

Evidence Discussion (PVD 7.1 and 7.3; PVI 104)

PVD 7.1

Introduction and natural history:

Peripheral arterial disease (PAD) is defined as chronic, atherosclerotic occlusive disease of the lower extremities. The vast majority of patients with PAD are asymptomatic. A much smaller group has symptomatic PAD, consisting of intermittent claudication(IC), rest pain or tissue loss.

The natural history of PAD for asymptomatic and IC patients is relatively benign. It is estimated that 7% (4%–11%) of asymptomatic patients deteriorate to IC over a 5-year period.¹ Multiple studies have established that patients with IC are at very low risk of major amputation (<1% per year).²

For these reasons, the first line of treatment for patient with IC is risk factor reduction/modification and exercise therapy.^{2,3} A meta-analysis of 1200 patients determined that exercise therapy, compared with placebo or usual care, provides an overall improvement in walking ability of 50% to 200%, with improvements maintained for up to 2 years.³ Additionally, with intensive medical management, <5% of patients will develop symptoms of advanced ischemia, such as ischemic rest pain, tissue loss, or require amputation.⁴

Diagnosis:

Measurement of the ankle-brachial index (ABI) is the primary method for establishing the diagnosis of PAD. An ABI of 0.90 has been demonstrated to have high sensitivity and specificity for the identification of PAD compared with the gold standard of conventional angiography (CA). It is a simple non-invasive method to assess for PAD. It avoids use of radiation, and contrast agents. It can be performed easily in an office setting and is cost-effective.⁵

Further studies for evaluation of anatomic location of disease are warranted if PAD is proven. Arterial duplex combines Doppler spectral analysis and B-mode imaging to evaluate blood flow and anatomy. It has been shown to be effective in localizing arterial vascular disease with comparable sensitivity and specificity to CT angiography (CTA), MR angiography (MRA) and CA. It is also non-invasive, cost-effective, and avoids radiation and contrast exposure.⁵

Due to their associated risks, CTA, MRA and CA should be reserved for patients in whom revascularization treatment is being considered. CTA risks include exposure to intravenous contrast and radiation. Contrast complications include allergy and contrast induced nephropathy. MRA risk includes exposure to gadolinium which confers the risk of nephrogenic systemic fibrosis in patients with renal insufficiency. MRA also is contraindicated in patients with metallic implants. CA risks include radiation and contrast exposure as well as access site complications. Since it is an invasive procedure, there is risk for arterial injury, embolization and thrombosis.

Indications for advanced imaging: ⁶⁻⁸

1. Limb-threatening disease including rest pain or tissue loss
2. Blue toe syndrome including concern for atheroembolic disease
3. IC with failed 3 month trial of risk factor modification and exercise program.

[PVI.AI.104.A](#), Indications for intervention. Treatment of stenotic or occluded arteries perfusing the lower extremities is medically necessary when **all** the following are met:⁶⁻⁸

1. For CLI
 - a. Documentation of non-healing wounds, gangrene or ischemic rest pain.
 - b. Rest pain must be supported with ABI's <0.5, or monophasic waveforms on duplex studies.
 - c. Imaging studies must confirm the location of disease and degree of stenosis ($\geq 70\%$)
2. For IC,
 - a. Failed three month trial of provider directed conservative therapy including structured walking program.
 - b. Risk factor modification (smoking cessation, lipid and glycemic control)
 - c. Symptoms must correspond to the location of arterial insufficiency
 - d. Imaging confirms the location of disease, and degree of stenosis ($>70\%$)

[PVD 7.3](#), Indications for surveillance imaging:

Once an intervention (open or endovascular) has been performed, surveillance imaging is supported. The rationale for this is to maintain patency of the treated lesions to avoid further symptoms and/or amputation. Surveillance imaging with ABI and duplex is supported at various intervals depending on the type of intervention, stent vs. bypass, and by bypass material. These are outlined in detail in the guideline.⁹

Advanced imaging is supported for any of the following:⁶⁻⁹

Worsening signs or symptoms

Reduction of ABI >0.15

Peak systolic velocities or PSV ratio suggestive of high grade stenosis

Duplex suggestive of threatened bypass graft

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