Ultrasound to verify lung-isolation during single-lung ventilation

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PROTOCOL TITLE:

Ultrasound to verify lung-isolation during single-lung ventilation

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
4	2/5/2019	Increasing the age limit to 21 years.	No

1.0 Study Summary

Study Title	Ultrasound to verify lung-isolation during single-lung ventilation
Study Design	Prospective study
Primary Objective	To determine the accuracy of auscultation and ultrasonography for confirming lung isolation during SLV, as compared to direct visualization using FOB (gold standard).
Secondary Objective(s)	To compare the time required to confirm lung isolation using the above-mentioned techniques including auscultation, FOB, and ultrasound.
Research Intervention(s)/ Investigational Agent(s)	Ultrasound and auscultation of the chest.
IND/IDE #	N/A
Study Population	Main OR surgical patients
Sample Size	80
Study Duration for individual participants	Less than 30 minutes total.
Study Specific Abbreviations/ Definitions	FOB – Fiberoptic bronchoscope SLV – Single-lung ventilation DLT – Double-lumen endotracheal tube ETT – Endotracheal tube

2.0 Objectives

2.1 The primary objective is to determine the accuracy of auscultation and ultrasonography for confirming lung isolation during SLV, as compared to direct visualization using FOB (gold standard). The secondary objective is to compare the time required to confirm lung isolation using the above-mentioned techniques including auscultation, FOB, and ultrasound.

2.2 The hypothesis is that ultrasonography will have at least 80% accuracy for verifying lung separation during SLV as confirmed by FOB; and will have greater accuracy than auscultation.

3.0 Background

3.1 During thoracic surgery, specific anesthetic techniques are used to isolate the lungs and allow for single-lung ventilation (SLV) so that the ipsilateral lung is not ventilated during the surgical procedure.[1-3] A motionless lung on the side of surgery is necessary to allow for the surgical procedure to proceed optimally. To accomplish SLV, there are several options including use of a specialized double-lumen

endotracheal tube (DLT), placement of a bronchial blocker into the main stem bronchus of the operative side, or selective main stem intubation with a standard endotracheal tube (ETT). All of these devices allow for selective ventilation of the non-operative lung. In common clinical practice, the placement of the device for SLV may be guided by direct vision using a fiberoptic bronchoscope (FOB) and/or differential auscultation of the two lungs.

More recently, there has been increased use of ultrasonography at the bedside in various clinical locations including the Pediatric ICU and the operating room. Ultrasonography is painless, non-invasive and cares no risk. Given its ease of use and non-invasive nature, ultrasound is being used more frequently to make thoracic diagnoses including hemothorax, pneumothorax, pneumonia, and ARDS.[3-8] More recently, preliminary data from three studies in adults suggest that ultrasound can be used to confirm lung isolation during SLV.[9-11] When the lung is not ventilated, there is no pleural movement noted (absence of lung sliding and no B-lines) and as the lung is non-mobile, the cardiac impulses may be transmitted through the lung to the chest wall and can be seen (presence of lung pulse). To date, there is only one anecdotal report of the intraoperative use of thoracic ultrasonography in the pediatric-aged patient.[12] The purpose of the current study is to prospectively evaluate the usefulness of thoracic ultrasonography is demonstrating effective lung isolation during SLV in the pediatric patient. Our primary hypothesis is that ltrasonography will accurately verify lung separation during SLV, as compared to FOB.

3.2 This would provide a rapid and non-invasive means to demonstrating effective lung isolation without the time, cost, and invasive nature of direct visualization using a FOB.

4.0 Study Endpoints

4.1 The accuracy of using ultrasound to assess lung isolation by visualizing lung movement or lack thereof of both the operative and non-operative lung fields.

4.2 Time to confirm lung isolation.

5.0 Study Intervention/Investigational Agent

5.1 The only intervention being used that is not normally used in general clinical practice is the use of ultrasonography. The technique is non-invasive and poses no risk. Ultrasonography will be performed by an anesthesiologist with training and experience and will add less than 10 minutes to the anesthetic time.

6.0 Procedures Involved*

6.1 The proposed study will be conducted in 80 patients, ranging in age age from 0 to 21 years. There will be no change in clinical practice regarding choice of anesthetic technique including premedication, device used for SLV, monitoring, induction, and maintenance of anesthesia. An investigator will identify patients in whom SLV is required for thoracic surgery. There will be total of three anesthesia providers and one surgeon involved in the study. One will be the primary anesthesiologist, who is one of the attending faculty and will be responsible for patient care during the perioperative period. They will decide prior to and during the case whether the patient is appropriate for and able to complete the study protocol. The other two anesthesia providers will be members of the study team or other anesthesia attending/fellow and will include an auscultator (may be a resident/CRNA/SRNA), the anesthesia provider who will perform the auscultation examination and the ultrasonographer, the anesthesia provider who will perform the ultrasound examination (see below). The surgeon will be the attending surgeon and will confirm the efficacy of one-lung ventilation during the surgical procedure. Both the auscultator and ultrasonographer will be blinded to the lung that is isolated.

The technique of SLV will be determined by the attending anesthesiology to include a DLT, bronchial blocker or main stem intubation with an ETT. The ventilator settings will be standardized until all of the study measurements and data have been collected:

Ventilation Mode: PRVC

RR titrated to achieve normocapnia

Inspiratory time 1 second

TV set at 6-8 ml/kg

PEEP: minimum of 5 cm H20

100% Fi02

6.2 After anesthetic induction the following ventilatory parameters will be recorded: tidal volume, peak inflating pressure, inspiratory time, respiratory rate, inspired oxygen concentration, end-tidal carbon dioxide, and oxygen saturation. After placement of the device for SLV, and isolation of the lung, the non-operative lung will be ventilated and the ventilatory parameters will be recorded again. Clinical confirmation of effective lung separation will include auscultation with documentation of absence of breath sounds on the operative side. Following this, correct placement of the DLT will be confirmed using FOB. The time to perform FOB will be determined.

6.3 Once SLV device placement is confirmed by bronchoscopy, the patient's face and airway management devices will be covered by a drape to blind to auscultator and ultrasonographer. The auscultator

and ultrasonographer will then enter the room. The auscultator will evaluate lung isolation and note the results. The ultrasonographer will then evaluate lung isolation with absence of lung sliding and the presence of lung pulse on the operative (non-ventilated) lung, and B-line. The procedure time for each (auscultation and ultrasonography) will be determined. Procedure time will be calculated from the time that the participant touches the patient to the completion of the examination (auscultation or ultrasonography). After the completion of the ultrasound examination, the patient will be placed in the surgical position. Following this, the surgical procedure will be started and lung separation documented by the surgeon. If lung separation was not successful, this will be noted. The intraoperative ventilation strategy will be at the discretion of the attending anesthesiologist.

7.0 Data and Specimen Banking*

N/A

8.0 Sharing of Results with Subjects*

8.1 Results will not be shared

9.0 Study Timelines*

- An individual study subject's participation in the study should last approximately 15-30 minutes total.
- All study subjects should be enrolled within 1 year of study start.
- The study should be completed within 2 years of study start.

10.0 Inclusion and Exclusion Criteria*

10.1 Potential subjects will be identified by reviewing the surgery schedule in Epic and will be recruited from the Surgery Unit pre-op area prior to their surgery.

10.2 Inclusion criteria: Age 0-21 years, requiring SLV for thoracic surgery.

Exclusion criteria: None.

10.3 We are including children, and will not include:

- Adults unable to consent
- Pregnant women
- Prisoners

11.0 Vulnerable Populations*

11.1 This study presents no more than minimal risk as it only involves ultrasound which is non-invasive, will add less than 10 minutes to the total anesthetic time, and written consent is normally not required.

12.0 Local Number of Subjects

12.1 80

12.2 Power calculation for this study was based on a previous study reporting the accuracy of ultrasonography (compared to FOB) for confirming lung isolation when using DLTs.[11] This study found the accuracy to be 84%-89% depending on which lung was isolated. Assuming that ultrasonography has an overall accuracy of 85%, a two-tailed, one-sample test of proportions would have >80% power to detect a difference of at least 10% when 80 patients are enrolled.

13.0 Recruitment Methods

13.1 Subjects will be recruited from the surgery unit pre-op area. They will be identified by reviewing OR schedules in Epic.

14.0 Withdrawal of Subjects*

N/A

15.0 Risks to Subjects*

15.1 Although not likely, there may be a potential risk for breach of patient health information. There are no study related physical risks to study subjects associated with this study. All study related procedures are non-invasive.

15.2 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study. Subject PHI will be stored in a locked cabinet, and will be stored and maintained in password protected computer files.

16.0 Potential Benefits to Subjects*

16.1 No direct benefit to the subject.

17.0 Data Management* and Confidentiality

17.1 We will compare the accuracy, sensitivity, and specificity of ultrasonography and auscultation (using FOB confirmation of one-lung isolation as the reference standard) using paired tests of proportions. As a secondary, exploratory aim, we will compare the time to perform each of the techniques using paired t-tests or sign-rank tests (according to the normality of the outcome distribution).

17.2 Research records will be stored in a locked cabinet and password protected computer. Only certified research personnel will be given access to identifiable subject information

17.3 Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 The study will only be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

20.0 Compensation for Research-Related Injury

20.1 None

21.0 Economic Burden to Subjects

21.1 None

22.0 Consent Process

22.1 We are requesting a waiver of informed consent documentation. Subjects will receive a complete explanation of the study and will be asked to consent verbally. Subjects will receive a written summary of the research as outlined in the attached written Study Information Sheet. Subjects will not be asked to sign a consent form.

23.0 Process to Document Consent in Writing

N/A

24.0 Setting

24.1 Subjects will be recruited from Surgery Unit and all study procedures will take place in the OR after the subject has been anesthetized.

25.0 Resources Available

25.1 The department of Anesthesiology and Pain Medicine has 2 research coordinators and 2 research associates that will be enrolling subjects for this study. All study staff will be trained on the study procedures.

26.0 Multi-Site Research*

N/A

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

- ☒ Name
- ☐ Complete Address
- ☐ Telephone or Fax Number
- ☐ Social Security Number (do not check if only used for ClinCard)
- ☒ Dates (treatment dates, birth date, date of death)
- ☐ Email address , IP address or url
- ☒ Medical Record Number or other account number
- ☐ Health Plan Beneficiary Identification Number
- ☐ Full face photographic images and/or any comparable images (x-rays)
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- ☐ Device Identifiers and Serial Numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Other number, characteristic or code that could be used to identify an individual
- ☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

- ☐ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)
- ☒ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)
- ☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)
- ☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)
- ☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

***Find the HIPAA forms in the IRB Website Library, Templates.**

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained?

Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

4.0 Describe any plans to code identifiable information collected about each participant. None

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

☒ **Research records will be stored in a locked cabinet in a secure location**

☒ **Research records will be stored in a password-protected computer file**

☐ **The list linking the assigned code number to the individual subject will be maintained separately from the other research data**

☒ **Only certified research personnel will be given access to identifiable subject information**

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)

Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

☒ Demographics (age, gender, educational level)
☒ Diagnosis
☐ Laboratory reports
☐ Radiology reports
☐ Discharge summaries
☒ Procedures/Treatments received
☒ Dates related to course of treatment (admission, surgery, discharge)
☐ Billing information
☐ Names of drugs and/or devices used as part of treatment
☐ Location of treatment
☐ Name of treatment provider

☐ Surgical reports
☒ Other information related to course of treatment
☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to meet the objectives of the study and to analyze the data.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No

References:

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11. Hu WC, Xu L, Zhang Q, Wei L, Zhang W. Point-of-care ultrasound versus auscultation in determining the position of double-lumen tube. Medicine 2018;97:e9311.

12. Nam JS, Park I, Seo H, Min HG. The use of lung ultrasonography to confirm lung isolation in an infant who underwent emergent video-assisted thoracoscopic surgery - a case report. Korean J Anesthesiol 2015;68:411-4.