American College of Radiology, with more than 30,000 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.

Revised 2022 (Resolution 30)*

ACR-AIUM-SIR-SRU PRACTICE PARAMETER FOR THE PERFORMANCE OF PHYSIOLOGIC EVALUATION OF EXTREMITY ARTERIES

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 &}lt;u>Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing</u> 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, <u>Stanley v. McCarver</u>, 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), the American Institute of Ultrasound in Medicine (AIUM), the Society of Interventional Radiology (SIR), and the Society of Radiologists in Ultrasound (SRU). Recommendations for physician requirements, written request for the examination, procedure documentation, and quality control vary between the 4 organizations and are addressed by each separately.

This practice parameter has been revised to assist physicians and allied health care professionals performing a noninvasive physiologic examination of the extremity arteries. Although it is not possible to detect every abnormality with physiologic testing, following this practice parameter will maximize the detection of abnormalities of arterial blood supply to the extremities.

II. INDICATIONS AND CONTRAINDICATIONS

Indications for the examination include, but are not limited to:

- 1. Evaluation of exercise-induced limb pain (claudication) [1]
- 2. Assessment of digital or extremity ulceration, gangrene, and/or pain at rest [1,2]
- 3. Follow-up of surgical and endovascular procedures [3]
- 4. Evaluation of wound healing potential [1]
- 5. Preprocedure assessment of patients with chronic kidney disease requiring dialysis [4,5]
- 6. Evaluation of cold sensitivity or discoloration of extremities or digits [6]
- 7. Evaluation of suspected thoracic outlet syndrome [6]
- 8. Evaluation of suspected steal distal to an arteriovenous fistula or graft [7,8]
- 9. Preoperative assessment for arterial harvesting [9,10]
- 10. Assessment for the presence of peripheral vascular disease as part of an assessment of overall atherosclerosis burden [2,11,12]
- 11. Preoperative assessment for renal transplantation
- 12. Screening in selected populations—patients 50 to 69 years with cardiovascular risk factors, all patients 70 years or greater, or patients with Framingham Risk Score of 10% to 20% [13]
- 13. Assessment of risk of amputation [14]
- 14. Allen test for preoperative evaluation prior to radial free arm flap

There are no absolute contraindications for this examination.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Core Privileging: This procedure is considered part of or amendable to image-guided core privileging.

See the <u>ACR-SPR-SRU Practice Parameter for the Performance and Interpretation of Diagnostic Ultrasound Examinations</u> [15].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for a physiologic evaluation of extremity arteries 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). 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)

Physiologic tests are noninvasive and indirect. Results are used to infer the presence or absence of peripheral arterial atherosclerotic and microvascular disease and its severity. Specific locations in the arterial tree are not assessed directly with physiologic techniques; instead, various segments of the arterial system are evaluated for presence of peripheral arterial disease based on pulse volume recordings (PVRs) and segmental pressures. Arterial waveforms are also commonly obtained during noninvasive testing. Perfusion testing may also be included as part of physiologic testing.

This is in contrast to duplex ultrasound, which provides direct visualization of the arterial lumen and wall and allows waveform analysis and assessment of absolute peak systolic velocities at any point of interest throughout the arterial system. See the <u>ACR-AIUM-SRU Practice Parameter for the Performance of Peripheral Arterial Ultrasound Using Color and Spectral Doppler [16] for duplex evaluation of the arteries.</u>

The physiologic examination may be done at a single level or multiple levels along the upper or lower extremity as required by the examination. The examination should be bilateral whenever possible so that flow in both limbs can be compared. Physiologic testing of the extremities may include PVRs and continuous wave (CW) Doppler ankle to be internally validated. This is particularly helpful in cases of non-compressible calcified arteries for which a toe-brachial index should be performed because the distal small caliber arteries are not as susceptible to medial arterial calcification [17].

The examination is best performed in a warm room so that the effects of peripheral vasoconstriction are minimized. The patient should be recumbent for the examination and ideally should be at rest for at least 5 minutes before starting the examination to diminish any effects that prior physical activity might have on the examination. Smoking should be prohibited for 10 minutes prior to the study because this may falsely lower the ABI [18]. Physiologic tests, particularly ankle pressure measurements, may be repeated after exercise of the involved limb when indicated [16]. This is particularly valuable for the assessment of claudication when the ABI at rest is normal or higher than would be clinically anticipated. When patients are exercised, use of a treadmill is recommended at 2 mph at a 12degree grade for 5 minutes or until they become symptomatic and cannot continue [19]. Treadmill exercise provides for reproducible quantification of exercise while allowing simultaneous assessment of symptoms produced during exercise. Symptoms that occur during exercise should also be recorded as well as the elapsed time from the start of exercise to the point at which the symptoms occurred. Total time of exercise should be recorded. Pressure measurements that are taken after cessation of exercise should be done as quickly as possible to achieve the highest accuracy and compared to the brachial pressure in the arm with the higher pressure. Serial postexercise pressure measurements can be obtained in both legs at 1- to 3- minute intervals for the first 5 to 10 minutes or until the ABI returns to baseline. Exercise performed without the use of a treadmill, such as calf raises, may also be used and may provide sufficient diagnostic information.

Description of the component parts of the examination:

1. Segmental limb

Ulnar Doppler waveforms should also be recorded at these locations. Segmental or digital blood pressure readings can be assessed using spectral Doppler tracings or photoplethysmography (PPG) to determine when blood flow returns as the blood pressure cuff is deflated. The method used to assess return of blood flow should be consistent. Digital pressure can be assessed using CW Doppler or PPG to determine when blood flow returns. Bilateral brachial pressure measurements are obtained when possible. The higher brachial pressure is the pressure used in index calculations (eg, ABI) for the lower extremities, upper extremities, or digits [12,20].

2. CW Doppler waveforms [8,20]

CW Doppler waveforms can be obtained from 1 or more arteries. In the lower extremity, the arteries most commonly assessed are the common femoral, superficial femoral, popliteal, posterior tibial, and dorsalis pedis. In the upper extremity, arteries that may be assessed are the subclavian, axillary, brachial, radial, and ulnar. Those performing the examination should be familiar with the appropriate external anatomic landmarks to ensure accurate performance of the examination. Waveforms should be audibly and visually optimized. Doppler angle should be constant throughout the examination when possible (technical constraints may prevent this), and either legs or arms should be evaluated using a similar technique. A consistent Doppler angle will allow waveforms at one site to more readily be compared with those from a different site and from the contralateral leg/arm.

3. Pulse volume recordings (PVRs)

Air-calibrated plethysmography PVRs can be obtained at 1 or more levels. In the lower extremity, the most common places to obtain waveforms are in the upper thigh, lower thigh, calf, ankle, and metatarsals. In the upper extremity, the analogous locations are the upper arm, upper forearm, and above the wrist. Waveforms can be obtained in the toes and digits using a PPG cell [8]. Unlike CW Doppler waveforms, plethysmographic tracings reflect global tissue perfusion at a particular location rather than a specific artery. Unlike segmental pressures, readings are not affected by arterial calcification.

4. Transcutaneous oxygen tension (tcPO₂) measurements

Measurement of the $tcPO_2$ can be used to assess the delivery of oxygen to the skin in an area of questionable viability [21]. The usual locations on the lower extremities are on the foot, ankle, and calf, with a reference point on the chest. After the desquamated cells are cleaned from the skin, a coupling solution such as distilled water is applied to the skin, and the $tcPO_2$ sensor is affixed to the testing site with an overlying occlusive adhesive dressing that prevents exposure to room air. $TcPO_2$ measurements, when used for a determination of ulcer healing, have had variable sensitivity and specificity.

5. Photoplethysmography (PPG)

PPG is a technique to measure the blood volume changes in a microvascular bed [22]. PPG probes can be placed on digits through which light emitting diodes and photodiode receptors will measure the transmission in the tissue creating waveforms. These waveforms provide additional information to the perfusion of the measured tissue bed and presence of atherosclerotic disease [23].

V. DOCUMENTATION

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the examination and its interpretation. Comparison with prior relevant studies should be performed when available. Data from all appropriate arterial segments, both normal and abnormal, should be recorded. There should be a permanent record of all obtained CW Doppler waveforms, plethysmographic waveforms, and segmental blood pressure measurements and their interpretation. The initials of the operator should be accessible on the study or electronically on PACS. The study should be labeled with the patient identification, facility identification, and examination date. An official interpretation (final report) of the examination should be included in the patient's medical record. Retention of data should be based on clinical need and relevant legal and local healthcare facility requirements.

Reporting and communication efforts should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [24].

VI. EQUIPMENT SPECIFICATIONS

Peripheral arterial waveforms are obtained with a CW Doppler instrument operating at 5 to 10 MHz with a zero-crossing detector (waveforms may also be sampled using standard duplex imaging equipment). The instrument should have audio output through a speaker or headphones. The instrument may also have digital or analog recording connectivity so that waveforms can be saved.

The same CW Doppler instrument can be used to detect arterial waveforms for the performance of segmental pressures. Appropriately sized blood pressure cuffs attached to a manometer are necessary to perform segmental blood pressures. A rapid inflation device is helpful. Small cuffs are necessary to measure digital pressures. A photoelectric plethysmograph can be used for digital pressure measurement. A treadmill with adjustable speed and incline is recommended for reproducible, quantifiable exercise testing for lower extremities. Exercise parameters used should be recorded.

PVRs can be performed with the same cuffs used to measure pressures, connected to an air-calibrated plethysmograph.

Equipment performance monitoring should be in accordance with the <u>ACR-AAPM Technical Standard for</u> <u>Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment</u> [25].

VII. 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 Quality Control & 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).

ACKNOWLEDGEMENTS

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

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Development Chronology for this Practice Parameter

^{*}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.

2007 (Resolution 32) Revised 2012 (Resolution 28) Amended 2014 (Resolution 39) Revised 2017 (Resolution 17) Amended 2019 (Resolution 23) Revised 2022 (Resolution 30) Amended 2023 (Resolution 2c)