The fundamental question regarding treatment of severe asymptomatic carotid stenosis is not whether patients should have endarterectomy (CEA), but who should perform it. When performed by a board-certified specialist with an excellent track record, concerns about CEA's safety recede. This realization will allow us to finally move beyond the controversy that has dogged CEA for decades.

In the early 1980s, endarterectomy was under attack by the medical community.\(^1\) In response to legitimate concerns about the overuse and morbidity of the operation,\(^3\) a series of randomized prospective trials were established. Prior to the completion of these trials, it was generally recommended that only patients with critical stenoses of ≥80 percent undergo operation, if the combined morbidity and mortality could be maintained under three percent.\(^5\) Many members of the vascular surgery community were concerned that the trials of asymptomatic patients included those with only moderate degrees of stenosis, inconsistent with contemporary standards. Trials based on such populations would dilute the value of CEA in the treatment of more severe degrees of stenosis.

The first of these trials to be completed, the Veterans Affairs (VA) study, included patients with only 50 percent diameter narrowing. While this is considered a negative trial, there was a statistically significant reduction in transient ischemic attacks and strokes ipsilateral to the operated side.\(^6\) The p-value for the endpoint of ipsilateral stroke alone was 0.06; therefore, the difference between endarterectomy and medical management was not significant. However, with a relatively small sample size the potential for a type II error exists. Of interest, none of the ipsilateral strokes in either the medical or surgical arms were preceded by transient ischemic attacks, contrary to prevailing opinion.

The Asymptomatic Carotid Atherosclerosis Study (ACAS) recruited nearly four times the number of patients as the VA trial. This pivotal study, including patients with ≥60 percent diameter stenosis, showed a 53 percent reduction in the five-year aggregate risk of ipsilateral strokes and perioperative stroke and death in the surgical patients (p=0.004).\(^7\) The difference between groups would have been amplified using current diagnostic techniques, since nearly one-half of the perioperative stroke and death rate (1.2 percent) was attributed to contrast arteriography. During the last decade, duplex scanning and CT and MR angiography have replaced invasive arteriography in the evaluation of asymptomatic patients.\(^8\)

The Asymptomatic Carotid Surgery Trial (ACST), reported in 2004, showed results similar to the ACAS.\(^7\) Unlike the North American Symptomatic Carotid Endarterectomy Trial,\(^10\) neither asymptomatic trial showed a correlation between increasing degree of stenosis and risk of stroke in the medically managed patients. Although the subgroups were relatively small, stroke risk in the medical arm of the ACAS was greatest in those with 60 to 69 percent stenosis. Therefore, if the validity of intervention for asymptomatic patients is accepted, neither of these trials support the traditional threshold of 80 percent stenosis or greater. Since the prevailing opinion is that most ipsilateral strokes are caused by artery-to-artery embolization, the critical value for plaque instability and ulceration may be lower than previously appreciated. One discrepancy between the ACAS and the ACST was the role of CEA in women. The ACAS did not demonstrate a protective effect of surgery in women. Presumably due to randomization of twice as many women, the larger ACST showed benefit from surgery for both sexes.

After expenditure of millions of dollars, randomization of thousands of patients, and 20 years of angst, the medical community finally has hard data to support the use of carotid endarterectomy in asymptomatic patients. Broad population and VA studies show a dramatic rise in CEA following publication of the ACAS.\(^11\) The general medical community appears to have embraced the concept of prophylactic endarterectomy. However, many neurology opinion leaders remain reluctant to endorse the widespread use of CEA.\(^13\) The primary concern is the small marginal benefit of surgery and extrapolation of the results of these randomized trials to community hospitals, where risks are presumably higher. The 30-day stroke/mortality rates of ACAS and ACST were 2.3 percent and 3.1 percent, respectively.\(^17\) Although these results are considered admirable compared to historical standards, similar and even better values are currently obtained in many community hospitals.

Between 1996 and 2003 we performed 1,602 CEAs at two community hospitals with a 30-day combined stroke/mortality rate of 0.6 percent.\(^14\) This is a substantial reduction from a prior

**Is Revascularization Warranted to Prevent Stroke In Asymptomatic Stenosis?**

**Endarterectomy is Still the Optimal Treatment for Asymptomatic Atherosclerosis**

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report from our practice encompassing 1976 to 1987, when the stroke/mortality rate was 2.2 percent.** An institutional peer review process at Stanford resulted in a similar decline in peri-procedural stroke rates from 3.8 percent to zero.** Recent audits of all CEAs performed in New York and Connecticut, including patients with preoperative neurologic symptoms, showed stroke/mortality rates of less than two percent.*** When discussing management of carotid disease it is critical to include contemporary results as outcomes continue to improve.

During the last decade a number of studies have demonstrated that outcomes from CEA are related to surgical volume and training. Using definitions ranging from 10-30 CEA/year, high volume surgeons had one-half to one-third the stroke/mortality rates of low-volume surgeons.** The highest complication rates are achieved by high-volume vascular surgeons with board certification.** The days of the occasional carotid surgeon should be over.

Regionalization of high-risk procedures has been advocated by the Leapfrog safety initiative, a coalition of large employers and health care purchasers. In order to reduce errors and limit morbidity, three safety standards have been recommended: (1) computerized physician order entry, (2) ICUs staffed by full-time intensivists and (3) volume standards for five selected high-risk procedures, including CEA. Birkmeyer has estimated that nationwide adoption of Leapfrog volume standards for these five procedures would save 2,581 lives.** Regionalization of health care is a controversial concept as it could result in loss of family support, imposes a travel burden on elderly patients and would certainly be met with resistance by low volume hospitals and surgeons.

In addition, performance of high volumes by an individual surgeon does not guarantee the best outcome. Finally, volume standards could encourage performance of unnecessary procedures. Despite these drawbacks, limiting performance to general surgeons who perform CEA.
The rapid adoption of carotid stenting (CAS) adds a new wrinkle to asymptomatic stenosis management. Medicare guidelines limit CAS to high-risk symptomatic patients with 270 percent stenosis and those in randomized trials. In the SAPPHIRE trial of high-risk patients, the cumulative incidence of death, MI or stroke in asymptomatic patients receiving a stent was 5.4 percent.*** The inordinately high rate of complications in both the CAS and CEA groups in this trial suggests that no intervention may be warranted in patients with severe coronary or pulmonary disease. It remains to be seen whether CAS in good-risk patients is equivalent to current surgical management. We are several years away from the conclusion of the CREST trial, which may shed considerable light on this issue.**