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Carotid Endarterectomy in Asymptomatic Patients with Limited Life Expectancy

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Abstract

Background and Purpose—Data from randomized trials asserts that asymptomatic patients undergoing carotid endarterectomy (CEA) must live 3-5 years to realize the benefit of surgery. We examined how commonly CEA is performed among asymptomatic patients with limited life expectancy.

Methods—Within the American College of Surgeons National Quality Improvement Project we identified eight conditions associated with limited life expectancy, based on survival estimates using external sources. We then compared rates of 30-day stroke, death and myocardial infarction following CEA, between asymptomatic patients with and without life limiting conditions.

Results—Of 12,631 CEAs performed in asymptomatic patients, 2,525 (20.0%) were in patients with life limiting conditions or diagnoses. The most common conditions were severe COPD and ASA class IV designation. Patients with life limiting conditions had significantly higher rates of perioperative complications, including stroke (1.8% vs 0.9%, $p<0.001$), death (1.4% vs. 0.3%, $p<0.001$), and stroke/death (2.9% vs 1.1%, $p<0.001$). Even after adjustment for other comorbidities, patients with life-limiting conditions were nearly three times more likely to suffer perioperative stroke or death than those without these conditions (OR 2.8, 95% CI 2.1-3.8, $p<0.001$).

Conclusion—CEA is performed commonly in asymptomatic patients with life limiting conditions. Given the high rates of postoperative stroke/death in these patients, as well as their limited life expectancy, the net benefit of CEA in this population remains uncertain. Health policy research examining the role of CEA in asymptomatic patients with life limiting conditions is necessary, and may serve as a potential source for significant health care savings in the future.

Keywords

carotid endarterectomy; asymptomatic; life expectancy; appropriate

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Introduction

Evidence supporting carotid endarterectomy (CEA) for the treatment of asymptomatic cerebrovascular disease is well established, as several randomized trials have demonstrated a significant reduction in stroke with CEA, as compared to medical treatment alone^{1, 2}. In terms of establishing “appropriate” candidates for CEA, the Society for Vascular Surgery (SVS) guidelines state that asymptomatic patients with 60% carotid artery stenosis should be considered for CEA only when life expectancy is greater than three years and perioperative stroke/death risk is less than 3%³. Similarly, other professional societies, including the American Heart Association (AHA), the American Stroke Association (ASA), and the American Academy of Neurology (AAN) stress the importance of assessing life expectancy prior to pursuing CEA in neurologically asymptomatic patients, asserting that appropriate candidates have a life expectancy greater than five years⁴⁻⁶. Further, the AAN only supports CEA for asymptomatic disease if patients are less than 75 years of age⁶.

While slight differences may exist regarding the exact definition of “appropriate” patient selection criteria for CEA, most physicians would agree that asymptomatic patients with life limiting conditions who are unlikely to survive long enough to realize the benefit of CEA are “inappropriate” candidates for carotid revascularization. However, it remains unclear how commonly patients with life limiting conditions might be offered surgery in real-world practice.

The purpose of our study was to examine utilization and outcomes of CEA in a large cohort of asymptomatic patients with and without life limiting conditions, using a national dataset representing actual practice.

Methods

Data and Databases

We studied all patients undergoing CEA in the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) Registry between 2007 and 2009. The ACS-NSQIP prospectively collects data on over 200 variables pertaining to patient characteristics, comorbid conditions, operative details, and 30-day postoperative outcomes for a variety of surgical procedures. In 2007 data were collected from 211,407 cases at 186 sites. By 2009, these numbers had increased to 336,190 cases at 237 sites. More information about ACS NSQIP is available at <http://www.acsnsqip.org>.

Establishing a cohort

To establish a cohort of patients undergoing CEA for asymptomatic stenosis, we used CPT code 35301 to identify patients in the registry who underwent CEA between 2007 and 2009. All CEAs performed concomitant with other procedures (defined as an additional operation performed by a different surgical team, such as combined CABG/CEA) were excluded. Symptomatic status was then assigned to any subject with a history of cerebrovascular accident (CVA) with or without neurologic deficit, or a history of transient ischemic attack (TIA). All remaining cases were defined as asymptomatic.

Next, to identify patients undergoing CEA who also had life limiting conditions, we evaluated all descriptive patient level covariates in NSQIP and selected those associated with a predicted 5-year mortality 40%. Because long-term survival data are not available in NSQIP, we used external sources (such as published medical literature and national registries) to estimate the 3 and 5-year mortalities of patients with each individual life limiting condition. The life limiting conditions used to define our cohort included disseminated cancer, advanced liver disease, symptomatic congestive heart failure (CHF),

dialysis dependence, and severe chronic obstructive pulmonary disease (COPD). In addition to these medical diagnoses, we also included age ≥ 90 , do not resuscitate (DNR) status, and patients designated as American Society of Anesthesiologists (ASA) class IV, a preoperative designation assigned by the operating anesthesiologist that implies a patient has “severe systemic disease that is a constant threat to life”⁷ [ENREF 3](#).” While the designation of ASA class IV is not a diagnosis, we characterized this variable as descriptive of the patient’s overall risk for surgery in the perioperative period⁸⁻¹⁰. Table I lists the predicted 3 and 5-year mortalities for patients with each condition (operational definitions for each condition are displayed in Data Supplement I, please see <http://stroke.ahajournals.org>). We found that predicted 3-year mortalities ranged from 37% for patients with severe COPD, to 76% for patients with disseminated cancer. Predicted 5-year mortalities were greater than 46% for all life limiting conditions. Of note, long-term mortality data pertaining to DNR status were not available.

Comparison between patients with and without life limiting conditions

We compared patient characteristics, such as age and comorbidities, between patients with and without life limiting conditions using t-tests (for continuous variables) and chi-squared with Fisher’s exact correction (for categorical variables) to identify statistically significant differences.

Next, to study surgeon and hospital characteristics associated with selecting patients with life limiting conditions for CEA in this observational dataset, we examined rates of CEA by surgeon specialty (includes vascular surgery, general surgery, orthopedic surgery, neurosurgery, cardiac and thoracic surgery), and hospital teaching status (teaching/non-teaching).

Finally, we compared rates of stroke, death, the combined outcome stroke/death, and postoperative myocardial infarction (MI, defined as a new transmural acute MI occurring during surgery or within 30 days, manifested by new Q-waves on ECG) between patients with and without life limiting conditions. We used multivariable logistic regression to examine the association between 30-day stroke/death rates and other patient level comorbidities, such as diabetes, smoking, or hypertension. These results were reported as odds ratios with surrounding 95% confidence intervals in a Data Supplement II (please see <http://stroke.ahajournals.org>).

Results

Patient Characteristics, by the presence or absence of a life limiting condition

Overall, 22,696 isolated CEAs were recorded in NSQIP between 2007 and 2009. More than half of CEAs (55.7%, 12,631) were performed in patients with asymptomatic carotid stenosis, while the remaining 44.3% (10,065) procedures were performed in patients with a documented history of CVA or TIA.

Among CEAs in asymptomatic patients (n=12,631), 20.0% (2,525) were performed in patients who also had at least one life limiting condition. Patients with life limiting conditions were, on average, slightly older (mean age 72 years versus 71 years, $p<0.001$), with more baseline comorbidities (independent of those categorized as life limiting comorbidities). For example, patients with life limiting conditions had a higher incidence of diabetes (30.9% vs 26.6%, $p<0.001$), coronary artery disease (47.8% vs 35.2%, $p<0.001$), and hypertension (87.5% vs 85.2%, $p=0.002$, Table II). The most common conditions occurring in asymptomatic patients were ASA class IV (10.2% of all asymptomatic CEAs), severe COPD (10.1%) and dialysis dependence (0.9%, Figure 1). Finally, nearly three

percent (n=369) of CEAs were performed in patients who had more than one life limiting condition.

Outcomes by the presence or absence of a life limiting condition

Overall, 1.4% (182) of all asymptomatic patients undergoing CEA experienced stroke or death within 30 days following surgery. The incidence of stroke/death within 30 days increased with age, reaching 1.2% (n=28) for all patients 75-80 years, and 2.2% (n=55) for all patients over the age of 80 years. Combined 30-day stroke/death rates were also significantly higher in those with life limiting conditions as compared to those without life limiting conditions (2.9% vs. 1.1%, $p<0.001$). The incidence of stroke and death at 30 days was also higher among patients with life limiting conditions as compared to those without life limiting conditions (stroke: 1.8% vs 0.9%, $p<0.001$; death: 1.4% vs. 0.3%, $p<0.001$, Figure 2).

In crude (unadjusted) analyses, the odds of mortality were nearly five times higher in asymptomatic patients with life limiting conditions (OR 4.6, 95% CI 2.8-7.4, $p<0.001$). After adjustment for other baseline comorbidities the presence of a life limiting condition remained independently associated with 30-day stroke/death (OR 2.8, 95% CI 2.1-3.8, $p<0.001$) (Data Supplement II).

Overall, fewer than 1% of asymptomatic patients undergoing CEA experienced postoperative MI (n=73). While patients with life limiting conditions experienced a higher incidence of postoperative MI than those without life limiting conditions (0.8% vs. 0.5%) this difference was not statistically significant ($p=0.06$).

Effect of ASA class IV and severe COPD on stroke and death

Because two of the most common life limiting conditions in our cohort, ASA class IV and severe COPD, were also the most subjective, we examined the effect of these variables independently on risk of stroke/death at 30 days. Compared to patients without life limiting conditions, patients designated as ASA class IV or with severe COPD had a higher incidence of stroke/death (2.9% versus 1.1%, $p<0.001$). Further, the risk of stroke/death was even higher in patients with life limiting conditions other than ASA class IV or severe COPD (3.4%, Figure 3).

Effect of surgeon specialty and hospital teaching status

When we examined the effect of surgeon specialty on outcome, we found that each surgical specialty examined performed approximately 20% of CEAs in patients with life limiting conditions (19.9% vascular vs. 21.0% other specialties combined, $p=0.497$). Further, hospital teaching status was not associated with the proportion of CEAs performed in asymptomatic patients with life limiting conditions (20.5% non-teaching vs. 19.6% teaching, $p=0.205$).

Comparison of findings in asymptomatic vs. symptomatic patients

Lastly, to provide context for our results, we examined the prevalence of life limiting conditions in patients undergoing CEA for symptomatic carotid stenosis, defined as CEA performed with a pre-operative diagnosis of stroke or TIA. Overall, 27.1% (2,731) of CEAs performed for symptomatic carotid stenosis occurred in patients with life limiting conditions. As with asymptomatic status, the most common life limiting conditions in symptomatic patients undergoing CEA were ASA Class IV designation (16.0% of all symptomatic CEA patients) and severe COPD (10.9% of all symptomatic CEA patients). As expected, symptomatic patients had significantly higher rates of stroke and death than asymptomatic patients (stroke: 2.3% vs 1.1%, $p<0.001$; death: 1.0% vs. 0.5%, $p<0.001$).

Among symptomatic patients, those with life limiting conditions experienced significantly higher rates of death and stroke/death at 30 days than those without life limiting conditions (death: 2.0% vs 0.7%, $p<0.001$; stroke/death: 4.3% vs 2.6%, $p<0.001$). The incidence of postoperative stroke was also higher among symptomatic patients with life limiting conditions, although this difference was not statistically significant (2.8% vs 2.2%, $p<0.095$, Figure 4).

Discussion

Our study demonstrates that among hospitals participating in a national surgical quality improvement program, CEA is performed commonly in asymptomatic patients with life limiting conditions, and these patients have poorer perioperative outcomes. Further, the cumulative effect of increased perioperative mortality, coupled with poor predicted five-year survival as a result of having a life limiting condition, makes it unlikely these patients will benefit, on average, from CEA for asymptomatic disease. Therefore, future efforts to examine the long-term benefit of CEA in patients with life limiting conditions are necessary, especially in the current era of cost-containment in healthcare.

After the Asymptomatic Carotid Atherosclerosis Study (ACAS) established the benefit of CEA for asymptomatic patients in 1995, many have examined the appropriateness of this procedure across a spectrum of patient risk. For example, in 1997 Cronenwett *et al* published a cost-effectiveness analysis of CEA for asymptomatic patients, based on trial data from ACAS. This study, which demonstrated an exponential increase in risk with increasing age over 70, attributed the low net benefit of CEA in patients over this age threshold to a decreased life expectancy, and therefore a reduced opportunity for stroke prevention¹⁸. Other studies have also described populations that fare poorly in obtaining benefit from carotid endarterectomy, including the very elderly, African Americans, and patients with chronic renal insufficiency¹⁹⁻²².

Our study finds that a significant proportion of asymptomatic patients selected for CEA in real-world practice are unlikely to experience durable long-term benefit from surgery. While indirect, our data suggest that patients with life limiting conditions have both increased perioperative mortality (1.4%) and increased predicted long-term mortality. These two elements make it unlikely that patients with life limiting conditions will achieve the 3-5 year survival necessary to experience the benefit of stroke prevention provided by CEA for asymptomatic carotid stenosis.

Further, in the present day, many argue that significant changes in the medical management of patients with asymptomatic carotid stenosis have occurred since ACAS was published. Specifically, rates of antiplatelet agent and statin use have increased²³, leading many to question whether CEA for asymptomatic patients still offers the same margin of benefit over non-operative treatment. For example, Abbott published a meta-analysis describing a 7% decline in stroke and TIA in patients with severe carotid stenosis since the mid-1980's, with the rate of ipsilateral stroke among medically treated patients falling below that of patients who received CEA in ACAS beginning in 2001²⁴. Given the uncertainty about the current effectiveness of CEA for asymptomatic carotid stenosis, many agree that a clinical trial is needed to compare newer methods of medical management for asymptomatic carotid stenosis with carotid revascularization, across a spectrum of patient risk.

Practice patterns in patients with symptomatic carotid stenosis were not strikingly different than patients with asymptomatic stenosis, in terms of the proportion of patients undergoing CEA in the setting of life limiting comorbidities. However, the implication of a life limiting condition is arguably much less important in patients with symptomatic carotid stenosis,

given their much higher potential risk of stroke in the near term. It is critical that patients undergoing surgery for asymptomatic carotid stenosis survive long enough to offset the up-front risk of surgery, whereas long term survival is a less important parameter in determining the absolute benefit of CEA in patients with symptomatic carotid stenosis.

Our study has several limitations. First, we designated asymptomatic status based on the absence of a concomitant diagnosis of stroke or TIA, not accounting for other potential symptoms not recorded in NSQIP such as ocular TIAs or dizziness. However, the proportion of CEAs we designated as asymptomatic in NSQIP is very similar to that of other regional registries, and is likely representative of significant symptomatic status. A second limitation relates to our use of medical literature to infer the mortality rates associated with conditions defined in NSQIP. We recognize that the operational definitions available in NSQIP may not precisely align with definitions used in each of the outside sources cited. However, for two reasons, we believe our designations accurately represent life limiting conditions. First, the studies we used to estimate mortality rates from life-limiting conditions were of high quality, including data from major randomized trials and federally supported registries. Second, the magnitude of differences in outcomes, such as mortality and stroke, observed between those with and without life limiting conditions suggests that our designation of these conditions as life limiting was likely accurate. A third limitation pertains to the diagnosis of postoperative stroke. Unfortunately, NSQIP does not require postoperative neurologic exams by personnel certified in the NIH Stroke Scale, and as such the diagnosis of this postoperative complication may vary from provider to provider. Fourth, our study is limited in the insight provided towards another important endpoint for patients undergoing carotid revascularization -- myocardial infarction. Most clinical trials studying carotid revascularization use a broad definition, encompassing troponinemia, non-ST elevation myocardial infarctions, and ST-elevation myocardial infarctions²⁵. We found a low myocardial infarction rate in our study (1%), but likely because NSQIP uses a strict definition encompassing the most advanced manifestations of myocardial ischemia. And finally, some may question our selection of any one of our individual life limiting comorbidities, especially variables indicative of overall patient risk, such as ASA class designation. However, the magnitude of the survival differences in the characteristics we selected imply that we succeeded in identifying a cohort of patients for whom prophylactic surgery incurs very high risk.

Summary

Data from NSQIP suggests that approximately 20% of CEAs among asymptomatic patients are performed in patients with life limiting conditions, who may not survive to realize the small, but measurable long-term benefit of surgery for stroke prevention. Additionally, these patients have significantly higher rates of postoperative stroke and death than patients without life-limiting conditions, further increasing the chance that they will not benefit from CEA. While current literature to guide surgeons in identifying patients at high risk for postoperative complications exists²⁶, these guidelines make little mention of patient selection for asymptomatic CEA based on long-term survival. Future efforts to examine actual (rather than predicted) rates of long-term stroke-free survival in patients with asymptomatic carotid stenosis and limited life expectancy are necessary.

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Figure 1.

Proportion of carotid endarterectomies (CEA) performed for asymptomatic carotid artery stenosis in patients with one of eight life limiting conditions.

DNR: do not resuscitate; CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease; ASA: American Society of Anesthesiology

Figure 2. Thirty-day stroke, death and combined stroke/death rates between patients with (black) and without (gray) life limiting conditions following carotid endarterectomy for **asymptomatic stenosis**.

Figure 3.

Thirty-day stroke (left), death (middle left) and combined stroke/death rates (middle right) between patients with and without one of eight life limiting conditions following carotid endarterectomy for asymptomatic stenosis. Subgroup analysis (right) demonstrates combined stroke/death rates among patients without a life limiting condition, with ASA Class IV or Severe COPD, and with any one of the remaining six life limiting conditions (advanced liver disease, disseminated cancer, DNR, symptomatic CHF, age 90, dialysis dependence).

Figure 4.

Thirty-day stroke, death and combined stroke/death rates between patients with (black) and without (gray) life limiting conditions following carotid endarterectomy for **symptomatic stenosis**.

Table I

Predicted 3 and 5-year mortality for patients with life-limiting conditions and the associated reference used to estimate mortality.

Life-Limiting Condition	Predicted 3-Year Mortality (%)	Predicted 5-Year Mortality (%)	Reference
Disseminated Cancer	76	83	Surveillance, Epidemiology, and End Results (SEER) Program ¹¹
Advanced Liver Disease	63	80	Survival data based on Child-Turcotte Criteria ¹²
Symptomatic CHF	62	69	Framingham Heart Study ¹³
Dialysis Dependence	50	67	United States Renal Data System (USRDS) Annual Data Report ¹⁴
Age ≥ 90 years	41	62	National Vital Statistics Report, 2006 Data ¹⁵
ASA Class IV	41	57	Virkkunen, et al. 2009 ¹⁶
Severe COPD	37	46	Third National Health and Nutrition Examination Survey ¹⁷
Do Not Resuscitate (DNR) *	-	-	-

* Data pertaining to DNR status were not available.

Table II

Characteristics between patients with and without life-limiting conditions undergoing carotid endarterectomy for asymptomatic carotid stenosis.

Patient Characteristic	YES Life Limiting Condition (N=2,525)	NO Life Limiting Condition (N=10,106)	P-Value
Age (%)			<0.001
<65 years	20.2	23.7	
65-70 years	17.7	18.4	
70-75 years	20.1	19.4	
75-80 years	19.4	19.1	
>80 years	22.7	19.5	
Male (%)	57.4	57.5	0.896
Race (%)			0.299
White	46.9	38.8	
Black, Hispanic, Other	53.1	61.2	
Diabetes (%)	30.9	26.6	<0.001
Coronary Artery Disease (%)	47.8	35.2	<0.001
Hypertension (%)	87.5	85.2	0.002
Smoker (%)	34.2	24.3	<0.001