Still Waiting for the Impact

The FDA approval and CMS coverage of carotid artery stenting (CAS) was predicted by many physicians and Wall Street analysts to have a practice-altering impact on the vascular community and market. Most people were of the opinion that CAS would likely replace carotid endarterectomy (CEA), which is the most commonly performed vascular surgical procedure in the US, with approximately 160,000 performed annually. In addition, unlike endovascular aneurysm repair or percutaneous transluminal angioplasty, for which stenting and open surgery can coexist due to the complimentary nature of the procedures, CAS can treat almost all patients who can undergo CEA, and thereby has the potential to replace it. In fact, the 2003 Morgan Stanley report predicted that 75% of all carotid procedures would be performed by CAS in 2006, which is now only 4 months away.

As forecasted, CAS made landfall on the dates that we predicted. Guidant's Acculink system was approved in August 2004, and the CMS national noncoverage policy that restricted CAS outside the confines of a clinical trial was revised in March 2005. It has already been 5 months since CAS became a practical therapeutic option for many physicians, but the predicted impact has yet to be felt, leaving many wondering why.

The CMS policy on reimbursement has single-handedly downgraded the storm. It has restricted reimbursement to high-surgical-risk patients with symptomatic stenosis >70%, which represents about 7% of the US CEA market. Also, the CMS policy has restricted hospitals as well as physicians to some extent by requiring certain criteria. All of this has been bad news for many interventionists and the industry that seeks to recover its investment. The group who has benefited is the vascular surgeons, many of whom were not ready for the change CAS was predicted to elicit. In fact, the gradual release of this new technology has allowed many vascular surgeons to play catch-up. Furthermore, the CMS document requires that every CAS procedure be approved and agreed upon by a surgeon to be "high risk."

In order for CMS to cover asymptomatic and low-risk patients, it will likely require more data to be derived from major trials, such as Abbott's ACT I trial, the CREST trial that started enrollment of asymptomatic patients, and Cordis' intermediate-risk trial, all of which will take another 2 to 3 years to complete. In the meantime, more CAS devices will be approved by the FDA. Within the next several months, physicians should have access to the Cordis, Abbott, Boston Scientific, and ev3 carotid stenting systems; the CAS market will rapidly become saturated with little hope of immediate expansion.

This issue of *Endovascular Today* provides a comprehensive look at the state of CAS, beginning with a feature from Rodney White, MD, a leading authority in the field. Dr. White discusses the evolution of endovascular technology's less-invasive appeal and some of the controversies surrounding current CAS treatment indications. We are also pleased to feature the latest results from the TACIT, CREST, and ACST trials, which explore the application of CAS in asymptomatic patients. I take a critical look at the issues of training and accreditation for CAS and the Guidant and proposed Cordis training programs, since there seems to be some confusion related to this matter. You'll also find the latest CAS trial clinical update chart, which outlines the current study designs and details on the available devices. We also interview Gary Ansel, MD, who is one of the best peripheral interventionists in the world. He is also a good friend who has helped me personally during rainy days.

As one of the founding editors of *Endovascular Today*, I am extremely pleased that we can provide the most timely and complete coverage of critical issues related to the development of this transformational technology. ■

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