

COVID-19 or not COVID-19, that is the question. The role of screening criteria and point-of-care lung ultrasound in the triage decision-making process in an Emergency Department during the phase 2 of the COVID-19 Italian epidemic

Erika Poggiali, Davide Bastoni, Mariachiara Ferrari, Dario Moretto, Federico Buttafava, Pau Mateo Ramos, Valentina Burzio, Jolanda Petri, Andrea Magnacavallo, Andrea Vercelli

Emergency Department, “Guglielmo da Saliceto” Hospital, Piacenza, Italy

Abstract

In the COVID-19 era the real challenge for the Emergency Departments (ED) is to avoid the spread of the viral infection within the so called “clean area” of the emergency room and the hospital. Different protocols have been proposed and adopted in the EDs to quickly identify suspected COVID-19 patients and to correctly

manage these patients, all based on clinical and epidemiological criteria. To the best of our knowledge, our pre-triage decisional making-process first integrates the pre-triage interview with point-of-care Lung Ultrasound (LUS) performed in the triage area. The aim of our study is to assess the sensitivity and specificity of our screening clinical and/or epidemiological criteria, and to investigate the role of LUS in the triage decision-making process during the “phase 2” of the COVID-19 Italian epidemic. Our study confirms the pivotal role of the triage in the decision-making process and the management of the entire ED, and it demonstrates that further studies are necessary to validate the role of LUS as tool to promptly identify COVID-19 patients, if combined with a correct pre-triage interview.

Correspondence: Erika Poggiali, Emergency Department, “Guglielmo da Saliceto” Hospital, Via Giuseppe Taverna 49, Piacenza, Italy.
Tel.: +39 0523 303044
E-mail: erikapoggiali2@gmail.com

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Introduction

The spread of coronavirus disease 2019 (COVID-19) has had a deep impact on the Italian healthcare system, forcing a dramatic and rapid change in the working daily routine of the Emergency Departments (ED). New roles and skills have been proposed to manage both the great influx of patients and to avoid the spread of the viral infection within the so called “clean area”.^{1,2}

Piacenza (Emilia-Romagna, Northern Italy) has reached the peak of COVID-19 epidemic into two weeks, between 9th to 23rd March 2020. In this period, the so called “phase 1”, quite all the accesses to the ED of the “Guglielmo da Saliceto” hospital were due to COVID-19. To avoid the complete collapse of our ED because of the high influx of critically ill COVID-19 patients, we developed a long-term plan against catastrophic consequences and to rearrange the patients’ pathway throughout our ED. We planned a deep structural and environmental re-organization of the ED,^{3,4} and designed a survival strategy based on a clear triage process starting from the strictly collaboration between the triage nurse, who interviewed the patient, and the emergency clinician, who performed the point-of-care Lung Ultrasound (LUS) in a “key area” of the triage room, in order to quickly identify ultrasound signs of pulmonary interstitial syndrome. In our experience, we confirmed the role of LUS as a safe, easy and sensitive imaging technique to assess the lung and pleural involvement in COVID-19 pneumonia,^{5,6} as reported in literature.⁷⁻¹¹ In our experience, during the “phase 1” of the Italian COVID-19 epidemic, LUS has been a powerful method to early detect lung damage even in patients who did not complain of respiratory symptoms and/or fever.¹² Our results highlighted and confirmed the role of LUS in the triage making-decision process, and its pivotal role in the “phase 1” to avoid the viral spread within the “clean area” of the ED and the “clean wards” of the hospital.² After the epidemic phase, in the so

called “phase 2”, since April 1st, 2020 we observed an increasing number of patients referred to our ED for no-COVID-19 related complaint. This evidence has changed again our perspectives, causing a new challenge for the organization of our ED: to discriminate a “COVID-19 pathway” from a “COVID-19 free pathway” from the door of the ED to avoid the spread of the virus in the ED, and therefore, in all the hospital. To the best of our knowledge, the protocols adopted in the EDs to quickly identify suspected COVID-19 patients and to correctly manage these patients, were all based on clinical and/or epidemiological criteria.^{13–16} None of these studies included LUS as a part of the triage decision-making process.

The aim of our study is to assess the sensitivity and specificity of our screening clinical and epidemiological criteria in detecting COVID-19 patients in the pre-triage area, and to investigate the role of LUS in the triage making-process during the “phase 2” of the COVID-19 Italian epidemic.

Materials and Methods

This is a retrospective observational study including 222 patients (115 males; 107 females) consecutively admitted to the ED of “Guglielmo da Saliceto” Hospital in Piacenza, Emilia-Romagna, Italy, from April 1st to April 7th, 2020. The study was approved by the local ethics committee.

Organization of the ED and pre-triage interview

During the phase 2 of the COVID-19 Italian epidemic, we decided to split the ED into two areas to avoid the spread of the coronavirus in our ED: a “COVID-19 area” and a “COVID-19 free area”. Each area had a dedicated and independent medical and nursing team, supplied with a LUS station. In both areas, medical and nursing staff wore proper Personal Protective Equipment (PPE) as follows: FFP2 or FFP3 mask, protective goggles or face shields, long-sleeved disposable gown (COVID-19 area) or plastic apron (COVID-19 free area), and double gloves.

Before being admitted to the ED, all the patients were interviewed by an expert nurse in the pre-triage area, located outside the hospital, close to the entrance of the ED, using a standard schedule to investigate clinical and epidemiological criteria for COVID-19.

When evaluated by the local pre-hospital Emergency Medicine System (EMS), the medical or nursing team had to fill in the same schedule adopted in the pre-triage area for each patient before their arrival to the emergency room.

Clinical criteria were considered positive in presence of one of the following conditions: i) at least one of the following symptoms in the previous 14 days: fever, cough, nausea or vomiting, diarrhea, abdominal pain; ii) respiratory failure at admission, defined as SpO₂ < 95% at room ambient or respiratory rate > 25 acts per minute; iii) a known positive real-time polymerase chain reaction (RT-PCR) nasopharyngeal swab for SARS-CoV-2.

Epidemiological criterion resulted positive if the patient has had a close contact in the last 14 days with a subject with a positive nasopharyngeal swab for SARS-CoV-2.

In the pre-triage area, all the patients had to wear a surgical mask and disinfect their hands with an alcoholic solution. Body temperature and respiratory parameters (peripheral blood saturation, SpO₂ - and respiratory rate) were always checked by the nurse and reported in the pre-triage schedule.

Lung Ultrasound (LUS)

We investigated all the patients using a rapid and simple lung ultrasound (LUS) protocol to explore all the pulmonary fields from the apex to the bases, both anterior and posterior, as follows: 2 anterior, 2 posterior and 2 lateral (total 12 areas). LUS was performed in the triage area using a portable ultrasound machine ESAOTE Mylab XPro30 equipped with a convex probe CA631 (frequency range 1–8 MHz) (ESAOTE Medical Systems, Florence, Italy). All the LUS were performed by a member of the medical team of our ED, including who were considered inexperienced in LUS, *i.e.* with less than 6 months of experience. Based on the observation that each pulmonary area should be scanned for 10 seconds, the mean time to perform a complete and correct LUS was 2 minutes. LUS was considered positive in presence of B-pattern (interstitial syndrome with B-lines in clusters, both with three or more separate or coalescent B-lines, and white lung) with spared areas in at least two fields for each hemithorax, as reported in the literature.¹⁷

To direct the patient to the correct area, we integrated the results of the pre-triage interview and LUS, as follows: i) if the epidemiological criterion or LUS were positive, the patient was admitted to the COVID-19 area; ii) if the clinical criteria were positive for fever and/or cough, the patient was admitted to the COVID-19 area; iii) if the clinical criteria were positive for nausea or vomiting, diarrhea, abdominal pain or acute respiratory failure (SpO₂ < 95%) with negative LUS, the patient was admitted to the COVID-19 free area; iv) if all the criteria (clinical, epidemiological and LUS) were negative, the patient was admitted to the COVID-19 free area.

Study participants

We enrolled all the adult patients (> 13 years old) admitted to the ED of Guglielmo da Saliceto Hospital, Piacenza, Italy, from April 1st to April 7th, 2020, during the so called “phase 2” of the Italian COVID-19 epidemic. The patients’ enrollment has been limited only to daytime (8 a.m. – 8 p.m.) due to the need to perform LUS in the triage area. For the limited medical resources during COVID-19 epidemic, the presence of an “extra” physician in the triage area could be guaranteed only during daytime.

Classification of the patients and data collection

All the data (clinical and epidemiological criteria, LUS, radiological and laboratory findings including RT-PCR nasopharyngeal swab) were collected anonymously in a database.

RT-PCR nasopharyngeal swab was performed in all the patients to be admitted, or in those with a strong clinical suspicion of SARS-CoV-2 infection. In our experience, a positive nasopharyngeal swab is sufficient to define the patient as “positive”, but a negative nasopharyngeal swab in presence of highly suspected clinical and radiological criteria cannot exclude COVID-19.¹⁸ To clearly define a patient as “negative”, a negative RT-PCR nasopharyngeal swab is mandatory but not sufficient, due to the high frequency of false negative and asymptomatic carriers.

As consequence, we defined as “positive” for COVID-19, a patient with: i) a RT-PCR nasopharyngeal swab positive for SARS-CoV-2 at admission in the ED or within 72 hours, or ii) a clinical criterion and signs of interstitial pneumonia at chest X-Ray or high-resolution CT-scan even with negative RT-PCR nasopharyngeal swab.

We defined as “negative”, a patient with a negative RT-PCR nasopharyngeal swab at admission in the ED or within 72 hours, and: i) neither clinical nor epidemiological criteria nor radiological signs of COVID-19 pneumonia, or ii) the absence of antibodies

(IgG) against SARS-CoV-2 in a period between 1 and 3 months after discharge.

We defined “indeterminate” a patient who did not meet neither the positive nor the negative criteria.

Outcome

The primary outcome of the study is to determine the different sensitivity and specificity for COVID-19 infection of the pre-triage interview alone or associated with LUS.

Statistical analysis

We analysed the patients classified as positive or negative according to the adopted criteria. We calculated sensitivity, specificity, positive and negative predictive values of the triage interview with or without LUS in detecting COVID-19 patients. We used 95% confidence intervals (CI) to compare the two groups.

Results

Two hundred twenty-two consecutive patients were enrolled in the study: 115 (52%) males, 107 (48%) females. The mean age was 59.7 years (ranging from 15 to 99).

Based on the criteria used to define a patient as positive or negative, 148/222 (67%) patients have been classified correctly. Seventy-four (34%) patients were considered as indeterminate and excluded from statistical analysis (Figure 1). LUS was not performed in 39/148 patients.

LUS was performed in 109/148 (73.6%) patients with a defined diagnosis. These patients have been considered for the statistical analysis: 37/109 (34%) were “positive” (infected) cases and 72/109 (66%) were “negative” (not infected) cases. Among the positive cases, 27/37 had a positive nasopharyngeal swab. Ten COVID-19 patients had a negative nasopharyngeal swab: 4/10 patients have been investigated with LUS, that resulted as positive. Chest HRCT has been performed in the emergency room in all the patients and confirmed the diagnosis of COVID-19 pneumonia.

In the Table 1 we reported the clinical characteristics of the 109 investigated patients at presentation in the triage area. The degree of acute respiratory failure has been based on the patient’s oxygen need at admission. The expert triage nurse treated immediately the patient’s respiratory failure with oxygen therapy in the triage area, based on peripheral blood oxygen saturation using different oxygen flows, as reported in Table 1.

The following 2×2 contingency tables (Table 2, 3 and 4) sum-

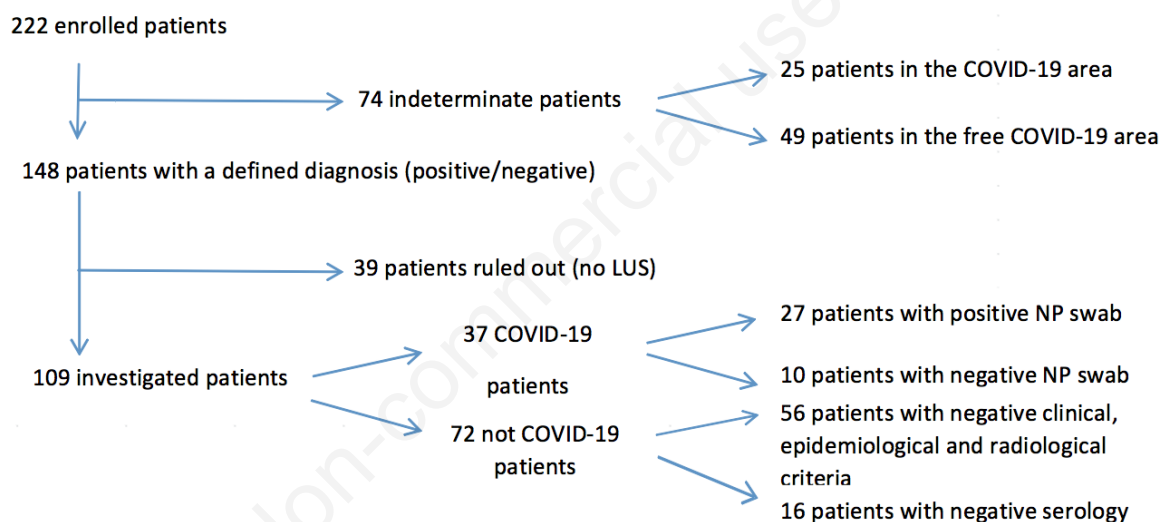


Figure 1. Flow-chart of the enrolled (222) and investigated (109) patients of the study. NP, nasopharyngeal. LUS, lung ultrasound.

Table 1. Patients’ demographic and clinical characteristics at presentation in the ED. M, male; F, female. Respiratory failure has been classified according to the patient’s oxygen need at admission in the triage as follows: mild till 6 LT/min in nasal cannulae; moderate for flow rate of 10 LT/min with non-rebreather mask; severe for flow of at least 15 LT/min with non-rebreather mask.

	COVID19 patients (n 37)	Not COVID19 patients (n 72)
Sex (M/F)	21/16	41/31
Mean age (years) (min-max)	69 (19 - 96)	61 (16 - 95)
fever	20	12
Respiratory symptoms	15	9
Gastrointestinal symptoms	9	8
Acute respiratory failure	17	6
Mild	8	4
Moderate	3	1
Severe	6	1

marize the results of the pre-triage interview, LUS and the two integrated tests. A positive test corresponds to the assignment to the COVID-19 area, while a negative test to the COVID-19 free area.

The performance of the pre-triage interview and LUS were evaluated for sensitivity, specificity, and Positive (PPV) and Negative Predictive Value (NPV), as reported in Table 5.

The pre-triage interview alone has a better sensitivity than combined with LUS: respectively, 97.3% (95% CI, 94-100) versus 94.6% (95% IC, 88-100), but the difference is not statistically significant. Even the specificity of the pre-triage interview alone and combined with LUS are not statistically significant: they are respectively 66.7% (95% IC, 56-78) and 69.4% (95% IC, 59-79). Interestingly the specificity of LUS is 77.8% (95% IC, 70-86), but this result is not statistically significant.

LUS resulted as negative in 9/37 (24%) COVID-19 patients: they complained upper respiratory symptoms (2/9), severe bilateral pleural effusion (2/9), nausea (1/9), anemia (1/9), diarrhea (1/9), palpitation (1/9) and acute chest pain (1/9). Only 2 out of these patients were addressed to the free COVID-19 area (false negative): one patient with a final diagnosis of anemia had a negative pre-triage interview and a negative LUS with no signs of pneumonia at chest X-ray; the other had a severe heart failure with massive bilateral pleural effusion. Based on LUS, the patient was addressed to the COVID-19 free area. Chest X-ray confirmed the diagnosis

of congestive heart failure. Both the patients can be considered "asymptomatic carriers".

Twelve out 14 COVID-19 negative patients referred to the ED for nausea, vomiting, diarrhea, abdominal pain or respiratory failure (see Table 1) were correctly addressed to the COVID-19 free area based on negative LUS. In our experience, 9/72 (12%) no COVID-19 patients were addressed to COVID-19 area based only on LUS.

Considering the patients with respiratory failure (23/109, 21%), both infected and not infected for COVID-19 (see Table 1), LUS has a sensitivity and specificity of 100% (95% IC, 98-100) in patients with severe respiratory failure. In patients with mild and moderate respiratory failure, the specificity of LUS is of 0%, while the sensitivity is respectively of 87.5% (95% IC, 85-89) and 66.7% (95% IC, 62-71). Since all the patients were investigated with the pre-triage interview, we calculated sensitivity and specificity of the test also for all the patients with a defined diagnosis (148/222), resulting respectively 96.8% and 65.1%. Among them, 60 patients resulted true positive, 2 false negative, 56 true negative and 30 false positive. Among the patients who were not investigated with LUS (39/148, 26.4%), 25/148 (13%) have been resulted positive. Among them, 17 patients were addressed to COVID-19 area for both clinical and epidemiological criteria at the pre-triage interview: LUS would not change the final destination of the patients, *i.e.* COVID-19 area. If we consider the indeterminate group, 25/74

Table 2. 2x2 contingency table for the pre-triage interview.

	N° of infected patients	N° of non-infected patients	Total
Positive pre-triage interview	36	24	60
Negative pre-triage interview	1	48	49
Total	37	72	

Table 3. 2x2 contingency table for LUS.

	N° of infected patients	N° of non-infected patients	Total
Positive LUS	28	16	44
Negative LUS	9	56	65
Total	37	72	

Table 4. 2x2 contingency table for the integrated approach: the pre-triage interview and LUS.

	N° of infected patients	N° of non-infected patients	Total
Positive interview + LUS	35	22	57
Negative interview + LUS	2	50	52
Total	37	72	

Table 5. Sensitivity, specificity, Positive and Negative Predictive Value (PPV, NPV) of the pre-triage interview, LUS and the combination of both the strategies.

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Pre-triage interview	97.3	66.7	60.0	97.9
LUS	75.7	77.8	63.6	86.1
Pre-triage interview + LUS	94.6	69.4	61.4	96.1

(34%) patients have been addressed to the COVID-19 area: in 8 patients we did not perform a nasopharyngeal swab because they had a positive epidemiological criterion in absence of symptoms suspected for COVID-19, and none of them were hospitalized. Forty-nine out of seventy-four (66%) patients have been assigned to the COVID-19 free area: none of them had a nasopharyngeal swab in absence of clinical and epidemiological criteria and they have been all discharged home from the ED.

Discussion

The real challenge for the ED is to identify COVID-19 patients from their arrival at the ED. Unfortunately, SARS-CoV-2 is the cause of an infection, which can run its course without symptoms (asymptomatic carrier) or with a very broad spectrum of symptoms, ranging from fatigue, dry cough, fever, gastrointestinal symptoms, anosmia or dysgeusia to acute respiratory distress syndrome with a high risk of death for multiorgan failure.^{12,19–21} In the pandemic phase of COVID-19, the most common cause of access to our ED was dyspnea of different severity, but we also observed a significant number of patients with gastrointestinal symptoms even in absence of fever and/or dyspnea.¹²

The main purpose of our study was to design a triage making-process to avoid the spread of the infection in the COVID-19 free area due to misdiagnoses. Our study demonstrated a prevalence of the disease of 42% in the sample of patients with a defined diagnosis (62/148). Unfortunately, a rapid and reliable test to identify COVID-19 patients in the pre-triage process is still unavailable. For this reason, we decided to give preference to sensitivity of our protocol strategy with the aim of losing as few positive cases as possible, reducing the risk of transmitting infection to non-infected patients.

Based on our previous experience, we decided to investigate in the pre-triage interview not only fever and respiratory symptoms, but also gastrointestinal symptoms to avoid and limit misdiagnoses. This led us to reach a sensitivity of 97.3% and a negative predictive value of 97.9% for the pre-triage interview. If we consider the sample of all the patients with a defined diagnosis (148/222), the sensitivity is of 96.8% due to two false negative patients, and the predictive negative value of 96.5%. The main limit of the pre-triage interview is the low specificity: of 66.7% in the analyzed sample (109/222), and of 65% in the overall sample with a defined diagnosis (148/222), and as consequence, the high risk of targeting incorrectly uninfected patients in the COVID-19 area: 24/60 (40%) patients addressed to COVID-19 area have been resulted negative. To try to solve this important limitation, we evaluated all the patients with LUS in the triage area. LUS was used with two main aims: to increase the sensitivity and specificity of the pre-triage interview, respectively through the identification of COVID-19 patients who did not complain of fever and respiratory symptoms, and the diagnosis of alternative diseases in case of respiratory failure, such as congestive heart failure, pneumothorax, or reactivation of chronic obstructive pulmonary disease. Our results demonstrated that LUS has a lower sensitivity compared to the pre-triage interview (respectively, 75.7% versus 97.3%), but a higher specificity (respectively, 77.8% versus 66.7%), even if not statistically significant. We are aware that the low sensitivity of LUS is related to the identification of radiological findings of a complication, *i.e.* COVID-19 related pneumonia, that can be absent at diagnosis and usually develops after 9 days from the infection, approximately 3-7 days after the emergence of clinical

signs and symptoms, as reported for chest CT-scan.²²

Considering only the patients with respiratory failure, we reported surprisingly different results. In the clinical scenario of COVID-19 pandemic, a patient with severe acute respiratory failure related to SARS CoV2 infection has surely LUS signs of pneumonia. As consequence, in this subgroup of patients, LUS has a sensitivity significantly higher compared to the population of the study. On the contrary, the significant difference of the specificity of LUS in patients with severe vs mild-moderate respiratory failure can be related to the expertise of the emergency clinician. In this context with a high prevalence of COVID-19 pneumonia, emergency clinicians can be led to overestimate pulmonary involvement.

Based on all these observations, we promptly interrupted the study after only one week, and we created a new pre-triage protocol with a third pathway, so called “intermediate”, and we also added three new criteria for suspected patients, including: anosmia or dysgeusia in the last 20 days; or at least two of these symptoms: headache, myalgia, joint pain, conjunctivitis; or SpO₂ < 92% at room ambient for patients with COPD. All the patients classified as “intermediate” by the pre-triage nurse, were addressed and evaluated in a new dedicated area of the ED called “intermediate area”.

We are aware that the main limits of our study are the small size of the patients’ sample and the difficulty to integrate LUS and the pre-triage interview. In addition, we did not routinely perform a nasopharyngeal swab in patients sent to the COVID-19 free area.

Anyway, starting from the strong conviction that further evidence is needed to confirm or disprove the role of LUS in the triage decision-making process in the phase 2 of the pandemic, we continued to evaluate all the patients with LUS, and we introduced in the working algorithm the so called “LUS score” based on the lung involvement for each of the 12 fields (2 anterior, 2 posterior and 2 lateral), as follows: 0 – normal; 1 – B lines ≥ 3 in a field; 2 – “white lung”; 3 – consolidations.⁸ We created a score based on the integration of LUS and the pre-triage interview to correctly address the patients to the three different area of the ED: a clean area, an infected area and an indeterminate area. Preliminary results confirm our hypothesis (data not shown).

Conclusions

Our study confirmed the pivotal role of the triage in the management of a medicine disaster scenario.²³ The study failed to demonstrate the utility of LUS in the triage setting, but we think that the small size of the patients’ sample is the main limit of our work and it surely affects the results. For this reason, we believe that further studies are necessary to validate the role of LUS as tool to promptly identify COVID-19 patients if combined with the pre-triage interview. Our data and experience suggest that is not possible to surely identify COVID-19 patients in the triage area in all the cases. As consequence, unrecognized positive patients can be addressed to the “COVID-19 free area” and put at risk of infection negative patients. Based on our results, we believe that an “intermediate area” is necessary to limit the contamination of the COVID-19 free area. We are aware that every change in the organization of the ED is a great challenge considering the limited resources, and it involves a deep effort of all the medical and nursing staff, but we strongly believe that the pre-triage protocol remains the most powerful tool to avoid the spread of the virus in the ED and in the hospital, particularly in the phase 2 of the pandemic.

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