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EDITORIAL

Proposed NICE Abdominal Aortic Aneurysm Repair Guidelines: Swinging the Pendulum too Far?

The impact of endovascular aneurysm repair (EVAR) has been transformative in the delivery of care to patients with intact and ruptured abdominal aortic aneurysms (AAAs). It demanded a revolutionary change in the technical skill set and surveillance mentality along with the need for complex rescue operations for failed endografts in the longer term. This led to a refinement of indications for open surgical repair (OSR) but not its elimination.

EVAR as a "less invasive" solution was anticipated to deliver a lower peri-operative mortality to allcomers and allow safe treatment for a population of "unfit" patients. While short term threefold survival benefits of EVAR *vs.* OSR for *elective* AAA have been shown in randomised trials, the long term survival has been challenged.[1–4]

With regard to ruptured AAAs, the IMPROVE trial has demonstrated equivalent in hospital mortality between EVAR and OSR.[5] However, large scale, nationwide, observational studies, meta-analyses, and on-treatment data from IMPROVE have shown EVAR to confer reduction in hospital mortality and morbidity in patients with favourable aneurysm morphology. Therefore, the current best evidence favours an "EVAR first" policy for ruptured AAA.[6,7]

In May 2018 the National Institute for Health and Care Excellence (NICE) released a draft of its updated guidelines for AAA diagnosis and management. The suggested guideline recommended against elective EVAR except for complex fenestrated EVAR, branched EVAR, or chimney EVAR within a randomised clinical trial. However the NICE draft guideline does recommend the treatment of *ruptured* AAA by EVAR, especially in women and men over the age of 70 years. For men under the age of 70 years, OSR is considered to provide a better balance of benefits and harms.

These proposed guidelines are currently in dispute by the European and US vascular community amidst repeatedly postponed publication (now set for July 2019), pointing to the uncertainty of the situation. To summarise the existing debate, there are five areas in question: (i) Are the NICE recommendations based on outdated data? (ii) Do the NICE recommendations comply with the new European Society for Vascular Surgery (ESVS) AAA guidelines? (iii) Will the loss of elective EVAR skills affect competence for EVAR in ruptured AAA? (iv) Will vascular specialists lose their EVAR skills completely and what is the impact of unsolved political issues between vascular surgeons and interventional radiologists in the UK? (v) Did NICE address patient preference for the clinical decision making process properly?

(i) The NICE committee used an economic analysis model and justified its evidence synthesis on the basis of high EVAR maintenance costs and reduced durability, using data from four historic randomised trials (1999–2008) of OSR *vs.* EVAR. However they dismiss large non-randomised cohorts and registries as well as the cost effectiveness analysis of the OVER trial that showed no cost difference between the two modalities after two years.[8] EVAR-1 indicated a late, beyond eight year, catch up in mortality for the EVAR arm largely associated with suboptimal follow up.[1] Long term analysis was based on few patients, was not statically powered, and did not appropriately capture re-interventions for open repair. Many of the patients who were enrolled in the trials 15–20 years ago would probably be offered very different technical solutions, materials, and techniques today, retaining the early mortality/morbidity advantage and promising better durability.[9] At the same time more targeted "smart" surveillance protocols seem to provide better long term security. Dynamic prognostic models have been developed with the potential to tailor surveillance by identifying a large proportion of patients who may require less intensive or more rigorous follow up.[10,11]

(ii) NICE may comply with the new ESVS AAA guidelines for ruptured AAA, but completely ignores the recommendations from the ESVS, that EVAR should be considered as the preferred treatment modality in most patients with suitable anatomy and reasonable life expectancy.[11] Obviously, the NICE working group has interpreted the evidence quite differently from the ESVS guideline group: NICE focusing on randomised controlled trials and health economics, ESVS adopting broader evidence and a patient oriented approach.

(iii) Should the NICE guidelines be implemented, the inevitable consequence will be a marked reduction in the number of practitioners able to train or maintain competence to perform EVAR. A report from the international Consortium of Vascular Registries demonstrated very clearly that countries with low elective EVAR rates (~30%) retain an extremely low EVAR usage rate for ruptures (5%–11%). Conversely countries with the highest elective EVAR rates (> 60%) retain high ruptured EVAR rates (> 30%).[12] Outcomes after AAA repair are related to experience. A risk adjusted analysis of 122 495 Medicare patients undergoing elective EVAR between 2001 and 2008 demonstrated that operative mortality is directly related to medical centre volume.[13]

(iv) Unlike in almost all other countries many EVAR procedures are being performed by interventional radiologists in the UK. To add to the problem, the

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Interventional Radiology Committee at The Royal College of Radiologists dictated that the future limited number of permitted EVAR cases, must be performed by interventional radiologists only in order to concentrate expertise, thus diminishing the expertise of vascular surgeons.[14] Such a policy would be in direct conflict with the long standing order in most European (and non-European) countries and would be forcefully opposed by international vascular surgical societies, including the ESVS. Currently, the certification guidelines for vascular surgery in the UK include 10 elective OSR and 10 elective EVAR. In the future even high volume centres will be in trouble fulfilling the EVAR numbers. Already unsolved political issues between vascular surgeons and interventional radiologists in the UK will therefore be amplified.

(v) Last but not least, the guidelines dismiss patient preference in the elective setting. Not everyone is willing to accept the higher OSR mortality/morbidity risk upfront, just because 10 years down the road EVAR will match the OSR mortality. The NICE Committee has arbitrarily chosen improved long term outcomes seen with open repair to be more important than safety issues and improved shorter term outcomes seen with EVAR. Alongside, based on the EVAR-2 trial results, patients who are unsuitable for open repair will not be offered any intervention at all.[15]

In summary the obviously economically driven NICE recommendations for the treatment of AAA are based on outdated data, will "Brexit" UK vascular surgeons from the rest of the world, and do not respect the perspective of patients properly. EVAR is by no means a gold standard treatment for allcomers and OSR has an important role in the management of several subgroups. There is however enough evidence to support EVAR as a standard of care for patients with appropriate anatomy, offered by vascular surgeons with appropriate expertise. NICE guidelines instead of dismissing should rather safeguard EVAR practices, implementing appropriateness of care and follow up strategies, thus keeping the scientific pendulum for the treatment of patients with AAA in balance. NICE stands for *National Institute for Health and Care Excellence.* We truly believe that *excellence in AAA treatment* must include open and endovascular surgery for AAA; NICE should therefore reconsider their recommendations for AAA treatment.

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Christos D. Liapis*
Department of Vascular & Endovascular Surgery, Athens Medical Centre, Athens, Greece

Efthymios D. Avgerinos
Division of Vascular Surgery, University of Pittsburgh Medical Centre, Pennsylvania, USA

Hans-Henning Eckstein
Department for Vascular and Endovascular Surgery and Munich Aortic Centre (MAC), Klinikum rechts der Isar, Technical University of Munich, Germany

*Corresponding author. Department of Vascular & Endovascular Surgery, Athens Medical Centre, Athens, Greece.
Email-address: liapis@med.uoa.gr (Christos D. Liapis)