

**THE USE OF LUNG-ULTRASOUND TO CONFIRM
CORRECT PLACEMENT OF LEFT SIDED DOUBLE
LUMEN TUBES**

RESEARCH REPORT FOR PARTIAL FULFILMENT
FOR THE MASTER'S DEGREE IN ANAESTHESIOLOGY

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DECLARATION OF OWN WORK

I hereby declare that the research paper titled **THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES** submitted by me is based on actual and original work carried out by me. Any references to work done by any other person or institution or any material obtained from other sources have been duly cited and referenced.

I further certify that the research paper has not been published or submitted for publication anywhere else.

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ACKNOWLEDGEMENTS

I would like to pay special thanks and appreciation to the persons below who made my research successful and assisted me at every point to cherish my goal:

My supervisor, Dr EW Turton, for his support and assistance.

Thank you to Prof G Joubert from the Department of Biostatistics with helping me with the statistical analysis of this research.

All the staff from Cardiothoracic Theatre, Universitas Hospital, as well as my fellow colleagues from the Department of Anaesthesiology who assisted me with the data collection process.

ABSTRACT

Study objective: To assess the accuracy of the ultrasonographic lung sliding sign in detecting correct positioning of the endotracheal double-lumen tube after intubation, compared to flexible bronchoscopy, in adult patients who present for thoracic surgery requiring one lung ventilation.

Design: Prospective clinical study.

Setting: Cardiothoracic theatre, Universitas Hospital, Bloemfontein.

Patients: 30 adult patients, 18 years of age or older, who present for elective thoracic surgery, and require endotracheal left sided double-lumen tube intubation after induction of anaesthesia for lung isolation.

Intervention and measurement: The presence of the lung sliding sign was determined with an ultrasound on all 30 patients before induction of anaesthesia and after intubation, as well as post lung isolation. All patients were intubated with a left sided double-lumen tube. The Anaesthetic consultant or registrar then performed a flexible bronchoscopy on all patients to verify the position of the double-lumen tube.

Results: A total of 17 patients were enrolled in the study. 1 Patient was excluded who was less than 18 years of age. In 1 case no bronchoscope was available to confirm correct position of the double-lumen tube. In 11 cases the presence of the lung sliding sign pre-intubation on the affected side was absent, and thus could not be used in comparing ultrasound findings with bronchoscopy. The overall sensitivity of the ultrasonographic lung-sliding to confirm correct placement was 94.1% (confidence interval 73.0 to 99.0%). The positive predictive value was 100%.

Conclusion: The presence of the lung-sliding sign before induction of anaesthesia was absent in a high number of patients (37.9%). Our study suggests that, for patients with the presence of the lung-sliding sign pre-induction of anaesthesia, the ultrasonographic lung-sliding sign can accurately detect correct positioning of the double-lumen tube as compared to the gold standard which is a flexible bronchoscope. We therefore recommend that patients should first be assessed for the presence of lung-sliding pre-intubation before deciding on ultrasound as the means to confirm correct double-lumen tube placement. Ultrasound will therefore not be able to replace bronchoscopy in thoracic surgery.

ABBREVIATIONS

DLT	double-lumen tube
LDLT	left double-lumen tube
ET	endotracheal
TB	Tuberculosis
RVD	Retroviral disease
mL	milliliters

INTRODUCTION

In thoracic surgery, the majority of procedures require one-lung ventilation which is achieved by placing a double-lumen tube in the airway of the patient. The lung to be operated on should be well collapsed to allow the surgeon proper visualization of the operating field¹.

The double-lumen tube is placed in the trachea, with one lumen in either the left or right bronchial main stem, while the other lumen remains in the trachea. This allows the clinician to ventilate both lungs or the right or left lung independently.

Absolute indications for one lung ventilation include isolation of each lung to prevent contamination of the healthy lung, to control of distribution of ventilation to only one lung (for example bronchopleural fistula), for unilateral lung lavage and video-assisted thoracoscopic surgery. Relative indications include pneumonectomy, thoracic aortic aneurysm repair and lobectomy.

Malposition of the DLT can occur either during insertion or after patient positioning. Precise positioning of DLT is therefore essential as a misplaced tube can cause several problems during thoracic surgery, such as hypoxia and hypoventilation, incomplete collapse of the operative lung, contamination of the dependent lung and of course jeopardize surgery².

Literature findings suggest that flexible bronchoscopy remains the gold standard to determine the correct position of a DLT and is recommended as the method of choice³. Despite this recommendation, some authors argue that bronchoscopy is expensive, time consuming and not universally available and should thus not be considered routine. It also poses the risk of potential mucosal lesions and danger of infections⁴.

Before the introduction of the bronchoscope, assessment of the tube position depended on clinical examination, which consisted of inspection, auscultation, and assessment of ventilation pressure with and without unilateral clamping of DLT limbs⁴. Unfortunately, clinical assessment alone does not always allow the anaesthesiologist to recognize a misplaced DLT^{1,4}. Previous studies have shown that 15.5-24% of left sided DLT could not be positioned using clinical signs alone, necessitating fiberoptic bronchoscopy^{5,6}.

AIM OF THE STUDY

To assess the accuracy of the ultrasonographic lung sliding sign in determining correct positioning of the left sided DLT, compared to flexible bronchoscopy, in adult patients presenting for thoracic surgery who require one lung ventilation.

Many international authors have produced several studies on the application of lung ultrasound in various settings⁷. It is used not only in critical care and emergency medicine, but is also becoming a more popular tool used in theatre by Anaesthesiologists for diagnostic or treatment purposes. Currently, in many academic institutions around the country, Registrars in Anaesthesiology are taught skills in ultrasound usage and are encouraged to use this skill more often in the theatre setting.

METHODS

Study design and setting

This was a prospective clinical study conducted between January 2014 and August 2014 at Universitas Hospital, Bloemfontein.

Ethical aspects

The Ethics Committee of the Faculty of Health Sciences of the University of the Free State approved the study protocol. Consent for performing the study was obtained from the Clinical Manager of Universitas Hospital in Bloemfontein. All subjects recruited for the study were inpatients of Universitas Hospital. Written informed consent was obtained from all participants. Patient data was handled confidentially during the study.

Selection of patients

30 Patients, 18 years of age or older, were enrolled who underwent thoracic surgery and needed left sided double-lumen tube intubation. Exclusion criteria included patients with no lung sliding sign on the affected side prior to intubation; patients who were to breath spontaneous intra-operatively; and patients with previous thoracic surgery as this may alter visualization of the lung sliding sign.

Measurement

A pilot study was first conducted consisting of 3 patients to detect flaws in the protocol and to get an indication of possible results. No changes were made to the protocol after performing the pilot study.

Before induction of anaesthesia, the presence of the lung sliding sign on both sides of the chest was assessed in all 30 patients. A Philips™ iE 33 model ultrasound machine equipped with a L 11 – 3 linear transducer was used for ultrasonography. A transducer was placed on both sides of the chest within the third to fifth rib interspaces, along the midclavicular and the anterior axillary line. For induction of anaesthesia all patients received fentanyl, propofol and either rocuronium or cisatracurium for muscle relaxation. The patients' lungs were ventilated with oxygen and air mixture, and Sevoflurane 2% to 2.5%. After induction of anaesthesia, all the patients underwent the same conventional procedure of DLT placement. The size of the DLT was chosen on the basis of both the patients' sex and height. Either a size 35, 37 or 39 left sided DLT was used. Manufactures of the DLT was either Mallinckrodt™ or Well Lead™ -

depending on the stock available in theatre. The DLT with stylet was passed through the larynx. The stylet was removed after the endobronchial cuff had passed the vocal cords. The tube was then rotated 90 degrees and advanced until moderate resistance was felt. The tracheal cuff was then inflated and clinical assessment of the DLT position was made by observing chest wall expansion and checking lung compliance by manual ventilation and by auscultation of both lungs. The presence of the ultrasonographic lung sliding sign on both lungs was evaluated. The endobronchial cuff was then inflated with 2 mL of air. Positioning of the LDLT was assessed by auscultation of the lung after selective clamping of the bronchial and tracheal limbs. The presence of the lung sliding sign was done again post lung isolation. Then finally correct positioning of the LDLT was addressed by a Storz™ 2.7mm paediatric flexible bronchoscope. Bronchoscopy criteria for correct left DLT were defined as an unobstructed view into the left upper and lower lobe bronchus through the endobronchial lumen with the bronchial cuff immediately below the carina and just visible in the main left bronchus through the tracheal lumen. Operators in this study, who performed the intubations, lung sliding sign and bronchoscopy, were senior Anaesthetic registrars or Anaesthetist consultants. All operators had to be familiar with using the ultrasound machine and identifying lung sliding sign, as well as skills in using a flexible pediatric bronchoscope. If the Anaesthetic registrar was not familiar with this, the Anaesthetic consultant was the operator. No time limits were placed on the operator for performing the ultrasound evaluation. All findings were recorded on a datasheet.

Outcome measures

The primary outcome measure was to assess the accuracy of the ultrasonographic lung sliding sign in detecting correct positioning of the DLT after intubation, compared to flexible bronchoscopy. Other secondary outcomes were to note the co-morbid condition(s) a patient might have, as well as the indication for surgery and to evaluate the presence of the lung sliding sign in these conditions.

Data collection and processing

A datasheet was provided for each case. It was the responsibility of the Anaesthetic registrar or consultant involved in each case to complete the sheet at the end of the surgical procedure. The presence of lung sliding sign pre- and post induction, post lung isolation, and bronchoscopy findings were filled in. The patient's age, sex, weight, indication for surgery, presence of co-morbid conditions and the size of the DLT used were also completed on the datasheet.

Statistical analysis

The statistical analyses were performed by the Department of Biostatistics of the University of the Free State. All statistical analysis was performed using frequencies, medians, percentages and confidence intervals.

RESULTS

A total of 30 patients were enrolled in this prospective clinical study. 30 Datasheets were completed. One datasheet was excluded from the statistical analysis as the patient was 17 years of age and accidentally included in the study.

From the 29 datasheets analyzed, the lung-sliding sign in the lung to be isolated for surgery was already absent in 11 (37.9%) of the cases prior to intubation. Those 11 cases were subsequently not included in the analysis of this study as the lung-sliding sign needed to be present prior to intubation to detect the change in presence of the lung-sliding sign after lung isolation.

No bronchoscope was available in theatre in one case and was excluded from the study.

17 cases were included for analysis in this study.

Table 1. Patients characteristics

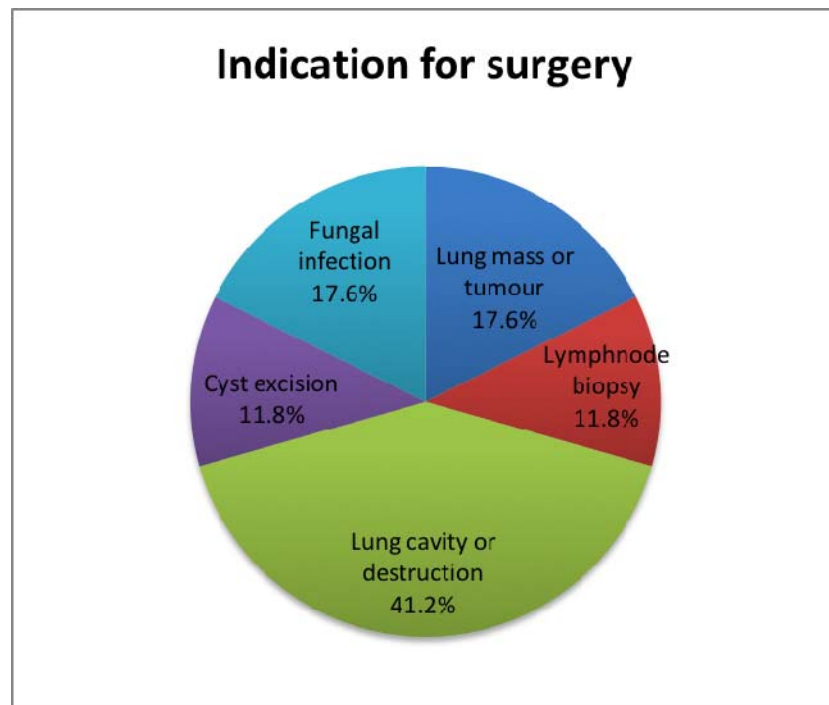
	Median	25% Lower quartile	75% Upper quartile
Age (years)	40.0	26.0	49.0
Weight (kg)	58.0	50.0	64.0

Table 2. Gender

	Frequency	Percent
Male	13	76.5
Female	4	23.5

The majority of patients included in the study were male.

Figure 1: Indication for surgery



The majority of patients presented for surgery had lung cavitation or lung destruction.

Table 3. Co-morbidities

	Frequency in patients with presence of lung-sliding pre-intubation	Percent	Frequency in patients with absence of lung-sliding pre-intubation	Percent
Pulmonary TB	8	30.8	3	27.3
RVD	7	26.9	3	27.3
COPD / Asthma	3	11.5	0	0
Cancer	1	3.8	0	0
Hypertension	3	11.5	0	0
Liver dysfunction	1	3.8	0	0
None	3	11.5	7	63.6

*some patients had more than one co-morbid conditions

Pulmonary TB and RVD were the most frequent co-morbid conditions present in patients with the presence of the lung-sliding pre-intubation.

Table 4. Size of left sided double lumen tube used (French size)

	Frequency	Percent
Size 35	1	5.9
Size 37	9	52.9
Size 39	7	41.2

Size 37 and size 39 DLT were mostly used.

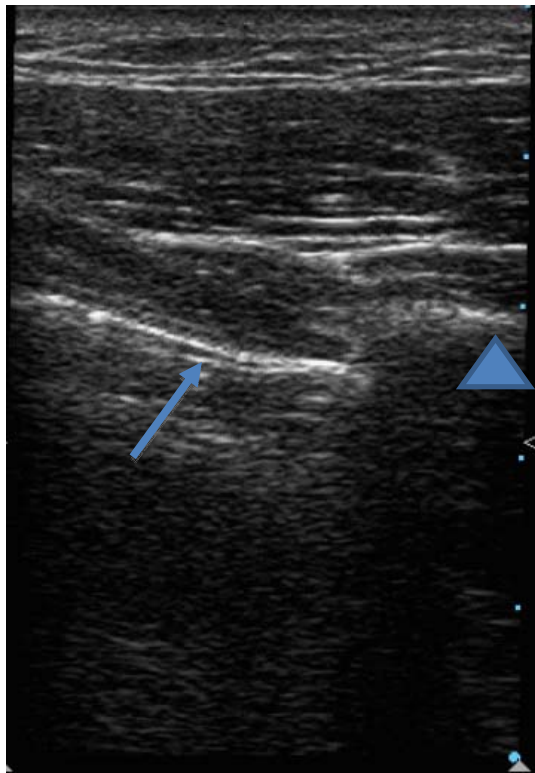


Figure 2: Demonstration of lung sliding on an ultrasound image: Longitudinal scan over an intercostal space. Pleural line (arrow), rib (triangle).



Figure 3: Anterior chest anatomy: Indicating positions of ultrasound imaging obtained for the lung sliding sign. Midclavicular line (red), anterior axillary line (blue).

The lung-sliding sign prior to intubation was present in all of the 17 cases on the side of the lungs which were to be isolated for surgery.

In 16 cases, the ultrasonographic lung-sliding sign correctly identified lung isolation as confirmed with a flexible bronchoscope. In one case only, the lung-sliding sign was still present after lung isolation and did not correlate with bronchoscopy findings (one false-positive).

Sensitivity for detecting lung isolation with ultrasonographic imaging was 94.1% (confidence interval 73.0 to 99.0%). The positive predictive value was 100%.

DISCUSSION

The concept of lung sliding was first introduced by Lichtenstein in the 1980's⁸. Lung sliding is the ultrasonographic observation of the movement of the visceral pleura against the parietal pleura. Lung sliding depends on the compliance and tidal volume and can be used for continuous monitoring of ventilation. On an ultrasound image, the parietal pleura appears as a bright echoic line but the visceral pleura is anatomically thin and hardly detectable. However, when the ultrasound beam passes through subcutaneous and intercostal muscle tissue and reaches the visceral pleura and aerated lung tissue, there is a high difference in the impedance, which causes total reflection. Thus, the visceral pleura appears echoic as well⁹. If a single-lumen ET is placed in one of the main bronchi, absence of the lung sliding sign would be noted over the contralateral side during ventilation. Accuracy can be enhanced with the addition of the M-mode found on most ultrasound machines. The presence of the lung sliding sign are visualized as the seashore sign. The stratosphere sign is visualized in the absence of lung sliding¹³.

Ultrasound is a common tool in various medical departments. The utility of ultrasound has been well described in confirmation of the single lumen ET placement. Previous studies have described the high sensitivity and specificity of ultrasonographic lung sliding sign in confirmation of correct placement of endotracheal tube¹⁰. Limited studies are found in the literature in using sonographic lung sliding sign in confirming placement of double-lumen tubes.

A study published in the Journal of Clinical Anaesthesia, *The addition of a brief ultrasound examination to clinical assessment increases the ability to confirm placement of double-lumen endotracheal tube*³, found that a brief ultrasound examination using the lung sliding sign, added to clinical assessment, ensured more precise placement of a left sided DLT. 50 Elective adult thoracic patients who required left sided DLT during anaesthesia were included in the study. The patients were randomized into two groups. Group A underwent clinical assessment of the LDLT, while Group B was examined clinically and by ultrasound. Sensitivity, accuracy and positive predictive value for detecting correct LDLT positioning in Group B was higher compared to group A.

The accuracy of the ultrasound lung sliding sign in identifying ET tube position after emergency intubation, compared to chest radiography, was compared in a study published in the journal Resuscitation in 2012¹⁰. The overall result suggests using ultrasound to confirm proper ET intubation is feasible, timely, and has a satisfactory predictive value among patients with cardiac arrest.

In the European Journal of Cardio-thoracic Surgery, *Is flexible bronchoscopy necessary to confirm the position of double-lumen tubes before thoracic surgery*¹, the usefulness of flexible bronchoscopy for confirming the position of DLT after blind intubation was described. 144 patients were enrolled in the study. Flexible bronchoscopy was performed on all patients to verify position of the tube. After blind intubation, 37% of double-lumen tubes required repositioning.

A study published in Signa Vitae, *Identification of lung sliding: a basic ultrasound technique with a steep learning curve*⁸, 57 4th year medical students were given a 20-minute lecture on sonographic identification of lung sliding. The study suggests that these students with no prior experience in lung ultrasonography, can easily acquire knowledge and skills needed to identify lung sliding with a high degree of sensitivity and specificity.

In a study *Confirmation of Endotracheal Tube Placement after Intubation Using the Ultrasound Sliding Lung Sign*¹¹, recently dead cadavers were intubated with a single lumen ET tube in the trachea, right main stem bronchus or in the oesophagus. Blinded sonographers performed the lung sliding sign imaging. The results showed that ultrasound imaging of the sliding sign in a cadaver model is an accurate method for confirmation of ET tube placement.

Point-of-Care Sonographic Detection of Left Endobronchial Main Stem Intubation and Obstruction Versus Endotracheal Intubation, a study published in 2008¹², concluded that the clinical use of lung sonography may decrease the need for chest radiography to confirm correct position of the ET tube, and may allow more rapid diagnosis of main stem intubation and bronchial obstruction.

Lung isolation is essential in several procedures. It is therefore important to confirm correct position of the double lumen tube placement. The flexible bronchoscope, which confirms correct double-lumen tube placement under direct vision, is the current method of choice. The paediatric fiberoptic bronchoscope is however not always available in a medical setting. It also requires practice and skill to perform.

As shown in the studies above, ultrasound examination has gained recent popularity in evaluating and identifying normal or pathological patterns in patients. It has been shown to be a useful tool, together with clinical assessment, in examining patients.

Data from this study suggests that there is a high incidence of patients (37.9%) in whom the lung-sliding sign was absent pre-induction of anaesthesia. When comparing co-morbidities between patients with and without the presence of the lung-sliding sign pre-induction, no clear correlation could be made to suggest the presence of a specific co-morbid condition and the absence of lung-sliding sign pre-intubation.

We found that in those patients in whom the lung-sliding sign was present pre-intubation, the ultrasonographic lung-sliding sign is a useful tool to confirm lung isolation after double-lumen placement with a high sensitivity.

There are limitations to this study. A small number of patients were enrolled in the study, which could affect the results obtained. Results should be confirmed in a larger population. Only left sided double-lumen tubes were used in the study. Right sided double-lumen tubes, which are not as commonly used in practice, can obstruct the right upper lung lobe and influence detection of the sliding sign in the apical regions. There is a low margin of safety and higher incidence of malposition associated with right sided DLT⁴. It is well known that the DLT can displace after repositioning of the patient and at anytime during surgery. In this study, we did not reassess the position of the DLT again using the lung-sliding sign technique after repositioning of the patient before the start of surgery. This is another short coming of the study, as we did not directly address the accuracy using the lung-sliding sign after repositioning, for example in the lateral position. It was assumed that operators in this study using the bronchoscope followed the criteria we provided to identify correct DLT placement. There was no second blinded Anaesthesiologist to confirm that the DLT fulfilled the criteria for correct placement with the bronchoscope, or to confirm the presence or absence of lung sliding. The findings thus depended on the operator's skill and experience.

In conclusion, data from this study suggests there is a high incidence of patients in whom the lung-sliding sign is absent before the start of anaesthesia. In cases where the lung-sliding sign was present before intubation, our data supports the use of the lung sliding sign to confirm correct lung isolation after left sided double-lumen tube placement with a high sensitivity. We therefore point out the need to assess patients prior to intubation for the absence or presence of the lung-sliding sign before deciding on ultrasound as the means to confirm DLT placement. Lung ultrasound will not be able to replace bronchoscopy in thoracic surgery.

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APPENDIX A

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2014-02-11

REC Reference nr 230408-011
IRB nr 00006240

DR NJ BERNARD
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Dear Dr Bernard

ECUFS 206/2013


**PROJECT TITLE: THE USE OF ULTRASONOGRAPHIC LUNG SLIDING SIGN IN CONFIRMING
CORRECT PLACEMENT OF DOUBLE-LUMEN TUBE INTUBATION.**

1. You are hereby kindly informed that at the meeting held on 4 February 2014 the Ethics Committee approved the above study after the coding blocks on the data sheet was finalised and approved by the Biostatistician.
2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.
3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.
4. The Committee must be informed of any serious adverse event and/or termination of the study.
5. All relevant documents e.g. signed permission letters from the authorities, institutions, changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).



6. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.
7. Kindly refer to the ETOVS/ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully



.....
PROF WH KRÜGER
CHAIR: ETHICS COMMITTEE

APPENDIX B

THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES

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30 OCTOBER 2013

DECLARATION BY INVESTIGATORS:

1. I hereby agree to conduct the Clinical Trial as specified in the protocol and obtain in writing the necessary authorization from the relevant ethics or clinical bodies.
2. I agree to obtain informed consent from patients who are legally competent in all cases.
3. I agree to obtain permission from the Ethics Committee in writing should I wish to deviate from the protocol.
4. I agree to render a full report of my findings at the end of this trial and a progress report periodically as instructed.

Signature: _____

Date: _____

Names: _____

Designation: _____

Qualification(s): _____

SUMMARY

Flexible bronchoscopy is recommended to confirm correct placement after intubation with double-lumen tubes used for thoracic anaesthesia¹. This study aims to assess the accuracy of the ultrasonographic lung sliding sign to confirm correct placement of double-lumen tubes.

Thirty adult patients, who present for elective thoracic surgery and require intubation with double-lumen tubes, will be included in this prospective study. A pilot study will first be conducted and include three patients. These patients will meet the same inclusion and exclusion criteria as for the patients in the main study.

The accuracy of determining correct placement of the double-lumen tube by using the ultrasonographic lung sliding sign will be compared to the findings obtained by the gold standard technique: flexible bronchoscopy.

INTRODUCTION

In thoracic surgery, the majority of procedures require one-lung ventilation which is achieved by placing a double-lumen tube in the airway of the patient. The lung should be well collapsed to allow the surgeon proper visualisation of the operating field.

This double-lumen tube is placed in the trachea, with one lumen in either the left or right bronchial main stem; the other lumen remains in the trachea. This allows the clinician to ventilate both lungs or the right/left lung independently².

Precise positioning of DLT is therefore essential as a misplaced tube can cause several problems during thoracic surgery, such as hypoxia and hypoventilation, incomplete collapse of the operative lung, contamination of the dependant lung and of course jeopardise surgery¹.

The flexible bronchoscopy remains the gold standard to determine the correct position of a double-lumen tube (DLT)³. However, before the scope is inserted into a DLT, confirmation of correct placement should also be achieved by auscultation.

The concept of lung-sliding was first introduced by Lichtenstein in the 1980's⁴. Lung sliding is the ultrasonographic observation of the movement of the visceral pleura against the parietal pleura. Lung sliding depends on the compliance and tidal volume and can be used for continuous monitoring of ventilation. On an ultrasound image, the parietal pleura appears as a bright echoic line but the visceral pleura is anatomically thin and hardly detectable. However, when the ultrasound beam passes through subcutaneous and intercostal muscle tissue and

reaches the visceral pleura and aerated lung tissue, there is a high difference in the impedance, which causes total reflection. Thus, the visceral pleura appears echoic as well. Lung sliding can be seen clearly and enables diagnostic interpretation⁵.

Ultrasound is a common tool in various medical departments. The utility of ultrasound has been well described in confirmation of endotracheal tube placement. Previous reports, including cadaver studies and case series, have described the high sensitivity and specificity of ultrasonographic lung sliding sign in confirmation of correct placement of endotracheal tube⁶. Limited studies are found in the literature in using sonographic lung sliding sign in confirming placement of double-lumen tubes.

AIM

The aim of the study is to assess the accuracy of the ultrasonographic lung sliding sign in detecting correct positioning of the left sided double-lumen tube, compared to flexible bronchoscopy, in adult patients for thoracic surgery requiring one lung ventilation.

STUDY DESIGN

Prospective clinical study to be conducted at the Universitas Hospital cardiothoracic theatre after approval by the Ethics Committee.

METHODS

30 patients booked for elective adult thoracic surgery, who require double-lumen tube intubation after induction of anaesthesia, will be enrolled in this prospective study.

The study will be conducted over a period of four months.

Exclusion criteria:

1. Patients with no lung sliding sign before the start of the procedure.
2. Patients who will be breathing spontaneously intra-operatively.
3. Patients with previous thoracic surgery as this may alter the visualisation of the lung sliding sign.

Before induction of anaesthesia, the presence of the lung sliding sign on both sides of the chest will be assessed in all 30 patients. After induction of anaesthesia, all 30 patients will undergo the same conventional procedure of left sided DLT placement. A brief ultrasound examination will then be done to assess correct placement, followed by confirmation with flexible bronchoscopy.

Findings of ultrasound examination will be compared to findings of the flexible bronchoscopy and the accuracy of the ultrasound technique in determining correct placement will be determined.

Ultrasound examination includes visualisation of pleural movements (lung sliding) on both sides of the chest within the third to fifth rib interspaces, along the anterior and mid axillary line, during positive-pressure ventilation. Pleural movement indicates a positive sliding sign. An experienced anaesthetist will be present in evaluating lung sliding in all 30 patients, as well as confirming correct placement by flexible bronchoscopy.

The ultrasound examination is a very safe and non-invasive procedure. There is no risk of an adverse effect.

A left-sided type of DLT will be used in this study. Manufacturers: Mallinckrodt™ or Well Lead™ – depending on the stock available in theatre. Either a size 35, 37 or 39 tube is normally used for an adult, depending on the length of the patient.

The type of ultrasonographic machine to be used is a Philips™ iE 33 model. Ultrasound probe: L 11 – 3 linear transducer.

A Storz™ 2.7mm Paediatric flexible bronchoscopy will be used in to confirm placement of the tubes.

PILOT STUDY

A pilot study will first be done to detect flaws in the protocol and to get an indication of possible results.

Three patients will be included and will have to meet the same inclusion and exclusion criteria as for patients in the main study. The same outcome as in the main study will be tested in these three patients.

COLLECTION OF DATA

Results of the findings will be written down on a data form by the researchers - Drs NJ Bernard or EW Turton. A data form will be available for each case.

STATISTICAL ANALYSIS

Results will be summarised by frequencies and percentages (categorical variables) and means, standard deviation or percentiles (numerical variables). Sensitivity and specificity of lung-sliding sign compared to the gold standard bronchoscopy will be calculated.

The Department of Biostatistics, Faculty of Health Sciences UFS, to assist with statistical analysis.

TIME SCHEDULE

The study will be conducted over a period of four months after which the dataforms will be analysed.

BUDGET

No funds are needed for this study. Insertion of a double lumen tube and routine confirmation with a flexible bronchoscope is a standard procedure for thoracic surgery requiring one lung ventilation. The ultrasound to be used in this study is always available in the theatre. Therefore no additional costs are needed to conduct this study.

ETHICS ASPECTS

This study is subject to the approval by the Ethics Committee of the Faculty of Health Sciences, University of the Free State, as well as the Clinical Head of Universitas Academic Hospital.

Patient data will be handled confidentially during this study.

REFERENCES

1. European Journal of Cardio-thoracic Surgery 40 (2011) 912-918; M de Bellis, R Accardo
2. Medscape: Double-Lumen Endotracheal Tube Placement, Author: Marc S Orlewicz, MD; Chief Editor: Arlen D Meyers
3. Korean Journal of Anesthesiology 2012 June; 62(6): 565-567; L Karabiyik
4. Signa Vitae 2013; 8(1): 31-35; MStrnad, S Zadel, Z Klemenc-Ketis, G Prosen
5. Resuscitation 83 (2012) 273-274; R Breitzkreutz, A Seibel
6. Resuscitation 83 (2012) 307-312; S Sim, W Lien, H Chou

APPENDIX C

INFORMED CONSENT

CONSENT TO PARTICIPATE IN RESEARCH

PROJECT TITLE: **THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES**

You have been asked to participate in a research study.

You have been informed about the study by Dr NJ Bernard or Dr EW Turton.

You may contact Dr NJ Bernard or Dr EW Turton at (051) 405 3911 any time if you have questions about the research or if you are injured as a result of the research.

You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research subject.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is a written summary of the research.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

Signature of Participant

Date

Signature of Witness

Date

Signature of Translator

Date

INFORMATION DOCUMENT

Study title: **THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES**

Good day

We, Drs NJ Bernard and EW Turton, are doing research on double-lumen tube intubation. Research is just the process to learn the answer to a question. In this study we want to learn if we can accurately confirm the correct placement of a double lumen tube by means of an ultrasound image.

We are asking you to participate in this research study.

For your scheduled thoracic surgery, we will put a double-lumen tube in your airway after induction of anaesthesia, so you will be asleep. A double-lumen tube is a tube through which the machine will help you breath during the surgery. The anaesthetist uses a flexible bronchoscope (works like a camera) to confirm correct placement of the tube. In this study we will confirm placement of the tube first with an ultrasound image, known as pleural sliding where we look for lung movement, and then followed by the conventional flexible bronchoscopy. We will then be looking at how accurate the ultrasound image is in confirming correct placement of the tube, when comparing the findings to the flexible bronchoscopy.

The ultrasound probe will be put on the front of your chest with some lubrication. This will be done after induction of anaesthesia – while you are sleeping. We will be looking at the movement of your lungs in three different places on your chest.

This is a non-invasive and very safe procedure. There is no risk of an adverse effect. The findings will be written down and surgery continued. You will not be followed up after your surgery.

This is a prospective study. Thirty patients who require intubation with double lumen tubes in the cardiothoracic theatre will be included in the study. The study will take place in the cardiothoracic theatre, Universitas Academic Hospital, over a three month period.

Should you require the results of the study after its completion, it will be available to you.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

There will be no costs payable by you as the participant, neither will you be remunerated for participating in the study.

You may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research record for quality assurance and data analysis include the Ethics Committee for Medical Research.

If results are published, this may lead to cohort identification.

Contact details of researchers for further information or reporting of study-related adverse events:

Name: Dr NJ Bernard

Dr EW Turton

Phone: (051) 405 3911

(051) 405 3911

Contact details of Secretariat and Chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State – for reporting of complaints/problems: Phone (051) 4052812.

APPENDIX D

Dr NRJ van Zyl

October 30, 2013

Clinical Head

Universitas Hospital

REQUEST FOR PERMISSION TO CONDUCT A STUDY

Dear Dr Van Zyl

I hereby apply for permission to conduct a study as part of my MMed degree in Anaesthesiology.

Study title: THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES

Flexible bronchoscopy is recommended to confirm correct placement after intubation with double-lumen tubes. This study aims to assess the accuracy of the ultrasonographic lung sliding sign to confirm correct placement of double-lumen tubes.

Thirty patients will be included in this prospective study that requires double-lumen tube intubation for elective thoracic surgery. The study will take place over a period of four months in the cardio-thoracic theatre, Universitas Hospital.

All participants will be handed an informed consent document and detail of the study will be explained. This should not take longer than 15 minutes of the participant's time.

The results of the study might be published and presented at a meeting or congress.

Researchers:

Drs NJ Bernard and EW Turton from the Department of Anaesthesiology. Phone: 083 3925167 or 082 8046839

Yours sincerely

NJ Bernard

nicojbernard@gmail.com

APPENDIX E

Prof Smit

October 30, 2013

Head: Cardiothoracic Surgery Department

Universitas Hospital

REQUEST FOR PERMISSION TO CONDUCT A STUDY

Dear Prof Smit

I hereby apply for permission to conduct a study as part of my MMed degree in Anaesthesiology.

Study title: THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES

Flexible bronchoscopy is recommended to confirm correct placement after intubation with double-lumen tubes. This study aims to assess the accuracy of the ultrasonographic lung sliding sign to confirm correct placement of double-lumen tubes.

Thirty patients will be included in this prospective study that requires double-lumen tube intubation for elective thoracic surgery. The study will take place over a period of four months in the cardio-thoracic theatre, Universitas Hospital.

All participants will be handed an informed consent document and detail of the study will be explained. This should not take longer than 15 minutes of the participant's time.

The results of the study might be published and presented at a meeting or congress.

Researchers:

Drs NJ Bernard and EW Turton from the Department of Anaesthesiology. Phone: 083 3925167 or 082 8046839

Yours sincerely

NJ Bernard

nicojbernard@gmail.com

APPENDIX F

Prof BJS Diedericks

October 30, 2013

Head: Department of Anaesthesiology

Universitas Hospital

REQUEST FOR PERMISSION TO CONDUCT A STUDY

Dear Professor Diedericks

I hereby apply for permission to conduct a study as part of my MMed degree in Anaesthesiology.

Study title: THE USE OF LUNG-ULTRASOUND TO CONFIRM CORRECT PLACEMENT OF LEFT SIDED DOUBLE LUMEN TUBES

Flexible bronchoscopy is recommended to confirm correct placement after intubation with double-lumen tubes. This study aims to assess the accuracy of the ultrasonographic lung sliding sign to confirm correct placement of double-lumen tubes.

Thirty patients will be included in this prospective study that requires double-lumen tube intubation for elective thoracic surgery. The study will take place over a period of four months in the cardio-thoracic theatre, Universitas Hospital.

All participants will be handed an informed consent document and detail of the study will be explained. This should not take longer than 15 minutes of the participant's time.

The results of the study might be published and presented at a meeting or congress.

Researchers:

Drs NJ Bernard and EW Turton from the Department of Anaesthesiology. Phone: 083 3925167 or 082 8046839

Yours sincerely

NJ Bernard

nicojbernard@gmail.com

APPENDIX G

DATASHEET

Fill in or tick appropriate block

1. Patient demographic

Age

Gender

MALE	FEMALE
------	--------

Weight

2. Indication for surgery

3. Lung to be isolated

LEFT	RIGHT
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4. Pre-operative clinical examination

5. Co-morbid conditions e.g. Pulmonary TB,

HIV status, Post traumatic lung injury.

6. Size of double lumen tube used

7. Lung-sliding sign prior to intubation

Left sided		Right sided	
Present	Absent	Present	Absent

8. Lung-sliding sign post intubation

Left sided		Right sided	
Present	Absent	Present	Absent

9. Lung sliding sign post lung isolation

Left sided		Right sided	
Present	Absent	Present	Absent

10. Flexible bronchoscopy findings post intubation

Confirmation of correct placement

YES	NO
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