
Endovascular therapy of common carotid bifurcation stenosis

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The emerging technology and expertise of endovascular therapy is expanding the treatment of carotid artery disease. Interventional radiologists have extensive experience in treating lesions in the noncoronary vasculature and possess the skills to treat disease of the common carotid artery bifurcation as well. Carotid angioplasty and stenting has shown beneficial results in the treatment of carotid atherosclerotic lesions. More in-depth studies are under way to compare stenting with carotid endarterectomy. Antiembolic neuroprotective devices are nearing Food and Drug Administration approval and may be capable of reducing procedural strokes and transient ischemic attacks. Patient and lesion characteristics optimal for carotid artery stenting are becoming better defined as more procedures are performed throughout the world. This article reviews the technique, outcomes, trials, neuroprotective devices, and guidelines for endovascular therapy of common carotid artery bifurcation stenosis.

Strokes affect approximately 600,000 Americans every year, leaving a large number with permanent and significant morbidity.¹ Approximately 20% to 30% of strokes arise from debris that embolize from carotid artery bifurcation atherosclerotic plaques.² Because the North American Symptomatic Endarterectomy Trial (NASCET)³ and the Asymptomatic Carotid Atherosclerosis Study (ACAS)⁴ showed morbidity reduction in patients who received carotid endarterectomy (CEA), treatment of carotid atherosclerotic disease has shifted from medical therapy to surgical intervention.

Carotid artery stenting (CAS) has emerged as a less-invasive technique to treat stenoses of the carotid bifurcation; however, stenting atherosclerotic lesions of carotid arteries may cause far more devastating effects than those found in other vascular territories. A small embolic shower to the leg or kidney may be tolerated, but similar embolization to the brain may have severe consequences. The very stroke to be prevented by surgery or endovascular therapy may be precipitated by these procedures. The morbidity of carotid stent placement is rapidly decreasing and has been shown to carry risks of cerebral

embolization similar to that of CEA.⁵⁻⁷ Many more than 5000 patients have been treated with CAS worldwide, with a significant number in Europe, where new technology tends to reach the market sooner.⁸ More comprehensive randomized studies are under way.^{9,10}

Carotid artery stenting

Procedure

At the 2001 Society of Cardiovascular and Interventional Radiology (SCVIR) Annual Meeting, Dr. Michael H. Wholey, among others, discussed the technique of carotid stenting. Thorough preprocedure neurologic evaluation, including the National Institutes of Health (NIH) Stroke Scale,¹¹ is performed. Next, a four-vessel cerebral angiogram and other imaging are completed. Most commonly, patients are premedicated with 325 mg aspirin qd and 75 mg Plavix (Bristol-Myers Squibb/Sandofi Pharmaceuticals Partnership, New York, NY) qd for 5 days.

After sedation, a femoral venous sheath is placed to facilitate transvenous pacer placement if needed. A pacer may be placed prophylactically in cases in which the lesion involves the carotid bulb. (A pacer should be readily accessible, as reflex bradycardia is seen with carotid angioplasty, especially of the carotid body.) Common

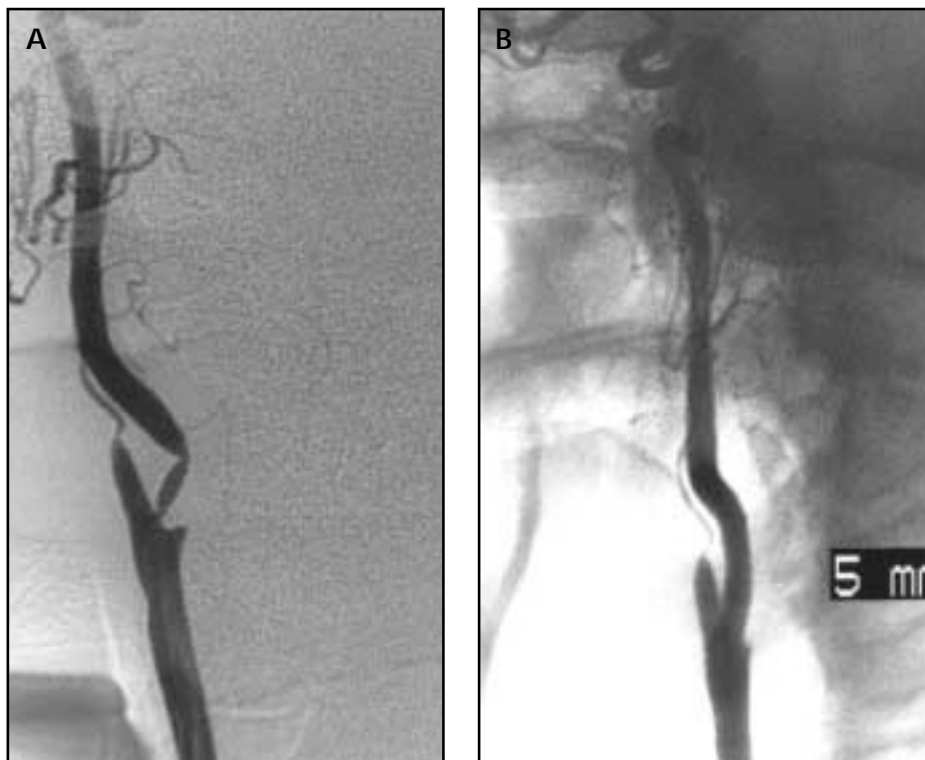


FIGURE 1. (A) A 68-year-old woman 16 years after radical neck dissection, tracheostomy, and radiation. (B) A 6 x 30-mm SMART stent and postdilation with 5-mm balloon.

femoral arterial access is made and a 9F sheath is placed prior to administration of 5000 units of heparin. Activated clotting time (ACT) is kept at 250 to 300 seconds.

Access is made to the external carotid artery and an exchange length stiff guidewire is placed. A 7F sheath or a guiding catheter loaded with a 7F introducer (DVI, Temecula, CA) is advanced into the distal common carotid artery, but not within 1 cm of the lesion. After removal of the guidewire and introducer, appropriate angiograms are obtained.

A 0.014-inch guidewire is advanced carefully through the lesion, and the tip is stabilized at the level of C2. If the Food and Drug Administration (FDA) approves a cerebral protective device designed for internal carotid artery use, as discussed below, or if the procedure is performed within a trial of these devices, then this device would be positioned at this point, instead of a guidewire.

A 3- to 4-mm X 2-cm Savvy balloon catheter (Cordis Corp., Warren, NJ) is positioned within the lesion, and 0.5 mg of atropine is given. The balloon is inflated gently (not briskly), deflated, and removed. Depending on the lesion's characteristics, a stent is chosen. The SMART stent (Cordis) or Wallstent (Boston Scientific, Minneapolis, MN) are two self-expanding stents used with excellent results. Alternatively, a balloon expandable Palmaz or Corinthian stent (Cordis) can be chosen. The stent is centered in the lesion, and final positioning prior to deployment may be performed during contrast injections through the guiding catheter or sheath. After self-expanding stent deployment, the stent is dilated with a 5- or 6-mm balloon for internal carotid lesions.

Balloon expandable stents have the advantage of easier tracking through tortuous arteries, greater precision in placement, and greater radial hoop-

strength, but are subject to external compression deformation. Self-expanding stents have an element of rebound to external compression and can be sized to conform to both internal and common carotid arteries. Stents are usually oversized 1 to 2 mm, and if deployed within both the internal and common carotid arteries, they are sized to the larger vessel. Many stents in development are better suited for carotid use, such as the Precise stent (Cordis). It has a 5.5F deployment system, is quite flexible, and has less friction during deployment, facilitating precision of placement.

Patients are hospitalized overnight and continue taking aspirin (which they must continue for life) and Plavix, 75 mg qd for 3 weeks. Postprocedure neurologic evaluation is performed and NIH Stroke Scale is utilized at 24 hours, 1 month, and 6 months.^{12,13} Figure 1 is an example of successful internal carotid origin stenting with a SMART stent (Cordis).

Results

Retrospective analyses of CAS⁵⁻⁷ show excellent results comparable with CEA.^{3,4} In comparing the complications of CAS, one must remember that patients are often treated in spite of their greater medical risks or having lesions that are not ideal for CEA.

Wholey et al⁵ published the results of 114 consecutive procedures in which 108 carotid arteries were stented. There were 6 technical failures, mostly due to tortuous atherosclerotic vessels that prevented safe positioning of the guiding sheath. The 30-day stroke and death rate was 5.3%, all occurring in symptomatic patients, with an additional 4.4% periprocedural TIAs. No antiembolic neuroprotective devices were used in this study.⁵

Roubin et al⁶ reported on 604 consecutive carotid arteries treated by stenting. The 30-day stroke and death rate was 7.4%. The major portion of the 30-day stroke and death rate was composed of minor strokes whose rate was decreased by >50% during the additional 5 years of experience gained during the study. A minor stroke was defined as a neurologic deficit, which was new and either resolved in 30 days or raised the NIH Stroke Scale by ≤ 3 . A nonfatal, major stroke was defined as a neurologic deficit, which was new and persisted >30 days and raised the NIH Stroke Scale by ≥ 4 . The 3-year rate of freedom from stroke and death in patients who survived the 30-day periprocedural period was 95%. No neuroprotective devices were used in this study.⁶

Theron's experience spans decades.⁷ Since stents became available in 1990, he has reported on 93 stenoses treated, with stents used in only 65. A distal 2.6F type of occlusion balloon catheter was used during angioplasty, but was removed for technical reasons when stenting was necessary. (Technological advances now allow his type of protective device to remain in place during stent-

ing.) He had 2.2% periprocedural emboli. These were treated with intra-arterial urokinase with excellent results. His follow-up showed 4% restenosis in stented carotids and 16% in those receiving angioplasty alone.⁷

Carotid Revascularization Endarterectomy versus Stent Trial (CREST) is a large NIH-funded trial comparing the efficacy, restenosis, and cost of carotid stenting with CEA. Randomization of 2500 patients has begun, and additional investigators are being sought. Investigators must pass through a credentialing phase before they may enroll patients in the trial.⁹ The Carotid Artery Vertebral Artery Transluminal Angioplasty Study (CAVATAS) is a completed trial that is currently following patients randomized between carotid or endovascular therapy and CEA in North America and Europe. Several other trials are under way in North America and Europe. The importance of these studies must be underscored, as further comparison is needed.¹⁰

Cerebral protective investigative technology

Significant amounts of debris can shower the cerebrum during CAS. Antiembolic devices will likely become standard during CAS due to the potential reduction in periprocedural morbidity. Martin et al⁷ evaluated the aspirate from 9 cases using protection by Theron's technique. This showed cholesterol crystals and lipid masses as the major component of embolic material. The cholesterol crystals ranged in size from 4 to 489 μm , and 115 to 8697 particles on average were recovered. Lipoid masses ranged from 7 to 600 μm and numbered 341 to 34,000. The amount of debris is likely an underestimation, because the debris flushed into the external carotid artery by saline before the balloon was removed could not be recovered for analysis. This strongly suggests the need for cerebral protection during CAS.¹³

There are various types of cerebral protection, and some are approaching FDA approval. At least three major types of devices are being developed. The distal occlusion balloon, the distal filter, and the proximal occlusion catheter are described below¹⁴⁻¹⁷:

1) A distal occlusion balloon interrupts distal internal carotid artery blood flow, preventing cerebral emboli, which is an obvious benefit; however, patients without a patent circle of Willis may not be candidates for this type of device. The Guardwire (PercuSurge, Sunnyvale, CA) is a promising example. A hollow, thin shaft can be used as a guidewire after the detachable inflator is used to inflate the distal balloon. Over the 0.014-inch shaft, angioplasty and stenting is performed. Aspiration and flushing of embolic material via the guiding catheter or sheath is performed before the balloon is deflated and withdrawn through the stent.

2) A distal filter allows antegrade flow of blood, trapping most emboli, and is removed at the completion of the procedure. Its ability to permit cerebral perfusion while providing cerebral protection is desirable. These devices must be inserted through the carotid lesion and removed through the newly deployed stent. The filters' relatively large size (3F to 5F) compared with other devices is a drawback when crossing tight or friable lesions. As with other devices in the field, size tends to diminish as technology increases. One such filter is the AngioGuard (Cordis).

3) A proximal occlusion catheter, such as the Parodi Anti-Embolization Catheter (ArteriA, San Francisco, CA), is an innovative concept. A balloon is located on the outside of a 7F or 8F guiding catheter in the common carotid artery, and an occlusion balloon is advanced through the guiding catheter into the external carotid artery. Both occlusion balloons are then inflated. Blood flows retrograde

from the internal carotid artery, through the guiding catheter, where it is filtered and flows to a sheath in the common femoral vein.

Stabilization of a device when in the distal internal carotid artery must be achieved to prevent spasm or dissection. If spasm is encountered, 100 µg of nitroglycerine may be administered intra-arterially. When removing devices that are pulled through a newly placed stent, care must be used so as not to dislodge or damage it.

Guidelines

In late 1999, 17 leaders in various fields involved in CAS met in New York, and a consensus of their meeting was published in early 2001.¹⁸ The specialties represented were interventional cardiology, interventional radiology, neurosurgery, and vascular surgery. They report that the indications for CAS are:

- 1) Symptomatic patients with high risk factors or those who are unfit for surgery;
- 2) Patients with recurrent stenosis;
- 3) Patients with a history of radical neck surgery or local radiation; and
- 4) Patients with high common carotid bifurcation.

Most of the participants believed that CAS was indicated in the presence of contralateral carotid occlusion.

Contraindications to CAS were stated to be:

- 1) Thrombus within the lesion;
- 2) Complex lesions containing multifocal disease or an angulated artery;
- 3) Severe tortuosity or calcification of the great vessels or extensive atherosclerotic plaque involving the arch or great vessels;
- 4) Common carotid bifurcation containing heavy ring-like calcification; and
- 5) Stroke within 3 weeks or neurologically unstable.

Many of the participants stated that CAS should be limited to high-risk patients until randomized studies are completed. It was noted that most

experts believe that neuroprotective devices should be used when available. Intra-arterial fibrinolysis must be available during and immediately after the procedure.¹⁸

Conclusion

Carotid angioplasty and stenting is a less-invasive technique to treat stenoses of the common carotid bifurcation. Stenting noncoronary arteries is accomplished by interventional radiologists, and similar skills are required to treat the common carotid bifurcation. CAS has complication rates comparable to CEA but lacks long-term follow-up of randomized patients; this process is currently under way. Antiembolic neuroprotective devices are rapidly approaching the market in the United States and are already used abroad and in controlled studies in this country. Patient and lesion selection are becoming more defined. In certain high-risk patients, treatment by CAS may be the procedure of choice. Its exact role in the overall treatment of carotid artery occlusive disease remains to be clarified. □

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