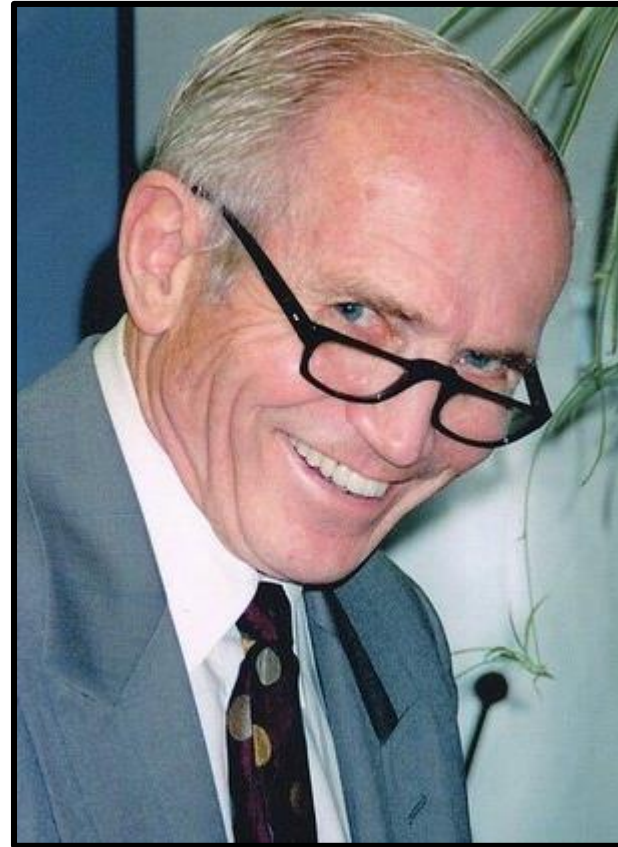


Aortic Aneurysm Clinical Decision-Making

Too Many Patients Are Being Treated Without Benefit

Strandness Symposium
March 21-24, 2022
Maui, Hawaii

Michael T. Caps, MD MPH
Chief, Vascular Surgery
Hawaii Permanente Medical Group
Honolulu, Hawaii

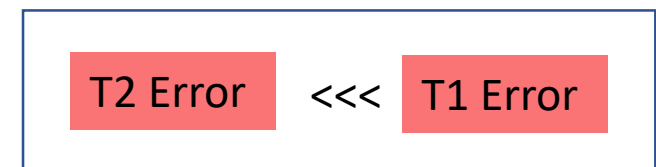


No Disclosures
No Financial Conflicts-of-Interest

*Aneurysms that should be repaired

- Diameter
 - ≥ 5.5 cm (males)
 - ≥ 5.0 cm (females)
- Acceptable risk for surgery
- Acceptable life expectancy
 - From non-aneurysm-related causes

		Aneurysm Should Be Repaired	
Aneurysm Is Repaired		Yes*	No
Yes			T1 Error
No		T2 Error	



* SVS Guidelines

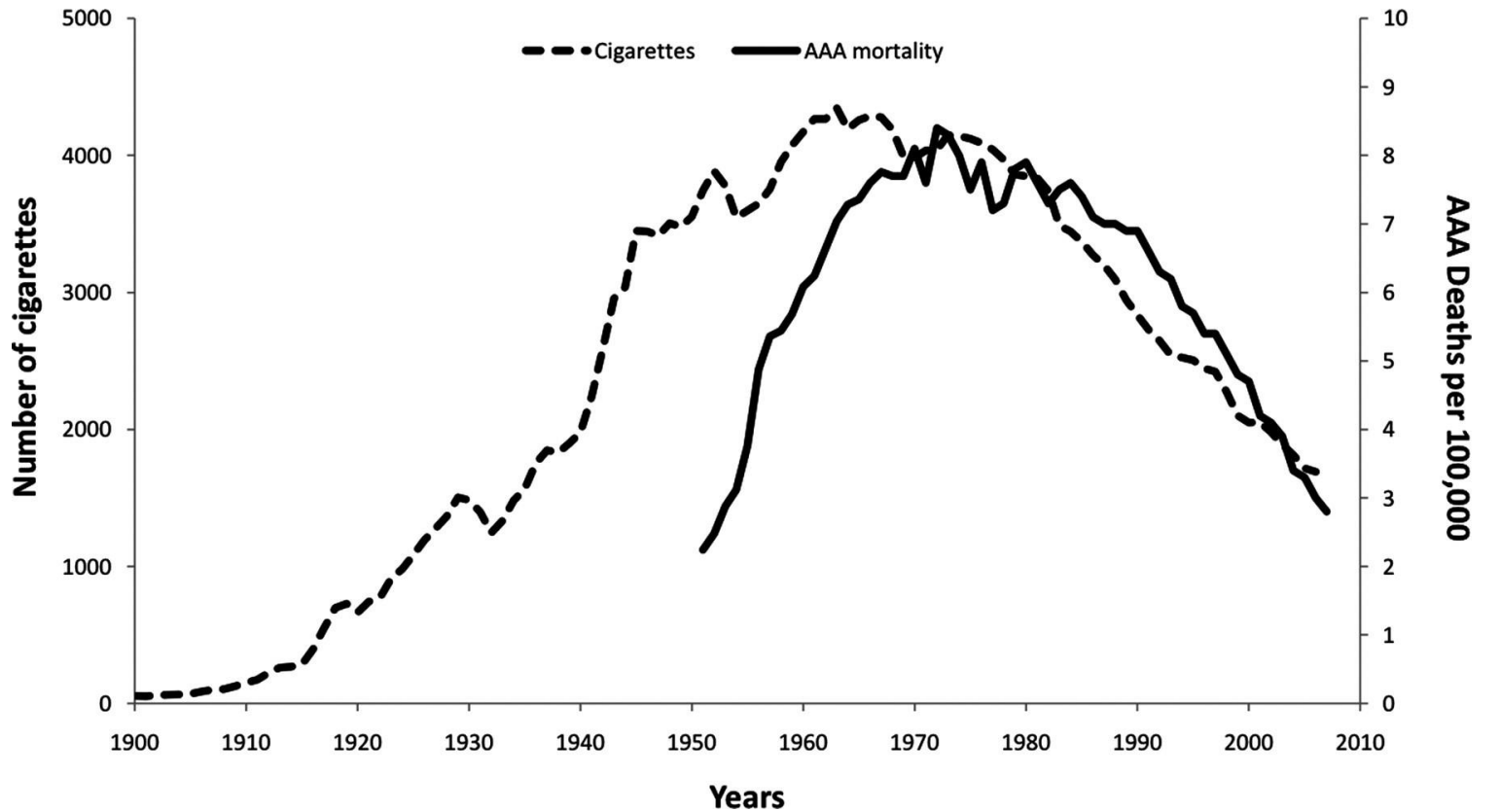
AAA Facts

1. Aortic aneurysm disease is declining *sharply*
2. Patients are getting *older* and *sicker*
3. AAA rupture risk by diameter is *lower* than previously thought
4. Repair at diameters < guideline is *very* common
5. The dominant repair procedure (EVAR) has questionable *durability*
6. Benefits of AAA repair in older/sicker patients are *marginal*

Trends in Age-Adjusted AAA Mortality

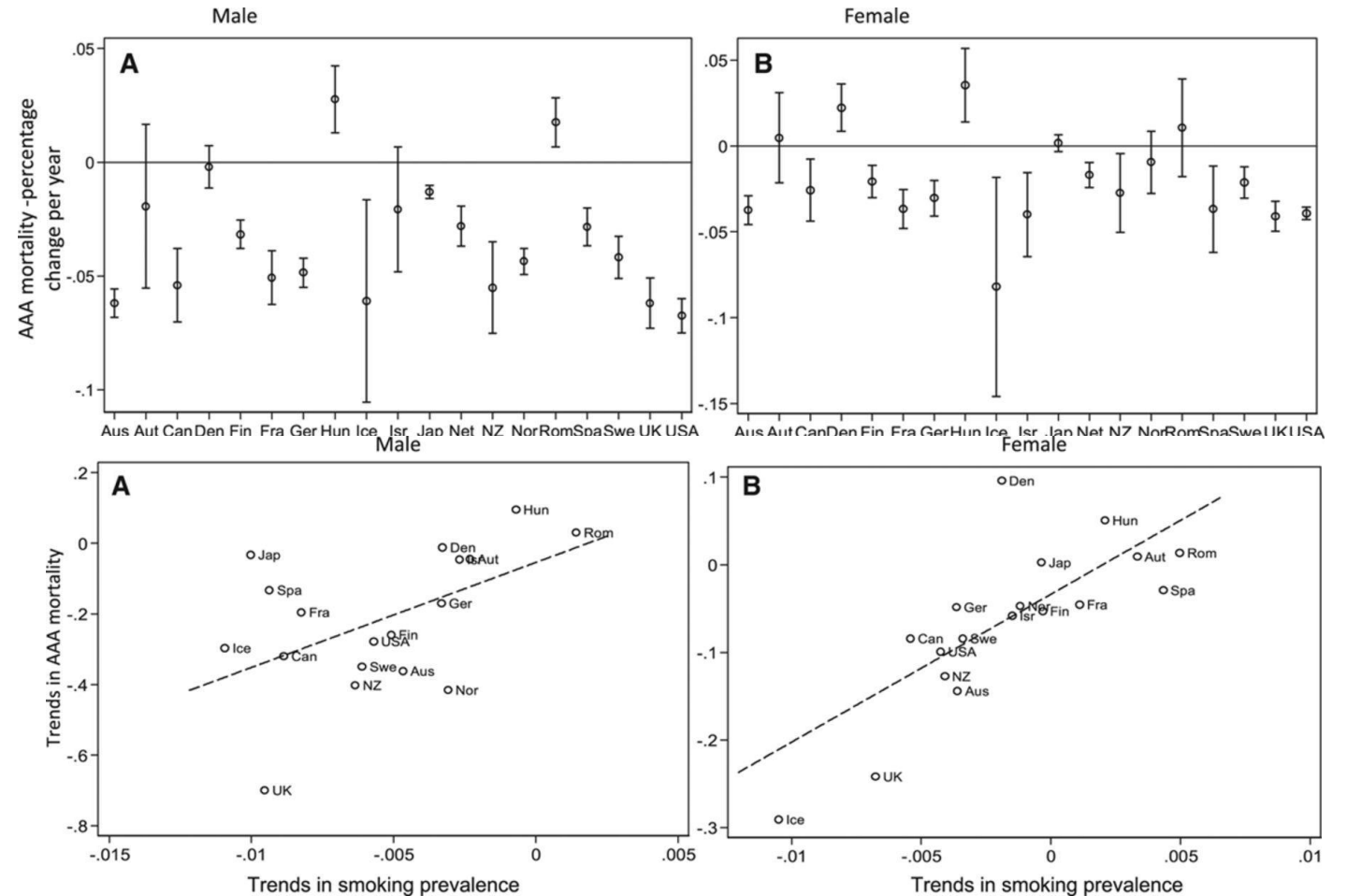
United States

- AAA mortality in the US
 - Peaked in the mid 1970s
 - Plateaued until late 1980s
 - Steep decline since 1990
- Tobacco use in the US
 - Peaked in the early 1960s
 - Steep decline since late 1970s
- AAA repair 1980-2005
 - No significant change



Temporal Trends in AAA Mortality (1994-2010)

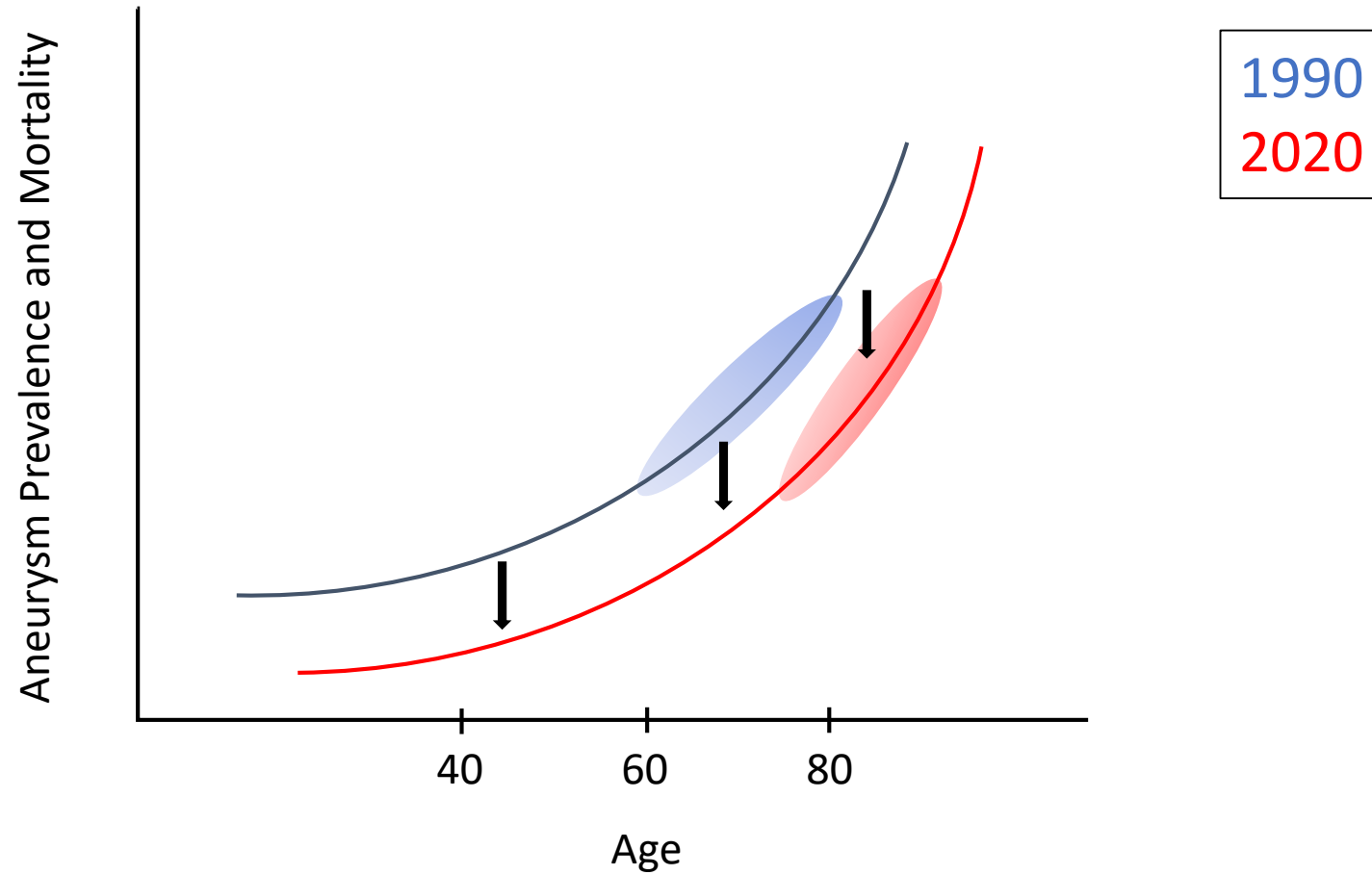
- AAA mortality has declined in most countries
 - Approx – 0.5%/year
 - Not uniform across countries



- This trend is strongly related to declines in smoking prevalence

Aneurysm-Related Mortality

Age-Adjusted Versus Crude



AAA Rupture Risk By Diameter

UK Small Aneurysm Trial (1999)	ADAM Trial (2002)
1090 patients w/ aneurysms 4.0-5.4 cm	1136 patients w/ aneurysms 4.0-5.4 cm
Randomized to OAR vs US surveillance	Randomized to OAR vs US surveillance
79% male	99% male
Operative mortality = 6.3%	Operative mortality = 2.7%
No difference in long-term survival	No difference in long-term survival
Rupture rate in non-repaired = 1%/year	Rupture rate in non-repaired = 0.6%/year



Aneurysms <5.5 cm in males
Ultrasound surveillance > Open Repair

Rupture Rates in the UK-SAT

Supplemental Analysis

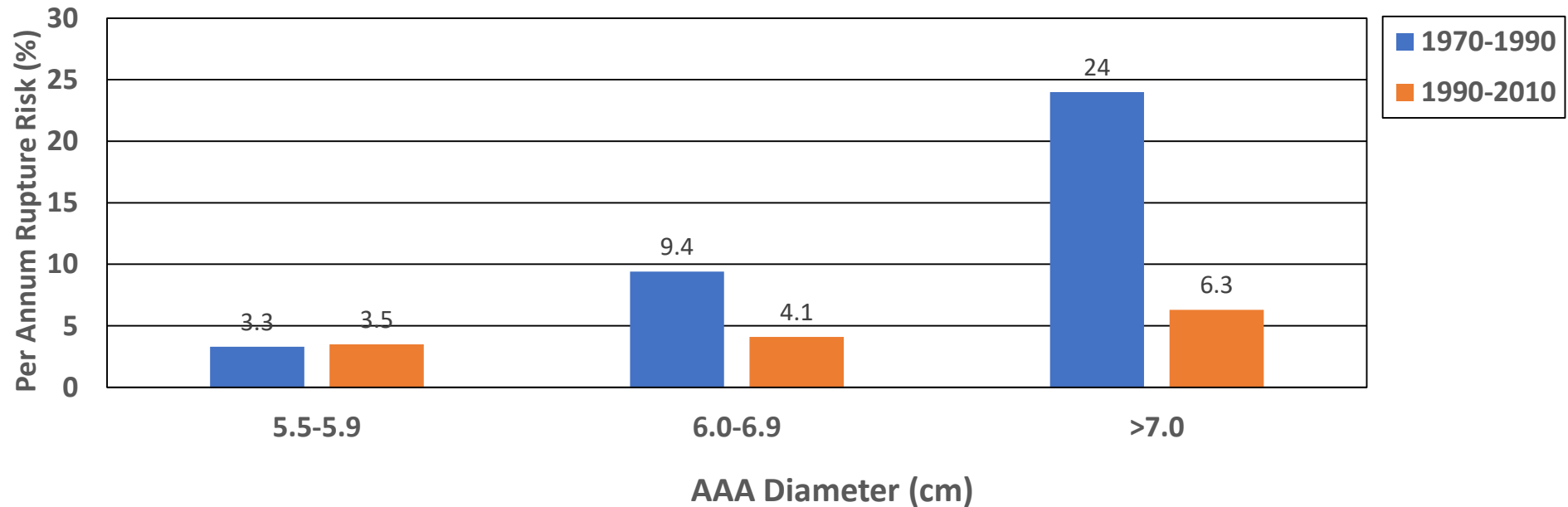
- 1090 UK-SAT patients pooled with 1167 non-randomized patients
 - More women
 - AAAs <4.0 and \geq 5.5 cm included
- Pooled rupture risk 2.2%/year

Baseline Variable	Hazard Ratio (95% CI)	p
Age (years)	1.02 (0.93–1.13)	0.67
Female sex	4.50 (1.98–10.2)	0.000
AAA diameter (cm)	2.51 (1.08–5.80)	0.032
Current smoker	2.11 (0.95–4.67)	0.066
Mean blood pressure (mmHg)	1.04 (1.02–1.07)	0.002

Cox regression analysis, all baseline variables adjusted for one another. For smoking, never-smokers and exsmokers were combined and compared with current smokers.

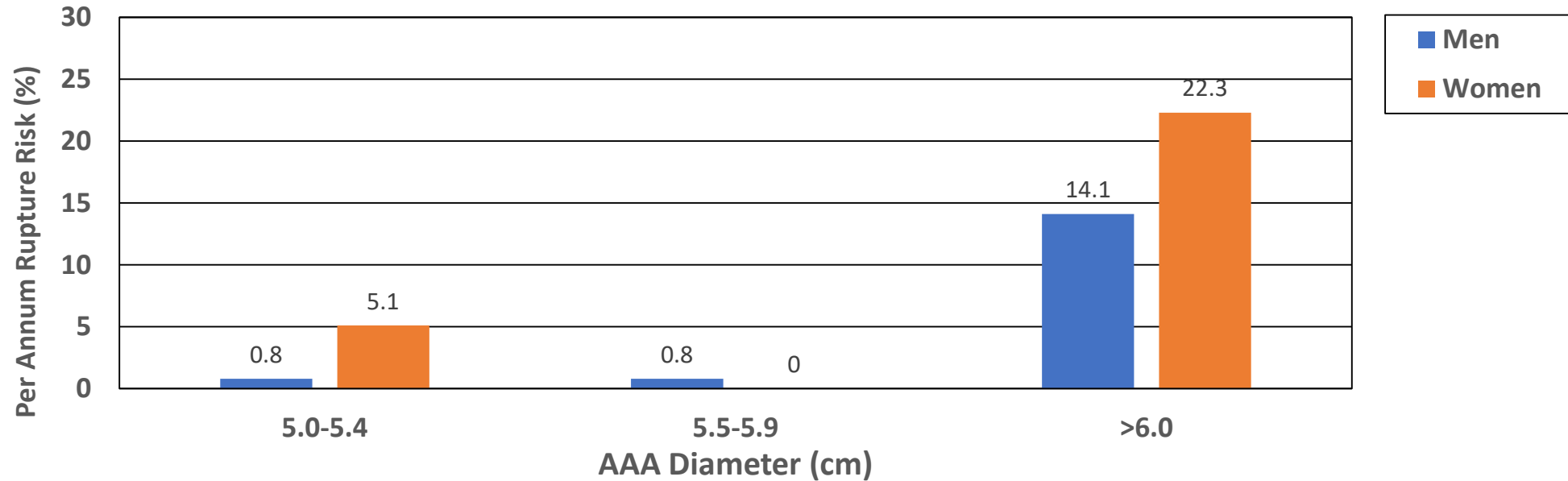
AAA Rupture Risk By Diameter

Temporal Comparison of Meta-Analyses



“More recent experience suggests that rupture estimates based on aortic diameter may need revision downward.” (SVS Guidelines AAA)

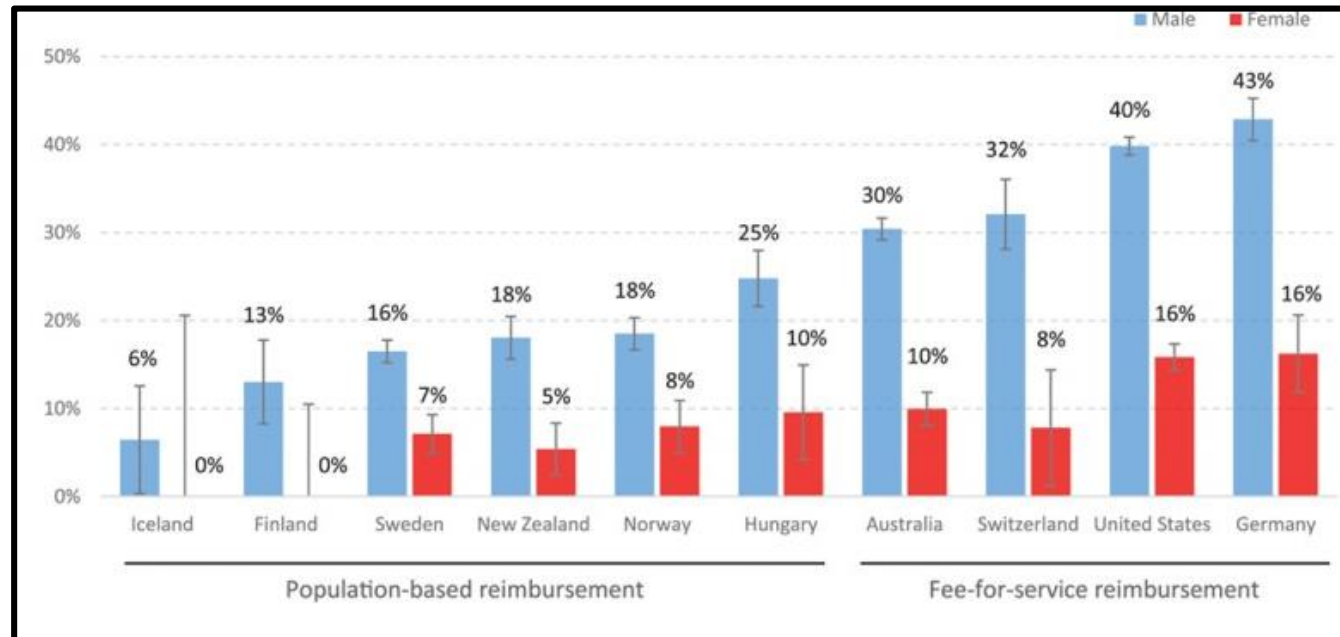
AAA Rupture Risk By Diameter Stratified By Gender



Inflection Point:
Males 6 cm
Females 5 cm

We Don't Adhere To Our Own Guidelines

- 43,992 elective AAA repairs
- International Consortium Vascular Registries (ICVR)
- Repair below guideline diam threshold more common in:
 - Males, EVAR and in countries with FFS reimbursement



* Octogenarian repair also more common in countries with FFS reimbursement

Beck et al, *Circulation*, 2016

We Don't Adhere To Our Own Guidelines

- 17,269 elective AAA repairs in Vascular Quality Initiative (VQI)
- Pre-operative CT scans independently assessed
- Proportion of patients treated at diameters < guideline:

Repair Type	Gender	Guideline	% < Guideline (Range)
EVAR	Males	≥ 5.5 cm	34% - 49%
Open	Males	≥ 5.5 cm	17% - 38%
EVAR	Females	≥ 5.0 cm	14% - 32%
Open	Females	≥ 5.0 cm	6% - 24%

AAA Rupture Risk By Diameter

CEASAR Trial (2011)	PIVOTAL Trial (2010)
360 patients w/ aneurysms 4.0-5.4 cm	728 patients w/ aneurysms 4.0-5.0 cm
Randomized to EVAR vs US surveillance	Randomized to EVAR vs US surveillance
96% male	87% male
Operative mortality = 0.5%	Operative mortality = 0.6%%
No difference in long-term survival	No difference in aneurysm-related survival
Rupture rate in non-repaired = 0.1%/year	Rupture rate in both groups = 0.2%/year
Secondary procedures after EVAR 5% in 4 years	Secondary procedures after EVAR 4.3% in 3 years

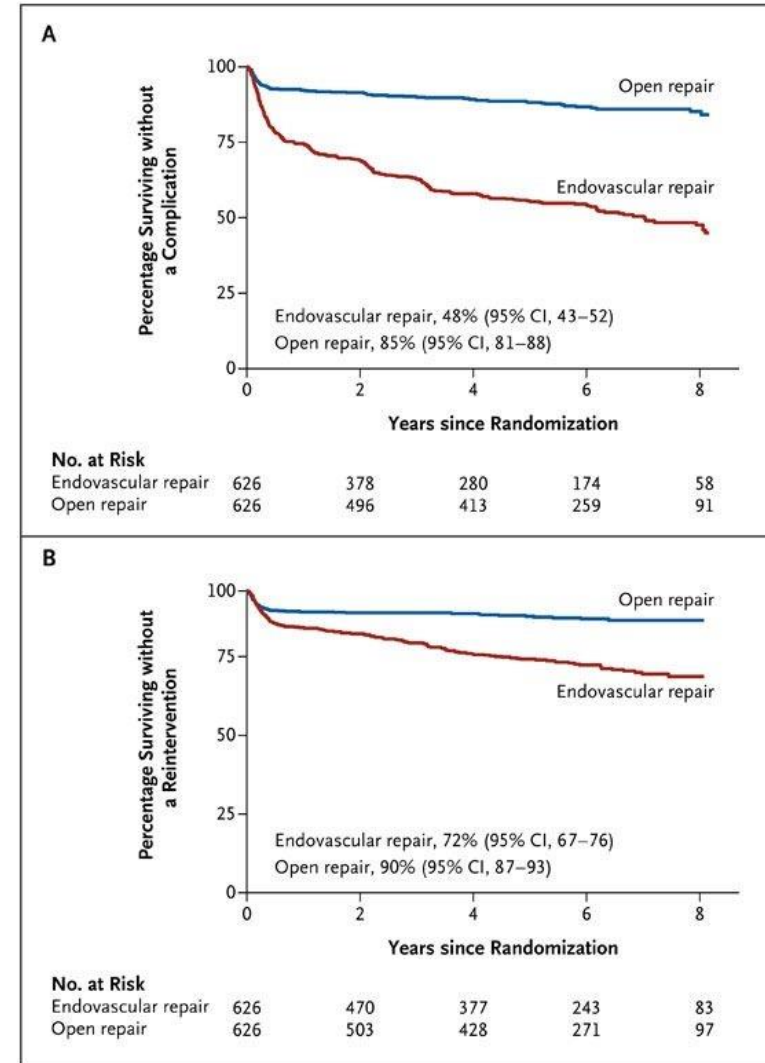


Aneurysms 4.0-5.5 cm in males
Ultrasound surveillance > EVAR

EVAR Has A Durability Problem

EVAR -1 Trial

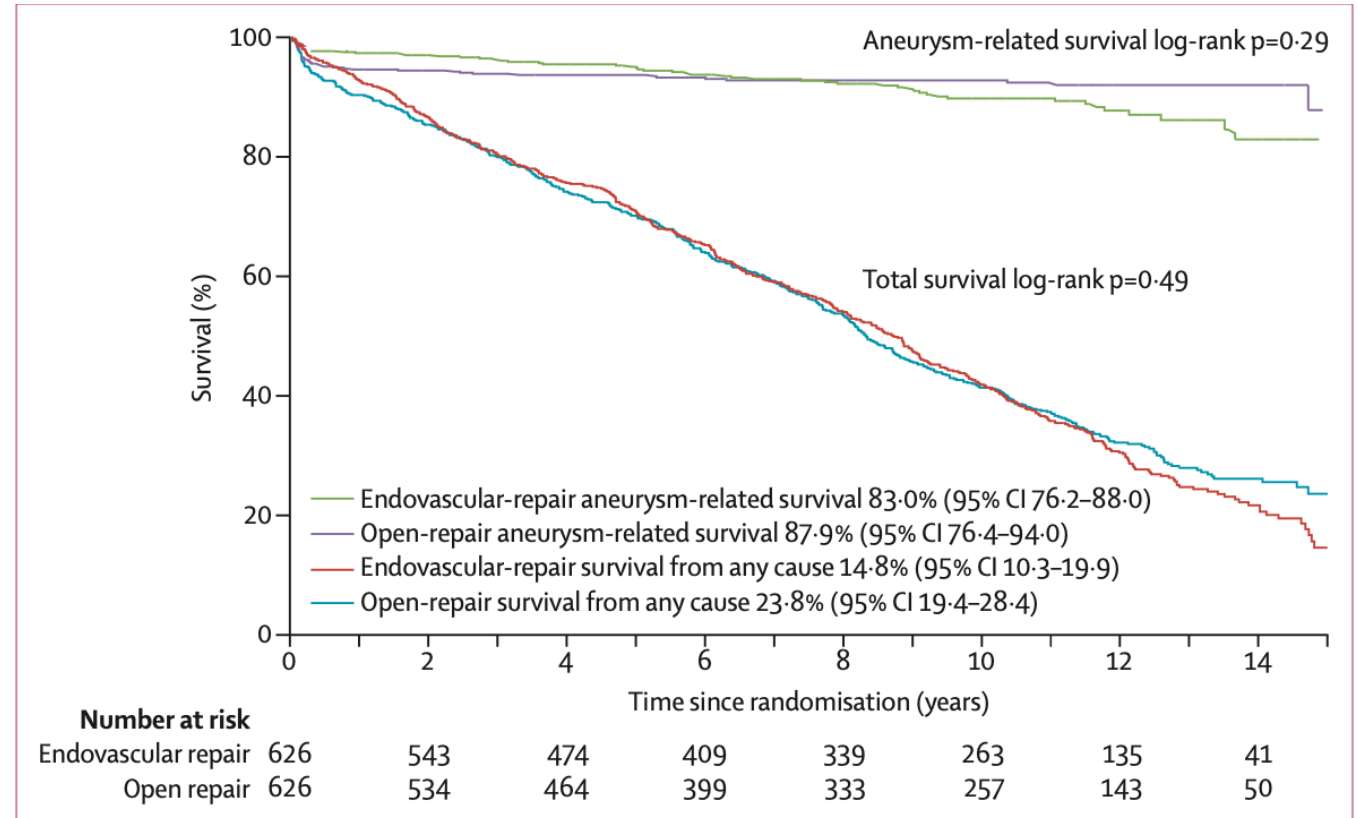
- 1,252 patients with aneurysms ≥ 5.5 cm
- Randomized to EVAR versus OAR
- Operative mortality
 - 1.8% EVAR
 - 4.3% OAR
- Follow-up
 - More complications
 - More secondary interventions



EVAR-1 Trial

Late Follow-Up

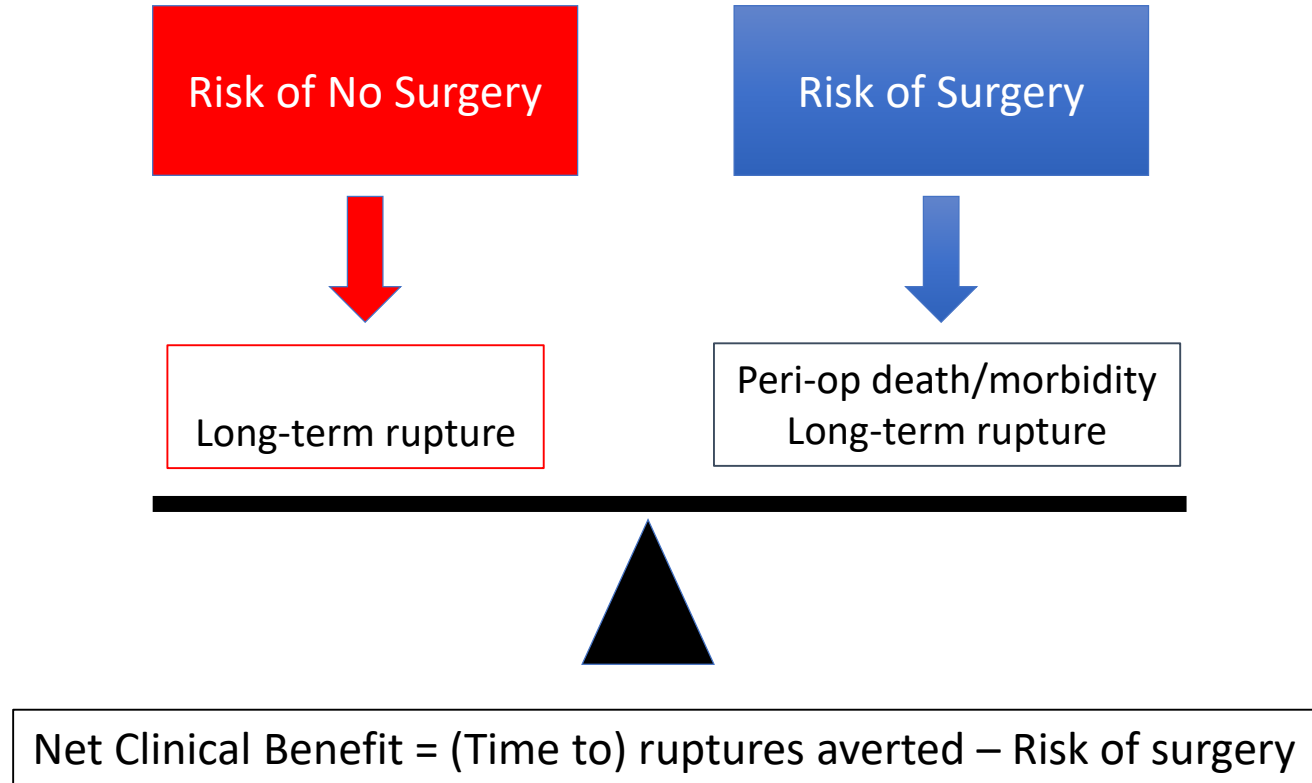
- Aneurysm-related and all-cause mortality curves cross
- OAR favored after 8 years
- Aneurysm-related death
 - EVAR 21
 - OAR 3



UK AAA NICE Guidelines

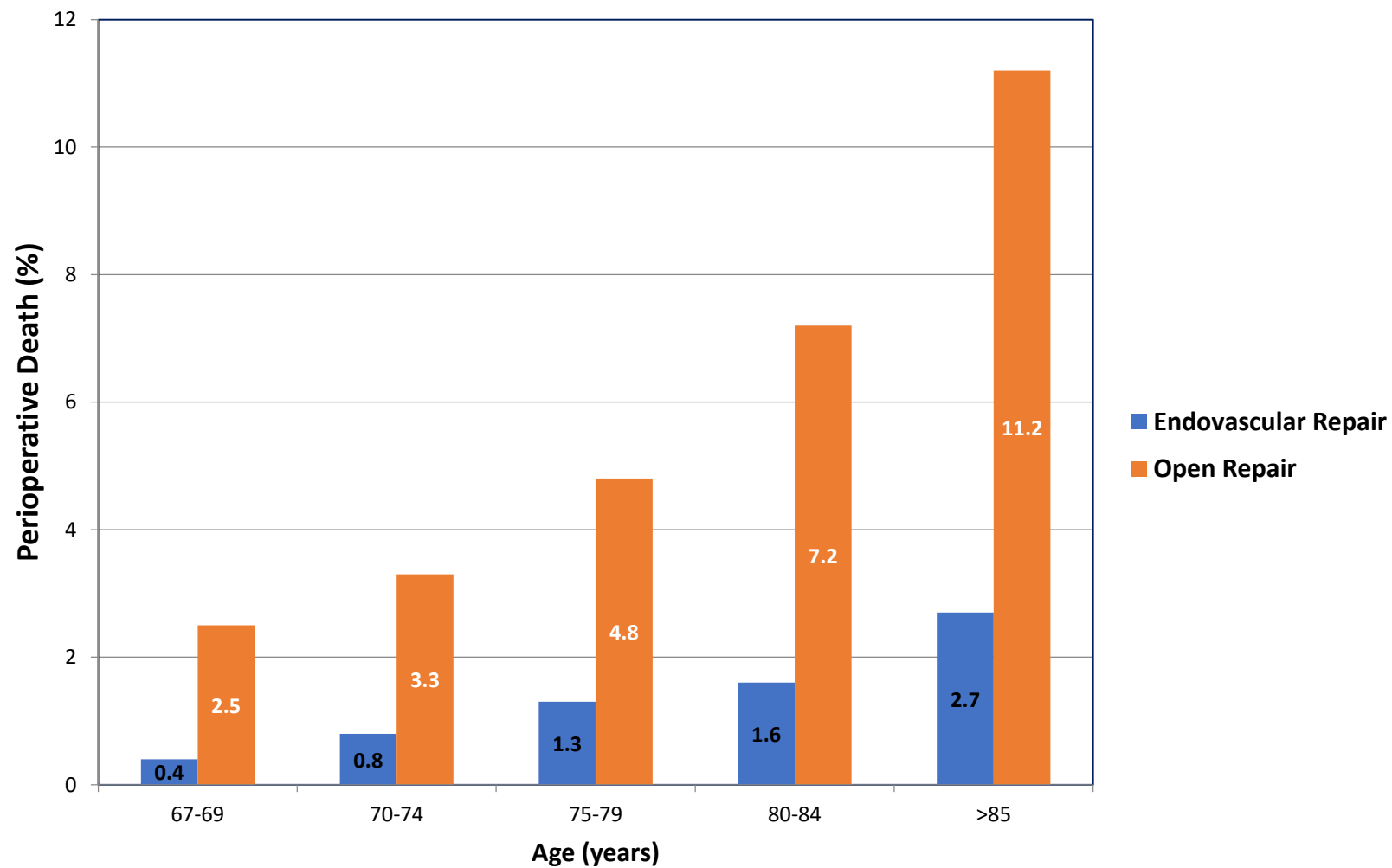
- Offer open surgical repair for people with unruptured AAAs unless it is contraindicated because of their abdominal co-pathology, anesthetic risks, and/or medical comorbidities.
- Consider EVAR or conservative management for people with unruptured AAAs who have anesthetic risks and/or medical comorbidities that would contraindicate open surgical repair.

Risk Calculation in AAA Repair

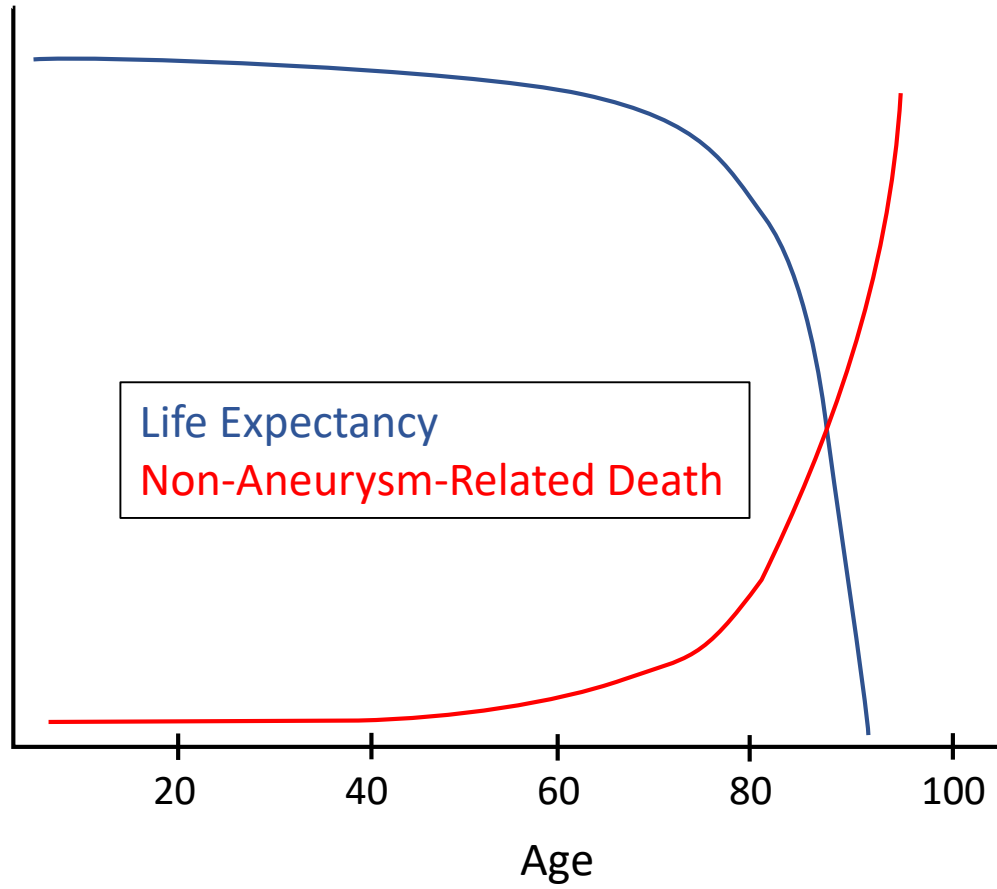


Perioperative Mortality Following AAA Repair

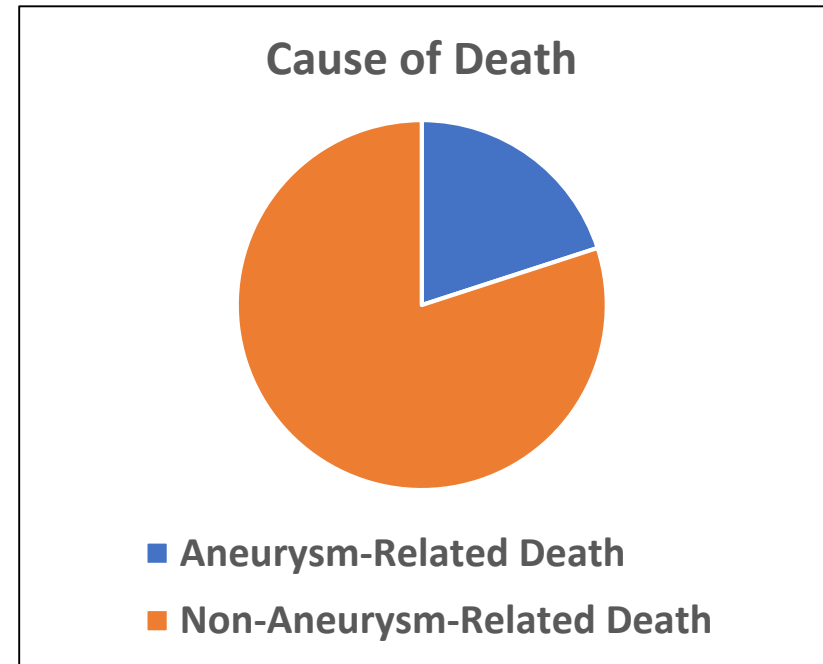
US Medicare Population



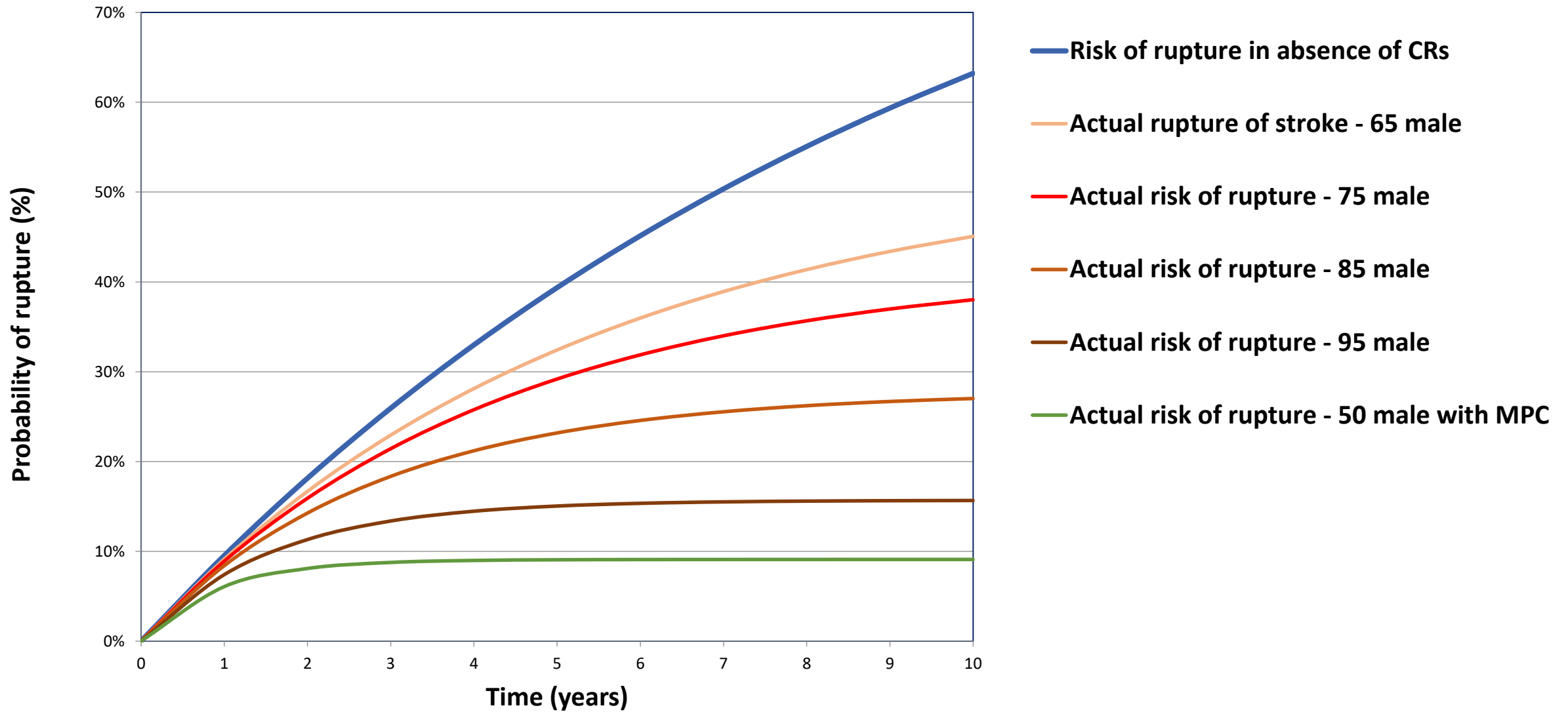
Increasing Age



Among elderly patients with AAA:



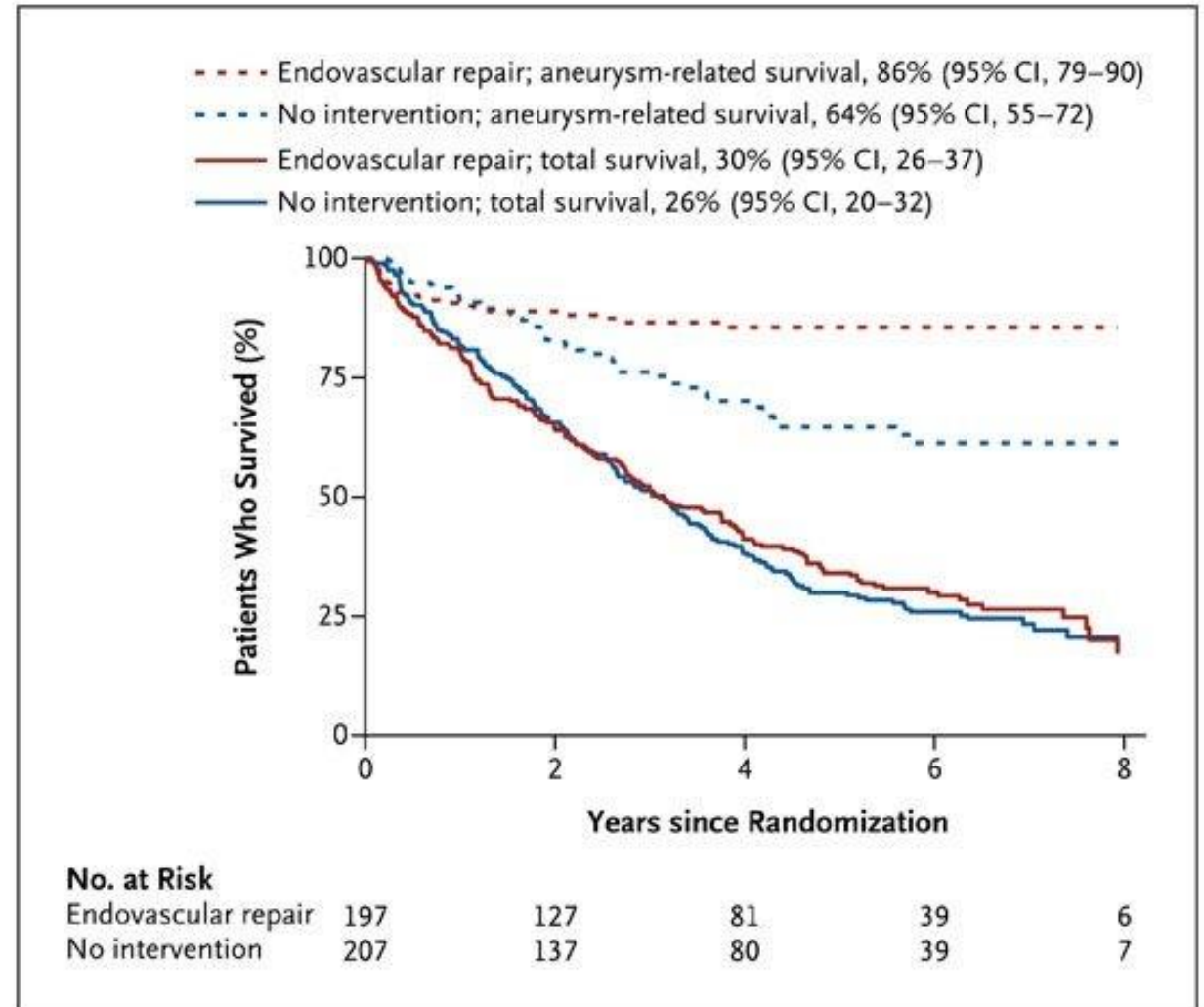
Male With 6.5 cm AAA



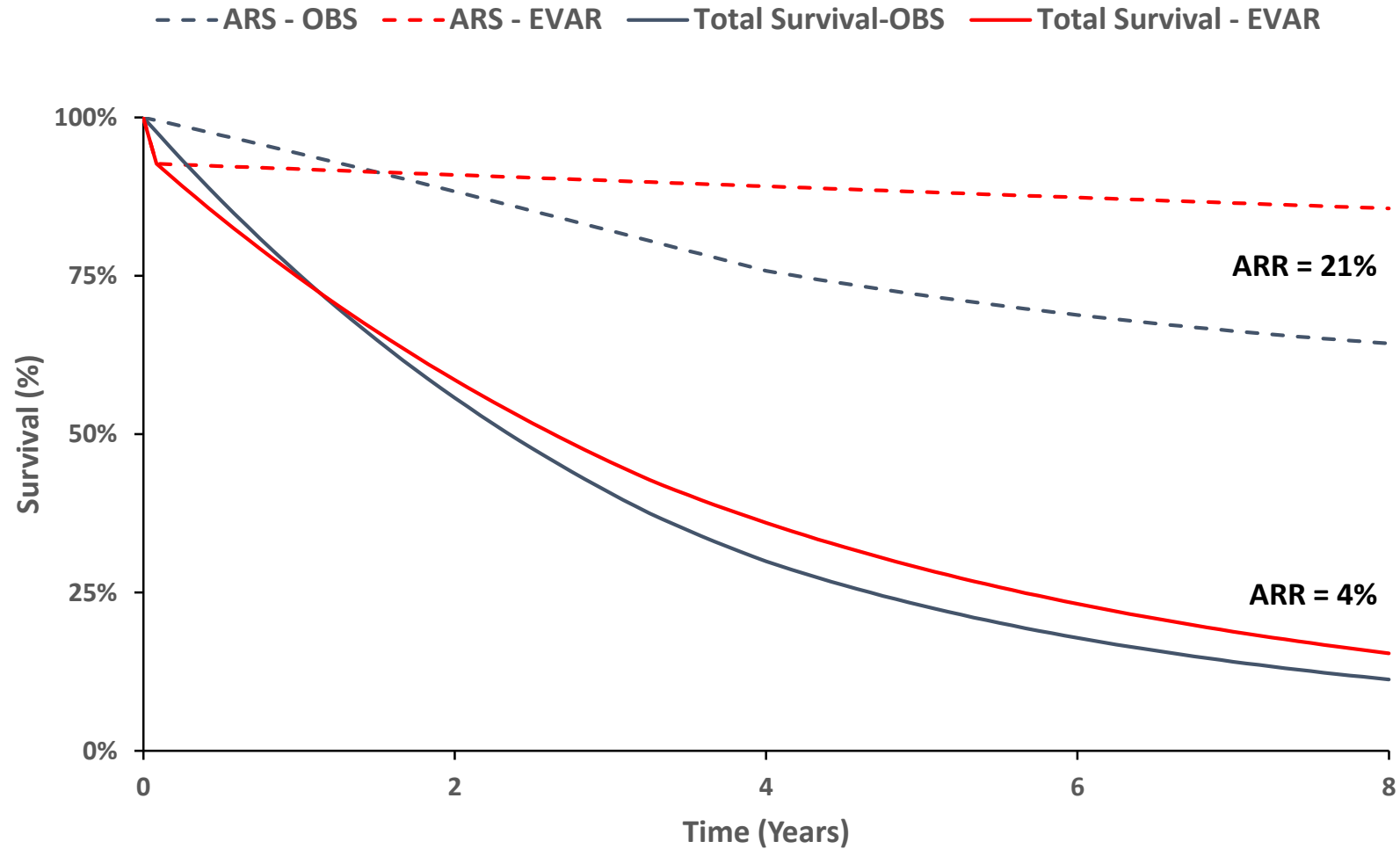
EVAR-2 Trial

404 patients physically unfit for OAR randomized to EVAR vs observation

- Aneurysms ≥ 5.5 cm
- Operative mortality:
 - EVAR1: 1.8%
 - EVAR2: 7.3%
- Non-aneurysm-related deaths 84%



Disease-Specific Versus All-Cause Survival



Assumes:
Op mortality 7.3%
NARM = 4X ARM

Conclusions

AAA Repair is Over-Utilized!

- Age-adjusted AAA disease and rupture are steeply declining!
- AAA prevalence has dramatically shifted toward older and sicker patients!
- AAA rupture rates (by diameter) have been over-estimated and are declining!
- If diameter guidelines were properly adhered to:
 - Repair rates would be 10%-40% lower than they currently are!
- The dominant repair type (EVAR) has a major durability problem!
- AAA repair in older/sicker patients is over-utilized
 - Benefits in these patients *can be* marginal to non-existent