Carotid Artery Occlusive Therapy

A review of the history, the current state of treatment, and the issues surrounding regulation and reimbursement.

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An Internet search of publications regarding the treatment of extracranial carotid disease yields thousands of reports and studies. The treatment of these lesions has evolved during the past 50 years, with the indications being continually redefined based on changes in our understanding of the natural history of the disease, improvements in diagnostic modalities, an improved understanding of the pathophysiology of peripheral vascular disease, and refinements in interventions and medical therapies. Carotid artery occlusive therapy is a significant topic because stoke remains the third leading cause of death costing hospitals billions of dollars in expenses and disability annually.

A BRIEF HISTORY OF CAROTID ARTERY OCCLUSIVE THERAPY

My interest in extracranial carotid disease spans nearly 30 years, and it began at a time when the thinking was based on the development of successful surgical intervention for extracranial carotid disease. Landmark articles had described the natural history of internal carotid artery atherosclerosis from thrombotic occlusion or hemorrhage into the arterial wall, to strokes due to embolization from ulcerated lesions or from rupture of atherosclerotic lesions. Indications for surgical intervention on symptomatic patients were clear, with the advantage of stroke prevention in the majority of patients diagnosed with these lesions. Surgical interest was focused on developing unique approaches to addressing unusual anatomic variations and to answering questions regarding the benefit of preserving cerebral vascular circulation during carotid endarterectomy compared to endarterectomy with carotid occlusion. The benefits of performing endarterectomy under local anesthesia compared to general anesthesia were being discussed with use of a "squeaky-toy" as the method to assess contralateral limb function during the procedure.

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Care of cerebrovascular disease was improved further by a better understanding of brain pathophysiology, the development of improved anticoagulants, and maximal medical care of vascular patients—the full effect of which is not yet known. Imaging modalities to assess the degree of brain injury, particularly MRI and positron emission tomography scans, are expanding our knowledge of the metabolic and physiologic status of the brain and continue to impact the evolution of therapy.

A change in indications for introduction was broadened by NASCET and ACAS, including asymptomatic stenosis of greater than 80%, with life expectancies of 5 years or more. In some practices, the degree of stenosis for treatment has been greater than 70%, with widespread agreement that earlier intervention in appropriate asymptomatic patients meeting these guidelines was justified.

CAROTID STENTS AND EMBOLIC PROTECTION

Just as the opinions over therapy (including applications to patients with greater than 70% asymptomatic lesions) became less controversial, carotid artery stenting (CAS) and protection devices entered the arena. The appeal of endovascular technologies as a less-invasive method to treat vascular disease captured the enthusi-

asm of patients and physicians, while the considerations regarding the appropriate indications for intervention, including symptomatology, lesion characterization, and candidacy for an endovascular approach, rekindled the recurring controversies over appropriate indications for treatment.

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Significant evidence regarding the utility of carotid stents and protection devices to treat a segment of patients with extracranial carotid occlusive disease has been presented during the past 10 years. Development of delivery systems has enhanced the utility and safety of the technique. Enthusiasm for the approach has been significant by some, whereas others have taken a more guarded stance. The consensus has been that carotid stents are an important adjunct to the treatment of carotid occlusive disease. The priorities at the moment are to define the appropriate role for carotid stent technologies and to maximize appropriate availability to patients.

It is now easier to define some of the parameters that will be required in the US before widespread use of this technology is accomplished, because guidelines for initial approval and payment have been decided. Earlier discussions were clouded by uncertainty over initial approval and funding issues, which have been resolved.

CMS COVERAGE ISSUES

Regardless of one's point of view regarding the utility of CAS, the current Centers of Medicare & Medicaid Services (CMS) coverage decision allows reimbursement for use in high-risk symptomatic patients with stenoses greater than 80%. Physicians continue to have the discretion to treat individual patients with other indications, although this is only possible if patients are willing to pay for their procedure using their own resources, or if a third-party payor other than CMS approves the procedure.

Of paramount consideration in the preliminary decisions regarding payment for CAS is appropriate recognition that cerebrovascular disease is a high-risk, complex entity that has devastating adverse outcomes if inappropriate therapies are chosen. The mere presence of an extracranial carotid lesion, or the technical ability to treat a lesion using surgical or endovascular methods, is not the indication for intervention. Aside from the indications to treat an internal carotid stenosis, an additional consideration is the assessment of a patient for local surgical incision and conventional repair versus endovascular catheter techniques from a remote site. As more patients with complicated carotid disease are treated, this consideration is paramount in selecting the appropriate patient for intervention.

Atherosclerotic disease in the thoracoabdominal aorta and the morphology of origins of the brachiocephalic vessels from the thoracic arch affect the difficulty of device deployment. Catheter manipulation in the thoracoabdominal aorta in a diffusely diseased patient is not without risk because embolic sources and tortuous, diseased vessels in the thoracoabdominal aorta can be the source of devastating complications, even if CAS is successful. Imaging of the entire length of the proposed access route is not part of a routine investigation for the carotid occlusive patient. Careful examination of a patient and consideration of the cardiovascular history are essential in establishing the risk profile for an individual patient because catastrophic failures related to catheter access techniques can be reduced only with compulsive consideration and with time-additional imaging assessment of these additional factors.

REGULATORY AND REIMBURSEMENT CONSIDERATIONS

Off-Label Use

Off-label use of medical devices has important implications due to the regulatory and fiscal considerations that must be made when devices are used outside of the indication specified in the labeling for the device. Device labels are determined at the time of FDA approval and outline indications for use of the device that are supported by the scientific data presented in the study. Uses not included in the label are considered off-label and should be performed only when the device is the sole available treatment for a condition when there are no other available treatment methods that would provide safe and effective therapy.

Confusion develops regarding off-label use when physicians believe that an off-label application is the best medical treatment. Although the FDA does not practice medicine, and in this regard does not prohibit use of devices if a medical indication in a specific instance is documented, the physician may not promote the off-label use of a device nor can manufacturers promote their devices for any indication other than those in the approved labeling. In addition, if manufacturers are aware the devices are being used off-label,

they are responsible for securing approval for the indication or discouraging further off-label use.

Off-label use also has implications on payment for the procedure. Payment for devices and associated procedures are determined by the CMS after FDA approval. This is done via either a national coverage decision, or if there is no national decision, by local coverage determinations. In the case of a national coverage decision, which is infrequently used, only the labeled indications can be paid for by CMS. There are no exceptions to this guideline, and billing for procedures in which there is noncovered use for a label device is not possible. There are exceptions for payment for devices being used in clinical trials, with specific codes being established before the labeling becomes effective.

If there is no national coverage decision, each local carrier has the ability to write a coverage decision that can vary locally. In general, off-label uses are not covered by local carriers, although the intention to perform and then bill for an off-label procedure should be discussed with the local carrier, and consent of the agency should be obtained before proceeding with billing.

There are other responsibilities required for physicians who use products for an indication not listed in the approved labeling. The physician must be well informed about the product based on scientific and medical evidence and must maintain records of products used with documentation of their effects. In an off-label situation, the physician takes the responsibility for determining the device's suitability for the intended use, with the physician and the local institution assuming liability.

The difference between labeled and off-label uses of devices is determined by the FDA based on scientific evidence for a particular use. An example is the approval of devices for use as biliary and tracheobronchial stents where patients usually survive a limited period of time. To acquire device approval for this indication, a limited testing is needed. When stents are approved for biliary or tracheobronchial use, but are then used for vascular applications, the long-term durability has not been documented, and approval for this use would require more extensive vascular testing.

Destination Therapy and Outcomes Analysis

Carotid stent therapy has been approved in a limited segment of patients based on a national coverage decision that was recently published. In this decision, the release of carotid stents on a limited basis with destination therapy not only limits the use of carotid stents, but also affects future decisions related to medical device introduction. The reimbursement of high-risk devices based on destination therapy is being developed as a new model that is clearly outlined in the recent CMS carotid stent decision. Critical components of this decision are the requirements for facility application to the agency meeting standards for facilities, physician training, and outcome data availability.

> "... CMS continues to await studies that address broader utility with long-term follow-up of this technology before considering broad-label coverage ..."

In this decision, CMS clearly made a distinction between lower-risk peripheral vascular applications of stents and the high-risk nature of cerebrovascular interventions. Although substantial data regarding the utility of carotid stents have been accumulated, CMS continues to await studies that address broader utility with long-term follow-up of this technology before considering broad-label coverage for these procedures. Because attempts to solicit studies from manufacturers and investigators addressing these issues have been futile, the agency viewed destination therapy as the most appropriate way to obtain long-term follow-up on these patients to evaluate use and funding.

The decision by CMS to apply the destination therapy model sets a precedent of mandatory auditing and outcomes analysis that contrasts a more desirable environment in which voluntary reporting could be acceptable. I believe that this decision was precipitated by unwise recommendations from interventionists and industrial regulatory personnel who assumed that narrow-label studies would translate to broad-label use. Although CMS stated that this history of narrow-label indications leading to broad coverage decisions would no longer apply with regard to funding for high-risk devices, this outcome was not anticipated, and narrow-label indication and mandatory auditing has resulted.

For these reasons, the appropriate path for this and other devices is for physicians and industry to recognize the need for broad-label studies that address clinical practice patterns. The adoption of outcome registries and potential volunteering reporting mechanisms may be a plausible option to prevent further mandatory auditing initiatives. ■

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