

Epidemiology of Peripheral Arterial Disease and Critical Limb Ischemia



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With a rise in the aging population, the prevalence of peripheral arterial disease (PAD) is markedly increasing. The overall disease prevalence of PAD is in the range of 3%-10%, which increases to 15%-20% in persons older than 70 years of age. Given this upward trend in disease prevalence, the economic and societal burden of PAD would be considerable. The subgroup of patients who develop critical limb ischemia (CLI) represents the most challenging population to manage medically, surgically, and endovascularly. Patients with symptomatic PAD and CLI have an increased risk for death and cardiovascular events, especially in those with CLI who carry with them a substantial risk of limb loss. Advances in medical, surgical, and endovascular techniques have shown excellent outcomes in the treatment of these patients, however the optimal management paradigm has not been elucidated. This article reviews the classification and epidemiology, risk factors, natural history, and health care costs associated with PAD and CLI.

Tech Vasc Interventional Rad 19:91-95 Published by Elsevier Inc.

KEYWORDS Critical Limb Ischemia, Peripheral Arterial Disease, Amputations, atherosclerosis, claudication

Introduction

Peripheral arterial disease (PAD) represents a local manifestation of a lethal systemic disease—atherosclerosis—and portends a 2–6-fold increase in both cardiovascular and cerebrovascular events. The diagnosis is also associated with an annual mortality rate of 4%–6%.¹ In addition to causing lifestyle-limiting claudication symptoms, uncontrolled disease can progress on to critical limb ischemia (CLI).^{2,3} Within the spectrum of PAD, CLI represents the end stage of PAD and the diagnosis portends a high rate of limb loss along with patient mortality. Leg amputation due to atherosclerotic PAD gives rise to an acute mortality rate of approximately 30% and a 5-year survival rate of less than 30%.^{2,3} Revascularization remains the cornerstone of limb salvage in patient with CLI, and surgical bypass is the established standard procedure. Endovascular therapies, such as angioplasty, atherectomy, and stenting offer a less invasive option, but evidence of efficacy is heterogeneous. Moreover, approximately 20%–30% of patients with CLI are not

considered candidates for open or endovascular revascularization with amputation often being the only option.³ Further, complicating this condition is the lack of effective pharmacologic treatments to alter the natural history of CLI.

Along with the management dilemma, the prevalence of PAD is dramatically increasing. Given the rising cost of healthcare, the economic and societal burden of PAD and CLI is poised to be tremendous. Likewise, the burden on providers treating with PAD and CLI continues to mount as physicians are constantly under scrutiny to control the rising costs associated with interventions.⁴ In the management of patients with PAD and CLI, costs are thought to be driven primarily by the need for multiple procedures that result in longer length of stay, regardless of whether revascularization or primary amputation is decided as treatment.⁵ An overview of PAD and its epidemiology and risk factors, along with cost of treating the disease is detailed in this article.

Epidemiology and Classification

In all, 8–10 million Americans suffer from PAD with an overall prevalence of 12% in the adult population.³ The prevalence of CLI is approximately 1.3%. Men are more

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Table Classification of Peripheral Arterial Disease

Classification of Peripheral Arterial Disease: Fontaine's and Rutherford-Becker				
Fontaine	Rutherford-Becker		Definition	Ankle-Brachial Index (ABI)/Toe Pressure (TP)
	Grade	Category		
Stage I	0	0	Asymptomatic	ABI > 0.95
Stage IIa	I	1	Mild claudication	ABI > 0.80
Stage IIb	I	2/3	Moderate-severe claudication	ABI > 0.40
III	II	4	Ischemic rest pain	ABI < 0.40
IV	III	5/6	Tissue loss (minor [5]/major [6])	TP < 30 mm Hg

likely to suffer from PAD than women and prevalence is age dependent, with nearly 20% of adults aged 70 years and older carrying the diagnosis.⁶ The annual incidence of PAD is reported at approximately 2.4% with CLI being reported at 0.4%.^{2,3}

The clinical presentation of PAD may vary from no symptoms to intermittent claudication (IC), atypical leg pain, rest pain, ischemic ulcers, or gangrene. PAD is first broadly classified into asymptomatic PAD and symptomatic PAD. Within the symptomatic PAD group, patients are further divided into IC and CLI. The disease prognosis and natural history is different between patients with asymptomatic PAD, IC, and CLI, hence distinction is important with respect to the long-term management of these patients.^{2,3}

The most widely used classification schemes to qualify the level of PAD are the Fontaine and Rutherford-Becker grading system with the latter being the most common (Table).⁷ Rutherford Grade I denotes asymptomatic patients or patients who have symptoms during high levels of activity. Rutherford Grade II patients develop symptoms at moderate level of activity. Rutherford Grade III patients develop symptoms at low level of activity and are limited in their lifestyle. These patients can be said to have disabling claudication. Clinical symptoms of CLI begin with "rest pain" defined as intractable foot and ankle pain at rest that have occurred for greater than 2 weeks, and fall into Rutherford Grade IV.⁷ Rutherford Grade V patients present with ischemic tissue loss, commonly presenting as foot ulcerations. Rutherford Grade VI patients present with tissue necrosis and gangrene. It is important to note that CLI does not always progress through the various stages of these classification systems and some patients may not even have PAD symptoms before the onset of CLI.

Asymptomatic PAD

The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) determined that the disease prevalence of asymptomatic PAD was between 3% and 10% of the population. This increases to a prevalence of 15%-20% in patients older than 70 years. A simple, office-based ankle-brachial systolic pressure index (ABI) examination is used to confirm the presence of disease. A resting ABI of <0.9 is deemed abnormal and is the objective definition of having PAD. Patients with an ABI

of 0.7-0.9 are classified as having mild PAD. ABIs in the range of 0.4-0.69 indicate moderate disease and <0.4 is denoted to have severe PAD.^{2,8,9}

If patients are asymptomatic then modification of lifestyle risk factors including smoking cessation, obesity, glucose control, and exercise is recommended. Prevalence of asymptomatic PAD has been primarily studied through screening subjects with noninvasive ABI testing. The ratio of symptomatic-to-asymptomatic PAD ranges from 1:3 to 1:4. Sex difference in asymptomatic PAD have not been well studied but current data reports suggest that women remain asymptomatic for longer periods of time and present later in life with more advanced disease.¹⁰

Symptomatic PAD

Intermittent Claudication (Rutherford Grade I-III)

IC is a clinical diagnosis revolving around a history of cramping lower extremity muscle pain that occurs with activity and is relieved by rest in a patient with objective confirmation of PAD (ABI < 0.9). The symptoms are reproducible with activity and occur in the same muscular bed, most commonly affecting the calves. IC is prevalent in approximately 3% of patients up to the age of 40 years and doubles in prevalence to 6% by the age of 60 years. In terms of sex, IC appears to be more common in men at a younger age but this sex difference is no longer significant in the elderly population. Data from the Framingham Study found the annual incidence of IC to increase from <0.4 per 1000 men aged 35-45 years to 6 out of 1000 men in the age group >65 years. In women, the incidence of IC was <0.2 per 1000 at the younger age but rose to similar values as their men counterparts in the 65-74 age group. It is postulated that the higher incidence of symptomatic PAD in men is reflective of greater disease severity.^{10,11} The data from the Multi-Ethnic Study of Atherosclerosis (MESA) reported that prevalence of PAD was the same in men and women at 3.7% but borderline values of ABI were significantly higher in women (10.6% vs 4.3%).¹²

The treatment goals of IC are to relieve symptoms, to improve exercise performance, and to improve the daily functional abilities. The initial approach to the treatment of limb symptoms should focus on structured exercise and, in selected patients, pharmacotherapy to treat the exercise limitation of claudication (cilostazol and statin).¹³ Risk

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