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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