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Revascularization of asymptomatic carotid stenosis is not appropriate in patients on dialysis

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Objective: **Outcomes of carotid endarterectomy (CEA) or carotid angioplasty and stenting (CAS) for asymptomatic disease in patients on dialysis are not well characterized, with questionable stroke prevention and survival. This study reports outcomes of carotid revascularization in asymptomatic dialysis patients in the United States.**

Methods: **Using United States Renal Data System (USRDS) databases, we identified all dialysis patients who underwent CEA or CAS for asymptomatic disease from 2005 to 2008. CEA and CAS were identified by Current Procedural Terminology (American Medical Association, Chicago, Ill) codes, and symptom status and comorbidities by International Classification of Diseases-9th Revision, Clinical Modification codes. Primary outcomes were stroke, cardiac complications, and death at 30 days and at 1 and 3 years. Predictors of death were identified using multivariate regression models.**

Results: **Of 738,561 dialysis patients, 2131 asymptomatic patients underwent carotid revascularization (1805 CEA, 326 CAS). The mortality rate was 4.7% at 30 days (4.6% CEA, 4.9% CAS; $P = .807$). Kaplan-Meier estimates of survival were 75.1% at 1 year (75.9% CEA, 70.7% CAS) and 43.4% at 3 years (43.7% CEA, 41.6% CAS). The stroke rate was 6.5% at 30 days (6.4% CEA, 6.9% CAS; $P = .774$) and 13.6% at 1 year (13.3% CEA, 15.0% CAS; $P = .490$). Cardiac complications occurred in 22.0% of patients (3.3% myocardial infarction) at 30 days (22.2% CEA, 20.6% CAS; $P = .525$). The combined stroke or death rate was 10.2% at 30 days (10.1% CEA, 10.9% CAS; $P = .490$) and 33.5% at 1 year (32.2% CEA, 39.6% CAS; $P = .025$). Age >70 years at the time of surgery and increased time on dialysis were predictive of death, whereas a history of renal transplant was a protective factor.**

Conclusions: **Patients on dialysis have high perioperative and long-term stroke or death rates after CEA or CAS for asymptomatic stenosis, with a median survival that is less than recommended by current guidelines. As a result, carotid intervention in these patients appears to be inappropriate. (J Vasc Surg 2015;61:670-4.)**

Extracranial carotid artery occlusive disease is a major cause of ischemic stroke, accounting for 10% to 20% of patients presenting with stroke.[1] Randomized controlled trials have demonstrated durable benefit from carotid endarterectomy (CEA) in symptomatic and asymptomatic patients who have been appropriately selected,[2,3] establishing CEA as the gold standard in carotid revascularization.[4]

Some patients with severe coronary, pulmonary, and renal disease are considered to be at high risk for CEA due to medical or anatomic factors, and they have been shown to have higher rates of morbidity and mortality after CEA than patients without such risk factors.[5] For these patients, carotid angioplasty and stenting (CAS) has been used as an alternative treatment option.[6]

The benefit of carotid revascularization is predicated on the patient's life expectancy, particularly in asymptomatic patients who are only expected to derive the full preventive advantages if they anticipate a life expectancy of at least 3 years.[7] This life expectancy may not be realized in patients with multiple medical comorbidities, particularly patients with end-stage renal disease (ESRD). Although such patients have been shown to have potentially acceptable perioperative outcomes after CEA,[8] long-term mortality rates are in general poor, leading some to call for a nonoperative approach to the management of asymptomatic carotid disease in this population.[5]

The current data on carotid revascularization in patients on dialysis is based on small series or subgroup analyses without significant longitudinal follow-up. We therefore sought to characterize the contemporary perioperative and long-term outcomes after carotid revascularization in asymptomatic patients with ESRD on dialysis in the United States using a large administrative database that includes all patients on dialysis. In addition, we sought to determine if ESRD patients with asymptomatic carotid disease who undergo carotid revascularization have sufficient life expectancy to justify the periprocedural risk of an intervention.

METHODS

Data source. After approval from the University of Pittsburgh Institutional Review Board, we obtained deidentified

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Disclaimer: The data reported here have been supplied by the United States Renal Data System (USRDS). The opinions expressed are those of the authors and do not necessarily represent the views or policy positions of the National Institute of Diabetes and Digestive and Kidney Diseases nor the Centers for Medicare and Medicaid Services.

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Table I. Definition of hemispheric cerebral ischemia or ophthalmic artery occlusion based on International Classification of Diseases, 9th Revision, Clinical Modification (*ICD-9-CM*) codes

ICD-9-CM diagnosis code	*Label*
362.30	Retinal vascular occlusion, unspecified
362.31	Central retinal artery occlusion
362.32	Retinal arterial branch occlusion
362.33	Partial retinal arterial occlusion, Hollenhorst plaque, retinal microembolism
362.34	Transient retinal arterial occlusion, amaurosis fugax
362.84	Retinal ischemia
433.11	Occlusion and stenosis of carotid artery with cerebral infarction
433.31	Occlusion and stenosis of multiple and bilateral arteries with cerebral infarction
434.01	Occlusion of cerebral arteries (cerebral thrombosis) with cerebral infarction
434.11	Cerebral embolism with cerebral infarction
434.91	Cerebral artery occlusion, unspecified, with cerebral infarction
435.8	Other specified transient cerebral ischemias
435.9	Unspecified transient cerebral ischemia: impending cerebrovascular accident; intermittent cerebral ischemia; transient ischemic attack

patient-specific data from the United States Renal Data System (USRDS) standard analytic files from 2005 through 2008. Explicit patient consent was not obtained, pursuant to Centers for Medicare and Medicaid Services rules allowing for release of limited data sets with a data use agreement executed with the USRDS Coordinating Center.[9] This database has been designed to be an integrated and consistent resource for investigating health outcomes for patients with ESRD.[10]

Available data include patient demographic and diagnosis data, biochemical values, dialysis claims, and information on treatment history, hospitalization events, and physician and supplier services. Physician services are encoded using Current Procedural Terminology (CPT) codes (American Medical Association, Chicago, Ill), which are accompanied by International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes.

We assembled a cohort of patients who underwent CEA or CAS, based on CPT codes (35301 for CEA, 37215-37216 for CAS) during the years 2005 through 2008 and then followed up until the end of 2008. We excluded any patient aged <30 years at the time of the procedure, those who started dialysis after the carotid revascularization, and those that had CEA and CAS. Hemodialysis and peritoneal dialysis patients were included in this study.

Medical comorbidities were assessed using Medical Evidence Report form CMS-2728, which is required to be completed for every new ESRD patient ≤45 days of initiation of dialysis.[11] We also used ICD-9-CM codes to discriminate neurologically symptomatic from asymptomatic patients using the following algorithm[12]: We first identified patients who underwent CAS or CEA as defined by CPT codes. Then, we looked at records in the 6 months before the intervention and determined if there were any diagnosis codes that were associated with hemispheric cerebral ischemia or ophthalmic artery occlusion or embolism (Table I). Due to this 6-month lead-in phase and also because we only included patients who had at least 30 days of follow-up, our analysis included patients who underwent carotid revascularization from the third quarter of 2005 through the end of November 2008. Patients with codes for cerebral ischemia or ophthalmic artery occlusion or embolism were characterized as being symptomatic and were removed from the analysis. Patients without such codes were defined as being asymptomatic and remained in the analysis. Postoperative stroke was defined by the presence of the same ICD-9-CM codes that suggested stroke, hemiplegia, or other manifestations of cerebral infarction.

Statistical analysis. Demographic and procedural result data were analyzed using χ^2 statistics for dichotomous variables, including perioperative stroke, death, and myocardial infarction (MI). Logistic regression models tested the effect of multiple comorbidities and background characteristics on the probability of death at 30 days and 1 year; among them were age, gender, available medical comorbidities, including the presence of ischemic heart disease, hypertension, diabetes, cancer, time on dialysis, and body mass index, and a history of previous renal transplants. We used Kaplan-Meier models to compare differences between procedures and genders with respect to time to death. The threshold for significance for all statistical analyses was $P < .05$. Statistical analysis was performed by a statistician with Stata/IC 12.1 software (StataCorp LP, College Station, Tex).

RESULTS

The primary outcomes of our study were perioperative (30-day) mortality and long-term survival. Secondary outcomes were perioperative (30-day) and long-term complications, including MI and stroke. We also created multivariate models to identify covariates that would predict the outcomes of interest.

Demographics and comorbidities. Our analysis identified 738,561 dialysis patients during the analysis years. In that group, 3610 CEA and CAS patients were identified, of which 2131 were asymptomatic and fulfilled the inclusion and exclusion criteria described above. Among the asymptomatic patients, 1805 underwent CEA and 326 underwent CAS (Fig 1). There were no statistically significant differences between the two groups based on the identified demographic and medical variables. (Table II).

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