Review

Draft NICE aneurysm guidelines: an end to the endovascular era?

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An abdominal aortic aneurysm (AAA) is the dilatation of the aorta to over 50% of its original diameter. The risk of life-threatening rupture increases as the aneurysm expands. Currently, a diameter of 5.5 cm is the threshold at which patients are referred for treatment, either by open surgical repair (OSR), where a synthetic tube graft is sutured in place after laparotomy, or by endovascular repair (EVAR), where a metal stent is placed in the aneurysm via small incisions in the groin. Over the last two decades, the uptake of EVAR has been significant; its minimally invasive nature means that it is associated with shorter hospital stays and it is suitable for older individuals with comorbidities who are deemed unfit for OSR. Nowadays, EVAR is a standard treatment for AAAs in the UK and across the world. The decision of whether to opt for OSR or EVAR is largely based on patient fitness, patient and clinician preference and aneurysm morphology.

In May 2018, the National Institute of Health and Care Excellence (NICE) proposed new draft guidelines stating that EVAR should not be offered for elective AAA repair, regardless of whether patients are suitable or unsuitable for OSR. The guidelines explain that there is a lack of evidence for long-term benefits of EVAR compared with OSR in non-ruptured AAAs, which means that national funding from the NHS is not justified.[1] The exceptions to this are emergency EVAR for ruptured AAAs, as the evidence for this is more compelling,[2] and the use of complex EVARs in randomised clinical trials.[1]

The evidence behind the guidelines stems from the EVAR1 trial, which enrolled patients between 1999 and 2004, comparing OSR against EVAR for elective AAA repair.[3] The study found that, although EVAR had superior outcomes compared with OSR at 30 days and 6 years, there was no longer a statistically significant difference between the two treatments in aneurysm-related and all-cause mortality rates at the 10-year follow-up, mainly as a result of secondary sac expansion and subsequent rupture[4]. A cost-effectiveness analysis also found EVAR to be more expensive than OSR.[5]

The draft guidelines generated much debate within the vascular community. A joint statement made by the Vascular Society of Great Britain and Ireland (VSGBI), the British Society of Interventional Radiologists (BSIR) and the Vascular Anaesthesia Society of Great Britain and Ireland (VASGBI) voiced concerns that the guidelines may prevent patients from receiving appropriate life-saving treatment that they would otherwise receive if residing in other areas of the Western world, as EVAR remains a first-line or OSR alternative for AAA repair according to the European Society of Vascular Surgery (ESVS) and the American Society of Vascular Surgery (SVS) guidelines.[6,7,8] The societies also highlighted the difficulty in assessing patient 'fitness' for OSR, since there are no validated tools or risk scores currently available, stating that as surgeons are likely to be risk averse, the incidence of aneurysm rupture would almost certainly increase.

Another main concern is the impact of the draft guidelines on current practice.[6] Since EVAR is often performed more frequently than OSR, a diverse group of medical professionals will need to make appropriate changes, from adjusting the current surgeon training curriculum, to re-allocation of resources in theatres, wards and intensive care or high-dependency units as a result of longer hospital stays and close monitoring after OSR. The provision of EVAR for ruptured AAAs may also be affected, since surgeons could lose the skills needed for the procedure as a result of a lack of elective EVARs, leading to suboptimal outcomes in ruptured cases. These challenges were recognised by NICE, but the committee believes that the recommendations will, nonetheless, minimise long-term mortality and re-intervention, as well as reduce costs.[1]

Finally, the external validity of the historic data from the EVAR1 trial has been called into question. The trial principally involved early-generation endografts, most of which have since been replaced by later iterations.[9] Although the long-term durability of these newer stents has not been evaluated, they would be likely to have lower associated rates of complications and re-interventions. In addition, other advances in vascular imaging, hybrid theatres and surgeon experience have dramatically improved EVAR outcomes over the last decade in the UK.[10]

The EVAR1 trial also suffered from loss to follow-up, with only 10% follow-up retention of all survivors at 9 years.[4] Therefore, aneurysmal degeneration may not be detected and re-intervention not performed, which can strongly predispose to late secondary rupture.[11] To address these uncertainties, an ongoing research group is using prognostic modelling to identify risk factors for secondary sac expansion after EVAR, based on the EVAR trial's dataset and validated by a contemporary dataset from Finland,[12] which could demonstrate the true outcomes of EVAR in a 'perfect follow-up' scenario.

Although the NICE draft guidelines for AAA management were originally scheduled to be published in November 2018, as a result of its controversial implications on current practice, there has been a significant delay in publication due to the appeals process. In March 2020, the guidelines were fully published by NICE, with the revisions now recognising that EVAR may be the optimum choice for patients under clearly defined circumstances, after anatomical and physiological considerations.[13] Whilst these new changes were well-received by the VSGBI,[14] a separate statement released by the AAA Guideline Development Committee (GDC) again voiced their concerns over the fact that the recommendations do not accurately reflect the evidence behind EVAR and OSR.[15] Whilst historic data and a tight NHS budget support the recommendations made in the draft guidelines, patient and clinician choice cannot be overlooked. Perhaps most importantly, the debate has highlighted the shortcomings of the current evidence base, and further research is a high priority.

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