



New Techniques in Carotid Stenting

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Oclusive lesions of the internal carotid artery (ICA) caused by atherosclerosis can cause embolic stroke or cerebral ischemia, which may result in significant morbidity, mortality, and long-term disability. Carotid stenosis can be accurately diagnosed by carotid duplex ultrasound imaging. Specific hemispheric symptoms related to potential embolism from a carotid stenosis include temporary ipsilateral vision loss, contralateral upper or lower extremity weakness or numbness, and speech disturbance (expressive aphasia).

Carotid surgery is considered if a patient has had hemispheric symptoms in the past 6 months and more than 50% ICA stenosis, or more than 60% ICA stenosis in an asymptomatic patient.¹ Based on the American Heart Association guidelines, carotid surgery should only be performed if the combined perioperative stroke and death rate is less than 3% in asymptomatic patients and 6% in symptomatic patients with high-grade ICA stenosis.²

Major landmark clinical trials (North American Symptomatic Carotid Endarterectomy Trial and Asymptomatic

Carotid Atherosclerosis Study) confirmed the superiority of carotid endarterectomy over best medical therapy in preventing stroke.^{3,4} Medical therapy, however, has continued to evolve since these trials. A reduction in stroke risk in patients with atherosclerotic disease has been attributed to the use of new antiplatelet agents, HMG-coenzyme A reductase inhibitors (statins), and more aggressive hypertension control. Studies comparing carotid intervention to the best present-day medical management are lacking, but experts feel carotid repair is still superior to drug therapy.⁵ The majority of clinical trials have enrolled only low-risk surgical patients. Higher-risk patients (patients over age 80) were typically excluded.

Endovascular techniques continue to evolve in vascular surgery as carotid stenting has moved to the forefront over the last several years. The most significant improvement in carotid stenting safety outcomes has been the development and utilization of embolic protection devices (EPDs).⁶ Carotid stenting is emerging as an equivalent alternative to carotid endarterectomy in the management of high-risk surgical patients with carotid occlusive disease, but long-

term studies on patient outcomes are not available yet and there is limited nursing literature on the technique.⁷

■ History

Surgery to prevent stroke has been shown to be better than medical therapy in appropriately selected patients. Use of carotid angioplasty initially began in the 1980s, and was associated with discouraging outcomes due to increased neurologic complications caused primarily by procedure-related emboli.^{8,9} Fifteen patients with recurrent carotid stenosis after endarterectomy had a 33% neurologic complication rate during carotid stenting.¹⁰ A few years later, the first prospective randomized trial comparing surgery with carotid angioplasty in patients with symptomatic ICA stenosis greater than 70% was started in Europe. This trial was halted when the results showed that five out of seven patients undergoing angioplasty suffered neurologic complications.¹¹ Findings from one study concluded that carotid artery stenting utilizing an EPD is not inferior to carotid endarterectomy.¹² Individual centers began publishing their results showing the safety of protected carotid stenting with EPDs if done by experienced operators.¹³

■ Preoperative Considerations

Beginning in 2000, the Centers for Medicare and Medicaid Services (CMS) only covered payment for carotid stenting in patients enrolled in clinical trials conducted prior to Food and Drug Administration approval and those in postapproval studies. In March 2005, CMS approved payment coverage for carotid stenting to treat symptomatic ICA stenosis greater than 50% and asymptomatic ICA stenosis greater than 80% in patients considered high-risk for open carotid surgery. Most of the literature separates high-risk patients into two main categories: medical criteria and anatomic criteria (see Table: “Common High-Risk Criteria Used in Carotid Stent Trials”). Outcome reports of the ACCULINK for Revascularization of Carotids in High-Risk Patients and Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy trials analyzed postoperative stroke and 30-day death rates in the treatment of high-risk patients and yielded equivalent adverse endpoints compared to open surgery.^{12,15}

There are several anatomic contraindications to carotid stenting (see Table: “Anatomic Findings Associated with Increased Procedural Risks with Carotid Stenting”). There are also certain medical conditions that should be considered prior to offering carotid stenting. Patients with chronic renal insufficiency, especially those with diabetes and a serum creatinine greater than 2.0 mg/dL, may benefit from open surgery. Due to exposure to contrast dye during the stenting procedure, renal impairment could worsen. Patients intolerant to antiplatelet therapy shouldn't be considered for stenting as all patients should be given aspirin and clopidogrel (Plavix) 5 days prior to the procedure and clopidogrel up to 6 weeks afterward; aspirin should be continued indefinitely.¹⁶

Common High-Risk Criteria Used in Carotid Stent Trials¹⁴

Medical criteria

- Unstable angina
- Myocardial infarction within 30 days
- New York Heart Association (NYHA) classification Class III or IV heart failure
- Multi-vessel coronary artery disease (nonrevascularized)
- Reduced left ventricular ejection fraction (<30%)
- Cardiac or vascular surgery required within 30 days
- Chronic obstructive pulmonary disease (FEV₁ <30% of predicted)
- Age greater than 75 years

Anatomic criteria

- Lesions higher than C2 or lower than C6
- Tandem carotid lesions requiring treatment
- Restenosis following ipsilateral CEA
- Ipsilateral radical neck dissection/irradiation
- Tracheostomy
- Bilateral severe carotid artery stenosis
- Contralateral carotid artery occlusion
- Contralateral CEA resulting in cranial nerve injury

Carotid artery revascularization is only justified if the procedure can be accomplished with a neurologic complication rate of less than 3% in an asymptomatic patient and less than 6% in a symptomatic patient. During preoperative patient counseling, studies have shown that the most important factor found to increase periprocedural complications is an age over 80. The Carotid Revascularization Endarterectomy versus Stent Trial (CREST) found that the risk of 30-day stroke and death rate among 749 patients was directly related to age (less than 60 years, 1.7%; 60 to 69 years, 1.3%; 70 to 79 years, 5.3%; and over 80 years, 12.1%, $P=0.006$).¹⁸ Patients with reduced cerebral reserve, for example, patients with dementia, prior stroke, multiple lacunar infarcts, or intracranial microangiopathy, don't tolerate cerebral embolization that occurs with either carotid stenting or endarterectomy. Improved neurologic outcomes have been shown in octogenarians who undergo carotid stenting with adjunctive distal embolic protection.¹⁹

It's imperative for the surgeon to have a risk/benefit discussion with the patient prior to any procedure. Risks of

carotid stenting include: carotid dissection or thrombosis, stroke (especially with advanced age), death, restenosis, sub-clinical embolization, dye allergy, cardiac dysrhythmias, pseudoaneurysm of the femoral artery, infection, and bleeding. Benefits to carotid stenting include: decreased risk of cranial nerve injury, avoidance of general anesthesia and neck incision, reduced pain, and reduced incidence of cardiac events.⁷

To ensure optimal outcomes and safe performance measures, CMS implemented competency guidelines for providers and facilities involved in carotid stenting.²⁰ Competency is based on clinical guidelines and specific standards that must be maintained, including physician training criteria, facility support requirements, and data collection to evaluate safety outcomes. In May 2007, the CMS elected not to implement changes proposed in February 2007. They did clarify that carotid stenting would only be covered when used in conjunction with an embolic protection device and that there were modifications to the process for completing facility certification data forms.²⁰

■ Intraoperative Techniques

Carotid endarterectomy is an open surgical procedure, typically performed under general anesthesia or using moderate sedation, in which carotid plaque is completely removed from the artery and the vessel is rebuilt. Often, a prosthetic or vein patch is used to close the artery, which can help reduce the incidence of restenosis. There is a risk of stroke, bleeding, cranial nerve injury, and cardiac events. Carotid stenting is generally performed without general anesthesia; the patient may receive moderate sedation. The plaque is simply displaced, the artery wall stretched and stented open. The self-expanding stent technology serves as a scaffold to prevent elastic recoil following balloon angioplasty. Not infrequently, modest residual stenosis remains after carotid stenting.¹⁷

Carotid artery stenting can be performed using a variety of techniques; following is an example of the protocol used at the authors' institution. The patient is positioned supine with the bilateral groins prepped and draped. The procedure is done with local anesthesia in the femoral puncture site, appropriate cardiac monitoring, and anesthesia support. The patient is awake and able to follow commands to allow for continuous neurologic monitoring. The procedure requires the use of a C-arm with vascular software.

Via femoral access, a 7 French 90 cm introducer sheath platform is delivered to the aortic arch. Systemic heparin is used to obtain an activated clotting time (ACT) of greater than 250 seconds. After the common carotid artery is accessed with a soft-tipped guide wire, the guide catheter is positioned into the common carotid artery (CCA) under

Anatomic Findings Associated with Increased Procedural Risks with Carotid Stenting^{16,17}

- Inability to obtain femoral access (for example, severe aortoiliac disease)
- Unfavorable arch anatomy
- Excessive tortuosity of the carotid anatomy defined as two or more bend points that exceed 90 degrees within 5 cm of the lesion
- Severely calcified/undilatable stenosis defined as concentric circumferential calcification width > 3 mm
- Lesions containing fresh thrombus
- Long (> 2 cm) or multiple lesions
- Critical stenosis (> 99%) stenosis known as "string sign"
- Lesions adjacent to carotid artery aneurysms
- Significant intracerebral disease and/or aneurysms

fluoroscopic guidance. A soft-tipped, 0.14 mm wire is used to cross the stenosis. A filter (cerebral protection device) is placed in the distal internal carotid artery to capture any embolic material from the aortic arch or ICA that may occur during the procedure.

There are several types of cerebral protection devices including filters and proximal or distal occlusive balloons. The occlusive balloons can't be used in patients with contralateral carotid occlusions. Using the proximal occluding balloon, the common carotid flow is occluded, which creates a reversal of flow in the ICA. Embolic particles are aspirated via the guiding catheter. Distal occlusive balloons occlude the flow in the distal ICA and the embolic materials created during stenting are trapped by the balloon and aspirated. Filters are deployed prior to stenting; they trap embolic particles generated during stenting.⁷

Hypotension can occur after balloon dilatation and can be treated with volume expanders, I.V. phenylephrine, and occasionally vasoactive infusions. Predilatation with an undersized 2-to-3mm balloon is sometimes needed for the stent delivery system to cross a much narrowed stenosis. A self-expanding nitinol stent is placed across the lesion and deployed with the proximal end typically in the CCA, extending to the distal ICA. Positioning the distal end of the stent in kinks or tortuosities of the ICA should be avoided. Covering the external carotid artery hasn't been shown to result in adverse events. Finally, the stent is postdilated with a 4.5 to 6 mm balloon to expand the stent against the artery wall to ensure good apposition. The cerebral protection device is removed. Stent patency and absence of intracerebral embolization is confirmed by completion angiography. The average length of the procedure is 30 to 45 minutes.²¹

Intravascular ultrasound (IVUS) can also be used during

Preparing the Carotid Stent Catheter Prior to Insertion



the procedure. There are several reasons for its use including: to limit dye load, stent/artery size measurement and selection, plaque morphology characteristics, and to gauge adequacy of stent expansion. The application of IVUS requires special training for the perioperative nurse, usually via a course or individual training with an equipment representative.

■ Postoperative Care

Once the carotid stenting procedure is complete, the patient is transferred to the PACU. The femoral sheath is kept in place until the neurologic exam is normal and the ACT is less than 180 seconds, which on average is less than 1 hour. Once the sheath is removed, pressure must be applied to the site until bleeding stops, which could take up to 2 hours. The patient needs to lie flat with the head of the bed at less than 30 degrees and the affected leg straight to prevent bleeding or hematoma for approximately 4 to 6 hours. Monitoring the femoral access site and the neurovascular assessment should be completed and documented. Vital signs should also be taken every 15 minutes for 2 hours postprocedure. The patient usually will be monitored in the intensive care unit or stepdown unit overnight if I.V. medication is needed for management of a hypertensive or hypotensive event.

Another rare complication after carotid stenting is reperfusion syndrome, which occurs mostly in patients who've had an extremely tight stenosis.²² In these patients, the cerebral vasculature loses its normal auto regulation and the patient may develop cerebral edema when normal blood flow is reestablished. These patients are at risk for cerebral hemorrhage and seizures. The patient usually complains of a severe unilateral headache in the ipsilateral temple. The patient should be monitored for a change in neurologic status and immediate brain imaging should be obtained to rule out in-

tracranial hemorrhage.

Duplex ultrasound testing in the PACU is useful to exclude stent thrombosis or immediate platelet aggregation, or residual stenosis, which can occur in 1% to 5% of cases. Dissection of the distal ICA from the embolic protection device is a serious complication of carotid stenting that can result in occlusion and stroke. ICA dissection is suspected when extremely elevated velocities and flow disturbance are detected in the distal ICA past the stent.²³

Use of a distal protective device doesn't completely prevent brain injury.²³ The reported rate of subclinical brain injury after carotid stenting secondary to micro-embolization seen on diffusion-weighted magnetic resonance imaging (DWI) varies from 10% to 40%. Protection devices prevent clinical and subclinical embolization during the procedure, but embolization may continue for at least 48 hours post-procedure. Therefore, DWI should be done as late as possible to accurately determine the rate of subclinical brain injury.²⁴ Unfortunately, there is limited literature that describes whether subclinical embolization causes long-term cognitive impairment.

Lastly, carotid artery stent fracture is an unexpected complication that was described in recent literature. In this case report, a nitinol stent fractured through the waist of the stent. The fracture was diagnosed on angiography and correlated to a stenosis seen on carotid duplex. The stent was surgically removed and the patient required open carotid endarterectomy with synthetic patching.²⁵

The majority of patients are discharged the day following the procedure on clopidogrel for at least 6 weeks and aspirin indefinitely. If carotid stenting was necessary because the patient had prior carotid endarterectomy or radiation, then clopidogrel should be continued for 1 year as these patients may have an increased incidence of restenosis.²⁶ Patients should be instructed to monitor blood pressure at home and to gradually increase activity. The patient should avoid lifting heavy objects and straining during bowel movements until after the follow-up visit to a vascular clinic.

■ Surveillance

Carotid duplex is the most common imaging study used in postoperative surveillance of carotid stents.²⁷ Follow-up duplex studies are performed on the day of the procedure, 3 months, 6 months, and every 6 to 12 months thereafter depending on the results. Duplex testing sometimes shows high velocities despite normal angiographic results. Evidence suggests that this doesn't predict progression of neointimal proliferation or restenosis.²⁸ Deployment of a carotid stent may cause changes in vessel wall compliance and blood flow. There's agreement that velocities are increased in the stented carotid arteries versus nonstented ones. Standard carotid ve-

locity criteria aren't applicable as they overestimate the degree of stenosis and don't correlate with angiography. A more sensitive indicator of recurrent stenosis may be a progressive stent velocity increase over time.¹⁷

A retrospective review of 605 patients who underwent carotid stenting showed that current carotid duplex velocity criteria weren't accurate. Of the 605 patients, 118 patients had both carotid duplex and angiography. Findings showed the peak systolic velocity (PSV) and ICA to CCA ratio increased with stenosis to a greater extent. They found that an in-stent stenosis of 70% or greater correlates with a PSV over 350 cm/sec and an ICA to CCA ratio greater than 4.75; stenosis of 50% or greater correlates with a PSV over 225 cm/sec and an ICA to CCA ratio greater than 2.5.²⁹ Similar results were reported from a prospective review of 260 patients with a stenosis on duplex of at least 50%. All patients underwent angiography and the authors concluded that a PSV over 450 cm/sec and an ICA to CCA ratio of greater than 4.3 were optimal thresholds for an in-stent stenosis greater than 70% and a PSV over 240 cm/sec and ICA to CCA ratio greater than 2.45 correlated to stenosis greater than 50%.³⁰

The incidence of restenosis after carotid stenting is still unknown. In our experience, duplex surveillance after carotid stenting identified a 5% procedural failure rate, due to the development of high grade greater than 75% diameter-reduction (DR) in-stent stenosis found on carotid duplex testing (6 of 114 patients). Angiography confirmed the presence of a greater than 75% DR carotid stenosis in all six patients. These lesions were treated with balloon angioplasty (n=3), stent angioplasty (n=2) and open endarterectomy with stent removal (n=1).²⁷ The long-term outcomes of stent durability are also unknown. Until the CREST study outcomes are known, the option of carotid stenting will only be to a select patient cohort. **NP**

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