

Feasibility and Safety of Substituting Lung Ultrasonography for Chest Radiography When Diagnosing Pneumonia in Children

A Randomized Controlled Trial



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BACKGROUND: Chest radiography (CXR) is the test of choice for diagnosing pneumonia. Lung ultrasonography (LUS) has been shown to be accurate for diagnosing pneumonia in children and may be an alternative to CXR. Our objective was to determine the feasibility and safety of substituting LUS for CXR when evaluating children suspected of having pneumonia.

METHODS: We conducted a randomized control trial comparing LUS with CXR in 191 children from birth to 21 years of age suspected of having pneumonia in an ED. Patients in the investigational arm underwent LUS. If there was clinical uncertainty after ultrasonography, physicians had the option to perform CXR. Patients in the control arm underwent sequential imaging with CXR followed by LUS. The primary outcome was the rate of CXR reduction; secondary outcomes were missed pneumonia, subsequent unscheduled health-care visits, and adverse events between the investigational and control arms.

RESULTS: There was a 38.8% reduction (95% CI, 30.0%-48.9%) in CXR among investigational subjects compared with no reduction (95% CI, 0.0%-3.6%) in the control group. Novice and experienced physician-sonologists achieved 30.0% and 60.6% reduction in CXR use, respectively. There were no cases of missed pneumonia among all study participants (investigational arm, 0.0%: 95% CI, 0.0%-2.9%; control arm, 0.0%: 95% CI, 0.0%-3.0%), or differences in adverse events, or subsequent unscheduled health-care visits between arms.

CONCLUSIONS: It may be feasible and safe to substitute LUS for CXR when evaluating children suspected of having pneumonia with no missed cases of pneumonia or increase in rates of adverse events.

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ABBREVIATIONS: CXR = chest radiography; EDLOS = ED length of stay; LUS = lung ultrasonography; PED = pediatric ED

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Pneumonia is the leading cause of death in children worldwide.¹ Children with pneumonia may initially present with fever, cough, and tachypnea. However, these signs and symptoms are commonly seen in viral respiratory infections as well and therefore do not reliably predict bacterial pneumonia.² Other clinical examination findings, including those obtained by means of auscultation, have also proven to be unreliable.³⁻⁵ Chest radiography (CXR) is considered the test of choice for diagnosing pneumonia in children. The World Health Organization, however, has estimated that as many as three-quarters of the world's population do not have access to diagnostic imaging.⁶

Use of point-of-care lung ultrasonography (LUS) is growing,⁷⁻⁹ with published international evidence-based recommendations available.¹⁰ LUS for diagnosing

pneumonia in children has been shown to be highly accurate in multiple settings.^{9,11,12}

Given the limited availability of radiography in the developing world, LUS may be a substitute for CXR in the diagnosis of pneumonia.⁶ In health-care settings with access to advanced imaging, LUS may also function as a triage instrument to determine the need for CT or magnetic resonance imaging (in cases of complex pneumonia) or as an add-on test when prior imaging, such as CXR, is nondiagnostic.¹³ Additionally, as ultrasonography is portable, less costly than radiography, and safe for children,¹⁴ it may be the imaging modality of choice for all health-care settings for the diagnosis of pneumonia. Our objective was to determine the feasibility and safety of substituting LUS for CXR when evaluating children suspected of having pneumonia.

Materials and Methods

We conducted a randomized control trial of diagnostic tests¹⁵ from August 1, 2012, to July 31, 2013, at an urban pediatric ED (PED). Our institutional review board, the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai, approved this study 12-00153. The study population was a convenience sample of patients (enrolled 24 hours a day, 7 days a week by available study physicians) who met predetermined inclusion criteria and from whom written informed consent and assent in those ≥ 7 years of age had been obtained from the patient or guardian prior to enrollment into the study.

Inclusion criteria consisted of patients from birth to 21 years of age presenting to the PED with clinical suspicion of having pneumonia requiring CXR for evaluation. Pneumonia was suspected in patients with a combination of fever, cough, tachypnea, or abnormal findings at auscultation. We excluded patients with a previously performed CXR or those who were hemodynamically unstable.

Before enrollment, study physicians assessed for signs and symptoms of pneumonia. Physicians obtained a history on a standardized data collection form, documenting presence or absence of fever, cough, difficulty breathing, chest pain, and abdominal pain. Triage vital signs were recorded.

Study sonologists (physicians who obtained and interpreted ultrasonographic images) consisted of 15 PED attending physicians and fellows with varying levels of point-of-care ultrasonographic experience. They underwent a 1-hour LUS training session prior to study start. A six-zone scanning protocol of the chest (video with scanning protocol, normal lung and pneumonia: <https://youtu.be/R60PgPKQNeU>)

was used as described by Shah et al,¹² imaging the chest in perpendicular planes in the midclavicular line anteriorly and posteriorly on the chest, and in the midaxillary line from the axillae to the diaphragm. Training consisted of a 30-minute lecture on recognition of disease¹⁶⁻¹⁸ (Fig 1) and potential errors followed by a 30-minute hands-on scanning session of normal models.¹² Similar to methods used in prior studies,^{11,12} study sonologists used the sonographic finding of lung consolidation with air bronchograms as the definition of pneumonia on LUS.¹⁰ For purposes of analysis, subcentimeter pneumonia was defined as focal lung consolidations with sonographic air bronchograms less than 1 cm in diameter that are undetectable with CXR (video: <https://www.youtube.com/watch?v=JHmBillu5oQ&feature=youtu.be>).¹² B-lines (defined as hyperechoic vertical reverberation artifact arising from the pleural line to the bottom of the ultrasound screen without fading, and move synchronously with lung sliding),¹⁰ confluent B-lines, and small subpleural consolidations (with no air bronchograms) as described by Caiulo et al¹⁷ and Tsung et al¹⁸ were considered ultrasonographic findings viral in etiology.

Random Assignment

Eligible subjects were randomly assigned using an Internet-based randomization program (www.SherlockMD.org). Patients were assigned to investigational and control arms with the use of permuted blocks of variable lengths, stratified by sonologist experience. All PED staff, patients, and guardians were aware of group assignments, as blinding of allocation was not feasible for this study.

Study Intervention

All subjects randomly assigned to the investigational arm underwent LUS with use of a 10- to 5-MHz linear-array transducer (M-Turbo; SonoSite). If there was clinical uncertainty, or if the referring physician, admitting service, or guardian requested CXR, the enrolling physician had the option of performing CXR. These reasons for performing CXR were documented on our data collection form. All subjects randomly assigned to the control arm underwent sequential imaging with CXR first followed by LUS. All treatment decisions were left to the physician's discretion. In the investigational arm, enrolling physicians documented LUS interpretations prior to CXR to maintain blinding to CXR results.

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