The State of CAS

With no recent device approvals and no changes in US-based reimbursement over the last 7 years, the carotid artery stenting (CAS) landscape has recently appeared, on the surface, fairly unchanged. However, significant shifts have occurred from the individual practice level to the global market. Examining what brought the field to its current state is crucial for understanding future changes. It is in that spirit that we've brought together members of the FDA, industry representatives, and physician experts to review the status of CAS.

Sadaf A. Toor, MS; Kenneth J. Cavanaugh Jr, PhD; and Lisa M. Lim, PhD, open our carotid focus with an explanation of the FDA's regulatory review process with regard to CAS and embolic protection devices and how this affects practice. They review early CAS clinical studies and device approvals, as well as the FDA's requirements for stent and embolic protection device use. We continue to seek answers to the question of which patient populations are most appropriate for the various devices available.

Perhaps more than any other vascular technology in recent years, carotid stenting has been severely affected by CMS's national coverage decisions. Our industry colleague Antoinette L. Sheen, MBA, summarizes the history of CMS policy, starting with the 1981 noncoverage policy decision for percutaneous transluminal angioplasty through the 2012 MEDCAC. Patrick Verta, MS Stat, MD, explains how lack of coverage expansion may negatively influence the future of technological refinement in this space.

The FDA requires manufacturers of approved CAS devices to conduct postmarket surveillance studies to ensure continued safety and effectiveness, but with no new devices for CAS on the horizon, we may face a period without any ongoing postmarket studies. Herbert D. Aronow, MD, MPH, details what this means for the CAS landscape.

Brajesh K. Lal, MD; James F. Meschia, MD; and Thomas G. Brott, MD, provide an overview of CREST-2, which will comprise two parallel, randomized trials comparing CEA plus medical management versus medical management alone and CAS plus medical management versus medical management alone. This multicenter study will make use of the infrastructure provided by CREST. Some aspects of the trial design will be finalized in the months ahead before enrollment begins. Later in our feature, Dr. Gray discusses the clinical and trial design challenges that must be overcome in order for CREST-2 to deliver the results this field is hoping for. There is much anticipation and excitement over future CAS study, but reimbursement issues and the possible lack of device availability could prove to be problematic.

The prospective, single-arm, multicenter ROADSTER trial began enrollment in early 2013. This trial is designed to study symptomatic and asymptomatic patients at high risk for CEA treated with transcarotid artery stenting with dynamic flow reversal. Christopher J. Kwolek, MD, and Silk Road Medical Vice President Richard M. Ruedy detail the procedure and how a direct approach combines the advantages of CEA and CAS with proximal reverse flow embolic protection.

This month's departments include a discussion from Ripal T. Gandhi, MD, and his colleagues on iliocaval DVT management, as well as an EVAR update from Peter R. Nelson, MD, MS, FACS, and Benjamin W. Starnes, MD, FACS, about the adoption of a percutaneous approach to treatment.

We wrap up our issue with Robert M. Bersin, MD, sharing his perspectives on CAS, percutaneous EVAR, and what it means to manage the whole patient. We welcome your feedback on this issue of *Endovascular Today*. ■

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