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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.

2019 (Resolution 26)

ACR–SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF ULTRASOUND ELASTOGRAPHY

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 care. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole 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, ___ N.W.2d ___ (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, breathing, or heartbeat of the patient, or an acoustic push using acoustic radiation force imaging (ARFI).

A second method of determining the stiffness of tissue is SWE. An ARFI pulse is used to generate shear waves, which propagate perpendicular to the ARFI pulse. The shear wave speed is estimated using B-mode imaging. SWE can be performed in a small region of interest (ROI), point shear wave imaging (pSWE), or over a larger FOV—2D-SWE. Two-dimensional--SWE can be performed either as a single image or can be performed in real time. Some vendors provide a quality measure in 2-D--SWE. The quality measure assesses the raw data collected to estimate the shear wave speed and provides information on the accuracy of the measurement. The SWE technique is quantitative, providing a stiffness value either by the shear wave speed in meters per second (m/s) or converting to the Young’s modulus in kilopascals (kPa) [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 World Federation of Ultrasound in Medicine and Biology (WFUMB) [3].

II. INDICATIONS

There are two major indications for ultrasound elastography: (1) determination of the stiffness of an organ (eg, liver in chronic liver disease) and (2) determination of the stiffness of a lesion (eg, a breast mass).

1. Indications for assessment of stiffness of an organ include, but are not limited to:
   a. Liver stiffness, for example in cirrhosis
   b. Spleen stiffness, for example in assessment of portal hypertension

2. Indications for assessment of stiffness of a lesion include, but are not limited to, lesions of the
   a. Breast
   b. Thyroid
   c. Prostate
   d. Tendons

III. QUALIFICATIONS OF PERSONNEL

To perform accurate elastography, the personnel should meet all requirements of the ACR–SPR–SRU Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations [4]
IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for an ultrasound elastography examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes (1) signs and symptoms and/or (2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient’s clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

V. SPECIFICATIONS OF THE EXAMINATION

All forms of elastography must be performed with minimal initial pressure applied with the transducer as this can substantially affect the results. In general, optimal B-mode images are required to obtain accurate elastography results [5].

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 should be used.
   c. For liver stiffness, the recommendations of the SRU consensus or the WFUMB guidelines should be used for performing the examination [3,6].
      i. The patient should fast for at least 4 hours
      ii. The examination should be performed in the supine or the slight left lateral position with the arm raised above the head to increase the intercostal space
      iii. The measurements should be taken through an intercostal approach at the location of the best acoustical window
      iv. The measurements should be taken 1.5 to 2.0 cm below the liver capsule to avoid reverberation artifact. The optimal location for maximum shear wave generation is 4.0 to 4.5 cm from the transducer
      v. The transducer should be perpendicular to the liver capsule in both planes
      vi. Placement of the ROI should avoid large blood vessels, bile ducts, and masses
      vii. Ten measurements should be obtained from 10 independent images, in the same location, with the median value used for pSWE.
      viii. Three to five measurements may be appropriate for 2-D–SWE when a quality assessment parameter is used.
      ix. The interquartile range of stiffness to the median (IQR/M) should be used as a measure of quality. The IQR/M should be <0.3 kPa and < 0.15 m/s for an accurate data set

2. Stiffness of a lesion
   a. Either SE or 2-D–SWE can be used [7-10]. Because many masses are heterogeneous, the use of pSWE is discouraged as the area of maximum stiffness cannot be determined [11]
   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 [12]
   c. When using the SR, the appropriate reference tissue should be used. When examining breast, 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. The number of measurements to be taken has not been well studied, but using three measurements is reasonable. General technique requirements for SE include:
      i. Scan with minimal initial compression on the tissue with the transducer
ii. Use the optimal compression/release for the system (this can vary from patient breathing/heart beat while holding the transducer still to having to compress and release the tissues with the transducer by 1-2 mm)

iii. Remain at the same plane through the lesion when acquiring data

iv. Have a large FOV containing several different 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 less than 4 cm deep to the transducer, if possible

f. Lesion stiffness can contribute to morphologic feature analysis of a breast lesion and its BI-RADS® assessment. SE or SWE should not be used as the sole criterion of likelihood of breast malignancy. Practitioners should refer further to the ACR Practice Parameter for the Breast Ultrasound Examination [13].

VI. 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. Variations from normal size should generally be accompanied by measurements. 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 [14].

Because of differences between equipment and scanning techniques, when reporting elastography results, the ultrasound system, transducer used, and patient positioning should be documented. 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 (ie, four-point color scale, five-point color scale). 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, 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 values were obtained using [pSWE, 2-D–SWE], [#] of measurements were obtained with a median value of [# (state results in m/s and/or (kPa)]. The IQR/M was [#], suggestive of a [good, poor] data set. [The variance in the measurements is large (ie, IQR/M > 0.3) and, therefore, the accuracy of the measurement may be in question].

i. This corresponds to [no to mild, moderate to severe, severe fibrosis, or cirrhosis]...

ii. If there is a complicating feature, the following should be added:
In the setting of [markedly elevated liver function tests, nonfasting, congestive heart failure, etc], the degree of liver fibrosis may be overestimated.

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 [# m/s and/or kPa]. This is suggestive of a [soft, indeterminate, stiff] lesion.

VII. EQUIPMENT SPECIFICATIONS

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.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

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).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment [15].

Quality Control and Improvement

The Quantitative Imaging Biomarker Alliance (QIBA), a consortium of the Radiological Society of North America (RSNA), 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 draft profile will be available after a limited public review is complete, but an easy to follow, step-by-step checklist based on the draft profile is available here [16]: https://qibawiki.rsna.org/images/1/15/SWS_BC_ProfileChecklist.pdf

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Ultrasound of the ACR Commission on Ultrasound in collaboration with the SRU.
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REFERENCES

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter
2019 (Resolution 26)