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Expert consensus document: Reporting checklist for quantification of pulmonary congestion by lung ultrasound in heart failure

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Abstract

Lung ultrasound is a useful tool for the assessment of patients with both acute and chronic heart failure. The use of different image acquisition methods, inconsistent reporting of the technique employed and variable quantification of “B-lines”, however, have all made it difficult to compare published reports. As a result, strategies to improve patient care by its use have been difficult to develop. There is a need to ensure future studies utilizing lung ultrasound in the assessment of heart failure adopt a standardized approach to reporting the quantification of pulmonary congestion. This consensus report includes a checklist to provide standardization in the preparation, review and analysis of manuscripts. This will serve as a guide for investigators and clinicians and enhance the quality and transparency of lung ultrasound research. Key aspects of standardization discussed include equipment used, number of chest zones assessed, the method of quantifying B-lines, the presence and timing of additional investigations (e.g., natriuretic peptides and echocardiography) and the impact of therapy.

Keywords: lung ultrasound, heart failure, methodology, reporting checklist

Introduction

Pulmonary congestion is one of the most important findings in heart failure (HF), yet traditional methods, e.g., clinical examination and chest x-ray, are relatively insensitive for its detection.¹⁻³ Lately, there has been tremendous growth in the use of lung ultrasound (LUS) for the detection of pulmonary congestion in HF both in research and, more recently, in clinical practice.^{2,4-10} LUS has been proposed as a useful tool in the assessment of patients with both acute and chronic HF.^{2,5,8,10} This technique enables the detection of pulmonary congestion in patients presenting with acute dyspnea with higher accuracy than chest auscultation or chest x-ray.⁵ The LUS findings of pulmonary congestion, commonly called B-lines, change dynamically with treatment for acute HF and can provide prognostic information in both acute and chronic HF.^{11,12} However, different methods and inconsistent reporting of the LUS technique used and the quantification of B-lines make it difficult to compare existing studies. This lack of standardization impedes the development of strategies to reduce pulmonary congestion and improve patient care.¹¹ One prior international consensus statement described a wide variety of LUS applications, but was not specifically focused on its use in HF or detailed in its description of the methodological aspects.⁴ With the anticipated growth in the use of LUS, and in subsequent potential publications, in patients with HF, there is a need to develop a standardized reporting guide for the quantification of pulmonary congestion by LUS in HF.

Methods and Aims

Our aim was to create a checklist to enhance the quality and transparency of LUS research and reporting. This consensus statement is intended to serve as a guide for investigators, reviewers, editors and readers in the preparation, evaluation and interpretation of manuscripts involving the use of LUS in HF.¹³ We convened a group of cardiologists and emergency physicians with expertise in LUS, HF, epidemiological studies, and clinical trials to review the current literature

in this area. Following discussion and agreement, they composed a succinct evidence-based reporting checklist. In contrast to other existing guidelines, we focused on unique aspects of LUS research, including study design and image analysis.

Reporting Checklist

Title, abstract and study design

All reports should follow previously published guidelines regarding the use of a structured abstract and appropriate title.¹⁴ The relevant guidelines for the design of the study e.g. observational vs. randomized clinical trial should be used.¹⁴ For diagnostic studies, the reference standard should be clearly described and for prognostic studies, authors should report how the primary outcome was adjudicated, as applicable.¹⁵ A description of the key aspects of both the general study design and LUS-specific components is provided in the reporting checklist (**Table 1 and Figure 1**).

Participant characteristics, co-morbidities and study setting

In studies of patients with known or suspected HF, the definition of HF used should be described in detail and should be consistent with recognized definitions.^{16,17} Standard patient descriptors should be reported as should how and where the patients were recruited and whether any inclusion and exclusion criteria were applied. Reported patient characteristics should include general demographics, such as age, sex, and body mass index, vital signs including respiratory rate, blood pressure and heart rate, as well as important comorbidities, symptoms and signs of heart failure, measures of cardiac function and natriuretic peptides. Diffuse B-lines, which usually reflect pulmonary congestion, can also be detected by LUS in other conditions such as pulmonary contusions, adult respiratory distress syndrome (ARDS), and interstitial lung disease.¹⁸⁻²² Pulmonary congestion can also result from conditions other than HF, e.g. end stage renal disease. Consequently, it is essential that studies designed to

detect potential pulmonary congestion in patients with suspected or established HF also make a statement about the presence or absence of these other co-morbidities known to lead to B-lines on LUS (**Table 1**).¹¹ Without a clear description of these variables, study results may be confounded or misleading. If these conditions are exclusion criteria, this should be clearly stated in the Methods section of the study. If patients having one of these conditions have been included, their potential significance must be evaluated, e.g. by undertaking stratified, sensitivity and other analyses to determine whether they have confounded the interpretation of potential pulmonary congestion and change in congestion over time and/or in response to treatment. Reporting of the setting of the study (e.g. pre-hospital, ambulatory care, emergency department, hospital ward, intensive care unit) is also important, as HF patients will demonstrate a different spectrum of B-lines reflecting the likely degree of pulmonary congestion in each setting and interpretation and comparison of studies must thus take study setting into account (**Figures 1 and 2**).^{5,11,23}

Ultrasound equipment, image acquisition and image analysis

The manufacturer and model of the ultrasound equipment used should be described. The type of transducer, transducer orientation (transverse vs. sagittal) and clip duration (which may be limited to shorter time periods on pocket ultrasound devices) can alter the number of detectable B-lines in patients with HF.^{24,25} Specifically, phased array transducers (as compared to curvilinear transducers) and longer clip duration (6-7 seconds/video clip) allow for observation of a higher number of B-lines in HF.^{24,25} Similarly, patient positioning during the LUS should be described and ideally performed in a standardized position due to its effect on B-line count, as patients with acute HF may have a higher number of B-lines in the supine vs. the sitting position.²⁶

The number and location of chest zones examined should be clearly described. Prior studies in HF cohorts have reported 4 to 28 chest zones (**Table 2**), and in 2012 an international guideline

recommended either the use of 8 or 28 zones (**Figure 3A**).⁴ Different approaches have since been described e.g. using 6 zones in the assessment of dyspneic patients in the emergency department and without apparent loss of diagnostic accuracy.^{4,5} Based on the currently available data, we suggest that at least 3 zones on each hemithorax (6 zones total; **Figure 3B**) should be examined and the B-line number reported in patients with HF.⁵

For B-line quantification, two general approaches have been reported in HF cohorts (**Table 2**):

1) A count-based method, in which the sum of B-lines in one intercostal space per zone across all zones is reported.^{10,23}

2) A scoring system, in which a minimum number of B-lines in one intercostal space per zone is used to define a zone as “positive”. Positive zones are then summed to delineate a cut-off value. For example, ≥ 3 B-lines in 2 zones on each hemithorax are consistent with a diagnosis of pulmonary edema in dyspneic patients presenting to the emergency department.^{5,27,28}

If software is used to quantify the number of B-lines, the manufacturer and version of the software should be reported, as the type of software could potentially contribute to variability in B-line number between vendors. In addition, the cut-off definition process or decision limits for the detection of HF should be accurately described, if applicable. As large pleural effusions may interfere with B-line quantification, the presence of pleural effusions (overall frequency of unilateral or bilateral pleural effusions) and how pleural effusions were assessed should be reported, when possible.

Blinding & central image interpretation

Blinding is an important methodologic feature in diagnostic and prognostic studies to minimize bias and maximize the validity of results. Sonographer knowledge of the findings on clinical

examination or results of other diagnostic modalities, therapies and medical history, should be described when reporting image acquisition. Blinding to these same aspects should be reported with respect to the individuals undertaking B-line quantification. The temporal aspects of blinding should be described for studies involving serial LUS examinations. Although HF studies investigating the impact of reader experience on both real-time and offline quantification of B-lines have demonstrated similar results between novice and expert readers, with high inter-reader agreement, the experience of the personnel involved in analyses and the setting in which the analyses are performed should be reported.^{25,29} Specifically, whether the LUS images were interpreted in real-time (at the bedside), off-line by investigators not involved in the image acquisition, or at a central core laboratory should be reported. In order to obtain unbiased results, blinded reading in a central core laboratory clearly is preferable.

Additional investigations

The results of additional investigations assessing hemodynamic or clinical congestion, such as chest radiography, echocardiography, invasive hemodynamic measurements or natriuretic peptide levels, should be documented. Importantly, the temporal relationship between these investigations and the assessment of pulmonary congestion by LUS should be reported. This information will also facilitate a better understanding of the sequence of the dynamic changes of these congestion markers.³⁰ For example, whether the chest radiograph was performed at the same time as the LUS study or whether it was performed 24 hours later affects the interpretation of the relationship between these investigations. Similarly, the initiation of any therapy directed at congestion, and any response that occurred between the LUS study and supporting investigations should be clearly documented (e.g. if pulmonary artery pressures were measured, after which the patient received diuretics, followed by the LUS study, should be documented).

Data reporting and analysis

Sonographic B-lines in patients with HF are known to be differentially distributed.^{12,31} As a higher prevalence of B-lines occurs in more dependent chest zones, the reporting of missing data in zones that could not be analyzed (e.g., due to cardiomegaly or large pleural effusions) is essential. More dependent zones are also those most likely influenced by the presence of pleural effusions or, in the left hemithorax, by cardiomegaly. The method or methods used to deal with missing B-line data or missing zones should be clearly described.

Statistical methods appropriate for the quantification method (e.g. score or count data) should be used and detailed in the statistical analysis section. As B-lines are frequently not normally distributed, the analysis should consider their distribution among the patients studied.

Results and discussion

The presentation of results should include the number of patients enrolled and excluded from analysis or follow-up, the proportion with adequate images and the number analyzed. Authors should provide reasons for non-participation at each stage, preferably using a CONSORT flow diagram for illustration.³² The LUS data description should include the number and variation of B-lines at baseline and at follow up, if applicable. In addition to the main study results, sources of potential bias and the generalizability of study findings should be discussed, as well as any implications for clinical practice with respect to the role of LUS.

Gaps in current knowledge

While there is general agreement on how to diagnose pulmonary edema with LUS in patients with undifferentiated dyspnea presenting to the emergency department, the wide range of LUS methods used, has made the establishment of a standardized approach and cut-off values in other settings challenging. This hampers the performance of meta-analyses of available evidence and consequently the genesis of a widely accepted consensus. Studies with larger

sample sizes comparing different imaging protocols with respect to the number of zones and B-line quantification method, in both ambulatory and hospitalized HF patients, including on admission and pre-discharge, would be useful to inform clinical guidelines and future clinical trials. Specifically, whether LUS provides incremental diagnostic or prognostic information beyond current methods in patients with suspected or known HF should be further addressed through well-designed, prospective investigations, with appropriate statistical analyses, e.g. including comprehensive multivariable models incorporating other important diagnostic and prognostic variables. In addition, studies investigating treatment response and the adequacy of decongestive therapy, for instance at the time of hospital discharge in large, well-defined HF cohorts will be important. Specifically, outcome randomized controlled trials assigning patients to a treatment intervention designed to maximize B-line resolution vs. standard of care could inform clinical practice in the future. Similarly, the value and frequency of LUS use during outpatient clinic follow up warrants further investigation. While B-lines can be detected irrespective of ejection fraction in both ambulatory and hospitalized patients with heart failure, recent reports in patients with reduced vs. preserved ejection fraction demonstrated differing results with respect to the number of B-lines in these HF cohorts^{23,33} These findings could be due to different degrees of pulmonary congestion or other confounders. Further research is needed to better understand the impact of these factors on LUS findings in patients with HF and how to best integrate LUS in the management of these patients.

Conclusions

Lung ultrasound can provide useful information regarding the presence and degree of pulmonary congestion in patients with heart failure. Consistent reporting of certain methodological aspects should be considered in studies employing lung ultrasound in heart failure populations to assure high-quality research result dissemination and allow for future standardization.

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Conflict of interest

Dr. Platz reports grants from NHLBI, during the conduct of the study; Dr. Jhund reports personal fees from Novartis, grants and personal fees from Boehringer Ingelheim, personal fees from Vifor pharma, personal fees from Amgen, outside the submitted work; and is Director of GCTP Ltd.; Dr. Girerd reports personal fees from Novartis, outside the submitted work; Dr. Maisel reports personal fees from critical diagnostics, personal fees from Abbott, outside the submitted work; Dr. Bueno reports grants from Instituto de Salud Carlos III, personal fees from Bayer, personal fees from Novartis, grants, personal fees and non-financial support from AstraZeneca, grants and personal fees from BMS-Pfizer, personal fees from Ferrer, personal fees from MEDSCAPE-the Heart-org, personal fees from Janssen, outside the submitted work; Dr. Mebazaa reports personal fees from Novartis, personal fees from Orion, personal fees from Roche, personal fees from Servier, grants and personal fees from Adrenomed, grants and personal fees from Abbott, personal fees from Sanofi, outside the submitted work; Dr. Gualandro reports personal fees and non-financial support from Servier, grants from FAPESP (Research Foundation of the State of Sao Paulo), outside the submitted work; Dr. Metra reports personal fees from Novartis, Bayer, outside the submitted work; Dr. Coats reports personal fees from Astra Zeneca, personal fees from Vifor, personal fees from Respicardia, personal fees from Impulse Dynamics, personal fees from Faraday, personal fees from WL Gore, personal fees from Actimed, personal fees from Menarini, personal fees from Novartis, personal fees from Servier, personal fees from Nutricia, personal fees from Stealth Peptides, personal fees from Verona, outside the submitted work; Dr. Ruschitzka reports grants and personal fees from

SJM / Abbott, grants and personal fees from Servier, personal fees from Zoll, personal fees from Astra Zeneca, personal fees from Sanofi, grants and personal fees from Novartis, personal fees from Amgen, personal fees from BMS, personal fees from Pfizer, personal fees from Fresenius, personal fees from Vifor, personal fees from Roche, grants and personal fees from Bayer, personal fees from Cardioentis, personal fees from Boehringer Ingelheim, other from Heartware, grants from Mars, outside the submitted work; Dr. Mueller reports grants, personal fees and non-financial support from several diagnostic companies, outside the submitted work; Dr. Pivetta, Dr. McMurray, Dr. Peacock, Dr. Masip, Dr. Martin-Sanchez, Dr. Miro, Dr. Price, Dr. Cullen, Dr. Vrints, Dr. Cowie, Dr. Di Somma, Dr. Tavares, and Dr. Severovic have no competing interests.

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Table 1. Reporting checklist for lung ultrasound studies in heart failure cohorts

	No.	Aspects for consideration	Literature
Title or abstract	1	Identification as a study employing lung ultrasound as a measure of pulmonary congestion	
Abstract	2	Structured summary of study design, methods, results, and conclusions	
Introduction	3	Scientific and clinical background, including the intended use and clinical role of lung ultrasound	
	4	Study hypothesis and objectives	
Methods			
Study design	5	Whether data collection was planned before the lung ultrasound was performed (prospective study) or after (retrospective study)	
	6	Description of how heart failure was defined	16,17
	7	Description of reference standard for the primary outcome and how it was adjudicated (if applicable)	15
Participants	8	Inclusion and exclusion criteria with particular attention to factors that could confound lung ultrasound findings (e.g. interstitial lung disease, pneumonitis, ARDS, dialysis)	18-22
	9	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	
	10	Where and when potentially eligible participants were identified (setting, location and dates)	5,11,23
Study size	11	Explain how the study size was arrived at	
Lung ultrasound method	12	Type of ultrasound equipment used (such as high-end ultrasound system or pocket size ultrasound device), including type and orientation (transverse vs. sagittal) of transducer	24,25
	13	Patient positioning during lung ultrasound examination	26
	14	Number and location of lung ultrasound zones examined	5,6,8,11,28
	15	Duration of recorded lung ultrasound clips (if image analysis was performed offline)	24,25
	16	Whether clinical information was available to the performers of the lung ultrasound	
Lung ultrasound image analysis	17	Whether clinical information was available to the readers of the lung ultrasound (image analysis blindly performed offline vs. real time)	
	18	For serial lung ultrasound assessment: Whether the timing of the lung ultrasound was available to the readers (temporal blinding)	11
	19	Method of B-line quantification (e.g. sum of all B-lines across all lung zones, or score based on B-line number in a given zone), including inter- and intra-observer variability. If automated software was used, type and version of software.	4,11
	20	Describe how pleural effusions were assessed by	

		ultrasound and report the number of patients with unilateral or bilateral pleural effusions on ultrasound.	
Additional investigations	21	Describe any additional investigations supporting the diagnosis or degree of congestion (e.g. echocardiography, natriuretic peptides, invasive hemodynamics) performed and their temporal relationship to the LUS examination, as well as to therapy targeted at congestion.	
Data analysis	22	Number of patients with missing LUS zones & how these patients were handled in the analysis. How lung ultrasound zones with pleural effusions that interfered with B-line quantification were handled in the analysis.	
Results	23	Report the number of patients enrolled, excluded, patients with adequate images and those analyzed, as well as outcomes. Give reasons for non-participation at each stage. Consider using a flow diagram.	
	24	Baseline demographic and clinical characteristics of participants	
	25	Number and variation of B-lines at baseline (and follow up, if applicable)	
Discussion	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalizability	
	27	Implications for clinical practice, including the intended use and clinical role of lung ultrasound	
Other information	28	Name of registry and registration number if applicable.	
	29	Sources of funding and other support; role of funders	

Legend:

Lung ultrasound-specific aspects are highlighted in light blue.

Table 2. Overview of common B-line quantification methods in patients with heart failure

Zones, n	Location of zones	Method	B-line quantification	Sample studies
28	Anterior & lateral chest	Count	Sum of B-lines in all zones	8,9,34,35
		Score	Mild: 6-15 B-lines in all zones Moderate: 16-30 B-lines in all zones Severe: >30 B-lines in all zones	7,8
11	Anterior & lateral chest	Score	0 points: <3 B-lines per zone 1 point: ≥3 B-lines per zone Score: Number of points	31
8	Anterior & lateral chest	Count	Sum of B-lines in all zones	8,10,23
		Score	0 points: <3 B-lines per zone 1 point: ≥3 B-lines per zone Score: Number of points	8,9,27,28
6	Anterior & lateral chest	Score	0 points: <3 B-lines per zone 1 point: ≥3 B-lines per zone Score: Number of points	5
5	Anterior & posterior chest	Count	Sum of B-lines in all zones	6
		Score	0 points: ≤3 B-lines per zone 1 point: >3 B-lines per zone Score: Number of points	6
4	Anterior & lateral chest	Score	0 points: <3 B-lines per zone 1 point: ≥3 B-lines per zone Score: Number of points	36

Figure 1. Overview of important methodological aspects in the quantification of pulmonary congestion by lung ultrasound in heart failure

Legend:

HF: heart failure, ED: emergency department, ESRD: end-stage renal disease

* Outcome measures could represent B-line count/score, a diagnosis or prognostically important event(s).

Figure 2. Practical aspects of lung ultrasound in heart failure cohorts

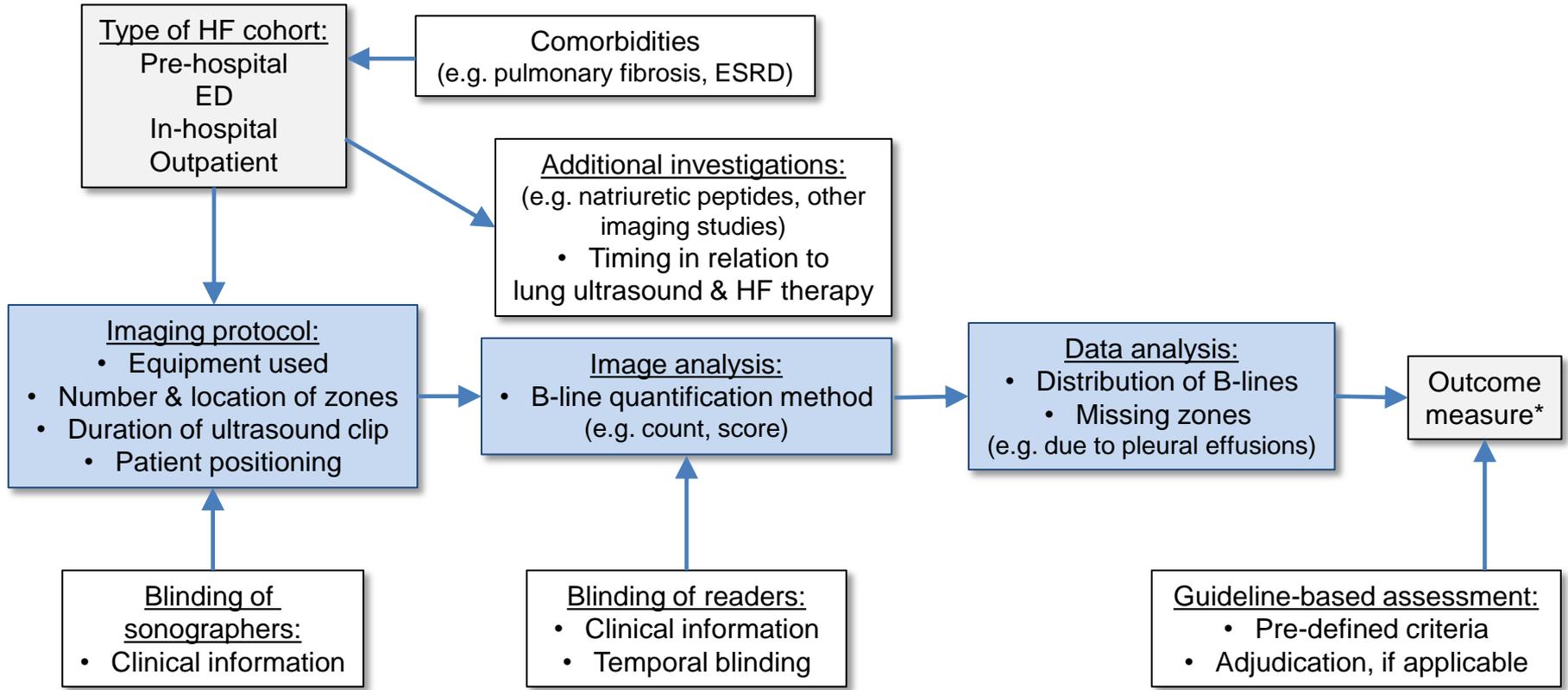
Legend:

HF: heart failure, LUS: lung ultrasound

Figure 3. Example of 8 and 6 chest zones for lung ultrasound imaging

Legend:

Adapted from: Platz E, Merz AA, Jhund PS, Vazir A, Campbell R, McMurray JJ. Dynamic changes and prognostic value of pulmonary congestion by lung ultrasound in acute and chronic heart failure: a systematic review. *Eur J Heart Fail.* 2017;19(9):1154-1163.



HF Patients

- Co-morbidities
- Setting (e.g. outpatient)

LUS Image Acquisition

- Type of ultrasound system & transducer
 - Transducer orientation
 - Patient positioning
- Number & location of LUS zones
- LUS clip duration

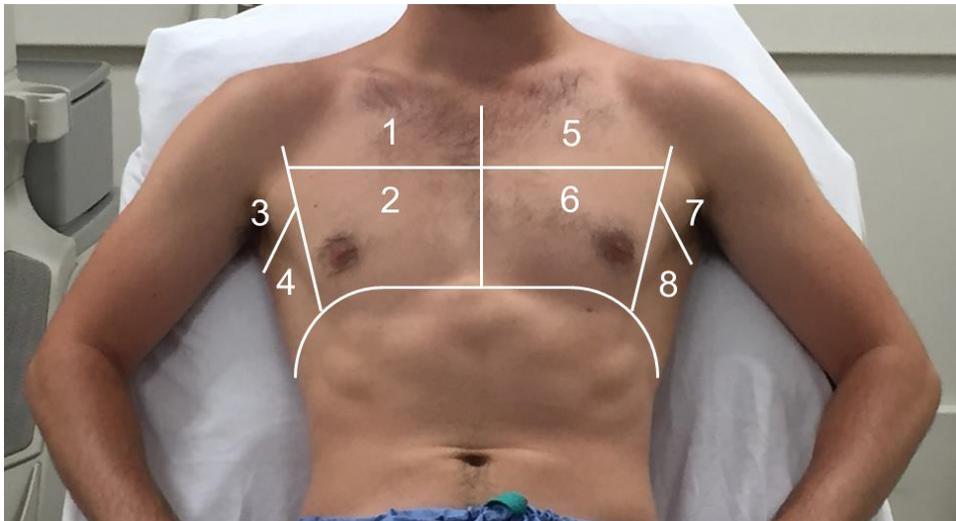
LUS Image Analysis

- Offline vs. real time analysis
- Blinding of readers (to which aspects?)
- Method of B-line quantification
- Frequency of pleural effusions

Data Analysis

- Number of patients with missing LUS zones
- Number and variation of B-lines

A) 8 zone method



B) 6 zone method

