

Carotid Angioplasty and Stenting: Current Status

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The main stay of treatment for atherosclerotic carotid artery disease has been endarterectomy. The North American Symptomatic Carotid Endarterectomy Trial (NASCET) clearly demonstrated that surgical endarterectomy was superior to medical therapy in the prevention of stroke in patients with symptomatic carotid stenosis (1). This also seems to be true, although somewhat less convincingly, for asymptomatic carotid stenoses as shown by the Asymptomatic Carotid Artery Stenosis Trial (ACAS) (2).

Percutaneous transluminal angioplasty with stenting has been used as an alternative to surgery in virtually all larger vessels of the body including the coronary and peripheral circulations. However, only recently has this procedure expanded into cervical carotid bifurcation lesions. At this point in time however, carotid angioplasty and stenting remains an experimental procedure. Although data is accumulating, it remains limited at this time.

Available data can basically be divided into case report/case series, database analyses, and controlled clinical trials. It is the latter of course that determines the actual clinical utility of the procedure.

Many case reports and small case series regarding various aspects of the procedure have been presented. Probably the single most important single center data base analysis was the original publication by Yadav, et al from the University of Alabama (3). This study included 107 patients with 126 carotid lesions and reported peri-operative complications (up to 30 days following the procedure). Minor strokes occurred in 7% of the patients, major strokes in 2%, and death in 1%. The importance of this study was that it actually demonstrated that carotid angioplasty with stenting could be performed relatively safely with reasonable results.

At this time, there have been two controlled clinical series. The original, the "Wallstent Trial" which was sponsored by Schneider (USA) Inc. and subsequently Boston Scientific Corp. began enrollment in January 1997. The results have only been presented in abstract form, but plans are in place to publish the final results in the Fall, 2002. This study randomized 221 patients and was discontinued July, 1999 because the primary hypothesis could not be proven based on a lower than expected stroke rate in the surgery arm and a higher than expected stroke rate in the stent arm. The other controlled trial is the European Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) (4). In this study published last year, 504 patients were randomized to endarterectomy versus endovascular treatment. It should be noted, that only 26% received stents and over 30% of those a balloon expandable stent. Peri-operatively (up to 30 days), there was no difference in major outcomes between the two arms. However, at one year, ipsilateral carotid stenosis was more frequent in the endovascular arm (14%) than in the surgical arm (4%). There was however no difference in ipsilateral stroke. This prompted the authors because of wide confidence intervals to not recommend the wide spread introduction of endovascular techniques for the treatment of carotid stenosis as an alternative to surgery.

There are currently two types of studies underway. The first are manufacturer-based studies. Although there are many such studies, the three major manufacturers Johnson & Johnson Corp., Boston Scientific Corp., and Advanced Cardiovascular Systems, Inc. are in trials regarding their protection device. All of these trials include a registry, although the Johnson & Johnson (SAPPHIRE Trial) has a randomization arm. All of these are in surgically “high risk” patients. A single controlled trial regarding carotid stenting is currently underway. This is sponsored by the National Institute of Neurological Diseases-National Institute of Health (NINDS-NIH) and is the Carotid Re-vascularization Endarterectomy versus Stent Trial (CREST). The study has a planned enrollment of 2500 patients between the two arms. As of this writing, 54 centers are approved, although only a few have begun the randomization phase.

Currently, carotid angioplasty and stenting is still under investigation. Clearly the early results are promising, but further studies will be required to determine where this treatment modality actually fits in the treatment of atherosclerotic disease of the carotid arteries, particularly relative to carotid endarterectomy.

References

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