The Use of Lung Ultrasound to Assess the Prevalence of Lung Interstitial Syndrome in Paediatric Cardiac Surgery Patients and the Measurement of Postoperative Length of Hospital Stay.

Research Report for MMed (Anaesthesiology)

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DECLARATION

I declare that this research report is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements.

Signed: _____

Date: _____

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- My father, Dr. Olaf D Larson for his review of and comments on earlier versions of this manuscript.

ABSTRACT

Background: In recent years, ultrasound has gained popularity in the assessment of pulmonary pathology, especially in the critical care setting. However, limited data are available for the use of lung ultrasound (LUS) for the diagnosis of lung interstitial syndrome (LIS) in the paediatric cardiac surgery population.

Methods: The aim of this observational cross-sectional study primarily was to assess the prevalence of LIS due to extravascular lung water (EVLW) in paediatric patients with high pulmonary-flow congenital cardiac lesions. Patients who underwent corrective open heart surgery were scanned immediately post-operatively and B-lines in each of eight thoracic areas were counted. LIS was diagnosed or ruled out based on this result. Secondary outcomes were postoperative length of stay (LOS) in Cardiothoracic Unit (CTU) and in hospital and whether LIS is associated with prolonged LOS.

Results: Twenty children aged between 6 months and 9 years were included in this study. The prevalence of LIS was found to be 25%. The median LOS in the CTU for children diagnosed with LIS was 4.0 days (range 3.0 to 6.0) and median length of hospital stay was 7.5 days (range 6.0 to 20.0). There was no statistical difference in CTU LOS ($p = 0.601$) or hospital LOS ($p = 0.544$) between the groups with or without LIS.

Conclusion: Pulmonary complications are common after surgery for congenital heart disease. This study showed a prevalence of LIS of 25%. This can potentially result in increased morbidity and mortality, but the study sample was too small to prove this. LUS can be used for early identification and management of complications.

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ABBREVIATIONS

ASD	Atrial Septal Defect
AVSD	Atrioventricular Septal Defect
CPB	Cardiopulmonary Bypass
CT	Computer Tomography
CTU	Cardiothoracic Unit
EVLW	Extravascular Lung Water
ICU	Intensive Care Unit
LIS	Lung Interstitial Syndrome
LOS	Length of Stay
LUS	Lung Ultrasound
Qp	Pulmonary Blood Flow
Qs	Systemic Blood Flow
VSD	Ventricular Septal Defect

CHAPTER 1 – PROTOCOL

INTRODUCTION

Current Knowledge

Lung ultrasound

For many years, the lung was believed to be unsuitable for examination by ultrasound[1]. Sonographic methods are based on the principle that ultrasound waves are reflected by an interface between media with different acoustic impedances[2]. In normally aerated lungs, where the ultrasound beam meets air, no image is visible because of the absence of acoustic mismatch. The beam is totally stopped when it reaches the lung or any gas filled structure[3].

In adults, the bones of the thoracic cage limit the use of lung ultrasound[4]. The attenuating effect of bone is much greater than that of other tissues and ultrasound waves are unable to pass through boney structures[2]. Waves reaching bone are completely reflected back to the transducer. The image reproduced on the screen shows a sonic shadow that obscures the structures below any bony obstruction[4]. The chests of young children have unossified costal cartilages and sternums which provide suitable acoustic windows[5].

The traditional school of thought regarding lung ultrasound has changed in recent years because it is now recognized that lung ultrasound is highly sensitive to variations in the pulmonary content of and the balance between air and fluid. A normally inflated lung is impermeable to ultrasound beams. The pleura can be regarded as the lung-wall interface and appears in ultrasound images as a thin hyperechoic structure just deep to the rib line.

Ultrasonography of lungs is based on the production of artefacts[6]. An ultrasound artefact is an incorrect interpretation by the ultrasound machine of a returning signal meaning that the machine does not represent the findings in true anatomical terms[7].

The seven principles of lung ultrasound

Ultrasound examination of the lung is based on the seven principles as described by Lichtenstein[3]:

- *The thorax is an area where air and water are closely related and have opposite gravitational dynamics.*

Air rises and water descends. This makes it easy to define dependent and nondependent disorders and to specify the patient's position and the area where the probe is applied.

- *The surface of the lung can be divided into well-defined areas. These areas describe the positions where the ultrasound probe can be applied:*

The anterior zone is defined by the clavicle superiorly, medially by the sternum, the anterior axillary line as the lateral border and inferiorly it is limited by the diaphragm.

The lateral zone extends from the anterior to the posterior axillary lines.

The posterior zone extends from the posterior axillary line to the spine. It can be divided into upper, middle and lower thirds. Posterior lung rockets in supine patients may be a common finding indicating that lung water preferentially accumulates in the dependent areas. Ultrasound examination for lung interstitial syndrome does therefore not include examination of the posterior zone.

- *All lung ultrasound patterns arise from the pleural line.*

The pleural line acts as the interface between the soft tissues of the chest wall and the aerated tissues of the lung. The pleural line represents the parietal pleura in all cases and the visceral pleura where it is against the parietal pleura. In a healthy lung, the pleura reflects the ultrasound waves back to the transducer, almost acting as a mirror. This effect disappears when the fluid content of the lung increases and gives rise to artefacts.

- *Lung ultrasound signs are based on the analysis of artefacts which are usually undesirable structures.*

The large difference in acoustic impedances of soft tissues and air-filled alveoli prevents the reconstruction of a real image of the lung and generates multiple artefacts[4].

- *Lung patterns and signs are dynamic.*

All lung patterns move with inspiration. The lung can thus be examined in real-time, at the bedside ("point-of-care" lung ultrasound).

- *Nearly all acute pathological lung conditions come into contact with the lung surface.*
- *The best machine for practicing lung ultrasound is probably the simplest.*

Lung ultrasound examination is achieved using natural images, avoiding filters, especially those designed to suppress artefacts. Older, more cost-effective, grey-scale machines without Doppler give optimal image resolution[8].

As the fluid content of the lung increases, such as in pathological conditions, the difference in acoustic impedance between the fluid and air increases. This creates the acoustic mismatch needed to reflect the ultrasound beam and reverberation artefacts are created.

A-lines

The A-line is a static artefact arising from the pleural line. It is a roughly horizontal, hyperechoic line, parallel to the pleural line and arising below it, at an interval that is equidistant than the interval between skin and pleura[3].

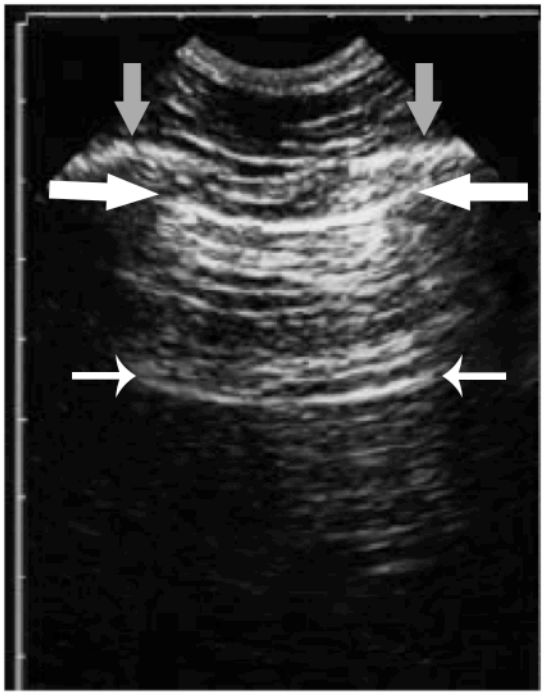

Figure 1 - Normal ultrasound lung pattern [3]
Ribs (vertical arrows), pleural line (large white arrows) and A-line (small white arrows)

Lung interstitial syndrome

Interstitial syndrome is defined as a condition with diffuse interstitial lung pathology due to inflammation, oedema, fibrosis or infiltration. Clinically significant alveolar oedema is always preceded by interstitial oedema but bedside radiological diagnosis at this early stage of the disease is difficult. In an acute condition, alveolar interstitial syndrome usually represents pulmonary oedema, but it may also be seen in ARDS and more chronic interstitial diseases. It may also be a focal finding in infectious or ischemic processes[2].

Computer tomography is the gold standard for diagnosing alveolar interstitial syndrome. It is often not a feasible examination to perform due to drawbacks such as exposure to high levels of irradiation and the difficulty of transporting a critically ill patient to the radiology suite. This makes LUS an attractive, easy-to-use diagnostic tool at the bedside[6].

Ultrasonography has been shown to be useful in the diagnosis of interstitial syndrome by recognition of B-lines[6,9,10].

B-lines have seven features[8] (figure 2):

- *They are comet-tail artefacts*
- *They arise from the pleural line*
- *They move with lung sliding*
- *They are hyperechoic*
- *They are well-defined and laser-like*
- *They spread to the edge of the screen without fading*
- *They erase normal A-lines*

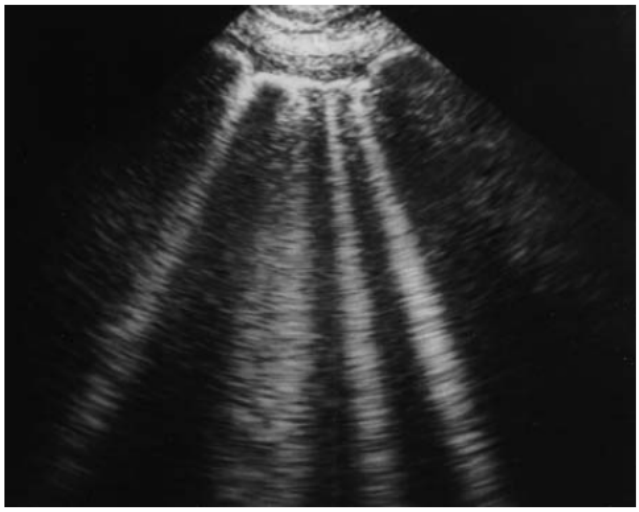

Figure 2 - B-lines

Congenital cardiac disease and interstitial oedema

High lung flow lesions

Several congenital cardiac lesions are associated with increased pulmonary blood flow but the septal and endocardial cushion defects – atrial septal and ventricular septal defects and atrioventricular canal defects are relevant to this study. The pathophysiological feature common to these conditions is shunting of blood across the defect[11].

Patients with increased pulmonary blood flow due to left-to-right shunting can be asymptomatic or have tachypnea or respiratory distress. Significant haemodynamic consequences are common in left-to-right shunts with Qp:Qs > 2:1. Typical clinical manifestations include:

- Tachypnea due to interstitial oedema
- Tachycardia and diaphoresis due to increased release of catecholamines
- Poor weight gain resulting from increased caloric and myocardial oxygen demands[11]

Large left-to-right shunts not only have haemodynamic consequences but also affect lung mechanics[11,12]. Tidal volume and lung compliance are usually lower and airway resistance higher. Decreased lung compliance may be exacerbated in patients who also have elevated pulmonary artery pressure.

Increased extravascular lung water is thought to be a contributing factor in the mechanism of abnormal pulmonary mechanics. EVLW appears to be directly related to the increase in Qp[13]. Increased pressure across capillary walls causes transudation of fluid at rates greater than can be accommodated by lymphatic drainage.

In complete AV canal defects, increased pulmonary blood flow due to excessive left-to-right shunting at atrial and ventricular levels can lead to elevated pulmonary vascular resistance and eventually, heart failure[14].

Cardiopulmonary bypass

The inflammatory process induced by the exposure of blood to the nonendothelial surfaces of the bypass circuit initiates a cascade of both pro- and anti-inflammatory events. The inflammatory mediators released during CPB cause increased vascular permeability and fluid shifts between the intravascular and interstitial fluid compartments. This is the so-called *capillary leak syndrome*[12].

Current controversies

There is little data available on the use of lung ultrasound in the paediatric cardiac surgery population although it has been described and found useful and comparable to CT in neonates and children[15].

Motivation for performing the study

The interest of the author in paediatric cardiac surgery and lung ultrasound is the main motivation for performing the study.

The author also believes that this study creates the potential for future research as it raises new questions that need to be answered. For example, what are the perioperative factors that contributed to the development of lung interstitial syndrome? How can the perioperative management of patients at risk of developing LIS be optimized?

The results of this study should add to the limited amount of literature available regarding the use of lung ultrasound in paediatric cardiac surgery.

If it is found that children with LIS after cardiac surgery for congenital heart disease do have a longer length of stay, lung ultrasound can be used to predict which patients will have a prolonged length of stay.

This research study forms part of the author's MMed (Anaes) qualification.

RESEARCH QUESTION

What is the prevalence of lung interstitial syndrome due to increased extravascular lung water in paediatric cardiac surgery patients?

Is LIS associated with a prolonged length of stay in the ICU and/or hospital?

The prevalence of lung interstitial syndrome due to increased extravascular lung water in paediatric cardiac surgery is uncertain. Ultrasound will be used to diagnose lung interstitial syndrome by recognition and quantification of B-lines.

METHODOLOGY

Study design

This study will be of a descriptive nature because it will be examining the prevalence of lung interstitial syndrome due to increased extravascular lung water in a paediatric cardiac surgery population. Length of hospital stay will also be measured and described in this analytical study.

Study participants

This study will include all paediatric cardiac surgery patients, previously diagnosed with high pulmonary flow lesions (Qp:Qs > 1.5) scheduled for palliative or corrective surgery. These cases will be limited to septal and endocardial cushion defects: atrial and ventricular septal defects and atrioventricular canal defects respectively.

Sample size

The aim is to include 20 children in this study.

Sample selection

Children who fit the following criteria will be included in this study:

- 0-12 years of age
- Diagnosed with congenital cardiac lesions with high pulmonary blood flow: Qp:Qs > 1.5
- For palliative or corrective surgery
- Cases performed using cardiopulmonary bypass
- Scheduled for admission to Cardiothoracic Unit postoperatively.

Exclusion criteria:

- Previous surgery
- Known lung pathology which can influence ultrasound images

Measurement

Post-operative lung ultrasound will be performed on all study participants to assess the amount of extravascular lung water present after surgery. This scan will be done with the patient still in theatre, prior to being transported to the CTU.

Scanning methodology

The method which will be used was described by Volpicelli et al in 2006[16] and later defined by the International Liaison Committee on Lung Ultrasound for the International Consensus Conference on Lung Ultrasound[17]. The bedside lung ultrasound examinations will evaluate eight regions in the supine patient: two anterior and two lateral per

hemithorax (figure 3). The anterior chest wall is defined as the region from the sternum to the anterior axillary line, whereas the lateral region is defined as the area from the anterior to the posterior axillary line.

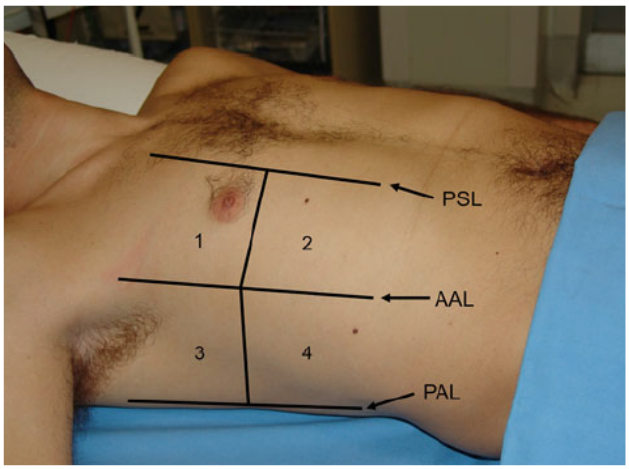

Figure 3 - Eight region lung ultrasound scan

Positive ultrasound

The sonographic pattern, where multiple B-lines are seen is known as a *B-pattern*. This is indicative of the presence of extravascular lung water.

A *scan* will be identified as positive by the visibility of three or more B-lines in one longitudinal plane between two ribs in a region of the chest wall. An *examination* is positive when there are two or more positive scans per hemithorax. A positive examination confirms the diagnosis of lung interstitial syndrome.

The 8-region ultrasound technique[16]

The chest wall is divided into eight regions as previously described. With the use of a basic 2-D scanner with any available transducer, each one of the regions is scanned and B-lines quantified.

Steps:

1. The ultrasound probe is applied perpendicularly to the long axis of the ribs to obtain an image of two ribs cut in a transverse fashion. The first point of scanning is the second intercostal space along the midclavicular line of area 1 of the anterior region – figure 2.
2. The probe is moved to the lower anterior area where it is positioned in the fourth intercostal space along the midclavicular line.
3. The probe is then positioned in the upper lateral region, in the third intercostal space and along the anterior axillary line.
4. The last area to be scanned is the lower lateral area where the probe is positioned in the fifth intercostal space between the anterior and posterior axillary lines.

5. Steps 1-4 are then repeated on the other hemithorax.

6. B-lines will be counted and noted on a data form (see appendix 1) for both the pre- and postoperative examinations.

Equipment needed for this study

Lung ultrasound examinations can be performed using any ultrasound machine[15]. Unsophisticated machines have been shown to provide very good results. The author will attempt to obtain an ultrasound machine on loan from a company representative for the duration of the study. If this is not possible, the ultrasound machine which is resident in theatre 7, Universitas Hospital, will be used. The most suitable transducer for lung examinations in neonates is a 12-MHz micro convex probe but the probe used in this study will depend on availability. Phased-array, linear array and convex probes have been used with good results[15,18].

Who will be doing the ultrasound examinations?

The author will be doing the ultrasound scans until the registrars rotating through paediatric cardiac surgery are familiar with the study and the method. In the planned three month period, there will be two registrars rotating through this theatre. Several studies have shown that diagnostic accuracy is easy to obtain with very limited training and that results obtained by novice sonographers are comparable to those obtained by sonographers experienced in lung ultrasound[19]. Minimal theoretical knowledge is needed to differentiate between A and B-lines, and a short presentation on the ultrasound findings in lung interstitial syndrome will be sufficient.

Where will these ultrasound examinations be done?

All paediatric cardiac surgery cases are done in theatre 7, Universitas Hospital. All scans will be done there.

Information collected

Data forms (appendix 1) will be used to collect the results of the ultrasound scans. The person doing the scan will note the number of B-lines found in each region of the chest. The completed forms will be kept in a file in theatre for later collection by the author.

Measurement errors

There is potential for measurement errors because more than one person will be doing these ultrasound examinations. Efforts to minimize these errors will include initially supervising the persons doing the scans and giving them a short presentation on the execution of the scans and recognition of the relevant sonographic lung signs.

ANALYSIS

Descriptive statistics namely means and standard deviations or medians and percentiles will be calculated for continuous data. Frequencies and percentages will be calculated for categorical data. The analysis will be done by the Department of Biostatistics.

TIME SCHEDULE

Submission of protocol to Ethics Committee

October 2015

Training of assistants and field workers

Theoretical training in the form of a short didactic presentation on the basics of lung ultrasonography and the recognition of lung ultrasound signs, specifically B-lines, will be completed before commencement of the data collection period. There is opportunity for such a presentation during the Department of Anaesthesia's Morbidity and Mortality meeting on a Friday morning. Practical training of the registrars who will be doing the ultrasound examinations will be hands-on and in theatre under the supervision of a more experience sonographer.

Duration of data collection

An average of three children are scheduled weekly for corrective or palliative cardiac surgery for ASD, VSD or AVSDs. It is planned to include at least 20 children in this study and to allow 3 months for data collection, starting in January 2016. If there are not enough study participants, the data collection period may have to be extended.

All admission and discharge data will have been collected in the month after completion of data collection. This data collection will be an ongoing process.

Capturing of data on computer and verification thereof

This will be an ongoing process and will be done as soon as the data are collected.

Analysis of data collected

Data analysis will commence after completion of collection.

Writing of research report

As soon as possible after data analysis.

Completion of the study

This study will be concluded at the end of 2016 when the author's registrar training ends.

ETHICAL ASPECTS

1. Permission to conduct this research study will need to be attained from the Ethics Committee of the Faculty of Health Sciences, UFS and the Department of Health.

2. Informed consent (appendix 2) will be taken from the participants' parents. If the child is old enough to understand, they will also be informed and consented.

3. Each potential participant and their parent will receive an information document (appendix 3) explaining the nature and process of the research study.

4. All confidential information will remain as such in the author's possession.

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CHAPTER 2 – THE RESEARCH ARTICLE

INTRODUCTION

Lung Ultrasound

For many years, the lung was believed to be unsuitable for examination by ultrasound[1]. This is because sonographic methods are based on the principle that ultrasound waves are reflected by an interface between media with different acoustic impedances[2]. In normally aerated lungs, where the ultrasound beam meets air, no image is visible because of the absence of acoustic mismatch which totally stops the beam when it reaches the lung or any other gas filled structure[3].

The traditional school of thought regarding lung ultrasound (LUS) has changed in recent years[4]. It is now recognized that LUS is highly sensitive to variations in the pulmonary content of fluid, and to the balance between air and fluid. A normally inflated lung is impermeable to ultrasound beams. The pleura can be regarded as the lung-wall interface and appears in ultrasound images as a thin hyperechoic structure just deep to the rib line.

Ultrasonography of the lungs is based on the production of artifacts[4]. An ultrasound artifact is an incorrect interpretation by the ultrasound machine of a returning signal causing the machine to misrepresent the findings in true anatomical terms[5].

An A-line is a static artifact arising from the pleural line in normal lungs. It is a roughly horizontal, repeated, hyperechoic line, parallel to the pleural line and arising below it, at intervals that are equal to the interval between skin and pleura[3] (figure 1).

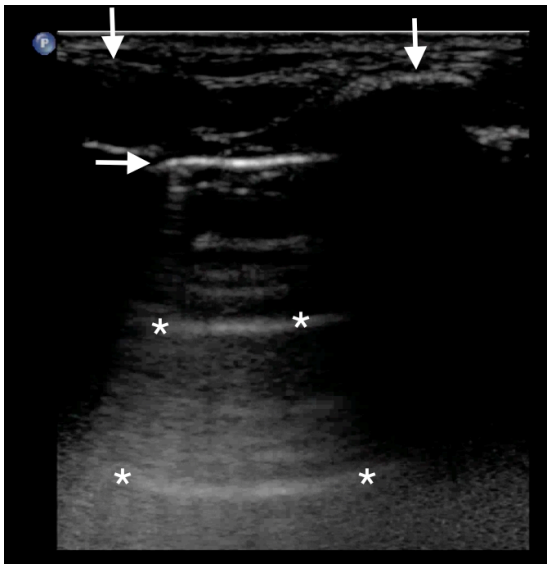

Figure 1- Normal ultrasound lung pattern:
Ribs (vertical arrows), pleural line (horizontal arrow) and A-lines (stars)

Lung Interstitial Syndrome

Lung Interstitial Syndrome (LIS) is defined as a condition with diffuse interstitial lung pathology due to inflammation, oedema, fibrosis or infiltration. Clinically significant alveolar oedema is always preceded by interstitial oedema, but bedside radiological diagnosis at this early stage of the disease is difficult. In an acute condition, LIS usually represents pulmonary oedema, but it may also be seen in the acute respiratory distress syndrome (ARDS) and more chronic interstitial diseases. It may also be a central finding in infectious or ischemic processes[2].

Computed tomography (CT) is the gold standard for diagnosing LIS. However, it is often not a feasible examination to perform due to drawbacks such as exposure to high levels of radiation and the difficulty of transporting a critically ill patient to the radiology suite. This makes lung ultrasound (LUS) an attractive, easy-to-use diagnostic tool at the bedside[4]. Ultrasonography has been shown to be useful in the diagnosis of LIS by recognition of B-lines[4,6,7].

The 'comet-tail artifact' was first described in 1982 by Ziskin et al[8] in relation to an intra-hepatic shotgun pellet. This artifact appears when there is a marked difference in acoustic impedance between an object and its surroundings. Narrow repetition artifacts generate the image suggesting a comet-tail on basic ultrasound.

The nomenclature and definition of the comet-tail artifact have changed over the years. The terms 'comet-tails', 'ultrasound lung comets' and 'B-line artifacts' have the same meaning but a recent review[9] suggests using the International Liaison Committee on Lung Ultrasound for the International Consensus Conference on Lung Ultrasound term 'B-line artifacts' (BLA). The Conference[10] defines BLA as 'discrete laser-like, vertical, hyperechoic reverberation artifacts that arise from the pleural line, extend to the bottom of the screen without fading and move synchronously with lung sliding'.

In 1997, Lichtenstein et al[4] described the comet-tail artifact as 'an ultrasound sign of alveolar-interstitial syndrome'. They believed that these artifacts were created by water-rich structures on the surface of the lung surrounded by air, resulting in a high impedance gradient and acoustic mismatch. On CT scan, these water-rich structures were identified as sub-pleural interlobular septa thickened by increased extravascular lung water (EVLW) and oedema. They compared CT, radiological and ultrasound findings and found that 'the artifact' of LUS had a sensitivity of 92.5% and a specificity of 65.1% for diagnosing radiologic 'alveolar-interstitial syndrome'.

Several studies have since then reported a positive correlation between radiographic and ultrasonographic modalities for the detection of increased EVLW and for the diagnosis of LIS[6,11,12]. Agricola et al[6] compared ultrasound with determination of wedge pressure and calculation of EVLW using the indicator dilution method. They found that the presence of lung comet-tail images correlated with increased wedge pressure and the presence of EVLW. A recent

study[11] performed at our institution, found that assessment of EVLW using LUS may correlate with the measurement of EVLW using the PiCCO® system.

Congenital Cardiac Disease and Interstitial Oedema

Several congenital cardiac lesions, especially the septal and endocardial cushion defects, are associated with increased pulmonary blood flow. The pathophysiological feature common to these conditions is shunting of blood across the defect[13].

Patients with increased pulmonary blood flow due to left-to-right shunting can be asymptomatic or have tachypnea or respiratory distress. Significant haemodynamic consequences are common in left-to-right shunts with a ratio of pulmonary blood flow (Qp) to systemic blood flow (Qs) greater than 2:1. Typical clinical manifestations include tachypnea due to interstitial oedema, tachycardia and diaphoresis due to increased release of catecholamines and poor weight gain resulting from increased caloric and myocardial oxygen demands[13].

Large left-to-right shunts do not only have haemodynamic consequences but also affect lung mechanics[13,14]. Tidal volume and lung compliance are usually lower and airway resistance higher. Decreased lung compliance may be exacerbated in patients who also have an elevated pulmonary artery pressure.

In complete AV canal defects, increased pulmonary blood flow due to excessive left-to-right shunting at atrial and ventricular levels can lead to elevated pulmonary vascular resistance and eventually, heart failure[15].

EVLW is the sum of water collecting outside the pulmonary vascular system. It is typically caused by excessive transudation of fluid due to increased pulmonary hydrostatic pressure, by decreased oncotic pressure or by increased permeability of the alveolar-capillary barrier. Increased EVLW is thought to be a contributing factor in the mechanism of abnormal pulmonary mechanics and appears to be directly related to the increase in Qp[9,16].

Cardiopulmonary Bypass

The inflammatory processes induced by the exposure of blood to the non-endothelial surfaces of the cardiopulmonary bypass (CPB) circuit initiate a cascade of both pro- and anti-inflammatory events. The inflammatory mediators released during CPB cause increased vascular permeability and fluid shifts between the intravascular and interstitial fluid compartments. This is the so-called *capillary leak syndrome*[14].

There is little data available on the use of LUS in the paediatric cardiac surgery population although it has been described and found useful and comparable to CT in neonates and children[17].

METHODS

Study Design

This research project took the form of an observational cross-sectional study. Twenty children were recruited over a period of eight months. All children were previously diagnosed with high pulmonary blood flow lesions (Qp:Qs > 1.5:1) and were scheduled for corrective surgery on the elective paediatric cardiac surgery list at Universitas Academic Hospital, Bloemfontein. Only children aged twelve years and younger were included. All procedures were done using CPB and patients were scheduled to be admitted to the Cardiothoracic Unit (CTU) postoperatively. Parents or legal guardians provided written consent and children aged seven years and older gave their assent to participate in the study.

Any child who had previously undergone cardiac surgery or who was known to have lung pathology with a potential to influence the ultrasound images was excluded from the study.

The primary outcome of this study was to determine the prevalence of LIS due to EVLW in paediatric cardiac surgery patients undergoing procedures with CPB. Secondary outcomes were to determine the postoperative length of stay (LOS) in the CTU and in hospital.

Lung Ultrasound

A post-operative LUS examination was performed on each patient to assess the amount of EVLW present after surgery. This LUS examination was done while the patient was still in theatre, under general anaesthesia and being mechanically ventilated before being transported to the CTU.

Scanning Methodology

The method used to scan the lung was described by Volpicelli et al in 2006[18] and later defined by the International Liaison Committee on Lung Ultrasound for the International Consensus Conference on Lung Ultrasound[10]. The bedside LUS examinations evaluated eight regions in the supine patient: two anterior and two lateral per hemithorax (figure 2).

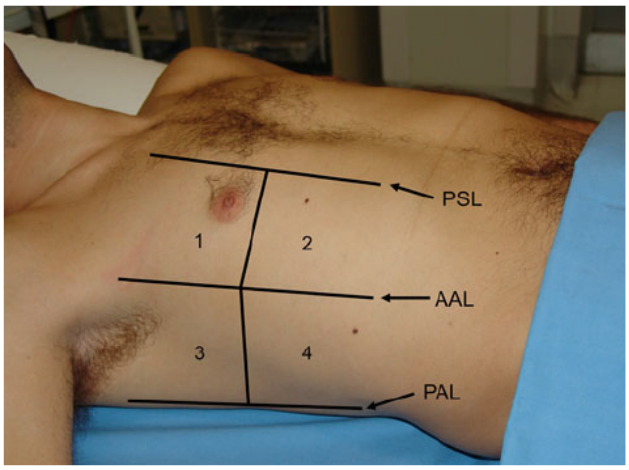

Figure 2 – Eight region lung ultrasound examination
The four chest areas per side considered for complete eight-zone lung ultrasound examination. These areas are used to evaluate for the presence of interstitial syndrome. Areas *1* and *2* denote the upper anterior and lower anterior chest areas, respectively. Areas *3* and *4* denote the upper lateral and basal lateral chest areas, respectively. *PSL* parasternal line, *AAL* anterior axillary line, *PAL* posterior axillary line (With permission of Springer)[10]

Each one of the eight regions was then scanned and B-lines counted and recorded on the data sheet. The first point of scanning was the second intercostal space along the midclavicular line of area 1 of the anterior region (see figure 2). The ultrasound probe was applied perpendicularly to the long axis of the ribs to obtain an image of two ribs cut in a transverse fashion. The probe was then moved to the lower anterior area where it was positioned in the fourth intercostal space. From there, the probe was positioned in the upper lateral region, in the third intercostal space and along the anterior axillary line and finally repositioned in the fifth intercostal space between the anterior and posterior axillary lines.

Positive Ultrasound Findings

The sonographic pattern, where multiple B-lines are seen, is known as a *B-pattern* (figure 3). This is indicative of the presence of EVLW[10].

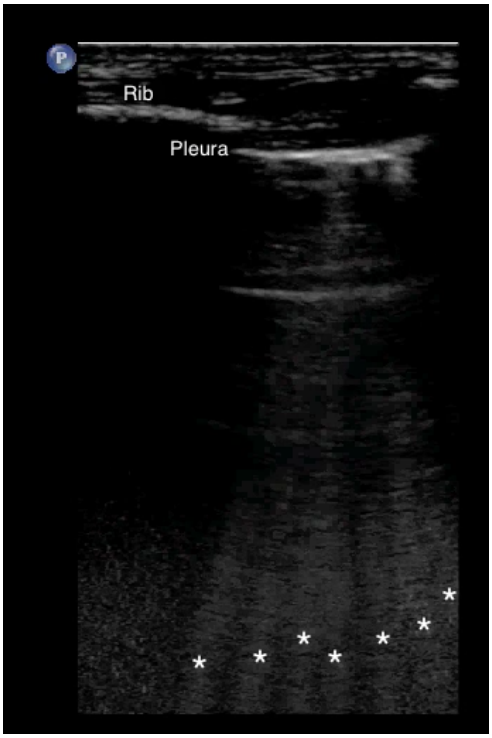

Figure 4 – B-lines (stars)

A positive *scan* was identified by the visibility of three or more B-lines in one longitudinal plane between two ribs in a region of the chest wall. A positive *examination* was defined by two or more positive scans per hemithorax and confirmed the diagnosis of LIS.

Equipment Used for This Study

LUS examinations can be performed using any ultrasound machine and unsophisticated machines have been shown to provide very good results[17]. Phased-array, linear array and convex probes have all been used with good results[17,19]. Eighteen LUS scans were done with the iE33 ultrasound machine (Philips™ Ultrasound, Bothell, WA) in theatre 7 using a 7 to 15 MHz linear array transducer (L15-7io, Philips™). The other two scans were done using an older model ultrasound machine (EnVisor, Philips™ Ultrasound, Andover, MA) using a 6 to 15 MHz linear transducer (15-6L, Philips™ Andover, MA) when the iE33 machine was already in use elsewhere.

Sonographers

The initial scans were performed by the researcher and subsequent scans performed by the anaesthesiology registrars rotating through the domain of cardiac surgery or the Consultant Anaesthesiologist responsible for the case. Several studies[20,21] have shown that diagnostic accuracy is easy to obtain with very limited training and that results obtained by novice sonographers are comparable to those obtained by sonographers experienced in LUS.

There is no standardised training protocol for LUS, but the literature[20,21] suggests a short (30 minute) didactic presentation on the ultrasound signs of pulmonary pathology and a practical demonstration of the scanning method as

described by Volpicelli[18]. A statement by the American College of Chest Physicians (ACCP) and La Société de Réanimation de Langue Française (SRLF)[22] has defined skills that a physician should have to be competent in the field of LUS. The anaesthesiology registrars training in this department are all familiar with ultrasound and the relevant anatomy. After a short presentation on the identification of a normal LUS pattern (A-lines) and identification of B-line artifacts, the registrars met the criteria for competency for performing LUS.

Further training took the form of a practical demonstration in theatre by the researcher (IL). The research protocol was left in theatre with detailed information about the scanning protocol for the registrars to refer to at any time.

Information Collected

The number of B-lines found in each region of the chest was recorded onto a data collection sheet (appendix 1). The total B-lines were then calculated. The diagnosis of LIS was made solely on the definition of a positive examination as described above. The data forms also noted the date of surgery, the date of discharge from the CTU and the date of discharge from the hospital.

Statistical analysis was done by Cornel van Rooyen from the Department of Biostatistics, University of the Free State. Descriptive statistics, namely medians and percentiles, were calculated for continuous data. Frequencies and percentages were calculated for categorical data. The LOS of the group that was diagnosed with LIS was compared to those without, using the Kruskall Wallis test. A p-value of <0.05 was statistically significant.

Ethics

This study was approved by the institution's ethics committee (ECUFS 208/2015) and registered with the Department of Health (FS_2016RP38_26). All confidential information remained as such in the possession of the researcher.

RESULTS

A total of twenty patients were recruited to participate in this study. No patients withdrew, but two patients were excluded from the analysis of LOS as one patient died in the CTU and another in the ward before discharge. Patient characteristics are summarized in table 1. The prevalence of LIS was found to be 25% when measured using LUS at Universitas Academic Hospital in Bloemfontein.

Table 1 - Patient characteristics

	Median (range) or n (%)	
Preoperative characteristics		
Age in months	17.0	(6.0-108.0)
Gender		
Male	10	(50%)
Female	10	(50%)
Diagnosis		
ASD	2	(10%)
VSD	13	(65%)
AVSD	5	(25%)
Lung interstitial syndrome		
Yes	5	(25%)
No	15	(75%)
Length of Stay		
CTU (d)[1]	4.0	(2.0 – 6.0)
Hospital (d)[2]	7.0	(6.0 – 27.0)

ASD, atrial septal defect; VSD, ventricular septal defect; AVSD, atrioventricular septal defect; CTU, cardiothoracic unit; (d), days
[1]n = 19 as one child died in CTU
[2]n = 18 as another child died in the ward

LOS in the CTU was calculated from the date of admission to CTU to date of discharge to the cardiothoracic ward. Length of hospital stay was calculated from the date of discharge from the CTU to the date of discharge home. LOS data are summarised in table 2.

Table 2 - Summary of Length of Stay

Length of Stay	n	Median (range)	
Total			
CTU (d)	19	4.0	(2.0 – 6.0)
Hospital (d)	18	7.0	(6.0 – 27.0)
With LIS			
CTU (d)	4	4.0	(3.0 – 6.0)
Hospital (d)	4	7.5	(6.0 – 20.0)
Without LIS			
CTU (d)	15	4.0	(2.0 – 5.0)
Hospital (d)	14	7.0	(6.0 – 27.0)

CTU, cardiothoracic unit; LIS, lung interstitial syndrome; (d), days

There was no statistical difference in LOS in the CTU (p=0.601) or LOS in the hospital (p=0.544) when comparing this group to the group without LIS.

DISCUSSION

To our knowledge, this is the first study that uses LUS to assess the prevalence of LIS due to EVLW in paediatric cardiac surgical patients undergoing CPB.

Postoperative cardiac and extracardiac complications are common in cardiac surgery[23]. Pulmonary complications are associated with longer mechanical ventilation and length of intensive care unit (ICU) and hospital stay with resultant increasing costs. Early diagnosis of postoperative pulmonary disease can have far-reaching effects. There are studies[12,24] that have proven the usefulness of LUS for the early identification of EVLW and diagnosis of LIS in patients but the prevalence of LIS in the paediatric cardiac surgery population is unknown.

The results of our study differ from those of other studies in which EVLW and LIS have been linked to longer mechanical ventilation, prolonged LOS and increased mortality[12,23,25]. However, our study is not directly comparable to these studies. Gillespie et al[25] aimed to identify factors that influence postoperative ICU LOS. They retrospectively studied 221 infants who underwent congenital heart surgery, with or without CPB and postoperative admission to cardiac ICU. A substantial portion of their study sample had to undergo urgent surgery. This 'nonelective' group showed significant preoperative morbidity and had a median age of 6 days. All the children in our study sample were scheduled for elective correction of atrial, ventricular or atrioventricular septum defects (ASD, VSD and AVSD respectively) with CPB and postoperative admission to the CTU. The age of the children included in the Gillespie study ranged from 1 to 182 days whereas the age of the youngest child in our study was 6 months 8 days (190 days).

A very recent study by Kaskinen et al[12] compared operation-related factors and short-term clinical outcome by using B-line scores on LUS and chest radiography lung oedema scores. In their study, the mean length of paediatric intensive care unit (PICU) stay for patients with a postoperative B-line score higher than the median was 6.0 days (IQR 3.3-9.8), where the median LOS for children diagnosed with LIS in our study was 4.0 days (range 2.0-6.0). Their scanning protocol differed from the one used in our study. They used a six-region ultrasound protocol, every day for 5 days, and evaluated the surface area of each region covered by B-lines. They analysed the severity of EVLW according to a 5-step scale which quantified the abundance of B-lines (B-line score) on LUS.

Both the Gillespie and Kaskinen studies used an ordinal score[26,27] to adjust for severity of the surgical procedures in determining postoperative LOS. As expected, higher severity scores resulted in longer LOS.

Two of the patients included in this study died in hospital. One died in the CTU on the xth postoperative day. A diagnosis of LIS was made in this case. The other patient died on the sixth postoperative day after being discharged from the CTU the previous day. A diagnosis of LIS was not made in this case.

Limitations

EVLW and LIS are common postoperative complications, especially in paediatric cardiac surgery population. Other pre-, intra- and postoperative factors[23,25,28] can also play a role in prolonging mechanical ventilation and LOS, but these were not considered in this study.

Other potential limitations of this study include the likelihood of inter- and intra-observer variability of LUS. Inter-observer variation is the extent of variation between the results obtained by two or more observers examining the same material. Intra-observer variation is the extent of variation one observer experiences when observing the same material more than once.

Due to factors beyond the author's control, the duration of data collection had to be extended – from the initial planned 3 months to 8 months, when enough patients had been scanned for the study. These factors included lists being cancelled due to staff shortages and patients not arriving on time for their scheduled procedures. The extended data collection period meant that different registrars rotated through paediatric cardiac surgery.

Due to the small number of study participants, the external validity of this study is limited. It is not certain if these results can be generalised to the paediatric cardiac surgery population. The fact that this study is institution based is also a limitation as the results are subject to local standards of practice and patient profile. Patients presenting for surgery often have a delayed presentation and diagnosis of their cardiac disease with more advanced pre-operative complications such as pulmonary hypertension.

Jambrik et al[29] described a more comprehensive 28 rib-space scanning technique. This technique allows for a more precise quantification of LIS and is useful in the settings of cardiology and nephrology. This technique was not used in this study as quantification of LIS was not necessary to measure the primary outcome and time constraints did not allow for a more elaborate examination in theatre.

CONCLUSION AND RECOMMENDATIONS

Pulmonary pathology after cardiac surgery increases the morbidity and mortality rates and requires serial testing, prolonged hospital stay and increased cost. Early diagnosis of LIS can direct management thereby potentially decreasing LOS and treatment cost. LUS is an easy to learn and use, point-of-care alternative to chest radiography and CT scanning for the diagnosis of postoperative pulmonary complications, especially EVLW and LIS. Establishing the prevalence of LIS can strengthen the argument for routine postoperative use of LUS in cardiac surgery.

Suggestions for further research include using a larger study sample size to increase external validity and to consider recruiting other institutions for a multicentre study. A larger cohort with a more detailed classification of other potential factors might be necessary to study the LOS of paediatric cardiac surgery patients in this institution.

A further study can be done to identify and assess other associations with LIS specific to this institution and whether they can be manipulated to lower the prevalence of LIS and LOS in this population. Data from a larger study can be used to draw up a standardised protocol for LUS in the paediatric cardiac surgery population for the early diagnosis and treatment of LIS.

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REC Reference nr 230408-011
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FWA00012784

26 February 2016

DR I LARSON
C/O PROF BJS DIEDERICKS
DEPARTMENT OF ANAESTHESIOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Larson

ECUFS NR 208/2015
PROJECT TITLE: THE USE OF LUNG ULTRASOUND TO ASSESS THE PREVALENCE OF LUNG INTERSTITIAL SYNDROME IN PAEDIATRIC CARDIAC SURGERY PATIENTS AND THE MEASUREMENT OF POSTOPERATIVE LENGTH OF HOSPITAL STAY

1. You are hereby kindly informed that, at the meeting held on 23 February 2016, the Health Sciences Research Ethics Committee (HSREC) approved the above project after all conditions were met when the signed permission letter from the Free State Department of Health was submitted.

2. The Committee must be informed of any serious adverse event and/or termination of the study.

3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.

4. A progress report should be submitted within one year of approval and annually for long term studies.

5. A final report should be submitted at the completion of the study.

6. Kindly use the ECUFS NR as reference in correspondence to the HSREC Secretariat.

7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
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health
Department of
Health
FREE STATE PROVINCE

16 February 2016

DR I Larson
C/OP Prof BJS Diedericks
Dept. of Anaesthesiology
Faculty of Health Science
UFS

Dear Dr I Larson

Subject: The use of lung ultrasound to assess the prevalence of lung interstitial syndrome in paediatric cardiac surgery patients and the measurement of postoperative length of hospital stay.

- Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participants must be obtained
- Serious adverse events to be reported and/or termination of the study.
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and no names will be used.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of the Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of the Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** khusemj@fshealth.gov.za or sebeelats@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution managers/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see http://nhrd.hst.org.za

Trust you find the above in order.

Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 16/02/2016

Appendix 1 - Patient information and consent forms (English and Sesotho)

The Use of Lung Ultrasound to Assess the Prevalence of Lung Interstitial Syndrome in Paediatric Cardiac Surgery Patients and the Measurement of Postoperative Length of Hospital Stay.

Dear Sir/Madam

We are doing research to determine the commonness of a condition called lung interstitial syndrome in children undergoing open heart surgery. Research is just the process to learn the answer to a question. In this study we want to use lung ultrasound to see how often this condition occurs in these children and then we would like to see how long your child stays in hospital after their operation. This will also tell us if lung ultrasound is useful to predict which children will have a longer hospital stay.

We are asking for your permission to include your child in this research study.

If you agree to include your child in this study, there will be no extra requirements on your part. The lung ultrasound scans will be done right before the start of the operation and again at the end, before your child is transferred to the Intensive Care Unit. Information collected from the hospital's computer system will be used to calculate how long your child had to stay in hospital.

There are no expected risks of being involved in this study nor any direct benefits. The information gained from this study can help to improve care of children with heart lesions after their operation.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you and your child are otherwise entitled; you may discontinue participation at any time without penalty or loss of benefits.

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

The results of this study may be published in a journal or presented at a meeting or congress.

For further information please contact Dr Ilke Larson at 0824403112

Tshebediso ya sehlahlobi se bontshang le ho utlwa matshwafo ka mokgwa wa maqhubu le modumo ho lekola ho ba teng hwa matshwao a tshwaetso ya matshwafo bakuding ba bana ba phunngwang pelo le tekano ya nako ya ho dula sepetlele kamora ho phunngwa.

Ntate/Mme ya ratehang

Re etsa patlisiso ho tiisa tlwaelo ya bothata bo bitswang matshwao a tshenyeho ya matshwafo baneng ba phunngwang pelo. Patlisiso ke tsela fela ya ho ithuta karabo ya potso. Patlisisong ena re batla ho sebedisa sehlahlobi se bontshang matshwafo ho bona kamoo bothata bona bo hlahellang kateng hangata baneng bana mme re rata ho bona hore ngwana wa hao o nka nako e kae a le sepetlele kamora ho phunngwa. Sena se tla re tsebisa haeba sehlahlobi se bontshang matshwafo se le molemo ho ka bonelapele hore ke bana bafeng ba tla lokela ho dula sepetlele nako e teletshana.

Re kopa tumello ya hao ho kenya ngwana wa hao boithuting bona ba patlisiso.

Ha o dumela ho kenya ngwana wa hao boithuting bona, ha hona ho ba le dintho tse ding tse tla batlehang ho tswa ho wena. Ditshwantsho tsa matshwafo di tla nkuwa pele ho ho phunngwa le kamora ho phunngwa, pele ngwana wa hao a fetisetswa uniting ya batho ba kulang haholo. Tlhahiso-lesedi e bokelleditsweng ho tswa hlohlomisong ya khomphuthara/komporo ya sepetlele e tla sebediswa ho bala hore ngwana wa hao o loketse ho dula nako e kae sepetlele.

Ha hona dikotsi tse lebelletsweng ho beng le seabo boithuting bona le ha e le melemo e itseng. Tlhahiso-lesedi e fumanweng ho tswa boithuting bona e ka thusa ho ntlafatsa tlhokomelo ya bana ba nang le mathata a pelo kamora ho phunngwa.

Ho ba le seabo ke boithaopo ba motho, mme ho hana ho ba le seabo ho ka se tlise kotlo kapa tahlehelo ya melemo eo wena le ngwana wa hao e le loketseng; o ka emisa ho ba le seabo neng kapa neng ntle le kotlo kapa tahlehelo ya melemo.

Boikgathatso bo tla etswa ho boloka tlhahiso-lesedi ya mong ka botshepehi. Ha hona kamoo Botshepehi bo phethahetseng bo ka nnetefatswang kateng. Tlhahiso-lesedi ya mong e ka utullwa haeba e hlokwa ho latela molao.

Diphetho tsa boithuti bona di ka phatlalatswa lesedinyaneng kapa tsa hlahiswa kopanong kapa sebokeng.

Ho fumana tlhahiso-lesedi ho feta mona ka kopo letsetsa Dr Ilke Larson mohala nomorong ena 0824403112.

The Use of Lung Ultrasound to Assess the Prevalence of Lung Interstitial Syndrome in Paediatric Cardiac Surgery Patients and the Measurement of Postoperative Length of Hospital Stay.

You have been asked for your child's participation in a research study.

You have been informed about the study by ……

You may contact Dr Ilke Larson at 0824403112 any time if you have questions about 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 child's rights as a research subject.

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

If you agree to your child's participation, 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 child's involvement in the study means and I voluntarily agree to participate.

_____	_____
Signature of Participant	Date
_____	_____
Signature of Witness	Date
_____	_____
Signature of Translator (Where applicable)	Date

Tshebediso ya sehlahlobi se bontshang le ho utlwa matshwafo ka mokgwa wa maqhubu le modumo ho lekola ho ba teng hwa matshwao a tshwaetso ya matshwafo bakuding ba bana ba phunngwang pelo le tekano ya nako ya ho dula sepetlele kamora ho phunngwa.

O kopuwe hore ngwana wa hao a be le seabo boithuting ba patlisiso.

O tsebisitswe ka boithuti ke ……

O ka letsetsa Dr Ilke Larson mohala nomorong ya (051) 4052812 neng kapa neng ha o na le dipotso mabapi le patlisiso.

O ka letsetsa Mongodi wa Komiti ya Boitshwaro ya Fakhalthi ya tsa Bophelo UFS nomorong ya (051) 4052812 ha o na le dipotso mabapi le ditokelo tsa ngwana wa hao jwalo ka mosebediswa wa patlisiso.

Seabo sa ngwana wa hao patlisisong ena ke sa boithaopo, mme ha o na ho otlwa kapa ho lahlehelwa ke melemo ha o hana ho ba le seabo kapa ha o nka qeto ya ho fedisa seabo sa hao.

Ha o dumella ngwana wa hao ho ba le seabo, o tla fuwa khopi e saennweng ya tokomane ena hammoho le pampiri ya tlhahiso-lesedi ya mokeni, eo e leng kakaretso e ngotsweng ya patlisiso.

Boithuti ba patlisiso, ho kenyelletsa le tlhahiso-lesedi e ka hodimo bo hlalositswe ka molomo ho nna. Ke utlwisisa se bolelwang ka seabo sa ngwana wa ka patlisisong mme ke dumela ka boithaopo ho ba le seabo.

_____	_____
Tshaeno ya Mokeni	Lehla
_____	_____
Tshaeno ya Paki	Lehla
_____	_____
Tshaeno ya Mofetoledi	Lehla

TITLE OF THE RESEARCH PROJECT: The Use of Lung Ultrasound to look at the Commonness of Lung Interstitial Syndrome in Children Undergoing Heart Operations and the Measurement of Postoperative Length Of Hospital Stay.

RESEARCHERS NAME(S): ***Dr Ilke Larson***

ADDRESS: ***Department of Anaesthesiology, University of the Free State and Universitas Hospital***

CONTACT NUMBER: ***082 440 3112***

What is RESEARCH?

Research is something we do to find new knowledge about the way things (and people) work. We use research projects or studies to help us find out more about disease or illness. Research also helps us to find better ways of helping, or treating children who are sick.

What is this research project all about?

We want to use ultrasound to have a look at your lungs after you have had the operation to fix your heart. Ultrasound takes pictures using sound waves to look at the inside of your body. These pictures will give us information which we cannot learn from just listening to your chest.

Why have I been invited to take part in this research project?

You were born with a heart that is different to other kids your age and you need an operation to fix it.

What will happen to me in this study?

We will take the pictures of your lungs with the ultrasound while you are sleeping, right after your operation. You do not have to do anything.

Can anything bad happen to me?

Nothing bad can happen to you. The ultrasound is the same as the one they used to look at your heart when you visited the children's heart clinic.

Can anything good happen to me?

This research will not help you directly. We do hope to learn something from this research though. And someday we hope it will help other kids who need heart operations like you do.

Will anyone know I am in the study?

Nobody will know that you are in the study. Your name will not be in any report of the results of this study.

Who can I talk to about the study?

If you have any questions about the study, you can contact Dr Ilke Larson at 0824403112.

What if I do not want to do this?

You do not have to be in this study if you don't want to, even if your parent has already given us permission. You may stop being in the study at any time. If you want to stop, just tell us so and we will stop right away. If you decide to stop, no one will be angry or upset with you. You can ask questions at any time.

Do you understand this research study and are you willing to take part in it?

YES	NO

Has the researcher answered all your questions?

YES	NO

Do you understand that you can pull out of the study at any time?

YES	NO

_____ _____

Signature of Child Date

_____ _____

Signature of Person Obtaining Assent Date

SEHLOHO SA PROJEKE YA PATLISISO: Tshebediso ya sehlahlobi se bontshang matshwafo ho lekola matshwao a tlwaelehileng a tshenyeho ya matshwafo baneng ba phunngwang pelo le tekano ya nako ya ho dula sepetlele kamora ho phunngwa.

LEBITSO LA MOFUPUTSI: ***Dr Ilke Larson***

ATERESE: ***Lefapha la Anaesthesiology, Univesithi ya Freistata le Sepetlele sa Universitas***

NOMORO YA MOHALA: ***082 440 3112***

PATLISISO ke eng?

Patlisiso ke ntho eo re e etsang ho fumana tsebo e ntjha mabapi le kamoo dintho (le batho) di sebetsang kateng. Re sebedisa diprojeke tsa patlisiso kapa dithuto ho re thusa ho fumana haholwanyana ka lefu kapa bolwetsi. Patlisiso hape e re thusa ho fumana ditsela tse lokileng tsa ho thusa kapa ho phekola bana ba kulang.

Projeke ena ya patlisiso e mabapi le eng?

Re batla ho sebedisa sehlahlobi se bontshang dikarolo tse ka hara mmele ho lekola matshwafo a hao kamora ho phunngwa ho lokisa pelo ya hao. Sehlahlobi se bontshang dikarolo tse ka hara mmele se nka ditshwantsho ka ho sebedisa maqhubu a modumo ho sheba ka hara mmele wa hao. Ditshwantsho tsena di tla re fa tlhahiso-lesedi eo re ke keng ra ithuta yona ka ho mamela sefuba sa hao feela.

Hobaneng ke menngwe ho ba le seabo projekeng ena ya patlisiso?

O tswetswe ka pelo e fapaneng le tsa bana ba bang ba dilemo tsa hao mme o hloka ho phunngwa ho e lokisa.

Ke eng se tlo etsahala ho nna boithuting bona?

Re tla nka ditshwantsho tsa matshwafo a hao ka sehlahlobi se bontshang dikarolo tse ka hara mmele nakong eo o robetseng, hang kamora ho phunngwa. Ha o a lokela ho etsa letho.

Nka etsahallwa ke hohong ho hobe?

Ha ho letho le lebe le ka o etsahallang.Sehlahlobi se bontshang dikarolo tse ka hara mmele se tshwana le seo ba se sebedisitseng ho sheba pelo ya hao mohlang o neng o tjhaketse kliniki ya bana ya pelo.

Nka etsahallwa ke hohong ho molemo?

Patlisiso ena e ka se o thuse hanghang. Le ha ho le jwalo re lebelletse ho ithuta ho itseng ho tswa patlisisong ena. Mme re lebelletse hore ka letsatsti le leng e tla thusa bana ba bang ba hlokang ho phunngwa pelo jwalo ka wena.

Ebe ho teng motho ya tla tseba ha ke kenetse boithuti bona?

Ha ho motho ya tla tseba hore o kenetse boithuti bona. Lebitso la hao ha le na ho ba teng pehelong efe kapa efe ya diphetho tsa boithuti bona.

Nka bua le mang mabapi le boithuti bona?

Ha o na le dipotso tse itseng mabapi le boithuti, o ka letsetsa Dr Ilke Larson mohala nomorong ena 0824403112.

Haebaneng ke sa batle ho etsa ntho ena?

Ha o sa batle ho kena boithuting bona o ka etsa jwalo le ha batswadi ba hao ba se ba re file tumello. O ka emisa ho ba le seabo boithuting neng kapa neng. Ha o batla ho emisa, re jwetse fela jwalo mme re tla emisa hang. Ha o nka qeto ya ho emisa, ha ho motho ya tla o kwatela kapa a se o thabele. O ka botsa dipotso neng kapa neng.

A o utlwisisa boithuti bona ba patlisiso mme o ikemiseditse ho ba le seabo ho bona?

	E	TJHE
A mmatlisisi o arabile dipotso tsa hao kaofela?		
A o a utlwisisa hore o ka tswa boithuting neng kapa neng?		

	E	TJHE

_____ _____

Tshaeno ya Ngwana Lehla

_____ _____

Tshaeno ya Motho ya Fumanang Tumello Lehla

For office use only:

Date: DD / MM / YYYY

UM No: _____

Gender: _____

Age: _____

Primary Heart Lesion: ASD | VSD | AVSD

8 Region lung ultrasound and quantification of B-lines

	Right	Left
Anterior Upper		
Anterior Lower		
Lateral Upper		
Lateral Basal		
Total B-lines		

For office use only:

Confirmed LIS? Y | N

Date of Discharge:

CTU: DD / MM / YYYY

Hospital: DD / MM / YYYY

Length of Stay:

CTU: _____

Hospital: _____

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UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

01 August 2016

DR I LARSON
C/O PROF BJS DIEDERICKS
DEPARTMENT OF ANAESTHESIOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Larson

ECUFS NR 208/2015
PROJECT TITLE: THE USE OF LUNG ULTRASOUND TO ASSESS THE PREVALENCE OF LUNG INTERSTITIAL SYNDROME IN PAEDIATRIC CARDIAC SURGERY PATIENTS AND THE MEASUREMENT OF POSTOPERATIVE LENGTH OF HOSPITAL STAY

1. You are hereby kindly informed that, at the meeting held on 26 July 2016, the Health Sciences Research Ethics Committee (HSREC) approved the following:

   - *Request for extension of study period for data collection until the end of the year*

2. The Committee must be informed of any serious adverse event and/or termination of the study.

3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.

4. A progress report should be submitted within one year of approval and annually for long term studies.

5. A final report should be submitted at the completion of the study.

6. Kindly use the ECUFS NR as reference in correspondence to the HSREC Secretariat.

7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
PROF WJ STEINBERG
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | F: +27 (0)51 444 4359 | E: ethicsfhs@ufs.ac.za
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