I General Information

A Randomized Comparison between the VivaSight DL and Standard Double-Lumen Tube Intubation in Thoracic Surgery Patients.

VDLT-01

28.01.2019

II Background Information

One of the key characteristics of thoracic surgery is the need for mechanical separation of ventilation between the two lungs. One-lung ventilation (OLV) is performed to provide access to the surgical field or isolate the pathological process in the other lung. It is achieved with the use of a double-lumen tube (DLT) or a single-lumen tube with a bronchial blocker. In recent years, despite the introduction of several new bronchial blockers, DLT has remained the most common method of OLV. To obtain proper DLT placement, which may in some cases be challenging, fiberoptic bronchoscopy (FOB) is applied as the gold standard since auscultation alone can be unreliable.

In 2012, a new option for OLV with DLT was proposed: a video DLT (VDLT), which enables constant visualization of the trachea and carina during insertion, placement, and operation of the tube during OLV. VDLT is significantly larger in diameter and more rigid than a standard single-lumen tube (SLT); hence, complications related to securing the airways are more prevalent.

Airway management is critical for general anaesthesia in thoracic surgery, and failure may lead to severe complications. Therefore, preoperative evaluation and proper prediction of difficult intubation play a crucial role in the safety of anaesthetic procedures. Several bedside airway assessment tests have been proposed, such as modified Mallampati test, thyromental distance, sternomental distance, upper lip bite test, or mouth opening; however, none of those turns out to provide satisfactory parameters as a single clinically helpful predictor of difficult intubation in general.

III Trial Objectives and Purpose

The main objective of the trial is to assess the characteristics of Video Double Lumen Tube compared to a standard Double Lumen Tube intubation in patients scheduled for elective surgical procedures.

IV Trial Design

This is a prospective, randomized trial. The primary outcome measure is intubation time and grade. The secondary outcome measures are thyromental height, thyromental distance, sternomental distance, Mallampati score, mouth opening, dentition, difficult intubation history, tube size, Cormack-Lehane grade, intubation attempts number, technique modification, VDLT image quality, fiberoptic bronchoscopy (FOB) need, lung separation quality, tube repositioning incidence, intubation complications, trachea temperature

During routine preoperative anaesthetic visits, that will be carried out at least 24 hours prior to the operation, an anaesthesiologist, one of the study team members, will collect anamnesis and perform a physical examination. The patient's age, sex, weight, body mass index, type of surgery, side of surgery, dentition, and history of difficult intubation will be noted. The following anthropometric measurements will be obtained:

- Thyromental height: The distance between the anterior border of the thyroid cartilage and the anterior border of the mentum will be measured with an electronic depth gauge (21460605, Limit, Alingsås, Sweden) with the patient in the supine position and mouth closed.

- Thyromental distance: The distance between the thyroid prominence and the most anterior part of the mental prominence of the mandible will be measured with a centigrade ruler (Standard, Hoechstmass, Sulzbach, Germany) with the patient in the supine position, head fully extended, and mouth closed.

- Sternomental distance: The distance between the superior border of the manubrium sterni and the bony point of the mentum will be measured with a centigrade ruler (Standard, Hoechstmass, Sulzbach, Germany) with the patient in the supine position, head fully extended, and mouth closed.

- Modified Mallampati test: The oropharyngeal view will be evaluated by using the modified Mallampati classification with the patient in the sitting position, mouth maximally open, tongue protruded, without phonation.

- Mouth opening: The mouth opening will be measured as a distance between the lower and upper incisors with a tape measure (Standard, Hoechstmass, Sulzbach, Germany). The patient will be sitting with their mouth maximally open, tongue retracted, and without phonation.

Several opaque, numbered randomization envelopes containing cards that read 'VDLT' or 'DLT' will be prepared with a random number generator by a research team member not involved with anaesthesia or intubation. Only the patients will be blinded to the allocation, as it was impossible to blind anaesthesiologists during the surgical procedures.

The anaesthesiologist performing the procedures in the operating theatre will have a minimum of three years of experience in thoracic anaesthesia and OLV with both DLT and VDLT, and will be blinded to the results of airway assessment.

During anaesthesia induction, the following variables will be recorded: intubation time (measured from the beginning of direct laryngoscopy to the proper placement of DLT or VDLT in the respective groups), Cormack-Lehane grade, number of intubation attempts, subjective assessment of intubation difficulty (defined as easy, moderate, or difficult), technique modification (the use of a McCoy blade, video laryngoscopy, or a bougie), and tube size. Next, the events of DLT dislocation and FOB use (during intubation, after repositioning the patient, or intraoperatively) will be noted throughout anaesthesia. When the chest wall will be opened, the lung collapse will be graded as follows: fully collapsed lung, non-collapsed lung with no visible ventilation, or fully ventilated lung. The temperature

of the tracheal port area will be measured at 15-minute intervals. In the VDLT group, the quality of the airways visualization will be determined in the intraoperative period and graded as (I) full visualization of airways, (II) partial visualization of airways enabling correct VDLT positioning, (III) partial visualization of airways preventing correct VDLT positioning.

After the surgery, the patients will be extubated, and the laryngeal mask will be introduced to secure the airways to perform FOB and assess potential airway trauma. Trauma, defined as redness, oedema, haematoma, or active bleeding, will be reported during FOB at the level of vocal cords, trachea, tracheal bifurcation, or main bronchus. Also, as part of a standard practice, the bronchial stump will be examined for closure failure, and excessive secretions will be suctioned.

After full emergence from anaesthesia, the patients will be moved to the recovery room and monitored for 2 hours; if no complications arise, the patients will then transferred to the Thoracic Surgery Ward. A member of the study team blinded to the results of the previous stages of the study will visit the patient in the Thoracic Surgery Ward 24 hours after the surgery and record the occurrence of the following potential complications: sore throat (during swallowing or constant), cough (occasional or moderate), hoarseness of voice (noticed by the patient only or by the patient and the study team member).

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

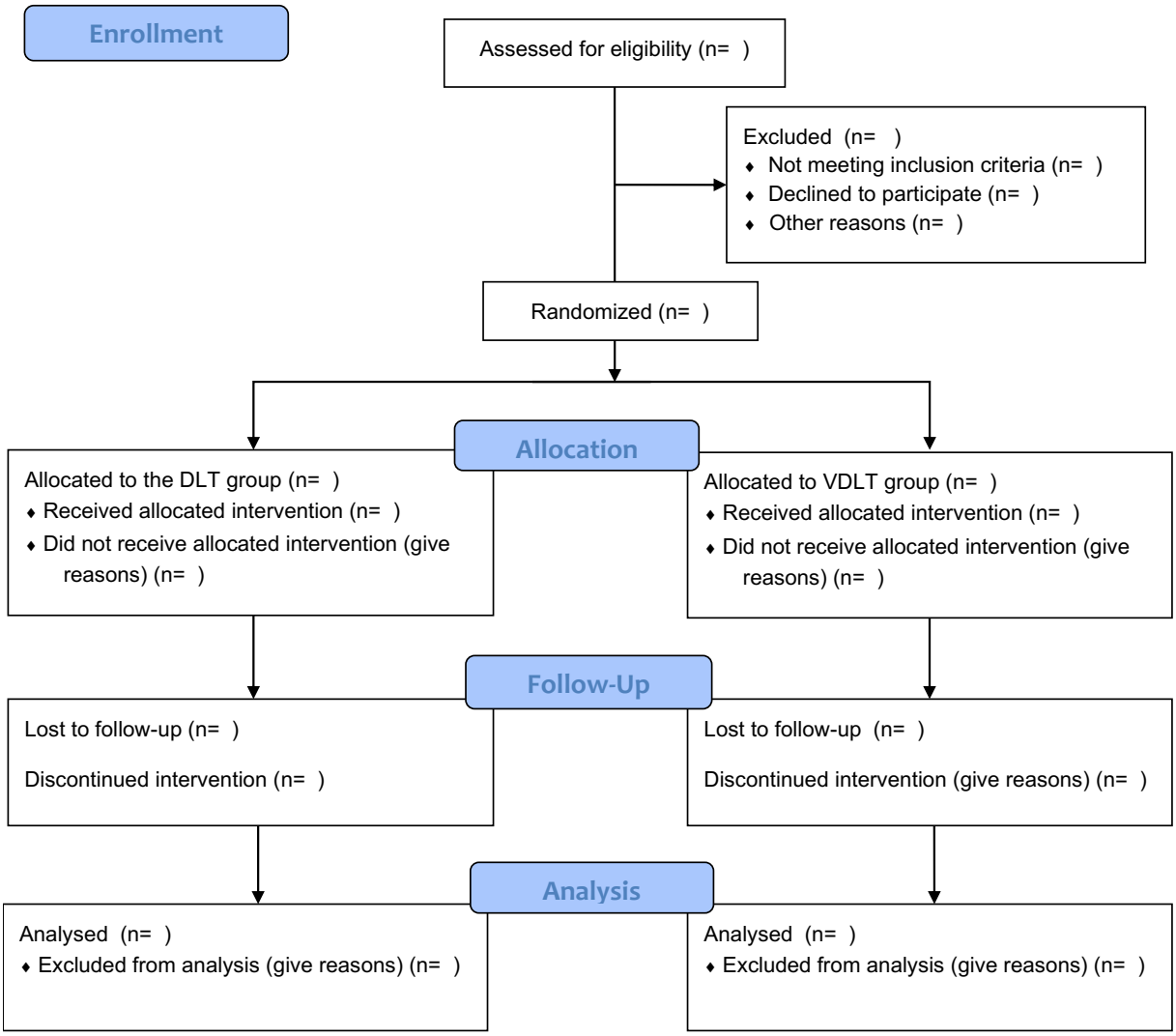

Figure 1. Flow chart of the study

V Selection and Withdrawal of Subjects

Inclusion Criteria:

patients scheduled for elective surgical procedures, requiring general anaesthesia, direct laryngoscopy and intubation

consent for participation in the trail

older than 18 years

Exclusion Criteria:

patients requiring emergency procedures

patients with visible anatomic abnormalities

patients scheduled for awake fiberoptic intubation

Patients amenable to exclusion criteria are withdrawn from the trial during preoperative anesthetic visit. No data is gathered from the excluded patients.

VI Treatment of Subjects

All patients will be anaesthetized in accordance with a standardized protocol. They will be routinely monitored with an electrocardiogram, non-invasive arterial blood pressure measurement, and pulse oximetry before the induction of anaesthesia. Premedication will be achieved with midazolam administered intravenously in a dose of 2 mg before the onset of anaesthesia. The patients will be placed in the supine position on the operating table and pre-oxygenated with 100% oxygen breathed through a face mask for 5 minutes. General anaesthesia will be induced with 2 mg · kg–1 propofol and 2 µg · kg–1 fentanyl. Muscle relaxation will be accomplished with cis-atracurium in a dose 0.15 mg · kg–1 and confirmed with muscular blockade monitoring when there were no palpable twitches in response to the train-of-four stimulation of the peripheral nerve. The direct laryngoscopy will be performed in an optimal sniffing position, with an appropriate Macintosh blade size 3 or 4. If a technique modification will be needed, the anaesthesiologist will use a McCoy blade size 4, a video laryngoscope (McGrath MAC, Medtronic, Minneapolis, USA), or a bougie (Single Use Bougie, Portex, Smiths Medical, Ashford, UK) in order to secure the airways.

In the DLT group, patients will be intubated with a left-side Robertshaw DLT size 35–39. The tube size will be chosen depending on the patient's height and gender; if any additional factors that could influence the choice exist, the anaesthesiologist may decide on a different tube size. The proper placement of the tube will be confirmed with auscultation. If the tube will not be inserted properly or displace during the operation, FOB will be performed for repositioning. Routinely, FOB will be performed after anaesthesia induction to confirm the proper tube position. The targeted position will be achieved during FOB when the main carina and the bronchial cuff edge in the left bronchus will be seen from the tracheal port.

In the VDLT group, patients will be intubated with a left-side VDLT size 35–39. The tube size will be chosen in the same way as in the DLT group. Before the insertion, the tube will be connected to the compatible monitor positioned beside the operating table. The patient will be intubated and the introduction of the tube through the airways will be observed on the monitor until the view of the main carina with the bronchial cuff edge in the left bronchus will be established. In the case of a dissatisfactory view of the airways owing to excessive secretions, the camera port may be repeatedly flushed with 0.9% saline and air. If the positioning of the tube will be unsuccessful, FOB will be performed in the same manner as in the DLT group.

In both groups, the tubes will be fixed with a bandage and the patients will be placed in a lateral position, adequately to the operated side. During the operation, in the VDLT group, the view of the airways will be monitored; in any case of dislocation, the position of the tube will be readjusted. In the DLT group, if a dislocation of the tube will be identified, FOB will be performed, and the position of the tube will be readjusted. Throughout the operation, the temperature at the edge of the tracheal port will be continuously monitored with a thermometer (CarestationTM 600, GE, USA)..

VII Assessment of Efficacy

Due to the character of the trial there was no need to assess the efficacy parameters.

VIII Assessment of Safety

Due to the character of the trial there was no need to assess the safety parameters.

IX Statistics

The sample size was calculated using the MedCalc software, version 14 (MedCalc, RRID:SCR_015044), to detect the area under the receiver operating characteristic (AUROC) curve of 0.70. The null hypothesis for the AUROC curve was set at 0.5. The minimum number of patients needed to provide a study power of 80% and alpha error of 0.05 equals 62 (at least 31 cases per group).

The normality of the data distribution will be assessed with the Shapiro-Wilk test and the quantile-quantile plot (Q–Q). The $\chi 2$ test will be used to compare variables on the nominal and ordinal scales, including dichotomous ones, and the $\chi 2$ test with Yates' correction (for two-way tables) will be applied if the size of the expected number was smaller than 5. The two-group comparison will be performed with the Student t-test for independent variables or the Mann-Whitney U test in accordance with the data distribution. The temperature measurement analysis will be based on the repeated measures analysis of variance with a post-hoc contrast analysis. Factors related to adverse events will be determined with multivariable (backward stepwise) logistic regression. Parameters will be considered statistically significant with $p < 0.05$. The following software will be used for calculations: Statistica 13.0 (STATISTICA, RRID:SCR_014213); Microsoft Office Excel (Microsoft Excel, RRID:SCR_016137).

X Direct Access to Source Data/Documents

The research group will provide access to source data and documents for trial related monitoring, inspections and reviews.

XI Quality Control and Quality Assurance

Before the onset of the trial all members of the research group are being trained in the proper way of conducting the measurements and only when minimal interobserver variability for measurements is observed, the trial may commence. During the trial internal audit may be conducted to assess the consistency of the measurements. Consistency between the gathered data in the database and Study log is checked monthly.

XII Ethics

The trial will be conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Ethics Committee of Medical University of Silesia in Katowice, Poland (protocol code KNW/0022/KB1/43/I/16) and informed consent will be taken from all individual participants.

XIII Data Handling and Record Keeping

Data gathered by a research group member during preoperative visit is being noted on the Study Protocol 1, data gathered by anesthetist in intra and postoperative period will be noted on the Study Protocol 2 and transcribed to an electronic database daily by a research group member. All patients included in the study are reported to the Study log. All deviations, possible bias and errors are reported to the Study log.

XIV Financing and Insurance

This work is supported by Wroclaw Medical University [SUB.E080.19.013. to J.S.].

XV Publication Policy

Results of this study will be published in a journal that covers the scope of this work.

Article information: https://dx.doi.org/10.21037/jtd-22-451