EVAR 2004: Lots of Good News and Some Bad News

It has been more than a year since we featured AAAs as the cover story. Since then, a number of significant events, mostly positive but also some negative, have taken place. In the US, two additional endografts gained FDA approval and were welcomed onto the market—the W.L. Gore Excluder and the Cook Zenith. The Excluder has the lowest profile delivery system among all endografts and, coupled with its user-friendly deployment mechanism, it has made endografting even quicker and safer. The Zenith can treat a larger assortment of patients because it provides larger proximal and distal stents. It has also proven to be extremely durable.

The Edwards Lifepath, the Endologix Powerlink, and the Cordis Fortron have completed pivotal US trials. In addition, there are exciting next-generation devices on the horizon, including Trivascular Enovus (the first percutaneous endograft), Vascutek/Terumo Anaconda, Nano Endoluminal Apolo, and Vascular Innovation's Parodi Endograft. Each device has unique assets and will most likely improve the outcomes and expand the indications of EVAR.

On the negative side, we lost the Ancure after Guidant withdrew it from the market in October 2003. In March 2001, Guidant admitted it had failed to submit 2,628 Medical Device Reports out of a total of 7,632 medical devices sold during 1999-2001. Interestingly, the vast majority of these events were benign, and did not result in clinical sequelae. However, some patients were hurt and the Department of Justice (DOJ) conducted a criminal investigation. The DOJ convicted the company on 10 felonies, for which Guidant pleaded guilty and paid $92.4 million. Ironically, none of the allegations were related to the long-term performance of the Ancure, which probably had the best long-term outcomes among existing endografts. The lessons to be learned from this event are: (1) medical device reporting applies to information gained from any source (eg, case reports and proctoring), and (2) breaking the rules can lead to actions by the FDA and/or DOJ, irrespective of device performance.

In 2003, the US endograft market size shrank ($243M for 2002, $230M for 2003) for the first time, despite the addition of two new endografts. This was probably due to the negative press related to the Ancure scandal. Also, the results of the UK small aneurysm trial and the ADAM trial both showed a better than expected natural history of untreated AAAs, and they have raised the threshold for aneurysm treatment.

This issue of *Endovascular Today* has several important articles. Peter Harris, MD, provides us with an update of the EUROSTAR registry, the oldest and largest EVAR registry, which has provided us with much useful and important information. Also, John Anderson, FACS, FRACS, the pioneer in fenestrated and branched endografting, provides us with an update of this technology. Such techniques hold great promise and will definitely further expand the indication of EVAR. Barry Katzen, MD, provides insight regarding an integrated team approach to treating AAAs. Regarding wireless pressure sensing of the aneurysm sac, both Remon Medical Technology and CardioMEMS have successfully performed implants in humans, and this technology will also become a hot topic in the days to come. Also, we will revisit closure devices.

Although the US endograft market shrank in 2003, world-wide market penetration is still less than 20%, and there is no approved endograft in Japan, we believe that EVAR holds great promise. The results of ongoing randomized trials comparing EVAR and open surgery, as well as the performance of next-generation devices, will determine the future of this technology. *Endovascular Today* will be there to cover these evolving stories. ■

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