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CONSENSUS DOCUMENT

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

**Elke Platz[1]*, Pardeep S. Jhund[2], Nicolas Girerd[3], Emanuele Pivetta[4], John J.V. McMurray[2], W. Frank Peacock[5], Josep Masip[6,7], Francisco Javier Martin-Sanchez[8], Òscar Miró[9], Susanna Price[10], Louise Cullen[11], Alan S. Maisel[12], Christiaan Vrints[13], Martin R. Cowie[10], Salvatore DiSomma[14], Hector Bueno[15], Alexandre Mebazaa[16], Danielle M. Gualandro[17,22], Mucio Tavares[17], Marco Metra[18], Andrew J.S. Coats[19], Frank Ruschitzka[20], Petar M. Seferovic[21], and Christian Mueller[22], on behalf of the Study Group on Acute Heart Failure of the Acute Cardiovascular Care Association and the Heart Failure Association of the European Society of Cardiology**

[1]Department of Emergency Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA; [2]BHF Cardiovascular Research Centre, Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, UK; [3]INSERM, Centre d'Investigations Cliniques Plurithématique, INSERM U1116, CHRU de Nancy, F-CRIN INI-CRCT, Université de Lorraine, Nancy, France; [4]Division of Emergency Medicine and High Dependency Unit, AOU Città della Salute e della Scienza di Torino, Cancer Epidemiology Unit and CPO Piemonte, Department of Medical Sciences, University of Turin, Turin, Italy; [5]Henry JN Taub Department of Emergency Medicine, Baylor College of Medicine, Houston, TX, USA; [6]ICU Department, Consorci Sanitari Integral, University of Barcelona, Barcelona, Spain; [7]Cardiology Department, Hospital Sanitas CIMA, Barcelona, Spain; [8]Department of Emergency Medicine, Hospital Clínico San Carlos, Instituto de Investigación Sanitaria Hospital Clínico San Carlos (IdISSC), Universidad Complutense de Madrid, Madrid, Spain; [9]Department of Emergency Medicine, Hospital Clínic, and Institut de Recerca Biomàdica August Pi i Sunyer (IDIBAPS), Barcelona, Spain; [10]Royal Brompton & Harefield NHS Foundation Trust, NHLI, Imperial College, London, UK; [11]Emergency and Trauma Centre, Royal Brisbane and Women's Hospital, Brisbane, Australia; [12]Coronary Care Unit and Heart Failure Program, Veteran Affairs (VA) San Diego, San Diego, CA, USA; [13]University of Antwerp, Antwerp University Hospital, Edegem, Belgium; [14]Emergency Medicine, Department of Medical-Surgery Sciences and Translational Medicine, Sant'Andrea Hospital, University La Sapienza, Rome, Italy; [15]Centro Nacional de Investigaciones Cardiovasculares (CNIC), Department of Cardiology and Cardiovascular Research Area, imas12 Research Institute; Hospital Universitario 12 de Octubre, Universidad Complutense de Madrid, Madrid, Spain; [16]University Paris Diderot; APHP Hôpitaux Universitaires Saint Louis Lariboisière; Inserm 942, Paris, France; [17]Heart Institute (INCOR), University of Sao Paulo Medical School, Sao Paulo, Brazil; [18]Cardiology, Department of Medical and Surgical Specialties, Radiological Sciences, Public Health, University of Brescia, Brescia, Italy; [19]San Raffaele Pisana Scientific Institute, Rome, Italy; [20]Department of Cardiology, University Heart Centre Zurich, Zurich, Switzerland; [21]University of Belgrade School of Medicine, Belgrade, Serbia; and [22]Department of Cardiology and Cardiovascular Research Institute Basel (CRIB), University Hospital Basel, University of Basel, Basel, Switzerland

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Lung ultrasound is a useful tool for the assessment of patients with both acute and chronic heart failure, but the use of different image acquisition methods, inconsistent reporting of the technique employed and variable quantification of 'B-lines,' have all made it difficult to compare published reports. We therefore need to ensure that future studies utilizing lung ultrasound in the assessment of heart failure adopt a standardized approach to reporting the quantification of pulmonary congestion. Strategies to improve patient care by use of lung ultrasound in the assessment of heart failure have been difficult to develop. In the present document, key aspects of standardization are discussed, including 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. 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.

**Keywords** Lung ultrasound • Heart failure • Methodology • Reporting checklist

*Corresponding author. Department of Emergency Medicine, Brigham and Women's Hospital and Harvard Medical School, 75 Francis Street, Boston, MA 02115, USA. Tel: +1 617 5257932, Fax: +1 617 2646848, Email: eplatz@partners.org

# Introduction

Pulmonary congestion is one of the most important findings in heart failure (HF), yet traditional methods, such as clinical examination and chest X-ray, are relatively insensitive for its detection.[1–3] Recently, 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 dyspnoea 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 previous international consensus statement described a wide variety of LUS applications, but was not specifically focused on its use in HF and lacked a detailed description of the methodological aspects.[4] With the anticipated growth in the use of LUS in patients with HF, and in subsequent potential publications, 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 co-morbidities, symptoms and signs of HF, 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, 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; interpretation and comparison of studies must therefore 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 (compared with curvilinear transducers) and longer clip duration (6–7 s/video clip) allow for observation of a greater number of B-lines in HF.[24,25] Similarly, patient positioning during the LUS should be described and ideally performed in a standardized position because of its effect on B-line count, as patients with acute HF may have a greater number of B-lines in the supine vs. the sitting postion.[26]

The number and location of chest zones examined should be clearly described. Previous studies in HF cohorts have reported

**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, acute respiratory distress syndrome, 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 | 5,6,8,11,27 |
| | 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 haemodynamics) performed and their temporal relationship to the lung ultrasound examination, as well as to therapy targeted at congestion | |
| *Data analysis* | 22 | Number of patients with missing lung ultrasound zones and 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 analysed, 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 | |

Lung ultrasound-specific aspects are highlighted in light blue.

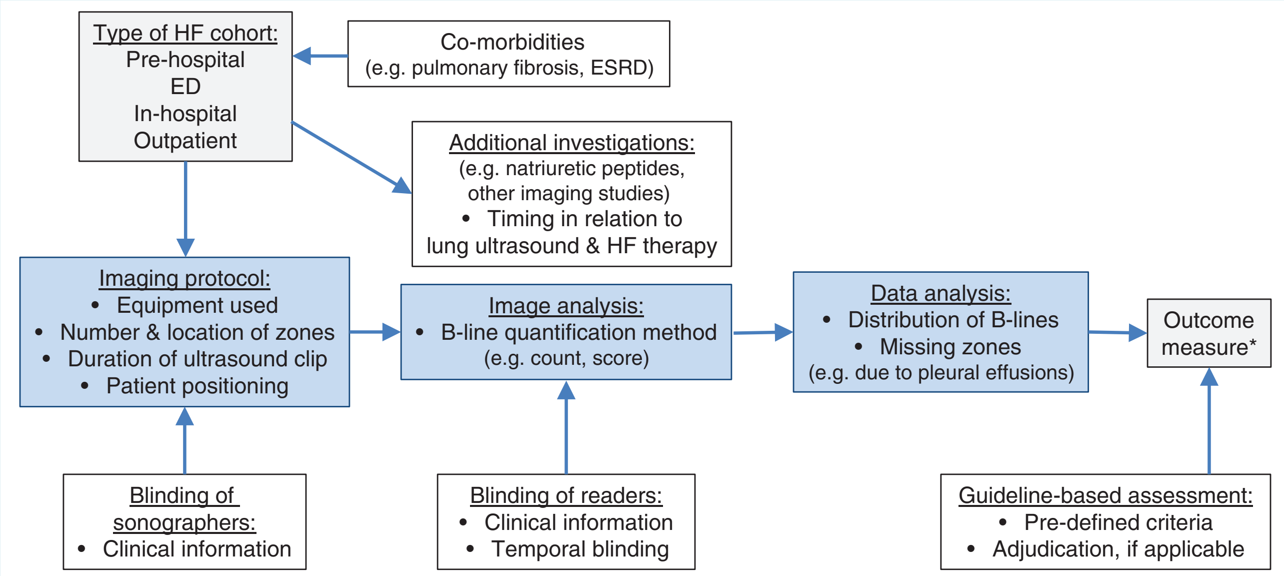


**Figure 1** Overview of important methodological aspects in the quantification of pulmonary congestion by lung ultrasound in heart failure (HF). ED, emergency department; ESRD, end-stage renal disease. *Outcome measures could represent B-line count/score, a diagnosis or prognostically important event(s).

4–28 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 six zones in the assessment of dyspnoeic patients in the emergency department, without apparent loss of diagnostic accuracy.[4,5] Based on the currently available data, we suggest that at least three zones on each hemithorax (six 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*):

(i) A count-based method, in which the sum of B-lines in one intercostal space per zone across all zones is reported.[10,23]
(ii) 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 two zones on each hemithorax are consistent with a diagnosis of pulmonary oedema in dyspnoeic patients presenting to the emergency department.[5,27,31]

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, definition of the cut-off 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 and central image interpretation

Blinding is an important methodological feature in diagnostic and prognostic studies to minimize bias and maximize the validity of results. Sonographer knowledge of 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:[25,33] 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 haemodynamic or clinical congestion, such as chest radiography, echocardiography, invasive haemodynamic 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

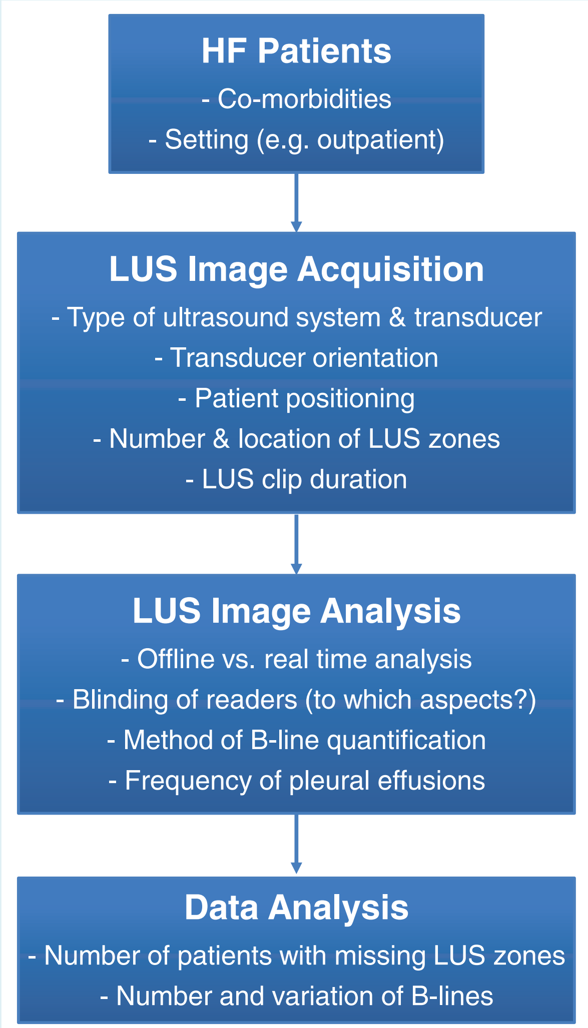


**Figure 2** Practical aspects of lung ultrasound (LUS) in heart failure (HF) cohorts.

will also facilitate a better understanding of the sequence of the dynamic changes of these congestion markers.[34] For example, the interpretation of the relationship between these investigations is affected by whether the chest radiograph was performed at the same time as the LUS study or whether it was performed 24 h later. 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: for example, 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.[12,30] As a higher prevalence of B-lines occurs in more dependent chest zones, the reporting of missing data in zones that could not be analysed (e.g. because of 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.

## Presentation of results

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 analysed. Authors should provide reasons for non-participation at each stage, preferably using a CONSORT flow diagram for illustration.[35] 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 oedema with LUS in patients with undifferentiated dyspnoea 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 creation 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 (both on admission and pre-discharge) would be useful to inform clinical guidelines and future clinical trials. 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 that include, for example, comprehensive multivariable models incorporating other important diagnostic and prognostic variables. In addition, studies investigating treatment response and the adequacy of decongestive therapy, for example at the time of hospital discharge in large, well-defined HF cohorts will be important. In particular, 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 HF, recent reports in patients with reduced vs. preserved ejection fraction demonstrated differing results

**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 and lateral chest | Count | Sum of B-lines in all zones | 8,9,28,29* |
| | | Score | Mild: 6–15 B-lines in all zones<br>Moderate: 16–30 B-lines in all zones<br>Severe: >30 B-lines in all zones | 7,8 |
| 11 | Anterior and lateral chest | Score | 0 points: <3 B-lines per zone<br>1 point: ≥3 B-lines per zone<br>Score: Number of points | 30 |
| 8 | Anterior and lateral chest | Count | Sum of B-lines in all zones | 8,10,23 |
| | | Score | 0 points: <3 B-lines per zone<br>1 point: ≥3 B-lines per zone<br>Score: Number of points | 8,9,27,31 |
| 6 | Anterior and lateral chest | Score | 0 points: <3 B-lines per zone<br>1 point: ≥3 B-lines per zone<br>Score: Number of points | 5 |
| 5 | Anterior and posterior chest | Count | Sum of B-lines in all zones | 6 |
| | | Score | 0 points: ≤3 B-lines per zone<br>1 point: >3 B-lines per zone<br>Score: Number of points | 6 |
| 4 | Anterior and lateral chest | Score | 0 points: <3 B-lines per zone<br>1 point: ≥3 B-lines per zone<br>Score: Number of points | 32 |

* Some studies used semi-quantitative count based approaches.

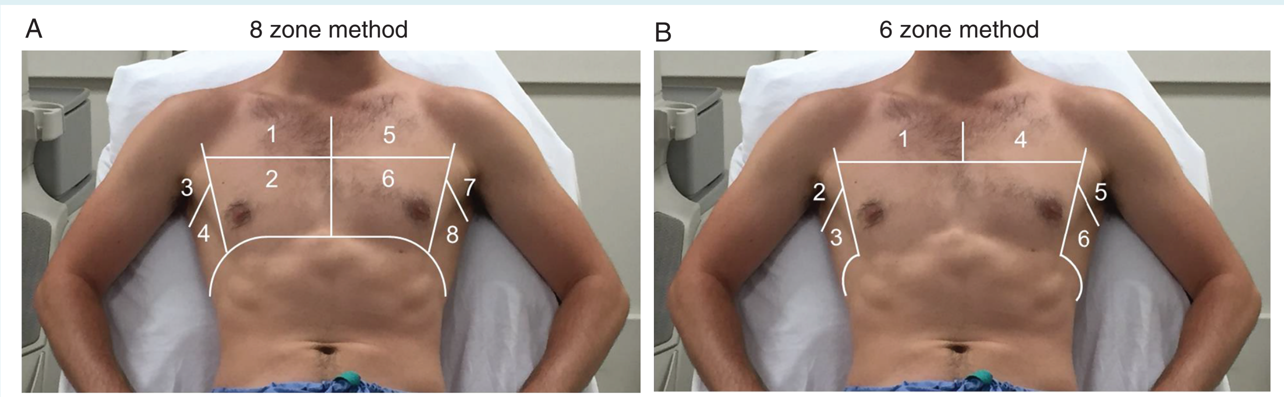


**Figure 3** Example of eight (*A*) and six (*B*) chest zone protocol for lung ultrasound imaging. Adapted with permission from Platz *et al.*[11], Copyright (2017).

with respect to the number of B-lines in these HF cohorts.[23,36] These findings could result from 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 HF. Consistent reporting of certain methodological aspects should be considered in studies employing LUS in HF populations to ensure the dissemination of high-quality research results and allow for future standardization.


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