

# Influence of Preoperative Risk Factors on Outcome After Carotid Endarterectomy

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**As supported by level 1 multicenter randomized trial data, carotid endarterectomy (CEA) has a very low risk of perioperative morbidity and excellent durability, and provides significant long-term reductions of the risk of stroke. At Ochsner, our 1.1% risk of major stroke or death after CEA (n=366) is a demonstration of the safety of this procedure in experienced hands. This treatment modality continues to be the gold standard for most patients with carotid artery occlusive disease. Almost half of these patients treated with CEA were considered “high-risk” as defined by ineligibility for past or present randomized carotid trials. Importantly, these “high-risk” patients had outcomes that were not statistically different from “low-risk” trial-eligible patients. Thus, evidence-based decision-making does not support the routine use of investigational carotid stenting in “high-risk” trial-ineligible patients. However, carotid stenting is clearly a valuable alternative for selected patients. Our challenge is to precisely define which patients will most benefit from medical, surgical, or catheter-based therapy for carotid artery occlusive disease.**

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It is axiomatic that interventional treatment of significant carotid artery occlusive disease should be performed by the method that provides the least periprocedural risk and best durability while providing long-term freedom from stroke. Until recently, the only viable nonmedical treatment of carotid artery occlusive disease was surgical endarterectomy. With the advent of investigational carotid treatment through the techniques of angioplasty and stenting, a second treatment modality is now available.

Evidence-based medical decision-making has become a mantra for practitioners in the past decade, and choices regarding carotid artery occlusive disease management should be no exception. However, the final choice of treatment must be individualized to each patient. Herein lies a significant current controversy surrounding interventional carotid therapy. Are there subgroups of patients which, when treated with carotid stenting, have equivalent or reduced neurologic morbidity compared with carotid endarterectomy (CEA)?

It has been suggested that the outcomes from CEA demonstrated in landmark randomized carotid trials (North American Symptomatic Carotid endarterectomy Trial [NASCET] [1] and Asymptomatic Carotid Atherosclerosis Study [ACAS] [2]) cannot be generalized to the general population. These trials provided level 1, statistically robust evidence demonstrating a benefit in long-term stroke

reduction for patients undergoing CEA compared with the best medical therapy. However, the entry criteria for these trials excluded many patients who might have a higher risk for perioperative stroke or other significant morbidity. This included those with crescendo transient ischemic attacks (TIAs), uncontrolled hypertension, recurrent carotid disease, or significant renal insufficiency. There is a pervasive impression by some that those trial-ineligible patients are globally at higher risk for perioperative stroke with CEA. Accordingly, carotid stenting may be perceived as a safer treatment than CEA in these patients. However, data supporting this position are anecdotal at best.

The purpose of this study was to provide data to assist in the evidence-based management of high-risk and low-risk patients with significant carotid artery occlusive disease (3). High-risk patients were defined as trial-ineligible, and low-risk patients were those who were trial-eligible.

## METHODS

Patients who underwent CEA during 2 consecutive years at the Ochsner Clinic Foundation were retrospectively identified by the hospital database. All patients were included with the exception of those undergoing combined or sequential procedures during the same hospitalization (i.e., coronary artery bypass grafting/CEA or vertebral artery transposition/CEA). All volumes of hospital admission charts and clinic charts were reviewed. A phone survey

**Table 1.** North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS) exclusion criteria.

	NASCET Exclusions	ACAS Exclusions
<b>Age</b>	> 79	< 40 or > 79
<b>Symptoms</b>	Asymptomatic ipsilateral >120 days prior History of FMD, tumor, AVM, etc., which could cause symptoms Stroke in evolution Prior CVA with profound deficit, on either side	Ipsilateral symptoms or VBI, ever contralateral symptoms within 45 days Same, + seizure disorder or migraines Same Same
<b>Lesion</b>	< 30% or occluded Tandem lesion > target stenosis Suitable for CEA	< 60% or occluded (by ACAS) Same Same
<b>Surgical Hx</b>	Prior ipsilateral CEA Prior contralateral CEA within 4 months Major surgery within 1 month Kidney failure	Same No exclusion Same Same (Cr. >3)
<b>Co-morbidities</b>	Lung failure Liver failure Cancer, <50% 5-year survival Atrial fibrillation Valvular heart disease Uncontrolled diabetes mellitus Uncontrolled hypertension Unstable angina MI within 6 months Symptomatic CHF No exclusion No exclusion	Same (impact 5-year survival) Same Same Same Same (including valve replacement) Same (fasting glucose > 400 mg/dL) Same (> 180 mmHg systolic, 115 mmHg diastolic, x3) Same No exclusion Same Radiation therapy to neck Active ulcer disease
<b>Allergies</b>	Aspirin use No exclusion	Same Warfarin use
VBI = vertebrobasilar insufficiency, FMD = fibromuscular dysplasia, AVM = arterial venous malformation, CVA = cerebrovascular accident, CEA = carotid endarterectomy, MI = myocardial infarction, CHF = congestive heart failure		

was performed if specific information was unavailable from the hospital record. Each patient was evaluated and categorized according to the original exclusion criteria (Table 1), NASCET (1) and ACAS (2) standards. In keeping within the criteria for age exclusion for the trials, age was evaluated as either < or  $\geq$  to 80 years. Complete exclusion criteria not provided within the published studies (i.e., ACAS) were obtained through personal correspondence. Patients were categorized as NASCET trial-eligible, ACAS trial-eligible, or trial-ineligible.

angiographic results as part of the institution's participation in the ACAS trial. Stenosis was separated into three categories:

1. **High-grade** (80%-99%): peak systolic velocity (PSV) >250, peak diastolic velocity (PDV) >100, systolic velocity ratio internal carotid artery/common carotid artery > 3.7
2. **Moderate** (60%-79%): PSV >130, PDV > 40, Ratio > 1.8
3. **Low-grade** (40%-59%): PSV 110-129, PDV < 40, Ratio < 1.8.

### Definitions

Patients were classified for analysis as having asymptomatic or symptomatic carotid stenosis. Lateralizing symptoms included TIA, prior stroke, or amaurosis fugax. Patients with nonlateralizing global ischemic symptoms of dizziness, syncope, or presyncope were considered to be asymptomatic. Symptomatic patients were classified as those patients who experienced an ipsilateral neurologic event within 120 days prior to the procedure. As per NASCET guidelines, patients with lateralizing symptoms occurring greater than 120 days after CEA were considered asymptomatic. Stroke was defined as a new neurologic sign that lasted for  $\geq 24$  hrs. Minor strokes were defined as those events causing minimal neurologic deficit that resolved with minimal or no deficit at the 30-day examination. Major strokes were defined as those deficits that lasted beyond 30 days and caused a change in the lifestyle of the patient (4). All events occurring within 30 days of surgery were included.

### Preoperative Evaluation

Patients were evaluated preoperatively by an accredited vascular laboratory using duplex ultrasonography and the Bluth criteria (5) to categorize degree of stenosis. The vascular laboratory was Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL)-certified, having satisfactorily correlated duplex ultrasonographic velocity criteria with anatomic

**Table 2.** Carotid endarterectomy trial patient characteristics.

	Total (N=366)	ACAS (N=127)	NASCET (N=70)	Ineligible (N=169)	P
Age/mean	68.9 ± 8.6	67.4 ± 7.7	66.2 ± 7.8	71.4 ± 8.9	0.016
Male	63.4%(232)	63.8%(81)	71.4%(50)	59.8%(101)	0.212
Coronary artery disease	56.6%(207)	52.8%(67)	58.6%(41)	58.6%(99)	0.585
Hypertension	80.9%(296)	78.0%(99)	77.1%(54)	84.6%(143)	0.246
Peripheral artery disease	39.6%(145)	30.7%(39)	37.1%(26)	47.3%(80)	0.016
Insulin-dependent diabetes mellitus	8.2%(30)	8.7%(11)	7.1%(5)	8.3%(14)	0.923
Non-insulin-dependent diabetes mellitus	19.9%(73)	18.9%(24)	14.3%(10)	23.1%(39)	0.312
Chronic renal insufficiency	4.4%(16)	2.4%(3)	1.4%(1)	7.1%(12)	0.081
Hypercholesterolemia	33.3%(122)	44.1%(56)	31.4%(22)	26.0%(44)	0.004
Chronic obstructive pulmonary disease	12.0%(44)	7.9%(10)	10.0%(7)	16.0%(27)	0.286
Atrial fibrillation	1.6%(6)	0.0%(0)	0.0%(0)	3.6%( 6)	0.020
Congestive heart failure	6.0%(22)	1.6%(2)	0.0%(0)	11.8%(20)	0.0001

ACAS = Asymptomatic Carotid Atherosclerosis Study, NASCET = North American Symptomatic Carotid Endarterectomy Trial

Most patients have duplex ultrasound as the sole imaging modality prior to CEA (6). Cerebral arteriography was utilized selectively at the discretion of the operating surgeon for cases in which the symptoms did not correlate with the vascular laboratory studies, recurrent stenoses, prior neck radiation, or having been previously obtained on another service. Angiography was performed in 109 (29.8%) of patients, which included 32 patients with recurrent stenosis, 100% of whom underwent angiography. The remaining 257 (70.2%) patients had duplex ultrasonography alone prior to operative intervention.

**Operative Details**

General anesthesia was used in the majority of operations, with cervical block or local anesthesia alone utilized less than 5%. While there were minor variations in technique, all surgeons employed classical endarterectomy as popularized by Thompson et al (7). Eversion endarterectomy was not performed. Most vessels were patched (81%), and shunts were used liberally (92%). Intraoperative postendarterectomy duplex ultrasonography or arteriography were employed sparingly.

**Statistics**

Statistical analysis was performed using chi-square analysis for more frequent occurrences. When chi-square analysis was not appropriate for less frequent occurrences, a Fisher exact test was performed. Any value expressed as P < 0.05 was considered to be significant.

**Table 3.** Carotid endarterectomy trial patient indications.

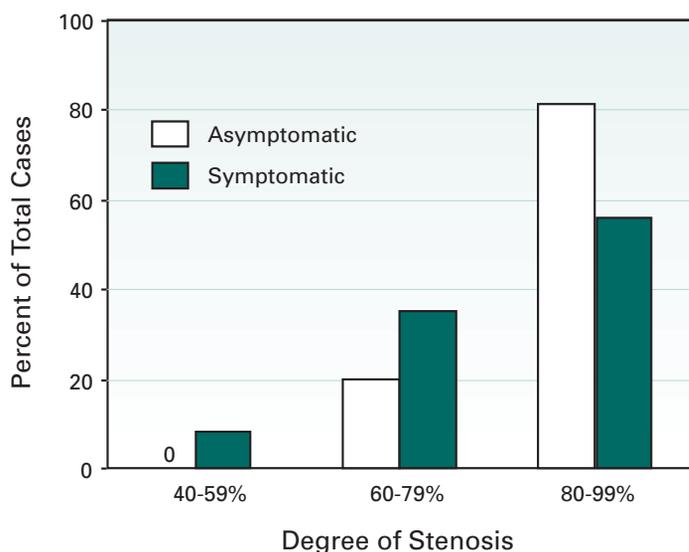
<p><b>Symptomatic: 40.4% (148/366)</b></p> <ul style="list-style-type: none"> <li>• Transient ischemic attack: 58.1% (86/148)</li> <li>• Cerebrovascular accident: 27.7% (41/148)</li> <li>• Amaurosis fugax: 14.1% (21/148)</li> </ul> <p><b>Asymptomatic: 59.6% (218/366)</b></p> <ul style="list-style-type: none"> <li>• Global ischemia: 4.1% (9/218)</li> <li>• No symptoms: 95.9% (209/218)</li> </ul>
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**PATIENTS**

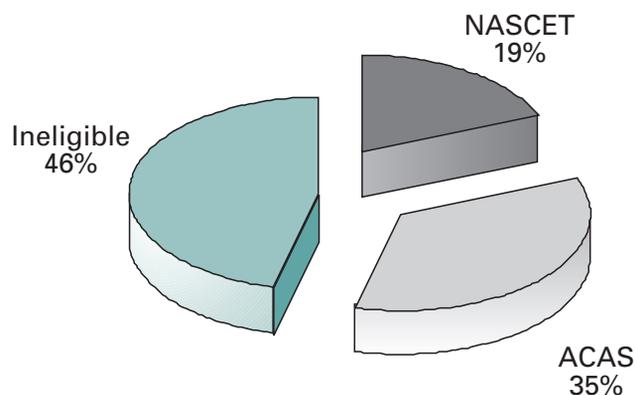
**Demographics**

There were 366 carotid endarterectomies performed in 348 patients. The study group was predominantly male (63.4%) with a mean age of 68.9 years (± 9.9). Table 2 lists the accompanying comorbidities of the study group with a breakdown based on trial eligibility. Trial-ineligible patients had a statistically higher prevalence of peripheral arterial disease (P=0.016), atrial fibrillation (P=0.02), congestive heart failure (P=0.0001) and a trend toward chronic renal insufficiency (P=0.08). Hypercholesterolemia was more common in patients who were ACAS-eligible (P=0.004).

Focal ipsilateral symptoms within 120 days of CEA (Table 3) were present in 148 patients (40.4%), 86 with TIAs, 41 with prior ipsilateral stroke, and 21 with amaurosis fugax. Patients with ipsilateral events occurring > 120 days prior to CEA were considered asymptomatic. Global ischemic symptoms were present in 2.5% (9) and were included in the 218 (59.6%) patients who were asymptomatic.



**Figure 1.** Degree of preoperative stenosis by carotid duplex for asymptomatic versus symptomatic patients with carotid stenosis.



**Figure 2.** Breakdown of patient sample based on trial eligibility (n=366).

**Table 4.** Neurologic events/preoperative symptomatology of patients in major carotid endarterectomy trials.

	Patients	Stroke	Major	Minor
<b>Symptomatic</b>	148 (40.4%)	4 (2.7%)	2 (1.4%)	2 (1.4%)
<b>Asmptomatic</b>	218 (59.6%)	5 (2.3%)	2 (0.9%)	3 (1.4%)
<b>Total</b>	366	9 (2.5%)	4 (1.1%)	5 (1.4%)

The severity of stenosis is presented in Figure 1. The majority of asymptomatic patients (81.2%) had high-grade (80%-99%) stenosis by duplex ultrasonography and the remainder moderate (60%-79%) stenosis. In symptomatic patients, 54.7% (81/148) had high-grade stenosis, 33.8% (50/148) had moderate stenosis, and the remaining 8 (5.4%) patients had low-grade stenosis. The 8 low-grade stenosis patients underwent angiography, and most were found to have significant associated ulceration.

## RESULTS

### Trial Eligibility

Patient breakdown by trial eligibility is depicted in Figure 2. Approximately half of these patients (169 or 46.2%) were ineligible by either NASCET or ACAS criteria. Approximately one third (34.7%) were ACAS-eligible and 19.1% were NASCET-eligible. Reoperative CEA was performed on 32 (8.7%) of the 366 patients. They are included in the trial-ineligible group, excluded from trial eligibility for recurrent stenosis.

### Perioperative Outcomes:

#### Neurologic Events and Death

The major stroke and death rate was 1.1% (4 major strokes and 1 death [0.3%] secondary to a major stroke). There were five minor strokes, giving an all stroke and death rate of 2.5%. Among the 148 (40.4%) patients who underwent CEA for symptomatic carotid stenosis, 4 strokes (2.7%) occurred (Table 4). Two of the strokes were major and two were minor with no deaths for an overall major stroke rate of 1.4%. A total of 218 (59.6%) CEAs were performed for asymptomatic carotid stenosis with five (2.3%) strokes seen in this group of patients. Two of these events were considered major strokes including a death for a major stroke and death rate of 0.9% seen in asymptomatic patients. There was no statistical difference between the stroke rates of symptomatic versus asymptomatic patients (P=0.39). Patients with recurrent stenosis had a stroke/death rate of 3.1% (1/32).

Neurologic events were further analyzed based upon NASCET or ACAS trial eligibility. Three strokes (1.5%) occurred in the trial-eligible patients (one major and two minor) giving a major stroke/death rate of 0.5%. The trial-ineligible patients experienced six strokes (3.5%; 3 minor and 3 major) for an overall major stroke and death rate of 1.8%. Differences in the neurologic morbidity between trial-ineligible patients and trial-eligible patients were not statistically significant (P=0.17).

In the entire patient sample, peripheral arterial occlusive disease was present in 39.6% and was associated with a nonsignificant trend (P=0.09) for perioperative stroke. No other patient demographic demonstrated an increased correlation with perioperative events.

### Octogenarians

Patients  $\geq 80$  years old were analyzed separately. The 42 such patients in this group had a mean age of 82.8 years. There were no deaths and one stroke for an overall stroke and death rate of 2.4%, not significantly different from the 2.5% in the entire patient cohort. Co-morbidities were similar except for less coronary artery disease (40.5% vs 56.6%) and hypercholesterolemia (21.4% vs. 33.3%) in the  $\geq 80$  year olds versus the entire patient cohort, respectively.

### Morbidity

Two (0.5%) perioperative myocardial infarctions were experienced in the entire cohort, one each in the trial-eligible and trial-ineligible arms. Both patients recovered with supportive care and minimal increase in length of hospitalization. Nine (2.5%) patients suffered some form of respiratory failure. Seven of those required aggressive pulmonary toilet to fully recover, while two needed ventilatory support. One also suffered a stroke and death. The other patient recovered and was discharged on postoperative day 10. One patient (0.3%) experienced acute renal failure (the same patient with a stroke and death due to respiratory failure and multisystem organ failure).

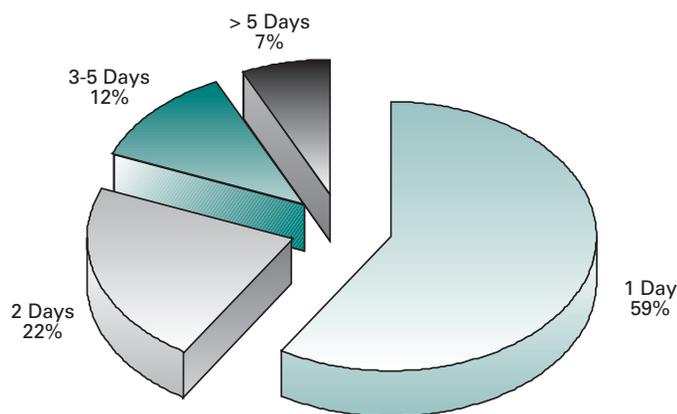
### Length of Stay

Length of stay (LOS) is presented in Figure 3. The majority of patients (59%) were discharged on the first postoperative day, with 81% being discharged by postoperative day 2. Median LOS was 1, with mean LOS  $2.07 \pm 0.23$ . Many of the patients with longer hospitalizations were originally admitted with acute neurologic changes such as TIA or CVA who, after neurologic evaluation and stabilization, underwent CEA during the same admission.

The patients who were  $\geq 80$  years old had a similar LOS (median 1, mean  $2.04 \pm 0.23$ ). The majority of these patients (61.9%) were also discharged on the first postoperative day, with all but one patient discharged by the second postoperative day. The only patient who remained in the hospital longer than the second postoperative day suffered the lone stroke in this subgroup.

## DISCUSSION

Patients defined as high-risk for CEA (trial-ineligible) are common in a tertiary care referral practice such as Ochsner. Importantly, there was no statistically significant difference in perioperative stroke/death rate in these patients compared with trial-eligible patients. The high-risk trial-ineligible patients had outcomes that fell within the American Heart Association (AHA) suggested guidelines for acceptable perioperative stroke/death after CEA (3% asymptomatic, 6% symptomatic) (8). In patients who were trial-eligible, our all stroke/death rate for asymptomatic patients (1.5%) was similar to that of ACAS (2.2%), and that for symptomatic patients (1.6%) compared favorably with NASCET (5.8%).



**Figure 3.** Average length of stay for entire cohort of carotid endarterectomy patients.

In the years following publication of the NASCET/ACAS trial data, much has been written regarding the relative limitations of generalizing those benchmark results. One issue has been that of surgical expertise: surgeons involved in the trials had a track record of excellent results. Reports of unacceptable neurologic perioperative complication rates published from uncontrolled community studies prompted some to suggest that the required surgical expertise was not available to most patients (9). Ochsner participated in the landmark ACAS carotid trial, and our vascular surgeons continue to actively participate in current carotid intervention trials.

Hallett et al compared a 25-year population-based result of CEA (n=297) with that of NASCET and found that the stroke/death rates were comparable (10). They concluded that NASCET results were applicable to “general community practice.” However, no attempt was made to stratify patients as to their trial eligibility.

In a study of 113,300 Medicare patients undergoing CEA, Wennberg et al found significantly higher mortality rates than those in NASCET (0.6%) and ACAS (0.1%)(11). In hospitals that had participated in the trials, a mortality rate of 1.4% was documented, which increased to 2.5% in non-trial low-volume hospitals. Wennberg and colleagues concluded that caution must be exercised in generalizing trial results to the general population. At Ochsner, there was no mortality in trial-eligible patients (n=197), and one death in a trial-ineligible patient (0.6%, n=169) for an overall mortality rate of 0.3% (1/366).

### Rx of Asymptomatic Carotid Disease

The ACAS carotid trial demonstrated a benefit of CEA over best medical therapy. However, to achieve this statistically significant benefit, the patient needed to have an excellent 5-year life expectancy. Any carotid artery intervention is a prophylactic procedure to reduce the long-term risk of stroke; if a patient does not live at least 5 years, the reduction in stroke risk for the asymptomatic patient is outweighed by the small but measurable

periprocedural morbidity. Moreover, “best medical therapy” during the ACAS trial, published in 1995 but conducted a decade ago, did not include more potent platelet inhibitors or routine aggressive use of statins and ACE inhibitors, all of which have been demonstrated to reduce the incidence of stroke. As such, maximal medical therapy may be the most appropriate treatment for asymptomatic patients with severe medical co-morbidities such as advanced cardiac disease, pulmonary disease, or malignancy that predict a less than 5-year life expectancy. While carotid stenting would seem to be an intuitive choice for these patients, the periprocedural neurologic morbidity would need to be significantly less than 2.2% (the ACAS trial result) to benefit the patient. As such, neither CEA nor carotid stenting is routinely indicated in the asymptomatic patient who has a limited life expectancy.

### **Age as a Risk Factor**

Carotid endarterectomy in octogenarians has been studied extensively with both supportive and cautionary conclusions as to its appropriateness and safety. The all stroke/death rate in the octogenarians in this series (2.4%) was comparable to the entire patient cohort (2.5%).

Advanced age is commonly felt to be an adverse risk factor for CEA, but data from Ochsner and many other centers have demonstrated equivalent outcomes in this patient population. Surprisingly, published data to date suggests that carotid stenting in the elderly appears to have a significantly higher risk of stroke. The group led by Dr. Roubin, a world recognized leader in carotid stenting, published a series of carotid angioplasty and stenting cases grouped according to age (12). They reported neurologic complication rates of 25% (one major and four minor strokes) in patients  $\geq 80$  years. They concluded that this group of patients was at increased risk and needed extensive counseling prior to carotid stenting. The stroke/death rate of 2.4% after CEA in patients  $\geq 80$  years at Ochsner is markedly lower and supports the safety of carotid endarterectomy in the aging population.

Why would carotid stenting have higher neurologic morbidity in this elderly population? The increased prevalence of aortic arch atherosclerotic disease in these patients may play a causative role. Catheter and guidewire manipulation in the aortic arch is an integral part of carotid stenting. Diagnostic cerebral angiography itself has a small but definable risk of stroke, presumably from embolization of aortic arch atherosclerotic disease. The risk of such an occurrence was 0.52% in a recent report from Ochsner (13). While any complication with a prevalence  $< 1\%$  must be considered rare, it does increase the stroke rate approximately 20% if the overall stroke rate is only 2.5%. In the ACAS carotid trial, fully half of the perioperative strokes in the surgical arm (1.2% overall) were actually due to the preoperative angiography, not the surgery. At Ochsner

and other leading centers, most patients need only a high quality duplex ultrasound study prior to CEA, thus avoiding the potential neurologic morbidity of cerebral angiography. However, it should be underscored that this preoperative algorithm should be employed only in those centers where the duplex ultrasound has been prospectively vetted for its positive predictive value compared with angiography. In most community practices, more routine use of preoperative cerebral angiography may be warranted.

The percentage of asymptomatic patients in the current series deserves comment. From 1997-1998, most patients (59.6%) were asymptomatic, which is similar to that of Hertzler et al (14). It should be noted that the definition of a symptomatic lesion in the current series was strict, with exclusion of patients with global ischemic symptoms as well as those patients with lateralizing symptoms  $> 120$  days before CEA. In 1994, only 34% of our patients undergoing CEA were asymptomatic (15). Our enthusiasm for treating asymptomatic severe stenosis was buoyed by our participation in, and the subsequent publication of, the ACAS results.

## **CONCLUSION**

As supported by level 1 multicenter randomized trial data, CEA in experienced hands has a very low risk of perioperative stroke or death and continues to be the gold standard for treatment of carotid artery occlusive disease. High-risk patients, as defined by carotid trial ineligibility, have outcomes that are not statistically different from low-risk trial-eligible patients. Evidence-based decision-making does not support the *routine* use of carotid stenting in high-risk trial-ineligible patients; however, carotid stenting is clearly a valuable alternative for selected patients. Our challenge is to precisely define which patients will most benefit from medical, surgical, or percutaneous therapy for their carotid occlusive disease.

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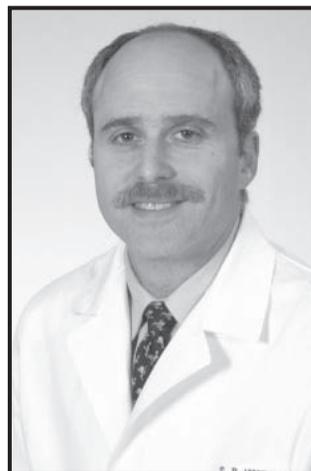
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