Effect of the VivaSight double-lumen tube on the incidence of hypoxaemia during one-lung ventilation in patients undergoing thoracoscopic surgery: a study protocol for a prospective randomised controlled trial

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ABSTRACT

Introduction A double-lumen tube (DLT) is a traditional one-lung ventilation tool that needs to be positioned under the guidance of a fibroptic bronchoscope or auscultation. The placement is complex, and poor positioning often causes hypoxaemia. In recent years, VivaSight double-lumen tubes (v-DLTs) have been widely used in thoracic surgery. Because the tubes can be continuously observed during intubation and the operation, malposition can be corrected at any time. However, the effect of v-DLT on perioperative hypoxaemia has been rarely reported. The aim of this study was to observe the incidence of hypoxaemia during one-lung ventilation with v-DLT and to compare the perioperative complications between v-DLT and conventional double-lumen tube (c-DLT).

Methods and analysis One hundred patients planning to undergo thoracoscopic surgery will be randomised into the c-DLT group and the v-DLT group. During one-lung ventilation, both groups of patients will receive low tidal volume for volume control ventilation. When the blood oxygen saturation falls below 95%, the DLT will be repositioned and the oxygen concentration will be increased to improve the respiratory parameters (5 cm H₂O Positive end-expiratory pressure (PEEP) on the ventilation side and 5 cm H₂O CPAP (continuous airway positive pressure) on the operation side), and double lung ventilation measures will be taken in sequence to prevent a further decline in blood oxygen saturation. The primary outcomes are the incidence and duration of hypoxaemia and the number of intraoperative hypoxaemia treatments, and the secondary outcomes will be postoperative complications and total hospitalisation expenses.

Ethics and dissemination The study protocol was approved by the Clinical Research Ethics Committee of The First Affiliated Hospital, Sun Yat-sen University (2020–418) and registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn). The results of the study will be analysed and reported.

Trial registration number ChiCTR2100046484.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a randomised controlled experiment with a relatively large sample size.
⇒ The depth of anaesthesia will be monitored by using Narcotrend to ensure that the depth of anaesthesia of the two groups of patients is consistent.
⇒ We will systematically train researchers on the preoperative and postoperative visit standards to ensure the reliability of the collected data.
⇒ We will not employ the double-blind method in this trial, which may fail to control the artificial differences during anaesthesia management.
⇒ The single-centre trial limits the universality of the results.

INTRODUCTION

During one-lung ventilation, 10–30% of patients develop severe hypoxaemia, which is the most common complication during one-lung ventilation.1–3 The main cause of hypoxaemia during one-lung ventilation is malpositioning and displacement of double-lumen tube (DLT).4 When the body position is changed during surgery, the bronchus is pulled and squeezed causing malpositioning of the DLT and therefore blocking the bronchial opening of the lung lobe, resulting in obvious insufficient ventilation and hypoxaemia.5 The second is the imbalance of the ventilation/perfusion ratio caused by one-lung ventilation, and ventilated lungs cannot tolerate one-lung ventilation.6

V-DLT is a video double-lumen tube with an embedded camera and light source between the bifurcation of the trachea and bronchus.7 Therefore, continuous airway visualisation can be realised during catheter positioning, and the placement process is simpler and
more convenient. It has been increasingly used in thoracic surgery.9

The v-DLT can dynamically observe the changes in tube position during the perioperative period and adjust it in time to prevent malposition during one-lung ventilation. We hypothesise that the incidence of hypoxaemia with v-DLT will be lower than that with conventional double-lumen tube (c-DLT) during one-lung ventilation. Existing studies have shown that the intubation time with v-DLT is significantly lower than that with c-DLT, but the effect on hypoxaemia has not been reported.9 10

The purpose of this study was to observe the occurrence of hypoxaemia during one-lung ventilation with v-DLT in patients undergoing thoracoscopy and to further identify the advantages and disadvantages of v-DLT and c-DLT.

METHODS AND ANALYSIS

Study design
The aim of this single-centre, single-blind, prospective controlled clinical trial is to study the occurrence of hypoxaemia with the v-DLT during one-lung ventilation and to compare the perioperative complications between the v-DLT and the c-DLT. Patients will be randomised into either the in vivo double-lumen group or the c-DLT group (figure 1). This study will be conducted in The First Affiliated Hospital, Sun Yat-sen University, Guangzhou, China.

Ethics
This study has been approved by the ethics committee of The First Affiliated Hospital, Sun Yat-sen University and registered in the China Clinical Trial Registration Center. Informed consent will be obtained from all relevant subjects (as shown in online supplemental material of the participant consent form).

Patient and public involvement
The patients nor the public will be involved in the design or implementation of the study. There is no plan to report or disseminate the results to the study participants.

Study population

Inclusion criteria
Patients with (1) an ASA (American Society of Anesthesiology) grade I–III; (2) a Mallampati airway assessment score I–II; and (3) scheduled to undergo elective thoracic surgery under thoracoscopy will be included and comprise the study population.

Exclusion criteria
Patients (1) younger than 18 years of age; (2) with a pulmonary function test showing moderate-to-severe lung ventilation or gas exchange dysfunction (moderate and severe pulmonary ventilation dysfunction: forced expiratory volume in the 1 s <60% of the expected value; moderate and severe gas exchange dysfunction: diffusion of carbon monoxide in the lung <60% of the expected value.); (3) history of thoracic surgery, systemic infection or suspected tuberculosis in the past month; (4) impaired liver and kidney function (Child-Pugh grade of liver function is B and C; patients with endogenous creatinine clearance rate ≤50 mL/min, blood creatinine ≥178 µmol/L or blood urea nitrogen ≥9 mmol/L in renal function test.); (5) severe cardiovascular and cerebrovascular diseases (complicated with severe cardio-cerebrovascular disease: high risk of hypertension, untreated coronary heart disease, valvular heart disease, previous history of myocardial infarction, cerebral infarction, cerebral thrombosis, cerebral haemorrhage); (6) who are unable to cooperate with the research for any reason, such as language comprehension disorder or mental illness; and (7) who have used other trial drugs or have participated in other clinical trials within 3 months before enrolment will be excluded.

Study group
One hundred patients who meet the criteria and plan to undergo thoracoscopic surgery will be selected. The subjects will be randomly divided into two groups: Group V (the v-DLT will be used) and Group C (the c-DLT will be used), with 50 cases in each group (figure 1).

Randomisation and blinding
The primary investigator is responsible for obtaining informed consent from the participants, and the secondary investigator is responsible for distributing the random numbers and personnel grouping. Each participant is numbered 1–100 according to the order of their enrolment time. Participants are randomly numbered. The randomly numbered patients are then randomly assigned through SPSS V.22.0 to either the v-DLT group or the c-DLT group. Neither the patient nor the chief anaesthesiologist will know which group they are assigned to before the operation. Because this study is based on the difference between the use of v-DLT or c-DLT, it is impossible to blind the researchers during the operation, and the researchers who do not know the grouping of the participants will conduct the follow-up assessments the day after the operation.

Interventions
The patients will undergo a preoperative examination to allow recording of the basic information and examination results, including sex, age, height, weight, relevant medical history, complications, chest CT, ECG and pulmonary function. Based on these results, the anaesthesiologists will determine ASA grades and Mallampati grades. The patients will sign informed consent forms. The anaesthesiologists will select the appropriate size of DLT according to their clinical experience and chest CT imaging data (according to Chow’s study, the measurement of the horizontal tracheal internal diameter of the clavicle and sternum of the chest CT before anaesthesia is the basis for selecting the DLT model. When the tracheal internal diameter measurement is ≥19 mm, 39 Fr will be selected, 37 Fr will be selected when ≥15 mm and 35 Fr will be selected when ≥13 mm.)11.
After entering the room, the patient will undergo ECG and pulse oxygen saturation (SpO₂), blood pressure and Narcotrend monitoring and preinhale 6 L/min oxygen with a mask. The values of various vital signs before anaesthesia (heart rate, SpO₂, blood pressure, Narcotrend reading) will be recorded.

The patients in the two groups will be induced by a routine scheme: After intravenous titration of

**Figure 1** Flow chart of this study. SpO₂, oxygen saturation.
dexamethasone (0.5–1.0 μg/kg), propofol (2–3 mg/kg), cisatracurium (2 mg/kg) and sufentanil (0.3–0.5 μg/kg) will be given successively. After successful induction, the DLT will be intubated under a video laryngoscope. The position of the DLT will be adjusted under the fibreoptic bronchoscope (FOB) in the conventional group, and the VivaSight tube will be adjusted to the best position under the video screen and FOB standby in the VivaSight group. The DLT size, intubation depth, intubation time, use times of FOB and intubation time of the DLT (from the beginning of intubation to the determination of the correct position) will be recorded. The anaesthesiologist will score the workload and satisfaction of each patient’s DLT based on 7-item criteria: (1) Is it more convenient to use this DLT? (2) Is the intubation time shorter with this DLT? (3) Is intubation easier with this DLT? (4) Is the success rate of intubation with this DLT higher? (5) Can this DLT reduce the workload? (6) Can this DLT improve work efficiency? (7) Are you satisfied with this DLT? Each item is scored on a scale of 1–5: 1 indicates no, 2 indicates some, 3 indicates moderate, 4 indicates relatively obvious and 5 indicates obvious.

After the DLT is fixed, the ventilator will be connected to perform double lung mechanical ventilation in volume control mode. The tidal volume of bilateral lung ventilation will be set at 5–10 mL/kg, the inspired oxygen concentration will be 50% and the ventilation frequency will be adjusted to keep the end-tidal carbon dioxide (ETCO₂) between 35 and 45 mm Hg. The values of the vital signs and the ventilation parameters (tidal volume, airway pressure, inhalation frequency) will be recorded 5 min after intubation. Anaesthesia will be maintained with sevoflurane, propofol, remifentanil, cisatracurium and sufentanil. The propofol (4–12 mg/kg/hour) and remifentanil (Target Controlled Infusion (TCI), 3–6 ng/mL) concentrations will be adjusted to maintain the Narcotrend reading between D2 and E0. Cisatracurium (intravenous, 0.05 mg/kg) and sufentanil (intravenous, 5 μg/time) will be added intermittently as needed. One-lung ventilation will be performed before pleural opening, the tidal volume will be set at 5–8 mL/kg, and the ventilation frequency will be adjusted to keep the ETCO₂ between 35 and 45 mm Hg. After opening the pleura, the surgeon will evaluate the quality of lung collapse: 1 represents no collapse, 2 represents partial collapse and 3 represents complete collapse. If SpO₂ falls below 95% during one-lung ventilation, it will be adjusted by (1) repositioning the tube and sucking the secretions from the trachea; (2) increasing the oxygen concentration (80–100%); (3) improving the ventilation parameters (tidal volume, frequency); (4) setting the PEEP at 5 cm H₂O for the healthy lung; (5) initiating intermittent resuscitation or CPAP at 5 cm H₂O for the operative lung; and (6) performing double lung ventilation. To maintain stable haemodynamics during the operation, the sevoflurane will be stopped 15 min before the end of the operation and the propofol and remifentanil will be stopped at the end of the operation. The times and duration of intraoperative treatment (SpO₂ <95% and SpO₂ >90%) will be recorded. In addition, the vital signs and ventilation parameters of the patients with double lung and one-lung ventilation will be recorded for each treatment.

After surgery, the patient will undergo postoperative extubation and analgesia in the postanaesthesia care unit. Patients will be followed-up to assess postoperative recovery and complications on the first day after surgery.

Study outcome variables
Primary outcomes
The primary outcomes of the trial are the incidence of hypoxaemia (SpO₂ <90%), the duration of SpO₂ lower than 95% and 90% and the number and times of adjustment during one-lung ventilation in the two groups.

Secondary outcomes
The secondary outcomes included postoperative pulmonary complications (hypoxaemia, pulmonary infection, cough and expectoration occurring within 24 hours after the operation), hospitalisation time/cost and anaesthesiologists’ workload and satisfaction scores in the two DLT groups.

Statistical methods
Sample size
This study is a randomised controlled trial. The subjects will be randomly divided into two groups. The experimental group is the in vivo DLT group, and the control group is the c-DLT group. The incidence of hypoxaemia in the research object is the main outcome index. According to the literature, the incidence of hypoxaemia in patients who receive the c-DLT is approximately 30%. According to the results of our pre-experiment, the incidence of hypoxaemia in v-DLT was about 8%, with a significance level of 5% and a power of 80%. The PASS software calculated that 46 patients are needed in the experimental group and 46 are needed in the control group. Considering a certain abscission rate (no more than 10%), at least 50 subjects are needed in each group, so a total of 100 subjects are needed for the trial.

Outcome analysis
Normally distributed variables will be expressed as the mean±SD, and statistical analysis will be carried out using a t-test. Non-normally distributed variables will be expressed using median and quartile values, and statistical analysis will be performed using the Mann-Whitney U test. Categorical variables will be expressed using sample size and percentage, using the χ² test or Fisher’s exact test. To compare other subgroup values, an analysis of variance will be used.

Statistical analyses will be performed with SPSS V.22.0 and GraphPad V.7.0. All tests are two-tailed, and p values of <0.05 are considered statistically significant.

Data management
In this study, paper case report form (CRF) forms will be used for data entry, storage and management. To ensure
that every step in the implementation process of the study can be accounted for; we will set the main responsible person, subject contact person and data entry personnel. The main person in charge is responsible for the training of data entry personnel, who are required to have relevant clinical experience. All data entry personnel will fill the CRF with the appropriate data in time to ensure the completeness and accuracy of medical history. When researchers find data problems, they should make fine adjustments, check the data quality and perform the final statistical analysis in time.

**Monitoring**
The supervisor must follow the Good Clinical Practice and Standard Operating Procedures for drug clinical trials, visit the research unit monthly or according to the actual situation to carry out clinical supervision, supervise the progress of clinical trials, check and confirm the correctness and completeness of all data records and reports, log the case report forms, ensure consistency with the original data and ensure that the clinical trials are carried out in accordance with the clinical trial plan. The researcher should actively cooperate with the work of the supervisor.

**Participant timeline**
We plan to start recruiting participants in August 2021 and will continue until enough participants (100) are recruited. We anticipate that recruitment will be completed in August 2023. A data analysis and discussion will be separately published at a later date.

**Ethics and dissemination**
The study protocol was approved by the Clinical Research Ethics Committee of The First Affiliated Hospital, Sun Yat-sen University (2020–418) and registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn).

The study results of the trial will be published in peer-reviewed journals and at national and international conferences to allow dissemination and interpretation of the research and results. All investigators will have access to the final data set.

**DISCUSSION**
DLT has been widely used in thoracic surgery to isolate the lung. It can effectively collapse the operative lung, provide a clear surgical view and protect the healthy lung to prevent the pollution of secretions, blood and tumour factors.10 FOB is the gold standard for verifying the positioning of DLTs, but it has many limitations.12 For example, when the ventilator is disconnected from the DLT for a long time, complications such as hypoxaemia and carbon dioxide accumulation are likely to occur and tube malposition may not be found in time, thus making the operation process cumbersome.13 At present, there is a new type of v-DLT used in clinic. Its appearance is similar to that of a c-DLT, but a high-definition camera is installed at the end of the main tube.14 Intubation can be successfully performed under direct vision. Because the carina and bronchus are visible through the microcamera rapid and accurate positioning is possible.15 At the same time, the position of the tube can be monitored in real time during the whole operation. If the tube is malposition, it can be repositioned immediately.16

From published clinical studies, we found that the v-DLT can significantly shorten the intubation positioning time, which can improve the visibility of the surgical field.17,18 During one-lung ventilation, the occurrence of hypoxaemia is often related to malposition of the DLT.19 Once the tube is malpositioned, the airway pressure becomes too high, thus causing hypoxaemia; however, we can immediately adjust the position of the v-DLT through the camera to prevent it from blocking the secondary bronchus too deeply and prevent the tube from being too shallow, which can lead to poor pulmonary isolation.20 We hypothesise that v-DLT may reduce the incidence of intraoperative hypoxaemia while providing good lung collapse.21

Because the v-DLT has a camera, it is thicker than the c-DLT.22 During intubation, the thick v-DLT may rub the tracheal wall when rotating into the glottis to the carina, causing tracheal injury and patients may have a sore throat, hoarseness and postoperative lung-related complications.

The aim of this single-centre, randomised controlled clinical trial is to test the hypothesis that the incidence of hypoxaemia during one-lung ventilation with v-DLT in thoracoscopic surgery is lower than that with c-DLT. At the same time, we also compared the advantages and disadvantages of c-DLT and v-DLT in thoracoscopic surgery.

**Contributors** RH and JG conceived the study, SL and YL participated in its design and coordination. SL and RH drafted the manuscript. All authors read and approved the final manuscript, and agreed to be accountable for all aspects of the work.

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**Competing interests** None declared.

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