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Real-world implications of 15 year EVAR results – has NICE got it right?

KING'S College LONDON
Guy's and St Thomas' NHS NHS Foundation Trust
King's College Hospital NHS NHS Foundation Trust
South London and Maudsley NHS NHS Foundation Trust

Petito Principii

NO!

(NICE hasn't got it right)

VASCULAR SOCIETY

Sent on behalf of the elected Council of the VSGBI.

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Should the final guidelines differ substantially to the draft document, a further statement will follow in due course.'

NICE Statement

Kind regards
Vascular Society

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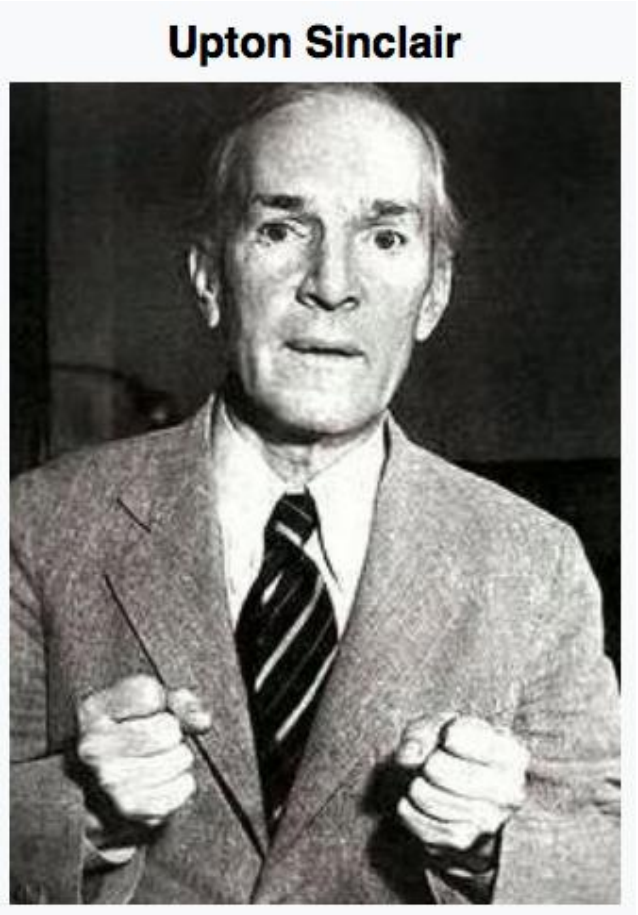
Disclosures

- "Johnny-come-lately" to EVAR
- Open aortic surgeon by training, experience & instinct
- Regular teaching courses based on Cook platform
  - SIR
  - PEAC
- Occasional paid/expenses talks for Cook Medical
  - EVC & PEAC
- Departmental income for EVAR courses

- No intellectual/pecuniary/personal interest in re-running "simple" EVAR trials

"It is difficult to get a man to understand something, when his salary depends upon his not understanding it." (1934)



"a man with every gift except humor and silence"

Time Magazine

20th September 1878 – 25th November 1968
American Author, Muckraker & Political Activist

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NICE vs. EVAR – The (apparent) upshot

2009

- ***"1.1 Endovascular stent–grafts are <u>recommended</u> 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."*

2018

- ***"1.5.3 Do not offer endovascular repair (EVAR) to people with an unruptured infrarenal AAA if open surgical repair is suitable.***
- ***1.5.4 Do not offer EVAR to people with an unruptured infrarenal AAA if open surgical repair is unsuitable because of their anaesthetic and medical condition.***

70 **Complex EVAR compared with open surgical repair of juxtarenal (complex) aneurysms**

Study	Details
Donas Konstantinos P, Eisenack Markus, Panuccio Giuseppe, Austermann Martin, Osada Nani, and Torsello Giovanni (2012) The role of open and endovascular treatment with fenestrated and chimney endografts for patients with juxtarenal aortic aneurysms. Journal of vascular surgery 56, 285-90	Study design: non-randomised comparative study Location: Germany Population: patients with primary degenerative juxtarenal AAAs Sample size: 90; 92% (83/90) male Follow-up: 30-days Intervention: complex EVAR (chimney-EVAR or fenestrated-EVAR) Comparators: open surgical repair Outcomes: 30-day mortality, the need for re-intervention and length of stay,

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15 year results EVAR I trial
(a Post-Hoc Analysis)

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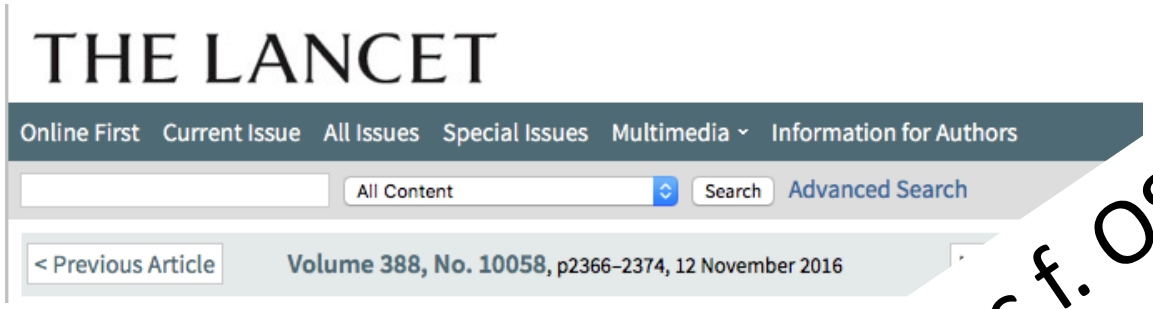
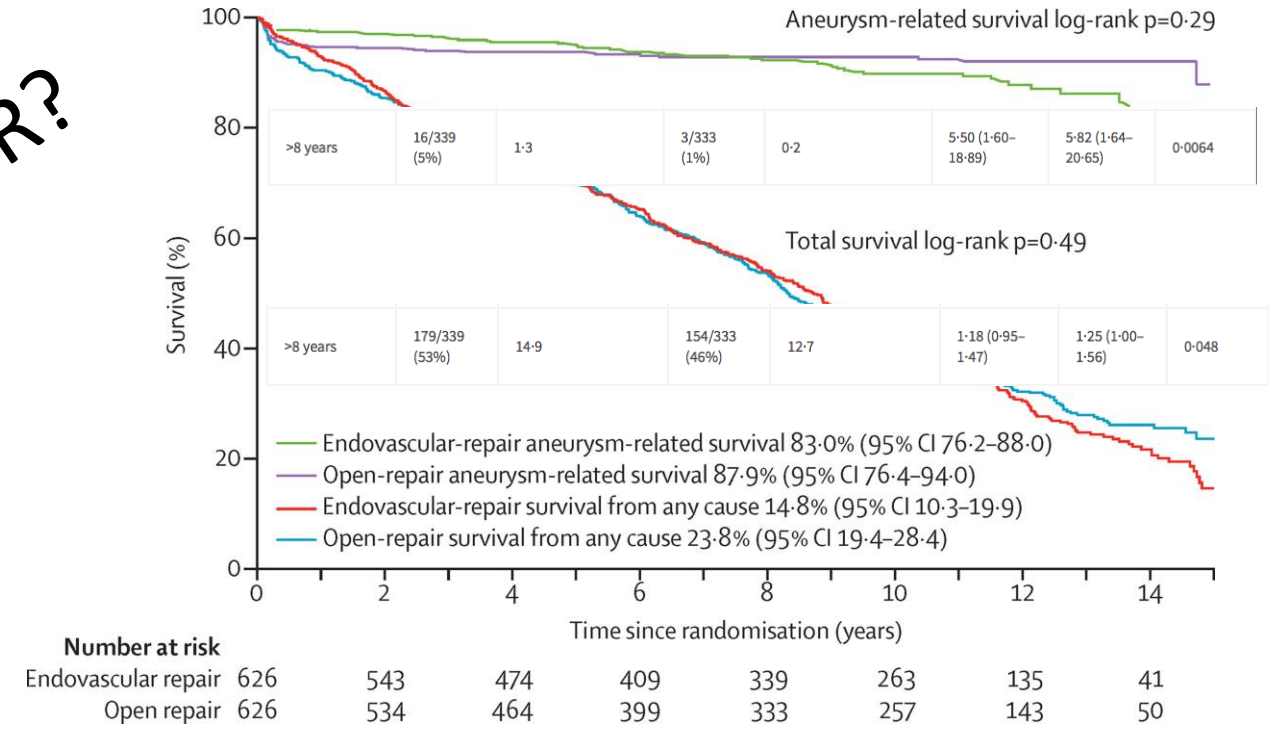


Is EVAR actually DANGEROUS c.f. OSR?

- 1252 "Fit" patients recruit[illegible]2004
  - n at risk: Year 10 - OSR [illegible] 263
  - n at risk: Year 14 - [illegible]AR 41
- Reintervention[illegible] EVAR
  - Occurred [illegible] the follow-up period
- Aneurys[illegible]d mortality throughout the fo[illegible] period
  - [illegible]ptures per 100 person-years
  - [illegible]e death rate associated with rupture - 67%
- Greater risk of cancer in the EVAR group



https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31135-7/fulltext

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…The NIC(e)R Economic model (HE.2)
(2 separate appendices - K & HE)

- Based largely on EVAR1 & EVAR2 patient-level data
- Further informed by NVR 2016 data for EVAR outcomes
- Device costs provided by the 3 clinicians involved & extrapolated…
- & Cochrane review for OSR outcomes

NICE Conclusions

1. No treatment is cheaper than EVAR (unfit)

468 *NICE model*

469 • One directly applicable cost–utility analysis with minor limitations found EVAR to be
470 associated with an ICER of £460,863 compared with no intervention, for the elective
471 repair of infrarenal AAAs in people for whom open repair is not considered to be a suitable
472 intervention. This result was robust to one-way sensitivity analyses. The ICER had 0%
473 probability of being £20,000 or better.

2. Elective EVAR is more expensive (always)

406 *NICE model*

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

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NICE vs. EVAR – How did we get here?

623 ***Which technique to use***

624 There is no evidence that EVAR for people with an unruptured infrarenal AAA
625 provides long-term benefit compared with open surgical repair. While EVAR is
626 associated with fewer perioperative deaths, it has more long-term complications, and
627 these complications mean that people will need further procedures. There is some
628 evidence that EVAR is associated with worse long-term survival than open surgical
629 repair. EVAR also has higher net costs than open surgical repair. The evidence

630 shows that, even if long-term benefits were achievable, they could not plausibly be
631 sufficient to outweigh these costs.

"It's the DURABILITY stupid!"

Actually – it's the COST!

"It's the ECONOMY stupid!"

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The Vascular community

How responsible have we been?

- Use the best solution for the patient in front of you
  - To extend/preserve lives of quality:
  - Consider ***all*** of the options, including Nothing/Another opinion, technique or surgeon
- EVAR – Stick to IFU, Proven platforms
- But it's too easy, too safe, too much fun
- Our collective failure to do this….

Ploughing on Regardless

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Scott's Parabola
…the rise (& fall) of the Medical-Industrial Complex

BMJ VOLUME 323 22–29 DECEMBER 2001 bmj.com

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NICE…

- On the basis of iffy data & analysis applied to cost of treatment…
- National Institute for Clinical Excellence

Becomes

- National Institute for Clinical RATIONING (Even NICeR)

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Stakeholders, Victims & Winners

- Patients
- Institutions
- Academia/Progress
- Industry
- Authorities….
- Individuals

- The public purse??
  - Do NIC(e)R's sums add up…
  - Compensation claims
    - Trusts
    - Post EVAR patients
- A few (isolated) Individuals….

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Stakeholders, Victims ~~& Winners~~

- **Patients**
  - Specifically:
  - Fear: Screening without resolution
  - Risk of death: Retired men (& their families/dependants)
    - Higher elective and emergency mortality
      - Regaining open AAA experience – RTT delay
      - Insufficient bedspace for longer open AAA repair – RTT delay
      - More RAAA (in turn-down group)
      - Fewer EVAR for RAAA (no stock), done less well
- Institutions
  - Wasted investment
  - Overwhelmed ITU/HDUs
- Academia
  - Loss of industry funding
  - Research arrest/wholesale transfer from U.K.
  - No chance of Redo EVAR Trials – no equipoise
- Industry
  - Graft & ancillary manufacturers
    - EVAR stock
  - Imaging hardware manufacturers
- Authorities….
  - Vascular Professional trust –
    - Previous EVAR patients have grounds for complaint
  - **NICE** reputational risk
    - Rigid methodology in the face of the “known unknowns”
    - Conclusions at complete variance with EU & USA – on the same available evidence base
    - Professional (& personal) isolation of 3 famous aortic surgeons
- Individuals (this audience)
  - Loss of application a hard-won skill
  - Medio-legal risks if NICE is not adhered to

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NICE reputational risk
- An organisation under Siege?

- Rigid methodology in the face of the “known unknowns”
- Conclusions at complete variance with EU & USA – on the same evidence base

- Professional (& personal) isolation of 3 famous aortic surgeons

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NICE Guidance…

Final publication date(s):

- First draft May 2018
  - 1253 pages, 24 appendices (Appendix K)
  - Costing models…
  - Complex EVAR conclusions based on 1 reference, 90 patients
- Response

- Embargoed Final version 2 weeks before general publication

- Initial date: “early November”
- Deferred
- Current date for completion of Stakeholder Confidentiality Form:

  30th November…

(When is the Brexit vote again?)

Guy’s and St Thomas’ NHS
NHS Foundation Trust

HOME » NEWS » UK NEWS

Sept 11: 'a good day to bury bad news'

By Andrew Sparrow, Political Correspondent
12:01AM BST 10 Oct 2001

A LABOUR aide who advised the Government to use **the attack on the World Trade Centre** to distract attention from "bad" news stories was fighting for her job last night.

Jo Moore, who works for Stephen Byers, the Secretary of State for Transport, Local Government and the Regions, was widely condemned for showing spin at its worst when her news management memo was leaked.

Miss Moore's memo, written at 2.55pm on **September 11**, when millions of people were transfixed by the terrible television images of the terrorist attack, said: "It is now a very good day to get out anything we want to bury. Councillors expenses?"

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Guy's and St Thomas' NHS
NHS Foundation Trust

My Opinion? C21: Personalised Medicine

- EVAR is a tool, it's best used for **some**, but not for **others**

- The other tools include:
  - Do nothing
  - Open AAA repair

- Match the tool to the problem

- **If anything - EVAR 1 15 should lead to *refinement* of case selection**

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NICE…

Throwing the baby out with the bathwater!

- Earliest record:

Narrenbeschwörung

Appeal to ***Fools***

(Fool incantation) by Thomas Murner, 1512

In Summary….

NO!

(NICE hasn’t got it right)

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