SOCIETY FOR VASCULAR ULTRASOUND

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Society for Vascular Ultrasound's Position on the Performance and Reporting of Screening Examinations

The Society for Vascular Ultrasound (SVU) is concerned that there is a lack of standardization regarding the performance and reporting of vascular disease screening services. As the SVU believes that appropriate credentialing (certification) of vascular technologists and accreditation of vascular testing facilities serves to protect the public health, and that public awareness and education are an integral component of the screening process, the SVU Board of Directors has approved the following position statement, with documentation supporting the position following the Summary of Position.

Summary of Position

- SVU defines a "screening" exam as a test performed without a physician referral and/or without medical necessity, which is intended to detect, but not quantify, disease. Screening exams are not intended to replace diagnostic exams. SVU defines a "diagnostic" exam as a test performed for medical necessity with a physician referral.

- Vascular screening exams should be performed only by physicians or professionals who are credentialed in the area of testing being performed, should be performed in a setting that has demonstrated an adherence to quality standards, such as an accredited laboratory, and should utilize equipment designed to accurately determine the presence or absence of disease.

- A screening report should record only the absence or presence of disease to warrant further diagnostic studies. There should be no attempts to characterize or quantify the disease process.

- The screening exam results should be generated by a qualified physician with experience in the area of testing being performed, and should be forwarded to the participant and his/her primary care physician(s).

- Informative education materials on vascular disease should be disseminated to the screening participants.

Issued: Oct. 8, 2003
Revised: March 30, 2011

Introduction and Background

Over the past several years, the Society for Vascular Ultrasound (SVU) has received numerous inquiries about its position on screening for vascular disease. In 2003, the SVU issued a statement regarding screening evaluations, and has now updated this statement to reflect changes that have occurred in the area of vascular screening, especially the creation of screening-specific accreditations, the development of screening programs, and the escalation in advertising aimed at increasing awareness of peripheral arterial disease (PAD), stroke, and abdominal aortic aneurysms (AAA).

In the medical community screening is a strategy used to detect a disease process in individuals without signs or symptoms of that disease. Screening tests may be performed in an effort to identify disease early, allowing early intervention and management of the disease process to reduce morbidity and mortality from a disease.

While screening may lead to earlier diagnosis, not all screening tests have been shown to benefit the population being screened. Misdiagnosis by over- or underestimating the presence and/or severity of the disease being screened has the potential to increase unnecessary, potentially dangerous testing or treatment, or may create a false sense of security if an exam is read as normal. For these reasons, the testing method, staff, and process used in a screening program, must assure good specificity in addition to acceptable sensitivity.

As a matter of clarification, SVU considers “screening” exams those exams performed when the patient has no signs or symptoms of the condition being evaluated, but an individual or medical professional may want performed due to risk factors, family history, or general concern for the status of one’s health and well being. “Diagnostic” studies are those performed when medical necessity for the examination is clearly established and the examination performed will impact the clinical course of the patient.

The SVU believes that while there is potential for abuse and an increased risk for some patients, that well organized and well informed providers and physicians can provide safe screening programs that minimize the risk of unnecessary procedures, including angiography and surgery. However, screenings should only be performed in appropriate settings by qualified personnel. Examples of qualified individuals include those credentialed and/or licensed to perform non-invasive vascular evaluations, and examples of appropriate settings include those who have demonstrated a commitment to quality by acquiring appropriate accreditation through a recognized accrediting body.

Screening for Abdominal Aortic Aneurysms

The United States Preventative Services Task Force (USPSTF) has recommended AAA screening due to "good evidence" that surgical repair of AAA in specific individuals decreases AAA-specific mortality, and that abdominal ultrasonography is "an accurate screening test for AAA." As of January 1, 2007, Medicare decided to pay for a one-time AAA screening for patients considered to be at risk including individuals with a family history of AAA or men age 65 to 75 who have smoked at least 100 cigarettes. Patients must receive a screening referral as part of their "Welcome to Medicare" physical exam which is only available in the first 6 months of Medicare eligibility.

The SVU supports screening for AAA by appropriate personnel in appropriate settings with appropriate equipment.

Screening for Carotid Artery Stenosis (CAS)

The USPSTF currently recommends against CAS screening stating that CAS is responsible for a "relatively small proportion…of disabling, unheralded strokes." The recommendation goes on to state that, while duplex ultrasound has "moderate sensitivity and specificity", the modality yields many false-positive results, and that alternate diagnostic testing, like digital subtraction angiography, can cause serious adverse events suggesting that the risk of CAS screening exceeds the benefits in asymptomatic patients. There is evidence in the literature that contradicts these statements, including that there are relatively few arteriograms performed to detect CAS, and that CAS accounts for approximately 80% of cerebral ischemic events.

It is SVU's position that CAS screening may be beneficial; however, additional research is needed to support routine CAS screening.

Screening for Peripheral Arterial Disease (PAD)

The USPSTF recommends against PAD screening, stating that there was "fair evidence that screening asymptomatic adults with ABI (ankle-brachial index) could lead to some degree of harm, including false-positive results and unnecessary work-ups." The recommendation also states that screening for PAD in asymptomatic adults has "few or no benefits because the prevalence of PAD in this group is low" and that "there is little evidence that treatment…, beyond treatment based on standard cardiovascular risk assessment, improves health outcomes."

In 2006, Beckman, et al, addressed the USPSTF statements, noting "the USPSTF statement omitted important peer-reviewed data on the prevalence, screening efficacy, and short-term adverse prognosis of patients with PAD and failed to consider the beneficial outcomes that probably would result from timely diagnosis and treatment of this important manifestation of atherosclerosis." They also noted that "most patients with PAD have neither classic symptoms of leg claudication nor threatened limbs but have an extraordinarily high rate of adverse cardiovascular events, such as myocardial infarction, stroke, and death--events that should serve as a key rationale for screening" concluding that "medical therapy, including risk factor modification and antiplatelet medications, is known to reduce cardiovascular morbidity and mortality rates in these patients."

There have been several organizations created to increase public awareness of PAD, a serious condition which can lead to disability and even death. Additionally, the presence of PAD puts individuals at increased risk for heart attack and stroke. Early detection of PAD has been touted as a way to decrease the mortality and morbidity associated with the above listed conditions.

The SVU clearly understands the advantages and benefits of early detection of PAD. SVU is a partner with the Vascular Disease Foundation (VDF), an organization dedicated to educating the public about vascular disease and its devastating effects. Through the "P.A.D. Coalition", the VDF is dedicated to raising public and health professional awareness about lower extremity PAD, and is committed to improving PAD patient outcomes. The VDF promotes free community PAD screenings and supports Legs for Life, a program developed by the Society of Interventional Radiology (SIR) that is also dedicated public education about PAD.

It is SVU's position that screening tests for the detection of PAD may be valuable in the detection and prevention of disease; however, it is not appropriate for unqualified practices, facilities and/or individuals to provide screening exams or to be used in making treatment decisions without proper clinical context or diagnostic testing.

Credentialing of Personnel Performing Examinations

Individuals with a credential in non-invasive vascular testing and ultrasound have demonstrated minimal entry level knowledge in the performance and theory of vascular testing. There are three credentialing bodies that are recognized by Medicare Administrative Contractors (MAC) as suppliers of appropriate credentials:

- The American Registry for Diagnostic Medical Sonography (ARDMS)- RVT credential
- Cardiovascular Credentialing International (CCI)- RVS credential
- American Registry of Radiologic Technologists (ARRT)- RT (VS) credential

These organizations have themselves sought and acquired accreditation through either the International Standards Organization/American National Standard Institute (ISO/ANSI) or the National Commission for Certifying Agencies (NCCA) for their credentials. This assures that the tests are valid and individuals taking the exams are being tested on accurate and appropriate subject matter.

MACs and CMS do not accept certificates or diplomas from schools or programs as appropriate credentials and are unlikely to do so in the future. With the recent move by several states to require licensure of individuals providing vascular ultrasound and testing, it is unlikely that these states will accept only a certificate or diploma from a school or program as proof of competency in performing vascular testing.

It is SVU's position that an individual must possess an appropriate credential from a recognized credentialing body before performing vascular testing of any kind, including screening.

Accreditation for Screening

Accreditation requires a laboratory to demonstrate standardization and adherence to quality standards in a particular area. The Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), which provides accreditation for non-invasive vascular laboratories, created a screening accreditation category in 2006, requiring that labs applying for this category have accreditation in the area for which they are applying for screening accreditation. Screening accreditation assures standardization in the lab and assures that laboratory personnel are experienced in performing screening exams.

It is SVU's position that screening accreditation is important to assure quality standards are met.

Reimbursement for Performing Screening Examinations

Medical necessity must be established before a test will be reimbursed by Medicare. The Centers for Medicare/Medicaid Services (CMS), as stated in the Local Coverage determinations (LCD) for National Government Services (NGS), a Medicare Administrative Contractor (MAC), is very clear about the reimbursement for screening studies:

- "Non-invasive vascular studies are considered medically necessary only if the outcome will potentially impact the clinical course of the patient. For example, if a patient is (or is not) proceeding on to other diagnostic and/or therapeutic procedures regardless of the outcome of non-invasive studies, and non-invasive vascular procedures will not provide any unique diagnostic information that would impact patient management, then the non-invasive procedures are not medically necessary."
- "Medicare does not pay for routine screening tests. ICD-9-CM diagnosis code V82.9 (Special screening of other conditions, unspecified condition) should be used to indicate screening tests performed in the absence of a specific sign, symptom, or complaint"
- "Non-invasive peripheral arterial examinations, performed to establish the level and/or degree of arterial occlusive disease, are medically necessary if (1) significant signs and/or symptoms of possible limb ischemia are present **and** (2) the patient is a candidate for invasive/surgical therapeutic interventions."
- "An ABI is not a reimbursable procedure by itself; rather, ABI may be reimbursed when derived from a more comprehensive procedure which includes a permanent chart copy of the measured pressures and waveforms in the examined vessels."

It is SVU's position that diagnostic testing should not be performed if signs or symptoms of PAD are not present of the time of the test, or if testing is performed with any methodology that is not approved by CMS or the MAC, which precludes screening examinations, by their very definition, from being reimbursed.

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