Supplement to

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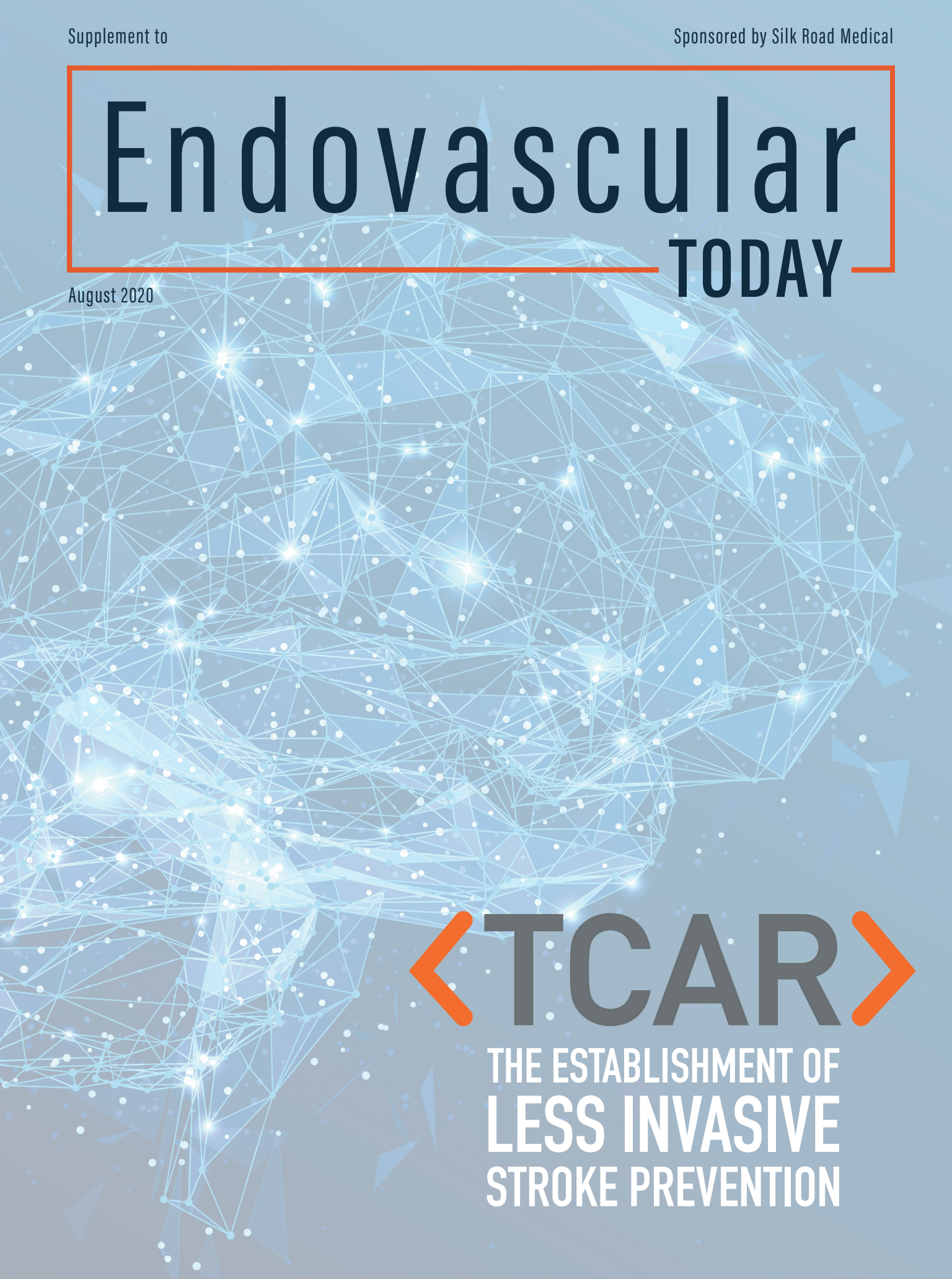

# TCAR

## THE ESTABLISHMENT OF LESS INVASIVE STROKE PREVENTION

# Contents



In this supplement, we aim to share important insights that have been gained in the last 4 years since transcarotid artery revascularization (TCAR) became commercially available.

In those 4 short years, TCAR has rapidly risen to become a powerful weapon in the armamentarium of stroke prevention by carotid revascularization. It has consistently shown procedural safety in terms of stroke hazard that is equivalent to carotid endarterectomy (CEA) and that far surpasses that of transfemoral carotid artery stenting (CAS) while affording additional efficiency advantages such as procedure time, "clamp time" equivalent, length of stay, etc.

Data analyzed from the Society for Vascular Surgery Vascular Quality Initiative (VQI) TCAR Surveillance Project are shared here in this supplement. These data are unique in that they are independent of Silk Road Medical Inc. and represent the "real world" in every sense. As data entry into the VQI is a condition of reimbursement for most TCARs performed in the United States, this data set represents the outcomes for first ever TCARs performed by first-time TCAR operators after attending a training program (TEST DRIVE). There is no allocation given to learning curve, thus the data assimilate first experiences.

We provide guidance in building your TCAR program, positioning of TCAR versus alternatives, advice on "conjoint" pathways for two specialties working together, practical tips on the "choreography" between team members in the operating room/hybrid suite environment, and answers to commonly asked question such as "what should one do when faced with stent restenosis," appreciating that this entity is uncommon. We share crucial details about bifurcation lesions that may prove challenging and those (the majority) that are straightforward for TCAR, provide guidance around "in the moment" decision-making in those infrequent cases in which early recognition of a potential problem will usually avert a complication. We detail shared decision-making, an often overlooked aspect of consent but one that is championed by Medicare. Last, but certainly not least, is a nod to the future; fellows and their unique training requirements.

Our overarching aim is the support of your TCAR patients and your TCAR program—we hope that you find this TCAR supplement both useful and interesting.

Finally, I would like to acknowledge early innovators, David W. Chang, MD, and Enrique Criado, MD, for their pioneering work in transcarotid therapies. ■

**Sumaira Macdonald, MD, PhD, MBChB, MRCP, FRCP, FRCR, EBIR**
Vascular Interventional Radiologist
Executive Medical Director
Silk Road Medical
Sunnyvale, California
*Disclosures: None.*

# The Evolution of TCAR Into First-Line Therapy for Carotid Revascularization

**BY RASESH M. SHAH, MD, FACS**

Since transcarotid artery revascularization (TCAR) was added to our armamentarium in 2012, we now have three options for carotid revascularization. Carotid endarterectomy (CEA), now into its 8th decade, arguably remains the gold standard therapy.[1,2] Transfemoral carotid artery stenting (TFCAS), now into its 4th decade, continues to demonstrate higher periprocedural stroke risk compared with CEA.[3] TCAR results continue to compare favorably against both TFCAS and CEA.[4]

Stroke reduction is the goal for any carotid revascularization therapy. This reduction is achieved with a program that must include best medical therapy (BMT)—antiplatelet/statin/blood pressure control/smoking cessation—in addition to optimal revascularization procedural technique. CEA has excellent neuroprotection (clamping), as demonstrated by low rates of diffusion-weighted (DW) MRI embolic new white lesions. TFCAS is limited by the need to actually traverse the aortic arch and cross the carotid stenosis before establishing neuroprotection with a filter. This has led to much higher rates of new DW MRI lesions as compared with CEA. A major advantage of the TCAR technique is the ability to avoid the aortic arch with direct carotid access and to establish excellent neuroprotection with robust flow reversal before any manipulation of the lesion itself occurs. This is again confirmed by the low periprocedural stroke rates in addition to the new DW MRI lesion rates that are equivalent to CEA.[5]

The continued impressive results of TCAR by an increasing number of unique operators is a testament to not only the procedure itself, but also to the excellent training paradigm that has been established for this technique. Although none of the steps of this hybrid procedure are unique, the technical details and the sequence of steps for lesion management are critical to the success of TCAR. TEST DRIVE is a unique opportunity for qualified surgeons and proceduralists to spend a day learning didactics of patient selection, BMT, pre/postprocedure care, and of course the TCAR procedure itself. The hands-on portion of the day includes a wet lab with the opportunity to perform TCAR on a simulated tissue model. This 1-day training is then enhanced with case support from clinical specialists and physician proctors, if needed. The results are speaking for themselves, as we continue to see the same low rates of stroke that were observed in the hands of a few ROADSTER 1 operators (1.4%) now being observed in the hands of hundreds of operators enrolling in the Vascular Quality Initiative (VQI) database (1.4%).[6,7]

Patient satisfaction and procedural efficiency are also becoming increasingly important. TCAR is quicker than CEA and has a shorter hospital stay, which translates into better patient satisfaction as well as a potential better margin for the hospital. The current limitation on patients that will qualify for TCAR is the requirement for meeting one high-risk criterion as defined in the National Coverage Decision (NCD) by the Centers for Medicare & Medicaid Services (CMS).[8] However, from retrospective review of all carotid interventions in the VQI data set, it is estimated that 70% of patients would meet at least one high-risk criterion. Under the current NCD that covers both TFCAS and TCAR outside of clinical studies, the patient is required to have a ≥ 70% symptomatic stenosis. However, the VQI TCAR Surveillance Project has afforded those who participate in the carotid module of the VQI the ability to offer TCAR to patients with an 80% asymptomatic carotid stenosis (most patients undergoing carotid revascularization in the United States) or a 50% symptomatic stenosis.

TCAR continues to demonstrate stroke rates that are better than TFCAS and equivalent to CEA. Patient satisfaction and physician efficiency, along with potential financial advantages to the institution, add to the positives of this exciting procedure. Are we moving to TCAR first as the strategy for carotid revascularization? The contributors to this supplement will present the case that we are. ■

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**Rasesh M. Shah, MD, FACS**
Clinical Chief
Sentara Vascular Specialists
Norfolk, Virginia
rmshah@sentara.com
*Disclosures: Consultant to Silk Road Medical.*

# Transitioning to the TCAR-First Strategy for Carotid Revascularization

**BY RASESH M. SHAH, MD, FACS, AND H. EDWARD GARRETT JR, MD, FACS**

**Rasesh M. Shah, MD, FACS**
Clinical Chief
Sentara Vascular Specialists
Norfolk, Virginia
rmshah@sentara.com
*Disclosures: Consultant to Silk Road Medical.*

**H. Edward Garrett Jr, MD, FACS**
University of Tennessee, Memphis
Memphis, Tennessee
egarrettmd@cvsclinic.com
*Disclosures*: *None.*

Carotid endarterectomy (CEA), introduced in the 1950s, has long been accepted as the gold standard for revascularization of the carotid bifurcation for occlusive disease. The procedure has been refined over the years, with excellent results overall for stroke prophylaxis.[1,2] Transfemoral carotid stenting (TFCAS), introduced in the 1990s, has become an attractive option for patients at high risk for surgery–but at the expense of higher procedural stroke morbidity.[3] Transcarotid artery revascularization (TCAR), introduced less than a decade ago, is rapidly establishing itself as a hybrid procedure with the advantages of both CEA and CAS. It is less invasive, quicker, and enjoys a shorter length of stay than CEA, and is therefore patient friendly (like CAS) but with stroke rates equivalent to CEA. Should this lead us to a TCAR-first strategy when evaluating patients for carotid revascularization?

## PERSONAL EXPERIENCE

In my experience (Dr. Shah) since starting practice in 1993, I have seen—and participated in—the evolution of all three techniques. I was trained in the era of CEA and when CAS was introduced early in my career, it seemed like a reckless and crazy idea. However, as stent technology improved and neuroprotection systems were optimized, I became a believer and offered CAS to many patients starting in the late 1990s. The results, however, did not meet the expectations of many surgeons; the idea of equipoise of CEA and CAS by adding stroke/death/myocardial infarction together was disappointing. The documented limitations of CAS include the following:

- There is a higher risk of stroke due to catheter manipulation in the aortic arch to achieve cannulation of the carotid artery and from crossing the carotid lesion with the filter prior to any neuroprotection
- CAS is not recommended for patients older than 80 years because of a higher risk of stroke, presumably secondary to manipulation of the diseased aortic arch
- CAS is more difficult in a challenging type II or III aortic arch
- Severe carotid calcification may leave a residual stenosis after CAS

After all, the goal of carotid revascularization is stroke prevention. In 2012, when approached to consider participating in the ROADSTER 1 trial for the procedure we now know as TCAR, I was intrigued. The minimally invasive era was clearly already here, and patients are always happier with a "smaller operation." The procedure intuitively made sense; avoiding the aortic arch and establishing robust neuroprotection before manipulating the lesion. With more than 10 years of CAS data on the durability of stents, that was not a significant downside to consider. I saw this as potentially the best of both worlds, so in January 2013 we enrolled our first patients in the trial.

Fast forward 7 years and > 250 patients later, I believe we definitely made the right decision to become involved with TCAR. I still remember speaking to my first patients about this new technique and asking them to participate in a trial to prove it was beneficial. I told them due to their high risk for surgery that stents were safer than CEA, but that this was going to be a safer way to get that stent placed. That is what I still tell my patients now, except it is supported by stroke risk data from ROADSTER 1 (1.4%; n = 219),[4] ROADSTER 2 (0.6%; n = 632),[5] and the Vascular Quality Initiative (VQI) TCAR Surveillance Project(1.4%; n = 5,716).[6] When these results are compared with CEA (2.3%; n = 1,240) or CAS (4.1%; n = 1,262) from the CREST trial (all standard surgical risk, rather than all the TCAR patients being high surgical risk), the argument only gets stronger.[7] And for those who would like imaging confirmation of safety, the comparison of new white lesions on diffusion-weighted MRI (DW MRI) after CAS/CEA/TCAR is striking. CAS rates range from 45% to 87%,

CEA rates range from 12% to 25%, and TCAR rates in the PROOF study were 18%.[8]

## DISCUSSION

As with any procedure, we do not believe in a one-size-fits-all approach. There are clearly patients who currently should not be offered any stent-based intervention (TCAR or CAS) due to heavy calcification. These patients should be offered CEA. There are also patients who will not meet the 5-cm distance requirement from clavicle to lesion to safely insert the ENROUTE® Transcarotid Neuroprotection System (Silk Road Medical). They should also be offered CEA or CAS depending on other risk factors. Intolerance to flow reversal has been raised as a possible reason patients would not qualify for TCAR. In practice, this has been observed only rarely. No correlation has been identified between collateral circulation and intolerance. In fact, with most cases still being done under general anesthesia, this is not even recognized. In those cases done under local anesthesia, the incidence is exceedingly low and is treated easily with raising pressure/increasing oxygenation/finishing the procedure expeditiously. The volume of dye used is less than in TFCAS and procedure times are shorter than in CEA.

Optimal medical therapy is a must for patients undergoing stent placement, so the inability to be on dual antiplatelet and statin therapy should be considered negatively for TCAR or CAS. Most patients undergoing CEA would remain on monotherapy alone. There will be a very few patients with other anatomic criteria not in favor of TCAR, such as severe radiation dermatitis or open tracheal stoma, but patients with fused spines are easily treated as the incision is at the clavicle and the neck does not necessarily need to be turned.

Based on these observations, we have adopted TCAR as the first line of treatment for symptomatic patients who meet the high-risk criteria. For centers participating in the VQI Registry, asymptomatic patients who meet the high-risk criteria can also be treated with TCAR as the first line of therapy.

## CONCLUSION

As the data continue to accumulate in support of TCAR, our approach has certainly changed from a "why TCAR" approach to a "why not TCAR" approach. Any patient seen for carotid stenosis should undergo CTA or MRA for full evaluation of the anatomy. There will be anatomic criteria in favor of (high lesion/contralateral occlusion) and against (short common carotid artery/heavy calcification) TCAR. Medical assessment will identify at least one high-risk criterion in the majority of our patients. Overall, it is estimated that at least 70% of our patients would quality for TCAR. So, if those patients are to be presented with a minimally invasive, safe, quick procedure with a short hospital stay—"why NOT TCAR?" ■

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# How to Effectively Initiate and Sustain a TCAR Program and Why This Might Change With Time

**Stephen P. Murray, MD, FACS**
Providence Sacred Heart Medical Center
Spokane, Washington
stephen.murray@providence.org
*Disclosures: None.*

I have been on the front lines of the peripheral endovascular turf battles and am familiar with the difficulties encountered in starting such programs. I often quote Tip O'Neill, who famously said: "All politics is local."

In the case of transcarotid artery revascularization (TCAR), the process was made easier by the knowledge, not only through the ROADSTER studies but now through the Vascular Quality Initiative (VQI) published data, that the results actually are at least as good if not better than that of the gold standard carotid endarterectomy. This is a distinct advantage in helping move this new technology into your treatment arena.

The elephant in the room is credentialing. Credentialing is the most common question we have heard concerning starting a program. Although I was the instigator of getting this technology into our hospital, I was not the first to perform it. Recognizing that there were others in our group of five who already had transfemoral carotid stenting privileges, it was they that were able to lead the group into the arena. We work within an institute composed of the usual cadre of cardiologists, cardiac surgeons, and vascular surgeons. We attend executive committee meetings where issues like this are discussed and approved prior to sending the recommendations on to the hospital credentialing committee. Beginning approximately a year prior to actually having access to the technology, we began having hallway discussions with the principle players about our growing enthusiasm for this new technique—touting its statical superiority in early studies. We lobbied the company for early access when it became approved. We attended meetings with the hospital new technologies committees and discussed the finances of the technology, acknowledging the increased cost, compared to carotid endarterectomy. We helped negotiate the final costs for the disposables.

Perhaps of equal importance was our participation in a national database in which outcomes were being measured and of which we were the charter signator when it was still the Vascular Study Group of New England, prior to becoming the VQI. This was key in our establishing across the board credentialing for all percutaneous peripheral vascular participants from the beginning. Having a robust database with implicit accountability for outcomes was important for arguing for a new technology that alleges to improve on the existing standard.

The mechanism we proposed and that was accepted was to send the surgeons that were already facile with transfemoral stenting to the training first. They then returned and were proctored for an agreed upon number of cases by proctors provided by Silk Road Medical. They then had to perform a larger number of cases on their own with acceptable results before being allowed to proctor those of us without prior transfemoral privileges for a yet larger number of cases. Through this process, we were able to quickly establish a robust program with good results and convince the referring physicians of the safety and decreased morbidity of TCAR.

Naturally, over time, surrounding centers have begun to adopt the technology as well, encountering most of the hurdles that we encountered. We have continued to adhere to the criteria for high-risk cases only as prescribed by Silk Road Medical. Clearly, as time passes and the technique evolves and improves, the results should either improve or at least remain stable and acceptable. When untoward events occur (as they always do), we have a regional morbidity and mortality remote meeting at which we discuss such outcomes on a monthly basis—the last arbiter of our quality assurance program.

**Laurel Hastings, MD**
CVT Surgical Center
Assistant Professor of Surgery
Louisiana State University New Orleans
New Orleans, Louisiana
laurel.hastings@cvtsc.com
*Disclosures: Teaching faculty and proctor for Silk Road Medical.*

I joined a private practice in the summer of 2018, after having finished a vascular integrated residency program. At the time of my training, TCAR had not yet been integrated into practice patterns with any of the groups with which I rotated. My first exposure to TCAR was at the fellow's TEST DRIVE program. I did my first TCAR procedure 2 weeks after having completed the training course. This—I believe—is the first step toward building an effective TCAR program. Integrated into the quick implementation of TCAR is the vital component of case selection. Together with our Silk Road Medical Therapy Development Specialists, selecting appropriate cases for the first few procedures built for a strong foundation for our TCAR program. I am fortunate in that my practice has a high volume of carotid work, both open and endovascular, in addition to being a strong catheter-based practice at its core. The high numbers that we treat made for a more comfortable transition to the TCAR procedure and it enabled an early adoption process. Additionally, at the start of the TCAR program, my partners and I frequently double-scrubbed, allowing us all to be exposed to a maximal amount of cases (more than 5 cases per week for the first several weeks), learning together and troubleshooting areas of concern. An overall understanding of more is better was key to the early implementation.

The second piece of the TCAR program, which I feel is vital, is your TCAR team. We appointed a designated "TCAR champion." This individual—who worked in our cardiovascular lab—had a strong interest in peripheral interventions and had a substantial knowledge base of the work we do, both in the cath lab and in our hybrid suite. This TCAR champion was sent to attend TEST DRIVE, to learn TCAR from both the clinical specialist's standpoint, as well as from the surgeon's perspective. From the start of our program, we had a dedicated TCAR team, from set individuals from our cardiac anesthesia team to a designated x-ray technician who was assigned to every case, as well as the scrub tech. All of this afforded an aspect of consistency to the procedure and built a knowledgeable multidisciplinary team that became skilled at getting patients in and out of the hybrid suite in a safe and efficient manner. Our anesthesia colleagues are specialized in cardiovascular anesthesia and several of them worked previously in a center with high volumes of awake carotid procedures. My group performs the majority (approximately 95%) of our TCARs awake, and the superficial cervical plexus blocks that anesthesia performs is one of the most important factors in our success in doing so.

Looking toward the future, I believe some of the aspects of implementing and sustaining a TCAR program will likely change. I had no exposure to this technology during my training, which in my experience both at TEST DRIVE and in my more recent encounters as TEST DRIVE faculty, seems to be more the exception than the rule these days. The pendulum truly seems to be shifting and I anticipate that this will continue to hold true as expanded indications for TCAR become increasingly likely. There seems to be more of an expectation in trainees coming out to be TCAR trained, and some colleagues have mentioned to me that TEST DRIVE was actually a requirement prior to starting their job. I also believe that there will be aspects that continue to hold great significance, including approaching your referral sources and educating them on new technologies and their advantages and indications, as well a strong TCAR multidisciplinary support team. With upward of 20,000 patients treated with TCAR in the VQI, collaborating and learning from one another's experiences will continue to be crucial in maintaining successful TCAR programs around the globe.

**Nate Aranson, MD, RPVI, FACS**
Staff Vascular Surgeon
Medical Director Maine Health Vascular Lab
Maine Medical Center
Portland, Maine
Assistant Professor of Surgery
Tufts University School of Medicine
naranson@mmc.org
*Disclosures: Senior teaching faculty and proctor for Silk Road Medical.*

As a third-generation physician, I have been afforded the luxury of direct observations of the dynamism of medicine. Often what worked for previous generations, no longer holds true for contemporary physicians. Many doctors are challenged by adjusting to the changing landscape of health care around them. On occasion, adages from the past hold true in health care practice of the future. Nothing typifies this more saliently than the three pillars of excellence in medicine; the key to success is being affable, available, and able. I believe that these tenets are the keys to being successful with the adoption of technological advances in medicine. I will delineate the challenges and successes I had

*(Continued on page 25)*

# Shared Decision-Making: Addressing the Medicare Directive and What This Means in a Busy Practice

How are busy vascular practices like the University of Rochester Medical Center proactively engaged in shared decision-making with their patients and families?

**BY MICHAEL C. STONER, MD, FACS, DFSVS, AND ALEX AU-YEUNG**

**Michael C. Stoner, MD, FACS, DFSVS**
Professor and Chief, Division of Vascular Surgery
University of Rochester
Rochester, New York
michael_stoner@urmc.rochester.edu
*Disclosures: Educational consultant and case proctor for Silk Road Medical.*

**Alex Au-Yeung**
VP, Health Economics & Reimbursement
Silk Road Medical
Sunnyvale, California
aauyeung@silkroadmed.com
*Disclosures: None.*

Even though Medicare has not mandated shared decision-making (SDM) requirements in all Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), variations of SDM are already incorporated in a vascular surgeon's everyday practice. The two primary components of SDM in all Medicare coverage guidance involve: (1) scheduling a separate SDM visit with the individual and family; and (2) using an evidence-based decision tool.

The Agency for Healthcare Research and Quality (AHRQ) provides some general guidelines for SDM in their document titled "Shared Decision-Making Tools for Lung Cancer Screening."[1] These include:

- Good communication between clinicians and patients
- Decision aids that provide a structured approach to providing information about options and trade-offs, values related to options and outcomes, and can help foster deliberation
- Tools that provide clinicians with a concise summary of the current clinical evidence and recommendations

## CHALLENGES

One of the primary challenges facing vascular surgeons, as well as other providers, is to develop a readable and understandable evidence-based decision tool that can be used during the SDM visit. Based on a 1992 National Assessment of Adult Literacy (NAAL) survey, Medicare beneficiaries read at the 5th grade level.[2] Another updated and more specific 2003 NAAL survey showed that adults aged 65 years and older had a lower average health literacy than adults in younger age groups. As a result, the Centers for Medicare & Medicaid Services developed an 11-part health literacy toolkit (www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit) for making written materials easier to understand and use.

The key takeaways are that written materials must be developed using a reader-centered approach and written from the mindset of the readers.[3] The materials must:

- Attract the intended readers' attention
- Hold their attention
- Make them feel respected and understood
- Help them understand the messages in the material
- Move them to take action

The University of Rochester Medical Center (URMC) Division of Vascular Surgery has developed a solution addressing SDM and authorizing patient consent using a module within their medical record system (Epic Systems Corporation) that can be adopted by other Epic system users.

## SHARED DECISION-MAKING IN THE URMC VASCULAR PRACTICE

At URMC, workflow for a patient with a flow-limiting or symptomatic carotid artery stenosis involves a well-established SDM process. After identification of a potential case via ultrasound, patients are screened for both indication (asymptomatic stenosis > 70% or symptomatic

**TABLE 1. CONTEMPORARY PERIPROCEDURAL STROKE/DEATH RATES ASSOCIATED WITH VARIOUS CAROTID REVASCULARIZATION STRATEGIES, NON-RISK-ADJUSTED (RAW DATA)**

| | Symptomatic Patients Stroke/Death/MI (%) | Asymptomatic Patients Stroke/Death/MI (%) |
|---|---|---|
| Carotid endarterectomy | 2-4 | 1-2 |
| Transfemoral stent | 5-7 | 3-5 |
| TCAR | 2-5 | 1-2 |

Abbreviations: MI, myocardial infarction; TCAR, transcarotid artery revascularization.

stenosis > 50%) and physiologic appropriateness for revascularization. All carotid stenosis patients are treated with best medical therapy via cardiovascular risk factor reduction, multimodal antiplatelet therapy, and statin class lipid-lowering therapy. Once a potential has been identified for possible revascularization, a brief discussion regarding the role of risk-reduction procedures is undertaken, including information regarding the need for further axial imaging via CTA, and a return visit to review the data is arranged. The patient is encouraged to bring family members and health care decision-makers to that second visit.

At the time of the second visit, patients are given information regarding the risks associated with carotid revascularization. Our site is fully vested in the Vascular Quality Initiative (VQI) and closely tracks internal data regarding treatment strategy and outcome. These data are validated and compared with regional and national benchmarks on a continuous basis. National data are used to quote stroke/death risks for each of the three procedural modalities for both symptomatic and asymptomatic patients (Table 1).[4,5]

Upon review of the anatomic data, patients are then offered one of the four possible treatments: (1) continued best medical therapy, (2) carotid endarterectomy, (3) transfemoral stenting, or (4) transcarotid artery revascularization (TCAR). Our institutional preference for minimal-access carotid surgery is toward TCAR based on internal experience and the strong literature supporting its role as a revascularization strategy for high-risk patients. Potential TCAR patients are screened for inclusion and exclusion criteria in the Society for Vascular Surgery VQI TCAR Surveillance Project.[6]

As a tool to assist with the SDM goal, an electronic consent is generated in the Epic medical record system using a standard template. Via modular and separately maintained rich text documents, the generated consent contains general and patient-specific risks and benefits associated with the procedure (Figure 1 on page 10). Several figures are used to illustrate key steps of the case and improve patient understanding. The patient is given both a hard copy and electronic copy of the document. The surgeon fully explains the document to the patient and addresses any questions or concerns with the patient and their representatives. Once a shared decision to proceed with the case is reached, the visit is concluded with the attending surgeon entering a formal case request order into the electronic medical system to ensure fidelity and laterality. ■

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# STRONG MEMORIAL HOSPITAL CONSENT FOR MEDICAL OR SURGICAL PROCEDURE SH 419 MR

Patient Name:_____ DOB: _____

- Please read this form or have someone read it to you.
- It's important to understand all parts of this form. If something isn't clear, ask us to explain.
- When you sign it, that means you understand the form and give us permission to do this surgery or procedure.
- I agree for Dr. Stoner, and other members of the Division of Vascular Surgery (Drs. Stoner, Ellis, Doyle, Raman, Glocker, Mix) along with any assistants* they may choose, to treat the following condition(s): Carotid artery blockage
- By doing this surgery or procedure on me: Place a stent in the carotid artery under flow reversal
- This is also known as: TransCarotid Arterial Revascularization (TCAR)
- Laterality: LEFT

*if you'd like a list of the assistants, please ask. We can give that to you.

**Patient information regarding TransCarotid Arterial Revascularization (TCAR)**

**Condition to be Addressed:**

You have been diagnosed with a blockage in the carotid artery, which supplies the brain and is a risk factor for a stroke. Your surgeon has recommended fixing this blockage with a small metal tube known as a stent. There are alternatives to TCAR such as using medications, placing a stent from the groin artery to the carotid artery, or a surgical procedure to clean out the blockage directly. Your surgeon feels TCAR is the safest way to deal with this blockage in your case.

**About TCAR Procedure:**

You will be admitted to the hospital and taken to an operating room. After you are made comfortable with anesthesia, the surgeon will make a small incision just above your collarbone to expose the carotid artery (Figure 1).

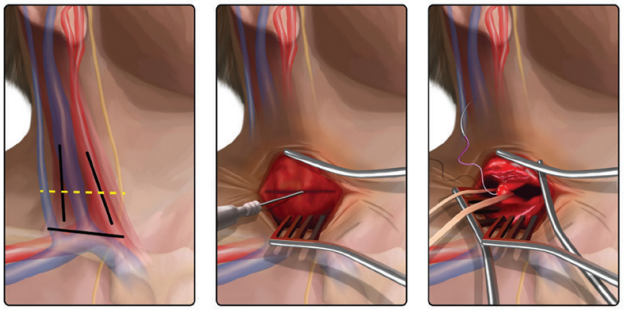

Figure 1. The carotid artery is exposed just above the collarbone.

After that, the surgeon will place a small catheter in your femoral (groin) vein (Figure 2). This catheter will be used to setup the flow-reversal which diverts blood from the carotid artery to the vein to keep any debris from getting dislodged and traveling to the brain.

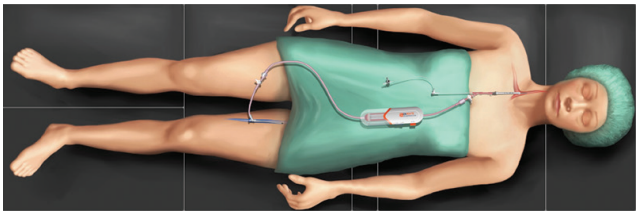

Figure 2. A catheter is placed in the carotid artery and femoral (groin) vein. This causes blood flow to temporarily flow away from the brain while the surgeon is working on the carotid artery. Any debris that is released is caught in a filter.

Once the catheters are in place, the blockage in the neck artery will be stretched with a balloon, and then covered with a small mesh metal tube called a stent (Figure 3). When this is complete, flow is restored to the brain. The catheters are then removed and the incision is closed up with sutures.

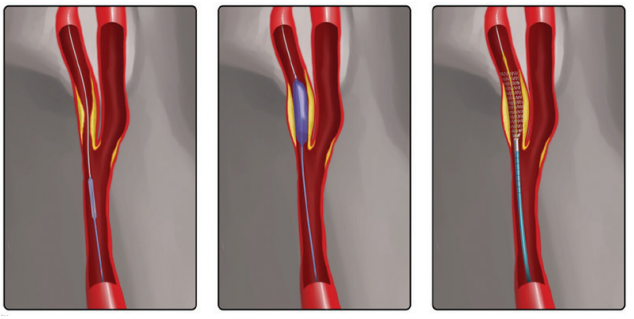

Figure 3. While blood is being diverted away from the brain, a small wire is used to cross the blockage. A balloon is temporarily inflated to push the blockage out of the way, then a stent is placed.

**Alternatives:**

There are several ways to treat a carotid artery blockage which include:

1. Medical treatment with blood thinners and drugs to improve cholesterol level
2. Placement of a stent routed from the femoral (groin) artery to the carotid artery
3. Carotid endarterectomy, which is a surgical procedure to open the carotid artery and clean out the blockage directly.

**Risks and Discomforts:**

**Stroke:** During the procedure there is a risk of stroke if material from your blood vessels should break off and travel to the brain. It is important to understand that while this procedure is designed to reduce your risk of stroke, there is a small risk of stroke associated with the surgery. Your surgeon feels that the risk of stroke is higher without surgery than with the surgery.

**Bleeding:** There is a risk during or after the procedure that either the carotid artery or femoral vein could bleed. This may result in the need for further surgery, blood transfusions or other procedures.

**Nerve Injury:** Temporary or permanent injury to nerves that lie next to the carotid artery could result in changes to your voice (hoarseness), difficulty swallowing or difficulty breathing. Nerve injury may require further surgery or procedures to address in some cases.

**Infection:** There is a risk that the incision or even stent could get infected. This could require additional medications or procedures to address.

**Need for a Prolonged Stay in the ICU:** This procedure is complex and as with any complex surgery there is a risk for you to become ill requiring prolonged complex medical care including, antibiotics, need for ventilator support, or need for a tracheostomy/feeding tube. Your family should know your wishes related to these treatments prior to your surgery.

**Figure 1. Informed consent document used at the URMC to facilitate SDM in patients undergoing TCAR procedure.**

**Reaction to the Intravenous Contrast Dye:** There is also a risk that you could have a reaction to the IV contrast dye given during the procedure. Sometimes this reaction is life threatening and could require that your breathing tube be kept in for a prolonged period of time. Sometimes the contrast dye can decrease your kidney function requiring need for temporary or permanent dialysis.

**Death:** This procedure is complex and involves changing the blood flow to your brain. Given the nature of this procedure there is a risk of death during the procedure related to the procedure itself or complications of the procedure. It is important to understand that the purpose of carotid repair is to prevent stroke and death but the procedure itself places you at risk for death. Your doctor has offered this procedure because he/she believes that the risk of not treating your carotid is greater than the risk of the surgery.

1. The care provider has explained my condition to me. They have told me how the procedure can help me. They have told me about other ways of treating my condition. I understand the care provider cannot guarantee the result of the procedure. If I don't have this procedure, my other choices are: No surgery with continued observation.
2. The care provider has told me the risks (problems that can happen) of the procedure. I understand there may be unwanted results. The risks that are related to this procedure include: Need for future revisions of implant due to leaks into aneurysm, excessive bleeding, infection of implant, paralysis, access site infection and/or wound break down in groins or neck, allergic reaction to contrast dye, kidney failure with potential need for temporary or lifelong dialysis, lung failure requiring dependence on ventilator or need for tracheostomy, heart attack, stroke, lowered or loss of blood flow to legs, blood clots in legs, pulmonary embolism, need for additional future or emergent procedures, death.
3. I understand that during the procedure, my care provider may find a condition that we didn't know about before the treatment started. Therefore, I agree that my care provider can perform any other treatment which they think is necessary and available.
4. I understand the care provider may remove tissue, body parts, or materials during this procedure. These materials may be used to help with my diagnosis and treatment. They might also be used for teaching purposes or for research studies that I have separately agreed to participate in. Otherwise they will be disposed of as required by law.
5. My care provider might want a representative from a medical device company to be there during my procedure. I understand that person works for: Representative from device company The ways they might help my care provider during my procedure include: providing information and support to hospital staff regarding the device, helping the OR staff prepare and other, including any hands on assistance (describe)
6. Here are my decisions about receiving blood, blood products, or tissues. I understand my decisions cover the time before, during and after my procedure, my treatment, and my time in the hospital. After my procedure, if my condition changes a lot, my care provider will talk with me again about receiving blood or blood products. At that time, my care provider might need me to review and sign another consent form, about getting or refusing blood.

I understand that the blood is from the community blood supply. Volunteers donated the blood, the volunteers were screened for health problems. The blood was examined with very sensitive and accurate tests to look for hepatitis, HIV/AIDS, and other diseases. Before I receive blood, it is tested again to make sure it is the correct type.

My chances of getting a sickness from blood products are small. But no transfusion is 100% safe. I understand that my care provider feels the good I will receive from the blood is greater than the chances of something going wrong. My care provider has answered my questions about blood products.

| | |
|---|---|
| **My decision about blood or blood products** | Yes |
| **My decision about tissue Implants** | N/A |
| **I understand this form.**<br>**My care provider or his/her assistants have explained:** | What I am having done and why I need it.<br>What other choices I can make instead of having this done.<br>The benefits and possible risks (problems) to me of having this done.<br>The benefits and possible risks (problems) to me of receiving transplants, blood, or blood products.<br>There is no guarantee of the results.<br>The care provider may not stay with me the entire time that I am in the operating or procedure room.<br>My provider has explained how this may affect my procedure. My provider has answered my questions about this. |

| | | | |
|---|---|---|---|
| **I give my permission for this surgery or procedure.** | _____<br>My signature (or parent or other person authorized to sign for you, if you are unable to sign for yourself or if you are under 18 years old) | _____<br>**Date** | _____<br>**Time** |

***Electronic Signatures will display at the bottom of the consent form.***

**Care provider's statement:** I have discussed the planned procedure, including the possibility for transfusion of blood products or receipt of tissue as necessary; expected benefits; the possible complications and risks; and possible alternatives and their benefits and risks with the patients or the patient's surrogate. In my opinion, the patient or the patient's surrogate understands the proposed procedure, its risks, benefits and alternatives.

| | | |
|---|---|---|
| Electronically signed by: Michael C Stoner, MD | 5/19/2020<br>**Date** | 8:50 AM<br>**Time** |

Electronically signed by Stoner, Michael C, MD at 5/19/2020 8:50 AM
*Note shared with patient*

# Playing Nice in the TCAR Sandbox

How to start and run a strong multidisciplinary TCAR program.

**BY MEGHAN DERMODY, MD, FACS, FSVS, AND TODD WOOD, MD, FACC, FSCAI, FSVM**

**Meghan Dermody, MD, FACS, FSVS**
Chief, Division of Vascular Surgery
Co-Medical Director, Interventional Vascular Unit
Lancaster General Hospital
Lancaster, Pennsylvania
meghan.dermody@pennmedicine.upenn.edu
*Disclosures: Clinical proctor for Silk Road Medical.*

**Todd Wood, MD, FACC, FSCAI, FSVM**
Chief Clinical Officer
Heart and Vascular Institute of Lancaster General Hospital
Chief
Division of Cardiology
Lancaster, Pennsylvania
todd.wood@pennmedicine.upenn.edu
*Disclosures: Common stock in Silk Road Medical.*

The transcarotid artery revascularization (TCAR) procedure was developed by vascular surgeons for vascular surgeons. Right? Well, like everything, it's complicated! As the era of transfemoral stenting goes by the wayside, given poorer stroke and complication rates, most vascular surgeons graduating from training programs in the United States do not meet hospital credentialing criteria for carotid stenting privileges due to low volume. Because of this, it can become difficult and political when attempting to start a TCAR program if the surgeon does not have carotid stenting privileges. Although one could argue that credentialing TCAR is very different than the transfemoral approach, despite this, roadblocks are everywhere and can seem daunting to a new attending surgeon. Without surgical training, TCAR cannot be performed, placing interventional cardiologists and radiologists in a difficult position to become capable of performing these procedures. We, at Lancaster General Hospital (LGH) in Lancaster, Pennsylvania, have approached TCAR in a multidisciplinary fashion, which we have found to be very rewarding. We share our experiences with the hope of expanding national viewpoints to performing TCAR across multiple disciplines.

## PROFESSIONAL STRUCTURE AND HOSPITAL CREDENTIALING

We are both employed physicians in separate practices but overall practice ownership is by the same system: Lancaster General Health, part of University of Pennsylvania Medicine. Cumulatively, we have performed 96% of our institution's cases, with the other 4% performed by two vascular surgeons and one interventional radiologist who are also credentialed in TCAR.

Dr. Dermody is a vascular surgeon who trained at the time TCAR received FDA approval, but never performed the procedure in her training and had < 10 transfemoral carotid stenting cases logged at the completion of her 2-year fellowship. She is board certified in general and vascular surgery. She currently serves as the Chief of the Division of Vascular Surgery and is the Co-Medical Director for the Interventional Vascular Unit at LGH.

Dr. Wood is an interventional cardiologist who did an additional vascular/endovascular medicine fellowship with extensive transfemoral carotid stenting training. He is board certified in cardiology, interventional cardiology, vascular medicine, and endovascular medicine. He currently serves as the Chief of the Division of Cardiology and Chief Medical Officer of the Heart and Vascular Institute.

When carotid stenting emerged as an entity, our institution addressed the "political" aspects of ownership of this field by stipulating a universal standard for carotid stenting privileges overseen by a governing body called the Multi-Disciplinary Angiography Committee (MDAC) outside of individual departmental/divisional control. Representation includes vascular surgery, interventional cardiology, interventional radiology, neurosurgery, and cardiothoracic surgery with a rotating chair. With the advent of TCAR and prior to any societal guidelines, this committee directed that TCAR requires inclusion of an operator with carotid stenting privileges via criteria outlined in previous multisocietal consensus documents. This position was further justified by the Centers for Medicare & Medicaid Services (CMS) reimbursement decision that TCAR falls under carotid stenting billing codes. MDAC is responsible for our TCAR program oversight and quality review.

## PREOPERATIVE COORDINATION

Once a patient has been diagnosed with carotid stenosis and referred to vascular surgery, the surgeon's office coordinates scheduling the operation, ordering (and following up) preoperative lab work, and obtaining insurance authorization. The surgeon also orders any necessary antiplatelet medication and coordinates cessation of other anticoagulation, as needed. Our collaborative involvement allows for nuanced management of antiplatelets and anticoagulants on the fly without necessitating separate cardiology/hematology/primary care consultation. Preoperative cardiac consultation is rarely required with direct cardiology involvement and for us has been limited to very high-risk cardiac patients, such as advanced heart failure.

If a patient is already followed by cardiology, generally speaking, carotid ultrasounds are performed through their practice until the study indicates severe stenosis. At this time, the cardiologist will usually evaluate the cases with Dr. Wood and order a CTA neck prior to referring the patient to surgical consultation. It is notable that this operational relationship has essentially captured the referral stream of nearly 30 cardiologists and their 20 nurse practitioners, as well as an almost 100% conversion of Dr. Wood's prior transfemoral carotid stenting cases over to TCAR. In a similar light, approximately 80% of Dr. Dermody's carotid interventions are now performed via TCAR rather than endarterectomy.

Should a patient present to the hospital with an acute stroke due to symptomatic carotid stenosis, the neuroradiology team will often consult surgery for TCAR planning. In these cases, we usually coordinate the procedure with an interventional radiologist to keep established care paths in line. Given the lack of blocked hybrid operating room (OR) time at our institution, the surgeons' and interventionalists' procedure schedulers work together months in advance to coordinate set days in the OR for TCAR procedures to occur. We usually book four procedures per day and have, on average, 3 full days per month to perform TCAR.

## INTRAOPERATIVE NUANCES

We perform nearly every TCAR under conscious sedation with either propofol or dexmedetomidine infusion and local anesthesia to the tune of 80% of total cases to date, with most of the 20% general anesthesia cases being early experience cases. After the time out, ultrasound is used to visualize the common carotid artery (CCA) and bifurcation, in an effort to plan out the incision. The surgeon begins with the carotid artery dissection. During this time, the interventionalist obtains ultrasound-guided contralateral femoral venous access. Once the artery is ready for puncture and systemic anticoagulation has been established, the surgeon punctures the CCA and threads the wire. The interventionalist assists in retracting the artery and manipulating the J wire during the sheath placement, making the most of short runways. With that, and with other two-operator techniques such as "telescoping" the sheath over a fixed position dilator, we are able to use a stop-short technique 80% of the time, which is well above the national average. Once in place, we switch sides of the table and the interventionalist takes over with angiography and wiring the lesion after clamp placement by the surgeon. The interventionalist performs the endovascular portion of the procedure; however, selection of the balloon and stent sizes is mutual. Wire management and equipment exchanges are brisk, with two sets of experienced hands manning the intervention. We have adopted some coronary techniques, including the use of high-pressure coronary noncompliant balloons for calcified lesion preparation and to deliver focused force on the underexpanded portion of the stent to avoid "dog-bone" balloon expansion. We also have a very low threshold to postdilate, particularly in the presence of calcium, performing pre and postdilation 76% of the time; again, well above national average. The use of coronary balloons also affords very precise sizing with balloons available down to quarter millimeter increments. We have experienced zero dissections or other balloon-related complications with our approach. We also have a wealth of 0.014-inch wires available from the coronary space but tend to use the provided wire predominantly. We have incorporated the use of a metal wire introducer, commonly used in cath labs with a Touhey, to significantly reduce the friction on the wire. This "defeats" the sheath's hemostatic valve, greatly improving torque control of the wire and ease of lesion traversal. After stent deployment and possible poststent angioplasty, the clamp is removed and we switch sides of the table again. Protamine is started during this time. The access is then removed by the surgeon who ties the purse-string suture down, obtains hemostasis, and closes the incision. During incision closure, the interventionalist removes the venous sheath and holds manual pressure. The incision is usually closed around the time that hemostasis is obtained in the groin, which allows for less overall operative time.

## POSTOPERATIVE MANAGEMENT

The surgeon writes all postoperative orders and dictates a standard operative note. The interventionalist dictates the angiography portion of the procedure within our imaging software application (McKesson). The patient is admitted to the vascular surgery service, which solely takes care of the patient postoperatively through discharge and follow-up. An ultrasound of the stent is ordered 3 weeks postop and is usually coordinated with same-day surgical

*(Continued on page 29)*

# Data Update From the VQI Registry

**WITH PATRIC LIANG, MD; MARC L. SCHERMERHORN, MD; HANAA DAKOUR-ARIDI, MD; MAHMOUD B. MALAS, MD, MHS, FACS; AND SCOTT S. BERMAN, MD, MHA, RVT, FACS, DFSVS**

**Patric Liang, MD**
Vascular Surgery Resident
Beth Israel Deaconess Medical Center
Fellow
T32 Harvard-Longwood Vascular Surgery Research Training Program
Boston, Massachusetts
*Disclosures: None.*

**Marc Schermerhorn, MD**
George H.A. Clowes Jr. Professor of Surgery
Harvard Medical School
Chief, Vascular and Endovascular Surgery Department
Beth Israel Deaconess Medical Center
Boston, Massachusetts
*Disclosures: Consultant for Silk Road Medical, Abbott Vascular, Cook Medical, Endologix, and Medtronic.*

The Vascular Quality Initiative transcarotid artery revascularization (VQI TCAR) Surveillance Project registry captures > 95% of all TCAR with flow reversal neuroprotection procedures performed in the United States. Given the detailed nature of this registry, which contains more than 200 patient- and procedure-specific variables, robust statistical comparisons can be made with other carotid revascularization procedures in the VQI. In particular, transfemoral carotid artery stenting procedures are captured in the VQI and its registry contains identical variables as those used in the TCAR registry. Therefore, utilizing propensity-score matched statistical methods, we have been able to carefully match patients on > 30 unique variables to compare stroke or death outcomes between similar patients undergoing the two methods of carotid stenting. The variables captured in the VQI not only include baseline comorbid conditions, such as presenting stroke severity, age, gender, race, coronary artery disease, congestive heart failure, or preoperative medication use (ie, aspirin, P2Y12 inhibitors or statins), but also contain details on physician and center volume data to account for carotid stenting experience.

In a recent peer-reviewed publication in *JAMA*, we detailed a propensity-matched analysis of 5,251 and 6,640 patients in the VQI who underwent TCAR and transfemoral carotid artery stenting, respectively, from

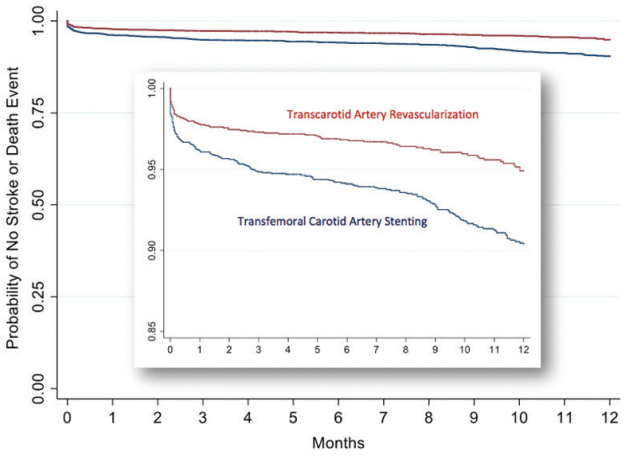


**Figure 1. Kaplan-Meier estimated freedom from stroke or death event in patients undergoing TCAR or transfemoral carotid artery stenting in a propensity score-matched study population.**

September 2016 to April 2019.[1] This analysis resulted in 3,296 matched pairs of patients, of which the mean age was 72 years, 35% were women, and 55% were treated for symptomatic carotid disease. We found that TCAR was associated with a significantly lower risk of both the combined endpoint of in-hospital stroke or death (1.6% vs 3.1%; relative risk [RR], 0.51; 95% CI, 0.37-0.72; $P < .001$), as well as the individual in-hospital endpoints of stroke (1.3% vs 2.4%; 95% CI, 0.38-0.79; $P = .001$) and death (0.4% vs 1%; RR, 0.44; 95% CI, 0.23-0.82; $P = .008$). Using Kaplan-Meier life-table estimation methods, we also found that the benefit for stroke or death with TCAR persisted up to 1-year follow-up, as TCAR was associated with a higher freedom from stroke or death events (94.9% vs 90.5%; hazard ratio [HR], 0.52; 95% CI, 1.02-2.61; $P < .001$) (Figure 1).

The lower risk of stroke or death after TCAR was found to be statistically significant in treatment of symptomatic patients (2.1% vs 4.2%; RR, 0.51; 95% CI, 0.35-0.75; $P < .001$), but not statistically different for treatment of asymptomatic patients (1% vs 1.5%; RR, 0.56; 95% CI, 0.26-1.20; $P = .13$). However, the effect size and direction favoring TCAR was similar to that of symptomatic patients, but with lower event rates, indicating that more patients would be needed to prove a statistical difference. These statistical discrepancies mirror findings from randomized trials in which statistically significant differences in stroke or death rates after transfemoral carotid stenting

**TABLE 1. PERIOPERATIVE IN-HOSPITAL OUTCOMES AFTER TCAR WITH AND WITHOUT PROTAMINE USE IN A PROPENSITY SCORE-MATCHED STUDY POPULATION**

| | No Protamine (N = 944) | Protamine (N = 944) | Relative Risk | *P* Value |
|---|---|---|---|---|
| Access site bleeding complication | 8.3% | 2.8% | 0.3 (0.2-0.5) | < .001 |
| Resulting in interventional treatment | 3.6% | 1.0% | 0.3 (0.1-0.5) | < .001 |
| Resulting in blood transfusion | 3.9% | 1.2% | 0.3 (0.2-0.5) | < .001 |
| Stroke or death | 2.2% | 1.6% | 0.7 (0.4-1.4) | .32 |
| Stroke | 2.0% | 1.1% | 0.5 (0.2-1.1) | .09 |
| Death | 0.7% | 0.5% | 0.7 (0.2-2.3) | .56 |
| Transient ischemic attack | 1.1% | 0.4% | 0.4 (0.1-1.3) | .11 |
| Myocardial infarction | 0.8% | 0.4% | 0.5 (0.2-1.7) | .25 |
| Congestive heart failure | 0.3% | 0.4% | 1.3 (0.3-6.0) | .71 |

compared with endarterectomy have been predominately demonstrated in trials of symptomatic disease and not in those of asymptomatic disease.[2-4]

A criticism of the transcarotid approach to carotid stenting is the need for a surgical incision, albeit an incision that is more minimally invasive than that for endarterectomy and one that obviates the need to manipulate multiple cranial nerves. Having to make a surgical incision rather than a percutaneous transfemoral puncture increases the risk of incision-related complications and, compared with those undergoing transfemoral carotid stenting, patients undergoing TCAR have higher associated rates of bleeding complications resulting in reintervention (1.3% vs 0.8%; RR, 1.63, 95% CI, 1.02-2.61; *P* = .04).[1] However, we found that nearly 21% of patients undergoing TCAR during our study period did not receive protamine. Protamine has been commonly used for heparin reversal in endarterectomy and has shown to be associated with decreased risk of bleeding complications without an increase in thromboembolic events.[5]

Utilizing the VQI, we also evaluated outcomes after protamine use in TCAR in a propensity score-matched patient population and found that protamine use was also associated with a significantly lower risk of bleeding complications (2.8% vs 8.3%; RR, 0.33; 95% CI, 0.21-0.52; *P* < .001), including bleeding that resulted in interventional treatment (1% vs 3.6%; RR, 0.26; 95% CI, 0.13-0.54; *P* < .001) and in blood transfusion (1.2% vs 3.9%; RR, 0.30; 95% CI, 0.15-0.58; *P* < .001), without any difference in in-hospital stroke or death (1.6% vs 2.2%; RR, 0.71; 95% CI, 0.37-1.39; *P* = .32) or other thromboembolic events.[6] Interestingly, we found a trend toward a lower risk of stroke in patients who received protamine (1.1% vs 2.0%; RR, 0.53; 95% CI, 0.24-1.13; *P* = .09), stressing the critical relationship between perioperative bleeding complications and stroke risk in carotid revascularization procedures. This study underscores the importance for TCAR users to routinely administer protamine after TCAR to help further decrease the risk of perioperative bleeding and strokes associated with the procedure.

There are currently no prospective, randomized trials comparing TCAR and transfemoral carotid artery stenting, and it is unlikely that such a trial will be designed based on the results of several pivotal trials documenting the increased stroke risk of transfemoral carotid stenting compared with endarterectomy.[2,3,7-9]

Future randomized studies should rather be aimed at comparing TCAR with endarterectomy or with medical management in asymptomatic patients. Nonetheless, based on data from our well-matched retrospective VQI data analysis, TCAR should largely replace transfemoral carotid artery stenting as the preferred carotid stenting approach, particularly in those who are symptomatic or at high surgical risk.

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# A New Era Of Endovascular Treatment Of Carotid Artery Stenosis?

**Hanaa Dakour-Aridi, MD**
Division of Vascular and Endovascular Surgery
University of California San Diego
La Jolla, California
*Disclosures: None.*

**Mahmoud B. Malas, MD, MHS, FACS**
Division of Vascular and Endovascular Surgery
University of California San Diego
La Jolla, California
malas@me.com
*Disclosures: Site principal investigator for ROADSTER 1 and ROADSTER 2; national principal investigator for the ROADSTER 1 long-term follow-up study.*

Since its introduction, TCAR has shown promising outcomes in high-risk patients with carotid artery stenosis.[1,2] TCAR offers a hybrid surgical and endovascular intervention in high-risk patients and mitigates the maneuvers associated with the increased stroke risk during transfemoral carotid artery stenting (TFCAS). In the pivotal United States FDA approval trial (ROADSTER 1), the overall stroke rate after TCAR using the ENROUTE® Transcarotid Neuroprotection System (Silk Road Medical) was 1.4%, the lowest reported stroke rate to date for any prospective, multicenter clinical trial of carotid stenting.[1] These favorable outcomes extended to 1 year after the procedure.[2] In the ROADSTER 2 study, which evaluated real-world usage of the ENROUTE® System in 632 high-surgical-risk patients, the combined 30-day stroke/death rate was 1%. The reported success rate was high despite that the fact that most operators (80%) were new TCAR operators.[3]

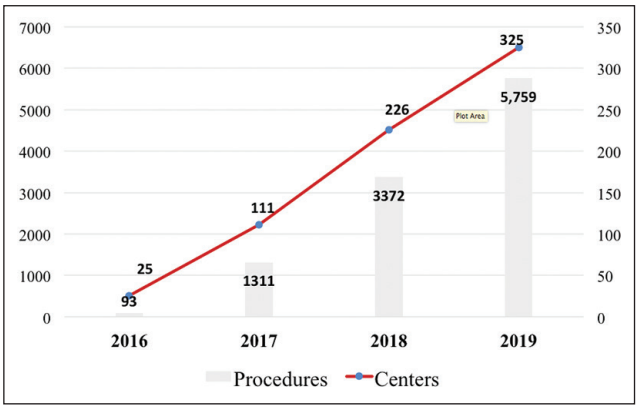


**Figure 1. Number of centers participating in the TCAR Surveillance Project between September 2016 and December 2019.**

The Center for Medicare & Medicaid Services (CMS) covers TCAR for patients in any institution who meet criteria for high surgical risk, are symptomatic, and have ≥ 70% stenosis. However, reimbursement could also be achieved for institutions approved for the VQI TCAR Surveillance Project, a postmarket quality initiative by the Society of Vascular Surgery in collaboration with the FDA and CMS to evaluate the outcomes of TCAR in real-world clinical practice. The

**TABLE 1. UNADJUSTED AND ADJUSTED ANALYSIS COMPARING TRANSCAROTID ARTERY STENTING WITH CEA**

| | Unadjusted Outcomes | | | Adjusted Outcomes* | |
|---|---|---|---|---|---|
| | CEA (N = 10,797) | TCAR (N = 1, 182) | | TCAR vs CEA | |
| | *Count (%)* | *Count (%)* | *P Value* | *OR (95% CI)* | *P Value* |
| Stroke/death | 1.4 | 1.6 | 0.33 | 1.3 (0.8-2.2) | 0.28 |
| Stroke/death/myocardial infarction | 1.9 | 2.5 | 0.16 | 1.4 (0.9-2.1) | 0.18 |
| Stroke | 1.2 | 1.4 | 0.33 | 1.4 (0.8-2.5) | 0.26 |
| In-hospital death | 0.3 | 0.3 | 0.88 | 0.7 (.3-2.1) | 0.58 |
| 30-day death | 0.4 | 0.9 | 0.06 | 1.5 (0.7-3.2) | 0.34 |
| Myocardial infarction | 0.6 | 1.1 | 0.11 | 1.5 (0.7-2.9) | 0.29 |

*Variables adjusted for: age, sex, ethnicity, symptom status, hypertension, COPD, CKD, prior smoker, current smoker, prior limb amputation, prior ipsilateral CAS or CEA, aspirin, platelet inhibitor, statin, and angiotensin-converting enzyme inhibitor use. (Data compiled from Schermerhorn et al., J Vasc Surg. 2020)[7]

VQI TCAR Surveillance Project thus allowed institutions to offer TCAR for a wider range of high-risk patients, including those who are symptomatic with ≥ 50% stenosis or are asymptomatic with ≥ 80% stenosis.[4] This is shown by the exponential increase of centers performing TCAR between September 2016 through December 2019 (Figure 1).

Initial data from the VQI TCAR Surveillance Projects showed a significant reduction in the risk of adverse neurological events after TCAR compared with TFCAS.[5] In a recent study from *JAMA*, TCAR was associated with a 49% reduction in the risk of stroke or death compared with TFCAS,[6] thus making TCAR a safe and durable revascularization option for patients who require a carotid revascularization procedure but who are at high risk for carotid endarterectomy (CEA). On the other hand, comparison of the outcomes of TCAR and CEA showed similar in-hospital stroke/death rates between the two procedures, despite a substantially higher medical risk in patients undergoing TCAR (Table 1). TCAR was also associated with lower rates of cranial nerve injury.[7]

The applicability of TCAR in patients with carotid occlusive disease and high-risk anatomic features continues to expand. TCAR has been shown to be safe in elderly patients and in patients with contralateral carotid artery occlusion.[8,9] Moreover, in a small institutional series, TCAR was shown to be safe in patients with restenotic carotid arteries with acceptable rates of ipsilateral stroke, myocardial infarction, and death.[10] Pending long-term results from the VQI TCAR Surveillance Project and ROADSTER 2 trial, more evidence-based data will be available to guide clinical decision-making within the next decade.

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## Impact Of Real-World Data On Clinical Vascular Surgery Practice

**Scott S. Berman, MD, MHA, RVT, FACS, DFSVS**
Director of Vascular Quality and Noninvasive Vascular Lab
Pima Heart and Vascular
Tucson, Arizona
*Disclosure: Member of the Silk Road Medical TEST DRIVE faculty and proctor for the TCAR procedure.*

The TCAR procedure is an alternative approach to carotid bifurcation stenting that received FDA approval (for the ENROUTE® Neuroprotection System) in September 2015. Following the procedure's approval, the unique relationship between Silk Road Medical (the company who brought the technology to the United States market), the CMS, and the VQI (the database of the Society for Vascular Surgery's Patient Safety Organization [PSO]) led to reimbursement for TCAR for high-surgical–risk patients contingent upon data entry into the VQI TCAR Surveillance Project in September 2016. Payment by CMS for the TCAR procedure for patients who met inclusion criteria was conditional upon participation by the institution in the carotid stenting module of the VQI. One of the unique characteristics of the VQI when compared with other procedural data registries is the requirement for long-term follow-up with a window of 9 to 21 months after the date of service for the index procedure. The result of this exclusive relationship is an enlarging, prospective data set of approximately 95% of the TCAR procedures performed in the United States collected within the VQI, which allows for contemporaneous comparisons of TCAR to not only carotid artery (CAS) stenting performed via TFCAS, but also to CEA.

One of the obvious challenges of such comparisons arises from the differences in volume of cases collected within the VQI for each procedure. When the VQI was incorporated into the PSO in 2009, CEA and CAS procedures were part of the initial modules available, thus resulting in 7 years of data collection for TFCAS and CEA ahead of the TCAR procedure. To address the differences in volume when performing statistical comparisons, investigators will use a technique known as propensity matching to develop data sets for comparison that only differ by the treatments being assessed. Specifically, each subject is assigned a propensity score based-upon presence and distribution of attributes. Subjects in each group are then matched by propensity score. This produces two groups who are similar in covariate attributes, but only differ by the treatment they received. This technique was employed by Malas et al

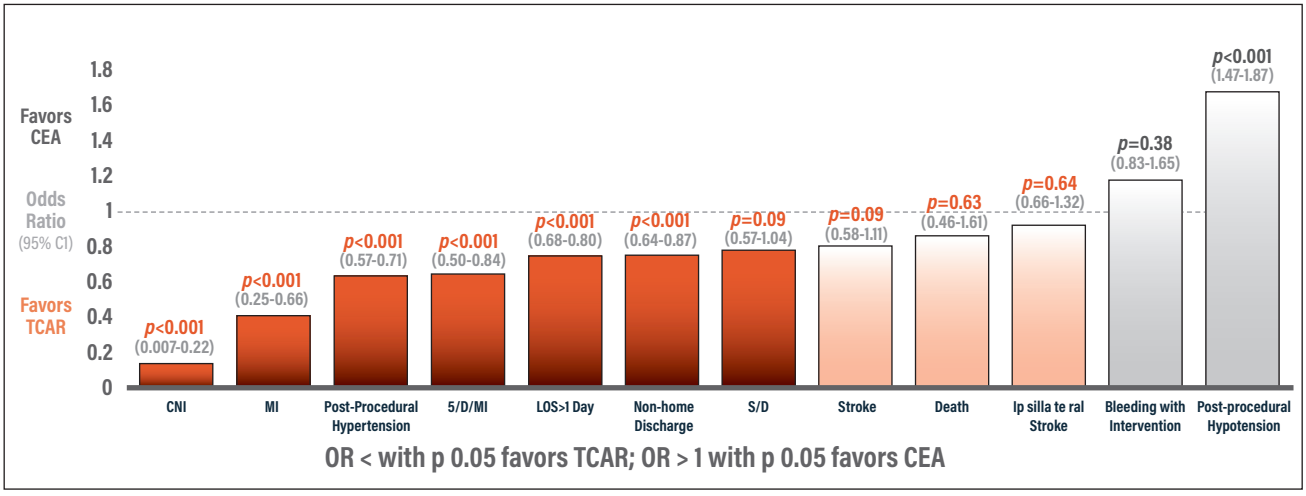


**Figure 1. Propensity matching results in patients in each of the TCAR and CEA groups.**

in their recent publication comparing TCAR to CEA using VQI data as part of the TCAR Surveillance Project.[1]

At the time of the data review, there were 5,716 TCAR procedures and 44,442 CEA procedures in the VQI CAS and CEA modules, respectively. A direct comparison of the full data set yielded a stroke and death rate of 1.5% for TCAR and 1.4% for CEA ($P$ = .67) as published by Schermerhorn et al.[2] It was estimated that 57,942 patients per group would be required to detect a statistical difference for this outcome within a randomized controlled trial. The statistical technique of propensity match was thus applied to provide a more meaningful comparison and eliminate the effect of disparate sample size. The two groups were then matched based upon symptomatic status, age, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, chronic kidney disease, previous ipsilateral CEA, previous ipsilateral CAS, contralateral occlusion, aspirin class, and statin use. Propensity matching resulted in 5,160 patients in each of the TCAR and CEA groups. The results are summarized in Figure 1. Compared with CEA, TCAR was more favorable in regard to incidence of cranial nerve injury, myocardial infarction (MI), postprocedural hypertension, stroke/death/MI, length of stay > 1 day, and nonhome discharge.

For the practicing vascular surgeon, the results of propensity matching of TCAR versus CEA are compelling. CEA, long considered the gold standard for care of carotid bifurcation disease and arguably one of vascular surgery's centerpiece operations for more than 60 years, is now facing competition regarding safety and efficacy for standard-risk patients by the TCAR approach to carotid stenting. Historically, TFCAS has never been able to achieve equipoise to CEA. Data from the VQI TCAR Surveillance project not only show superiority of TCAR over TFCAS for traditional indications for carotid stenting, but now provide evidentiary support to potentially expand the indication to standard-risk patients who currently do not meet the high-risk inclusion criteria for TCAR. In my own practice, the outcomes of TCAR have been so compelling, combined with the VQI TCAR Surveillance Project results, that I have virtually abandoned TFCAS for any patient who otherwise meets current criteria for TCAR. Based upon the propensity matching data for TCAR versus CEA, I would welcome the opportunity to offer TCAR to standard-risk patients who meet anatomic criteria. ■

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# The Cadence of the TCAR Procedure

## WITH DOUGLAS MASSOP, MD, AND FRANK R. ARKO, III, MD

**Douglas Massop, MD**
Vascular Surgeon
The Iowa Clinic
Des Moines, Iowa
dmassop@iowaclinic.com
*Disclosures: Consultant and proctor for Silk Road Medical.*

In simplest terms, a *cadence* is defined as a rhythmic sequence. Within a medical therapeutic environment, a cadence refers to the frequency, format, and sequence with which a manager/operator meets with the individuals on their team to achieve common goals, teach all aspects of the intervention, and define the attributes of the interaction to ensure satisfactory results. With the transcarotid artery revascularization (TCAR) procedure, the team's common goal is to efficiently reduce the risk of procedural and long-term stroke compared to best medical therapy. This efficiency is optimally displayed in the procedural speed, fluidity, team confidence, and the perioperative and long-term results of the intervention.

Attaining optimal cadence for the TCAR procedure can be divided into multiple areas of consideration. These include (1) the preoperative evaluation of the patient and relevant noninvasive imaging to have a good understanding of what is being treated and how to approach the lesion in question, (2) the preoperative teaching of staff for their important role as a therapeutic team member and having appropriate equipment available, (3) the preoperative/intraoperative teaching of anesthesia staff and their very important role in the successful outcome of the procedure with their hematologic and physiologic assistance, and (4) the combined efficient completion of the procedure by the entire team and the importance of this for a successful short and long-term outcome for the mutual satisfaction of the patient and operator.

### PREOPERATIVE EVALUATION

The preoperative evaluation will typically first focus on the indication for a carotid intervention based on the patient's history, examination, and carotid duplex. If the patient appears to be a good candidate for the TCAR procedure, a CTA examination will typically be performed. The combination of the duplex and CTA will offer information of the quality of the arch inflow; the length, diameter, and quality relationships of the common carotid artery; the procedural considerations for the lesion being treated (quality of the plaque and the wire crossability of the lesion); and the quality of collateral flow intracranially for flow reversal. This information is critical to placement of the arterial access sheath, optimal angle of therapeutic imaging, sizing of percutaneous transluminal angioplasty (PTA) predilatation, and sizing of stent. All this information should be considered prior to going to the operating room. All sizing choices regarding PTA balloons and stents should be made preoperatively and not intraoperatively.

### PREOPERATIVE TEACHING OF STAFF

The preoperative teaching of staff must ensure that all equipment is available for the procedure. This will include the intraoperative ultrasound, appropriate drapes for the access sites, ACT machine and cuvettes, heparin dosing, separate micropuncture kit for venous access, proprietary Silk Road Medical flow reversal kits, and an adequate selection of 0.014-inch access wires, PTA monorail balloons, and stents. The operative staff will typically have experience with 0.035-inch wires and over-the-wire systems for aortic endografting. However, they may have little understanding of monorail 0.014-inch systems. They should be instructed on the fundamentals of monorails systems and the length relationships of the arterial sheath (33 cm from tip to diaphragm) and of the monorails balloons/stents (22 cm from tip to wire exit). The entire team should also understand the absolute importance of the depth of the wire relationships. The 0.035-inch J-wire needs deliberate placement—either short (just below the lesion) or long (well into the external carotid artery) as the lesion being treated allows. Furthermore, once the lesion is crossed with the therapeutic 0.014-inch wire, there should be a good understanding of the depth of position of this wire to maintain access but not cause intracranial complication. The goal should be to maintain the weld-point junction at the base of the skull, with the floppy platinum portion in the petrous portion of the internal carotid and the stiff portion in treated cervical carotid.

### PREOPERATIVE/INTRAOPERATIVE TEACHING OF ANESTHESIA STAFF

It is essential to ensure the preoperative teaching of the anesthesia staff regarding the importance of an arterial blood pressure line in the appropriate extremity for reliable continuous measurement of central arterial pressure. Their role in the maintenance of adequate rate/blood pressure product (rate > 70 and blood pressure

> 140-160/70) is essential to flow reversal. They need to understand that heparin needs to be given at the time of the neck incision to avoid procedural delay. Also, we frequently give glycopyrolate prior to carotid manipulation to support heart rate. Approximately 3 minutes after heparin administration, an ACT should be checked. The ACT goal should be > 250 seconds at the time of carotid intervention. When the procedure is completed, protamine should be given due to the short length of the procedure. There are ample data that this will lower the bleeding rate but not adversely affect the stroke rate. A test dose of protamine should be given first and then the therapeutic ½ reversal dose relative to the amount of heparin given.

## EFFICIENT COMPLETION OF THE PROCEDURE

If these first three categories are well understood and taught to all team members, the efficient completion of the case is likely. During proctoring experiences that we have witnessed, the main limitation of efficient and successful outcome falls short when these foundational minimums have not been addressed.

Once the patient is prepared and draped, intraoperative ultrasound should be used for the following four reasons.

*Reason 1.* The accuracy of venous puncture in the groin is improved. If patients are obese, the early saphenous vein can be punctured and used as a safer more superficial site of venous access. The tip of the 8-F venous sheath will still be in the external iliac vein for optimal reversal flow.

*Reason 2.* The position of the carotid can be marked on the skin relative to the clavicle and window between the sternocleidomastoid heads. Confidence is gained from observing the relationship of the carotid to the jugular and the musculoskeletal landmarks. I find this helpful for operators' early cases, especially on the left side where the artery is deeper.

*Reason 3.* Examine the site of sheath entry for a quick recheck for any calcification and overall quality of artery.

*Reason 4.* Assess the carotid bifurcation with the patient in the surgical position to predict the best orthogonal angle of imaging. This facilitates obtaining a best-quality digital subtraction angiography (DSA) and avoids unnecessary multiple injections to find this angle.

The efficient steps of optimal imaging are as follows. We typically perform five DSA runs to do the TCAR procedure. Each of these is performed with 3-5 mL of half-strength contrast. The assistants/technicians for the procedure need to understand that the contrast syringes need to be drawn up gently so that air is not sonicated in the contrast. We typically draw up our five syringes early and let them lay on the field so that any microbubbles can come out of solution prior to use.

*DSA 1.* An initial arterial micropuncture image needs to be obtained in a plane perpendicular to the carotid bifurcation and is determined by the preoperative ultrasound. This image will guide the insertion of the 0.035-inch J-wire for placement of the arterial sheath.

*DSA 2.* Once the arterial sheath is placed, the opposite orthogonal view will show the relationship of the sheath tip to the back wall of the common carotid artery to be sure that the arterial access is uncomplicated.

*DSA 3.* An ipsilateral oblique working view with the image intensifier close to the patient will show the treatment site from the tip of the sheath to the base of the skull with the bifurcation profiled to ease lesion crossing of the working 0.014-inch wire.

*DSA 4 and 5.* Bi-plane completion views after PTA and stenting to be sure the stent is fully opened and no complications are noted.

A helpful hint is that once the stent is deployed and we are waiting the mandatory reversal time for clearance of possible debris, orthogonal noncontrast images of the stent can be taken to see if the stent is fully opened. If needed, larger poststent PTA balloons can be selected, prepared, and deployed. This is needed in only approximately 5% of cases.

Another very important consideration is the appropriate shaping of the 0.014-inch working wire. The operator needs to consider the bias of the arterial sheath relative to the axis of the common carotid artery and how that will affect the delivery of the wire from the sheath toward the lesion being crossed. Furthermore, the actual course of the true lumen through the lesion needs to be assessed to properly shape the wire tip for a highly successful first attempt at lesion crossing.

When these tenants are followed, we typically find that flow reversal times are < 7-8 minutes and total procedural times are < 60 minutes. This can easily occur with no one feeling rushed. The cadence of the procedural completion occurs in a relaxed and successful team environment.

## TCAR Cadence in the Carolinas

**Frank R. Arko III, MD**
Chief, Vascular and Endovascular Surgery
Professor, Cardiovascular Surgery
Co-Director, Aortic Institute
Sanger Heart and Vascular Institute
Atrium Health
Charlotte, North Carolina
frank.arko@carolinashealthcare.org
*Disclosures: Consultant to Silk Road Medical.*

As has been discussed, the cadence and understanding of a procedure is paramount to maximizing the preferred outcomes while implementing it through the group to increase efficiency and improve quality. I certainly agree with all of Dr. Massop's thoughts as well as his methodology for completing TCAR, with a few minor caveats.

### OUR EXPERIENCE

A brief history of our TCAR procedure is helpful in understanding where we were and how we got to where we wanted to be, and will enlighten the reader to any potential learning curves, as well as how to navigate any potential credentialing issues that may be roadblocks. Our initial experience was part of the ROADSTER 2 trial, as well as the enrollment in the Vascular Quality Initiative. The standard proctoring as part of the ROADSTER 2 trial was the initial experience for learning TCAR. I had at the time full credentials for transfemoral carotid stenting. Three different proctors were utilized during the initial phase in of the trial. Each proctor had a different cadence and steps for the procedure and each one was successful. After this roll in phase, I then proctored those in the group as part of the trial. Our group consisted of three surgeons at the time with transfemoral carotid artery stenting (CAS) privileges. Credentialing required a total of 20 CAS as the primary or assistant operator, with 10 as the primary surgeon. During introduction of TCAR to our group of surgeons, we had three with CAS priviliges. With a total of 10 surgeons in the group we wanted to train each surgeon who had a robust carotid practice. Thus, we had to train a total of seven surgeons. Over the 4 year period, we have trained all of them but one, who is just four procedures short of getting full credentials. The reason for training all was due to the fact that each surgeon in the group had a robust carotid practice, and we believed that this was a procedure that was safe, effective, and important in the management of certain patients with carotid disease. Over a 4-year period, six of the seven were trained and credentialed, with the last one very close, and most have adopted a single method of doing the procedure. We believed that adopting a single method was important as we have nearly standardized our methodology for CEA as well to reduce variance. Table 1 shows the number of cases of TCAR and CEA performed by our group over a 24-month time frame, demonstrating the location and outcomes at three hospitals of varying size (300 to 1,000 beds) for both asymptomatic and symptomatic patients (not separated).

Dr. Massop lists these four criteria to obtain optimal cadence for TCAR and I wholeheartedly agree: (1) the preoperative evaluation of the patient and relevant noninvasive imaging to have a good understanding of what is being treated and how to approach the lesion in question, (2) the preoperative teaching of staff for their important role as a therapeutic team member and having appropriate equipment available, (3) the preoperative/intraoperative teaching of anesthesia staff and their very important role in the successful outcome of the procedure

**TABLE 1. TCAR AND CEA CASES PERFORMED OVER A 24-MONTH PERIOD**

| | TCAR | | | |
|---|---|---|---|---|
| Operator (Time frame) | Volume | Mortality | Stroke | Myocardial Infarction |
| CMC (1/18-4/20) | 89 | 0 | 1 | 0 |
| PV (1/19-4/20) | 19 | 0 | 0 | 0 |
| NE (1/19-4/20) | 36 | 0 | 0 | 0 |
| | CEA | | | |
| CMC (1/18-4/20) | 232 | 1 | 2 | 0 |
| PV (1/19-4/20) | 102 | 0 | 1 | 0 |
| NE (1/20-4/20) | 18 | 0 | 0 | 0 |

with their hematologic and physiologic assistance, and (4) the combined efficient completion of the procedure by the entire team and the importance of this for a successful short and long-term outcome for the mutual satisfaction of the patient and operator.

## OUR TCAR PROCEDURE

Our preoperative evaluation of the patient includes appropriate noninvasive imaging, as well as CTA of the head and neck to look at both the characteristics of the lesion and the access vessel of the carotid, as well as the intracranial circulation. Preoperative medications for TCAR are standardized across the group with protocols, including a high-dose statin if the patient is not currently on statin therapy as well as dual antiplatelet therapy with aspirin and clopidogrel. Our preference is for 7 days of clopidogrel therapy prior to the procedure. We also agree with the pre-decision planning with review of the preoperative CTA. Based on the CTA, the size of the balloon is determined, as well as the size and length of the stent that will be used. We no longer use ultrasound prior to intervention in the operating room because it adds time and does not offer anything over the preoperative CTA.

We continue to perform all cases under general anesthesia, with patients receiving an arterial line but we do not use a Foley catheter. All patients are premedicated at the start of the procedure with glycopyrrolate if there are no contraindications. We use a small longitudinal incision just above the clavicle. The carotid is dissected out and encircled with a vessel loop. The patient is systemically anticoagulated with 100 U/kg of heparin while simultaneously gaining venous access under ultrasound guidance. The sheath is then flushed. Concurrently, we aim for a mean arterial pressure of 100 mm Hg or a systolic pressure of ≥150 mm Hg. We do not place a Prolene suture (Johnson & Johnson) prior to accessing the carotid artery. Because every procedure is performed similarly, the anesthesia team, as well as the operating room team and our cardiac catheterization team, are simultaneously doing their respective portions of the procedure.

Preoperative teaching of the anesthesia team, operating room team, and catheterization lab team has been instituted in the past but even prior to the procedure a team huddle is utilized to go over the steps, including the hemodynamics and the sizes of the balloons and stents to be chosen. The stent and balloon are opened for predilatation and the wire of choice is preloaded onto the rapid exchange balloon, simultaneous to the cutdown and the venous access sheath.

The carotid artery is then accessed with the micropuncture set. Arteriography is then performed. We use only a single plane and the angle chosen is again based on the preoperative imaging. We do not do two-plane angiography to assess for dissection because we believe our technique has improved since the very early learning curve that we no longer have dissection.

We mark the bifurcation and typically use the stiff wire to land short of the bifurcation. We always predilate entry into the carotid with venous sheath dilator. We then place the flow reversal catheter, suture it in, and place the proximal clamp. We always use high flow on the reversal and flow reversal is evaluated and confirmed prior to crossing. We do use cerebral oximetry during the case and most patients with flow reversal have had little change in their oximetry. The predilatation balloon is loaded with wire and the combination are advanced to just below the lesion. Arteriography with roadmapping is performed and any adjustments to gantry angle are made at this time. The 0.014-inch wire used to cross the lesion varies among operators but all use a 190-cm wire with appropriate shaping based on the arteriogram. Careful evaluation of the depth of the wire is assessed and maintained through the case. Once the lesion is crossed, the balloon is advanced to the lesion and the lesion is predilated. The balloon is removed and the chosen stent is advanced to the lesion and deployed. Final angiography is performed and any postdilation is decided upon at that point.

Once we complete the procedure, we shut off the flow reversal and we return any blood back through the venous sheath. The operating room team moves to the incision, the access sheath is removed, the carotid is allowed to back bleed out of the arteriotomy, the artery is controlled, and two interrupted 5-0 Prolene sutures are placed and the arteriotomy is closed after appropriate flushing of the vessels. Protamine is used for reversal and the venous sheath is removed simultaneously. After hemostasis is achieved, the wound is closed. Patients are awakened in the operating room, neurologically assessed, and sent to the postanesthesia care unit and then to a telemetry bed. Patients are typically discharged the next day.

## SUMMARY

By utilizing a standard protocol, being comfortable with the steps and the preprocedure imaging, teaching and allowing team members to do their part of the procedures, avoiding the use of indwelling urinary catheters, and premedication with heparin and glycopyrrolate, we have significantly reduced our procedural time. Most are performed in well under 60 minutes, with flow reversal times under 10 minutes in nearly all patients treated throughout a large health system in the western Carolinas. This method as allowed us to rapidly spread the technology throughout the system while maintaining the excellent results we achieved at the main quaternary hospital. ■

# Carotid Bifurcation: An Analysis of Straightforward Lesions and Those With Additional Challenges

Recommended anatomy for carotid stenting.

**BY ANGELA A. KOKKOSIS, MD, AND PETER A. SCHNEIDER, MD**

**Angela A. Kokkosis, MD**
Division of Vascular and Endovascular Surgery
Stony Brook University Hospital
Stony Brook, New York
angela.kokkosis@stonybrookmedicine.edu
*Disclsoures: Consultant for Silk Road Medical.*

**Peter A. Schneider, MD**
Division of Vascular Surgery
University of California San Francisco
San Francisco, California
peteraschneidermd@gmail.com
*Disclosures: Served as a member of the advisory board for Philips, Boston Scientific, and Medtronic; consultant for Cagent, Cardiovascular Systems, Inc, Intact Vascular, Medtronic, Profusa, Silk Road Medical, and Surmodics.*

Carotid endarterectomy (CEA) has been the gold standard for carotid revascularization for more than 50 years due to its low perioperative morbidity and excellent long-term patency. With the advent of endovascular technology and the promise of good outcomes using a minimally invasive technique, it was thought that the carotid bifurcation would be amenable to stenting and would provide similar benefits of minimally invasive outcomes as in other vascular territories. However, after many carotid revascularization trials published results demonstrating that transfemoral carotid artery stenting (TFCAS) was not superior and may even carry a high perioperative stroke risk, consideration of replacing CEA with CAS was abandoned.[1,2] Although most carotid bifurcation lesions could be well treated with stent placement, the quality of cerebral protection with TFCAS was inadequate. Instead, TFCAS has generally been reserved for special circumstances in which CEA was deemed high-risk, or not surgically possible. With the 2016 FDA approval of a new approach to CAS (transcarotid artery revascularization [TCAR]) via transcarotid open exposure and embolic protection with flow reversal, and its associated promising data, there has been a revival in the consideration of using CAS as a revascularization option. The TCAR approach affords better cerebral protection, earlier protection from dislodgement of emboli (as seen during key steps of TFCAS traversing the aortic arch and crossing the carotid lesion), as well as more complete particulate capture throughout the procedure as a consequence of flow reversal. With the availability of better cerebral protection, a major driver of patient selection is analysis of the "stentability" of the carotid lesion itself. Currently approved carotid stent designs (ie, open cell, closed cell, self expanding) are still limited for use in heavily calcified lesions, acute thrombus to include a subset of lesions considered to be intraluminal filling defects, and severe tortuosity. This article will address standard and challenging carotid bifurcation anatomy for the application of CAS, which is also applicable to TCAR.

## "STENTABLE" CAROTID BIFURCATION LESIONS

In general, the optimal carotid lesion for CAS should have minimal calcification, minimal tortuosity, and no acute or mobile thrombus. Absence of these features will ensure that there is adequate stent expansion, no evidence of stent kinking, and reduced risk of plaque protrusion or plaque prolapse. Ultimately, the goal is to avoid stent thrombosis and/or a nidus for distal embolization to the brain. Figures 1 and 2 contain examples of two cases of carotid bifurcation lesions that are suitable for placement of a carotid stent.

## UNSUITABLE CAROTID BIFURCATION LESIONS

Currently available carotid stents have some limitations

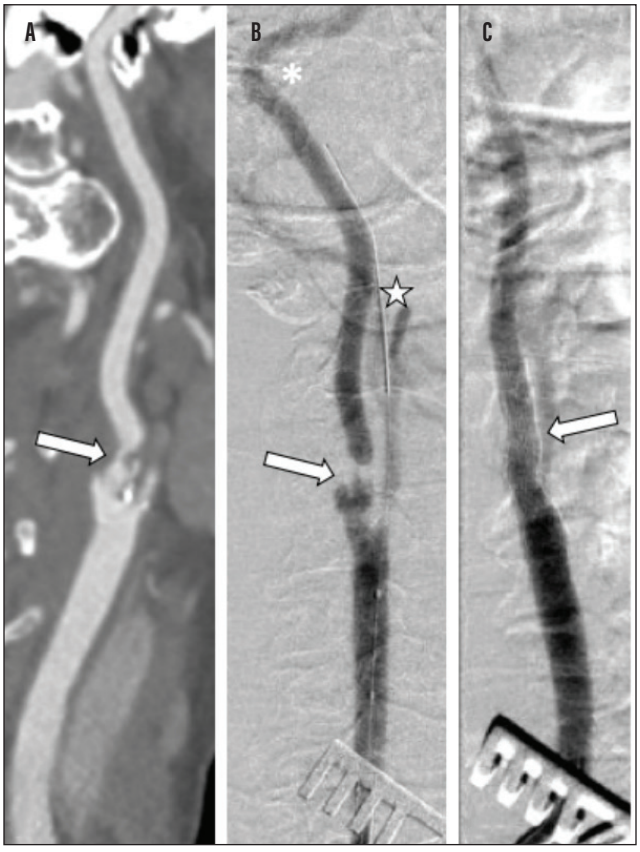


**Figure 1. CT angiogram image of a proximal internal carotid lesion (arrow) with minimal calcium and of relatively short length (A). Intraoperative digital subtraction angiography of the same carotid lesion (arrow). Note: the wire is traversing the ascending pharyngeal artery, which typically mirrors the course of the internal carotid artery (B). However, the ascending pharyngeal artery does not demonstrate a right angle turn (asterisk) at the petrous ridge, and thus special attention must be made in this scenario to advance the wire to the distal internal carotid artery to ensure accurate stent placement in the internal carotid artery. Successful stent placement across the internal carotid lesion (arrow) via TCAR (C).**

with regard to what types of atherosclerotic lesions they can be used to treat. The first hurdle to consider is calcification. These flexible, self-expanding stents are incapable of combating heavy calcification, and typically with > 2/3 circumferential calcification that is ≥ 3 mm thick (an example of this is given in the article starting on page 26), the residual lumen is too small to allow complete stent expansion. Another morphology that will lend to stent compression is the exophytic calcified lesion, in which a "rock" of calcium impinges on the carotid lumen (Figure 3A).

If the contents of a carotid lesion consist of acute mobile or fixed intraluminal thrombus, bare-metal carotid stents may not sufficiently scaffold, the

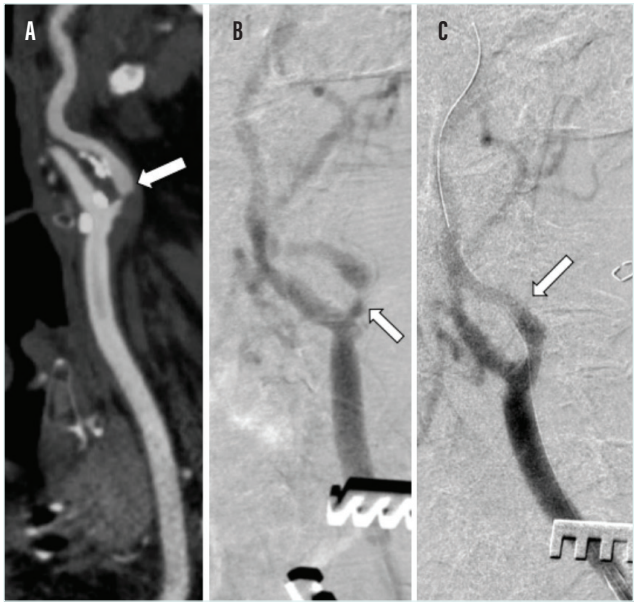


**Figure 2. The arrow points to an internal carotid artery lesion with mild calcification and mild tortuosity on a CT angiogram image (A). Digital subtraction angiogram of the same carotid lesion (arrow) (B). Successful stent placement(arrow) across the internal carotid artery lesion via TCAR (C).**

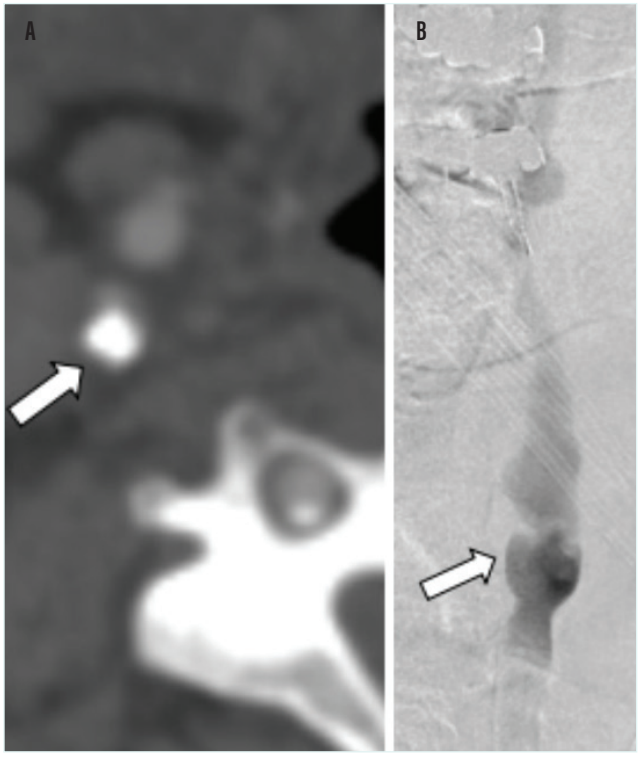


**Figure 3. The arrow points to heavy exophytic calcium within the internal carotid artery that will not yield to carotid stenting (A). The arrow points to the appearance of an intraluminal filling defect on digital subtraction angiogram, that may suggest unstable or mobile thrombus (B).**

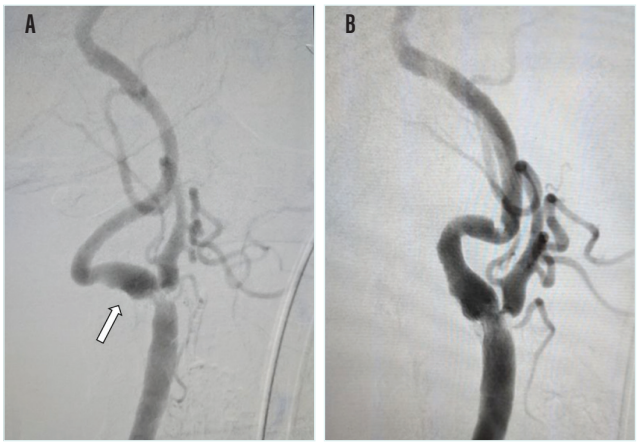


**Figure 4. 90° angulated take off of the internal carotid artery, a challenging anatomy for any carotid stent (white arrow) (A). Poststent appearances in angulated anatomy (B).**

thrombus may protrude through the stent interstices, and potentially lead to distal embolization. Although scattered case reports have used covered stents for this application, the safety and durability of a covered stent in this area has not been established (Figure 3B).

As patients age, another phenomenon seen in the carotid vasculature is elongation and redundancy. This process results in the presence of tortuosity or kinks. Tortuosity present immediately proximal, distal, or at the site of a lesion may result in propagation of the kink with vessel occlusion or crimping of the stent, and subsequent stent occlusion (Figures 4A and 4B).

## CONCLUSIONS

Carotid stenting is a viable option for carotid revascularization in the appropriate patient population. One important determination is the stentability of the carotid lesion itself, regardless of which carotid stenting approach is utilized. In our experience, approximately 80% of carotid lesions can be well treated with a carotid stent. To achieve the greatest technical and postprocedural success, it is ideal to select carotid lesions without severe calcification, severe tortuosity, or mobile thrombus. ■

1. Mantese VA, Timaran CH, Chiu D, Begg RJ, Brott TG. The Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST): stenting versus carotid endarterectomy for carotid disease. Stroke. 2010;41(Supplement 1):S31-S34.
2. Bonati LH, Jongen LM, Haller S, et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). Lancet Neurol. 2010;9:353-362.

*(Aranson continued from page 7)*
as an early adopter of TCAR and how I relied heavily on these tenets.

In speaking with a former mentor, I was given sage advice: only when referring providers trust you as a surgeon will they start sending you carotid patients. Because I knew that I would need to develop this referral pattern for carotid disease to become adept with TCAR and offer it with confidence, I sought to develop this referral pattern. I began to "pound the pavement." I set up visits with primary care providers locally and regionally to educate on general vascular care with a focus on the advances and advantages in the surgical treatment of carotid disease. In the end, I would hand them my personal cell phone number and empower them to call me if I could be of use in the care of their patients and I would facilitate clinic visits to shorten the wait time to see me. By making myself available, I was able to build a solid foundation of vascular disease referrals and eventually carotid disease.

A challenge with adopting new technology is gaining product approval. I identified the value analysis team decision makers and conversed with them to open a collegial dialogue prior to arranging formal meetings. In the beginning, the meetings were challenging as the members were solely focused on material cost. Eventually, they were influenced by the profitability of the procedure, which is able to exceed that of carotid endarterectomy with the heightened medical complexity of TCAR patients. I did not aim to steamroll them nor assume an adversarial role and instead offered to meet with PowerPoint slides in hand whenever they wanted. Eventually, the approval went through and this has allowed me to help other surgeons on the same path. By being affable and collegial, I was able to meet the challenge posed by standard administrative impediment.

As a newly minted vascular surgeon looking to launch a new procedure in my hospital, I knew the importance of excellent surgical outcomes leading up to our first TCAR. I understood the necessity of being known as a safe surgeon within my hospital prior to being labeled a "cowboy." It is imperative that you have a solid track record for excellent carotid endarterectomy outcomes before you move into the realm of TCAR. In addition, it is highly recommended, if not mandatory, that you choose appropriate first cases that will lead to successful outcomes. All eyes will be on you in the beginning, so it behooves you to stack the deck in your favor in order to maximize the propensity for excellent outcomes and showcasing your ability.

Although seemingly archaic, the adage of the three pillars of excellence still hold true today with respect to the adoption of new technology; one must always be prepared to adapt in the dynamic field of medicine. Success is maintained by following the available literature on the outcomes and durability of the platform and being able to effectively communicate it to referring physicians and patients. Surgeons must stay vigilant to only use this platform where indicated and if success is predicted. In addition, the creation of competitive platforms may be intriguing but the excellent results obtained with TCAR will be challenging to best. ■

# Intraoperative Decision-Making for TCAR Complications

**BY EDGAR GUZMAN, MD, FACS, AND SUMAIRA MACDONALD, MD, PHD, MBCHB, MRCP, FRCP, FRCR, EBIR**

**Edgar Guzman, MD, FACS**
Vascular Surgeon
Orlando Regional Medical Center
Orlando, Florida
edgar_guzman@sbcglobal.net
*Disclosures: Consultant to Silk Road Medical.*

**Sumaira Macdonald, MD, PhD, MBChB, MRCP, FRCP, FRCR, EBIR**
Vascular Interventional Radiologist
Executive Medical Director
Silk Road Medical
Sunnyvale, California
*Disclosures: None.*

The technical strengths of transcarotid artery revascularization (TCAR) are leading to ever broader application in complex anatomy, often in the face of substantial physiologic challenges. Although careful preoperative planning and openness to consider all treatment modalities can reduce intraprocedural complications, these are not fully avoidable. As with any complication, the single most important step in salvage is recognition of the problem, which may be difficult in the context of angiography under flow reversal and rendered more so given that these events are so infrequently encountered and may not be immediately identified.

Given the low overall incidence of intraprocedural complications and youth of TCAR as a surgical technique, there is no high-level evidence to guide management of these events. However, much has been learned in the field, as well as from case reviews. We offer experience-based recommendations to manage three scenarios that may be encountered.

## CAROTID DISSECTION

In our experience, the etiology of carotid dissection (Figure 1) was mostly traceable to difficulties with needle or microsheath dislodgement, often coupled with unfavorable conditions at the intended access zone. Preoperative CTA assessment from the aortic arch to the circle of Willis allows identification of significant disease at the "clamp and stick" zones of the common carotid artery (CCA), as well as other anatomic features that may lead to complication. Highlighting the importance of access acquisition during TCAR, the use of the neuroprotection system (NPS) through a poor-quality CCA is considered off-label.

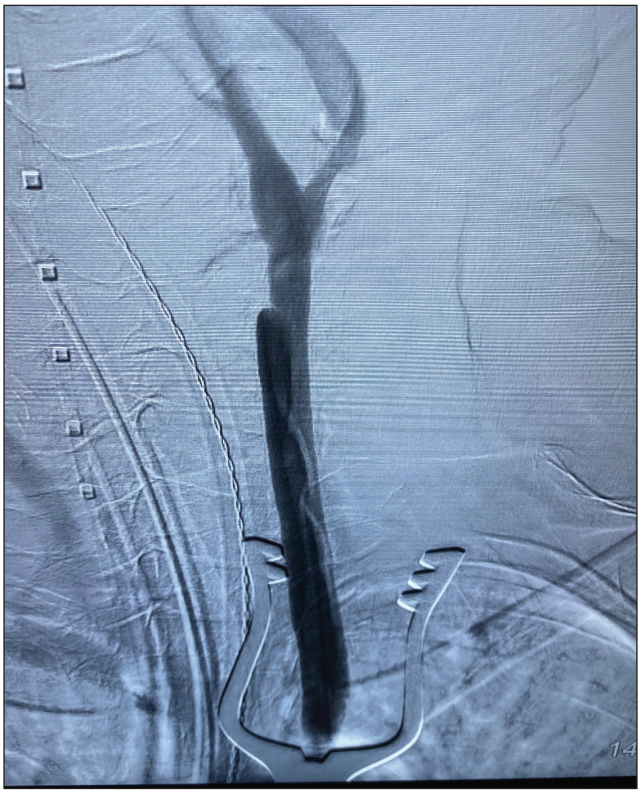

**Figure 1. Carotid dissection propagating from the microsheath access site in the common carotid artery.**

In the event of loss of access, the limited CCA exposure

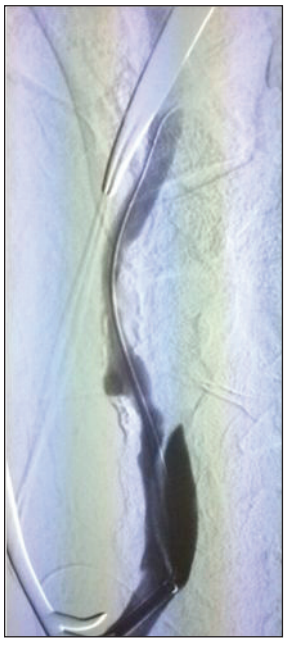

**Figure 2. Carotid dissection imaged under flow reversal. Note the tip of the sheath abutting the vessel wall and presence of an intimal flap.**

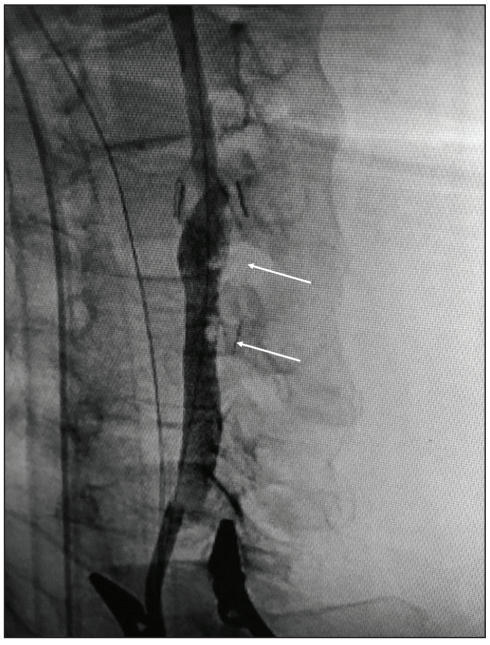

**Figure 3. Plaque prolapse through stent struts.**

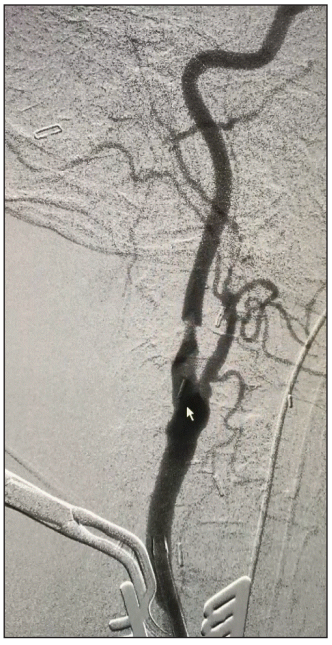

**Figure 4. Carotid flame sign.**

in TCAR and the presence of a preclosure suture make it tempting to reuse the arteriotomy site, but this can lead to entry into a false plane. It is best to close the original arteriotomy and obtain a new access in a more proximal location.

Identification of a dissection from a microsheath is challenging, even with antegrade flow, and may be extremely difficult under flow reversal (Figure 2). The diagnosis of this complication is insinuated by subtle changes in wire behavior, which are much less pronounced than what is often experienced in the arteries of the lower extremities. The inability to complete what should be straightforward access into the external carotid artery (ECA) through the micropuncture sheath or internal carotid artery (ICA) (after the arterial sheath of the NPS is placed) may be the only clue. If one finds it necessary to try multiple wires and catheters to traverse the area of stenosis, there is a high possibility that a dissection has occurred.

Even if distal true lumen access is established and a stent is successfully deployed, there can be a gap of untreated dissection between the caudal aspect of the stent and the access site. Angiographic diagnosis of this anatomy is difficult, leading to identification during postoperative surveillance.

The mechanisms of stroke from a carotid dissection include thrombosis, embolization, and static occlusion. The dynamics of flow reversal address all of these concerns. Flow reversal should be maintained until definitive repair is achieved. Given the inability to stent down to the access site, open repair is our preferred approach. Early recognition should avoid wire dissection distal to what is surgically accessible.

Although transfemoral CCA stenting is possible, it does require giving up flow reversal and potentially deploying an embolic protection device across a newly placed carotid stent, neither of which are desirable. Although we have performed deferred transfemoral CCA stenting to manage this scenario, we think it best to address the issue at the time of the original procedure. Endarterectomy and CCA to ICA bypass are both viable options, the suitability of which is best judged in the context of the status of the vessel.

## PLAQUE PROLAPSE

Plaque prolapse consists of extrusion of thrombotic or atherosclerotic debris across the interstices of the stent (Figure 3). It is highly correlated with plaque morphology and, as such, potentially avoidable with careful patient selection. Intraluminal filling defects, described as a "flame sign" (Figure 4) and "life saver sign" (Figure 5) on preoperative CTA are both easily recognizable and indicative of a lesion with high potential for extrusion. Movement of the filling defect during intraprocedural

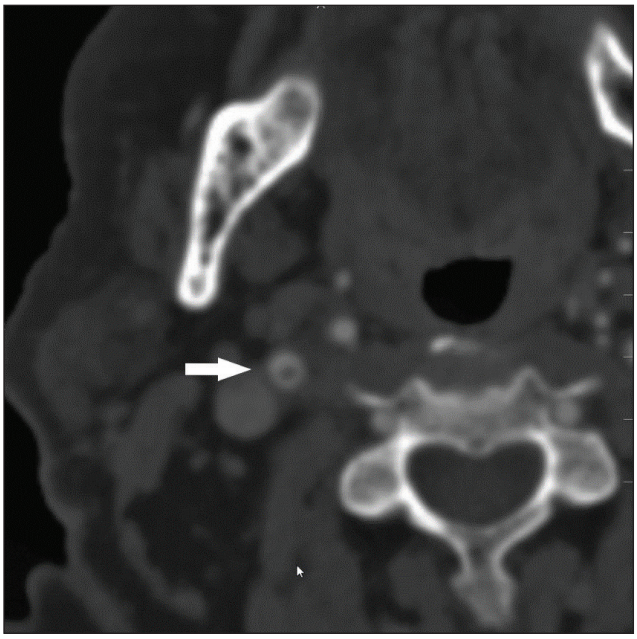

**Figure 5. Life-Saver sign.**

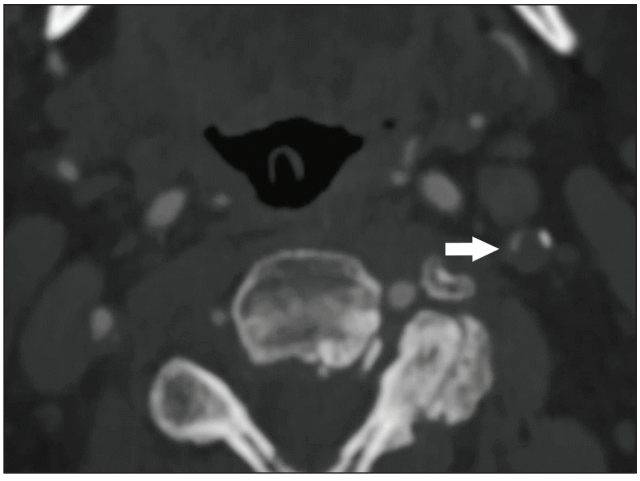

**Figure 6. Swollen carotid sign.**

angiography (mobile thrombus) is an ominous finding. A more subtle lesion morphology with a high risk of extrusion is the "swollen carotid sign" (Figure 6). This consists of the presence of soft, low-density plaque, often devoid of calcification, in a vessel that is noticeably larger than the contralateral counterpart (eg, 9 mm in diameter at the level of maximal disease compared with 4 mm contralaterally), without necessarily reaching aneurysmal dimensions.

If any of these described lesions are identified intraoperatively, or if plaque prolapse is noticed after stent deployment, preservation of flow reversal is the first step in management as these lesions are highly thrombogenic and carry elevated embolic potential.

Open repair, either via endarterectomy or bypass is recommended. Endovascular repair with layered bare-metal stents has been performed with good outcomes; however, there is the potential for extrusion of smaller emboli. The deployment of a self-expanding stent graft, such as the Viabahn (Gore & Associates) or Covera (BD Interventional) through the flow reversal system is an off-label application of these devices. This bailout maneuver has been successful, however, there is no evidence base to support it in this clinical scenario. There are also size constraints in terms of NPS sheath compatibility, as well as the potential for wire length issues as these are all over-the wire systems. Furthermore, these stent grafts lack the tapering capacity of bare-metal stents, leading to pleat formation. The failure to develop a neointima within these stent grafts generates concerns for ongoing platelet aggregation and thrombosis. In a manner analogous to what is seen in peripheral vessels, a covered stent graft may fail suddenly and catastrophically.

It should be stressed that the flow reversal system is not an embolectomy system. Therefore, attempts at balloon disruption or even pull-back embolectomy are to be discouraged. The debris may occlude the flow reversal sheath or become trapped between the sheath and the CCA, waiting to embolize once antegrade flow is restored.

## CAROTID RUPTURE

The vessels most susceptible to carotic rupture are those that present heavy calcification, be it in a circumferential fashion (napkin ring sign, Figure 7) or with exophytic intraluminal projection (coral reef sign, Figure 8). These lesions often require high-pressure predilation and are associated with incomplete stent expansion leading to further high-pressure postdilatation. In the awake patient, acute pain during angioplasty should be considered a warning of possible rupture.

Once rupture has occurred (Figure 9), hemorrhage control is facilitated by the flow reversal system because it impedes antegrade flow into the area of injury and reduces the pressure within the carotid. Low-pressure inflation of a balloon sized to the intact ICA eliminates the main source of retrograde flow and pressure, leaving the ECA as the only bleeding branch. After the hemorrhage has been temporized, assessment and protection of the airway are critical steps for the awake patient. Furthermore, establishment of general anesthesia leads to a more expedient surgical exposure.

Definitive repair usually takes the form of CCA to ICA bypass. Given the circumstances, use of a prosthetic graft is usually most practical. Covered stenting of the lesion leads to the limitations of self-expanding stent grafts described previously. Furthermore, depending on plaque morphology, persistent failure of stent expansion may be

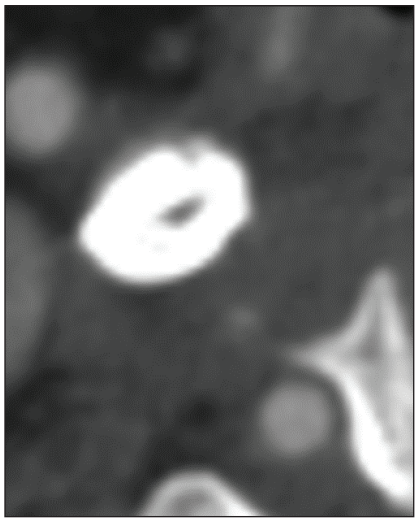

Figure 7. Napkin ring sign.

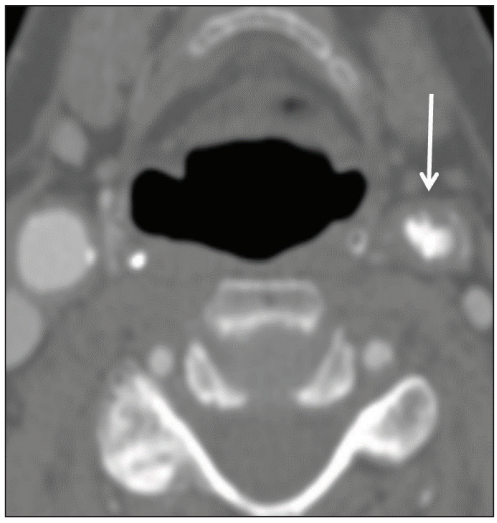

Figure 8. Coral reef sign.

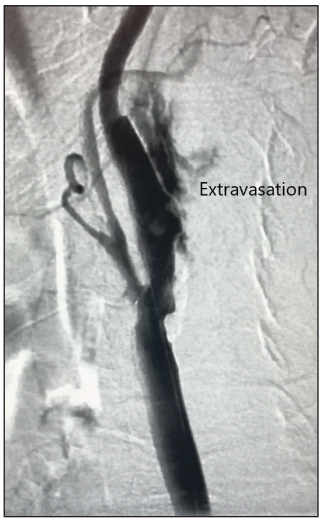


Figure 9. Carotid rupture with extravasation.

an issue. Even with successful bridging from intact CCA to ICA, covered stenting does not address bleeding from the ECA. The use of balloon-expandable stents or stent grafts is ill advised in the carotid arteries given the risk for extrinsic compression on neck movements.

Open repair has the added benefit of allowing hematoma evacuation. Ongoing airway compression is a concern after endovascular repair.

## CONCLUSION

Although growing familiarity with TCAR may allow treatment of cases of higher complexity, familiarity alone does not overcome the anatomic limits of the technique; especially given that these scenarios occur with low frequency. Fortunately, in the event of complication, flow reversal provides a valuable bridge to definitive care. ■

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follow-up. The patient is only referred back to cardiology if there is a chronic cardiac condition already being followed, in which case all subsequent carotid ultrasounds are done through the cardiologist's office. Otherwise, surveillance imaging is done through the surgeon's office indefinitely.

## BILLING/CODING

Given concomitant employment, billing attribution is largely a spread sheet accounting effort. We have adopted a 60/40 surgical/interventionalist cost center split relative to professional and technical fee attribution. Relative value unit (RVU) allocation uses a shadow-charting attribution of RVUs for the 2nd operator by our institution.

## LGH OUTCOMES

Since beginning our program in July 2018, we have had 100% technical success after 88 TCAR procedures to date. Our average procedure time is 53.4 minutes, average flow reversal time is 10 minutes, and our stroke rate is 0%. One patient had a contralateral stroke in the postoperative period and was ultimately deemed to have a cryptogenic (possibly undiagnosed cardiac) source for her bilateral embolic strokes. We also had a symptomatic patient with an ipsilateral transient ischemic attack event after TCAR who refused MRI due to claustrophobia but never had another event thereafter. We currently place JP drains and reverse heparin in all patients to avoid pocket hematomas, although the JP drain is likely superfluous with protamine reversal.

Given that we all treat a similar population of patients, our multidisciplinary approach to care goes beyond carotid disease. We have successfully built a system-wide abdominal aortic aneurysm screening and remote monitoring program, we have a streamlined referral process for a vascular rehab walking claudication program, and we are piloting a claudication screening tool in the cardiology practice. Our vascular imaging services utilize the same protocols and Intersocietal Accreditation Commission (IAC) accreditation, even sharing sonographer allocation, when needed.

Above all else, it is important for anyone who is considering initiation of a TCAR program to remember that there are several subspecialists with extensive carotid stenting experience that are excellent resources for surgeons without case numbers to support credentialing. Although we respect the fact that it does take a certain personality type to be able to work well together in teams, we truly believe that this approach is ideal for the care of our patients and ultimate program and procedural success. ■

# Management of Carotid Stent Restenosis Whether It Be From Previous TFCAS or TCAR: A Primer on Differential Entities and Their Optimal Management

Background and evidence base regarding carotid restenosis after previous carotid stent placement or carotid endarterectomy.

**BY BRIAN KUHN, MD, RPVI, AND SUMAIRA MACDONALD, MD, PHD, MBCHB, MRCP, FRCP, FRCR, EBIR**

**Brian Kuhn, MD, RPVI**
Chief Vascular Surgery
Bethesda North Hospital
Co-Director of Aortic and Cerebrovascular Diseases at TriHealth
Associate Program Director Vascular Fellowship and Integrated Residency at TriHealth.
Cincinnati, Ohio
bkuhn100@hotmail.com
*Disclosures: Consultant to Silk Road Medical.*

**Sumaira Macdonald, MD, PhD, MBChB, MRCP, FRCP, FRCR, EBIR**
Vascular Interventional Radiologist
Executive Medical Director
Silk Road Medical
Sunnyvale, California
*Disclosures: None.*

Ischemic stroke represents a significant health-related problem and is a major cause of disability throughout the world. Atherosclerosis of the carotid bifurcation is thought to account for approximately 20% of all ischemic strokes.[1] Most of these (nearly 80%) may occur without warning. Multiple trials and studies have been performed to evaluate the safety and effectiveness of carotid endarterectomy (CEA) and carotid artery stenting (CAS). Recent randomized controlled trials suggest that CEA and CAS achieve similar long-term outcomes in terms of ischemic stroke reduction for up to 10 years.[2-4] The 10-year data from the CREST trial have also shown no difference in restenosis or revascularization between CEA and CAS at 10 years.[3] Compared with CEA, CAS is associated with significantly lower risks of myocardial infarction (MI), cranial nerve palsy, and access site hematoma.[2] However, in every randomized trial and analysis comparing CAS with CEA, CAS is associated with a two- to three-fold increase in 30-day minor stroke compared with CEA, which has significant impact on quality of life. Concerns for restenosis after CAS have been expressed by many surgeons. Restenosis and occlusion after CEA and CAS have been reported to have a low incidence and no difference at 2 years in a large randomized controlled trial. A restenosis rate of > 70% by duplex criteria at 2 years was found to be 6% in CAS and 6.3% in CEA.[5] Risk factors for CAS restenosis have been described and include female sex, dyslipidemia, and diabetes. There is some uncertainty on the significance of CAS in-stent restenosis (ISR). A recent systematic review and meta-analysis showed a weighted incidence of restenosis > 70% was 5.8% after CEA (median, 47 months) and 10% after CAS (median, 62 months). In CAS patients with untreated asymptomatic > 70% restenosis, the rate of ipsilateral stroke was extremely low (0.8% over 50 months). CEA patients with untreated, asymptomatic > 70% restenosis had a higher rate of ipsilateral stroke but it was only 5% at 37 months.[6] Another large randomized, controlled trial also reported restenosis and risk of stroke after stenting or endarterectomy for symptomatic carotid stenosis. Moderate (≥ 50%) restenosis was more common in the stenting group compared to the endarterectomy group. Patients with moderate stenosis

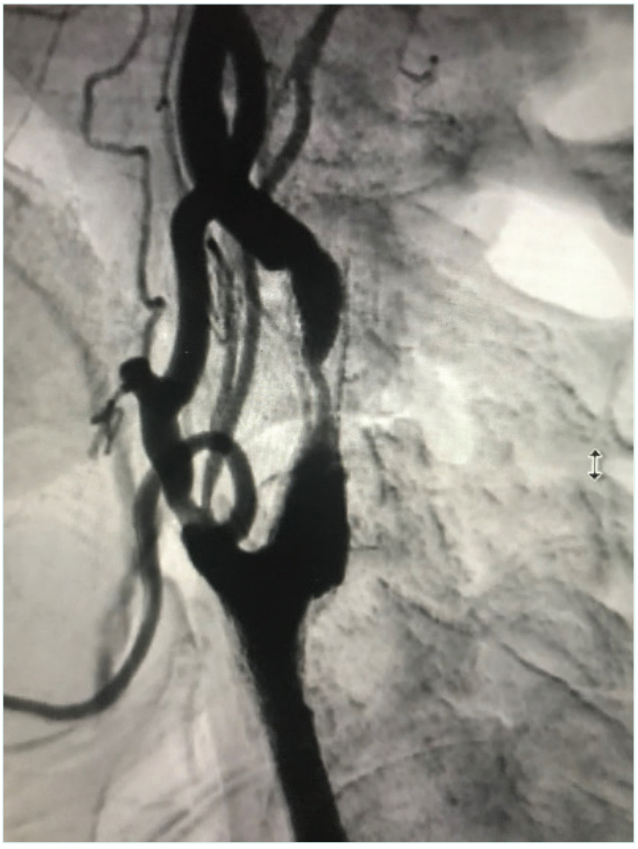

**Figure 1. Lateral image depicting diffuse carotid ISR secondary to neointimal hyperplasia.**

had a higher rate of ipsilateral stroke than did individuals without restenosis in the overall population and in the endarterectomy group alone, but no significant increase in stroke risk after restenosis was recorded in the stenting group. There was also no difference in the risk of severe restenosis (≥ 70%) or subsequent stroke between the two treatment groups.[4]

## TREATMENT OPTIONS

Despite the well-known entity of CAS ISR, there are discordant data on treatment strategies. No clear treatment algorithm has been accepted at this time. Treatment options include medical management and balloon or cutting balloon angioplasty performed alone or in conjunction with stenting. Reports of percutaneous transluminal angioplasty with drug-coated balloons have been reported after 2005. CEA with explantation of the carotid stent and carotid artery interposition grafting has also been described. There is also a report of a balloon-expandable zotarolimus-eluting stent used to treat significant ISR after CAS.[7] The interventional strategies of drug-coated balloons, drug-eluting stents, or cutting balloons do not have an FDA-approved labelled indication for the management of carotid ISR.

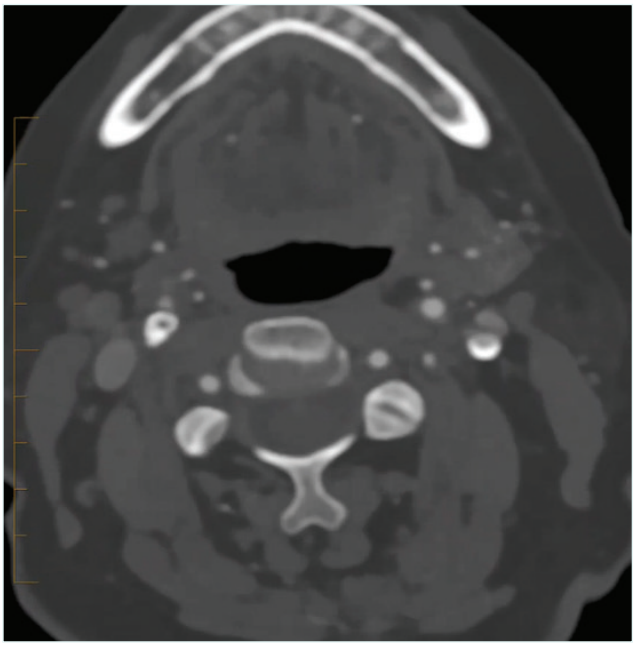

**Figure 2. Occluded right carotid stent due to calcification.**

## PATHOETIOLOGIES OF RESTENOSIS

The pathology of carotid ISR is not fully understood, but likely results from vessel trauma causing endothelial dysfunction and chronic inflammation leading to subsequent neointimal hyperplasia (Figure 1). This generally occurs < 24 months after the first procedure or later as de novo atherosclerosis. The clinical impact of neointimal hyperplasia is uncertain, but is thought to be associated with reduced potential for embolization compared to native lesions.

Another etiology for carotid ISR is underexpansion of the initial stent, possibly from external compression due to significant calcification (Figure 2). Heavily calcified carotid arteries have traditionally been excluded from all major clinical trials, although there are reports of successful CAS in this setting.[8,9]

## DIAGNOSTIC CRITERIA

Multiple tests can be performed to make the diagnosis of carotid ISR, including carotid duplex ultrasound, CTA, MRA, and digital subtraction angiography. Most institutions start with duplex ultrasound given that it is noninvasive, does not require contrast exposure or radiation, and has a relatively high sensitivity and specificity when compared with digital subtraction angiography or CTA. Metallic artifacts can hamper the use of MRA for surveillance of carotid ISR and thus are often not performed. Multiple studies have reported different parameters and cut-off values for ISR definition. Stented arteries have different biomechanical properties than native vessels, resulting in more rigidity and stiffness

(essentially reduced compliance) leading to increased velocities. The Society for Vascular Surgery has established an optimal velocity threshold criteria for varying severity of ISR after CAS.[10] It has been suggested to obtain a new baseline carotid duplex ultrasound after CAS and use this as reference going forward to help in diagnosis of significant CAS ISR. The timing of the diagnosis also plays a factor in decision making and treatment of the patient. Early detection (< 24 mo from procedure) of CAS ISR usually results from neointimal hyperplasia, but stent compression or lack of stent expansion also needs to be considered. This can usually be determined by duplex ultrasound, but if there is significant acoustic shadowing from the calcification, other diagnostic modalities such as CTA might be helpful. If the diagnosis is made > 24 months from the initial procedure, atherosclerotic disease is generally considered to be the etiology.

## PATTERNS OF ISR

There have also been different patterns of restenosis identified, with implications for long-term outcomes and a need for target lesion revascularization. Patterns of carotid ISR with diffuse proliferative disease demonstrated the highest rates of reintervention.[11]

## MEDICAL MANAGEMENT OF ISR

Despite knowing for many years that endovascular treatment of carotid stenosis can lead to CAS ISR, the treatment of CAS ISR is still largely debated with no clear treatment protocols given the paucity of sufficient data. A reasonable first step to prevent CAS ISR is to identify and treat modifiable risk factors. Diabetes, dyslipidemia, and smoking have all been identified as predictors of restenosis or occlusion after CAS. Thus, good glycemic control and low levels of HgA1C should be recommended. Statins have also been recognized for their integral role is dyslipidemia management and their pleotropic effects, such as plaque stabilization. Their use is associated with a decreased perioperative and long-term ischemic stroke risk. Finally, tobacco cessation should strongly be encouraged. There are no specific pharmacologic agents to reduce the incidence of carotid ISR. A meta-analysis has shown promising effects for cilostazol. In this analysis, 1,297 patients were treated with CAS and cilostazol showed a significant reduction in CAS ISR after a mean follow-up of 20 months without affecting MI/stroke/death.[12]

## RE-INTERVENTIONAL STRATEGIES

When looking to treat CAS ISR patient selection at the initial procedure is very important. Risk factors for CAS ISR have been identified, as mentioned previously, and if possible the procedure should potentially be avoided if other treatment options exist. If CAS is determined to be the best treatment option for that patient, close follow up and surveillance for ISR should be performed.

Who, when, and how to intervene on patients that develop CAS ISR is up for debate. Many TCAR users might not have significant or any experience with transfemoral CAS and thus have not traditionally had to deal with carotid ISR until now.

## SYMPTOMATIC PATIENTS

In symptomatic patients on maximal medical therapy with dual antiplatelet therapy and high-intensity statin with > 50% ISR and no other source for ischemic stroke, re-intervention seems reasonable for that vast majority of patients unless a palliative approach is taken due to stroke severity or other comorbid conditions. The interventional approach can include a transfemoral, transcarotid, or open surgical repair. The transfemoral and transcarotid approach can include balloon or cutting balloon angioplasty with or without stent implantation. The transcarotid approach offers the potential benefit of improved neuroprotection and avoidance of any aortic arch disease compared to a transfemoral approach, but could be limited by the access length required to safely insert the sheath given the prior stent. Although there are reports of drug-eluting balloon and stent technology used in the carotid bifurcation, currently there are no FDA-approved devices for this indication. Open surgical repair with carotid stent removal is also another potential option. This can include primary repair of the artery, interposition grafting or closure with vein or prosthetic patch. The artery can often be very thin after removal of stent and gaining proximal or distal control for open repair can be challenging depending on the patient's anatomy and previous stent placement.

My personal approach in this patient population would include a transcarotid approach if there is adequate length to safely place my sheath and there was no significant disease at my access site. This would include a redo cutdown on the common carotid artery if the prior stent was placed from a transcarotid approach. My initial trepidation with this and concern for significant scarring associated with redo surgery has not been realized when performing the redo cutdown at the base of the neck. Because the lesion is symptomatic there is often concern about thrombus or lose debris within the stent/lesion. With this in mind, placing another stent in the target lesion may be preferable. If a transcarotid approach is not possible, I would evaluate for a transfemoral or open approach. If the symptomatic CAS ISR is amenable to open repair, this is my preference. If it is related to external stent compression from a calcified lesion and underexpanded stent, open surgical repair is preferable. If neither a transcarotid nor open approach is feasible

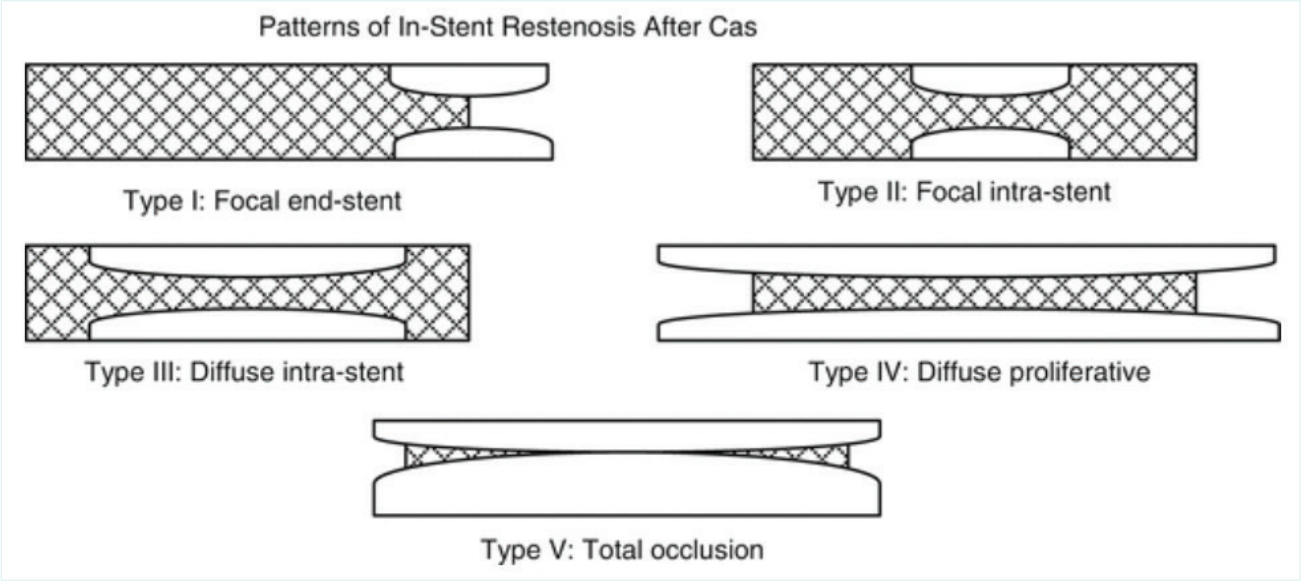


**Figure 3. Patterns of ISR after CAS. Reprinted with permission from Lal BK. Recurrent carotid stenosis after CEA and CAS: diagnosis and management. Semin Vasc Surg. 2007;20:259-266.**

and the arch does not have significant disease, a transfemoral approach would be discussed. If performed, the intervention would be the same as a transcarotid approach.

## ASYMPTOMATIC PATIENTS

A somewhat more difficult clinical scenario is an asymptomatic patient who develops significant CAS ISR. In patients who are asymptomatic and have < 70% ISR, medical management with antiplatelet agents, high-intensity statin therapy, good BP control, and tobacco cessation seems to be most appropriate. What about patients who develop > 70% ISR and are asymptomatic? The optimal treatment for this patient population is also unclear at this time, but we do have some data to help guide our patients. Certainly, maximal medical therapy with risk factor modification is the mainstay but who, if any, should be intervened on? Does the pathology of the CAS ISR make a difference on who to intervene on? What about the timing of CAS ISR if it is ≤ 2 years from the time of the initial procedure? What if there is a contralateral occlusion? These are the difficult clinical scenarios we face every day in our profession. Fortunately, the risk of ipsilateral stroke from a recurrent CAS ISR appears to very low. A systematic review and meta-analysis has demonstrated a low rate of late ipsilateral stroke of 0.8% over 50 months in patients with untreated asymptomatic > 70% CAS ISR.[5] In addition, the use of a percutaneous intervention for CAS ISR does not appear to improve outcomes compared with nonoperative management.[13]

Given the current data, a noninterventional approach seems to be reasonable until further studies address this issue. These clinical scenarios can often be confusing and worrisome to the patients we treat. Why did we recommend treating the initial carotid lesion that might have been > 70% , but now we might recommend medical management alone for > 70% CAS ISR? This is when patience, time, and good communication pays off in our clinic visits. ■

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# The Future of Vascular Surgery: Training Fellows for Success

**WITH JEFFREY JIM, MD, MPHS, FACS; MURRAY SHAMES, MD, FACS; AND BERNARDINO C. BRANCO, MD, RPVI**

**Jeffrey Jim, MD, MPHS, FACS**
Chair, Vascular & Endovascular Surgery
Abbott Northwestern Hospital
Minneapolis Heart Institute
Minneapolis, Minnesota
jeffrey.jim@allina.com
*Disclosure: National Director of TEST DRIVE course and proctor for Silk Road Medical; consultant for Medtronic.*

**Murray Shames, MD, FACS**
**Chief, Division of Vascular Surgery**
Vice Chair of Research, Department of Surgery
University of South Florida
Tampa, Florida
President, Association of Program Directors in Vascular Surgery
mshames@usf.edu
*Disclosure: Speaker for Cook, Gore and Medtronic; scientific Advisory Board for Medtronic.*

Surgical education has significantly evolved over the past several decades. Completing apprenticeships under Halsted's principles has long been replaced by a focus on achievement of "milestones" structured under defined core competencies. Vascular surgery (VS) is perhaps the specialty that has undergone the most change. The introduction of endovascular procedures help to distinguish vascular surgeons from general surgeons who in the past had training in open vascular techniques. The approval of a primary certificate in VS in 2005 allowed introduction of an independent ("0+5" residency) training pathway after medical school. Simulation training is also now incorporated into most training programs and also offered at many hands-on courses provided at VS society meetings. The use of simulation, especially for new procedures, is an effective learning tool that introduces new procedures and can be used to assess technical competence.

Just as there have been changes in surgical education, the practice of medicine has also significantly evolved. VS graduates have to achieve clinical competency with adequate case experience and surgical expertise. In addition, our graduates must also learn to navigate the financial and political challenges of entering a new practice. Cost-efficient value-based care is emphasized and competing specialties are expanding their services to provide vascular care. To have successful careers, it is imperative that our trainees successfully navigate these challenges as they enter the workforce. Although several vascular surgical societies and institutions put on "fellows" programs that focus on transition to practice, there is a lack of a standardized curriculum emphasizing "the practice of medicine" in our formal training programs. With the COVID-19 pandemic affecting all aspects of our lives in 2020, our graduating trainees will perhaps face even more pronounced challenges as they integrate into the workforce.

Transcarotid artery revascularization (TCAR) is increasingly used as the preferred treatment option for patients with carotid occlusive disease. More VS trainees are being exposed to TCAR early in their training as clinicians across the country are increasingly performing TCAR at their institutions. To better prepare VS graduates to adopt TCAR into their practice, Silk Road Medical has developed a specific training program for them. There is an official TCAR certification process that begins with attendance at the "Fellows TEST DRIVE" course in July. This program begins with a series of didactic lectures from national experts. This is followed by TCAR simulation training on procedural technique. There are also educational sessions to guide graduates as they enter clinical practice. These modules include how to navigate value analysis committees, supply chain management, reimbursement, network with referring physicians, as well as developing relationship with industry partners. The graduates are also partnered with a faculty mentor to help promote continued success after the course. The attendance of the first program in 2018 was capped at 50 graduates. In 2019, 80 graduates attended the program, accounting for almost half of total VS graduates in the United States that year. Although the COVID-19 pandemic and the need for social distancing will prohibit a live course in 2020, we have converted to a virtual format for the

didactic portion of the program. For those who may not have the required prerequisite clinical experience during their training, regional courses will be offered to allow for them to complete their certification process as soon as possible. Graduates will also be provided with clinical specialists to proctor their cases if deemed necessary.

Throughout their training, VS trainees are guided to become safe physicians and future leaders who provide excellent clinical care. They will become patient advocates in our ever changing and demanding health care delivery system. Upon graduation, program directors sign a "graduation letter" that certify VS trainees as competent and ready for independent practice. To that end, we are proud to have signed many of these letters over the past many years for our successful graduates. However, we understand that although their "training" is over, our graduates require continued guidance and mentorship from the program directors, faculty members, and their partners to ensure life-long success. We are grateful that our partners in industry, such as Silk Road Medical, have placed an emphasis on helping VS graduates become successful practicing physicians.

## My Experience As a Recent Graduate

**Bernardino C. Branco, MD, RPVI**
Vascular Surgeon
Mercy Clinic
Springfield, Illinois
brancobcua@gmail.com
*Disclosure: Educational consultant for Silk Road Medical.*

I graduated from Baylor College of Medicine in Houston in 2018 as a "5+2" vascular surgery fellow. At that time, because TCAR was still in the validation and implementation phase across many centers in the United States, most cases of carotid artery occlusive disease requiring intervention at my training institution were managed by carotid endarterectomy (CEA) or transfemoral carotid artery stenting (TFCAS). My vascular surgery fellowship graduating case volume certainly reflected that experience (CEA, 41; TFCAS, 26; TCAR, 4). Despite limited experience with TCAR, I was comfortable with the key procedural steps of TCAR, such as neck cutdown for direct transcervical carotid access and carotid stent placement with my overall carotid experience. I attended the Fellows TEST DRIVE Program in July 2018. It helped me to develop and practice other essential aspects of performing TCAR, such as direct carotid access using a hands-on angioscopy model and patient selection for good outcomes through a comprehensive didactic program administered by expert faculty. In addition, tips for building a TCAR practice, coding, and documentation were also provided.

After my graduation, my transition into practice in the "real world" was facilitated by joining one of the busiest TCAR centers in the United States. At our center, three vascular surgeons (including myself) have performed > 300 TCAR over the past 2 years, with excellent clinical results and no perioperative stokes. I am grateful for the support from Silk Road Medical in my practice to not only provide excellent clinical care, but also to develop other aspects of my career. Despite not having a traditional VS training program here, my partners and I are involved in proctoring practicing physicians who wish to learn the technique to expand their stroke prevention armamentarium. Our site also provides education to clinical specialists for Silk Road Medical during their training before they go on to support TCAR procedures across the country. In July 2019, I was invited back to the Fellows TEST DRIVE program as part of the faculty. I was grateful for the opportunity to help shape the next group of graduates and look forward to contributing to the continued success of future VS graduates.

Endovascular TODAY