Transitioning to the TCAR-First Strategy for Carotid Revascularization

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



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



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

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

PERSONAL EXPERIENCE

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

documented limitations of CAS include the following:

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

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

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

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

DISCUSSION

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

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

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

CONCLUSION

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

- Barnett HJ, Taylor DW, Eliasziw M, et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. North American symptomatic carotid endarterectomy trial collaborators. N Engl J Med. 1998;339:1415-1425. doi: 10.1056/NEJM199811123392002
- 2. Endarterectomy for asymptomatic carotid artery stenosis. Executive committee for the asymptomatic carotid atherosclerosis study. JAMA. 1995;273:1421–1428.
- 3. Lal BK, Meschia JF, Howard G, Brott TG. Carotid stenting vs. carotid endarterectomy: what did thecCarotid revascularization endarterectomy versus stenting trial (CREST) show and where do we go from here? Angiology. 2016;68:675-682. doi: 10.1177/0003319716661661
- 4. Kwolek CJ, Jaff MR, Leal JI, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015;62:1227–1234. doi: 10.1016/j.jvs.2015.04.460
- 5. Kashyap V. ROADSTER-2 demonstrates positive patient outcomes with Silk Road's Enroute TCAR systems. Presented at: SVS Vascular Annual Meeting; June 12-15, 2019; National Harbor, Maryland.
- VQI TCAR Surveillance. Presented at the Society for Vascular Surgery Vascular Annual Meeting, June 12-15, 2019;
 National Harbor, Maryland.
- 7. Brott TG, Hobson RW, Howard G, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. N Engl J Med. 2010;363:11-23. doi: 10.1056/NEJMoa0912321
- Alpaslan A, Wintermark M, Pintér L, et al. Transcarotid artery revascularization with flow reversal. J Endovasc Ther. 2017;24:265-270. doi: 10.1177/1526602817693607