

Carotid Stenting and Angioplasty

A Statement for Healthcare Professionals From the Councils on Cardiovascular Radiology, Stroke, Cardio-Thoracic and Vascular Surgery, Epidemiology and Prevention, and Clinical Cardiology, American Heart Association

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Carotid artery stenosis, particularly involving the origin of the internal carotid artery, is a frequent clinical problem. These stenoses, almost invariably atherosclerotic, can present as asymptomatic bruits discovered on physical examination, one or more transient ischemic attacks related to embolization of thrombus from stenotic lesions or to hypoperfusion, or less commonly, as an ischemic stroke. From the results of three high-quality prospective randomized trials,¹⁻³ it has become apparent that symptomatic stenoses that narrow the diameter of the carotid artery more than 60% to 70% lead to a significant incidence of stroke if treated medically. The risk of stroke associated with such a lesion in symptomatic patients treated with antiplatelet therapy alone is thought to be 26%.³ With carotid endarterectomy and aspirin, this risk is lowered to 9%, a statistically significant difference.³ In patients with or without symptoms who have a stenosis $\leq 60\%$, the effectiveness of either medical therapy or carotid endarterectomy in preventing significant neurological events is not known. In symptomatic patients with $< 30\%$ stenosis, medical therapy is superior to surgical therapy.² Studies attempting to define the benefit of therapy in symptomatic patients with $< 60\%$ stenosis are currently under way. Accrual of patients has slowed, however, because data show clear efficacy in symptomatic patients with stenoses $\geq 70\%$, leading to a bias toward surgery in symptomatic patients with less severe stenoses. In general the role of surgery for asymptomatic stenosis remains controversial, with some recent opinions suggesting that it may not be indicated.⁴ In one high-quality trial with selected experienced surgeons, there was a modest reduction in absolute risk in asymptomatic patients with stenosis $\geq 60\%$, but the significance of this finding has been debated.^{5,6}

Although mortality associated with conventional antiplatelet therapy has been minimal,⁷ surgery clearly has significant

perioperative morbidity and mortality. This risk varies as a function of the skill and experience of the surgeon and ancillary personnel. In one large study of symptomatic patients,³ surgical complication rates were 0.6% mortality; 5.5% perioperative cerebrovascular events; and 2.1% major stroke. By contrast, over the same 32-day observation period, patients treated medically had a 0.3% fatality rate, a 3.3% risk of a cerebrovascular event, and a 0.9% risk of a major event. In a recent review of the published literature, risk of stroke and/or death following carotid endarterectomy in symptomatic patients was found to be 5.6%, although there was substantial variation in incidence as a function of the type of study and the nature of postoperative evaluation and surveillance.⁸ Surgery, then, in this symptomatic group of patients with significant carotid artery stenosis has a low but significant incidence of periprocedural complications. More importantly, however, according to actuarial analysis, by 2 years the risk of an ipsilateral stroke was 9% for surgical patients and 26% for medically treated patients, a 17% reduction in absolute risk with surgery.³

Since its development by Gruentzig⁹ in the early 1970s, use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses has gained wide acceptance. In many trials involving many organ systems, percutaneous transluminal angioplasty (PTA) has been shown to be effective. Despite several large studies, however, there is still debate about its relative efficacy and applicability compared with surgery, primarily because long-term patency after PTA is limited by restenosis as well documented in coronary, renal, and peripheral applications.¹⁰⁻¹²

Vascular stents have gained wide popularity over the last several years. There are many types with different characteristics, in different stages of clinical use and FDA approval. More

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than a dozen companies are actively marketing or investigating stents in the United States. In almost all studies directly comparing PTA and stents, the patency rate with stenting has been at least slightly higher compared with angioplasty alone.^{13,14} A direct comparison of primary stent placement and surgery in any vascular system, however, has not been completed.

Over the last 2 to 3 years there has been a great deal of interest in treating extracranial carotid stenoses with either angioplasty or stents. Extracranial carotid PTA has been in use for nearly a decade, although no large studies have been reported. Several reports of carotid angioplasty and stenting have been published or presented at recent medical meetings, including the annual scientific sessions of the AHA.¹⁵⁻¹⁷ The relative technical ease of performing carotid angioplasty or stenting has attracted considerable attention in the clinical community. A randomized multicenter clinical trial sponsored by the Medical Research Council is in progress in the United Kingdom,¹⁸ and one or more are under consideration in the United States. The potential for both relative technical ease of performing carotid PTA and stenting and the low cost of these procedures, although perhaps illusory, are appealing and justify consideration of a percutaneous approach as an alternative to carotid endarterectomy. Before widespread clinical use can be proposed, however, several important points must be considered.

First, the benefit of carotid endarterectomy in symptomatic patients has been convincingly demonstrated in well-controlled prospective randomized trials. The complication rates have been well defined and, although varied in the literature, appear to be acceptably low in the hands of experienced surgeons.

Second, although carotid angioplasty and stenting are less invasive than surgery, the risks of diagnostic carotid angiography alone with its attendant catheter manipulation are not trivial. In some reports the risks approach those of carotid endarterectomy. Before carotid PTA and stenting can be considered for wide use, morbidity and mortality rates must be clearly and definitively elucidated, and training criteria must be established.

Third, unlike with coronary or iliac angioplasty, acute occlusion of the carotid artery may not be amenable to emergency surgical correction. Furthermore, if restenosis occurs after stenting, the standard surgical therapy may be either impossible or substantially more difficult to perform because of the stent. This is not true for percutaneous interventions in other vascular systems. Neither of these concerns has been borne out in experience to date, but more data are clearly necessary to address these potential problems.

Fourth, carotid endarterectomy is relatively safe and inexpensive with a generally brief associated hospitalization. It is now frequently performed, using regional or local anesthesia, with good results. This is not true for other surgical alternatives to stenting, such as coronary bypass surgery or aortobifemoral or femoral-popliteal grafting. Success rates, complication rates, and hospital length of stay are all favorable when carotid endarterectomy is performed by experienced surgeons, even in patients considered to be at very high risk for other interventions. As a minimum, the equivalence of percutaneous approaches to surgical carotid endarterectomy must therefore be established in sufficiently powered, prospective randomized trials.

The question that must be addressed, then, is whether carotid angioplasty or carotid stenting should be performed at all and, if so, by whom: persons with extensive experience in other vascular systems or persons trained in neurovascular percutaneous procedures? Unlike many areas of medicine in which clear answers are elusive, in this case an answer emerges. At this point, carotid angioplasty and carotid stenting, with rare and infrequent exceptions, should be undertaken only as part of a prospective, randomized trial with independent, dispassionate oversight. In addition to the British study already underway and the proposed large-scale US studies of carotid stenting versus endarterectomy, other trials may be justifiable, but certain requirements must be met. First, symptoms and signs of cerebrovascular disease in eligible patients should be well delineated, and enrollment of all such patients should be attempted. Second, such trials should allow for standardized training of participants to overcome the problems of a learning curve as much as possible. Third, sufficient numbers of patients must be enrolled and followed for a sufficient period of time, a minimum of 2 years, to allow relevant comparisons to be made with adequate statistical power. To show equivalency of the two treatments, assuming that there is a major event rate of 5% with surgery and that event rates differ by 2% or less, at least 3000 patients would be necessary.

Obviously there are difficulties with such randomized studies. Perhaps most glaringly, carotid angioplasty and stenting are already being used and reported by a number of institutions. In addition, stent technology is evolving, and the best currently available stents may be rapidly supplanted. Any study must allow for inclusion of significant technological advances. In this regard, collaboration with industry and the Food and Drug Administration is imperative; at least two small industry-sponsored studies are under way. Additionally, to ensure that such studies are not unduly biased by lack of experience, in certain situations a supervised, carefully defined registry may be advisable. This approach would require establishment of a team (including a neurologist, interventional radiologist, vascular surgeon, interventional cardiologist, and neurosurgeon) that, under careful institutional surveillance, could develop experience and a track record.

The techniques of carotid angioplasty and carotid stenting are available, as are a limited degree of experience and a high level of interest. The existence of a technique, however, does not justify or mandate its use. We must remember a basic tenet of medicine: *primum non nocere*—first do no harm. At this point, with few exceptions, use of carotid stenting should be limited to well-designed, well-controlled randomized studies with careful, dispassionate oversight. This will allow accurate comparison of a promising tool with the well-described, relatively safe gold standard of surgical carotid endarterectomy. Use of the technology because it and the patient it is to benefit exist is not at this point justified or justifiable.

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