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The prognostic value of lung ultrasound score (LUSS) in patients with COVID-19 admitted in Emergency Department: a prospective observational study.

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Abstract

Background: The Lung Ultrasound (LUS) is routinely used as a point-of-care imaging tool in Emergency Department (ED) and its role in COVID-19 is being studied. The Lung UltraSound Score (LUSS) is a semi quantitative score of lung damage severity. Alongside instrumental diagnostic, the PaO2/FiO2 (P/F) ratio, obtained from arterial blood gas analysis, is the index used to assess the severity of the acute respiratory distress syndrome (ARDS), according to the Berlin definition. Objectives: The primary objective of the study was to evaluate a possible correlation between the LUSS score and the P/F Ratio, obtained from the arterial sampling in COVID-19 positive patients. Materials and Methods: This was a cross-perspective monocentric observational study and it was carried out in the Emergency Department of the "AOU delle Marche" (Ancona, Italy), from 1 January 2023 to 28 February 2023. The study foresaw, once the patient was admitted to the ED, the execution of the LUS exam and the subsequent calculation of the LUSS score.

Results: The sample selected for the study was of 158 patients. The proportion of LUSS ≤4 was statistically higher in those with a P/F >300 (76.2%), compared to those with a P/F ≤300 (13.2%). On the other end, the proportion of LUSS >4 was lower in those who have P/F >300 (23.8%), while it was higher in those who have P/F ≤300 (86.8%). Those patients with a LUSS > 4 were 1.76 (95% CI: 1.57 - 1.99) times more likely to have a P/F ≤300, compared to those with LUSS ≤4. The Odds Ratio of having a P/F ≤300 value in those achieving a LUSS >4, compared to those achieving a LUSS ≤4, was 21.0 (95% CI: 8.4 - 52.4). The study identified pO2, Hb and dichotomous LUSS as predictors of the level of P/F ≤300 or P/F >300.

Discussion: We found that the LUSS score defined by our study was closely related to the P/F ratio COVID-19 positive patients. Our study presented provides evidence on the potential rule of the LUSS for detecting the stage of lung impairment and the need for oxygen therapy in COVID-19 positive patients.

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INTRODUCTION

Pulmonary ultrasonography (Lung ultrasound, LUS), in recent years, has proven to be an effective tool for the study of lung and pleural space[1,2]. Recent scientific evidence also identifies it as a reliable diagnostic examination to assess the extent of organ damage from COVID-193.

The LUS has some unique advantages compared to other imaging techniques: use at the patient's bed, avoiding displacements, absence of radiation, low cost and reduced execution times[4]. These features make it an excellent first-level tool for the diagnosis of pneumonia by COVID-19 in the setting of emergency departments (ED) 5.6. In the literature several protocols of execution of the LUS in the course of infection with SARS-CoV-2 are available, without unanimous international consent [7,8,9]. In this regard, Soldati et al. highlighted the need to standardize the procedure, in order to develop a common language among the physicians involved in this practice and thus ensure reproducibility of method[10].

The Lung ultrasound Score (LUSS) is a semi quantitative score of lung damage severity based on the presence of diagnostic findings, such as pleural line abnormalities, B lines, and lung consolidation[11,12,13,14]. Recent studies show that LUSS is very useful for the diagnosis, monitoring and follow-up of COVID-19 patients [15,16,17].

Chen et al.18 suggested intervening early in the treatment of COVID-19 patients in order to limit viral replication. The early evaluation of LUS is a very promising approach to investigate the presence of lung involvement from COVID-19 and thus to optimize, through clinical decision-making, the measures of care and protective[19,20,21,22].

In parallel to instrumental diagnostics, arterial blood gas analysis is commonly used to evaluate oxygenation in patients with SARS-CoV-2 infection and related respiratory symptoms. In particular, the PaO2/FiO2[23] (P/F) ratio is the index used to assess the severity of ARDS, according to the Berlin definition. The latter uses the P/F ratio for the classification of acute respiratory distress syndrome (ARDS) in mild (200< P/F ratio ≤300), moderate (100< P/F 200 ratio ≤200) and severe (P/F ≤100 ratio) syndrome form[24].

It would therefore be desirable to identify a possible correlation between the LUSS score and the P/F value obtained from arterial sampling on COVID-19 patients.

The next epidemic "waves" could be characterized, as the last, by a mixture of patients with frank COVID-19 related pneumonia and patients who are positive for the nose-swab pharyngeal, in the absence of immediate lung involvement and which are indicated to hospitalization for other reasons.

In this context, the LUS could be useful to discriminate which patients could benefit from starting antiviral therapy and which not. What is still unclear, however, is what the optimal LUSS score should be used as a cut off. Recent studies suggest possible severity classifications of lung impairment compared to the LUSS score, but a standardized approach[25,26] is not recognized to date.

The primary objective of the study is to evaluate, in patients diagnosed with COVID-19, whether the incidence of a P/F Ratio ≤300 (cutoff for the recognition of acute respiratory distress), obtained by blood analysis on arterial blood, performed at the patient's access to ED, in those with a LUSS score >4, it is higher than those with a LUSS score ≤4.

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Secondly, the objective is to assess the positive predictive value of a LUSS score >4 in the early recognition of an interstitial pneumonia picture in COVID-19 patients.

MATERIALS AND METHODS

Study Design and Population

This is a cross-perspective monocentric observational study and it was carried out in the Emergency Department of the "AOU delle Marche" (Ancona, Italy) from 1 January 2023 to 28 February 2023.

The planned sampling was of a consecutive non-probability type. The inclusion criteria were: adult patient aged 18 or older; confirmed diagnosis of COVID-19: PCR-positive reverse transcriptase (RT-PCR); admission to the COVID area of the ED; ability of providing informed consent. The exclusion criteria were: pregnancy; conditions that technically affect, in the opinion of the ED physician, the execution of the LUS (for example: patients in critical conditions that require immediate assistance in danger of life, patients with forced postures that prevent ultrasound examination).

Patients were followed according to goodpractice, which provides, for each patient diagnosed with COVID-19, the history, the objective examination, blood tests (venous and arterial sampling), imaging including LUS, chest x-ray (RX) and computed tomography (CT) of the chest, at the discretion of the ED physician. Routine blood tests include arterial blood sampling for those with respiratory symptoms, which plays a key role in the study of gas exchange and lung function. The withdrawal is carried out routinely upon arrival of the patient with SARS-CoV-2 infection at a value of FiO2 equal to 21%. The study involved the execution of the LUS access in ED and the subsequent calculation of the LUSS score.

Method of recruitment

1. Screening: all patients entering the COVID area of the ED with proven rapid or molecular antigenic nasal buffer for SARS-CoV-2 positive shall be considered eligible for inclusion in the study.

2. Recruitment: the physician responsible for the recruitment and clinical evaluation of patients assessed whether the latter are recruited, based on the defined inclusion and exclusion criteria, and shall obtained informed consent.

3. Where recruitment is not carried out, a record was drawn up specifying the reason for exclusion from the study.

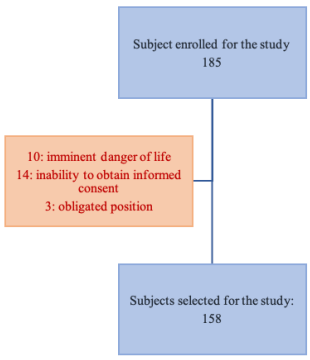

Figure 1. Flow-chart – Recruitment

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Data collection

The data was collected in an Excel spreadsheet. Patient personal data was encrypted for privacy protection.

At the time of enrolment, the following general characteristics of the patients recruited was recorded on the data collection folder: personal data; personal code of the patient; main comorbidities; cardiovascular risk factors; blood tests and instrumental examinations (chest X-ray, chest CT), carried out only if necessary for the sole purpose of diagnosis; the LUSS score; vaccination and previous positive COVID-19 virus.

LUS procedure and LUSS score

A Logiq P5 GE® ultrasound device with GE® 1.5/4.5 MHz convex probe, supplied to the ER and routinely used in all patients with COVID-19 diagnosis, was used.

In view of the importance of the LUSS score in this study, meetings and training days were held by an ED physician, who is an expert in the procedure, in order to uniform and standardize the scoring.

In particular, each hemithorax is divided into 6 bilateral areas (2 anterior, 2 middle and 2 posterior areas), for a total of 12 areas. Each area was analysed in order to detect ultrasound abnormalities and a score from 0 to 3 was assigned, where a higher score equals a degree of worse lung involvement. The values of the individual areas were then summed up to obtain an overall LUSS score.

Pulmonary diseases or those conditions that could overestimate the LUSS score, in the opinion of the ED physician, were considered as possible confounding factors.

Statistical analysis

The binary and categorical variables are presented as absolute frequencies (n) and percentages (%). Continuous data were presented as mean standard deviation (SD) if normally distributed; otherwise as median and interquartile range (IQR: Q1-Q3). The normality of the distribution of continuous quantitative variables is assessed through the Shapiro-Wilk test and data were expressed at a 95% confidence interval (95%CI). In order to identify differences in continuous variables, t-tests and U-Mann-Withney tests are used to compare independent sample groups. The differences in dichotomous and categorical variables between two groups are compared through the chi-square test. The ROC curves of the regression models under study are represented and the concordance index (or C-index) was calculated.

The sample size was calculated using preliminary data from a previous cohort of 22 patients diagnosed with COVID-19 in our Sub-Intensive Medicine ward. The incidence of the P/F 300 ratio was 65% in 10 patients with LUSS score >4, while it was 35% in 12 patients with LUSS 4 score.

Based on those data, 110 patients (55 per group) are required to have a 90% chance of detecting, at a significance level of 5%, an increase in primary outcome (incidence of a P/F 300 ratio) of 35% in the control group (LUSS 4 patients) and 65% in the experimental group (LUSS >4 patients). Estimating a drop-out of about 20%, based on previous studies conducted in patients admitted to the ED, 140 patients are to be studied (70 per group).

For the primary outcome, it has been used a contingency tables 2x2 (Crosstabs), associating a chi-square test for the comparison of proportions with dichotomous variables.

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To evaluate the success of the dichotomous variable LUSS (4 or >4) and to predict the dichotomous variable P/F (>300 or 300), we used a binary logistic regression analysis. In addition, a multiple logistical analysis was carried out to assess the role of possible demographic characteristics, vital parameters and blood values, blood gas values, vaccine doses and previous positive episodes. The multiple logistic regression used provides a stepwise mode for the selection of independent variables. Initially, the missing values were eliminated. The regression model was selected using the stepwise method. The obtained logistic regression model had as independent variables pO2, glucose, GB, Hb, dichotomous LUSS and vaccine doses. The model explains 86.0% (Nagelkerke R2) of the variance in the P/F Ratio. For the analysis of the regression model, we considered the exponential of the coefficients β and therefore the Odds Ratio.

The results of the regression analyses were expressed as Odds Ratio (OR), the significance p-value of the regression coefficients and the adaptation goodness of the model is evaluated by means of the Nagelkerke coefficient R2.

Subsequently, the inter-operator variability is calculated in order to obtain the reproducibility of the LUS: the LUS examination was performed in the same patient using the same ultrasound device by five different operators under the same conditions and on the same day. In particular, the K of Cohen intra-operator is equal to 0.63, the inter-operator to 0.65, so it can be said that there is a considerable degree of agreement.

The statistical analyses are carried out through the statistical software R 4.2.3.

Characteristics	Patients evaluated	All patients	LUSS ≤4 (N=87)	LUSS >4 (N=71)	p-value
Sex: female n (%)	158	78 (49.4)	49 (56.3)	29 (40.8)	0.053 *(Chi test)*
Age: year	158	72.5 [62.0;81.0]	68.0 [51.0; 78.0]	77.0 [67.0; 82.0]	**<0.001** *(UMW test)*
Respiratory diseases: n (%)	158	24 (15.2)	8 (9.2)	16 (22.5)	**0.020** *(Chi test)*
Cardiovascular disease: n (%)	158	37 (23.4)	15 (17.2)	22 (31.0)	**0.042** *(Chi test)*
Diabetes: n (%)	158	19 (12)	8 (9.2)	11 (15.5)	0.226 *(Chi test)*
Systemic Arterial Hypertension: n (%)	158	57 (36.1)	24 (27.6)	33 (46.5)	**0.014** *(Chi test)*
n° comorbidity: n (%)	158				**0.022** *(Chi test)*
0		28 (17.7)	22 (25.3)	6 (8.5)	
1		45 (28.5)	23 (26.4)	22 (31.0)	
≥2		85 (53.8)	42 (48.3)	43 (60.6)	
Systolic Blood Pressure: mmHg	156	131 (±20 **SD**)	134(±17 **SD**)	127 (±23 **SD**)	**<0.001** *(t-test)*
Dyastolic Blood Pressure: mmHg	156	70 [65; 80]	75.0 [70; 80]	68 [60; 78]	**<0.001** *(UMW test)*
Heat rate: bpm	156	82 (±14 **SD**)	82 (±14 **SD**)	83 (15 **SD**)	**P<0.001** *(t-test)*
SpO2: %	156	96 [95; 98]	97 [96; 98]	95[93; 97]	**<0.001** *(UMW test)*
Respiratory rate: rpm	127	16 [15; 18]	16 [15; 18]	17 [15;20]	0.082 *(UMW test)*
Body temperature: °C	155	36.5 [36.0; 36.9]	36.5 [36.0; 37.1]	36.5 [36.0; 37.5]	**0.017** *(UMW test)*
Creatinine: mg/dl	156	0.95 [1.05; 2.00]	0.95 [0.74; 1.13]	1.02 [0.84; 1.40]	0.065 *(UMW test)*
AST: U/l	149	24 [27; 45]	24 [16; 35]	23 [16; 46]	0.550 *(UMW test)*
ALT: U/l	152	26 [31; 43]	26 [19; 36]	25[18; 38]	0.803 *(UMW test)*
CPK: U/l	116	94 [56;158]	114[77; 241]	82 [43; 138]	**0.007** *(UMW test)*
LDH: U/l	89	218[184;276]	215 [177; 272]	219 [185; 288]	0.721 *(UMW test)*
Reactive c protein: mg/dl	147	3.0[1.2; 9.2]	1.5 [0.7; 3.0]	7.2 [3.0; 12.4]	**<0.001** *(UMW test)*
Reactive c protein > 0.6 mg/dl: n, (%)	147	126 (79.7)	60 (69.0)	66 (93.0)	**<0.001** *(UMW test)*
Troponine: ng/L	128	14 [8; 40]	11 [5; 24]	30 [10;60]	**<0.001** *(UMW test)*
pO2: mmHg	158	71 [61; 88]	84.0 [70.0; 90.0]	61.0 [54.0; 73.0]	**<0.001** *(UMW test)*
pCO2: mmHg	157	35 [32;39]	35.0 [32.0; 38.0]	35.0 [32.0; 40.2]	0.419 *(UMW test)*
Lactate: mmol/l	126	1.2 [0.8; 1.6]	1.0 [0.8; 1.5]	1.3 [0.9; 1.7]	**0.026** *(UMW test)*
Glucose: mg/dl	153	124 [102; 152]	115 [98; 140]	135 [107 157]	**0.003** *(UMW test)*
P/F Ratio ≤300			7 (8.0)	46 (64.8)	**<0.001** *(Chi test)*
WBC: mil/mm^3	158	7.00 [5.40; 9.50]	6.67 [5.26; 8.96]	8.01 [5.50; 11.04]	**0.032** *(UMW test)*
Hb: g/dl	158	12.8 [11.1; 14.3]	13.3 [11.6; 14.4]	12.1 [10.8; 13.2]	**0.012** *(UMW test)*
PLT: n/ µl	156	192 [155; 240]	195 [161; 253]	181 [141;221]	0.104 *(UMW test)*
aPTT: sec	123	31[27; 36]	30 [26; 34]	32 [30; 38]	**0.006** *(UMW test)*
INR	123	1.08 [1.02; 1.18]	1.04 [1.00; 1.11]	1.13 [1.06; 1.23]	**<0.001** *(UMW test)*
Procalcitonin: ng/ml	123	0.09 [0.04; 0.23]	0.06 [0.30; 0.14]	0.10 [0.05; 0.28]	**<0.001** *(UMW test)*
Procalcitonin > 0.20 ng/ml: n (%)	123	34 (21.5)	12 (13.8)	22 (31.0)	**<0.001** *(test Chi)*
Hospitalization: n (%)	158	78(49.4)	23 (26.4)	55 (77.5)	0.065 *(Chi test)*
Infectious Diseases		46 (29.1)	13 (14.9)	33 (46.5)	
Subintensive Medicine		19 (12.0)	3 (3.4)	16 (22.5)	
Other wards		13 (8.2)	7 (8.0)	6 (8.5)	
Vaccine doses: n (%)	158				0.745 *(Chi test)*
0		12 (7.6)	7 (8.0)	5 (7.0)	
1		2 (1.3)	1 (1.1)	1 (1.4)	
2		18 (11.4)	12 (13.8)	6 (8.5)	
≥3		126 (79.7)	67 (77.0)	59 (83.1)	
Previous episodes of positivity: n (%)	158				0.192 *(Chi test)*
0		130 (82.3)	69 (79.3)	61 (85.9)	
≥1		28 (17.7)	18 (19.7)	10 (14.1)	

Dichotomous variables: absolute frequency, n (percentage frequency, %); normally distributed continuous variables: mean (standard deviation or SD); not normally distributed continuous variables: median [interquartile range or IQR: Q1;Q3]. UMW test= Mann-Whitney test; Chi test: Chi-squared test χ^2.

Table 1. Descriptive statistics of the study population.

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Ethical considerations

Subjects selected for the study were subject to informed consent.

This study obtained a favourable opinion from the Regional Ethics Committee of the Marche (protocol no. 2022-320). In carrying out the study, the main ethical lines regulating clinical research with humans are respected.

RESULTS

185 patients were enrolled. 27 subjects were excluded because they did not meet the inclusion criteria.

So, the sample selected for the study therefore included 158 patients. The female/male ratio is 0.97 (woman, 49.4%, 78/158), the average age was 72.5 (SD 15.9) years. More than half of the patients in the sample had at least two conditions of comorbidity (53.8%, 85/158). 12 (7.6%) subjects were not vaccinated, 2 (1.3%) had a single vaccination, 18 (11.4%) had two vaccinations and 126 patients (79.7%) had at least 3 vaccinations. Only 28 subjects (17.7%) of the sample had previous positive episodes at COVID-19. Half of the patients in the sample (80/158, 50.6%) were discharged. The age was statistically greater in the group with LUSS >4 ($p<0.001$). Moreover, subjects belonging to the LUSS >4 category are more affected by respiratory diseases ($p=0.020$), cardiovascular diseases ($p=0.042$) and hypertension ($p=0.014$).

Table 2 shows that the rate of LUSS ≤4 was statistically ($p<0.001$) higher in those with a P/F >300 (76.2%), compared to those with a P/F ≤300 (13.2%). In the same way, the proportion of LUSS >4 was lower in those who had P/F >300 (23.8%), while it was higher in those who had P/F ≤300 (86.8%). Moreover, we found that among those patients whose score LUSS was ≤4, a significantly higher rate had a P/F >300 (92.0% vs 8.0%). Similarly, in those patients who get LUSS >4, a significantly higher proportion showed a P/F ≤300 value (64.8% vs 35.2%).

The Odds Ratio of getting a P/F ≤300 in those who have a LUSS >4, compared to those who get a LUSS ≤4, was 21.0 (95% CI: 8.4 - 52.4). The dichotomous LUSS predictive variable is statistically significant ($p<0.001$): those who have a LUSS >4 have a 1.76 times higher probability of having a P/F ≤300, compared to those who have LUSS ≤4.

Subsequently, a logistic regression was carried out. Only three of the six predictive variables are statistically significant: po2, Hb, and dichotomous LUSS.

The unit reduction of pO2 is associated with an increase in the probability of belonging to group P/F ≤300 of 1.01. Similarly, the unit reduction of Hb correlates with an increase in the probability of belonging to group P/F ≤300 of 1.09. Finally, those with a LUSS score >4 are more likely to have a P/F ≤300.

In order to analyse how the dichotomous LUSS score predicts admission with diagnosis of pneumonia, a further regression has been carried out. The logistic regression model is statistically significant $\chi^2(1)= 86.56$, $p<0.001$.

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			P/F Ratio		
			P/F >300	P/F ≤300	Total
LUSS	LUSS ≤4	Absolute Frequency	80_a	7_b	87
		Expected Absolute Frequency	57.8	29.2	87.0
		% within LUSS	92.0%	8.0%	100.0%
		% within P/F ratio	76.2%	13.2%	55.1%
		% on the total	50.6%	4.4%	55.1%
	LUSS >4	Absolute Frequency	25_a	46_b	71
		Expected Absolute Frequency	47.2	23.8	71.0
		% within LUSS	35.2%	64.8%	100.0%
		% within P/F ratio	23.8%	86.8%	44.9%
		% on the total	15.8%	29.1%	44.9%
Total		Absolute Frequency	105	53	158
		Expected Absolute Frequency	105.0	53.0	158.0
		% within LUSS	66.5%	33.5%	100.0%
		% within P/F ratio	100.0%	100.0%	100.0%
		% on the total	66.5%	33.5%	100.0%

P<0.001 (Pearson Chi-squared). Each subscript letter denotes a subset of P/F ratio categories whose column proportions do not differ significantly from each other at the level. 05.

Table 2. Crosstabulation P/F Ratio (>300 vs ≤ 300)—LUSS (≤4 vs >4)

DISCUSSION

LUS is a minimally invasive imaging tool aimed at assessing the severity, predicting the course of the interstitial pneumonia and assisting in treatment decisions in patients with Sars-Cov2 infection[27].

Recent studies indicate that higher LUSS scores at baseline are associated with higher risk of developing adverse outcomes, such as death, hospitalization in intensive care or the need for invasive ventilatory support[28,29].

The presented study provides evidence on the potential of the LUS as a diagnostic tool, as, in addition to detect the stage of lung impairment, and to identify the need for oxygen therapy and, potentially, for anti-inflammatory and antiviral therapy.

According to recent literature, we found a robust correlation between LUSS and the P/F ratio at a FiO2 value of 21%30. In particular, we found that the probability of obtaining a LUSS score >4, in those who have a P/F ≤300 ratio is statistically higher than those who have a P/F >300, therefore suggesting a correlation with the severity of lung damage[31,32].

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The study also identified pO2, Hb, dichotomous LUSS as predictors of P/F level ≤300 or P/F >300. This result is in line with the multiple regression model resulting in the study by Kadkhodai et al[33].

Just as preliminary result, we observed that a LUSS score >4 increased the probability of being hospitalized for COVID-19 pneumonia.

Possible limitations to the validity of this study could be due to the type of sampling used and the fact that it was conducted in a single centre. Another limitation may arise from the mean age of our patients, which was > 60 years and age may determine lower pO2 values.

In addition, the ultrasound technique has inherent limitations. Obese patients are often difficult to evaluate due to the thickness of the subcutaneous tissue of the rib cage; the presence of subcutaneous emphysema or extensive chest dressings and bedside positions may preclude the propagation of ultrasonic rays to the lungs and make LUS examination difficult. In parallel with other ultrasound techniques, the LUS at the patient's bed may be operator-dependent. However, a high intra and inter-observing reproducibility[34,35] has been reported in our study. Another limit was the missing data because ED physician prescribed diagnostic exams based on the good clinical practice and so diagnostic reports of CT, X-ray, blood and arterial blood gas values could not be always available. However, missing data were < 10% for the majority (80%) of the variables.

Our study also shows several advantages, including the prospective design and the statistical calculation of the sample size based on previous data.

Finally, this study was conducted in a period in which virus containment measures, high vaccination coverage, completion of vaccination and maintenance of a high immune response through the booster dose mitigated the clinical impact of the epidemic. As described by the weekly monitoring of the Ministry of Health, there has been a decrease in the load on hospitals, with an essentially stable bed occupancy rate in the medical areas, but a slight decrease in intensive care[36].

Inevitably, therefore, it can be stated that the disease is in positive evolution, so the LUS examination conducted on patients affected by COVID-19 could be useful for new pandemic infections that could appear in the future or for other diseases involving the pulmonary system.

CONCLUSIONS

The LUSS score defined by our study is closely related to the P/F ratio. The LUS diagnostic examination conducted at the patient's bedside is a valuable tool for assessing the severity of pulmonary compromise in patients affected by COVID-19 in the ED and for predicting hospitalization in an intensive or semi-intensive environment for the diagnosis of pneumonia. This tool, if associated with a correct clinical evaluation, could facilitate early relevant clinical data, as well as the evaluation process of intra-hospital triage. Currently, one could also hypothesize a role for this imaging technique in the out-of-hospital evaluation of patients, which appears particularly important in current pandemics as a first aid tool for triaging patients already at home.

Further studies are needed to standardize the protocol for using the LUS diagnostic technique, in order to optimize its role in the diagnosis of pathologies, which, such as SARS-CoV-2 infection, affect the pulmonary interstitium.

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AUTHORSHIP CONTRIBUTION

AG, VGM, MM: designed the study design and conducted the research. AG: statistical analysis and interpretation data, writing the report interpretation data and drafting of the manuscript. AG, VGM, MM, FYP: interpretation data, writing the report and drafting of the manuscript. VDP, GPS, SS, SDP, LG: carrying out the LUS and assigning the LUSS score.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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