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The Benefits of Proximal Protection During Carotid Stenting

By Antonio Micari, MD, and Roberto Nerla, MD

Carotid atherosclerotic plaque is friable and can cause stenosis, embolization, and thrombosis. Carotid artery stenting (CAS) remains a strategy for preventing plaque embolism and stroke in patients at risk of cerebral infarction, especially those who are unable to undergo surgery.[1] Although there is a lack of large, prospective, randomized controlled trials supporting their use, embolic protection devices are routinely used to prevent and reduce embolization of particles during CAS. Proximal protection, which avoids the need to cross the lesion before a stent is put in place, has become the standard of care at our institution during CAS procedures. This article reports on two cases from our center, with a focus on procedural techniques to optimize outcomes.

CASE 1

A man in his mid-30s was referred to our center to undergo carotid angiography after experiencing a minor stroke—faciobrachiocrural hyposthenia during intense effort. On duplex ultrasound, the referring physicians noted evidence of dissected plaque in the left common carotid artery (CCA) and internal carotid artery (ICA) (peak systolic velocity within dissection, 430 cm/s). A recent CT perfusion scan showed a significant perfusion abnormality in the left hemisphere.

After aortic arch angiography, selective carotid artery catheterization was performed using a 5-F Judkins right 4 diagnostic catheter advanced over a 0.035-inch soft hydrophilic wire (Glidewire™* Standard, Terumo Interventional Systems). A carotid dissection was confirmed, and the decision was made to proceed with stenting (Figure 1).

After diagnostic angiography was performed, the wire was advanced in a distal branch of the external carotid artery (ECA), the diagnostic catheter was advanced in the distal ECA, and the hydrophilic wire was exchanged for a 0.035-inch, 300-cm stiff wire (Hi-Torque Supra Core™*, Abbott).

The Mo.Ma Ultra™ cerebral protection device (Medtronic) was guided over the stiff wire until the radiopaque marker of the distal balloon was located in the ECA, at approximately 1 cm beyond the bifurcation and in proximity to or at the superior thyroid artery. The distal balloon was then inflated in the ECA and the proximal balloon was inflated in the CCA, thus blocking antegrade and retrograde flow across the target vessel. A 0.014-inch wire was then navigated through the ICA stenosis. Direct stenting with a 9- X 30-mm Roadsaver™* stent (Terumo Europe) was performed. The stent was postdilated with a 5- X 20-mm standard angioplasty balloon (Figure 2).

After dilation, 60 mL of blood was aspirated and filtered through sieves, checking for visible plaque debris. Blood flow was restored only after three consecutive debris-free aspirations, first deflating the distal balloon and then the proximal balloon. The final angiographic result was satisfactory, and no neurologic complications occurred (Figure 3).

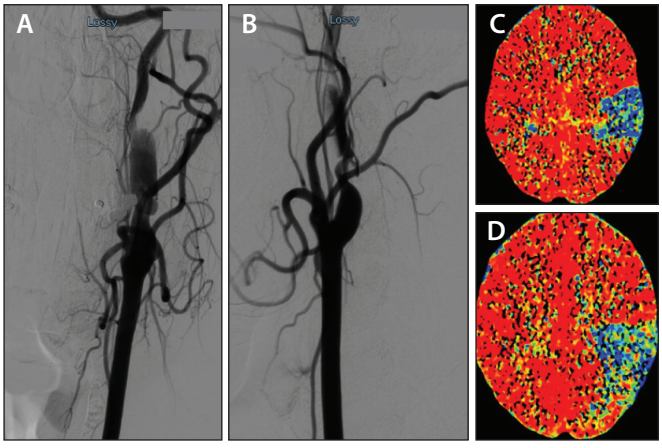

Figure 1. Basal angiography (A, B). Perfusion CT showing the ischemic area (C, D).

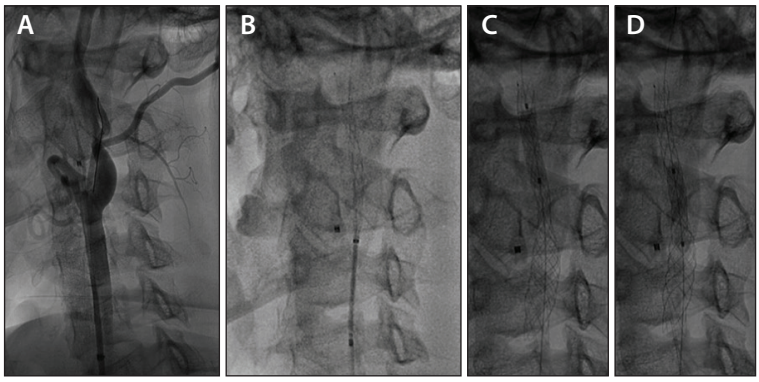

Figure 2. Mo.Ma Ultra device positioning (A). Stent deployment (B). Imaging postdilatation with a 5- X 20-mm standard balloon (C, D).

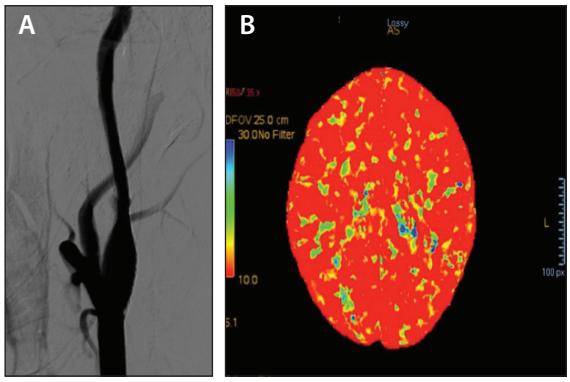

Figure 3. Final angiographic result (A). Follow-up perfusion CT scan showing no ischemic defect (B).

CASE 2

A woman in her 70s with a history of left carotid endarterectomy performed 1 year previously and recent acute transient ischemic attack was referred to our center to undergo CAS. Duplex ultrasound showed severe left ICA restenosis with significant Doppler flow acceleration.

The case began with aortic arch angiography. Selective carotid artery catheterization was performed using a 5-F Judkins right 4 diagnostic catheter advanced over a 0.035-inch soft hydrophilic wire (Glidewire Standard).

After diagnostic angiography, the wire was advanced in one of the left ECA distal branches, the diagnostic catheter was advanced in the distal ECA, and the hydrophilic wire was exchanged for a 0.035-inch, 300-cm stiff wire (Hi-Torque Supra Core, Abbott). The Mo.Ma Ultra device was guided over the stiff wire until the radiopaque marker of the distal balloon was located in the ECA. Then, the distal balloon was inflated in the ECA and the proximal balloon in the CCA, thus blocking antegrade and retrograde flow across the target vessel, as confirmed by contrast injection. A 0.014-inch wire was then navigated through the ICA stenosis. Direct stenting with a 7- to 10- X 40-mm Protégé™ Rx carotid stent system (Medtronic) was performed. Finally, the stent was postdilated with a 5- X 20-mm balloon (Figure 4).

After dilation, 60 mL of blood was aspirated and filtered through sieves, checking for visible plaque debris. Blood flow was restored only after three consecutive debris-free aspirations, deflating first the distal balloon and then the proximal balloon. The final angiographic result was satisfactory, and there were no neurologic complications (Figure 5).

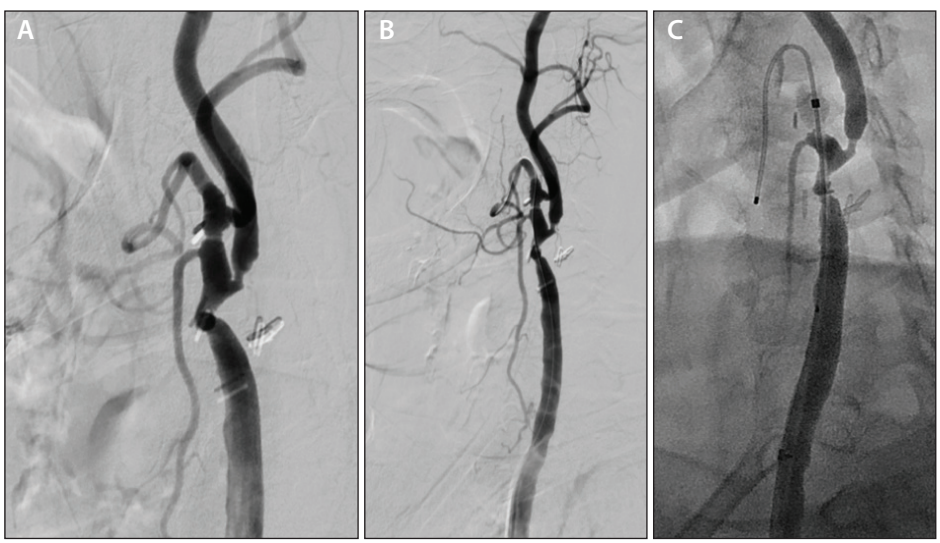

Figure 4. Basal carotid angiography (A, B). Carotid angiography after external Mo.Ma Ultra device balloon inflation (C).

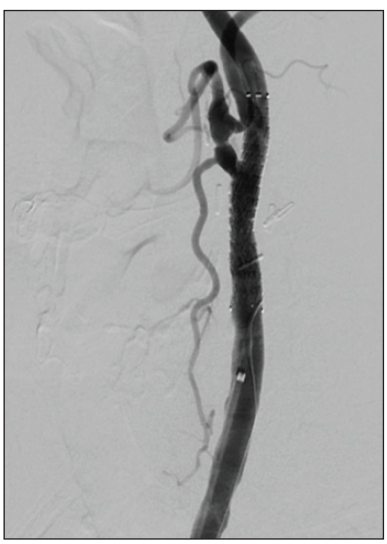

Figure 5. Final angiographic result.

THE BENEFITS OF PROXIMAL PROTECTION DURING CAS

There are two types of distal embolic protection devices available (occlusive or filter), as well as proximal occlusion embolic protection devices.[1] Both types of distal devices need to be advanced through the lesion before they can be placed. Additionally, partial wall apposition can occur (especially in specific anatomies), and filter recapture can be challenging. Distal filters allow for antegrade flow during the procedure. Proximal occlusion devices block antegrade flow from the CCA and retrograde flow coming from the ECA, but they do not require manipulation at the level of the lesion before protection is established. However, proximal occlusion devices require a larger sheath size than distal filters (8–9 F), some patients are intolerant to procedural occlusion, and, like any other procedure using a balloon, dissection is a very rare possibility.

Our institution does not use the Mo.Ma Ultra device in the presence of significant common carotid disease at the site of common balloon inflation. Although the presence of an occluded ECA makes it impossible to use the double-balloon Mo.Ma Ultra device, the single-balloon Mo.Ma Ultra device is still a possibility. CAS procedures and use of the Mo.Ma Ultra device require training, but our institution has found the Mo.Ma Ultra to be easy and straightforward to use, providing support for stenting and additional protection against neurologic events for patients.

There are no large, prospective, randomized studies comparing protection methodologies, and there is no robust evidence appropriately defining the candidates who would benefit the most from this technology. However, meta-analyses that acknowledge the heterogeneity present in these studies confirm that distal and proximal protection devices provide a benefit in terms of periprocedural stroke and mortality through 30 days.[2] To understand more about the different outcomes between distal and proximal protection devices, microembolic signals (MES) can be a surrogate endpoint to help define the rate of embolism. A 2004 trial compared the treatment of CAS with a distal filter (n = 21) versus the Mo.Ma device (n = 21).[3] There was no difference in clinical or angiographic outcomes in this study, but the Mo.Ma device reduced the occurrence of MES as measured by transcranial Doppler ultrasound.[3] A second trial randomized patients to CAS either with proximal protection using the Mo.Ma Ultra device (n = 26) or with a distal filter (n = 27), concluding that the Mo.Ma Ultra device significantly reduced MES counts during the procedure ($P < .0001$).[4]

Regarding larger studies investigating proximal occlusion devices, a registry enrolling 1,300 patients undergoing CAS and using proximal occlusion devices from 2004 to 2009 demonstrated their safety, although adverse events were predicted by symptomatic status, hypertension, and operator experience.[5] Finally, a 2012 meta-analysis of 2,397 patients treated with proximal occlusion devices during CAS (including the aforementioned 1,300 patients) reported a low incidence of adverse events through 30 days, with independent risk factors of age and diabetes.[6]

Ultimately, the Mo.Ma Ultra device has become standard at our institution for providing proximal protection during all interventional steps in every feasible CAS case, and we use it in almost all of our cases, including high-risk cases with certain clinical (symptomatic patients, young patients) and anatomic (ulcerated plaque, thrombus-containing lesions, soft plaques) features. ■

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1. Vos JA. Evidence overview: benefit of cerebral protection devices during carotid artery stenting. J Cardiovasc Surg (Torino). 2017;58:170-177.
2. Omran J, Mahmud E, White CJ, et al. Proximal balloon occlusion versus distal filter protection in carotid artery stenting: a meta-analysis and review of the literature. Catheter Cardiovasc Interv. 2017;89:923-931.
3. Schmidt A, Diederich KW, Scheinert S, et al. Effect of two different neuroprotection systems on microembolization during carotid artery stenting. J Am Coll Cardiol. 2004;44:1966-1969.
4. Montorsi P, Caputi L, Galli S, et al. Microembolization during carotid artery stenting in patients with high-risk, lipid-rich plaque. A randomized trial of proximal versus distal cerebral protection. J Am Coll Cardiol. 2011;58:1656-1663.
5. Stabile E, Salemme L, Sorropago G, et al. Proximal endovascular occlusion for carotid artery stenting: results from a prospective registry of 1,300 patients. J Am Coll Cardiol. 2010;55:1661-1667.
6. Bersin RM, Stabile E, Ansel GM, et al. A meta-analysis of proximal occlusion device outcomes in carotid artery stenting. Catheter Cardiovasc Interv. 2012;80:1072-1078.

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Mo.Ma™ Ultra proximal cerebral protection device Reference Statement (for U.S. audience)
Important Information: Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, suggested procedure, warnings and precautions.
Indications for Use: The Mo.Ma Ultra proximal cerebral protection device is indicated as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures involving lesions of the internal carotid artery and/or the carotid bifurcation.
The reference diameter of the external carotid artery should be between 3-6 mm and the reference diameter of the common carotid artery should be between 5-13 mm.
CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.
Test data is on file at Medtronic Inc. Bench test results may not be indicative of clinical performance.

Protégé Rx Brief Statement
Indications: The Protégé™ RX carotid stent system, when used in conjunction with the ev3 embolic protection system, is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require percutaneous carotid revascularization and meet the following criteria: 1. Patients with carotid artery stenosis (≥ 50% for symptomatic patients by ultrasound or angiography or ≥ 80% for asymptomatic patients by ultrasound or angiography) of the Common or Internal Carotid Artery, AND 2. Patients must have a reference vessel diameter within the range of 4.5 mm and 9.5 mm at the target lesion.
Contraindications: Use of the Protégé RX carotid stent system is contraindicated under these circumstances: Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs is contraindicated; patients with vascular tortuosity or anatomy, which precludes the safe introduction of the sheath, guide catheter, embolic protection system, or stent system; patients with known hypersensitivity to nickel-titanium; patients with uncorrected bleeding disorders; lesions in the ostium of the common carotid artery.
WARNING: Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device

Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the common and/or external iliac arteries include, but are not limited to: Abrupt closure, Allergic reactions to procedural medications, contrast dye or device materials, Amaurosis fugax, Aneurysm, Angina/coronary ischemia, Arrhythmia, Arterial occlusion or thrombosis at puncture site or remote site, Arteriovenous fistula, Bacteremia or septicemia, Bleeding from anticoagulant or antiplatelet medications, Bleeding, with or without transfusion, Cerebral edema, Cerebral hemorrhage, Cerebral ischemia or transient ischemic attack (TIA), Congestive heart failure (CHF), Death, Detachment of a component of the device system, Embolism (air, tissue, thrombus), Emergent or urgent endarterectomy surgery (CEA), Fever, Filter thrombosis or occlusion, Fluid overload, Groin hematoma, with or without surgical repair, Hemorrhage, with or without transfusion, Hyperperfusion syndrome, Hypotension or hypertension. Infection and/or pain at the puncture site, Ischemia or infarction of tissue/organ, Myocardial infarction (MI), Pain (head, neck), Pseudoaneurysm, femoral, Renal failure/insufficiency (new or worsening), Restenosis of stented segment, Seizure, Severe unilateral headache, Slow/no flow during procedure, Stent/filter collapse or fracture, Stent/filter entanglement or damage, Stent/filter failure to deploy, Stent embolization, migration or misplacement, Stent or vessel thrombosis/occlusion, Stroke/cerebrovascular accident (CVA), Total occlusion of carotid artery, Vessel dissection, flap, perforation, or rupture, vessel spasm or recoil.

See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.