Same evidence base, different guidelines; What is correct?

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Disclosures

- Cook Medical, Inc.
  - Consultant & Proctor
- Oscor, Inc.
  - Scientific Advisory Board
  - Consultant
- Terumo Aortic (Bolton Medical, Inc.)
  - Scientific Advisory Board
  - Consultant
- W.L. Gore and Associates, Inc.
  - Consultant

SVS Guidelines

- “EVAR has rapidly expanded as the preferred approach for treatment of AAA since the first report >25 years ago”
- We suggest that elective EVAR be performed at centers with a volume of at least 10 EVAR cases each year and a documented perioperative mortality and conversion rate to OSR of 2% or less.
- “Open Surgical Repair of an AAA continues to be used for patients who do not meet the anatomic requirements for endovascular repair”
- We suggest that elective OSR for AAA be performed at centers with an annual volume of at least 10 open aortic operations of any type and a documented perioperative mortality of 5% or less.
- If it is anatomically feasible, **we recommend EVAR over open repair for treatment of a ruptured AAA.**

European SVS Guidelines

- In most patients with suitable anatomy and reasonable life expectancy, **EVAR should be considered as the preferred treatment modality**.
- In patients with long life expectancy(>10-15 years) open abdominal aortic aneurysm repair should be considered as the preferred treatment modality.
- In patients with limited life expectancy(<2-3 years), elective abdominal aortic aneurysm repair is not recommended.
- In patients with ruptured abdominal aortic aneurysm and suitable anatomy, **endovascular repair is recommended as a first option**.

NICE

- The National Institute for Health and Care Excellence (NICE) is an independent public body that provides national guidance and advice to improve health and social care in England.
- NICE guidance offers evidence-based recommendations made by independent Committees on a broad range of topics.
- Ultimately NICE determines for what treatments the NHS will pay

NICE Principles

- Guidance is based on the best available ***evidence*** of what works, and what it costs.
- Guidance is developed by independent and ***unbiased*** Committees of ***experts***.
- All our Committees ***include at least 2 lay members*** (people with personal experience of using health or care services, or from a community affected by the guideline).
- Regular ***consultation*** allows organisations and individuals to comment on our recommendations.
- Once published, all NICE guidance is regularly checked, and ***updated in light of new evidence*** if necessary.
- We are committed to advancing equality of opportunity and ensuring that the ***social value judgements*** we make ***reflect the values of society***.
- We ensure that our processes, methods and policies remain ***up-to-date***.

NICE National Institute for Health and Care Excellence

NICE guidance

Endovascular stent–grafts for the treatment of abdominal aortic aneurysms

Technology appraisal guidance
Published: 25 February 2009
nice.org.uk/guidance/ta167

1 Guidance

This guidance refers to the use of endovascular stent–grafts or open surgical repair only for the treatment of infra-renal abdominal aortic aneurysms. This guidance should be read in conjunction with 'Stent–graft placement in abdominal aortic aneurysm' (NICE interventional procedure guidance 163).

1.1 Endovascular stent–grafts are recommended as a treatment option for patients with unruptured infra-renal abdominal aortic aneurysms, for whom surgical intervention (open surgical repair or endovascular aneurysm repair) is considered appropriate.

1.2 The decision on whether endovascular aneurysm repair is preferred over open surgical repair should be made jointly by the patient and their clinician after assessment of a number of factors including:

- aneurysm size and morphology
- patient age, general life expectancy and fitness for open surgery
- the short- and long-term benefits and risks of the procedures including aneurysm-related mortality and operative mortality.

1.3 Endovascular aneurysm repair should only be performed in specialist centres by clinical teams experienced in the management of abdominal aortic aneurysms. The teams should have appropriate expertise in all aspects of patient assessment and the use of endovascular aortic stent–grafts.

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poor fitness would be similar. The Committee therefore concluded that EVAR would be an acceptable use of NHS resources in patients considered unfit for OSR in whom EVAR was considered appropriate.

1.4 Endovascular aortic stent–grafts are not recommended for patients with ruptured aneurysms except in the context of research. Given the difficulties of conducting randomised controlled trials, it is recommended that data should be collected through existing registries to enable further research.

NICE AAA Draft Guidance

- Consider aneurysm repair for people with an unruptured abdominal aortic aneurysm (AAA), if it is:
  - Symptomatic
  - asymptomatic and 5.5 cm or larger
  - asymptomatic, larger than 4.0 cm and has grown by more than 1 cm in 1 year
- For people with unruptured AAAs meeting the above criteria, offer open surgical repair (OSR) unless there are anaesthetic or medical contraindications.
- Do not offer endovascular repair (EVAR) to people with an unruptured infrarenal AAA if OSR is suitable.
- Do not offer EVAR to people with an unruptured infrarenal AAA if OSR is unsuitable because of their anaesthetic and medical condition.
- Consider endovascular repair (EVAR) or open surgical repair for people with a ruptured infrarenal abdominal aortic aneurysm (AAA). Be aware that:
  - EVAR provides more benefit than OSR for most people, especially for women and for men over the age of 70
  - OSR is likely to provide a better balance of benefits and harms in men under the age of 70

So What Changed Since 2009?

- 15 Year Outcomes of EVAR-1 Published
- 8 Year EVAR-2 Outcomes Published
- AJAX, IMPROVE, ECAR Published
- Registries Reported rAAA Outcomes
- Different Committee

Is Bias at Play Within NICE?

- "Guidance is developed by independent and ***unbiased*** Committees of experts"
- Impossible…
- SVS & European SVS committees also biased…

Cognitive Bias

- Cognitive bias is a limitation in objective thinking that is caused by the tendency for the human brain to perceive information through a filter of personal experience and preferences.

- The filtering process is called *heuristics*; it's a mental shortcut that allows the brain to prioritize and process the vast amount of input it receives each second

- While the mechanism is very effective, its limitations can cause errors that can skew our decisions

Selection Bias

- Selection Bias is the bias introduced by the *selection* of individuals, groups or data for analysis in such a way that proper evaluation is not achieved, thereby ensuring that the sample obtained is not representative of the population(treatment) intended to be analyzed.

- *Same* Evidence Base, Different Guidelines; What is Correct?

- Is it really the same evidence base?
  - NICE focuses on RCT's
    - ***EVAR-1***, DREAM, OVER, ACE, ***EVAR-2***
  - Society Guidelines included more contemporary high volume registries
    - Deemphasized importance of EVAR-1 and EVAR-2

How Do We Avoid Selection Bias?

- Randomize the Process if Possible

- Critically evaluate the studies and/or population to make sure that the outcomes are truly relevant to the question one is attempting to answer

Confirmation Bias

- Confirmation bias is the tendency to search for, interpret, favor, and recall information in a way that confirms one's preexisting beliefs or hypotheses

- Common Bias in Medicine
  - Present around controversial subjects
    - Statin Therapy
    - TAVR vs SAVR
    - CEA vs TCAR
    - **FEVAR vs BEVAR**

How Do We Avoid Confirmation Bias?

- Take a Step Back and Leave Emotions at the Door
- Be Aware of Your Own Pre-existing Beliefs/Position
- Identify the Source or Sources of that Beliefs
  - Financially driven
  - Security
  - Ego

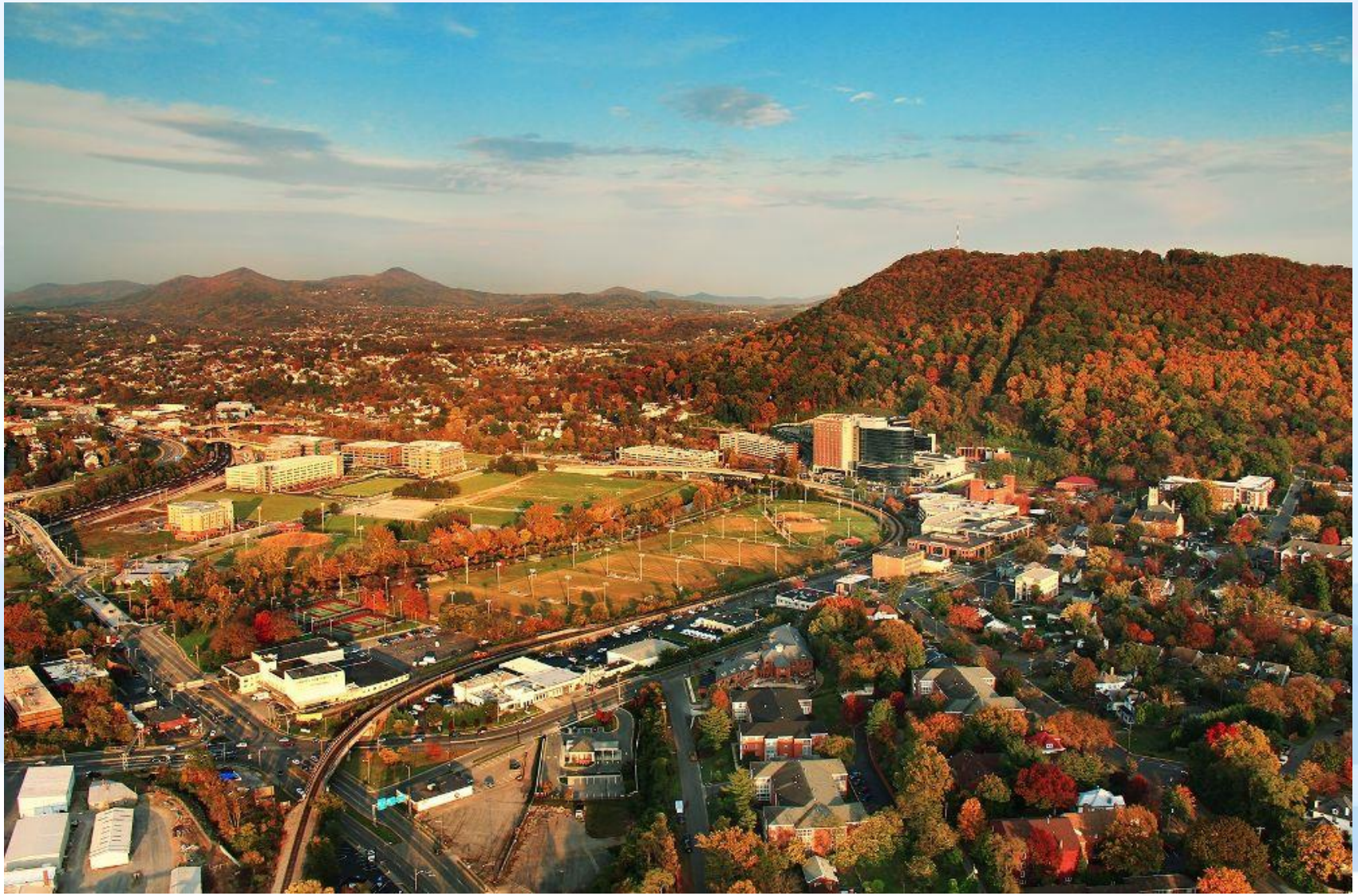
How Do We Avoid Confirmation Bias?

- Ask Questions to Disprove Your Own Hypothesis
- Actively seek out information which is contrary to your position
- Try to Find Common Ground
- Reframe it as an Opportunity

Take Away Messages

- NICE's Points:
  - Cost matters and there is a finite amount of funding
  - Need to Prove a Treatment Works **AND** it is Cost-effective

- Societies' Points:
  - Don't Take Away a Beneficial and Widely Accepted Procedure
  - We must acknowledge that we have work to do:
    - Emphasize Durability of Initial Repair and Follow up
    - Responsibly Refer to Centers of Excellence
    - Continue to accrue Data in Registries



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