Editorial

Carotid artery disease: is the debate over?

There have been few issues in cardiovascular medicine that have been of more concern and contention than the role of carotid artery surgery for the prevention of stroke. Interestingly, the first randomized trial concerning this operation was reported in 1970 and showed that patients who underwent an operation had a lower stroke rate in the long-term than those in the non-surgical arm of the trial, but this benefit was lost when the surgical morbidity and mortality rates were taken into account. The debate became more acute with the report of Easton and Sherman in 1977, who noted that the combined morbidity and mortality from carotid endarterectomy in a single community was 21%. Following these reports articles began to appear challenging the role of endarterectomy and pushing for randomized clinical trials to settle this debate. While there were reports showing that the morbidity and mortality from the operation did not approach those seen in the first randomized trial or the report by Easton and Sherman, the results were considered to be highly suspect because they were not reported from a randomized trial. However, there were objective follow-up studies that examined the relationship between the degree of stenosis and its rate of progression. These studies showed that the ischemic event rate could be related to the degree of stenosis with the >80% diameter-reducing lesions being the most dangerous. These early observations made in the 1980s will be important to remember when the results of the randomized trials are examined.

There were three major, large clinical trials mounted to examine this issue. The two devoted to the study of the symptomatic patients were the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the European Carotid Surgery Trial (ECST). The NIH-supported study of asymptomatic patients (ACAS) was the only large trial that examined this important subset of patients. It is important to emphasize that there were considerable differences in these trials both in terms of the design and diagnostic approaches used that are not often mentioned. The NASCET and ECST trial results were reported over two time periods – up to 1991, with the final results reported in 1999. The early reports from 1991 showed that individuals with arteries that were narrowed by >70% had a lower stroke rate in the surgical treatment groups than those in the medical arm of the trial. It must be mentioned that a 70% stenosis is not the same in these two trials owing to the methods used to evaluate the arteriograms. Interestingly, the final reports of the NASCET study showed that operation provided significant benefit, even with lesions that were in the >50% diameter-reducing category. Thus, it appears and no one disputes this level one evidence that carotid endarterectomy was more effective in stroke prevention than conventional medical therapy.

The ACAS trial, while well designed and carried out, has been the source of a great deal of controversy. The trial design was different in that the degree of diameter reduction examined was predetermined to be those that narrowed the artery by 60% or more. Arteriography was done only in the surgical arm of the trial so there is no information on the relationship between the degree of narrowing above 60% and stroke in the medically treated group. This is unfortunate. However, the trial did show that the stroke and death rates were lower in the surgical arm of the trial than in the medically treated patients. The level of risk reduction was not what some had hoped for and in fact has led many to challenge the widespread use of this operation in asymptomatic patients because anywhere between 10 and 20 patients would have to have the operation to prevent one stroke. ACAS did show that the perioperative stroke rate in the surgical arm of the trial was remarkably low (2.7%). This number included the strokes associated with arteriography. A sobering fact noted was that arteriography carried nearly the same risk of stroke as operation (1.2%). The dangers of arteriography have always been known but have been accepted as a necessary occurrence given the need for documentation of the location and degree of involvement.

Since the evolution of ultrasonic duplex scanning, there are some, including the present author, who believe that the studies are adequate in over 90% of cases to proceed directly with operation and avoid the cost and potential risk of arteriography. This is hotly debated, with Dr Henry Barnett taking the stand that this should not be done. While it is up to the reader to decide which course should be followed, there is no evidence that using ultrasound alone (properly carried out) will add to the risk of the procedure. This approach will save a great deal of money, shorten the hospital stay and totally eliminate the complications associated with arteriography.

While the clinical trials provide what could be classified as level one evidence in favor of carotid endarterectomy, the ACAS trial has been criticized as not providing convincing evidence that a >60% stenosis should be treated surgically. This debate leaves the physician with another dilemma because there are many patients who possess such a lesion and how should they be approached?

Since there is so much debate remaining with regard to the asymptomatic patient, even though the one large NIH-supported trial concluded that operation was beneficial, what sort of stance should one take? It is clear that another comparable trial is not going to be done to answer this question. Here I am going to have to rely on the natural history data with regard to asymptomatic patients that were reported in the 1980s and more recently in 1995. We concluded from these studies that the lesions of greatest risk were the >80% diameter-reducing lesions and these were the ones that deserved our surgical attention. Interestingly, it is just these lesions in the symptomatic patient that carry the greatest risk for a completed stroke when the patients are treated medically. Can we extrapolate that similar degrees of narrowing carry the same risk in these two
groups (a/symptomatic) of patients? The skeptics would clearly say no because it has not been proven by another trial, yet our own data show that the risk is very high with the >80% lesions and this fact has never been refuted. Can a reasonable stand be taken with regard to the 60% stenosis? My own view is that careful prospective follow-up every 6 months by duplex scanning can detect progression, permitting this to be the indication for intervention. This is the practice of many physicians and it does represent a satisfactory compromise in my view.

There is a view that I do believe is wrong and must be aired. A consortium of Canadian neurologists have essentially taken the stand that no one should be screened for carotid artery disease, even those with risk factors associated with carotid artery disease. They are urging the medical community to ignore the asymptomatic patient who may harbor a carotid artery lesion, and thereby recommending a head-in-the-sand approach to this disease. I would hope that most American neurologists would join me in condemning this approach.

Finally, a new debate has surfaced which will be with us for some time. Given the success of stents in some areas of the circulation, this is now being proposed for the carotid artery as well. This is now the source of considerable debate. The debate has led to the mounting of a randomized clinical trial against endarterectomy. The NIH has approved this trial with randomization to begin sometime in the spring of the year 2000. An excellent editorial appeared in Vascular Medicine by Mr Peter Bell concerning the debate over the role of stenting and I urge that those who are interested in this problem review this considered opinion.

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