Comparison of Displacement Between Polyvinyl Chloride(PVC) and Silicon Double-Lumen Endobronchial Tubes(DLT) During Change of Position

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Study Protocol

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This prospective, randomized single-blind study was approved by the Institutional Review Board and registered with ClinicalTrials.gov (NCT02691468). After written informed consent was obtained. 108 adult patients, aged 18 to 75 years, ASA physical status 1-3, scheduled for elective thoracic surgery with the use of left-sided DLT were enrolled for this study. Patients with absolute indication for a right-sided DLT insertion or single-lumen tube with bronchial blocker, emergency surgery, surgery requiring sternotomy, an intraluminal lesion in the left bronchus, or a distorted tracheobronchial tree anatomy due to intraluminal tumor or extrinsic mass on the

preoperative chest radiograph were excluded from the study.

Before surgery, the length of left main bronchus was measured as the distance from the tracheal bifurcation point to the bronchial bifurcation point between left upper and lower lobe bronchus on two-dimensional (2D) chest computed tomography (CT) imaging. The anteroposterior and transverse diameters of the left main bronchus were measured 2 cm below the tracheal carina, where the bronchial cuff of left-sided DLT is conventionally placed. The right and left bronchial angles were defined as the deviation of the central axis of each bronchus from a vertical line passing through the inferior point of the tracheal bifurcation.

All patients received glycopyrrolate 0.2 mg intramuscularly to decrease secretion 30 minutes before anesthesia. After arriving in the preoperative holding area, they were randomly allocated into two groups using a computer-generated random assignment scheme: group P (PVC DLT, Broncho-Cath™, Covidien, Mansfield, MA, USA) and group S (Silicone DLT, Human Broncho®, Insung Medical Co., Wonju, Korea, Fig.1). Anesthesia was induced and maintained with total intravenous anesthesia using target-controlled infusion of propofol and remifentanil under monitoring of blood pressure, oxygen saturation, electrocardiogram and bispectral index for measurement of hypnotic depth. After inducing adequate neuromuscular relaxation with administration of 0.8 mg/kg of rocuronium intravenously, a left-sided DLT was inserted into the trachea until the depth would be approximately 12 + (height/10) cm at the teeth by direct laryngoscopy in supine position [1]. The endobronchial cuff was inflated to the minimal volume that seals the air leak during OLV using air-filled syringe. The position of the DLT was initially determined by auscultation of breathing sounds with clamping the tracheal lumen and bronchial lumen alternately. Pressure-controlled ventilation was performed. The inspiratory fraction of oxygen and delivered tidal volume was closely monitored to maintain SaO_2 greater than 95%. Respiratory rate was set to maintain $PaCO_2$ between 35 and 45 mmHg during OLV and two-lung ventilation (TLV). Lateral positioning for thoracic surgery was performed with the endobronchial cuff inflated by holding the DLT at the level of the incisors and keeping the patient's head and neck immobile in the neutral position.

A single independent investigator performed bronchoscopy through tracheal and bronchial lumens using a FOB (Olympus LF-2, Olympus Optical Co., Tokyo, Japan). The initial position of the DLT was observed after blind insertion of tube in the supine position. The correct position of the DLT was defined as both tracheal and bronchial carinas were clearly visualized and the upper edge of endobronchial cuff was 5 mm below the tracheal carina in the left main bronchus [2] and was achieved using FOB guidance. When a FOB was introduced into the tracheal lumen until upper edge of bronchial cuff was in line with tracheal carina, a piece of tape was placed on the external surface of bronchoscope at the point where it entered the self-sealing diaphragm in the elbow connector. And then

the DLT was advanced 5 mm into the left main bronchus from the external marking on the bronchoscope so that the upper edge of endobronchial cuff was positioned to be 5 mm below the tracheal carina in the left main bronchus. The position of the DLT was observed at 4 time-points: (1) after correctly repositioning tube in the supine position, (2) after change of position from supine to lateral decubitus, (3) at start of surgery after correctly repositioning tube in the lateral decubitus position, (4) at the end of surgery in the lateral decubitus position. The tracheal distance was defined as the distance between the distal tip of the tracheal lumen and tracheal carina whereas the bronchial distance was defined as that between the bronchial carina and distal tip of endobronchial lumen. The displacement of DLT was determined by changes in tracheal and bronchial distances, obtained by subtracting supine measurements from lateral measurements and subtracting measurements at start of surgery from measurements at the end of surgery, respectively. Clinically significant displacement was defined when the DLT was deviated by more than 10 mm from the initial correct position, regardless of the direction of displacement [3]. A critical malposition requiring immediate reposition of DLT for successful OLV was defined as obstruction of the left upper or lower lobe bronchus by the distal tip of endobronchial lumen or the intratracheal dislocation of more than half of the endobronchial cuff. The primary endpoint of this study was the incidence of clinically significant displacement of left-sided PVC and silicone DLTs during change of patient position from supine to lateral decubitus. The secondary endpoint of this study was the incidence of critical malposition of DLTs requiring reposition for successful OLV during position change.

Statistical analysis plan

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The sample size is calculated using G*Power ver. 3.1.5. It is ascertained that 48 patients are required in each group to detect an intergroup difference of 30% in the incidence of clinically significant DLT displacement during positional change with α of 0.05 and a power of 80%. Fifty-four participants per group are recruited to compensate for a 10% dropout rate. Statistical analysis is performed using SPSS 22.0 for Windows (IBM Corp., USA). Categorical data are presented as number of patients (percentages) and analyzed using Chi-square test or Fischer's exact test as appropriate. Continuous data are presented as mean ± standard deviation (SD) for normally distributed variables and analyzed using the independent Student's t test and the Mann-Whitney U test, respectively. A P-

value < 0.05 is considered statistically significant.