Editorial

Concern About Safety of Carotid Angioplasty

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Stroke risk reduction for the large majority of patients with high-grade carotid stenosis is presently best accomplished by carotid endarterectomy. When properly applied according to clearly identified standards and guidelines, this treatment is effective, safe, and durable.1,2 The results of recent large randomized trials demonstrate conclusively not only the effectiveness of surgical therapy for symptomatic and asymptomatic patients in reducing stroke incidence but also the importance of careful studies in providing definitive information.3,4

With this background of hard-won experience, we view with concern the application of catheter-based angioplasty techniques to carotid artery bifurcation and internal carotid artery disease. Reports of such techniques can be found in small published series characterized by lack of complete descriptive information and absent or limited outcome and follow-up data.5-18 Carotid angioplasty with or without stenting has also been promoted widely in continuing education programs, suggesting that it is an established procedure when in fact it is an experimental procedure.

Legal and ethical considerations require that any patient subjected to unproven therapy be completely informed about its experimental nature and the availability and expected outcomes of proven safe and effective alternatives. Only then can a patient freely choose an experimental therapy with unknown safety or efficacy and acknowledge informed consent. Currently, carotid artery dilatation is not an approved indication for percutaneous transluminal angioplasty catheters. Carotid angioplasty applied with devices not authorized for such use in an experimental setting requires documentation of approval by oversight authorities, including an institutional review board.

We are in favor of well-controlled, scientifically valid exploration of any new therapy with potential for improving patient outcomes and/or reducing cost. We recognize that carotid bifurcation angioplasty has the potential of achieving these objectives. However, it also could carry the risk of increased stroke, death, and disability. Therefore, it must be carefully evaluated for both safety and efficacy before widespread use or randomized comparison with carotid endarterectomy is undertaken.

Contemporary reports of broadly based carotid endarterectomy trials have shown short-term major morbidity and mortality risk in the range of 3% or less. Morbidity from diagnostic arteriography alone has been reported to be similar to that of endarterectomy.6,19,20 No report has been published describing a carotid endarterectomy for recurrent disease after carotid bifurcation angioplasty and stenting. Therefore, it is unknown whether such an angioplasty obviates a patient's subsequent access to the standard treatment option.

We believe that to undertake a meaningful evaluation of carotid angioplasty, with or without stenting, a trial for evaluation of safety and efficacy must be the first step. Absolute requirements for such a trial would include (1) independent qualified neurological assessment before and after the procedure; (2) carotid duplex imaging before and after the procedure, including plaque characterization data; (3) brain imaging, such as MRI, before and after the procedure to document evidence of possible embolism; (4) life-table reporting of follow-up information for at least 1 year to include neurological status and anatomic status of the treated arterial segment; and (5) interdisciplinary peer review with data monitoring by experts not otherwise connected with the trial and in compliance with accepted conflict-of-interest principles.

The use of catheter-based angioplasty and stenting techniques for treatment of carotid bifurcation or inter-
nal carotid artery atherosclerotic disease currently lacks proof of safety or efficacy. Uncontrolled use of these methods is inappropriate and does not provide results that can be understood and interpreted by the general medical community. We are concerned to see angioplasty with or without stenting adopted prematurely as an alternative to carotid endarterectomy, which has been scientifically studied and proven to be effective.

References

Key Words: angioplasty • carotid artery diseases • carotid endarterectomy • risk factors