INFORMED CONSENT FORM

Single Lung Ventilation versus Two Lung Ventilation in Video Assisted Thoracoscopic Lung Surgeries

2021

Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for patients who are invited to participate in the research

Patient name: Age: Sex:

Research title:

Single Lung Ventilation versus Two Lung Ventilation in Video Assisted Thoracoscopic Lung Surgeries

Introduction and aim of the work:

Single-lung ventilation has been preferred for lung surgeries to provide better surgical field, but its role and drawbacks compared with two-lung ventilation have not been fully evaluated.

Single lung ventilation is a technique commonly used in thoracic anesthesia to make thoracic surgery easier. It is used to create a silent operative field and to improve surgical exposure. Single lung ventilation can be accomplished using different tools. However, double-lumen tubes still considered the most popular and reliable choice for single lung ventilation in adult patients. The use of video-assisted thoracoscopic surgery has become widespread, and the traditional open thoracotomy has been replaced by video-assisted thoracoscopic surgeries due to its minimal invasiveness and associated low morbidity.

Hypoxemia used to be the primary concern during one lung ventilation. However, hypoxemia has become less frequent due to more effective lung isolation techniques, particularly the routine use of fiberoptic bronchoscopy, and

the use of anesthetic agents with little or no detrimental effects on hypoxic pulmonary vasoconstriction. Acute lung injury has replaced hypoxia as the chief concern associated with one lung ventilation.

The aim of the study is to evaluate single lung ventilation as an alternative to conventional ventilation in video assisted thoracoscopic lung surgeries despite the claimed intra operative and post-operative hypoxemia which could be avoided or even minimized by changing ventilatory setting.

Methodology:

Type of the study: Interventional, prospective randomized clinical trial.

Study Setting: The operating theaters of Ain Shams University Hospitals.

Study period: Over four to six months, after the approval of Medical Research Ethical Committee.

Study population:

Inclusion criteria:

Age group: Adult patients from age of 21 years to 60 years

Sex: Both sexes

ASA Classification: patients with ASA classification II, III.

Elective lung surgeries using video assisted thoracoscopic surgeries.

Exclusion criteria:

Patients refuse to give informed consent.
ASA Classification: ASA IV.
Failure of thoracoscopic surgeries and continue as open thoracotomy
Patients with ischemic heart diseases.
Emergency lung surgeries.
Patients underwent previous lung surgeries of any cause.
Patients with pathology to the non-operated side.

Sampling method:

Patients are randomly allocated by computer generated randomization into two groups A and B.

Group A: patients doing lung surgeries with single lung ventilation using double lumen endotracheal tube.

Group B: patients doing lung surgeries with two lung ventilation using conventional single lumen endotracheal tube without isolation (two lung ventilation).

Ethical considerations:

The study protocol received ethical approval from the Medical Research Ethical Committee, Faculty of Medicine Ain Shams University.

Informed consent will be obtained from each patient before patients' allocation.

Study Procedures:

Patients are randomly allocated into two equal groups.

Preoperative setting: pre-operative assessment by accurate history taking, full physical examination, laboratory and radiological investigations.

Intraoperative setting:

Standard perioperative monitoring will include pulse oximetry, electrocardiogram, end-tidal CO_2 measurement, inhaled volatile agent concentration, invasive blood pressure measurement, and arterial blood gas measurement.

Baseline parameters such as oxygen saturation, systolic, diastolic and mean blood pressure, heart rate will be recorded.

Intravenous line will be inserted.

Invasive arterial line will be inserted for monitoring arterial blood pressure and continuous arterial blood gases sampling.

For all patients, general anesthesia will be induced as recommended by American Society of Anesthesiologists.

This will be followed by endotracheal intubation and mechanical ventilation.

Arterial blood gases will be sampled every hour or in any change in oxygen saturation, end tidal CO2, or vital data.

Group A: (the Single lung ventilation)

After induction of anesthesia intubation will be done by double lumen endotracheal tube, the operated lung will be deflated on starting the surgical procedure and single lung ventilation will be started.
The patient will be placed in the lateral position ready for surgery. Single-lung ventilation of the dependent lung will be initiated by clamping the double-lumen tube connector to the nondependent lung at end expiration. Ventilator settings will be set to keep optimum percentage of oxygen and end tidal CO_2. Airway management including double lumen endotracheal tube placement will be performed by the anesthesia consultant.

Group B: (the two-lung ventilation)

After induction of anesthesia intubation will be done by conventional single lumen endotracheal tube, the two lungs will be inflated together and if lung inflation would interfere with the surgical procedure, both lungs will be deflated for brief time that no significant hypoxia will occur, then the two lungs will be re-inflated again.

Same ventilator setting will be applied at the beginning of surgical procedure, inspiratory oxygen fraction of 1.0, tidal volume of 6-8 ml/kg, respiratory rate set to maintain an end tidal CO2 between 30 and 35 mmHg peak inspiratory pressure limit of 35 cm H2O and this will be maintained during starting two lung ventilation.

<u>Post-operative setting</u>:

A Common complication in the postoperative period include sputum retention, collapse, consolidation and edema on the operative side.

Postoperative pain management will be intravenous adequate dose of morphine. Adequate pain relief and ability to cough are the most important factors in preventing chest complications.

Patients will be nursed in a high-dependency area where meticulous attention is required in managing oxygen therapy, pain relief, physiotherapy, inhaler therapy, chest drains and fluid balance.

Postoperative chest X-ray will be performed in recovery to exclude pneumothorax, hemothorax, misplaced chest drains and collapse.

Measured outcomes:

Primary outcome:

Incidence of hypoxemia intra and post operative in 1st 24 hours in intensive care unit by monitoring oxygen saturation using pulse oximetry and by serial arterial blood gases (pH, PO2, SO2, CO2, HCO3).

Secondary outcome:

- Incidence of failure to correct hypoxemia during single lung ventilation by all measures.
- Incidence of failure of two lung ventilation to achieve optimum surgical field so that it is changed to single lung ventilation.
- Occurrence of any complications intra operative and first 24 hours post-operative in intensive care unit.

End point:

- Persistent hypoxemia despite doing all recommended measures.
- 24 hours post-operative in the intensive care unit.

Number and Selection of participants:

- 60 participants, 30 participants are patients undergoing video assisted thoracoscopic lung surgeries with single lung ventilation using double lumen endotracheal tube and 30 participants are patients undergoing video assisted thoracoscopic lung surgeries with two lung ventilation.

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

1. **Clinical parameters:**

Complete history taking and thorough clinical examination.

2. **Laboratory parameters:**

1. CBC.
2. Chemistry profile (liver functions, kidney functions, electrolyte).
3. Coagulation profile.
4. Viral markers.
5. Arterial blood gases.
6. ECG.
7. ECHO.

Patients of both groups will be followed in first 24 hours in ICU

1. **Clinical:**

- Oxygen saturation by pulse oximetry.

2. **Laboratory:**

- Arterial blood gases intraoperative and first 24 hours in ICU.

3**. Radiological:**

- Chest x rays post-operative in ICU.

Benefits expected from the study:

Benefits to the participants:

The patients who are supposed to do video assisted lung surgeries will undergo surgery with the type of ventilation of choice for them and accurate preoperative investigation and postoperative follow up for them.

Benefits to the community:

To evaluate the effectiveness of single lung ventilation and its safety with the best ventilator setting to avoid intraoperative and post-operative hypoxemia in lung surgeries and decrease the period of post-operative ICU stay.

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, resident Esraa Abd El-latif Mohamed Shawky in the Anesthesia, Intensive care and pain management Department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

The risk of blood sampling: The blood sample will be obtained by a trained, professional nurse using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. However, the volume of blood (5 milliliters) is small, and will be replaced quickly by your body.

- ***The risk of video assisted lung surgeries*:** Pneumothorax, hemothorax, misplaced chest drains and collapse. Postoperative chest X-ray will be performed in ICU to exclude them and early management.
- ***The risk of single lung ventilation***: Hypoxia, acute lung injury. However, it will be minimized by the best ventilator setting. If significant hypoxia occurs, we will continue by two lung ventilation by declamping the bronchial side of double lumen endotracheal tube.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, resident Esraa Abd El-latif Mohamed Shawky will provide first-aid management and resuscitation even if the patient will be excluded from the research.

Alternatives to participating:

In case of refusing to participate in this research, the patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient`s research results and also further information regarding your patient`s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at any time. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, Esraa Abd El-latif Mohamed Shawky at phone number: 42180513, mobile number: 01119895491. You can also call the assistant supervisor Prof. Omar Mohamed Taha Abdallah El-Safty at mobile phone number: 01000665666. If you have any

problems or concerns about the study, you can also call the main supervisor Prof Ayman Mokhtar at mobile number:01001453563.

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature of legal guardian:
- Or participant:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Esraa Abd El-latif Mohamed Shawky
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:
Name:
Address:
Telephone number: