The impact of cardiac comorbidity after carotid endarterectomy

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Purpose: **Myocardial infarction and other comorbidities contribute to complications after carotid endarterectomy (CEA). However, because the combined stroke and death rate after CEA is less than 5%, even relatively large series have small numbers of adverse events that preclude a detailed analysis of the association between the outcome and the patient factors, such as comorbidity and age. We sought to overcome this limitation by studying patients who underwent CEA in a large random sample of Medicare beneficiaries.**

Methods: **We used a database that contained a 20% random sample of all Medicare beneficiaries to identify patients who underwent CEA between the years 1988 to 1990 (n = 22,165), and we followed these cases until 1992. With multivariate logistic regression and Cox proportional hazards regression models, we examined the impact of age, race, gender, geographic location, hospital characteristics, and comorbidity, including acute myocardial infarction (AMI) and congestive heart failure (CHF), on the risk of stroke and death after CEA.**

Results: **AMI and CHF had the greatest negative impact on the long-term survival rates (adjusted hazard ratio [HR]: 2.40, $P < .0001$, and 2.85, $P < .0001$, respectively). Other variables with a significant impact on the long-term survival rates were an age of >80 years (HR, 2.16; $P < .0001$), an acute stroke (HR, 1.51; $P < .0001$), diabetes mellitus (DM; HR, 1.52; $P < .0001$), and male sex (HR, 1.32; $P < .0001$). In addition, AMI, CHF, DM, and advanced age were associated with an increased risk of perioperative stroke and death.**

Conclusion: **Patients with AMI, CHF, DM, and an age of >80 years have diminished perioperative and long-term survival rates after CEA. These results may alter the risk/benefit analysis for such patients, especially those with asymptomatic disease. (J Vasc Surg 1998;28:577-84.)**

Carotid endarterectomy (CEA) is a commonly performed vascular procedure. The efficacy of CEA for patients who are asymptomatic with carotid bifurcation atherosclerosis has been quantified in the Veterans Affairs Cooperative Study[1] (VACS) and the Asymptomatic Carotid Atherosclerosis Study[2] (ACAS). These studies also documented the high incidence rate of medical comorbidity in this population. In particular, coronary artery disease was the most prevalent medical risk factor and was identified in 58% and 69% of patients in the VACS and ACAS studies, respectively. The impact of cardiovascular disease in both studies was reflected in the mortality rate statistics: 20% of the deaths in the VACS and 49% in the ACAS were results of cardiac causes, with myocardial infarction accounting for about half of these deaths.

The ACAS study showed a stroke/mortality rate of 5% in the operated group versus 11% for medically treated cases in a 5-year period. In the design and analysis of the trial, the authors acknowledge the requirement of low perioperative morbidity and mortality rates to confer benefit from surgery in patients who are asymptomatic. In support of this conclusion, a survey of 1511 CEAs performed by

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Table I. Patients excluded from analysis

Reason for exclusion	*No.*	*Percent of original sample*
Race unknown or other	937	3.9
No coding for carotid stenosis	598	2.5
CEA during previous year (1988 patients)	162	0.7
No information on hospital teaching status	47	0.2
Date of death unknown	14	< 0.1
No information on number of hospital beds	11	< 0.1
Missing other data	15	< 0.1
Total	1625*	6.8

CEA, Carotid endarterectomy.
*Some patients were missing more than 1 parameter.

the ACAS participating surgeons revealed a stroke/mortality rate of 1.7%.[3] This observation highlights the potential importance of medical comorbidity on outcome, particularly in patients with asymptomatic carotid disease.

The benefits of CEA in patients who are asymptomatic are realized over time. Those patients with significant comorbidity and increased operative risk or diminished life expectancy may not accrue a significant reduction in stroke risk. These issues are addressed in a multidisciplinary consensus statement from the American Heart Association.[4] The authors state that CEA for patients who are asymptomatic with critical carotid stenosis is appropriate if the stroke/mortality rate is less than 3% and inappropriate if the stroke/mortality rate is more than 6%. The prevalence of pre-existing coronary artery disease and its contribution to postoperative death by myocardial infarction may be among the major factors that determine the outcome and the benefits of CEA.

In addition to coronary artery disease, patients with carotid atherosclerosis have a high prevalence of other illnesses, such as hypertension and diabetes mellitus[5] (DM), and attempts have been made to quantify the impact of these comorbidities and other factors on the outcome after CEA. A recent study found an association of death within 3 years after CEA with ischemic heart disease and DM.[6] Perler[7] examined the outcome after CEA in elderly patients and found no differences in early results, with respect to age, but long-term data were not available. In light of the low incidence rate of stroke and death after CEA, most of these studies have insufficient numbers of patients with those endpoints to adequately examine the association between comorbid disease and adverse events.

We sought to examine the impact of comorbidity and demographic factors on early and late outcome after CEA with a large sample of Medicare beneficiaries. We focused on the presence of myocardial infarction and other common risk factors associated with atherosclerosis. These parameters, along with age, demographic variables, other comorbid illnesses, and hospital characteristics, were assessed for their impact on the early stroke and death rates (ie, within 30 days of CEA) and on late mortality rates. With multivariate logistic regression and Cox proportional hazards regression models, we quantified the relative contributions of each parameter on the endpoints examined.

METHODS

Data sources. We selected our sample from the Health Care Financing Administration (HCFA) Medical Provider Analysis and Review (MEDPAR) files, which contain a random sample of approximately 20% of all Medicare beneficiaries with part A coverage during 1988, 1989, and 1990. The randomization process was on the basis of the last digit of a beneficiary's social security number. Each record in the data set represents an admission to a hospital and contains up to five diagnostic codes and up to three procedure codes from the International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM). The diagnostic codes do not contain information regarding the laterality of a procedure or event (ie, right versus left). We also obtained each patient's age, race, gender, and state of residence from this data set.

We used unique patient and hospital identifiers to link MEDPAR files with HCFA's Health Insurance Skeleton Eligibility Write-off file to obtain the date of death for all patients who died during the study period (1988 to 1992). The Health Insurance Skeleton Eligibility Write-off file reflects account information that is updated at the time of a patient's death and, therefore, reliably captures all deaths in the study population without regard to cause. We used HCFA's Provider of Service file to obtain the number of resident trainees and the number of beds at each hospital represented in the sample.

Patient sample. We selected patients who were 66 years of age or older with an ICD-9-CM procedure code of 38.12 (endarterectomy of the vessels of the head and the neck other than intracranial vessels) and a diagnosis code of 433 (occlusion or stenosis of the precerebral arteries) in the years 1988, 1989, and 1990 (n = 23,730). The earliest occurrence of this event was designated as the index procedure. For those patients with an index procedure in 1988, we excluded patients (<1.0%) with a procedure code of 38.12 during the year before their 1988 procedure date. We did this to remove patients who might have had early re-exploration after a previous CEA. We also excluded patients whose residence was not in 1 of the 50 states or the District of Columbia, whose race was listed as something other than black or white, and whose information on date of death, number of resident trainees at treating hospital, or number of beds at treating hospital was missing. After exclusions, 22,165 patients met eligibility criteria (Table I).

Variable definitions. We coded indications for the index CEA as transient ischemic attack/amaurosis fugax (ICD-9-CM codes 435 or 362.34), stroke (codes 434, 436, or 437), and stenosis (code 433). We created indicators for comorbid disease by searching ICD-9-CM codes for acute myocardial infarction (code 410), congestive heart failure (codes 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, or 428), other cardiovascular disease (codes 411-414 or 429.2), hypertension (codes 401-405, excluding the congestive heart failure codes mentioned above), diabetes (code 250), atherosclerosis (code 440), and malignant disease (codes 140-239). We also created an indicator for coronary artery bypass graft surgery (CAB; procedure codes 35.2, 35.3, and 36.1) that occurred on the same day as the CEA. Each patient's state of residence was coded into 1 of the following 4 census regions: west, midwest, southeast, and northeast. Hospital teaching status was determined from the ratio of the number of the resident trainees in a hospital to the number of the beds and classified as major (ratio >0.25), minor (ratio >0 and <0.25), or nonteaching (ratio = 0).

Statistical analysis. All analyses were conducted with SAS software (SAS/Stat, Release 6.12, SAS Institute, Cary, NC). We used logistic regression analysis to examine the influence of acute myocardial infarction (AMI), congestive heart failure (CHF), and CAB during the index admission on both death and stroke rates within 30 days of the index procedure. Other covariates in the models included patient demographic characteristics, indications for surgery, other comorbid conditions, and hospital characteristics. The reported odds ratios were adjusted for all of the variables in the models. Each model satisfied the goodness-of-fit criteria proposed by Hosmer and Lemeshow.[8]

We used the Cox proportional hazards regression model to examine the influence of the variables of interest on death rates through 1992, controlling for the covariates listed above. Analysis of the residuals from the fitted data using the SAS software guidelines confirmed adequacy of the model.[9]

Table II. Prevalence of demographic and comorbidity variables in Medicare patients who undergo carotid endarterectomy

Variable	*No.*	*Percent*
Age (years)		
66 to 70	6959	31.4
71 to 75	7365	33.2
76 to 80	5153	23.2
>80	2688	12.1
Female sex	9587	43.3
Black race	538	2.4
Hypertension	7711	34.8
Diabetes mellitus	3242	14.6
Atherosclerosis	1357	6.1
Acute myocardial infarction	315	1.4
Congestive heart failure	817	3.7
Other Cardiovascular disease	5993	27
Malignant disease	448	2
TIA or amaurosis	3680	16.6
Recent stroke	2122	9.6
CAB with CEA	457	2.1
Geographic region		
West	3242	14.6
Northeast	3508	15.8
Southeast	8501	38.4
Midwest	6279	28.3

TIA, transient ischemic attack; *CAB,* Coronary artery bypass graft; *CEA,* carotid endarterectomy.

RESULTS

Characteristics of patient sample. Table II outlines the demographic and comorbidity characteristics of the study population. There was a slight preponderance of men (56.7%). Nearly 10% of the patients were first seen with a recent stroke, and 16.6% had transient ischemic attack (TIA) as one of the admitting diagnoses, which represented a combined proportion of 26.2% for patients with symptomatic carotid disease. Hypertension (34.8%), DM (14.6%), cardiovascular disease (28%), and CHF (3.7%) were the major comorbid conditions coded in the admitting diag-

Table III. Impact of age, sex, race, and comorbidity on perioperative stroke after carotid endarterectomy

Parameter	*Adjusted risk ratio*	*95% Confidence interval*
Age (years)		0.859 - 1.355
71 to 75	1.079	
76 to 80	1.298*	1.024 - 1.646
≥81	1.13	0.839 - 1.523
Race: black vs Caucasian	1.165	0.694 - 1.955
Female vs male	1.165	0.975 - 1.393
Diabetes	1.329*	1.054 - 1.677
CHF	1.699†	1.171 - 2.466
Hypertension	1.008	0.833 - 1.220
Acute myocardial infarction	1.714	0.970 - 3.028
Other cardiovascular disease	0.896	0.721 - 1.112
Malignant disease	1.351	0.781 - 2.339
Recent stroke	5.439‡	4.461 - 6.631
CEA with CAB	0.943	0.470 - 1.890

CHF, Congestive heart failure; *CEA,* carotid endarterectomy; *CAB,* coronary artery bypass graft.
Risk ratios are adjusted for covariates. Age categories are compared with patients aged 65 to 70 years.
*Indicates statistical significance (χ^2 test, $P < .05$).
†$P < .01$.
‡$P < .001$.

noses. Patients who underwent simultaneous coronary bypass grafting and CEA (2.1%) represented a small sample of the group. The geographic region with the largest number of patients was the southeast (38.4%) and the smallest was the northeast (15.8%).

Perioperative morbidity and mortality rates. Overall, the rates of stroke and death within 30 days of the operation were 2.4% and 2.3%, respectively, which represents a combined rate of 4.7%. Table III shows the relationship between the demographic and comorbidity parameters and the likelihood of a perioperative stroke. We controlled for all other variables and found that the patients who were first seen with an acute stroke had over a 5-fold increased likelihood of an early postoperative stroke. The patients with DM, AMI, and CHF were 32%, 71%, and 80% more likely, respectively, to suffer an early stroke then the other patients without these diagnoses. Although there was a trend toward increased stroke risk with age, this reached statistical significance only with the group aged 76 to 80 years. These patients were 30% more likely than the others to experience a postoperative stroke. There were no differences in the perioperative stroke rates on the basis of hospital teaching status or geographic region (data not shown).

Advanced age and comorbidity had a greater impact on the likelihood of perioperative death (Table IV). For patients who were more than 75 years of age, the odds of death were increased by 50% and were doubled for those more than 80 years of age. Patients who were first seen with an acute stroke had a 3.5-fold greater likelihood of perioperative death. Cardiac disease conferred the greatest risk of perioperative mortality: patients with AMI were 9 times more likely to die and those patients with CHF were 3 times more likely to die in the postoperative period than those patients without these diagnoses. Patients with DM had a 29% increased likelihood of death, and a diagnosis of hypertension was associated with a reduced incidence rate of perioperative mortality after CEA. Combined CEA and CAB increased the perioperative death rate 3-fold. There were no differences in perioperative death rates on the basis of the hospital teaching status or the geographic region (data not shown).

Long-term follow-up. The sample of Medicare beneficiaries who underwent CEA during the years 1988 to 1990 was followed for a mean period of 3.1 years. During this sampling interval, 6132 patients died, which represented 27.7% of the total.

The results of the Cox proportional hazards model are shown in Table V. The effects of age were roughly linear with respect to death during the follow-up period, such that those patients who were more than 80 years of age had more than a 2-fold greater chance of death. Women were 25% less likely to die than men.

Cardiac comorbidity had a substantial impact on late outcome. CHF represented the most significant risk factor for late death, with a hazard ratio of 2.73. AMI conferred a similar risk of long-term death (hazard ratio, 2.40), and DM conferred a 51% increase in the risk of late death. As observed with the results of perioperative mortality rates, a diagnosis of hypertension appeared to confer improved late

Table IV. Impact of age, sex, race, and comorbidity on perioperative death after carotid endarterectomy

Parameter	*Adjusted odds ratio*	*95% Confidence interval*
Age (years)		0.924 - 1.511
71 to 75	1.182	
76 to 80	1.499*	1.163 - 1.933
≥81	2.174†	1.643 - 2.876
Race: black vs Caucasian	1.429	0.827 - 2.469
Female vs male	0.898	0.745 - 1.083
Diabetes	1.330‡	1.044 - 1.696
CHF	3.085†	2.334 - 4.077
Hypertension	0.641†	0.513 - 0.801
Acute myocardial infarction	9.050†	6.631 - 12.351
Other cardiovascular disease	0.946	0.761 - 1.176
Malignant disease	2.235†	1.431 - 3.491
Recent stroke	3.589†	2.911 - 4.425
CEA with CAB	3.260†	2.214 - 4.799

CHF, Congestive heart failure; *CEA,* carotid endarterectomy; *CAB,* coronary artery bypass graft.
Risk ratios for age categories are compared with patients aged 65 to 70 years.
*$P < .01$.
†$P < .001$.
‡Indicates statistical significance (χ^2 test, $P < .05$).

survival rates after CEA. Malignant disease was present in 2% of the sample and was associated with a 2-fold increase in the long-term death rate. The performance of simultaneous CEA and CAB, which was associated with greater perioperative mortality rates, had no impact on long-term survival rates. There were no differences in late outcome on the basis of the hospital teaching status or the geographic region (data not shown).

As a test of the homogeneity in the mortality rates of our study population, we studied late death rates separately for each of the years from which our sample population was drawn (1988 to 1990). There were no differences observed (data not shown).

DISCUSSION

CEA has been established as a safe and effective treatment to prevent stroke in patients with significant atherosclerosis of the carotid bifurcation.[1,2,5] However, the small improvement in the outcome of CEA versus medical treatment for asymptomatic disease emphasizes the importance of a low perioperative complication rate and acceptable patient comorbidity to confer the benefit of surgery.

Because the perioperative stroke and death rate after CEA is less than 5% in most recent studies, even large multicenter trials accrue a relatively small number of patients with these endpoints, which thereby limits the statistical analysis of the subgroups. To overcome this limitation and to examine the relationship of demographic and comorbid illness parameters with surgical outcome, we used a large, nationwide database of Medicare beneficiaries.

We found that cardiovascular disease was a prominent risk factor for poor perioperative and long-term outcome. AMI increased the likelihood of perioperative and late death by factors of 9.0 and 2.4, respectively, and CHF contributed to an increased likelihood of early and late death by factors of 3.1 and 2.6, respectively. The small group of patients who underwent combined CAB and CEA had an increased perioperative mortality rate (likely as a result of CAB) but no increase in late death rates. This suggests that patients who undergo combined CAB and CEA have similar long-term survival rates as those who undergo CEA alone.

It is unclear why CHF contributes to an increased stroke rate after CEA. CHF may be a marker for more severe and diffuse cerebrovascular disease or may capture patients with atrial arrhythmias who are at an increased risk of embolic stroke. Plecha et al[10] documented similar findings in a series of nearly 10,000 CEAs.

Increasing age also was associated with increased perioperative death rates after CEA. This finding was significant for patients who were older than 76 years and especially for those older than 80 years, who had a 2-fold increased rate of death after surgery. A recent study by Hsia et al[11] is consistent with our observations. They found a reduction in the death rate after CEA in all Medicare beneficiaries from 3.0% to 1.6% during the period from 1985 to 1996. The death rates for patients who were more than 84 years of age were twice that of the patients who were aged 65 to 74 years throughout the 9-year study.

Table V. Impact of age, sex, race, and comorbidity on late death after carotid endarterectomy

Parameter	*Hazard ratio*	*95% Confidence interval*
Age (years)		
71 to 75	1.250*	1.168 - 1.337
76 to 80	1.537*	1.432 - 1.649
≥81	2.161*	1.996 - 2.339
Race: black vs Caucasian	1.187†	1.017 - 1.385
Female vs male	0.752*	0.713 - 0.792
Diabetes	1.519*	1.423 - 1.621
CHF	2.569*	2.331 - 2.831
Hypertension	0.865*	0.818 - 0.915
Acute myocardial infarction	2.405*	2.066 - 2.801
Other cardiovascular disease	1.025	0.967 - 1.086
Malignant disease	2.112*	1.844 - 2.420
Recent stroke	1.513*	1.402 - 1.632
CEA with CAB	1.06	0.891 - 1.261

CHF, Congestive heart failure; *CEA,* carotid endarterectomy; *CAB,* coronary artery bypass graft.
Hazard ratios for age categories are compared with patients aged 65 to 70 years.
*$P < .001$.
†Indicates statistical significance (χ^2 test, $P < .05$).

Hsia et al[12] from the United States Department of Health and Human Services also studied the epidemiology of CEA between 1985 and 1989 with Medicare files from the Health Care Financing Administration. They found a decreasing trend in the CEAs performed during their study period—the rate of CEA per 10,000 patients declined from 20.6 in 1985 to 14.2 in 1989. During this period, the surgical mortality rate decreased from 3.0% to 2.5%, with an increased risk of death in older patients who underwent surgery in low-volume hospitals. Interestingly, high-volume hospitals (ie, greater than 75 CEAs per year) accounted for 25% of all the CEAs in 1985 but only 16% in 1989. They also reported that 84% of the patients had TIA or stroke as presenting symptoms. However, they erroneously identified these patients with ICD-9-CM diagnostic codes 433.3 and 433.1, respectively. These codes actually identify patients with extracranial carotid artery stenosis generically without regard to symptoms. For our analysis, we used codes 362.34, 435, 436, and 437, which encompass patients with amaurosis fugax, transient cerebral ischemia, and stroke.

Several prior reports also have studied the outcome after CEA for Medicare beneficiaries. Richardson and Main[13] identified 705 patients, who underwent CEA in 1983 in the state of Kentucky, with Medicare claims data and chart review. In their sample, they found a 3.7% incidence rate of perioperative stroke and a 2.0% death rate after CEA, which was similar to our results. They also found an inverse relationship between a surgeon's annual case volume and perioperative stroke. However, 82% of the patients who underwent operation were described as having transient cerebral ischemia, amaurosis fugax, or stroke as compared with 26% in our study.

Other contemporaneous reports also highlight the lower-than-expected proportion of patients observed in our study who were symptomatic. For example, in 1989, Callow and Mackey[14] reported on the results of CEA in 619 patients, 71% of whom were symptomatic. We considered coding omissions during the preparation of the claim forms as a potential cause for these results. The undercoding of chronic illnesses, such as hypertension, has been documented in Medicare patients[15] and is discussed below. However, of the 5 diagnostic codes available in our patient database, the first code is reserved for the primary diagnosis that prompted hospital admission. Because the hospital compensation is related to Diagnosis-Related Group classification, it seems less likely that a TIA or a stroke would be omitted from the admitting diagnosis than a chronic illness, such as hypertension.

We assume that our data are subject to some undercoding bias related to presenting symptoms. However, the consistency of the CEA rates for asymptomatic disease across geographic regions (data not shown) and hospital types suggests that many more CEAs were performed for asymptomatic disease between 1988 and 1990 than previously reported.

Our results regarding the impact of comorbidity on outcome also warrant further discussion. A recent stroke substantially increased the risk of perioperative stroke. The stroke rate for patients who were first seen with a diagnostic code for a recent stroke was more than twice that compared with data from the NASCET trial, which showed a perioperative stroke risk of 5% in patients who were first seen with a nondisabling infarction.[16] This discrepancy between the NASCET data and our observations likely resulted from coding errors, whereby a preoperative diagnosis of recent stroke was carried over for any subsequent hospital admission after CEA. This observation suggests that the other parameters examined for perioperative stroke risk may be subject to inaccuracy on the basis of these coding irregularities.

A diagnosis of hypertension was associated with a decreased rate of early and late death after CEA. There are several explanations for this paradoxical observation. First, the Medicare database in 1988 through 1990 captured only 5 diagnostic codes, including the primary diagnosis that mandated hospital admission. Therefore, the potential for a coding bias and omission exists when the patient's medical record is examined. Jencks et al[15] from the Health Care Financing Administration have documented the undercoding of chronic illnesses, especially hypertension, in patients who were hospitalized, which was associated with inexplicably lower-than-average in-hospital death rates. They concluded that chronic illnesses with high prevalence, such as hypertension, are subject to coding omissions and bias when insurance claim forms are prepared. Presumably, patients with fewer comorbidities are more likely to have hypertension coded, thus accounting for an improved outcome. The undercoding was observed in our study because the incidence rate of hypertension (34%) was significantly less than the 50% to 60% incidence rate that was documented in the NASCET trial,[5] the ACAS study,[2] and in another large series.[14]

We considered that our data, which examined comorbidities other than hypertension, may also be subject to the same coding irregularities. We observed that CHF had a strong negative impact on perioperative outcome and on late survival rates. This diagnostic code was present in 3.7% of our study group, which is similar to the 5% incidence rate documented in the VACS.[1] Also, 15% of our sample had the diagnostic code for DM as compared with 19% in the NASCET study. We therefore concluded that diagnostic coding for DM and CHF was more consistently applied when compared with hypertension in our patient sample.

These observations highlight the strengths and the weaknesses of this large database analysis. As a result of limited input-field size and coding inefficiencies, the MEDPAR files did not accurately capture the true incidence rate of common diagnoses, such as hypertension, and may not have accurately identified all of the patients who were first seen with an acute stroke or TIA. Because the observed prevalence of more serious comorbidities, such as AMI, CHF, and DM, were comparable with other series, the strength of our study stems from the analysis of short-term and long-term death rates with respect to these comorbidities and age. For patients of ages 65 years and older, we found that advanced age and medical comorbidity, particularly active coronary artery disease, CHF, and DM, were associated with an increased risk of perioperative and late death. Our observations may influence the risk-benefit analysis for CEA in patients who are asymptomatic, particularly octogenarians with 1 or more of these diagnoses.

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