



Position Statement on Noninvasive Imaging of Peripheral Arterial Disease by the Society of Interventional Radiology and the Canadian Interventional Radiology Association

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ABBREVIATIONS

ABI = ankle-brachial index, PAD = peripheral artery disease, PSV = peak systolic velocity, PVR = pulse volume recording, TBI = toe brachial index

INTRODUCTION

Noninvasive evaluation of peripheral artery disease (PAD) has defined usefulness for patient screening and patient stratification. In addition, this evaluation also facilitates proper patient selection and objective outcome evaluation for PAD interventions (1,2). As part of the Affordable Care Act, alternative payment models have emerged to enact the intended paradigm shift from merit-based toward more value- and outcome-oriented delivery of medical care. Hence, the appropriate use of such noninvasive tools to improve preprocedure patient selection, as well as to objectively document postprocedure outcomes, deserves particular consideration. At the same time, no recent document is available that provides official Society of Interventional Radiology (SIR) guidance or comprehensively addresses the topic within the dedicated interventional radiology literature. Finally, use of noninvasive evaluation tools may vary considerably across specialties that are involved in the care of patients with PAD.

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The present document therefore reviews and provides recommendations for noninvasive lower-extremity imaging of PAD, which includes two broad categories: (i) functional tests and (ii) anatomic tests. The functional or physiologic tests include the ankle-brachial index (ABI), segmental limb pressures, pulse volume recordings (PVRs), segmental Doppler waveforms, and oxygen testing. The anatomic tests include duplex ultrasound (US), computed tomography (CT), and magnetic resonance (MR) imaging. Because of the complexities and degree of discussion needed for each study, CT and MR imaging will be discussed in a future document. The intent of the present document is to outline the principles of noninvasive investigations for screening, pretreatment, and follow-up of PAD.

A noninvasive evaluation of patients with PAD is composed of a number of different testing modalities, each with specific purposes to identify various patient attributes. These components may differ among laboratories depending on local practice, availability of testing modalities, and training of the physicians and technologists. For instance, an ABI measurement alone does not constitute a complete noninvasive examination. A typical noninvasive examination should always include an ABI and may include PVRs, continuous-wave Doppler analysis, segmental pressures, and exercise testing. Many laboratories use all components to increase accuracy. Each of these tests has advantages and disadvantages. Together, with the use of each component, these noninvasive tests constitute a highly reproducible and accurate examination.

STANDARD TESTING MODALITIES

ABI

The ABI is the ankle systolic blood pressure divided by the brachial artery systolic blood pressure. Both upper-extremity brachial pressures should be taken, and, if there is more than a 15-mm Hg difference between the two sides, hemodynamically significant disease should be considered to be present proximal to the brachial artery with the lower pressure. If there is a brachial pressure discrepancy, the higher pressure should be used. The greater of the dorsalis pedis or posterior tibial artery blood pressure from each side is taken for the ankle reading. The blood pressure readings can be obtained by stethoscope auscultation or

by a Doppler US probe. Because auscultation is generally less accurate and less reproducible, Doppler reading is the preferred method (3,4).

The range for a normal ABI is between 1.0 and 1.1 (5–8). There is an association between increasing severity of lower-extremity symptoms caused by PAD and a decreasing ABI (9). Although there is overlap between intervals, early work by Yao (9) has suggested the following thresholds for the practical classification of the severity of PAD: no symptoms, ABI more than 1.0; claudication, ABI between 0.5 and 1.0; rest pain, ABI between 0.25 and 0.50; and impending tissue loss, ABI less than 0.25 (9). The sensitivity and specificity rates of ABI for the diagnosis of PAD are 72% and 96%, respectively (4,10,11).

An alternative classification of ABI ranges is included in **Table 1**. One of the limitations of the ABI is the possible underestimation of the degree of disease in the case of tissue loss, such as a nonhealing arterial ulcer, as the higher of the two ankle blood pressures are taken for the calculation. Hence, ABI reporting should take the clinical scenario into context and also include absolute ankle pressures. If one were to use the lower of the pressures between the dorsalis pedis and the posterior tibial artery, the sensitivity would increase but the specificity in detecting disease would decrease. This is performed by some laboratories when PAD is known and the examination is not being performed for screening or detection of new disease. In fact, if the ABI is obtained as a prognostic marker for cardiovascular disease, the lower value should be used (4).

Another limitation of the ABI is its false elevation in patients with calcified arterial vessels. If the patient has heavily calcified vessels, a toe brachial index (TBI) can be taken with a pressure reading from the great toe, in which vessels rarely show calcification. An index > 0.65 is considered normal for the TBI. Generally, severe PAD is present with a TBI of less than 0.40. It is important to note that ABI does not localize disease within the lower extremities. The ABI measurement serves as a preliminary test to determine if the patient's symptoms are related to PAD. The ABI is also used as part of a surveillance test for patients as a follow-up study. Finally, it is well documented that decreasing ABIs are associated with increased morbidity and mortality from cardiovascular disease (12–14).

PAD is an independent risk factor for coronary artery disease. Therefore, discovery of PAD with a decreased ABI often mandates a further workup for patients and should lead to assessment of cardiovascular risk factors. In fact, cardiovascular risk screening is often performed by measuring an ABI.

Recommendations. Bilateral ABI calculations should be performed, which include bilateral brachial arteries and bilateral ankle pressures. The ABI should take the clinical situation into context to avoid false-negative calculations. The absolute ankle pressures should also be included in conjunction with the ABI calculation. Finally, in heavily calcified arteries, a TBI should be considered.

Segmental Limb Pressures

Because the ABI does not localize disease within the lower extremities, segmental limb pressures can be used. Segmental pressures are similar to the ABI, with the addition of two or three appropriately sized blood

pressure cuffs placed in the high and/or low thigh and in the upper calf. The blood pressure cuff is inflated to occlude the arterial inflow; the cuff is then slowly deflated while detecting the pressure at which blood flow resumes distal to the cuff. Doppler instrumentation or plethysmography can be used to determine the resumption of blood flow. Additional cuffs are placed just below the knee, and one large cuff or two narrow cuffs are placed above the knee and at the upper thigh. The cuffs are then inflated to greater than systolic blood pressure and then slowly deflated. A gradient of greater than 30 mm Hg between two consecutive ipsilateral segments or a gradient of greater than 20–30 mm Hg from one limb to the other at the same level suggests significant arterial stenosis (15). Segmental limb pressures serve as a preliminary test to determine if the patient may have PAD. It can also be used as a separate test after the ABI, if the ABI is abnormal, to further localize the diseased area in the affected extremity. Segmental pressures may be difficult to interpret when significant proximal disease is present. The use of segmental pressures is helpful as an adjunct to PVRs, which are much more sensitive in detecting multilevel disease.

Recommendations. An ABI is a mandatory part of a physiologic examination. For segmental pressures, four cuffs can be used. The recommended location of the blood pressure cuffs are the upper thigh, lower thigh, upper calf, and ankle.

Segmental PVRs

Similar to segmental limb pressures, segmental PVRs use dedicated pressure cuffs at the different limb segments. A PVR is an air plethysmographic study used to detect segmental volume changes in the limb during the cardiac cycle (16). The cuffs are typically inflated to 65 mm Hg to occlude venous return while maintaining arterial flow. Cuffs are placed at the superior thigh, inferior thigh, calf, ankle, and transmetatarsal levels. Toe PVR can be performed as well. An ankle PVR cuff is left in place during exercise, and the PVR tracings at the ankle are repeated after exercise along with the ABI. The pneumoplethysmographic waveform signals, which are derived from the segmental volume changes of blood flow, are recorded. Waveforms are generated as air is displaced in the nonoccluded cuff. These waveforms are markedly different than Doppler arterial waveforms and should not be confused with arterial waveforms. The normal waveform typically consists of four phases: (i) a rapid systolic upstroke, (ii) a rapid diastolic downstroke, (iii) a prominent dicrotic notch, and (iv) normalization to baseline before the next rapid systolic upstroke occurs. With PAD, when significant occlusive disease is present, the waveforms may first lose the dicrotic notch, and then, as the upstroke and downstroke slow, the waveform becomes more rounded and the amplitude decreases. The amplitude of the waveform will decrease with distal stenosis and will become flat in occlusive disease. Interpretation of PVRs should be performed quantitatively and qualitatively. Comparison of each limb's waveforms is an important element of interpretation. When blood flow is normal, the calf waveform augments as much as 30% more than the high thigh waveform. If augmentation is not present, even with a qualitatively good waveform, disease in the femoral popliteal segment should be suspected (17).

Segmental PVRs are part of the complete noninvasive examination. The indications for segmental PVRs as a component of noninvasive testing are to evaluate whether a patient's symptoms are related to arterial insufficiency or as surveillance in patients who have undergone revascularization to determine if additional intervention is needed. Advantages of segmental PVRs include the ability to identify and localize segmental disease. In addition, segmental PVRs are not altered by calcium and are highly reproducible. This is probably the most reliable and accurate component of the noninvasive examination, and is considered a standard portion of the complete examination in many laboratories (17,18).

Table 1. ABI-Based Grading of PAD

ABI	Comment
> 1.3	Falsely high value (suspicion of medial sclerosis)
0.9–1.3	Normal finding
0.75–0.9	Mild PAD
0.4–0.75	Moderate PAD
< 0.4	Severe PAD

Source—Stiegler H, Brandl R. Importance of ultrasound for diagnosing peripheral artery disease. *Ultraschall in Med* 2009; 30:334–363.

ABI = ankle brachial index; PAD = peripheral artery disease.

Recommendations. PVRs are ideal for evaluating segmental disease and are not affected by calcification. They should be considered as part of a complete noninvasive examination.

Continuous-Wave Doppler Waveforms

Doppler waveform analysis should be performed at multiple segments, including the common femoral artery, popliteal artery, at the ankle over any of the trifurcation vessels, and over the dorsum of the foot. It is most important to perform this over the common femoral artery, and this should be considered a necessary part of the noninvasive examination. The common femoral Doppler waveform analysis is often performed in conjunction with PVRs. Because upper thigh PVRs cannot distinguish proximal superficial artery disease from common femoral artery or iliac inflow disease, the common femoral Doppler waveform plays a critical role in localizing disease. An abnormal upper-thigh PVR waveform with a normal triphasic common femoral Doppler waveform indicates proximal superficial femoral artery disease, whereas an abnormal upper-thigh PVR waveform with an abnormal common femoral Doppler waveform indicates aortoiliac disease. Errors in interpretation can occasionally occur as a result of the variability in location of the common femoral artery in relation to the groin; Doppler US is the most precise modality to evaluate the common femoral artery.

A normal arterial Doppler waveform in the lower extremity has a high resistance pattern and is triphasic. The dip below baseline reflects the high resistance characteristic that distinguishes this waveform from the classic low-resistance waveform that may be seen in the internal carotid artery. The triphasic components consist of a sharp systolic upstroke, a reversal of flow below baseline, and then a short forward flow component in late diastole. With mild disease, the waveform becomes biphasic with loss of the late diastolic forward flow component of the waveform. With more severe disease, the waveform becomes monophasic with loss of the flow reversal. The waveform will flatten and become rounded, with a slower upstroke and downstroke creating the classic postobstructive tardus parvus signal.

Doppler waveforms have limitations that include difficulty in reproducibility based on the angle of insonation. The angle of insonation can alter the waveform morphology and can lead to discordant information. Another limitation of Doppler waveform analysis occurs when disease is present in a proximal segment and the waveform becomes abnormal, as in tandem stenoses or occlusions. In such cases, the test is not as reliable for detecting disease distally. For this reason, Doppler waveform analysis is a poor test to detect multilevel disease. This component of the noninvasive examination is therefore less valuable than PVRs, and, in many laboratories, Doppler waveforms are obtained only at the common femoral artery.

Recommendations. Continuous-wave Doppler analysis should be performed at multiple segments when assessing the lower extremities for PAD. Continuous-wave Doppler analysis should be available as part of a complete noninvasive examination.

Exercise Testing

Exercise testing is a necessary requirement for noninvasive testing in patients with claudication. Testing can be performed on a treadmill with a standardized protocol. If a treadmill is unavailable, walking tests may be performed (even though treadmill testing is the best way to ensure reproducibility and accuracy).

The purpose of exercise testing is twofold. First, it confirms that the patient's symptoms are the result of vascular occlusive disease. Second, it can unmask disease not detectable at rest. It is common to see patients who have normal ABIs at rest and have significant decompensation after exercise. Therefore, the ABI should be measured at rest and after exercise if resting ABI is normal. Many vascular laboratories repeat the ABI and ankle PVR after exercise. The postexercise ankle ABI and the postexercise PVR are important components of the noninvasive examination.

The Gardner protocol is the most common exercise protocol for noninvasive testing. It uses a constant speed and constant grade on a treadmill. Patients walk for 5 minutes on the treadmill or until symptoms limit ambulation. This is performed on a 12° incline at 2 mph.

Recommendations. Exercise testing is useful to assist in the diagnosis of PAD in patients with claudication, and should be available as a component of the evaluation because it unmasks PAD not evident at rest. Exercise testing is mandatory in all patients with normal resting examinations who have exertional symptoms. Exercise testing can also be used as a part of surveillance testing in posttherapeutic PAD patients.

SUMMARY OF STANDARD TESTING MODALITIES

There are a number of modalities that can be used to assist in the diagnosis of PAD. Each modality has inherent advantages and disadvantages. The practitioner must be aware of the limitations of each and understand their respective strengths and weaknesses for various clinical subscenarios of PAD presentation. These modalities can also be used in posttherapeutic surveillance of the lower extremities. A complete noninvasive examination includes an ABI as well as PVRs at all levels. At a minimum, Doppler waveform analysis of the common femoral artery should be performed. Exercise testing should be available as part of the noninvasive examination when indicated. Segmental pressures and segmental Doppler waveforms may be added to provide additional information.

ANCILLARY NONINVASIVE TESTS

Reflection Photoplethysmography

Reflection photoplethysmography uses peripheral blood volume pulsation by temporally detecting skin-backscattered optical radiation. Contact probes can be placed at various anatomic positions, including fingertips, earlobes, forearms, and toes. The arterial compliance is measured by using the heartbeat pulse-wave transit time. A pulse-wave transit time average delay in the range of $23 \text{ ms} \pm 9$ can be used as the diagnostic threshold for lower-extremity arterial stenosis, with high reliability at more than 32 ms (19). It has also been suggested that photoplethysmography has greater sensitivity in assessing patients with diabetes and chronic renal failure for PAD compared with Doppler ABI testing (20).

Recommendations. Reflection photoplethysmography has utility in patients PAD and should be considered in the diabetic and chronic renal failure PAD subgroups.

Oxygen Tension

Oxygen plays a central role in wound healing. Tissue hypoxia has been shown in wounds that do not heal adequately (21–23). Transcutaneous oximetry estimates the partial pressure of oxygen on the skin surface by using noninvasive heated electrodes. This diagnostic tool assesses the approximate oxygenation of tissues in skin flaps, wounds, and ulcerations, and consequently has beneficial value for patients with PAD. Clark first developed the prototype electrode measurement, which was later miniaturized by Silver (24). Transcutaneous oximetry is the only noninvasive method to quantify tissue oxygenation. Its advantages are that it does not disrupt tissue around the wound and that it eliminates the risk of infection as a result of its noninvasive origins. A limitation of oxygen tension is that it does not directly measure the oxygen tension within the wound. It instead measures the oxygen tension in the tissues adjacent to the wound, which is an important distinction, as the wound oxygenation will be lower than that of the surrounding tissues. Oxygen-deprived tissues surrounding the wounds would have typical oxygen tension values less than 20 mm Hg, compared with control/normal values of 30–50 mm Hg (23). The average oxygen tension in the

feet of healthy subjects breathing normobaric room air at sea level is 50 mm Hg (23). In the setting of chronic conditions such as renal failure and diabetes, impairment or prevention of wound healing can be observed at oxygen tensions less than 50 mm Hg (23).

There are several major limitations to transcutaneous oximetry. The examination takes a long time to perform, and the results are highly sensitive to surrounding conditions such as temperature in the room. Therefore, results may be difficult to reproduce unless conditions are standardized. This valuable test for assessing oxygenation is not part of a standard noninvasive test and is only performed in situations in which tissue viability is in question.

Recommendations. Oxygen tension can be used as an adjunctive tool to predict benefit for revascularization therapy. Oxygen tension measurements should be made with the patient at rest in a supine or recumbent position in a comfortable, warm room with the extremity covered by a sheet or blanket, breathing normobaric oxygen for at least 10 minutes (23). An increase of greater than 10 mm Hg of foot oxygen tension between normobaric room air and at least 10 minutes of a normobaric 100% oxygen challenge with a pulmonary oxygen saturation of greater than 90% is recommended as a positive outcome from a revascularization procedure of the lower extremities (25). In the setting of tissue loss, oxygen tension studies should be considered before and after revascularization procedures to serve as the baseline and surveillance after intervention (23). Postintervention oxygen tension studies should be performed more than 1 week after the revascularization procedure, although oxygen tension values can exhibit continual increase for as long as 28 days (23).

US

US evaluation of the lower extremities for PAD evaluation is a rapid and inexpensive noninvasive imaging test that adequately provides the location, number, and severity of lesions, including assessment for occlusions. Color Doppler examination localizes regions of abnormal flow, determines direction of flow, and can confirm lack of flow. Pulsed Doppler examination evaluates the peak systolic velocity (PSV) and provides waveform assessment, including directionality of flow.

The normal waveform in the lower extremities follows a triphasic pattern. The first positive deflection reflects forward systolic flow, the first negative deflection waveform shows reverse diastolic flow, and the second, smaller, positive waveform shows forward diastolic flow. Severe stenosis is manifested on Doppler assessment with increased PSVs typically greater than 200 cm/s, a monophasic waveform, and spectral broadening. Spectral broadening, defined as sampling of higher variable velocities suggestive of nonlaminar flow, can also be observed with pulsed Doppler waveform assessment. A normal PSV ranges between 45 and 180 cm/s (26). PSV ratios should be included in the evaluation, with a PSV ratio of 2.0 corresponding to 50% stenosis and a ratio of 4.0 corresponding to 70% stenosis across the sampled sites. With respect to grafts, the factors affecting flow velocity measurements are conduit diameter, status of the inflow and outflow arteries, and cardiac output. The mean graft flow velocity is the average of PSVs recorded from three or four normal nonstenotic graft segments along the length of the bypass, and typically ranges from 50 to 80 cm/s (25–27). In addition, the PSV for a graft with a diameter of less than

6 mm should be at least 40 cm/s. The respective PSV and graft flow velocity ranges for infrainguinal graft bypasses are detailed in Table 2.

Regarding velocity criteria for US evaluation, they can be incorrectly measured if taken at the incorrect angle. The ideal Doppler angle for vascular assessment of flow velocities is 60° taken at the center of the vessel lumen and parallel to the vessel wall. PSVs are believed to be abnormal if greater than 125 cm/s in the lower extremities (28). Flow velocities are variable, and absolute velocities should not be taken independently. Velocities should be taken as ratios measuring the velocity proximal to the stenosis and at the site of the most severe stenosis. Diameter reduction on grayscale imaging is also supportive of stenosis. Finally, color bruit or color persistence provides evidence of sonographic vibration in the tissues surrounding arterial narrowing and is also supportive of arterial stenosis.

Surveillance after endovascular intervention and bypass graft surveillance surgery should routinely be performed by using US. A standard surveillance protocol should include US evaluation twice in the first postinterventional year and annually thereafter, if available. The endovascular treatment area and the bypass graft is sampled at three or four sites, and the PSVs are measured.

The indications for peripheral arterial US examination include but are not limited to:

1. Assessment of stenosis or occlusions in the lower-extremity peripheral arteries in patients with suspected arterial occlusive disease. The patients may or may not have clinical indicators such as claudication, rest pain, tissue loss, and suspicion of arterial embolization.
2. Surveillance of previous endovascular interventions, including angioplasty, stent placement, thrombolysis, thrombectomy, and atherectomy.
3. Surveillance of previous surgical interventions, including bypass grafting.
4. Surveillance of previously documented PAD in patients who have not undergone initial intervention.
5. Anatomic US mapping before endovascular or surgical intervention.
6. Further assessment of vascular abnormalities detected by other imaging modalities, such as pseudoaneurysms, masses, arterial dissection, vascular injuries, vascular malformation, and thromboembolism (29).

Recommendations. US grayscale imaging and Doppler imaging are recommended for assessment of PAD of the lower extremities. Periodic follow-up in patients who have undergone interventions and surveillance of patients with PAD should occur with US imaging; a standard surveillance protocol should include US evaluation twice in the first postinterventional year and annually thereafter. Multiple sonographic modes (eg, grayscale, power Doppler, color Doppler) are required to appropriately assess PAD in a single imaging session.

Screening Examinations and Programs. Screening examinations and programs are becoming more and more common. Screening for PAD by using an ABI is an important tool. The ABI is a mandatory component of patient assessment, but alone does not constitute a

Table 2. Hemodynamic Criteria and Management of Graft Stenosis of Infrainguinal Bypass

Category	Risk	PSV (cm/s)	PSV Ratio	GFV (cm/s)	Management
I	Maximal	> 300	> 3.5	< 45	Anticoagulation, immediate intervention
II	High	> 300	> 3.5	> 45	Elective intervention in 15 d
III	Moderate	< 300	> 2	> 45	Observation; correction if progression
IV	Low	< 180	< 2	> 45	Observation

GFV = graft flow velocity; PSV = peak systolic velocity.

complete noninvasive examination. Other modalities are required based on the clinical need.

VASCULAR LABORATORY ACCREDITATION

Vascular laboratory accreditation is available through the Intersocietal Accreditation Commission or the American Board of Radiology. Accreditation helps to ensure that quality examinations are performed. Physicians are required to be trained readers via one of several pathways. Dedicated noninvasive Continuing Medical Education is required for physicians reading in the laboratory. Reports must adhere to laboratory protocols. Technologists' examinations are reviewed to assess for standardization, compliance with protocols, and quality of examination. The facility is evaluated for adequate equipment, proper space, and testing facilities.

CONCLUSIONS

Noninvasive evaluation of patients with PAD is composed of a number of different testing modalities. Each testing component adds information, thereby increasing diagnostic accuracy. A combination of these modalities is necessary to properly evaluate blood flow. These components may differ among laboratories depending on local practice, availability of testing modalities, and training of the physicians and technologists. Alone, none of these constitute a complete examination. With the appropriate use of each of its available components, noninvasive testing is a highly reproducible and accurate examination.

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