

Decreasing the Learning Curve for Carotid Artery Stenting

An experienced interventionist's procedural guidelines to facilitate safe CAS outcomes.

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Seldom has a procedure in medicine created the avalanche of attention from multiple specialties that carotid artery stenting (CAS) has. CAS continues to receive intense scrutiny, certainly more than which has been directed at its counterpart, carotid endarterectomy (CEA). This attention is justified, because CAS is still in its infancy in many areas, including patient selection, lesion characteristics, device use and design, and adequate training of individuals performing the procedure. CAS has developed in a somewhat unusual fashion, with multiple specialties involved. This unique facet, at least in the endovascular arena, has created its share of problems. In spite of these challenges, CAS has survived the learning curve and is on its way to becoming a very acceptable procedure that will only get better as the devices improve and physicians come to have the necessary training. Much of this training will come in the form of avoiding the steep learning curve of the early investigators.

Interventional endovascular therapy has always been about controlled injury, in which all possible aspects are planned and controlled in advance of the actual procedure. Over the years since the Centers for Medicare & Medicaid Services (CMS) has required cerebral protection devices (CPDs), I have become a reluctant believer that this is necessary.¹⁻⁵ If one cannot safely use a CPD, then I think in most cases, CEA is a safer procedure. To allow CAS to survive and find its proper place in the treatment of atherosclerotic carotid artery disease, we must recognize when we are at an increased risk and seek the alternative of CEA. I have recently been involved with two cases in which

the patients would have had significant strokes without the CPD and the knowledge of how to safely correct the problem. The CPDs were life saving for the patients and for me.

A recent publication in the *European Heart Journal* by Grumm and associates showed their meta-analysis comparing CEA with CAS, ultimately settling on four randomized trials comparing CAS with CEA—SPACE, EVA-3S, KENTUCKY, and WALLSTENT—for the treatment of symptomatic patients, and SAPPHERE, which enrolled both symptomatic and asymptomatic patients. The investigators found no significant difference between CAS and CEA.⁶ This is a striking statement for CAS. Because the meta-analysis is overwhelmed by two European studies, both have significant breaches of good CAS protocol—particularly the lack of CPD use, as well as the lack of adequate training in CAS procedures. To let a flawed trial such as EVA-3S have an impact on this analysis to the extent that it has, unfairly favors CEA and does a disservice to CAS. Even with this breach of acceptable CAS performance, there was no statistical significance to favor CEA over CAS. Absent the flawed European trials, CAS should be at least on par with CEA in appropriately selected patients.⁷⁻⁹

I have been actively involved in CAS training and teaching for the past 8 years. My main focus has been on the meticulous requirements necessary to perform a successful and safe CAS procedure. Fortunately, today many very experienced CAS experts are in agreement and are sharing their experience and insight in the literature and in training courses.¹⁰⁻¹¹ CAS is a procedure that can be performed only when careful attention is applied to every detail of the procedure. Equal attention must be applied to both patient selection¹²⁻¹⁴ and lesion characteristics.¹⁵ Stenting of the carotid artery

is not simply opening up the artery with a balloon or placing a stent and casually moving on. The impact of adverse events for carotid artery revascularization is so serious that some specialty societies have questioned its performance in any group other than the high-risk surgical patient. There are many others who feel that in virtually all settings, CAS is comparable to CEA.¹⁶ There are many programs where CAS is being performed in a safe manner where the complication rate is very low. For the past 100 cases in my facility, the complication rate is approaching 0%. This is true of many other programs across the country.⁷

With the introduction of improved intravascular stent technology, the early problems of stent closure and crushing of stents from external forces have been effectively eliminated. The problem of distal embolization has been significantly improved with the addition of CPDs. Although CPD use has increased safety, it has also increased the complexity of the procedure. What follows will be a carefully organized and coordinated approach to the performance of safe extracranial carotid artery revascularization procedures. If followed as outlined, this will significantly improve the likelihood of a safe outcome. Included in this article is a patient checklist form with virtually every detail outlining the CAS procedure. Also included is a patient form for CAS, post-carotid stent orders, and patient discharge and follow-up instructions.

TECHNICAL ASPECTS OF CAROTID ARTERY REVASCLARIZATION

Preprocedure

The patient should undergo a complete neurological history and examination, including a baseline National Institutes of Health Stroke Scale and other functional assessments. A baseline CT scan or MRI examination is considered useful and is recommended in most cases based on personal preference. Baseline laboratory values, including hemoglobin and hematocrit levels, serum creatinine, blood urea nitrogen, electrolyte levels, prothrombin time, and partial thromboplastin time, as well as preprocedure electrocardiograms, are also recommended. The patients are fasted from midnight before the procedure. We also recommend withholding anti-hypertensive agents due to the carotid bifurcation-related hypotension during the procedure. Anticoagulants, such as warfarin, are discontinued 3 days before the procedure. Patients needing ongoing anticoagulation will be placed on antithrombotic, low-molecular-weight heparin until the day of the procedure. Patients with renal disease may be admitted 1 day earlier for intravenous hydration, and patients with renal compromise are also given a sodium bicarbonate renal failure protocol at the time of the procedure. Patients are also pretreated with aspirin, 325 mg daily and clopidogrel 75 mg twice a day for at least 5 days before the procedure. In an emergent situation, the patient may be given a loading dose of clopidogrel (525–600 mg).

Periprocedural

Before starting the procedure, all patients are given 0.2 mg of glycopyrrolate. Glycopyrrolate is an anticholinergic drug similar to atropine, which seems to decrease the adverse effects of the carotid bifurcation. You may still use atropine at the time of stenting or angioplasty if needed. One inch of topical 2% nitroglycerin paste may be applied to reduce the likelihood of mechanically induced vasospasm. The procedure is performed under conscious sedation. This is not a painful procedure, and having the patient alert and able to communicate throughout the entire examination is considered an important aspect of safely performing the procedure. Many clinicians will perform CAS without sedation. Pedal pulses are examined either manually or with Doppler ultrasound and marked. A Foley catheter is considered necessary in all cases. Cardiac leads are placed before sterile draping making sure that these leads are not in any of the necessary fluoroscopic fields, particularly over the aortic arch with the image intensifier in a right anterior oblique position. An external cardiac pacemaker should be in the room and readily available with the appropriate assistance from knowledgeable personnel. Neurological status, electrocardiograms, heart rate, and blood pressure are monitored throughout the procedure. Bradycardia and hypotension are not uncommon during predilatation and stent postdilatation. This is particularly true if the stenosis involves the ostium or the bulb of the internal carotid artery (ICA).

Procedure

Using a micropuncture system, a sheath is placed in the common femoral artery. This is an optimal time to obtain a baseline activated clotting time (ACT). This is done to make certain that the ACT device is operational and that trained personnel are available. Complete brachiocephalic angiography is performed if it has not been recently performed. At a minimum, the cerebral circulation of the vessel in question is evaluated before any stenting procedure. Diagnostic angiography is performed in a minimum of two planes. Intracranial circulation is carefully evaluated for vascular abnormalities, aneurysms, arteriovenous (AV) malformations, venous sinus thrombosis, intact circle of Willis, and ipsilateral external carotid artery occlusion. The arch aortogram is essential and provides extremely valuable information necessary for selection of devices and performance of the carotid stent procedure.

After the diagnostic angiography is performed and the anatomy is determined to be amenable to stenting, the patient receives an intravenous loading dose of heparin (70 to 100 units per kg of body weight). Alternatively, the patient may be dosed with 5,000 to 6,000 units of heparin and then adjusted as per ACT. The ACT should be 2 to 2.5 times the baseline or 250 to 300 seconds. If the arch anatomy is significantly challenging, one may choose to give 2,000 to 3,000 units of heparin during the diagnostic part

of the procedure. The loading dose is followed by continuous infusion of heparin at 15 to 20 units per kg per hour or hourly doses of 1,000 to 2,000 units of heparin and monitoring the ACT. Alternatively, the patient may be anticoagulated with intravenous bivalirudin. The patient is given a loading dose of 0.75 mg per kg of bivalirudin followed by an infusion rate of 2.5 mg per kg per hour.

After the diagnostic angiograms are obtained, the ipsilateral external carotid artery is carefully catheterized generally using a 4-F diagnostic catheter. The catheter is placed safely in the external carotid system. With the 4-F diagnostic catheter in the ipsilateral external carotid system, a long exchange guidewire, such as the Amplatz Super Stiff .035-inch X 300-cm guidewire (Boston Scientific Corporation, Natick, MA), is placed, taking care to make certain the tip of the stiff wire does not extend beyond the 4-F catheter position. A guiding sheath, such as the 6-F Shuttle Sheath (Cook Medical, Bloomington, IN) or an 8-F guiding catheter, is advanced into the distal common carotid artery using the coaxial system. The position of the sheath or guiding catheter should be proximal to the area of stent placement; however, it is important to have the tip of the sheath or the guiding catheter as far distal as it can safely be positioned. Once the sheath or guiding catheter is in a proper position, it is connected to a pressurized, heparinized saline flush solution using 1 unit of heparin per mL of normal saline. A mechanical pump is used at a flow rate of 300 mL per hour via a large bore Touhy-Borst connection.

Patient selection, aortic arch type, and carotid lesion characteristics are the most important considerations for successful carotid stenting. Careful consideration of the arch type and lesion characteristics will determine the success and the safety of the procedure. Type 2 and type 3 arches and the bovine arch, when dealing with the left carotid artery, can prove to be challenging to even very experienced angiographers. The guiding catheter or Shuttle Sheath will have a tendency to buckle in to the arch, which can be disastrous, pulling down the CPD in the process. Generally keeping the arch and the tip of the guiding sheath in the visual field during all exchanges will decrease the risk of this occurring. If, during the diagnostic portion of the examination, selecting the carotid artery of interest is significantly challenging, consider referring this patient for CEA.

Alternatively, if the aortic arch anatomy is suitable, one may use the Slip Cath technology offered by Cook Medical with their Shuttle Select system. The Shuttle Select guiding sheath may be used with the following Slip Cath 6.5 catheter configurations: the JB1, the VTK, the H1, the SIM2, and the JB1. This procedure is performed by placing the selected Slip Cath 6.5-F X 125-cm catheter selectively into the common carotid artery. Under direct visualization, the shuttle introducer sheath is advanced until it is at the desired position below the carotid bifurcation. This may eliminate the need for the long stiff exchange wire

and system described above. However, it should be noted that both systems work well. The Slip Cath technology will also work well with the Amplatz Super Stiff exchange wire positioned in the external carotid system.

With the Shuttle Sheath in the appropriate position in the common carotid artery, the Slip Cath selective catheter is carefully removed. The Shuttle Sheath is then carefully aspirated and connected to a pressurized, heparinized saline flush solution using the large bore Touhy-Borst provided with the Shuttle System. This is best handled with a mechanical pump; a rate of 300 mL per hour has been satisfactory. Before starting the heparin flush, completely purge the system so it is free of any air bubbles, including flushing out the catheter port of the Touhy-Borst so it is free of blood as well as air. The guiding catheter is aspirated before turning on the heparin flush. At this point, the guiding catheter should be positioned just below the carotid bifurcation, allowing sufficient room for stent deployment into the common carotid artery. If the lesion is located higher in the cervical internal carotid artery, the tip of the sheath may be near the carotid bifurcation. The guiding sheath in the carotid artery may be used as a reference for precise measurement of the internal and common carotid arteries. The interventionist may also tape a quarter on the patient's skin near the mandibular condyle and use this as a measurement; a quarter has a 25-mm diameter.

CEREBRAL PROTECTION DEVICE SELECTION AND PLACEMENT

Generally, the internal carotid artery and the area of stenosis are traversed in the lateral or lateral oblique position using direct visualization. One may use the fluoroscopic roadmap or fluoro fade systems (Siemens Medical Solutions USA Inc., Malvern, PA) to accomplish this. The area of pathology is traversed with the selected embolic protection system; all of the systems found on page 146 of this Buyer's Guide work well. They do have some nuances that are peculiar to each device. All of the manufacturers have trained personnel for assistance. The CPD should be sized appropriately so that it makes contact with the walls of the internal carotid artery. These protection devices come in a variety of sizes (see page 146). The CPD should be positioned in a relatively straight portion of the cervical internal carotid artery at least 2 cm above the superior margin of the stent deployment. If the minimal diameter of the area of vessel pathology is 2 mm or less, it is dilated with a 3- to 3.5-mm monorail angioplasty balloon.

At this point in the procedure, the operator should have a CPD in place and deployed in the cervical portion of the internal carotid artery. Occasionally, in cases where there is extreme tortuosity, this will not be the ideal location, and the CPD will need to be advanced into a more cephalad position. The CPD should be located in the internal carotid artery in a position that allows all margins of the artery to

be in contact with the CPD. The system you are now working with is a monorail system. All subsequent devices need to be of the monorail type. All manufacturers currently make the monorail-type CPDs, angioplasty balloons, and self-expanding stents. The monorail-type system has proven to be less cumbersome than the longer, over-the-wire systems. All currently available CPDs are developed with a .014-inch guidewire system. These .014-inch guidewire and CPD systems are very atraumatic. However, they can occasionally create spasm, particularly in the region of the deployed CPD. If necessary, you may treat iatrogenic vasospasm with an injection of nimodipine (200 μm diluted in a 10-mL solution of normal saline and injected slowly as a 2- to 3-mL bolus), or nitroglycerin 100 to 150 μm may be injected into the carotid artery to treat mechanically induced vasospasm.

CAS with the use of the appropriate guidewires, CPDs, angioplasty balloons, and stents requires meticulous technique. Always wipe the guidewire clean with moist saline wipes, and keep it moist when advancing the stent, the angioplasty balloon, and the retrieval device. Before balloon inflation, have available 0.6 to 1 mg of atropine that can be given quickly when needed. Many interventionists will give the atropine before balloon angioplasty in virtually all cases. Frequently, accompanying the symptomatic bradycardia that occurs after the stenting or balloon angioplasty of the carotid bifurcation, patients will experience hypotension. Be prepared to treat with increasing administration of fluids, as well as administration of dopamine, if necessary. In our experience, it has been important to have a dopamine drip available and ready to use expeditiously—for adults: 5 to 20 μg per kg per minute as a continuous intravenous infusion. It should be noted that these patients are often very fragile cardiac-wise; therefore, dopamine should be used with great caution because the patients may be prone to arrhythmias. Balloon inflation should not exceed 30 seconds. The balloon should be inflated slowly and deflated slowly.

CAROTID STENT SELECTION AND PLACEMENT

Several stents have been approved and are available for placement (see page 100). They all have some nuances. The vendor representative is an excellent resource and should be available for the procedure.

In placing the stent in addition to road mapping and/or fluoro fade, boney landmarks should be identified and marked on the monitor as well as the exact position of the lesion and desired position of the stent, taking care to be certain nothing has moved. When the stent is satisfactorily positioned, deployment of the self-expanding stent is accomplished by retracting the outer sleeve. The stents tend to have some variation in their

deployment, and some may advance slightly during deployment. It is necessary to be familiar with the stent you are going to deploy.

After stent deployment, the delivery catheter is withdrawn under direct fluoroscopic visualization, making certain that the stent is not caught or moved by the delivery device. Poststent deployment angioplasty is performed by using a high-pressure monorail semicompliant balloon. Balloon sizes are tailored to the smallest diameter of the stent. Although it is not mandatory to postdilate all stents, in all cases, the operator should use an angioplasty balloon that is smaller in diameter than the internal carotid artery for dilatation after placement. The angioplasty balloon should be inflated within the confines of the stented vessel. The maximum angioplasty balloon for the internal carotid artery seldom exceeds 5 mm. By undersizing the poststent angioplasty balloon slightly, the hemodynamic problems have been significantly reduced. Generally, a single inflation is adequate. There should be sufficient pauses between inflations to allow restoration of cerebral perfusion. The interventionist should also make certain that the patient is hemodynamically stable before additional inflations are performed. Residual ulceration external to the stent is usually of no clinical importance. Iatrogenic vasospasm usually resolves shortly after removal of the guidewire and the CPD from the internal carotid artery. When vasospasm persists, as previously noted, one may consider the injection of nimodipine (200 μm diluted in a 10-mm solution injected slowly as a 2- to 3-mm bolus) or nitroglycerin (100 to 150 μm injected into the carotid artery to treat mechanically induced vasospasm). If the iatrogenic vasospasm after CPD removal does not resolve with the medication suggested above, this will respond well to low-pressure balloon angioplasty (<3 atm).

On occasion, the capturing catheter may engage the proximal edge of the stent. Generally, rotating the head toward the contralateral side will facilitate passage of the retrieval catheter. An additional stent may be required to create a vertical stent position to allow the retrieval catheter to pass the edge of the carotid stent. Advancing the shuttle sheath into the stent to get the retrieval device to pass the stent's inferior margin may also be necessary.

At the conclusion of the stent procedure, final angiograms are acquired in the same projections as the initial angiograms, as well as the projection that demonstrated the maximum severity of the lesion. It is important to acquire cerebral angiograms after the stenting procedure is completed, and a direct comparison with the preinterventional angiograms should be made to assess the possibility of "silent embolization" and to document the improvement in the cerebral flow.

The Shuttle Sheath is then carefully removed over a guidewire in the iliac artery and is exchanged for a short

sheath, generally 7 F. This 7-F sheath may be removed in 3 to 4 hours when the ACT is ≥ 150 seconds. The interventionist may choose to obtain access homeostasis at the end of the procedure using a vascular closure device. If there is any possibility of going back to repeat the cerebral angiogram, leave the sheath in the groin and send the patient to the ICU. The sheath may be removed the next morning. A postprocedure neurological evaluation is carefully performed in the ICU using nurses that have been trained in careful neurological evaluation and follow-up.

POSTPROCEDURE CARE

Careful attention to the postprocedural period is critical for a safe CAS procedure. The patients are admitted to a monitored bed, and vital signs are followed continuously. Before stent deployment, the mean arterial blood pressure should be maintained at or above baseline. However, after successful revascularization, the mean arterial pressure may be lowered 10% to 20% below baseline to prevent cerebral reperfusion injury. In a patient with a high-grade carotid stenosis, it is desirable that the patient remains somewhat hypotensive following restoration of flow. Generally, any systolic blood pressure greater than 80 mm Hg is adequate. Mean pressure should not exceed 60 to 70 mm Hg. The effective heparin is allowed to taper physiologically rather than being reversed with protamine. The patient is monitored in the ICU for 12 to 24 hours after treatment. Some patients may need further monitoring until they become hemodynamically stable. Clopidogrel 75 mg a day is continued for 3 months and aspirin 325 mg per day is continued indefinitely. The patient is advised to avoid neck manipulations or deep massage for at least 6 months. A follow-up ultrasound of the carotid is performed at 1, 6, and 12 months to document continued patency. Most restenosis occurs within the first 6 months. Ultrasounds are then obtained on a yearly basis. It is essential to follow these patients long-term. ■

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For more information, including postcarotid stent orders, a patient form for CAS, and carotid stent discharge instructions, see this article online, available at <http://www.evtoday.com/PDFarticles/0708/>.

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