Carotid Artery Stenting

A perspective on the CMS decision memo regarding CAS.

BY KIERAN P. MURPHY, MD

The purpose of carotid stenting is to reduce the risk of stroke. We need to consider whether any intervention is better than maximal medical therapy. We always need to factor in the age, health, and gender of each individual patient. For example, there are virtually no data to support the use of carotid intervention in asymptomatic women. To benefit from a carotid intervention in the NASCET or ECAS study, patients need to live 2.7 to 5 years after the procedure. It is critical for physicians who intend to perform carotid artery stenting to be aware of the "number needed to treat" (the NNT). To prevent one stroke in patients with symptomatic stenoses >70%, eight patients must be treated safely. To prevent just one stroke in patients with asymptomatic stenoses >80%, 20 patients must be treated safely. This debate, therefore, needs to evaluate the procedure risks versus natural history risks, not endartectomy versus carotid stenting.

THE CMS REPORT

The Centers for Medicare & Medicaid Services (CMS) report is "a must read" document for anybody interested in stroke risk reduction and cerebral revascularization. It is a great and thoughtful summary, and the CMS should be commended for their efforts. The document can be found at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=157. With this document, CMS commits to covering patients with symptomatic 70% stenoses, if they are surgically high-risk candidates. If an interventionist is a participant in a postmarket surveillance study or an FDA/IDE study, then stenoses between 50% and 70% that are symptomatic, or stenoses >80% that are asymptomatic, may also be treated in high-surgical-risk patients.

The CMS prudently demands that all patients who have ultrasound determination of the degree of stenosis must be checked angiographically and measured, and that if the angiographic measurement is <70% for symptomatic disease, the procedure should not go forward in noninvestigational device or postmarket surveillance patients. The CMS defines high risk as a series of comorbidities (Table 1). All patients must receive a surgical opinion as to the resectability of the lesion prior to an endovascular treatment.

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The challenge with the CMS document arises in the application that the individual institution must send to them. CMS defines requirements for the level of angiographic equipment, resuscitation support, and postprocedural care for each patient. They ask each individual center to define their privilege and credentialing requirements for carotid stenting.

Alas, the CMS considers the consensus documents of SIR/AANS/ASNR and the SVS/ACC document as equal. There is a gulf between these documents, and that is where the heart of the matter lies. Each center must define for itself what it considers to be acceptable. The SIR/AANS/ASNR document states that a physician intending to stent carotid arteries must have performed 100 cerebral angiograms safely before beginning training. The SVS/ACC document states that a physician must have performed 30 cerebral angiograms (15 as primary operator), and 25 carotid stentings (13 as primary operator) before beginning the program, and that the diagnostic angiogram can be a component of the interventional procedure, thus reducing the number of cerebral angiograms necessary to 15. In many institutions, the SIR/AANS/ASNR consensus document will exclude a large number of radiologists from performing this procedure. It should be clear, therefore, that this document should not be seen as sectarian or preferring radiologists over any other group. The only groups that easily meet these cerebral angiographic carotid stenting

numbers will be relatively rarefied groups or interventional neuroradiologists with high cerebral angiographic volumes. What CMS has done is essentially drive groups to collaborate or cooperate in a way that was previously not possible. Each institution must apply with a single standard for the right to treat CMS-covered CAS patients.

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Ideally, patients who are eligible for carotid intervention, whether it is surgical or stenting, will be reviewed by a vascular surgeon or neurosurgeon skilled in the art of carotid endarterectomy, and this person will have to agree that a patient is at high risk for endarterectomy. The case may then be reviewed by a group of interventionists from cardiology, vascular surgery, or radiology, and the procedure will be performed after they agree that it is appropriate. There needs to be postprocedural review of the patient by a stroke neurologist and accurate and unbiased data collection to ensure appropriate analysis or complications, as well as presentation at a morbidity and mortality conference. CMS mandates biannual individual and site-specific reporting of complication rates, which may ultimately be available nationally in the same way that coronary artery bypass grating and surgical cardiac intervention data are available in New York State. I believe this is one of the strongest aspects of the CMS document. I think that in the beginning, there will be a lot of people that will want to be involved in carotid stenting. But, when they find that the results are making them look less expert and that distal flow protection is not absolution from lack of technique or inexperience, there will be a contraction of the number of practitioners and the centralization of stenting skills into key regional centers, as has happened with abdominal aortic aneurysm repair and intracranial aneurysm repair. This may parallel the experience with carotid endarterectomy.

STUDY DATA

It is important for anybody participating in a carotid stenting program to be familiar with the entire range of devices that can be applied to opening carotid stenoses. Perhaps the most interesting published article is not from the SAPPHIRE or ARCHeR studies, but from the CAVATAS study, in which 505 patients were randomized to surgery or endovascular intervention. The complication rate was the same in both arms. Two hundred fifty-four patients underwent surgery and 251 underwent angioplasty or stenting. The key fact in the study is that only 55 of the patients were stented and 196 had angioplasty alone. At the time of this study, angioplasty was performed with .035-inch guidewires and larger, thicker, bulkier, older balloons with 8-F guiding catheters instead of the new sheaths, and with a much poorer understanding of antiplatelet therapy than we utilize today. If angioplasty alone can achieve such excellent results, we need to seriously evaluate the design of our current stent platforms and reconsider the focus on distal flow protection. The interventionalist must be willing at a certain point in the procedure to decide that it is more prudent to perform angioplasty alone and to accept a nonhemodynamically significant stenosis than to proceed with increasing risk of complication to deploy a stent. I believe that the decrease in complication rates since the introduction of distal flow protection devices is as much due to the significant improvement in the preprocedural protocol use of antiplatelets, the use of .014-inch guidewires, the use of 6-F guiding sheaths, and better postprocedural management, as it is to the use of 3-F and 2.7-F distal flow protection devices. In the ARCHeR study, it became apparent that to demonstrate a 1% benefit of distal flow protection over no distal flow protection, a study of 8,000 patients would be required.

The complication rates of all of these stent trials and surgical carotid revascularization trials are in the region

TABLE 1. SIGNIFICANT COMORBID CONDITIONS AND CONTRAINDICATIONS

- Congestive heart failure class III/IV;
- Left ventricular ejection fraction <30%;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction;
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the previous carotid artery stenting trials and studies (ie, ARCHeR, CABERNET, SAPPHIRE, BEACH, and MAVERIC II).

of 5.8% to 12%. What has happened to the NASCET acceptable 3% complication rate beyond which there was no benefit to carotid intervention? The argument is made that the SAPPHIRE patients would not have been eligible for NASCET. This is partially true because 55% of patients in the SAPPHIRE study were asymptomatic, and 45% were symptomatic. The data regarding the degree of stenosis of that 45% are not available. Most patients, however, had stenosis less than 70%. Further muddying the waters is the fact that only the stented patients received postprocedural antiplatelet therapy, which must be considered a cotreatment. These drugs may be the principal reason for the differentiation between the two treatment options.

So, what happened to the NASCET 3% cutoff? Our role as physicians is to prudently assess data in a scientific fashion and establish a signal-to-noise ratio. It is more difficult not to do a procedure than to do it. But that is also in the best Hippocratic tradition. Stenting carotid arteries need not be a badge of honor or membership of some club. It is essential that all patients be reviewed by a multidisciplinary team that will view the patient as a whole, not as a stenosis, to ensure that balanced and prudent decisions are made. The data that we are working from are shaky at best, and our focus must not be shifted from the true purpose of carotid interventions (stroke reduction) by slick marketing. Maximal medical therapy at the time of the NASCET trial was an aspirin at best. The use of modern maximal medical therapy, including ACE inhibitors, cholesterol-lowering agents, and more advanced antiplatelet agents could potentially reverse the benefit of surgical/interventional management over medical management.

CONCLUSION

Today's endovascular therapists require an intellectual flexibility and breadth of vision so that they may ensure that appropriate interventions and technologies are applied to all patients. In the heat of the debate about whether carotid stenting is superior to carotid endarterectomy and who should be performing it, this is frequently forgotten. The debate is far too influenced by Wall Street and financial considerations. As physicians, we must remember that companies drive us to perform these procedures because they have to recoup the cost of the purchase of devices and patents. After all, that is the purpose of marketing. ■

Kieran P. Murphy, MD, is Director, Interventional Neuroradiology at Johns Hopkins, Department of Radiology, Baltimore, Maryland. Dr. Murphy may be reached at (410) 955-8525; kmurphy@jhmi.edu.