



23<sup>RD</sup> INTERNATIONAL EXPERTS SYMPOSIUM  
**CRITICAL ISSUES** in aortic endografting 2019  
LIVERPOOL UNITED KINGDOM **MAY 23-24**

Why is NICE thinking of turning NASTY?  
(No Aneurysm Stenting from Today)

Patient choice and high risk patients in the 'NASTY' era

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[www.critical-issues-congress.com](http://www.critical-issues-congress.com)

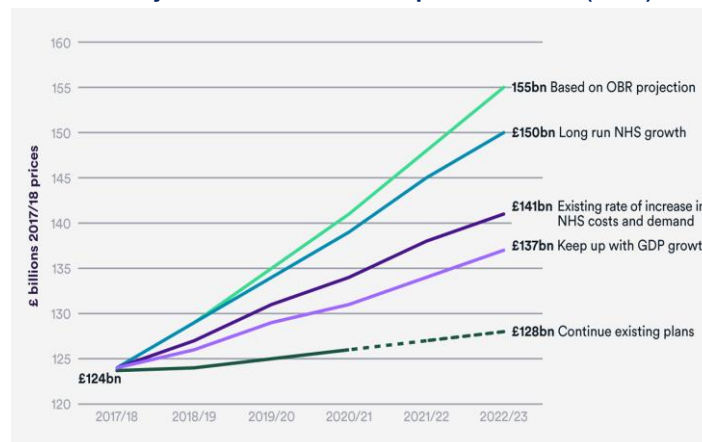
**I HAVE NO CONFLICT OF INTEREST**

# NICE - EVALUATION OF NEW THERAPIES

<https://www.nice.org.uk/process/pmg20/chapter/>



Projected health expenditure (UK)



Nuffield Trust calculations

Reliance on RCTs and systematic reviews, where available

Comparison with established techniques/therapies

Incorporation of economic evaluation (QALY - ICER)

Consideration of social impact, ethics and practicalities

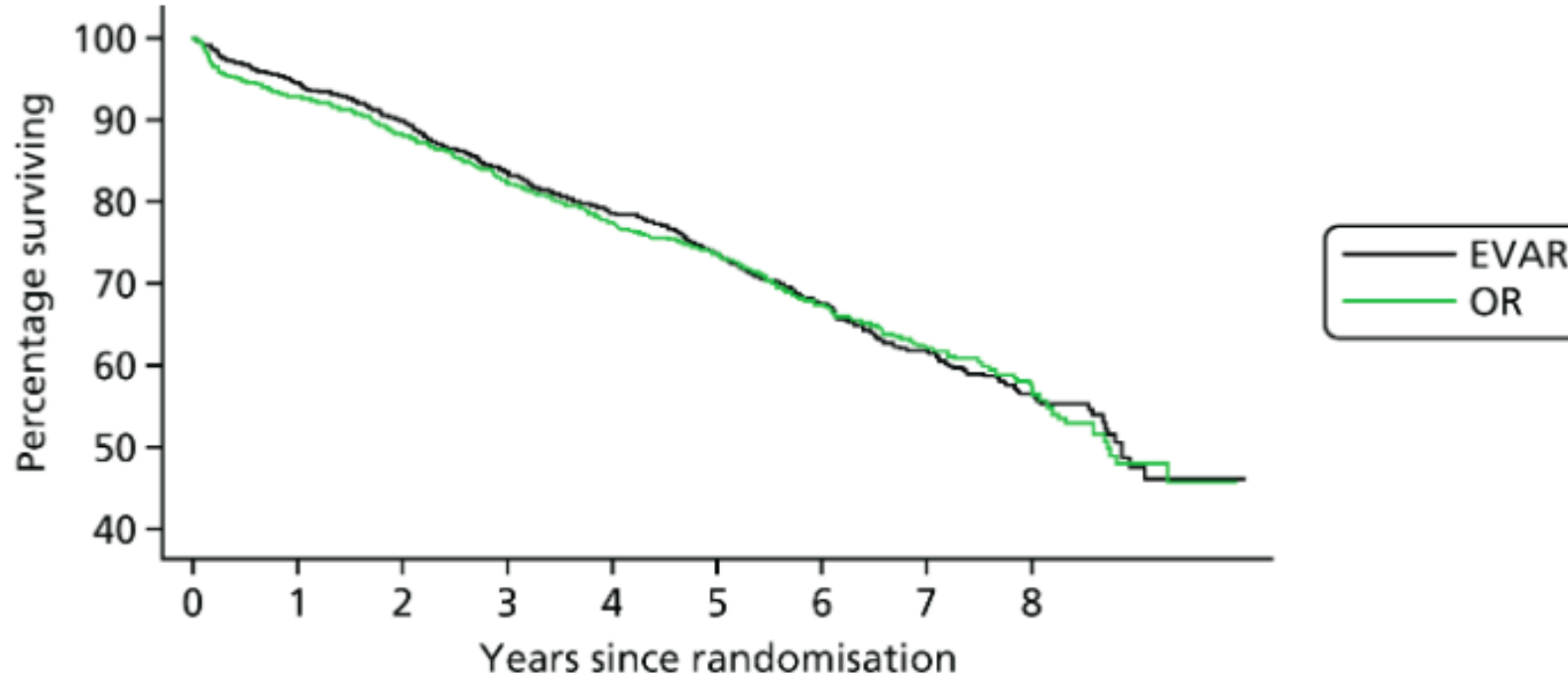
On behalf of the NHS

Patient's choice not a major consideration

*"...individual 'willingness to pay' (WTP) is likely to be more than public-sector WTP, sometimes by quite a margin"*

# EVAR I + OVER + DREAM + ACE

2783 patients



Number at risk

EVAR	1393	1313	1228	1114	988	832	556	309	137
OR	1390	1279	1200	1088	959	836	564	327	147

Same incidence as in patients with 5-5.4 cm AAA in UK small aneurysm screening program

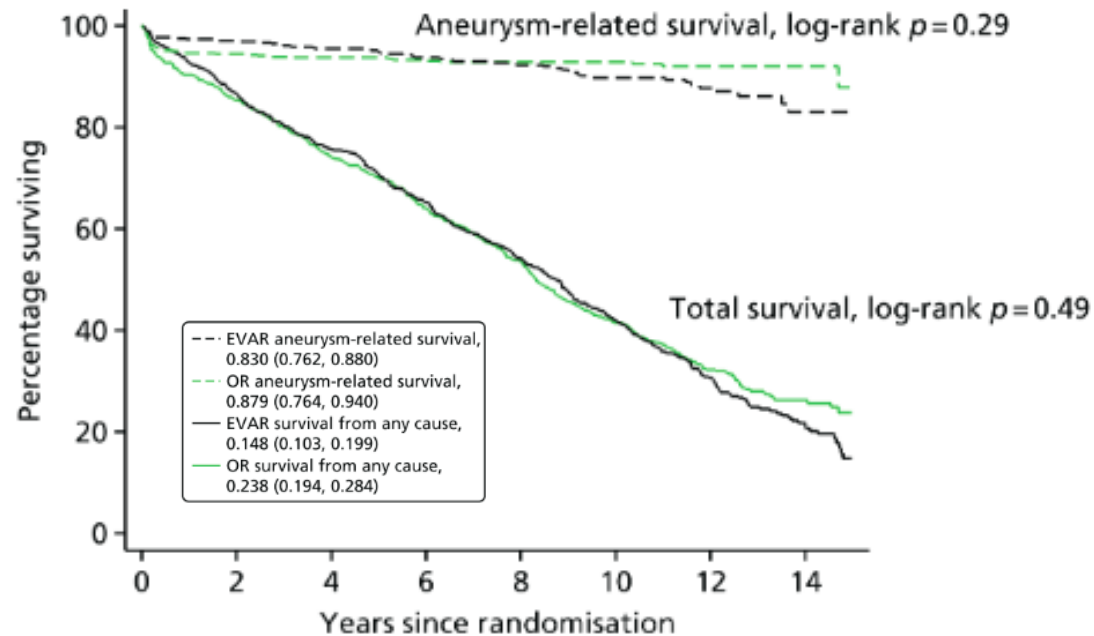
*Circulation. 2019;139:1371-80*

Incidence of rAAA in EVAR patients: 0.5/100/year

# EVAR I TRIAL

## 1252 patients (1999-2004)

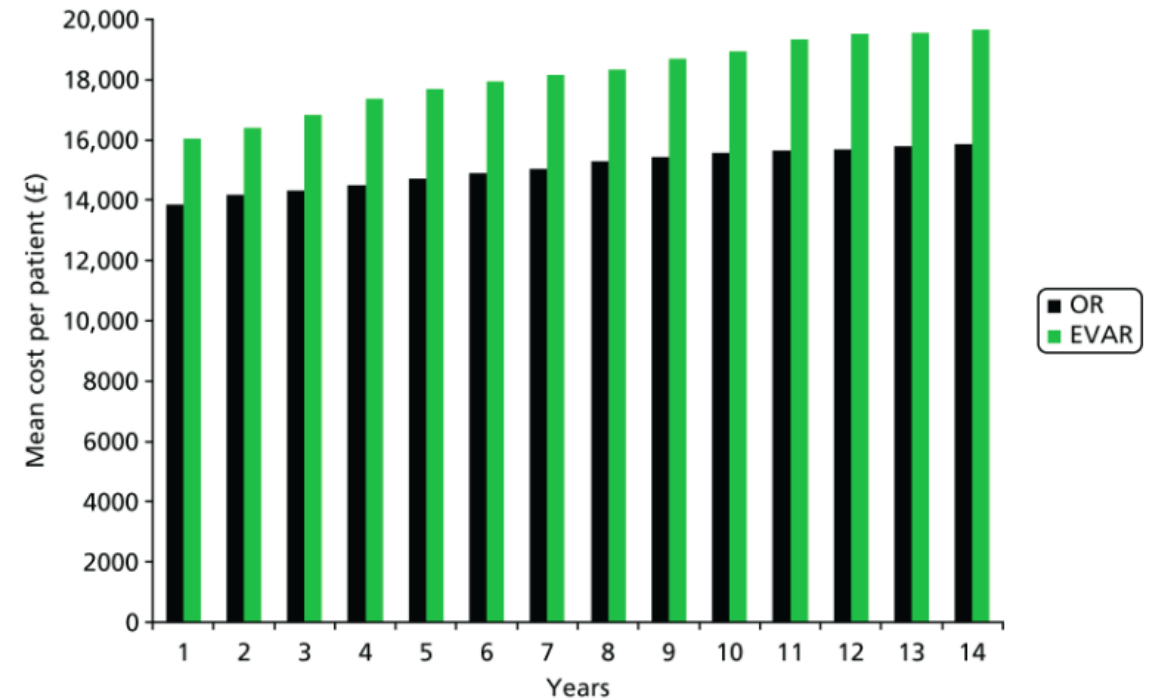
### Survival



Number at risk

EVAR	626	543	474	409	339	263	135	41
OR	626	534	464	399	333	257	143	50

### Evolution of cost



# INFORMED CONSENT - UK

## General Medical Council

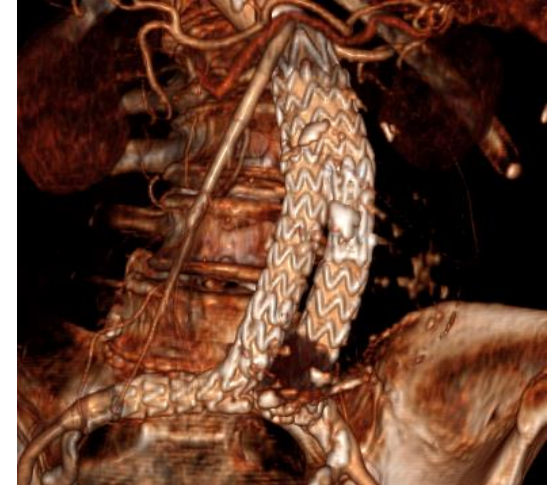
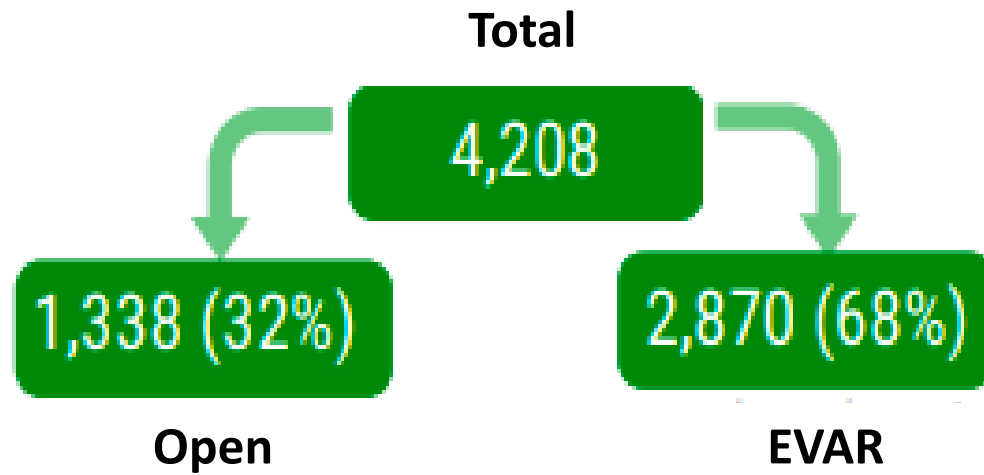
## Montgomery v Lanarkshire ruling

*“You must give patients the information they want or need about... options for treating or managing the condition, including the option not to treat...”*

*“The doctor is... under a duty to... ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative... The test of materiality is whether... a reasonable person in the patient’s position would be likely to attach significance to the risk....”*



# INFRARENAL AAA REPAIR - UK



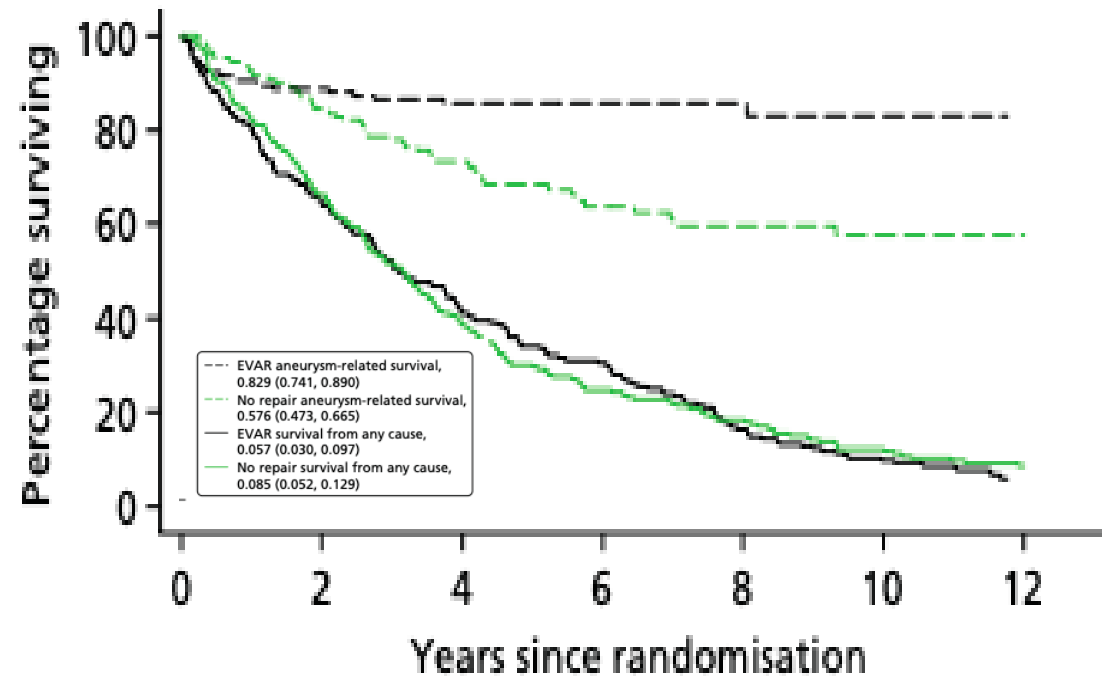
## WHAT IS THE EXTERNAL VALIDITY OF THE TRIALS?





# EVAR II TRIAL

## 404 patients (1999-2004)



404 patients – mean AAA diameter: 68 mm

9 rAAAs before EVAR

7% elective operative mortality (9% with ruptures)

rupture risk in surveillance arm ~ 9%/year

same quality of life

increased cost

64 elective repairs in surveillance arm

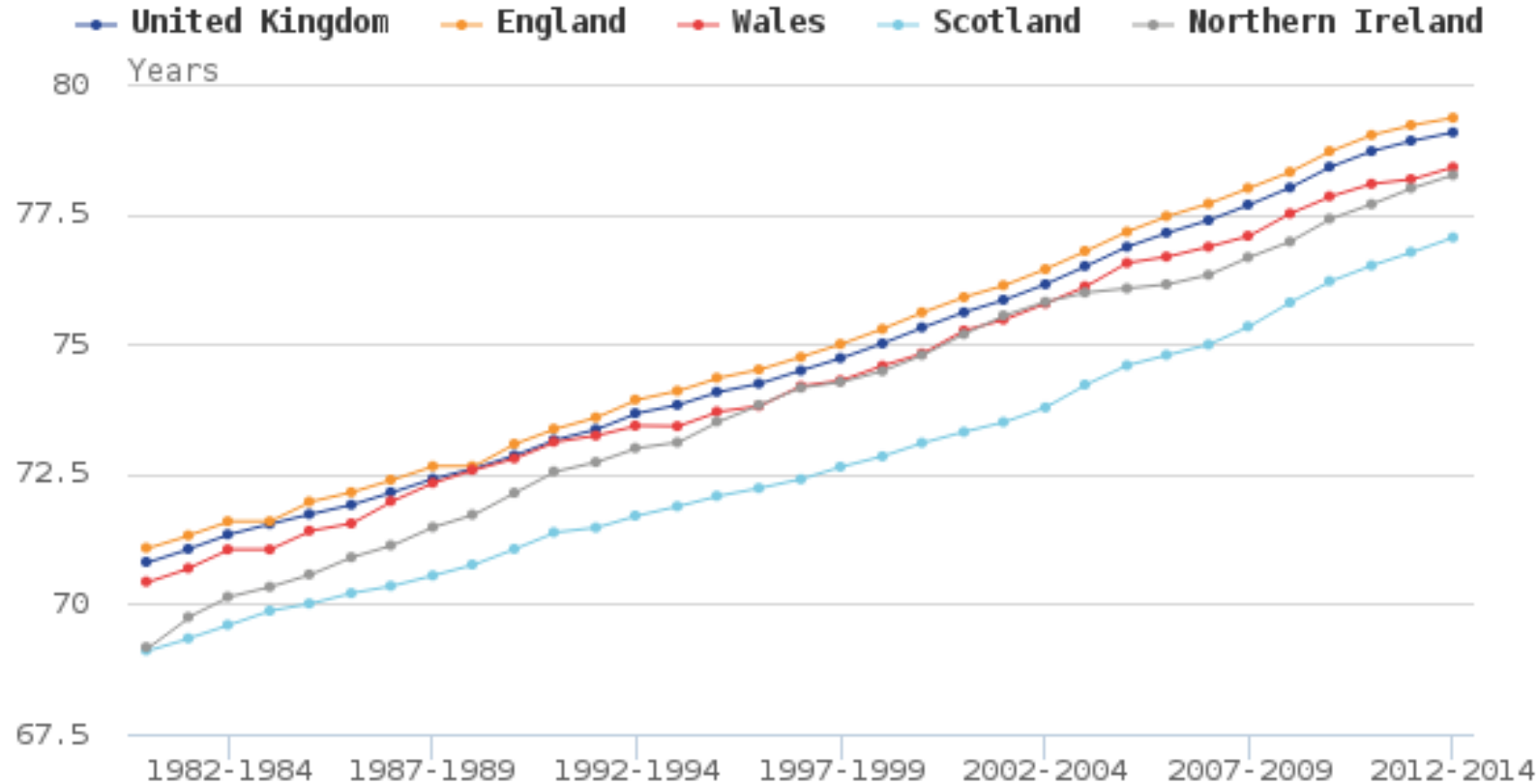
Cost of QALY: £ 400,000-£500,000

Of 96 patients alive in September 2009, all but 13 had their AAA repaired

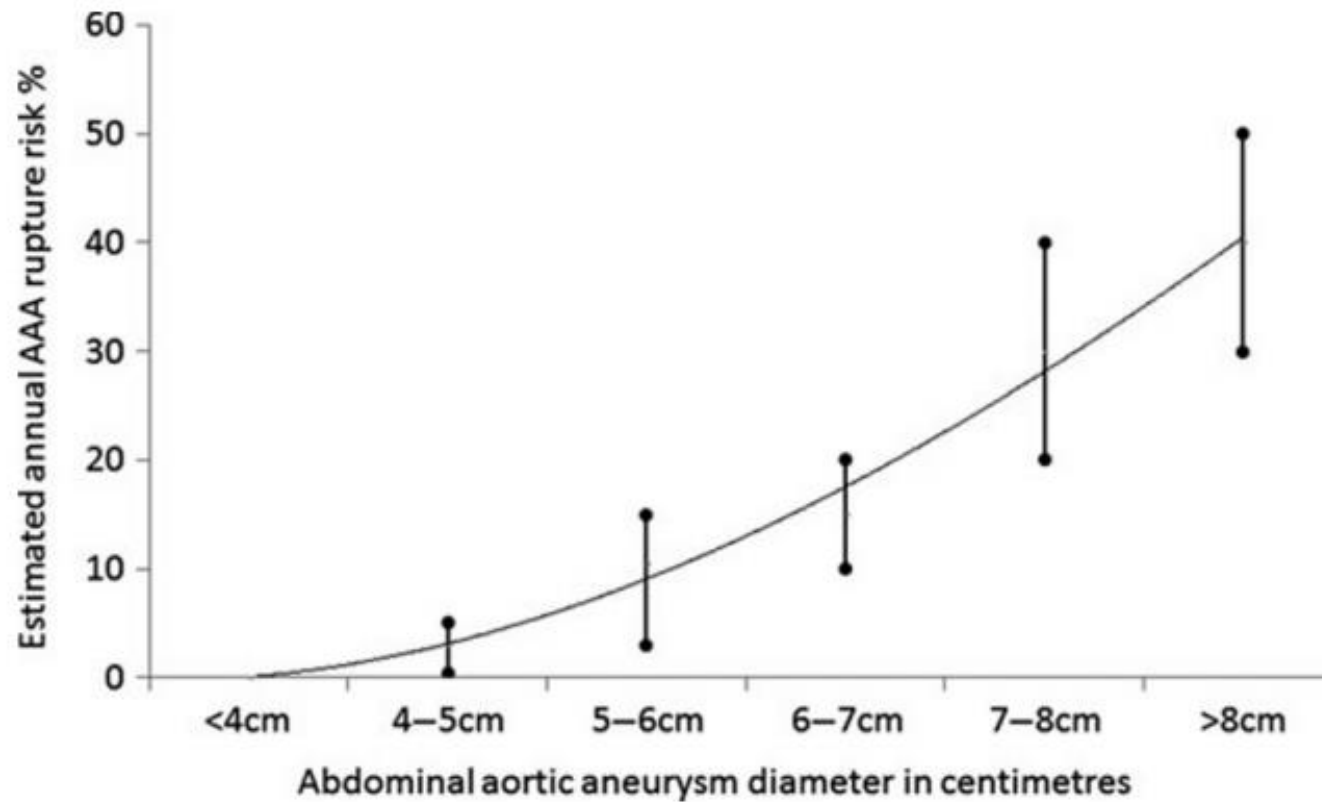
Of 23 patients alive in June 2015, all but 2 had their AAA repaired

# WHAT HAS CHANGED SINCE THE TRIALS?

## Life expectancy at age 65 in the UK



# HOW DO YOU FACTOR IN THE RISK OF AAA RUPTURE?



Brewster et al., J Vasc Surg 2003;37:1106–17.

## SHOULD EVAR STILL BE AN OPTION?

YES, IF:

patient is not a “trial candidate”  
very large or symptomatic AAA with poor fitness  
there is “willingness to pay” AND acceptance of risk of late failure

**Do we need a new RCT in “unfit” patients?**