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Abstract

Objective: To assess the value of abnormal findings of lung POCUS performed by PCPs in patients with SARS-CoV-2 virus infection in predicting hospitalisations, intensive care admissions, and mortality. Additionally, this study aims to assess the validity of lung POCUS performed by PCPs for COVID-19 pneumonia diagnosis.

Methods: This prospective observational study, conducted in Mallorca and Salamanca, Spain, during 2021, assessed 624 consecutive adult patients with confirmed SARS-CoV-2 infection and worsening symptoms. Eight PCPs with 5-hour standardized training performed 12-zone lung POCUS. POCUS was considered positive if pleural abnormalities with ≥ 3 B-lines, subpleural consolidation, or lobar consolidation were present. Patients were followed for 30 days to confirm pneumonia diagnosis via chest X-ray or CT scan. Multivariate models using Poisson regression were performed to identify independent predictors for hospitalization and ICU admission/death.

Results: Abnormal POCUS findings were observed in 58.8% of patients, of whom 50.3% presented pleural abnormalities with 3 or more B-lines in at least one scanned area, 27.6% subpleural consolidations, and 3.4% lobar consolidations. Patients with positive POCUS were referred to the hospital more frequently (72.4% vs. 22.8%; OR = 8.83). Abnormal lung POCUS was independently associated with an increased risk of hospitalization (RR 1.34; 95% CI 1.07–1.67), along with age >50 years, SpO₂ <95%, hypertension, and diabetes. POCUS was not independently associated with the composite outcome of ICU admission or death (RR 1.27; 95% CI 0.62–2.61). For the diagnosis of COVID-19 pneumonia, overall POCUS sensitivity was 68.3%, specificity 43.6%, positive predictive value 78.7%, and negative predictive value 31.1%.

Conclusions: Lung POCUS performed by PCPs is a valuable independent predictor for hospitalization in COVID-19 patients within community settings. While its incremental prognostic benefit over simple clinical variables is modest and its diagnostic accuracy for pneumonia is limited compared to conventional imaging, it could remain as a useful tool for risk stratification in resource-limited environments or home-based care. These findings support its use in resource-limited environments and highlight the need for standardised scanning protocols and training.

Background

The COVID-19 pandemic meant a major challenge for healthcare services worldwide, requiring them to adapt their services to the urgent needs of these patients. COVID-19 has a highly variable course, ranging from asymptomatic to extremely severe and often fatal. Many nearly asymptomatic or mildly symptomatic patients developed after 5-8 days viral pneumonia with hypoxemia and pulmonary infiltrates that led to hospitalization in 14% of the patients and acute respiratory distress syndrome in 12% of hospitalised patients¹⁻³.

Early in the outbreak, studies suggested that lung ultrasound (LUS) could be a valuable tool for predicting the probability of clinical worsening of COVID-19, defined as the deterioration of several disease severity markers or other outcomes, such as hospitalization, intensive inpatient care, or death. The results of these studies demonstrate consistency in supporting the use of LUS as a predictive tool for patients with COVID-19, despite the diversity of the population and the variability in LUS measurements and scores. Most of these studies have been conducted in hospital wards⁴⁻⁷ or emergency departments⁸⁻¹⁰. However, very few studies have assessed the value of lung point-of-care ultrasound (POCUS) in patients with suspected or confirmed COVID-19 in primary care settings^{11,12}. In the last decade, Spain has adopted POCUS as an imaging tool at the patient's bedside with the goal of improving primary care's resolution capability. Additionally, primary care physicians' (PCPs) training in lung POCUS had a significant boost with the COVID-19 pandemic^{13,14}. In this context, it is necessary to get evidence to support the use of lung POCUS by PCPs to follow up patients with mild to moderate symptoms of SARS-CoV-2 infection in the community. Such evidence might lessen treatment uncertainty for patients, aid in the early detection of lung involvement, and prevent referring patients with minimal potential benefit, thereby alleviating stress on hospital emergency departments.

The most common approach for diagnosing pneumonia involves a combination of plain chest X-rays, clinical findings, and symptomatology. Nonetheless, chest X-rays have demonstrated limited sensitivity for this purpose^{15,16}. Although chest CT scans are more sensitive, they have drawbacks in terms of cost, accessibility, and radiation exposure. Furthermore, the requirement to transport the patient to a radiology centre for an imaging test

was an additional restriction on its use in the context of COVID-19, given the uncertainty and lack of knowledge surrounding the situation, which encouraged limiting visits to hospitals and health centres as much as possible to avoid contagion¹⁷. Prior to the COVID-19 pandemic, several studies found LUS to be more sensitive than chest X-rays in diagnosing pneumonia¹⁸. LUS was already considered for the diagnosis of pneumonia in emergency medicine¹⁹ and paediatrics²⁰. LUS offers good repeatability across operators with varying degrees of experience between them²¹. Sonographic findings associated with COVID-19 pneumonia (anomalies in the pleural line thickness, focal, multifocal, and merging B-lines, and consolidations with sporadic mobile air bronchograms) are comparable to those reported in patients diagnosed with pneumonia prior to the COVID-19 pandemic²²⁻²⁴. A recent systematic review and meta-analysis have indicated that LUS has a sensitivity of 87.2% and a specificity of 69.5% for the diagnosis of COVID-19 pneumonia in high-prevalence settings²⁵. LUS is more sensitive (97.6%) than chest X-ray (69.9%) in identifying COVID-19 pneumonia²⁶ and has a diagnostic accuracy equivalent to chest CT for COVID-19 pneumonia²⁷.

Nevertheless, there are few studies assessing the diagnostic accuracy of lung POCUS in COVID-19 patients with suspected pneumonia visited in primary care. Two retrospective studies found sensitivity values ranging from 82% to 93% in primary care, comparable to those obtained in hospital settings.^{28,29} The only prospective study on the diagnostic value of lung POCUS for the diagnosis of COVID-19 pneumonia found a sensitivity of 87.8% and a specificity of 58.5% using the radiologist's report of the chest X-ray as the reference test³⁰.

Although diagnostic accuracy of lung POCUS is of undeniable importance and interest, its ability to identify patients at risk of deterioration—regardless of formal pneumonia diagnosis—was considered clinically relevant in the context of primary care during the COVID-19 pandemic. Our study reflects real world clinical decision making in PHC during the pandemic, where POCUS was used for triage and risk stratification at patients' homes, and therefore the focus was on the prognostic utility for clinical decision making. The main objective of this study is to assess the value of abnormal findings of lung POCUS performed by PCPs in patients with SARS-CoV-2 virus infection confined at home in predicting hospitalizations, intensive care admissions, and

mortality. Additionally, this study aims to assess the validity of lung POCUS performed by PCPs for COVID-19 pneumonia diagnosis.

Methods

Study design and setting

Our study is a prospective observational study conducted on the island of Mallorca and in the Salamanca region (Spain) by specific units dedicated to attending COVID-19 patients. In Mallorca, the study was carried out by the 'UVACs' (COVID-19 Mobile Care Units). These units, comprising PCPs, nurses, and health technicians, attended to patients with confirmed or suspected COVID-19 at home. In Salamanca, the study was conducted at the so-called 'Point Covid', a community health centre where PCPs and primary care nurses attended patients with confirmed or suspected COVID-19.

We included all consecutive patients over 18 years old who attended both units between January and December 2021, with a positive SARS-CoV-2 test whose symptoms had worsened in previous days. Symptoms may include high fever, generalized malaise, persistent cough, dyspnoea, or digestive symptoms. Patients were excluded if they were not in good condition to sign informed consent. In the first visit, the doctor validated the inclusion and exclusion criteria, explained the study, and required signed consent. If the patient accepted, the PCP performed a lung POCUS, and the nurse measured the clinical parameters. The UProbe-C5PL (Sonostar, Guangzhou, China) portable ultrasound device was used for examinations performed at patients' homes by the Mallorca 'UVACs', and the cart-based Versana Premier (GE HealthCare, Chicago, USA) was used for examinations at the 'Point Covid' in Salamanca. Lung POCUS was performed according to the 12-area method^{31,32}. The eight participating physicians received a 5-hour training course in lung ultrasound before participating in the COVID-19 community Units. Patients were followed up for up to 30 days after the index visit to confirm the pneumonia diagnosis.

For the main objective, accepting an alpha risk of 0.05 and a statistical power greater than 0.8 in a two-tailed test, 62 subjects with LUS abnormalities and 62 subjects without them were

needed to detect the difference in hospital admission between both groups as statistically significant, which for group with LUS abnormalities is expected to be 22.4% and for the group without them 3.33%¹². A loss to follow-up rate of 10% has been estimated. For the secondary objective, with an estimated sensitivity of lung POCUS for the diagnosis of pneumonia of 81%³³, an expected prevalence of COVID-19 pneumonia of 14%³, and a precision of 10%, the calculated sample size was 61 patients with pneumonia and a total sample of 429 patients.

Variables

Sociodemographic data (age, sex), study site, clinical data (days of evolution, temperature, pulse oximetry, respiratory rate, and heart rate), and ultrasound findings (B-lines, subpleural consolidations, and lobar consolidations) were registered at the index visit. Hospital referrals or follow-up at home were also recorded. Ultrasound was considered positive for COVID-19 pneumonia when the patient had a positive SARS-CoV-2 test and at least one of the following lung POCUS alterations in at least one scanned area: pleural abnormalities with 3 or more B-lines, subpleural consolidations and lobar consolidation^{27,34}. Lung POCUS findings were not the only reason for the patient's further management. PCPs probably decided to refer patients, considering the clinical situation, family and social support, and the possibility of isolation at the patient's home.

Subsequently, 30 days after the index visit, an independent data manager collected pneumonia diagnosis either in chest X-ray reports, CT scan reports, or inpatient electronic medical records. The radiologists responsible for interpreting the tests were unaware of the findings of the LUS performed in primary care. Furthermore, hospitalization, ICU admission and patient death were recorded, as well as the realization and results of chest X-ray and/or chest CT scan.

Analysis

We performed a descriptive analysis of all selected variables to describe sample characteristics. A bivariate analysis was conducted comparing the presence of lung POCUS findings with the baseline characteristics of the patients. We used the chi-square test for

categorical variables and the Student's T-test for continuous variables. Multivariable models for both hospitalization and ICU admissions/death were performed using Poisson regression. To assess the risk of overfitting we calculated the events-per-variable (EPV) ratio for each model. Discrimination was quantified using the area under the receiver operating characteristic curve (AUC) with 95%CI for both outcomes calculated using DeLong's method. Calibration was evaluated using multiple approaches: calibration-in-the-large assessed by the ratio of observed to expected events (O/E ratio), calibration slope, the Normalized Residual Sum of Squares (NRSS), and visual calibration plots. Finally, internal validation was performed using bootstrap resampling with 200 replications.

To explore the incremental prognostic value of adding POCUS to clinical predictors, we performed likelihood ratio tests comparing nested models and AUC comparison using DeLong's test. We estimated the net reclassification improvement (NRI), using clinically relevant risk thresholds (30% and 50% for hospitalization: 5% and 10% for ICU admission/death) and calculating the proportions of patients correctly reclassified upward (events) and downward (non-events). The integrated discrimination improvement (IDI) metrics was also estimated. Finally, decision curve analysis was performed to examine the clinical utility of incorporating POCUS into both models.

We performed multiple imputations by chained equations (MICE) to utilize all 624 participants and address missing data comprehensively. Twenty imputed datasets were generated using predictive means matching for continuous variables and logistic regression for binary variables. Then we re-fitted both prognostic models using the multiply imputed datasets (n=624) and compared risk ratios, 95% confidence intervals, and model discrimination metrics (AUC) with those from the complete-case analysis (n=591) to assess the robustness of our findings to different approaches for handling missing data (*See Supplementary Information for more detailed multivariate statistical analysis*).

Sensitivity, specificity, positive and negative predictive values (PPVs, NPVs), and positive and negative likelihood ratios (LR+, LR-) were calculated for the overall lung POCUS findings and for each of them independently. We considered true positive cases of those patients with positive ultrasound findings for pneumonia, in which, after a hospital contact, pneumonia was confirmed

either with X-ray or CT-scan after 30 days of the index visit. False positive cases were those with ultrasound positive findings for pneumonia that were not confirmed in the hospital through X-ray or CT-scan after 30 days of the index visit. We considered true negatives for those patients with negative ultrasound findings for pneumonia and no verified pneumonia through X-ray or CT scan after 30 days of the index visit. Finally, false negative cases were defined as patients without ultrasound findings for pneumonia who were confirmed to have pneumonia through chest X-ray or CT scan after 30 days of the index visit. SPSS software version 26 and STATA software version 13 were used.

Results

During the period of the study, 624 patients were included, 527 by the Mallorca COVID-19 Mobile Care Units and 97 at the COVID-Point in Salamanca. The flowchart of patients included is shown in Figure 1. Baseline characteristics of patients included in the study are presented in Table 1. The mean age was 52.5 years (SD=18.3), and 45.7% of them were female. The mean number of days from the beginning of symptoms until POCUS was performed was 7.2 (SD=4.3), and 5.3 days (SD=4.1) since a positive SARS-CoV-2 result was reported. Out of the 624 patients, 30% had a temperature higher than 37°C, 69.5% had pulse oximetry readings of peripheral oxygen saturation (SpO₂) lower than 95%, 34.3% had tachypnoea, and 22.1% had tachycardia.

Figure 1: Flowchart

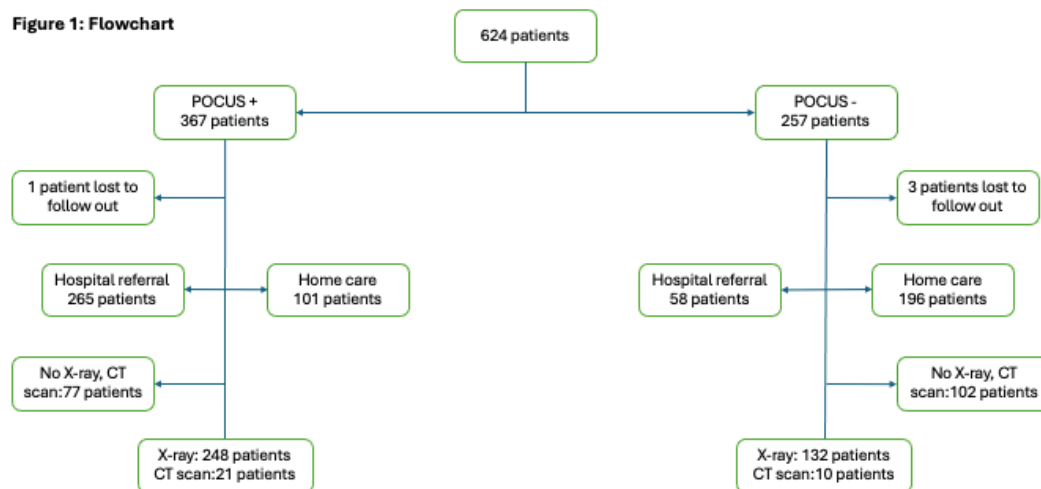


Table 1: Baseline characteristics

Total sample 624		N, %
Age (mean ± SD) (623)		52.5 ± 18.3 years
Age	≤50 years	299/623 (48.0)
	>50 years	324/623 (52.0)
Sex	Female	285/624 (45.7)
	Male	339/624 (54.3)
Site of study (POCUS device)	Mallorca (Portable)	527/624 (84.5)
	Salamanca (Cart-based)	97/624 (15.5)
Days since symptoms until POCUS (mean ± SD) (605)		7.2 ± 4.3
Days since COVID diagnosis until POCUS (mean ± SD)		5.3 ± 4.1
Temperature °C (mean ± SD) (496)		36.6 ± 0.82
Temperature °C	<37°C	347/496 (70.0)
	≥37°C	149/496 (30.0)
Pulse oximetry (mean ± SD) (623)		95.1 ± 4.3
Pulse oximetry	<95%	433/623 (69.5)
	≥95%	190/623 (30.4)

Respiratory rate bpm (mean \pm SD) (548)		20.4 \pm 5.6
Respiratory rate	\leq 20 bpm	360/548 (65.7)
	$>$ 20 bpm	188/548 (34.3)
Cardiac rate bpm (mean \pm SD) (615)		88.6 \pm 16.0
Cardiac rate	\leq 100 bpm	479/615 (77.9)
	$>$ 100 bpm	136/615 (22.1)
POCUS findings (624)	Pleural line abnormalities & \geq 3 B-lines	314/624 (50.3)
	Sub-pleural consolidation	172/624 (27.6)
	Lobar consolidation	21/624 (3.4)
POCUS positive findings for pneumonia		367/624 (58.8)
GP decision-making (620)	Referral to the hospital	323/620 (52.1)
	Home care	297/620 (47.9)

Overall, 58.8% of patients had lung POCUS findings compatible with pneumonia, which were more frequent in Mallorca than in Salamanca. The most common abnormalities were pleural line irregularities with \geq 3 B-lines (50.3%), followed by subpleural consolidations (27.6%) and lobar consolidations (3.4%). Patients with positive lung POCUS findings were older, more often had hypertension, diabetes, COPD and heart failure, and showed higher temperature, lower oxygen saturation, and higher respiratory and heart rates than those with normal POCUS (Table 2). Abnormal lung POCUS findings were associated with more frequent referral to hospital (72.4% vs 22.8%) and hospital admission (54.3% vs 31.7%), as well as higher 30-day mortality (4.3% vs 0.8%), while ICU admission rates did not differ significantly (Table 2).

Table 2. Bivariate analysis of comparative findings in patients with positive POCUS findings versus negative POCUS findings

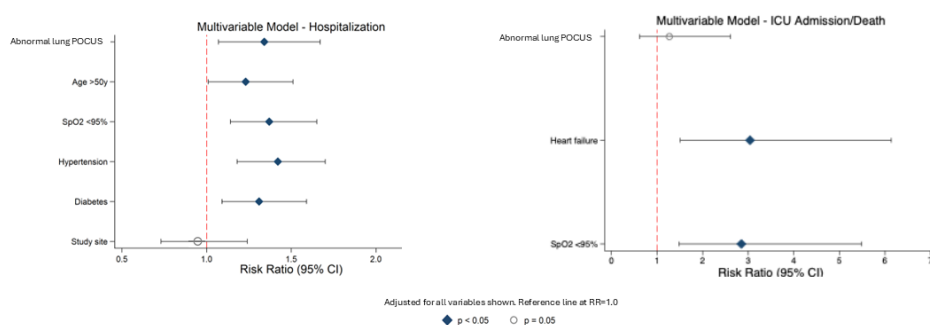
		Positive POCUS findings 367/624 (58.8%) N (%)	Negative POCUS findings 257/624 (41.2%) N (%)	p-value
Age (mean ± SD) (623)		55.8 ± 17.6 years	47.9 ± 18.4 years	<0.001
Age	≤50 years	147/366 (40.2)	152/257 (59.1)	<0.001
	>50 years	219/366 (59.8)	105/257 (40.9)	
Sex	Female	188/367 (51.2)	151/257 (58.8)	0.07
	Male	179/367 (48.8)	106/257 (41.2)	
Site of study (POCUS device)	Mallorca (Portable)	324/527 (61.5)	203/527 (38.5)	0.02
	Salamanca (Cart-based)	43/97 (44.3)	54/97 (55.7)	
Days since symptoms until POCUS (mean ± SD)		7.25 ± 4.2 days	7.1 ± 4.4	0.60
Days since COVID diagnosis until POCUS (mean ± SD)		5.4 ± 3.8 days	5.2 ± 4.6	0.01
Temperature °C (mean ± SD) (496)		36.7 ± 0.9	36.4 ± 0.7	<0.001
Temperature	<37°C	194/304 (63.8)	153/192 (79.7)	<0.001
	≥37.0°C	110/304 (36.2)	39/192 (20.3)	
Pulse oximetry (mean ± SD) (623)		93.9 ± 5.0	96.7 ± 2.0	<0.001
Pulse oximetry	<95%	204/367 (55.6)	229/256 (89.5)	<0.001
	≥95%	163/367 (44.4)	27/256 (10.5)	
Respiratory rate bpm (mean ± SD) (548)		21.5 ± 6.1	18.6 ± 4.2	<0.001
Respiratory rate	≤20 bpm	188/331 (56.8)	172/217 (79.3)	<0.001
	>20 bpm	143/331 (43.2)	45/217 (20.7)	
Cardiac rate bpm (mean ± SD) (615)		89.7 ± 16.4 bpm	87.0 ± 15.1	0.04
Cardiac rate	≤100 bpm	271/364 (74.5)	208/251 (82.9)	0.01
	>100 bpm	93/364 (25.5)	43/251 (17.1)	
Comorbidities				

	High blood pressure	118/347 (34.0)	50/247 (20.2)	<0.001
	Type 2 Diabetes	61/347 (17.6)	20/247 (8.1)	0.01
	Anxiety	24/347 (6.9)	30/247 (12.1)	0.03
	Thyroid disorders	30/347 (8.6)	23/247 (9.3)	0.77
	Asthma	20/347 (5.8)	25/247 (10.1)	0.06
	COPD	27/347 (7.8)	5/247 (2.0)	0.01
	Heart failure	23/347 (6.6)	7/247 (2.8)	0.04
	Arrhythmias	17/347 (4.9)	12/247 (4.9)	1.00
	Depression	17/347 (4.9)	13/247 (5.3)	0.85
	Ischemic heart disease	18/347 (5.2)	7/247 (2.8)	0.21
Outcomes				
GP Decision making	Referral	265/366 (72.4)	58/254 (22.8)	<0.001
	Home care	101/366 (27.6)	196/254 (77.2)	
Hospitalised		188/346 (54.3)	78/247 (31.7)	<0.001
Intensive care		25/347 (7.2)	9/247 (3.6)	0.07
Death		15/347 (4.3)	2/247 (0.8)	0.01

Figure 2 shows the results of multivariate analysis for hospitalization and a composite outcome of ICU admission and death. For the hospitalization model, abnormal lung POCUS findings were independently associated with hospitalization (RR 1.34, 95%CI 1.07–1.67, $p=0.011$). Other independent predictors of hospitalization included age above 50 years (RR 1.23, 95% CI 1.01–1.51, $p=0.041$), oxygen saturation <95% (RR 1.37, 95% CI 1.14–1.65, $p=0.001$), hypertension (RR 1.42, 95% CI 1.18–1.70, $p<0.001$), and diabetes mellitus (RR 1.31, 95% CI 1.09–1.59, $p=0.005$). No significant difference was observed between study sites (Salamanca vs. Mallorca: RR 0.95, 95% CI 0.73–1.24, $p=0.729$). We constructed a more parsimonious model for a composite outcome of ICU admission/death given the lower event rate (44 events, 7.5%). Abnormal lung POCUS findings were not independently associated with ICU admission or death (RR 1.27, 95% CI 0.62–2.61, $p=0.510$). The only independent predictors were heart failure (RR 3.04, 95% CI 1.51–6.14, $p=0.002$) and oxygen saturation lower than 95% (RR 2.85, 95% CI 1.48–5.49, $p=0.002$). Study site (POCUS device) was excluded from the model, as we encountered complete

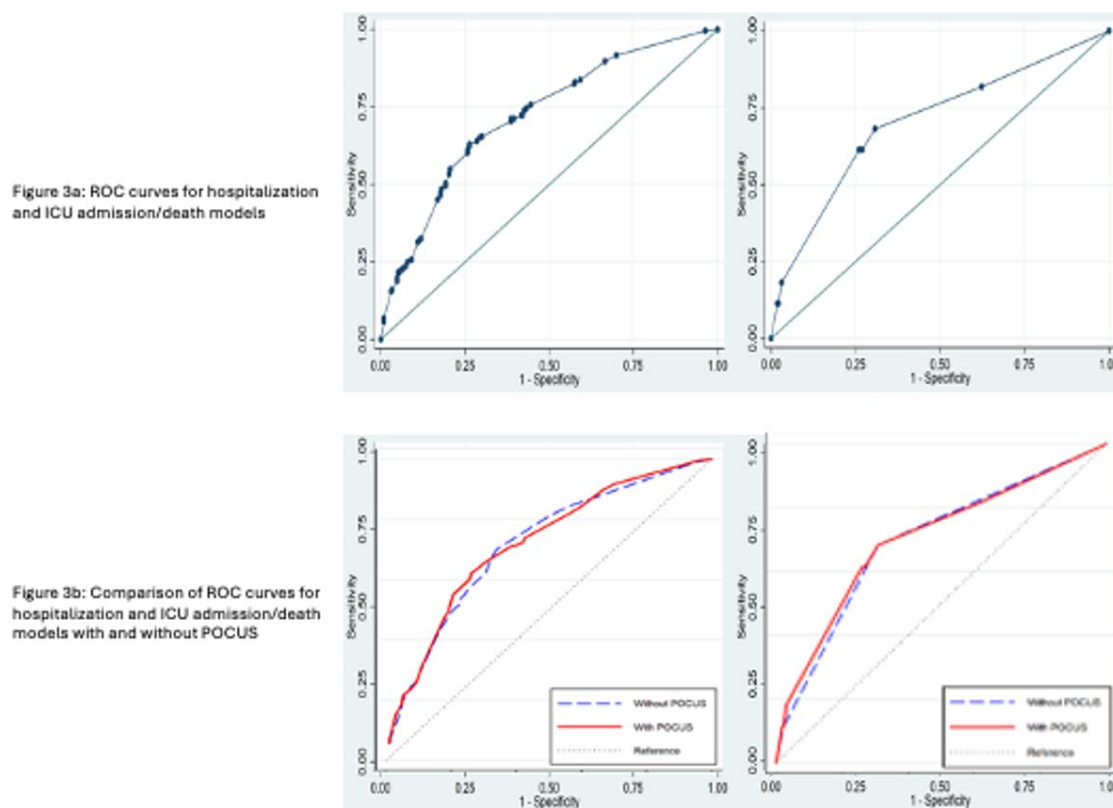
separation: all 44 events ICU admission/death occurred at the Mallorca site, precluding reliable estimations probably due to the smaller sample size at Salamanca size (15.6% of total cohort).

Figure 2: Adjusted Risk Ratios for Hospitalization and ICU/Death



The hospitalization model showed good discrimination (AUC 0.72, 95% CI 0.68–0.76) and correctly classified 68.6% of patients; the ICU/death model had an AUC of 0.70 (95% CI 0.62–0.79) and correctly classified 69.2% of patients (Figure 3a). Both models displayed excellent calibration and stable performance after bootstrapping internal validation, with minimal optimism in discrimination and calibration slopes. Multiple imputation including all 624 participants produced effect estimates and AUCs almost identical to complete-case analyses, confirming the robustness of the findings (Supplementary Information). Adding POCUS to clinical predictors produced only a negligible, non-significant increase in AUC for hospitalization (from 0.716 to 0.720) and did not improve prediction of ICU admission or death (Figure 3b). Reclassification indices and decision-curve analyses showed that POCUS provided no clinically meaningful incremental benefit over simple clinical variables and, for hospitalization, tended to up-classify non-hospitalized patients into higher-risk categories.

Figure 3: ROC curves for hospitalization and ICU admission/death models



In the diagnostic sub study (n=381 patients with chest X-ray), lung POCUS showed a sensitivity of 68.3% and specificity of 43.6% for COVID-19 pneumonia, with a positive predictive value of 78.7% (Table 3). Pleural abnormalities with ≥ 3 B-lines had a sensitivity of 58.5%, a specificity of 56.4%, and a positive likelihood ratio of 1.34, while lobar consolidation was highly specific (94.7%) but infrequent.

Table 3. POCUS estimated validity parameters for pneumonia in COVID-19 patients.

		Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	LR+ (95% CI)	LR- (95% CI)
<i>Overall (381)</i>		68.3 (196/287) (62.7-73.4)	43.6 (41/94) (34-53.7)	78.7 (196/249) (73.2-83.3)	31.1 (41/132) (23.8-39.4)	1.21 (1.16-1.26)	0.73 (0.67-0.79)
<i>POCUS findings (381)</i>	Pleural abnormalities with ≥ 3 B-lines	58.5 (168/287) (52.8-64.1)	56.4 (53/94) (46.3-66.0)	80.4 (168/209) (74.5-85.2)	30.9 (53/172) (24.4-38.1)	1.34 (1.27-1.42)	0.74 (0.7-0.77)
	Sub-pleural consolidation	32.8 (94/287) (27.6-38.4)	72.3% (68/94) (62.6-80.4)	78.3% (94/120) (70.2-84.8)	26.1% (68/261) (23.5-31.7)	1.18 (1.05-1.33)	0.93 (0.91-0.95)
	Lobar consolidation	3.1 (9/287) (1.7-5.9)	94.7 (89/94) (88.2-97.7)	64.3 (9/14) (38.8-83.7)	24.3 (89/367) (20.2-28.9)	0.59 (0.00-728.2)	1.02 (1.02-1.03)

Discussion

This study is one of the few studies conducted in primary care to assess the predictive value of lung POCUS, performed by PCPs in a primary care health centre or in the patient's home, for adverse events in COVID-19 patients. The study shows a limited value for lung POCUS findings for predicting hospitalization of COVID-19 patients. The most common findings on lung POCUS were the presence of three or more B-lines with pleural line abnormalities (50.3%), followed by subpleural consolidation (27.6%) and lobar consolidation (3.4%). Patients with positive lung POCUS findings were more frequently referred to a hospital emergency department, and the risk of being admitted to the hospital was significantly more frequent than those without lung involvement. The likelihood that their illness would require ICU admission or turn out to be fatal was higher in univariate analysis but not confirmed in multivariate analysis. We have also observed that lung POCUS abnormalities in COVID-19 patients are independently associated with SpO₂ lower 95%, age over 50 years old, and certain comorbidities as hypertension and diabetes in predicting hospitalization. The results reveal a modest diagnostic value for COVID-19 pneumonia compared to chest X-rays.

Previous studies conducted in hospital settings have shown good predictive performance of lung POCUS performed on patients with SARS-CoV-2 infection. Studies with hospitalised patients found a significant positive correlation between LUS findings and several markers of disease severity, including C-reactive protein ^{5,9,35}, ferritin ³⁵, D-dimer, hypersensitive troponin I, creatine kinase muscle-brain ⁵, lactate dehydrogenase, and fibrinogen ⁹. LUS findings have also been associated with an elevated risk of intensive care unit admission and death in several studies ^{4-9,36,37}, while others, probably due to small sample size, did not find this association ³⁵. When comparing the two studies performed in a primary care environment, we found that their results correlate well with the findings in our study in terms of hospitalisation risk and ultrasound findings. Calvo-Cebrian et al. observed an association between the severity of lung POCUS findings and the appropriateness of referral to the hospital emergency department, defining appropriateness as the referral that benefits patients in terms of hospital admission or prescription of a specific treatment ¹¹. Another study carried out in a health centre in Catalonia showed that evolutionary patterns, diffuse, attenuated diffuse, and unilateral predominant

interstitial patterns represented risk factors for hospitalization¹². These two studies have some differences from ours. Our patients had SARS-CoV-2 infection confirmed by RT-PCR, whereas the Calvo et al.¹¹ study only includes patients with suspected infection, and the Martinez et al. study includes patients with and without laboratory confirmation. Furthermore, there are notable variations in the expertise of the medical professionals who conducted the ultrasounds. In Martínez's study¹², all ultrasounds were performed by a single doctor who was an expert in ultrasound. In Calvo's study, however, five experts participated. Our research was conducted in two distinct regions, with the involvement of a range of medical professionals with varying degrees of experience. In our study, lung POCUS abnormalities were frequent and were associated with a higher likelihood of hospital referral and admission, while their association with mortality and ICU admission disappeared after multivariable adjustment. In fully adjusted Poisson models, abnormal lung POCUS findings remained independently associated with hospitalization, together with age ≥ 50 years, oxygen saturation below 95%, hypertension, and diabetes, whereas for ICU admission/death only heart failure and low oxygen saturation emerged as independent predictors. Both prognostic models showed good discrimination and excellent calibration, supporting their overall performance in a high-prevalence, pre-Omicron primary care setting. The extended analyses indicate that adding lung POCUS findings to a clinical model (age, oxygen saturation, comorbidities, and study site) leads to only a minimal, non-significant increase in AUC for hospitalization (from 0.716 to 0.720), and no clinically relevant improvement in discrimination for ICU admission or death. Reclassification metrics reinforce this limited added value: for hospitalization, categorical NRI was slightly negative and IDI very small, mainly because POCUS tended to up-classify non-hospitalized patients into higher-risk categories, thus increasing false-positive risk estimates. For ICU admission/death, POCUS did not improve model performance, showed no independent association with the outcome, and decision-curve analysis demonstrated virtually overlapping net benefit curves for models with and without POCUS across clinically relevant thresholds.

The diagnostic value of lung POCUS in this study is lower than the results achieved in previous studies, both in the hospital and emergency department^{27,38-40} and in primary care^{12,28}. Several circumstances may partly explain the differences found. Several meta-analyses

conducted before and after the pandemic show high variability in the way the outcome of pneumonia is defined.^{19,25} Some studies define the outcome according to the result of the PCR performed, with or without the opinion of a multidisciplinary team^{27,28,38,40}. Other studies compare lung POCUS with hospital admission and certain clinical findings in patients¹². Few studies used CT scans as the gold standard diagnostic test^{18,41}, and in some studies, CT scans were only performed in patients with abnormalities on lung POCUS or chest X-ray²⁶. In our study, all patients had a positive RT-PCR at the time of enrolment, and all but one of the patients included in the diagnostic validation analysis received a chest X-ray.

The external validity of these findings should be interpreted considering the current clinical landscape, which has evolved substantially since the study period. The emergence of new SARS-CoV-2 variants, and widespread vaccination have altered disease presentation and management. Consequently, the predictive and diagnostic utility of POCUS observed in this study primarily reflects a high prevalence setting during the pre-Omicron era, when vaccination coverage was incomplete. Moreover, the increasing adoption POCUS in primary care, with more and better-trained family doctors, might produce different results if the study were repeated today.

Strengths and limitations

The prospective design of this study facilitates accurate and comprehensive data collection, thereby minimizing recall and selection biases. The sample size of this study is the largest among studies on the diagnosis of COVID-19 using lung POCUS in a primary care setting. The use of POCUS in primary care has experienced a surge in recent years and evaluating its diagnostic value in conditions as close to real-life scenarios as possible, including patients visited in their own homes, is of paramount importance. A key strength of this study lies in the advantages of performing lung POCUS within primary care settings, particularly its immediacy at the point of clinical decision-making and its portability, which enables examinations to be conducted even in patients' homes.

The use of Poisson regression with robust variance estimators, explicit assessment of EPV, and a comprehensive evaluation of discrimination, calibration, and internal validity strengthens the reliability of the prognostic findings. Calibration-in-the-large, calibration slope, NRSS, and graphical calibration plots all indicated excellent agreement between predicted and observed risks for both models, with only modest overfitting that remained within acceptable limits after bootstrap correction. Multiple imputation analyses yielded risk ratios, confidence intervals, and AUC estimates that were almost identical to complete-case results, supporting the missing-at-random assumption and the robustness of the main conclusions regarding both hospitalization and ICU/death.

Our patients have fewer comorbidities than those in previous studies conducted in hospital departments^{10,35,37,42}. These differences could be explained by the fact that patients in primary care generally present less severe symptoms and fewer concomitant diseases than those attended in hospitals. In this sense, 58% of our patients had POCUS abnormal findings, compared with 81% in patients in emergency departments³⁵, and 91-96% in studies done in hospital wards.^{8,36} In any case, studies conducted in primary care do not document the presence of comorbidities. This limitation hinders the capacity to undertake direct comparisons. The same applies to the clinical signs recorded. Studies that collect data such as heart rate, respiratory rate, SpO₂, and temperature show variable results, although, in general, their patients present a worse clinical situation than ours^{10,37,43}. Social and family support, as well as the availability of home isolation as required by existing protocols, may have influenced the decision to refer patients to hospital emergency departments in some cases. We do not know the extent of this influence on our results but, given that home isolation depended on a positive SARS-CoV-2 test result, not on the severity of the illness, we assume it had a similar impact on both the referred and non-referred patient groups.

Our study was unable to use CT scan as a gold standard due to the circumstances at the time of the study, when its use was restricted as much as possible. The use of different reference standards—chest X-ray and CT scan—may have introduced a differential verification bias. The small number of chest CT scans performed (31) seriously limited the robustness of subgroup

analysis. Despite the existence of previous recommendations for the use of lung POCUS⁴⁴, there is a high variability in different aspects of the methodology used. The findings to be considered, the number of zones scanned, and the competency of LUS examiners remain undefined^{22,23}. The most common recommendations were adopted, including the findings to be considered and the 12-zone protocol. The 12-zone protocol has the advantage of being more specific and thus provides a general impression of lung compromise³¹. B-lines, the ultrasound most frequently observed sign in cases of COVID-19 pneumonia, have been identified in a range of other lung conditions, including pulmonary oedema of various aetiologies (e.g. heart failure), diffuse parenchymal lung disease (pulmonary fibrosis), lymphangitic neoplastic dissemination, and ARDS (adult respiratory distress syndrome)⁴⁴.

Training time in lung POCUS also needs to be addressed. PCPs who participated in the study received a 5-hour training supervised by LUS experts. due to the urgency in assessing COVID-19 patients with worsening symptoms in the community. It was designed to be highly focused and practical, tailored to the urgent context of the COVID-19 pandemic and based on existing national protocols for lung POCUS in primary care. The training included theoretical instruction, supervised hands-on practice, and standardised image interpretation criteria. All physicians had prior experience in clinical ultrasound and were part of regional ultrasound training programs. Although basic ultrasound image acquisition and interpretation skills can be learned by physicians of varying experience after a brief training course⁴⁵, there is a lack of clear guidelines for LUS training and certification⁴⁶. A consensus of 28 experts considered that LUS has a steep learning curve in the evaluation of interstitial syndrome⁴⁰. Other authors have proposed at least 10-25 LUS scans supervised by experts to acquire sufficient competence⁴⁷. A study on the use of LUS in the diagnosis of pneumonia in children found significant differences in performance between novice and LUS-experienced professionals²⁰. Nevertheless, even among LUS experts, the levels of inter- and intra-observer agreement tend to be moderate, with higher disagreement specifically in findings related to COVID-19 pneumonia, like pleural thickening and B-lines⁴⁸. Our study did not evaluate inter-observer agreement.

The use of mobile devices for performing and registering POCUS can be considered both as a strength and as a limitation. A strength because mobile devices allow POCUS outside health

centres, and a limitation due to the possible discrepancy in performance between portable ultrasound scanners and the high-end devices available in healthcare centres. We could not adjust for study site and type of device on the ICU/death outcome due to complete separation as all outcomes' events occurred exclusively at the Mallorca site. Nevertheless, the model showed good discrimination and calibration, with an adequate EPV ratio (14.7). A systematic review on this topic found that portable devices demonstrated comparable performance to high-end devices in specific domains, such as the detection of ascites, hydronephrosis, screening for abdominal aortic aneurysms, and care of obstetric and gynaecological patients ⁴⁹. Nonetheless, the review determined that there remained a paucity of evidence to support the utilization of portable devices in the abdominal or pleural regions.

In conclusion, this study indicates that lung POCUS performed by PCPs in primary care settings or at the patient's home could help identify COVID-19 patients at increased risk of hospitalization, although its diagnostic value for COVID-19 pneumonia compared to chest X-ray appears to be limited. These findings may be of interest in settings with limited access to radiology, whether due to availability or distance. They may also be of interest to home-based patients whose mobility is compromised for one reason or another. Furthermore, the findings presented here emphasise the importance of the development of standardised guidelines and highlight the relevance of achieving consensus on lung ultrasound scanning methodology, as well as on the training requirements for PCPs. This standardisation work will help to ensure the reliable use of lung POCUS in primary care settings. Moreover, further research is necessary to evaluate the role of lung POCUS in diagnosing COVID-19 pneumonia under contemporary variants and vaccination patterns, as well as community acquired pneumonia of any aetiology in primary care.

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Data availability

The anonymized database will be available at the Zenodo website <https://zenodo.org/records/18325908>

Competing interests

All authors declare no financial or non-financial competing interests.

Author's contribution

ME, JIRM, JC, CG, AM, and AA conceptualised the study. JC and AA participated in training PCPs. ME, CG, AM, JIRM, and AA designed the research. ME, CG, AM, and OB coordinated data acquisition and information management. OB performed the statistical analysis. BO, OB, and ME wrote the original draft. All authors reviewed and edited all draft versions and the final one and approved it for submission.

Ethics

This study obtained the approval of the Balearic Islands (IB 4530/21 PI) and the Salamanca (PI-2021-10881) Research Ethics Committees.

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Figure titles and legends

- Figure 1:
 - Title: Flowchart of included patients
- Figure 2:
 - Title: Adjusted Risk Ratios for Hospitalization and ICU/death
 - Legend: Adjusted for all shown variables.
◆ $p < 0.05$ ○ $p > 0.05$
- Figure 3:
 - Title: ROC curves for the prediction of hospitalization and ICU admission/death
 - Title Figure 3a: ROC curves for the prediction of hospitalization and ICU admission/death
 - Title Figure 3b: Comparison of ROC curves for the prediction of hospitalization and ICU admission/death with and without lung POCUS
- Table 1: Baseline characteristics of included patients
- Table 2: Bivariate analysis of comparative findings in patients with positive POCUS findings versus negative POCUS findings
- Table 3: POCUS estimated validity parameters for pneumonia in COVID-19 patients.

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