

BMJ Open Effect of lateral positioning on the bronchial cuff pressure of a left-sided double-lumen endotracheal tube during thoracic surgery: study protocol for a prospective observational study

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ABSTRACT

Introduction Correct pressure is important when using a double-lumen endotracheal tube (DLT), especially in thoracic surgery. An inadequate bronchial cuff pressure (BCP) can cause air leak and interfere with visualisation of the surgical field, whereas an excessive pressure BCP can lead to cuff-related complications. Based on several reports that cuff pressure could alter after a positional change when using an endotracheal tube, we hypothesise that a change from the supine position to the lateral decubitus position, which is essential for thoracic surgery, would affect the BCP of the DLT.

Methods and analysis This prospective, single-centre, observational study will enrol 74 patients aged 18–70 years undergoing elective lung surgery from September 2018 to April 2019. The primary outcome will be the change in the ‘initially established BCP’ (maximum BCP not exceeding 40 cm H₂O with no air leak in the supine position) after lateral decubitus positioning. BCP and air leak will be assessed in each patient position during inflation of the cuff with air in 0.5 mL increments from 0 to 3 mL. Secondary outcomes will include the incidence of BCP exceeding 40 cm H₂O after the initial established value and that of a change in the smallest bronchial cuff volume without air leak after a change to the lateral position. The relationship between the change in BCP and airway pressure, compliance and body mass index after lateral positioning will be investigated.

Ethics and dissemination The study will be conducted in accordance with the Declaration of Helsinki and supervised by the Daegu Catholic University Medical Center institutional review board (study approval number CR-18-111). All patients will receive information about the study and will need to provide written informed consent before enrolment. The results will be presented at an international meeting and published in a peer-reviewed journal.

Trial registration number NCT03656406; Pre-results.

INTRODUCTION

It is important to maintain a correct cuff pressure when placing an endotracheal tube (ETT) in the trachea in patients undergoing

Strengths and limitations of this study

- Although there have been several studies of changes in the cuff pressure of a single-lumen endotracheal tube in response to a change in patient position, this will be the first to investigate whether the bronchial cuff pressure (BCP) of a double-lumen tube is affected by lateral positioning.
- Factors suspected to influence BCP will be identified. An understanding of these factors may aid the future management of BCP during changes in patient position.
- When equilibrating the cuff manometer and measuring BCP, manual deflation and inflation of the bronchial cuff with 0.5 mL of air may cause slight measurement errors.
- BCP and other study variables will be recorded until the start of surgery only, so the study will be unable to determine how BCP may be affected by other factors, for example, manipulation of the lung intraoperatively.
- The sample size was calculated for the primary outcome, that is, any change in BCP during lateral positioning, and may be too small for analysis of the secondary outcomes.

general anaesthesia. The usual recommendation is to maintain a pressure of 20–30 cm H₂O to prevent cuff-related complications, such as micro-aspiration or airway trauma.^{1–5} Correct pressure is also important when using double-lumen endotracheal tubes (DLTs) in thoracic surgery.⁶ Excessive pressure damages the mucosa of the tracheobronchial tree,⁶ and various values in the range of 30–58 cm H₂O have been recommended as the upper limit for cuff pressure.^{2 5 7} However, air leak caused by underinflation of the bronchial cuff of the DLT can interfere with surgery by obstructing the surgeon’s view of the operative field,⁸ particularly in video-assisted thoracoscopic surgery (VATS). Therefore, the initial

bronchial cuff pressure (BCP) that can be effectively sealed to avoid air leak around the cuff while avoiding bronchial damage has been set at 35 cm H₂O.^{9–11}

Caution is needed after the correct BCP is initially established. Several studies have demonstrated alterations in the cuff pressure of the ETT in response to repositioning of the patient. The cuff pressure of single-lumen ETTs has been found to change when patients undergoing general surgery are moved from the supine position to the prone¹² or lateral frank¹³ position and when the head is shifted from the neutral position to another position.^{14 15} Such changes in cuff pressure have been reported to occur primarily because of displacement of the tube within the trachea.¹³ However, in a study performed in patients undergoing laparoscopic surgery, gravity-related conformational changes in the trachea (resulting from a combination of CO₂ insufflation and head-down tilt) were attributed to increased cuff pressure.¹ Therefore, a change in cuff pressure could be brought about by not only displacement of the tube but also the change in morphology of the trachea in response to a change in body positioning.

At present, there is no published research on whether the BCP of the DLT is affected by a change in patient positioning. We hypothesise that a change from the supine position to the lateral decubitus position, which is essential for thoracic surgery, would affect the BCP of the DLT, even when the problem of tube displacement has been eliminated by fibre-optic confirmation that the bronchial cuff is correctly positioned. The purpose of this study is to evaluate the effect of a change in patient positioning on the BCP of the DLT by observing the pressure of the bronchial cuff before and after a shift to the lateral decubitus position in patients undergoing thoracic surgery.

METHODS AND ANALYSIS

Study design

This prospective, single-centre, observational study is being conducted at the tertiary university hospital in Daegu, South Korea, from September 2018 to April 2019. It will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology statement (online additional files 1).

Study population

Patients aged 18–70 years and with an American Society of Anesthesiologists physical status of 1 or 2 who are scheduled to undergo elective lung surgery requiring lateral decubitus positioning and one-lung ventilation (OLV) using a left-sided DLT will be enrolled. The following exclusion criteria will be applied: need for a right-sided DLT; an intraluminal lesion in the left main bronchus (LMB); an anatomical problem in the tracheobronchial tree; lung impairment, such as chronic obstructive pulmonary disease; and refusal to participate in the study. A researcher (I-YK) will contact patients who are potential candidates for the study at the time of their preoperative

visit. After providing information regarding the purpose, procedures and potential risks and benefits of the study, each prospective study participant will be asked to sign informed consent.

Baseline demographics and surgical details

The baseline characteristics of the study population will be collected preoperatively. The data collected will include age, sex, height, weight, body mass index (BMI, kg/m²), size of the LMB, operative side (right or left) and the angle at which the operating table will be tilted.

Anaesthesia and DLT intubation

Standard monitoring, including ECG, non-invasive blood pressure measurement and pulse oximetry, will be performed after arrival in the operating room in all cases. A disposable bispectral index sensor (BIS, Aspect Medical Systems, Newton, Massachusetts, USA) will be used to monitor the depth of anaesthesia. All patients will undergo induction of anaesthesia with propofol and remifentanyl using target-controlled infusion based on bispectral index monitoring of depth of anaesthesia and will receive rocuronium 0.8 mg/kg as a muscle relaxant to facilitate tracheal intubation. A disposable left-sided polyvinyl chloride DLT (Broncho-Cath, Mallinckrodt Medical Ltd., Athlone, Ireland) will be used for OLV in all patients. The size of the DLT will be chosen according to the diameter of the patient's LMB as measured on a CT scan of the chest (35 French for <11 mm, 37 French for 11–12 mm and 39 French for ≥12 mm).⁸ All patients will be intubated with the DLT under direct laryngoscopy, and correct positioning of the DLT in the LMB will be checked by fibre-optic bronchoscopy (FOB; Olympus Optical Co., Tokyo, Japan). Accurate placement of the DLT will be confirmed under the FOB view using the method described by Campos.¹⁶ A blue-coloured bronchial cuff will be positioned just below the carina without herniation when inflating the DLT cuff. After confirmation that the DLT is positioned correctly, the tube will be fixed temporarily at the patient's mouth using tape.

Measurement of outcomes and data collection

Bronchial cuff pressure

Given that the aim of this study is to investigate the effect of a change from the supine to lateral position on BCP, the pressure will be measured by a cuff manometer (VBM Medizintechnik GmbH, Sulz, Germany) at a series of time points in the supine and lateral decubitus positions. A cuff manometer will be connected to the valve of the pilot balloon of the bronchial cuff via a three-way stopcock. The pressure measurements will start 2 min after confirmation of DLT placement in each patient position. The pressure of the tracheal cuff will be modified using a cuff manometer to maintain a pressure in the range of 20–30 cm H₂O, and the volume of air administered will be recorded. The BCP will then be assessed while inflating the cuff with air in 0.5 mL increments from 0 to 3 mL. Before injection of

air into the bronchial cuff, the intracuff pressure will be equilibrated at atmospheric pressure by keeping the three-way stopcock open to the outside in order to maintain the resting volume of the cuff. If the pressure has a range of values, we will calculate the average of the maximum and minimum values and record it as the BCP. If the BCP exceeds 40 cm H₂O during expansion in 0.5 mL increments from 0 to 3 mL, inflation of the bronchial cuff with air will be stopped and the bronchial cuff volume (BCV) and BCP will be recorded up to the last numerical value. Reports of the value that is acceptable as the upper limit of BCP for the DLT vary from 30 cm H₂O to 44 cm H₂O.^{9–11} Therefore, we have set an upper limit of 40 cm H₂O for the BCP in this study. Air leak will be monitored in both patient positions, so pressures will be measured under OLV by clamping the tracheal or bronchial lumen (operative side) of the DLT even in the supine position. The ventilation mode and setting will be kept constant in both patient positions during OLV to observe the effect of positional change on peak inspiratory pressure (PIP) and mean inspiratory pressure (Pmean), which may affect the pressure of the cuff. Ventilation will be maintained at a tidal volume of 6–8 mL/kg body weight and the respiration rate will be adjusted to maintain an end-tidal carbon dioxide (EtCO₂) value of 30–35 mm Hg and a positive end-expiratory pressure (PEEP) of 5 cm H₂O.

Air leak and respiratory variables

As mentioned earlier, whether or not there is an air leak around the bronchial cuff will be assessed at each time point while inflating the cuff in 0.5 mL increments. Various methods can be used to detect air leak,¹⁷ including bubbling air into water and the EtCO₂ waveform.^{8 18–20} However, there has been a suggestion that the minimum BCV needed to achieve an air seal using these techniques could be different from (usually larger than) the minimum volume that triggers collapse of the lung in the surgical field,¹⁷ and this is consistent with our unpublished experience. Air leak can also be tested simply by capnography or the pressure-volume loop seen on the respiratory monitor on the anaesthetic machine^{9 10} or by measuring the exhaled return tidal volume (VTe).²¹ We will use these simple methods, and if the configuration on capnography or the pressure-volume loop is distorted and VTe is delivered at less than 80% of the established TV (TVset), an air leak will be considered to be present. TVset, VTe, PIP, Pmean and PEEP will be recorded at each time point, and a check will be performed for air leak.

Determination of maximum and minimum BCP and BCV

► The maximum pressure at which the BCP does not exceed 40 cm H₂O without air leak and the volume at that point in time will be denoted as the ‘maximum BCP’ and ‘maximum BCV’, respectively, and as the ‘initial established BCP’ and ‘initial established BCV’ if in the supine position

► The smallest BCV without air leak and the pressure at that time point will be denoted as ‘minimum BCV’ and ‘minimum BCP’.

After measuring these values, the bronchial cuff will be aspirated completely and equilibrated at atmospheric pressure, thereby returning to its resting state under two-lung ventilation.

Length of the LMB

The length of the LMB will be measured before and after lateral positioning to check for a conformational change. As described in our previous report,²² when the tip of the FOB reaches the tracheal or bronchial carina, the point of contact with the elbow connector of the DLT will be marked on the tape previously attached to the shaft of the FOB, and the length between these two markers will be taken as the length of the LMB. All the FOB procedures, including confirmation of the correct position of the DLT and measurement of length, will be performed by two experienced investigators (EK, S-HB) with at least 5 years of experience in thoracic anaesthesia.

Repeated outcomes measurements after lateral positioning

Outcomes measurements, as mentioned above, will be repeated in the lateral decubitus position and at the start of the operation. The patient will be placed in the lateral decubitus position with an axillary roll under the dependent axilla, and the operating table will be flexed enough to allow the shoulder and hip to be placed on the horizontal line and the intercostal space to be widened maximally. All the positioning procedures will be undertaken by an independent senior resident. Whether the position of the DLT, that is, the bronchial cuff position just below the carina without herniation, is the same as that before moving the patient into the lateral position will be determined by the same investigator and the length of the LMB will be measured using another FOB. The tracheal cuff will be inflated using the administered volume of air in the supine position. The cuff pressure will then be checked using a cuff manometer and modified to maintain pressure in the range of 20–30 cm H₂O if necessary. Like in the supine position, the BCP and air leak will then be checked while expanding the cuff from 0 to 3 mL in 0.5 mL increments as long as the BCP does not exceed 40 cm H₂O. The maximum and minimum BCP and BCV and the TVset, VTe, PIP, Pmean and PEEP will be recorded in the lateral decubitus position at each time point. After the maximum BCP is recorded, the BCP will be lowered to the minimum value; the cuff manometer will remain connected to the pilot balloon until the start of the operation. Two minutes after incision and insertion of the trocar for thoracoscopy, the BCP measured by the cuff manometer will be recorded and whether the operative lung collapses correctly in the operative field will be recorded by the operating surgeon. Next, the higher BCP values will be measured and recorded in 0.5 mL increments up to the maximum BCP, which will be maintained throughout the operation.

Primary and secondary outcomes

The primary outcome of this study will be the change in 'initial established BCP' (maximum BCP established initially in the supine position that does not exceed 40 cm H₂O with no air leak) after lateral decubitus positioning, that is, the difference in BCP between the supine and lateral positions when injecting the 'initial established BCV' (maximum BCV established in the supine position).

The secondary outcomes will include the proportion of patients whose BCP exceeds 40 cm H₂O when injecting the 'initial established BCV' and the proportion with a change (decrease or increase) in the minimum BCV without air leak after lateral positioning. An increase in the minimum BCV would mean that the minimum BCV in the supine position would cause an air leak in the lateral position. Analysing this relationship may help in the management of BCP in the future. The relationship between the change in BCP and other clinical variables, including airway pressure (PIP, Pmean), airway compliance ($C_{\text{dyn}} = \frac{TV_c}{PIP - PEEP}$), and BMI after lateral positioning, will be analysed.

Sample size

The primary outcome of the study will be the change in 'initial established BCP' in the supine and lateral positions. In a preliminary study, the difference in BCP when injecting the 'initial established BCV' between the two positions was 2.3 and the SD was 6.53. Based on that result, we calculated that 66 patients would be required to achieve a power of 80% and a significance level of 5% (two-sided). Seventy-four patients will be included to allow for a 10% dropout rate.

Statistical analysis

The data will be analysed on an intention-to-treat basis, and missing data will be handled using the last observation carried forward method. The distribution of the data will be checked for normality using the Kolmogorov-Smirnov test. Normally distributed data will be presented as the mean±SD deviation and analysed using the paired t-test. Data that are not distributed normally will be expressed as the median (IQR) and analysed using the Wilcoxon signed-rank test. Categorical data will be expressed as the number (percentage). Pearson's correlations will be calculated to determine the relationships between airway pressure, compliance, BMI and the change in BCP after lateral positioning. A p value < 0.05 will be considered statistically significant. All statistical analyses will be performed using IBM SPSS Statistics V.19.0.0 (IBM Corp.).

Patient and public involvement

No patients or members of the public were involved in the design of the study. Patients in this study can request the results from the research team if they are interested.

Ethics and dissemination

The study will be conducted in accordance with the principles of the Declaration of Helsinki. The institutional

review board and all study participants will be notified if any important protocol modifications or violations arise. The results of the study will be presented at an international congress and published in a peer-reviewed journal. The data collected will also be made available in a public data repository.

DISCUSSION

This study has been designed as an observational study where the investigators will perform thoracic anaesthesia as per routine practice, without the intended intervention, and only observe the outcomes. Although measurement of the cuff pressure is not a routine practice, the overall procedure, including confirmation of the DLT position and repositioning of the DLT under the FOB after lateral positioning of the patients, follows the standard protocol for thoracic anaesthesia. With regard to measurement of the ETT cuff pressure, it is already known that connection of the manometer to the pilot balloon results in loss of cuff pressure.²³ Unfortunately, DLT displacement is very common after a change in the patient's posture, and deflation or inflation of the tracheal and bronchial cuffs using the syringe should be repeated each time the DLT position changes. Therefore, we will inject the same volume of air into the cuff in order to create equal conditions in both patients' posture and decided to measure the BCP by addition of air in 0.5 mL increments from 0 to 3 mL.

Limitations

This protocol has some limitations. First, manipulation of the cuff manometer or manual deflation and inflation of the cuff with the established volume of air for equilibrating the intracuff pressure with the atmospheric pressure or measuring the tracheal and BCPs will inevitably result in slight measurement errors. Second, the cuff pressure and other study variables will be checked only until the start of surgery, because there have been wide variations in the operating time during VATS at our institution. Such variations can complicate accurate evaluation of the postoperative outcomes. Furthermore, prolonged surgery involving considerable surgical manipulation of the lungs or bronchi can cause airway oedema or mucus hypersecretion and affect the cuff pressure or other respiratory variables. If this limitation can be overcome in the future, we will perform further studies of the postoperative outcomes to determine the effects of other factors on the BCP. Third, the same investigator will be observing the DLT position at two time points (the supine position and the lateral position) in order to confirm whether the DLT is placed at the same site within the LMB. In order to reduce the risk of bias, at least two investigators will be involved, and measurement of the LMB length will be repeated using another FOB. Finally, the sample size was calculated for the primary outcome, that is, the change in the BCP during lateral positioning. Accordingly, it may be insufficient for analysis of the secondary outcomes.

Contributors EK and S-HB drafted the manuscript. EK, I-YK and S-HB will be responsible for the screening and enrolment of patients. S-HB revised this manuscript and will supervise the study. All authors have read and approved the final version of this manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study protocol has been approved by the Daegu Catholic University Medical Center institutional review board (CR-18-111).

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