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# Success of Carotid Endarterectomy in Veterans: High Medical Risk Does Not Equate with High Surgical Risk

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- BACKGROUND:** The safety and efficacy of carotid endarterectomy (CEA) in stroke prevention has been well documented. But “high-risk” patients have traditionally been excluded from these studies and may be offered alternate therapies. We examined the safety of CEA in veterans, a medically high-risk group with multiple comorbidities.
- STUDY DESIGN:** The records of all patients having CEAs performed between 1995 and 1999 in the Connecticut Veterans Affairs (VA) hospital were reviewed. Survival and freedom from stroke were determined using Kaplan-Meier survival analysis. The effects of risk factors on outcomes were analyzed with Cox regression.
- RESULTS:** There were 128 CEAs performed in 120 patients, with a mean followup of 8.5 years. Most patients were symptomatic preoperatively and had a high incidence of hypertension (83%), coronary artery disease (64%), diabetes (37%), and pulmonary disease (22%). Incidences of perioperative (30-day) mortality (0.8%), stroke (1.6%), and myocardial infarction (0.8%) were low. Survival rates at 8.9 and 12 years were 50% and 13%, respectively, with 90% patient followup. Freedom from ipsilateral stroke was 90% at 12 years. Age (hazards ratio [HR] 1.1,  $p = 0.004$ ), hypertension (HR 2.6,  $p = 0.04$ ), and elevated creatinine (HR 3.7,  $p = 0.001$ ) were significant risk factors for mortality. Age (HR 0.8,  $p = 0.07$ ) and diastolic blood pressure (HR 1.2,  $p = 0.06$ ) were predictive of ipsilateral stroke.
- CONCLUSIONS:** Despite poor health and symptomatic presentation, patients treated with CEA achieved excellent perioperative outcomes and were protected from stroke for the remainder of their lives. Multiple medical comorbidities should not be used as exclusion criteria for CEA. (J Am Coll Surg 2008;207:219–226. © 2008 by the American College of Surgeons)
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The efficacy of carotid endarterectomy (CEA) to prevent stroke has been well documented in several multicenter, randomized controlled trials.<sup>1–4</sup> But some clinicians suggest that patients with a large number of medical conditions form a “high-risk” group and should be offered alternative therapies to avoid complications associated with surgery. For example, carotid artery angioplasty and stenting might be more suitable than CEA in some medically high-risk patients to avoid potential perioperative morbidity and

mortality associated with the open procedure.<sup>5,6</sup> But with the excellent safety of CEA documented in many trials, some vascular surgeons believe that these “high-risk” patients do not exist and that patients with multiple medical comorbidities do not necessarily have higher surgical complication rates.<sup>7,8</sup> It is only a small subset of patients with anatomic criteria placing them at risk for surgical complications, such as previous radiation exposure to the neck or tracheostomy, that likely benefit from carotid artery angioplasty and stenting.<sup>9</sup>

Unfortunately for patients and their physicians, current risk stratification paradigms are not well established. In particular, the term *high-risk* has not been well defined. We believe that the term *medical high-risk* is related to the presence of multiple comorbidities that have impact on the patient’s longterm survival and ultimately the risk-benefit ratio of treatment of the patient’s carotid artery stenosis. Medical high-risk criteria must be distinguished from surgical high-risk criteria, which implies a likelihood that a patient will develop a complication in the postoperative

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**Abbreviations and Acronyms**

CEA	=	carotid endarterectomy
HR	=	hazards ratio
TIA	=	transient ischemic attack
VA	=	Department of Veterans Affairs

period, such as perioperative myocardial infarction or cranial nerve injury. But the concept of medical high risk is also controversial; there have been several recent clinical trials examining high-risk patients,<sup>6,7,10-14</sup> and there is great variation in the physiologic factors considered medical high-risk inclusion criteria.<sup>15</sup>

So the purpose of this study was to examine medically high-risk patients and to determine whether being medically high risk affects longterm survival after CEA and if being medically high risk is associated with increased perioperative complications, ie, whether the patients are also surgically high risk for CEA. This study is based on the premise that veterans constitute a medically high-risk population. We have previously shown that patients treated with CEA in Veterans Affairs (VA) hospitals have a greater number of comorbid conditions and form a medically high-risk group, compared with a matched group of patients treated with CEA outside of the VA system.<sup>15</sup> So to determine the safety and longterm efficacy of CEA in stroke prevention for medically high-risk patients, we examined perioperative complications, longterm survival, and freedom from stroke in veterans treated with CEA.

**METHODS**

All CEAs performed at the VA Connecticut Healthcare System (West Haven Veterans Affairs Hospital) between January 1995 and December 1999 were identified within the VA database. Cases were excluded if they were revisions. The West Haven VA Medical Center contains 200 beds. Perioperative demographics, comorbid medical conditions, laboratory values, and longterm outcomes were obtained through systematic electronic chart review. Cause of death was determined from chart review and verified by examination of death certificates (Department of Vital Records, State of Connecticut). This study was approved by the Institutional Review Board at the West Haven VA Medical Center.

Preoperative demographic variables were recorded for each patient and included age, gender, race, and the presence of coronary artery disease, peripheral arterial disease exclusive of carotid disease, diabetes, hypertension, smoking history, renal disease, chronic obstructive pulmonary disease, and hepatic disease. Renal disease was defined by a creatinine value greater than 1.5 mg/dL, and hepatic dis-

ease was defined by a history of cirrhosis, hepatitis, or liver cancer. Patients were considered asymptomatic at presentation if there was no history of stroke, transient ischemic attack (TIA), or amaurosis fugax. Preoperative laboratory values, including albumin and creatinine, were recorded. Perioperative outcomes included mortality, any neurologic event, myocardial infarction (defined as electrocardiogram changes or elevation of cardiac enzymes), arrhythmia (any ventricular arrhythmia, including bradycardia and tachycardia or atrial fibrillation), or other events that occurred within 30 days of surgery. Longterm outcomes included any neurologic event or death that occurred until December 31, 2006. Postoperative variables were recorded as the value at most recent followup and included systolic blood pressure, diastolic blood pressure, body mass index, and hemoglobin A1c.

Surgeons performing CEA at the VA Connecticut Healthcare System are in the Department of Surgery at the Yale University School of Medicine and typically also perform cases at Yale New Haven Hospital, so surgeons performing CEA at the VA Connecticut are not low-volume surgeons.<sup>16-18</sup>

Longterm cumulative survival and freedom from stroke were determined using Kaplan-Meier analysis. The Charlson Index and the Charlson Comorbidity-Age Score (a modified version of the Charlson Index that adds 1 point for each decade of life after 40 years) were used to classify comorbidity.<sup>19</sup> The effects of risk factors on outcomes were analyzed by Cox regression (StatView, version 5.0; SAS Institute). The funding sources had no role in the design or implementation of this study.

**RESULTS****Patient demographics**

Over a 5-year period, 128 CEAs were performed in 120 patients at the VA Connecticut Healthcare System; 1 procedure was excluded because it was a revision. Patient followup was 100%, and the mean time of followup was 8.5 years (range 0.03 to 12 years).

At the time of operation, mean patient age was  $69.7 \pm 0.7$  years, and the majority of patients were Caucasian men (Table 1). As an aggregate measure of comorbidity, the mean Charlson Index was  $3.98 \pm 0.01$ , and the mean Charlson Comorbidity-Age Score was  $7.2 \pm 0.02$ . The majority of patients (52%) were symptomatic on presentation (Table 1).

**Perioperative events**

Perioperative events included 1 death (0.8%), 2 strokes (1.6%), 1 myocardial infarction (0.8%), 3 arrhythmias (2.4%), and 1 episode of congestive heart failure (0.8%;

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