Predictors of Stroke Complicating Carotid Artery Stenting

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Background—The evolving technique of carotid stenting is being evaluated as an alternative to endarterectomy. Identification of the factors that predispose a patient to neurological complications would facilitate further refinement of the technique and optimize patient selection.

Methods and Results—We analyzed the impact of various clinical, morphological, and procedural determinants on the development of procedural strokes in 231 patients who underwent elective (primary) stenting of 271 extracranial carotid arteries. The mean age of the patients was 68.7±10 years, 165 (71%) were males, and 139 (60%) had symptoms attributed to the lesion treated. This series represented a high-risk subset with 164 patients (71%) having significant coronary artery disease, 91 (39%) having bilateral disease, and 28 (12%) having contralateral carotid occlusion. Of the treated vessels, 59 (22%) had prior carotid endarterectomy, 66 (24%) had ulcerated plaques, and 87 (32%) had calcified lesions. Only 37 treated vessels (14%) would have been eligible for inclusion in the North American Symptomatic Carotid Endarterectomy Trial (NASCET). There were 17 (6.2%) minor and 2 (0.7%) major strokes during and within 30 days of the procedure. NASCET-eligible patients had a low (2.7%) risk of procedural strokes after carotid stenting. The results of multivariate analysis revealed advanced age ($P=.006$) and presence of long or multiple stenoses ($P=.006$) as independent predictors of procedural strokes.

Conclusions—During this procedural developmental phase of carotid stenting, neurological complications were highly dependent on patient selection. Advanced age and long or multiple stenoses were independent predictors of procedural stroke. **(*Circulation*. 1998;97:1239-1245.)**

Key Words: stroke ■ carotid arteries ■ stents

There are nearly 500 000 strokes and 150 000 deaths due to cerebrovascular disease each year in the United States. There is sufficient evidence of the benefit of relieving high-grade symptomatic and asymptomatic carotid artery atherosclerotic obstruction by surgical endarterectomy.[1–5] The North American Symptomatic Carotid Endarterectomy Trial (NASCET) demonstrated the superiority of endarterectomy over medical management of symptomatic carotid artery plaques causing stenoses of ≥70%.[1] The Asymptomatic Carotid Atherosclerosis Study (ACAS) showed that endarterectomy in patients with asymptomatic carotid artery stenosis of ≥60% was statistically superior to conservative management in the prevention of stroke.[2] Carotid angioplasty and stenting are also being investigated as an alternative treatment for extracranial carotid artery disease.[6–10] The feasibility and relative safety of percutaneous transfemoral extracranial carotid stenting has been reported recently in a high-risk group of patients.[11]

The risk of neurological complications related to surgical and nonsurgical cerebral revascularization procedures concerns both surgeons and vascular interventionists. The risk of procedural stroke or death with surgery was 5.8% in NASCET and 2.3% in ACAS. However, in high-risk patients undergoing endarterectomy, morbidity and mortality rates as high as 18% have been reported.[12,13] Ongoing refinements in the technique of carotid stenting are aimed at reducing the incidence of neurological complications. The clinical and anatomic heterogeneity of patients with carotid disease might expectedly lead to differences in outcomes with this procedure. The present report describes the impact of various clinical, morphological, and procedural substrates on the development of short-term complications of carotid stenting. This will help standardize the characterization of patients considered for this procedure and formulate strategies to reduce these complications.

Methods

Patient Population

Two hundred thirty-one consecutive patients referred for elective stenting of extracranial carotid arteries at the University of Alabama at Birmingham Hospital between September 1994 and January 1997 constituted the study population. Symptomatic and asymptomatic patients with ≥60% stenosis in the extracranial carotid arteries were included in a protocol approved by the Institutional Review Board. For patient screening and enrollment purposes, stenoses were mea-

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sured manually with calipers from radiographic films recorded during previous diagnostic cerebral angiography.

Patients were excluded from the study in case of (1) presence of an intracranial tumor or arteriovenous malformation, (2) presence of intracranial stenosis that exceeded the severity of extracranial stenosis, (3) presence of peripheral vascular disease sufficiently severe to prevent adequate vascular access, (4) presence of severe disability due to previous stroke or dementia, or (5) inability to give informed consent.

Carotid Stenting Protocol

All patients took aspirin 325 mg/d beginning at least 2 days before the procedure and ticlopidine 250 mg twice daily starting a day before the procedure. Heparin, given as an intra-arterial bolus, was titrated to maintain the activated clotting time between 200 and 250 seconds. Neurological status was monitored constantly during the procedure. Femoral venous access was gained in patients, and a transvenous pacemaker was immediately available. Atropine 1 mg was given as required during balloon inflation. Blood pressure was monitored throughout the procedure and was modulated by administration of intravenous metaraminol or nitroglycerin as required.

Carotid stenting was performed by use of coaxial catheterization techniques adopted from coronary and other endovascular interventions. Percutaneous access was gained through the femoral artery. Appropriately sized guiding catheters or sheaths were placed in the carotid artery just proximal to the segment to be treated. Angulated angiographic views were recorded to fully display the stenosis. On-line quantitative coronary angiography was performed to measure the vessel diameter to facilitate sizing of balloons and stents. Stenoses were crossed with flexible coronary guidewires, which were replaced with extra-support, coronary-type guidewires before balloon dilation of the lesions. Peripheral balloons were used for predilation until January 1995, after which coronary balloons of lower profile were used.

In the 231 patients, a total of 363 stents were implanted. Of these, 166 (46%) were Palmaz medium biliary (Johnson & Johnson Interventional Systems Co), 38 (10%) were Gianturco-Roubin Flexstents (Cook Inc), and 159 (44%) were Wallstents (Schneider). The Palmaz medium biliary stents were deployed over noncompliant balloons that were sized to give a balloon-to-artery ratio of 1.1:1. Wallstents were usually sized to the diameter of the common carotid artery. High-pressure (10 to 16 atm) balloon inflations were routinely performed within the stents after placement.

Vascular sheaths were removed the same day, and patients were discharged and instructed to take aspirin 325 mg BID and ticlopidine 250 mg BID for 3 weeks. Aspirin 325 mg/d was continued indefinitely.

Clinical and Imaging Protocol

A complete neurological evaluation was performed on all patients by an experienced neurologist, and the National Institutes of Health (NIH) Stroke Scale was recorded before the procedure and at 24 hours, 4 weeks, and 6 months after the procedure.[14] MRI or computed tomography of the head was performed before the procedure and repeated if the patient had neurological complications. Quantitative coronary angiography was performed on all vessels before angioplasty, after stenting, and at 6-month follow-up by use of an on-line system (Integris-Phillips Medical Systems). Diameter stenosis was determined by use of the NASCET criteria, with the distal nontapering portion of the internal carotid artery serving as the reference segment.[1] Minimum lumen diameter was measured after calibration of the system with the known diameter of the guiding catheter.

Definitions

Significant neurological complications were defined as follows:

Category 1 minor stroke—a new neurological deficit that changed the NIH stroke scale by 1 point and persisted for >24 hours but completely resolved or returned to baseline within 1 week.

Category 2 minor stroke—a new neurological deficit that either resolved completely or returned to baseline within 30 days or that changed the NIH stroke scale by 2 or 3 points. By definition, both categories of minor strokes are nondisabling neurological events.

Major stroke—a new neurological deficit that persisted after 30 days and that changed the NIH stroke scale by ≥4 points. The definitions of minor and major stroke have been adopted from those previously used at our center.[11]

Eccentric lesion—angiographic appearance of the stenotic lumen in the outer one-quarter diameter of the apparent normal lumen.[15]

Bifurcation lesion—the external carotid artery originated within the stenosis and was completely surrounded by significant stenotic portions of the lesion to be dilated.

Lesion calcification—radiological densities readily seen within the apparent vascular wall of the artery at the site of the stenosis.[15]

Residual irregularity—vascular margin after stent deployment was rough or had a saw-toothed appearance.[15]

Ulcerated lesion—plaque was classified as ulcerated if it fulfilled radiographic criteria of ulcer niche, seen in profile as a crater from the lumen into a stenotic plaque and (when visible) a double density on face view.[16]

Long/multiple lesions—lesion length (measured with calipers as distance from proximal to distal shoulder of lesion in a projection that best elongates the stenosis) >10 mm and/or presence of >1 lesion separated by normal vessel wall.[10]

Bilateral carotid disease—presence of ≥60% diameter narrowing in internal and/or common carotid arteries on both sides or presence of ≥60% diameter narrowing in left internal and/or common carotid artery with ≥60% diameter narrowing of the innominate artery.

Combined procedure—performance of carotid artery stenting and coronary angioplasty during the same procedure.

Bilateral simultaneous stenting performance of carotid stenting on both right and left arteries during the same procedure.

Data Collection

All baseline clinical and stenting data and angiographic measurements were prospectively recorded on standard forms. Clinical and laboratory details were continuously recorded during the hospitalization. Primary clinical end points analyzed in this study were minor or major strokes and death within 30 days of the procedure. The clinical end points were critically reviewed by the surgical members at this institution. Morphological data were recorded retrospectively by reviewing the angiographic films. The clinical and demographic variables analyzed were age, sex, presence of symptoms in the last 120 days, presence of coronary artery disease, diabetes mellitus, hypertension, hypercholesterolemia, current smoking habit, bilateral carotid disease, prior endarterectomy on same side, and contralateral occlusion. The morphological variables considered were site (right or left carotid arteries), lesion location at bifurcation, lesion length and presence of multiple stenoses, eccentricity, calcification, plaque ulceration, lesion severity, residual stenosis, and residual irregularity. The procedural variables considered were the use of noncoronary balloons for predilating lesions and the performance of combined or simultaneous procedures.

Statistical Analysis

All values are expressed as mean±SD. Univariate analysis was performed on all clinical, morphological, and procedural variables with χ^2 test used for categorical variables and Student's t test for continuous variables. The χ^2 test for linear trend was used to analyze the trend of event occurrence for different groups of age and lesion severity. A value of $P<.05$ was considered to be statistically significant. Multivariate analysis was performed with the use of multiple logistic regression analysis to determine the independent correlates of postprocedural neurological events. Age and lesion severity were considered as continuous variables for multivariate analysis. We designed the study model by selecting variables considered likely to influence neurological complications on the basis of our experience over the past 3 years. The logistic model was tested for goodness of fit using the −2 log-likelihood statistic, which was significant with a value of $P=.0003$.

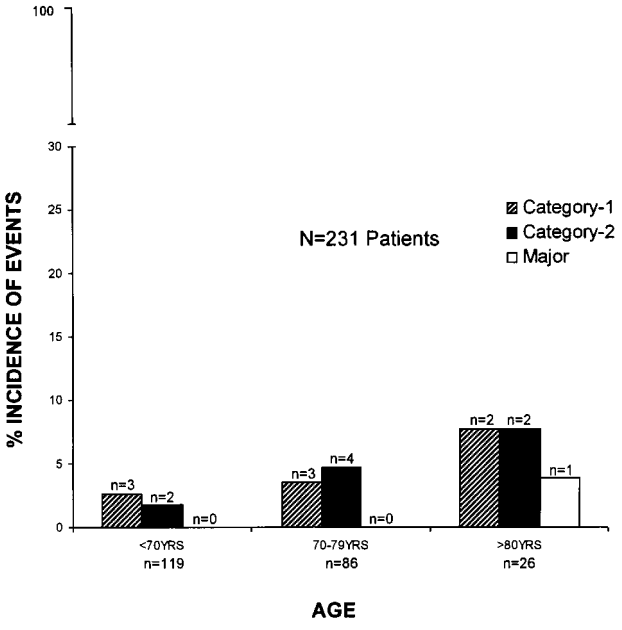

Figure 1. Incidence of minor (category 1 and category 2) and major strokes in relation to age in 231 patients.

Results

Demographic, Clinical, and Morphological Characteristics

In the 231 patients, a total of 271 vessels were treated during 259 procedures. The demographic, clinical, and morphological characteristics of the patients are shown in Tables 1, 2, and 3. The mean age of the patients was 68.7±10 years. One hundred nineteen patients (52%) were younger than 70, 86 (37%) were between 70 and 79, and 26 (11%) were older than 79 years of age. Significant coronary artery disease was present in 164 patients (71%). Significant disease in both carotid arteries was present in 91 patients (39%), and contralateral carotid artery occlusion was present in 28 (12%).

Prior carotid endarterectomy of the stented carotid artery had been performed in 59 patients (22%). Lesion severity of ≥90% was present in 47 vessels (17%), and long or multiple lesions were present in 88 (33%). Ulcerated lesions were present in 66 vessels (24%), and calcified lesions were present in 87 (32%). A bilateral carotid procedure was undertaken in 19 patients (8%), whereas combined carotid and coronary procedures were performed in 32 (14%).

Of the 139 patients (60%) with symptomatic carotid stenosis in this series who met the angiographic criteria, only 37 would have been eligible for inclusion in NASCET. The reasons for NASCET exclusion were as follows: age older than 79 years (30 patients); severe comorbidity, ie, severe coronary artery, pulmonary, or renal disease or any cancer that would limit survival to <5 years (97 patients); substrate for cardiogenic embolism (14 patients); and prior ipsilateral endarterectomy (59 patients).

Procedural Outcomes

A total of 19 significant neurological events (7%) were noted after stenting of 271 carotid arteries. These included 8 category 1 minor strokes (2.9%) , 9 category 2 minor strokes (3.3%), and 2 major strokes (0.7%). None of the patients developed a Q-wave myocardial infarction within 30 days of the procedure. There was 1 in-hospital death resulting from retroperitoneal bleeding and a second sudden cardiac death that occurred 4 days after discharge.

Two neurological events with known etiology, which were not directly related to the defined clinical or morphological variables being evaluated, were excluded from our univariate and multivariate analysis of stroke predictors. These events, however, were included in the overall computation of significant procedural neurological complications. One of these was a minor stroke from air embolism that occurred during angiography, and the second was a major nonprocedural stroke due to a cardiogenic embolus to the contralateral middle cerebral artery. Thus, of the 19 total neurological events, 17 were entered into the univariate and multivariate analysis.

Predictors of Neurological Events

On univariate analysis, increased age was associated with the risk of procedural strokes (Fig 1). Patients younger than 70 had a 2.6%, 1.7%, and 0% incidence of category 1 minor strokes, category 2 minor strokes, and major strokes, respectively. Patients aged 70 to 79 years had a 3.5%, 4.7%, and 0% incidence of these events, and patients ≥80 years had a 7.7%, 7.7%, and 3.8% incidence of these events ($P<.001$). Sex, presence or absence of neurological symptoms, and presence of coronary artery disease, diabetes mellitus, hypercholesterolemia, or smoking did not show a significant association with procedural neurological events (Table 1). Prior endarterectomy, presence of bilateral carotid lesions, or contralateral carotid occlusion also did not significantly influence the incidence of neurological complications.

Lesion severity was also associated with the risk of stroke (Fig 2). Lesions with <70% diameter narrowing had a 1.2%, 2.4%, and 0% incidence of category 1 minor strokes, category 2 minor strokes, and major strokes, respectively. Lesions with 70% to 89% diameter narrowing had a 2.9%, 1.5%, and 0.7% incidence of these events, whereas lesions ≥90% diameter narrowing had a 6.4%, 8.5%, and 0% incidence of these events ($P=.007$). Long and/or multiple lesions were associated with increased risk of stroke. Single discrete lesions had a 2.2%, 1.6%, and 0% incidence of category 1 minor strokes, category 2 minor strokes, and major strokes, respectively, whereas long and/or multiple lesions had a 4.6%, 5.7%, and 1.1% incidence of these events ($P=.012$). Lesions at the common carotid bifurcation, ulcerated lesions, and residual irregularity after carotid stenting did not have any significant association with procedural neurological events (Table 2). The type of stents used, performance of bilateral carotid stenting during the same procedure, or performance of combined carotid stenting and coronary angioplasty during the same procedure also did not have a significant association with procedural strokes (Table 3).

On multivariate analysis, the odds ratios for increasing age and long and/or multiple lesions were significant at the .05 level at 80% power. The odds ratio for lesion severity did not reach significance at the .05 level, suggesting that its significance by univariate analysis was an artifact of arbitrary

TABLE 1. Correlation of Demographics and Clinical Characteristics With Postprocedural Events

	Patients, n (%)	Minor Strokes, n (%)		Major Strokes, n (%)	Total Events, n (%)	*P*
		Category 1	Category 2			
n	231	8 (3.5)	8 (3.5)	1 (0.4)	17 (7.4)	
Age, y						
<70	119 (51.5)	3 (2.6)	2 (1.7)	0	5 (4.2)	
70–79	86 (37.2)	3 (3.5)	4 (4.7)	0	7 (8.1)	.001*
≥80	26 (11.3)	2 (7.7)	2 (7.7)	1 (3.8)	5 (19.2)	
Sex						
Male	165 (71.4)	7 (4.2)	6 (3.6)	0	13 (7.9)	.842
Female	66 (28.6)	1 (1.5)	2 (3.0)	1 (1.5)	4 (6.1)	
Symptomatic						
Yes	139 (60.2)	5 (3.6)	4 (2.9)	1 (0.7)	10 (7.2)	.883
No	92 (39.8)	5 (5.4)	2 (2.2)	0	7 (7.6)	
Coronary disease						
Yes	164 (70.9)	6 (3.7)	7 (4.3)	0	13 (7.9)	.811
No	67 (29.0)	2 (2.9)	1 (1.5)	1 (1.5)	4 (5.9)	
Hypertension						
Yes	179 (77.5)	8 (4.5)	6 (3.4)	0	14 (7.8)	.423
No	52 (22.5)	0	2 (3.9)	1 (1.9)	3 (5.8)	
Smoking						
Yes	145 (62.8)	6 (4.1)	7 (4.8)	0	13 (8.9)	.340
No	86 (37.2)	2 (2.3)	1 (1.2)	1 (1.2)	4 (4.7)	
Bilateral disease						
Yes	91 (39.4)	5 (5.5)	1 (1.1)	0	6 (6.6)	.352
No	140 (60.6)	3 (2.1)	7 (5.0)	1 (0.7)	11 (7.9)	
Contralateral occlusion						
Yes	28 (12.1)	1 (3.6)	0	0	1 (3.6)	.860
No	203 (87.9)	7 (3.5)	8 (3.9)	1 (0.5)	16 (7.9)	

*χ^2 test for linear trend.

division into the groups and the small number of neurological events (Table 4).

Discussion

The rapidly evolving technique of carotid stenting is currently undergoing investigation in a number of centers as an alternative to surgical endarterectomy. This study is the first to critically analyze the neurological complications of carotid artery stenting and examine their clinical, morphological, and procedural descriptors. Our findings suggest that advanced age, presence of long or multiple lesions, and severe stenosis are significant predictors of procedural strokes after carotid stenting.

It has been suggested[17–19] that if the neurological complications and mortality are higher than that observed in the recent carotid endarterectomy trials (4% to 8%), the overall benefit of the procedure would be eliminated. When the safety of carotid stenting is evaluated, it is important to note that our patient population has more significant comorbidity than that included in the recent randomized endarterectomy trials. In addition to patients aged 80 years and older, the present series included patients with previous carotid endarterectomy, contralateral carotid occlusion, and severe cardiopulmonary disease, all characteristics that constitute increased risk for endarterectomy. Despite the unfavorable risk profile, the overall incidence of procedural stroke and death in the present study was 7.7% of the treated vessels, whereas in the subpopulation of NASCET-eligible patients (ie, low-risk subgroup) the risk of any stroke or death was only 2.7%. This compares well with endarterectomy, keeping in mind that the prospective critical scrutiny of a new technique is likely to detect more adverse events.

The description of the neurological end points used in recent carotid endarterectomy trials has not been uniform. In the MRC European carotid surgery trial,[3] the primary end points were fatal or disabling strokes and surgical death, and the secondary end points included nondisabling strokes lasting >7 days. In the ACAS[2] and NASCET[5] studies, any new focal neurological deficit lasting >24 hours and occurring anytime within 30 days after randomization for surgery was called perioperative stroke. Major stroke in ACAS[2] was defined as one resulting in moderate or severe disability, persistent vegetative state, or death, and this included categories 2 to 5 of the Glasgow Outcome Scale.

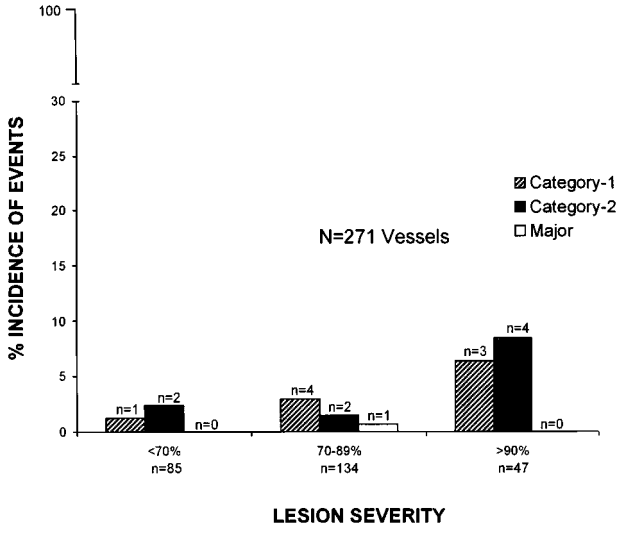

Figure 2. Incidence of minor (category 1 and category 2) and major strokes in relation to lesion severity in 271 vessels.

It is important that a realistic and comprehensive classification of the neurological complications be used when a newly evolving technique such as carotid stenting is evaluated. The temporal sequence of ischemic brain damage may be regarded as a physiological continuum. The duration and severity of hypoperfusion dictate the amount of tissue injury that follows arterial occlusion. Stable neurological signs lasting beyond 24 hours represent some degree of permanent tissue injury and have been recognized as completed brain infarcts that are often too small to be detected by imaging studies. The definition of minor and major strokes used in the present study incorporates both the extent of neurological deficit and the degree of functional disability produced. Minor strokes are essentially nondisabling and in this study have been further categorized to draw attention to those minimal neurological deficits that are only detected by detailed neurological examination, often not noted by the patient, and that resolve within a week. In the present study, major disabling strokes were uncommon (0.7%). Minor nondisabling strokes occurred in 6.3% of vessels treated, and half of these represented rapidly resolving category 1 minimal neurological deficits that were probably due to small amounts of embolic debris. Comparison with similar events after endarterectomy must await the results of prospective randomized trials.

The importance of independent neurological oversight when the incidence of neurological complications is assessed cannot be overemphasized. In a recent comprehensive review, Rothwell et al[20] documented the increased incidence of neurological complications of carotid endarterectomy when a neurologist was a coauthor of the report. On average, the mean risk of a stroke and death in this meta-analysis was 5.6%, but it was only 2.3% in studies with a single author affiliated with the department of surgery, whereas it was 7.7% in studies in which patients were assessed by a neurologist after surgery. Each patient in the present study was closely evaluated by a neurologist at frequent intervals for recording and classifying of neurological complications, and the clinical end points were critically reviewed by members of the surgical team at the institution.

Recently, McCrory et al[21] retrospectively analyzed clinical data of 1160 patients who underwent carotid endarterectomy and correlated it with occurrence of postoperative adverse events, ie, nonfatal strokes, myocardial infarction, and death. Significant predictors of adverse events in that study were age ≥75 years, presence of ipsilateral hemispheric neurological instability, severe hypertension, endarterectomy performed in preparation of bypass surgery, evidence of internal carotid artery thrombus, and internal carotid artery stenosis near the carotid siphon. The presence of two or more factors was associated with a twofold increase in risk of an adverse event. Similarly, in the present study we correlated various clinical, morphological, and procedural factors with neurological adverse events.

Advanced age is the most important predictor of procedural neurological events in the present study. The overall incidence of strokes in patients <80 years of age after carotid stenting was only 5.6% versus 19.2% in patients ≥80 years old. Results of medical management in patients >80 years old with significant carotid disease are not known. Most randomized surgical endarterectomy trials have excluded such patients.[21,22] A few surgical series that have included elderly patients have not commented specifically on this subgroup.[23,24] The appropriateness of carotid stenting in patients aged >80 years needs to be addressed in a larger randomized cohort of patients.

We observed that increasing lesion severity, especially >90% diameter stenosis, and long or multiple lesions were associated with increased incidence of neurological complications. This significance for lesion severity, however, could not be reproduced by multivariate analysis. It is not known whether surgical risk also increases with lesion length. Long or multiple lesions have a larger atherosclerotic plaque burden and carry a risk of dislodging embolic particles during balloon dilation and stenting. If these findings can be reproduced in additional studies, they may have implications in terms of patient selection and evolution of the technique. The availability of low-profile embolic capture devices for use in carotid interventions may have particular application in these patient subsets to further reduce complications.

In contrast, the present study has demonstrated a relatively low incidence of complications in patients with prior endarterectomy of the treated site, those with contralateral carotid occlusions, and those undergoing combined carotid and coronary interventions. These subsets have been shown to have a high incidence (11%, 14%, and 24%, respectively) of complications when they undergo carotid endarterectomy.[21,24,25] Ulcerated carotid lesions represent a poor prognosis for the development of neurological complications with medical management alone. In NASCET, it was observed that the risk of ipsilateral stroke within 24 months in medically treated patients with ulcerated plaques increased incrementally (from 26% to 73%) as the degree of stenosis increased (from 75% to 95%). For patients without ulcers, the risk of stroke remained constant at 21% for all degree of stenosis.[16] Endarterectomy in patients with ulcerated plaques also involves a higher risk of neurological complications.[5] In contrast, patients with ulcerated lesions who underwent stenting in the present study had a low incidence of procedural strokes.

TABLE 2. Correlation of Morphological Features With Postprocedural Events

	Vessels, n (%)	Minor Strokes, n (%)		Major Strokes, n (%)	Total Events, n (%)	*P*
		Category 1	Category 2			
n	271	8 (2.9)	8 (2.9)	1 (0.4)	17 (6.3)	
Post CEA						
Yes	59 (21.8)	2 (3.4)	1 (1.7)	0	3 (5.1)	.890
No	212 (78.2)	6 (2.8)	7 (3.3)	1 (0.5)	14 (6.6)	
Lesion severity						
<70%	85 (31.4)	1 (1.2)	2 (2.4)	0	3 (3.5)	
70–89%	137 (50.6)	4 (2.9)	2 (1.5)	1 (0.7)	7 (5.1)	.007*
≥90%	47 (17.3)	3 (6.4)	4 (8.5)	0	7 (14.9)	
Long/multiple stenoses						
Yes	88 (32.5)	4 (4.6)	5 (5.7)	1 (1.1)	10 (11.4)	.012
No	183 (67.5)	4 (2.2)	3 (1.6)	0	7 (3.8)	
Eccentric						
Yes	209 (77.1)	7 (3.3)	8 (3.8)	1 (0.5)	16 (7.7)	.168
No	62 (22.9)	1 (1.6)	0	0	1 (1.6)	
Ulcerated						
Yes	66 (24.4)	2 (3.0)	3 (4.6)	1 (1.5)	6 (9.1)	.212
No	205 (75.6)	6 (2.9)	5 (2.4)	0	11 (5.4)	
Calcified						
Yes	87 (32.1)	6 (6.9)	2 (2.3)	0	8 (9.2)	.108
No	184 (67.9)	2 (1.1)	6 (3.3)	1 (0.5)	9 (4.9)	
Residual irregularity						
Yes	87 (32.1)	3 (3.5)	5 (5.8)	0	8 (9.2)	.108
No	184 (67.9)	5 (2.7)	3 (1.6)	1 (0.5)	9 (4.9)	
NASCET eligible						
Yes	37 (13.7)	1 (2.7)	0	0	1 (2.7)	.582
No	234 (86.3)	7 (2.9)	8 (3.4)	1 (0.4)	16 (6.8)	

CEA indicates carotid endarterectomy.
*χ^2 test for linear trend.

In the present study, we noted a similar complication rate in asymptomatic and symptomatic patients (P=.883). The asymptomatic patients, like the overall study group, had a higher risk profile than patients included in randomized surgery trials, and only 20% of these patients met ACAS eligibility criteria. Although the present study is the largest of its kind, it lacks statistical power to adequately differentiate the relative importance of several other variables, which occurred at a low frequency in the study group. Validation of these risk factors requires larger prospective studies. Assessment of carotid artery morphology is subjective, and the use of these data in clinical decision making will require strict attention to the details of the definitions used.

Conclusions

This study carefully defined the demographic, clinical, and anatomic characteristics of a large population of patients undergoing carotid stenting. In this high-risk cohort of

TABLE 3. Correlation of Procedural Variables With Neurological Events

	Patients, n (%)	Minor Strokes, n (%)		Major Strokes, n (%)	Total Events, n (%)	*P*
		Category 1	Category 2			
n	231	8 (3.5)	8 (3.5)	1 (0.4)	17 (7.4)	
Combined procedure						
Yes	32 (13.9)	3 (9.4)	0	0	3 (9.4)	.404
No	199 (86.1)	5 (2.5)	8 (4.0)	1 (0.5)	14 (7.0)	
Bilateral procedure						
Yes	19 (8.2)	1 (5.3)	0	0	1 (5.3)	.926
No	212 (91.8)	7 (3.3)	8 (3.8)	1 (0.5)	16 (7.6)	

TABLE 4. Result of Multivariate Analysis for Predictors of Minor and Major Strokes After Carotid Stenting

Predictor	Coefficient	Odds Ratio	*P*	95% Confidence Limits
Age	0.117	1.1249	.0057	1.0348, 1.2228
Long/multiple stenoses	1.6376	5.1429	.0056	1.6145, 16.3824
Lesion severity	0.0464	1.0474	.0618	0.9977, 1.0996
Residual irregularity	0.9583	2.6073	.0852	0.8756, 7.7642

patients, multivariate analysis identified advanced age and long or multiple stenoses as independent predictors of a neurological complication.

Alternatively, patients at high risk for endarterectomy in the present study, ie, contralateral carotid occlusion, prior carotid endarterectomy, and combined carotid and coronary procedures, had a low risk of complications with carotid stenting. In addition, NASCET-eligible patients had a low (2.7%) risk of complications. Technical advances including the development of low-profile stents and emboli filter devices are needed to enhance results in the higher-risk subsets of patients.

The complications of carotid stenting and endarterectomy are both highly dependent on patient selection. The relative roles of these methods must await the results of prospective randomized trials that study comparable patient subsets. However, some well-established, high-risk subsets for endarterectomy appear to have lower complication rates with carotid stenting.

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