Current Management of Extracranial Carotid Occlusive Disease

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Stroke continues to be a major public health concern, with more than 750,000 strokes occurring per year in the United States, making it the third most common cause of death and the leading neurologic cause of longterm disability.[1] The majority of strokes are ischemic in nature, and up to 20% of ischemic strokes are a result of carotid artery atherosclerotic disease. Treatment of carotid artery stenosis is aimed at preventing ischemic events caused by embolization of components of the atherosclerotic plaque, and less commonly, by hemodynamic compromise secondary to progression to occlusion of a previously narrowed but patent internal carotid artery.

Management of carotid occlusive disease continues to evolve today. Carotid endarterectomy (CEA), first introduced in the 1950s, was established as the gold standard for treatment of carotid stenosis by several landmark trials in the 1990s.[2-8] More recently, carotid angioplasty and stenting (CAS) emerged as a minimally invasive alternative, and several trials ensued to determine its safety and efficacy, and the indications for its use. Although CAS has proved feasible and relatively safe, the appropriate clinical setting for its preferential use over CEA remains unclear and continues to be the subject of many ongoing clinical trials. The purpose of this article is to review the literature on treatment of carotid occlusive disease, and to attempt to elucidate the current status of CAS and its proper place and indication in the therapeutic management of stroke associated with carotid artery stenosis.

Carotid endarterectomy

Early landmark CEA trials sought primarily to evaluate the efficacy of CEA as compared with medical management, identify the appropriate patient population that would derive benefit from CEA, and establish an acceptable complication rate for the procedure.

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Symptomatic carotid stenosis

The North American Symptomatic Carotid Endarterectomy Trial (NASCET)[2,3] and the European Carotid Surgery Trial (ECST) [4] addressed the use of CEA in symptomatic patients. Patients who had experienced a recent transient ischemic attack or nondisabling hemispheric stroke secondary to stenosis of the internal carotid artery were randomized to CEA or best medical management. Although NASCET and ECST used slightly different methods to calculate lesion severity, they both demonstrated substantial benefit for patients with significant stenosis. The NASCET method, which uses the normal distal internal carotid artery, tends to underestimate the degree of stenosis as compared with the ECST method, which uses an estimate of the original carotid artery width at the point of maximal narrowing. The more commonly cited findings from NASCET reflected an impressive decrease in the rate of ipsilateral stroke at 2-year followup for symptomatic patients with high-grade stenosis (70% to 99%) from 26% in the medical group to 9% in the CEA group, yielding an absolute risk reduction of 17% ($p < 0.001$). Patients with moderate stenosis were further subdivided into two subsets: 50% to 69% and 30% to 49%. Although patients with <50% stenosis did not derive any significant benefit from CEA, with nearly equivalent 5-year ipsilateral stroke risk of 18.7% in the medical group versus 14.9% in the CEA group, patients with 50% to 69% stenosis were found to derive modest benefit from CEA, as illustrated by a 5-year ipsilateral stroke risk of 22.2% in the medical group versus 15.7% in the CEA group (absolute risk reduction of 6.5%, $p = 0.045$). Surgical complication rates reported from NASCET were low, with the risk of permanent disabling stroke and death at 90 days of 2.0%, and the benefits from revascularization were found to be durable over the longterm.[5]

Asymptomatic carotid stenosis

The Asymptomatic Carotid Arteriosclerosis Study (ACAS), Asymptomatic Carotid Surgery Trial (ACST), and Veterans Affairs Cooperative Trial were designed to examine whether CEA may be appropriate in the treatment of asymptomatic patients with hemodynamically significant lesions of greater than 60% stenosis as identified by duplex ultrasound. ACST was the largest trial, randomizing 3,120 asymptomatic patients equally between immediate CEA

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Abbreviations and Acronyms

ACAS = Asymptomatic Carotid Arteriosclerosis Study
ACST = Asymptomatic Carotid Surgery Trial
CAS = carotid angioplasty and stenting
CEA = carotid endarterectomy
ECST = European Carotid Surgery Trial
EPD = embolic protection device
EVA-3S = Endarterectomy Versus Stenting in Patients with Symptomatic Severe Carotid Stenosis
NASCET = North American Symptomatic Carotid Endarterectomy Trial
SAPPHIRE = Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy
SPACE = Stent-Protected Angioplasty versus Carotid Endarterectomy

and indefinite deferral of CEA. With a 30-day perioperative stroke and death risk of 3.1%, the findings from ACST demonstrated a significant net reduction in 5-year stroke risk from 11.8% to 6.4%, producing a 5.4% absolute risk reduction for patients undergoing immediate CEA ($p<0.0001$).[6] The ACAS was a smaller study, which randomized a total of 1,662 asymptomatic patients to CEA or medical management, and produced similar results, with estimated 5-year risk of ipsilateral stroke and any perioperative stroke or death of 11.0% for the medical group and 5.1% for the surgical group ($p = 0.004$). Of note, the perioperative complication rate in ACAS was extremely low, at 2.3%, which included a 1.2% risk associated with mandatory preoperative arteriography for all patients randomized to the surgical arm, indicating that only one-half of perioperative strokes were related to the actual surgical procedure itself.[7] Finally, although its sample size was modest ($n = 444$), the Veterans Affairs study also demonstrated that CEA reduced the incidence of ipsilateral neurologic events in a select group of asymptomatic male patients with carotid stenosis.[8]

Subgroup analysis in the previously mentioned studies was limited but offered some insight pertaining to the influence of age and severity of stenosis. With respect to age, findings from ACST suggested no benefit from CEA for patients older than age 75; roughly half of these patients died within the subsequent 5 years from unrelated causes, obviating any durable benefit secondary to a shortened life expectancy.[6] Although ACAS and ACST did not specifically address the impact of degree of stenosis, the ECST study, in the investigation of stroke risk in asymptomatic disease, was able to shed some light on the topic. Of their 2,295 patients, they found that although the overall 3-year risk of stroke was 2.1% in medically treated patients, this rate increased to 5.7% for patients with 70% to 99% stenosis, 9.8% for patients with 80% to 89% stenosis, and 14.4% for those with 90% to 99% stenosis, implying that patients with severe stenosis may comprise a subgroup in whom CEA provides greater benefit.[9]

Indications for carotid endarterectomy

Based on the major landmark CEA trials discussed earlier, the American Heart Association issued treatment recommendations. Symptomatic patients with >50% to 99% stenosis are best treated by CEA if the risk of perioperative stroke or death is <6%, with greatest benefit in those with severe stenosis (>70% to 99%). For asymptomatic patients, the criteria are more stringent, recommending CEA for those with 60% to 99% stenosis if the perioperative risk of stroke or death is <3% and if the patient has a life expectancy greater than 5 years.[10,11]

In practice, few surgeons doubt the benefit of CEA in symptomatic patients with high-grade stenosis, but they are understandably more cautious when evaluating asymptomatic patients or symptomatic patients with only moderate degrees of stenosis. There is a great deal of complexity about risk assessment in these latter groups of patients. So the decision to operate is often made only after careful consideration of patient characteristics and comorbidities reveals reasonable life expectancy, higher risk of stroke with medical management alone, and acceptable perioperative risk. To further complicate matters, medical management has changed considerably since the early CEA trials, perhaps indicating that the stroke risk reduction benefit from operative therapy may be overstated. For example, ACAS used lone aspirin therapy, and ACST, the most recent trial, reported a significant increase in the number of patients on lipid lowering agents who were randomized between 1993 and 1996 (17%) and between 2000 and 2003 (58%).[6,7]

In addition, treatment recommendations as outlined by the American Heart Association are often considered inadequate because they pertain to only a carefully selected subgroup of low-risk patients as defined by study exclusion criteria. For example, NASCET exclusion criteria included, but were not limited to age greater than 80 years, failure of the kidney, liver, or lung, cancer judged likely to cause death within 5 years, and presence of cardiac valvular or rhythm disorder. Patients were also temporarily ineligible if they had uncontrolled hypertension or diabetes mellitus, unstable angina, myocardial infarction within the previous 6 months, and recent major surgery.[2] Based on similar exclusion criteria, patients were also deemed ineligible from ACAS, necessitating the screening of 25 patients for every 1 randomized.[7] As a result, there is valid concern that the general population of patients with carotid stenosis has significantly different demographics than those patients who met strict eligibility criteria in the randomized trials, and in fact, it has been noted that the general popu-

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