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)

(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. ■