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Non-invasive Vascular Testing Technology

to Support a Collaborative Care Model for the

Diagnosis of Peripheral Arterial Disease

by William L. Rogers

Abstract: Innovative care models that support collaborative diagnosis between primary care providers and specialists aim to provide patients with an earlier diagnosis of peripheral arterial disease (PAD) and other cardiovascular diseases. An essential component of such models is the ability of primary care providers to perform accurate non-invasive vascular tests that can be used in consultation with a vascular specialist to render a diagnosis and develop a management plan for patients with PAD. This study assesses the equivalency of ankle-brachial index (ABI) and pulse volume recording (PVR) obtained by the PADnet diagnostic system with the ABI and PVR data obtained by diagnostic equipment commonly used in vascular laboratories. Ankle brachial indexes (ABI) obtained by the PADnet technology were clinically equivalent to those produced by the Doppler methodology used in vascular laboratories. The PADnet diagnostic technology also produced PVR waveforms that were clinically equivalent to those produced by technology commonly used in vascular laboratories.

Background:

Peripheral arterial disease (PAD) is under-diagnosed and under-treated. [1, 2] Diagnosing patients at an earlier time in the course of their disease has two significant advantages. If PAD is diagnosed when the symptoms are mild, serious morbidity associated with vascular dysfunction of the limbs may be avoided with the application of evidence-based care guidelines. Repeated hospitalizations, chronic wound care problems, and even amputations can be reduced. Additionally, diagnosing PAD earlier often reveals the extent to which patients are at increased risk for the other atherosclerotic disease processes - primarily cardiac and cerebrovascular. [3] Implementing recommendations to reduce these risk factors can further improve patient outcomes.

There are several challenges in addressing the delay in diagnosis for patients with PAD. Identifying all patients at risk and who also exhibit symptoms associated with PAD is necessary to uncover this diagnosis at an earlier stage. Minor

symptoms are often overlooked or not specifically sought out, even in patients who are in high risk categories for PAD. It is accepted that the majority of patients with PAD do not exhibit the classic symptoms of ischemia in the lower limb and have even been labeled "asymptomatic" by many authors. The ACC/AHA Practice Guidelines recognized this unfortunate use of terms and for the purposes of the guidelines, stated that "asymptomatic…implies the absence of classic leg claudication symptoms." [4] The guidelines further state that "asymptomatic" patients with PAD often have leg dysfunction, diminished functional status, and increased cardiovascular risk. A different strategy is required to identify and diagnose patients with non-classic symptoms of PAD. The primary care physician can play a significant role in focusing on patients who are symptomatic of PAD but do not have the classic symptom of claudication.

Non-invasive vascular testing when used at the primary care level often relies on using Doppler ultrasound technology to obtain pressures to calculate the ankle/brachial blood pressure index (ABI). ABI is the ratio of the highest systolic pressure at the ankle to the highest systolic pressure at the brachia. This straightforward measurement and calculation is, however, infrequently performed in the primary care setting because of the lack of equipment, the time required to do the procedure, and the operator dependency and technical difficulties involved in obtaining the measurements. [5] Oscillometric (automated) blood pressure measurement is less dependent upon technical skill, takes less time and can produce reliable accurate measurements, and therefore more suitable for use in the primary care setting. The oscillometric method has been used in many clinical settings for several decades with good success. [6]

The PADnet System of Care

The technology imbedded in the PADnet system of care was designed to produce accurate PAD diagnostic data at the primary care level by producing both oscillometric blood pressure measurements used to calculate the ABI

and segmental pulse volume recording (PVR) waveforms. PVR waveforms alone produce an 85% diagnostic accuracy rate for PAD when compared with angiography. Combining the PVR waveforms with a calculation of the ankle/brachial index (ABI) increases the diagnostic accuracy to above 95% compared to angiography. [7] Obtaining PVR waveforms at the initial assessment also avoids the difficulty of measuring arterial pressures in non-compressible vessels in some patients, most notably severe diabetics. The PADnet system of care is a collaborative diagnostic and management system. Briefly, the primary care provider specifically questions patients who are at risk for PAD about symptoms (typical and atypical) associated with PAD. In those patients who report symptoms or have physical findings suggestive of PAD, data is collected using PADnet to obtain both the ABI and the PVR waveform. This data is uploaded to a secure website so that a vascular specialist, who is part of the PADnet regional network, can interpret the findings, provide a diagnosis and give recommendations to the primary care provider on the next step in management. This approach can avoid unnecessary referrals for patients who do not have PAD or have mild disease where medical management can be provided by the primary care physician. The focus on earlier diagnosis at the primary care level with collaboration with a vascular specialist addresses many of the existing challenges in the current approach to this disease.

Purpose of the study: This study was designed to compare the findings obtained with the PADnet device with standard non-invasive testing approaches often used in vascular laboratories in a group of normal subjects. The oscillometric technology used in the PADnet system of care is compared to the frequently used Doppler ultrasound technique to obtain pressures to calculate the ABI. The PADnet technology is similar to that tested in numerous other comparison studies [8-13]. The study also compares PVR waveforms generated using the Parks Flo-Lab device with the PADnet device.

Methods:

Subjects

Forty normal subjects agreed to participate in the study. None of the subjects had been diagnosed with PAD or reported symptoms associated with PAD.

Testing and calculation

In each of the forty subjects at least one right and one left ankle systolic pressure was obtained using each technology. At least one brachial systolic pressure was obtained in each subject. For each technology used, the highest systolic ankle pressure was divided by the highest systolic brachial pressure to calculate an ABI.

Additionally in 25 subjects, PVR waveforms were obtained using the two different devices. The PVR waveforms were compared based upon amplitude and morphology.

Results

Of the 40 subjects tested, 4 subjects were eliminated from comparing the ABI measures because of pressure readings above 200 mm Hg and therefore, the ABI could not be reliably calculated. Two of these four subjects were included, however, in the waveform analysis.

Ankle Brachial Index (ABI):

ABI's for the 36 normal subjects were compared between PADnet derived readings and the Doppler ultrasound derived readings. There was no difference in the mean of the ABI ratios obtained from each method. Both averaged 1.197 to three decimal places. ABI's ranged from .974 to 1.424 in the Doppler readings, and 1.014 to 1.339 in the PADnet readings. All of these are in the normal range which is defined as ABI > .85. The paired-sample t-test comparing the means, was not significant: $t35 = 0.06$, $p=.950$. The correlation between the two ABI readings was .723. (Table 1)

The ankle pressure readings and the brachial pressure readings of the PADnet method with the Doppler method were also compared. The ankle readings averaged 3.89 mm lower for the PADnet ($t35 = 3.41$, $p < .001$). The brachial readings averaged 3.53 mm lower for the PADnet ($t35 = 3.10$, $p< .001$). The correlation between the ankle readings was $r = .900$, and for the brachial, $r= .887$. These differences did not impact the ABI calculations for the two approaches which were the same (1.197).

PVR Waveforms:

In a subset of 25 of the subjects, PVR waveforms were obtained from the PADnet system and the Parks Flo-Lab system. Waveforms were obtained from both ankles with each device. The waveforms were compared for morphology and amplitude. There were no differences in the morphology of the waveforms between the two methods and were interpreted as normal in all cases. Additionally, there were no significant differences in amplitude between the devices, for either the right or left ankles ($t24 = 0.99$, ns and $t24 = 0.78$, ns respectively). The correlations between the two techniques were $r = .98$ for the right ankle and $r = .94$ for the left ankle. (Table 2)

In all cases, the amplitude readings were within two units of each other, with two exceptions on different subjects: 1) the Parks Flo-Lab right ankle reading was 10 mm of amplitude higher than the PADnet reading (37 v. 27) whereas the left ankle measurements of 29 and 30 were recorded. 2) the PADnet left ankle was 21 units higher than the Park Flow reading (56 v. 35) and the right ankle measurements of 38 and 37 were recorded. All the subjects had normal amplitude measurements.

Discussion:

Among normal subjects, the PADnet diagnostic technology produced ABI's and PVR waveforms that were clinically equivalent to those produced by the Doppler methodology and the Parks Flo-Lab system both commonly used in vascular laboratories. There were no significant differences in the ABI's of the PADnet and Doppler techniques, nor in the morphology and amplitudes of the PVR waveforms produced by the PADnet and Park Flo-Lab methods.

The PADnet methodology produces reliable and accurate measures required for diagnosis of PAD. The PADnet measurement technology is an integral part of a system of care designed to identify patients with PAD at an earlier time in the course of the disease to improve the outcomes of treatment. The technology is designed to be used by properly trained staff at the primary care level after uncovering symptoms associated with PAD. This study further establishes its usefulness in addressing this major health issue.

Table 1

ABI Ratios for the PADnet and Doppler readings

	Mean	SD	Min	Max	t	df	p	corr
ABI PADnet	1.197	.080	1.014	1.339				
ABI Doppler	1.197	.101	0.974	1.424	0.06	35	.950	.723
difference	*0*	*.070*	*-.141*	*0.165*				
Ankle:								
PADnet	147.1	15.1	115	179				
Doppler	151.0	15.4	122	184	3.41	35	<.001	.900
difference	*3.89*	*6.84*	*-11*	*22*				
Brachial:								
PADnet	123.2	12.7	99	146				
Doppler	126.7	14.8	98	158	3.10	35	<.001	.887
difference	*3.53*	*6.84*	*-11*	*17*				

Table 2

Amplitude Comparisons of PADnet and Park Flow

	Mean	SD	Min	Max	t	df	p	corr
Right Ankle:								
PADnet	23.60	9.76	8	46				
Flow	24.04	9.75	8	47	0.99	24	.331	.975
difference	*0.44*	*2.22*	*-2*	*10*				
Left Ankle:								
PADnet	16.60	10.40	6	56				
Flow	15.92	7.40	6	35	-0.78	24	.441	.936
difference	*-0.68*	*4.34*	*-21*	*2*				

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Will Rogers is the Chief Technology Officer for BioMedix, Inc. with 25 years experience in non-invasive vascular technology and a background in cardiac perfusion. Mr. Rogers was a lead member of the team responsible for the development of the PADnet.