Evaluating New EVAR Device Technology

Andrew Holden, MBChB, FRANZCR, provides his unique perspective on EVAR and a look at his latest trial experiences with new technologies.

How is your perspective as a New Zealand practitioner particularly unique regarding the current treatment of aneurysms?

Dr. Holden: Australian and New Zealand interventionists were early innovators of endovascular aneurysm repair (EVAR) technology. I was fortunate to be involved in my first EVAR case in 1994, and during the following 15 years, there has been tremendous development in endovascular technology. Based on our experience of very low periprocedural morbidity and mortality associated with EVAR procedures, we evaluate all infrarenal abdominal aortic aneurysms (AAAs) for possible endoluminal repair. We also have extensive and positive experience with advanced techniques to treat thoracoabdominal aneurysms, such as fenestrated and branch grafts and debranching procedures.

How would you describe the regulatory and reimbursement environments for EVAR in New Zealand?

Dr. Holden: The regulatory environment in New Zealand facilitates early access to new technologies. Although national and regional ethics committees rigorously evaluate research proposals for patient safety and informed consent, generally, there is a supportive environment working toward thorough scientific evaluation and introduction of promising new technologies. This regulatory approach, combined with high-quality, state-funded tertiary hospitals attached to internationally recognized universities, provides an ideal environment for the evaluation of new technologies such as advanced EVAR systems.

What are the strengths and weaknesses of the current EVAR systems?

Dr. Holden: Current EVAR devices can achieve immediate exclusion in up to 60% of infrarenal AAAs. However, the vast majority of modern devices require proximal and distal attachment site sealing to successfully exclude the aneurysm. Challenging proximal neck anatomy (ie, short, angulated, conical, or diseased neck) is the most common contraindication to treatment with routine EVAR devices; however, challenging distal attachment site anatomy (ie, iliac artery dilatation or tortuosity) may also exclude an EVAR approach.

The durability of current EVAR devices is also a concern, with most published trials reporting significant reintervention rates for complications such as endoleak and limb kinking. The cost of reintervention and rigorous postprocedural surveillance means that EVAR with current technology is less cost effective than open surgical repair.

As one of the early trialists using the Nellix fillable EVAR technology (Nellix Endovascular, Palo Alto, CA), what can you tell us about the trial's design and goals?

Dr. Holden: At Auckland Hospital, we have been participating in a multicenter, prospective, single-arm, nonrandomized trial evaluating the Nellix EVAR technology. A comparative control arm is derived from patient data drawn from the AAA open-surgical control arms of four

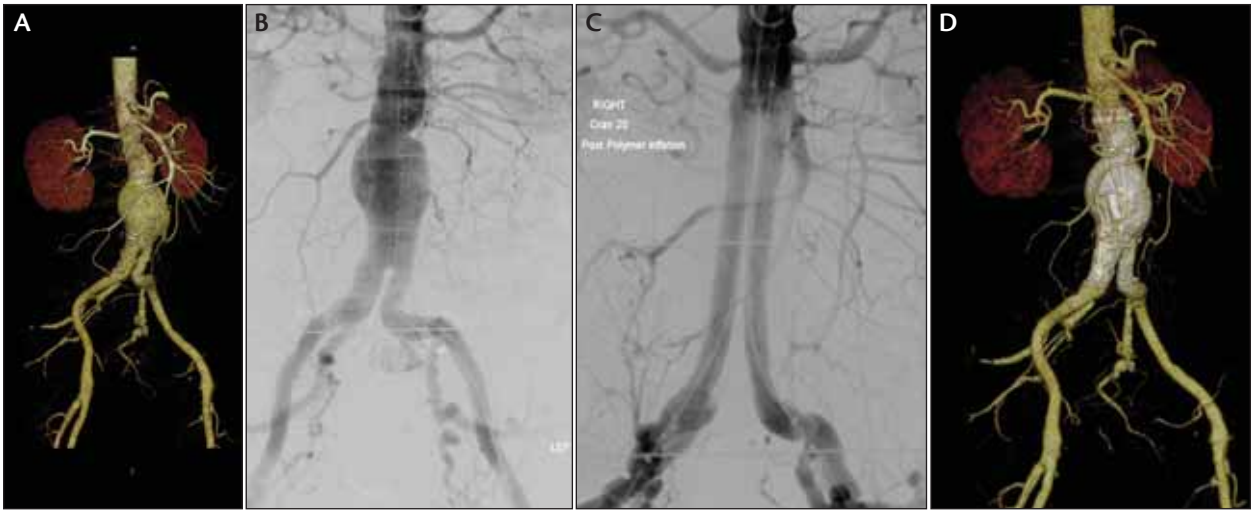

Figure 1. Infrarenal AAA volume demonstrated on volume-rendered computed tomographic angiography. Note the inferior mesenteric artery arises from the aneurysm (A). Calibrated catheter angiogram before EVAR (B). Completion angiography following aneurysm exclusion by the Nellix EVAR technology. The endoframes maintain flow lumens through the aneurysm while the aneurysm sac is excluded by polymer-filled endobags. The endobags are not visible on digital subtraction angiography (C). Computed tomographic angiography performed after EVAR. The endobags fill the aneurysm sac. Note the inferior mesenteric artery trunk is occluded (D).

commercially approved EVAR devices. These data were obtained from the Society for Vascular Surgery.

Patients in the trial are screened to meet a predetermined set of inclusion and exclusion criteria. The primary goals of the study are to determine the technical success of the device, the ability to deliver and place the device in the desired target area, freedom from the need for additional intervention, and freedom from enlargement of the aneurysm sac.

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With the goal of the Nellix system to anchor the graft by filling the aneurysm with a polymer, have you seen an improvement in fixation?

Dr. Holden: Although long-term data are limited (five patients at 1 year and 16 patients at 6 months), the preliminary observations of the Nellix system have shown no device migration. Because the majority of the blood volume within the aneurysm sac is occupied by polymer-filled endobags with this technology, fixation should not conceptually be a problem, and our early observations are consistent with this.

Have you seen any evidence suggesting that Nellix could offer EVAR treatment to patients with difficult anatomy (ie, small or angled necks, limited landing zones)?

Dr. Holden: Early fixation results have been encouraging. The major appeal of the Nellix system is its potential to seal infrarenal AAAs with challenging neck and iliac anatomies. This is because sealing with this device is not achieved by graft-wall apposition (as with current EVAR device technologies), but via the polymer-filled endobags (Figure 1). Our experience is limited, but short and angulated infrarenal necks, as well as dilated iliac arteries, have been successfully treated with the endobags conforming to underlying anatomy, including neck geometry. To date, 100% aneurysm exclusion has been achieved with no endoleaks.

Although filling the aneurysm could theoretically improve stability and promote fixation, foreign matter is left permanently in the vessel. Do you have any concerns about how this may affect long-term outcomes?

Dr. Holden: The Nellix EVAR technology involves a cured, biocompatible polymer inside enclosed endobags. The outcomes, based on successful preclinical studies (including long-term animal studies), have demonstrated excellent polymer-filled endobag durability. The clinical results to date have supported these findings.

(Continued on page 69)

(Continued from page 68)

One of the clinical endpoints monitored after an EVAR procedure has been regression or remodeling of the aneurysmal sac. If, by its natural course, the aneurysmal sac did shrink or change shape after use of the Nellix system, is there any indication of how the polymer will react within the vessel, or the vessel's reaction to the prevention of movement?

Dr. Holden: It is too early to adequately answer this question. However, it should be pointed out that the degree of aneurysm shrinkage occurring with the Nellix system is less than that with standard EVAR devices, because much of the original blood volume within the aneurysm sac is occupied by endobags. Absence of sac enlargement is likely to be the most important endpoint after EVAR with the Nellix system, rather than aneurysm shrinkage. That being said, our early experience has indicated that there is resorption of mural thrombus after EVAR with the Nellix system, and the degree of overall aneurysm shrinkage is likely to depend on the volume of mural thrombus within the pretreatment aneurysm sac. It may be that the endobags surrounding the endoframes prevent major morphological changes after sac shrinkage, but this is just a postulate at this stage.

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What are some of the other technologies you have been studying, or trials in which you have recently participated?

Dr. Holden: We have been involved in a number of EVAR-related studies, including strategies to prevent rather than treat type II endoleaks, the development of magnetic resonance–visible EVAR devices, and the evaluation of branch graft technologies. Other recent peripheral arterial studies have included first-in-man studies evaluating lower limb arterial stents, closure devices, and hemodialysis access devices. We have also been major contributors to the ICSS (carotid stent versus endarterectomy) and CORAL (renal stent versus medical therapy) trials. ■

Andrew Holden, MBChB, FRANZCR, is Director and Associate Professor of Interventional Radiology at Auckland Hospital and Auckland University School of Medicine in Auckland, New Zealand. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Holden may be reached at +64 21575227; andrewh@adhb.govt.nz.