1	Point-of-care Lung Sonography:
2	an Audit of 1150 Exams
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26	Running Head: Lung Ultrasound in Clinical Practice
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29	Declarations
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- 61 Abbreviation list
- 62 *CAP:* community-acquired pneumonia;
- 63 *CI*: confidence interval:
- 64 *COPD*: chronic obstructive pulmonary disease;
- 65 *CT:* computed tomography scan.

- 67 Abstract
- 68 Background: Point-of-care lung ultrasonography has theoretical usefulness in
- numerous diseases, however clinical indications and impact of this technique remain
- 70 not fully investigated. We aimed to describe the current use of lung ultrasonography.
- 71 Methods: A two years prospective observational study was performed by
- 72 pulmonologists in an Italian University Hospital. Technique, indications,
- 73 consequences of lung ultrasound and barriers to the examination were analyzed.
- Results: 1150 lung ultrasounds were performed on 951 subjects. The most common
- 75 indications were diagnosis and follow-up of pleural effusion in 361 cases (31%),
- evaluation of lung consolidation (322, 28%), acute heart failure (195, 17%), guide to
- pleural procedures (117, 10%), pneumothorax (54, 5%) and acute exacerbations of
- 78 chronic obstructive pulmonary disease (30, 3%). The mean duration time of the
- examination was 6 ± 4 minutes. The probes most frequently used were convex (746,
- 80 65%) and linear (161, 14%), while in 205 examinations (18%) both probes were used.
- According to the judgment of the caring clinician, 51% of the exams were clinically
- 82 relevant.

Conclusions: Point-of-care lung ultrasound performed by pulmonologists is quick, feasible, and could be widely employed in different clinical indications with a potential high clinical impact. The widespread use of the technique may have a relevant clinical impact in several indications.

Key words: lung imaging, community-acquired pneumonia (CAP), pneumonia diagnostics, lung ultrasound, pleural effusion, pneumothorax.

INTRODUCTION

In the past decades, point-of-care clinical ultrasound received a growing attention particularly in emergency and critical care medicine. In these settings, the technique proved to be clinically relevant in the assessment of various organs, such as the heart, vessels and the abdominal parenchymal organs. Ultrasound has the advantages of being a radiation free procedure, does not require patient transportation and is less expensive than computed tomography (CT). Point-of-care ultrasonography may be performed and interpreted at bedside by the same clinician in charge of the patient. The caring physician has the deepest knowledge of the patient clinical condition and history and, if adequately trained to the interpretation of point-of-care ultrasound, may provide immediate answer to key questions regarding early diagnosis and treatment. In many acute respiratory conditions quick answers to diagnostic dilemmas may potentially affect patient outcome. In this field, a consolidated application of chest ultrasound is the diagnosis and management of pleural effusion. However, ultrasound may also diagnose and monitor pneumothorax, community-acquired (CAP) and ventilator associated pneumonia, pulmonary congestion and

atelectasis, (13-16) and may be useful in the bedside differentiation between acute exacerbation of chronic obstructive pulmonary disease (COPD) and acute decompensated heart failure. (17) The growing evidences on the efficacy of these new applications are summed up in dedicated international recommendations. (18) However, there are scanty data concerning the application of the technique in the clinical practice of respiratory medicine. (19) Despite the theoretical usefulness of the technique, there could be barriers in the execution of the exam, and accuracy may show differences compared to study protocols, where only dedicated and high skill personnel perform the examinations.

The primary aim of our study was to describe the current use of point-of-care lung ultrasound in an academic Italian hospital. Second aims were to assess: clinical impact, barriers, and overall accuracy of lung ultrasound.

121 METHODS

Setting and timing

This prospective study took place in a 605-bed Italian University Hospital (San Paolo, Milan) from May 2012 to April 2014. Patients were consecutively enrolled in the different settings where pulmonologists were working permanently or on call. The study settings were: pulmonology ward and the related outpatient service, emergency department, pediatric, obstetrics and gynecology department, and internal medicine and surgical wards. The study was approved by the local Ethics Committee (San Paolo Hospital, protocol number: 0006368).

Ultrasound machines

5 ultrasound systems were used, three cart-based (My Lab 50, Esaote, Genoa, Italy;
Logiq P5 Pro, General Electric, Wauwatosa, USA; Aloka IPC 1231V, 6-22-1, Mure,
Mitakashi, Tokyo, Japan) and two hand-held (My Lab 25 and 30CV, Esaote, Genoa,
Italy). All systems had B- and M-mode, color-Doppler functions with pulsed wave,
and convex and linear probes.

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Study protocol

Lung ultrasound examinations were performed at the bedside on patients both hospitalized and referred for ambulatory consultation according to the current standard clinical practice of our institution and strictly following clinical practice requests and timing. Operators were respiratory physicians, or residents under tutor supervision. All of them observed the most accredited international recommendations⁽¹⁸⁾ and had expertise in the field of respiratory medicine, performing yearly an average of 100 chest ultrasonography procedures. On the basis of image quality and patient cooperation, after each ultrasound examination the operator scored the quality of the exam as adequate, sufficient or poor, similarly to the method published by Schacherer et al.. (20) After the examination the operator recorded the main clinical indication, the most important findings of the exam standardized in patterns, probes used, imaging modalities applied (B-mode, M-mode, color-Doppler), duration time and the significant clinical consequences of the ultrasound examination. The operator also reported whether there were any kind of barriers to the execution of the exam and, if present, described them. Data were recorded on a dedicated webdatabase. The final diagnosis was made by the treating physician at the end of the diagnostic work-up (i.e. at discharge for inpatients).

156 We considered a predefined list of sonographic clinical indications that included 157 pneumonia, pleural effusion, acute exacerbations of COPD, acute heart failure, 158 pneumothorax, lung or pleural cancer, pulmonary embolism, guidance for pleural procedures, evaluation of undifferentiated dyspnea and of diaphragmatic function. (18, 159 21) 160 161 The ultrasound findings were standardized in patterns according to international 162 guidelines for point-of-care lung ultrasound as described in the online supplement. (18) 163 164 Assessment of diagnostic accuracy 165 The final diagnosis was confirmed by the treating physician at the end of the 166 comprehensive diagnostic workup of the patient, which corresponded to the hospital 167 discharge in case of inpatients or at the conclusion of consultation in outpatients. The 168 overall diagnostic accuracy for the first diagnosis of lung consolidation, interstitial 169 syndrome, and pneumothorax was analyzed by comparing the ultrasound pattern with 170 the final diagnosis verified by an independent committee of two pulmonologists. 171 Follow-up exams were excluded from accuracy analysis. 172 173 **Assessment of clinical impact** 174 After the execution of lung ultrasound, the operator was asked whether the ultrasound 175 examination was decisive to take specific clinical decisions, was orienting for further 176 imaging (computed tomography), or whether it had no consequences on the decision-177 making process. Similarly to Medford and Entwisle, the clinical impact of ultrasound was considered significant if one of the following criteria was encountered: (22) 178

1. Resolution of equivocal findings on chest X-ray (such as pleural effusion, lung

congestion, lung consolidation or pneumothorax);

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- 181 2. Detection of effusion, congestion, consolidation, subpleural infarction or
- pneumothorax not visible on chest X-ray;
- 3. Localization of safe/optimal site for performing pleural procedures;
- 4. Detection of significant unexpected complex effusion and clarification of the solid
- or fluid nature of radiologic opacities detected at chest X-ray;
- 186 5. Resolution of equivocal clinical examination findings;
- 6. Conclusion of the diagnostic process without the need of chest X-ray or CT scan.

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Statistical analysis

- Demographic data and results of exams were reported as means (±SD) for continuous
- 191 data. Ordinal and discrete variables were described as counts and proportions.
- 192 Confidence Intervals (CIs) were used when appropriate. Descriptive statistics were
- 193 performed by using a commercially available software (SPSS version 21.0 for
- 194 Windows; SPSS Inc.).

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196 RESULTS

- We performed 1150 lung ultrasounds on 951 patients (table 1). The examining
- 198 physicians were 16: 7 certified pulmonologists and 9 residents under direct
- supervision. Study settings are reported in figure 1.
- There were barriers to the execution of the ultrasound in 12 (1%) cases. These
- 201 limitations were due to difficulties in assessing posterior regions in patients under
- mechanical ventilation (5 cases) or impaired patient mobility (2 cases), in patients
- with severe obesity (3 cases), in one case of severe cognitive impairment, one case of
- agitation in acute severe thoracic pain and one non collaborating 2 year-old patient.

205 Main lung ultrasound clinical indications are reported in figure 2. In suspected lung 206 consolidation, the final diagnosis was pneumonia in 205 cases (63.4%), lung or 207 pleural cancer in 15 (4.7%), bronchiolitis in 10 (3.1%), pleuritis in 9 (2.8%), acute 208 bronchitis in 7 (2.2%), empyema in 3 (0.9%), acute decompensated heart failure in 3 209 (0.9%) and pulmonary fibrosis in 2 (0.6%). Finally, in 68 cases (21.1%) no 210 pulmonary disease was found. 211 Ultrasound patterns observed were: simple pleural effusion in 375 exams (32.6%), 212 normal in 217 (18.8%), lung consolidation in 163 (14.3%), consolidation with pleural 213 effusion in 98 (8.5%), acute cardiogenic pulmonary edema with or without pleural 214 effusion in 123 (10.7%), complex pleural effusion in 66 (5.7%), atelectasis in 51 215 (4.5%), pulmonary fibrosis in 46 (4.0%), pneumothorax in 11 (1.0%). 216 The overall diagnostic accuracy was limited to cases in which ultrasound was 217 performed as first evaluation (574 exams). In this population the observed lung 218 ultrasound pattern was concordant with the final diagnosis in 564/574 patients, 98.3% 219 of the cases (CI 95%, 96.6-99.1%). There were 4 false positives: 3 cases of small 220 subpleural lung consolidations, 2 in pediatric patients with bronchiolitis and 1 in an 221 asthmatic exacerbation with negative chest X-ray; in another case pericardial fat was 222 misdiagnosed as a lung consolidation. Six false negative cases were reported. Four 223 central lesions (3 consolidations and a ground glass opacity) not reaching the pleural 224 line, 2 cases of subpleural infarctions, radio-occult at chest X-ray but detected at chest 225 CT scan. 226 Lung ultrasound correctly influenced the clinical decision, including treatment, in 584 227 cases (51%), oriented the diagnostic work-up for further imaging in 134 (12%), and 228 had no consequences in 432 (38%).

DISCUSSION

We analyzed a large number of lung ultrasound exams performed during the daily
clinical work-up by a large number of operators with different skills and expertise. To
our knowledge, no audit had previously evaluated such a large number of lung
ultrasound exams with various indications. We observed that, when lung ultrasound
was used, it led to a significant clinical impact in approximately half of the cases.
Recently published guidelines state that ultrasound should be the standard of care in
the management of pleural effusion. (6) Rahman et al. described the use of respiratory
physician-delivered ultrasound, consisting of 960 scans performed in 645 patients
over three years. (23) Similarly to our study, the authors reported an overall diagnostic
accuracy of 99.6% and concluded that lung ultrasound performed by clinicians is safe
and effective in the management of pleural effusion. Moreover, Qureshi et al.
described the usefulness of lung ultrasound in differentiating malignant from benign
effusions, showing that the usefulness of ultrasound may be extended to more
advanced diagnostic targets. (24) Concerning all the other indications of lung
ultrasound, there are several research studies validating the application for CAP,
ventilator associated pneumonia, pneumothorax and acute respiratory failure.
However, the use of lung ultrasound outside research protocols and the conventional
application for pleural effusion still remains to be evaluated. Medford and Entwisle
assessed prospectively all the clinical indications and impact of thoracic ultrasound in
80 patients. Pleural effusion was the most common indication (75%), but
ultrasound was also used to assess diaphragmatic function and pleural thickening or
chest masses. Similarly, our data reflect the real clinical practice. However, we also
included some new indications for lung ultrasound, such as the evaluation of the lung
parenchyma for consolidations and interstitial syndromes, the diagnosis of CAP, acute

decompensated heart failure, pulmonary fibrosis, exacerbation of COPD, and pneumothorax. Despite our analysis was targeted to a vast list of pulmonary conditions, reflecting heterogeneity of the real clinical use, we found a good overall accuracy value, similar to the one obtained in the study by Rahman et al.

The distinctive feature of point-of-care ultrasound is to provide rapid answer to crucial clinical questions arising at bedside. This is particularly applied in critical care settings such as the intensive care unit and the emergency department. The lung ultrasound technique that was applied in our study allowed, on average, the execution of examinations in a very short time and was mostly performed by using basic sonography. Notably, in our series lung ultrasound influenced an immediate clinical decision in more than half of cases. Our results are in line with the study of Medford and Entwisle, who found that lung ultrasound modified patient's management in 65% of cases. In the study of Lichtenstein et al. the systematic application of lung ultrasound changed the therapeutic plans in only 22% of critically ill patients admitted to the intensive care unit, a discrepancy that may be explained by the high complexity of selected critically ill patients.

Limitations and strengths of the study

The first limitation of our study is that it is monocentric. As such, it is not said that our results can be extended to other institutions. However, we analyzed a large number of patients from different specialty departments and wards, and lung ultrasound examinations were performed by several operators with different levels of skill and expertise. This large heterogeneity should mitigate the limitation of a monocenter enrollment. In our study the operators encountered barriers to the ultrasound

280 lung ultrasound. 281 A second limitation of our study is combining the audit of the current clinical practice 282 with the prospective evaluation of the diagnostic accuracy of lung ultrasound. This 283 may have influenced the results, because the operator was not blinded to the clinical 284 data of the patient, as this reflects the standard of care. However, our primary aim was 285 to represent the real world of the practice of lung ultrasound in an academic 286 institution. This limitation should be considered for a correct interpretation of results 287 in the overall accuracy of lung ultrasound. 288 A further limitation is that we did not measure the inter-operator variability of the 289 diagnostic application of lung ultrasound. However, lung ultrasound is based on quite 290 simple signs and many previous studies showed very low inter-operator variability for 291 many applications. 292 Finally, even if we showed that lung ultrasound changed the clinical decision in more 293 than half of our cases, the study was not conceived to evaluate the impact of lung 294 ultrasound on the clinical outcome. Future studies should investigate this issue. (25) 295 296 **CONCLUSIONS** 297 Lung ultrasound is a feasible, rapid, and accurate procedure applicable to many 298 pathological conditions, with a significant clinical impact. Further studies are required 299 to better define the role of lung ultrasound in patient diagnosis and management and 300 to assess its impact on patient outcome.

examination in a very low percentage of the exams, supporting the high feasibility of

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383 Table

Table 1. Characteristics of patients and lung ultrasounds performed

Characteristics Number (%) **Patients** 951 53% Males Age, years 60 ± 28 **Pediatrics** 161 (17%) Lung ultrasound (follow-up) 1150 (17%) Exam quality (adequate, sufficient, poor) (89%, 10%, <1%)Duration, min. 6 ± 4 One probe (convex, linear, sector) 914, 80% (65%, 14%, 1%) Two probes (convex and linear, sector and linear, 226, 20% (18%, 2%, <1%) sector and convex) B-mode alone 1065 (93%) Other modes or combinations* 85 (7%)

387 *Other modes or combinations includes M-mode and Color-Doppler alone or in 388 combination with B-mode. 389 390 391 392 393 394 Figure Legends 395 Figure 1. 396 The figure shows the settings where point-of-care lung ultrasound was performed in 397 our Institution. Data are expressed as absolute values and percentage. Pulm. amb. = 398 Pulmonology Ambulatory, Pulm. ward = Pulmonology ward, Med. ward. = Internal 399 medicine ward, Pediatric = Pediatric Department, E.D. = Emergency Department, 400 others = other medical and surgical wards. 401 Figure 2. 402 The figure shows the main indications for the lung ultrasound examinations recorded 403 in our series. AHF = acute heart failure, PNX = pneumothorax, AECOPD = acute 404 exacerbations of chronic obstructive pulmonary disease, others include pulmonary 405 embolism and evaluation of diaphragmatic function.