Standard duplex criteria overestimate the degree of stenosis after eversion carotid endarterectomy

Travis Benzing, BS,[b] Cameron Wilhoit, BA,[b] Sharee Wright, MD,[b] P. Aaron McCann, BE, BS,[c] Susan Lessner, PhD,[c] and Thomas E. Brothers, MD,[a,b] *Charleston and Columbia, SC*

Objective: **The eversion technique for carotid endarterectomy (eCEA) offers an alternative to longitudinal arteriotomy and patch closure (pCEA) for open carotid revascularization. In some reports, eCEA has been associated with a higher rate of >50% restenosis of the internal carotid when it is defined as peak systolic velocity (PSV) >125 cm/s by duplex imaging. Because the conformation of the carotid bifurcation may differ after eCEA compared with native carotid arteries, it was hypothesized that standard duplex criteria might not accurately reflect the presence of restenosis after eCEA.**

Methods: **In a case-control study, the outcomes of all patients undergoing carotid endarterectomy by one surgeon during the last 10 years were analyzed retrospectively, with a primary end point of PSV >125 cm/s. Duplex flow velocities were compared with luminal diameter measurements for any carotid computed tomography arteriography or magnetic resonance angiography study obtained within 2 months of duplex imaging, with the degree of stenosis calculated by the methodology used in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the European Carotid Surgery Trial (ECST) as well as cross-sectional area (CSA) reduction. Simulations were generated and analyzed by computational model simulations of the eCEA and pCEA arteries.**

Results: **Eversion and longitudinal arteriotomy with patch techniques were used in 118 and 177 carotid arteries, respectively. Duplex follow-up was available in 90 eCEA arteries at a median of 16 (range, 2-136) months and in 150 pCEA arteries at a median of 41 (range, 3-115) months postoperatively. PSV >125 cm/s was present at some time during follow-up in 31% of eCEA and pCEA carotid arteries, each, and in the most recent duplex examination in 7% after eCEA and 21% after pCEA ($P = .003$), with no eCEA and two pCEA arteries occluding completely during follow-up ($P = .29$). In 19 carotid arteries with PSV >125 cm/s after angle correction (median, 160 cm/s; interquartile range, 146-432 cm/s) after eCEA that were subsequently examined by axial imaging, the mean percentage stenosis was 8% ± 11% by NASCET, 11% ± 5% by ECST, and 20% ± 9% by CSA criteria. For eight pCEA arteries with PSV >125 cm/s (median velocity, 148 cm/s; interquartile range, 139-242 cm/s), the corresponding NASCET, ECST, and CSA stenoses were 8% ± 35%, 26% ± 32%, and 25% ± 33%, respectively. NASCET internal carotid diameter reduction of at least 50% was noted by axial imaging after two of the eight pCEAs, and the PSV exceeded 200 cm/s in each case.**

Conclusions: **The presence of hemodynamically significant carotid artery restenosis may be overestimated by standard duplex criteria after eCEA and perhaps after pCEA. Insufficient information currently exists to determine what PSV does correspond to hemodynamically significant restenosis. (J Vasc Surg 2015;61:1457-63.)**

Atherosclerotic disease of the carotid artery accounts for 10% to 30% of all strokes and 25% to 60% of ischemic strokes in the United States, with the type of stroke related to the degree of stenosis.[1-5] With 85% of strokes now reported to be ischemic in nature, between 10% and 30% of all strokes result from carotid artery disease.[6] Removal of the plaque (endarterectomy) of the common and proximal internal carotid artery (ICA) has been proven in multiple prospective, randomized, multi-institutional studies to reduce the incidence of stroke in patients with symptoms of transient ischemic attack or prior stroke with a reduction in the diameter of the ICA of at least 50% as well as in asymptomatic patients with a reduction in the internal carotid diameter of at least 60% or 70%.[7-11] Unfortunately, significant restenosis has been described in between 5% and 20% of patients within 5 to 10 years, depending on the method of surgical reconstruction, with most of the restenosis occurring within 2 years of operation.[12-14]

The eversion technique for carotid endarterectomy (eCEA) offers an alternative to longitudinal arteriotomy and patch closure (pCEA) for open carotid revascularization. However, in at least one report, eCEA has been associated with a higher rate of >50% restenosis of the internal carotid when it is defined as peak systolic velocity (PSV) >125 cm/s by duplex imaging.[15] There is currently a lack of appropriate and validated criteria for determining the presence of hemodynamically significant carotid artery stenosis after eCEA. Whereas it has been recognized that the duplex criteria for hemodynamically significant stenosis are affected by prior endarterectomy performed by longitudinal arteriotomy with patch closure as well as by carotid stenting, explicit duplex criteria to define stenosis after eCEA have not been addressed.[16-21] Because the

From the Ralph H. Johnson Department of Veterans Affairs Medical Center, Charleston[a]; the Department of Surgery, Medical University of South Carolina, Charleston[b]; and the Department of Cell Biology and Anatomy, University of South Carolina School of Medicine, Columbia.[c]

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Reprint requests: Thomas E. Brothers, MD, 25 Courtenay Dr, Ste 7018, Charleston, SC 29425-2950 (e-mail: brothete@musc.edu).

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conformation of the carotid bifurcation may differ after eCEA, it was hypothesized that standard duplex criteria might not accurately reflect the presence or absence of narrowing of the cervical ICA.

The objective of this study was to analyze duplex flow velocity within the ICA after eCEA. The hypothesis tested was that carotid artery PSV above 125 cm/s after eCEA does not represent an accurate threshold to indicate >50% diameter reduction in the ICA.

METHODS

Study design. This retrospective case-control study of the postoperative duplex results of patients undergoing carotid endarterectomy by the eCEA or pCEA technique was approved with waiver of consent by the Institutional Review Board of the Medical University of South Carolina and the Research and Development Committee of the Ralph H. Johnson Department of Veterans Affairs Medical Center in Charleston, South Carolina. The primary outcome end point was an abnormal carotid duplex examination with an ICA PSV >125 cm/s. Comparisons were subsequently made with any axial carotid arterial contrast imaging within 2 months of an abnormal duplex examination, including computed tomography angiography (CTA) and magnetic resonance angiography (MRA). Secondary outcome end points included stroke and death rates at 30 days and the long-term major stroke rate.

Operations. All patients undergoing carotid endarterectomy by a single vascular surgeon during a 10-year period were identified. Before the study period, this surgeon had performed at least 100 carotid endarterectomies with each technique. The type of carotid endarterectomy performed (eCEA or pCEA) was determined by intraoperative findings and personal bias. Duplex ultrasound measurement was performed intraoperatively at the conclusion of the procedure. Follow-up surveillance duplex ultrasound was performed at 4 months and then annually thereafter.

Data collection. The medical records were abstracted for the following information: demographic data; indication for operation; intraoperative use of a shunt for cerebral protection; concomitant coronary bypass operation; all duplex ultrasound, MRA, or CTA studies of the carotid arteries subsequent to operation; and occurrence of stroke or death at any time.

Carotid imaging. Color flow imaging and waveform velocities were determined from duplex imaging. For the purposes of this study, the velocity at peak systole was not translated to represent a specific degree of stenosis by duplex imaging. Absence of detectable flow in the internal carotid and lack of significant diastolic flow in the common carotid indicated carotid occlusion. Duplex flow velocities were compared with any carotid CTA or MRA study obtained within 2 months of duplex imaging. Diameter measurements of the common and internal carotid arteries were performed using data transformed with AquariusNET (version 4.4.7.102; TeraRecon, Inc, Foster City, Calif). Luminal diameter was measured using the electronic calipers provided by the software and performed independently by two trained observers who were blinded to the duplex findings at the time the axial imaging measurements were performed.

The degree of stenosis was calculated according to the following criteria:

North American Symptomatic Carotid Endarterectomy Trial (NASCET)[7]:

% stenosis = 1 − (minimum ICA lumen diameter/post-stenotic ICA lumen diameter)

European Carotid Surgery Trial (ECST)[10]:

% stenosis = 1 − (minimum ICA lumen diameter/outer diameter at same level)

Cross-sectional area (CSA) reduction[22]:

% stenosis = 1 − (minimum ICA lumen area/outer ICA area at same level)

(The minimum ICA lumen area and outer ICA area were calculated using an average of the diameters measured in a perpendicular axis.)

Adjusted PSV. To compensate for any errors in the original studies, direct measurement of the actual incident angle for the Doppler flow assessment was performed three times for each abnormal duplex study and averaged for comparison to the originally derived angle. The following equation was used to calculate the adjusted PSV, as previously reported[23]:

Adjusted velocity = Site velocity × [cos (site angle)/cos (new angle)]

Computational fluid dynamics. Patient-specific computational fluid dynamics models were constructed from post-carotid endarterectomy contrast-enhanced CTAs. Approximately 5 cm of the carotid artery lumen in the region around the carotid bifurcation was segmented using ITK-SNAP (University of Pennsylvania, Philadelphia, Pa). Segmented artery reconstruction and model surface smoothing were performed using Geomagic Studio (3D Systems, Rock Hill, SC). A volume mesh was created from linear tetrahedral elements using COMSOL Multiphysics 4.3 b (COMSOL, Inc, Burlington, Mass), resulting in approximately 150,000 elements. Blood was considered to be an incompressible Newtonian fluid, with a dynamic viscosity of 0.0033 Pa·s and a density of 1060 kg/m^3. The common carotid artery entry length was extended to allow fully developed laminar flow at the inlet boundary. The arterial wall was assumed to be rigid with a no-slip boundary condition at the wall. The same pressure inlet and outlet boundary conditions were used for all constructed patient models. COMSOL Multiphysics 4.3 b was used to obtain a computational solution for the velocity profile, with the solution considered converged if the relative error was $<10^{-3}$.

Statistical analysis. The χ^2 or Fisher exact test was used to compare proportional demographic data as appropriate. The *t*-test was used to compare continuous demographic data. The α error rates < .05 were considered significant. Pearson correlation coefficient was employed to compare the duplex PSV, with the degree of stenosis