NICE AAA Guidance: Where We Are Now and How We Got Here

An overview of the criticism, support, and validity of the draft guidelines for managing abdominal aortic aneurysms, plus a first look at the finalized guidance.

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The National Institute for Health and Care Excellence (NICE) is a well-respected body in the United Kingdom (UK), operating independently of the government and Royal Colleges and with a long history of advisory publications regarding new drugs, new medical techniques, and the management of a wide range of conditions. NICE guidance is advisory rather than mandatory but is seen as "best practice" and, as such, is usually adopted by commissioners and can be cited by lawyers in medicolegal cases. Traditionally, NICE has looked at new drugs and devices but also reviews health conditions and pathways. In May 2018, NICE issued draft guidelines on the management of abdominal aortic aneurysms (AAAs).[1] This resulted in an unprecedented response from individuals, hospitals, specialist societies (including the Vascular Society for Great Britain and Ireland, the British Society of Interventional Radiology, and the British Society of Endovascular Therapy), and industry partners.

THE CONVERSATION SURROUNDING THE GUIDELINES

The main reason for the magnitude of the response was the controversial recommendation that elective endovascular aneurysm repair (EVAR) should not be offered in any circumstances. Bearing in mind that EVAR is regarded as a mature technology and an established treatment for AAA in all UK vascular units, the potential impact would have been significant. The draft guidance suggested that patients deemed fit for open surgery should undergo such surgery; those thought to be unfit (which is not actually defined) should not be treated at all, other than for control of risk factors. Among other recommendations, it was also suggested that surveillance post-EVAR be performed by annual CT scan, even though the majority of institutions employ noninvasive duplex surveillance as first-line treatment.

Both of these recommendations were out of tune with guidelines from the European Society for Vascular Surgery and the Society for Vascular Surgery and are contrary to surgical intervention's direction in general. Throughout the last 3 decades, there has been a sustained drive toward minimally invasive treatment, and this has been welcomed by an increasingly aging population base, allowing a reduced length of hospital stay, faster recovery, and improved early mortality and morbidity rates. This drive has occurred as a result of technologic advancement and has influenced all surgical specialties in one way or another.

Despite all the criticism, there is some clear sense in what NICE had highlighted. Aortic aneurysms are largely asymptomatic and occur in the elderly, who often have limited life expectancy secondary to comorbid conditions such as ischemic heart disease, chronic obstructive pulmonary disease, cancer, and dementia. Because there is no symptomatic benefit with AAA treatment, we have to be sure that treatment does prolong life. Moreover, in the financial austerity of the National Health Service and health provision globally, treatment must achieve this in the most cost-effective way possible. Furthermore, it must preserve quality of life, and therefore, ongoing surveillance or further reinterventions should not be intrusive.

BACKGROUND

So, how did we get here? The obvious advantages of EVAR were always clear and appreciated by clinicians, health care providers, and patients. Early advantageous outcomes dominated the literature, and registries rarely progressed much beyond 2 years. The increasing usability of new devices encouraged their use in more difficult anatomy and more elderly patients, and there was little concern about durability. It became clear that EVAR seemed to work, at least in the short term, even in patients with anatomy outside the device instructions for use (IFU), and clinicians became adept at using the devices in more difficult scenarios.

However, over the last few years, vascular surgeons have noticed increasing durability problems. Early endoleaks and their management have been widely discussed. However, the phenomenon of midterm sac size increase (with or without endoleak) no longer seems to be rare, and reports of late ruptures and conversions to open repair and explants are now widespread. Questions began to be asked about the fundamental concept of EVAR design.

Although stent grafts have evolved over a period of 25 years, the main technique and device concepts have changed very little, with the one noticeable exception of endovascular aneurysm sealing (EVAS), a technique that focuses on treating the sac using polymer-filled bags rather than relying on the radial force of a stent graft. The ease of use and early promise of EVAS precipitated rapid uptake before sound longer-term outcome data were available. When it then failed, it came as a shock and something of a wake-up call to the vascular world.

When the NICE draft guidelines were published, the endovascular fraternity was already dealing with the fallout from the failure of EVAS and clear durability concerns with conventional EVAR. Over the last 5 years, numerous publications have highlighted problems associated with fixation and seal in short, conical, angulated, and wide proximal necks. These isolated findings were seen in a new light with the publication of late outcomes from the EVAR 1 and DREAM trials, which suggested that the early survival benefit from EVAR was lost by 4 years, and after 8 years, patients who had underwent open surgical repair survived longer and with fewer interventions.[2]

Although the trials investigated patients treated within the IFU, those treated outside the IFU with short, conical, angulated, or wide necks fared even worse. Large cohort studies from the United States revealed aneurysm growth rates of over 40% in 5 years and significantly increased rates of reintervention and late rupture post-EVAR compared with open surgical repair.[3] Despite such data, the vascular community remained reluctant to acknowledge the shortcomings of EVAR and the seduction by the technology, and EVAR's clear early benefits for patients continued.

ANATOMIC FACTORS

In my opinion, the question of anatomy is vitally important here. Almost all reports on the subject show that the outcome for EVAR performed in patients with adverse proximal neck anatomy (angulated, conical, short landing zone, larger diameter) is worse than for those with straighter, parallel-walled, longer, narrower necks. Previously, neck length was seen as the main determinant of IFU, and thus durability, but increasingly, I believe neck diameter may be more important. Aortic neck dilatation is now a recognized entity and is thought to occur in approximately 25% of cases.[4] This means that a well-sized graft deployed perfectly in a proximal seal zone 8 or 10 years ago may ultimately fail if the neck dilates beyond the maximum diameter of the graft. Whether this is secondary to the aging process of the aorta or precipitated by radial force from the stent is uncertain. However, it is acknowledged that aortic diameter does increase over time and that dilatation also occurs after open repair, meaning that excess radial force is unlikely to be the only reason. Even within what is currently considered to be IFU compatible, we need to reconsider the use of larger stent grafts. A 36-mm graft could be used for a 30-mm-diameter neck within IFU, but a 30-mm-diameter aorta is actually an aneurysm and, if diagnosed with an aneurysm screening program, would be expected to dilate over time. Therefore, it is not surprising that a proportion of aortas dilate to such an extent that the seal is lost.

DURABILITY VERSUS EARLY BENEFIT

Longer-term durability concerns have to be offset against the up-front benefits of an endovascular approach for elderly patients. Patients' wishes must be prioritized, and we all have to acknowledge the greater importance an elderly population attaches to early benefit compared with what might happen in a decade's time. The benefits of a minimally invasive approach that results in reduced perioperative mortality and allows a faster recovery and return to normalcy cannot be underestimated.

THE GUIDELINES ARE PUBLISHED

As we go to press, the final NICE guidelines have just been published,[5] and they acknowledge many of the concerns voiced by stakeholders. Individual doc-

tor–patient decision-making is championed, and it is accepted that there is a place for EVAR for aneurysm repair under certain circumstances that now include patients with comorbidity who will benefit from a minimally invasive approach.

What this does not mean, however, is that a "business as usual" mentality can continue. Open repair is still considered to be the first choice where possible, for now at least. Although anatomic considerations are not prominent in the final guidance, there is an implication that such factors will be considered in the decision-making process and uncertainty about durability be discussed with patients.

It is also important that NICE has recognized the need for custom devices. The mandate that these should be used under scrutiny with ongoing data collection within the National Vascular Registry is sensible and will allow us to assess their longer-term performance in a robust environment.

CONCLUSION

Whether it was the proposed NICE guidelines (per se), the growing realization of EVAR durability worries, or fallout from the early failure of EVAS, there has been an impact on EVAR use. National Vascular Registry annual reports reveal that the ratio of EVAR to open surgery for elective infrarenal AAA treatment in the UK has been about 70:30 for a number of years now. In the United States, EVAR is used in > 80% of cases, and there are concerns that the lack of open surgery is impacting training.[6] In the screen-detected cohort, the ratio is approximately 50:50 because screen-detected patients (who tend to be up to a decade younger) are generally fitter and have a longer life expectancy, thereby mandating better durability.[7]

Even before the final publication of the guidelines, there had already been a shift in practice in favor of open surgery. Data from the latest National Vascular Registry report show that the percentages of EVAR and open surgery for elective AAA repair were 68% and 32% in 2017 but changed to 63% and 37% in 2018. Although there was a marginal increase in open surgery in 2018, there were 520 fewer EVARs performed,[8] suggesting a shift toward conservative management in some patients. There has been a gradual decline in AAA rates; however, the magnitude of this change is too large to be secondary to a year-on-year prevalence change and therefore represents a real change in practice.

We should now accept that although there may be a good endovascular solution for some patients, this group is much smaller than the group currently treated with standard EVAR. However, just because EVAR does not work in all patients, it should not be denied in appropriate situations where it is effective and durable. Crucially, the acknowledgement by NICE that there is a place for EVAR will facilitate ongoing research in and industry development of solutions that are more applicable to adverse anatomy so that a greater proportion of patients with AAA will have an endovascular solution in the future. ■

1. National Institute for Health and Care Excellence (NICE). Abdominal aortic aneurysm: diagnosis and management. NICE guideline, draft for consultation, May 2018. https://www.nice.org.uk/guidance/gid-cgwave0769/documents/short-version-of-draft-guideline. Accessed February 7, 2020.
2. Patel R, Sweeting MJ, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular repair trial 1 (EVAR 1): a randomised controlled trial. Lancet. 2016;12:2366-2374.
3. Shanzer A, Greenberg RK, Hevelone N, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation. 2011;123:2848-2855.
4. Kouvelos GN, Oikonomou K, Antoniou GA, et al. A systematic review of proximal neck dilatation after endovascular repair for abdominal aneurysm. J Endovasc Ther. 2017;24:59-67.
5. National Institute for Health and Care Excellence (NICE). Abdominal aortic aneurysm: diagnosis and management. NICE guideline, March 2020. https://www.nice.org.uk/guidance/ng156. Accessed March 19, 2020.
6. Smith ME, Andraska EA, Sutzko DC, et al. The decline of open abdominal aortic surgery among individual training programs and vascular surgery trainees [published online September 26, 2019]. J Vasc Surg.
7. Meecham L, Jacomelli J, Pherwani AD, Earnshaw J. Self referral to the NHS Abdominal Aortic Aneurysm Screening Programme. Eur J Vasc Endovasc Surg. 2016;52:317-321.
8. National Vascular Registry. 2019 annual report. https://www.vsqip.org.uk/content/uploads/2019/12/NVR-2019-Annual-Report.pdf. Accessed February 7, 2020.

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