The NICE guidelines are misleading and unfairly biased against EVAR

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Disclosures

• Contributed evidence during the consultation process on behalf of the following stakeholders:
  • VSGBI
  • BSET
  • Circulation Foundation
  • Imperial College Healthcare NHS Trust

NICE draft guidelines

• Much sensible advice with regard to the management of patients with AAA

NICE draft guidelines

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NICE draft guidelines

• Much sensible advice with regard to the management of patients with AAA
  • No elective patient should have EVAR
  • Complex EVAR should only be performed within a RCT
  • Any patients unfit for Open surgery should have no intervention
  • EVAR should be used in emergency cases for rupture
  • Surveillance should be by CTA

NICE draft guidelines - update

• Consultation period – unprecedented feedback response
• Publication deadlines missed
• Committee discharged July 2019
• Still no publication date
Background

Why unfair?

- NICE rules:
  - Only consider RCT evidence
  - Cost effectiveness and QALY
- Unable to consider contemporary data
- No consideration of anatomical suitability/IFU
- No consideration of patient views
- No definition of fitness
- No equipoise for a complex EVAR vs Open RCT

Evidence

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy


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Evidence

Aortic valve operation with current commercially available self-expanding stentless prostheses is well-documented, validated, and an important parameter when planning individualized AAA repair. This study was a prospective, single-center, observational, cohort of patients with AAA undergoing stentless aortic valve operation, and the outcome and follow-up are strongly correlated, especially in patients who have undergone IFU pre-op or post-op.

Durability

Conclusions

Aortic valve operation with current commercially available self-expanding stentless prostheses is well-documented, validated, and an important parameter when planning individualized AAA repair. This study was a prospective, single-center, observational, cohort of patients with AAA undergoing stentless aortic valve operation, and the outcome and follow-up are strongly correlated, especially in patients who have undergone IFU pre-op or post-op.

Outside IFU / off label use

Circulation

Outside IFU / off label use

Patient views:

IFU pre-op or post-op?
Patient views:

- Complex EVAR

Why unfair?

- Cost analysis unfair in this population
- Not all EVAR is equal
- Patients' priorities differ
- Assessment of fitness is a variable
- Fitness = longevity
- Complex EVAR trial unworkable – UK Compass

Summary

- NICE draft guidelines have a point
- But, they don't give EVAR a chance:
  - Blanket ban
  - No consideration of anatomy
  - No consideration IFU
  - No allowance for recent data
  - RCT for complex EVAR not feasible
  - Crucially would stifle ongoing R&D in endovascular aortic field