

Pulmonary Congestion in Heart Failure With Reduced Ejection Fraction: Comparison Between Lung Ultrasound and Remote Dielectric Sensing

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Abstract

Background: Outpatient assessment of pulmonary congestion in patients with heart failure with reduced ejection fraction (HFrEF) can minimize hospitalizations due to decompensation and optimize the use of diuretics.

Objective: To compare the remote dielectric sensor (REDS), a validated device for detecting pulmonary extravascular fluid, with clinical parameters, transthoracic echocardiogram (TTE) and lung ultrasound (ULSP).

Methods: We included 38 patients from heart failure clinic (63±12 years; 21 men). All were submitted within 24 hours to clinical evaluation with description of paroxysmal nocturnal dyspnea, leg edema (LE), presence of dizziness; laboratory evaluation of NT-ProBNP; evaluation by REDS and TTE with analysis of parameters of systemic congestion by the inferior vena cava evaluation, function of the right ventricle and of pulmonary congestion, such as evaluation of filling pressures by average of E/e' and indexed left atrial volume. The ULSP was performed using the 8 points anterior quadrants protocol, counting B lines in one respiratory cycle.

Results: 22 patients had REDS ≥ 35% (indicative of pulmonary congestion) and 16 patients REDS < 35%. Clinical and echocardiographic parameters were compared with REDS ≥ 35%. In the multivariate analysis, the variables body surface area, B lines and LE were associated with REDS ≥ 35%. NT-ProBNP was similar and elevated in both groups.

Conclusions: Outpatient monitoring of HFrEF for volume control can be sensitized by the presence of B lines on the ULSP with good correlation to REDS ≥ 35%. NT pro BNP was not able to differentiate patients with congestion detected by REDS.

Keywords: Ultrasonography; Lung; Heart Failure.

Introduction

Outpatient evaluation of the blood volume status of patients with heart failure with reduced ejection fraction (HFrEF), regardless of etiology, is complex and requires the integration of clinical and laboratory signs.^{1,2} Early detection of higher blood volume by invasive methods was able to improve the optimization of pharmacological treatment, as well as avoid hospitalizations and complications, such as renal failure and inappropriate increase of diuretics.³ However, the outpatient management of patients with HFrEF cannot use invasive methods, needing the analysis of clinical parameters associated with imaging methods, such as echocardiography⁴⁻⁶ and lung ultrasound (LUS).⁷⁻⁹

Recently, a new volume assessment technology,¹⁰ called ReDS (Remote Dielectric Sensing: Sensible Medical Innovations, Ltd, Klar Neter, Israel), has shown promising results in monitoring extravascular lung fluid, including validation by tomography.¹¹ Nevertheless, LUS has not been compared with ReDS performed in outpatient clinics to monitor patients with HFrEF and difficult therapeutic management. The advantage of using LUS associated with physical examination and laboratory analysis is its low cost, easy training, and good reproducibility.^{8,9,12,13}

Thus, this study aimed to compare LUS with ReDS as the gold standard for extravascular lung fluid analysis in the diagnosis of pulmonary congestion among outpatients with HFrEF and difficult therapeutic management. Moreover, clinical, echocardiographic, and laboratory parameters were added to this analysis to provide sensitivity to the detection of systemic blood volume balance in this patient group.

Methods

In this prospective cohort pilot study, conducted from December 2021 to February 2022, we included patients

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over 18 years selected from the cardiomyopathy outpatient clinic of the Instituto Dante Pazzanese de Cardiologia (IDPC) who receive serial follow-up at the volume outpatient clinic because they have HFrEF with difficult volume control. Informed consent was obtained from each patient, and the study protocol complies with the ethical guidelines of the 1975 Helsinki Declaration. The IDPC Research Committee approved the protocol under the Certificate of Presentation for Ethical Consideration number 53224821.0.0000.5462.

Cases and study design

Patients with HFrEF and difficult volume control are evaluated in a specific IDPC outpatient clinic to reduce complications that may occur by the use of high doses of diuretics and earlier returns. In this scenario, the inclusion of patients could be concentrated on these days so that ReDS could be available for IDPC once a week, with echocardiography — focused on the analysis of parameters related to volume — and LUS — for the evaluation of B-lines — performed on the same day or in the next morning. The researchers responsible for ultrasound evaluations were not aware of the volume result obtained by ReDS.

We included 38 consecutive patients with HFrEF of various etiologies. Inclusion was based on the availability of ReDS and the possibility of timely performing the echocardiography and LUS.

Clinical evaluation

The selected patients were evaluated in routine outpatient visits. The following clinical data were chosen for comparison with the volume state: weight, body surface area (BSA), body mass index (BMI), lower extremity edema (LEE), and functional class by the *New York Heart Association*.¹ An experienced clinical cardiologist supervised and checked all clinical examinations.

Laboratory evaluation

Following the clinical evaluation, NT-proBNP was collected. The collection and analysis of blood tests were performed by IDPC's clinical laboratory. Collection standardization, methods, and analysis equipment are in accordance with the service routine.

Use of ReDS

After the collection of laboratory tests, the volunteers underwent a ReDS (Sensible Medical Innovations, Ltd, Klar Neter, Israel) evaluation. The ReDS technology consists of a miniature radar that transmits low-power electromagnetic signals to the body.^{11,14} It can be used to evaluate the patient with a chest vest (Figure 1). Two sensors integrated into the vest are attached to the body: one in the anterior chest, on the right side, and the other in the posterior back. Each sensor can transmit and receive the beam of electromagnetic waves passing through the lung. The reflected signal is analyzed, translating the dielectric properties of the lung tissue between the sensors. Because water has a very high dielectric coefficient, tissue dielectric



Figure 1 – ReDS. Image provided by the ReDS manufacturer (Remote Dielectric Sensing: Sensible Medical Innovations, Ltd, Klar Neter, Israel).

coefficients are predominantly determined by their fluid content.¹⁵ A healthy human lung (for an average person with 70 kg) has 450 to 500 mL of blood. The extravascular compartment usually has another 250 to 700 mL of fluid. As the normal total lung air volume is 1.8 to 2.2 L, considering a tidal volume of 500 mL, the normal intrathoracic fluid content can be estimated to vary between 20 and 34% of the total volume.¹⁶ This range was confirmed by density measurements performed by different quantitative imaging technologies.^{11,14}

ReDS measurements were taken by professionals trained to use the device. These patients remained seated at rest with the ReDS for 45 seconds, after which the device automatically provided the percentage of thoracic fluid. The normal value is defined as up to 34%, possible hypervolemia as 35–50%, significant hypervolemia as above 50%, and hypovolemia as below 20% (manufacturer data).

LUS

LUS was performed on GE Vivid E95 equipment (GE Health Care, Norway), using the eight-point anterior segment protocol with a 2-5 MHz sector transducer and the echocardiography device adjusted for “abdominal” mode. Images were acquired in 6 seconds, allowing the evaluation of a respiratory cycle. This protocol is called BLUE (Bedside Lung Ultrasound in Emergency),^{12,17–19} with the patient at a 45-degree chest inclination in the bed. The protocol aims to evaluate the presence of B-lines — artifacts formed in the LUS due to the increase in parenchymal fluid — and count them in each segment during a respiratory cycle (Figure 2).¹⁹ The finding of more than three B-lines in 2 quadrants of each hemithorax means congestion in patients with HFrEF. We chose to count the total of B-lines in both hemithorax.^{9,19} This evaluation was performed by a trained examiner, who had no knowledge of the patient's clinical condition or of the results of laboratory tests and the estimated blood volume in the ReDS. Images were recorded and saved on specific media so that another professional involved in the study could analyze the B-line count variability.

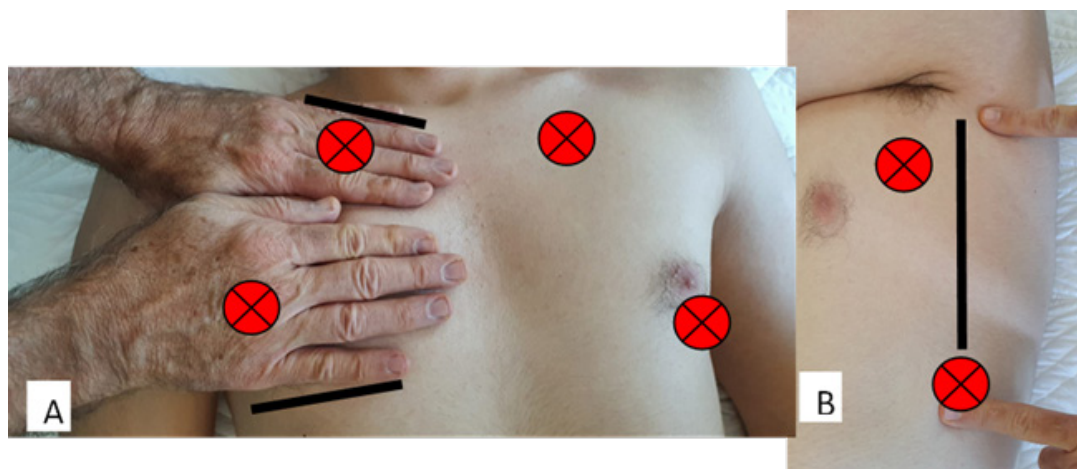


Figure 2 – Schematic representation of the Bedside LUS in Emergency (BLUE) protocol. A) Analysis of the anterior thorax; B) Analysis of the lateral area using the posterior axillary line as a reference.

Location model of points to be assessed in LUS using the BLUE protocol. A) Both hands are placed in the patient's hemithorax with the upper little finger right below the clavicle (black line above the little finger); excluding the thumbs, the lower part of the other hand is placed at the level of the diaphragm line (black line). The point called "upper BLUE" (red dot) is in the middle of the upper hand. The "lower BLUE point" is in the middle of the lower palm. These four points roughly follow the lung anatomy and avoid the heart area. B) The point of the costophrenic recess area (red dot) is built from the horizontal line continuing from the lower BLUE point and the vertical line continuing the posterior axillary line (black line). Lastly, an upper point can be added between the posterior and anterior axillary lines in the upper thorax. That way, we would have 4 points in each hemithorax. Image created by Maria Estefânia Bosco Otto, MD.¹⁹

Echocardiography

The echocardiography with assessment measurements for the biventricular function and specific parameters related to blood volume was performed concomitantly with LUS, on the same equipment, and by the same professional, who only changed the image analysis mode to "adult echocardiography". We evaluated the following left ventricle (LV) parameters: systolic diameter, diastolic diameter, and ejection fraction (EF) by Simpson's biplane method; LV outflow tract velocity time integral (LVOT VTI); integrated measures of diastolic function, such as mitral E-wave velocity, mitral A-wave velocity, E/A ratio, tissue Doppler of the septal and lateral mitral annulus to evaluate the e' wave velocity, mean E/e' ratio, left atrial volume (LAV), and pulmonary artery systolic pressure by continuous Doppler of tricuspid regurgitation; semi-quantitative assessment of right ventricular function with tricuspid annular plane systolic excursion (TAPSE) analysis, tricuspid lateral annular systolic velocity, and subjective evaluation; right atrial pressure (RAP) assessment with analysis of the inferior vena cava (IVC) according to guidelines of the American Society of Echocardiography.^{20,21}

Echocardiographic images were recorded and saved in specific media.

Statistical analysis

We compared imaging and clinical parameters among patients with ReDS <35% and ≥35% using Student's *t* test or the non-parametric Mann-Whitney test for quantitative variables and the chi-square test or exact chi-square test for qualitative variables.

Evaluation of independent indicators of pulmonary congestion consisted of comparing heart and clinical parameters and adjustment of Poisson regression models with robust variance for the ReDS ≥35% result associated with epidemiological, vital signs, and anthropometric variables, LV mass, volume, and function, diastolic function, right ventricle (RV), IVC, and clinical variables, adopting prevalence ratio and their respective confidence intervals as the effect measure. The analysis had two stages: univariate and multivariate. In both, we calculated prevalence ratios and their respective 95% confidence intervals.

The univariate analysis revealed an association between each independent variable and ReDS ≥35%; those with $p < 0.25$ were included in the multivariate analysis. In the multivariate analysis, the models were constructed by the consecutive exclusion of a variable with the highest *p*-value in the Wald test from each complete model, as described by Hosmer and Lemeshow, followed by the readjustment and verification of the model stability after the removal of each variable, in order to obtain a more parsimonious model, with a better fit to the data. Once the final model was obtained, the variables that had been excluded after the univariate analysis were added one by one, repeating the Poisson regression analysis to identify the variables that could contribute to the model.

We also evaluated the multicollinearity between independent variables. The multicollinearity threshold was defined as a tolerance indicator with values less than 0.40.

In addition, $p < 0.05$ was considered significant. The analyses were performed in the SAS 9.4 application.

Results

Among the 38 patients, 22 (58%) had pulmonary congestion with ReDS $\geq 35\%$, and 16 did not have congestion (patients with ReDS $< 35\%$). Tables 1 (qualitative variables) and 2 (quantitative variables) describe the characteristics of the patient sample. Table 3 compares the groups with ReDS $\geq 35\%$ and $< 35\%$ as to systemic and pulmonary congestion parameters. ReDS $\geq 35\%$ group was older than ReDS $< 35\%$, $\geq 35\%$ group (pulmonary congestion). Although the mean number of B-lines was higher in the ReDS $\geq 35\%$ group than in the ReDS $< 35\%$ group, no statistical significance was found. The remaining parameters showed no differences.

Clinical data — such as BSA, gender, dizziness, paroxysmal nocturnal dyspnea, and LEE —, NT-proBNP, and TTE measurements — such as LAV, LVOT VTI, mean E/e' ratio, RV peak lateral tricuspid annular systolic velocity (RV S'), TAPSE, IVC analysis, and B-line count — were compared with Poisson models with robust variance adjusted for ReDS $\geq 35\%$. In the multivariate analysis, these were the variables associated with ReDS $\geq 35\%$ and their adjusted prevalence ratio (aPR): BSA: 8.7 (2.7; 27.8), $p = 0.003$; RV S': 1.12 (1.00; 1.04), $p = 0.03$; B-lines: 1.02 (1.00; 1.04), $p = 0.04$; and LEE: 1.56 (1.00; 2.57), $p = 0.04$ (Table 4).

NT-proBNP was similar and high in both groups, with no correlation with ReDS (4311 ± 3289 mg/dL for ReDS $< 35\%$ and 4267 ± 4136 mg/dL for ReDS $\geq 35\%$, $p = 0.97$) (Table 4).

The B-line count variability among observers was assessed based on stored images from 20 patients, with a 97% correlation coefficient.

Discussion

The main finding of this pilot study of patients with HFrEF and difficult therapeutic volume management was the significant correlation between LUS B-lines and a high-accuracy device for the detection of pulmonary congestion (ReDS). Thus, LUS can be adopted in the outpatient management of pulmonary congestion, reducing the costs of frequent hospitalizations and optimizing the use of diuretics.

ReDS has an excellent correlation with chest computed tomography for the detection of pulmonary congestion, using software that analyzes the pulmonary density of patients with decompensated HFrEF and normal volunteers,¹¹ as well as those with pulmonary capillary pressure by an invasive method.¹⁴ However, no studies have compared the number of B-lines in outpatient LUS among patients with HFrEF and ReDS as the gold standard.

The use of LUS to evaluate pulmonary congestion is well established. A multicenter study conducted by the Study and Research Center of the Italian Society of Emergency Medicine (*Società Italiana di Medicina di Emergenza Urgenza* — SIMEU) found that clinical evaluation associated with the detection of B-lines in LUS had a 97% accuracy in detecting pulmonary congestion, a number that exceeded even that of NT-proBNP, which presented only 62% accuracy.⁹ These findings agree with those of our study, with B-lines correlated with ReDS $\geq 35\%$, and NT-proBNP, although high in both groups, showing no correlation with ReDS.

Table 1 – Categorical variables (n = 38)

Variables	Frequency (n)	Percentage (%)
ReDS		
<35%	16	42%
$\geq 35\%$	22	58%
Gender		
Female	17	45
Male	21	55
Mitral regurgitation		
None	2	5.3
Mild	7	18.4
Moderate	12	31.6
Severe	17	44.7
Tricuspid regurgitation		
None	4	10.5
Mild	18	47.4
Moderate	8	21.1
Severe	8	21.1
Etiology of cardiomyopathy		
Idiopathic	26	68.4
Chagas	9	23.6
Ischemic	3	7.8

ReDS: Remote Dielectric Sensing.

Table 2 – Continuous variables

Parameters	Mean	SD	Minimum	Maximum
Age (years)	63.2	12.4	26	81
Systolic blood pressure (mmHg)	112.8	21.4	70	160
Diastolic blood pressure (mmHg)	72.5	14.4	50	100
BSA (m ²)	1.8	0.2	1.41	2.3
BMI (kg/m ²)	29.5	8.1	16.5	55.7
LV diastolic diameter (mm)	66.5	7.9	55	84
Simpson's LV EF (%)	23.9	6.7	15	40
LV mass index (g/m ²)	126.5	39.4	69	246
LA volume index (mL/m ²)	65.1	23.4	31	158
RA volume index (mL/m ²)	48.9	32.9	14	172
RV basal diameter (mm)	40.9	9.3	20	61
RV lateral annular tissue velocity	8.2	2.6	4	16
TAPSE (mmHg)	14.5	4.6	4	26

SD: standard deviation; LV: left ventricle; RV: right ventricle; LA: left atrium; RA: right atrium; TAPSE: tricuspid annular plane systolic excursion; BSA: body surface area; BMI: body mass index; EF: ejection fraction.

Table 3 – Comparison between REDs $\geq 35\%$ and REDs $< 35\%$ groups

Parameters	ReDS		p-value
	$< 35\%$	$\geq 35\%$	
Age (years)	59 $\pm$ 14.5	67 $\pm$ 8.3	0.03
LVOT VTI	12.5 $\pm$ 4.8	12.8 $\pm$ 4.1	0.82
Mean E/e'	16.1 $\pm$ 7.2	17.1 $\pm$ 7.1	0.69
IVC (mm)	17.4 $\pm$ 7.3	17.95 $\pm$ 4.6	0.76
Vena cava collapse (%)	42.5 $\pm$ 41.5	33.36 $\pm$ 25.4	0.89
RA estimated blood pressure (mmHg)	6.6 $\pm$ 5.3	7.23 $\pm$ 4.41	0.44
NT-proBNP (pcg/mL)	4311.4 $\pm$ 3289.7	4267.7 $\pm$ 4136.9	0.97
B-lines (units)	7.19 $\pm$ 4.43	9.82 $\pm$ 7.43	0.18
Dizziness			0.97
No	11 (42.31)	15 (57.69)	
Yes	5 (41.67)	7 (58.33)	
Paroxysmal nocturnal dyspnea			0.19
No	12 (50.00)	12 (50.00)	
Yes	4 (28.57)	10 (71.43)	
Jugular vein distention			0.11
No	4 (26.67)	11 (73.33)	
Yes	12 (52.17)	11 (47.83)	
LEE			0.08
No	11 (50.00)	9 (45.00)	
Yes	5 (27.78)	13 (72.22)	
Hepatomegaly			0.57
No	8 (38.10)	13 (61.90)	
Yes	8 (47.06)	9 (52.94)	
Troponin			0.24
Abnormal (≥ 0.04 ng/mL)	11 (50.00)	11 (50.00)	
Normal (< 0.04 ng/mL)	5 (31.25)	11 (68.75)	
Creatinine			0.66
Normal (< 1.4 mg/dL)	8 (42.11)	11 (57.89)	
Mild abnormality (1.4–2.0 mg/dL)	5 (35.71)	9 (64.29)	
Moderate abnormality (> 2.1 mg/dL)	3 (60.00)	2 (40.00)	
NYHA FC HF			0.82
I	0 (0.00)	2 (100.00)	
II	8 (47.06)	9 (52.94)	
III	7 (41.18)	10 (58.82)	
IV	1 (50.00)	1 (50.00)	

ReDS: Remote Dielectric Sensing; LVOT VTI: left ventricular outflow tract velocity time integral; E/e': ratio between the mitral inflow E velocity and the mean lateral and medial annular tissue Doppler; RA: right atrium; NT-proBNP: N-terminal pro-B-type natriuretic peptide; LEE: lower extremity edema; IVC: inferior vena cava; NYHA FC HF: New York Heart Association Functional Class of Heart Failure.

Table 4 – Multivariate analysis with adjusted variance for ReDS $\geq$ 35%

Variables	Crude PR		Adjusted PR*	
	PR (95%CI)	p-value	PR (95%CI)	p-value
Gender		0.0862	-	-
Female	1	-	-	-
Male	1.73 (0.92; 3.25)	0.09	-	-
Systolic blood pressure	1.01 (1.00; 1.03)	0.05	-	-
Diastolic blood pressure	1.01 (0.99; 1.03)	0.16	-	-
BSA	5.41 (2.2; 13.6)	0.0003	8.67 (2.71; 27.82)	0.0003
BMI	1.02 (0.99; 1.06)	0.25	-	-
End-diastolic diameter	1.02 (0.99; 1.05)	0.23	-	-
LA volume index	1.00 (1.00; 1.01)	0.34	-	-
RV S'	1.07 (0.99; 1.20)	0.06	1.12 (1.01; 1.24)	0.0262
TAPSE	1.03 (0.97; 1.09)	0.36	-	-
LVOT VTI	1.01 (0.94; 1.07)	0.82	-	-
Mean E/e'	1.01 (0.97; 1.05)	0.68	-	-
IVC	1.01 (0.96; 1.06)	0.78	-	-
Vena cava collapse	1.00 (0.99; 1.01)	0.43	-	-
RA estimated blood pressure	1.01 (0.95; 1.07)	0.70	-	-
NT-proBNP	1.00 (1.00; 1.00)	0.97	-	-
B-lines	1.03 (0.99; 1.06)	0.09	1.02 (1.00; 1.04)	0.0403
Dizziness/BP drop		0.97	-	-
No	1	-	-	-
Yes	1.01 (0.57; 1.81)	0.97	-	-
Paroxysmal nocturnal dyspnea		0.17	-	-
No	1	-	-	-
Yes	1.43 (0.85; 2.40)	0.18	-	-
LEE		0.09		0.0479
No	1	-	1	-
Yes	1.60 (0.91; 2.82)	0.09	1.56 (1.00; 2.57)	0.0479

ReDS: Remote Dielectric Sensing; PR: prevalence ratio; 95%CI: 95% confidence interval; LA: left atrium; RV S': right ventricle tricuspid annular systolic velocity by tissue Doppler imaging; TAPSE: tricuspid annular plane systolic excursion; LVOT VTI: left ventricular outflow tract velocity time integral; E/e': ratio between the mitral inflow E velocity and the mean lateral and medial annular tissue Doppler; RA: right atrium; NT-proBNP: N-terminal pro-B-type natriuretic peptide; BP: blood pressure; LEE: lower extremity edema; BSA: body surface area; BMI: body mass index; IVC: inferior vena cava.

The increase in B-lines identified in LUS, in addition to improve diagnose the cause of dyspnea in the emergency department,²² is associated with a higher number of hospitalizations²³ and worse prognosis in post-myocardial infarction patients.²⁴ Miglioranza et al.⁸ revealed that the finding of 15 B-lines in LUS indicated the possibility of imminent decompensation among patients in outpatient follow-up, but did not compare the congestion results from LUS with any gold standard. Our study found that, compared to a gold standard (ReDS), B-lines were correlated with increased pulmonary congestion in outpatients with HFREF and difficult volume control.

Regarding systemic congestion parameters, we detected a correlation with ReDS $\geq$ 35% only in the evaluation of the

longitudinal function of RV S' by tissue Doppler imaging and in the finding of LEE on physical examination. ReDS was not expected to correlate with systemic congestion parameters, since it measures the amount of extravascular lung fluid. Nonetheless, patients with greater pulmonary congestion and RV dysfunction might present higher systemic congestion and, consequently, LEE.^{1,2}

BSA had a good correlation with ReDS, as the calculation used by the device depends on the patient's weight and height.¹¹

Potential limitations and strengths of the study

The main study limitation is the small number of patients, all recruited from a single center. Another possible limitation was the lack of invasive measures that could directly detect

filling pressures for comparison with the number of B-lines and ReDS.

Given the significant correlation of B-lines with $\text{ReDS} \geq 35\%$, despite the reduced number of individuals included in the study, this result is the main strength of the research, due to the high sensitivity of B-line detection by LUS among patients with difficult volume control.

Conclusions

In this pilot study, LUS presented a good correlation with pulmonary congestion measured by a high-accuracy device (ReDS) and can be a particularly useful tool in the outpatient management of patients with HFrEF, reducing hospitalizations and improving blood volume control among these individuals.

Regarding systemic congestion parameters, only RV S' was significant, indicating that patients with greater RV dysfunction have concomitant pulmonary congestion and systemic congestion.

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Author Contributions

Conception and design of the research: Otto MEB, Vilela AA, Paladino Filho AT, Assef JE; acquisition of data: Otto

MEB, Esmanhoto VA, Vilela AA, Paladino Filho AT; analysis and interpretation of the data and critical revision of the manuscript for intellectual content: Otto MEB, Esmanhoto VA, Vilela AA, Paladino Filho AT, Assef JE; statistical analysis: Otto MEB; writing of the manuscript: Otto MEB, Esmanhoto VA, Assef JE.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation work.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Instituto Dante Pazzanese under the protocol number 532248210.0000.5462. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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