

**Can you accept the EVAR Trials 10-year results
and still justify EVAR for all-comers?**

Janet Powell

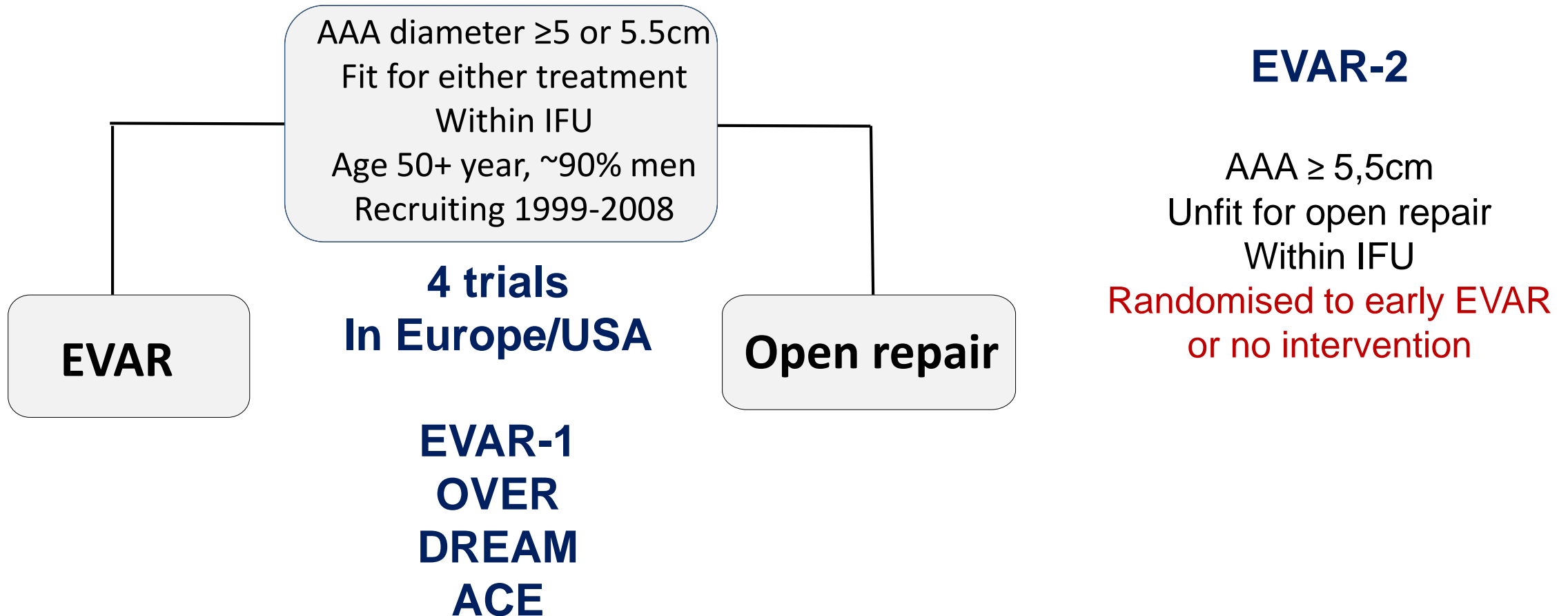
Imperial College London

Questions to be addressed

- What did the analyses show?
- Is continued enthusiasm for EVAR technology justified if we accept this high quality evidence?
- Is there a place for patient selection based on risk assessment?

The EVAR randomised trials for elective AAA repair

All had selective recruitment: not all-comers
Predated widespread screening, so large AAAs



The EVAR 2 trial for those unfit for open repair

Aneurysm-related mortality

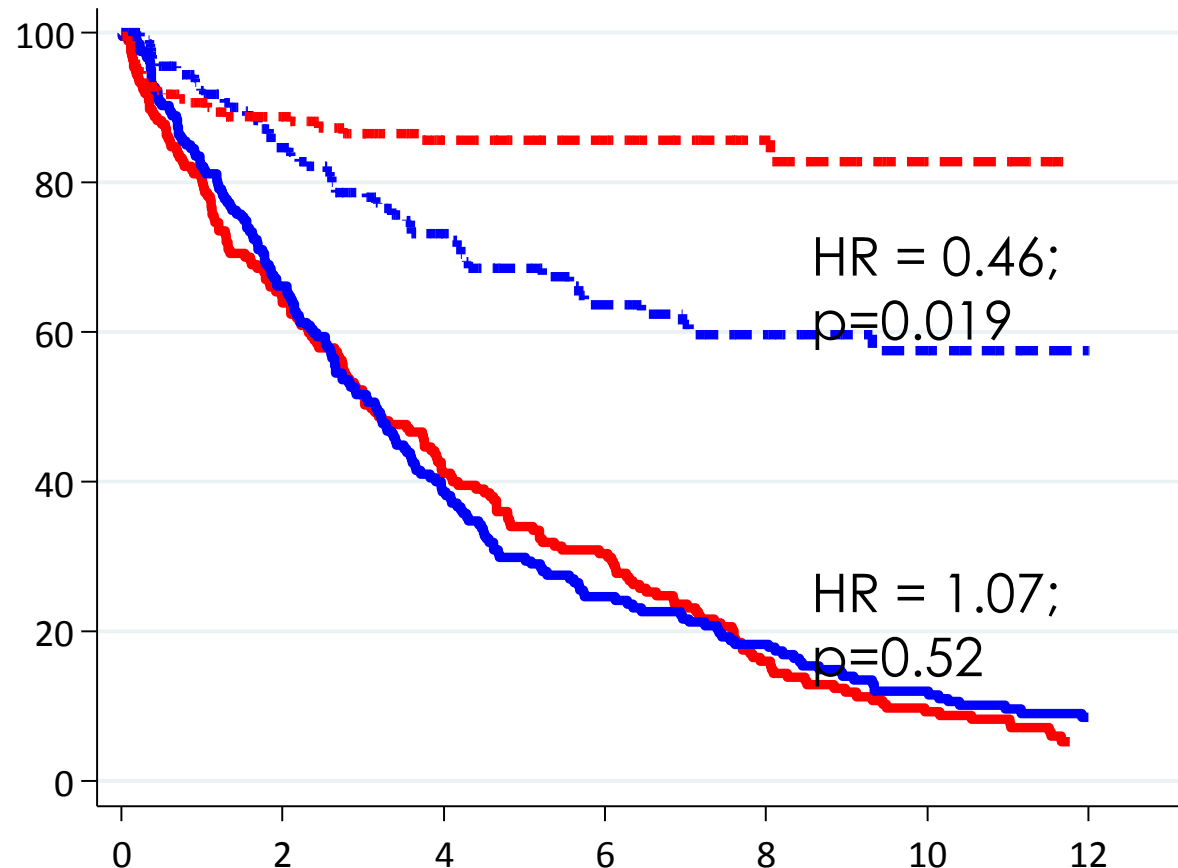
--- EVAR

--- No intervention

All-cause mortality

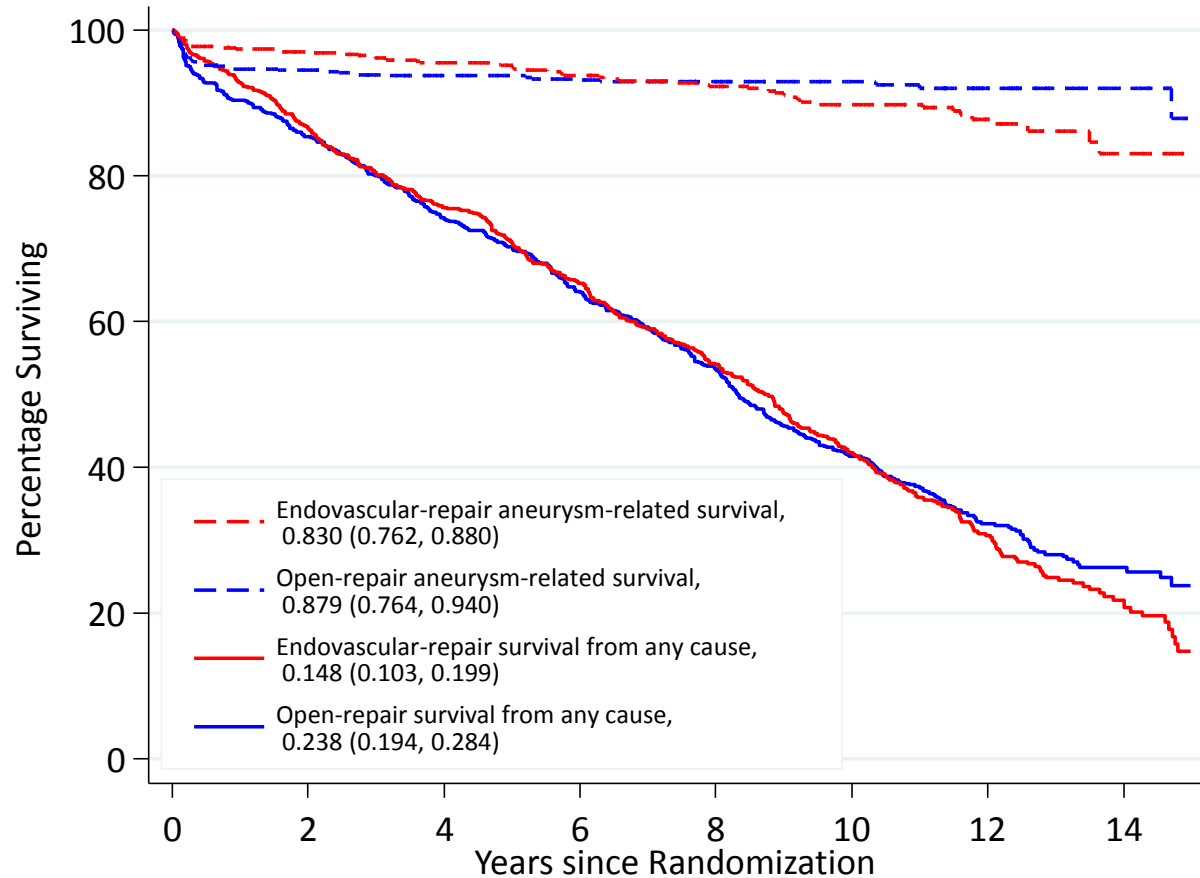
— EVAR

— No intervention



- Lower aneurysm-related mortality: HR=0.46; p=0.02
- No benefit in terms of total mortality: HR=1.07; p=0.52
- 7% survival probability at 12-years
- **Unfit patients, never any survival benefit from EVAR: cost burden**

The EVAR 1 trial of EVAR vs open repair in fit patients within IFU: Survival over 15 years



AAA-related mortality

dream
 Showed the same &
 more reinterventions in EVAR group

	0	2	4	6	8	10	12	14
Number at risk								
Endovascular repair	626	543	474	409	339	263	135	41
Open repair	626	534	464	399	333	257	143	50

Lancet 2016

Decreasing cost-effectiveness of EVAR vs open repair after 10 years: why?

After 10 years <50% patients remain alive

- Increasing mortality **NASTY**

Increased secondary rupture & aneurysm-related mortality

Increased risk of abdominal cancer & deaths from cancer

- Increasing costs **NASTY**

More surveillance & increasing numbers of re-interventions

The fading promise of EVAR: blamed on old technology

Unlikely



Device modifications have extended EVAR-eligibility: no guarantee newer devices will perform better: **NASTY!**

- Lifetime of devices needs to be 20 years
- Increasing use of low profile devices: the fabric is subject to compression-induced crimping & wrinkling: increased risk of tears & porosity
- Despite improvements in the purity of nitinol, supports still liable to fractures with time

**But,
better imaging should allow for more accurate placement**

2 Unsolved or insoluble contributors to EVAR failure NASTY

- Proximal seal in regions of unidentified aortic disease
- Progression of aneurysmal disease over time
- Poor compliance with surveillance

Who wants EVAR?

2 Is there still enthusiasm for EVAR?

Patients	√√√
Clinicians	√√
Industry	√√√√

EVAR is here to stay

So it has to get better, with appropriate patient selection

Precision medicine, for patients exiting NAAASP

3 Treatment based on risk assessment

Defer



Alfred

68 years, married
AAA 5.6 cm
Sedentary lifestyle
Smoker, recent MI
Morphology not quite IFU

EVAR



Bill

75 years, married
AAA 5.5 cm
Keen golfer
Morphology within IFU
Compliant with BP drugs

Open repair



Chris

74 years, divorced
AAA now 6.3 cm
Emigrating to Spain?
Morphology close to IFU
Defaulted from surveillance

Although EVAR cannot be justified in all-comers, there is a future for EVAR



- Learn from history
- Careful selection of fit patients
- Address the NASTY issues
- Better devices
 - Non-metallic fixation, more applicable to women, more durable, inbuilt sensors for early remote warning of problems