Cardiopulmonary Medicine

Clinical Practice

Kelly M. Rudd*, PharmD, BCPS, CACP, FCCP, Kristie K. Roberts, MS and Cooper M. Hamilton, MS

Improving peripheral artery disease screening and treatment: a screening, diagnosis, and treatment tool for use across multiple care settings

https://doi.org/10.1515/jom-2024-0050 Received March 14, 2024; accepted September 9, 2024; published online October 31, 2024

Abstract: Peripheral artery disease (PAD) is an atherosclerotic disease that contributes to significant morbidity and mortality, including loss of limb, myocardial infarction (MI), stroke, and death. Treatment options are often underutilized. A major limiting factor in PAD care is the ability to efficiently identify and screen at-risk patients. A PAD patient screening and clinician decision support tool was created to improve access to high-quality, evidence-based care to drive improved clinical outcomes. The tool identifies known PAD risk factors and presenting symptoms, in combination with objective data obtained via the ankle-brachial index (ABI). The tool utilizes this data to drive PAD diagnosis, risk assessment, and treatment, and it is adaptable across multiple care settings, by varied health professions. The implementation of a PAD screening and treatment toolkit enhances anticoagulation and PAD stewardship, and it has been integrated into use across various care settings.

Keywords: anticoagulation; health equity; peripheral artery disease

Peripheral artery disease (PAD) is an atherosclerotic disease that strongly correlates with the pathophysiology and clinical trajectory of coronary and carotid atherosclerosis. PAD is associated with multiple complications, which if left untreated or undertreated places patients at risk for critical limb ischemia, nontraumatic amputations, stroke, heart

*Corresponding author: Kelly M. Rudd, PharmD, BCPS, CACP, FCCP, Clinical Associate Professor of Medicine, Department of Medical Education, Oklahoma State University Center for Health Sciences Center College of Osteopathic Medicine, 1111 West 17th Street, Tulsa, OK 74107, USA, E-mail: kelly.rudd@okstate.edu

Kristie K. Roberts, MS **and Cooper M. Hamilton**, MS, Oklahoma State University Center for Health Sciences Center College of Osteopathic Medicine, Tahlequah, OK, USA

attack, and death [1, 2]. Approximately 8-10 million adults aged 40 and above in the United States have been diagnosed with PAD [3, 4]. Patients diagnosed with PAD frequently undergo revascularization surgeries and limb-saving operations and face a mortality risk exceeding 60 % within a 5-year postoperative period. The financial burden of PAD on the healthcare system is also high, with treatment costs estimated at \$11 billion annually [5-7]. Effective therapies, including medications for the management of PAD and underlying contributing health conditions (i.e., hypertension, hyperlipidemia, diabetes, tobacco use, etc.), exercise therapy, and revascularization procedures are significantly underutilized, and the incidence of nontraumatic amputations is on the rise [8, 9]. The combination of these factors indicates a need for early detection, comprehensive treatment, and implementation of efficient evidence-based stewardship programs for PAD.

Clinical summary

To meet the demands of PAD stewardship, it is essential to effectively and efficiently screen, diagnose, and offer treatment early in the disease process. Best practices include obtaining a clinical history, review of system and physical examination, and assessing the presence and severity of PAD-specific symptoms, which may vary between patients [10]. This data, combined with objective vascular testing, drives diagnosis and treatment. A query of PubMed and leading society organizations failed to identify a comprehensive PAD risk assessment and treatment tool that captures the above elements and guides evidence-based treatment.

To meet this need, a PAD Patient Screening and Provider Decision Support Tool for clinicians was created (Figure 1; a version translated into Spanish is available as Appendix A). Key elements include patient-facing PAD risk factors, symptoms, clinical features screening, and a provider-facing decision tool to support diagnosis, staging, and guideline-driven PAD treatment. The Oklahoma State University (OSU)

Health Sciences Center Office of Educational Development included instructional-design best practices to support patient engagement, including considerations for varying literacy levels. A native-speaking healthcare professional translated the patient-facing materials into Spanish. The final tool was reviewed by local and national experts in the field of antithrombosis, cardiology, and vascular surgery for completeness and correlation to the evidence-based guidelines (the 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/ SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease.) [11].

The goals of this manuscript are to: (1) provide a review of PAD and the associated risk amplifiers, assessment, and treatment modalities; (2) detail the creation of a PAD Patient Screening and Provider Decision Support Tool that captures these essential elements in a comprehensive format for clinical use; and (3) provide examples on how this tool has been utilized in patient care. The elements contained within the PAD Patient Screening and Provider Decision Support Tool are described below.

Peripheral artery disease (PAD) risk factors

The development of PAD is a multifactorial process involving nonmodifiable and modifiable risk factors. Data indicate that PAD disproportionately affects people of older age, Hispanic and African American race, tobacco users, diabetics, and people with chronic kidney disease, dyslipidemia, and hypertension [1, 6, 9]. More than 95 % of patients with PAD have a concurrent traditional cardiovascular risk factor, with the majority of patients having multiple risk factors [4]. The odds of developing PAD, critical limb ischemia, and amputation increase with the addition of each risk factor, from a 1.5-fold increase with one risk factor to a 10-fold increased risk with the presence of three or more risk factors [12]. Given this marked increase in risk, several factors are considered "PAD risk amplifiers." The following sections will briefly detail the known PAD risk factors and amplifiers (Table 1).

Age

Increasing age is considered both a PAD risk factor and a risk amplifier. PAD prevalence is estimated to double per decade of life, increasing from approximately 5 % for ages 60-69 to greater than 15 % for ages 80 and older [4, 9, 13]. PAD risk varies both by age and the presence of concurrent risk factors (Table 2), with age greater than 75 years considered a PAD risk amplifier [10, 11, 13, 14]. Sex-based differences between men and women are variable, with some literature

describing moderate risk increases for women, which may abate with increasing age [9, 13]. The presence of geriatric syndromes (i.e., frailty, mobility impairment, cognitive decline, sarcopenia, malnutrition, cognitive decline, etc.) are considered PAD risk amplifiers because they may obscure the symptoms of PAD [11].

Depression

A concurrent diagnosis of depression is considered a PAD risk amplifier. Studies have shown up to 16 % of patients with PAD also have symptoms or a concurrent diagnosis of depression, self-perceived stress (~28 %), and anxiety (~8 %) [11]. Concurrent depression has also been associated with higher rates of amputation (+13 % higher) and mortality (+17 % higher) over an approximate 6-year period [11].

Diabetes

Diabetes has been associated with a 2- to 4-fold increase in the prevalence of PAD by accelerating disease progression, worsening lower-extremity arterial perfusion, and increasing amputation rates [4, 9, 10]. A cohort study found that concomitant diagnoses of PAD and diabetes mellitus increase the risk of amputation by four-fold, attributing to approximately 50,000 major leg amputations annually in the United States [8]. Although a majority of patients will require treatment with endovascular interventions, research suggests that inexpensive and evidence-based measures such as monitoring the hemoglobin A1c, diabetic foot examinations, diabetic foot care, and vascular assessments are underutilized. Tight glycemic control remains a core guideline recommendation in comprehensive PAD treatment [10, 14].

Hyperlipidemia

Atherosclerotic disease plays a pivotal role in more than 90 % of PAD cases and is a significant risk factor for PAD development and progression [15-17]. A total cholesterol greater than 200 mg/dl is associated with a 10-25 % increase in PAD development, increasing by 15 % for each additional rise of 30 mg/dL [10]. Randomized controlled trials have demonstrated that lowering low-density lipoprotein cholesterol (LDL-C) to less than 55 mg/dL (or ≥50 % reduction) reduces major adverse limb events (MALE), including amputations, by approximately 25 % [16]. Raising the high-density lipoprotein (HDL) levels above 40 mg/dL in men and 50 mg/dL in women is associated with a decreased risk of mortality [16]. Current guidelines endorse treatment with high-intensity statins at maximum doses to achieve a ≥50 % reduction in LDL-C levels and endorse adding proprotein convertase subtilisin/kexin

MRN: Biological Gender:		- 5 4 5	Birthdate: _/Today's date:/ Male Female Ethnicity: Hispanic or Latino Asian			
		-				
_ An	nerican Indian or Alask				☐ Native Hawaiian or Other Pacific ☐ White	
		Ankle E	trachial Pressure Ind	lex Mea	surement (ABPI)	
			ABPI RIGHT =		= ABPI LEFT = =	
	Systolic Readings		ABI Value		Interpretation	
	DP: dorsalis pedis	Learn how:	Greater than	1.4	Noncompressible: seek alternate testing	
	PT: posterior tibial	okla.st/abl	1.0-1.4		Normal	
	RIGHT	LEFT	0.91-0.99		Borderline	
DP	Systolic Readings	DP	0.8-0.9		Abnormal: Mild arterial disease	
PT		PT	0.5-0.79		Abnormal: Moderate arterial disease	
			Less than 0.5		Abnormal: Severe arterial disease	
ABP	PI = Highest ankle pressure (E Highest SBP arm (right or		*Foot ulceration may	occur at	high ABPIs in patients with diabetes as PAD is often one of many cause	
	Highest see ann (right o	i ieit)	including infection, r	europath	y and microvascular disease.	
	Risk Factor Ass	essment & Modif	ication		Patient Diagnosis & Management	
	Risk-Amplit	fying Comorbidit	les		No PAD	
	Age >75 or Geriatric S	>75 or Geriatric Syndrome			Asymptomatic Aspirin 81mg daily	
	Current tobacco use	obacco use			PAD Cloplodogrel 75mg daily	
	Diabetes		☐ Uncontrolled	PAD with Rivaroxaban 2.5mg twice daily + Aspirin 8Img daily		
	Chronic or End-Stage Kidney Disease	☐ Controlled	Uncontrolled	-	(if normal bleeding risk) Aspirin 81mg daily	
П	Polyvascular Disease	☐ Controlled	□ Uncontrolled		Claudication Clostazol 75mg twice dail	
Ħ	Microvascular Disease				(contraindicated in heart failure)	
	Depression	☐ Controlled	☐ Uncontrolled		PAD plus other Current therapy plus aspir indication for AC Simg daily	
	High-Risk	Limb Presentation	on		Risk Reduction Strategies	
	Limb pain or numbnes	ss at rest			Cardiovascular disease risk reduction strategies	
	Previous amputation of	or revascularizati	on		(diet, exercise, etc.)	
	Necrosis or gangrene	of limb			Evaluation for barriers to care and/or health disparities	
	ABI less than 0.8				Optimize comorbidity management	
		dity Assessment		F	PAD quality of life questionnaire administration	
		ssation: Offe	_		Assessment & Score:	
	Hyperlipidemia	Controlled	Not optimized		Preventative foot care	
	Hypertension	Controlled	Not optimized		Referral to Vascular Specialist	
					Structured exercise program	
therapy, Gluicer:	tors for increased bleeding includ , or OAC therapy, history of hemo ation, active malignant neoplasm	orrhagic stroke, ICH or st is at risk of bleeding, esi	gnificant bleeding, recent		Update vaccinations as needed (Influenza, coronavirus, RSV, pneumonia, etc.)	
	ms and history of coagulopathies	s/bleeding disorders.				

Figure 1: The Oklahoma State University (OSU) PAD patient screening and provider decision support tool (revised).

MEDICINE

type 9 (PCSK9) inhibitor or ezetimibe therapy in patients on maximally tolerated statin therapy who have not achieved an LDL-C of 70 mg/dL [11]. Statin-based treatment has been shown to decrease pain symptoms during walking and improve walking distance and duration [16].

Hypertension

DE GRUYTER

Uncontrolled blood pressure also contributes to negative PAD outcomes. Data from the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) demonstrated that a systolic blood pressure (SBP) ≥160 mm Hg was associated with a 21 % higher rate of lower-extremity PAD events (n=33.357, mean age 67.4 years, 53.1 % male) [18]. The Canadian Cardiovascular Guidelines for PAD recommend targeting a blood pressure of <140/90 mm Hg to reduce the risk of myocardial infarction (MI), stroke, heart failure, and death, whereas the 2024 US-based multi-society guidelines recommend targeting a blood pressure of <130/80 mm Hg [11, 19]. In addition to nonpharmacologic and lifestyle modifications, angiotensin receptor blockers (ARBs), and angiotensin-converting enzyme (ACE) inhibitors are recommended to reduce the risk of major adverse cardiovascular events (MACE) [11, 19].

The Canadian guidelines also endorse calcium channel blockers and diuretics for blood pressure management in patients with PAD [19].

Microvascular disease

Microvascular disease, a PAD risk amplifier, manifests as abnormalities in the microvasculature, often leading to, and manifesting as, retinopathy, neuropathy, nephropathy, etc. The presence of microvascular disease increases the risk of PAD development by approximately 14-fold [11]. Additionally, studies have shown that patients with both PAD and concurrent microvascular disease have an increased risk of requiring limb amputation, approximately 12- to 23-fold, in a 2-year longitudinal assessment, compared to patients without microvascular disease [11].

Polyvascular disease

In addition to peripheral arteries, the cardiac and cerebral vascular beds are commonly impacted by arterial atherosclerosis. The concurrent presence of peripheral, cardiac, or cerebrovascular atherosclerotic manifestations is referred to as polyvascular disease and is classified as a PAD risk

Table 1: PAD risk amplifiers.

High-risk comorbidities

- African American race
- Concurrent geriatric syndromes
- Concurrent microvascular disease
- Current tobacco use
- Depression
- Diabetes
- History of MI, CVA, TIA, or heart failure
- Hyperlipidemia
- Hypertension
- Increasing age (>75 years)
- Polyvascular disease: vascular disease in 2 or more beds
- Renal dysfunction (eGFR<60 mL/min or end-stage kidney disease)

CVA. cerebral vascular accident: eGFR. estimated glomerular filtration rate: MI, myocardial infarction; PAD, peripheral artery disease; TIA, transient ischemic attack. Adapted from Gornik et al. [11].

Table 2: Patients at increased risk for PAD by age [11].

Patient characteristic

- ≥65 years
- Age 50-64 years with atherosclerotic risk factors^a
- Age <50 years with diabetes plus one additional atherosclerotic risk factor^a, chronic kidney disease, or family history of PAD
- Any age with known atherosclerotic disease in another vascular bed^b

PAD, peripheral artery disease. ^aAtherosclerotic risk factors: diabetes, history of smoking, dyslipidemia, hypertension. ^bCoronary, carotid, subclavian, renal, mesenteric artery stenosis, abdominal aortic aneurysm, etc. Adapted from Gornik et al. [11].

amplifier. An estimated 65% of patients with PAD have concurrent, clinically relevant cerebral or coronary artery disease, manifested by a history of MI, cerebrovascular accident (CVA), or transient ischemic attack (TIA), and up to 45% of patients with known atherosclerotic disease have polyvascular disease [2, 11]. Current estimates indicate a twofold increase in the rates of death, MI, CVA, TIA, and ischemic limb events with two-bed vascular disease and a 3-to-6 fold increase with involvement in three vascular beds, making it imperative to assess the overall atherosclerotic burden in PAD patients [2, 10, 20–23].

Race and ethnicity

Compared to other ethnic and racial groups, Black patients have a 2- to 3-fold higher incidence of PAD [4, 6, 9, 24, 25]. The cumulative risk of lifetime PAD incidence is also highest in Black men and women, at approximately 30.0 %, with similar risk estimates existing between Hispanic and White patients (22 and 19%, respectively.) [9, 13] PAD-related amputation rates also vary based on race and ethnicity, with significantly higher critical limb ischemia and amputation rates seen in Black, Native American, and Hispanic populations as compared to the White population [7, 25, 26]. Due to the impact of race on the trajectory of PAD, an increase in research focusing on screening, intervention, and treatment in disproportionally impacted races and ethnicities has been designated a healthcare priority [6].

Renal dysfunction and chronic kidney disease

Renal insufficiency is strongly associated with PAD, although it remains undetermined if underlying kidney disease is a risk factor for, or consequence of, PAD. Atherosclerotic renal arterial changes may signal advancing vascular atherosclerotic disease and may progress to decreased renal perfusion and damage [4, 9, 10]. While PAD is prevalent in up to 20-25 % of individuals with an estimated glomerular filtration rate (eGFR) less than 60 mL/min, routine renal artery vasculature screening in patients with PAD is not currently recommended [4, 10, 11].

Tobacco use

Like atherosclerotic disease in other vascular beds, current or former smoking is one of the strongest risk factors for PAD. Smoking tobacco increases the incidence of PAD development two-fold to five-fold and exacerbates current PAD symptoms [4, 8–10, 13, 27–29]. Smoking cessation decreases the risk of PAD, amputation MI, and death, and smoking is a Class 1 guideline recommendation in the treatment of PAD [8, 10, 17–19]. Behavioral counseling in combination with pharmacologic therapy can be considered, ranging from nicotine replacement therapy to bupropion, or varenicline [19].

Peripheral artery disease (PAD) clinical presentations and diagnosis

There are known high-risk clinical presentations linked with increasing PAD severity and negative outcomes. These presentations are grouped into two categories, major adverse limb events (MALE) and major adverse cardiovascular events (MACE.) The clinical manifestations of MALE include symptoms of critical limb ischemia such as sudden-onset lower extremity pain that is associated with cold, pale extremities. Patients may also present with high-risk and low-risk clinical features, as precursors to MACE and MALE (Table 3).

It is important to note that many patients may underreport lower-risk clinical symptoms and/or attribute these symptoms to other medical conditions, such as osteoarthritis,

Table 3: PAD clinical features.

High-risk presentation				
_	ABI less than 0.8			
_	Limb pain or numbness at rest			
_	Necrosis or gangrene of the limb			
_	Previous amputation			
-	Previous revascularization			

Lower-risk presentation

- Aching, cramping, or pain in your legs, calves, buttocks, or thighs when you walk or exercise
- Feet that are cold to the touch or one foot that is colder than the other
- Leg pain that disturbs your sleep or pain at rest
- Loss of feeling or tingling in your legs or feet
- Sores, wounds or ulcers on your legs or feet
- Toes that are pale, discolored, or bluish

ABI, ankle-brachial index; PAD, peripheral artery disease.

and may go unappreciated or underappreciated due to the slow nature of PAD disease progression [2]. Patients may also display varying degrees of symptomatology, which may not always correlate with disease severity, making objective testing necessary to confirm the diagnosis and stage the severity of the disease [10, 14].

Several objective testing modalities are available, including ankle-brachial index (ABI), duplex ultrasound, digital subtraction angiography, computed tomography angiography, and magnetic resonance angiography [14]. Of these modalities, only ABI testing may be performed by a variety of healthcare providers without the requirement for specialized training and licensing [30]. The ABI has high interobserver reliability (kappa statistic 0.77-1.0), strong sensitivity and specificity (97 and 100 %, respectively), and low variability when results between ultrasound technologists and other healthcare providers [31].

The ABI vascular doppler equipment is inexpensive, noninvasive, portable, and able to be utilized in a variety of healthcare settings. High-quality ABI technique training is readily available from OSU (okla.st/abi), the American Heart Association, and the European Society of Cardiology [14, 32]. The ABI is a validated method of diagnosing and staging PAD severity, independent of risk factors, and is utilized within the OSU-developed Provider Decision Support Tool [14, 31–33] (p2). The ABI value to PAD clinical interpretation is found in Table 4.

Discussion

Following the PAD diagnosis, early stewardship initiatives increase the opportunity for limb-preserving interventions. In

Table 4: ABI clinical interpretation.

ABI value	Interpretation		
Greater than 1.4	Noncompressible: seek alternate testing		
1.0-1.4	Normal		
0.91-0.99	Borderline		
0.8-0.9	Abnormal: Mild arterial disease		
0.5-0.79	Abnormal: Moderate arterial disease		
Less than 0.5	Abnormal: Severe arterial disease		

ABI, ankle-brachial index. ABI clinical interpretation is derived from published guidance in concert with expert opinion where guidance differences exist [2, 11, 13, 14].

addition to vascular stenting and revascularization procedures, several pharmacological and nonpharmacological therapies have been shown to decrease PAD disease progression. increase limb salvage, and decrease mortality. Evidence-based guidance recommends initiating antiplatelet therapy, smoking cessation, statin therapy for hyperlipidemia, antihypertensive, and exercise therapy for patients with these conditions [10, 13, 14, 34, 35]. Data from the Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial (COMPASS) and Total ischemic event reduction with Rivaroxaban after peripheral arterial revascularization in the VOYAGER PAD trial (VOYAGER PAD) trials indicate the benefit of dual pathway inhibition with a direct-Factor Xa inhibitor in combination with antiplatelet therapy in reducing major cardiac and limb events [36, 37]. These benefits are driven by the ability to effectively and efficiently identify, screen, diagnose, and treat PAD in at-risk patients. Risks and benefits are associated with medical management strategies, particularly with antithrombotic medications, necessitating the need for strong anticoagulation stewardship and shared decision-making as a component of PAD stewardship. The OSU-developed Provider Decision Support Tool utilizes evidence-based medicine to support clinicians in pharmacologic clinical decision-making, particularly in antithrombotic medication selection by PAD clinical situation (Table 5).

In addition to clinical barriers to care, patients may experience barriers within the key social determinants of health (SDOH) that have been shown to affect a wide range of health, functioning, and quality-of-life outcomes and risks [38]. These key SDOH conditions exist in the environment where people are born, live, work, play, worship, and age. The SDOH conditions include economic stability, healthcare and quality, social and community context, neighborhood and built environment, and education access and quality [38]. The literature also confirms that health disparities also exist within the recognition, diagnosis, and treatment of PAD. Disparities have been documented in patients of Black, Hispanic, and Native

Table 5: Summary of the PAD therapy recommendations from the 2024 multi-society guideline for the management of lower extremity PAD included in the clinical decision support tool.

Clinical situation	Guideline recommendation
Asymptomatic PAD: treatment	SAPT (aspirin or clopidogrel)
	monotherapy
Symptomatic PAD: treatment	Rivaroxaban plus aspirin <i>if low</i>
	bleeding risk ^a
	SAPT (aspirin or clopidogrel)
	monotherapy ^b
All patients	Cardiovascular disease risk reduction
	strategies
	Structured exercise program
	Aggressive mitigation of PAD risk amplifiers ^c
	Evaluation for SDOH barriers and
	health disparities
	Avoid warfarin as PAD treatment
	strategy (ineffective)
PAD plus additional indication for	Standard of care AC <i>plus</i> SAPT (aspirin
AC (i.e., AF, VTE, etc.)	or clopidogrel)
Claudication symptoms	Cilostazol ^d

^aTherapy reduces MACE and MALE for this indication. ^bTherapy reduces MACE for this indication; AC, anticoagulation; AF, atrial fibrillation; MACE, major adverse cardiovascular events; MALE, major adverse limb events; PAD, peripheral artery disease; SAPT, single-antiplatelet therapy; SDOH, social determinants of health; VTE, venous thromboembolic disease. CPAD risk amplifiers: concurrent geriatric syndromes, diabetes, tobacco use, kidney disease, poly- and micro-vascular disease, and depression. Age is also a non-modifiable risk amplifier. Risk factors for increased bleeding include the need for dual antiplatelet therapy, other nonaspirin antiplatelet therapy, history of hemorrhagic stroke, intracranial hemorrhage or other significant bleeding, recent gastrointestinal ulceration, active malignant neoplasms at risk of bleeding, esophageal varices, vascular aneurysms, history of coagulopathies or bleeding disorders, etc. Adapted from Gornik et al. [11]. dContraindicated in heart failure.

American descent, in rural areas or those with decreased access to healthcare, and in situations where structural racism or implicit bias manifests [11]. It is important to note that while the Provider Decision Support Tool was designed to specifically capture the objective health information for use in driving diagnosis and treatment, clinicians should also strive to incorporate an assessment of these factors when designing a patient-specific treatment plan.

Practice-setting adaptability: implementation of the patient screening and provider decision support tool in varied settings

A main goal in the development of the PAD Patient Screening and Provider Decision Support Tool was adaptability for use in various clinical settings and across varied PAD Stewardship program initiatives. To date, the developed tool has been implemented in four distinct clinical settings. In all settings, patients have been presented with high-quality PAD patient education materials as developed by the American Heart Association [39].

Setting 1: office use

In this model, the PAD Patient Screening and Provider Decision Support Tool is utilized within the traditional provider office. The patient either completes the patient screening component (A) in the office lobby; (B) in the examination room before seeing their provider; or (C) during their visit intake interview before seeing the clinician. Following a positive PAD screen by symptoms or risk factors, the ABI assessment may be conducted in the office, either as a standing reflex order or in the office or post-visit as individually ordered by the clinician. Upon receipt of the ABI results, the clinician utilizes the Provider Decision Support element to determine the severity of PAD, and to assess the patient's symptoms and risk factors, using these elements to guide antithrombotic therapy per the included algorithm. The tool has also been utilized as clinical encounter documentation. To date, the Provider Decision Support Tool has been utilized in printed form, with electronic health record (EHR) integration and converstion to an app under exploration.

Setting 2: community use

At-risk individuals are often encountered at health fairs or other community events. Given the noninvasive nature and ease of use of vascular dopplers, health fairs present an opportunity to screen and educate the public on PAD. The PAD Patient Screening and Provider Decision Support Tool has been printed in a two-sided copy and has extensively been utilized in this setting. Patients may either self-screen during the health fair or be assisted by participating healthcare professionals, students, or trainees. The ABI assessment results have been recorded on the clinicianfacing component, with patients instructed to share the results and tool with their next healthcare provider. When no privacy or legal barriers exist, the tool and patient assessment results have been directly communicated to the patient's healthcare provider.

Setting 3: PAD specialty clinic

The PAD Patient Screening and Provider Decision Support Tool has been employed by specialty clinics to optimize anticoagulation and PAD stewardship. Currently, the tool is utilized in two specialty clinic settings, both under the direction of anticoagulation stewardship pharmacists. The first model is housed within an ambulatory anticoagulation management service as an extension of the current care offerings. The clinic identifies PAD patients and those at elevated risk via EHR query utilizing keywords for PAD, peripheral vascular disease, and the known PAD risk factors previously discussed. Patients are contacted by clinic staff and offered PAD screening during the scheduled clinic hours. The pharmacist conducts the patient symptom assessment, risk factor screening, and ABI measurement during the encounter. Anticoagulation therapy is initiated, if indicated, under a collaborative drug therapy management agreement. Patients requiring additional risk factor mitigation, such as hypertension, hyperlipidemia, or diabetes, are referred to the partner pharmacist-run pharmacotherapy clinic, providing wrap-around care. One PAD specialty clinic utilizing the tool in this manner is collecting data, for a planned analysis of patient demographics, rates of PAD diagnosis and severity, therapy changes because of screening, and long-term assessment of patient outcomes.

The second PAD specialty clinic includes a pharmacist partnership with an established nurse-led diabetic education program within a safety net clinic. In this clinic, newly diagnosed diabetic patients are required to attend six education sessions to qualify for no- or low-cost diabetic care. Because diabetes is a strong predictor for PAD development and severity acceleration, all new patients to the program receive patient symptom assessment, risk factor screening, and ABI measurement. The obtained results are communicated to the patient's safety net clinic primary care provider, with the clinicians utilizing the care modalities recommended within the Provider Decision Support Tool to guide care.

Setting 4: patient self-directed or self-selected

Lastly, several offerings for self-driven patient identification have been utilized. Printed educational PAD material containing a copy of the PAD Patient Screening and Provider Decision Support Tool has been made freely available in healthcare patient waiting rooms, pharmacies, food banks, and other locations within the community. Patients are encouraged to review the educational material and return the completed patient screening component to their care provider, initiating the conversation regarding personal risks and goals of care. Local patient and provider feedback has been positive.

Conclusions

PAD is a leading cause of limb loss, MI, stroke, and death. Even though the risk factors and contributing health conditions are known, many patients remain undiagnosed and undertreated. There are many factors contributing to this health inequity, including, but not limited to, barriers within the key areas of the SDOH, known health disparities, lack of patient and provider awareness, and varying disease presentation [38].

The Patient Screening and Provider Decision Support Tool is designed to improve the effectiveness and efficiency in screening, diagnosing, and offering PAD treatment, ideally early in the disease process. This tool is the first tool described in the literature and is made openly available for implementation in multiple care settings, by varied disciplines of healthcare providers. Beyond the initial screening and diagnosis of PAD, providers also need to be cognizant that effective management of PAD requires continuous monitoring and adjustment of the treatment plan, as the strategies to combat the negative outcomes associated with PAD often include significant medical and lifestyle changes. Patient motivation and encouragement to maintain compliance are also essential. The Patient Screening and Provider Decision Support Tool described here provides a starting point by which to integrate the evidence-based guidelines when individualizing patient care in the treatment pathways for PAD.

Research ethics: Not applicable. **Informed consent:** Not applicable.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Use of Large Language Models, AI and Machine Learning

Tools: None declared.

Conflict of interest: None declared. Research funding: None declared. Data availability: Not applicable.

References

- 1. CDC. Peripheral arterial disease (PAD) | cdc.gov. Centers for Disease Control and Prevention; 2021. https://www.cdc.gov/heartdisease/PAD. htm [Accessed 10 Nov 2022].
- 2. Peach G, Griffin M, Jones KG, Thompson MM, Hinchliffe RJ. Diagnosis and management of peripheral arterial disease. BMJ 2012;345:e5208.
- 3. Peripheral artery disease what is peripheral artery disease? | NHLBI, NIH; 2022. https://www.nhlbi.nih.gov/health/peripheral-arterydisease [Accessed 7 Nov 2023].

- 4. Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999–2000. Circulation 2004;110: 738-43.
- 5. Home. Dartmouth Atlas of Health Care. https://www.dartmouthatlas. org/ [Accessed 12 Dec 2022].
- 6. Bryce Y, Katzen B, Patel P, Moreira CC, Fakorede FA, Arya S, et al. Closing the gaps in racial disparities in critical limb ischemia outcome and amputation rates: proceedings from a society of interventional radiology foundation research consensus panel. J Vasc Interv Radiol 2022;33:593-602.
- 7. Jindeel A, Narahara KA. Nontraumatic amputation: incidence and cost analysis. Int J Low Extrem Wounds 2012;11:177-9.
- 8. Barnes JA, Eid MA, Creager MA, Goodney PP. Epidemiology and risk of amputation in patients with diabetes mellitus and peripheral artery disease. Arterioscler Thromb Vasc Biol 2020:40:1808-17.
- 9. Matsushita K, Sang Y, Ning H, Ballew SH, Chow EK, Grams ME, et al. Lifetime risk of lower-extremity peripheral artery disease defined by ankle-brachial index in the United States. J Am Heart Assoc 2019;8: e012177.
- 10. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary. J Am Coll Cardiol 2017;69:1465-508.
- 11. Gornik HL, Aronow HD, Goodney PP, Arya S, Brewster LP, Byrd L, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of cardiology/American heart association joint committee on clinical practice guidelines. Circulation 2024;149:e1313-410.
- 12. Feringa HHH, Bax JJ, Hoeks S. A prognostic risk index for long-term mortality in patients with peripheral arterial disease. Arch Intern Med 2007;167:2482-9.
- 13. Heart disease and stroke statistics 2021 update. Circulation. https:// www.ahajournals.org/doi/10.1161/CIR.000000000000950 [Accessed
- 14. Aboyans V, Ricco JB, Bartelink MLEL, Björck M, Brodmann M, Cohnert T, et al. 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European society for vascular surgery (ESVS): document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European stroke organization (ESO) the task force for the diagnosis and treatment of peripheral arterial diseases of the European society of cardiology (ESC) and of the European society for vascular surgery (ESVS). Eur Heart J 2018;39: 763-816.
- 15. Høyer C, Sandermann J, Petersen LJ. The toe-brachial index in the diagnosis of peripheral arterial disease. J Vasc Surg 2013;58:231-8.
- 16. Belch JJF, Brodmann M, Baumgartner I, Binder CJ, Casula M, Heiss C, et al. Lipid-lowering and anti-thrombotic therapy in patients with peripheral arterial disease: European atherosclerosis society/European society of vascular medicine joint statement. Atherosclerosis 2021;338:
- 17. Thukkani AK, Kinlay S. Endovascular intervention for peripheral artery disease. Circ Res 2015;116:1599-613.
- 18. Itoga NK, Tawfik DS, Lee CK, Maruyama S, Leeper NJ, Chang TI. Association of blood pressure measurements with peripheral arterial disease events: a reanalysis of the ALLHAT data. Circulation 2018;138: 1805-14.

- 19. Abramson BL, Al-Omran M, Anand SS, Albalawi Z, Coutinho T, de Mestral C, et al. Canadian cardiovascular society 2022 guidelines for peripheral arterial disease. Can J Cardiol 2022;38:560-87.
- 20. Sabouret P, Cacoub P, Dallongeville J, Krempf M, Mas J, Pinel J, et al. REACH: international prospective observational registry in patients at risk of atherothrombotic events. Results for the French arm at baseline and one year. Arch Cardiovasc Dis 2008;101:81-8.
- 21. Bhatt DL. Peterson ED. Harrington RA. Ou FS. Cannon CP. Gibson CM. et al. Prior polyvascular disease: risk factor for adverse ischaemic outcomes in acute coronary syndromes. Eur Heart J 2009;30: 1195-202.
- 22. Gutierrez JA, Scirica BM, Bonaca MP, Steg PG, Mosenzon O, Hirshberg B, et al. Prevalence and outcomes of polyvascular (coronary, peripheral, or cerebrovascular) disease in patients with diabetes mellitus (from the SAVOR-TIMI 53 trial). Am J Cardiol 2019; 123:145-52.
- 23. Hirsh J, Bhatt DL. Comparative benefits of Clopidogrel and Aspirin in high-risk patient populations: lessons from the CAPRIE and CURE studies. Arch Intern Med 2004;164:2106-10.
- 24. Shu J, Santulli G. Update on peripheral artery disease: epidemiology and evidence-based facts. Atherosclerosis 2018;275:379-81.
- 25. Home. Dartmouth Atlas of Health Care. https://www.dartmouthatlas. org/ [Accessed 12 Dec 2023].
- 26. Rizzo JA, Chen J, Laurich C, Santos A, Martinsen BJ, Ryan MP, et al. Racial disparities in PAD-related amputation rates among native Americans and non-Hispanic Whites: an HCUP analysis. J Health Care Poor Underserved 2018;29:782-800.
- 27. Armstrong EJ, Wu J, Singh GD, Dawson DL, Pevec WC, Amsterdam EA, et al. Smoking cessation is associated with decreased mortality and improved amputation-free survival among patients with symptomatic peripheral artery disease. J Vasc Surg 2014;60:1565-71.
- 28. Ding N, Sang Y, Chen J, Ballew SH, Kalbaugh CA, Salameh MJ, et al. Cigarette smoking, smoking cessation, and long-term risk of 3 major atherosclerotic diseases. J Am Coll Cardiol 2019;74:498-507.
- 29. Jonason T, Bergström R. Cessation of smoking in patients with intermittent claudication. Effects on the risk of peripheral vascular complications, myocardial infarction and mortality. Acta Med Scand 1987;221:253-60.
- 30. Bryce Y, Katzen B, Patel P, Moreira CC, Fakorede FA, Arya S, et al. Closing the gaps in racial disparities in critical limb ischemia outcome and amputation rates: proceedings from a society of interventional radiology foundation research consensus panel. J Vasc Interv Radiol 2022;33:593-602.
- 31. Al-Qaisi M, Nott DM, King DH, Kaddoura S. Ankle brachial pressure index (ABPI): an update for practitioners. Vasc Health Risk Manag 2009; 5:833-41.
- 32. Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al. Measurement and interpretation of the ankle-brachial index. Circulation 2012;126:2890-909.
- 33. Barrera-Guarderas F, Carrasco-Tenezaca F, De la Torre-Cisneros K. Peripheral artery disease in type 2 diabetes mellitus: survival analysis of an Ecuadorian population in primary care. J Prim Care Community Health 2020;11. https://doi.org/10.1177/2150132720957449.
- 34. Aboyans V, Bauersachs R, Mazzolai L, Brodmann M, Palomares JFR, Debus S, et al. Antithrombotic therapies in aortic and peripheral arterial diseases in 2021: a consensus document from the ESC working group on aorta and peripheral vascular diseases, the ESC working group on thrombosis, and the ESC working group on cardiovascular pharmacotherapy. Eur Heart J 2021;42:4013-24.

- 35. Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. Eur J Vasc Endovasc Surg Off J Eur Soc Vasc Surg 2019;58: S1-109.e33.
- 36. Anand SS, Bosch J, Eikelboom JW, Connolly SJ, Diaz R, Widimsky P, et al, COMPASS Investigators. Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial. Lancet 2018;391:219-29.
- 37. Bauersachs RM, Szarek M, Brodmann M, Gudz I, Debus ES, Nehler MR, et al, VOYAGER PAD Committees and Investigators. Total ischemic event reduction with Rivaroxaban after peripheral arterial

- revascularization in the VOYAGER PAD trial. J Am Coll Cardiol 2021;78: 317-26.
- 38. Social determinants of health healthy people 2030 | health.gov. https://health.gov/healthypeople/priority-areas/social-determinantshealth [Accessed 8 Jul 2024].
- 39. PAD resources. www.heart.org. https://www.heart.org/en/healthtopics/peripheral-artery-disease/pad-resources [Accessed 27 Dec 2023].

Supplementary Material: This article contains supplementary material (https://doi.org/10.1515/jom-2024-0050).