Referral-Based, Reimbursable Screening

A new program offers a unique opportunity to improve patient care by making the primary physician your partner in detecting peripheral arterial disease at its early stages.

AN INTERVIEW WITH MICHAEL R. JAFF, DO, RVT, FACC

Dr. Jaff has disclosed that he has no financial interest in BioMedix.

Endovascular Today: Why should we be interested in screening for peripheral arterial disease (PAD)?

Michael R. Jaff, DO: Vascular specialists understand that PAD is both underdiagnosed and undertreated. The statistics are staggering: the prevalence of PAD is higher than that of stroke and similar to that of MI. Between 3 and 5 million Americans have intermittent claudication or exertional leg pain due to vascular disease, and between 8 and 10 million have PAD. Mortality for established PAD is estimated at 4-6% per year. For those with critical limb ischemia and the lowest ankle-brachial index (ABI), the outcomes are even worse. This group has an annual mortality rate approaching 10%. Failure to diagnose PAD in its early stages leads to increased morbidity and mortality, as well as a marked decrease in quality of life. The strong correlation between PAD and coronary artery disease (CAD) also makes PAD a reliable indicator of CAD in otherwise asymptomatic patients.

These statistics have prompted recent efforts by vascular specialists to identify patients at risk for PAD, confirm the diagnosis, and refer them for the optimal treatment at earlier stages of the disease. Yet most patients are not referred to a vascular specialist until their disease has progressed, at which point treatment options become limited. These patients may have signs or symptoms of PAD, but due to lack of knowledge by their primary physicians, they are not treated until their disease has reached advanced stages. The principal challenge for vascular specialists is to help referring physicians accurately detect the symptoms of the disease earlier, when multiple treatment options are available.

Figure 1. The BioMedix system consists of a small sensing unit, a laptop computer, a color printer, and a medical-grade cart.

EVT: How does the BioMedix PADnet referral-based program do this?

Dr. Jaff: BioMedix (St. Paul, MN), together with Cordis Endovascular (a Johnson & Johnson company, Warren, NJ) has a program that I participated in while practicing vascular medicine in New York City. The BioMedix PADnet program helped me develop my referral network's ability to identify patients with PAD. The BioMedix PADnet program was also a great way to build my vascular practice by working with referring physicians as partners.

EDUCATION IS THE KEY

PAD Prevalence

EVT: Is the lack of awareness of PAD among primary care physicians a problem?

Dr. Jaff: Absolutely. The amount of training that family practitioners, internists, and even podiatrists receive in the diagnosis and man-

agement options in vascular medicine and peripheral vascular disease is extremely low. Our first challenge is to educate our primary care colleagues that they are seeing patients with PAD as often as they are seeing patients with CAD. Approximately 3 to 5 million Americans have intermittent claudication, and more than half think they have arthritis or that their symptoms are merely a part of getting old. In fact, PAD is a potentially remediable cause of their limitations in quality of life.

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PAD Diagnosis

EVT: What is the most common sign or symptom of the disease?

Dr. Jaff: Fewer than 50% of patients with symptoms and PAD have classic symptoms of intermittent claudication. Classic (Rose) claudication is defined as onset of symptoms in a major muscle group of a limb that begins at reproducible distances and resolves when the patient stops and stands still. The majority present with atypical symptoms, describing discomfort after walking variable distances or sometimes while at rest. These patients also must sit or lay down for relief of their symptoms.

EVT: How do you find out for sure if patients have PAD?

Dr. Jaff: A thorough pulse exam and the ABI are important components of the diagnosis for these patients. Patients should remove their shoes, socks, and slacks. All four pulses should be palpated in a limb, and the feet should be examined for skin breakdown, ulcers, paleness, and other indicators. It is a misconception that all PAD patients present with cold feet, no hair on their legs, and dystrophic toenails. Many with normal circulation present this way, while others with advanced PAD may not have these signs.

An ABI should also be obtained. The ABI is our single best screening test for cardiovascular disease. It is even better than the EKG, a common test performed by primary care physicians. The ABI is superior to a cholesterol level, blood sugar, or hemoglobin A1C test in identifying significant risk of MI, stroke, and risk of cardiovascular death. ABI testing is simple, and medical assistants can be taught onsite how to perform this test in 15 minutes or so. The ABI result identifies whether the patient has PAD, but also establishes his or her risk of heart attack and stroke, and ultimately, mortality. If an ABI value is abnormal, but symptoms do not support a diagnosis of PAD, the mere presence of an abnormal ABI remains vitally important because of its value in predicting heart attack, stroke, and death. The 5-year mortality rate approaches 30%, so it is quite possible that 30% of these patients with an abnormal ABI will die in 5 years. The ABI is also noninvasive, can be performed quickly, and is easily performed by all primary care physicians in their practices.

Test Equipment

EVT: Do primary care physicians already have the equipment needed to do these tests?

Dr. Jaff: Most primary care physicians do not have the Doppler ultrasound devices traditionally used to perform ABI exams. They could purchase a hand-held Doppler for less than $500, or use the BioMedix option, which incorporates a sensing device for the performance of an automatic ABI along with plethysmography. Although less expensive, the handheld Doppler option only performs an ABI, which by itself is considered part of the routine physical examination and is not separately reimbursable. The BioMedix device qualifies for reimbursement under Medicare for patients with approved indications for this exam because it combines more than a single test modality. It includes the plethysmographic pulse volume recording, a simple test demonstrating perfusion in multiple segments of the limb. The BioMedix device consists of a small sensing unit, a laptop computer, a color printer, and a medical-grade cart (Figure 1).

Patient Selection

EVT: Who should be tested?

Dr. Jaff: The ABI should be a standard diagnostic test for many patients. A formal program of PAD detection should include testing any patient over 50 years of age with a history of tobacco use or has diabetes, or anyone over age 70 regardless of risk factors (PARTNERS Study, Hirsch, AT, et al. JAMA 2001;286). You should expect that one in three of these patients will have PAD, either isolated or in combination with CAD.

Clinical Limitations to the ABI

EVT: Is the ABI accurate in all patients?

Dr. Jaff: Forty percent of PAD patients will have diabetes mellitus. Diabetics and many elderly patients have stiff, noncompliant arteries at the ankles due to calcium in the walls that cannot be compressed with a blood pressure cuff. If the examiner can still hear a Doppler signal at a pressure level of 250 mm Hg or more, the patient should be referred to a specialist. Despite the "supranormal" ankle pressures, these patients probably have PAD.

Another limitation is in patients with aortoiliac disease, or

disease above the groin. In this case, patients may have normal ABIs at rest. In fact, you can feel their pulses in their feet, but the history suggests claudication. These could even be patients reporting classic symptoms of exertional (Rose) leg pain. Even with a normal ABI at rest and a normal pulse, these patients should be exercised and can be referred to a specialist to have a stress ABI performed. After stress testing, the ABI will likely fall, and they will lose their palpable pulse.

Care Coordination: "Hubs and Spokes"

EVT: How does the referral program you used work?

Dr. Jaff: The BioMedix model relies on a "hub and spoke" arrangement. At Lenox Hill, the "hub" was the vascular specialist and "spokes" were their primary care referral sources. The primary care and podiatric specialists referred abnormal studies to the vascular specialists. We trained our primary care and podiatry colleagues ("spokes") with the BioMedix team support to identify patients eligible for testing, instructed them on how to perform the test and then transmit it back to our specialists. When the results of individual tests were abnormal, we discussed the clinical cases with the primary care and/or podiatric specialists, and decided as a team when the patients would benefit from referral to the vascular specialist.

PADnet Program

EVT: How did you set up the referral networks?

Dr. Jaff: At our invitation, BioMedix went to our referral sites. They showed the staff at our referral sites how to perform the tests and how to send and receive completed studies and interpretations. The program uses a secure, HIPAA-compliant Web site. As a "hub" (specialist), I was able to easily access each study on my computer, see the collected data, ABI values, and pulse volume recordings, make my interpretation directly, and electronically sign it, save it, and send it back over that same secure site for viewing and printing by the primary care doctor. This arrangement is similar to the way many primary care physicians utilize radiologists to read their chest x-rays. Usually a radiologist will arrive at the end of the day to read collected x-rays and dictate a report. The PADnet operates on the same principle, but it is more efficient because the vascular specialist does not have to be physically present to read the reports.

Reimbursement

EVT: Is this a reimbursable test?

Dr. Jaff: Test revenue will vary by state, since most patients will be medicare eligible, and medicare reimbursements vary by state. In New York, using the PADnet test, the medicare global fee is about $180, so 80%, or $150, was payable to the primary care doctor for performing the test

(technical component), and 20%, or $30, was payable to the specialist for interpreting the study (professional component). For specialists who currently perform these physiologic tests in their offices, but might be worried about a loss of test revenue, it is not really a concern because the equipment already in place can be used for exercise ABI testing. In addition, more comprehensive studies like duplex ultrasound, magnetic resonance arteriography (MRA) or computerized tomographic arteriography (CTA) will be needed in many cases. Here is an example from my practice. One of our "spokes" (a podiatry practice we trained in pulse palpation and PADnet testing) sent us an abnormal BioMedix test and said they could not obtain a pulse in the particular patient's foot who required podiatric surgery. Because we had the results of the BioMedix test, I did not need another physiologic test. A duplex ultrasound test demonstrated a lesion in the superficial femoral artery that was treated with percutaneous angioplasty and stent placement at Lenox Hill Hospital. This was a new patient to me, to the interventionist, and to the hospital from a new referral source. This podiatric specialist attended a lecture I gave to market my practice, and based on his interest in participating as a "spoke," we set him up with the BioMedix program. This case is a good example of the kind of practice building that can be done for all parties, including the hospital.

Competition

EVT: Does this program compete with existing lab services performed in hospitals?

Dr. Jaff: Many specialty practices now refer PAD testing to their affiliated hospital labs. A legitimate concern is how this might affect their relations with their hospital. In my case, this was not a problem. Our program identified patients who probably would not have been referred to our hospital and physicians. From a financial standpoint, a "hub and spoke" arrangement is beneficial for everyone. It is phenomenal for patients because they are already in the PCP or podiatrist's office and the test is immediately available. They can have a test performed, read by an expert, and have the result returned before they walk out of the office.

Marketing

EVT: What is your opinion on marketing of vascular screening programs?

Dr. Jaff: I have concerns about mass public screening for PAD. The yield of patients is low. However, in targeted populations, vascular screening is extremely important. With the PADnet system, a more formal risk assessment can be performed in the doctor's office. Only those at-risk patients with signs and symptoms are tested. This differs greatly from screening of the general population in which the yield will be much lower.

In my opinion, the best marketing for a vascular program is a process of education to physicians and patients. With regard to patient marketing, I like talking directly to groups of patients. I go to libraries, churches, synagogues, and community centers and discuss the risks and treatments for PAD. I think this community marketing will become more commonplace as more public awareness programs develop. Future public awareness campaigns like the upcoming PAD Coalition, the first truly collaborative multispecialty public and professional awareness campaign, which includes the National Heart, Lung, and Blood Institute (NHLBI) will markedly increase the appreciation for PAD as a critical health care issue. ■

Michael R. Jaff, DO, RVT, FACC, is Medical Director of the Vascular Diagnostic Laboratory, Massachusetts General Hospital in Boston. He has disclosed that he holds no financial interest in any product mentioned herein, however, he does serve as a consultant to Cordis Endovascular. Dr. Jaff may be reached at (617) 726-3784; mjaff@partners.org.