CAS Has Arrived!

The past several months have been exciting due to the advancement of a new, less-invasive therapy for carotid artery stenoses. The recent approval of the Acculink and Accunet devices manufactured by Guidant Corporation, and the preliminary approval of the Angioguard and Precise stent by Cordis, represent a landmark advance in the application of less-invasive therapy for carotid artery disease.

Data presented in the SAPPHIRE Trial, as well as the ARCHeR Trial, and other registries currently completed or near completion, have demonstrated clear benefit to patients with critical carotid artery stenosis (>80%) who are considered high risk for endarterectomy based on clearly defined parameters.

In this month's issue of *Endovascular Today*, Bernard Reimers, MD, and colleagues have provided an excellent overview of many of the principles, as well as the specifics of carotid angioplasty and stenting. I have found it interesting that throughout the world, technical approaches to carotid artery stenting have become relatively uniform. Adherence to proven techniques and, in particular, indications will be critical as this technology moves forward and new operators are trained.

In the US, the outcomes of dissemination of this technology will be highly monitored by FDA-mandated postmarket surveillance studies. Hopefully, these studies will prove that the techniques and skills that have been learned by clinical investigators participating in many trials can be safely transferred to more novice operators.

Adherence to appropriate indications for therapy will be an important part of these postmarket surveillance studies. In this regard, Thomas G. Brott, MD, and Robert W. Hobson, MD, make a compelling argument for the conservative application of carotid revascularization, whether by stenting or endarterectomy, particularly in asymptomatic patients.

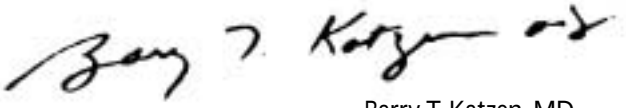
Most patients in the US currently undergoing revascularization therapy are asymptomatic patients. One of the positive aspects regarding the clinical trials in treatment of asymptomatic patients was the fact that the level for therapy was raised to >80% based on angiographic criteria. This is an extremely high bar to reach and, hopefully, can prevent unnecessary revascularization in patients with <80% stenosis who have had no significant symptoms.

In an enlightening interview regarding the regulatory process for carotid stents, Dorothy B. Abel, Acting Chief of the FDA's Peripheral Vascular Device Branch, and Glenn Steigman, Biomedical Engineer, address many of the questions that have been raised by this particular approval process.

On September 1st, CMS announced its intention to expand coverage of percutaneous transluminal angioplasty of the carotid artery with placement of Guidant's newly approved system. Certainly, this close collaboration between CMS and FDA to provide a timely solution to reimbursement is greatly appreciated and appropriate. Specifically, they support reimbursement to allow the postapproval studies to move forward to determine whether this technology can be generalized to other populations, settings, and treatments, with equal outcomes. The interview with Marcel E. Salive, MD, will provide great insight to the position of CMS in this regard.

Finally, Robert L. Worthington-Kirsch, MD, discusses uterine fibroid embolization (UFE), a valuable endovascular procedure that offers an important alternative to hysterectomy. UFE has clearly proven to be an effective procedure, yet its dissemination has been limited by the fact that physicians providing the service are not the ones providing primary care to patients as they present. This fact has generated several recent news stories, including those in *The Wall Street Journal*, and a recent feature on ABC's *20/20*, regarding the reluctance of OB/GYN physicians to recommend a procedure that they do not perform.

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. I'm sure you will find this one of the most "power packed" and relevant issues of *Endovascular Today*, adhering to our original mission of bringing you the most timely and important information that will affect your practice. ■



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