National variation in preoperative imaging, carotid duplex ultrasound criteria, and threshold for surgery for asymptomatic carotid artery stenosis

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Objective: Carotid endarterectomy (CEA) for asymptomatic carotid artery stenosis is among the most common procedures performed in the United States. However, consensus is lacking regarding optimal preoperative imaging, carotid duplex ultrasound criteria, and ultimately, the threshold for surgery. We sought to characterize national variation in preoperative imaging, carotid duplex ultrasound criteria, and threshold for surgery for asymptomatic CEA.

Methods: The Society for Vascular Surgery Vascular Quality Initiative (VQI) database was used to identify all CEA procedures performed for asymptomatic carotid artery stenosis between 2003 and 2014. VQI currently captures 100% of CEA procedures performed at >300 centers by >2000 physicians nationwide. Three analyses were performed to quantify the variation in (1) preoperative imaging, (2) carotid duplex ultrasound criteria, and (3) threshold for surgery. Results: Of 35,695 CEA procedures in 33,488 patients, the study cohort was limited to 19,610 CEA procedures (55%) performed for asymptomatic disease. The preoperative imaging modality used before CEA varied widely, with 57% of patients receiving a single preoperative imaging study (duplex ultrasound imaging, 46%; computed tomography angiography, 7.5%; magnetic resonance angiography, 2.0%; cerebral angiography, 1.3%) and 43% of patients receiving multiple preoperative imaging studies. Of the 16,452 asymptomatic patients (89%) who underwent preoperative duplex ultrasound imaging, there was significant variability between centers in the degree of stenosis (50%-69%, 70%-79%, 80%-99%) designated for a given peak systolic velocity, end diastolic velocity, and internal carotid artery-to-common carotid artery ratio. Although 68% of CEA procedures in asymptomatic patients were performed for an 80% to 99% stenosis, 26% were performed for a 70% to 79% stenosis, and 4.1% were performed for a 50% to 69% stenosis. At the surgeon level, the range in the percentage of CEA procedures performed for a <80% asymptomatic carotid artery stenosis is from 0% to 100%. Similarly, at the center level, institutions range in the percentage of CEA procedures performed for a <80% asymptomatic carotid artery stenosis from 0% to 100%. Conclusions: Despite CEA being an extremely common procedure, there is widespread variation in the three primary determinants-preoperative imaging, carotid duplex ultrasound criteria, and threshold for surgery-of whether CEA is performed for asymptomatic carotid stenosis. Standardizing the approach to care for asymptomatic carotid artery stenosis will mitigate the significant downstream effects of this variation on health care costs. (J Vasc Surg 2015;62:937-44.)

Carotid endarterectomy (CEA) is a proven, effective treatment for stroke prevention in patients with asymptomatic and symptomatic carotid artery stenosis.¹⁻⁴

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The decision to offer CEA typically depends on preoperative imaging, carotid duplex ultrasound criteria, and the threshold for surgery; however, each aspect of care lacks standardization.

There is no consensus among surgeons on the requisite imaging study on which to base the decision to offer CEA. Although historically cerebral angiography was used to classify the degree of carotid stenosis,^{1,2} in the current era, multiple noninvasive imaging modalities are used, including duplex ultrasound imaging, computed tomography (CT) angiography, and magnetic resonance angiography. The selection of a preferred imaging modality may depend on surgeon preference or institutional availability of various testing modalities. Furthermore, select surgeons or institutions may use multiple imaging modalities before the intervention, whereas others may rely on a single imaging modality.

Despite the publication of five multispecialty guideline documents during the last decade, none have included standardized criteria for classifying carotid duplex parameters into discrete ranges of stenosis.⁵⁻¹⁰ Furthermore, although some vascular laboratories are certified by the Intersocietal Accreditation Committee (IAC),¹¹ many are not. A recent white paper publication by the IAC has recommended the use of the velocities provided at the Society of Radiologists in Ultrasound Consensus Conference.^{12,13} This white paper also advocated that facilities with internal validation may continue to use their own criteria.¹² Our group previously demonstrated significant regional variation in the diagnostic criteria of carotid duplex ultrasound studies, with widely disparate velocity criteria used among centers to assign degrees of carotid stenosis.¹⁴

Finally, there is no standardized stenosis threshold warranting revascularization. Prior work, including the Asymptomatic Carotid Atherosclerosis Study (ACAS),¹ demonstrated that patients with carotid artery stenosis of $\geq 60\%$ had a significantly lower rate of stroke than did patients receiving best medical therapy. However, cerebral angiography was used to determine the degree of carotid stenosis in that study. Currently, cerebral angiography is rarely used to determine the degree of carotid stenosis. Rather, various noninvasive diagnostic modalities are used to determine the degree of stenosis and then interpreted using widely varying diagnostic interpretive criteria. This variability could result in different thresholds of carotid stenosis that are used to recommend CEA to patients with asymptomatic carotid stenosis.

The purpose of this study was to quantify the variation across the United States in the management of asymptomatic carotid stenosis with regards to preoperative imaging, carotid duplex ultrasound criteria, and the threshold for surgery. We hypothesized that practice varies widely, across surgeons and across institutions, with a clinically relevant effect on the management of asymptomatic carotid artery stenosis.

METHODS

This study was approved by the University of Massachusetts Medical School Institutional Review Board.

Vascular Quality Initiative database. The Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) is an approved Patient Safety Organization by the Agency for Healthcare Research and Quality. The VQI contains >35,000 CEA and stenting procedures, with 100% procedure capture at >300 centers performed by >2000 physicians nationwide. Patient demographics and medical history, procedural and postoperative data, and 1-year follow-up data are collected in the registry. The SVS VQI data set was queried to identify all CEA procedures performed between 2003 and 2014. Data for this study were collected through the SVS Patient Safety Organization, which waives patient consent.

Cohort selection. The study cohort included all patients who underwent CEA documented in the VQI database and was ultimately limited to those patients with asymptomatic disease, defined as no evidence of prior ipsilateral neurologic symptoms. The unit of analysis was the CEA procedure and not the patient; if a patient underwent CEA on one side and a subsequent CEA on the other side, each procedure was considered independently.

Comorbidities. Associated comorbidities were examined, including hypertension, hyperlipidemia, coronary

artery disease, chronic obstructive pulmonary disease, congestive heart failure, end-stage renal disease, tobacco abuse, and diabetes mellitus. Hypertension was defined as any history of hypertension or blood pressure $\geq 140/90$ mm Hg. Hyperlipidemia included taking a cholesterol-lowering medication. Coronary artery disease was defined as a history of coronary artery bypass grafting, coronary artery percutaneous intervention, myocardial infarction, stable angina, or unstable angina. Chronic obstructive pulmonary disease included a documented history, both treated and untreated. Congestive heart failure was defined as documented asymptomatic or symptomatic heart failure. Tobacco abuse was defined as any current or former smoker. Diabetes mellitus included any type of diabetes, including patients on diet control or medications.

Carotid duplex ultrasound velocities. The carotid duplex ultrasound velocity for each patient was examined. The absolute value was used for calculation of the internal carotid artery peak systolic velocity (PSV), end diastolic velocity (EDV), and internal carotid artery-to-common carotid artery (ICA/CCA) ratio. Two patients (0.01%) with EDVs >999 cm/s were excluded from the analysis, as were a small percentage (3.2%) of patients with an ICA/CCA ratio >10, because these were believed to likely be errors in data entry. In the VQI data set, it is not possible to discern what vascular laboratory performed each carotid artery duplex and whether the vascular laboratory was IAC accredited.

Although B-mode characteristics of carotid duplex ultrasound imaging are used at some institutions, this is less common and more subjective; therefore, B-mode characteristics were excluded. For the purposes of this analysis, PSV, EDV, and ICA/CCA ratios were examined.

Institutions vary in their range of stenosis thresholds as determined by their vascular laboratory; for example, some centers use 50% to 69%, and others describe 50% to 79%, which may reflect an institution-wide decision not to offer revascularization for <80% stenosis. For each patient in the data set, the degree of carotid stenosis that was obtained from each imaging modality was specifically entered into the VQI database. For any evaluation of duplex parameters (PSV, EDV, ICA/CCA ratio), the degree of stenosis obtained from the duplex imaging was analyzed. For any analysis evaluating the threshold of stenosis at which surgery was offered, the maximum degree of stenosis obtained on any imaging study that a patient received was analyzed.

Statistical analysis. Descriptive statistics were performed using the Student *t*-test for comparison of continuous variables and the χ^2 test for comparison of categoric variables. A two-tailed P = .05 was considered statistically significant. Analyses were performed using SAS 9.3 software (SAS Institute Inc, Cary, NC).¹⁵

RESULTS

Of the 33,488 patients who underwent CEA in the VQI data set between 2003 and 2014, 19,610 CEA procedures in 18,524 patients were performed for asymptomatic carotid artery stenosis and constitute the study cohort. The

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