Commentary on ‘EVAR Deployment in Anatomically Challenging Necks Outside the IFU’

A. Chaudhuri
Bedfordshire Vascular Unit, Bedford Hospital NHS Trust, Kempston Road, Bedford MK42 9DJ, United Kingdom

Although neck-related IFU for most devices is similar, this is becoming a movable feast with newer devices that accept shorter/hyperangulated/conical necks. Lee et al.1 look at deployments of devices (exemplified by demonstrative graphics) outside the typical neck IFU of 15 mm length with <60° angulation. The devices, among the Cook Zenith and Gore Excluder, however, include the AneuRx, which (despite the undisputed knowledge of the authors and notwithstanding its role in device evolution about a decade ago2) is now an archaic device that is still being used surprisingly, despite concerns regarding integrity, narrow application scope, high delayed rupture rates,3–5 and even an FDA warning in April 2001.6 Furthermore, FDA approval for devices to be used for short necks (Ovation; January 2013) and neck angulations up to 90° (Aorfix; February 2013) relaxes the relatively narrow IFU constraints that the authors have been working within, and this highlights the evolution of EVAR itself and regional variations in practice, both with devices and procedure. The Nellix device, as the authors know, offers similar potential.7

An issue raised by some is whether treating patients outside IFUs represents an ethical challenge, and, although higher graft-related adverse events were reported for the AneuRx, events as a result of deployments outside of IFU were not device-specific.8 Although disagreeing somewhat with the ethical concerns given that there must be an element of flexibility in how we use devices (no one in their right minds would use a standard device for 5 mm neck length), I would agree that there is enough in the literature to suggest moving away from the AneuRx altogether now. As migration is an issue in this scenario, moving towards the Cook Zenith makes sense, and, importantly, the re-emphasis on ballooning the top (which is my standard practice) is welcome.

Another significant issue is that as screening programmes pick up people with smaller aneurysms, it is much more likely that they will have favourable necks and therefore the need to deploy devices out of IFU will likely diminish once screening becomes more widely established, which relates conversely to this paper. Parallels from small AAA EVAR trials9 also imply driving down the numbers of devices deployed outside of IFU, potentially reducing the cost associated with the recognised high re-intervention rate in this scenario and, as an extension, perhaps even lower numbers of fenestrated EVARs undertaken.

Thus, although most centres will typically have a ‘workhorse’ device, and this study indicates that EVAR may be undertaken in patients with unfavourable neck anatomy (which is a boundary most advanced endovascular operators push even when discounting modern CHIMPS applications, exemplified by Fig. 1), perhaps the choice of device in the first place is open to question. In particular, when the non-IFU patients were largely treated with the Cook Zenith—if applicable to the “adverse” scenario, why not use it in the “friendly” scenario? Having said that, this is a real-life presentation of their practice, including issues such as patients lost to follow-up, and I agree this is the world we live in, but then, we must also move on.

REFERENCES