Hinchliffe, R. J., & Earnshaw, J. J. (2020). Endovascular treatment of abdominal aortic aneurysm: a NICE U-turn. *British Journal of Surgery*. <https://doi.org/10.1002/bjs.11054>

Peer reviewed version

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Endovascular treatment of abdominal aortic aneurysm: NICE does a u-turn.

Robert Hinchliffe, FRCS, Professor of Vascular Surgery

Jonothan J Earnshaw, FRCS, Consultant Vascular Surgeon

Correspondence to: Mr. J.J. Earnshaw DM FRCS

Department of Vascular Surgery

Cheltenham General Hospital

Sandford Road, Cheltenham

Gloucestershire GL53 7AN

Tel. 08454226190, Fax 08454226788

Email: jonothanearnshaw@gmail.com or Jonothan.earnshaw@nhs.net

In 2001, Collin and Murie challenged the concept of endovascular repair (EVAR) for abdominal aortic aneurysm (AAA) in an editorial that remains controversial even now (1). Around 18 months ago, two guideline documents on the management of AAA were released: one by the European Society for Vascular and Endovascular Surgery (ESVS) (2) and one in draft by the UK National Institute of health and Care Excellence (NICE) (3). The ESVS document is a clinical review, and acknowledges the way that EVAR has become the treatment of choice for many people worldwide. EVAR offers minimally invasive treatment which can be done under local or regional anaesthesia, reducing postoperative pain, hospital stay and 30-day mortality compared with conventional open aortic aneurysm repair (OAR) (4). It has extended the options available for patients with juxtarenal and suprarenal aortic aneurysms using branched and fenestrated devices (5). There is also some evidence of advantage in emergency EVAR for patients with ruptured AAA (6).

In 2018, NICE had a somewhat different view, based on a formal cost-effectiveness analysis of RCTs comparing EVAR with OAR (3). It concluded EVAR is not cost effective, even if the devices, which are currently expensive, could be produced at low cost. This should not come as a surprise to vascular surgeons, since a previously published cost effectiveness analysis of EVAR also found it to be less cost effective than open repair (7). The main reason seems to be the ongoing cost of stent maintenance after insertion, compared to OAR. There is also a risk of late rupture after EVAR, not seen after OAR (8). NICE draft guidelines suggested that patients with a large intact AAA should not be offered EVAR if they are fit enough for OAR. NICE also suggested that those who are not suitable for OAR because of their anaesthetic or medical condition, should not be offered EVAR. This was perhaps the inevitable conclusion

of a cold, clinical analysis of the EVAR 2 trial, which has been an elephant in the room of vascular surgery for over a decade (9). In patients unfit for OAR (the EVAR 2 cohort), EVAR is pretty well tolerated and can minimise the risk of death from subsequent AAA rupture. However, it does not prolong life, and almost all patients in both groups of the EVAR 2 trial died within a decade (9).

The draft NICE guidelines were inevitably controversial among vascular surgeons who have espoused the endovascular revolution for the treatment of both aortic and peripheral arterial diseases. Enormous effort and resource has been poured into training the next generation of vascular specialists with endovascular skills. An industry of devices has grown up around these endovascular interventions, which have elevated the costs of many allied vascular treatments. It was argued NICE relied on old RCTs which studied the generation of EVAR devices of a decade ago. Modern devices are safer and more effective, and with lower re-intervention rates. Reducing the costs of life-long surveillance with modern schedules should also improve cost-effectiveness (10). Yet, even now, some new devices launched with enthusiasm only recently appear to have problems and seem unlikely to endure (11).

In March 2020, NICE published its final version of the Guidelines for management of AAA (12). They have done a u-turn, and now accept that EVAR is a reasonable option for the management of AAA under certain conditions: hostile abdomen, medical problems etc. But they also seem to introduce an element of patient choice, such that EVAR may be considered for patients who have anaesthetic risks and/or medical comorbidities that would contraindicate open surgical repair. This extraordinary decision appears to fly in the face of NICE's own technical and scientific analysis, and the reasons are not explained. The

Guideline Development Committee has released a strongly worded statement distancing itself from the revised conclusions, which were apparently not discussed with the Committee, or its Chair (13). Although there was a strong reaction to the draft guidelines for vascular surgeons around the world, NICE has never before succumbed to peer pressure before, and the only logical conclusion is that it has yielded to external pressure from stakeholders who stood to lose considerably if the number of EVARs diminished. Yet the original analysis done by NICE cannot be undone, and the subsequent discussions among vascular surgeons still pertain. For example, It is well known that complications and re-interventions are more common when the EVAR device is inserted outside ideal anatomical conditions (manufacturer's instructions for use: IFU). If IFU is followed strictly, the risk of re-intervention is much lower, but only two thirds of infrarenal AAA fall into this category, and one third would therefore be denied EVAR. It is often argued that for an individual patient the risk of inserting a stent off IFU may be better than a high risk open repair. Manufacturers of stent grafts are unlikely to agree, but it could be argued they bear some responsibility, having observed so many stents inserted under suboptimal conditions. If the draft guidelines simply make vascular surgeons think more carefully before using an EVAR off IFU, they will have improved things.

Complex EVAR for juxta- and suprarenal AAA are an option for some patients. Good studies on fenestrated and branched endovascular interventions are few, and generally only reported by enthusiasts (5). The intervention is complex and considerably more expensive even than EVAR, and there are few data on the outcomes for all-comers. Whereas the ESVS guidelines endorse complex EVAR for juxtarenal and suprarenal aortic aneurysms, NICE was

originally clear: endovascular treatment must not be offered for intact aneurysms outside the confines of an RCT, and then only in patients fit for open surgery. The final version of the guidelines has a softer attitude. Complex EVAR may be considered in patients fit for open repair if the risks and benefits have been discussed with the patient. It may even be considered in patients unfit for open repair as long as the uncertainties around outcome have been discussed. NICE previously recommended a well-conducted study of clinical and cost effectiveness of treatments for complex aneurysms remains fundamental, and the opportunity to encourage this should not be lost by NICE's change of heart (14).

The UK has been at the forefront of screening for AAA in men, and a national programme has been running for five years (17). The NICE guidelines endorse the ultrasound methodology used in the UK screening programmes and also their revised (prolonged) surveillance intervals. The draft guidelines posed certain challenges, and started a debate in screening circles. The aim of screening is to reduce the rate of death from AAA rupture in the population. Since some of those found by screening to have large AAA will not be fit for OAR, reduction in the rate of EVAR would mean screening will inevitably fail to fulfil its potential. Perhaps of more concern is that some men with small AAA may remain in surveillance for many years, finally reaching the threshold for treatment late in life, when unfit for OAR. To avoid this potentially uncomfortable situation, a baseline fitness assessment may need to be introduced before surveillance is started, and repeated at intervals. Surveillance would be terminated, or not even commenced, in men found unlikely ever to be fit for OAR.

Relaxation of the draft NICE guidelines may be welcomed by many vascular surgeons, but the technical cost effectiveness analyses cannot be ignored. All countries wish to see patients have access to treatments that are cost effective. Some vascular surgeons may be accused of adopting EVAR too enthusiastically and uncritically, pushing the boundaries beyond the technical capabilities of the devices. The rise in the number of AAA treated has largely been in the elderly, those who stand to gain least. A measured response would be to think more carefully in multidisciplinary meetings about patients with an AAA at the extremes of age and fitness, and also to offer enthusiasm to conduct or even repeat RCTs with current devices. Partnership with the device manufacturers will be needed to fund and complete these trials, which are also in their interests. Finally, it remains to be seen how badly damaged NICE's reputation will be by this incredible volte face. Although UK vascular surgeons and the Vascular Society of Great Britain and Ireland may feel that their pressure on NICE has encouraged this decision, from the outside, the only logical explanation for this change is external pressure. NICE's reputation for firm and fair decision-making, and its transparent processes may be tainted. An explanation for its revised decision should be forthcoming, and NICE processes for examining new technology should be reviewed 18 . Producing guidelines is a responsible task, with no excuse for complacent totalitarianism. This has been a painful process for vascular surgeons, but has meant they have reassessed decision-making for intervention on AAA, and already there has been a reduction in the number of people treated with EVAR where the benefit was questionable. The revised NICE guidelines are generally aligned with those from the ESVS, which will benefit patients with an AAA.

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