

## POSITION STATEMENT

# Recommendations on the Use of Open Surgical and Endovascular Aneurysm Repair for the Management of Unruptured Abdominal Aortic Aneurysm from the Guideline Development Committee Appointed by the UK National Institute for Health and Care Excellence

In 2015, the UK National Institute of Health and Care Excellence (NICE) appointed an Abdominal Aortic Aneurysm (AAA) Guideline Development Committee (GDC), which comprised multidisciplinary professional members and two patient representatives with lived experience of AAA. Conflicts of interest (CoI) were not permitted. The Chair received £500 per GDC meeting; members received only expenses.

In accordance with the NICE Guideline Development Manual,<sup>1</sup> a scoping exercise led to a series of Population, Intervention, Comparator and Outcome (PICO) questions for the NICE Technical Analysis Team (TAT) to address.<sup>2</sup> At 17 all day face to face meetings, the NICE TAT presented their detailed evidence to the GDC, which led to the drafting of recommendations that were published in May 2018 for comment by NICE registered stakeholders.<sup>3</sup> Of note, stakeholders are not required to declare CoI.

The draft recommendations on unruptured AAA proscribed (prohibited) endovascular aneurysm repair (EVAR) in favour of open surgical repair (OSR) for people deemed fit for OSR, and in favour of no intervention for people deemed unfit for OSR. NICE and the GDC realised this was a marked departure from established practice but agreed that this change in practice reflected the evidence presented to the GDC by the NICE TAT, as well as the principles underpinning guideline development published by NICE.

Substantial critical feedback was received from stakeholders on the basis that:

- The NICE TAT analysis of randomised controlled trials (RCT) was incorrect.
- The RCT evidence was not applicable to subgroups (especially women).
- RCT data were no longer relevant as EVAR outcomes had improved.
- Patient choice was being ignored.
- The recommendations could not be implemented because of inadequate retention of EVAR skills for ruptured AAA and the increased demand for OSR; in particular, the need for more critical care beds.

NICE and GDC agreed that the draft recommendations required modification and better explanation. Further face

to face GDC meetings took place in July 2018 and February 2019, with the latter attended by NICE senior management. The GDC worked closely with NICE for over a year making iterative changes to the wording of the draft EVAR/OSR recommendations. NICE placed considerable pressure on the GDC to agree recommendations that, in the unanimous opinion of the GDC, were inconsistent with NICE's own TAT analysis and evidence, as well as with the guideline development principles published by NICE, which the GDC had been instructed to follow. It became known to the GDC that members of the NICE senior management team were consulting with other parties and stakeholders regarding the EVAR/OSR recommendations. In March 2020, NICE published its own final EVAR/OSR recommendations against the advice of its GDC.<sup>4</sup>

From appointment in 2015 through to publication in March 2020, GDC members were compliant with instructions from NICE not to discuss guideline development publicly. However, following publication, the GDC published a unanimous statement and then an opinion piece expressing its concerns about the OSR/EVAR recommendations and the process that led to their publication.<sup>5,6</sup> Others have also expressed concerns about NICE's U turn.<sup>7</sup> While there has been some attempt to explain NICE's behaviour, it still remains unclear who wrote, vetted, and approved the final published EVAR/OSR recommendations.<sup>8,9</sup>

Here, the final recommendations on EVAR/OSR for unruptured AAA that the GDC advised NICE to publish, but which NICE rejected, are presented (Table 1).

## STANDARD ENDOVASCULAR ANEURYSM REPAIR

NICE and the GDC agreed that "standard EVAR" should be defined as any procedure using an unmodified EVAR device implanted in accordance with the manufacturer's "instructions for use" (on IFU) and without the use of adjunctive procedures.

### *Standard endovascular aneurysm repair in people for whom open surgical repair is deemed suitable*

In people for whom OSR is suitable, the NICE TAT evidence is that OSR dominates EVAR; that is, OSR provides more quality adjusted life years (QALYs) and is less expensive than EVAR.<sup>10</sup> Furthermore, the TAT found no clinically plausible

<b>Table 1. National Institute for Health and Care Excellence Guideline Development Committee (GDC) recommendations on elective open surgical (OSR) or endovascular (EVAR) repair of unruptured abdominal aortic aneurysm (AAA)</b>	
<b>Theme</b>	<b>GDC final recommendation</b>
When to offer AAA repair and discussion of risks and benefits	<p>1.5.1 Consider repair for people with an unruptured AAA if it is:</p> <ul style="list-style-type: none"> <li>• Symptomatic</li> <li>• Asymptomatic, larger than 4.0 cm and has grown by more than 1 cm in 1 year (measured inner to inner maximum anterior-posterior aortic diameter on ultrasound)</li> <li>• Asymptomatic and 5.5 cm or larger on ultrasound (measured inner to inner maximum anterior-posterior aortic diameter on ultrasound)</li> </ul> <p>1.5.2 When discussing AAA repair with people who have an unruptured AAA, explain the overall balance of benefits and risks with repair and with no repair, based on their current health and their expected future health. Cover the:</p> <ul style="list-style-type: none"> <li>• Short and long term risks and other disadvantages of repair (such as having to stay in hospital, the risks of the operation, the recovery period, the potential need for further procedures, and the need for surveillance imaging appointments)</li> <li>• Long term benefits of repair, taking into account the person's health and any other conditions they have</li> <li>• Risk of AAA rupture if they do not have repair</li> <li>• Uncertainties around estimates of rupture risk of AAA larger than 5.5 cm</li> </ul>
Standard EVAR in patients suitable for OSR	<p>1.5.3 For people with unruptured AAA meeting the criteria in 1.5.1, offer OSR unless it is contraindicated because of their anaesthetic and/or medical comorbidity</p> <p>1.5.5 Do not offer standard EVAR to people if OSR is suitable for them</p>
Standard EVAR in patients for whom OSR is not suitable because of comorbidity*	<p>1.5.4 Offer best medical therapy with no AAA repair to people with unruptured AAA meeting the criteria in 1.5.1 but for whom OSR is unsuitable because of their anaesthetic and/or medical comorbidity</p> <p>1.5.7 Be aware that for people with unruptured AAA in whom OSR is unsuitable because of their anaesthetic and/or medical comorbidity:</p> <ul style="list-style-type: none"> <li>• There is evidence that for many people standard EVAR is neither clinically effective nor cost effective.</li> <li>• There are no clinical, biochemical or imaging features or risk prediction models which can be used to identify: <ul style="list-style-type: none"> <li>• Who will benefit from or be harmed by standard EVAR</li> <li>• For whom standard EVAR will be cost effective</li> </ul> </li> </ul> <p>1.5.8 In people for whom OSR is unsuitable because of their anaesthetic and/or comorbidity only consider standard EVAR where all of the evidence statements in 1.5.7 have been discussed with the person.</p>
Complex EVAR in people for whom OSR is suitable	<p>1.5.9 If OSR and complex EVAR are both suitable options, only consider complex EVAR where:</p> <ul style="list-style-type: none"> <li>• The following has been discussed with the person: <ul style="list-style-type: none"> <li>• The risks of complex EVAR (including the potential need for further procedures and the need for lifelong monitoring), compared with the risks of OSR</li> <li>• The lack of evidence for improved peri-operative survival with complex EVAR, compared with OSR</li> <li>• The lack of evidence about long term outcome of complex EVAR compared with OSR</li> <li>• The reduced time spent in hospital for people who have complex EVAR, compared with OSR</li> </ul> </li> </ul> <p>Complex EVAR, if performed, should only be performed within a randomised controlled trial comparing the clinical and cost effectiveness of complex EVAR with OSR, or with delayed (or no) intervention</p>
Complex EVAR in people for whom OSR is unsuitable because of comorbidity	<p>1.5.10 Be aware that, if OSR is not suitable for a person because of their medical and/or anaesthetic comorbidities:</p> <ul style="list-style-type: none"> <li>• There is no evidence to support how to identify subgroups of people who would benefit or be harmed by complex EVAR compared with no intervention</li> <li>• There is no evidence to support how to identify subgroups of people for whom complex EVAR would be cost effective, compared with no intervention</li> <li>• It is unlikely that there are any subgroups who would benefit from complex EVAR</li> <li>• It is unlikely that complex EVAR is cost effective compared with no intervention</li> </ul>

EVAR = endovascular aneurysm repair; OSR = open surgical repair.

\* Recommendation 1.5.6 related to people with a hostile abdomen: Consider standard EVAR for people who do not have anaesthetic and/or medical comorbidity that would contraindicate OSR, but who have abdominal co-pathology that makes OSR unsuitable (e.g., hostile abdomen, horseshoe kidney, or a stoma).

scenarios where this is not the case. This means that, within the UK National Health Service (NHS), offering people for whom OSR is suitable a choice of EVAR instead will result in an overall loss of population health and also means that

other clinically and cost effective NHS treatments will necessarily go unfunded.<sup>11</sup> Proscribing (prohibiting) EVAR in this patient group, except in special circumstances, is consistent with NICE's "Social Value Judgements"<sup>12</sup> and

“Principles Document”.<sup>13</sup> The former, which was in force during AAA guideline development, clearly states “Although NICE agrees that respect for autonomy and individual choice are important for the NHS and its users, this should not mean that NHS users as a whole are disadvantaged by guidance recommending interventions that are not clinically and / or cost effective”. A post-consultation NICE TAT analysis of more contemporary non-randomised EVAR/OSR data supported the RCT findings.<sup>14</sup> In particular, the NICE TAT found no evidence that the relative risks and benefits of OSR vs. EVAR for unruptured AAA had changed since publication of the RCTs. For these reasons, the GDC maintained its recommendation that people with unruptured AAA for whom OSR is suitable should not be offered standard EVAR except in special circumstances.

### ***Standard endovascular aneurysm repair in people for whom open surgical repair is not suitable because of comorbidity***

The main evidence presented to the GDC by the NICE TAT was from the EVAR 2 trial, which showed that EVAR was not cost effective. The incremental cost effectiveness ratio (ICER) of EVAR in this trial cohort was around 20 times the current UK willingness to pay threshold (£20K per QALY).<sup>10</sup> Offering such people EVAR will result in a reduction in overall UK population health and in other people inevitably being denied clinically and cost effective NHS treatments. However, the GDC accepted that EVAR 2 trial patients might represent a particularly comorbid cohort and that EVAR might be cost effective in a less comorbid population. But, if such people do exist, it is not possible currently to prospectively identify them, and so the GDC recommended further research in this area. Pending the results of such research, the GDC drafted evidence statements and also recommended that EVAR be considered only once this had been explicitly discussed with the person. The GDC believes this facilitates honest and transparent shared decision making and recognises the limitations of the current evidence base.

### **COMPLEX ENDOVASCULAR ANEURYSM REPAIR**

NICE and the GDC agreed that complex EVAR should be defined as any EVAR procedure not falling within the above definition of standard EVAR. Of note, this includes standard EVAR devices implanted “off IFU” and/or in combination with adjunctive procedures.

### ***Complex endovascular aneurysm repair in people for whom open surgical repair is suitable***

Complex EVAR has a very limited evidence base, has not been assessed in an RCT, and is much more expensive than standard EVAR. The NICE TAT analysis suggested that there were some very limited circumstances where complex EVAR was likely to be a clinically and cost effective alternative to

OSR. However, because of the poor quality of the evidence available, the GDC had much less confidence in this analysis than it did in the standard EVAR modelling. The GDC agreed that more evidence was required before complex EVAR could be recommended for the NHS and considered ways in which this evidence could be obtained. NICE argued that complex EVAR should be considered as long as there were “special arrangements for consent and for audit and research”. However, the GDC believed this wording to be too vague and insufficiently robust, very unlikely to result in the generation of an adequate evidence base, and therefore recommended that complex EVAR be undertaken only as part of an RCT.

### ***Complex endovascular aneurysm repair in people for whom open surgical repair is unsuitable because of comorbidity***

Because of the poor evidence base, the GDC initially considered making only a research recommendation. However, given the costs of complex EVAR, and the likely long term outcomes, which could not plausibly be better than for people for whom OSR is unsuitable but who could have standard EVAR, the GDC agreed that it is very unlikely that complex EVAR could ever be clinically and cost effective in this group. As such, the GDC felt unable to make a “consider” recommendation. However, as there is no evidence of no benefit, the GDC felt unable to make a “do not offer” recommendation. For these reasons, the GDC recommended the publication of evidence statements.

### **IMPLEMENTATION**

The GDC believed that although its recommendations would result in an increase in OSR and critical care bed usage, they would lead to an overall reduction in NHS resource utilisation for AAA because of a larger decrease in EVAR. The GDC noted the continuing declining prevalence of AAA and the evidence from the UK National AAA Screening Programme showing that AAA growth and rupture rates were very much lower than anticipated.<sup>15</sup> The GDC believed that as the recommendations still permit EVAR to be considered for people for whom OSR is not suitable because of their comorbidity or special circumstances, the opportunity for EVAR training and skill maintenance would be maintained. The GDC considered its revised recommendations were implementable across the NHS without substantial service re-organisation or training impact.

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