

IMPROVE trial 3 year results Interim results for Vascular Society

1st December 2016, Manchester

Immediate **M**anagement of the **P**atient with **R**upture:
Open **V**ersus **E**ndovascular Repair

IMPROVE  **trial** investigators

www.improvetrial.org



@IMPROVETrial

NHS

*National Institute for
Health Research*

Project number 07/37/64

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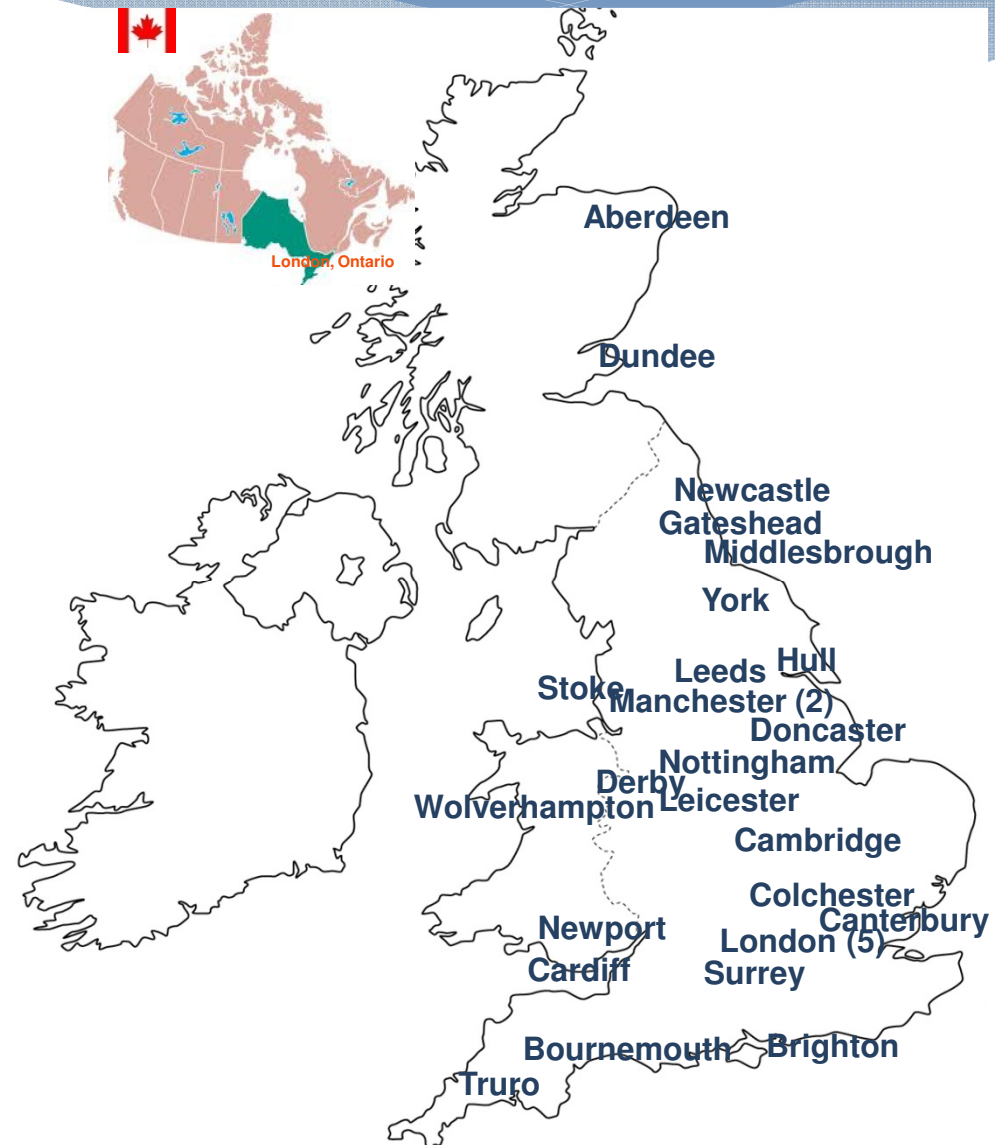
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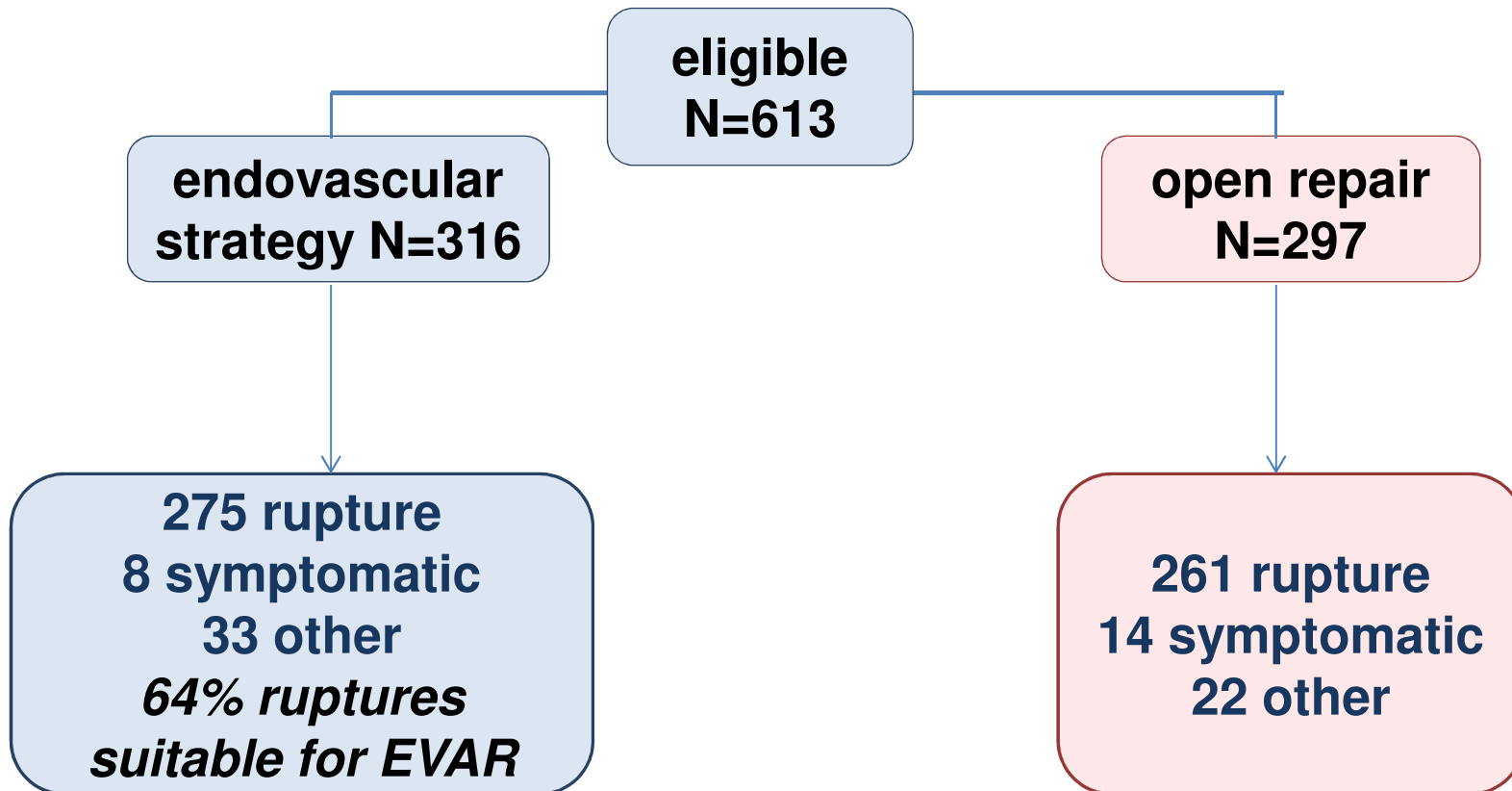
Credentialled centres 29 UK, 1 Canada



CONSORT diagram

final diagnoses

For patients with an in-hospital clinical diagnosis of rupture, before CT



Rupture = blood outside aneurysm sac, core laboratory
Other diagnoses 45/55 with asymptomatic AAA + 1/55 TAAA

Baseline characteristics by randomised group

Variable	Endovascular strategy, N=316	Open repair N=297
Age (years)	76.7 (7.4)	76.7 (7.8)
Males (%)	246 (78%)	234 (79%)
Hardman Index n (%)		
0	93 (33%)	69 (27%)
1	130 (46%)	126 (49%)
2+	59 (21%)	62 (24%)
Max aortic diameter (cm)	8.4 (1.9)	8.1 (1.8)

BMJ

BMJ 2014;348:f7661 doi: 10.1136/bmj.f7661 (Published 13 January 2014)

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RESEARCH

Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial

OPEN ACCESS

IMPROVE trial investigators

Abstract

Introduction

Objective To assess whether a strategy of endovascular repair is

30-day mortality
Endovascular strategy 35%
Open repair 37%

Endovascular strategy more effective in women



European Heart Journal (2015) 36, 2061–2069
doi:10.1093/eurheartj/ehv125

FASTTRACK CLINICAL RESEARCH

Cardiovascular surgery

Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial

IMPROVE Trial Investigators†

Received 7 March 2015; revised 23 March 2015; accepted 26 March 2015; online published-ahead-of-print 8 April 2015

See page 2031 for the editorial comment on this article (doi:10.1093/eurheartj/ehv221)

1 year
Endovascular strategy
Better quality of life
Lower costs
Cost-effective

But no difference in mortality, although still more effective in women

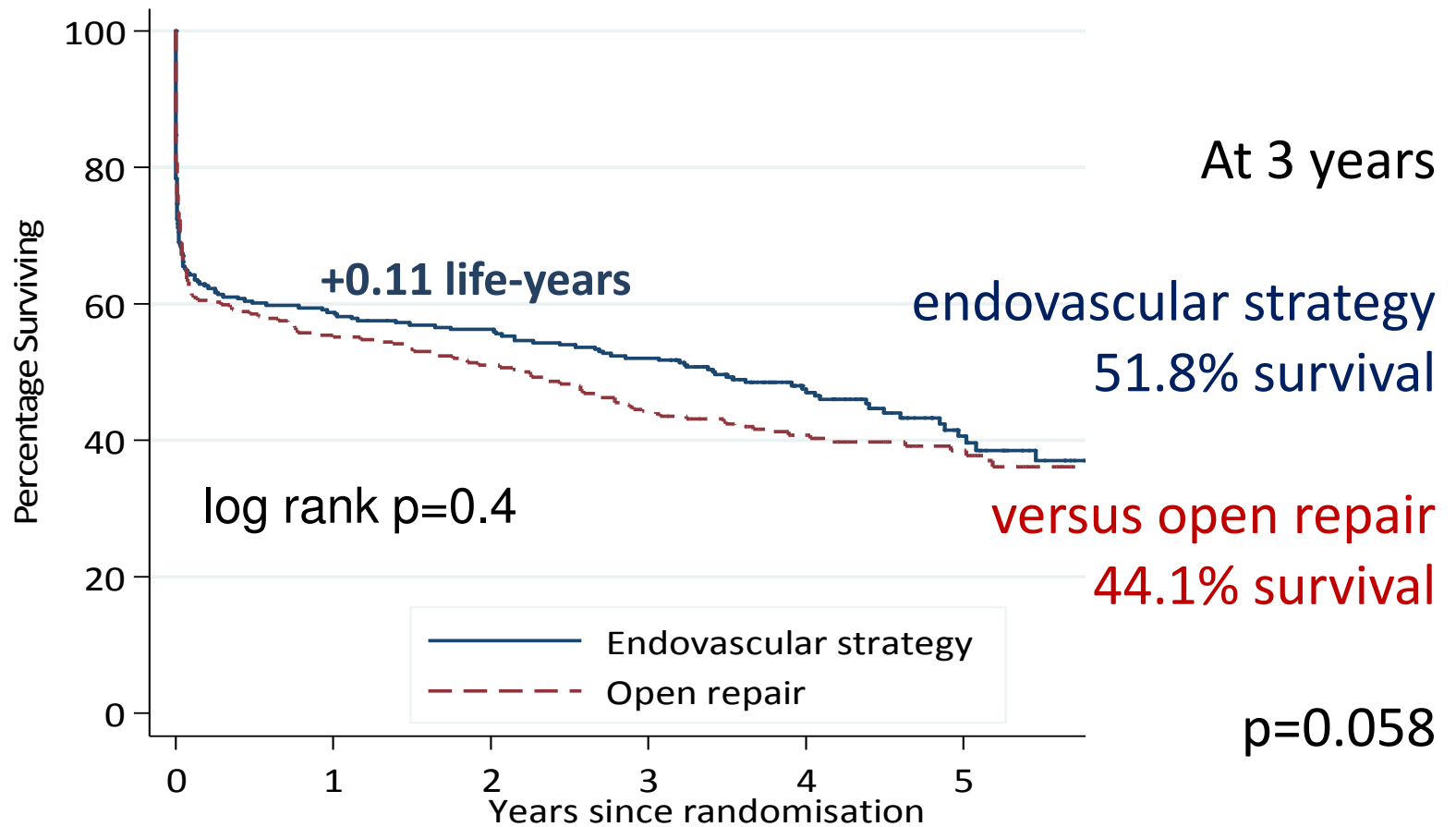
To assess for an endovascular strategy vs open repair:

- **Mid-term survival** ✓
- **Impact of re-interventions** interim
- **Quality of life** ✓
- **Mid-term costs** interim
- **Full cost-effectiveness** interim

Delays at NHS Digital to provide re-intervention data at non-trial hospitals & causes of death

Survival to 3 years and beyond

0-3m 91% deaths AAA-related
3m-3y 13% deaths AAA-related



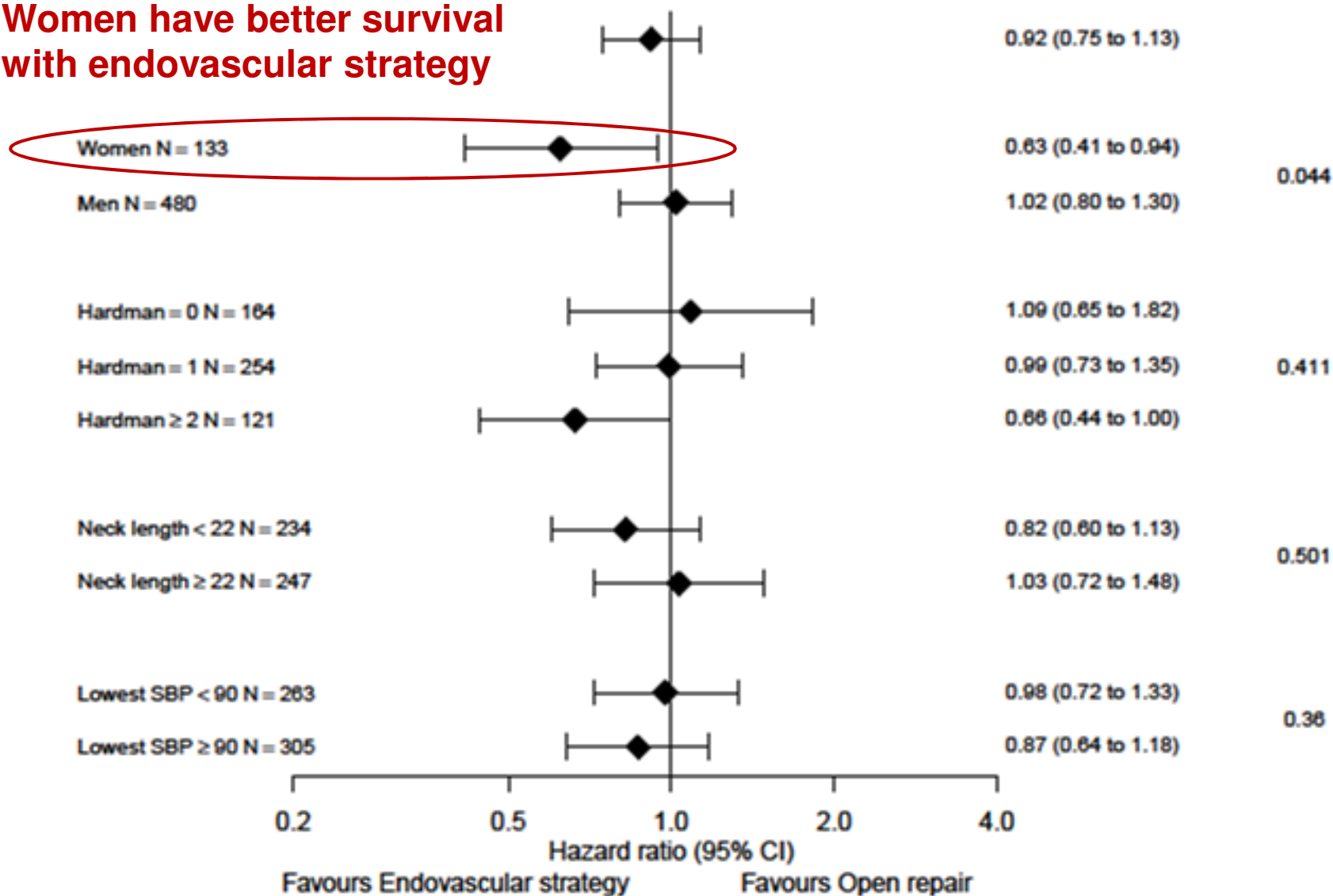
Number at risk		0	1	2	3	4	5
Endovascular strategy	316	185	175	162	96	41	
Open repair	297	163	150	130	86	54	

5 patients lost to follow up

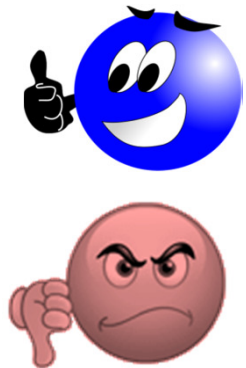
Subgroup analyses: again endovascular strategy is most effective in women

At 3 years

Women have better survival with endovascular strategy



Quality of life is better in the endovascular strategy group in year 1, but similar by 3 years



Group	EQ5D utility score mean (SD) at		
	3m	12m	3 years
Endovascular strategy	0.76 (0.24)	0.77 (0.20)	0.72 (0.27)
Open repair	0.67 (0.32)	0.71 (0.33)	0.73 (0.32)
	P=0.015	P=0.059	P=0.894

>0.03 difference is clinically significant

85% response rate at 3y

At 3y quality adjusted life years higher in the endovascular strategy group



Group	QALYs at 3 years	
	Mean (SD)	Mean difference (95% CI)
Endovascular strategy	1.21 (1.11)	0.171 [-0.006, 0.349]
Open repair	1.04 (1.10)	<i>P=0.058</i>

At 3 years EVAR strategy is on average £2263 (12%) cheaper
Endovascular strategy is likely to be cost-effective over 3 years

Re-interventions to 3 years

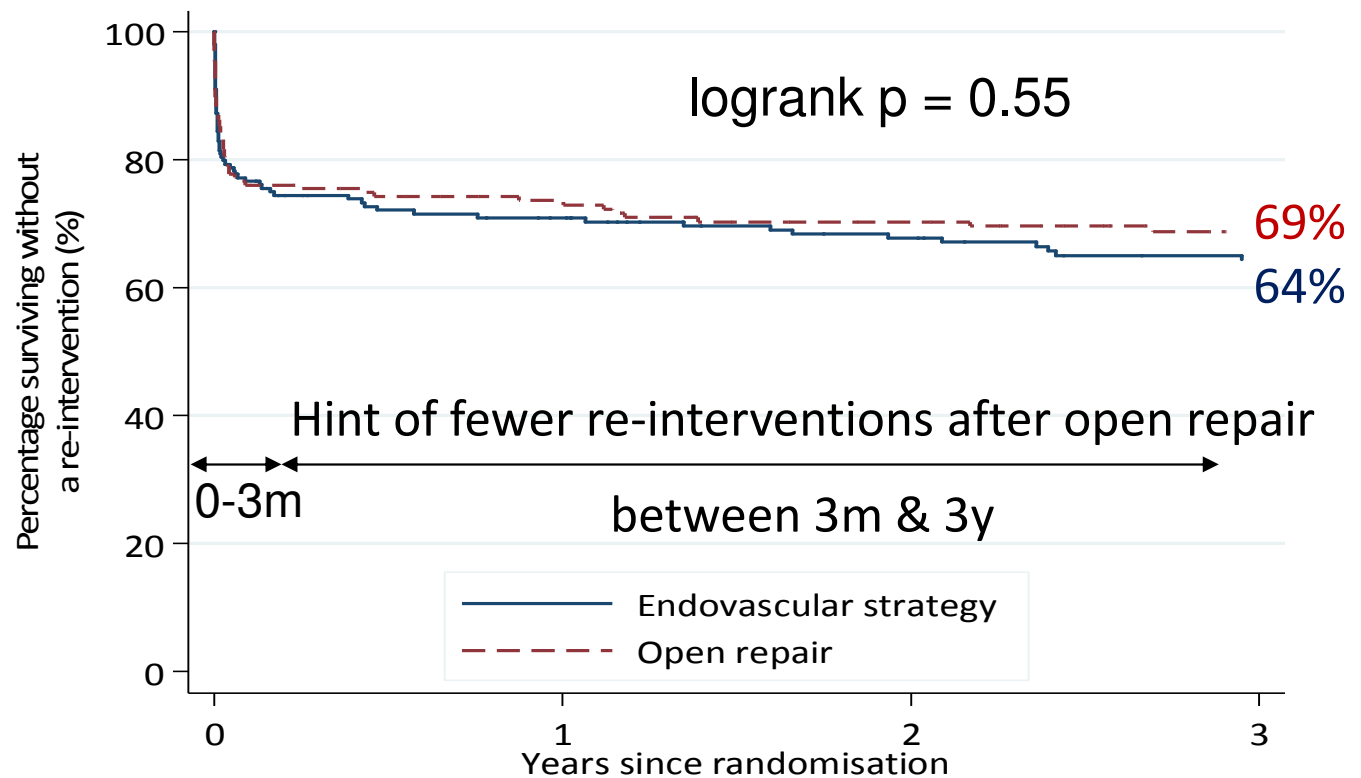
Interim data

- **HES data for re-interventions at non-trial hospitals pending**
- **AAA-related re-interventions (502 patients with repair of rupture)**
- **Categorized as arterial, laparotomy-related, other**
- **Categorized by a severity scoring system**
- **Also reported by potentially life-changing effects for patients**

Survival without an AAA-related re-intervention

502 patients with repair ruptured AAA started

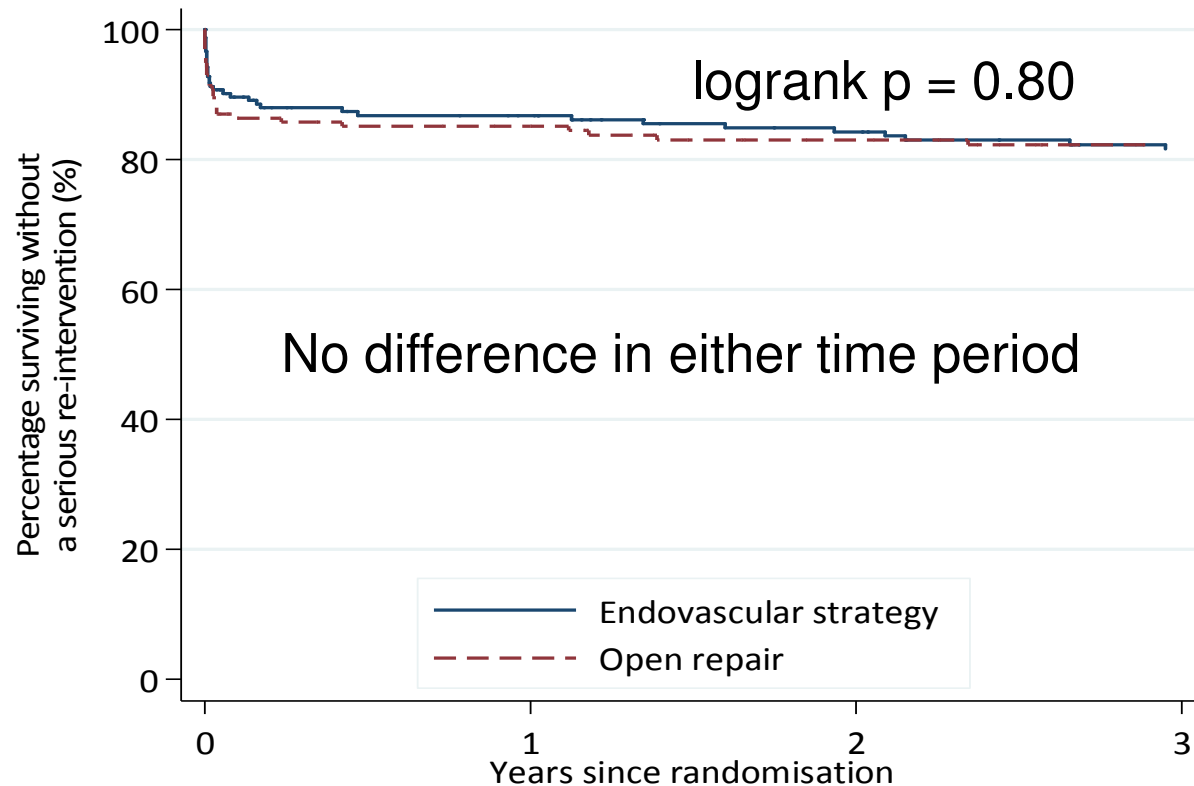
Interim results



Number at risk		0	1	2	3
Endovascular strategy	259	119	104	94	
Open repair	243	115	99	83	

Time to first serious re-intervention

3m to 3y possibly more minor re-interventions in endovascular strategy group



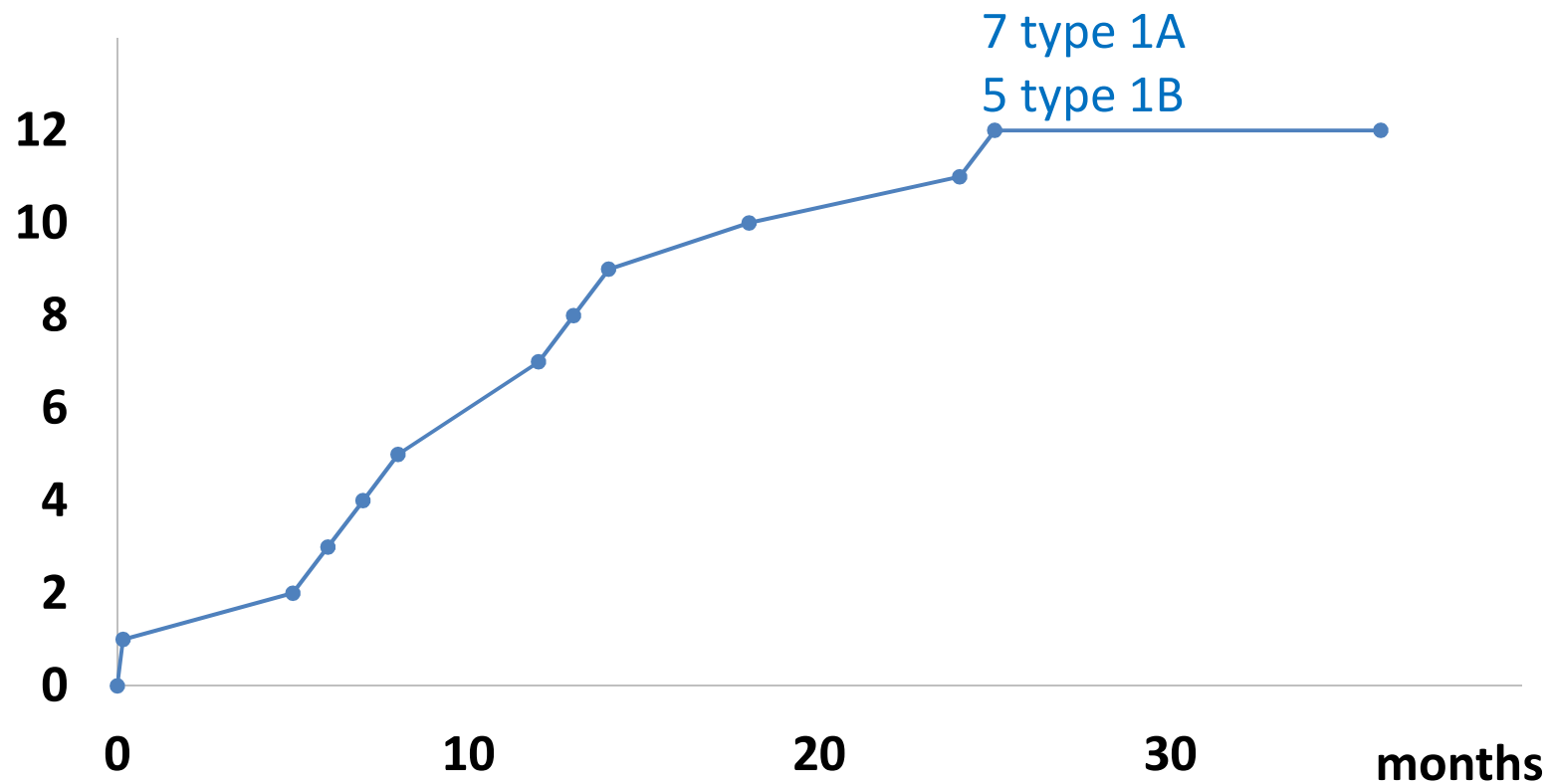
Number at risk		0	1	2	3
Endovascular strategy	259	145	131	121	
Open repair	243	125	111	94	

Type 1 endoleaks after completed EVAR

total 186, 140 alive at 30 days

interim

Cumulative incidence of re-interventions for type 1 endoleak



Potentially life-changing events for patients by treatment received interim

Event	EVAR N=186	Open repair N=316
2° rupture	3	
Graft infection	2 both fem-fem total 36 AUI	4 all aortic
Delayed conversion to open repair	1	
Major amputation	1	7
Unclosed ileostomy/ colostomy	1	7

Interim 3 year results: endovascular strategy probably remains cost-effective

Outcome	Endovascular strategy (compared with open repair)
Survival	No benefit at 30d, 1y Borderline benefit at 3y Better for women throughout
Re-interventions	Probably little difference but fewer severe outcomes for patients
Quality of life	Better at 3m & 1y, no difference at 3y
QALYs	Gain at all time points
Costs	Non-significantly lower throughout

