Reimbursement and Future Coverage for Transcarotid Artery Revascularization

Discussing the objectives for the TCAR Surveillance Project and how outcomes will influence CMS coverage with CMS's former Director of Coverage and Analysis Group, Dr. Louis Jacques, and study investigator, Dr. Marc L. Schermerhorn.

WITH LOUIS JACQUES, MD, AND MARC L. SCHERMERHORN, MD

What is the overall objective of the transcarotid artery revascularization (TCAR) Surveillance Project?

Dr. Schermerhorn: Our primary objective is to evaluate the 1-year stroke and perioperative stroke and death rates after TCAR and carotid endarterectomy using the Society of Vascular Surgery Vascular Quality Initiative registry.

How will data be mined from the TCAR Surveillance Project?

Dr. Schermerhorn: We're also charged with looking at periprocedural outcomes. There will be many more analyses to look at certain subgroups; the steering committee's primary focus will include symptomatic versus asymptomatic, gender, and percent stenosis. We will approve others' doing additional analyses with the data as well.

How did the TCAR Surveillance Project garner CMS coverage without a formal reconsideration of the national coverage determination (NCD)?

Dr. Jacques: The existing NCD has contained a provision that covered FDA-approved studies, and the TCAR Surveillance Project—through the work of the societies and the sponsorship of the societies—was approved by the FDA and thus was eligible for Medicare coverage.

Why would Centers for Medicare & Medicaid Services (CMS) be interested in patient outcomes with transcarotid artery stenting (TCAR)?

Dr. Jacques: CMS is fundamentally interested in the health of Medicare beneficiaries, and any technology that is designed or intended to reduce the patient's risk of stroke would be speaking to a health outcome that is of great interest to patients because of its devastating impact on patients' lives and their ability to function independently. CMS's interest reflects the significance of the condition.

How do you think TCAR is positioned in light of value- and outcomes-based payments?

Dr. Jacques: I think TCAR occupies a very interesting niche in that context. Traditionally, catheter-based technologies have involved a tradeoff between the effectiveness of a surgical procedure versus the risks or burdens of an open surgical procedure. TCAR is unique, at least based on the available evidence to date, in that it appears that patients can derive the same benefits as they would from an open surgical procedure but with less burden, fewer adverse events, and an overall simpler treatment paradigm.

How does TCAR compare to carotid endarterectomy (CEA) in terms of unadjusted and risk-adjusted evaluations?

Dr. Schermerhorn: Unadjusted analyses are always an appropriate place to start, but it's not really a fair comparison because the patients undergoing TCAR are different than those undergoing CEA. We're comparing people who are older and sicker, have a lot more cardiac disease, and were more likely to be symptomatic compared to patients undergoing CEA. In the unadjusted analysis, there was no difference in our primary outcomes of in-hospital stroke and death. As a secondary analysis, we looked at stroke, death, and myocardial infarction separately. We are able to review 30-day mortality using the Social Security Death Index.

For all those outcomes, there were no differences on the unadjusted analysis, which I think speaks strongly in favor of TCAR. For certain other outcomes such as cranial nerve injury, prolonged length of stay, and operating room time, TCAR actually did better. The adjusted analysis results were still the same for stroke, death, and myocardial infarction

outcomes between TCAR and CEA, either as individual or combined endpoints.

What happens if the current NCD is reconsidered during or after CREST 2?

Dr. Jacques: I think it's reasonable to expect that the NCD would be reconsidered at some point in the future, more likely after the completion of CREST 2. At that point, based on Medicare precedents, CMS would look at the available evidence for the various carotid revascularization technologies that are subject to the current NCD and attempt to make a definitive coverage decision that does not require ongoing data collection. If that were to take place (several years from now, at the earliest), I would think that the TCAR Surveillance Project would have accumulated enough data to inform definitive decisions about the coverability of TCAR. If the current trends from the ROADSTER studies and ongoing study remain, then I would anticipate that TCAR would simply be covered outright without the need to include it in any sort of study protocol.

What are the long-term goals of the TCAR Surveillance Project? The number of patients being evaluated was recently updated to 15,000 on clinicaltrials.gov—is it the intention of the TCAR Surveillance Project to amass tens of thousands of patients like they have for CEA?

Dr. Schermerhorn: Absolutely.

As far as long-term goals, many questions remain. Other analyses suggest that stenting is more dangerous for people who have had a stroke as their symptom, particularly if the intervention was performed soon after a stroke. It is not clear whether TCAR provides protection in that subgroup of patients, so I think that will be interesting to study.

Looking at the effect of age will also be important. We know that with transfemoral stenting, older age is a marker for poor outcomes. It is not clear if that is because older patients have more debris in their arches (in which case TCAR should be protective), or if a typical distal filter causes problems (again making flow reversal a potentially better option for those patients).

We know in some analyses for CEA that women do not fare as well as men and stand to benefit less. A gender comparison will be interesting. Once we have a larger number of patients, we can determine if those variables have an impact.

Additionally, as we have more surgeons involved in the procedure, we can observe experience. These early results with TCAR are excellent and comparable to CEA, and it will be interesting to see if they can improve further, and if experience brings further improvement. In this study, many of the operators were fairly new to the procedure. ■

Louis Jacques, MD
Chief Clinical Officer
ADVI Health, LLC
Washington, DC
louis.jacques@advi.com
Disclosures: Consultant for Silk Road Medical.

Marc L. Schermerhorn, MD
Chief, Division of Vascular and Endovascular Surgery
Beth Israel Deaconess Medical Center
George H.A. Clowes Jr. Professor of Surgery
Harvard Medical School
Boston, Massachusetts
Disclosures: Consultant for Abbott Vascular, Cook Medical, Endologix, Medtronic.