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

(Continued on page 8)

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.

1. Liang P, Cronenwett J, Secemsky E, et al. Expansion of transcarotid artery revascularization to standard risk patients for treatment of carotid artery stenosis. J Vasc Surg. 2021;74:e27–8. doi: 10.1016/j.jvs.2021.06.048

(Continued from page 5)

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. ■

1. AbuRahma AF, Avgerinos EM, Chang R, et al. The Society for Vascular Surgery implementation document for management of extracranial cerebrovascular disease [online ahead of print]. J Vasc Surg. 2021 Jun 19. doi: 10.1016/j.jvs.2021.04.074
2. Kokkosis AA, MacDonald S, Jim J, et al. Assessing the suitability of the carotid bifurcation for stenting: anatomic and morphologic considerations [online ahead of print]. J Vasc Surg. 2021 Jun 24. doi: 10.1016/j.jvs.2021.05.048
3. Wu WW, Liang P, O'Donnell TFX, et al. Anatomic eligibility for transcarotid artery revascularization and transfemoral carotid artery stenting. J Vasc Surg. 2019;69:1452-1460. doi: 10.1016/j.jvs.2018.11.051
4. Kumins NH, King AH, Ambani RN, et al. Anatomic criteria in the selection of treatment modality for atherosclerotic carotid artery disease. J Vasc Surg. 2020;72:1395-1404. doi: 10.1016/j.jvs.2020.01.041
5. 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
6. Kashyap VS, Schneider PA, Foteh M, et al. Early outcomes in the ROADSTER 2 study of transcarotid artery revascularization in patients with significant carotid artery disease. Stroke. 2020;51:2620-2629. doi: 10.1161/STROKEAHA.120.030550
7. Brott TG, Hobson 2nd 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
8. Malas MB, Dakour-Aridi H, Kashyap VS, et al. Transcarotid Revascularization with dynamic flow reversal versus carotid endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. Published online September 15, 2020. doi: 10.1097/SLA.0000000000004496
9. Schermerhorn ML, Liang P, Eldrup-Jorgensen J, et al. Association of transcarotid artery revascularization vs tranesfemoral carotid artery stenting with stroke or death among patients with carotid artery stenosis. JAMA. 2019;322:2313-2322. doi: 10.1001/jama.2019.18441
10. Lal BK, Beach KW, Roubin GS, et al. Restenosis after carotid artery stenting and endarterectcomy: a secondary analysis of CREST, a randomised controlled trial. Lancet Neurol. 2012;11:755-763. doi: 10.1016/S1474-4422(12)70159-X
11. Brott TG, Howard G, Roubin GS, et al. Long-term results of stenting versus endarterectomy for carotid artery stenosis. N Engl J Med. 2016:374:1021-1031. doi: 10.1056/NEJMoa1505215
12. 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. doi: 10.1001/jamanetworkopen.2020.37885
13. Kashyap VS, King AH, Liang P, et al. Learning curve for surgeons adopting transcarotid artery revascularization based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project. J Am Coll Surg. 2020;230:113-120. doi: 10.1016/j.jamcollsurg.2019.09.020