

Is open repair an outdated operation for rupture?



NIHR Health Technology Assessment programme funded project

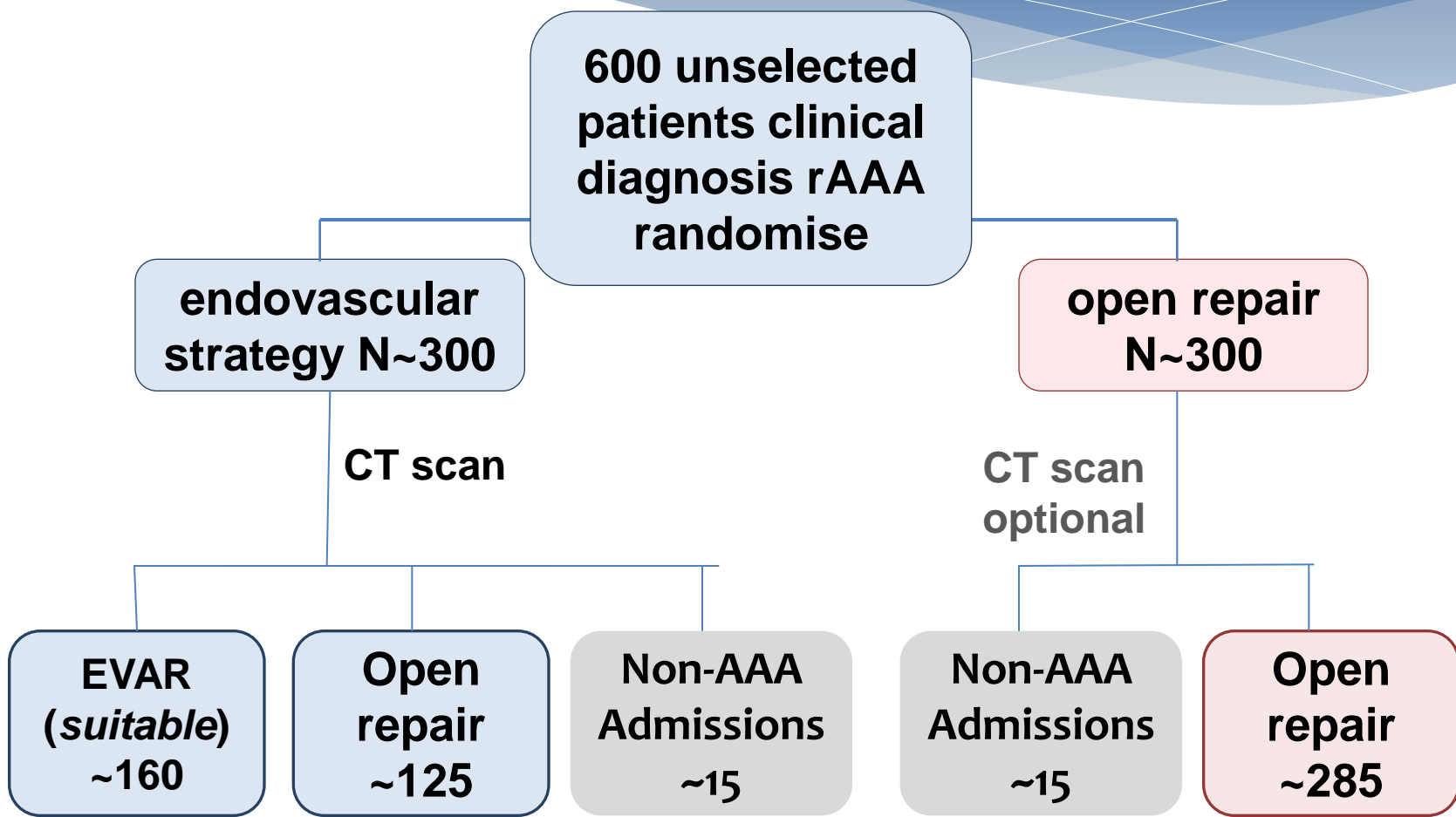
Disclosure of interests

Janet Powell for the IMPROVE trial investigators

The trial management team has no conflict of interest



IMPROVE trial design



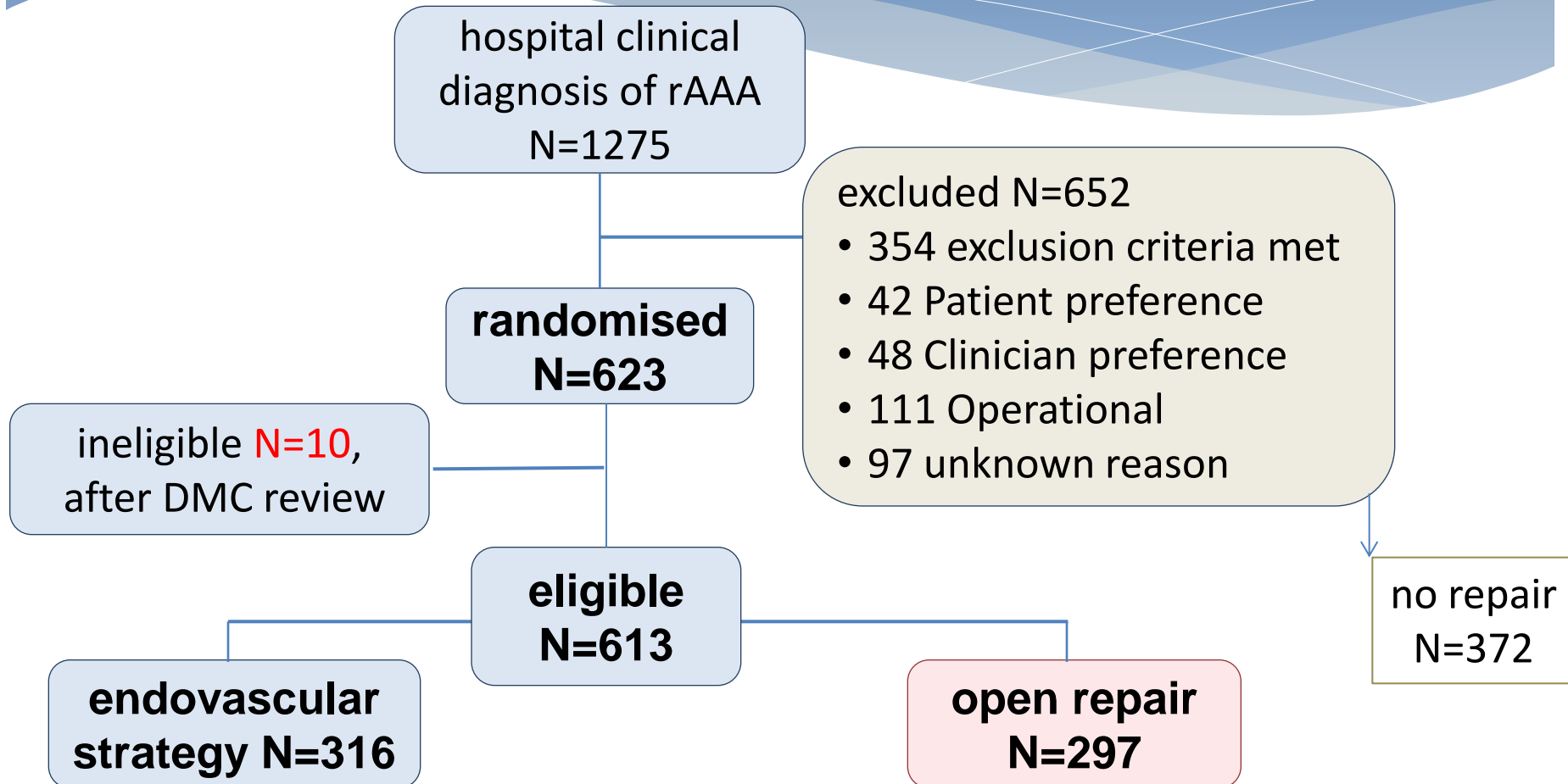
Primary outcome – 30-day mortality

33%

47%

CONSORT diagram 1

Flow of patients through trial 2009-13



Baseline characteristics by randomised group

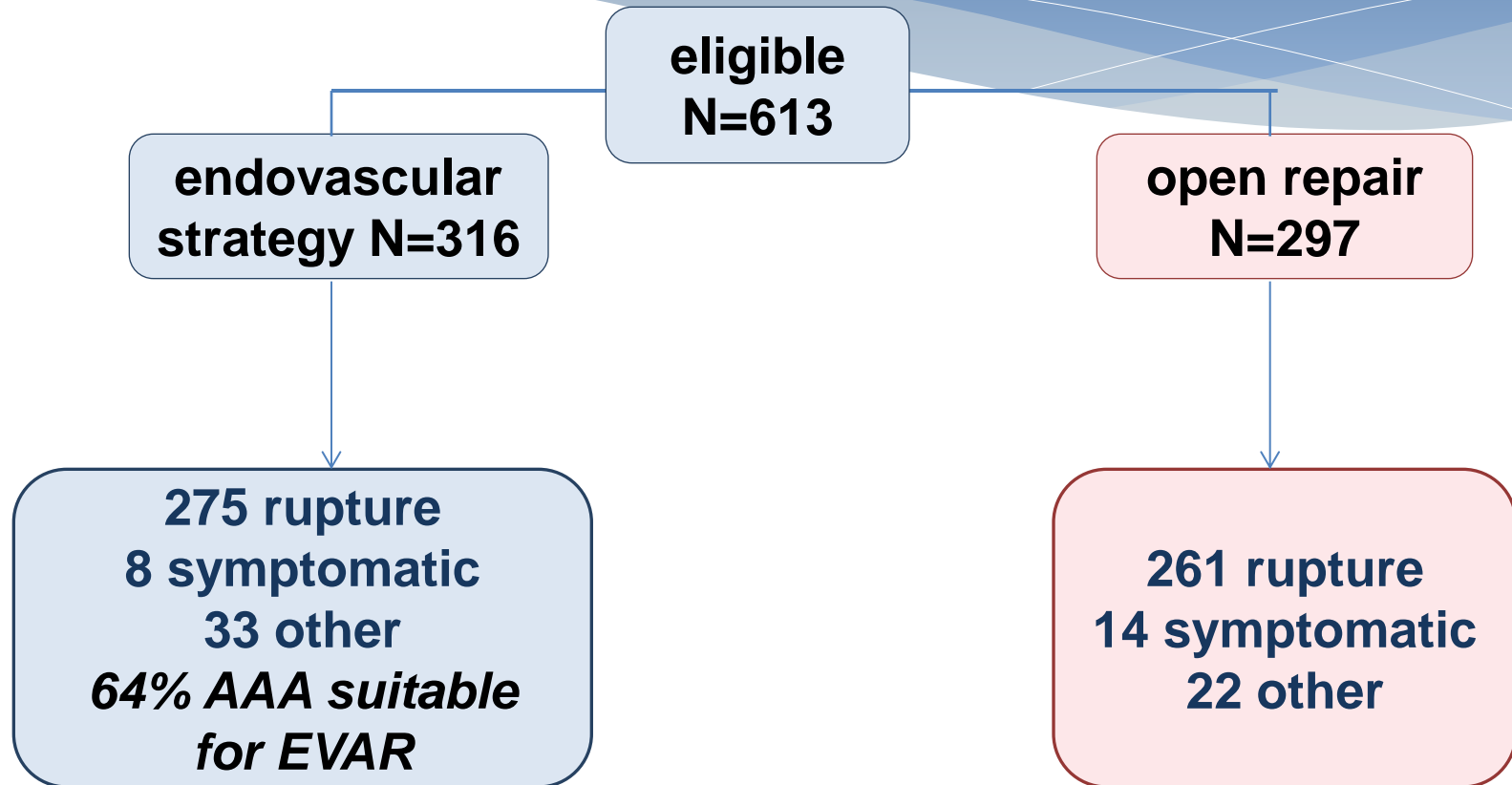
Variable	Endovascular strategy, N=316	Open repair N=297
Age (years)	76.7 (7.4)	76.7 (7.8)
Males (%)	246 (78%)	234 (79%)
Hardman Index n (%)		
0	93 (33%)	69 (27%)
1	130 (46%)	126 (49%)
2+	59 (21%)	62 (24%)
CT scan performed	305 (97%)	266 (90%)
Max aortic diameter (cm)	8.4 (1.9)	8.1 (1.8)



Big ones

CONSORT diagram 2

Final diagnoses



Rupture = blood outside aneurysm sac, core laboratory

Aneurysm repairs by randomised group - 1

Variable	EVAR strategy n=283	Open strategy n=283
Time, randomisation-theatre (median IQR)		
Ruptures (min)	47 (28,73)	37 (22,62)
Symptomatics (hr)	3.6 (3.1,15.6)	3.0 (1.5,17.6)
Lowest systolic BP before arrival in theatre (mmHg), %		
<90 (<70)	51% (20%)	51% (20%)
EVAR started, n(%)	154 (54%)	154 (54%)
AUI/bifurcated/tube	35/104/5	35/104/5
Converted to open	4	4
Open repair started, n(%)	112 (84+28) (40%)	220 (80%)
AUI/bifurcated/tube	0/24/72	2/31/166
No operation, n(%)	17 (6%)	19 (7%)

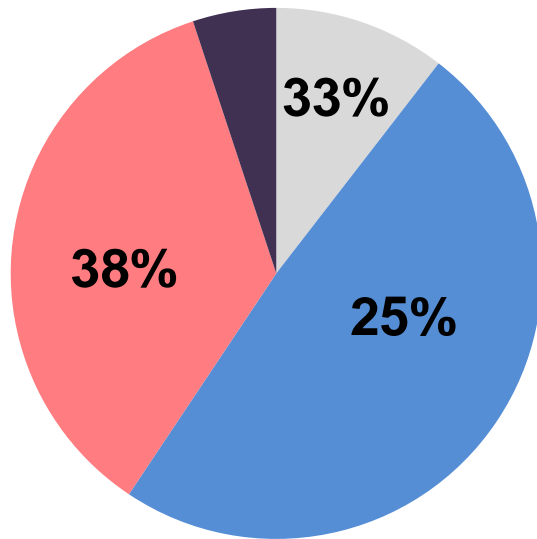
Longer time to assemble EVAR team

Bad news all died

30-day mortality results

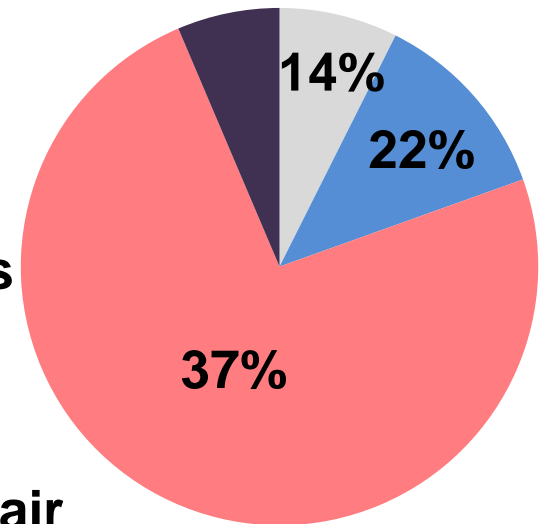
Patients with clinical diagnosis of rupture

Endovascular strategy

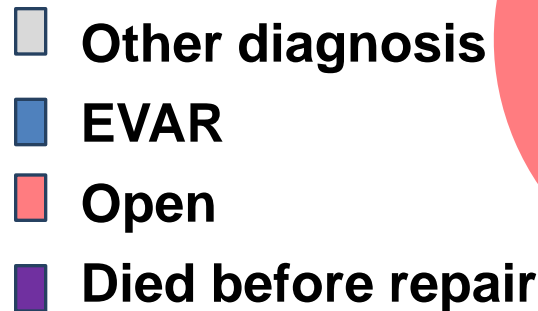


Overall mortality
112/316 (35%)

Open repair



Overall mortality
111/297 (37%)

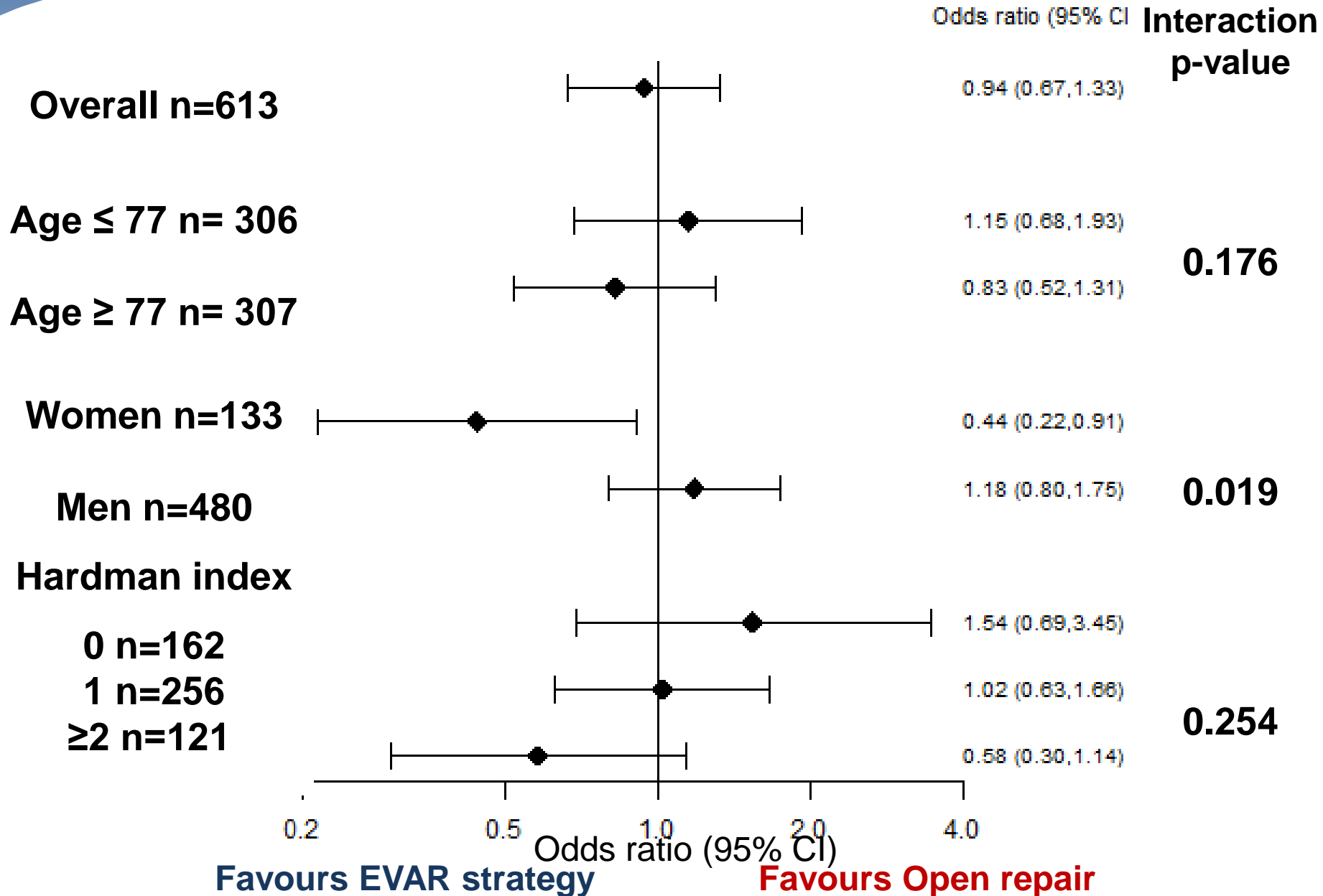


30d mortality for ruptures only

Subgroup	Endovascular strategy	Open repair	Odds ratio
Ruptures only	100/275 (36%)	106/261 (41%)	0.84 [95%CI 0.59,1.18]
Ruptures repaired only	84/259 (32%)	87/242 (36%)	0.86 [95%CI 0.59,1.24]

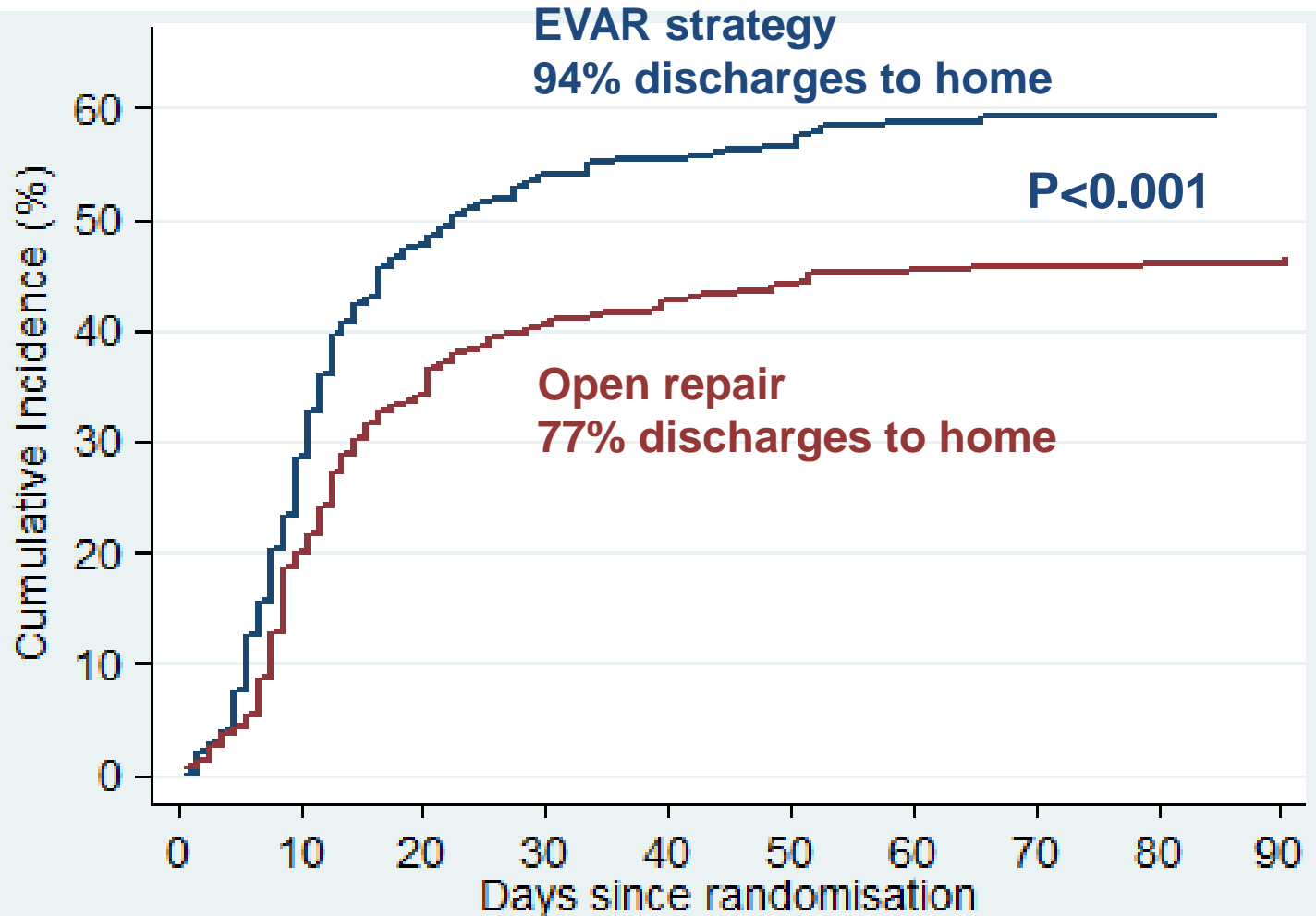
Causal analysis (ruptures adhering to allocated treatment) OR 0.82 [0.59-1.32]

Subgroup analysis 30d mortality



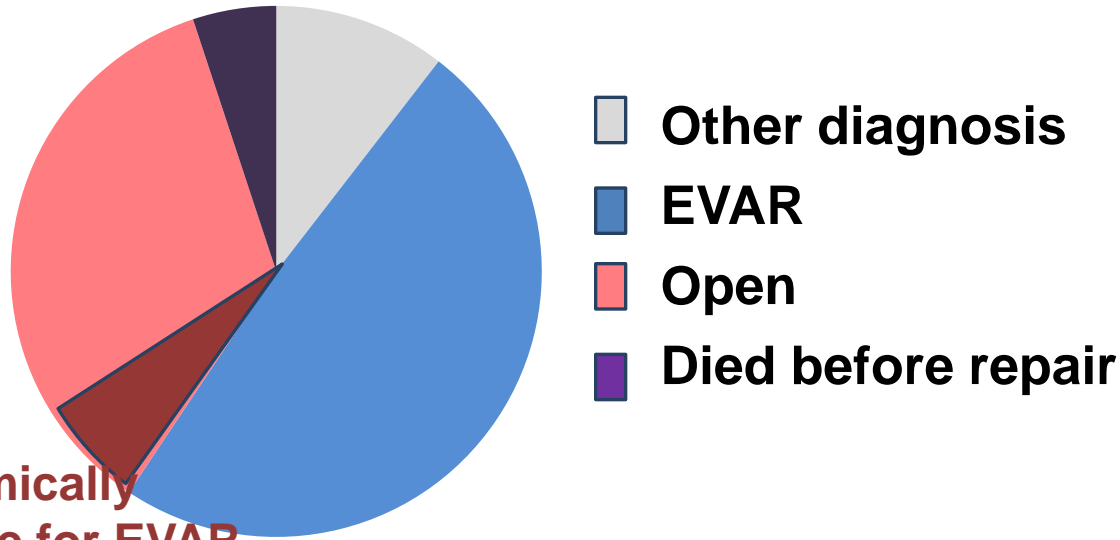
Time to discharge home

full 30 day results from IMPROVE in BMJ 2014;348:f6771



Best quality endovascular & open repair are still needed

Endovascular strategy



Anatomically suitable for EVAR

Cohort study of patients with confirmed rupture

To drive quality improvement

Blood pressure

Lowest systolic pressure before theatre (mm Hg)	30-day mortality
<70	48/95 (51%)
70-83	43/114 (38%)
84-98	47/103 (46%)
99-119	29/101 (29%)
120+	27/110 (25%)



per 10 mm Hg increase
OR 0.88 [0.82, 0.94]
p<0.001

Fluids administered not associated with mortality

Anaesthesia for EVAR

Based on completed EVARs

Type of anaesthesia	30-day mortality (%)
General	28/83 (34%)
Local, then general	9/30 (31%)
Local	9/69 (13%)

OR 0.25 [0.1, 0.7]
P<0.001

For rupture, open repair is not yet an
outdated procedure

January 2014



Coming next:

Impact of morphology on outcomes June 2014

12 month outcomes & cost-effectiveness December 2014