

# SOCIETY FOR VASCULAR SURGERY® DOCUMENT

## Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease: Executive summary

John J. Ricotta, MD,<sup>a</sup> Ali AbuRahma, MD, FACS,<sup>b</sup> Enrico Ascher, MD,<sup>c</sup> Mark Eskandari, MD,<sup>d</sup> Peter Faries, MD,<sup>e</sup> and Brajesh K. Lal, MD,<sup>f</sup> *Washington, DC; Charleston, WV; Brooklyn, NY; Chicago, Ill; New York, NY; and Baltimore, Md*

In 2008, the Society for Vascular Surgery published guidelines for the treatment of carotid bifurcation stenosis. Since that time, a number of prospective randomized trials have been completed and have shed additional light on the best treatment of extracranial carotid disease. This has prompted the Society for Vascular Surgery to form a committee to update and expand guidelines in this area. The review was done using the GRADE methodology.

The committee recommends carotid endarterectomy (CEA) as first line treatment for most symptomatic patients with stenosis 50% to 99% and asymptomatic patients with stenosis 60% to 99%. The perioperative risk of stroke and death in asymptomatic patients must be below 3% to ensure benefit for the patient. Carotid artery stenting (CAS) should be reserved for symptomatic patients with stenosis 50% to 99% at high risk for CEA for anatomic or medical reasons. CAS is not recommended for asymptomatic patients at this time. Asymptomatic patients at high risk for intervention or with <3 years life expectancy should be considered for medical management as first line therapy.

In this Executive Summary, we only outline the specifics of the recommendations made in the six areas evaluated. The full text of these guidelines can be found on the on-line version of the Journal of Vascular Surgery at <http://journals.elsevierhealth.com/periodicals/jmva>. (J Vasc Surg 2011;54:832-6.)

Carotid endarterectomy (CEA) has been a cornerstone of stroke prevention for five decades, and has been the subject of extensive clinical investigation, including multiple controlled randomized trials. The appropriate treatment of patients with carotid bifurcation disease is of major interest to the community of vascular surgeons. Over the last decade, carotid artery stenting (CAS) has emerged as an alternative therapy for treatment of carotid bifurcation stenosis. In 2008, the Society for Vascular Surgery (SVS) published guidelines for treatment of carotid artery disease. At the time, only one randomized trial, comparing carotid endarterectomy and carotid stenting had been published. Since that publication, four major randomized trials comparing carotid endarterectomy and carotid stenting have been published. These trials have further clarified the relative indications for CEA and CAS, and have

refocused attention on the medical management of carotid bifurcation disease. The publication of these trials has prompted the SVS to update its 2008 recommendations. The current publication expands the scope of the 2008 guidelines to include recommendations on: imaging in identification and characterization of carotid stenosis, medical therapy (both as stand-alone management and in conjunction with intervention in patients with carotid bifurcation stenosis), risk stratification to select patients for appropriate interventional management (CEA or CAS), technical standards for performing CEA and CAS, the relative roles of CEA and CAS, and management of unusual conditions associated with extracranial carotid pathology. The committee reviewed the extant literature and made recommendations after extensive discussion using the GRADE system, as has been done with other SVS guidelines documents. The recommendations made in this document represent the unanimous opinion of the committee in each instance. Recommendations are characterized as *strong* grade 1 or *weak* grade 2, based on the quality of evidence, the balance between desirable effects and undesirable ones, the values and preferences, and the resources and costs. Grade 1 recommendations are meant to identify practices where benefit clearly outweighs risk. These recommendations can be made by clinicians and accepted by patients with a high degree of confidence. Grade 2 recommendations are made when the benefits and risks are more closely matched and are more dependent on specific clinical scenarios. In general, physician and patient preference plays a more important role in

From the Washington Hospital Center, Georgetown University School of Medicine, Washington, DC<sup>a</sup>; University of West Virginia, Charleston<sup>b</sup>; Maimonides Medical Center, Brooklyn<sup>c</sup>; Northwestern University, Chicago<sup>d</sup>; Mount Sinai University School of Medicine, New York<sup>e</sup>; and University Maryland, Baltimore.<sup>f</sup>

Competition of interest: none.

Reprint requests: John J. Ricotta, MD, Department of Surgery, Washington Hospital Center, 110 Irving Street NW, Suite G253, Washington, DC 20010 (e-mail: [John.J.Ricotta@medstar.net](mailto:John.J.Ricotta@medstar.net)).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest.

0741-5214/\$36.00

Copyright © 2011 by the Society for Vascular Surgery.

doi:10.1016/j.jvs.2011.07.004

the decision making process in these circumstances. In addition to the GRADE of recommendation, the level of evidence to support the recommendation is noted. Evidence is divided into three categories: A (high quality), B (moderate quality), and C (low quality). Conclusions based on high quality evidence is unlikely to change with further study, those based on moderate quality evidence are more likely to be effected by further investigation, and those based on low quality evidence are the least supported by current data and the most likely to be subject to change in the future. It is important to note that a grade 1 recommendation can be made based on low quality (C) evidence based on the effect on patient outcome. For example, while there are little data on the efficacy of CEA in asymptomatic patients with <60% stenosis, one can recommend with confidence that CEA not be performed in this group of patients.

Recently, the SVS was a cosponsor of recommendations made by a multispecialty group under the leadership of the American Heart Association and the American College of Cardiology. This extensive document represents an effort to evaluate the existing literature on extracranial carotid and vertebral disease and is an important reference.

For the purposes of this review, the committee placed the highest priorities on reducing overall stroke risk, periprocedural stroke risk, and periprocedural mortality. Lesser importance was given to reducing nonfatal myocardial infarction, cost, and the ability to perform a percutaneous procedure.

## I. RECOMMENDATIONS FOR THE USE OF CAROTID BIFURCATION IMAGING

- (1) Imaging of the cervical carotid artery is recommended in all patients with symptoms of carotid territory ischemia. This recommendation is based on the significant incidence of clinically relevant carotid stenosis in this patient group and the efficacy of carotid endarterectomy (CEA) for clinically significant lesions in reducing overall stroke (Grade 1, level of evidence A).
- (2) Imaging should be strongly considered for patients who present with amaurosis fugax, evidence of retinal artery embolization on fundoscopic examination, or asymptomatic cerebral infarction and are candidates for CEA. This recommendation is based on the intermediate stroke risk in this group of patients and the efficacy of CEA in reducing risk of subsequent stroke (Grade 1, level of evidence A).
- (3) Routine screening is not recommended to detect clinically asymptomatic carotid stenosis in the general population. Screening is not recommended for presence of a neck bruit alone without other risk factors. This recommendation is based on the low prevalence of disease in the population at large, including those with neck bruits, as well as the potential harm of indiscriminate application of carotid bifurcation intervention to a large number of asymptomatic individuals (Grade 1, level of evidence A).
- (4) Screening for asymptomatic clinically significant carotid bifurcation stenosis should be considered in certain groups of patients with multiple risk factors that increase the incidence of disease as long as the patients are fit for

and willing to consider carotid intervention if a significant stenosis is discovered. The presence of a carotid bruit in these patients increases the likelihood of a significant stenosis (Grade 1, level of evidence B).

Such groups of patients include:

- (a) Patients with evidence of clinically significant peripheral vascular disease regardless of age.
  - (b) Patients 65 years or older with a history of one or more of the following atherosclerotic risk factors: coronary artery disease, smoking, or hypercholesterolemia. In general, the more risk factors present, the higher the yield of screening should be expected.
- (5) Carotid screening may be considered in patients prior to coronary artery bypass. This is most likely to be fruitful if the patients are greater than 65, have left main disease or a history of peripheral vascular disease. The strongest indication for screening these patients from the data available is to identify patients at high risk for perioperative stroke. (Grade 2, level of evidence B)
  - (6) Carotid screening is not recommended for patients with abdominal aortic aneurysm who do not fit into one of the above categories (Grade 2, level of evidence B).
  - (7) Carotid screening is not recommended for asymptomatic patients who have undergone prior head and neck radiation. While the incidence of disease is increased in this group of patients, the utility of intervention in the absence of neurologic symptoms has not been clearly established (Grade 2, level of evidence B).

## II. RECOMMENDATIONS FOR SELECTION OF CAROTID IMAGING MODALITIES

- (1) Carotid duplex ultrasound in an accredited vascular laboratory is the initial diagnostic imaging of choice for evaluating the severity of stenosis in both symptomatic and asymptomatic patients. Under these conditions unequivocal identification of stenosis of 50% to 99% in neurologically symptomatic patients or 70% to 99% in asymptomatic patients is sufficient to make a decision regarding intervention (Grade 1, level of evidence A).
- (2) Carotid duplex ultrasound (CDUS) in an accredited vascular laboratory is the imaging modality of choice to screen asymptomatic populations at high risk (Grade 1, level of evidence B).
- (3) When CDUS is nondiagnostic, or suggests stenosis of intermediate severity (50%-69%) in an asymptomatic patient, additional imaging with magnetic resonance angiography (MRA), computed tomographic angiography (CTA), or digital subtraction angiography (DSA) is required prior to embarking on any intervention (Grade 1, level of evidence B).
- (4) When evaluation of the vessels proximal or distal to the cervical carotid arteries is needed for diagnosis or to plan therapy, imaging in addition to CDUS (either CTA, MRA, or catheter angiography) is indicated. CTA is preferable to magnetic resonance imaging/MRA for delineating calcium. When there is

discordance between two minimally invasive imaging studies (CDUS, MRA, CTA), DSA is indicated to resolve conflicting results. DSA is generally reserved for situations where there is inconclusive evidence of stenosis on less invasive studies or when CAS is planned (Grade 1, level of evidence B).

- (5) A postoperative duplex ultrasound, within 30 days, is recommended to assess the status of the endarterectomized vessel. In patients with 50% or greater stenosis on this study, further follow-up imaging to assess progression or resolution is indicated. In patients with a normal duplex and primary closure of the endarterectomy site, ongoing imaging is recommended to identify recurrent stenosis. In patients with a normal duplex ultrasound after patch or eversion endarterectomy, further imaging of the endarterectomized vessel may be indicated if the patient has multiple risk factors for progression of atherosclerosis. There are insufficient data to make recommendations on imaging after CAS (Grade 2, level of evidence C). While the data in this area are not robust concerning intervals for follow-up imaging, the committee was unanimous in this recommendation, recognizing that follow-up duplex ultrasound carries little risk.
- (6) Imaging after CAS or CEA is indicated to follow contralateral disease progression in patients with contralateral stenosis  $\geq 50\%$ . In patients with multiple risk factors for vascular disease, follow-up duplex may be indicated with lesser degrees of stenosis. The likelihood of disease progression is related to the initial severity of stenosis (Grade 2, level of evidence C). While the data in this area are not robust concerning intervals for follow-up imaging, the committee was unanimous in this recommendation, recognizing that follow up duplex ultrasound carries little risk.

### III. RECOMMENDATIONS FOR MEDICAL MANAGEMENT OF PATIENTS WITH CAROTID ATHEROSCLEROSIS

- (1) In patients with carotid artery stenosis, regardless of whether or not intervention is planned, treatment of hypertension, hypercholesterolemia, and efforts at smoking cessation are recommended to reduce overall cardiovascular risk and risk of stroke. Targets are those defined by the National Cholesterol Education Program guidelines (Grade 1, level of evidence A).
- (2) Aggressive treatment of hypertension in the setting of acute stroke is not recommended, however, treatment of hypertension after this period has passed is associated with reduced risk of subsequent stroke. The target parameters are not well defined (Grade 1, level of evidence C).
- (3) Treatment of diabetes with the goal of tight glucose control has not been shown to reduce stroke risk, or decrease complication rates after CEA, and is not recommended for these purposes (Grade 2, level of evidence A).

- (4) Anticoagulation is not recommended for the treatment of transient ischemic attack or acute stroke unless there is evidence of a cardioembolic source (Grade 1, level of evidence B).
- (5) Antiplatelet therapy in asymptomatic patients with carotid atherosclerosis is recommended to reduce overall cardiovascular morbidity although it has not been shown to be effective in the primary prevention of stroke (Grade 1, level of evidence A).
- (6) Antiplatelet therapy is recommended for secondary stroke prevention: aspirin, aspirin combined with dipyridamole and clopidogrel are all effective. Clopidogrel combined with aspirin is not more effective than either drug alone (Grade 1, level of evidence B).
- (7) Perioperative medical management of patients undergoing carotid revascularization should include blood pressure control ( $<140/80$ ), beta blockade (HR 60-80), and statin therapy (LDL  $<100$  mg/dL) (Grade 1, level of evidence B).
- (8) Perioperative antithrombotic therapy for CEA should include aspirin, (81-325 mg) (Grade 1, level of evidence A). The use of clopidogrel in the perioperative period should be decided on a case by case basis (Grade 2, level of evidence B).
- (9) Perioperative antithrombotic management of CAS patients should include dual antiplatelet therapy with aspirin and either ticlopidine or clopidogrel. Dual antiplatelet therapy should be initiated at least 3 days prior to CAS and continued for 1 month and aspirin therapy should be continued indefinitely (Grade 1, level of evidence C).

### IV. RECOMMENDATIONS REGARDING CEA AND CAS TECHNIQUE

- (1) Patch angioplasty or eversion endarterectomy is recommended over primary closure to reduce the early and late complications of CEA (Grade 1, level of evidence A).
- (2) Use of an embolic protection device (proximal or distal occlusion, distal filter) is recommended during CAS to reduce the risk of cerebral embolization (Grade 1, level of evidence B).

### V. RECOMMENDATIONS FOR SELECTING THERAPY

- (1) For neurologically symptomatic patients with stenosis  $<50\%$  or asymptomatic patients with stenosis  $<60\%$  diameter reduction optimal medical therapy is indicated. There are no data to support either CAS or CEA in this patient group (Grade 1, level of evidence B).
- (2) In the majority of patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all cause stroke and periprocedural mortality (Grade 1, level of evidence B). Data from CREST suggest that patients  $<70$  years of age may be better treated by CAS. These data need further confirmation.

- (3) Neurologically asymptomatic patients with equal or >60% diameter stenosis, should be considered for CEA for reduction of long-term risk of stroke provided the patient has a 3- to 5-year life expectancy and perioperative stroke/death rates can be equal to or <3% (Grade 1, level of evidence A).
- (4) CEA is preferred over CAS in patients >70 years of age, with long (>15 mm) lesions, preocclusive stenosis, or lipid-rich plaques that can be completely removed safely by a cervical incision in patients who have a virgin, nonradiated neck (Grade 1, level of evidence A).
- (5) CAS is preferred over CEA in *symptomatic* patients with  $\geq 50\%$  stenosis and prior ipsilateral operation, tracheal stoma, external beam irradiation resulting in fibrosis of the tissues of the ipsilateral neck, or prior cranial nerve injury and lesions that extend proximal to the clavicle or distal to the C2 vertebral body (Grade 2, level of evidence B).
- (6) CAS is preferred over CEA in *symptomatic* patients with  $\geq 50\%$  stenosis and severe uncorrectable CAD, CHF, or COPD (Grade 2, level of evidence C). In making this a grade 2 recommendation, the committee recognized the difficulty in clearly defining this group of individuals, both in terms of symptomatology and risk assessment and acknowledged the potential increased role of aggressive medical management as primary therapy in this high risk group.
- (7) Neurologically asymptomatic patients deemed "high risk" for CEA should be considered for primary medical management. CEA can be considered in these patients only with evidence that perioperative morbidity and mortality is <3%. CAS should not be performed in these patients except as part of an ongoing clinical trial (Grade 1, level of evidence B).
- (8) There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70% to 99% diameter stenosis. Data from CREST suggest that in properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists. Operators and institutions performing CAS must exhibit expertise sufficient to meet the previously established American Heart Association guidelines for treatment of patients with asymptomatic carotid stenosis. Specifically, the combined stroke and death rate must be below 3% to ensure benefit for the patient (Grade 2, level of evidence B).

## VI. UNUSUAL CONDITIONS ASSOCIATED WITH CAROTID STENOSIS

### A. Recommendations for management of acute neurologic syndromes

- (1) Patients who present within 6 hours of the onset of stroke should be considered for acute intervention to reduce the ultimate neurologic deficit. Interventions may include local or systemic thrombolysis (Grade 1, level of evidence A). The role of endoluminal mechanical lysis or extraction remains to be defined.
- (2) Patients who present with fixed neurologic deficit of more than 6 hours duration should be considered for CEA once their condition has been stabilized. CEA should be performed within 2 weeks of the neurologic event (Grade 1, level of evidence B).
- (3) Patients who present with repetitive (crescendo) episodes of transient cerebral ischemia unresponsive to antiplatelet therapy should be considered for urgent CEA. The risk of intervention is increased over elective surgery for neurologic symptoms, but not as much as for patients with stroke in evolution. CEA is preferred to CAS in these patients based on the presumptive increased embolic potential of bifurcation plaque in this clinical situation (Grade 1, level of evidence C).
- (4) For acute stroke after CEA, emergent imaging (ultrasound or fast CTA) is indicated to evaluate the endarterectomy site. When imaging suggests thrombosis, is indeterminate or not available, immediate operative re-exploration is indicated (Grade 1, level of evidence B).
- (5) When the endarterectomy site is patent, other modalities such as CT and angiography should be used to better identify the cause of the stroke. If CT excludes intracranial hemorrhage, anticoagulation is reasonable until a definitive decision regarding the appropriate diagnosis and therapy can be made (Grade 2, level of evidence C). While the committee acknowledged the lack of robust data in this small group of patients, it was unanimous in its endorsement of this recommendation based on the data available and the low likelihood that new data would emerge in the near future.
- (6) No firm recommendations can be made on treatment of stent thrombosis associated with CAS. It is reasonable to attempt to restore patency by use of chemical lysis or clot extraction (Grade 2, level of evidence C). While the committee acknowledged the lack of robust data in this small group of patients, it was unanimous in its endorsement of this recommendation based on the data available and the low likelihood that new data would emerge in the near future.

### B. Recommendations for management of symptomatic internal carotid occlusion

- (1) Patients with known internal carotid occlusion and persistent ipsilateral neurologic symptoms can be treated by endarterectomy of the common and external carotid artery with transection and ligation of the internal carotid origin. The addition of oral anticoagulation is likely to reduce the rate of recurrent stroke (Grade 1, level of evidence C).

**C. Recommendations for management of carotid dissection:**

- (1) Patients with carotid dissection should be initially treated with antithrombotic therapy (antiplatelet agents or anticoagulation) (Grade 1, level of evidence C).
- (2) Patients who remain symptomatic on medical therapy may be considered for intervention. While there are insufficient data to make firm recommendations, the committee unanimously felt that balloon angioplasty and stenting is currently preferred over open surgery after failed medical management (Grade 2, level of evidence C).

**D. Recommendations for management of combined carotid and coronary disease**

- (1) Patients with symptomatic carotid stenosis will benefit from carotid endarterectomy prior to or concomitant

with coronary artery bypass graft. The timing of the intervention depends on clinical presentation and institutional experience (Grade 1, level of evidence B).

- (2) Patients with severe bilateral asymptomatic carotid stenosis (including stenosis and contralateral occlusion) should be considered for carotid endarterectomy prior to or concomitant with coronary artery bypass graft (Grade 2, level of evidence B).

The above recommendations are meant to inform the practice of physicians and surgeons caring for patients with carotid bifurcation stenosis. They are unanimously supported by all members of the Guidelines Committee, who believe that they represent the current best practice based on available data. The Committee recognizes that these guidelines are likely to be a “living document” that will be altered in the future as techniques are further refined, technology develops, medical therapy improves, and new data emerges.