



Safety considerations for shear-wave elastography of the infant brain

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In this issue of *Pediatric Radiology*, El-Ali et al. [1] presented their experience of using shear-wave elastography with cranial ultrasound of the infant brain. The article points to the need for two considerations with regard to neurosonography. First, there is the potential for shear-wave elastography (SWE) to contribute to the diagnostic capabilities of US imaging in the evaluation of the neonatal brain. The ability to perform exquisite US imaging through the anterior fontanelle is useful as a means to assess the brain and identify pathology. The addition of SWE as an US imaging mode and measurement has been proven effective in the assessment of liver stiffness so it is only logical to examine whether the same capabilities can be found in the neonatal brain. Second, the expanded use of SWE to the neonatal brain points to the range of applications where ultrasonography can be used — and the need to ensure that we have adequate education on the safety aspects of ultrasonography. Because the brain is a particularly sensitive organ, we have an obligation not only to find the best diagnostic methodologies but to utilize these in the safest possible way by understanding the benefits and risks.

There is certainly rationale for the use of ultrasonography in the context of the neonate, with the modality's portability, excellent imaging of the brain, lack of ionizing radiation, and real-time imaging that eliminates the motion artifacts seen in other imaging modalities. This is not the first evaluation of SWE in the pediatric brain [2, 3], as pointed out by the authors, and transcranial Doppler is used for evaluating conditions such as stroke risk in people with sickle cell disease. There are reasons why ultrasound, beyond gray-scale imaging, has utility in pediatrics. The authors made the reasonable argument that the logical motivation

for their study was to understand how SWE would be performed by sonographers in the examination of intracranial abnormalities, although in the end they had only eight cases with pathology. It is certainly true that we need to determine the diagnostic capability of any modality under controlled studies where one can reasonably expect a safe and efficacious evaluation. The results of this study are encouraging because differences in shear-wave speed were seen between groups and at statistically significant levels in specific comparisons [1]. Although the limited number of pathological cases likely limited the study, there were trends of increased stiffness in both white matter and deep gray nuclei in the presence of intraparenchymal hemorrhage. So this research is worth pursuing in further studies.

At the same time, the study points to the need to educate those performing ultrasonography about how to limit US exposure. The decrease in examination time with practice (comparison of first and second months) is encouraging because this would be in keeping with the ALARA (as low as reasonably achievable) principle and should be part of all efforts to make US examinations as efficient as possible, thus lowering the overall US exposure. The authors recognized in the discussion section the potential bioeffects associated with ultrasound and the need to reduce exposure time by efficient scanning [1]. They pointed to studies in a small animal model examining effects of extended exposure to ultrasound as used in elastography, where effects appeared transient. It is understood that extrapolation of small animal studies to the conditions found in humans can be challenging but it is appreciated that there is a need to understand the potential for ultrasound bioeffects in what would be a still-developing brain. To this end, the fact that the studies performed in this research were in some cases many days after birth might be more conservative in that the brain was more mature than that in an early study [3].

However, there is concern that no consideration was given to whether the maximum mechanical index was necessary for this research. While it is understood that the authors were using the standard SWE presets, these were developed for other applications such as liver imaging. Use of the higher mechanical index could aid in the signal-to-noise ratio in the

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SWE measurement, particularly at depth, but depth of penetration might not have been an issue in these cases, particularly the preterm and extremely preterm infants. An analysis of the technical failures with an eye toward the relative positions within the brain and their depths might have shed some light on this. The need to educate everyone involved in US imaging to use the ALARA principle is important, not only in terms of overall exposure time but in using the minimum acoustic output necessary for a given examination. There was mention of “educational material and a classroom session on optimal SWE technique,” but the question is whether there was any discussion of the appropriate safety considerations. Although the mechanical index was relatively high, the thermal index used in these studies was 0.7 or less, which is at the level recommended for more extended examination times [4]. But to be clear, the operating conditions for this study [1] were still within the U.S. Food and Drug Administration (FDA)’s regulatory limits and there are other applications in the literature such as ocular imaging where US imaging systems are used outside the appropriate regulatory bounds.

According to the authors, two regions were evaluated and three regions-of-interest attempted in each region, suggesting a total of six SWE evaluations in a given case. In a select number of cases an interobserver comparison was performed where 41 repeat examinations were performed in 14 children. This would be an average of ~3 exams per subject. The interval between these exams was given as 8.8 ± 9.7 days, suggesting that in some cases these could have been closely spaced in some subjects. Again there is no known causal relationship between ultrasonography and an adverse effect, based on data where exposures were limited and the US outputs used were limited at the current FDA regulations [5]. As the authors pointed out, serial US evaluations have been shown to have higher sensitivity [6], so there is rationale for subjects to have such evaluations. Arguably this is no different from serial fetal examinations, particularly with the frequency associated with at-risk subjects. But there should be some recognition of the safety considerations in these subjects.

In the end, we know we need studies to determine the efficacy of SWE in the evaluation of pediatric conditions and we need to balance potential bioeffects with the benefits of the diagnostic information that is obtained. This balance also includes eliminating alternative exams involving other potentially greater risks such as ionizing radiation and requisite sedation. The balance will always be an understanding of risks (and minimizing these) and benefits to the patient.

Compliance with ethical standards

Conflicts of interest Dr. Fowlkes has research collaborations with Philips Healthcare and GE Healthcare.

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