Clinical Research and Methods

An Absent Pulse Is Not Sensitive for the Early Detection of Peripheral Arterial Disease

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Background: *This study's objective was to determine the test characteristics of pedal pulse palpation in the diagnosis of peripheral arterial disease (PAD) when compared to the more widely recommended screening tool, the ankle-brachial index (ABI).* Methods: *We screened patients ≥ 50 years of age for PAD within primary care clinics in Houston. PAD was diagnosed by an ABI of <0.9. At each visit, pedal pulse palpation was performed for each leg. Of the patients who screened positive for PAD by ABI, we determined the sensitivity, specificity, and positive predictive value of pulse palpation.* Results: *We enrolled 403 patients with a mean age of 63.8 ± .36 years. The prevalence of PAD was 16.6% (67 patients total). Of the 45 patients with disease involving their left leg, 37 (82.2%) had a palpable pulse. Of the 37 patients with disease involving their right leg, 25 (67.6%) had a palpable pulse. The sensitivity of a non-detectable pulse for the diagnosis of PAD was 17.8% and 32.4% for the left leg and the right leg, respectively. The specificity of pulse palpation for the detection of PAD was 98.7% and 97.8% for the left leg and the right leg, respectively.* Conclusions: *Pulse palpation is not sensitive for the detection of PAD compared to ABI. More than two thirds of the patients within our cohort with PAD of either the left or right leg had a detectable pulse.*

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Peripheral arterial disease (PAD) is atherosclerosis of the abdominal aorta and arteries of the lower extremities.[1] PAD affects 20% to 30% of patients ≥ 50 years of age.[2-4] The annual age-specific incidence of PAD is 61 per 10,000 men and 54 per 10,000 women ages 65 to 74 years. [5]

Direct comparisons of the prevalence of PAD have been compromised by the use of different measures to detect disease and the varying prevalence of atherosclerotic risk factors among the population screened. For example, in asymptomatic patients older than age 55 years, the prevalence of PAD has been reported to be 10%, and the diagnosis was based on the ankle brachial index (ABI) or additional testing in the vascular laboratory.[2] Based on an ABI < 0.90, Hirsch et al reported a 29% prevalence of disease in patients 70 years or older or 50–69 years with smoking or diabetes mellitus as a risk factor.[3] In contrast, the prevalence of intermittent claudication, as captured by patient history, was reported to be 5% and 2.5% for men and women, respectively, older than 60 years.[6]

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The most reliable and simple objective assessment of PAD is the bedside measurement of the ABI, which is a ratio of the systolic blood pressure in the ankle to that in the arm.[2,7,8] Although the cut-off value of the ABI for the diagnosis of PAD can vary from <0.80 to as high as < 0.97,[9,10] a value of < 0.90 is reported to be 97% sensitive for isolated aortoiliac disease and 89% sensitive for isolated femoropopliteal disease.[11] Thus, for most cross-sectional or prospective studies conducted within the past 2 decades and that involve screening for PAD, the presence of disease was defined by a resting ABI ≤ 0.90.[3,12-17]

Screening for PAD is controversial, as many physicians and some organizations question the validity of defining disease if it will not change the management. Indeed, the United States Preventive Services Task Force (USPSTF) 1996 recommendations only advocated screening for disease in the presence of symptoms. In contrast, the American Diabetes Association (ADA) 2003 Consensus Statement[18] recommends screening for PAD, using the ABI, for asymtomatic or symptomatic patients with diabetes who are older than 50 years. For patients younger than 50 years with diabetes, the ADA recommends screening for PAD if there are risk factors for PAD (eg, smoking, hypertension, hyperlipidemia),

or the presence of diabetes for more than 10 years. The rationale for screening is that PAD is prevalent in patients with diabetes mellitus and is more commonly asymptomatic and more likely to lead to limb loss if a clinician waits until the onset of symptoms to identify disease.

In practice, most clinicians rely on both the history and the physical examination (ie, pulse palpation) before deciding to determine the ABI. This study's purpose was to determine the predictability of absent pulses when compared to the ABI for the diagnosis of PAD in a primary care setting.

Methods

Recruitment Strategies

The Baylor College of Medicine Institutional Review Board approved this study. We screened patients from the Houston Veterans Affairs Medical Center (HVAMC) and three primary care clinics within the Harris County (Texas) Hospital District from September 2000 through August 2001. For each facility and prior to the date of each patient's enrollment, we obtained a clinic printout of all patients who were scheduled for an appointment with their primary care clinician.

Only patients who had a primary care provider were selected. Primary care provider was defined as any clinician providing general outpatient medical care. In addition, patients were only entered into the study if they self-identified as African American, white, or Hispanic (English speaking or Spanish speaking). Patients were excluded because of an inability to complete a consent form in English or Spanish, dementia, COPD requiring oxygen, or leg ulcers or gangrene.

All patients who were approached at the time of their clinic visit were asked to complete an eligibility screening form. Patients who were eligible and willing to participate then signed a consent form. Patients were subsequently enrolled and screened for PAD using pulse palpation and ABI. Patients also completed the San Diego Claudication Questionnaire,[19] the Walking Impairment Questionnaire,[20] and a comprehensive health history questionnaire (the Lifestyle and Clinical Survey, developed by and available from the principal investigator).

Pulse Palpation and Measurement of the Ankle-Brachial Index

Trained research assistants performed pulse palpations on all patients prior to measuring their ABI. Each research assistant had completed training in pulse palpation and measurement of the ABI. Initially, the results of the research assistants were compared to that of the principal investigator as part of practice training; assistants practiced on as many persons as necessary until they were comfortable with being tested and their pulse palpation agreed with the results of palpation by the investigator. No more than 10 patients per assistant were required before they each felt comfortable. After mastering pulse palpation, the research assistants measured ABIs, using study equipment, for five patients who had been referred to the vascular laboratory and their ABI results were compared to those of the vascular laboratory technician. The research assistants were blinded to the vascular technicians' results. Neither the patient nor the technician informed the research assistant of the vascular laboratory results. The principal investigator compared the research assistants' ABI results with that of the vascular technicians, and they were considered valid if the results for each leg did not differ by more than ± 0.15. In addition, we assessed intra-rater reliability by having each nurse measure ABIs on five unique volunteers at two separate time points with no more than 2 weeks' time between the initial and follow-up measurements. For reliability, the difference in the results for each leg at the two time points could not vary by more than ± 0.15. The research assistants fulfilled the criteria for validity and reliability for 10 test patients prior to screening any of the actual cohort patients.

PAD was defined by a resting ABI below 0.90. A 5-mHz handheld Doppler with an attached stethoscope was used to measure systolic blood pressures at rest in both brachial arteries and in the arteries of the lower extremities (eg, anterior tibial artery), which is captured by placing the probe over the dorsalis pedis and posterior tibialis arteries. All patients rested in the supine position for 5 minutes before the blood pressures were taken. Appropriately sized blood pressure cuffs were placed over each brachial artery and above each malleolus. The ABI was calculated for each leg by dividing the higher ankle pressure by the higher brachial pressure. If the resting ABI of either leg was less then 0.9 (normal is 0.9–1.3), the patient was defined as having PAD. All patients, with or without PAD, completed all questionnaires.

Sample Size

The sample size required to determine the prevalence of PAD was calculated using the following formula: $n = z^2\pi(1-\alpha) / d^2$. To obtain a 95% $(1-\alpha)$ confidence interval with half width d around the estimated value of the prevalence, the sample size formula is as above, based on the normal approximation. For PAD, we assumed the prevalence (α) is at least 10%. By using a d value of .05, the sample size required to detect asymptomatic disease is 138 per ethnic group.

Statistical Analysis

We examined the association of a non-palpable pulse and an ABI<0.90 (a diagnosis of PAD) using the chi-square test. We also assessed for the association between certain risk factors and the presence of PAD using a *t* test for continuous variables and chi-square for categorical variables. All analyses were performed using SAS 6.12 for Unix.

Results

We approached 457 patients and enrolled 403 (88%) of them. A total of 151 patients were enrolled from the Michael E. DeBakey VA Medical Center and 252 from the Harris County Hospital District. Of the 403 patients enrolled, 67 (16.6%) had PAD (Table 1).

The population was similarly divided by race, with 136 whites, 136 African Americans, and 131 Hispanics. PAD (based on the ABI) was more prevalent in African Americans (22.8%) than in whites and Hispanics (13.5%), both English and Spanish speaking (P=.02). For the entire cohort, within the African American and Hispanic racial groups, there was a slighter greater number of women compared to men, with 82 versus 54 African American women and men, respectively, and 71 versus 60 Hispanic women and men, respectively. In contrast, among the white patients, there were 55 women compared to 81 men.

The mean ABI was .72 ± .02 for patients with PAD and 1.13 ± .01 for patients without PAD (P<.0001) (Table 2). For patients with PAD, 25 (37.3%) had no leg symptoms, 37 (55.2%) had atypical leg symptoms, and five (7.5%) had symptoms of classic intermittent claudication. Using the Walking Impairment Questionnaire, the walking distance score was 43.3 (SE 5.1) for patients with PAD, compared to 60.4 (SE 2.2) for patients without PAD (P=0.001). Similarly, the stair-climbing score was 40.3 (SE 4.8) for patients with PAD, compared to 50.6 (SE 2.1) for patients without PAD (P=.04). There was no significant difference in walking speed for patients with and without PAD.

Since the ABI can be falsely elevated in patients with diabetes mellitus (ie, non-compressible tibial arteries), we determined the proportion of our patients with and without diabetes mellitus who had an ABI >1.3. Twenty-three (15%) of our patients with diabetes mellitus had an ABI > 1.3 and 40 (16%) of our patients without diabetes mellitus had an ABI of > 1.3 (P=.79). There was no difference in the prevalence of a palpable pulse among PAD-defined patients with versus without diabetes. Data on predictability of pedal pulse palpation for PAD are shown in Table 3.

While there was no difference by gender or ethnicity in the ability to palpate a pedal pulse in patients with PAD, the odds ratio (OR) of a palpable pulse was lower for patients with an ABI in the range of 0.51 to 0.69—moderate severity (OR=.07, 95% confidence interval=.01, .85) when compared to a higher ABI in the range of 0.7 to 0.89—mild severity.

Discussion

Among a racially diverse population of patients, pulse palpation was not a sensitive tool for the detection of PAD. The specificity of an absent pulse for the diagnosis of PAD, however, was excellent.

To date, few studies have evaluated the role of pulse palpation in a primary care clinic population screened for PAD; no studies have evaluated the sensitivity of this physical examination finding in an ethnically diverse population of patients with a significant number of women. Most studies evaluating the role of pulse palpation for defining PAD involved patients who either had a specific risk factor profile (ie, diabetes mellitus)[21] or were referred to a vascular surgery clinic.[22,23]

We identified one cohort study[24] that determined the sensitivity of pulse palpation for the diagnosis of PAD when compared to the ABI among white middle-class patients within a defined geographic area. Criqui

Table 1

Demographics of the Cohort[28]

	Total Cohort 403 (100%)	*PAD 67 (16.6%)*	*Non-PAD 336 (83.4%)*	*P Value*
Race and ethnicity, n (%)				
White	136 (33.8%)	18 (13.2%)	118 (86.8%)	.06
African American	136 (33.8%)	31 (22.8%)	105 (77.2%)	
Hispanic*	131 (32.5%)	18 (13.7%)	113 (86.3%)	
Race and ethnicity, n (%)				
White/Hispanic*	267 (66.2%)	36 (13.5%)	231 (86.5%)	.02
African American	136 (33.8%)	31 (22.8%)	105 (77.2%)	
Age, mean ± SE	63.8 ± .36	65.3 ± .85	63.5 ± .40	.06
Men, n (%)	195 (48.4%)	34 (50.7%)	161 (47.9%)	.67
Women, n (%)	208 (51.6%)	33 (49.3%)	175 (52.1%)	
Income				
< $5,000	65 (16.3%)	12 (17.9%)	53 (16.0%)	.14
$5,000–$30,000	253 (63.4%)	44 (65.7%)	209 (63.0%)	
$30,000–$50,000	30 (7.5%)	3 (4.5%)	27 (8.1%)	
$50,000 or greater	20 (5.0%)	0	20 (6.0%)	
Decline to answer or unknown	31 (7.8%)	8 (11.9%)	23 (6.9%)	

PAD—peripheral arterial disease

* Hispanic includes both English- and Spanish-speaking patients. Percentage refers to column percent.

Table 2

Medical History and Physical Activity by PAD Versus Non-PAD

	PAD	*Non-PAD*	P *Value*
Ankle-brachial index, mean ± SE	.72 ± .02	1.13 ± .01	<. 0001
Smoking status % Current Past Never	 20 (29.9%) 26 (38.8%) 21 (31.3%)	 56 (16.7%) 130 (38.7%) 150 (44.6%)	 .02
History of diabetes	37 (55.2%)	116 (34.5%)	.001
History of hypertension	55 (82.1%)	223 (66.4%)	.01
History of elevated cholesterol	30 (44.8%)	153 (45.5%)	.91
History of myocadial infarction	11 (16.4%)	37 (11.0%)	.21
History of stroke	7 (10.5%)	19 (5.7%)	.14
Systolic blood pressure mean ± SE	156.5 ± 3.1	145.4 ± 1.2	.0002
Use of antiplatelet therapy, n (%)	26 (38.8%)	107 (31.9%)	.27
Blood pressure medication, n (%)	56 (83.6%)	211 (62.8%)	.001

PAD—peripheral arterial disease
SE—standard error

et al reported an overestimation of the prevalence of PAD when based on palpation of abnormal femoral or posterior tibial pulses.[24] Specifically, while 11.7% of the population was found to have ABI-defined PAD, abnormal pulse palpation was identified in more than 20% of these patients.

In addition to differences in patient population, Criqui's study differed from ours in that Criqui defined the abnormal pulse palpation as diminished or absent pulses; we reported only absent pulses. Our rationale for only assessing an absent pulse versus a palpable pulse was that, in our experience, clinicians within our local facilities usually do not refer patients for an ABI measurement unless there is an absent pulse; any degree of pulse palpation is considered evidence of some blood flow to the lower extremities and not worthy of additional testing and/or invasive treatment.

Waiting until patients have developed symptoms of disease before referring them for definitive testing is concerning since patients with asymptomatic PAD are at increased risk for systemic ischemic events, walking impairment, poor quality of life, and limb loss. For patients with an ABI of less than 0.85, the relative risk (RR) of death at 10 years has been found to be 2.4 (95% CI=1.60, 3.48).[25] Criqui et al demonstrated that within a cohort of patients with PAD whose mean age was 66 years, the RR for coronary heart disease (CHD) and cardiovascular disease (CVD) mortality for patients, without evidence of CVD at baseline, was 4.3 and 6.3, respectively.[26]

Despite the increased risk for ischemic events among patients with PAD, there is no evidence that early disease detection will reduce these poor outcomes. We do know that patients with diabetes mellitus are often diagnosed with PAD after the development of symptoms (eg, tissue loss or gangrene), and the disease is often advanced at the time of diagnosis. In addition, patients with diabetes mellitus often have flow-limiting disease that is confined to the tibioperoneal tree and is less amenable to revascularization. These findings, along with the presence of peripheral neuropathy that minimizes patients' awareness of symptoms until the disease has progressed, have led to the ADA's recommendation for screening for patients with diabetes mellitus.[18] Unfortunately, physicians have not readily adopted this practice.

Recently, researchers have begun to address barriers to physicians utilizing the ABI in primary care practices.[27] The PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) program,[3] a national investigation to assess the feasibility of measuring the ABI in practice, identified that physicians agreed that the ABI was a useful screening test, and they were willing to use it in their practice, but their concerns were a lack of reimbursement, a lack of staff, and a lack of time to obtain the

Table 3

Predictability of an Absent Pulse for Peripheral Arterial Disease

	Left leg (n=45)*	Right leg (n=37)*
Parameters	n (%)**	n (%)**
Palpable pulse	37 (82.2%)	25 (67.6%)
Non-palpable pulse	8	12
Sensitivity	0.18	0.32
Specificity	0.99	0.98
Predictive value positive	0.67	0.63

ABI—ankle-brachial index

* n=number with an ABI < 0.9

** Of the patients with an ABI < 0.9, the number with a palpable pulse. For the left leg, 308 patients did not have disease and, of these, four had a non-palpable pulse. For the right leg, 321 patients did not have disease and, of these, seven had a non-palpable pulse.

measurements. These barriers must be addressed prior to widespread implementation of measuring the ABI in primary care practices.

Limitations

Our study limitations include a lack of blinding of the research assistants who performed both the pulse palpation and the ABI measurements. Although the research assistants were never informed as to how pulse palpation related to the diagnosis of PAD, the possibility of bias still remains.

There may also be concern that the personnel measuring the ABI were nonphysicians. However, nonphysicians commonly work in vascular laboratories throughout the country and are responsible for measuring the ABI. In addition, most prior cross-sectional screening studies have used nonphysicians to obtain the ABI. Finally, we did not confirm our diagnosis of PAD by further testing in the vascular laboratory, but, as previously discussed, the ABI is a reliable screening test for PAD.

Conclusions

Pulse palpation is an inappropriate screening tool for PAD. A more appropriate tool is the ABI. Although defining the benefits of screening to reduce poor outcomes in patients with PAD requires further research, we recommend the use of the ABI in primary care settings for patients 70 years and older or 50–69 years with a history of smoking or diabetes mellitus.[3,28] The ultimate goal is to identify those patients at risk for impaired walking,[28,29] poor quality of life,[28] limb loss,[30,31] and death. [16,17,26]

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