

From the Southern Association for Vascular Surgery

Anatomical and technical predictors of perioperative clinical outcomes after carotid artery stenting

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ABSTRACT

Background: A few other studies have reported the effects of anatomical and technical factors on clinical outcomes of carotid artery stenting (CAS). This study analyzed the effect of these factors on perioperative stroke/myocardial infarction/death after CAS.

Methods: This was a retrospective analysis of prospectively collected data of 409 of 456 patients who underwent CAS during the study period. A logistic regression analysis was used to determine the effects of anatomical and technical factors on perioperative stroke, death, and myocardial infarction (major adverse events [MAEs]).

Results: The MAE rate for the entire series was 4.7% (19 of 409), and the stroke rate was 2.2% (9 of 409). The stroke rate for asymptomatic patients was 0.46% (1 of 218; $P = .01$). The MAE rates for patients with transient ischemic attack (TIA) were 7% (11 of 158) vs 3.2% (8 of 251) for other indications ($P = .077$). The stroke rates for heavily calcified lesions were 6.3% (3 of 48) vs 1.2% (4 of 332) for mildly calcified/noncalcified lesions ($P = .046$). Differences in stroke and MAE rates regarding other anatomical features were not significant. The stroke rate for patients with percutaneous transluminal angioplasty (PTA) before embolic protection device (EPD) insertion was 9.1% (2 of 22) vs 1.8% (7 of 387) for patients without ($P = .07$) and 2.6% (9 of 341) for patients with poststenting PTA vs 0% (0 of 68) for patients without. The MAE rate for patients with poststenting PTA was 5.6% (19 of 341) vs 0% (0 of 68) for patients without ($P = .0536$). The MAE rate for patients with the ACCUNET (Abbott, Abbott Park, Ill) EPD was 1.9% (3 of 158) vs 6.7% (16 of 240) for others ($P = .029$). The differences between stroke and MAE rates for other technical features were not significant. A regression analysis showed that the odds ratio for stroke was 0.1 ($P = .031$) for asymptomatic indications, 13.7 ($P = .014$) for TIA indications, 6.1 ($P = .0303$) for PTA performed before EPD insertion, 1.7 for PTA performed before stenting, and 5.4 ($P = .0315$) for heavily calcified lesions. The MAE odds ratio was 0.46 ($P = .0858$) for asymptomatic indications, 2.1 for PTAs performed before EPD insertion, 2.2 for poststent PTAs, and 2.2 ($P = .1888$) for heavily calcified lesions. A multivariate analysis showed that patients with TIA had an odds ratio of stroke of 11.05 ($P = .029$). Patients with PTAs performed before EPD insertion had an OR of 6.15 ($P = .062$). Patients with heavily calcified lesions had an odds ratio of stroke of 4.25 ($P = .0871$). The MAE odds ratio for ACCUNET vs others was 0.27 ($P = .0389$).

Conclusions: Calcific lesions and PTA before EPD insertion or after stenting were associated with higher stroke or MAE rates, or both. The ACCUNET EPD was associated with lower MAE rates. There was no correlation between other anatomical/technical variables and CAS outcome. (J Vasc Surg 2017;■:1-10.)

Carotid artery stenting (CAS) has become an alternative to carotid endarterectomy (CEA) and minimally invasive therapy for significant carotid stenosis, particularly in high-risk surgical patients. Currently, ~9000

CAS procedures are performed annually in the United States.¹ With the publication of the Carotid Revascularization Endarterectomy vs stenting Trial (CREST),² a significant proportion of patients with severe carotid artery stenosis have undergone CEA or CAS with somewhat similar results.² Better selection of high-risk surgical patients or high-risk CAS patients is critical in providing the best therapy for each individual patient.

Because percutaneous transluminal angioplasty (PTA) is a key component of CAS procedures and carries significant embolic risk,³⁻⁷ its use before or after stent deployment is being scrutinized. Only a few studies have reported the effects of anatomical and technical factors on the clinical outcomes of CAS. This study analyzed the effect of these factors on perioperative stroke and on stroke, myocardial infarction (MI), and death (major adverse events [MAEs]) after CAS.

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METHODS

Between January 2004 and October 2015, 456 CAS procedures were performed at our institution, and this was a retrospective analysis of prospectively collected data of 409 of these CAS patients. We excluded 47 CAS patients because of missing data or no embolic protection device (EPD) was used. This study was approved by the Institutional Review Board of West Virginia University/Charleston Area Medical Center. Informed consent was not necessary because all data were anonymous and no personal patient information was identified.

Every effort was made to identify missing data (anatomical/technical factors) by a review of the electronic medical records and progress notes at our Vascular Center of Excellence. Indications for CAS were asymptomatic patients with $\geq 80\%$ carotid artery stenosis and symptomatic patients (transient ischemic attacks [TIAs] and stroke) with $\geq 50\%$ ipsilateral carotid stenosis by conventional arteriography or $\geq 70\%$ stenosis by duplex ultrasound imaging in our Intersocietal Accreditation Commission-accredited vascular laboratory, computed tomography angiography, or magnetic resonance angiography.

All patients were treated with aspirin (325 mg) and clopidogrel (75 mg) for 48 to 72 hours before the procedure. Clopidogrel was continued for 30 days after the procedure, whereas aspirin therapy was continued indefinitely.

All CAS procedures were done according to their carotid trial protocol and using cerebral protection devices. Overall, CAS was selected for high-risk surgical patients, which included physiological high-risk (severe coronary artery disease, congestive heart failure with ejection fraction of $<30\%$, cardiopulmonary disease, etc) or anatomical high-risk (post-CEA restenosis, high cervical lesions, tracheostomy, neck irradiation, or past cranial nerve injury).⁸ It should be noted that the number of CEAs performed in our tertiary medical center (950 beds) averaged 300 to 400 annually during the past 10 years. All demographic and clinical characteristics were recorded.

Specific anatomical factors that may affect perioperative CAS outcomes were also recorded. These included lesion length, lesion location, severity, calcification, and aortic arch type. Lesion length was measured as the distance, in millimeters, from the proximal to the distal shoulder of the lesion. Lesion location was defined at the distal common carotid artery or proximal internal carotid artery (ICA), including the bulb, or a combination of the distal common carotid and ICA (bifurcational lesion). They were also classified as right carotid or left carotid lesions. Severity of carotid stenosis was classified as 50% to 69% or 70% to 99%. Target site calcification was defined as no or mild calcification vs heavily calcified

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of a prospectively collected single-center database
- **Take Home Message:** In 409 patients, including 191 with symptoms, carotid artery stenting resulted in a stroke rate of 2.2%. It was 6.3% for heavily calcified lesions, 9.1% in those who received angioplasty before embolic protection device placement and 2.6% in those who had angioplasty after stenting.
- **Recommendation:** This study suggests that heavily calcified carotid lesions and angioplasty before embolic protection device placement or after stent placement are risk factors for stroke and major adverse events after carotid artery stenting.

lesions ($>50\%$ circumferential calcification), which was based primarily on computed tomography angiography or ultrasound imaging, or both.

Aortic arch types were defined as type I arch when the vessels arise from the top of the arch, type II when they arise between parallel planes delineated by the outer and inner curves of the arch, and type III when they arise caudal to the inner surface of the arch or the ascending aorta. CAS was done as a primary procedure or for post-CEA stenosis (the CEA in 44 of 147 patients was done in <24 months).

The following technical factors were also identified and recorded: stent type (RX Acculink [Abbott, Abbott Park, Ill], Xact [Abbott], and others), number of stents (1 vs ≥ 2), stent length, stent diameter, EPD type (RX ACCUNET [Abbott], Emboshield NAV6 [Abbott], and others), EPD insertion to recovery time, pre-PTA before deployment of the distal EPD, pre-PTA before stenting, PTA after stenting, or any combination of pre-PTA or post-PTA. Prestenting PTA was done using 3- to 4-mm Viatrac balloons (Abbott) and poststenting PTA using 5-mm balloons. No specific balloons were used for calcific lesions in this location.

Excluded from the analysis were 47 CAS in patients with significant stenosis in the proximal common carotid artery or patients without the use of EPD.

Study end points. The primary end point of the study was 30-day perioperative stroke and the composite outcome of MAEs, which included stroke, MI, or death, or a combination of these. Periprocedural neurologic evaluations were performed before and immediately after CAS and at 24 to 48 hours after CAS. Minor stroke was defined as a neurologic deficit lasting >24 hours, resulting in a grade I or II Rankin scale, and a major stroke as grades III to V Rankin scale. Stroke was also referred to as an ipsilateral stroke if it affected the same cerebral hemisphere of the carotid intervention or a

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