubation, any remaining dye was suctioned from above the tracheal cuff.

Statistical analysis

A power calculation, based on previous research [6], showed that to have a 90% chance of showing a 50% reduction in dye leakage at a significance level of 0.05, a total sample size of $n = 50$ with 25 in each group was required. Analysis was done using descriptive statistics. Student's *t*-test was used for continuous variables and Fisher's exact test was used for categorical variables. A p-value of < 0.05 was considered statistically significant.

Results

This study was conducted between September 2002 and August 2003. Of 55 patients, three patients were excluded from the study. In one patient from the lubricated group, the tracheal cuff was inadvertently punctured during surgery. Two patients (one from each group) were withdrawn because of DLT displacement and subsequent DLT repositioning during the study period. There were no significant differences in age, sex, weight, height, ASA status, type of operation, cuff volume, cuff pressure, size or side of DLT between the groups for the 52 patients analysed (Table 1).

The proportion of patients with leakage of dye past the tracheal cuff was significantly higher in the unlubricated group (12/27, 44%) compared to the proportion in the lubricated group (3/25, 12%, p = 0.014). Dye leakage occurred earlier in the un-lubricated group. In the lubricated group, there was no dye leakage within 10 min of instillation, in one patient dye leakage had

Table 1 Patient and operative details.

Patient and operative details	Non-lubricated $n = 27$	Lubricated $n = 25$
Gender; M/F	15/12	13/12
Age; year	52 (16)	60 (15)
Height; cm	163 (9)	170 (10)
ASA; I/II/III	10/7/10	11/9/5
Weight; kg	70 (11)	74 (15)
Type of operation; thoracotomy/oesophagectomy/VAT	16/3/8	13/4/8
Cuff pressure; cm H_2O	22 (5)	22 (4)
Cuff volume; ml	7 (3)	6 (2)
Side dependent; R/L	17/10	15/10
DLT FG size; 35/37/41	6/6/15	6/6/13

Age, height, weight, cuff volume and cuff pressure are expressed as mean (SD). Sex, ASA, type of operation, side dependent and DLT size are expressed as number of patients.
DLT, double lumen tube. VAT, video assisted thoracoscopy.
There are no significant differences between the groups.

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occurred at 30 min and in two patients dye leakage was first seen at 60 min. In the unlubricated group, dye leakage occurred within 10 min of instillation in eight patients, dye leakage had occurred at 30 min in a further three patients, and dye leakage was first seen at 60 min in one patient.

Discussion

Cuffed tracheal tubes are routinely used in adults. One of the functions of the tracheal cuff is to provide an adequate seal and thereby minimise the seepage of fluid or secretions from the oropharynx and subglottic region into the lower airways. In cases of aspiration, leakage of fluid past the cuff of a tracheal tube is the final passage by which fluid enters the lower airways.

With the unlubricated tracheal cuff of a DLT inflated sufficiently to prevent an audible air leak on testing, dye leakage past the cuff occurred in 44% of patients in this study. The clinical significance of this is not clear. It has previously been shown that gastro-oesophageal reflux occurs in 28% of patients undergoing surgery in the thoracotomy position and that tracheal acid aspiration occurs in 8% of these patients [2]. We did not quantify the rate of fluid leakage past the tracheal cuff. It is likely that small volume or micro aspiration occurs past an adequately inflated tracheal cuff. Although the effects of aspirating large volumes of gastric contents are well known and potentially fatal, less is known about the consequences of micro aspiration. Leakage of oropharyngeal secretions past the tracheal cuff of tracheal tubes has been shown to be an important cause of ventilator-associated pneumonia [7]. It is similarly possible that micro aspiration of refluxed material contributes to the development of post thoracotomy pulmonary complications.

There are a number of factors that may potentially influence the leakage of fluid past the tracheal cuff of a DLT: the patient position, the type of DLT, the size of DLT, the technique of cuff inflation and the use of gel lubrication. In addition, movement of the DLT in the trachea and the use of suction on the non-dependent lung, increasing the pressure gradient across the tracheal cuff, could allow leakage to occur.

The trachea is usually almost horizontal when patients are placed in the lateral position and a bridge, at the level of the xiphoid process, is elevated. In some patients, the carinal end of the trachea is slightly higher then the pharyngeal end and dye leakage through the tracheal cuff is unlikely to occur. Dye leaked from the trachea appeared in the mouth of a number of our patients and we may have underestimated the incidence of dye leakage through the tracheal cuff as a result of the pharyngeal end of the trachea being lower. We did not adjust the patient's position to ensure the carinal end of the trachea was dependent because we wanted our study to represent clinical practice. Similarly, the incidence of dye leakage past the tracheal cuff might have been reduced had we adjusted the position of patients to lower the pharyngeal end of the trachea relative to the carinal end. One way of doing this would have been to break or angulate the table instead of using a bridge or wedge.

Low-volume, high-pressure cuffs, once widely used, have been gradually replaced with HVLP cuffs [8]. With HVLP cuffs, a tracheal seal can be obtained at a low intracuff pressure. Pressure exerted by these cuffs is low enough to allow tracheal capillary mucosal blood flow and prevent tracheal dilation, yet high enough to avoid eccentric positioning of the tube in the trachea. The DLT we studied (Mallinckrodt®, Broncho-Cath) utilises an HVLP cuff. The design of the tracheal cuff on some other makes of DLT is different, some using a low-volume, high-pressure cuff.

The size of the Mallinckrodt DLT relative to the trachea may affect the incidence of dye leakage. A characteristic of HVLP cuff design is an overly large cuff diameter relative to the tracheal diameter. This results in the cuff being disposed such that there are invaginations longitudinally along the cuff when inflated within the confines of the trachea. Dye leakage is postulated to occur along these channels. The relative dimensions of the trachea and the DLT used would also be expected to influence the adequacy of the seal. The DLT size can be chosen with reference to rather subjective criteria [9]. A post mortem study found the mean [range] diameter of adult male and female tracheas was 22 [15–27] mm and 17 [13–25] mm, respectively [10]. Similar dimensions were found by measuring the diameter of the trachea on the posterior-anterior chest radiograph [9]. In our study, the intention was to use the largest DLT that passed the glottis without resistance or with only mild resistance. Gender, height, weight and tracheal diameter, measured at the level of the clavicles from a posterior-anterior chest radiograph, were used to inform DLT size selection. We used a 41 FG DLT in 29 of the male patients studied and a 39 FG DLT in one male patient, withdrawn from the study because of DLT displacement. Brodsky similarly found that a 41 FG DLT could be passed atraumatically in 36 of 38 male patients [9]. Fear of airway injury results in some anaesthetists intentionally selecting a small DLT [11]. It could be hypothesised that selecting a smaller DLT would have reduced fluid leakage as the cuff would be more fully inflated, and therefore have fewer folds. A smaller DLT was used in female patients, but in the non-lubricated group, fluid leakage past the tracheal cuff occurred in seven of the 12 female patients (58%). The

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increased incidence in females could be attributable to a more elliptically configured trachea [12].

We could have inflated the tracheal cuff to a predetermined pressure, but instead inflated the trachea cuff until there was no audible leak on inspiration, as this represents common clinical practice. The optimal tracheal cuff pressure is not known, although previous studies with tracheal tubes have shown that leakage is more likely to occur when cuff pressures are less than 25 cm H_2O [13]. However, during hypotensive states, cuff pressures as low as 15 cm H_2O can compromise tracheal mucosal blood flow [14] and mucosal blood flow is totally obstructed over cartilaginous rings at 50 cm H_2O [15]. High cuff pressures, even up to 50 cm H_2O, may not reliably prevent leakage [3]. In our study, the mean cuff pressure was 22 cm H_2O and there was no significant difference between the two groups. Exhaled tidal volume was routinely measured during anaesthesia and, except for the two patients withdrawn from the study because of tube displacement, there was no evidence of a tracheal leak in any patient at any time.

Lubrication of tracheal tubes was initially introduced to decrease the incidence of intubation-related sore throats [16] and to ease the passage of the tracheal tube into the trachea. Subsequently, lubricating the cuffs of tracheal tubes has been shown to reduce fluid leakage past the cuff during anaesthesia [6]. The proposed mechanism by which the jelly protects against aspiration is that it tends to fill the folds in the cuff, thereby obstructing the flow of material along the folds. The optimal amount of gel required to lubricate a cuff is unclear, although in our study, 5 g sachets of gel were used and it was ensured that lubrication was uniform. In our unit, prior to this study, gel lubrication of the tracheal cuff of DLTs was not standard practice.

This is the first study to determine the incidence of fluid leakage past the tracheal cuff of a DLT and to assess the effect of gel lubrication of the tracheal cuff on this incidence. The lower incidence of leakage past the tracheal cuff of DLTs found in this study compared to studies of single lumen tracheal tubes may be due to differences in design. The tracheal cuffs of this DLT are longer and the tubes have a greater external diameter. Gravity may have been a significant factor because of the different orientation of the trachea.

We have shown that fluid leakage past the tracheal cuff occurs in almost half of patients receiving an unlubricated Mallinckrodt, Broncho-Cath DLT, the tracheal cuff of which is inflated sufficiently to prevent an audible air leak. Furthermore, in three of the 55 patients (5%) studied, the tracheal cuff was deflated or dislodged during the procedure.

We recommend that for all patients scheduled to undergo a thoracotomy in the lateral position, manoeuvres to reduce the incidence and potential adverse effects of tracheal aspiration be considered. It may be advisable routinely to administer drugs that reduce gastric acid production to patients as has previously been suggested [2]. The bronchial cuff of the DLT can provide additional protection and consideration should be given to intubating the dependent lung. It may be beneficial to position the patient so that the proximal trachea is lower than the distal trachea. We recommend routine gel lubrication of the tracheal cuff of the DLT for patients undergoing thoracic procedures in the lateral position.

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