PANEL DISCUSSION

Effects of the Carotid Artery Stenting NCD on Current Decision-Making for Carotid Disease

Impact of the NCD on referrals and volumes of transfemoral carotid artery stenting, the multidisciplinary approach to evaluation and treatment, considering patient factors and patient preference, device selection, and approaches to concomitant stroke and carotid disease.

With Meghan Dermody, MD, and Adnan Siddiqui, MD, PhD

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Did the 2023 National Coverage Determination (NCD) update have any impact on the referrals that you or your team are seeing with carotid disease?

Dr. Dermody: Thankfully, no. Neurointerventional physicians and interventional cardiologists at our institution do not perform a significant volume of transfemoral carotid artery stenting (TF-CAS), either electively or for symptomatic lesions. This was the case even before the NCD update and seems to be secondary to their training and societal guidelines, which indicate a higher risk of stroke with TF-CAS. Our vascular surgeons are not credentialed to perform TF-CAS due to the lack of volume in cases needed for privileging. Given this, our referral patterns have remained stable given that we are a surgical-focused practice, primarily offering carotid endarterectomy (CEA) and transcarotid artery revascularization (TCAR) unless anatomically unsuitable.

What were your TF-CAS volumes like before the 2023 NCD update? Approximately how many cases per month would you perform via this approach?

Dr. Siddiqui: We have historically had very high TF-CAS volumes because of our engagement in essentially all United States–based investigational device exemption (IDE) studies for CAS. Even in more recent years when most carotid artery high-risk registries had closed, we have had access to the Gore carotid stent (Gore & Associates), followed by the Roadsaver carotid stent system (Terumo Interventional Systems), and, more recently, the CGuard Prime carotid stent system (InspireMD) and Neuroguard IEP (Contego Medical). In addition, we have enrolled patients in the CREST-2 study, and by virtue of that, we have had access to CREST-2 registries. That said, we were unable to treat standard-risk patients with asymptomatic carotid stenosis > 80% and symptomatic patients with stenosis of 50% to 70%. My personal preexisting high volume is > 100 cases performed transfemorally each

year and about 10 each month; collectively, we do about 350 TF-CAS cases per year.

Has there been much, if any, change since then? How do you see this trending in the near future?

Dr. Siddiqui: The NCD has changed everything. Now, we can select patients based on true patient-specific criteria rather than regulatory constraints, and because of this, we have seen a significant increase in our volumes for TF-CAS. Most of these changes have occurred due to elimination of the requirement that the patient has high-risk criteria, which would be employed for previous TF-CAS selection. Further, volume has increased from expansion of criteria for treatment from symptomatic disease > 70% with high-risk criteria to > 50% symptomatic disease with standard-risk criteria. These changes in Centers for Medicare & Medicaid rules have profoundly changed the number of cases we are now seeing for treatment. Although we perform both TCAR and CEA, our TF-CAS volume massively overshadows these procedures for treating carotid artery stenosis. I expect this trend to continue to increase as more interventionalists gain familiarity with the TF-CAS approach. Given the high-quality results from the most recent second-generation TF-CAS devices IDEs, I remain highly optimistic that TF-CAS will become the standard of care for cervical carotid revascularization.

Dr. Dermody: We have not seen a change in volume of TF-CAS since the NCD update. We continue to field consults from neurology for patients who underwent cerebral mechanical thrombectomy for stroke and were found to have a carotid lesion that was felt to be the embolic source, as interventionalists are not stenting these lesions at the index procedure. There is opportunity to determine the best approach for a stroke patient undergoing neurointervention. For the rest of the population, I feel we should be honing our revascularization strategies more to the anatomy-specific lesion characteristics, rather than percentage of stenosis.

Does your team take a multidisciplinary approach to carotid care, particularly with respect to decisions on which therapy is best for a particular patient? If so, what does this process entail?

Dr. Dermody: Yes. Generally speaking, for asymptomatic patients aged < 70 years, we tend to recommend CEA unless the anatomy is not suitable or the patient has too many high-risk factors for general anesthesia. In 2018, we launched a TCAR program requiring that an interventional cardiologist with TF-CAS privileging and a vascular surgeon be co-operators. At the beginning of the program, both physicians met with the patient prior to surgery and reviewed duplex ultrasound and CTA imaging to determine the best approach to revascularization. After significant experience performing TCAR together, the vascular surgeons became independently privileged to perform TCAR without cardiology presence, as we created a pathway for credentialing that did not require TF-CAS experience. (This was prior to vascular surgeons learning TCAR in training.) This multidisciplinary approach allows us to determine the best revascularization option for our patients, because not all lesions are optimal for CEA or CAS.

Dr. Siddiqui: Yes, the team always takes a multidisciplinary approach for all of our elective carotid disease cases. The only instance in which we have no ability to discuss multidisciplinary approaches is during emergent carotid disease encountered during treatment for acute stroke. Our traditional approach is that we hold a once-weekly peer review conference with colleagues from vascular neurology, neurosurgery, vascular surgery, and additional participation from cardiology, in which individual cases are presented for selection of optimal treatment methodology, including CEA, TCAR, TF-CAS, and optimal medical therapy. We further discuss imaging protocols and additional studies that should be performed in these cases prior to offering treatment. A consensus approach is used for final decision-making.

Which patient factors most affect your decision-making regarding whether a patient is ideal for CEA, TCAR, or TF-CAS?

Dr. Dermody: In general, we try to reserve TCAR or TF-CAS for patients aged > 70 years. There are several anatomic factors that favor CEA over stenting: heavily calcified plaque, concentric calcium, low bifurcation, inability to use dual antiplatelet therapy (DAPT), and statin intolerance. Factors favoring stenting include high risk for general anesthesia (we perform TCAR with monitored anesthesia care/local only), which includes unrevascularized coronary disease (patients awaiting coronary artery bypass grafting are typically treated with cangrelor for DAPT perioperatively), high lesion, concurrent lesions, prior neck surgery or radiation, and contralateral carotid occlusion. We reserve TF-CAS for patients with a type I or II arch free from significant atherosclerotic disease and with a contraindication to CEA or TCAR (which is rare). TF-CAS is predominately used for in-stent restenosis or proximal CEA patch stenosis (lack of common carotid artery runway for TCAR).

Dr. Siddiqui: The principal means to decide on treatment is a two-tiered approach. The first is to establish that the patient has adequate life expectancy. We use 2 years for symptomatic disease and 5 years for asymptomatic disease. The second tier of selection is based on screening Doppler ultrasound, giving extra focus on patients with increasing Doppler velocities over a period of time. Finally, once the likely threshold for stenosis of > 70% for asymptomatic disease and > 50% for symptomatic disease is established based on results of Doppler studies, we then use CTA of the head, neck, and aortic arch as a principal modality to select a revascularization strategy.

We use a rather simple algorithm to decide on optimal revascularization approach. The first thing we look at is the aortic arch itself. If we encounter severe tortuosity and proximal carotid severe angulations or an atherosclerotic arch, which appears fragile or shaggy, we then abort any plans for a TF-CAS approach. The second thing we evaluate is the carotid artery stenosis lesion itself. If the lesion is concentrically densely calcified or has severe angulation within the lesion or immediately next to it, we then abort any stenting procedure, including both TF-CAS or TCAR, leaving CEA as the best choice. Finally, if the lesion itself is amenable to endovascular treatment because it is not densely concentrically calcified or severely angulated, we then make the choice between TF-CAS and TCAR based on whether the aortic arch is safe for access, in which case we lean toward TF-CAS or, if the arch is hostile, in which case we perform TCAR. In all these cases, we have additional criteria for each procedure (TF-CAS, CEA, TCAR) that we consider if the patient has a high-risk profile and anatomy. We carefully consider all these additional considerations in our decision-making process.

What about patient preference? How do you ensure you're providing true shared decision-making?

Dr. Siddiqui: Like all surgical procedures, especially elective ones, it's all about gaining patient approval and consent for the preferred treatment. We perform this process in a formulaic, repetitive, and consistent approach. In all discussions, we begin with the known natural history of the disease (symptomatic and asymptomatic) based on landmark trials. We then introduce to the patient the concept of carotid artery revascularization. In this regard, we always begin discussions with CEA and its historic superiority over maximum medical therapy for both symptomatic and asymptomatic disease. We next discuss the value of introducing new medical therapies that have transformed the care of vascular disease, including DAPT and statin therapy. Given the introduction of these novel agents, which are significantly more disease-modifying than the original aspirin tried in the multiple historic landmark trials, we present the concept that perhaps intervention for asymptomatic disease may not be the best option for prevention of stroke. We essentially establish our equipoise for this cohort of patients. In this regard, we use this line of discussion to offer patients enrollment in the CREST-2 trial if they are asymptomatic. On the other hand, if they are symptomatic or asymptomatic but do not desire to enroll in the CREST-2 trial, then we explain the two new approaches for treatment of carotid disease, including TF-CAS and TCAR. We then take time to explain to the patient, based on the above-mentioned algorithm and using clinical and imaging (CTA) data, why we are preferring or suggesting a particular approach. We always make sure that the patient knows that all approaches are equally effective for most patients. There are certain patients where one approach may be superior to others, but those are less frequent cases. After a thorough discussion of pros and cons, including specific revascularization strategy–related complications, we typically arrive at the decision from the patient. In most cases, it's congruent with the presented approach by the physician.

Dr. Dermody: I tell my patients that I do not perform TF-CAS and therefore cannot speak directly to its benefits. However, I tell them that the surgical literature indicates this approach has a higher risk of stroke due to arch manipulation and the need to obtain distal embolic protection. In my hands, CEA or TCAR are the best options for carotid revascularization. I show patients their CTA images and tell them what makes stenting and CEA different. If patients are looking to return to work within 1 week or limit their anesthetic needs, we tend to schedule TCAR given the faster recovery and lack of need for general anesthesia, as long as their anatomy is suitable. I tend to recommend TCAR to patients aged > 80 years to avoid general anesthesia.

What is your approach to CAS device selection? As more devices come to the market, will you have a variety of options on the shelf or primarily use one platform?

Dr. Siddiqui: In terms of device selection, we clearly differentiate between symptomatic and asymptomatic disease. We have been influenced over the years by the concept that closed-cell designs and smaller area for plaque protrusion after angioplasty and stenting can help mitigate stroke risk during and after the procedure. Given this fact, we tend to treat most of our

symptomatic patients with closed-cell stents. The most common stent that we have used historically has been the Wallstent (Boston Scientific Corporation). However, if the plaque is more calcified or not very soft, we elect to use the Xact stent (Abbott) instead. It is rare for us to use an open-cell stent, like the Precise Pro (Cordis) for symptomatic disease. For asymptomatic disease, we tend to have a more ambivalent approach in terms of stent device selection. We prefer not to use the Wallstent given its limited radial outward force; we instead prefer the Xact stent for straight anatomy and the Precise stent for mildly to moderately angulated anatomy. This is all about to change given the recent approvals of three new devices (Roadsaver, Neuroguard, and CGuard) for carotid artery revascularization. All three of these are second-generation devices that have their own unique mechanisms to reduce embolic debris production during performance of the TF-CAS. We will have access to all three devices on our shelves, and I believe this is going to transform how we treat patients.

If you work in a stroke center, what percentage of patients presenting with stroke have carotid bifurcation disease? In patients with carotid bifurcation disease, either as a source of stroke or as a concomitant finding, what is your approach to treatment?

Dr. Dermody: I don't have the data on how many stroke patients have carotid bifurcation disease on CTA imaging at our stroke center. However, when carotid disease is identified, vascular surgery is typically consulted by the admitting team. Once the source of stroke is determined, if it is felt to be secondary to the carotid disease, neurology and vascular surgery typically discuss the case to determine medical management and timing of revascularization. We ultimately schedule carotid surgery within 14 days of the event. If the carotid disease was not deemed to be symptomatic, vascular surgery will schedule the patient for outpatient follow-up with duplex ultrasound for surveillance.

Dr. Siddiqui: As the leading neurointerventional stroke center in the Northeast, we have very well-described patient data and workflow associated with detection of carotid artery disease. In our center, about 20% to 25% of acute stroke patients have concurrent carotid artery stenosis. This is one of the first things we look at when a new stroke patient arrives to the emergency department. The workup includes a CT stroke study, which includes a plain head CT, a CTA from the aortic arch to the head vertex, and a CT perfusion study of the whole brain. Based on this, we screen specifically for patients who may have tandem carotid artery stenosis. Our decision for acute revascularization is based on patient deficits and the established intracranial location for occlusion. Typically, we offer treatment for large vessel occlusion in patients who present within a timely fashion with a significant deficit as measured by the National Institutes of Health Stroke Scale (NIHSS) score and have no other major contraindications to revascularization.

Carotid disease is not managed during acute stroke care unless one cannot safely deliver a guide catheter to the base of the skull for the actual intracranial thrombectomy. If intracranial thrombectomy can be performed without carotid revascularization, even though the degree of stenosis may be ≥ 50%, we elect to defer carotid artery revascularization for a few days to make sure there's no concern for postthrombectomy hemorrhagic transformation. This also allows us to delay acute loading of DAPT, which can increase the risk of intracranial hemorrhage.

However, if the patient presents with a severe carotid artery stenosis or complete carotid artery occlusion and has a tandem intracranial lesion that requires revascularization or has severe perfusion deficit (corroborated by a high NIHSS score), we elect at that point to perform acute carotid angioplasty and stenting. In these cases, our choices are typically placement of a nasogastric tube and delivery of aspirin and ticagrelor as an acute load within the emergency department prior to transfer to the interventional suite. Once we are there, we use balloon guides to establish common carotid artery access and cross the lesion in standard fashion under flow reversal, followed by angioplasty and anterograde stenting of the cervical carotid artery as a first step. Following this, the balloon guide is deflated and advanced through the stent to the skull base, at which point, after aggressive aspiration, we perform an angiogram to evaluate the intracranial occlusion. ■

Disclosures
Dr. Dermody: Speaking consultant for and receives honoraria from Silk Road Medical (now Boston Scientific Vascular) and Medtronic Aortic.
Dr. Siddiqui: Financial interest/investor/stock options/ownership in InspireMD, Silk Road Medical; consultant/advisory board for Boston Scientific, Cordis, InspireMD, Medtronic, MicroVention, and Silk Road Medical.