Original Paper

Neonatology

Neonatology 2019;115:77–84
DOI: 10.1159/000493001

Received: May 5, 2018
Accepted after revision: August 17, 2018
Published online: October 10, 2018

Lung Ultrasound for the Differential Diagnosis of Respiratory Distress in Neonates

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Keywords
Neonatal intensive care · Point-of-care ultrasound · Chest X-ray

Abstract
Background: Respiratory distress (RD) is the most common neonatal illness. Lung ultrasound (LUS) is a technique previously tested in neonatal studies on RD, but literature regarding its routine clinical applicability is still lacking. ***Objective:*** To assess the concordance between LUS performed by neonatologists with different training levels and chest X-ray (CXR) for the diagnosis of RD in newborns during the first 24 h of life. ***Methods:*** We enrolled newborns with RD during the first 24 h of life. Patients underwent LUS and CXR. LUS and CXR diagnosis were compared to evaluate concordance. Twenty percent of patients received two LUS (one from an experienced and one from a novice sonographer) to calculate the interobserver agreement. The difference in time needed to reach a diagnosis with LUS and CXR, and from novice and expert operators, was measured. ***Results:*** We studied 124 patients; 134 diagnoses were reported. The concordance between LUS and CXR diagnosis was 91% (95% CI 86–96%) with a κ statistic of 0.88 (95% CI 0.81–0.94). The median time to diagnosis was shorter for LUS (9.5 min, IQR 5–15) than for CXR (50 min, IQR 33–64) ($p < 0.0001$). In 25/124 patients, LUS was performed by both novice and experienced sonographers with complete concordance. The median time to diagnosis was shorter for expert (9 min, IQR 5–15) than novice operators (15 min, IQR 10–20) ($p < 0.0002$). ***Conclusion:*** LUS and CXR have a high concordance in the differential diagnosis of neonatal RD in the first 24 h of life. LUS has a shorter operation time than CXR.

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Introduction

Neonatal respiratory distress (RD) during the first 24 h after birth is one of the most common neonatal pathologies and requires timely and appropriate treatment. It is the most frequent reason of admission to neonatal intensive care units (NICUs), and the differential diagnosis may be challenging [1–3].

In clinical practice, the standard management of infants with RD always includes chest X-ray (CXR) as first-line imaging technique [4–7]. CXR has a wide inter- and intraobserver variability and exposes patients to the risk of radiation [8].

Bedside lung ultrasound (LUS) has gained considerable interest, and recent studies suggest that ultrasound assessment is a promising diagnostic tool in neonates with RD [1, 3–5, 7, 9–16]. However, the main limitation of most previous studies is that a single experienced sonographer performed all the examinations, which does not allow generalization of findings and definitive consideration of LUS as a screening and/or diagnostic tool in neonates. Indeed, Nguyen [17] pointed out the question of LUS training regimen implementation for standardizing the interpretation of findings and favoring the diffusion of this examination in pediatric patients.

The aim of our study was to evaluate the concordance rate between LUS and CXR in diagnosing the etiology of neonatal RD during the first 24 h of life by neonatologists having different training levels.

Methods

Study Design and Setting

This prospective single-center study was carried out in the NICU of Careggi University Hospital of Florence (Italy) and ran from September 2015 to December 2016 with approval from the local ethics committee. The study adhered to the Standards for Reporting of Diagnostic Accuracy (STARD) criteria for research [18].

Infants were enrolled if they were ≥23 weeks of gestational age and had RD requiring CXR in the first 24 h of life. Signs of RD were tachypnea (respiratory rate >60/min), dyspnea (grunting, nasal flaring, chest retraction), and need of oxygen supplementation or other respiratory support. Exclusion criteria were lack of parental consent or necessity of cardiopulmonary resuscitation. Infants with a prenatal diagnosis of congenital disease were enrolled when sonographers were blinded to the prenatal diagnosis.

Interventions

All infants who were admitted to the NICU for RD during the first 24 h of life received CXR, and those eligible for the study underwent LUS. Clinical decisions were not driven by LUS findings. Sonographers were blinded to the patient's medical history, gestational age, ventilation mode, and CXR results during LUS. The same applies to the neonatologist who performed the radiological diagnosis.

LUS were performed by novice neonatologists (E.G., C.C., V.L., C.P., M.G., T.B.), with one exception (I.C.). Novice sonographers, defined as neonatologists with no previous experience with LUS, attended a 2-h training session and a 30-min hands-on training.

Table 1. Lung ultrasound diagnostic criteria for various neonatal respiratory diseases

Respiratory distress syndrome [8]
Bilateral sign of
1 abnormalities of the pleural line (thickened and irregular pleural line)
2 white lung image
3 absence of spared area in all lung fields
Transient tachypnea of the newborn [3]
1 normal, thickened, or blurry pleural line, and
2 double lung point (presence of very compact B-lines in the inferior pulmonary fields and less compact B-lines in the superior fields) (in one or both lungs) or
3 numerous noncompact B-lines (in one or both lungs)
Pneumothorax [19]
1 absence of sliding sign
2 presence of lung point
3 absence of B-line in the affected area
Pneumonia [16]
1 pleural line abnormalities: disappearance, irregularity, disruption, and coarse appearance
2 lung consolidation: hepatization of the subpleural lung tissues determined by air or fluid bronchograms
3 disappearance of lung sliding
4 lung pulse (not essential criteria): replacement of lung sliding by pulsation that is synchronized with the heart rate
Meconium aspiration syndrome [20]
1 lung consolidation with air bronchogram and irregular margin
2 coalescent B-lines and subpleural consolidations alternating with spared areas
3 different pattern and distribution of the images in the two lungs
Congenital diaphragmatic hernia [21]
1 absence of part of the diaphragm muscle
2 absence of pleural line in the affected side of the chest
3 presence of parenchymal organs in the chest (spleen, liver)
4 presence of bowel loops in the chest
Congenital pulmonary airway malformations
1 absence of pleural line in the affected area
2 lung consolidation in the affected area
3 cystic lesions in the affected area
Pleural effusion
1 anechoic area separating the two pleura

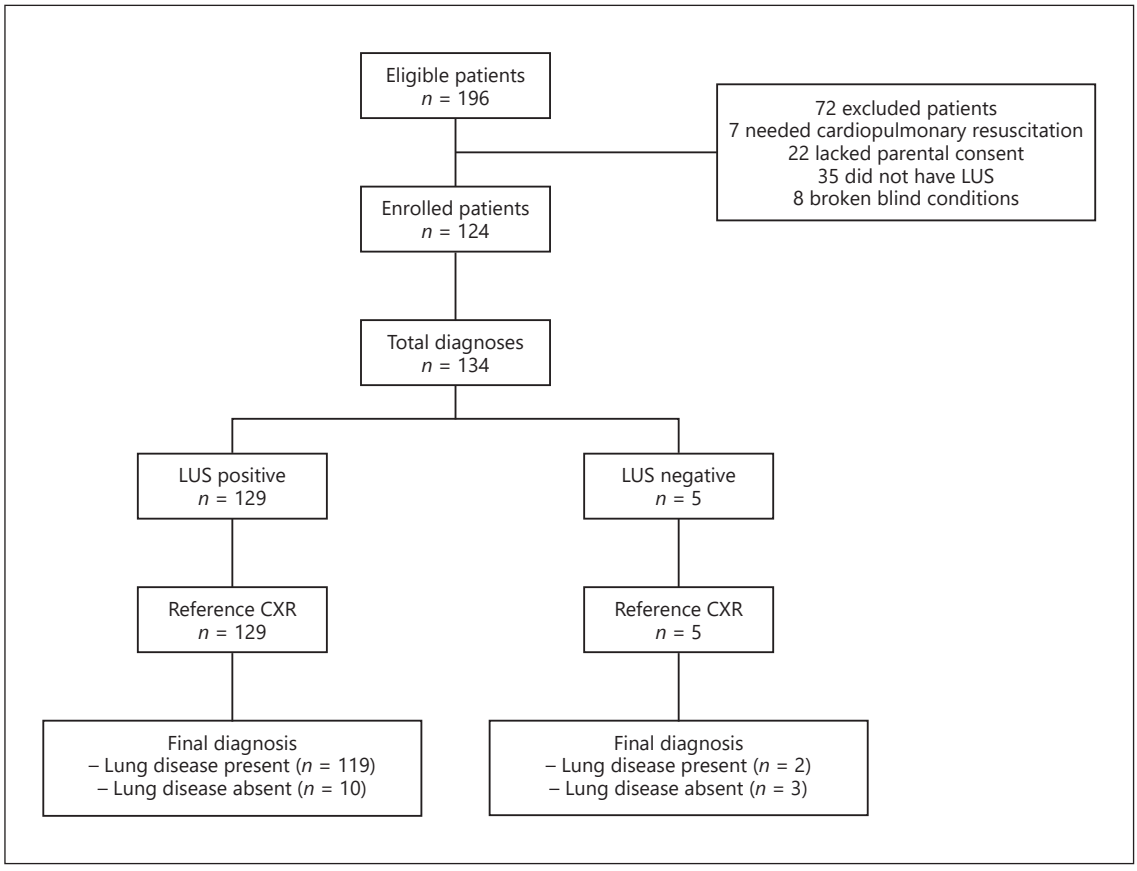

Fig. 1. Standards for Reporting of Diagnostic Accuracy flowchart. CXR, chest X-ray; LUS, lung ultrasound.

After this training session, each neonatologist sonographer had to perform 25 LUS examinations (the number of ultrasounds needed to start enrollment was chosen arbitrarily) in neonates under the supervision of a senior sonographer (I.C., N.P.) to complete the training.

LUS was performed at the bedside with a Philips CX50 ultrasound machine (Philips, Eindhoven, The Netherlands) using a high-frequency (10–12 MHz) linear transducer. Enrolled patients were scanned in six anatomic lung zones: bilateral anterior (parasternal line to anterior axillary line), lateral (anterior axillary line to posterior axillary line), and posterior (posterior axillary line to paravertebral line) chest walls in sagittal planes with patients in the supine or lateral recumbent position. One scan for each zone was obtained and one video clip of each anatomical area was recorded on the machine hard disk. Transverse intercostal planes with maximum extension of the visible pleura were obtained at the discretion of the clinician to highlight the presence of focal artifacts. Transabdominal scanning for lung bases was done by transhepatic and transsplenic views. Subcostal view was also used to investigate the diaphragm.

The LUS diagnostic criteria for various neonatal respiratory diseases are detailed in Table 1 [3, 8, 16, 19–21]. In case the diagnostic criteria for each disease were fulfilled only partially, we assigned the diagnosis that satisfied the largest number of criteria.

Moreover, to evaluate interobserver agreement and operation time variability, a random sample of 20% of enrolled patients had two consecutive LUS, one from an experienced and one from a novice sonographer.

To assess the learning curve of novice sonographers for the use of LUS, we calculated the total number of LUS necessary to achieve perfect agreement with CXR. This number resulted from the 25 supervised LUS examinations (training described above) added to the variable number of LUS necessary to be performed by novice sonographers in order to reach agreement with CXR.

CXRs were obtained in anterior-posterior view and lateral views were performed as needed. Radiograph interpretations, diagnosis, and management decisions were made by senior neonatologists according to local protocols.

A senior pediatrician (N.P.) with 8 years of point-of-care ultrasound clinical and teaching experience, who was blind to the patients' clinical condition and the enrolling sonographer's diagnosis, checked the accuracy of the LUS reports and compared LUS and CXR diagnoses to provide a measure of agreement.

We also measured the operation time for LUS and CXR, defined as the interval between the decision to perform the diagnostic test and the final report. Both ultrasound and radiograph equipment were available in the NICU on a 24/7 basis.

Table 2. Demographic and clinical data of the studied population

	Overall population (n = 124)	Term infants (n = 36)	Late preterm infants (n = 17)	Preterm infants <34^{+0} weeks of gestational age (n = 71)
Birth weight, g	1,918±1,152	3,287±552	2,406±756	1,186±640
Gestational age, weeks	33±5	39±3	36±1	30±1
Cesarean section	92 (74%)	29 (47%)	11 (35%)	62 (87%)
Female	48 (39%)	10 (28%)	8 (47%)	30 (42%)
Singleton	75 (61%)	33 (92%)	12 (71%)	30 (42%)
Apgar score				
1 min	7 (6–8)	8 (7–9)	7 (7–8)	7 (6–8)
5 min	8 (8–9)	9 (8–9)	8 (8–9)	8 (8–9)
Mechanical ventilation	21 (17%)	5 (14%)	2 (12%)	14 (20%)

Values are presented as mean ± SD, median (IQR), or n (%).

Endpoints

The primary endpoint was the evaluation of concordance between LUS and CXR diagnoses. The secondary endpoints were the comparison of LUS versus CXR operation time, the evaluation of the number of LUS necessary to obtain the best possible agreement with CXR, the evaluation of interobserver diagnosis concordance, and the difference in operation time between novice and expert LUS sonographers.

Statistical Analysis

The quantitative clinical characteristics of infants were described as mean and SD for normally distributed values or as median and IQR for nonnormally distributed variables. Categorical variables were reported with frequencies and 95% CIs. Continuous and categorical variables were compared using the Student t test or the χ^2 test, respectively. Concordance between LUS and CXR in the differential diagnosis of RD and between novice and expert sonographers was evaluated with the Cohen unweighted κ statistic. We calculated LUS sensitivity and specificity for each disease using CXR diagnosis as the gold standard. Finally, the operation time of LUS compared to CXR and the operation time of expert versus novice operators was compared using the Wilcoxon rank-sum test due to the nonnormal data distribution.

Assuming a κ coefficient of correlation of 0.85 between CXR and LUS diagnoses, a sample size of 115 patients was calculated to obtain a statistical power of 80% with $\alpha = 0.05$. Data analyses were performed with STATA version 13.0 (StataCorp, College Station, TX, USA).

Results

During the study period, 196 patients were eligible for enrollment, but 72 were excluded because they did not meet the inclusion criteria. Thus, 124 infants were studied and their data analyzed. Moreover, 10 patients had multiple diagnoses, resulting in a total of 134 diagnoses (Fig. 1).

Thirty-six (27%) patients were term infants, 17 (14%) were late preterm infants (34^{+0}–36^{+6} weeks of gestational age), and 71 (59%) were infants <34^{+0} weeks of gestational age. The patients' demographic and clinical characteristics are presented in Table 2. Diagnoses and clinical characteristics were similar in studied patients and in missed eligible patients.

LUS were performed at a median age of 4 h (IQR 1–2 h) of life. The concordance between LUS and the reference standard CXR in the differential diagnosis of RD is reported in Table 3. The 3 patients with normal LUS and CXR findings presented with symptoms that mimicked RD and had a final diagnosis of early-onset sepsis in all cases.

LUS, compared to CXR, had an overall concordance of 91% (122/134 diagnoses, 95% CI 86–96), with a κ statistic of 0.88 (95% CI 0.81–0.94).

The diagnostic test results for each LUS diagnosis (n = 134) performed by neonatologists compared with CXR diagnosis as reference standard is shown in Figure 2a. The LUS test characteristics for each neonatal etiology of RD are reported in Table 4.

The disagreement between LUS and CXR in the classification of RD diseases was due to 6 false-positive LUS diagnoses, 5 pleural effusions (PEs), 1 congenital pulmonary airway malformation (CPAM), 2 false-negative LUS diagnoses of pneumothorax (PNX), and 4 discordant diagnoses. These latter were due to 2 cases of LUS diagnosis of respiratory distress syndrome (RDS) that were classified as transient tachypnea of the newborn (TTN) at CXR and 2 cases of LUS diagnosis of TTN that were classified as RDS at CXR.

The agreement between neonatologists for each LUS and CXR scan is reported in Figure 2b. Six neonatologists performed a median of 20.5 scans each (IQR 19.25–22.5).

Table 3. Concordance between LUS and CXR in the differential diagnosis of respiratory distress in neonates

	CXR (reference standard)									
	RDS	TTN	pneu-monia	MAS	CDH	PE	PNX	CPAM	normal findings	total
LUS										
RDS	**58**	2	0	0	0	0	0	0	0	60
TTN	2	**30**	0	0	0	0	0	0	0	32
Pneumonia	0	0	**6**	0	0	0	0	0	0	6
MAS	0	0	0	**6**	0	0	0	0	0	6
CDH	0	0	0	0	**7**	0	0	0	0	7
PE	0	0	0	0	0	**2**	0	0	5	7
PNX	0	0	0	0	0	0	**8**	0	0	8
CPAM	0	0	0	0	0	0	0	**2**	1	3
Normal findings	0	0	0	0	0	0	2	0	**3**	5
Total	60	32	6	6	7	2	10	2	9	**134**

CDH, congenital diaphragmatic hernia; CPAM, congenital pulmonary airway malformation; CXR, chest X-ray; LUS, lung ultrasound; MAS, meconium aspiration syndrome; PE, pleural effusion; PNX, pneumothorax; RDS, respiratory distress syndrome; TTN, transient tachypnea of the newborn.

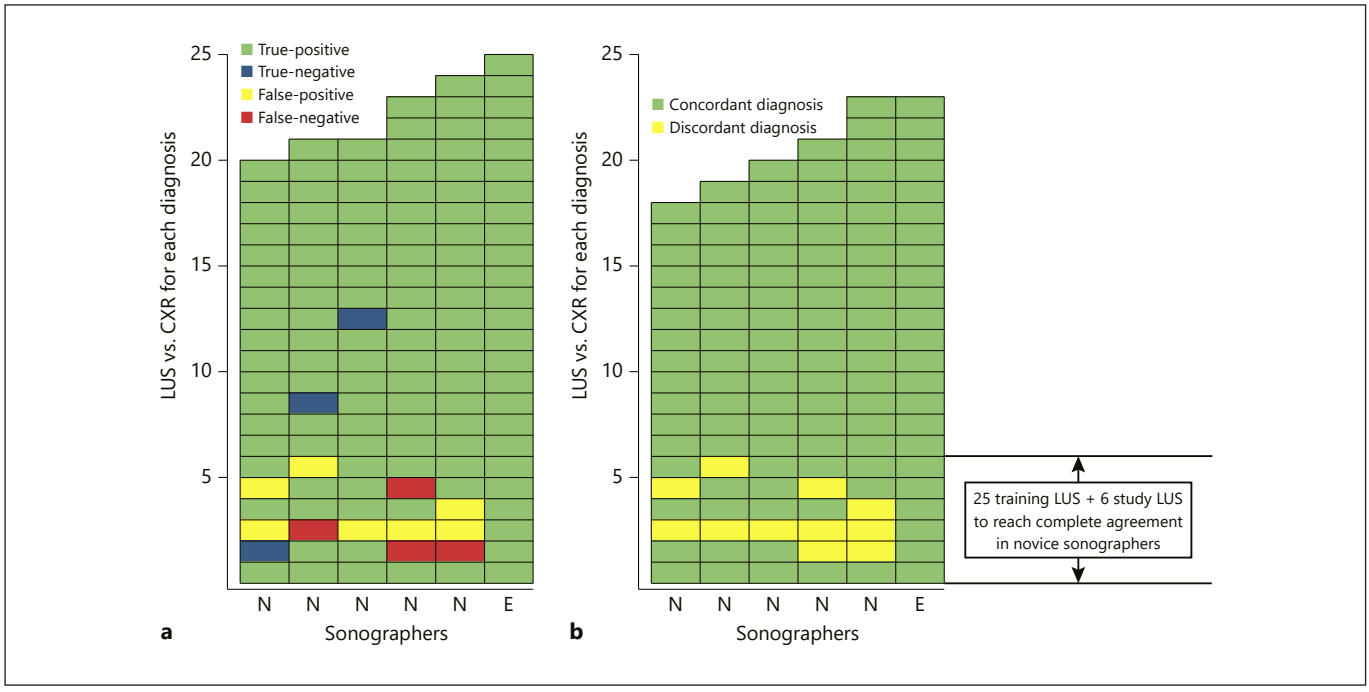

Fig. 2. a Diagnostic results for each LUS diagnosis (n = 134) performed by neonatologists compared with CXR diagnosis as reference standard. Each block represents a single diagnosis performed by the neonatologist. **b** Agreement between neonatologist-performed LUS (n = 124) and CXR as reference standard. Each block represents a patient and therefore the number of LUS scans performed by each novice and expert neonatologist. Colors indicate the test result compared with the reference standard. The blocks are arranged vertically in chronological order with the first LUS scan at the bottom. CXR, chest X-ray; LUS, lung ultrasound; E, expert sonographer; N, novice sonographer.

Table 4. Lung ultrasound test characteristics for each respiratory condition

	n (%)	Sensitivity (95% CI)	Specificity (95% CI)	Agreement	κ statistic (95% CI)
RDS	60 (45%)	96.7 (88.5–99.6)	100.0 (94.4–100.0.0)	96.7%	0.97 (0.92–1.00)
TTN	32 (24%)	100.0 (89.1–100.0)	97.8 (92.4–99.7)	98.4%	0.96 (0.90–1.00)
Pneumonia	6 (5%)	100.0 (54.1–100.0)	100.0 (96.9–100.0)	100%	1 (1.00–1.00)
CDH	7 (5%)	100.0 (59.0–100.0)	100.0 (96.9–100.0)	100%	1 (1.00–1.00)
MAS	6 (5%)	100.0 (54.1–100.0)	100.0 (96.9–100.0)	100%	1 (1.00–1.00)
PNX	10 (7%)	80 (44.4–97.5)	100.0 (96.8–100.0)	98.3%	0.88 (0.72–1.00)
PE	7 (5%)	100.0 (15.8–100.0)	95.9 (90.7–98.7)	95.9%	0.43 (0.03–0.83)
CPAM	3 (2%)	100.0 (15.8–100.0)	99.2 (95.5–99.9)	99.2%	0.80 (0.41–1.00)

CDH, congenital diaphragmatic hernia; CPAM, congenital pulmonary airway malformation; MAS, meconium aspiration syndrome; PE, pleural effusion; PNX, pneumothorax; RDS, respiratory distress syndrome; TTN, transient tachypnea of the newborn.

It took a maximum of 6 LUS per neonatologist during the study period to obtain a complete agreement with CXR. Thus, 31 LUS (25 supervised LUS during the training period and 6 LUS during the enrollment phase) may be the minimum number of ultrasound examinations that warrant a complete agreement with CXR.

The median operation time was shorter for LUS (9.5 min, IQR 5–15) than for CXR (50 min, IQR 33–64) ($p < 0.0001$).

In 25 (19%) patients LUS was performed both by novice and senior sonographers. These patients accounted for 29 diagnoses: 11 RDS, 10 TTN, 3 pneumonia, 2 PNX, 2 PE, and 1 congenital diaphragmatic hernia (CDH). Two LUS were negative, with a complete concordance between novice and senior sonographers and between LUS and CXR.

The median operation time was shorter for senior (9 min, IQR 5–15) than for novice operators (15 min, IQR 10–20) ($p < 0.0002$).

Conclusions

In this study, we evaluated the concordance between LUS and CXR in diagnosing the etiology of neonatal RD when LUS was performed during the first 24 h of life by neonatologists with different training levels. We found that concordance was high in our setting (91%). The high level of agreement between LUS and CXR, even in operators with different levels of training, suggests that LUS could be used in routine clinical practice to overcome the main limitation of previous studies in which LUS was performed by a single experienced sonographer. On the other hand, our findings are consistent with those of Brusa et al. [22], who previously demonstrated that LUS has high interobserver agreement, even between sonographers with different levels of experience.

Our study confirms the high level of accuracy of LUS for diagnosing the most common respiratory neonatal diseases, such as RDS, TTN, and pneumonia [9, 10, 12, 16]. Moreover, in agreement with Liu et al. [20] and Piastra et al. [23], we found that LUS is accurate also for diagnosing meconium aspiration syndrome. With regards to the diagnosis of PNX, we found that LUS is more accurate than previously reported [24], considering that our two false-negative diagnoses of PNX were made in neonates with small and not clinically relevant PNX. Thus, our data confirm that LUS is excellent for the detection of critical and clinically relevant PNX, as recently reported by Raimondi et al. [19]. With the exception of a case report [21], we report for the first time data on the diagnosis of CDH by LUS, detailing that LUS may play a role in the postnatal diagnosis of this disease. Studies designed specifically to assess this role will be necessary.

Analyzing the discordant diagnoses between LUS and CXR, we noted 6 false-positive LUS diagnoses (1 CPAM and 5 PE). However, we believe that this limit could be overcome by performing serial LUS to disclose discordant diagnoses, as occurs in the clinical practice for other ultrasound examinations, such as cerebral echography. Nevertheless, these results negatively affect LUS and CXR concordance, but they do not mean that the accuracy of LUS is worse than that of CXR. In fact, the patient with the discordant diagnosis of CPAM subsequently underwent routine chest computed tomography which confirmed the LUS diagnosis, denying the CXR result. For ethical reasons the 5 patients with an LUS diagnosis of PE did not undergo further imaging (i.e., computed tomography) which would have potentially supported or ex-

cluded the LUS finding. Of note, previous literature demonstrated that LUS is more accurate than CXR in the diagnosis of small PEs in adults [25].

LUS takes a short training time to achieve a complete agreement with the reference standard CXR. We found that 31 LUS (25 supervised LUS during the training period and 6 LUS during the enrollment phase) may be the minimum number of ultrasound examinations that may warrant a complete agreement with CXR.

We have shown through our experience that the operator's skills in LUS and the corresponding accuracy naturally improve over time as the operator gains experience. LUS can be performed after a relatively brief learning curve, although it requires proper training and the correct clinical interpretation of the LUS patterns. Although the number of 25 LUS we adopted was arbitrary and far from being validated, it can be regarded as a threshold to compare sonographers' ability to perform LUS examinations, an ever-growing technique with a strong interoperator variability.

We confirmed that LUS needs a shorter execution time than CXR (9.5 vs. 50 min), particularly in the hands of expert ultrasonographers. The complete concordance between expert and novice sonographers confirms that the little training necessary for novice sonographers was effective. Thus, our results suggest that the implementation of LUS in clinical practice can favor a prompt differential diagnosis and treatment of RD in term and preterm infants. However, our results on the shorter duration of execution of LUS compared to CXR must be critically evaluated and contextualized within the organization of a single department. Each NICU presents its own organization, and therefore such results may not be generalizable.

The major limitation of this study was the relatively small size of our population which does not allow for a robust evaluation of the concordance between LUS and CXR for some uncommon conditions (i.e., CPAM, PE, CDH), although this was not the objective of our study. Another weakness was the monocentric design of the study. In our investigation, novice and expert sonographers demonstrated a perfect interobserver agreement that may be due to the small sample size of patients selected for this secondary outcome. Of note, we were able to describe the number of LUS required by novice sonographers to reach a perfect agreement by the time they began the training to enroll patients. A multicenter study might better evaluate the accuracy of LUS as a diagnostic tool, interobserver agreement, and the possibility of implementing LUS in clinical practice.

LUS, as supported by our results, has many advantages, but we should acknowledge other limitations and risks, such as patient discomfort due to the use of ultrasound gel, temperature control in neonates, and the risk of transmitting infections via the ultrasound probe, which are absent with the use of CXR.

In conclusion, this study proves that LUS and CXR have a high concordance in the differential diagnosis of RD in term and preterm infants during the first 24 h of life. LUS had a shorter operation time than CXR and was effectively performed by novice sonographers after a short training period. Our results support the implementation of LUS in clinical practice as a diagnostic tool in the neonatal care of patients with RD.

Acknowledgments

We gratefully acknowledge Ron Berant, MD from the Pediatric Emergency Medicine Department, Schneider Children's Medical Center of Israel, for reviewing the manuscript for and conceptual advice.

Statement of Ethics

This prospective single-center study was carried out in the NICU of Careggi University Hospital of Florence (Italy) with approval from the local ethics committee.

Disclosure Statement

None of the authors have any financial relationships relevant to this article or potential conflicts of interest to disclose. No external funding was received for this paper.

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