

Complication Avoidance for Intracranial Angioplasty

Techniques for treating intracranial stenosis.

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Stroke is the third leading cause of death in the US and the leading cause of adult disability.¹ Approximately 10% of all ischemic strokes are secondary to intracranial atherosclerotic disease.² In Asian, African, and Hispanic populations, the incidence of stroke secondary to intracranial atherosclerotic disease may be even higher.³ In the US, approximately 40,000 to 60,000 new strokes per year are due to intracranial atherosclerotic disease.⁴

Surgical revascularization for intracranial stenosis is accomplished by connecting a branch of the external carotid artery to an intracranial vessel. This intracranial-extracranial bypass was studied in a prospective multicenter randomized study with 1,377 patients in 1985.⁵ The trial failed to demonstrate benefit of surgery for any of the subgroups. This included patients with middle cerebral artery stenosis. There was no clear benefit demonstrated for intracranial-extracranial bypass as a treatment for intracranial stenosis.⁶

The WASID study evaluated the safety of aspirin versus warfarin for symptomatic intracranial stenosis. The study attempted to prove if aspirin or warfarin provided better medical therapy for intracranial stenosis by preventing stroke and death.⁷ The retrospective pilot studied patients with large intracranial artery stenosis >50%. In the warfarin-treated group, there was an 8.4% stroke and death rate after a mean follow-up of 14.7 months. In the aspirin-treated group, there was an 18.1% stroke and death rate. This retrospective analysis also reported a 10.7% stroke and death rate for basilar artery stenosis.⁸ Based upon these data, a second multicenter randomized double-blinded study was performed comparing aspirin and warfarin for intracranial stenosis. A total of 569 patients were enrolled before the study was stopped

prematurely. Death in the aspirin group was 4.3%; death in the warfarin group was 9.7%.⁹ As a result of this study, warfarin is rarely used for treating intracranial stenosis.

Intracranial angioplasty has been used increasingly as a treatment for symptomatic intracranial stenosis for more than a decade.¹⁰ Results reported in one 70-patient series, in which patients were enrolled over a 9-year interval, demonstrated 14% vessel dissection, 4% vessel thrombosis requiring thrombolysis, approximately 9% restenosis, and one death.¹¹ It was clear that stent-assisted angioplasty might be beneficial in some cases. Smart Therapeutics (now part of Boston Scientific Corporation,

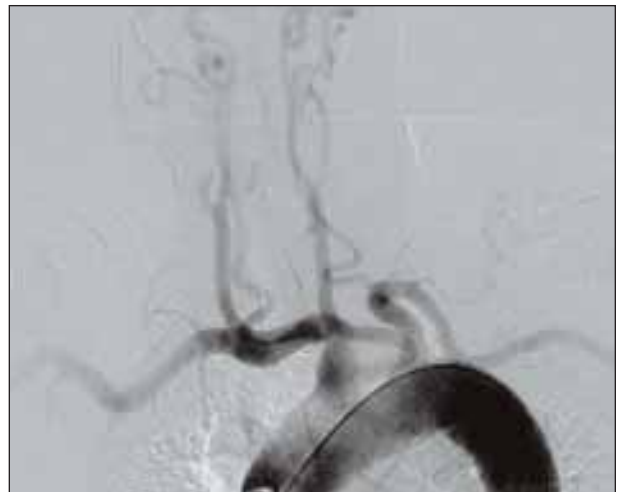


Figure 1. Aortic arch injection. Note bovine origin of left common carotid artery. The proximal common carotid artery has a hairpin turn making access difficult. The left subclavian artery and left vertebral artery are angulated. There is a long innominate artery where the takeoff of the right common carotid and right subclavian arteries overlap.

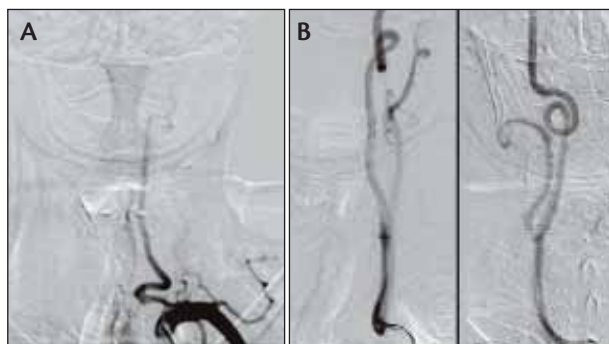


Figure 2. Lateral and anterior posterior projection of the right common carotid artery injection. Left subclavian artery injection. Anterior posterior projection demonstrating severe proximal tortuosity of the proximal right vertebral artery (A). Note the tortuous right internal carotid artery, which would limit access to the distal extracranial internal carotid artery and make device delivery more difficult (B).

Natick, MA) developed two nitinol self-expanding intracranial stents: the Neuroform, used for intracranial aneurysms, and the Wingspan, used for intracranial stenosis. The first trial describing the use of the Wingspan stent for intracranial stenosis reported on 15 symptomatic patients with a mean intracranial stenosis of 78%. After angioplasty, the stenosis was reduced to 54%, and after stent placement, it was reduced to 38%.¹²

There has not been a randomized prospective study comparing intracranial angioplasty to oral-antiplatelet therapy. Intracranial angioplasty and stent trials in acute stroke are in progress at multiple centers. The natural history of intracranial stenosis remains poorly defined, yet rates of major stroke and death for asymptomatic and symptomatic lesions have been reported to be as high as 20%.^{13,14} Treatment with aspirin and clopidogrel has been adopted by many physicians without a randomized prospective trial being performed.

INDICATIONS FOR ANGIOPLASTY

Intracranial angioplasty should be considered for patients with symptomatic intracranial atherosclerotic disease with >50% stenosis who have

experienced stroke or transient ischemic attack (TIA) while on oral antiplatelet therapy. Symptoms should be referable to the hemisphere that is ipsilateral to the stenosis. In addition, patients who present with acute stroke who require urgent revascularization of an intracranial vessel may benefit from intracranial angioplasty. Patients with asymptomatic high-grade intracranial stenosis should be treated with great care. If asymptomatic patients with high-grade stenosis also have documented hypoperfusion using SPECT or PET nuclear imaging and display severe vascular reserve compromise upon Diamox challenge, then it is reasonable to consider intracranial angioplasty. Unfortunately, there is no evidence in the literature to support treatment of asymptomatic intracranial stenosis. Great caution should be used when considering treatment of patients with asymptomatic intracranial stenosis given that the natural history of this disease is not well defined. Recent improvement in magnetic resonance angiographic imaging has enabled precise imaging of the intracranial circulation. As a result, diagnosis of asymptomatic intracranial atherosclerotic disease is increasing. Unless patients have documented evidence of severe vascular reserve compromise, on nuclear magnetic resonance or CT perfusion imaging intracranial angioplasty, should be used cautiously in asymptomatic patients.

ACCESS

The majority of neurointerventional catheter-based devices are designed to be used with 6-F guide catheters. Hence, gaining femoral access using a short 6-F guide sheath is usually adequate. When aortoiliac bifurcation tortuosity exists or curves in the thoracic aorta affect the operator's ability to torque the catheter, a 45-cm access sheath can be very helpful. If, before the procedure, it has been determined that an intracranial stent will be placed and the aortic arch contains acute angulations at the origin of the brachiocephalic vasculature, then a 90- or 100-cm 6-F guide sheath can be used as a coaxial platform. A 6-F guide catheter can be placed through the guide sheath providing increased stability in the common carotid artery or subclavian artery. This coaxial catheter construct will enhance



Figure 3. Microcatheter injection, left middle cerebral artery anterior posterior projection with 20° cranial angulation. Note the proximal middle cerebral artery is not seen; rather, a lenticulostriate vessel has been microcatheterized, and the contrast travels down the lenticulostriate artery into the small vessels of the deep nuclei and drain out toward the internal cerebral vein.

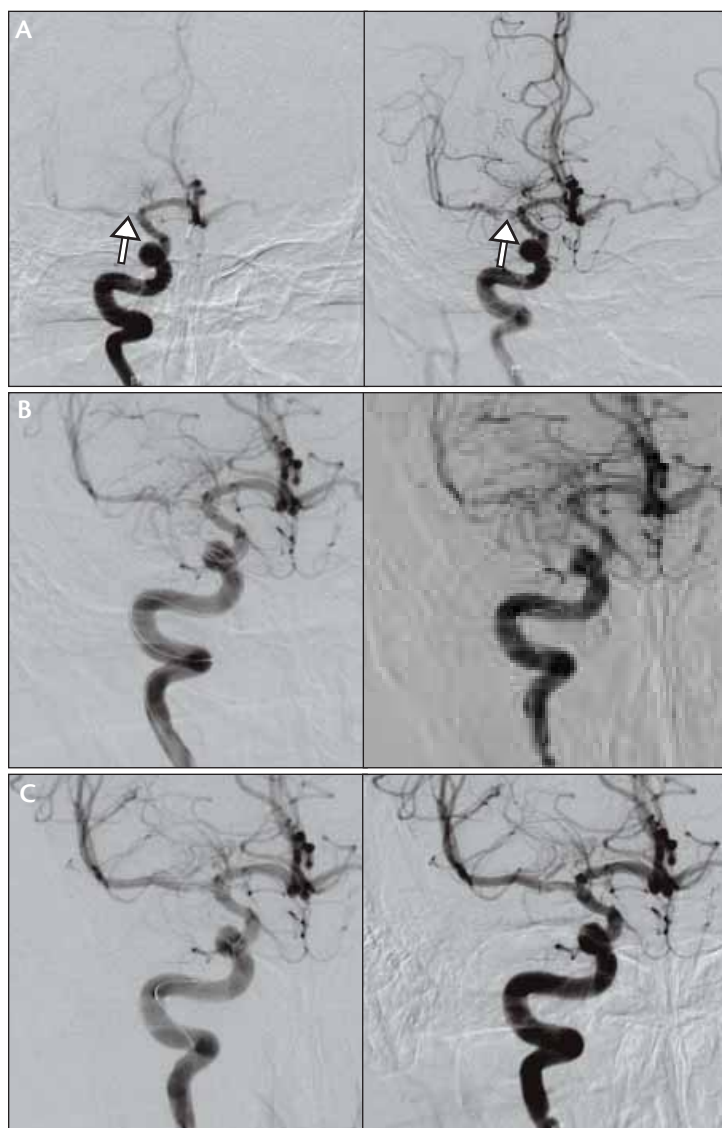


Figure 4. Early phase and midphase arterial right internal carotid artery injection. Anterior posterior view showing a high-grade symptomatic right middle cerebral artery stenosis (arrow). Note in the midphase arteriogram both anterior cerebral arteries and the left middle cerebral artery can be seen on the right internal carotid artery injection (A). Right internal carotid artery anterior posterior projection after placement of a Transcend wire across the middle cerebral artery stenosis. The tip of a Boston Scientific Gateway intracranial angioplasty balloon can be seen proximal to the stenosis (B). Right internal carotid artery projection anterior posterior view after angioplasty with a 2-mm Boston Scientific Gateway intracranial angioplasty balloon (C).

pushability of the microcatheter stent platform. Otherwise, intracranial stent delivery can result in prolapse of guide catheter position and prevent intracranial stent deployment. This can also be true for angioplasty

balloon delivery in the intracranial circulation.

If the aortic arch contains acute angles, guide placement may require over-the-wire exchange techniques. Catheterization of the brachiocephalic vasculature can be challenging and frustrating. Some aortic arches have proximal angulations that may be better left untreated (Figure 1).

Proficiency with SIM II-shaped diagnostic and guide catheters can facilitate gaining carotid access in all types of tortuous arch anatomy. The Cordis Envoy guide catheters (Cordis Neurovascular, Inc., Miami Lakes, FL) can enable catheterization of even the most angulated and tortuous arch anatomy. This 6-F guide catheter has a soft distal tip and a braided proximal shaft that facilitates access in difficult anatomy. The Cordis 6-F SIM II and MPC guide catheters are used in the overwhelming majority of our intracranial angioplasty cases.

All guide catheters are configured with rotating hemostatic adapters enabling use of continuous heparinized saline flush of the guide throughout the procedure. This technique serves to minimize blood loss and helps prevent distal embolic events secondary to guide catheter thrombus formation. Rotating hemostatic adapters with heparinized saline flush should be used in all neurointerventional procedures.

The landing zones for the distal guide catheters in the majority of intracranial angioplasty procedures are either the extracranial internal carotid or extracranial vertebral artery. Proximal tortuosity within the first 3 cm of the vertebral artery can include hairpin turns and loops. This can also be seen in the extracranial internal carotid artery (Figure 2). Straightening of this portion of the vertebral or carotid artery with stiff wires and guide catheters can result in dissection and longitudinal telescoping. Dissection can be prevalent in women with fibromuscular dysplasia. Severe spasm induced by straightening of the proximal vertebral or carotid artery can lead to occlusion.

Recently, Penumbra Inc. (Alameda, CA) has produced guide catheters with a soft distal tip and a 5- to 6-F proximal-to-distal taper. These Neuron guide catheters conform to the course of the vessel rather than straightening proximal tortuous segments. This enables distal guide catheter placement in



Figure 5. A Gateway intracranial angioplasty balloon and Wingspan nitinol intracranial stent.

the extracranial internal carotid and vertebral artery. The catheter's flexible distal segments combine with its proximal strength providing pushability and minimizing guide catheter prolapse.

Guide catheters can be placed into the horizontal petrous segment (intracranial segment) of the carotid and the distal vertebral artery using careful catheter and wire techniques. Dramatic alteration of the course of the extracranial internal carotid and vertebral artery can result in occlusion, dissection, and stroke. Careful guide catheter technique requires use of heparinized saline flush packs and rotating hemostatic adapters.

NEUROINTERVENTIONAL WIRES

Wires used for catheterization of the intracranial vasculature are different from coronary or peripheral wires. Wires constructed for neurointerventional applications from .014-inch wire platforms are machined to maximize strength while providing soft, shapeable, and atraumatic distal tips. One-to-one torque helps make neurointerventional wires easy to turn enabling the operator to precisely aim the tip. Neurointerventional wires conform to the vascular turns and twist rather than encourage straightening of the vascular pathway. Boston Scientific has produced a new generation of wires; the Synchro² wires are produced by etching defined patterns onto a nitinol wire core. This technique enhances stability without sacrificing steering and trackability. The Synchro² wires are excellent for gaining wire access into the distal intracranial circulation. They are available in exchange and standard lengths.

CROSSING THE LESION

After the guide catheter(s) have been positioned, time

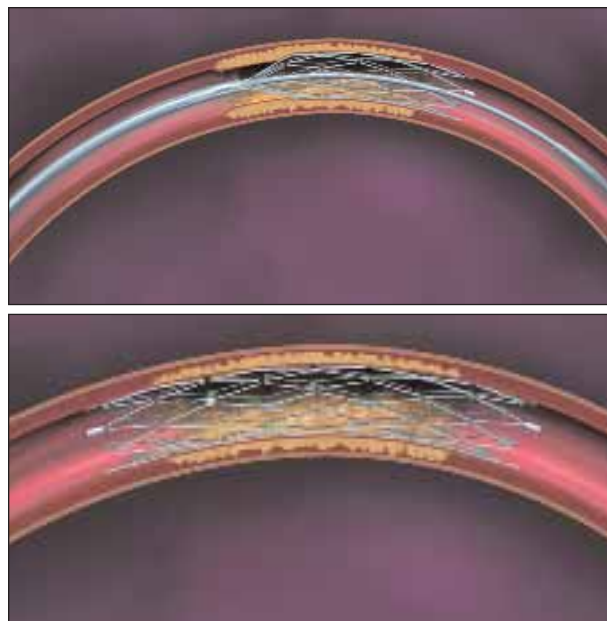


Figure 6. A schematic representation of intracranial artery with stenosis. A Wingspan self-expanding stent is partially deployed across the lesion. The tapered delivery tip can be seen distal to the lesion (top panel). The stent has been deployed, the delivery system is removed, and the markers can be seen at the proximal and distal end of the tip (bottom panel).

should be devoted to choosing the best projections for intracranial catheterization. The carotid siphon is best negotiated in the lateral projection. Typically, this projection is used to position the microcatheter or device in the supraclinoid segment of the internal carotid artery bypassing the origin of the posterior communicating artery. Access to the anterior or middle cerebral artery is facilitated by using the anterior posterior projection with 10° to 20° of cranial angulation. This projection brings the middle cerebral artery away from the skull base, facilitating better visualization of the microcatheter and wire when using roadmap fluoroscopy during intracranial catheterization.

Many neurointerventional products are over-the-wire devices. If a microcatheter and wire are used to cross the stenosis, then balloon placement requires an exchange over a 300-cm Synchro² or Transcend exchange wire. These exchanges usually require two operators to prevent wire movement during the exchange as well as to avoid contamination of the proximal end of the wire and microcatheter. The microcatheter system is assembled with a rotating hemostatic adapter and heparinized saline flush pack. A standard length neurointerventional wire, such as Transcend, is threaded through the micro-

catheter and purged of all air. The microcatheter wire combination is then inserted into the rotating hemostatic adapter attached to the guide. Roadmap fluoroscopy is then used to navigate the wire and microcatheter into the intracranial circulation proximal to the lesion. Once the lesion is crossed with the wire, the microcatheter can be passed into the distal cerebral circulation. Great care must be taken not to cannulate a perforator (small-end arteries) from the major vessels (Figure 3). This can be achieved with careful technique and thorough evaluation of the preoperative digital subtraction angiograms.

Great care must be taken when exchanging microcatheters and devices into the intracranial circulation over 300-cm exchange wires. During removal of the microcatheter, the exchange wire can easily be pulled proximal to the lesion. During delivery of the angioplasty balloon or stent, the exchange wires can jump to an unwanted distal position in a small blood vessel, which can result in distal vessel perforation. These vessel perforations can be angiographically occult and may not be realized until after the procedure has been concluded. Given that patients are typically on aspirin and clopidogrel as well as heparin during the procedure, hemorrhages can be fatal.

“Undersizing balloon diameter helps prevent vessel dissections that mandate stent bailout.”

TOOLS FOR INTRACRANIAL ANGIOPLASTY

Over the years, numerous angioplasty balloon platforms have been utilized for the treatment of intracranial atherosclerotic disease. Initially, silicone valve wire balloons were the only products that could navigate the tortuous anatomy of the cerebral circulation. Silicone balloons were prone to nonlinear inflation and therefore subject to overinflation and even vessel rupture. Noncompliant coronary angioplasty balloons are available in small diameters (1.5-, 2-, and 2.5-mm diameter). Small-diameter monorail coronary balloons are easier to deliver by a single operator, but trackability can be difficult in the tortuous intracranial circulation.

It is possible to back load a monorail over-the-wire balloon onto a neurointerventional wire and deliver this system directly into the intracranial circulation. Recently, Boston Scientific Corporation has marketed Gateway—an excellent over-the-wire intracranial angioplasty balloon that tracks around tortuous anatomy with ease. It is

possible to use this balloon in conjunction with a Transcend wire and cross the lesion primarily with the wire and balloon. This obviates the need for a microcatheter and excludes the exchange wire step. If stent deployment is required after angioplasty, an exchange wire can be delivered through the balloon, and an exchange can be performed to deliver the stent device. Using the balloon to maintain distal access after angioplasty can risk loss of distal access. Care should be taken to advance the balloon distal to the stenosis if a wire exchange is required.

Typically, balloons are undersized to 80% of native vessel diameter proximal and distal to the stenosis. Undersizing balloon diameter helps prevent vessel dissections that mandate stent bailout. Inflation pressures are typically 6 to 8 atm, and inflation and deflation should be performed slowly. Multiple inflations can be performed especially in long lesions. Delivering angioplasty balloons into the intracranial circulation becomes more difficult as the length of the balloon increases; therefore, using the shortest balloon appropriate for the target lesion is desirable. Inflation and deflation of the balloon should be performed slowly.

CASE STUDY

The patient is a 41-year-old woman with a history of TIA producing left-side weakness and numbness. A magnetic resonance angiogram demonstrated a high-grade right proximal middle cerebral artery stenosis. The patient was placed on antiplatelet therapy 75 mg of oral clopidogrel daily with 325 mg of aspirin daily. One week later, she developed transient arm weakness. She had a diagnostic angiogram that confirmed the high-grade right middle cerebral artery stenosis. Heparin was administered at 50 U/kg, and activated clotting time was approximately 300 seconds. A 6-F Cordis Envoy guide was placed into the right internal carotid artery, and a 2-mm Boston Scientific Gateway balloon was delivered across the lesion with a Transcend floppy-tip guidewire (Boston Scientific Corporation). No wire exchanges were made. The balloon was inflated to 6 atm, and lumen diameter was restored (Figure 4).

STENT BAILOUT

The use of stents to treat intracranial stenosis has been gaining popularity as stent devices have been produced specifically for the intracranial circulation. The Wingspan product has the highest radial outward force of all the intracranial stent products presently on the market (Figure 5). The delivery system is compatible with a 6-F guide catheter and has good trackability even when traversing tortuous intracranial anatomy. Wingspan is easily

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delivered. This device requires institutional review board approval secondary to its compassionate-use investigational device exemption status. The Wingspan delivery system can be delivered over an exchange wire or delivered primarily as previously described for the angioplasty balloon. These highly flexible nitinol stents are invisible intracranially. Markers placed on the proximal and distal ends of the stent are visible using fluoroscopy and careful inspection. CT scans display the stent and marker more precisely than fluoroscopy (Figure 6). ■

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