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Ankle/Brachial Index in the Primary Care Setting

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Peripheral arterial disease (PAD) is an underdiagnosed circulatory problem in the primary care setting. Individuals are at increased risk for cardiovascular disease; therefore, there is the need for a technique capable of early identification and detection of patients with PAD. The focus of this study was to compare the accuracy of a new operator-independent method of measuring ankle brachial index (ABI) with the traditional Doppler ultrasound method of determining ABI. In 246 limbs the authors compared ankle systolic pressures and ABI measured by a new automated oscillatory method called the ABIgram with those measured by standard Doppler ultrasound. In phase 1, the 2 methods for measuring ankle systolic pressure had a mean difference of 2 mm Hg with a standard deviation of 6.7 mm Hg. In phase 2 the mean difference was 3.1 mm Hg with a standard deviation of 5.1 mm Hg. Further, ABI as measured by the 2 methods fell within 1% and demonstrated a 5% error in reproducibility. These numbers pass the SP-10 standard for medical devices established by the FDA. The ABIgram module of the Vasocor® Vascular Diagnostic Center offers primary care physicians the ability to rapidly obtain ABI measurements comparable to the standard technique. Further, the ABIgram may be operated by staff commonly found in the primary care setting.

Introduction

Peripheral vascular disease (PVD) is a common circulatory problem that includes a group of diseases in which venous and/or arterial vessels become occluded or partially occluded (stenotic) in the periphery. PVD is nearly inevitable with the onset of aging, and statistics reveal that in the next 40 years, the US population will consist of 67 million people over the age of 65.[1] Some of the risk factors associated with the development of PVD in an individual include smoking, hypertension, diabetes, elevated blood lipids, and sedentary life style.[1] When PVD is arterial, it is referred to as peripheral arterial disease (PAD). PAD affects 8 to 12 million individuals in the United States and is often underdiagnosed in primary care practice.[2] This underdiagnosis subsequently puts patients at higher risk of ischemic heart disease, myocardial infarction (MI), stroke, and cardiovascular mortality, in addition to the complications of the debilitating peripheral ef-

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fects of PAD.[1] The most common cause of PAD is atherosclerosis.

Atherosclerosis is a complex disorder that initially affects the intima, or innermost layer of the artery that is coated with endothelial cells, and then continues to affect the media, the middle layer, as well. Atherosclerosis, in part, is the result of high blood plasma concentrations of low-density lipoprotein (LDL), which can readily pass through the endothelial layer and contribute to the development of plaque along the inner arterial wall, otherwise known as atheromas. Atheromatous plaques are composed of foam cells (macrophages that have large amounts of cholesterol esters stored in them), smooth muscle cells, fibrous tissue, and inflammatory cells. The deposition of these various components, such as lipids and cholesterol crystals within the plaque, results in the arteries becoming rigid (loss of compliance), narrow (stenotic), and calcified. This hardening and narrowing of the arteries has a substantial effect on arterial resistance, blood flow, and, importantly, blood pressure.[1]

As time elapses, the disease gradually progresses, and arterial thickening continues. This also substantially decreases the diameter of the lumen and ultimately leads to loss of compliance, decreased blood flow, and reduction of oxygen levels in the tissue fed by the diseased arterial bed.[1] Finally, the fibrous cap, which separates the atheroma from the arterial wall, can rupture with the resulting deposition of platelets and blood clots at the site of rupture. Damage and loss of continuity of the endothelial lining is what induces blood platelets to adhere and contributes to blood clot formation. Blood clot formation is another factor that contributes to further restriction of blood flow in blood vessels, and a partial or complete occlusion may occur when a blood clot rapidly develops in a vessel already restricted by an atherosclerotic plaque.[1]

Peripheral arterial disease is progressive, and its symptomatic nature and consequences can be primarily attributed to restricted blood flow, either partial or complete. The processes associated with PAD can result in restriction of the lumen size of the artery and subsequent ischemic symptoms or even occlusion of the diseased artery.

Epidemiologic studies have shown patients who suffer from moderately severe or even asymptomatic PVD have a substantially increased risk of death due to coronary heart disease and cardiovascular disease.[3] Techniques that can detect and help manage PAD at the primary care level may be helpful in the earlier identification of patients with cardiovascular disease.

The ankle/brachial index (ABI) is obtained noninvasively and has been shown to be suggestive of PAD and also to have a direct inverse relation to the risk of cardiovascular disease (CVD). The lower the ABI score, the greater the risk of CVD development. Even those individuals who display a moderate decrease of ABI and are asymptomatic appear to be at increased risk.[4]

The focus of this study was to compare the accuracy of a new method of measuring ankle brachial index with the traditional Doppler ultrasound method of determining ABI.

Methods

The newly designed Vasocor® Vascular Diagnostic Center provides comprehensive tools for assessing and managing cardiovascular and peripheral vascular disease. The ABIgram ankle/brachial index is a tool for performing an ABI. This quantitative methodology is oriented toward clinical use in the primary care setting and includes a noninvasive blood pressure module (NIBP). NIBP systems are widely used to measure systolic, diastolic, and mean pressures in the brachial artery.

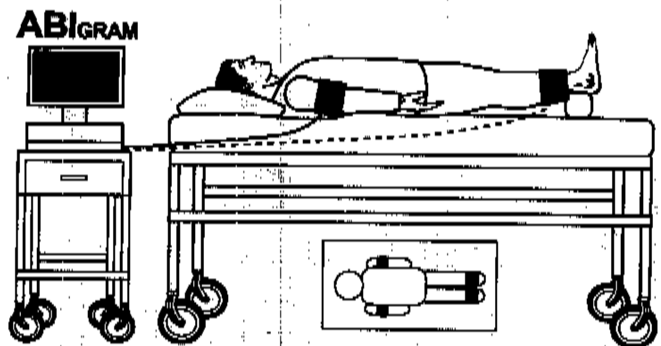
ABIgram™ Ankle Brachial Index

The ABIgram module in the Vasocor® Vascular Diagnostic Center is designed to aid the physician in the assessment and management of PVD by measurement of ankle systolic pressure and ABI. Before beginning the ABIgram procedure, the technologist enters the patient's demographic information into the system. Standard NIBP cuffs are applied to the upper arms and ankles bilaterally (Figure 1). By use of the oscillatory method, systolic pressure is determined at each of these 4 levels (Figure 2). ABI is determined by dividing the minimum ankle systolic pressure by the maximum brachial systolic pressure. This system is completely automated and requires only that the technologist input demographic data and apply the cuffs properly.[5]

ABI by Doppler Ultrasound

With the introduction of continuous-wave Doppler ultrasound in the late 1960s, vascular specialists

Figure 1. Illustration of ABIgram cuff placement. The subject is in the supine position. Appropriate blood pressure cuffs are placed at the brachial and ankle levels bilaterally and connected to the instrumentation. All measurements are taken sequentially; 3 measurements at each site are averaged automatically.



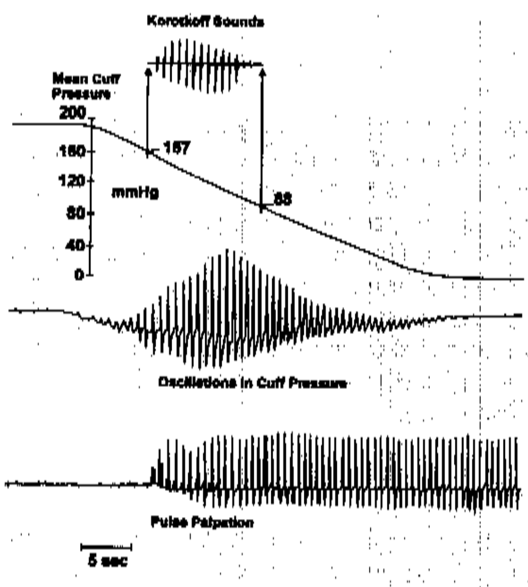


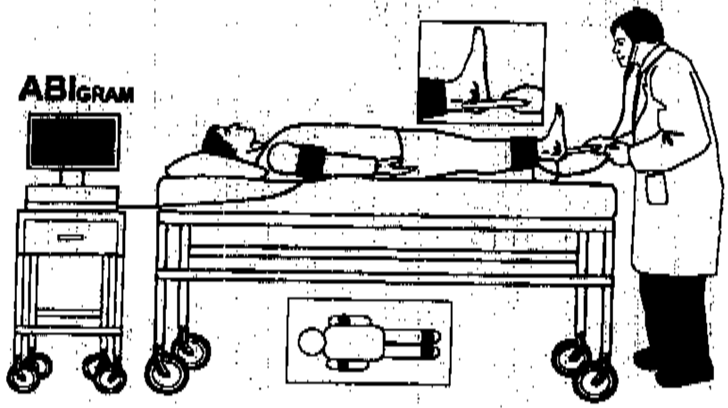
Figure 2. Illustration of the oscillatory method for measuring blood pressure. Note the temporal relationship between Korotkoff sounds, oscillations in cuff pressure, and pulse palpation as mean cuff pressure is reduced from above systemic systolic pressure to below diastolic pressure.

embraced the technique for the noninvasive evaluation of peripheral arterial disease. Measurements of segmental limb systolic pressures by Doppler ultrasound have been used to diagnose the presence of PAD, as well as locate disease level and define severity.

In this study, Doppler ultrasound served as the "gold standard" for determining ankle systolic pressure. The system used was the Hokanson Model 312 hand-held Doppler. To expedite cuff inflation and deflation, the Hokanson TD312 cuff inflator was used to complement the Doppler.[6] The Doppler method detects the frequency shift (ie, velocity) of moving blood cells in a superficial targeted blood vessel and converts this information into an audible signal, which can be evaluated by an operator.[7]

In the general application of this technique, brachial artery systolic pressure is determined bilaterally by use of the standard auscultatory method. Blood pressure cuffs are placed around both ankles with the subject in the supine position (Figure 3). By use of the Doppler probe, velocity signals are identified at the level of the posterior and anterior tibial pulses. The most audible signal is used in the remainder of the testing. While listening to the signal, the technologist elevates the cuff pressure approximately 20 mm Hg above the expected systolic blood pressure. This should cause the signal to disappear. At this point, the operator slowly reduces

Figure 3. Illustration of the standard Doppler method for the measurement of ankle systolic pressure. Appropriate blood pressure cuffs are placed at the brachial and ankle levels bilaterally. For the studies reported in this paper, the ABIgram (oscillatory method) was used to measure brachial systolic pressure. Ankle systolic pressures were measured by a vascular technologist using a continuous-wave Doppler at a tibial artery and a blood pressure cuff at the ankle level inflated/deflated by a hand bulb. Pressures were measured with an aneroid gauge.



the cuff pressure. The cuff pressure at which the velocity signal returns is the ankle systolic pressure. This same procedure is repeated for the remaining limb. As in the case of the ABIgram, ABI is determined by dividing the minimum ankle systolic pressure by the maximum brachial systolic pressure.

Systolic Pressure Study (SPS) Design

The study was conducted at the Comprehensive Vascular Laboratory of the University of Miami/Jackson Memorial Medical Center in Miami, Florida, in 2 phases with different patient populations. The overall study was designed to demonstrate that the ABIgram is capable of achieving the accuracy requirements of the American National Standard ANSI/AAMI SP10-1992 for electronic or automated sphygmomanometers at the ankle level.[8] This standard requires that NIBP devices meet accuracy criteria. This is achieved by comparing blood pressure measurements taken with NIBP devices with blood pressure measurements taken at the same time using the auscultatory method at the brachial level. To meet the standard, mean pressures taken by the 2 methods must agree within ±5 mm Hg, and the standard deviation must be 8 mm Hg or less. In a previous study, with 104 subjects, the NIBP device in the Vasocor® Vascular Diagnostic Center demonstrated a 3.8 mm Hg difference in mean brachial systolic pressure with a standard deviation of 7.9 mm Hg. For diastolic pressure at the same level, the mean difference was −0.49 mm Hg with a standard deviation of 6.8 mm Hg. This study indicated that the system met the standard for brachial level measurements of diastolic and systolic pressure.[9]

Phase 1

Subject demographics were entered; these also included circumference measurements at the ankle level bilaterally. An experienced registered vascular technologist performed all ankle Doppler ultrasound measurements and tibial pulse grading. The NIBP module in the Vasocor® Vascular Diagnostic Center was used to measure brachial systolic pressure bilaterally. If the right and left systolic blood pressures were within 10 mm Hg, the measurements were immediately accepted. If the 2 arm systolic pressures differed by more than 10 mm Hg, the measurements were repeated. If after 2 measurements the systolic pressures still differed by more than 10 mm Hg, the last measurement was accepted.

With the subjects in the supine position and after 10 minutes of rest in a quiet room with subdued lighting, systolic pressures at the ankle level bilaterally were taken with the ABIgram module. On completion of this procedure, the registered vascular technologist, using Doppler ultrasound, measured ankle systolic pressures bilaterally.

Data were collected from 54 subjects with 108 limb measurements. SP10-1992 requires a minimum of 85 limbs. The mean subject age was 39.5 (sd = 15.8) years with a minimum age of 18 and maximum of 73; this demonstrated good subject diversity. The mean ankle circumference of the 108 measurements was 21 (sd = 2.0) cm.

Phase 2

There are 2 differences between phase 1 and phase 2. First, while the patient selection criteria were the same, the subject population was different. Second, in phase 2, brachial artery pressures (systolic and diastolic) were measured by the ABIgram module and the auscultatory method. Data were collected from 69 subjects with 138 limb measurements. The mean subject age was 42.6 (sd = 14.2) years with a minimum age of 20 and maximum of 77; this again demonstrated good subject diversity.

Results

For phase 1, mean ankle systolic pressure determined by Doppler ultrasound was 135 mm Hg (sd = 18). Mean ankle systolic pressure obtained with the ABIgram for this population was 138 mm Hg (sd = 19). Analysis of the data showed that the device met the SP10-1992 standard for ankle systolic pressure with a mean difference of +2 mm Hg and a standard deviation of 6.7 mm Hg.[10]

For phase 2, mean ankle systolic pressure determined by Doppler ultrasound was 136 mm Hg (sd = 20). Mean ankle systolic pressure obtained with the device for this population was 139 mm Hg (sd = 20). Analysis of the data showed that the ABIgram again met the SP10-1992 standard with a mean difference of +3.1 mm Hg and a standard deviation of 5.1 mm Hg.[11]

In phase 2, in addition to evaluating actual systolic pressures alone, it was possible to analyze error associated with ankle/brachial index (ABI). Mean ABI as determined by the combination of the auscultatory method for brachial systolic pressure and Doppler ultrasound for ankle systolic pressure was 1.06 (sd = 0.074). The ABI measurements obtained using the ABIgram had a mean value of 1.05 (sd = 0.075). Statistical analysis of this study suggests the ABIgram can measure ABI within 1% of the traditional method with a reproducibility of 5%, which is consistent with SP-10 standards.

Conclusions

Peripheral arterial disease is often underdiagnosed in the primary care setting, and the presence of PAD is highly correlated with coronary artery disease. Currently, Doppler ultrasound is the standard for measuring ankle systolic pressure for the purpose of obtaining ABI, which has been shown to be suggestive of PAD. Doppler ultrasound requires special instrumentation and a well-trained technician, neither of which is commonly found in primary care office settings. The ABIgram module of the Vasocor® Vascular Diagnostic Center offers the primary care physician the ability to rapidly obtain ABI measurements comparable to the standard technique. Further, the ABIgram may be used rapidly by staff commonly found in traditional primary care settings. This may facilitate implementation of this important measure in primary care.

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