Carotid endarterectomy is a proven effective treatment for stroke prevention in patients with asymptomatic and symptomatic carotid artery stenosis. Although historically angiography was used to classify the degree of carotid artery stenosis, in the current era, duplex ultrasonography is used almost exclusively as the sole imaging modality. Thus, the decision to intervene is often based on carotid duplex ultrasound results alone. Accordingly, current Society for Vascular Surgery guidelines state that carotid duplex ultrasound is the most appropriate first-line imaging modality for symptomatic and asymptomatic carotid disease. In addition, these guidelines report grade 1, level A evidence for carotid duplex ultrasound and selecting revascularization for symptomatic 50% to 99% stenosis and asymptomatic 70% to 99% stenosis. Therefore, carotid duplex ultrasounds play a key role in determining when carotid revascularization should be performed.

Although standardized protocols to perform carotid duplex ultrasound have been published, no uniform criteria to interpret these studies have been mandated and implemented by all laboratories nationwide. For example, the Carotid Duplex Consensus Criteria did propose specific peak systolic velocities consistent with a 50% to 69% and ≥70% carotid stenosis. However, these criteria have been criticized and revised by subsequent authors, leading to the absence of a universally accepted set of consensus carotid duplex ultrasound criteria.

The Intersocietal Accreditation Commission (IAC), formerly the Intersocietal Commission for the Accreditation of Noninvasive Vascular Laboratories shows large variation in the diagnostic criteria used to classify degree of carotid artery stenosis. We hypothesize that variability of these diagnostic criteria causes significant variation in stenosis classification directly affecting the number of revascularizations and associated costs.

Methods and Results—The diagnostic criteria to interpret carotid duplex ultrasounds were obtained from 10 New England institutions. All carotid duplex scans performed at our institution were reviewed from 2008 to 2012. Using the diagnostic criteria from each institution, the degree of stenosis that would have been reported was classified as 70% to 99% asymptomatic, 80% to 99% asymptomatic, and 50% to 99% symptomatic. We then calculated the theoretical number of carotid revascularization procedures that this cohort would be offered using each institution’s diagnostic criteria and the costs of these procedures based on reimbursement rates. Among 10,614 patients who underwent 15,534 carotid duplex scans, 31,025 arteries were reviewed. Application of the 10 institutions’ criteria to the patients from our institution yielded marked variation in the number classified as 70% to 99% asymptomatic (range, 186–2201), 80% to 99% asymptomatic (range, 78–426), and 50% to 99% symptomatic (range, 157–781). If revascularizations were based on these results, costs would range from $2.2 to $26 million, $0.9 to $5.0 million, and $1.9 to $9.2 million, respectively.

Conclusions—Differences in diagnostic criteria to interpret carotid ultrasound result in significant variation in classification of carotid artery stenosis, likely leading to differences in the number and subsequent costs of revascularizations. This theoretical model highlights the need for standardization of carotid duplex criteria. (Circ Cardiovasc Qual Outcomes. 2014;7:423-429.)
WHAT IS KNOWN

• Current Society for Vascular Surgery guidelines state that carotid duplex ultrasound is the most appropriate first-line imaging modality for symptomatic and asymptomatic carotid disease. The Intersocietal Accreditation Commission does not advocate for standardized criteria to interpret carotid duplex ultrasound examinations.

• Noninvasive vascular laboratories show large variation in the diagnostic criteria used to classify degree of carotid artery stenosis, thereby affecting the number of revascularizations and the subsequent costs.

WHAT THE STUDY ADDS

• An analysis of 10 regional institutions demonstrated an 11-fold difference in number of theoretical carotid revascularizations during a 5-year period, as well as an associated $24 million cost to payers. Standardization of carotid duplex ultrasound criteria is a longstanding substantial unmet need that will help to standardize the care of patients with carotid artery occlusive disease and may assist to control healthcare costs.

Vascular Laboratories, has continued to accredit programs for vascular testing in addition to echocardiography and other noninvasive tests. Accreditation includes meeting several standards for the medical director, technical director, technical staff, and testing facility, as well as being subject to random site visits and audits. However, the use of standardized criteria to interpret carotid duplex ultrasound examinations is not a component of this accreditation process.

Despite the publication of 5 multispecialty guideline documents during the past decade, none has included standardized criteria to interpret carotid duplex ultrasound examinations. Therefore, each vascular laboratory, regardless of IAC accreditation status, develops or adopts from other laboratories its own diagnostic criteria for carotid stenosis. We hypothesize that variability of these diagnostic criteria causes significant variation in stenosis classification, likely affecting the number of revascularizations and the subsequent costs.

Methods

Study Cohort

All consecutive carotid duplex scans performed at the University of Massachusetts inpatient and outpatient noninvasive vascular laboratories from 2008 to 2012 were retrospectively reviewed. After approval from the University of Massachusetts Medical School institutional review board, we obtained patient demographics including sex, age, date of examination, and an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code for each patient. For each carotid duplex examination performed, the right and left peak systolic velocity (PSV), end-diastolic velocity (EDV), and internal carotid artery to common carotid artery (ICA:CCA) ratio were recorded.

In patients with multiple unilateral scans, the examination with the greatest internal carotid artery PSV was selected for analysis of the right side. Arteries with a PSV of 0 were considered to be occluded.

Each carotid artery was classified as asymptomatic or symptomatic based on the associated ICD-9-CM code entered as the indication for the carotid duplex scan. The codes used to classify patients as asymptomatic (Table 1) are consistent with those used in prior publications. Carotid duplex scans missing an ICD-9-CM code were excluded from analysis.

Multicenter Vascular Laboratory Carotid Duplex Criteria Variation

Ten New England vascular laboratories, from 10 distinct institutions, provided the carotid duplex ultrasound criteria that they use to classify degree of carotid artery stenosis. Seven of the 10 institutions were accredited by the IAC and ranged in the mean number of annual carotid duplex examinations performed (range, 200–4400; Table 2). Each institution’s carotid duplex ultrasound diagnostic criteria were applied to the UMass study cohort to classify each carotid duplex scan into one of the following stenosis categories: <50%, 50% to 59%, 60% to 69%, 70% to 79%, 80% to 99%, or occluded. Although there was some similarity in the criteria used at each institution (Table 2), this overlap was minimal, and clear differences were present between the way in which each laboratory used PSV, EDV, and ICA:CCA ratio to calculate degree of stenosis.

Theoretical Number of Carotid Revascularizations Performed and Associated Costs

The provided criteria from each of the 10 institutions were used to calculate the total number of carotid revascularizations at 3 clinically relevant potential treatment thresholds (70%–99% asymptomatic, 80%–99% asymptomatic, and 50%–99% symptomatic). PSV, EDV, and ICA:CCA ratio were all required to meet the provided threshold to meet criteria for each degree of stenosis. Furthermore, for each institution, the theoretical cost to payers for performing these carotid revascularization procedures was determined using the 2011 average Medicare reimbursement for carotid endarterectomy (Current Procedural Terminology code 35301) of $11802.21.

Results

Between January 1, 2008, and December 31, 2012, at the University of Massachusetts vascular laboratory, 10614 patients underwent 15534 carotid duplex scans on 31025 arteries. Among these patients undergoing carotid duplex scans, 424 Circ Cardiovasc Qual Outcomes May 2014

Table 1. ICD-9-CM Codes Used for Symptomatic Carotid Duplex Scans

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>342</td>
<td>Stroke, hemiplegia, hemiparesis</td>
</tr>
<tr>
<td>344</td>
<td>Stroke, other paralytic syndromes</td>
</tr>
<tr>
<td>362.3</td>
<td>Amaurosis fugax, retinal artery occlusion</td>
</tr>
<tr>
<td>362.34</td>
<td>Transient monocular blindness</td>
</tr>
<tr>
<td>362.84</td>
<td>Amaurosis fugax, retinal ischemia</td>
</tr>
<tr>
<td>433.11</td>
<td>Carotid stenosis or occlusion, symptomatic</td>
</tr>
<tr>
<td>434.91</td>
<td>CVA, NOS</td>
</tr>
<tr>
<td>435</td>
<td>Transient ischemic attacks, TIA</td>
</tr>
<tr>
<td>435.8</td>
<td>TIA, other</td>
</tr>
<tr>
<td>435.9</td>
<td>TIA, unspecified</td>
</tr>
<tr>
<td>781.4</td>
<td>TIA, transient limb paralysis</td>
</tr>
<tr>
<td>784.3</td>
<td>Aphasia</td>
</tr>
<tr>
<td>784.5</td>
<td>Dysarthria/dysphasia/slurred speech</td>
</tr>
</tbody>
</table>

CVA indicates cerebrovascular accident; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; NOS, not otherwise specified; and TIA, transient ischemic attack.
53.3% were men with a mean age of 67.9 years (SD, 12.8). The majority of carotid duplex scans were performed for an indication of asymptomatic carotid artery disease (asymptomatic, 77.0%; symptomatic, 23.0%; Table 3).

Table 2. Carotid Duplex Diagnostic Criteria Used at 10 Institutions

<table>
<thead>
<tr>
<th>Institution</th>
<th>Annual No. of Studies</th>
<th>Department Directing Vascular Laboratory</th>
<th>Carotid Duplex Diagnostic Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td></td>
<td></td>
<td>&lt;50%</td>
</tr>
<tr>
<td>A*</td>
<td>4400</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>C*</td>
<td>4200</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>D</td>
<td>200</td>
<td>Radiology</td>
<td>PSV</td>
</tr>
<tr>
<td>E*</td>
<td>1267</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>F*</td>
<td>700</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>G</td>
<td>938</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>H</td>
<td>2541</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td>I*</td>
<td>841</td>
<td>Vascular surgery and cardiology</td>
<td>PSV</td>
</tr>
<tr>
<td>J*</td>
<td>2674</td>
<td>Vascular surgery</td>
<td>PSV</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EDV</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ICA:CCA</td>
</tr>
</tbody>
</table>

EDV indicates end-diastolic velocity; ICA:CCA, internal carotid artery to common carotid artery ratio; and PSV, peak systolic velocity.

Variation of Carotid Duplex Scan Criteria Across 10 New England Institutions

Each institution’s noninvasive vascular laboratory used different criteria to determine the degree of carotid artery stenosis (Table 2). All institutions had specific criteria for ≥50% stenosis, but only 5 institutions, A, B, F, I, and J, use specific criteria for 70% to 79% stenosis. Institutions C and D characterize high-grade stenosis as 70% to 99% and do not distinguish ≥70% from ≥80%. Institutions E and H characterize 50% to 79% stenosis, whereas institution G describes 60% to 79% stenosis.

Similarly, there are wide ranges in the criteria used for each level of stenosis (Table 2). For example, the minimum PSV for ≥80% stenosis ranges from 125 cm/s at institution A to 430 cm/s at institution J. In addition, select centers use EDV and ICA:CCA ratio with different hierarchical priority assigned to each.
Theoretical Number of Carotid Revascularization Procedures Performed According to Different Potential Treatment Thresholds

Using a potential intervention threshold of 70% to 99% stenosis for asymptomatic carotid stenosis, the 10 institutions, sites A to J, had significant variation in the number of patients who would be offered carotid revascularization based on this level of asymptomatic stenosis (Figure 1). Of the 7650 patients evaluated for asymptomatic carotid artery disease in the UMass study cohort, institution J would have offered revascularization to 186 patients, compared with 2201 patients at institution G, an 11.8-fold difference. Institution E does not use criteria for 70% to 99% stenosis and was therefore excluded from this subgroup analysis.

Similarly, using a potential intervention threshold of 80% to 99% stenosis for asymptomatic carotid stenosis, the 10 institutions demonstrated significant variation in the number of patients who would be offered revascularization to 186 patients, compared with 2201 patients at institution G, an 11.8-fold difference. Institution E does not use criteria for 70% to 99% stenosis and was therefore excluded from this subgroup analysis.

Analysis of the symptomatic carotid duplex scan cohort of 2964 patients yielded significant variation among the 10 institutions when using the intervention threshold of 50% to 99% stenosis (Figure 1). Institution J would have offered revascularization to 157 patients, whereas institution E would have offered revascularization to 781 patients, a 5-fold difference.

Theoretical Costs of Carotid Revascularization Procedures Performed According to Different Potential Treatment Thresholds

Using the 2011 carotid endarterectomy Medicare diagnosis-related group reimbursement rate of $11,802.21 as a proxy for costs to payers, there was a marked difference in the theoretical total costs of revascularization among the 10 institutions. Based on the calculated number of carotid revascularization procedures that would be performed at each treatment threshold, the range in costs would be $2.2 to $26 million, $0.9 to $5.0 million, and $1.9 to $9.2 million for a 70% to 99% asymptomatic treatment threshold, an 80% to 99% asymptomatic treatment threshold, and a 50% to 99% symptomatic treatment threshold, respectively (Figure 2).

Discussion

This comprehensive analysis of the effect of the variability of diagnostic criteria used to interpret carotid duplex scans shows significant effects on the treatment of patients being evaluated for carotid artery occlusive disease, as well as on the subsequent costs of this treatment. Although some institutions choose to emphasize peak systolic velocities as the only relevant criterion, others use end-diastolic velocities, ICA:CCA velocity ratios, or a combination thereof. The variation observed in this study implies that patients likely receive dramatically different treatment recommendations as a direct function of which institution performs their carotid duplex scan.

Contributing further to the variation in which patients may be offered carotid revascularization, consensus does not exist about the degree of stenosis that warrants asymptomatic carotid stenosis intervention. Ultimately, these decisions are often institution or surgeon dependent. In addition, some vascular laboratories (eg, institution E) do not use a 70% to 99% stenosis category and choose to report only 80% to 99% stenosis. Therefore, the carotid duplex ultrasound criteria used by each vascular laboratory, the categories of stenosis used for reporting, and institution/surgeon treatment thresholds all play a critical role in determining when a patient is offered a carotid revascularization procedure.

We observed marked variation in the classification of carotid stenosis at all 3 ranges of stenoses analyzed, 70% to 99%...
asymptomatic, 80% to 99% asymptomatic, and 50% to 99% symptomatic, when applying each institution’s criteria to the UMass cohort of patients. The theoretical impact of this variation is as high as 11-fold among institutions, with significant downstream morbidity, mortality, and cost implications. Using the carotid endarterectomy diagnosis-related group as a proxy for costs to payers, we saw variation ranges ≤$24 million depending on which treatment threshold was studied.

It is clear that some vascular laboratories use more conservative criteria than do others for the classification of high-grade carotid stenosis. As an example, the most conservative site (institution J) requires a PSV ≥450, EDV ≥151, and ICA:CCA ≥7.5 to classify a lesion as 80% to 99%. In contrast, at the most liberal site (institution H), to classify a lesion as 80% to 99%, only a PSV ≥125 and EDV ≥105 are necessary, without any ICA:CCA ratio minimum criteria. Furthermore, IAC accreditation does not seem to have any impact on the hemodynamic criteria selected by an institution’s vascular laboratory—the most conservative criteria and the most liberal criteria are used at 2 different institutions that are both IAC accredited.

IAC accreditation status does not seem to influence whether a given vascular laboratory is conservative or liberal with regard to their carotid duplex classification criteria. Institutions D, G, and H are the 3 non–IAC-accredited laboratories used in this study. Despite the Society for Vascular Surgery guideline recommendation that duplex ultrasound examinations be performed at accredited laboratories, 3 of the 10 New England institutions studied use a non–IAC-accredited vascular laboratory to aid in the diagnosis of carotid artery stenosis. For 70% to 99% asymptomatic stenosis, institutions D, G, and H are the third, tenth, and ninth most conservative sites, respectively. Similarly for 80% to 99% asymptomatic stenosis, they rank sixth, eighth, and tenth, and for 50% to 99% symptomatic stenosis, they rank fifth, sixth, and third.

This study documents the extent of variation that currently exists in the classification of carotid artery stenosis based on nonstandardized carotid duplex criteria. In an era where diagnostic cerebral angiography is becoming virtually nonexistent, standardization across centers is of increasing importance. A critical question in establishing appropriate criteria that must be addressed is what imaging study should serve as the gold standard for comparison and calibration of duplex ultrasound criteria. It is our opinion that computed tomography angiography will likely emerge as the current gold standard, although this has not yet been established. Regardless, it is clear that the extent of variation documented in this study likely results in significant differences between institutions in the way patients are treated for carotid artery stenosis. At an institution with conservative criteria, it may be that patients with significant disease are being undertreated. Conversely, at an institution with liberal criteria, it may be that patients with mild disease are being overtreated. In a healthcare environment where cost-effectiveness, quality, and value are being heavily scrutinized, reduction in this variation represents an actionable item warranting further study.

Standardized carotid duplex criteria are needed to help address this need. As previously mentioned, prior publications, including those in 2003 by the Carotid Duplex Consensus Criteria, may provide a foundation for the development and implementation of nationwide criteria.

Several limitations are inherent to the current study design. Most importantly, it was not possible to include the important subjective role of the interpreting vascular specialist in the classification of each stenosis. Although it is known that ultrasonography is operator dependent as well as interpreter dependent, analysis of these data relied entirely on objective hemodynamic variables. In addition, select centers and institutions may prefer to obtain adjunctive vascular imaging, including computed tomography.
angiography or magnetic resonance angiography, to confirm their findings and increase the accuracy of their duplex imaging. In this analysis, we were unable to determine whether secondary imaging studies were obtained or whether certain physicians would obtain additional imaging based on the specific duplex findings. Further limitations include the inability to determine symptomatic laterality based on ICD-9-CM code. Unfortunately, although most carotid duplex scans are bilateral, the associated ICD-9-CM code does not refer specifically to one side of the examination. Plaque phenotypic characteristics such as ulceration, intraplaque hemorrhage, thin-cap plaque, or a large necrotic lipid core may certainly affect the way in which a carotid duplex ultrasound is interpreted. For the purpose of this study, we elected not to include plaque phenotypic characteristics because they are measured and reported differently across different institutions.

This study demonstrates the significant variation in carotid duplex criteria used by 10 institutions with both accredited and nonaccredited vascular laboratories. The downstream effects of this variation on treatment and costs are significant. Standardization of carotid duplex ultrasound criteria is a long-standing substantial unmet need that will help to standardize the care of patients with carotid artery occlusive disease and may assist to control healthcare costs.

Acknowledgments
We thank Denise Kush for her assistance providing all of the carotid duplex line item data for the University of Massachusetts cohort.

Disclosures
None.

References


Institutional Differences in Carotid Artery Duplex Diagnostic Criteria Result in Significant Variability in Classification of Carotid Artery Stenoses and Likely Lead to Disparities in Care

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