

ACR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND ELASTOGRAPHY

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

The clinical aspects contained in specific sections of this practice parameter (Introduction, Indications, Specifications of the Examination, and Equipment Specifications) were developed collaboratively by the American College of Radiology (ACR) and the Society of Radiologists in Ultrasound (SRU). Recommendations for Qualifications and Responsibilities of Personnel, Written Requests for the Examination, Documentation, and Quality Control and Improvement, Safety, Infection Control, and Patient Education vary among different organizations and are addressed by each separately.

Elastography measures the deformation of tissues after an external stress is applied. Softer tissues deform more than stiffer tissues. There are two major types of imaging-based elastography, strain elastography (SE) and shear wave elastography (SWE).

SE is a qualitative form of elastography that compares relative stiffness between tissues in a field of view (FOV). The stress can be by compression and subsequent release of the tissue by the transducer, intrinsic motion such as breathing or vessel pulsations, or from an acoustic push using acoustic radiation force impulse (ARFI).

A second, quantitative method of determining the stiffness of tissue is SWE. An ARFI pulse is used to generate shear waves within a small area, which propagate perpendicular to the direction of the ARFI pulse. The shear wave speed (SWS) is estimated using B-mode imaging to track micromotion of perturbed tissues. SWE is performed in a small region of interest (ROI), as in point shear wave imaging (pSWE), or over a larger 2-D FOV (2-D SWE). Two-dimensional SWE can be performed either as a single image or in real time. Some vendors provide a quality measure in 2-D SWE. The quality measure assesses the collected raw data and provides information on the reliability of the SWS measurement. The SWE technique is quantitative, measuring SWS in meters per second, which can be converted to stiffness using Young's modulus in kilopascals [1,2].

Each elastography measure has advantages and disadvantages, and the appropriate technique should be used for the specific indication. The appropriate nomenclature should be used when describing the technique used, as recommended by the SRU and World Federation of Ultrasound in Medicine and Biology [3,4].

II. INDICATIONS

There are two major indications for ultrasound elastography: 1) determination of the stiffness of parenchyma of an organ and 2) determination of the stiffness of a lesion.

1. Indications for assessment of stiffness of an organ include, but are not limited to:

a. Liver stiffness

i. Ultrasound elastography is validated in estimating liver fibrosis in adult patients with nonalcoholic fatty liver disease, autoimmune hepatitis, and viral hepatitis [5,6].

ii. Ultrasound elastography can be used to assess the liver in pediatric patients. Examples of conditions where US elastography has been used include nonalcoholic/metabolic fatty liver disease, congenital heart disease (including after corrective surgery), biliary atresia, cystic fibrosis, and glycogen storage disease [37-39]

b. Spleen stiffness

i. Spleen elastography may be added as adjunct to liver elastography or performed separately.

ii. Early studies suggest spleen stiffness may be a surrogate measure of portal pressures in patients at risk for portal hypertension [8].

iii. Spleen stiffness can predict high risk varices [9].

c. Renal stiffness

i. Renal elastography has been studied as a biomarker to predict chronic kidney disease [10], although due to variability in techniques in determining shear wave velocities, previously published data may not be accurate.

ii. Newer, accurate algorithms for measuring renal shear wave velocities have been developed but still need further validation [11].

d. Cervix

- i. Cervical elastography in pregnancy is a marker of cervical softening and may predict pregnancy loss [12].
- ii. Elastography may help differentiate benign from malignant lesions and help predict depth of invasion [12].

2. Indications for assessment of stiffness of a lesion include, but are not limited to, lesions of the:

a. Breast

- i. Addition of elastography to traditional B-Mode evaluation may increase detection of breast cancers in screening patients [13].
- ii. Elastography during diagnostic evaluation may be able to downgrade lesions to avoid unnecessary biopsy [14].

b. Thyroid

- i. Elastography is not used in current thyroid nodule grading schemes, notably ACR Thyroid Imaging Reporting & Data System [15].
- ii. Data are mixed on the added value of elastography to differentiate benign and malignant thyroid nodules. For example, follicular thyroid carcinomas have the same stiffness as normal thyroid, resulting in false-negative evaluation [16-18].

c. Prostate

- i. Elastography in conjunction with B-mode evaluation of the prostate has been shown to improve detection of peripheral zone prostate cancers [19,20].

d. Musculoskeletal

- i. Supraspinatus and infraspinatus tendons show increased stiffness in adhesive capsulitis.
- ii. Tendinopathies present as softening of the tendon, and stiffness can be monitored to evaluate interval healing.
- iii. Median nerve shows increased stiffness in carpal tunnel syndrome [21].

e. Bowel

- i. Elastography when combined with contrast enhanced ultrasound can assess both bowel stiffness and inflammation in patients with inflammatory bowel diseases [22]

2. Eye

- i. Elastography of the eye should be avoided due to energy output to the retina exceeding allowable FDA limits [23].

III. QUALIFICATIONS OF PERSONNEL

To perform accurate elastography, the personnel should meet all requirements of the [ACR–SPR–SRU Practice Parameter for The Performance and Interpretation of Diagnostic Ultrasound Examinations](#) [24]

IV. SPECIFICATIONS OF THE EXAMINATION

All forms of elastography must be performed with minimal initial pressure applied with the transducer because this can substantially affect the results. In general, optimal B-mode images are required to obtain accurate shear wave tracking and elastography results [25]. The Quantitative Imaging Biomarker Alliance (QIBA) SWS biomarker profile provides requirements to minimize bias and optimize reproducibility to achieve specific measurement confidence (https://qibawiki.rsna.org/index.php/Ultrasound_SWS_Biomarker_Ctte).

1. Stiffness of an organ

- a. SE should not be used as it is qualitative and does not give a quantitative stiffness value.
- b. Either pSWE or 2-D SWE (preferred because 2-D SWE allows for visualization of artifacts so that ROI placement can avoid artifacts) should be used.
- c. For liver stiffness, the recommendations of the updated 2020 SRU consensus ("rule of 4") [4] should be used for performing and interpreting the examination [3,26].
- d. For ultrasound evaluation of the liver, the patient should fast for at least 4 hours before the examination. Fasting requirements may be different for neonates. Fasting is not required for ultrasound elastography of other organs (eg, breast, thyroid, and musculoskeletal applications).
- e. The measurements should be taken at a location optimizing the acoustical window. For the liver, this is typically through an intercostal approach.
- f. The examination should be performed in either the supine or the slight lateral position with the right arm raised (for evaluation of the liver) or left arm raised (for evaluation of the spleen) above the head to increase the intercostal space.
- g. The measurements should be taken 1.5–2.0 cm below the liver capsule (1.5 cm for splenic capsule) to avoid reverberation artifact. The optimal location for maximum shear wave generation is generally 4.0–4.5 cm from the transducer.
- h. The transducer should be perpendicular to the organ capsule in both planes.
 - i. Placement of the ROI should avoid large blood vessels, bile ducts, and masses.
 - j. Ten measurements should be obtained from 10 independent images, in the same location, with the median value used for pSWE.
 - k. At least five measurements may be appropriate for 2-D SWE when a quality assessment parameter is used [4].
 - l. The interquartile range to the median ratio (IQR/M) should be used as a measure of quality. A IQR/M $\leq 30\%$ for kPa, and $\leq 15\%$ for m/s, is generally accepted as indicating an accurate data set.
- m. Liver fibrosis may be overestimated if patient has transaminitis, biliary obstruction, acute hepatitis, an infiltrative hepatic disease, or congestive hepatopathy at the time of examination.

2. Stiffness of a lesion

- a. Either SE or 2-D–SWE can be used [27-30]. Because many masses are heterogeneous, the use of pSWE is discouraged because the area of maximum stiffness cannot be determined [31]
- b. SE results can be interpreted either using the elastographic to B-mode ratio (E/B) (breast only), strain ratio (SR), or a five-point color scale [32]
- c. When using the SR, an appropriate reference tissue should be used. When examining breast, adjacent fat is used as the reference tissue. When examining other organs, the normal tissue at a similar distance from the transducer is used as a reference
- d. General technique requirements for SE include:
 - i. Scan with minimal initial transducer compression on the tissue
 - ii. For systems that require manual compression/release, tissue displacement by 1–2 mm is needed
 - iii. For systems that rely on intrinsic motion from patient breathing/vascular pulsations, or from ARFI, transducer should be held stationary
 - iv. Remain at the same plane through the lesion when acquiring data for a given lesion
 - v. Have a large FOV containing several different areas and adjacent normal tissues
- e. General technique requirements for SWE include:
 - i. Scan with minimal compression on the tissues with the transducer
 - ii. Minimize movement
 - iii. Position the patient so the lesion is at least 5 mm deep and < 4 cm deep to the transducer, if possible
- f. The number of measurements to be taken has not been well studied for focal lesions, but at least three measurements may be reasonable.
- g. Lesion stiffness and elastography assessment may assist with breast lesion evaluation but should not override the more predictive morphologic features of malignancy. Practitioners should refer further to the [ACR Practice Parameter for the Performance of a Diagnostic Breast Ultrasound Examination](#)

[33].

V. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Cine clips may be useful. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Images should be labeled with the patient identification, facility identification, examination date, and image orientation. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. Retention of the ultrasound examination images should be consistent both with clinical need and with relevant legal and local health care facility requirements.

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings \[34\]](#).

Because of differences between equipment and scanning techniques, when reporting elastography results, the ultrasound system, transducer used, and patient positioning should be documented.

For liver fibrosis assessment, vendor neutral cutoffs should be used when interpreting median liver stiffness. For SE, the ultrasound system and the display scale should be documented. For breast SE, the E/B distance ratio is recommended and should be reported. If the SR is used, then the tissue used for reference should be documented. For SE, if a color scale is used, the scale should be documented (eg, four-point color scale, five-point color scale, and include which color map is used). For liver stiffness SWE, the number of measurements taken, the median value, and the IQR/M should be reported.

Examples of such documentation include:

1. Strain

SE using manual compression (or ARFI) was performed on the lesion(s). The E/B distance ratio, SR [include reference tissue], color scale [state which one] was used to analyze the data.

- a. For breast: The E/B distance ratio was [#]; this is suggestive of a [soft, stiff] lesion.
- b. For other organs: The strain imaging was interpreted using the SR [include reference tissue] or color scale [state which one]. The result is [give result], which is suggestive of a [soft, stiff] lesion.

2. SWE

a. Liver

Liver stiffness measurements were obtained on a [vendor and machine] using a [probe]; [n] number of valid measurements were obtained using a [pSWE or 2-D SWE] method.

The IQR-to-median ratio was [x], suggesting [an adequate data set [if ratio =30% for kPa and =15% for m/s] or a poor-quality data set].

The media liver stiffness was [x], suggesting [rule of 4 recommended wording [4] or rule of 5 recommend wording if using transient elastography [7]]

b. Breast

Two-dimensional SWE was performed on the lesion(s). The highest stiffness value in the lesion or surrounding tissue was [# m/s and/or kPa]. This is suggestive of a [soft, indeterminate, stiff] lesion. If both SE and SWE are performed, a statement should be made if they are concordant or not.

c. Other single organs

Stiffness values were obtained using [pSWE, 2-D-SWE]. [#] measurements were made with a median value of [# m/s and/or kPa]. [Give conclusion: normal, indeterminate, or abnormal].

d. Other lesions

Two-dimensional SWE was performed on [specify lesion]. The stiffness value was [x m/s and/or kPa]. This is suggestive of a [soft, indeterminate, stiff] lesion.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [35].

The ultrasound equipment should have Food and Drug Administration (FDA)-approved elastography techniques. The power control on all systems should maintain the energy output within the recommended guidelines.

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

Quality Control and Improvement

QIBA, a consortium of the Radiological Society of North America, academia, industry, clinical practitioners, and government, has created a "profile" that describes a consensus standard approach for acquiring reliable shear wave elastographic measurements in chronic liver disease. It also contains requirements for equipment calibration and assessment of personnel performing the acquisitions. The profile makes claims for accuracy of the results (bias and variability) across different machines, operators, and sites that will be met if the profile is followed. The 2022 version is available here:

https://qibawiki.rsna.org/images/1/1b/QIBA_US_SWS_Profile_04.25.2022-clean_version.pdf [36]

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