ABSTRACT
The safety of ultrasound is of particular importance when examining the lungs, due to specific bioeffects occurring at the alveolar air-tissue interface. Lung is significantly more sensitive than solid tissue to mechanical stress. The causal biological effects due to the total reflection of sound waves have also not been investigated comprehensively.

On the other hand, the clinical benefit of lung ultrasound is outstanding. It has gained considerable importance during the pandemic, showing comparable diagnostic value with other radiological imaging modalities.

Therefore, based on currently available literature, this work aims to determine possible effects caused by ultrasound on the lung parenchyma and evaluate existing recommendations for acoustic output power limits when performing lung sonography.

This work recommends a stepwise approach to obtain clinically relevant images while ensuring lung ultrasound safety. A special focus was set on the safety of new ultrasound modalities, which had not yet been introduced at the time of previous recommendations.

Finally, necessary research and training steps are recommended in order to close knowledge gaps in the field of lung ultrasound safety in the future.

These recommendations for practice were prepared by ECMUS, the safety committee of the EFSUMB, with participation of international experts in the field of lung sonography and ultrasound bioeffects.

ZUSAMMENFASSUNG

Andererseits ist der klinische Nutzen des Lungenultraschalls beträchtlich und hat aufgrund der Pandemiesituation einen erheblichen Stellenwert dazugewonnen. Dabei erweist sich dieser bisweilen dem anderer radiologischer Bildgebungsmethoden als ebenbürtig.

Deshalb widmet sich diese Arbeit, basierend auf derzeit verfügbaren Literaturreden, dem Einfluss von Schalleffekten auf das Lungenparenchym und evaluiert bestehende Empfeh-
Introduction

This best practice recommendation gives an overview of current statements and novel findings regarding the safety aspects on the interaction of ultrasound on lung tissue. Based on these data, a best practice recommendation is given to minimise potential risks during routine lung ultrasound applications.

The use of sonography on lung tissue is a valuable Point of Care diagnostic covering almost all medical disciplines [1–4] which is currently summarised by an international consensus [5]. However, due to total reflection at the air-tissue interface, such as occurs during pleural sonography, potential bio-effects of this interaction should be considered. Consideration of these bio-effects should always be balanced with the clinical benefits of using a non-ionising imaging modality such as sonography.

Current literature status concerning lung ultrasound safety

Ultrasound, when used under diagnostic exposure conditions, can cause pulmonary capillary haemorrhage (PCH) in peripheral lung which has been investigated extensively on several animal models [6]. Lung ultrasound (LUS) induced PCH has not been investigated in humans on a pathological level such as in animals. In contrast, observational safety studies in children [7] and during transoesophageal sonography [8] showed no complications including no symptomatic pulmonary haemorrhage.

In large animal models, it was clearly shown that PCH occurred over an acoustic output range that is typical of that emitted during clinical sonographic B-mode (brightness mode) imaging [9]. In addition, it has been shown that sonographic modes with longer pulses such as those used in Doppler induce PCH at lower output levels (low Mechanical Index (MI)) [10]. In addition, shear wave elastography (SWE) and acoustic radiation force impulse (ARFI) sonography techniques emit push pulses with higher intensity and longer durations, that induce reliable PCH on direct pleural exposure as shown in pre-clinical studies [11, 12].

Even though ultrasound induced PCH seems to be a threshold phenomenon, reduction of scan duration, independent of scanning mode, significantly decreases the likelihood of PCH induction and its extent [13, 14]. In obese patients, PCH is much less likely to occur during lung sonography due to the high attenuation of the soft tissue of the chest wall [15].

Earlier statements of the British Medical Ultrasound Society (BMUS) and American Institute of Ultrasound in Medicine (AIUM) point to the likelihood of PCH induction at MI values greater than 0.3 [16, 17].

Sonography induced PCH was shown to be limited to a peripheral depth of 1–2 mm and is related to the size of the transducer. PCH is asymptomatic, does not cause alveolar rupture and does not require interventions [18, 19]. Diagnostic concerns arise, however, due to the fact that PCH can generate LUS signs such as the vertical hyperechoic artefacts (B Lines) and White Lung Syndrome (WLS) and may lead to an incorrect presentation of LUS artefacts and therefore diagnosis [11, 13].

To the best of our knowledge, there is no literature on LUS safety in diseased lung nor regarding effects of contrast enhanced sonography on lung. Due to lower MI values, typically used during contrast enhanced ultrasound (CEUS), it may not affect the lung. But studies are required to prove the safety of CEUS on lung tissue.

Therapeutic ultrasound applications are emerging, where focal ablation in proximity to lung is performed [20]. Pre-clinical animal studies showed PCH induction in lung tissue during shock wave treatment of liver [21] and heart tissue at peak negative pressures (PNP) above 1.5 MPa. Such values are similar to diagnostic ultrasound thresholds [22], however due to the use of higher intensities and lower frequencies than in diagnostic sonography, PCH may arise on a larger surface. Even though the lung is not directly targeted, pre-focal and post-focal intensities may expose the lung surface above the PCH threshold. Therefore, treatment planning should consider a sufficient safety margin between focal position and lung during application of therapeutic ultrasound in proximity to lung.

Best Practice Recommendations

Scan Settings and Preparation

A LUS specific Pre-Set should be used or scanner settings in line with the guidelines should be set up prior to any LUS examination [23, 24]. LUS specific Pre-Sets are nowadays available on modern scanners but cover a wide acoustic output range (0.4–1.4 MI). Therefore, the initial output should be adjusted (MI ≤ 0.4) independent of PreSet configuration before any lung examination.

Safety Indices during applications

Independent of mode, sonography of the lung with an MI value of less than or equal to 0.4 can be performed safely without limits on exposure time. Use overall gain and TGC (time gain compensation) for optimal imaging adjustments. For specific diagnostic...
imaging requirements, the output can be increased up to an MI value of 0.7.

In clinical cases where adiposity may limit the field of view, or acoustic obstacles exist in the sonication path, a maximal MI value of 1.0 should not be exceeded in order to minimise the probability of cavitation. In such cases, justified by diagnostic needs, the operator should be aware of the likelihood of PCH induction falsifying diagnostic findings.

The use of the ALARA (As Low As Reasonable Achievable) principle is strongly recommended whenever LUS is performed. When exceeding the initial MI value and depending on the examination requirements, exposure times should be kept as short as possible (1–2 breath cycles).

The use of Doppler during LUS should be applied with an MI ≤ 0.5 and with exposure times as short as possible.

SWE and ARFI sonography techniques should be performed only if the region of interest (ROI—where the shear wave is generated) is located in consolidated, peripheral lung tissue, avoiding direct pleural exposure.

Lung sonography in the neonate should always be performed with the lowest MI value possible and not exceeding 0.4. The use of Doppler as well as SWE and ARFI should not be applied on neonatal subjects until further studies have shown that it is safe to use for this vulnerable patient class.

A summary of output setting recommendations is shown in Table 1.

<table>
<thead>
<tr>
<th>Mode/MI</th>
<th>B Mode</th>
<th>Pulsed Doppler</th>
<th>Elastography (SWE, ARFI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Imaging Initial setting (start) maximum (if needed)</td>
<td>≤ 0.4 ≤ 0.7</td>
<td>always ≤ 0.5</td>
<td>peripheral consolidations only, not recommended for pleural examination</td>
</tr>
<tr>
<td>Neonatal</td>
<td>≤ 0.4</td>
<td>not recommended</td>
<td>not recommended</td>
</tr>
</tbody>
</table>

**Conflict of Interest**

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**References**


