Why The NICE AAA Guidelines Reached The Wrong Conclusions That EVAR Benefits Were Not Worth The Costs

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Disclosures – Dittmar Boeckler MD

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  - Cook, Gore, Maquet, Medtronic, Siemens
- Advisory Board
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- Paid speaker
  - Cook, Endologix, Gore, Maquet, Medtronic, Siemens
- Major stokeholder
  - none

A Joint Society Answer

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President of the VSGBI

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President of the DGG
German Society of Vascular Surgery

NICE addresses variation in practice and ensures cost and clinical effectiveness in the NHS England

Factors considered by NICE
National Institute for Health and Care Excellence (NICE) executive non-departmental public body of the Department of Health in the United Kingdom

Net benefit for the patients
- Treatment Costs
- Risk of AAA Rupture
- Perioperative risks and long-term complications

The evidence shows that the average person receiving EVAR has an uncertain chance of a small net benefit, compared with the large and certain increase in costs. Therefore, the committee agreed that EVAR for unruptured AAA (elective repair) cannot be considered an effective use of NHS resources in this population.

Nice Guideline AAA Committee Members

No conflicts of interest
9 Major Conclusions of NICE Guideline for AAA

(Draft of Consultation May 2018)

- For unruptured and 6 for ruptured AAA

No elective patient should have EVAR

Any patient unfit for open surgery should be offered any intervention at all

EVAR should be offered in ruptured AAAs

Surveillance should be performed by CT

Based on Longterm Data of RCT’s ...

- Historical trials with 1. generation devices
- RCT’s represent 0.5% of globally implanted EVARS (first generation)
- Naive assumptions of durability
- Naive assumptions regarding hostile anatomy
- Inferior imaging technique
- Poor compliance with surveillance

Further Challenges to Implement NICE Guidelines

- No objective tools and score to measure fitness in OR
- Patient’s choice is not respected
- Training ability to avoid safe open repair service
- Resource provision for surgery in open repair

Implications of „Open Repair only”

- If all patients currently undergoing EVAR underwent OR at equivalent risk:
  - doubles mortality
  - Increase in bed days ~ 17,000
  - Increase in critical care days ~ 3000
  - Increase in returns to theatre ~ 150
- Likely to be significantly worse, as current selection for OR probably the fittest patients
- Significant increase in “turn down rate” for open surgery
NICE and rAAA (IMPROVE Trial)

if you were not routinely performing elective EVAR in your hospital would you be able to deliver an emergency EVAR service for rAAA as recommended?

the Answer is: NO!

• EVAR better survival than OR
• EVAR better QOL than OR
• EVAR more cost effective than OR
• EVAR preferential for rAAA
• under local anasthesia
• especially women
• especially if > 70

Not feasible to deliver NICE guidance in rAAA

• untreated elective EVAR will present as ruptures
  ➢ including screening programme patients
• lack of current practice > fewer patients will be treated
  ➢ 24/7/365 service will not be provided
• Low elective rate (<30%) > low EVAR rate (510%) for rAAA

Conclusion on Cost Effectiveness

Table 3: NICE cost–utility model results. Population for whom open surgical repair is an option

<table>
<thead>
<tr>
<th>Treatment strategy</th>
<th>Costs (£)</th>
<th>QALYs</th>
<th>Incremental Costs (£)</th>
<th>QALYs</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrarenal AAA repair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OOR EVAR</td>
<td>£15,456</td>
<td>0.940</td>
<td>£10,720</td>
<td>0.640</td>
<td>-4.03</td>
</tr>
</tbody>
</table>

NICE model
• One directly applicable cost–utility analysis with minor limitations found EVAR to produce fewer QALYs per patient at a higher cost per patient than open repair, for the elective repair of infrarenal AAs in people for whom open repair may be an appropriate intervention. This result was robust to one-way sensitivity analyses. The ICER had <1% probability of being £20,000 or better.

NICE Guideline contradicts good clinical practice in 2019

• New generation stentgrafts perform better (Böckler et al. JCVS 2019 in press)
• Ultrasound surveillance rather than CT scan
• FEVAR in complex AAA shows satisfying outcome

Summary

NICE AAA guideline is misleading and reached wrong conclusions, because it
• is judging clinical effectiveness based on old RCT’s of the early days of EVAR
• is judging cost effectiveness with a new model of economic analysis
  ➢ with limitations and not validated outside NICE and UK
• is recommending OR only or no intervention which is unacceptable
• is actively withdrawing EVAR despite safety and efficacy evidence
• is contradicting good clinical daily practice in AAA treatment
• is restricted to primary treatment of AAA in UK - but the world is watching carefully...