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Pulmonary congestion evaluated by lung ultrasound predicts decompensation in heart failure outpatients☆

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ABSTRACT

Background: Pulmonary congestion is the main cause of hospital admission among heart failure (HF) patients. Lung ultrasound (LUS) assessment of B-lines has been recently proposed as a reliable and easy tool for evaluating pulmonary congestion.
Objective: To determine the prognostic value of LUS in predicting adverse events in HF outpatients.
Methods: Single-center prospective cohort of 97 moderate-to-severe systolic HF patients (53 ± 13 years; 61% males) consecutively enrolled between November 2011 and October 2012. LUS evaluation was performed during the regular outpatient visit to evaluate the presence of pulmonary congestion, determined by B-lines number. Patients were followed up for 4 months to assess admission due to acute pulmonary edema.
Results: During follow-up period (106 ± 12 days), 21 hospitalizations for acute pulmonary edema occurred. At Cox regression analysis, B-lines number ≥ 30 (HR 8.62; 95%CI: 1.8–40.1; p = 0.006) identified a group at high risk for acute pulmonary edema admission at 120 days, and was the strongest predictor of events compared to other established clinical, laboratory and instrumental findings. No acute pulmonary edema occurred in patients without significant pulmonary congestion at LUS (number of B-lines < 15).
Conclusion: In a HF outpatient setting, B-line assessment by LUS identifies patients more likely to be admitted for decompensated HF in the following 4 months. This simple evaluation could allow prompt therapy optimization in those patients who, although asymptomatic, carry a significant degree of extravascular lung water.
Condensed abstract: Pulmonary congestion is the main cause of hospital admissions among heart failure patients. Lung ultrasound can be used as a reliable and easy way to evaluate pulmonary congestion through assessment of B-lines. In a cohort of heart failure outpatients, a B-lines cutoff ≥ 30 (HR 8.62; 95%CI: 1.8–40.1) identified patients most likely to develop acute pulmonary edema at 120-days.

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1. Background

Heart failure (HF) outpatient care is usually based on clinical status and physical examination. However, clinical evaluation has limitations even for the most skilled doctors, showing high specificity but low sensitivity for the detection of pulmonary congestion (PC) [1,2]. Thus, cases of decompensation may not be recognized in time to avoid rehospitalization.

Reducing HF admissions improves patient outcomes and reduces costs. Different tools have been proposed to improve clinical assessment. Natriuretic peptides and echocardiography could help identify clinically silent decompensation and titrating therapy during follow-up [3–5]. Nevertheless, neither method is usually performed during outpatient visits, due to logistical and cost limitations. Ideally, tools for assessing decompensation should be low-cost, feasible, fast, safe, and predictive of adverse outcomes.

Lung ultrasound (LUS) evaluation of B-lines has been proposed as a simple, non-invasive and semi-quantitative tool to assess PC [6,7]. B-lines have been related to extravascular lung water, pulmonary

Abbreviation: CCS, clinical congestion score; CXR, Chest X-ray; EACVI, European Association of Cardiovascular Imaging; E/e′, ratio of early diastolic mitral inflow velocity to early diastolic velocity of the mitral annulus; EVLW, extravascular lung water; HF, heart failure; LUS, lung ultrasound; LV, left ventricular; MLHFQ, *Minnesota Living with Heart Failure Questionnaire*; NT-proBNP, amino-terminal portion of the brain natriuretic peptide; PC, pulmonary congestion; ROC, receiver operating characteristic; 6mWT, 6-minute walk test.

☆ The authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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capillary wedge pressure [8], NT-proBNP [9] and E/e′ in HF patients [10]. LUS can also identify clinically silent pulmonary edema [10–12], suggesting its additional value to improve hemodynamic profiling and treatment optimization [13].

Currently, B-lines are mostly used for the differential diagnosis of acute dyspnea, whereas prognostic data on HF patients are scarce. This study aimed to determine the prognostic value of LUS to predict adverse events, compared to clinical, radiographic, echocardiographic, and biochemical parameters in a cohort of moderate-to-severe systolic HF patients in an outpatient setting.

2. Methods

2.1. Study design and population

Single-center prospective cohort study of 132 consecutive patients (Supplemental material – Fig. 1) from a HF outpatient clinic at the Cardiology Institute of Rio Grande do Sul, Brazil, between November 2011 and October 2012, as part of a project aimed to study the LUS in HF outpatients. This same study population was already included in a previous paper describing the capability of LUS to diagnose pulmonary congestion in a cross-sectional study design [10]. Here, the data on the midterm follow-up are shown. Inclusion criteria: 1) Age > 18 years; 2) Diagnosis of left ventricular (LV) systolic dysfunction for >6 months regardless of cause as defined by Framingham criteria [14] and European Society of Cardiology guidelines [15]; 3) Moderate-to-severe systolic dysfunction (ejection fraction ≤ 40%); 4) No prior diagnosis of pulmonary fibrosis; 5) Absence of congenital heart disease.

Clinical assessment, NT-proBNP analysis, echocardiography, chest X-ray (CXR), and LUS were independently performed after the clinical appointment (T0) with at most 5-h in-between. Then, all patients filled out the *Minnesota Living with Heart Failure Questionnaire* (MLHFQ) and 100-mm analog-visual dyspnea scale (AVDS), and performed the 6-min walk test (6mWT). There was no interference with the patient's treatment, which was defined by their assistant physician based only on clinical judgment. The study protocol was approved by the Ethics Committee of our Institution (UP4467.11).

A previously validated clinical congestion score (CCS, ranging from 1 to 22 points) [16] was used to objectively classify the patients, by summing the values obtained in clinical assessment of HF signs and symptoms and consisted of: orthopnea (0–4); pulmonary rales (0–4); increased central venous pressure (0–4); peripheral edema (0–4); third heart sound (0–1); hepato-jugular reflux (0–1); functional NYHA class (1–4). Patients with ≥3 points were considered decompensated [16].

Peripheral venous blood samples were obtained at T0. An NT-proBNP level > 1000 pg/ml was the cut-off for decompensated HF.

A comprehensive transthoracic echocardiogram was performed using a Vivid-I (GE Vingmed, Horten, Norway) equipped with 3S probe (1.5–3.6 MHz). All measurements were performed by experienced sonographers according to the American Society of Echocardiography and the European Association of Cardiovascular Imaging recommendations [17,18].

2.2. Lung ultrasound

After routine clinical visit, and just before 6mWT, patients underwent LUS to assess B-lines using the same probe and echocardiographic machine adjusted for a 10 cm deep and 75° wide sector. We analyzed the anterior and lateral hemithoraces, scanning along parasternal, midclavicular, anterior axillary and mid-axillary lines from the second to the fifth intercostal space on the right hemithorax and the second to the fourth intercostal space on the left, totalizing twenty-eight chest scanned sites as previously described [19]. A B-line was defined as a discrete laser-like vertical hyperechoic reverberation artifact starting from the pleural line, extending to the bottom of the screen and moving synchronously with lung sliding (Supplemental material - Figs. 2 and 3 and Videos 1 and 2) [7]. The total number of B-lines among the 28 scanned sites (0–10 for each site) was recorded generating a B-lines score (total score from 0 to 280) [20–22]. B-lines ≥ 15 was considered the cut-off for significant PC [10]. All LUS and echocardiographic examinations were recorded and reviewed in a blind manner.

The interobserver variability of the B-lines scores was assessed by 2 independent observers (MHM and LG, who had received standardized training and had extensive experience in joint reading) in a set of 49 videos. The intraclass correlation coefficient (ICC) for single measures is 0.96 (95%CI: 0.93–0.98; $p < 0.0001$), and for average measures is 0.98 (95%CI: 0.96–0.99; $p < 0.0001$). The intraobserver variability of MHM, who performed all examinations, was assessed in a set of 20 consecutive patients resulting in $1.4 \pm 6\%$ (95%CI: 0.29–3.12) with an ICC for single measures of 0.97 (95%CI: 0.96–0.99; $p < 0.0001$), and for average measures of 0.98 (95%CI: 0.98–0.99; $p < 0.0001$).

2.3. Follow-up and adverse outcomes

Follow-up data were collected by telephone 4 months after T0 to assess the patient's clinical status and inquire about adverse outcomes. Occurrence of endpoints such as need for emergency department evaluation, hospital admission, need for intravenous loop diuretics and death were sought [23]. Data collection was based on a standardized clinical questionnaire performed by a researcher blind to all clinical records. In case of an endpoint, all information regarding this event was collected from medical records, emergency department reports, and the patient.

The primary outcome was admission due to acute pulmonary edema (APE), defined as acutely decompensated chronic HF with respiratory distress with alveolar edema on chest X-ray, O_2 saturation < 90% on room air, pulmonary crackles, and orthopnea [23]. Secondary outcomes were: 1) Major adverse cardiovascular events (acute myocardial infarction, ischemic stroke, cardiac arrest, and death); 2) All fatal and non-fatal events [23].

2.4. Statistical analysis

Continuous variables are expressed as mean ± standard deviation or 25th, 50th, and 75th quantiles; categorical variables as counts and percentages. Univariate comparisons were made with χ^2, two-sample *t*-test or Mann-Whitney *U* test. Diagnostic utility of LUS (as well as any other diagnostic methods) in predicting adverse events was determined using the receiver operating characteristic (ROC) curve and expressed using the C statistic. The best threshold for APE was obtained by selecting the ROC point that maximized both sensitivity and specificity. The prognostic capacity of LUS, compared to other diagnostic methods, was studied using univariable and multivariable COX regression analyses, considering first all dichotomous variables according to the cut-off point obtained from ROC and/or defined by the literature. The selection of variables in a multivariate Cox regression analysis was performed using the positive likelihood ratio statistics interactive method of backward elimination. Assumption of hazards proportionality was assessed by the Schoenfeld residuals correlation over time. The prognostic capacity of LUS in association with MLHFQ was determined using a parallel testing. Survival probabilities were estimated by Kaplan-Meier method and differences between survival curves analyzed using the log-rank test. Statistical significance was set at $p < 0.05$. Statistical analyses were performed using the IBM SPSS Statistics version 21.0.0.

3. Results

3.1. Baseline evaluation

Thirty-five patients were excluded (Supplemental material – Fig. 1). Demographic characteristics, baseline evaluation parameters, and

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