Smarter, Safer Carotid Stenting

A new era of technical innovation with the Neuroguard IEP® System.

With Tudor G. Jovin, MD; John R. Gaughen Jr, MD; Adnan Siddiqui, MD, PhD; and Ramesh Grandhi, MD, MS

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The 2023 national coverage determination on carotid stenting reimbursement has been one of the most impactful shifts in recent years for the treatment of carotid artery disease.

Carotid artery stenting (CAS) was previously subjected to "bad press" stemming from 20-year-old studies at a time when CAS was still at its inception. As with any new procedure, the technology, operator skills, and overall procedural knowledge were still evolving, and the first generation of trials overall favored carotid endarterectomy (CEA). As the procedure gained momentum, subsequent trials used more rigorous operator vetting criteria, among other improvements in design and execution, leading to better results. Indeed, the most recent CAS trials have shown remarkably low periprocedural complication rates, most notably the CREST-2 registry,[1] which reported a combined 30-day rate of stroke or death of 1.4% for asymptomatic patients, 2.8% for symptomatic patients, and 2% overall—dramatically better numbers than those reported in the early CAS trials and equivalent to CEA.

Unfortunately, these improved results have not translated into increased access to CAS for most patients with carotid disease requiring revascularization in the United States. Furthermore, limited reimbursement led to little incentive to innovate, and technologic advances lagged behind.

By dramatically increasing the number of patients eligible for coverage, the Centers for Medicare & Medicaid Services' decision brought forth a huge shift in how carotid stenosis is treated. A wave of technologic innovation was unleashed in an area that had stalled since the early days of carotid stenting.

One such device is the 3-in-1 Neuroguard IEP® System (Contego Medical). The system was created by operators with vast procedural experience, enabling them to identify and address limitations inherent to previous embolic protection devices (EPDs), such as a filter pore size that was too large. The Neuroguard IEP System features an integrated 40-µm filter to catch microemboli that other more porous protection systems cannot.

With a carotid stent, dilation balloon, and integrated embolic protection (IEP) filter for added safety, the system also allows for three steps in one, minimizing manipulation of balloons and stents on the wire. A closed-cell design of the stent itself is coupled with very good conformability.

There are still major questions left unanswered in the treatment of carotid stenosis. Results of the landmark CREST-2 trial regarding the benefit of carotid revascularization in asymptomatic patients will be key in driving CAS volumes in the United States. However, if evidence of benefit is found for both CEA and CAS compared to best medical therapy in CREST-2, the number of carotid stenting procedures performed will likely increase tremendously, at the expense of surgical revascularization.

There is a bright future ahead for CAS, and the Neuroguard IEP System is a step in the right direction. I'm delighted that Medtronic has made this commercialization agreement with Contego Medical. A carotid stent that is commercialized through the neurovascular division is an important step forward that will offer patients and physicians more treatment options; since patients typically prefer the least invasive revascularization procedure, this will also lead to a higher use rate of CAS.

1. Lal BK, Roubin GS, Rosenfield K, et al. Quality assurance for carotid stenting in the CREST-2 registry. J Am Coll Cardiol. 2019;74:3071–3079. doi: 10.1016/j.jacc.2019.10.032

Retreatment of ICA In-Stent Restenosis With Neuroguard IEP

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PATIENT PRESENTATION

A man in his early 80s with multiple medical comorbidities presented for potential retreatment of his right internal carotid artery (ICA) in-stent restenosis (ISR). The patient had undergone catheter cerebral angiography and right carotid artery (RCA) stenting a few years prior. Comorbidities included aortic stenosis after a left ICA occlusion, right ICA stenosis poststenting, transcatheter aortic valve replacement, mitral stenosis, paroxysmal atrial fibrillation, second-degree heart block after pacemaker placement, coronary artery disease after coronary artery bypass graft surgery, and hypertension. The patient had undergone a Watchman (Boston Scientific Corporation) procedure 1 month previously.

Most recently, the patient had presented to the emergency department (ED) from his ophthalmologist's office after four episodes of right temporary monocular vision loss over the past 2 months, each lasting approximately 15 minutes and resolving spontaneously. The patient denied any associated neurologic complaints, specifically numbness, weakness, slurred speech, dizziness, vertigo, or ataxia. Medications included dual antiplatelet therapy (DAPT) with aspirin 81 mg and clopidogrel 75 mg daily, in addition to rivaroxaban 20 mg daily.

CTA and ultrasound imaging performed during the patient's ED visit identified an occluded cervical left ICA and prior stenting of the cervical right ICA, with severe ISR from heavily calcified plaque (Figure 1). MRI identified no acute ischemic or hemorrhagic intracranial disease.

A conversation was had with the patient regarding management options for his symptomatic severe right ICA ISR (measuring 80% by NASCET criteria); procedural considerations included medical management with risk factor modification, CEA, repeat carotid stenting, and transcarotid artery revascularization (TCAR).

INTERVENTION

Given the prior right ICA stenting and contralateral ICA occlusion, the patient was an optimal candidate for repeat endovascular treatment, and he elected to proceed with CAS. The relative risks and benefits of the procedure were discussed, including the inherent risk of stroke and hemorrhage.

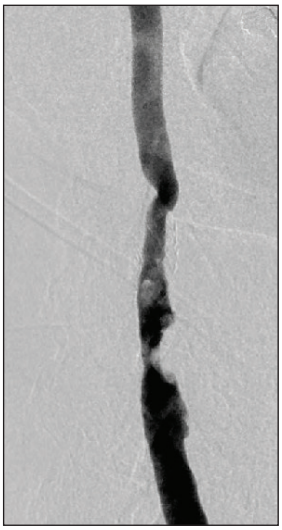

Figure 1. Preoperative digital subtraction angiography (DSA) of the cervical right carotid system identified previous RCA stenting, with bulky, calcific ISR measuring 80% by NASCET criteria.

Endovascular treatment of the symptomatic right ICA ISR began from a right transradial (TR) approach under monitored anesthesia care. The right radial artery was accessed with a micropuncture set and ultrasound guidance, and a 6-F sheath was placed into the right radial artery. Through the right radial sheath, 2 mg of verapamil and 100 µg of nitroglycerin were administered, followed by systemic intravenous administration of 5,000 units of heparin. Heparin activity was measured with intermittent activated clotting time (250-300 seconds).

The 6-F sheath was exchanged for a 90-cm BMX96 guiding sheath (Penumbra, Inc.), which was advanced into the right common carotid artery over a 6-F Simmons 2 guiding catheter. Diagnostic catheter cerebral angiography identified an 80% in-stent right ICA stenosis, with intracranial runoff identifying and filling the right middle cerebral and both anterior cerebral arteries from this injection. Endovascular treatment with percutaneous transluminal angioplasty (PTA) and endovascular stenting was performed. A 5-mm SpiderFX distal EPD (Medtronic) was advanced across the stenosis and into the distal cervical segment of the right ICA and deployed under fluoroscopic surveillance. PTA was initially performed on the stenosis with sequential 4- x 40-mm and 5- x 30-mm balloons, followed by deployment of the 9/7/8- x 40-mm Neuroguard IEP System (Figure 2). After removal of the Neuroguard IEP System and SpiderFX, postprocedural imaging demonstrated near-complete interval resolution of the heavily calcified right ICA stenosis (Figure 3). The BMX catheter was removed, and the right radial arteriotomy was closed with a TR band.

The patient was admitted for overnight observation, with strict blood pressure control for blood pressures < 160 mm Hg. DAPT was reinitiated, and the rivaroxaban was discontinued. After an uncomplicated hospital course, the patient was discharged the next day. Carotid duplex ultrasound imaging performed prior to discharge identified no flow-limiting residual carotid stenosis.

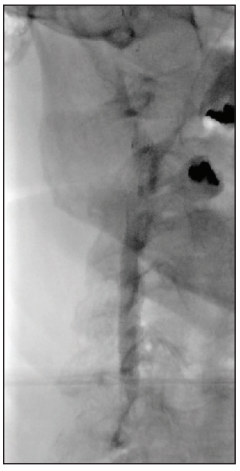

Figure 2. Intraoperative fluoroscopic image showing balloon inflation during deployment of the 9/7/8- x 40-mm Neuroguard IEP System, with the distal EPD in the distal cervical ICA.

Figure 3. Postoperative DSA of the cervical RCA system identified significant interval improvement in the luminal caliber of the stenotic segment after right ICA stenting with the 9/7/8- x 40-mm Neuroguard IEP System.

DISCUSSION

Results with the Neuroguard IEP System at our institution have been excellent. To date, we have had no procedural or postoperative complications. Scientifically, the 40-µm pore size of the Neuroguard integrated embolic protection filter affords a significant amount of added protection during both stent deployment and stent postdilation. Importantly, these two parts of the CAS procedure have high embolic potential based on historic transcranial Doppler studies. This enhanced safety, in addition to the primary distal EPD device, likely contributed to the excellent results found in the PERFORMANCE II study.

In our experience, the 3-in-1 design has allowed for an easier and quicker deployment than conventional stenting, with the outward radial force provided by the FlexRing stent construct allowing for excellent results, even in heavily calcified lesions.

At our institution, follow-up is identical to our other carotid stenting patients. Patients return for carotid duplex ultrasound imaging at 3 months, at which time we consider discontinuing DAPT, continuing with antiplatelet monotherapy, and continued secondary stroke risk factor modification.

3-in-1 Neuroguard IEP System for Carotid Stenting

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PATIENT PRESENTATION

A female patient in her 50s presented with a history of moderately differentiated laryngeal squamous cell carcinoma and previous neck radiation and tracheostomy. Follow-up CTA revealed asymptomatic high-grade bilateral carotid stenosis. She underwent right-sided CAS and presented to our center for treatment of the left carotid stenosis (Figure 1), which had a Doppler velocity of 472/129 cm/second. The patient is a daily smoker and had taken aspirin (81 mg) and clopidogrel (75 mg) daily since her recent right CAS. On examination, she was neurologically intact.

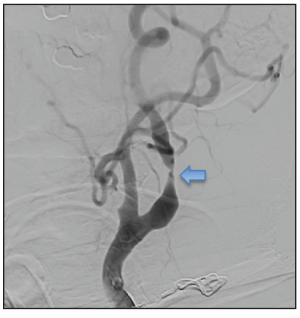

Figure 1. MRA showing severe stenosis at the ICA, distal to the carotid bifurcation.

TREATMENT OPTIONS

Current treatment options for carotid stenosis include transfemoral (TF)- or TR-CAS, CEA, TCAR, and observation. Given the severity (> 80%) and tortuosity of the carotid stenosis, as well as the history of neck radiation and contralateral CAS, CAS with embolic protection was considered the best option in this case. TF stenting has an advantage over the TR approach because a larger-bore 8-F balloon guide catheter can be used for proximal embolic protection for flow reversal and to provide added support to deliver stent platforms. The Neuroguard IEP System, a 3-in-1 CAS platform, was selected for this case. This new system includes an integrated embolic protection filter with 40-µm pores, a carotid stent, and a PTA balloon for

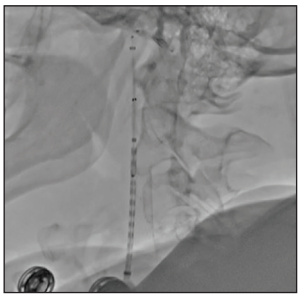

Figure 2. After the 3-in-1 Neuroguard IEP System was brought to the desired location, the Neuroguard 40-µm integrated filter was unsheathed and deployed. The Neuroguard stent is now in position over the stenosis before deployment.

poststenting angioplasty, obviating the need for multiple exchanges during the procedure, translating then into decreased time and increased safety and effectiveness of the procedure. With the 40-µm filter pores, smaller embolic material can be captured, which should decrease the risk of periprocedural complications.

INTERVENTION

An Emboshield NAV6 EPD (Abbott) was first used to cross the lesion under flow arrest with a Walrus balloon guide catheter (Q'Apel Medical Inc.), and the filter was deployed. The NAV6 distal filter was used to provide extra embolic protection for subsequent crossing of the stenosis with the larger Neuroguard IEP. Once the Neuroguard IEP's FlexRing stent was in position (Figure 2), the system's distal integrated embolic protection filter with smaller pores was deployed to protect against smaller debris that might become loose during stent deployment and poststenting PTA. Immediately after stent deployment and angioplasty was performed, the Neuroguard IEP delivery system was removed and routine intravascular ultrasound imaging was obtained to confirm no plaque protrusion within the stent. The NAV6 filter was captured, and routine biplane cervical and cerebral angiography were performed, followed by removal of the Walrus balloon guide catheter and femoral 8-F closure.

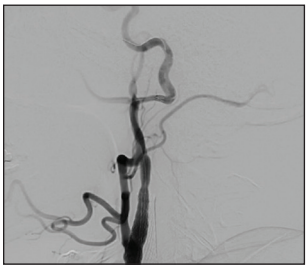

Figure 3. After postdilation with the Neuroguard integrated balloon, the final angiogram showed minimal stenosis.

The procedure resulted in reduction of the stenosis (Figure 3). Postprocedurally, the patient did well and was neurologically intact. Updated carotid Doppler imaging demonstrated a significant decrease in velocity to 128/42 cm/second, and routine brain MRI demonstrated no infarcts. She was discharged on postprocedure day 1. The patient was doing well at 4-week follow-up evaluation.

DISCUSSION

This case illustrates the Neuroguard IEP as a safe and efficient system. It minimized the need for multiple exchanges during CAS, resulting in decreased procedure time and increased safety. This also makes the CAS procedure quicker and safer than in 2010 when CREST was initially published and showed higher periprocedural stroke rates in the CAS group than the CEA group.

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Neuroguard IEP Used in Symptomatic, Severe Left ICA Stenosis

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PATIENT PRESENTATION

A man in his mid 70s with a past medical history of coronary artery disease, hyperlipidemia, hypertension, and obstructive sleep apnea presented to the ED with right-sided paresthesias and hand clumsiness. The patient was on aspirin and a statin at baseline. On evaluation, his National Institutes of Health Stroke Scale was 1. Head CT demonstrated no intracranial hemorrhage and hypodensity in the left frontal and occipital lobe consistent with acute left hemispheric ischemia in a watershed distribution. A CTA of the head and neck as part of the stroke workup demonstrated 85% stenosis within the proximal left ICA and no significant RCA stenosis (Figure 1). Noncontrast MRI of the brain demonstrated diffusion restriction in the left frontal and occipital lobe.

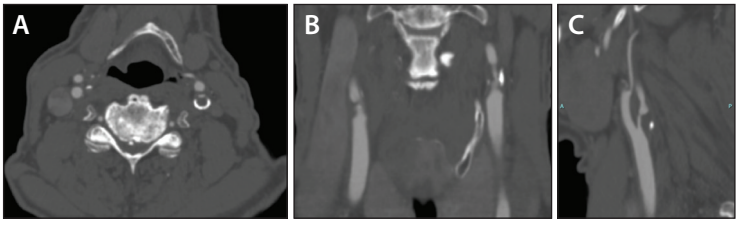

Figure 1. Preoperative axial (A), coronal (B), and sagittal (C) images demonstrated symptomatic severe left ICA stenosis.

TREATMENT OPTIONS

Given the symptomatic, severe left ICA stenosis, carotid revascularization was recommended. CEA and TCAR were both considered, but given the isolated hemisphere on the left side with poor visualization of an intact circle of Willis on the CTA, TF-CAS was suggested as the best approach.

INTERVENTION

The patient was given a load of clopidogrel in addition to his daily aspirin and underwent TF-CAS the following day under moderate sedation. After femoral access, a guide catheter was advanced into the left common carotid artery. A 5-mm SpiderFX EPD was deployed in the petrous carotid artery, and a 5- x 20-mm Paladin® IEP balloon (Contego Medical) with integrated embolic protection (IEP) was used for prestenting balloon angioplasty, after which the 9/7/8- x 40-mm Neuroguard IEP System was utilized (Figure 2).

The patient had no unanticipated events during the case. He was discharged the next day on DAPT. At his 1-month follow-up appointment, the patient was neurologically intact, and a carotid ultrasound revealed a patent carotid stent with normal velocities.

DISCUSSION

The Neuroguard IEP System was deemed a great first-line option for CAS in this patient based on the excellent periprocedural clinical outcomes noted in the PERFORMANCE II study. Key take-home points for success in this case included: (1) studying the patient's arch anatomy to determine difficulty of access to the symptomatic carotid artery and (2) using a highly trackable, supportive guide catheter to establish a good position for placement of the Neuroguard IEP carotid stent. ■

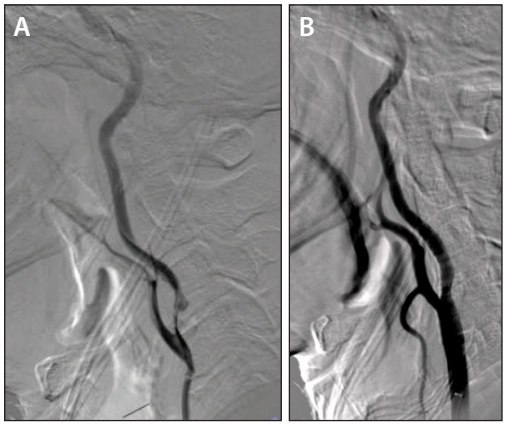

Figure 2. Prestenting (A) and poststenting (B) lateral DSA imaging.

Disclosures

Dr. Jovin: Consultant/advisory board for Contego Medical, Silk Road Medical, Viz.ai, Corindus, Anaconda, and Methinks; member of steering committee/data and safety monitoring board for Cerenovus; consultant to Stryker and Medtronic; consultant/advisory board (ownership interest) for Blockade Medical, FreeOx Biotech, Route 92, and NeuroTrauma Sciences LLC.

Dr. Gaughen: None.

Dr. Siddiqui: Financial interest/investor/stock options/ownership, Contego Medical, Inc., Q'Apel Medical, Inc.; consultant/advisory Board, Abbott, Contego Medical, Inc., Q'Apel Medical, Inc.

Dr. Grandhi: Consultant to Medtronic Neurovascular, J&J Neurovascular, Stryker Neurovascular, Balt, and Rapid Medical.