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Background and Purpose—Because there is considerable variation in practice patterns and outcomes for carotid endarterectomy (CE), there is a need to study the processes of care that are associated with adverse outcomes. The purpose of this study was to examine the impact of processes of care and surgical specialty on adverse outcomes for CE.

Methods—A retrospective cohort study based on a voluntary CE registry containing 3644 patients undergoing CE between April 1, 1997, and March 31, 1999, in New York hospitals was used in the study. A multivariable statistical model was used to identify significant independent patient risk factors and to examine the association of processes of care and surgical specialty with outcomes after adjustment for differences in patient risk factors.

Results—The overall adverse outcome (in-hospital death or stroke) rate was 1.84%. After adjustment for differences in 7 patient risk factors that were significantly related to adverse outcomes, the use of ≥1 specific processes of care (eversion endarterectomy, protamine, or shunts) was found to be associated with lower odds of an adverse outcome relative to patients undergoing CE without the processes (OR=0.42, $P=0.006$). Similarly, patients undergoing surgery performed by vascular surgeons had lower odds of experiencing an adverse outcome (OR=0.36, $P=0.009$). Processes of care and surgical specialty were highly correlated with one another.

Conclusions—Processes of care and surgical specialty are significant interrelated determinants of adverse outcome for CE.
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Key Words: carotid endarterectomy ■ surgical treatment ■ treatment outcome

Carotid endarterectomy (CE) is a surgical procedure used to remove atherosclerotic stenosis from the carotid artery in an attempt to prevent strokes caused by embolization and/or compromised cerebral blood flow. Randomized clinical trials have demonstrated that CE is an effective treatment for both symptomatic[1,2] and asymptomatic carotid occlusive disease.[3] However, there has been considerable controversy regarding the appropriate use of CE,[4] and there have been large temporal and geographic variations in practice patterns.[5–7] For example, Tu et al[5] found that in New York, the rate of CE dropped from 65 to 40 per 100 000 adults ≥40 years of age between 1984 and 1989 and then rose again to 96 per 100 000 adults between 1989 and 1995. Large declines followed by large increases also occurred in California and Ontario, Canada.[5] These trends most likely reflect growing concerns about efficacy, followed by an upsurge in frequency after the favorable results of randomized trials became known. However, despite these randomized trials, the CE rates per 100 000 adults were quite different in the 3 regions, ranging from 38 in Ontario to 99 in California in 1995.[5]

The patient outcomes for CE, as for many other invasive surgical procedures, have been found to be associated with the volume of procedures performed in a hospital and the volume performed by the surgeon.[8–14] Despite the availability of this information, the large increases in CE rates in California, New York, and Ontario between 1989 and 1995 were not associated with proportionately greater numbers of referrals to higher-volume hospitals or to hospitals with lower mortality rates.[5] Furthermore, research has demonstrated that patients treated at many hospitals experience operative mortality rates substantially greater than those achieved in the clinical trials that demonstrated that CE leads to lower mortality than the best medical treatment.[13] This finding suggests that many patients may not receive the full benefit of this procedure. For example, some investigators have estimated that for asymptomatic patients to benefit from CE, a provider's perioperative mortality and morbidity would need to be <3%.[3]

These practice pattern and outcome variations suggest that there is still much to be learned about the determinants of outcome for CE and about what can be done to render the procedure more effective.[4,15] The purposes of this study were to (1) identify the patient risk factors that are significant independent predictors of adverse outcome (death/major neu-

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rological deficit/minor neurological deficit); (2) explore differences in the prevalence of patient risk factors by surgical specialty; (3) examine the association of processes of care and surgical specialty with outcome, controlling for patient risk factors; and (4) determine whether there is an interactive effect of processes of care and surgical specialty on outcome, controlling for patient risk factors.

Methods

Data Collection and Measurements

With funding from the New York State Department of Health through the New York State Task Force on Clinical Guidelines and Medical Technology Assessment, a voluntary CE registry was created after institutional review board approval in each participating hospital. An administrative database in New York, the Statewide Planning and Research Cooperative System (SPARCS), was used to identify all surgeons who performed the procedure in 1996, and these surgeons were invited by mail to participate in the study. Sixty surgeons representing 37 hospitals participated in the study, which accrued cases from April 1997 to March 1999.

A subgroup of surgeons performing CE or physicians caring for stroke patients (ie, neurologists and neuroradiologists) developed the data entry form used in the reporting process. Patient data on the form included demographics (age, sex, race); admission, surgery, and discharge dates; and a variety of clinical risk factors for adverse outcomes of CE. One of the risk factors is a set of mutually exclusive hierarchical indications for surgery [asymptomatic, amaurosis fugax, first transient ischemic attack (TIA), multiple TIAs, crescendo TIAs, mild reversible neurological deficit, stroke in evolution, mild stroke, and moderate stroke]. Other risk factors included preoperative comorbidities (previous myocardial infarction, hypertension, cardiac valve disease, coronary artery disease, atrial fibrillation, congestive heart failure, diabetes, previous stroke, and smoking) and degree of ipsilateral and contralateral stenoses (mild, moderate, severe, or occluded). Surgeon and hospital data included unique surgeon and hospital identifiers and surgical specialty (neurosurgeon, vascular surgeon, or general surgeon). Each individual surgeon was responsible for the accuracy of coding of data for his or her patients, including the coding of perioperative strokes. The coding was performed just after discharge by either the surgeon or a clinical nurse designated by the surgeon.

Processes of care included the type of procedure (CE, CE with patch graft, or eversion endarterectomy) and adjunctive measures (protamine, shunt, or heparin). These processes are described in the Appendix. There is also information as to whether coronary artery bypass graft (CABG) surgery was performed during the same admission; however, this study is limited to patients undergoing CE without CABG surgery. Outcomes were subdivided into in-hospital and 30-day outcomes, and a mutually exclusive hierarchy was used to describe outcomes (no neurological deficit, temporary neurological deficit or TIA, minor permanent neurological deficit, major permanent neurological deficit, or death).

To ensure that data from the registry were accurate and complete, the Department of Health's SPARCS, which is an administrative data system containing information on all acute care discharges from nonfederal hospitals in the state, was used to identify all CEs performed by each surgeon during his or her participation in the registry. These procedures were matched with procedures in the registry by the use of hospital and surgeon identifiers and medical record number. According to SPARCS, 3337 patients underwent CEs without CABG surgery by participating surgeons during the period that they participated in the registry. Of these patients, a total of 3019 (90.4%) were matched to the registry, and 318 records could not be matched. However, there were another 625 patients with records in the registry that were not contained in SPARCS, so it is very likely that most, if not all, of the unmatched SPARCS cases were contained in the registry but could not be matched because of coding errors in SPARCS in provider identifiers and medical record numbers.

SPARCS was also used to confirm the accuracy of deaths reported in the registry. Only 1 case had a death reported in SPARCS that was not reported as a death in the registry. This was confirmed to be accurate in SPARCS and changed to a death in the registry. Perioperative strokes could not be checked with SPARCS.

Analysis Plan

The relationship between surgical specialty and each of the patient risk factors (demographics, indications, preoperative comorbidities, symptomatic vascular territory, and contralateral and ipsilateral stenoses) was examined, and χ^2 tests were used to test for a significant difference in the prevalences of each risk factor by surgical specialty. Also, the relationship between each of the risk factors and the adverse outcome (death, major neurological deficit, or minor neurological deficit) was studied, and a χ^2 test was used to test for the difference in adverse outcome rates (death or perioperative stroke) for patients with and without each risk factor.

Differences in the use of various processes of care (protamine, heparin, shunts, eversion endarterectomy, and patch grafts) by surgical specialty were investigated by use of χ^2 tests. Also, the adverse outcome rate associated with each of these processes of care was calculated, and a χ^2 test was used to test for the difference in adverse outcome rates for patients undergoing CE with and without the process of care.

In the next step, we determined which patient risk factors and volume measures are independently associated with adverse outcomes. Because the database has a hierarchical structure with patients assigned to surgeons, a generalized linear hierarchical model (also called a multilevel or mixed model) was used as the analytical tool.[16,17] The GLIMMIX macro (SAS, version 6.12) was the software package used to conduct the analyses because the dependent variable was dichotomous (an adverse outcome in the hospital during or after the procedure was performed, discharge without an adverse outcome). A 1-way analysis of covariance (ANCOVA) with random (surgeon) effects was the specific mixed model used within GLIMMIX. The candidate patient risk factors included patient age, the comorbidities mentioned above, ipsilateral and contralateral stenoses, and clinical indication. Linear and quadratic functions of age were tested in the models, and these forms were compared with categorical variables (age intervals) to find the best possible functional form, which turned out to be a dichotomous categorization (age $\leq$80 or $>$80 years). For categorical variables with $>$2 categories (ipsilateral stenosis, contralateral stenosis, and indication), categories with similar adverse outcome rates were combined. Two provider volume measures were also investigated in the initial model. The mean annual surgeon volume was identified by use of the registry, and SPARCS was used to identify the mean annual hospital volume because not all surgeons in each hospital participated in the registry.

After all variables in the initial model that were significantly related to adverse outcome ($P<0.10$) were identified, they were retained and indicator variables were added to test for the independent and combined effects of processes of care and surgical specialty while controlling for differences in significant patient risk factors. The presence of $\geq$1 of 3 process measures (protamine, shunt, or eversion endarterectomy) was treated as an indicator variable and added to the patient risk factors in the model. The use of heparin had been examined earlier; it was not included as one of the processes in the indicator variable because almost all patients (98%) were given heparin. Patch grafts were not included in the indicator variable because the risk-adjusted adverse outcome associated with patch grafts was higher, although not significantly higher, than the outcome without patch grafts. Indicator variables were also defined for "neurosurgeon" and "general surgeon," with "vascular surgeon" serving as a reference category. Then, vascular surgeon was treated as an indicator variable, with nonvascular surgeon as the reference category.

Later, indicator variables for both surgical specialty and the process measures were added to the model simultaneously to determine whether processes of care had an effect on surgical specialty differences and vice versa. The models used for these

TABLE 1. Prevalence and Adverse Outcome Rates for Patient Risk Factors for Carotid Endarterectomy by Surgical Specialty

Risk Factors	Prevalence, %			Prevalence, All Cases, %	Adverse Outcome Rate, All Cases, %
	Vascular Surgeons	Neurosurgeons	General Surgeons		
Age >80 y	18.5	9.2	21.7	17.8‡	3.08‖
Sex					
M	57.1	52.3	60.0	56.8	1.79
F	42.9	47.7	40.0	43.2	1.90
Previous myocardial infarction	25.8	21.4	18.3	25.2†	2.72
Hypertension	69.5	37.2	42.5	65.9‡	1.54§
Cardiac valve disease	7.1	7.2	7.5	7.1*	3.86§
Coronary artery disease	53.4	54.3	43.3	53.1	2.17
Atrial fibrillation	5.9	4.9	4.2	5.8†	4.76‖
Congestive heart failure	7.4	2.3	3.3	6.9‡	2.80
Diabetes	26.8	23.0	20.0	26.2‡	2.72§
Contralateral stenosis				‡	§
Missing	33.3	14.5	19.2	31.3	1.40
<30%	24.4	41.5	35.8	25.9	1.80
30–70%	17.7	20.7	19.2	18.0	0.91
>70%, Not occluded	18.6	17.8	18.3	18.5	2.97
Occluded	6.3	5.6	7.5	6.3	3.48
Ipsilateral stenosis				‡	¶
Missing	5.1	6.9	3.3	5.2	2.77
<30%	0.6	0.7	0.8	0.6	0.00
30–70%	2.7	7.2	9.2	3.3	2.48
>70%, Not occluded	90.9	84.2	85.8	90.2	1.67
Occluded	0.7	1.0	0.8	0.7	14.81
Symptomatic	33.0	46.7	53.3	34.8‡	2.92¶
Asymptomatic	67.0	53.3	46.7	65.2	1.26

*$P<0.05$, †$P<0.01$, ‡$P<0.001$, differences in prevalence by surgical specialty.
§$P<0.05$, ‖$P<0.01$, ¶$P<0.001$, differences in adverse outcome rate with and without risk factor.

additional analyses were also 1-way ANCOVAs with random effects.

Results

Table 1 presents the prevalence of several putative patient risk factors for each of the 3 surgical specialties, along with the adverse outcome rates for each of these risk factors. Risk factors identified as having significantly different prevalence rates by surgical specialty include age >80 years, previous myocardial infarction, hypertension, cardiac valve disease, atrial fibrillation, congestive heart failure, diabetes, ipsilateral stenosis, contralateral stenosis, and symptomatic status (ie, amaurosis fugax, TIA, mild reversible neurological deficit, stroke in evolution, or stroke). Patients undergoing surgery performed by vascular surgeons had higher prevalence rates for previous myocardial infarction, hypertension, atrial fibrillation, congestive heart failure, and diabetes. Neurosurgeons had the highest prevalence of patients with coronary artery disease; general surgeons had the highest prevalence of patients who were symptomatic, were >80 years of age, or had cardiac valve disease.

All patient risk factors except sex, previous myocardial infarction, coronary artery disease, and congestive heart failure were associated with significantly higher adverse outcome rates than the overall adverse outcome rate for the study, which was 1.84%. Patients with a history of atrial fibrillation (4.76%, $P<0.01$), cardiac valve disease (3.86%, $P<0.05$), age >80 years (3.08%, $P<0.01$), or occluded contralateral or ipsilateral carotid arteries (3.48%, $P<0.05$, and 14.81%, $P<0.001$, respectively) or who were symptomatic (2.92%, $P<0.001$) had the highest adverse outcome rates.

Table 2 presents the utilization rates for various processes of care (protamine, heparin, shunt, eversion endarterectomy, and patch graft) by surgical specialty, as well as the overall prevalences and outcome rates associated with the use of each of the processes of care. There were significant differences in the utilization of 4 of the 5 processes of care (protamine, heparin, shunt, eversion endarterectomy, and patch graft). Vascular surgeons and general surgeons had similar average utilization percentages for protamine (37.3% and 35.8%, respectively), but this was significantly different ($P<0.001$) from the utilization percentage of protamine by neurosur-

TABLE 2. Prevalence and Adverse Outcome Rates for Processes of Care for Carotid Endarterectomy by Surgical Specialty

	Prevalence, %			Total, %		
Processes of Care	Vascular Surgeons	Neurosurgeons	General Surgeons	Prevalence	Adverse Outcome Rate With Process	Adverse Outcome Rate Without Process
Protamine	37.3	2.0	35.8	34.3*	1.52	2.00
Heparin	97.2	98.7	100.0	97.5	1.86	1.49
Shunt	49.5	0.3	55.8	45.6*	1.44	2.17
Eversion endarterectomy	23.2	0.0	0.0	20.6*	1.60	1.90
Patch graft	60.5	1.6	26.7	54.5*	1.51	2.23
Protamine, shunt, and/or eversion	90.3	2.3	80.0	82.6	1.50†	3.46

*$P<0.001$, differences in prevalence by surgical specialty.
†$P<0.001$, differences in adverse outcome rates with and without the process.

geons (2.0%). Also, vascular surgeons and general surgeons had relatively similar average utilization for shunts (49.5% and 55.8%, respectively), and these percentages were significantly different ($P<0.001$) from the usage of shunts by neurosurgeons (0.3%).

Vascular surgeons used eversion endarterectomy, a technique not used by neurosurgeons or general surgeons, for 23.2% of their patients. This difference in utilization was significant ($P<0.001$). The utilization of patch grafts also differed significantly ($P<0.001$), with 60.5% of vascular surgeons' patients receiving patch grafts compared with 26.7% for patients of general surgeons and 1.6% for patients of neurosurgeons. All surgical specialists used heparin extensively, with 97.5% of all patients having received heparin. The adverse outcome rates for all processes in Table 2 except heparin were lower than the overall adverse outcome rate of 1.84%, but none of the differences were statistically significant. However, the use of ≥1 of protamine, shunt, or eversion endarterectomy was found to have an adverse outcome rate of 1.50%, which was significantly lower ($P<0.001$) than the adverse outcome rate (3.46%) for the 17% of patients receiving none of these processes of care.

Table 3 presents the number of patients, number of surgeons, unadjusted adverse outcome rates, and adjusted ORs by surgical specialty. A total of 3644 patients underwent CE without CABG surgery in the same admission. Sixty surgeons performed the surgery in 37 hospitals. A total of 58.6% of the patients underwent the procedure in teaching hospitals, and 22.0% underwent the procedure in academic medical centers. Also, 39 of the 60 surgeons performed the procedure in teaching hospitals or academic medical centers. With regard to specialty, a total of 3220 patients (88.4%)

TABLE 3. Numbers of Patients, Numbers of Surgeons, and Adverse Outcome Rates by Surgical Specialty for Carotid Endarterectomy

	Vascular Surgeons	Neurosurgeons	General Surgeons	Total
Patients, n (%)	3220 (88.4)	304 (8.3)	120 (3.3)	3644 (100.0)
Surgeons, n (%)	43 (71.7)	8 (13.3)	9 (15.0)	60 (100.0)
Surgeon volume, n				
Mean	73.8	37.4	12.9	60.7
Median	18.5	18.0	10.0	14.0
Range	1–525	1–86	2–21	1–493
In-patient mortality rate, %	0.60	1.26	1.65	0.69
Unadjusted Adverse Outcome Rate, %	1.55	4.28	3.33	1.84†
Unadjusted OR for Adverse Outcome (95% CI)	1.00 (Reference)	2.84 (1.15–6.09)	2.19 (0.69–6.05)	NA
P	1.00	0.001	0.005	
Adjusted OR for Adverse Outcome* (95% CI)	1.00 (Reference)	3.17 (1.26–7.97)	2.18 (0.69–6.93)	NA
P	1.00	0.014	0.187	

Adverse outcome is in-hospital death, major neurological deficit, or minor neurological deficit.
*Risk adjusted with age <80 years, previous myocardial infarction, cardiac valve disease, diabetes, contralateral stenosis (severe or occluded), ipsilateral occlusion, and symptomatic (amaurosis fugax, multiple TIAs, crescendo TIAs, reversible neurological deficit, stroke in evolution, mild stroke, or moderate stroke).
†$P=0.002$.

underwent surgery performed by the 43 vascular surgeons in the study. The 8 neurosurgeons in the study performed 304 CEs (8.3%), and the remaining 120 procedures (3.3%) were performed by 9 general surgeons. The overall adverse outcome (in-hospital death, major neurological deficit, or minor neurological deficit) rate was 1.84% (67 adverse outcomes), and the mortality rate was 0.52% (19 deaths). The unadjusted adverse outcome rate for vascular surgeons was 1.55%, whereas the adverse outcome rates for neurosurgeons and general surgeons were 4.28% and 3.33%, respectively. These 3 rates were significantly different ($P=0.002$). Adjusted rates were calculated by adjusting for variables that proved to be significant predictors of adverse outcome in the initial analysis [age, comorbidities (previous myocardial infarction, cardiac valve disease, diabetes), ipsilateral stenosis, contralateral stenosis, and symptom status]. Note that neither hospital nor surgeon volume was used in the adjustment because neither proved to be significant predictors of adverse outcome in this database. After adjustment for the variables mentioned above, patients of neurosurgeons were found to have significantly higher odds of experiencing an adverse outcome than patients of vascular surgeons (OR=3.17, $P=0.014$). Patients of general surgeons were found to have nonsignificantly higher odds of adverse outcomes than patients of vascular surgeons (OR=2.18, $P=0.187$).

When neither differences in patient risk factors nor process measures were adjusted for, patients of vascular surgeons had odds of an adverse outcome that were 0.38 times the odds for patients of other surgeons, and this ratio was statistically significant ($P=0.002$). When the odds were adjusted for differences in patient risk factors, the OR was very similar and still significant (OR=0.36, $P=0.009$). When the adjustment included the set of process measures in addition to the patient risk factors, the OR increased to 0.50 and was no longer significant ($P=0.106$).

Similarly, patients receiving ≥1 of the 3 processes of care (protamine, eversion, or shunt) had significantly lower odds of experiencing an adverse outcome than patients receiving none of the 3 processes (OR=0.43, $P=0.002$), and those odds did not change much when they were adjusted for differences in patient risk factors (OR=0.42, $P=0.006$). However, when the odds were adjusted for differences in surgical specialty, they were no longer significant (OR=0.53, $P=0.074$).

Discussion

The overall adverse outcome (in-hospital death or stroke) rate in this study for CE patients without CABG surgery in the same admission was 1.84%, and the in-hospital mortality rate was 0.52%. This mortality rate is lower than the 0.7% mortality rate reported in Pennsylvania,[18] and the adverse event rate is lower than the 2.7% adverse event rate reported by Maxwell et al[19] in North Carolina, the 4.0% rate reported by Kresowik et al[20] in Iowa, the multistate study by Kresowik et al,[21] or the 4.7% 30-day rate reported by Cebul et al[14] in Ohio. However, the Kresowik et al[20] and Cebul et al[14] studies were limited to Medicare patients who clearly have higher adverse event rates because of their age.

The North American Symptomatic Carotid Endarterectomy Trial (NASCET) reported a rate of 6.5% for stroke or death among symptomatic patients within 30 days[1]; the Asymptomatic Carotid Atherosclerosis Study (ACAS) reported a rate of 2.3% for stroke or death among asymptomatic patients within 30 days[3]; and a multicenter trial in Veterans Administration hospitals among asymptomatic patients with >50% stenosis reported a 30-day mortality of 1.9% and a 30-day adverse event rate of 4.7%.[22] The higher rates reported in these studies reflect outcomes from several years earlier, and the 30-day rates tend to be somewhat higher in general than in-hospital rates, which were reported in our study. Although 30-day outcomes were collected in our study, some were missing, and we were not as confident of the data accuracy as we were for in-hospital outcomes. Nevertheless, when 30-day adverse outcomes were used in lieu of in-hospital adverse outcomes, the results were very similar because most adverse events within 30 days in this study occurred during the index hospitalization.

Another reason for the relatively low rates reported in our study was that the outcome rates reported here are for a group of surgeons with better outcomes than in the entire state. With SPARCS used as a complete accounting of all CEs performed in New York in the same time period, a total of 23% of the cases and 7% of the surgeons are represented in the registry. The mortality rate for all CEs in the state of New York (including patients undergoing CABG surgery in the same admission) during this time frame was 1.10%, whereas the rate for patients in the study (including CABG surgery patients) was 0.69%. Thus, it should be emphasized that the mortality and adverse outcomes rates reported in this study are not representative of the experience in an entire state but instead are an indication of the achievable performance by a biased sample of surgeons.

Our study found 7 patient-related factors [age of ≥80 years, previous myocardial infarction, cardiac valve disease, diabetes, contralateral stenosis >70%, ipsilateral occlusion, and symptomatic status (an indication for surgery of amaurosis fugax, TIA, reversible neurological deficit, or stroke)] that were significant independent predictors of an adverse outcome. Of these factors, age, contralateral stenosis, ipsilateral stenosis, and indication are in common with those found in a meta-analysis of 36 recent studies on CE by Rothwell et al.[23] However, they were defined somewhat differently by Rothwell et al (as age >75 years, occluded contralateral internal carotid artery, stenosis of ipsilateral external and of distal ipsilateral internal carotid arteries, and cerebral TIA).[23] Other factors that they found to be significant predictors of adverse outcomes were peripheral vascular disease, hypertension, and female sex. However, the studies in their meta-analysis did not generally use multivariable methods to identify significant independent risk factors, so some of the factors they identified may not have proven to be significant in multivariable analyses. Of the 6 risk factors, 3 identified as being significant in this study were not found to be significant by Rothwell et al; 2 of them (previous myocardial infarction and diabetes) were examined by them, and the other (cardiac valve disease) was not.

A major finding of this study was that after controlling for the preoperative patient risk factors mentioned above, processes of care and surgical specialty were found to be

significantly related to adverse outcome. Patients undergoing CE with protamine, shunts, and/or eversion endarterectomy had significantly lower risk-adjusted odds of experiencing adverse outcomes than patients without these processes of care (OR=0.42, P=0.006), and patients of vascular surgeons had significantly lower odds of adverse outcomes than patients undergoing CE performed by other surgeons (OR=0.36, P=0.009). It should be noted that the finding that patients of vascular surgeons experience better outcomes is in contrast to a study that found that patients of neurosurgeons experience better outcomes[18] and to studies that found no differences by surgical specialty.[1,24,25] It is possible that neurosurgeons reported a higher number of postoperative strokes because of greater expertise in performing neurological exams.

Another important finding is that vascular surgeons tended to more frequently use what appear to be effective processes of care such as eversion endarterectomy, shunts, and protamine than other surgeons, particularly neurosurgeons. Furthermore, the differences in risk-adjusted adverse outcome rates between vascular surgeons and other surgical specialties seem to be related in part, but not entirely, to the use of these processes of care. When the processes were controlled for, as well as patient severity of illness, the OR for adverse outcomes for vascular surgeons related to other surgeons increased by 39% from 0.36 to 0.50 and was no longer statistically significant (P=0.106). Similarly, the use of the processes of care was no longer associated with significantly lower adverse outcome rates when controlling for surgical specialty (OR=0.53, P=0.074). Several studies have investigated the impact of processes of care such as protamine,[21,26] patch grafts,[21,27–29] and anesthetic technique.[30,31] Also, there has been a limited number of studies of the impact of surgical specialty on outcomes for CE.[1,24,25] However, for the most part, studies of processes of care and surgical specialty were limited to a single institution and/or had relatively small samples, and they did not examine the simultaneous impact of processes and surgical specialty. To the best of our knowledge, this is the first study in which an interaction between specialty training and the use of specific techniques and therapy has been demonstrated in surgery.

Because there were large differences in the volume of cases per surgeon and because the appropriate unit of analysis is the surgeon rather than the patient, hierarchical (also called mixed or multilevel) models were used as an analysis strategy. It should be noted that the estimated surgical specialty effects and process effects are stronger when a logistic regression model is used instead of a hierarchical model in the modeling process. Although hierarchical models tend to protect against overvaluing the effect of a few high-volume providers, we further tested the sensitivity of our results by removing a very high-volume vascular surgeon from the analyses and by removing a neurosurgeon with a high adverse event rate from the analyses. In both cases, the results remained essentially the same.

There are a few caveats pertaining to the study. First, ≈10% of the cases that were reported in the state's administrative database for participating surgeons were not reported in the registry. We know from corresponding administrative data that none of these patients died, but some undoubtedly experienced strokes, and if they were disproportionally represented by specialty or processes of care, this could result in changes in the reported findings. Second, some studies note that there is a tendency for self-reporting of complication rates to result in underreporting.[32,33] If reporting of perioperative strokes occurred disproportionately by specialty or processes of care, the results of this study could be inaccurate. However, it should be noted that the ORs for specialty and processes of care did not change substantially when mortality was used as the sole adverse outcome, and we were able to confirm the accuracy of mortality using the state administrative database.

Third, the measurement of carotid stenosis differs as a function of the technique used. We found that only a relatively small percentage of patients (26%) received angiograms, so we used ultrasound as the measure of carotid stenosis for the 94% of all patients for whom ultrasound results were available. Stenosis was measured with magnetic resonance angiography (MRA) for the remaining 6% of patients (MRA was available for a total of 40% of all patients). Also, the correspondence between ultrasound and MRA was found to be very good (correlation=0.93) for the group of patients for whom both were used, so we were comfortable using MRA for a small percentage of patients. Nevertheless, the results could be biased if angiogram stenosis determinations were done and did not correlate well with the ultrasound/MRA results. However, a recent study by Eckstein et al[34] concluded that the ultrasound findings correlated well with angiography results.

Fourth, although the ratio of vascular surgeons to neurosurgeons performing CEs in the registry (5.4:1) was similar to that in the state performing CEs (3.5:1) and the ratio of their procedures performed was also similar (10.6:1 versus 9.9:1, respectively), general surgeons were very underrepresented in the registry relative to the state (13% of the surgeons in the registry and 62% in the state; 3% of patients in the registry and 28% in the state). Thus, it is conceivable that the outcomes reported in this study for general surgeons may not be representative of the state as a whole. However, the group of general surgeons in the registry has an mean volume of 13 CEs performed compared with a mean volume of 7 in the state for general surgeons, so it seems unlikely that the general surgeons not in the registry have better outcomes or use processes of care like eversion, protamine, and shunts more often than the general surgeons in the registry. Nevertheless, the relative outcomes associated with processes of care and surgical specialty that we found may not be representative of other regions or even of the state of New York because the study did not include all surgeons in the state.

Fifth, we were not able to judge the appropriateness of surgery because the data set did not enable us to further classify stenosis in the 30% to 70% range, which we now know is an important distinction.[1–3] This could have influenced the surgical specialty findings if vascular surgeons operated on patients who did not meet currently accepted indications for CE and the statistical model underpredicted adverse events for these patients. However, we think that this

is unlikely. For instance, when we restricted the data to symptomatic patients, the respective proportions of patients with ipsilateral stenosis with >70% stenosis were 88.5%, 89.4%, and 84.4% for vascular surgeons, neurosurgeons, and general surgeons, respectively ($P=0.45$).

It should be noted that neither hospital volume nor surgeon volume proved to be significantly related to adverse outcome after adjustment for differences in patient risk factors. However, the surgeons participating in this study tended to have much higher-than-average volumes compared with other surgeons performing CEs in the state. Furthermore, an earlier study of the volume-mortality relationship in New York reported that the major differences in mortality occurred between surgeons performing ≤5 procedures per year and surgeons performing >5 procedures per year.[12] We hypothesize that because the majority of surgeons performing ≤5 procedures per year did not participate in the study, the volume-mortality relationship demonstrated in the study mentioned above was not exhibited in this study.

We look forward to new studies that explore additional processes of care and that have access to even larger, more representative samples for exploring the relationship between surgeon specialty, processes of care, and adverse outcomes for CE. Studies of this nature that identify specific aspects of care associated with risk-adjusted outcomes have enormous potential for spawning successful quality improvement and quality assurance efforts.

Appendix

Definitions of Processes of Care for CE

Protamine

Protamine sulfate is a drug used in CE to reverse the coagulopathy induced by intraoperative heparin treatment.

Eversion Endarterectomy

This is a variation of the standard endarterectomy whereby the incision is simply a transection of the internal carotid artery at its origin rather than an incision beginning in the common carotid artery that extends to the internal carotid artery beyond the level of the lesion. In eversion endarterectomy, the internal carotid artery is inverted, and plaque is peeled from the arterial wall until it "feathers" at the distal end of the atherosclerotic plaque.

Intraoperative Shunting

A shunt tube is placed within the arterial lumen during the course of the endarterectomy. The proximal portion of the tube is placed in the common carotid artery, and the distal portion is placed in the internal carotid artery beyond the level of stenosis. The presence of the shunt allows oxygenated blood to continue to perfuse the brain during cross-clamping.

Heparin

Heparin is an anticoagulant used to prevent thrombus formation.

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