improvement of quality in terms of delivery of health care, specifically for interventional cardiologic care: data collection and benchmarking, appropriate use indicators, process of care indicators, clinical privilege indicators, and clinical outcomes indicators.

For data collection and benchmarking, a patient-specific data collection system should be used that enables consistent data collection from all patients. From this, parameters such as number of specific procedures, number of complications, or time elapsed can be tracked, graphed, and reviewed against a comparison population. Outlier values can be opportunities to learn, because they can represent a particularly complex case, or they may represent areas in which improvement is needed to move the outlier value closer to the median.

The appropriate use of a procedure was guided by experience and intuition about 30 years ago, and in turn it became guided by professional society guidelines about 20 years ago [Stone GW, Moses JW. *Nat Rev Cardiol.* 2011]. Today, Prof Eteiba indicated that appropriate use criteria should be used. For example, the appropriate use criteria for coronary revascularization support the use of clinical judgment and experience, and allow for the assessment of use patterns for procedures (eg, that which was defined in data collection and benchmarking), yet do not eliminate the challenge of decision making. Appropriateness is typically classified within 3 ranges: 1 to 3 represents inappropriate use, because the procedure is unlikely to improve health outcomes or survival; 4 to 6 represents uncertain use, because it is not clear if the procedure would improve outcomes or survival; and 7 to 9 represents appropriate use, because the procedure would likely improve outcomes or survival [Patel MR et al. *J Am Coll Cardiol.* 2009].

For process of care indicators, it is important to look at the entire process leading up to, during, and after the procedure. For example, protective measures such as renal and radiation protection are important to track. In addition, process efficiency and transport times are particularly important in revascularization, because door-to-balloon time is critical. Prof Eteiba demonstrated the use of data tracking, in which the times of symptom onset, call for help, paramedical contact, first electrocardiograph, arrival, and procedure start can be documented, tracked, and assessed.

Clinical privilege indicators include staff credentialing and proficiency. Formal training requirements and competency should be reviewed, and the role of noninvasive specialties should be recognized as well. Proficiency can be maintained through various mechanisms, such as assessment of annual caseload of a specific procedure per year, institutional measures of proficiency, attending morbidity and mortality conferences, and peer review of random cases.

Clinical outcomes indicators, such as major adverse cardiac and cerebrovascular events and percutaneous coronary intervention success rate, should be monitored on a regular basis. The data, as well as catheterization laboratory statistics, should be shared and reported in both compiled and physician-specific formats, with a focus on quality improvement.

In conclusion, Prof Eteiba stated that quality improvement begins with fostering an environment of quality and clinical governance, which requires a commitment from the entire health care system. Operator and staff proficiency are crucial in assuring quality; however, other aspects such as process, data collection and benchmarking, and outcome indicators are important to continue to provide quality health care and to enable improvement in quality.

Vascular Disease: Take a Head-to-Foot Approach

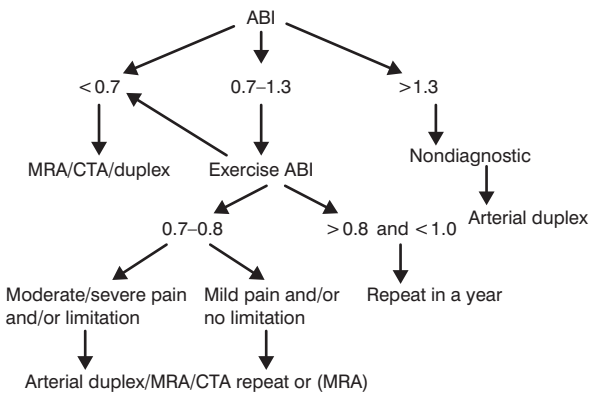
Written by Mary Mosley

Atherosclerotic disease often occurs in the vasculature beyond the heart; however, cardiologists do not always take a head-to-foot approach to identify related circulatory conditions. Khusrow Niazi, MD, Emory University, Atlanta, Georgia, USA, described the importance of a head-to-foot evaluation for vascular disease.

In patients who present with symptoms such as leg weakness, it is important to ask specific questions to learn about all associated symptoms that the patient has experienced. For example, in transient ischemic attack (TIA), many patients ignore multiple symptoms of TIA because the symptoms last for only a few seconds or minutes. For patients with suspected TIA, retinal ischemic events, or ipsilateral ischemic stroke, auscultation for carotid bruit was found in a landmark 1994 NASCET trial to detect >70% stenosis in symptomatic patients, with a sensitivity of 63% and a specificity of 61% during the clinical examination. A much more sensitive technique, however, that is easily performed by cardiologists is Duplex ultrasound with a vascular probe, which can diagnose stenosis anywhere in the vasculature.

Patients' leg pain can be broadly categorized as being due to arterial insufficiency, venous insufficiency, or other causes. Peripheral artery disease (PAD) is a common disease that affects up to 12 million individuals in the United States and is most typically a result of

Figure 1. Algorithm for Ankle-Brachial Index Assessment of Arterial Insufficiency



ABI, ankle-brachial index; CTA, computed tomography angiography; MRA, magnetic resonance angiography.

Reproduced with permission from K Niazi, MD.

atherosclerosis. Hallmark symptoms of PAD include claudication with resulting decreased function and exercise capacity, with symptoms ranging from Rutherford–Becker Classification 0 (no symptoms) to 6 (gangrene). In addition, PAD is associated with a heightened risk of all-cause mortality. Therefore, it is important that clinicians do not miss a diagnosis of PAD. To diagnose PAD, an ankle-brachial index (ABI) should be performed. In patients with a compelling story but a normal rest ABI, an exercise ABI should be considered (Figure 1).

Venous issues are a substantial problem in the United States, because, according to Dr Niazi, almost 5% (about 25 million) of individuals in the United States suffer from leg vein abnormalities, and venous stasis ulcer is the most common leg ulcer that presents in wound centers. Despite this large number, only 1.7 million patients seek treatment for their vein issues. Multiple risk factors for vein problems exist, including age, female sex, genetic predisposition, an occupation that requires a lot of standing, pregnancy, and taller height. Vein problems encompass a variety of conditions such as varicose or spider veins, leg cramps, restless legs, itching, ulcers, aching or heaviness, and swelling.

Dr Niazi recommends that all cardiologists have new patients remove their socks and shoes to examine the legs and feet; abnormal pigmentation of the lower legs is very common in patients with venous insufficiency. A common cause of venous insufficiency is malfunction of the venous valves, which do not close completely and allow the blood to travel back; the resulting increased venous pressure can cause distention of the veins and result in bleeding. The diagnosis of venous insufficiency can be made easily with venous ultrasound, which is performed while the patient is standing. The calf region should be compressed, causing blood to surge upward; in patients with venous insufficiency, the blood will fall downward again.

In conclusion, it is important that cardiologists are aware of vasculature issues that occur beyond the heart. Many potentially serious issues are a result of atherosclerotic disease, which often exists in multiple vascular beds.

Bioresorbable DESs May Address Traditional DES Limitations

Written by Mary Mosley

Patients with coronary artery disease (CAD) undergoing percutaneous revascularization are treated with either drug-eluting stents (DESs) or bare metal stents. Although new generations of DESs have been developed, these stents continue to have some limitations. Bernard Chevalier, MD, Institut Cardiovasculaire Paris Sud, Massy, France, presented current data on the bioresorbable DESs that are in development.

First-generation, polymer-based DESs had multiple limitations. The polymer was fragile, resulting in uneven drug distribution that increased the risk of focal in-stent restenosis. The kinetics of drug release were not consistent and increased the risk of diffuse restenosis. Some stents had prolonged elution of the medications designed to prevent restenosis that delayed endothelialization of the stents and increased the risk of stent thrombosis. Subsequent generations of DESs have sought to eliminate these issues.

DESs with biodegradable polymers are under development in an effort to avoid long-term inflammation and improve clinical outcomes. In the LEADERS trial [Stefanini GG et al. *Lancet*. 2011], patients with CAD were randomized to either a biodegradable biolimus-eluting stent (BES) or a durable polymer sirolimus-eluting stent (SES) and were followed for 4 years. The biodegradable BES was noninferior to the durable polymer SES for the end points of target lesion revascularization (TLR) and definite stent thrombosis (Figure 1).

The NEXT trial [Natsuaki M et al. *J Am Coll Cardiol.* 2013] demonstrated that TLR and stent thrombosis occurred at similar, but very low, rates among patients who received the biodegradable BES compared with the durable polymer SES.

The CENTURY II trial [Saito S et al. *Eur Heart J.* 2014] randomized patients to either the bioresorbable Ultimaster SES or the permanent Xience everolimus-eluting stent. The Ultimaster stent is made of a PDLLA-PCL copolymer that is resorbed within 3 to 4 [illegible] Xience DES

Continued on page 16.