

USWR 23: Outcome Measure: Non Invasive Arterial Assessment of patients with lower extremity wounds or ulcers for determination of healing potential

MEASURE STEWARD:

The US Wound Registry

[Note: This measure has been under testing as part of the “Do The Right Thing™” initiative in 6 New York state hospitals based outpatient wound centers]

This measure was developed via a consensus process in collaboration with the Alliance of Wound Care Stakeholders Member Organizations, which include 16 wound care related clinical associations.

DESCRIPTION:

Percentage of patients aged 18 years or older with a non healing lower extremity wounds or ulcers that underwent a non-invasive arterial assessment once in a 12 month period, stratified by ABI, perfusion pressure, or oximetry.

There are four rates reported for this measure. The four rates will be risk stratified into three buckets which are the following:

1. No evidence of arterial disease and ischemia is not a contributor to non-healing
2. Possible arterial compromise (possible reduced flow), but the patient may still be able to heal the wound(s) or ulcer(s)
3. Evidence of arterial disease- patient should be referred to specialist for vascular assessment if not currently in the care of a vascular expert. Ischemia may be the reason the patient has failed to heal.
4. The average of the three risk stratified buckets which will be the performance rate in the XML submitted.

NUMERATOR:

All patients with lower extremity DFU, VLU and pressure ulcers and all chronic wounds of the lower extremity that have been non-healing for >30 days (e.g. surgical and traumatic) that underwent a non-invasive baseline vascular assessment once in a 12 month period.

DENOMINATOR:

All patients with lower extremity DFU, VLU and pressure ulcers and all chronic wounds of the lower extremity that have been non-healing for >30 days (e.g. surgical and traumatic)

DENOMINATOR EXCLUSIONS/EXCEPTIONS

EXCLUSIONS: Palliative care patients, patients with only 1 visit during the reporting period

EXCEPTIONS: Arterial assessment not performed for Medical, Patient or System Reasons

Testing method	No evidence of arterial disease (able to heal and can tolerate high stretch compression for venous disease)	Possible arterial compromise (should tolerate short stretch compression with warnings, may be able to heal)	Evidence of Arterial disease, refer to a vascular specialist if not currently in vascular care, may not be able to heal
ABI	>0.8- 1.3	0.6 – 0.8 Or > 1.3	<0.6
SPP	>40 mmHg	30 – 40 mmHg	<30 mmHg
TCOM	>40 mmHg	30 – 40 mmHg	<30 mmHg

RATIONALE:

Definition of arterial vascular evaluation: measurement of the ankle-brachial index, skin perfusion pressure measurements, transcutaneous oximetry, toe pressures or arterial Doppler studies.

Peripheral occlusive arterial disease can be a contributory factor in the etiology and healing of any leg ulcer, and the benefit of therapeutic interventions is reduced in the absence of adequate tissue oxygen levels. Thus all patients with leg ulcers should undergo appropriate vascular evaluation. Such evaluation includes measurement of the ankle-brachial index, skin perfusion pressure measurements, transcutaneous oximetry, and arterial Doppler studies. Current data document that lower extremity PAD is common, that the traditional term “asymptomatic” may inaccurately imply that limb function is normal, and that lower extremity PAD is invariably and independently associated with impaired lower extremity functioning. Thus, most individuals with lower extremity PAD do not have classic (typical) claudication but may have more subtle impairments of lower extremity function.

Individuals with asymptomatic lower extremity PAD are characterized by a risk factor profile comparable to that of those with symptomatic lower extremity PAD. The high prevalence of diabetes, a history of past or current smoking, hypertension, and/or hypercholesterolemia place such individuals at a markedly increased risk of atherosclerotic ischemic events, including MI and stroke and higher degrees of internal carotid artery stenosis. Given these data, current U.S. national hypertension, lipid, and antiplatelet treatment guidelines include all patients with lower extremity PAD, regardless of symptom status, as a “high-risk” category. All patients with lower extremity PAD should achieve risk reduction and specific treatment targets comparable to those of individuals with established coronary artery disease.

Clinical guidelines for vascular screening of patients with diabetic foot ulcers have recently been updated by the Society for Vascular Surgery and the American Podiatric Medical Association ([http://www.jvascsurg.org/article/S0741-5214\(15\)02025-X/fulltext#sec1.5](http://www.jvascsurg.org/article/S0741-5214(15)02025-X/fulltext#sec1.5)). The American Diabetes Association recommends that all people with diabetes have ABI measurements performed when they reach 50 years of age, and all people with diabetes and a foot wound should have pedal perfusion assessed by ABI and either toe pressure or transcutaneous oximetry (TcPO2). An ABI <0.8 increases amputation risk in the presence of a foot wound in a patient with diabetes. Amputation risk increases as perfusion decreases, especially when ABI is <0.4 and toe systolic pressure is <30 mm Hg.

Based on the systematic review commissioned by the SVS to support their DFU treatment guidelines, most of the available evidence evaluates only TcPO2 and ABI. TcPO2 may be more predictive test than ABI because this measurement may be falsely elevated among diabetics due to calcified vessels,

but both tests predicted healing and the risk of amputation. Recent data suggests that skin perfusion pressure (SPP) may be more predictive than TcPO₂ because SPP is not affected by edema.

Guideline Statement: The SVS and APMA guidelines recommend that patients with a DFU have perfusion assessed by ABI, ankle and pedal Doppler arterial waveforms, and toe systolic pressure or transcutaneous oxygen pressure (TcPo₂) annually (Grade 1B evidence). The Wound Healing Society (WHS) recommends that all patients with lower extremity ulcers be assessed for adequate perfusion.

Principle: Poor vascular supply to the leg is a frequent contributor to the development of an ulcer as well as causing healing impairment. Moreover the presence of peripheral arterial occlusive disease may require treatment modifications for certain types of ulcer (e.g., compression for venous stasis ulcers). When the disease is severe, vascular surgery or hyperbaric oxygen therapy may need to be undertaken (depending on the ulcer etiology) to improve the blood supply, or the ulcer may not heal. Therefore vascular evaluation to identify the presence of peripheral arterial occlusive disease is an important factor in the assessment of a leg ulcer, particularly a chronic ulcer that is not healing.

Clinical Importance: Tissue ischemia and hypoxia are the final common denominator of limb loss. Failure to identify ischemia is believed to be the most common reason for limb loss among patients with chronic lower extremity ulcers (see clinical guideline statements below) and failure to identify ischemia is a common reason for failure to heal. All advanced therapeutics require demonstration of adequate perfusion prior to application or initiation.

Gap in Practice

Data from the USWR indicates that fewer than 10% of patients with chronic non-healing leg ulcers undergo any type of vascular assessment (ABI, transcutaneous oximetry or skin perfusion pressure) even at hospital based outpatient wound centers.

EVIDENCE:

1. "The resting ABI should be used to establish the lower extremity PAD diagnosis in patients with suspected lower extremity PAD, defined as individuals with exertional leg symptoms, with nonhealing wounds, who are 70 years and older or who are 50 years and older with a history of smoking or diabetes. Individuals with asymptomatic lower extremity PAD should be identified by examination and/or measurement of the ankle-brachial index (ABI) so that therapeutic interventions known to diminish their increased risk of myocardial infarction (MI), stroke, and death may be offered. (ACC/AHA Guidelines)"
Verbatim from Peter Sheehan, MD Commentary in Clinical Diabetes-Volume 22, Number 4, 2004:" Peripheral Arterial Disease in People With Diabetes: Consensus Statement Recommends Screening"
2. "The consensus development panel for this statement was charged with addressing four issues around peripheral artery disease (PAD) and diabetes: 1) the epidemiology and impact, 2) the biology, 3) patient evaluation, and 4) best treatments. The consensus panel worked from an underlying assumption that PAD in people with diabetes is different from the vascular disease from other risk factors in its biology, in its clinical presentation, and in its management. As far as the prevalence and impact, diabetes is the most powerful risk factor for PAD. Among those with diabetes, age, duration of diabetes, and the presence of neuropathy are particularly important

as risk factors for the development of PAD. With diabetes, there is usually a unique involvement of the tibial vessels below the knee. Because of the pattern of involvement distally, the majority of patients lack classic symptoms, such as claudication. In addition, there is an almost invariable association with neuropathy with blunted pain perception. Patients are therefore likely to experience more subtle symptoms than with classic claudication, for example, fatigue or poor functioning. A more devastating consequence of neuropathy is that PAD patients with diabetes present late, having already developed limb-threatening ischemia with tissue loss, gangrene, or rest pain. This unfortunate progression lends urgency to the task of uncovering PAD in asymptomatic individuals in order to prevent amputation. Beyond the threat to the limb, these patients face enormous cardiovascular and cerebrovascular risk. Over 5 years, 20% of PAD patients will sustain nonfatal myocardial infarction or stroke, and 30% will die, largely from cardiovascular disease.(1) For those with critical limb ischemia, the prognosis is worse: 30% will have amputations, and 20% will die within 6 months.(2) While the exact risk increment among diabetic patients with PAD is unknown, prospective cardiovascular clinical trial data assure us that patients with diabetes fare worse than their nondiabetic counterparts. The true prevalence of PAD in individuals with diabetes has been difficult to determine because of the lack of symptoms and insensitive means of diagnosis. The ankle brachial index (ABI) has a high sensitivity and specificity for angiographically proven disease. Diagnosing PAD through ABI, the prevalence in individuals with diabetes > 40 years of age was 20%.(3) That figure is higher than would be anticipated using only symptoms and absent pulses. In PAD patients > 50 years of age, the diabetes prevalence was 29%, again higher than anticipated.(4) The unexpected high prevalence of PAD in the population with diabetes in a sense makes PAD a new public health issue.”

Elhadd TA, Robb R, Jung RT, Stonebridge PA, Belch JF: Pilot study of prevalence of asymptomatic peripheral arterial occlusive disease in patients with diabetes attending a hospital clinic. *Pract Diabetes Int* 16:163–166, 1999

3. Peripheral arterial occlusive disease (PAOD) affects approximately 10 million people in the United States and is highly associated with significant morbidity and mortality. Because of its high prevalence and associated co-morbidities, there must be an effort to detect arterial disease in patients with wounds and to select appropriate therapy when arterial insufficiency is identified as a significant or primary etiology for an ulcer. Arterial insufficiency frequently contributes to poor healing in ulcers with another primary etiology such as diabetic neuropathy or venous insufficiency. All patients with lower extremity ulcers should be assessed for arterial disease. (Level 1A evidence) (Wound Healing Society 2007). Available at: <http://www3.interscience.wiley.com/cgi-bin/fulltext/118605281/HTMLSTART>
4. In diabetic foot ulcers, arterial perfusion is a vital component for healing and must be assessed in the ulcerated patient, since impaired circulation contributes significantly to nonhealing of ulcers and subsequent risk for amputation. Early evaluation and referral are important. The initial evaluation of the diabetic foot ulcer must be comprehensive and systematic to ascertain the parameters that might have led to its onset as well as determine the presence of factors that can impair wound healing. Critical in this regard are assessments for vascular perfusion (ischemia). Noninvasive arterial studies (NIAS) should be performed to determine lower extremity perfusion. Such studies may include Doppler segmental arterial pressures and

waveform analysis, ankle-brachial indices (ABI), toe blood pressures, and TcPO₂. American College of Foot and Ankle Surgeons - Medical Specialty Society. 2000 Sep (revised 2006 Sep). Available at "Guidelines.gov":

(<http://www.guideline.gov/search/searchresults.aspx?Type=3&txtSearch=diabetic+foot+ulcers&num=20>)

5. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. Hingorani, et al. February 2016, Volume 63, Issue 2, Supplement, Pages 3S–21S DOI: <http://dx.doi.org/10.1016/j.jvs.2015.10.003>
6. Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, Krook SH, Hunninghake DB, Comerota AJ, Walsh ME, McDermott MM, Hiatt WR: Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA 286:1317–1324, 2001
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8. Dormandy JA, Rutherford RB: Management of peripheral arterial disease (PAD). TransAtlantic Inter-Society Consensus. J Vasc Surg 31(1 Pt. 2):S1–S296, 2000.