The NICE Guidelines: NICE or not so NICE?

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Disclosures: Dr. Andrew Holden

• Dr. Holden is a Medical Advisory Board Member for Medtronic, Boston Scientific, and Gore

• Dr. Holden is a Clinical Investigator for Medtronic, Boston Scientific, Gore, Abbott, Cagent, Endologix, Intact Vascular, Shockwave, Bard, Cook, Endospan, Intervene, Spectranetics, TriReme, Merit, Reflow, Terumo, Surmodics

• No other relevant disclosures
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Andrew Bradbury
Professor Vascular Surgery
University of Birmingham
Chair, UK NICE AAA National Guideline Committee
The UK’s National Institute for Health and Care Excellence (NICE) issued draft guidelines on abdominal aortic aneurysm (AAA) diagnosis and management in May 2018.

The most controversial recommendations related to repairing unruptured aneurysms:

For people with *unruptured* AAAs:

- Offer OSR unless there are anaesthetic or medical contraindications
- Do not offer EVAR if OSR is suitable
- Do not offer EVAR to people if OSR is unsuitable because of their anaesthetic and medical condition

**Do not offer EVAR for the elective repair of AAA at all!**
Background

• Further recommendations included:

For patients with **unruptured** AAAs:
  ➢ Do not offer complex EVAR unless the patient is part of a RCT

For patients with **ruptured** AAAs:
  ➢ Consider EVAR* or OSR

Maintain skills in acute EVAR without any elective EVAR experience??

* Especially consider EVAR in rAAA in women and men > 70 years
How Can NICE Justify This?

• When creating guidelines, NICE Committees consider:
  ➢ Does the treatment work (clinically effective)
  ➢ Is it affordable (cost effective)
  ➢ Are the guidelines realistic (implementable)
  ➢ Will the guidelines be acceptable (patients, healthcare professionals)

• NICE AAA National Guideline Committee draft guidelines were produced in a setting of:
  ➢ Falling incidence and prevalence of AAA
  ➢ AAA growth slower than previously thought (surveillance periods extended?)
  ➢ AAA less likely to rupture (change thresholds)
  ➢ Falling mortality of EVAR
Falling Mortality of AAA and the Impact of EVAR?
How Can NICE Justify This?

- The draft guidelines are primarily based on historic, pivotal randomized trials comparing EVAR to OSR for elective repair of AAA
- These trials, including EVAR-1 and DREAM showed an early mortality benefit for EVAR was lost in the mid-term with EVAR-1 showing increased OCM and ARM @ 15 years!
- Other trials considered included EVAR-2 (high risk) and the IMPROVE Trial (rAAA)
- All trials showed a significantly higher reintervention rate for EVAR
Response to NICE Committee Draft Guidelines

Although NICE guidelines are only applicable in the United Kingdom, it is not surprising that there has been a tremendous global response – some positive but many negative concerns raised:

- Criticism of the expertise of the NICE committee creating the guidelines
- Quality and relevance of the data informing the NICE guidelines
- Difficulty in delivering these guidelines in current vascular practice
- Difficulty in assessing fitness for open surgery
- Concerns regarding cost effectiveness and quality of life calculations
- Taking into account patient preference
- Ability to provide an endovascular service for ruptured AAA without an elective EVAR programme
Expertise of the NICE Committee

- The committee does include two Vascular Surgeons and one Interventional Radiologist
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- Their primary interest may not be in AAA management, this shouldn’t interfere with their ability to objectively evaluate data! However more balance might help!
Quality and Relevance of Data Informing NICE Guidelines

- The RCTs largely informing NICE used early generation devices with relatively undeveloped procedural steps, surveillance programmes and indications for reintervention.

- Recent generation EVAR devices have been shown to have significantly lower rates of device migration, type 1 and 3 endoleak, limb occlusion and aneurysm rupture compared to the early devices used in the pivotal trials.

*Tadros et al, J Vasc Surg 2014;59:1518-1527*
Quality and Relevance of Data Informing NICE Guidelines

- Reintervention rates have also decreased, at least in part because of better device performance but also because type 2 endoleak with a stable or decreasing aneurysm sac is not now routinely treated.
- There has also been a recent appreciation of adherence to “instructions for use” (IFU).

<table>
<thead>
<tr>
<th>Meta-analysis N=1559</th>
<th>Outcome</th>
<th>Hostile Neck Anatomy (n=714)</th>
<th>Friendly Neck Anatomy (n=845)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Early outcomes</strong></td>
<td>Secondary Procedures</td>
<td>22%</td>
<td>9%</td>
<td>&lt; 0.001</td>
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<td></td>
<td>Technical Success</td>
<td>97%</td>
<td>100%</td>
<td>0.081</td>
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<td></td>
<td>30 day mortality</td>
<td>2%</td>
<td>2%</td>
<td>0.962</td>
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<tr>
<td></td>
<td><strong>30 day morbidity</strong></td>
<td>15%</td>
<td>7%</td>
<td>0.043</td>
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<tr>
<td></td>
<td>Type I Endoleak</td>
<td>2%</td>
<td>1%</td>
<td>0.232</td>
</tr>
<tr>
<td><strong>Late (1yr) outcomes</strong></td>
<td><strong>Type I endoleak</strong></td>
<td>10%</td>
<td>1%</td>
<td>0.010</td>
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<tr>
<td></td>
<td>Aneurysm-related mortality</td>
<td>4%</td>
<td>0%</td>
<td>0.013</td>
</tr>
</tbody>
</table>
Difficulty in Delivering the Guidelines

• If the draft guidelines were implemented, it is unlikely the current vascular service and hospital service could cope with the demands of increased open repair.
• It has been estimated in the UK that such a decision would result in an increase in over 17,000 annual bed stays and 3000 extra critical care days!
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- It has been estimated in the UK that such a decision would result in an increase in over 17,000 annual bed stays and 3000 extra critical care days!
- It is also estimated that only 5/510 current UK Vascular Surgeons have sufficient current experience in OSR to meet optimum care guidelines for elective AAA repair!

‘Safe’ threshold for Open AAA repair
- Unit volume: 32/year
- Surgeon volume: 10/year

Current status for OR
- Median case/surgeon/year: 2
- Only 10/79 Units meet threshold
- Only 5/510 surgeons meet threshold

Courtesy Ian Loftus
Assessment of Fitness for OSR

- The guidelines treat this as a relatively straightforward binary decision whereas this is seldom the case.
- There have been tremendous recent advances in the pre-operative assessment of life-expectancy based on age, gender and co-morbidities.
- Pre-operative “high risk” multidisciplinary meetings predicted life expectancy and peri-operative risk make recommendations on an individual patient basis for OSR, EVAR or conservative therapy.
- These tools were not available in the era of EVAR RCTs including EVAR-1 and EVAR-2.
The NICE Committee found inferior cost effectiveness for EVAR over OSR:

- Based on the EVAR-2 Trial, the committee concluded EVAR-2 intervention denied 23.5 other people clinically and cost-effective NHS treatment!
- However, a UK Health Technology Assessment did note EVAR might be more cost-effective if reinterventions and AAA-related mortality is reduced.
Cost Effectiveness and Quality of Life

- The survey tools used to assess QOL have been criticised
- Under-estimation of the emotional effect of patients knowing they have a AAA
- Some studies have shown that the diagnosis of AAA at treatment threshold causes a similar emotional impact as a diagnosis of cancer

### Quality of Life (QoL) Measurement

- **Examples:**
  - Short-Form Health Survey (SF-36)
  - European Quality of Life–5 Dimensions instrument (EQ-5D)

### Quality-Adjusted Life Years

- 1 QALY = 1 year of life in perfect health
- QALY = [Years of Life] x [Quality of Life]

Incremental Cost Effectiveness Ratio (ICER)

- **US:** $50,000 / QALY
- **UK:** £30,000 / QALY
Cost Effectiveness and Quality of Life

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- Under-estimation of the emotional effect of patients knowing they have a AAA.
- Some studies have shown that the diagnosis of AAA at treatment threshold causes a similar emotional impact as a diagnosis of cancer.
- Implementation of the draft NICE guidelines would question the ethics of a AAA screening programmes – discovering a threshold AAA that is not treatable leaves a patient much worse off than before.
- Patient choice should always be a key component of any treatment algorithm and it appears this is not respected in the NICE guidelines.
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- **84% of AAA patients on surveillance would opt for EVAR over OR despite durability and surveillance concerns**

1. Winterborn et al, JVS 2009:49;567-81
Selective Use of EVAR for Ruptured AAA

- Outcomes of both elective and acute EVAR for AAA are better in high volume centres and with clinicians with greater case experience.
- It is unlikely to be feasible to offer an acute EVAR service country-wide and maintain sufficient skill base.
- In a recent UK survey, 88% of vascular surgeons did not feel EVAR for ruptured AAA was feasible without an EVAR for elective repair programme.

Inclusion criteria for the IMPROVE Trial: 20 elective EVAR cases/year !!
The draft NICE guidelines clearly have major flaws and are not workable or appropriate for many healthcare systems and geographies.

- In conflict with guidelines from the European Society of Vascular Surgery (Wanhainen 2019) and the American Society of Vascular Surgery (Chaikof 2018)

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- The draft NICE guidelines clearly have major flaws and are not workable or appropriate for many healthcare systems and geographies.
- However, there have been some positive outcomes of this process!
- The discussion has reminded us all that satisfactory long-term durability of EVAR has not yet been proven and there is a need for further device development to improve applicability and durability.
- In the meantime, we should adhere to company IFUs, perform these procedures in optimum environments and continue to monitor patients post-procedure.
- The guidelines have also reminded us of the importance of cost-effective analysis with current and new treatments.
So Where To From Here?

- The NICE Committee has worked closely with stakeholders to modify these guidelines
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- Andrew Bradbury:

  “A final version of the guideline (with recommendations), based upon NICE's post-2018 consultation, extensive clinical and cost-effectiveness analysis, and which has been unanimously agreed by the Guideline Committee, was sent to the NICE Executive Board in early November 2019

  We are still awaiting a publication date”
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