

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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31 Committee (San Paolo Hospital, Milan, Italy, protocol number: 0006368).

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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.

66

67 *Abstract*

68 Background: Point-of-care lung ultrasonography has theoretical usefulness in
69 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.

74 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%),
76 evaluation of lung consolidation (322, 28%), acute heart failure (195, 17%), guide to
77 pleural procedures (117, 10%), pneumothorax (54, 5%) and acute exacerbations of
78 chronic obstructive pulmonary disease (30, 3%). The mean duration time of the
79 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.
81 According to the judgment of the caring clinician, 51% of the exams were clinically
82 relevant.

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

87

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

90

91

92 **INTRODUCTION**

93 In the past decades, point-of-care clinical ultrasound received a growing attention
94 particularly in emergency and critical care medicine.⁽¹⁾ In these settings, the technique
95 proved to be clinically relevant in the assessment of various organs, such as the heart,
96 vessels and the abdominal parenchymal organs.⁽²⁻⁴⁾ Ultrasound has the advantages of
97 being a radiation free procedure, does not require patient transportation and is less
98 expensive than computed tomography (CT). Point-of-care ultrasonography may be
99 performed and interpreted at bedside by the same clinician in charge of the patient.
100 The caring physician has the deepest knowledge of the patient clinical condition and
101 history and, if adequately trained to the interpretation of point-of-care ultrasound, may
102 provide immediate answer to key questions regarding early diagnosis and treatment.⁽⁵⁾
103 In many acute respiratory conditions quick answers to diagnostic dilemmas may
104 potentially affect patient outcome. In this field, a consolidated application of chest
105 ultrasound is the diagnosis and management of pleural effusion.⁽⁶⁾ However,
106 ultrasound may also diagnose and monitor pneumothorax,⁽⁷⁻⁹⁾ community-acquired
107 (CAP) and ventilator associated pneumonia,⁽¹⁰⁻¹²⁾ pulmonary congestion and

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

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

120

121

METHODS

122 **Setting and timing**

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

130

131 **Ultrasound machines**

132 5 ultrasound systems were used, three cart-based (My Lab 50, Esaote, Genoa, Italy;
133 Logiq P5 Pro, General Electric, Wauwatosa, USA; Aloka IPC 1231V, 6-22-1, Mure,
134 Mitakashi, Tokyo, Japan) and two hand-held (My Lab 25 and 30CV, Esaote, Genoa,
135 Italy). All systems had B- and M-mode, color-Doppler functions with pulsed wave,
136 and convex and linear probes.

137

138 **Study protocol**

139 Lung ultrasound examinations were performed at the bedside on patients both
140 hospitalized and referred for ambulatory consultation according to the current
141 standard clinical practice of our institution and strictly following clinical practice
142 requests and timing. Operators were respiratory physicians, or residents under tutor
143 supervision. All of them observed the most accredited international
144 recommendations⁽¹⁸⁾ and had expertise in the field of respiratory medicine,
145 performing yearly an average of 100 chest ultrasonography procedures. On the basis
146 of image quality and patient cooperation, after each ultrasound examination the
147 operator scored the quality of the exam as adequate, sufficient or poor, similarly to the
148 method published by Schacherer et al.⁽²⁰⁾ After the examination the operator recorded
149 the main clinical indication, the most important findings of the exam standardized in
150 patterns, probes used, imaging modalities applied (B-mode, M-mode, color-Doppler),
151 duration time and the significant clinical consequences of the ultrasound examination.
152 The operator also reported whether there were any kind of barriers to the execution of
153 the exam and, if present, described them. Data were recorded on a dedicated web-
154 database. The final diagnosis was made by the treating physician at the end of the
155 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
159 procedures, evaluation of undifferentiated dyspnea and of diaphragmatic function.^{(18,}
160 ²¹⁾

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
178 was considered significant if one of the following criteria was encountered:⁽²²⁾

179 1. Resolution of equivocal findings on chest X-ray (such as pleural effusion, lung
180 congestion, lung consolidation or pneumothorax);

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

188

189 **Statistical analysis**

190 Demographic data and results of exams were reported as means (\pm 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.).

195

196

RESULTS

197 We performed 1150 lung ultrasounds on 951 patients (table 1). The examining
198 physicians were 16: 7 certified pulmonologists and 9 residents under direct
199 supervision. Study settings are reported in figure 1.

200 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
202 mechanical ventilation (5 cases) or impaired patient mobility (2 cases), in patients
203 with severe obesity (3 cases), in one case of severe cognitive impairment, one case of
204 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%).

229

DISCUSSION

230

231 We analyzed a large number of lung ultrasound exams performed during the daily
232 clinical work-up by a large number of operators with different skills and expertise. To
233 our knowledge, no audit had previously evaluated such a large number of lung
234 ultrasound exams with various indications. We observed that, when lung ultrasound
235 was used, it led to a significant clinical impact in approximately half of the cases.

236 Recently published guidelines state that ultrasound should be the standard of care in
237 the management of pleural effusion.⁽⁶⁾ Rahman et al. described the use of respiratory
238 physician-delivered ultrasound, consisting of 960 scans performed in 645 patients
239 over three years.⁽²³⁾ Similarly to our study, the authors reported an overall diagnostic
240 accuracy of 99.6% and concluded that lung ultrasound performed by clinicians is safe
241 and effective in the management of pleural effusion. Moreover, Qureshi et al.
242 described the usefulness of lung ultrasound in differentiating malignant from benign
243 effusions, showing that the usefulness of ultrasound may be extended to more
244 advanced diagnostic targets.⁽²⁴⁾ Concerning all the other indications of lung
245 ultrasound, there are several research studies validating the application for CAP,
246 ventilator associated pneumonia, pneumothorax and acute respiratory failure.
247 However, the use of lung ultrasound outside research protocols and the conventional
248 application for pleural effusion still remains to be evaluated. Medford and Entwisle
249 assessed prospectively all the clinical indications and impact of thoracic ultrasound in
250 80 patients.⁽²²⁾ Pleural effusion was the most common indication (75%), but
251 ultrasound was also used to assess diaphragmatic function and pleural thickening or
252 chest masses. Similarly, our data reflect the real clinical practice. However, we also
253 included some new indications for lung ultrasound, such as the evaluation of the lung
254 parenchyma for consolidations and interstitial syndromes, the diagnosis of CAP, acute

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

259 The distinctive feature of point-of-care ultrasound is to provide rapid answer to
260 crucial clinical questions arising at bedside.⁽¹⁾ This is particularly applied in critical
261 care settings such as the intensive care unit and the emergency department.^(4, 20) The
262 lung ultrasound technique that was applied in our study allowed, on average, the
263 execution of examinations in a very short time and was mostly performed by using
264 basic sonography. Notably, in our series lung ultrasound influenced an immediate
265 clinical decision in more than half of cases. Our results are in line with the study of
266 Medford and Entwisle, who found that lung ultrasound modified patient's
267 management in 65% of cases.⁽²²⁾ In the study of Lichtenstein et al. the systematic
268 application of lung ultrasound changed the therapeutic plans in only 22% of critically
269 ill patients admitted to the intensive care unit, a discrepancy that may be explained by
270 the high complexity of selected critically ill patients.⁽⁴⁾

271

272 *Limitations and strengths of the study*

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

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

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383 Table

384 **Table 1. Characteristics of patients and lung ultrasounds performed**

385

Characteristics	Number (%)
Patients	951
Males	53%
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, sector and convex)	226, 20% (18%, 2%, <1%)
B-mode alone	1065 (93%)
Other modes or combinations*	85 (7%)

386

387 *Other modes or combinations includes M-mode and Color-Doppler alone or in
388 combination with B-mode.

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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.