Carotid Angioplasty and Stenting versus Endarterectomy: Larger Trials Needed

Brooks WH, McClure RR, Jones MR, et al. Carotid angioplasty and stenting versus carotid endarterectomy: randomized trial in a community hospital. J Am Coll Cardiol 2001;38:1589–95.

Study Overview

Objective. To determine if carotid angioplasty and stenting (CAS) is equivalent to carotid endarterectomy (CEA) for symptomatic, high-grade carotid stenosis.

Design. Randomized controlled trial. Allocation concealment and blinding were not described.

Setting and participants. 104 subjects recruited from a single community hospital. Subjects were eligible if they had more than 70% stenosis of carotid bifurcation with ipsilateral symptoms (eg, stroke, transient ischemia, or amaurosis fugax) within the past 3 months. Subjects were excluded for life expectancy less than 5 years; inability to give consent; National Institutes of Health stroke scale score greater than 4; arrhythmia; allergy to the drugs used; history of bleeding diathesis; vertebral-basilar or intracranial occlusive disease; or intracranial hemorrhage in the past 2 months.

Intervention. Subjects were randomly assigned to CAS with heparin and abciximab when necessary (3 patients) or to CEA. All patients received aspirin and clopidogrel.

Main outcome measures. The primary endpoint was not described. The number of deaths, stroke, transient ischemic attacks, and several other major and minor complications were reported. Serial ultrasound measurements of internal/common carotid velocity were taken at 1, 3, 6, 12, and 24 months. Magnetic resonance imaging (MRI) was performed at 6 and 12 months, and a neurologic examination was done before and after each procedure. Pain perception, hospital length of stay, and costs were assessed as well.

Main results. 1 death occurred in the CEA group. There were no strokes. 1 person in the CAS group had arterial thrombosis requiring lower extremity amputation. Overall, there were 24/53 complications in the CAS group and 9/51 in the CEA group. Carotid patency was good in both groups. No strokes were detected by MRI in either group.

Conclusion. The authors conclude that CAS is equivalent to CEA in reducing carotid stenosis without increasing the risk of major complication.

Commentary

Showing the equivalence of 2 treatments is difficult. The authors achieved a very low rate of death or stroke (1%) for the entire study group. This rate is lower than in larger earlier studies of either percutaneous or surgical treatment for carotid disease [1,2]. These differences could be due to chance, different patient characteristics, excellent operator skills, or a combination of factors. While the low event rate is a blessing for the patients, it leaves the authors with little they can accurately say about how CAS and CEA compare with each other. At the outset, it would require about 3000 subjects in each group to exclude with 90% certainty a twofold difference in the risk of stroke or death occurring at the rates of 1% and 2% respectively in the CEA and CAS groups. Even for outcome rates of 6% and 12%, over 400 subjects in each arm would be needed to exclude this twofold difference. It should have been clear before the study began that 50 patients in each arm would not exclude clinically important differences in outcomes and could never support the conclusions that the authors reach. The authors do cite some limitations of their study but seem unaware of the critical limitation imposed by sample size. The authors' statistical analysis and conclusions regarding length of stay and costs are also inappropriate.

Percutaneous interventions have changed dramatically over the past decade. Intravascular stents have been introduced and refined, new antiplatelet agents have been put into use, and new procedural techniques have been developed. The Carotid and Vertebral Artery Transluminal Angioplasty Study trial published this year is already outdated given the fact that only 26% of the percutaneously treated patients received stents [1]. This trial found generally similar results for percutaneous and CEA treated patients although it, too, was limited by its small sample size (504 patients). Two other trials that compared CAS with CEA were stopped early because of significantly worse outcomes in the CAS groups [3,4]. Poor outcomes due to CAS in some trials have been attributed to the inexperience of the operators performing CAS [5]. A large