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Detection of Flow Obstruction in Peripheral Arteries by Primary Care Providers: A Population-Based Registry Study

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Abstract

Peripheral arterial disease (PAD) is a condition with serious comorbidities and mortality that is frequently under-diagnosed because it is not typically associated with the classic symptoms of claudication. In primary care settings, measurement of the ankle-brachial index (ABI) with pressure cuff Doppler systems is problematic due to the necessity of a vascular technician, the time required to perform the test, and the cost of a specialized vascular diagnostic unit or laboratory facility. One cost-effective approach that has been studied to identify PAD is to use a blood volume plethysmography system (VPS) at the point of care. Quantitative VPS gives primary care physicians and other clinicians a PAD test for use in the office setting that is practical in terms of time and cost and is operator independent.

This paper reports on the use of VPS in a registry of 226,565 patients presenting to participating primary care practices in the United States.

All patients were given a standardized, self-administered questionnaire to identify PAD symptoms and cardiovascular risk factors either in clinic or at home. Patients who met the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for screening for PAD were then tested with VPS for assessing flow obstruction in the lower extremities.

Of the 226,565 patients registered, results showed 70,651 (31.3%) had moderate to severe flow impairment. The subset analysis of 27,079 patients for whom more detailed severity data was available showed 70.0% had no to mild flow disturbance, 17.2% had moderate flow obstruction, 7.9% had significant flow impairment and 4.9% had severe flow abnormalities.

The registry study showed that clinical symptoms were unreliable in being able to discriminate disease from no disease. Earlier recognition of PAD might lead to earlier secondary preventive measures and improved outcomes for a population with documented high risk of cardiovascular morbidity and mortality.

Keywords: Peripheral artery disease; Volume plethysmography system; Doppler ABI; PAD diagnosis; Ankle brachial index testing

Abbreviations: ABI: Ankle-Brachial Index; ACC: American College of Cardiology; AHA: American Heart Association; CA: Contrast Angiography; MI: Myocardial Infarction; PAD: Peripheral Artery Disease; VPS: Volume Plethysmography System

Introduction

According to recent estimates, peripheral artery disease (PAD) affects between 8 and 18 million Americans with an estimated cost of care of $290 billion per year [1]. More than half of patients with PAD also have cardiovascular disease involving the coronary, carotid or aortic arteries [2-4] and thus PAD is a marker for systemic atherosclerosis. Moreover, patients with PAD have a 21% chance of suffering a myocardial infarction (MI), manifesting coronary heart disease (CHD), stroke, or transient ischemic attack (TIA), or being hospitalized or dying of cardiovascular complications within one year [5] Clinical manifestations range from 75% of PAD patients who are asymptomatic to 2 million affected with critical limb ischemia [6,7]. Thus, most PAD patients are asymptomatic and physical examination is known to be unreliable, which results in PAD being under-diagnosed and appropriate secondary preventive care measures not recommended [8-10].

However, once PAD is identified, preventive strategies can be effective in managing PAD patients and preventing cardiovascular sequela. Treatments for hypertension, hyperlipidemia, and smoking cessation have been shown to mitigate PAD progression, reduce mortality, and decrease stroke and amputations [11-13].

Blood pressure cuff Doppler devices to determine the ankle-brachial index (ABI) are the standard tools of the vascular laboratory as a first step in the detection of PAD [14,15]. Previous studies have reported barriers to implementation, including the time to conduct the tests, training and equipment needed, and technical skills required [16]. These technical issues combined with the absence of symptoms may lead to under-diagnosis in the ambulatory care setting, which in turn

could affect the institution of effective secondary preventive care approaches [2,13,17].

VPS is a blood volume waveform visualization and evaluation system that can identify flow obstructions in the anterior tibial arterial and posterior tibial arterial distributions. It is performed in less than 5 minutes by routine office staff using a digital transducer placed sequentially on the extremities without bulky cuffs, experienced technical personnel, or the time required by current standard ABI Doppler systems [14,15]. This specialized volume plethysmography system (VPS) is intended to provide primary care physicians and other clinicians with an accessible test for use in the office or home setting that is accurate and reproducible. Studies have demonstrated the relative ease and speed in the detection of flow obstruction when in the hands of generalists and their routine office staff [16].

Today, this FDA-cleared, patented VPS test for PAD is in widespread use across the United States for the detection of lower extremity peripheral vascular flow obstruction in the primary care setting.

This report is an analysis of a registry of screening PAD testing with VPS performed at participating primary care medical practices.

Materials and Methods

From January to July 2017, participating United States primary care practices conducted a study based on a device-specific, voluntary data registry captured through physician-reported results on adult patients. A standardized, self-administered questionnaire was used to identify PAD symptoms and cardiovascular risk factors in patients presenting to primary care practices or visited at home. Patients who met the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for screening for PAD were then tested with a specialized VPS for assessing flow obstruction in the extremities [17,18].

All data was de-identified. Measurements were performed bilaterally on the lower and upper extremities. Immediately after the measurements, the VPS software determined the degree of flow obstruction in each lower extremity relative to the upper extremities without operator intervention. Standard threshold values for flow obstruction were: no abnormality=>0.99, mild <0.99 but=>0.90, moderate <0.9 but=>0.60, significant <0.6 but >0.30 and severe=<0.30.

The data storage software enabled analysis of the

1) The frequency of detection of flow abnormality for the entire registry

2) More detailed severity data available for a patient subset of the registry and

3) Clinical characteristics available for a different patient subset of the registry. The degree of overlap between the two subsets was not analyzed.

Results

The study registered 226,565 patients of which 70,651 (31.3%) had moderate to severe flow impairment.

Figure 1 shows the subset analysis of 27,079 patients for whom more detailed severity data was available: 70.0% had no or mild flow disturbance, 17.2% had moderate flow obstruction, 7.9% had significant flow impairment and 4.9% had severe flow abnormalities.

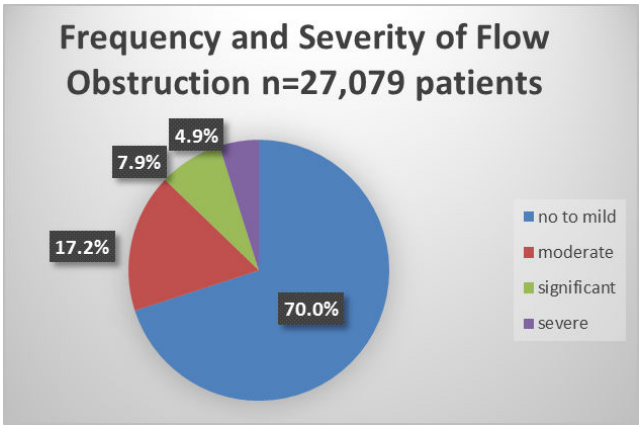

Figure 1: The frequency and severity of flow obstruction in 27,079 patients tested at primary care facilities.

Table 1 shows the subset analysis of 26,459 patients for whom clinical characteristics were available. In order of frequency, 59.9% were hypertensive, 42.9% had hyperlipidemia, 33.2% were diabetic, 6.6% had history of coronary artery disease, 5.0% had symptoms of claudication, 3.9% had history of cerebrovascular disease and 0.8% presented with non-healing leg ulceration. The data set did not include any information on pharmacological regimens or other more detailed clinical data.

Clinical Data	Subset of Patients (n=26,459)
Claudication	5.0%
Non-healing wound	0.8%
Hyperlipidemia	42.9%
Hypertension	59.9%
Diabetes	33.2%
Smoking history	19.4%
Stroke/TIA	3.9%
CAD	6.6%

Table 1: The subset analysis of 26,459 patients with clinical characteristics.

Discussion

Primary care physicians are using VPS as a screening tool for the diagnosis of PAD and to document the severity of lower extremity flow obstruction in order to begin risk factor modification or, if necessary, to refer patients to vascular specialists.

Previous studies have compared the specialized VPS to pressure cuff ABI Doppler tests performing both tests on the same patients [14]. Subsequent Duplex scans or contrast angiography results were then performed as the determinant of definite diagnosis of PAD. Results showed that VPS has higher sensitivity, equivalent specificity and greater accuracy than the older standard technology.

In this presented study, registry data are examined of 226,565 patients who were screened with VPS, usually in primary physician offices or at home. The purpose of identifying persons with flow obstruction in the lower extremities is to determine who is at increased risk for heart disease, stroke, or amputation as the rationale to initiate risk factor modification management. The vast majority of patients in the registry reported no symptoms of claudication and thus was unaware of their condition.

The importance of early recognition and management of the PAD population has been analyzed previously. One study estimated that 5,000,000 US adults have PAD without known cardiovascular disease [11]. In that study, the weighted all-cause mortality rate over a 4.4 year mean follow-up period was 22.6%. This data lead to the conclusion that about 1,100,000 deaths would occur in the follow up period in these estimated 5,000,000 lives. The authors' analysis provides evidence that secondary prevention can reduce all-cause mortality by 65%, which would result in 700,000 US adult lives saved. Thus, it is imperative for primary care physicians to perform screening of patients at risk for PAD and provide secondary prevention of the sequela of diffuse atherosclerosis.

Clinical experience in the primary care setting has shown that VPS is equally or more accurate than pressure cuff Doppler systems. Routine clinical personnel can implement VPS testing in five minutes or less without operator intervention to obtain results. VPS is also relatively inexpensive without the need for a specialized vascular technician or use of a vascular diagnostic unit or laboratory facility, making screening for PAD testing feasible in the primary care setting.

The current practice is for primary care physicians who participated in the registry reported herein is to evaluate patients based on the criteria established by the AHA and the ACC [18]. Many studies have determined that neither the history nor physical examination are adequate to identify the presence or absence of peripheral arterial disease [19,20].

This registry showed approximately 13% of patients had previously unrecognized significant to severe PAD and the vast majority of these patients did not report symptoms of claudication. Further, it is well established that the presence or absence of symptoms does not affect the morbidity and mortality related to PAD [21,22].

Treatment for PAD has two major goals: to manage claudication and to alter the progression of diffuse atherosclerosis in vascular beds. Lifestyle modifications in addition to diet include exercise and smoking cessation as key steps. The former may mitigate claudication if present and the latter is associated with a reduced risk of critical limb ischemia and stroke. A large study of 1,160 patients has shown that care managers are highly effective in increasing patient health knowledge, self-management skills and readiness to make changes in health behaviors [23].

Other proven interventions include statins, claudication management drugs, antihypertensives, and blood glucose medications for diabetic patients, particularly those associated with a reduction in cardiovascular events. Other options include the use of antiplatelet therapies, thrombolytics, and the use of anticoagulants including NOACs. For intractable claudication and/or critical limb ischemia, endovascular interventions or vascular surgical bypass may be required [24,25].

Conclusion

In this registry of primary care medical practices that employ the ACC/AHA criteria for assessment of vascular disease, the use of a screening test for PAD (VPS) identified the 13% of patients with at least significant flow obstruction and the 5% of patients with severe flow reduction. Clinical symptoms were unreliable to discriminate disease from no disease. Earlier recognition of PAD may lead to earlier secondary preventive measures and improved outcomes for a population with a high-risk of cardiovascular morbidity and mortality.

Limitations of the Study

This study is a retrospective analysis of de-identified data that was collected during routine clinical practice at many primary care locations. The clinical factors of these patients were recorded and available for only approximately 10% of the registry, or about 26,000 patients. The medical aides who performed the tests included the clinical factors on the test report forms based on questionnaires completed in the examination room by the patients. It was intended that clinical characteristics data generally be indicative of the typical profile of the population tested. However, there was no protocol in the study to collect such data in a manner suitable to enable statistical analyses such as investigating for confounding factors. The study is limited in that the assessment of the population to be tested was chosen based on the ACC/AHA recommendations and that the large majority of patients did not have symptomatic PAD, i.e. claudication.

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