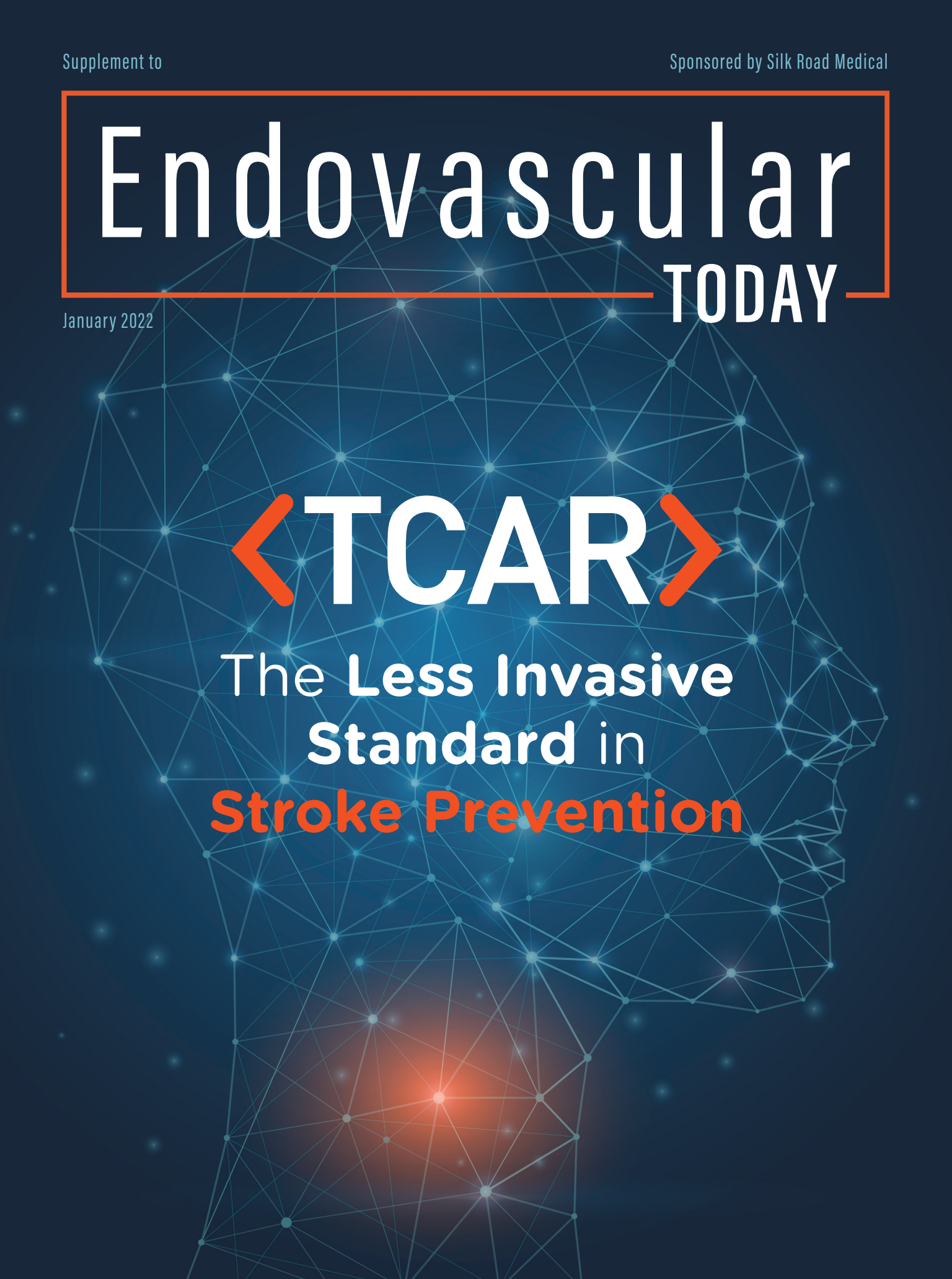
Supplement to

Sponsored by Silk Road Medical

Endovascular TODAY

January 2022



TCAR

The **Less Invasive Standard** in **Stroke Prevention**

TCAR

The Less Invasive Standard in Stroke Prevention

Contents

TCAR: TransCarotid Artery Revascularization

The less invasive standard in stroke prevention and a favorite tool in our armamentarium.

By Mila H. Ju, MD, MS, RPVI, FSVS, FACS

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"Is TCAR your favorite surgery?" I was recently asked by one of my medical students after we performed three transcarotid artery revascularizations (TCAR) in one day. I paused and had to think hard before I could answer. For many of us and our trainees, carotid endarterectomy (CEA) had been the common answer whenever we were asked "what is your favorite surgery?" or "what sparked your interest in the field?" There is something elegant about the fine dissection required for CEA, and something oddly satisfactory about it when every bit of atherosclerotic plaque is removed from the carotid artery. No wonder CEA had been our favorite for years. But recently, as I had answered my medical student, "TCAR is now my favorite."

I had not always known TCAR. As a matter of fact, I did not learn how to perform TCAR until I attended "Test Drive," the hands-on training program put together by Silk Road Medical, during my second year as an attending. When I finished the program, I had a feeling that TCAR was going to change how I treated carotid disease because the procedure just made sense. The procedure starts with a neck dissection just like a CEA, although lower in the neck. A few steps later, the ingeniously developed neuroprotection device is inserted, and reverse flow is established. While the brain is protected from distal embolization, the carotid lesion is crossed and treated with balloon angioplasty and stent. With the appropriate amount of time passed and a satisfactory angiogram, the neuroprotection device is removed and the arteriotomy is closed. Hemostasis is achieved and skin closure completes the procedure. As stated in the article by Drs. Jim, Dermody, and Schermerhorn, TCAR should be considered "as the 'new' standard for carotid revascularization." Whereas it has the equivalent perioperative stroke risk as CEA, TCAR has a lower risk of myocardial infarction and cranial nerve injury. TCAR had combined the elegance of CEA with the technical savviness of endovascular procedures.

However, as with many procedures, TCAR actually does not start in the operating room; it starts when one meets the patient for potential carotid revascularization for future stroke prevention. As detailed in the article "Patient Selection in My Practice" by Drs. Divinagracia and Watch, planning is key to TCAR. Adequate imaging is necessary to assess patient anatomy, which must suit the instructions for use so that flow reversal with the neuroprotection device can be safely established and a carotid stent can be safely deployed. Once it has been determined that TCAR can be performed, one must see that the patient has high-risk surgical factors (with significant comorbidities and/or unfavorable anatomy) that are indications for TCAR. High surgical risk is also a key element to Medicare reimbursement, as detailed in Mr. Au-Yeung's article. For comprehensive planning, one must also know the limitations of TCAR. Dr. Shah mentioned in his article the anatomic limitations such as a heavy calcified lesion, and a short and deep common carotid artery. In addition, for ongoing success of TCAR, adequate dual antiplatelet therapy is a must for stent patency, which is detailed in the section on "Platelet Function Testing and TCAR."

As Dr. Shafii commented in her article, TCAR is to carotid surgery as endovascular repair of aortic aneurysm is to open aortic surgical repair. Many of us, like Drs. Aranson and Ricotta, have noticed that there is a domino effect with the adoption of TCAR in our practice. With better patient selection and a refined protocol, the outcomes of open and endovascular carotid procedures had all improved. TCAR is providing "the less invasive standard in stroke prevention," and it has become one of my favorite tools in my armamentarium. ■

The Case for TCAR as the "New" Standard for Carotid Revascularization

An assessment of patient selection, patient preference, and excellent outcomes.

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Since its introduction several decades ago, carotid endarterectomy (CEA) had been considered as the "gold standard" for carotid revascularization. Transfemoral (TF) carotid angioplasty and stenting (CAS) was introduced as a less invasive alternative to CEA more than 2 decades ago. However, the higher periprocedural stroke risk associated with TF-CAS prevented the broad adoption of this technique. Transcarotid artery revascularization (TCAR) is a hybrid procedure that allows stent delivery while maintaining CEA-like neuroprotection. TCAR received FDA approval in 2015 and since that time, we have adopted TCAR as our preferred procedure of choice. In this article, we discuss our approach to treating patients and why we consider TCAR as the "new" standard for carotid revascularization.

Consistent with treatment guidelines, we reserve carotid revascularization for symptomatic patients or appropriate asymptomatic patients with severe stenoses.[1] In choosing the appropriate procedure for each patient, we evaluate the following areas.

PATIENT ANATOMY

To ensure the best clinical outcomes for our patients, we adhere to the anatomic requirements in the Instructions for Use for TCAR: 5-cm common carotid artery (CCA) length between access site and lesion, and 6-mm CCA diameter as well as healthy CCA for access and inflow occlusion. We also carefully choose lesions that are amenable to stent placement, therefore avoiding certain types of uncommon thrombus, such as intraluminal filling defect, or severe calcification.[2] Even with these stringent criteria, imaging analysis has shown that 70% to 85% of patients undergoing carotid revascularization have anatomy suitable for TCAR.[3,4]

STROKE RATE

Although there are several important clinical outcomes to consider when discussing carotid revascularization options, the avoidance of a periprocedural stroke is the primary concern for most patients. TCAR has consistently been shown to have a low rate of stroke in both clinical trials as well as real-world settings. The 1.4% stroke rate in the ROADSTER trial was the "lowest reported to date for any prospective, multicenter trial of carotid stenting."[5] This improved to 0.6% in per protocol patients in the ROADSTER 2 trial, despite having the vast majority of procedures performed by TCAR-naïve investigators.[6] The clinical efficacy of TCAR in high-surgical-risk patients compares very favorably to the strokes rates for CEA (2.3%) and TF-CAS (4.1%) for standard-risk patients in CREST.[7] This clinical efficacy has translated to the real-world setting with a 1.4% stroke rate in TCAR procedures,

equivalent to CEA (1.4%) and lower than TF-CAS (2.5%) in the Vascular Quality Initiative (VQI).[8,9]

MYOCARDIAL INFARCTION/CRANIAL NERVE INJURY RATES

In addition to stroke, other potential periprocedural complications remain important considerations. In CREST, surgical intervention with CEA was found to have a significantly higher rate of myocardial infarction (MI) compared to percutaneous-based TF-CAS.[7] Despite the need for surgical exposure of the CCA, TCAR is associated with a low rate of MI (0.2%), which mirrors that in TF-CAS (0.3%).[9] There are likely several factors that contribute to this: less-invasive nature of the procedure, shorter duration of "clamping," and higher compliance to "best medical" dual antiplatelet therapy (DAPT) therapy in TCAR patients. In addition to MI, the development of cranial nerve injury (CNI) should also be considered. With meticulous surgical technique, the likelihood of CNI is low with CEA. Nonetheless, clinical data do show the occurrence of persistent CNI that can be quite disabling to patients. With a much less involved dissection field, TCAR has almost eliminated the occurrence of CNI (0.4%), which continues to plague CEA (2.7%).[8]

DURABILITY

In addition to periprocedural outcomes, we also demand long-term durability with carotid revascularization. Previous clinical trial data have shown that after the periprocedural period, CEA and CAS have similar stroke and restenosis rates, with durability demonstrated up to 10 years.[10,11] It is important to note that TCAR differs by offering transcarotid access and utilizing robust flow reversal for neuroprotection. This offers an alternative method to deliver a stent to the carotid bifurcation. However, TCAR still relies on the same stent technology that had been refined during the decades-long development of TF-CAS. As such, TCAR patients benefit from reduced periprocedural complication rates, as noted previously, but can still depend on the long-term advantages previously shown with CAS technology.

PATIENT PREFERENCE

In addition to the standard metrics (stroke, MI, CNI), TCAR does offer several other important advantages compared to the other alternatives. Patients demand the best experience possible with their carotid revascularization procedures. TCAR has a favorable discharge profile, with a higher likelihood of discharge to home and home after an overnight stay.[8] The minimally invasive nature of TCAR allows for the procedure to be done with local anesthesia alone. This is preferable for many patients who prefer to avoid general anesthesia. Although harder to quantify, TCAR patients do note less neck discomfort, especially noticeable for those who had undergone a CEA in the past. We rarely need to prescribe narcotic medications on discharge for TCAR patients. We also have patients returning to work much sooner than typical with CEA. One item worth noting is that TCAR patients must adhere to the recommended medication regimen including dual antiplatelet therapy (DAPT) and a statin. If a patient prefers to not take the prescribed medications, then we may look for an alternative treatment option as we believe that TCAR without DAPT is an unsafe procedure.

CONCLUSION

Considering these factors, it is not surprising we offer TCAR as an equivalent treatment option for our patients with appropriate anatomy requiring carotid revascularization. TCAR allows for a straightforward and easy procedure for those with otherwise challenging anatomy (eg, high lesions) for CEA. Given that "low lesions" are the most common reason a patient cannot undergo a TCAR procedure, performing CEA in these patients is technically easier than usual. It is thus no surprise that centers that adopt TCAR have a 10% reduction

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DISCUSSION ON REIMBURSEMENT

In clinical practice in the United States, reimbursement for TCAR is currently limited to high-risk patients under the diction of the Centers for Medicare & Medicaid Services. As such, much of the clinical data available on TCAR are focused solely on this subgroup of patients. However, as recently presented at the Society for Vascular Surgery's Vascular Annual Meeting,[1] a propensity-matched analysis of 14,949 CEA and 4,993 TCAR standard-risk patients in VQI demonstrated equivalent risks of perioperative stroke, death, or MI, as well as risk of ipsilateral stroke through 1 year. This study provides data that support TCAR to be a safe and effective carotid revascularization option, regardless of patient risk status. With the wealth of compelling evidence, we believe it is time to reconsider the National Coverage Decision on carotid stenting. We believe there should be an expansion of coverage for TCAR to all patients, including those at standard risk. TCAR not only has a similar stroke/death rate to CEA, but it is also safer with a lower rate of MI/CNI and is preferred by patients. There is no reason to continue to restrict reimbursement. Physicians should be able to work together with their patients to freely decide which carotid revascularization option is best for them.

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TCAR Limitations: Separating Fact From Fiction

With Rasesh M. Shah, MD, FACS, and Susan M. Shafii, MD, MHSA, FACS, FSVS

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With the ROADSTER 1 and ROADSTER 2 trials demonstrating stellar outcomes that continue to be supported by the rapidly growing number of transcarotid artery revascularization (TCAR) procedures in the TCAR Surveillance Project/Vascular Quality Initiative (TSP/VQI) database,[1-3] the role of TCAR in our carotid revascularization program is constantly being refined. As we are in the 9th year of offering TCAR as an alternative to carotid endarterectomy (CEA) and transfemoral carotid artery stenting (TF-CAS), there have been lessons learned that might be helpful to others who are just starting their TCAR programs. This is a hybrid procedure that combines the open surgical and advanced endovascular skills that are used every day in our carotid practices. However, just like any new procedure, adoption must be done appropriately and evolve continuously.

Offering TCAR to patients is currently limited by the mandate that they meet at least one high-risk criterion as outlined by the Centers for Medicare & Medicaid Services (CMS), documented to be approximately 70% of our clinic population. The remaining 30% of patients may be treated as standard risk with prior approval from their payor, but more likely will need to wait for standard risk approval by CMS. There are, however, a number of patients who should not be offered TCAR for a variety of reasons, to be discussed in this article.

In our large vascular practice, I have the privilege of being "the carotid guy." Having been in practice for 28 years, I have seen the full evolution of carotid therapies—from CEA only when I started in 1993 to the introduction of TF-CAS in 2001, and finally starting TCAR in ROADSTER 1 in 2013. All three therapies clearly still have a role, but that role continues to be redefined as the technology evolves. There are indications and, perhaps more importantly, contraindications for all three therapies. Strict attention to these is mandatory for optimizing outcomes. The choice of which treatment to offer which patient is outlined in the Society for Vascular Surgery (SVS) implementation document.[4] Interestingly, many of the considerations that may increase difficulty are actually CMS-approved indications for TCAR (Figure 1).

Neck irradiation causes a very wide variation in skin changes, which may or may not result in poor wound healing. The incision, however, for TCAR is very low and many times outside of the radiation field, resulting in no difficulty with healing. This indication for TCAR is a very good one for most patients with radiation unless they truly have severe skin changes.

Hostile neck with immobility, kyphosis, or obesity are also good indications for choosing TCAR over CEA. The incision, again, is in such a low position that even a frozen or kyphotic neck is amenable to the proximal common carotid exposure without too much difficulty. Obesity is a geometry problem, as a very deep and relatively short common carotid will make this difficult, whereas a very deep but very long common carotid will not be as difficult.

Medically high-risk patients are also another good indication for TCAR versus CEA as the data continue to support excellent results. Shorter operative times, optimal medical therapy with dual antiplatelet therapy/high-dose statin, and the ability to perform under local anesthesia all make TCAR favorable.

Heavily calcified lesions are an issue with any stent-based intervention (TF-CAS or TCAR) and are best treated at this time with CEA. There are calcium mitigation strategies that are being explored but these are not the best cases to undertake at the beginning of a TCAR program.

A short common carotid artery (CCA) (< 5 cm from access to lesion) and a small CCA (< 6 mm) are contraindications to TCAR, as stated in the instructions for use. There are ways to increase the CCA length being explored but, again, these cases are not the best ones to start a program with. A small CCA is an uncommonly encountered problem, and unless the size is due to a proximal lesion resulting in underfilling that can be corrected, these patients should not undergo TCAR.

Lastly, tracheal stomas are a problem only in the management of the incision and sterility. The TCAR incision is generally far enough away from the stoma that,

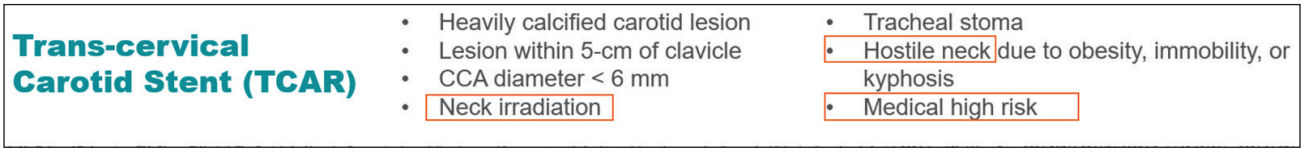

Figure 1. Treatment considerations that may increase difficulty. Reprinted with permission from AbuRahma AF, et al. J Vasc Surg. 2021;S0741-5214.

Figure 2. The learning curve for surgeons adopting TCAR based on the TSP/VQI project. Reprinted with permission from Kashyap VS, et al. J Am Coll Surg. 2020;230:113-120.

with strict attention to isolating the two, these cases can be accomplished safely. Once again, these are not the best cases with which to begin a program.

The TSP/VQI database continues to document excellent results with even first cases being done by new operators/programs; this is testament to paying attention to the details of patient selection (Figure 2). Novice operators would be best served in choosing a patient that is 75 years old with a thin, nonradiated neck, a long CCA, and a not heavily calcified lesion. Intermediate/advanced operators may feel comfortable taking on more challenging cases, such as medically high risk or with challenging anatomy. Finally, expert operators may be willing to consider patients needing advanced strategies to deal with problems such as heavy calcium burden and short CCA lengths.

In summary, TCAR is a compelling procedure that must be in the toolkit for all comprehensive carotid therapy programs. CEA and TF-CAS must also be options for revascularization, and the indications/contraindications for each must be carefully adhered to for optimizing patient outcomes. As the technology continues to evolve, we must also evolve our protocols for which patients are offered which therapy to continue to provide the best care possible.

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4. AbuRahma AF, Avgerinos E(M), Chang RW, et al. The Society for Vascular Surgery implementation document for management of extracranial cerebrovascular disease. J Vasc Surg. 2021; doi: https://doi.org/10.1016/j.jvs.2021.04.074

Fact Versus Fiction: Why I Prefer TCAR Over CEA in My Practice

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As all the surgical fields have been undergoing a minimally invasive revolution, new techniques and technologies have been developed and brought to market. They have provided equally or improved high-level, quality surgical care compared to more traditional open surgical techniques. The technology and less invasive surgical techniques have improved the quality of life by decreasing the morbidity and mortality for the entire spectrum of patients, but especially for our aging population. General surgery has adopted laparoscopic techniques, expanding beyond laparoscopic cholecystectomies to single-incision laparoscopic Heller myotomy, robotic or laparoscopic colon resection, and robotic Whipple procedures. Cardiothoracic surgery has also begun a transition from open valve replacements to transcatheter aortic valve replacement (TAVR) procedures,

mitral leaflet clipping, and robotic valve surgery and robotic lung resections.

A little more than 10 years ago, when I was contemplating a career in vascular surgery, I weighed many pros and cons. One of the deciding factors in my choice to pursue the field was the ability to be adept in both open and endovascular surgery, as well as the upcoming technologic hybrid endovascular train that was on the horizon. Our field of vascular surgery has been at the forefront of innovation in minimally invasive techniques. We have been extremely successful in bringing endovascular aneurysm repair (EVAR) to the table, equating it to open aneurysm repair, and offering new and safe techniques for patients that may never have been offered surgery in the past. Thoracic endovascular aortic repair (TEVAR) has followed suit, providing decreased morbidity and mortality for a whole host of aortic pathology. Fenestrated endografts are now launching minimally invasive endovascular surgery to the next level, providing further options for patients who do not meet the standard indications for conventional EVAR. We have tackled transforming open aortic aneurysm surgery to minimally invasive endovascular aortic aneurysm surgery, and now are becoming successful in hybrid procedures for aortoiliac disease with the newer covered endovascular reconstruction of the aortic bifurcation (CERAB) techniques and advanced aortoiliac stenting + femoral endarterectomy. We have been and continue to be at the forefront of treating infrainguinal peripheral vascular disease with stenting, drug-coated technology, and atherectomy. The vascular surgery field has even begun to create minimally invasive permanent dialysis access options with the recent technology of percutaneous arteriovenous fistula creation. Carotid artery disease is also now undergoing surgical therapy transformation.

TF-CAS has not gained widespread acceptance within the vascular surgery community, nor within the payor mix, as an acceptable alternative to open CEA in the absence of high surgical risk factors. The periprocedural stroke risk varies within the literature enough to not seek this as an appropriate treatment option for asymptomatic patients. TCAR has been demonstrated to be safe and equal as an alternative to CEA in both asymptomatic and symptomatic high-surgical-risk patients in a propensity matched analysis.[1] In fact, the procedure is best suited for these patient populations and now offers improved outcomes concerning morbidity and mortality in patients who may not have been offered therapy. The outcomes have been replicated across a variety of practices, from academic to community to rural hospitals. ■

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in cardiovascular morbidity in all carotid procedures.[12] Practitioners who are reluctant to broadly adopt TCAR offer the counterpoint that there is a lack of level 1 randomized controlled trial data comparing TCAR versus CEA. Although that may be true, it is irresponsible to ignore the wealth of currently available clinical trial and real-world data. It is also not realistic to expect completion of a randomized trial with approximately 60,000 patients in each arm, the calculated number of participants necessary to provide adequate statistical power to determine superiority between the two procedures.

TCAR is a procedure that can be easily adopted by new physicians as it leverages pre-existing surgical and endovascular skills. This procedure has a short learning curve and practitioners can expect to replicate the reported clinical outcomes even in their early experience.[13] There is no difference in the major in-hospital outcomes regardless of experience level, including stroke, death, or composite stroke/death/MI. However, increasing experience did lead to improved procedural efficiency with a decrease in operative time of > 20 minutes. With the excellent clinical outcomes, shorter procedure time, ease of adoption, as well as patient preference, we believe TCAR has proven itself to be the "new" standard for carotid revascularization. ■

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Patient Selection in My Practice

How adding TCAR to my carotid disease treatment algorithm has changed my practice.

With Thomas Divinagracia, MD, and Libby Watch, MD, FACS

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I should begin by saying that transcarotid artery revascularization (TCAR) has changed the whole work-up process for carotid patients in my practice. My evaluation of patients with critical and/or symptomatic stenosis who need revascularization now will always include the performance of a dedicated CTA of the head and neck.

When I began practice in 2008, we were operating often (particularly with asymptomatic patients) based on the duplex alone. This would come with measurements from the sternal notch to the carotid to bifurcation, as well as the angle of the mandible. So, we did have an idea about what lesions were higher lesions. But, again, many carotid endarterectomies (CEAs) and transfemoral carotid angioplasty and stent implantations were performed without a CTA being part of the imaging workup.

Patient selection involves careful consideration of patient anatomy; one initial factor being whether there is an adequate length of healthy common carotid artery for safe access. Obviously, higher (more distal) lesions are preferable. Lesions with an appropriate "runway" are more ideal than patients with a lower bifurcation and < 5 cm of common carotid artery (short runway) although, as stated by Dr. Shah, techniques to extend the runway are being explored and may be employed by experienced operators. These patients are, in general, likely better suited for open endarterectomy.

There are other anatomic features to consider. The most notable is prohibitive calcification. Highly calcified lesions with areas of dense circumferential calcium ≥ 3 mm thick are not good candidates. Conversely, patients with the less calcified "softer" lesions are more preferable for TCAR.

Extreme tortuosity noted in the carotid artery within the intended treatment area, and/or just proximal or distal to these areas, may also result in a less than desirable outcome. In my opinion, these atomic features often deter me from TCAR in such patients.

Other concerns involve a patient's medical risk factors, with a preference toward TCAR if patients are older with more comorbidities. I will admit there is an unfounded prejudice toward doing CEA on younger patients.

Pharmacologic considerations are also important to patient selection for TCAR. The need for patients to be placed on dual antiplatelet therapy (DAPT) (in particular ticagrelor, which has increasingly been our practice) is noteworthy. Although most of the physicians in our practice place patients on aspirin and clopidogrel for CEA, the need for DAPT in TCAR patients is clearly more definitive. And, with the potential need for ticagrelor and the absolute need to be maintained on DAPT for at least 1 month after stent placement, patient selection for TCAR may be affected if patients are known to be resistant to clopidogrel.

Access to (and cost of) ticagrelor and/or potential need for other invasive procedures that require patients to be off of antiplatelet therapy can make TCAR less appropriate in some patients and the same considerations would also apply to patients who have coronary drug-eluting stents.

What We Talk About When We Talk About TCAR

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I have been excited about TCAR since I completed my fellowship in 2011, but I did not perform my first TCAR until 2019. My proficiency in this technique has significantly improved my ability to deliver excellent care to my patients with carotid disease.

PATIENT CARE PLAN

Patients with carotid disease are usually referred to me by cardiologists and primary care physicians. They typically arrive with printed reports stating a percentage of stenosis and description of the plaque. Often absent from these reports are the criteria for stenosis and a report of the velocities. Thus, in some of these patients, I will repeat the carotid duplex ultrasound. If the duplex ultrasound the patient brings in is reliable and I am considering intervention, I will order CTA (if the patient is able to receive contrast).

At the first patient visit, I will talk with my patients about my philosophy and approach to carotid disease. I will explain the difference between symptomatic and asymptomatic disease. And, while sitting with the patient, I sketch the carotid bifurcation on a sheet of paper and talk about the anatomy. I shade in plaque on the drawing to demonstrate > 50% and > 80% stenoses.

During the first visit, I also discuss four treatment options with the patient and let them know which ones we should consider. These options are (1) CEA, (2) TCAR, (3) transfemoral stenting, and (4) best medical therapy. Once I have the CT angiogram and a reliable carotid duplex ultrasound, the patient and I review all available treatment options.

Patients with > 50% symptomatic carotid stenosis and > 80% asymptomatic carotid stenosis are evaluated for treatment. I look at cardiac, pulmonary, and neurologic status to determine if they can tolerate monitored anesthesia care or general anesthesia. A patient who is considered to be at prohibitive surgical risk by a cardiologist or pulmonologist is generally treated with medical therapy and an evaluation by my neurointerventional radiology colleagues for transfemoral stenting. Patients who are not suitable for TCAR due to common carotid disease or low bifurcation who have acceptable aortic arch are referred for transfemoral carotid stenting. Patients with prohibitive aortic arch disease or circumferential calcification are managed with best medical therapy.

CHOOSING TCAR

I follow the Centers for Medicare & Medicaid Services (CMS) definition for high surgical risk (Table 1)[1] to determine whether patients should undergo CEA or TCAR. Comorbid conditions that will determine a patient to be high risk for CEA include age > 75 years, unstable angina, abnormal stress test, congestive heart failure, uncontrolled diabetes, and others. The anatomic risk factors include surgically inaccessible lesion, recurrent carotid stenosis, previous neck irradiation, spinal immobility, high risk for wound infection, and contralateral occlusion. If patients meet any of these criteria, and the anatomy is acceptable, I will offer TCAR as the first option.

Patients being considered for TCAR must be able to receive dual antiplatelet therapy (DAPT) for 30 days postprocedure and not have a metal allergy. Triple therapy is defined as anticoagulant and DAPT. If the patient is on anticoagulant therapy, there is an increased risk of

TABLE 1. CMS DEFINITIONS OF HIGH-SURGICAL RISK

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection) and would be poor candidates for CEA. The determination that a patient is at high risk for CEA and the patient's symptoms of carotid artery stenosis shall be available in the patient medical records prior to performing any procedure. The definitions used to determine patients at high risk for CEA include those criteria used in the prior carotid artery stenting trials and studies.

An amalgamation of the "High Risk for CEA" inclusion criteria of those studies is as follows; patients must have one or more criteria:

Comorbid Conditions	Anatomic Conditions
▪ Age ≥ 75 years	▪ Prior head/neck surgery or irradiation
▪ Congestive heart failure	▪ Spinal immobility
▪ Left ventricular ejection fraction ≤ 35%	▪ At risk for wound infection
▪ Two or more diseased coronary arteries with ≥ 70% stenosis▪	▪ Restenosis after CEA
▪ Unstable angina	▪ Tracheostomy or tracheostoma
▪ Myocardial infarction within 6 weeks	▪ Surgically inaccessible lesion
▪ Abnormal stress test	▪ Laryngeal palsy; laryngectomy; permanent contralateral cranial nerve injury
▪ Need for open heart surgery	▪ Contralateral occlusion
▪ Need for major surgery (including vascular)	▪ Severe tandem lesions
▪ Uncontrolled diabetes	▪ Bilateral stenosis requiring treatment
▪ Severe pulmonary disease	▪ Dissection
▪ History of liver failure with elevated prothrombin time	

spontaneous bleeding, surgical bleeding, and intracranial bleeding (including reperfusion hemorrhage) with triple therapy. The American College of Cardiology has issued an expert consensus decision pathway for patients requiring anticoagulant and DAPT.[2] Recommendations state that the duration of triple therapy shall not exceed 30 days. Additionally, gastrointestinal prophylaxis should be utilized and anti-inflammatory medications avoided. Direct oral anticoagulants are preferred over vitamin K antagonists.

Patients with carotid disease with known hypercoagulable state, recent history of venous thromboembolism, or atrial fibrillation with a CHADS2 score of ≥ 4 who are prescribed an anticoagulant are all evaluated on an individual basis to determine the risk/benefit ratio of TCAR versus CEA.[3] TCAR may require a 30-day course of triple therapy. Patients undergoing CEA will restart anticoagulation 24 hours after surgery and a 30-day course of single antiplatelet therapy (aspirin, 81-mg dose). I discuss these risks with each patient—the risks and consequences of a neck hematoma after CEA (infection/airway compromise) versus the risk of intracranial bleeding after TCAR requiring 30 days of triple therapy. Symptomatic patients with documented stroke who are considered for TCAR are also individually evaluated with the help of neurology and my neurointerventional colleagues. Usually, these patients will be restarted on anticoagulation prior to intervention when cleared by neurology and will require interval imaging to evaluate for hemorrhagic transformation of the stroke. To arrive at the optimal treatment plan for each individual patient requires a thoughtful discussion between the surgeon and patient, as well as input from the involved cardiologists and neurologists. This can be the most rewarding aspect of the preoperative experience.

CONCLUSION

So, how has TCAR changed how I approach carotid disease? The cases that are challenging for surgery—high bifurcations, patients who have undergone neck radiation, and posteriorly located carotid arteries—are now straightforward TCAR cases. Patients who were previously poor surgical candidates due to medical comorbidities are very reasonable TCAR candidates. In the past, I've turned down these patients with significant comorbidities for surgery and referred them for transfemoral stenting. However, a significant number of these patients have a diseased arch and are at increased risk for intraprocedural stroke. That risk is lowered by avoiding the arch and establishing flow reversal before crossing the lesion during TCAR.

There is still a role for CEA in my practice. I have patients who have previously undergone contralateral CEA and were pleased with the outcome. I have had patients with aspirin and metal allergy unable to be treated with a stent. With expanded treatment options, carotid disease patients have been thoughtfully screened and the surgically challenging cases have been offered TCAR. So, by definition, the patients undergoing CEA have better anatomy and fewer comorbidities. Outcomes, patient satisfaction, and surgeon satisfaction are improved all around. This is the benefit of adding TCAR to my treatment algorithm. ■

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Medicare Reimbursement for TransCarotid Arterial Revascularization (TCAR)

How are hospitals and physicians reimbursed by Medicare for TCAR procedures?

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Understanding reimbursement for the transcarotid artery revascularization (TCAR) procedure requires identifying the primary payer, what specific payer coverage policies apply to TCAR, what is the correct diagnosis and procedure coding, and finally, what are the hospital and physician procedural payments (Figure 1).

The TCAR procedure uses the FDA-approved ENROUTE Transcarotid Stent and Neuroprotection system (Silk Road Medical) and has a distinct Centers for Medicare & Medicaid (CMS) reimbursement pathway as of September 2016.

PAYER

The first step to understanding reimbursement is to identify the patient's primary payer. Based on the Society of Vascular Surgery/Vascular Quality Initiative transcarotid artery revascularization (SVS/VQI TCAR) Surveillance Project (TSP), > 65%[1] of the patients are Medicare beneficiaries and will therefore follow Medicare coverage policies, coding guidance, and payment systems.

For commercial payers, such as Blue Cross Blue Shield, United Healthcare, and Aetna, extracranial carotid angioplasty and stenting policies differ and require case-by-case review.

COVERAGE

The Medicare Coverage policy for TCAR is based on a broad CMS National Coverage Determination (NCD) 20.7 titled Percutaneous Transluminal Angioplasty (PTA).[2] Within this policy, which was last revised on January 1, 2013, there are two key nationally covered indications that

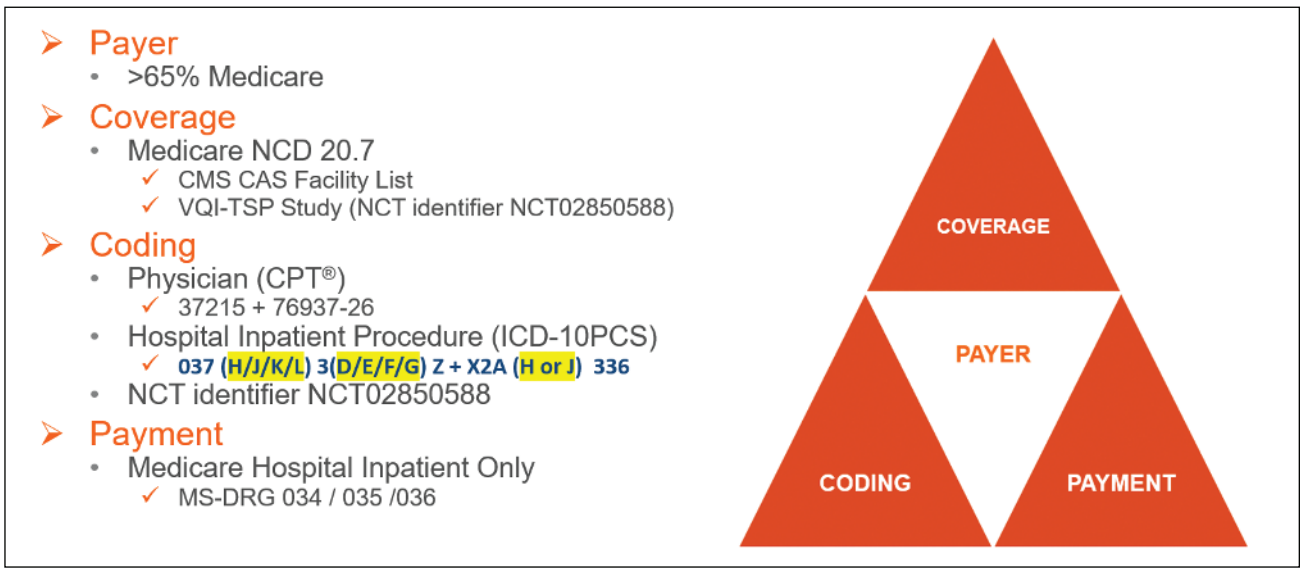

Figure 1. Four key components for TCAR reimbursement.

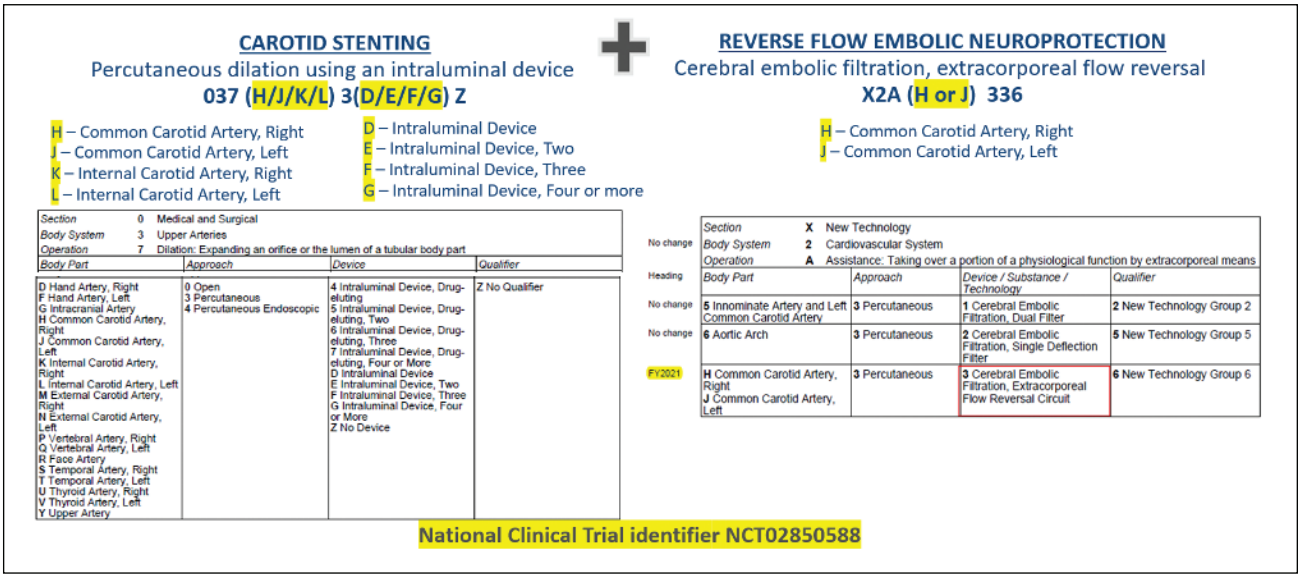

Figure 2. Hospital inpatient only procedure coding (ICD-10 PCS) (https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs).

apply to carotid artery stent placement (which includes TCAR):

"B. Nationally Covered Indications

3. Concurrent with Carotid Artery Stent Placement in FDA-Approved Post Approval Studies
4. Concurrent with Carotid Artery Stent Placement in Patients at High Risk for Carotid Endarterectomy"

A letter from CMS to the Society of Vascular Surgery Patient Safety Organization (SVS PSO) dated 09/01/2016 states "patients participating in the VQI-TCAR Surveillance Project are included in the currently covered population of patients participating in FDA-approved post-approval studies (Pub. 100-3, 20.7, B3)." Therefore, TCAR cases performed at facilities participating in the VQI Carotid Artery Stenting (CAS) Registry are part of the CMS-approved CAS Investigational Studies – VQI-TSP as referenced on the CMS website (https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-CAS-Investigational-Studies). Hospital and physician claims document their participation in the VQI-TSP by adding the National Clinical Trial identifier NCT02850588 to their claims. To date, most patients treated with TCAR are enrolled in the VQI-TSP, which expands coverage to include the patients at high risk for carotid endarterectomy (CEA) and symptomatic with ≥ 50% stenosis or asymptomatic with > 80% stenosis.

As of September 2021, 726 (85%) of the 855 SVS/VQI participating centers subscribe to the CAS Registry. To learn more about participating in the SVS/VQI CAS Registry you can contact the SVS/VQI directly (https://www.vqi.org/directory/join-the-vqi/).

The other key requirement for Medicare CAS coverage is for the facilities to be listed on the Carotid Artery Stenting Facilities list of hospitals that have met the CMS minimum facility standards for performing CAS for high-risk patients.

As of September 2021, there are 1,458 facilities on the CMS Carotid Artery Stenting Facilities website (https://

TABLE 1. TCAR AND OTHER CAS PROCEDURES ARE GROUPED INTO DIFFERENT MS-DRGS

TCAR and CAS MS-DRG Description	FY2022 Estimate National Payment
034 – Carotid artery stent procedure with major complications and comorbidities (MCC)	$ 26,233
035 – Carotid artery stent procedure with complications and comorbidities (CC)	$ 15,429
036 – Carotid artery stent procedure without MCC/CC	$ 12,215
CEA MS-DRG Descriptions	**FY2022 Estimate National Payment**
037 – Extracranial procedure with major complications and comorbidities (MCC)	$ 21,614
038 – Extracranial procedure with complications and comorbidities (CC)	$ 10,939
039 – Extracranial procedure without MCC/CC	$ 7,512
Source: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page	

TABLE 2. MEDICARE PHYSICIAN FEE SCHEDULE PAYMENTS FOR TCAR ASSIGNED TO NATIONAL MEDICARE PAYMENTS AND RELATIVE VALUE UNITS (RVUs)	
CPT Description	**CY2022 National Payment and RVUs**
37215 - Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection **90-day Global period** **Co-surgeons (-62 modifier) not permitted**	$ 1,009 W-RVU – 17.75 PE-RVU – 6.97 MP-RVU – 4.43
76937-26 – Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real-time ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure) – professional component (-26) **ZZZ Global period assigned to primary procedure** **Co-surgeons (-62 modifier) not permitted**	$ 14 W-RVU – 0.30 PE-RVU – 0.08 MP-RVU – 0.02
Source: OPTUM 360® EncoderPro.com; https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched	

www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-Facilities).

CODING

The primary physician procedural coding for TCAR is the same as for CAS—CPT procedure code 37215. However, for TCAR, when ultrasound guidance for vascular access in the femoral vein is required with permanent recording and reporting, CPT 76937-26 may also be documented and coded.

CPT 37215—Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection

CPT 76937-26—Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent real-time ultrasound visualization of vascular needle entry, with permanent recording and reporting (List separately in addition to code for primary procedure) – professional component (-26)

For hospital inpatient procedure coding, TCAR has two distinct ICD-10 PCS codes to identify the carotid stenting and the reverse flow neuroprotection components (Figure 2).

PAYMENT

Medicare hospital TCAR payment policies are aligned with CAS procedures. Medicare updates annually in the Hospital Outpatient Prospective Payment System Rule a list of procedures that are deemed as hospital inpatient only procedures. The CPT code 37215 for CAS is on the CY 2021 list (https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-fc).

The Medicare Hospital Inpatient Payment System for TCAR, is paid according to Medicare Severity–Diagnosis Related Groups (MS-DRGs) assigned to an inpatient discharge. Hospital-specific MS-DRG payments can differ significantly based on hospital locality wage index, graduate teaching status, and uncompensated care status. TCAR and other CAS procedures are grouped into different MS-DRGs (MS-DRGs 034/035/036) from CEA procedures (MS-DRGs 037/038/039) based on ICD-10 diagnoses and procedures (Table 1).

The Medicare Physician Fee Schedule payments for TCAR are assigned to the following National Medicare payments and relative value units (RVUs) (Table 2).

SUMMARY

Hospital and physician reimbursement for medical procedures such as TCAR are based on four key components: payer, coverage, coding, and payment. Because the primary payer for TCAR is Medicare, we focused our coverage, coding, and payment policies on Medicare. Updates to Medicare hospital inpatient payments are effective as of October 1, 2021, and physician payment updates are effective as of January 1, 2022. ■

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2. CMS Manual System Pub. 100-3 Medicare National Coverage Determination 20.7 Percutaneous Transluminal Angioplasty (PTA) ; February 8, 2013; https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=201&ncdver=10&bc=0

Platelet Function Testing and TCAR

With Edgar Guzman, MD, FACS; Katherine Teter, MD; Tom Hawken, MD, Hernan Bazan, MD, DFSVS, FACS; and Angela Martin, MD

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Preoperative confirmation of dual antiplatelet therapy (DAPT) compliance is essential to transcarotid artery revascularization (TCAR) practitioners. Unfortunately, even with this emphasis, a recent analysis of the Vascular Quality Initiative (VQI) data set reports that only 79% of patients received DAPT.[1] With > 40,000 cases performed to date worldwide, breaches in DAPT compliance have been implicated as the single most important factor in perioperative stroke events.

Given that the incidence of TCAR-related stroke is very low at 1.4%,[1] it is difficult for a single practitioner or institution to discern meaningful trends in their negative outcomes. It is in assessing the totality of data that actionable patterns emerge as we strive toward a zero-stroke therapy for carotid stenosis. From this vantage point, testing for clopidogrel resistance and first-line use of more reliable (albeit more expensive) antiplatelet agents emerge as the main strategies with the potential to improve outcomes in this population.

In this collection of articles the authors present their perspectives on the magnitude of the clopidogrel resistance problem and awareness among practitioners, primers on testing protocols available, and pointers on incorporating platelet function testing in a TCAR practice.

The authors recognize there are currently no data proving the superiority of platelet function testing-guided clopidogrel therapy over blind therapy in improving TCAR outcomes; nor are there specific data supporting the use of ticagrelor to the same end. Given the low frequency of stroke events with TCAR, it will take very large numbers to demonstrate either hypothesis. And yet, there are presently two reliable, affordable, and widely available methods to estimate the effectiveness of DAPT as well as pharmacologic alternatives to clopidogrel. With these options, accepting a therapy that is at best 80% effective is no longer necessary or, for that matter, justifiable. We hope that, over time, efforts to optimize DAPT will prove beneficial not only in further improving TCAR outcomes but in bettering the care of vascular patients at large.

THROMBOELASTOGRAPHY

Thromboelastography (TEG) is a whole blood assay that records the kinetics of the coagulation process from initial activation to clot lysis. It does so by tracking the viscoelastic changes of blood as it transitions from a liquid to a gel. These changes are reflective of the functional contributions of the various hemostatic components.

In its original form, TEG assessed global platelet function via determination of the peak viscosity of the sample, expressed by the maximum amplitude (MA) in the tracing. This result is representative of platelets binding to the developing fibrin mesh and is therefore affected by both platelets and fibrin with an 80%/20% contribution between the two. However, in its basic form, the test is unable to determine whether variations in MA are due to changes in platelet number or function and does not offer therapeutic ranges to guide antiplatelet therapy. Furthermore, full activation of the platelets in the sample by the addition of kaolin and calcium chloride overshadows the effect of platelet inhibitors.[2]

To address this, TEG with platelet mapping (TEG-PM) was developed. This assay consists of four parallel TEG tests carried out with different agonists. Maximum platelet function is determined in one channel with kaolin and calcium chloride, as described previously, for standard TEG.[3]

The contribution of fibrin to MA is determined in a second channel by the addition of activator F. This activator is a combination of reptilase (which has a thrombin-like effect transforming fibrinogen to fibrin) and factor XIIIa (which crosslinks fibrin). In effect, these two agonists bypass the coagulation cascade and elicit fibrin formation and crosslinking from the sample without directly activating platelets. The addition of abciximab (IIb/IIIa receptor blocker) inhibits platelet activation.

The P2Y12 receptor binds adenosine diphosphate (ADP) on the platelet surface and activates them. Estimation of the effect of P2Y12 inhibitors, such as clopidogrel, is determined by the addition of activator F

and ADP to the sample. Comparison to the activator F channel allows the estimation of the incremental contribution of platelets activated by ADP to the MA. Comparison to the standard TEG channel may identify a deficit in MA amplitude attributable to the presence of a P2Y12 inhibitor.

Cyclooxygenase in platelets converts arachidonic acid (AA) into thromboxane, which in turn promotes platelet activation. Assessment of the inhibitory effect of aspirin on this enzyme is estimated similarly by the addition of activator F and arachidonic acid to the sample. In parallel to what has been described previously; comparison to the activator F channel allows the estimation of the incremental contribution of platelets activated by AA to the MA. Comparison to the standard TEG channel may identify a deficit in MA amplitude attributable to the presence of a cyclooxygenase inhibitor. In either case, the degree of inhibition can be expressed as an absolute MA in millimeters or as a percentage of the MA in relation to the maximally activated sample.

Until relatively recently, TEG-PM measurements were carried out in a moving cuvette system in which a filament immersed in the sample recorded varying degrees of resistance as the cuvette moved and the sample shifted phases. This process was labor-intensive and required four parallel tests to be performed, as described previously. This has been improved upon by the introduction of an automated cartridge-based system that replaces the moving cuvette and filament method by observations of the oscillations in the sample as it is subjected to vibrations across a frequency spectrum. Generally speaking, as the sample shifts from liquid to gel the resonant frequency increases as does the amplitude of oscillations.[4]

From a pragmatic approach, interpretation of a TEG-PM result for TCAR need only focus on two reported values.

- A maximum amplitude induced by ADP (MA-ADP) of ≤ 47 mm
- A percent inhibition of platelet function by AA (AA%) of ≥ 50%

In my experience, the use of these two values has proven enough to adjudicate most cases, with further analysis needed sporadically in equivocal scenarios; mostly when there is a poor correlation between expected and actual results.

Implementation of TEG testing into a TCAR practice can be very straightforward if the technology is already available at the organization. This is often the case in centers that practice trauma surgery and cardiac surgery. However, some barriers I have encountered at different institutions include the availability of TEG but not TEG-PM and the competing use of resources with other service lines that may have "blocked time" on the analyzer.

TEG-PM is affordable at a laboratory cost of $250 per study. Full results are available in approximately an hour, but real-time reporting yields MA data in 20 to 30 minutes. The test is usually available to order directly by the physician through the electronic medical record and I would advise colleagues to do just that. Administrative discussions can be had in the future if objections arise.

Performing TEG-PM the day of surgery versus during presurgery testing is a logistical decision heavily influenced by local practice and resource availability. The advantage of the former is that it provides the most up-to-date information possible and may identify intervening factors beyond resistance; the latter minimizes disruptions in scheduling due to unexpected results.

TEG-PM can be very useful in the management of bleeding complications within the 30 days of recommended DAPT after TCAR. I have observed a few cases of gastrointestinal bleeding and found that these patients had very intense platelet inhibition by both aspirin and clopidogrel. Using TEG-PM, we were able to safely hold both drugs until values returned to the low end of the therapeutic range, at which point patients would often settle into alternating day aspirin and clopidogrel dosing.

In closing, I believe present-day TEG-PM represents a very elegant implementation of a complex testing algorithm that nonetheless yields results that are broad in scope, reproducible, and easy to interpret having the potential to modify day-to-day clinical practice.

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4. Coramed Technologies LLC. 501(k) substantial equivalence determination decision memorandum – coagulation resonance analysis system with platelet mapping assay. Available from https://www.accessdata.fda.gov/cdrh_docs/reviews/K140893.pdf. Accessed on September 24, 2021.

Acknowledgment:
I would like to thank Dan Mason, MSN, Medical Science Liaison at Haemonetics Corporation for his unwavering support in promoting a thorough understanding of TEG and assistance in ensuring the technical accuracy of this article.

Clopidogrel Resistance in the Vascular Patient

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Although clopidogrel resistance (CR) may be underrecognized in routine vascular practice, our experience with CR and routine testing suggests that patients exist on a spectrum of response to clopidogrel. A level of response below normal is common, although complete nonresponse remains rare. Further study is needed to characterize which patients are at the highest risk of adverse events given the degree of CR and to determine if a quantitative measurement of CR is a sufficient risk measurement tool.

In our subgroup analysis of 300 patients enrolled in the Platelet Activity and Cardiovascular Events (PACE) study, 104 patients taking clopidogrel were identified. Patients were then followed for a median of 18 months to assess for major adverse limb events (MALEs), including major amputation or reoperation and major cardiovascular events. Patients were stratified as poor responders or normal responders for platelet aggregation ≥ 50% or < 50%, respectively (VerifyNow P2Y12, Accumetrics, Inc.). Approximately 25% of patients taking clopidogrel were poor-responders based on platelet aggregation, and this was significantly associated with increased MALEs, suggesting that CR is a key component in the risk of adverse outcomes after lower-extremity revascularization.[1]

CR was similarly common among patients undergoing TCAR at several data-sharing institutions. Sixty-seven patients who underwent TCAR between January 2018 and January 2021 were identified. Of these, 38% of patients met the criteria for CR based on light transmission aggregometry (VerifyNow P2Y12) and 13% were hyper-responders. No significant differences were identified in postoperative ischemia or hemorrhagic complications between patient groups; however, the overall complication rate of TCAR is exceedingly low. Larger studies will be necessary to assess for a statistically significant difference, although this highlights the frequency of CR in the usual vascular patient.[2]

These studies illustrate that CR is significantly prevalent in vascular patients being treated for peripheral and cerebrovascular disease, and there is a need for a greater understanding of risk stratification based on the degree of responsiveness, as a poor response may be associated with adverse outcomes. As we know from patients enrolled but excluded from ROADSTER 2 due to procedural violations (largely medication noncompliance), patients who did not take dual antiplatelet/statin therapy as instructed had substantially higher adverse events, particularly symptomatic patients.[3] This implies that CR may confer the same substantial risk.

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Platelet Function Testing and TCAR

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To better understand how common CR is among a mixed cohort of cardiovascular patients, we identified 3,301 patients who underwent CR testing in our health care system from October 2014 to January 2020.

The test used in our system is the VerifyNow P2Y12 rapid platelet-function assay. Results are expressed in P2Y12 reaction units (PRU). A PRU value ≥ 200 while on clopidogrel suggests an insufficient antiplatelet effect of the drug.

Of the 3,301 patients identified with a PRU test, 1,789 patients (54%) had a PRU value ≥ 200 while on clopidogrel.

Next, using CPT codes, we identified subgroupings of patients undergoing endovascular peripheral procedures (n = 260) and patients undergoing coronary procedures

(n = 935). This comprises a wide mix of endovascular interventions, including carotid/vertebral interventions 55/260 (20.7%), iliac and infrainguinal 117/260 (45%), mesenteric 36/260 (13.9%), intracranial 24/260 (9.2%), and venous intervention 28/260 (10.8%).

In the endovascular cohort, 137 (53%) of 260 patients had a PRU value ≥ 200. In the coronary cohort, 503 (54%) of 935 patients had a PRU value ≥ 200.

In statistical analysis of the groups, patients with a PRU value ≥ 200 were more likely to be older (69.3 vs 66 years; $P < .0001$), less likely to be male (54.4% vs 64%; $P < .0001$); more likely to have a history of smoking (76.1% vs 70.1%; $P < .0001$), diabetes mellitus (54.4% vs 39.9%; $P < .0001$), have chronic kidney disease (56.4% vs 39.8%; $P < .0001$), and more likely to be anemic (38.2% vs 25.8%; $P < .0001$).

The prevalence of inadequate antiplatelet effect of clopidogrel in our cohort of patients undergoing peripheral endovascular and coronary interventions was high (53%-54%). The study did not ascertain whether CR leads to negative clinical effects. Future prospective studies are needed to determine the clinical effect of CR on patients undergoing peripheral intervention.

Understanding P2Y12 Inhibitors, Clopidogrel Resistance, and Alternative Drugs

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While aspirin and clopidogrel are the dominant first-line medications to achieve adequate antiplatelet effect in patients undergoing peripheral, coronary, and carotid endovascular interventions, recent literature suggests that CR could be as high as 53% in patients undergoing peripheral endovascular interventions, as highlighted in the previous commentary by Drs. Hawken and Bazan.[1]

A recent polling of vascular surgeons was conducted regarding their overall understanding of antiplatelet therapies (Macdonald S. Focus group survey. Internal Silk Road Medical Report, unpublished. 2021). They were queried about their practice patterns regarding choice of medication and testing for resistance to these drugs for patients undergoing noncarotid and carotid revascularization procedures. One hundred forty-six surgeons responded across 36 states. The mean years in practice was 15, with an average of 62 carotid revascularization procedures annually. The vast majority (80%) responded that they frequently use clopidogrel, while ticagrelor is less commonly utilized. Prasugrel and intravenous cangrelor were used to a far lesser extent.

The respondents estimated on average that 16% of their vascular patients have resistance to antiplatelet medications. Nineteen percent of surgeons routinely tested for clopidogrel resistance before carotid procedures and slightly fewer tested patients before noncarotid vascular procedures; 43% selectively tested patients receiving carotid revascularizations if they thought their patients were likely resistant to clopidogrel. Characteristics that respondents believed would indicate CR included (in decreasing importance): history of prior stent or graft thrombosis, concurrent medication usage that interferes with clopidogrel metabolism, active smoking, Asian heritage, diabetes, age > 75 years, and having a body mass index > 30.

More than a third of surgeons did not test for CR before carotid procedures and this was not influenced by their years in practice. Of those who did test for CR, 54% utilized the VerifyNow P2Y12 inhibitor assay, whereas 24% used TEG-PM (Haemonetics). Six percent utilized genetic testing while the remaining employed aggregometry, routine clotting labs, or deferred to another specialist.

As evidence mounts that CR is much more common than previously recognized, our testing and understanding of optimal platelet inhibition are evolving. This poll emphasizes the gap between the technical excellence we have achieved with carotid and other major revascularizations and the precise medical management of these patients. Our willingness to adapt with ever-expanding technology will allow our patients to have the best possible outcomes from not only carotid revascularizations but all vascular procedures. ■

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Unpacking the 'Association of Adoption of Transcarotid Artery Revascularization with Center-Level Perioperative Outcomes' Article

All boats rise with TCAR.

With Nathan J. Aranson, MD, FACS, RPVI, and Joseph J. Ricotta, MD, MS, DFSVS, FACS

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As an early adopter and enthusiast of transcarotid artery revascularization (TCAR), I read with great interest, the article by Columbo et al entitled "Association of Adoption of Transcarotid Artery Revascularization with Center-Level Perioperative Outcomes."[1] Like many of my colleagues, I am often viscerally satisfied with reading literature that supports my intuition and practice. We all enter medicine with the hope of providing safe, high-quality care and adopt technology only after we can justify its safety and efficacy. Despite myriad publications supporting the beneficial outcomes of TCAR in the treatment of patients with carotid atherosclerotic disease, this is the first to suggest that utilization of this platform improves the care of patients with the disease process as a whole, regardless of surgical intervention type.

In brief, this comparative effectiveness study utilizes the Vascular Quality Initiative (VQI) to conduct a difference-in-difference analysis to estimate the association that the adoption of TCAR has on the rate of major adverse cardiovascular events (MACE), a composite of in-hospital stroke, myocardial infarction, or death at 30 days after carotid revascularization. This is then compared to the rate at which a center was predicted to perform had they not adopted the new technology. Many readers, like myself, are unfamiliar with this analysis. Typically, it is utilized to analyze the association between policy changes and their eventual outcome when the rollout occurs over a period of time (continuous). Statisticians then utilize regression modeling, creating a variable to divide the groups to estimate statistical significance.[2] In the article by Dimick and Ryan, the "policy change" is the adoption of the TCAR procedure in certain centers. This variable is continuous as new users are continuously attending the "Test Drive" courses conducted by Silk Road Medical to gain training on the TCAR procedure. These surgeons then bring this platform back to their hospitals to be utilized in the surgical treatment of their patients. All of these surgeons operate at centers that have purchased the VQI carotid stenting module to gain reimbursement through the TCAR Surveillance Project (TSP) and some of these centers also have the carotid endarterectomy (CEA) module allowing the data for this study to be collected.

The validated hypothesis of this study is not surprising given the heightened MACE shown in the publication by Schermerhorn et al.[3] This article revealed that the same high-risk criteria that allow Centers for Medicare & Medicaid (CMS) coverage for TCAR also heightens the risk of MACE when these patients undergo CEA. It would suppose that if this subset of patients were to transition to TCAR from CEA, then the CEA outcomes would improve. Looking at the demographic data and univariate analysis, the TCAR cohort does represent this high-risk population with increased age, comorbidities, and reoperations. Presuming that these patients are preferentially going to be selected for TCAR, which provides them an equivalent stroke/death risk and reduced MI hazard in standard-risk patients undergoing CEA, instead of undergoing CEA that has an elevated MACE risk in high-risk patients, the overall MACE incidence should drop. Columbo et al reveals this to be true with a 10% lower incidence of perioperative MACE after carotid intervention in centers after the adoption of

TCAR.[1] It also suggests that the individual surgeons are playing an important role by selecting the correct patients to undergo TCAR.

Although my inherent bias on the positive outcome of the TCAR procedure allows me easily to trust the findings of such a study, I must ponder the limitations to offer a true critical analysis. The authors suggested their reasoning behind the complex statistical analysis to limit the suspicion of most selection and reporting bias. Regardless, the reality is that even though all centers performing TCAR must have the VQI carotid stenting module to collect CMS reimbursement, those same centers are not mandated to have the CEA module. This does extend the possibility of selection bias as predictively, centers more supportive of the VQI are more interested in outcomes data collection and thus tend to more likely be academic centers. Not entirely suggesting that academic centers are synonymous for high-quality centers, they often are tertiary care referral centers with increased surgical volume and case complexity. This may certainly account for selection bias and lack of heterogeneity of data, making this less applicable to the 90% of patients who undergo annual CEA at hospitals that are not utilizing the VQI during the period of this study.

If you are a surgeon treating carotid occlusive disease and have not yet adopted TCAR, this publication gives you yet another reason to do so. If you are concerned about the learning curve, Kashyap et al reveals both the safety for the novice operator along with the short learning curve, becoming an expert after approximately 25 procedures.[4] If you are worried about being able to find enough patients to utilize this platform on, the literature suggests that two-thirds of patients undergoing carotid intervention meet one high-risk criterion, and 72% of those have anatomy amenable to TCAR.[5] If you are skeptical about the lack of long-term data, meta-analyses validate the safety and efficacy of this stent and reveal acceptable long-term patency up to 10-years.[6,7] Indeed, the rates of significant restenosis and the survival free of stroke for CEA and stent placement at the carotid bifurcation are equivalent. And if you have already adopted this technology, take comfort in the positive outcome that having this surgical option available to your patients has on the overall reduction in MACE. For those who have eagerly adopted TCAR and are continuing to perform this on an increasing number of patients, you are the flood tide raising all boats.

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President John F. Kennedy popularized the phrase "A rising tide floats all boats" to describe the concept that when an economy is doing well, all people will benefit from it. This same message can be extrapolated to the treatment of carotid disease for the prevention of stroke. When a new technology with proven benefit, such as TCAR, is introduced it not only provides another tool in the toolkit but allows for more appropriate usage and application of those tools that inevitably translate into improved results. Continuing with the tool analogy, the psychologist Abraham Maslow famously wrote in his 1966 book, *The Psychology of Science*, "It is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail."[1] This concept has led to a cognitive bias that has been perpetuated for decades among vascular surgeons and nonsurgical interventionalists who perform procedures to treat patients with carotid disease. Many vascular surgeons who perform CEA do not perform transfemoral carotid stenting (TF-CAS), and nonsurgeon interventionalists perform TF-CAS but do not perform CEA. This "hammer–nail" bias can lead to patients undergoing procedures for which they may not be optimal candidates. In other words, matching the patient to the intervention instead of matching the intervention to the patient.

The adoption of TCAR as a safe and effective treatment for carotid revascularization has provided an alternative to CEA and TF-CAS. The simplicity of the TCAR system allows for a short learning curve,[2,3] enabling vascular surgeons

INVITED EXPERT COMMENTARY

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Readers of ***Endovascular Today*** have been introduced to an additional favorable concept relative to the adoption of transcarotid artery revascularization (TCAR)—that such adoption is accompanied by improved results in all available carotid revascularization options. I certainly agree with Dr. Aranson that the statistical modeling employed in the article by Columbo et al[1] is indeed complex, and the nuances of data collection in the Vascular Quality Initiative (VQI) TCAR Surveillance Project potentially add selection bias. At the same time, the available volume and in particular the consistency of the TCAR data make both the authors' data and the perspectives of Drs. Aranson and Ricotta soundly supported by all available evidence. And yes, it is rewarding to see one's own perspective and opinion supported by rigorous evidence and the opinions of fellow vascular surgeons whose work I hold in high esteem.

Although in a comparative sense it is true that I was an early adopter of TCAR, it is more precise to state that I was an early investigator of TCAR because I had the privilege of serving as National Principal Investigator for the ROADSTER 1 pivotal trial, organized almost a decade ago. The background thereof is of interest because at the time, while serving as President of the Society for Vascular Surgery (SVS), there was a surfeit of both investigative (eg, publication of the CREST 1 study) and regulatory activity (eg, a CMS MEDCAC on carotid atherosclerosis and the SVS position on the NCD for transfemoral carotid artery stenosis [CAS]) referable to transfemoral CAS. Indeed, at my June 2012 SVS presidential address that focused on carotid disease, I suggested that transfemoral CAS with distal filter protection was an experiment that had failed and further refinements in CAS would be needed before such endovascular treatment of the carotid bifurcation could achieve the admirable safety and efficacy track record of CEA. Accordingly, it is gratifying and a great advance for our patients that TCAR with its documented superior flow reversal protection strategy has proven to be THE technical evolution of CAS. A substantial body of evidence at this time indicates that overall periprocedural results are favorable compared to CEA, and decidedly superior to the now outmoded transfemoral CAS.

In this regard, neither of my coauthors has cited the work of Schermerhorn et al, wherein utilizing the CMS CAS registry (recall that an institution needed CMS approval to be CAS certified with a requirement for data reporting) in a study published in ***JAMA*** in November 2019, the authors documented significantly improved results with TCAR as compared to transfemoral CAS in the hard endpoints of periprocedural stroke and death![2]

Furthermore, the data are most compelling in the management of symptomatic patients, wherein transfemoral CAS is accompanied by simply unacceptable complication rates. Perhaps there is a patient with carotid disease in contemporary practice in whom transfemoral CAS is the best option, it is just that I have not observed such a patient in 35 years of clinical practice. In the comparison of carotid revascularization procedures, it is important to emphasize (and in fact this was somewhat of a surprise to me) that long-term protection from stroke is equivalent for CEA and CAS. A decade ago, I would never have guessed that luminal expansion of the carotid lesion with an uncovered stent would afford equivalent long-term stroke prophylaxis compared to removing the plaque. Yet, multiple high-quality data sources, including that available from CREST, the European cooperative study group for the randomized symptomatic carotid trials, and now ACST-2, have documented that this is indeed the case. Accordingly, because TCAR has proven equivalent or superior to CEA, patients can benefit from a less invasive procedure.

Worthy of further emphasis and the essence of the articles is the issue of TCAR adoption, which is in fact sporadic among the community of vascular surgeons. Obviously, this is partly related to regulatory considerations because both the ROADSTER studies and the TCAR Surveillance Project (wherein participation in VQI is required) are limited to high-risk patients. As emphasized by Dr. Aranson, VQI data indicate that overall results with CEA in this patient subgroup are inferior to CREST results, for example, and many cumulative series of CEA, including those published by our group. Obviously, it is a powerful statement that the admirable results with TCAR to date have been achieved in high-risk patients; further prospective studies in average risk patients are imminent and it is hoped that the TCAR Surveillance Project will be expanded to these patients as well. Finally, it is abundantly clear to this author, that in the important realm of patient-centered outcomes, TCAR will prove to be the preferred revascularization strategy in many, if not most, patients.

1. Columbo JA, Martinez-Camblor P, O'Malley AJ, et al. Association of adoption of transcarotid artery revascularization with center-level perioperative outcomes. JAMA Netw Open. 2021;4. doi: 10.1001/jamanetworkopen.2020.37885
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with basic wire and catheter skills to become rapidly proficient. In addition, several studies have demonstrated superior outcomes for TCAR when compared to CEA and TF-CAS in certain subgroups of patients. This is in contrast to TF-CAS, where the outcome benefits have not been as demonstrable when compared to CEA in recent trials (CREST, ICSS) and where a more sophisticated endovascular skill set is often required.

The article by Columbo et al was cleverly designed and quite provocative.[4] The idea that expanding treatment options available to patients translates into better patient selection for a specific procedure that in turn leads to better outcomes across the board is intuitive, yet not obvious. Columbo et al have elegantly described that careful selection of procedure and patient leads to improved outcomes not just for one carotid revascularization procedure (TCAR), but for all (10% reduction in MACE at 12 months).[4]

We have experienced similar results at our institution where we began performing TCAR in 2018. Since that time, the number of TCAR procedures has risen significantly, while the number of TF-CAS has decreased significantly to almost zero and that of CEA has decreased slightly. All our procedural outcomes are independently adjudicated and entered into the VQI database. Over the last 3 years, the outcomes for CEA, TF-CAS, and TCAR have all improved without exception. We are therefore able to offer all treatment modalities to our patients with carotid stenosis in need of intervention without bias and with confidence that they are receiving the best possible solution to their problem. In addition, when you can offer all available treatments to patients without bias, the dialogue between patient and physician is more open, patients are more informed regarding their options, and they feel empowered to choose the option that is best suited for them.

In summary, for the betterment of patient care, the "hammer–nail" concept must fade away. The excellent results with TCAR and its quick learning curve have allowed it to become enthusiastically adopted at most centers throughout the United States. This has led to improved patient selection for carotid revascularization procedures, resulting in improved patient outcomes. Not having the capacity to offer all treatment options to patients with carotid stenosis does them a disservice. The greatest success is attained by matching the intervention to each specific, unique patient and not forcing the patient to match an intervention. ■

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Why Not TCAR?

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We are seeing a revolution in the treatment of carotid artery occlusive disease unfold right before our eyes in a field that has seen little progressive change in the past several decades. Winston Churchill once said, "To improve is to change. To be perfect is to change often." We have just heard from the top experts in their field on how transcarotid artery revascularization (TCAR) is changing their practice, decision-making, and treatment of patients. Dr. Jim and colleagues stated, "TCAR is the new standard." Excellent clinical outcomes, patient preference, shorter procedure times, and ease of adoption are a few examples mentioned driving this adaptation. TCAR has not only become an adjunct to carotid intervention but has expanded our treatment of the disease in patients who may otherwise not have been great candidates for alternate interventions. Dr. Watch mentioned regarding her practice, "…with expanded treatment options, carotid disease patients have been screened, and the surgically challenging cases have been offered TCAR." The jury is out; the data and clinical outcomes speak for themselves—TCAR is here to stay. The question is no longer, should we be doing TCAR? Instead, it should be, why not TCAR? A procedure that was once reserved for the high-risk patient proves to be a promising alternative to the gold standard treatment of carotid disease. There is consensus on keeping endarterectomy and transfemoral stenting in the toolkit, though, as the procedure has some limitations and pitfalls. Dr. Shah said it best, "TCAR is a compelling procedure that must be in the toolkit."

As discussed earlier, our indications for treatment utilizing the TCAR system are based on Medicare guidelines, whose policies are aligned with transfemoral stenting. As we continue to see the positive outcomes and safety profile of TCAR pull away from transfemoral stenting, we will see new guidelines, treatment indications, and reimbursement in the very near future. Dr. Aranson kindly "unpacked" the TCAR data demonstrating that there is almost a decade of long-term data, a short learning curve, and two-thirds of patients undergoing carotid intervention meet high-risk criteria.

These ongoing studies, reviews, and analyses in the world of carotid disease continue to solidify that TCAR is a safe, effective, durable, and straightforward treatment modality that requires proficiency. As stated earlier, "expert level" can be obtained in as little as 25 procedures. I, for one, have embraced the TCAR revolution and have a TCAR-first approach to all my patients who qualify for the procedure. In our practice, not only are we able to reproduce the success and safety presented in the literature but we have seen an overwhelmingly positive response from both patients and referring doctors. Dr. Ricotta said it best, "…not having the capacity to offer all treatment options to patients with carotid stenosis does them a disservice." With TCAR in your tool belt, terms like high lesion, bad arch, or this patient is too high risk become less of a factor when considering carotid intervention. Instead, for me, new terms like patient satisfaction, smaller incision site, benefits of local anesthesia, and fewer risks of cranial nerve injuries have been added. It has been a win-win for the practice and our patients.

I congratulate and applaud the authors on their efforts to educate us on carotid disease and their insight and experiences with TCAR and carotid interventions. It allows us all to continue to change as physicians and surgeons to provide the best care and treatment options to our patients. "Progress is impossible without change, and those who cannot change their minds cannot change anything." – George Bernard Shaw. ■

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