

WHAT IT TAKES FOR EVAR TO BE CLINICALLY EFFECTIVE AT A FAIR PRICE

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
-
- I do not have any potential conflict of interest

Perspective for the management of peptic ulcer



Billroth

Gastrectomy

Polya

Polya gastrectomy



Roux

Roux en Y gastrectomy



Dragstedt

Vagotomy (1940)

Drainage **Vomiting**
Diarrhoea

Highly selective vagotomy (1973)

Protein pump inhibitors



Factors associated with rupture

Wyss et al. Annals of Surgery 2010 Nov;252(5):805-12

Covariate	adjusted hazard ratio [95% CI]	p-value
top neck diameter (cm)	2.07 [0.59 – 7.20]	0.253
neck length (cm)	0.82 [0.28 – 2.38]	0.711
maximum common iliac diameter (cm)	0.97 [0.30 – 3.17]	0.956
complications: endoleaks type I, II with sac growth, III, migration or kinking	8.83 [3.76 – 20.76]	< 0.0001

**Secondary
rupture
67%
mortality**

Aneurysm-related deaths according to time since randomisation

Time since randomisation	Endovascular repair (n=626) n/total (rate/100 person-yr)	Open repair (n=626) n/total (rate/100 person-yr)	Adjusted Hazard Ratio (95% CI)	P Value
All Patients	56/626 (1.1)	45/626 (0.9)	1.31 (0.86, 1.99)	0.21
0-6 mo	14/626 (4.6)	30/626 (10.0)	0.47 (0.23, 0.93)	0.03
> 6 mo- 4 yr	12/599 (0.6)	8/581 (0.4)	1.46 (0.56, 3.83)	0.44
> 4yr – 8 yr	14/474 (0.9)	4/464 (0.2)	3.11 (0.99, 9.72)	0.05
> 8 yr	16/339 (1.3)	3/333 (0.2)	5.82 (1.64, 20.65)	0.006

Aneurysm-related deaths from a per-protocol analysis

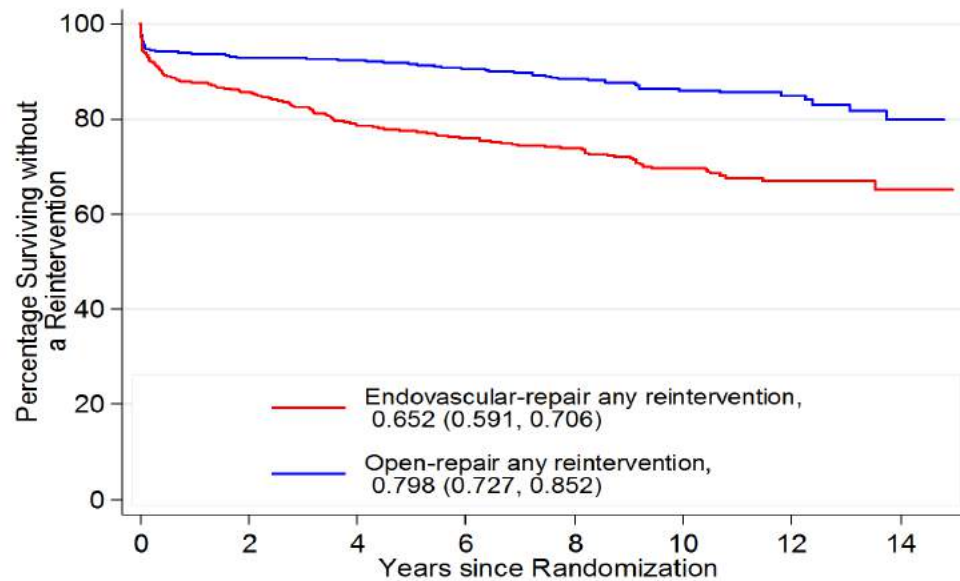
Time since randomisation	Endovascular Repair (n=626) n/total (rate/100 person-yr)	Open repair (n=626) n/total (rate/100 person-yr)	Adjusted Hazard Ratio (95% CI)	P Value
All Patients	49/598 (1.0)	29/567 (0.6)	1.76 (1.07, 2.89)	0.03
0-6 mo	9/598 (3.1)	23/567 (8.4)	0.36 (0.15, 0.85)	0.02
> 6 mo- 4 yr	10/580 (0.6)	2/533 (0.1)	4.36 (0.92, 20.67)	0.06
> 4yr – 8 yr	14/461 (0.9)	2/437 (0.1)	5.80 (1.29, 26.08)	0.02
> 8 yr	16/331 (1.4)	2/314 (0.2)	9.43 (2.09, 42.59)	0.004

Causes of death after 8 years

Cause of death	Endovascular repair (n=179)	Open repair (n=154)
Aneurysm rupture before repair (primary)	0	2
Aneurysm-related after repair	3	0
Aneurysm rupture after repair (secondary)	13	1
Coronary heart disease	33	35
Stroke	10	15
Other vascular disease	4	12
Cancer, Lung	13	10
Cancer, Other	37	21
Respiratory	29	30
Renal	5	4
Other	31	24
Unknown	1	0

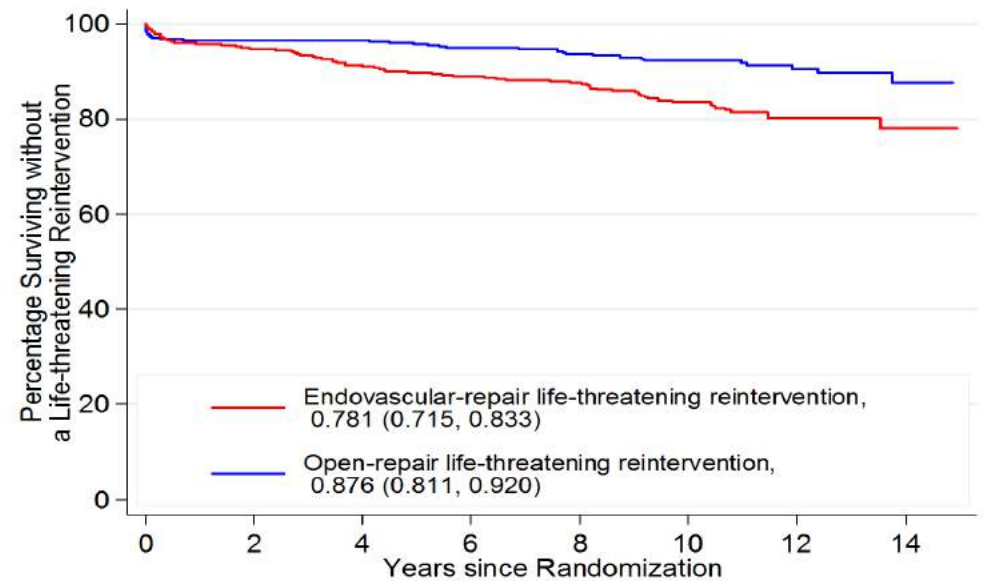
Time to first re-intervention over 15 years

All re-interventions



Number at risk		0	2	4	6	8	10	12	14
Endovascular repair		626	469	381	323	264	192	90	28
Open repair		626	506	436	357	282	214	112	35

Re-interventions for life-threatening condition

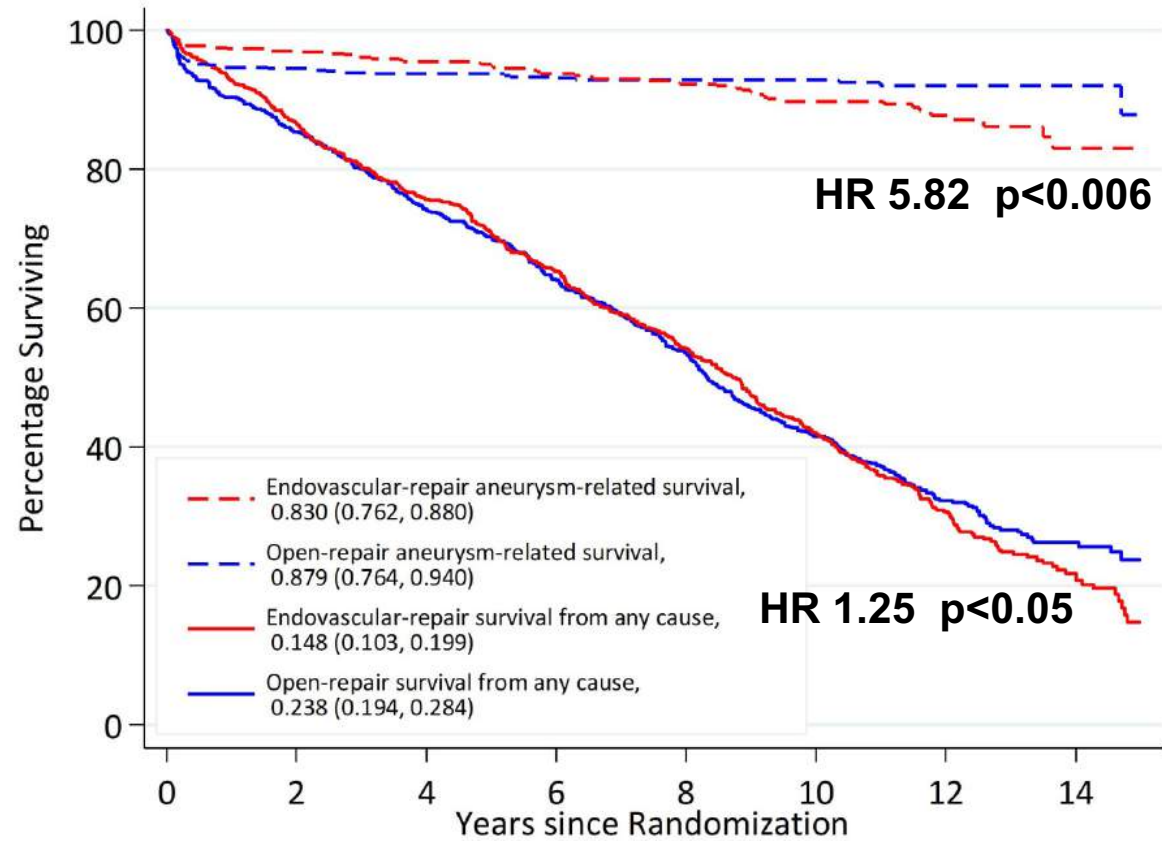


Number at risk		0	2	4	6	8	10	12	14
Endovascular repair		626	514	434	367	302	223	101	30
Open repair		626	520	450	373	300	233	118	38

Re-interventions for life-threatening complications by time period

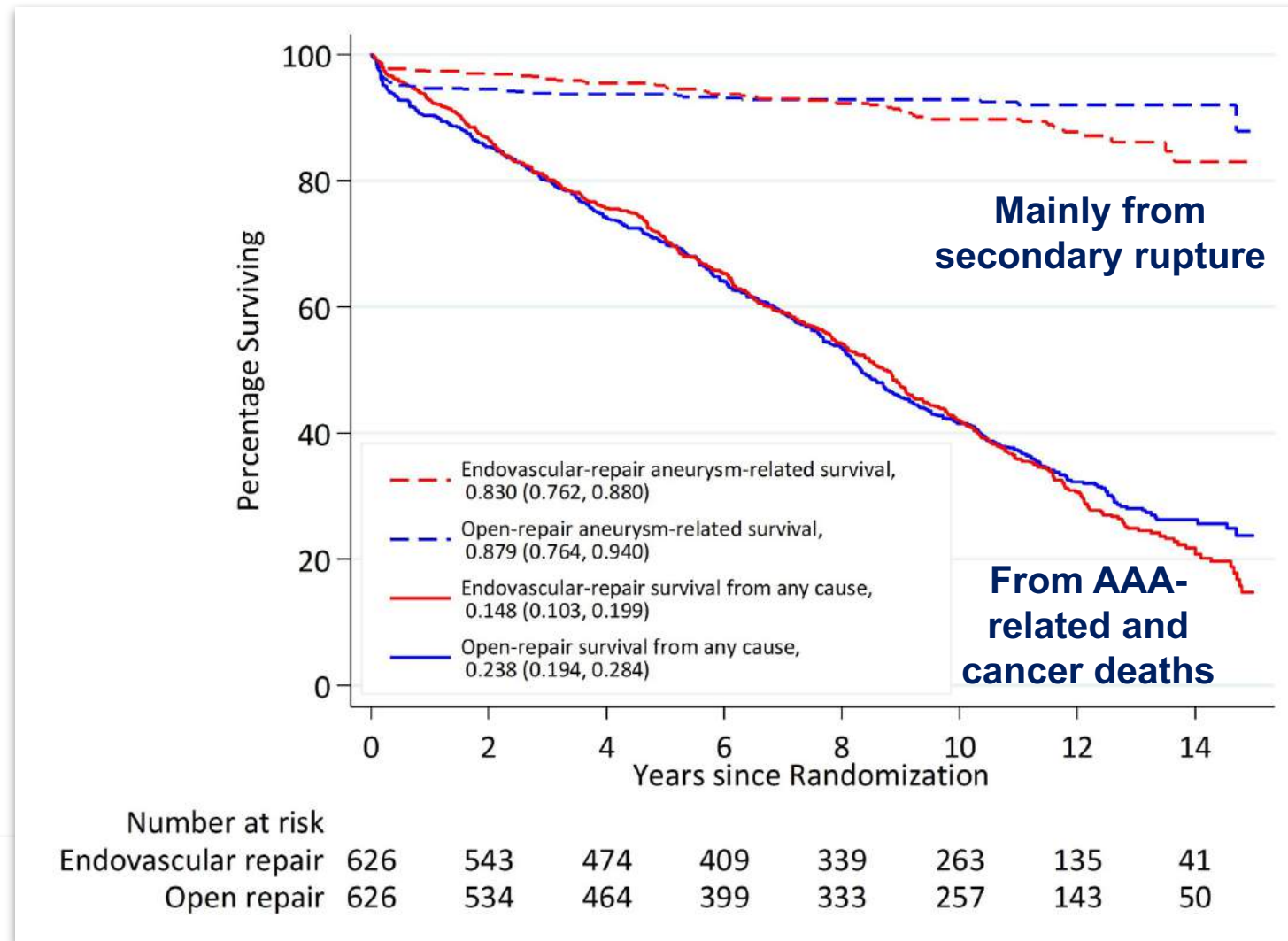
Time since randomisation	Endovascular repair (n=626) n/total (rate/100 person-yr)	Open repair (n=626) n/total (rate/100 person-yr)	Adjusted Hazard Ratio (95% CI)	P Value
Overall	85/626 (1.9)	41/626 (0.9)	2.10 (1.42, 3.09)	<0.001
0-6 mo	22/626 (7.4)	19/626 (6.5)	1.08 (0.57, 2.08)	0.809
> 6 mo- 4 yr	27/576 (1.5)	2/570 (0.1)	12.78 (3.01, 54.23)	0.001
> 4yr – 8 yr	15/435 (1.0)	11/450 (0.7)	1.42 (0.64, 3.16)	0.391
> 8 yr	21/306 (2.1)	9/310 (0.8)	2.48 (1.07, 5.75)	0.035

What happened in 8-15 years of EVAR 1 follow-up?



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

What happened in 8-15 years of EVAR 1 follow-up?



What happened in 8-15 years of EVAR 1 follow-up?



Secondary rupture over 15 years by time period

	EVAR group	OR group
Randomisation to 6 months	2	1
6 months to 4 years	8	1
4 years to 8 years	8	1
>8 years	<u>13</u>	<u>2</u>
	31	5

4 EVAR

1 OR

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

What happened in 8-15 years of EVAR 1 follow-up?



EVAR deaths after 8 years

Secondary rupture: 13

9 “cluster”

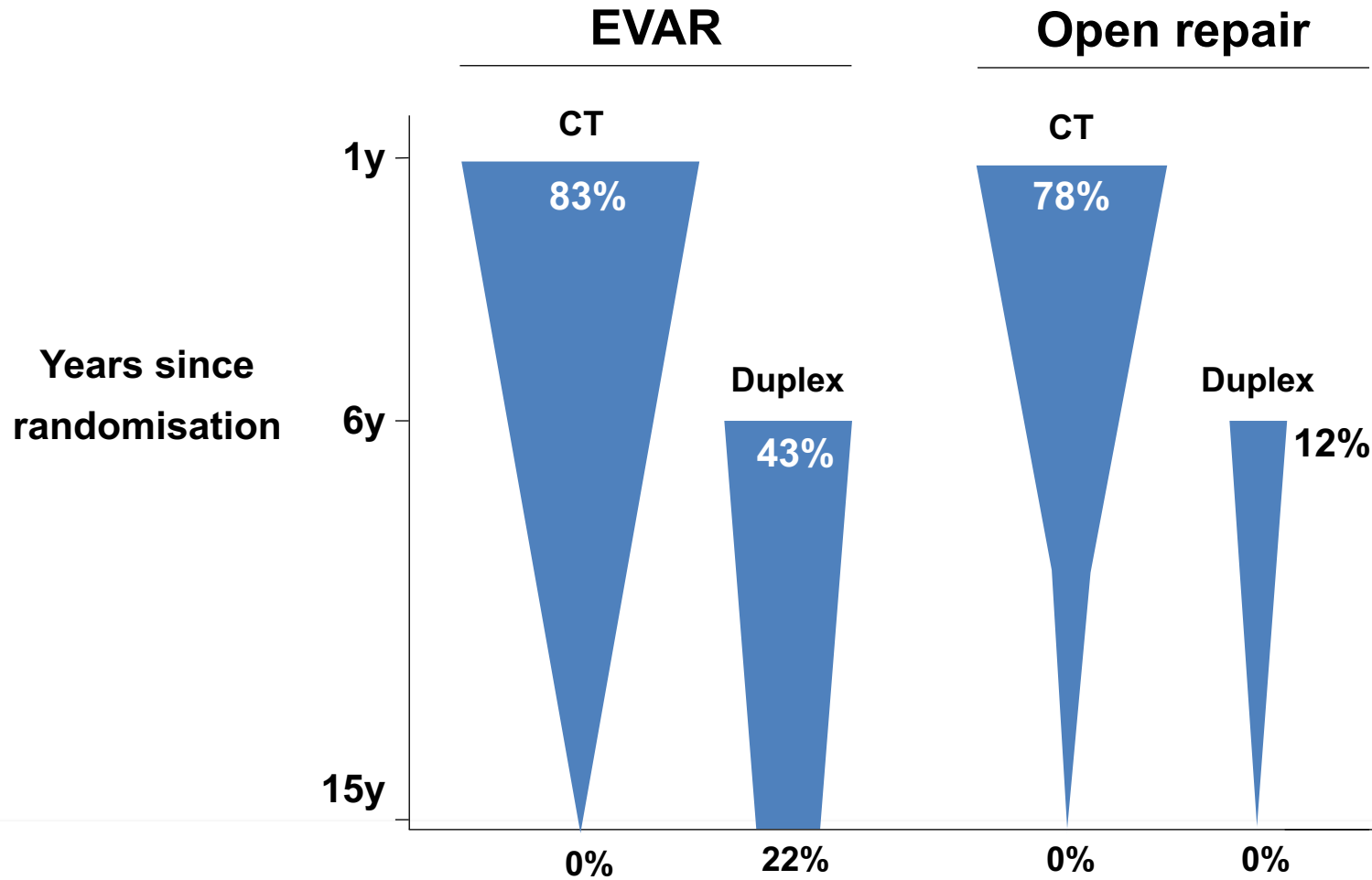
3 out of the blue

1 conversion

Reintervention: 3

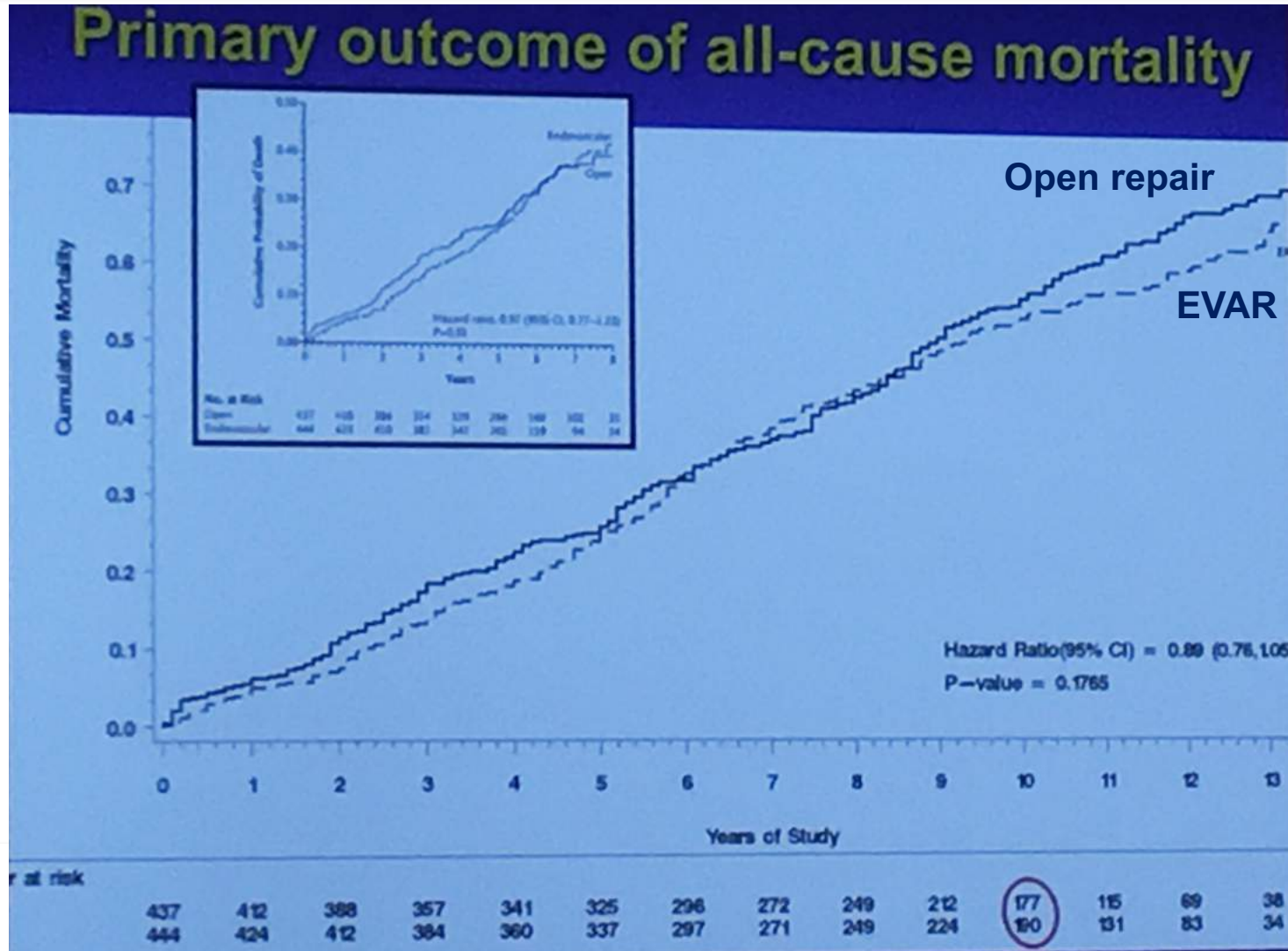
	0	2	4	6	8	10	12	14
Number at risk								
Endovascular repair	626	543	474	409	339	263	135	41
Open repair	626	534	464	399	333	257	143	50

CT and duplex scan follow-up



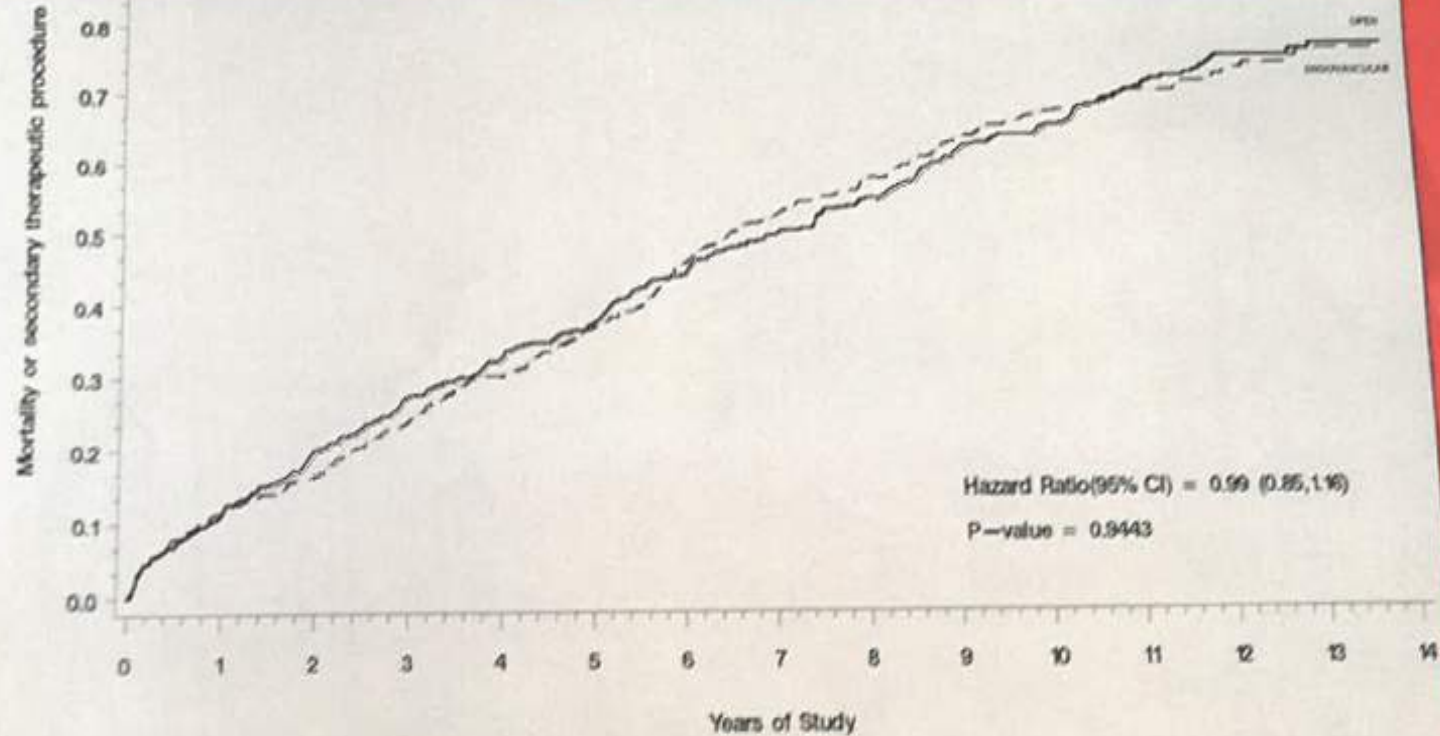
Is this a UK problem?

OVER trial



OVER trial

Death or Secondary Therapeutic Procedure



OPEN:															
At Risk:	437	386	347	314	296	275	245	220	200	171	144	89	50	29	10
EVR:															
At Risk:	443	392	370	339	309	282	241	213	194	165	139	91	58	23	4

Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators*

www.thelancet.com Vol 388 November 12, 2016

“Rupture after aneurysm repair resulted in 31 deaths in the EVAR group and five in the open-repair group.”

(vs 7 and 1 in OVER)

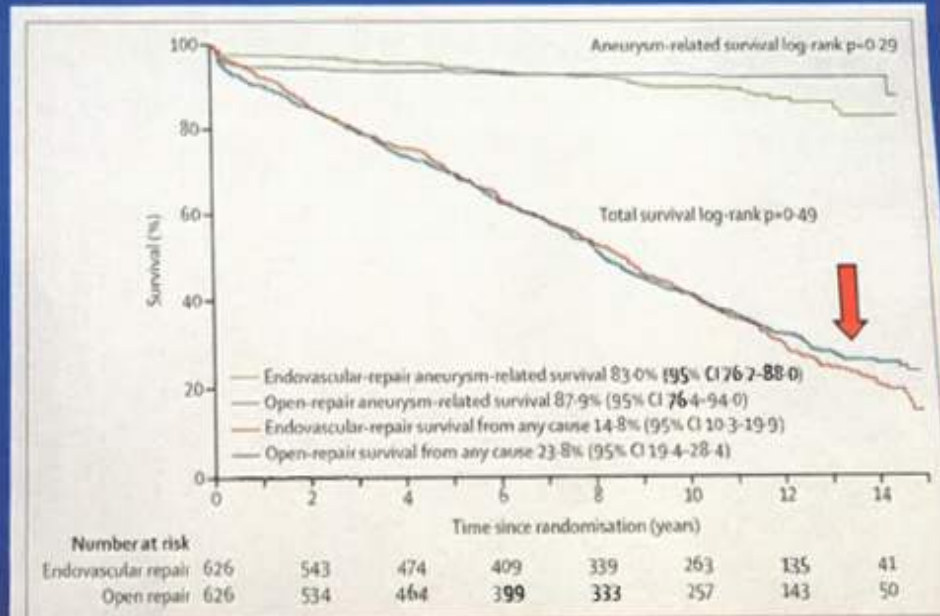
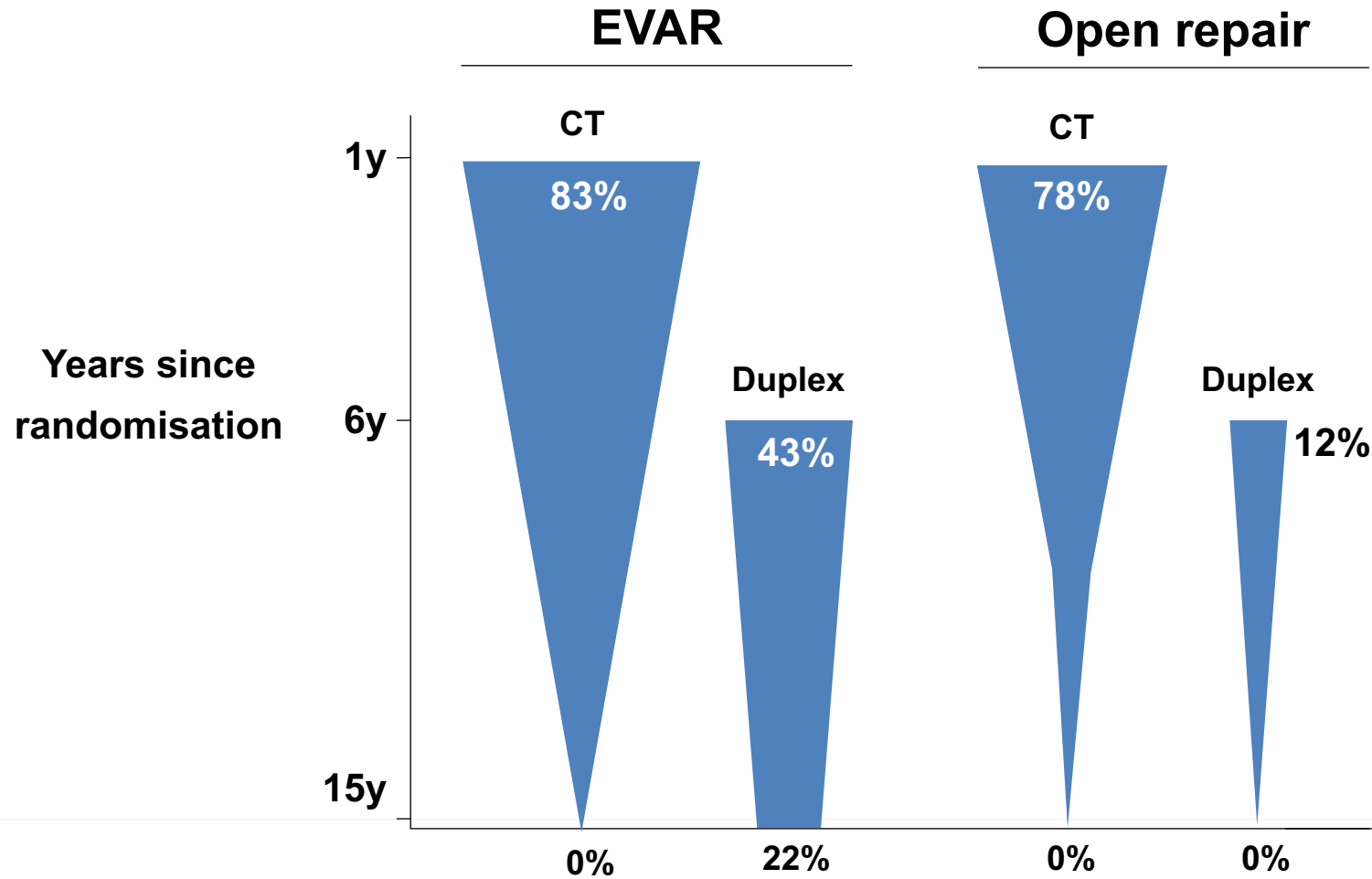


Figure 2: Kaplan-Meier estimates for total survival and aneurysm-related survival up to 15 years of follow-up. The hazard ratio is 1.05 (95% CI 0.92-1.19) for total mortality, and is 1.24 (0.84-1.83) for aneurysm-related mortality.

Summary of OVER

“There was no difference in the primary outcome of all-cause mortality but, unlike EVAR 1, late trend favours the EVAR group and aneurysm rupture after repair was uncommon (much lower than in EVAR 1) but mainly in the EVAR group”

CT and duplex scan follow-up



**What next is
NICE Aortic
Guidelines
2018**

J Vasc Surg. 2015 Jan;61(1):16-22.e1. doi: 10.1016/j.jvs.2014.06.006. Epub 2014 Nov 1.

Follow-up compliance after endovascular abdominal aortic aneurysm repair in Medicare beneficiaries.

Schanzer A¹, Messina LM², Ghosh K³, Simons JP², Robinson WP 3rd², Aiello FA², Goldberg RJ², Rosen AB⁴.

Lifelong imaging follow-up is essential to the safe and appropriate management of patients who undergo EVAR.

Among 19,962 patients who underwent EVAR, the incidence of loss to annual imaging follow-up at 5 years after EVAR was 50%.

Predicting reinterventions after open and endovascular aneurysm repair using the St George's Vascular Institute score.

de Bruin JL¹, [Karthikesalingam A](#)², Holt PJ², [Prinssen M](#)³, [Thompson MM](#)², [Blankensteijn JD](#)⁴; Dutch Randomised Endovascular Aneurysm Management (DREAM) Study Group.

The goal of this study was to validate the St George's Vascular Institute (SGVI) score to identify patients at risk for a secondary intervention after elective aneurysm repair.

Information on survival and reinterventions was available for all patients at 5 years postoperatively, for 79% at 6 years, and for 53% at 7 years.

The SGVI score, which is calculated from preoperative AAA morphology using aneurysm and iliac diameter, predictively dichotomised patients into groups at high-risk or low-risk for a secondary intervention.

A Systematic Review of Predictors of Reintervention After EVAR: Guidance for Risk-Stratified Surveillance.

Patel SR¹, Allen C¹, Grima MJ¹, Brownrigg JRW¹, Patterson BO¹, Holt PJE¹, Thompson MM¹, Karthikesalingam A¹.

Current surveillance protocols after EVAR are ineffective and costly.

Large preoperative abdominal aortic aneurysm diameter was the most commonly observed risk factor for reintervention after EVAR.

There is a need to refine risk prediction for EVAR failure and to conduct prospective comparative studies of personalised surveillance with standard practice.

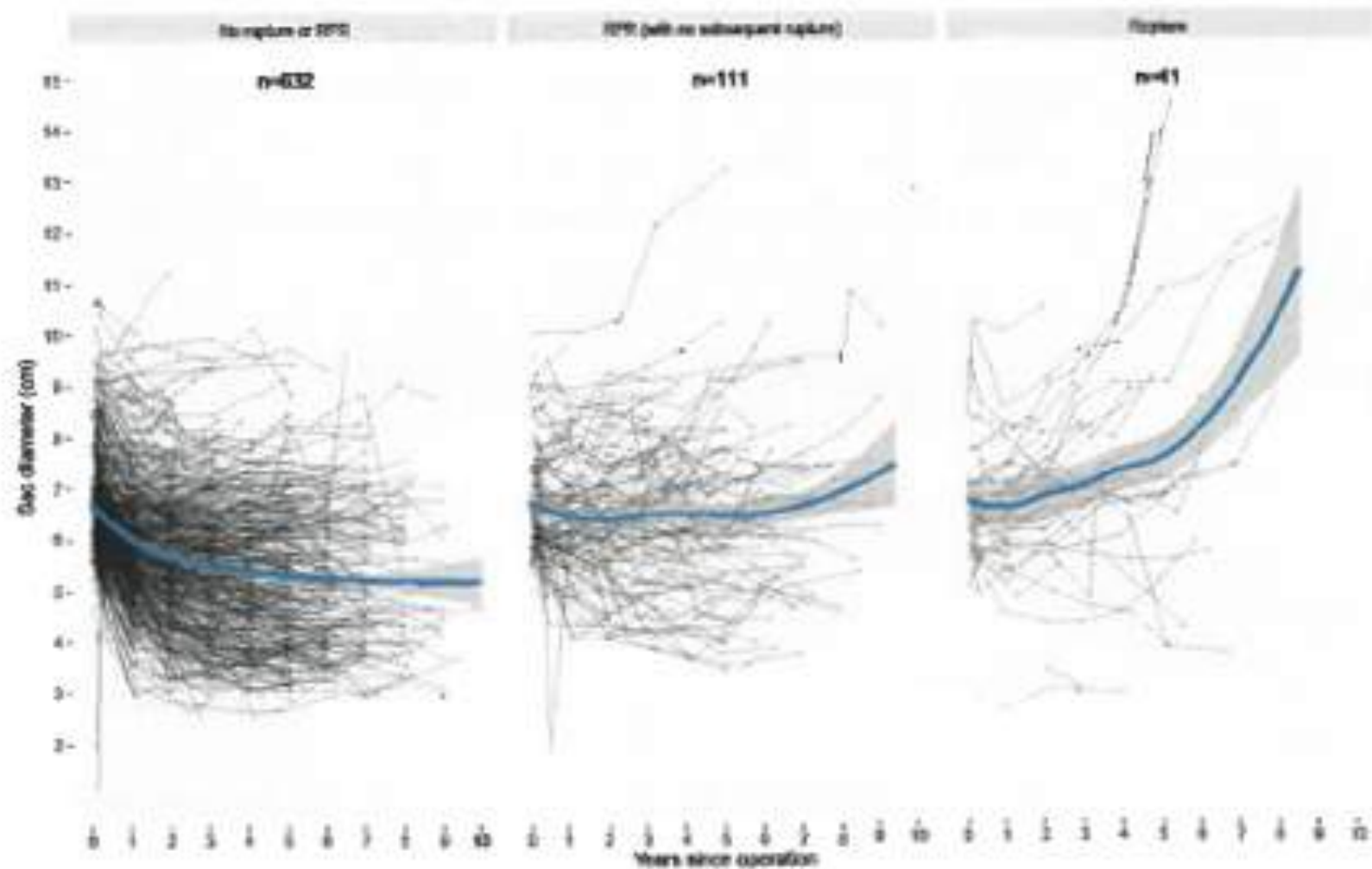
By demand of the National Institute for Health Research (NIHR), meet deadline of April 2018

Conduct an economic evaluation of different surveillance schedules following elective repair of an abdominal aortic aneurysm by EVAR



*National Institute for
Health Research*

Trajectories of aneurysm sac diameter over follow-up by type of event, with loess smoothers superimposed



AIM

To conduct an economic evaluation of different surveillance schedules following elective repair of an abdominal aortic aneurysm by EVAR.

HYPOTHESIS

The surveillance schedule in the EVAR trial and current recommended surveillance schedules are sub-optimal.