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Risk Factors for Death or Stroke After Carotid Endarterectomy: Observations From the Ontario Carotid Endarterectomy Registry

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Risk Factors for Death or Stroke After Carotid Endarterectomy

Observations From the Ontario Carotid Endarterectomy Registry

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Background and Purpose—Carotid endarterectomy is an effective method for preventing strokes if patients do not suffer adverse perioperative outcomes. The purpose of this study was to identify preoperative patient risk factors for adverse outcomes (death or nonfatal stroke) after carotid endarterectomy through the use of a large population-based registry from Ontario, Canada.

Methods—Medical records of all 6038 patients who underwent carotid endarterectomy in Ontario between January 1, 1994, and December 31, 1997, were abstracted from 34 hospitals. Patient characteristics (demographic data, past medical history, neurological symptoms, comorbidities, radiological findings) and 30-day postoperative death or stroke rates were analyzed with logistic regression analysis.

Results—The overall 30-day death or stroke rate after surgery was 6.0%. A history of transient ischemic attack or stroke (odds ratio [OR], 1.75; 95% confidence interval [CI], 1.39 to 2.20), atrial fibrillation (OR, 1.89; 95% CI, 1.29 to 2.76), contralateral carotid occlusion (OR, 1.72; 95% C.I., 1.25 to 2.38), congestive heart failure (OR, 1.80; 95% CI, 1.15 to 2.81), and diabetes (OR, 1.28; 95% CI, 1.01 to 1.63) were significant independent predictors for 30-day death or stroke. These 5 factors were combined into a simple risk score that can be used to stratify patients into different risk groups for complications after surgery.

Conclusions—Several patient characteristics predict the development of stroke and death after carotid endarterectomy. These characteristics may help clinicians in patient counseling and contribute to studies "benchmarking" the outcomes of carotid surgery in the community setting. **(*Stroke*. 2003;34:2568-2575.)**

Key Words: carotid endarterectomy ■ carotid stenosis ■ Ontario ■ risk factors ■ stroke

Since the publication of positive findings from several large randomized controlled clinical trials, including the North American Symptomatic Carotid Endarterectomy Trial (NASCET), European Carotid Surgery Trial (ECST), and Asymptomatic Carotid Atherosclerosis Study (ACAS), rates of carotid endarterectomy (CEA) have increased dramatically as a method for preventing stroke in patients with high-grade carotid artery stenosis.[1–6] However, the development of perioperative complications such as stroke or death is still a major concern because these complications may negate the benefits of the procedure. Identification of risk factors for adverse outcomes after carotid surgery is very important in surgical patient selection and patient counseling. Previous studies of surgical risk factors have a number of limitations, including relatively small sample sizes, use of univariate statistical methods, and enrollment of selected patient populations (eg, clinical trial patients), limiting the generalizability of the findings.[7–9] To overcome these limitations, we conducted a study to identify preoperative patient risk factors for the development of perioperative complications after carotid surgery using a large population-based multicenter registry from Ontario, Canada.

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Methods

Data Sources

The Ontario Carotid Endarterectomy Registry contains information collected on all CEAs performed in Ontario, Canada, between January 1, 1994, and December 31, 1997. It builds on a pilot study of 1280 patients having surgery at 8 hospitals in metropolitan Toronto.[10] The Canadian Institute for Health Information (CIHI) hospital discharge database was used to identify all CEAs performed between 1994 and 1997 in Ontario by searching for Canadian Classification of Procedures code 50.12.[11] A total of 34 hospitals and 102 surgeons performed carotid surgery in Ontario during the study period. The complete list of participating hospitals and surgeons is

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given in the Appendix. All the hospitals agreed to participate in a confidential audit of their surgical results.

Data Elements

A simple 1-page chart abstraction form was developed with Microsoft Access for Windows 95. The data abstracted included information on the timing of the index admission, patient demographics (eg, age and sex), neurological status before CEA, the degree of carotid stenosis, medical history and comorbidities, preoperative medications, surgery-related technical factors, and adverse outcomes within 30 days of surgery (eg, death, stroke, myocardial infarction). Most variable definitions were the same as those used in NASCET.[1,2] (Chart abstraction form and data dictionary are available from the authors on request.) Results of cerebral angiography were used to measure the degree of carotid stenosis, which was classified as mild (<50%), moderate (50% to 69%), severe (70% to 99%), or occlusion (100%). Angiographic results were available for 85% of the patients. Carotid Doppler results were used when angiography was not performed or the results were unavailable. Patients were considered symptomatic if they had a history of stroke, transient ischemic attack (TIA), or amaurosis fugax within 6 months of surgery. Comorbidities (eg, congestive heart failure [CHF], atrial fibrillation) were defined on the basis of a history of these conditions as documented in the preoperative notes. A postoperative stroke was defined as a persistent neurological deficit lasting >24 hours. All data were abstracted by 2 experienced neurological research nurses. When the abstractors were uncertain about the coding of certain variables, they were discussed with the physician-investigators or a consultant neurologist. A total of 6116 patient charts were abstracted. A few charts at some hospitals could not be abstracted because they could not be found or were being used for other purposes (eg, other studies). Seventy-eight cases with coronary artery bypass graft (CABG) procedures in the same hospital admission were excluded from this analysis.

Data Linkage

To enhance the utility of the data, data from the chart abstraction were linked together with administrative data from the CIHI hospital discharge administrative database. Recurrent stroke hospitalizations within 30 days of the initial surgery were identified from record linkage, with recurrent hospitalizations identified through the use of *International Classification of Diseases*, ninth revision (ICD-9), codes 431, 434, and 436. The accuracy of these ICD-9 codes in identifying stroke patients in the CIHI database has been established in previous studies.[12] Out-of-hospital deaths within 30 days of surgery were identified through the Ontario Registered Persons Database. Unique encrypted health card numbers were used to conduct the linkages across databases. These linkages enabled us to determine 30-day stroke or death rates for the entire cohort with complete follow-up.

Statistical Analysis

The associations between potential surgical risk factors and 30-day perioperative outcomes were assessed first by univariate methods and then by multivariate logistic regression methods. Variables were considered for inclusion in the multivariate models if they were significant at the $P<0.10$ level in the univariate analysis. Backward stepwise regression was used for model selection, with variables in the final model considered significant at $P<0.05$. The main outcome measure was the 30-day stroke and death rate, with 30-day death rates and 30-day nonfatal stroke rates considered secondary outcomes. Odds ratios and 95% confidence intervals (CIs) were calculated for each risk factor. A simple risk score for complications after surgery was developed by assigning a score of 1 point to each risk factor. Risk-adjusted 30-day stroke and death rates for each hospital in Ontario were determined by taking the observed complication rate and dividing it by the expected complication rate (based on the case mix of that hospital) and then multiplying it by the overall complication rate in the province. This can be interpreted as the complication rate that would be expected if each hospital in the province had the same case mix.[13] SAS statistical software version 8.2 was used for data analysis.[14]

Results

Overall, 6038 isolated CEA surgeries were performed in Ontario during the study period. The study cohort had an average age of 68.3 years (range, 32 to 94 years). Approximately two thirds of the patients were male. A review of the neurological history showed that 69.4% of the patients were symptomatic, with 15.8% having had amaurosis fugax or retinal infarct within 6 months of the operation and 53.6% having had a TIA or stroke. Most patients had moderate to severe ipsilateral carotid stenosis. Among the symptomatic patients, 87% had severe stenoses in the ipsilateral artery ≥70%, whereas 97% of the asymptomatic patients had stenoses ≥60%.

Table 1 presents patient characteristics and 30-day CEA outcomes (death, nonfatal stroke, combined death and stroke). The overall 30-day death rate was 1.6%; the nonfatal stroke rate was 4.5%; and the combined death or stroke rate was 6.0%. Age and sex were not significant predictors of the combined outcome of death and stroke. Symptomatic patients with a TIA or stroke before CEA had significantly higher rates of death or stroke (7.3%) than patients with amaurosis fugax or retinal infarct (3.9%) or those who were asymptomatic (4.7%) ($P<0.0001$). Several comorbidities were significantly related to the higher death or stroke rate in the univariate analysis. Higher rates of adverse outcomes were found in patients with a history of CHF, atrial fibrillation, and diabetes, whereas a lower adverse outcome rate was found in patients with previous CABG. In addition, patients with an occluded contralateral carotid artery or severe contralateral carotid stenosis had a higher death or stroke rate. Patients who had surgery on their left carotid artery had a higher rate of postoperative complications than those with right-side surgery (6.6% versus 5.3%, $P=0.0364$).

Multivariate logistic regression models for predicting 30-day death rates, nonfatal stroke rates, and death and stroke rates are shown in Table 2. A history of CHF was the only independent predictor of all 3 outcomes. Contralateral carotid artery occlusion and diabetes predicted both death and the combined outcome of death and stroke. A history of atrial fibrillation and a history of TIA or stroke predicted the development of perioperative strokes and stroke and death.

The risk factors for stroke and death were combined into a simple risk score as shown in Table 3. Table 4 demonstrates that higher risk scores were associated with higher rates of complications after carotid surgery, ranging from 3.3% in those patients with a risk score of 0 to 15.8% in patients with a risk score of 4. Thirty-day stroke and death rates were chosen as the main outcome of interest because death after surgery is relatively infrequent and the combined outcome is the one most relevant for benchmarking with clinical trial results.

Interhospital variations in 30-day risk-adjusted stroke or deaths rates are shown in the Figure. These rates were calculated with the logistic regression models that were developed. Overall, the vast majority of hospitals had mortality rates that were not statistically significantly different

TABLE 1. Patient Characteristics and Complications After CEA in Ontario, Canada

Patient Characteristics	n	%	Death Rate, %	Nonfatal Stroke Rate, %	Death or Stroke Rate, %	*P* (Combined Outcome)
Age, yr						
20–64	1801	29.8	1.1	4.1	5.2	0.1744
65–74	2782	46.1	1.6	4.7	6.2	
≥75	1455	24.1	2.2	4.6	6.7	
Sex						
M	3942	65.3	1.8	4.2	5.9	0.5933
F	2096	34.7	1.2	5.0	6.2	
Neurological symptoms						
Asymptomatic	1846	30.6	1.6	3.3	4.7	<0.0001
Amaurosis fugax or retinal infarct	957	15.8	0.8	3.0	3.9	
TIA or stroke	3235	53.6	1.7	5.7	7.3	
Medical history/comorbidities						
CAD	2156	35.7	1.9	4.2	5.9	0.9185
Previous CABG	740	12.3	0.7	3.2	3.9	0.0116
Previous PTCA	191	3.2	0.0	3.1	3.1	0.0928
CHF	208	3.4	3.9	9.1	12.0	0.0002
Atrial fibrillation	309	5.1	3.2	8.4	11.3	<0.0001
PVD	1639	27.1	2.4	4.6	6.8	0.1124
Dialysis	13	0.2	0.0	0.0	0.0	0.3627
Hypertension	3890	64.4	1.8	4.6	6.3	0.2372
COPD	897	14.9	2.5	4.8	7.3	0.0827
Diabetes	1393	23.1	2.6	5.0	7.4	0.0111
Smoking						
Never	1737	28.8	1.7	4.5	6.0	0.3029
Past	2575	42.6	1.6	4.9	6.4	
Present	1726	28.9	1.5	3.9	5.3	
Dementia	32	0.5	3.1	6.3	9.4	0.4165
Previous CEA	92	1.5	4.4	5.4	9.8	0.1210
Degree of carotid stenosis						
Ipsilateral						
Mild	94	1.6	1.1	5.3	6.4	0.5692
Moderate	572	9.5	1.1	4.9	5.9	
Occluded/severe	5152	85.3	1.5	4.4	5.9	
Unavailable	220	3.6	3.6	5.0	8.2	
Contralateral						
Mild/normal	3779	62.6	1.3	4.4	5.7	0.0165
Moderate	812	13.4	1.0	3.7	4.7	
Severe	775	12.8	1.8	5.3	7.0	
Occlude	533	8.8	3.4	5.8	8.8	
Unavailable	139	2.3	3.6	2.2	5.8	
Side of surgery						
Right	2946	48.8	1.4	3.9	5.3	0.0364
Left	3074	50.9	1.7	5.0	6.6	
Overall	6038	100.0	1.6	4.5	6.0	...

CAD denotes coronary artery disease; PTCA, percutaneous transluminal coronary angioplasty; PVD, peripheral vascular disease; and COPD, chronic obstructive pulmonary disease.

TABLE 2. Prognostic Models for 30-Day Perioperative Outcomes After CEA in Ontario

Outcome/Risk Factor	Coefficient	Odds Ratio (95% CI)	*P*
Death			
Intercept	−5.2209		
Age 65–74 y	0.3726	1.45 (0.84–2.51)	0.1816
Age ≥75 y	0.8255	2.28 (1.28–4.07)	0.0052
Diabetes	0.7570	2.13 (1.39–3.26)	0.0005
Contralateral carotid occlusion	0.8889	2.43 (1.43–4.13)	0.0010
PVD	0.5321	1.70 (1.12–2.59)	0.0132
COPD	0.5477	1.73 (1.06–2.82)	0.0282
CHF	0.6909	2.00 (0.94–4.22)	0.0707
Nonfatal stroke			
Intercept	−3.5004		
TIA or stroke	0.6116	1.84 (1.42–2.39)	<0.0001
Atrial fibrillation	0.6038	1.83 (1.18–2.83)	0.0065
CHF	0.6209	1.86 (1.12–3.08)	0.0157
Combined death or stroke			
Intercept	−3.2831		
TIA or stroke	0.5590	1.75 (1.39–2.20)	<0.0001
Atrial fibrillation	0.6350	1.89 (1.29–2.76)	0.0011
Contralateral carotid occlusion	0.5440	1.72 (1.25–2.38)	0.0010
CHF	0.5865	1.80 (1.15–2.81)	0.0102
Diabetes	0.2470	1.28 (1.01–1.63)	0.0435

PVD indicates peripheral vascular disease; COPD, chronic obstructive pulmonary disease. These prognostic models were developed through logistic regression analysis as described in the text.

from the provincial average of 6.0% or the benchmark 6.0% complication rate required for hospitals to be entered into NASCET.[1] However, 4 hospitals had average results that were significantly above the benchmark (ie, high outliers), whereas no hospital was significantly below the benchmark (ie, low outlier). The number of cases performed at several of the high outlier hospitals was relatively small, so some of these results could simply be the result of random variation. Overall, 83% of the Ontario patients in our cohort underwent surgery at institutions where the results were within an acceptable range (ie, not significantly >6.0%).

Discussion

In this study, we conducted a population-based review to identify risk factors for the development of perioperative stroke and/or death after CEA in Ontario during the mid-1990s. A history of TIA or stroke before surgery, CHF, atrial fibrillation, and contralateral carotid artery occlusion were identified as important risk factors for adverse outcomes after carotid surgery. These risk factors were combined into logistic regression models and a simple risk score that may be useful to clinicians who wish to counsel patients about the risks of surgery and benchmark their results against the outcomes from this population-based cohort from Ontario. Our study represents an important complement to other studies of risk factors for complications after surgery such as those reported using the NASCET and ECST clinical trial databases.[8,9] Awareness of the risk factors identified in our study may help clinicians in making decisions about the performance of the procedure and may facilitate quality improvement initiatives in carotid surgery.

TABLE 3. Risk Score for 30-Day Stroke and Death After Carotid Endarterectomy

Number of Points	Risk Factor
1	History of stroke or TIA within 6 months of surgery
1	Contralateral occlusion of the carotid artery
1	History of atrial fibrillation
1	History of CHF
1	History of diabetes

Total: 0 to 5. Add up the number of points to calculate the risk score.

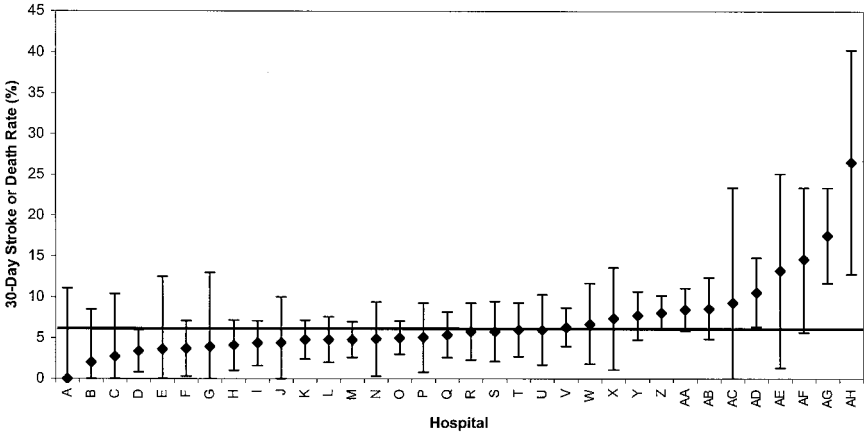
TABLE 4. Perioperative Stroke and Death Rates After Carotid Endarterectomy by Risk Score

Risk Score	No. of Cases	30-Day Stroke or Death	
		n	%
0	1847	60	3.3
1	2915	178	6.1
2	1084	103	9.5
3	173	17	9.8
4	19	3	15.8

The overall death or stroke rate (6.0%) suggests that the results of the large symptomatic carotid surgery trials are generalizable to Ontario, even though patients in Ontario are older and sicker than those enrolled in these trials. Of greater concern is the relatively high rate of stroke or death (4.7%) in asymptomatic patients and the large proportion of asymptomatic patients (30.6%) in this broad community-based series. The high rate of complications in this group suggests that many asymptomatic patients in Ontario may not be receiving benefits from the surgery found in ACAS, where the 30-day death and stroke rate was only 2.3%.[5]

Several risk factors identified in our study are consistent with recent multivariate analyses from the NASCET and ECST databases. Patients with a history of TIA or stroke before surgery had a higher risk of perioperative complications that those with amaurosis fugax in all 3 data sources, suggesting that this is a universal risk factor for surgery. Also consistent with the finding from NASCET was our finding that severe contralateral carotid stenosis was an adverse predictor of outcomes.[8] Patients with severe contralateral stenosis may not have sufficient collateral flow to withstand the stresses of surgery and may be more likely to have a perioperative stroke.

A history of atrial fibrillation and a history of CHF were identified as risk factors for stroke. Both are well-known risk factors for embolic stroke, and our findings are consistent with the observation that many perioperative strokes after endarterectomy are thromboembolic in nature.[8] However, these risk factors may not have been identified in the clinical trial databases because patients who were at high risk for cardioembolic stroke were excluded from NASCET.[1]



Thirty-day risk-adjusted stroke and death rates after CEA in Ontario by hospital, 1994 through 1997. Risk-adjusted point estimates are shown by diamonds; 95% CIs, by vertical bars; and provincial average (6.0%), by the horizontal bar.

Our data suggest that comorbidities such as heart failure and diabetes significantly increase the risks of endarterectomy and should be taken into consideration in making decisions about the performance of the procedure. Of particular concern are patients with risk scores of ≥ 2, who have a particularly high risk of perioperative complications. These patients probably should have operations performed only at centers with the best surgical results.

In contrast to the results from a recent systematic review of the CEA outcomes literature and results from ECST, we did not find that female sex, peripheral vascular disease, or systolic blood pressure >180 mm Hg was a significant predictor of the combined outcome of stroke and death.[7] The studies on which this review were based had smaller sample sizes than the present one, and differences in the patient enrolled in these various studies could account for the inconsistency in the results.

Many experts have called for independent audits of the outcomes of carotid surgery in the community setting to ensure that the results from the landmark clinical trials are translated into effective clinical practice.[15,16] Our study demonstrates the feasibility of conducting such a large population-based audit and suggests that most Ontario hospitals have excellent surgical results that are comparable to those found in the major clinical trials. However, several hospitals in Ontario clearly had suboptimal results that may require further quality improvement initiatives. A critical issue in any interhospital comparison is the need for statistical models to adjust for case-mix differences in patient severity across hospitals. We developed logistic regression models and a simpler integer-based risk score that can be used for such benchmarking purposes and to calculate risk-adjusted complication rates. Further testing of the utility of our models in other jurisdictions is required.

Our study has both strengths and important limitations. First, our data were collected retrospectively from patient charts, not gathered prospectively as in the large clinical trials. Data gathered from patient charts may be less accurate than those gathered prospectively, and important comorbidities may not be consistently documented, yet they are likely the only means by which clinicians in the field will be able to review the outcomes of surgery outside the trial setting. The consistency of many of our findings with those reported elsewhere supports the robustness and validity of the data. Second, the generalizability of our findings outside Ontario remains to be determined. However, we believe our data may represent one of the most accurate estimates of the risks of carotid surgery in a community setting because it was population based, used an independent audit mechanism, captured out-of-hospital events through record linkage, and had a much larger sample size than most other studies of risk factors for complications after carotid surgery. Third, we focused on patient risk factors in this study and did not evaluate whether surgeon characteristics (eg, volume, specialty) affected patient outcomes. Such studies are planned in the future.

In summary, the rate of complications after carotid surgery in Ontario appears to be comparable to those found in the large clinical trials of symptomatic carotid surgery but higher than those found in ACAS for asymptomatic patients. Risk factors that appear to be generalizable across trial and community settings include a history of TIA or stroke and contralateral carotid stenosis. A history of CHF and atrial fibrillation also increases the risks of surgery, but many of these patients were likely excluded from the clinical trials. Our study represents an important step toward quantifying the risks of CEA in the community setting.

Appendix

Participating Hospitals and Surgeons in the Ontario Carotid Endarterectomy Registry

Brampton: K. Louis. Chedoke McMaster Hamilton: A. Ashe, C. Cina, G. Evans. Hamilton Civic & General: A. Ashe, C. Cina, B. Doobay, G. Evans, A. Parisi, K. Reddy, J.G. Tittley, R.A. De Villiers, J.D. Wells. Hotel Dieu Grace, Windsor: R.R. Anderson, C.B. Agbi, S. Chakravarthi, C.M. Iannicello, A.G. North, C.R. Pearce, M. Ristic. Humber Regional: C. Cina, H. Nasser. Kingston General: P.M. Brown, P. Ellis, F. Saunders, D. Zelt. Mount Sinai: M.R. Goldberg. North Bay: R.C. Moffat. North York Branson: I. Forrest. Ottawa Civic: C.B. Agbi, B.G. Benoit, C.W. Cole, V.F. Da Silva, G. Hajjar, H. Hugenholtz, H.J. Lesiuk, N.V. McPhail, D.J. Morassutti. Ottawa General: C.B. Agbi, T. Brandys, C.W. Cole, J. Dennery, A. Hill, H. Hugenholtz, M.T. Richard, J. Wellington. Peterborough Civic: A.A. Thompson, R.T. Sivan. Port Arthur: A. Kirk, J.T. Gooding. Royal Victoria: B.S. McDonald. Scarborough General: R.A. Huhlewych, M.G. O'Dwyer, N.V. Perera. St Catharine's: S. Rammohan. St Joseph's Hamilton: J.F. Mosakoski, A. Parisi, K. Reddy. St Joseph's London: S.E. Carroll, J.P. Sweeney. St Joseph's Sudbury: A. Adegbite, F. Ogundimu. St Joseph's Toronto:

D. Szalay, D. Wooster. St Michael's: F. Ameli, M. Cusimano, A. Lossing, R.J. Moulton, P.J. Muller, R. Perrin, W.S. Tucker. Sudbury Memorial: S. Aul, J.A. Fenton, P. Field, A. Garg, E. Knight, A.N. Mathur. Sunnybrook & Women's College Health Sciences Centre: M. Fazl, D.S. Kucey, A. Lossing, R. Maggisano, R. Midha, D.W. Rowed, M. Schwartz. Thunder Bay: A. Chaudhuri. Timmins: A.G. De la Rocha. Toronto East General: V. Campbell, W.R. Tanner. Trillium Health Centre, Mississauga: E.G. Duncan, D. Izukawa, H. Schutz, R.G. Vanderlinden. University Health Network, Toronto General Division: H. Basian, K.W. Johnston, P. Kalman, T.F. Lindsay, B. Rubin, P. Walker. University Health Network, Toronto Western Hospital: H. Basian, J. Fleming, F. Gentili, M. Tymianski, P. Walker, C. Wallace. University Hospital, London: H.W. Barr, G. Ferguson, S. Lownie, A. Parrent, H. Reichman, R. Sahjpaul. Victoria Hospital, London: H.W. Barr, G. DeRose, K.A. Harris, W.G. Jamieson. Wellesley Hospital: F. Ameli, A. Lossing, R.G. Perrin, H. Smyth. Windsor Western/Regional: M. Ristic. York County: D. Gupta.

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Editorial Comment

Identifying Risk Factors for Perioperative Outcomes After Carotid Endarterectomy: The Story Continues

Given that the perioperative stroke and death rate associated with carotid endarterectomy (CEA) ranges from 2% to 8%,[1–5] identification of subgroups of patients with differential risk is critically important. Given this relatively high average rate, an absolute difference of 2% to 4% in the perioperative risk of CEA could easily occur and may be sufficient to change the positive overall efficacy of CEA to negative. The growing literature[5–11] suggests that substantial differences by patient characteristics exist in perioperative risk associated with CEA.

The study by Tu and colleagues[11] is an important contribution to our understanding of the perioperative risk associated with CEA, reporting risk factors for 30-day stroke and death associated with CEA performed in Ontario, Canada, from 1994 through 1997. This report is unique for several reasons. The first has to do with statistical power. The proportion of patients suffering events is relatively low, so a very large sample size is required for there to be a sufficient number of patients with "events" to permit appropriate statistical analyses to identify risk factors with reasonable precision. With a sample size of >6000 procedures and 361 "events," the present study is among the largest studies to date, therefore providing the most precise estimates of the impact of risk factors on perioperative stroke and death. Second, although the study was retrospective, a major focus of effort was the standardization of procedures for chart abstraction and assessment of risk factors; thus, this data collec-

tion effort was likely more robust than many surgeon- or institution-specific retrospective chart reviews. Indeed, many of the definitions were the same as those used in North American Symptomatic Carotid Endarterectomy Trial (NASCET), so there was more standardization than in most other published CEA series. Finally, the linkage through the Canadian Institute for Health Information system and the Ontario Registered Persons Database makes it unlikely that major stroke events during the 30-day follow-up period went undetected. This feature is particularly important because in many locations privacy regulations restrict the ability to conduct record linkage to evaluate nonfatal outcomes in retrospectively identified cohorts without consent.

These results are presented in a format that can be used easily by practicing clinicians. A simple score, calculated by adding the number of risk factors present (history of stroke or transient ischemic attack, presence of contralateral occlusion, history of atrial fibrillation, history of congestive heart failure, and history of diabetes), was shown to be associated with the differential risk from a rate of 3.3% for those with no risk factors to a rate of 9.5% and higher for those with ≥2 risk factors. This simple "checklist" can be applied quickly in the counseling of patients.

Rothwell et al[6] conducted a systematic review of CEA studies published from 1981 to 1996 that reported perioperative risk data by ≥1 clinical or angiographic characteristics. This effort carefully reviewed the literature to select only studies meeting strict criteria; of 126 studies reviewed, only 35 met the criteria. The selected studies included a variety of study designs ranging from retrospective case series to prospective randomized clinical trials. Although overall a high-quality systematic review according to the Oxman and Guyatt[12] index, the review of potential studies was likely problematic because of a lack of standardization in the definition of many variables of interest. Rothwell et al found cerebral versus ocular transient ischemic attack, age >75 years, systolic hypertension, female sex, and peripheral vascular disease to be significant independent predictors of perioperative stroke and death.[6] It is notable that these risk factors differ substantially from those identified in the present study, in which differences in risk were found by symptomatic status, atrial fibrillation, contralateral carotid occlusion, congestive heart failure, and diabetes.[11] The differences between these 2 reports could arise from differences in populations or methods, publication bias, or chance, all of which underscore the importance of more work in this area.

Although the present report has many strengths, limitations exist. The registry was not designed to tell us about the perioperative stroke and death risk of the patients who were screened but did not have CEA. There can be differential use of the procedure in patients with and without the risk factor. Selection bias is one of the most important sources of bias in observational studies. It is difficult to control for confounding by indication in these types of studies, so variables (such as history of diabetes) that are associated with the use (or nonuse) of CEA can influence the outcome measures. This type of bias can affect the estimates of the 30-day stroke and death rate and the direction of the effect.

In interpreting these results, we should also remember that this report focuses on the increased risk associated with CEA and does not address the equally likely differences between subgroups of patients in the benefit of the procedure during the subsequent postoperative period. An equal effort could be directed at determining those patients who, without CEA, would be at higher-than-average risk of subsequent stroke and whose stroke risk could be substantially reduced by the surgery. For example, patients with a contralateral carotid occlusion were found to be at greater perioperative risk of stroke and death; however, this may be a subgroup for which the successful completion of the procedure that maintains patent flow through a single remaining carotid artery warrants the increased risk through potentially greater reduction of events over the subsequent follow-up period. Conversely, age and degree of carotid stenosis were not identified as major predictors of perioperative events. However, that the surgery can be performed safely in young patients with a low level of carotid stenosis may not be warranted given the low likelihood of subsequent events during the follow-up. Thus, the counseling of patients should focus on both the risk of the procedure that was described by Tu et al[11] and the likely benefit of the procedure. This difference in both risk and benefit is best described by randomized clinical trials and underscores why information arising from registry efforts should be interpreted with caution.

This report by Tu and colleagues[11] clearly and precisely describes the risks associated with the conduct of endarterectomy. In the ever-growing CEA literature describing the differential risk of subpopulations, the report is exceptional and can serve as the basis for the counseling of patients before the procedure. Differences in perioperative risk faced by specific patients are important components in the decision as to whether to proceed with CEA.

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