

From the Eastern Vascular Society

Long-term comparative effectiveness of carotid stenting versus carotid endarterectomy in a large tertiary care vascular surgery practice

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ABSTRACT

Objective: Carotid interventional trials have strict inclusion and exclusion criteria that make translation of their results to the real-world population challenging. Furthermore, the specialty of the operating surgeon and the role of clinical decision-making are not well studied. This study compares the effectiveness of carotid endarterectomy (CEA) vs carotid artery stenting (CAS) in a real-world setting when the procedure is performed by fellowship-trained vascular surgeons.

Methods: A retrospective study was conducted of all consecutive patients undergoing CEA and CAS performed by vascular surgeons in a large rural tertiary health care system from 2004 to 2014. Postoperative outcomes of stroke, acute myocardial infarction (AMI), and death were analyzed at 30 days and during the long term (median follow-up of 5.5 years for CEA and 4.8 years for CAS). Standard statistical analysis was performed. Differences in long-term outcomes were expressed as cumulative incidence functions for nondeath outcomes (stroke and AMI), which account for the high death rate in this population of vascular patients, and as Kaplan-Meier curves for death itself.

Results: From January 1, 2004, through December 31, 2014, there were 2331 carotid interventions performed (CEA, 1853; CAS, 478), all by fellowship-trained vascular surgeons. The average age of the patients was 71 years, and 63% were male, with more men in the CAS group (61.5% vs 67.8%; $P = .011$). Preoperatively, 30% of patients were symptomatic, and 77% of patients had high-grade stenosis in the 70% to 99% range. CEA patients were more likely to have preoperative hypertension (89.7% vs 86.2%; $P = .029$) and were less likely to have a history of cardiovascular disease (53.4% vs 59.4%; $P = .018$). There were no significant differences in 30-day outcomes between CEA and CAS (stroke, 1.1% vs 1.3% [$P = .743$]; AMI, 2.2% vs 1.7% [$P = .474$]; death, 0.7% vs 0.6% [$P = .859$]) or long-term outcomes (stroke, 6.8% vs 7.7% [$P = .321$]; AMI, 22.7% vs 21.0% [$P = .886$]; death, 28.4% vs 28.2% [$P = .122$]).

Conclusions: The short- and long-term outcomes after CEA vs CAS are similar when the procedure is performed in a real-world setting by fellowship-trained vascular surgeons. (*J Vasc Surg* 2018;■:1-8.)

The role of stenting in the management of extracranial carotid artery occlusive disease continues to evolve. Randomized trials¹⁻⁴ of specific populations of patients have demonstrated carotid artery stenting (CAS) to be an acceptable alternative to carotid endarterectomy (CEA) for patients with symptomatic and asymptomatic carotid stenosis, but how these results apply in the real-world setting is uncertain. Results of the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST)⁴ demonstrated that cardiac morbidity was

worse with CEA and neurologic morbidity was worse with CAS; however, when the composite end point of stroke/myocardial infarction/death was analyzed, the two procedures were deemed comparable. One of the limitations of CREST was that patients had to be medically fit for either intervention, thus excluding high-risk patients from the study. However, in routine clinical practice, managing high-risk patients is part of the job, and clinicians are faced with making decisions for high-risk patients as well as for average-risk patients. Therefore, the results of randomized controlled trials of very specific populations of patients may not provide adequate data to guide clinical decision-making in the real world. Interestingly, data are emerging suggesting that the story in the real world is, in fact, quite different from that in randomized trials, with higher rates of stroke being reported after CAS compared with CEA.^{5,6} One of the confounders in large administrative data sets is that the physician's specialty is variable, so results of stenting performed by different specialties may influence outcomes, such as those reported by Hussain et al,⁶ in which 95% of CAS procedures in Ontario, Canada, are performed by radiologists and neurosurgeons. Whether results differ when the procedure is performed

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exclusively by vascular surgeons has not been well studied.

Therefore, we sought to perform a comparative effectiveness study on the short- and long-term outcomes of carotid interventions at a large integrated rural tertiary health care system using an in-house administrative data set to compare CEA with CAS in a real-world clinical vascular surgery practice. This study design allows the clinical acumen of the treating vascular surgeon to guide treatment decisions and to influence the overall outcomes because the treating surgeon is able to offer either procedure, CEA or CAS. Our hypothesis is that the results of CEA vs CAS, when it is performed by fellowship-trained vascular surgeons, would be similar over time with respect to short- and long-term risks of postprocedure stroke, acute myocardial infarction (AMI), and death.

METHODS

This study was approved by the Institutional Review Board of Geisinger Medical Center. Because this was a retrospective review of administrative data, individual informed consent was not required from each patient. With the use of a data warehouse system called Clinical Decision Intelligence System (CDIS) that receives updated discrete patient data elements every 24 hours from the electronic health record, billing data, and third-party data, a retrospective review was performed of all patients treated with CEA and CAS within our health system from January 1, 2004, through December 31, 2014, with outcomes tracked through October 31, 2015. Baseline demographic data and all outcome data were compiled on the basis of *Current Procedural Terminology* codes, *International Classification of Diseases, Ninth Edition* codes, and Diagnostic Related Group codes abstracted from the CDIS warehouse using custom-designed data search algorithms developed by a data broker from the CDIS team at Geisinger Medical Center along with input from the study authors. If a patient underwent more than one carotid intervention during the study period, only the first procedure was captured as the index procedure, and outcome events were tracked from the time of that procedure. Any patient who underwent a carotid intervention by a practitioner other than a fellowship-trained vascular surgeon was excluded. Postprocedural outcomes of acute ischemic stroke, AMI, and death were analyzed both at 30 days and for long-term follow-up through October 31, 2015.

The standard medical therapy protocol for CEA patients was single antiplatelet therapy with aspirin initiated preoperatively and continued indefinitely and treatment with beta blockers initiated preoperatively and continued postoperatively for at least 30 days. The standard medical therapy protocol for CAS patients was dual antiplatelet therapy with aspirin and

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective, single-center, cohort study
- **Take Home Message:** During a 10-year period, 2331 carotid interventions were performed by a group of vascular surgeons. Comparing results of 1853 carotid endarterectomies with 478 carotid stenting procedures, 30-day and long-term risks of stroke, myocardial infarction, and death were similar.
- **Recommendation:** This study suggests that carotid endarterectomy and carotid artery stenting can be performed with excellent outcomes by a group of vascular surgeons at a large-volume hospital.

clopidogrel initiated preoperatively. Dual antiplatelet therapy was then continued postoperatively for at least 30 days, with at least single antiplatelet therapy continued indefinitely. Intense statin therapy use was implemented in 2013 when our practice joined the Vascular Quality Initiative (VQI).

Technical execution of each procedure was performed per the standard practice of each operating surgeon with routine use of distal embolic protection for each CAS procedure and routine patching for endarterectomy procedures unless eversion endarterectomy was performed. CAS procedures were routinely performed through transfemoral access under sedation, and CEA procedures were routinely performed under general anesthesia. Hospital privileges for CAS procedures mandated a minimum of 25 procedures to become initially privileged and a minimum of 10 procedures per year after that to maintain privileges. Shunting for CEA procedures was performed either routinely for some surgeons or selectively for other surgeons, according to each surgeon's standard practice. Neuromonitoring was used only for those surgeons who shunted selectively. There were 13 different surgeons performing carotid interventions in our practice during this time, with each surgeon able to perform either procedure as he or she thought was clinically indicated. Cardiac biomarkers and electrocardiograms were not routinely ordered after the procedure but were selectively ordered if clinically warranted. After hospital discharge, patients were routinely evaluated in the outpatient clinic setting at 1 month with a carotid duplex ultrasound examination and then were observed routinely every 6 to 12 months thereafter at the discretion of the treating surgeon.

Symptomatic stenosis was defined as any transient ischemic attack, stroke, or episode of amaurosis fugax occurring within 180 days of the procedure. Because of the nature of the data search algorithms, it was not possible to assign laterality to each case, so it was assumed that any procedure performed was ipsilateral to the side of transient ischemic attack, stroke, or

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