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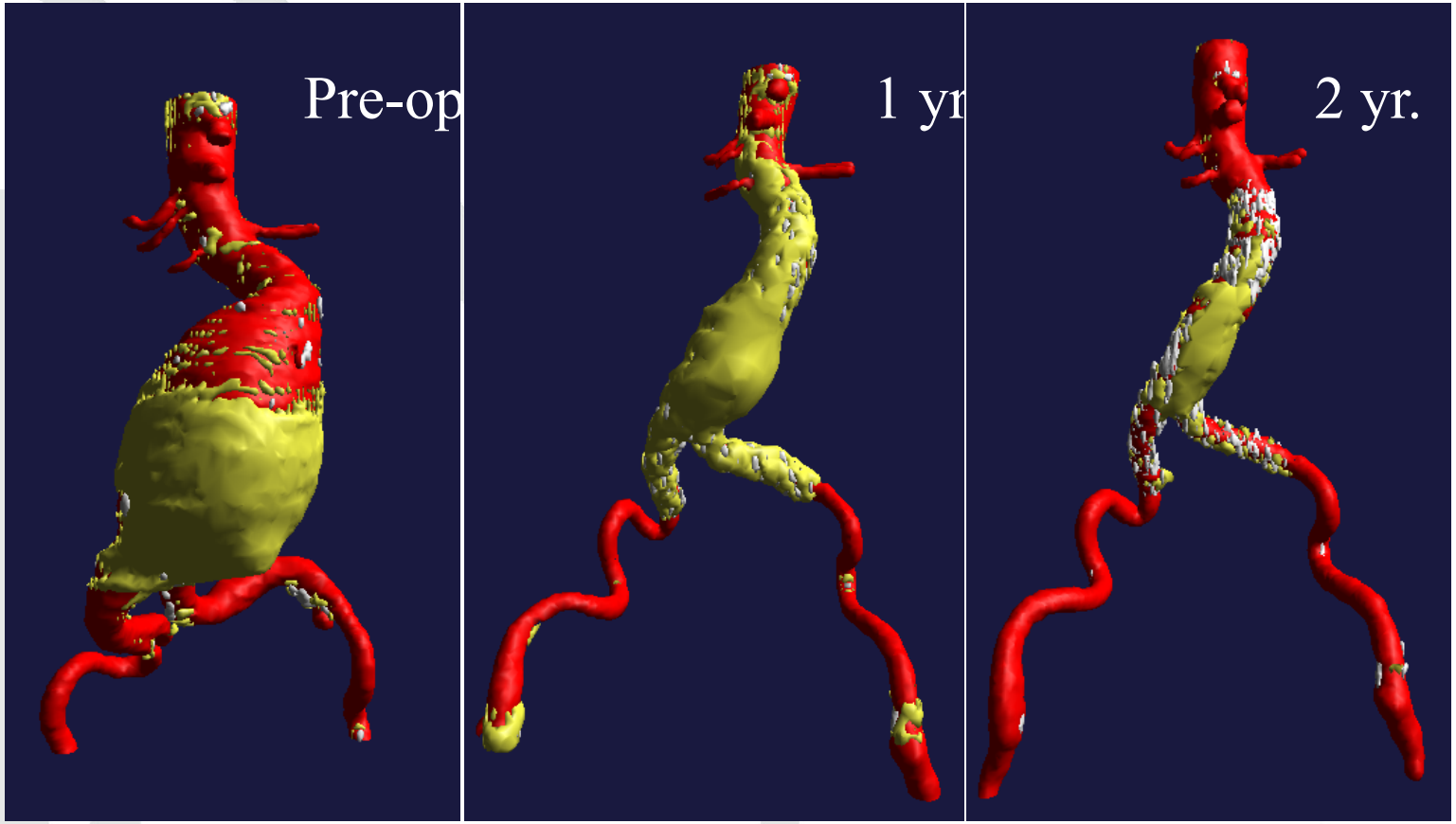
Optimal evolution after EVAR



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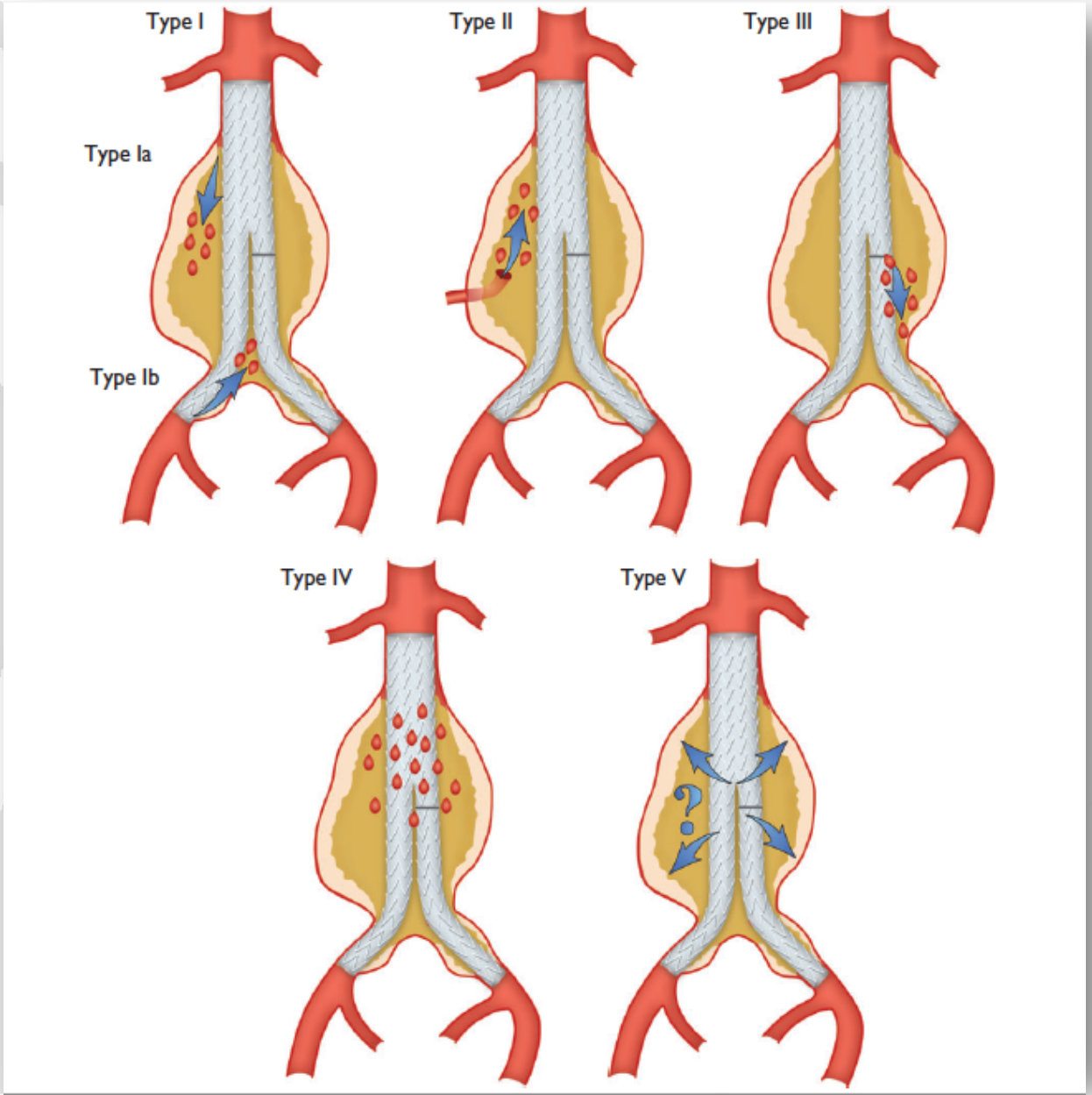
Endoleaks



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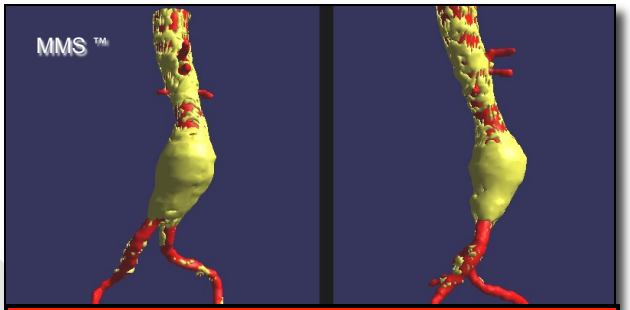
EVAR success depends on…

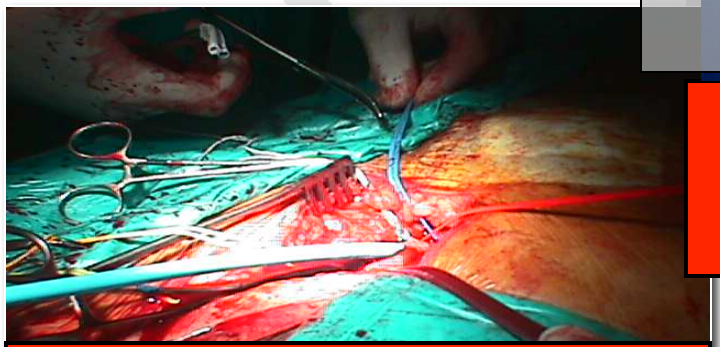


Patient selection

Surveillance

EVAR
Success

Endograft selection



Procedure experience

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OR vs EVAR

Risk prediction for perioperative mortality of endovascular vs open repair of abdominal aortic aneurysms using the Medicare population

Kristina A. Giles, MD,* Marc L. Schermerhorn, MD,* A. James O'Malley, PhD,† Philip Cotterill, PhD,‡ Ami Jhaveri, MD,* Frank B. Pomposelli, MD,* and Bruce E. Landon, MD, MBA,‡ *Boston, Mass, and Baltimore, Md*

Objectives: The impact of risk factors upon perioperative mortality might differ for patients undergoing open vs endovascular repair (EVAR) of abdominal aortic aneurysms (AAA). In order to investigate this, we developed a differential predictive model of perioperative mortality after AAA repair.

Methods: A total of 45,660 propensity score matched Medicare beneficiaries undergoing elective open or endovascular AAA repair from 2001 to 2004 were studied. Using half the dataset we developed a multiple logistic regression model for a matched cohort of open and EVAR patients and used this to derive an easily evaluable risk prediction score. The remainder of the dataset formed a validation cohort used to confirm results.

Results: The derivation cohort included 11,415 open and 11,415 endovascular repairs. Perioperative mortality was 5.3% and 1.8%, respectively. Independent predictors of mortality (relative risk [RR], 95% confidence interval [CI]) were open repair (3.2, 2.7-3.8); age (71-75 years 1.2, 0.9-1.6; 76-80 years 1.9, 1.4-2.5; >80 years 3.1, 2.4-4.2); female gender (1.5, 1.3-1.8); dialysis (2.6, 1.5-4.6); chronic renal insufficiency (2.0, 1.6-2.6); congestive heart failure (1.7, 1.5-2.1); and vascular disease (1.3, 1.2-1.6). There were no differential predictors of mortality across the two procedures. A simple scoring system was developed from a logistic regression model fit to both endovascular and open patients (area under the receiver operator curve [ROC] curve of 72.6) from which low, medium, and high risk groups were developed. The absolute predicted mortality ranged from 0.7% for an EVAR patient ≤70 years of age with no comorbidities to 38% for an open patient >80 with all the comorbidities considered. Although relative risk was similar among age groups, the absolute difference was greater for older patients (with higher baseline risk).

Conclusions: Mortality after AAA repair is predicted by comorbidities, gender, and age, and these predictors have similar effects for both methods of AAA repair. This simple scoring system can predict repair mortality for both treatment options and thus may help guide clinical decisions. (J Vasc Surg 2009;50:256-62.)

Open abdominal aortic aneurysm (AAA) repair has been shown to have higher early mortality compared to endovascular (EVAR) repair.[1-3] For this reason, when anatomic factors allow, there is a mounting preference toward using EVAR, particularly for older and sicker patients who would be less likely to survive open surgery. Long-term outcomes, however, eventually converge with similar survival after several years of follow-up.[1,4,5] Also favoring endovascular repair are shorter duration hospital stays, quicker functional recovery, fewer postoperative complications, fewer laparotomy-related reinterventions, and lower initial costs. Follow-up monitoring regimens, however, are more intensive after endovascular repair, and aneurysm-related re-interventions are more frequent.[1] Thus, the decision to pursue open vs endovascular repair hinges on many factors and is not always straightforward.

Using comprehensive data on elderly enrollees in the Medicare program, we previously found that in-hospital mortality for endovascular AAA repair and open repair were 1.2% and 4.8%, respectively, but that early mortality differences increased with age.[1] What remains unknown, however, is if there are specific clinical factors that might differentially impact early survival after open and endovascular AAA repair and thus influence the decision to perform one procedure over the other.

Predictive risk models such as the Glasgow Aneurysm Score (GAS), Leiden Score, and Hardman Index have been derived for open AAA repair and, while they have variable utility for open repair, they over-predict mortality in the EVAR population.[6-10] To our knowledge, no independent predictive models have been devised from EVAR data nor have these studies attempted to assess outcomes in terms of whether factors may differentially affect mortality after EVAR vs open repair. We therefore sought to identify clinical and demographic factors related to perioperative mortality for both types of repairs and to identify specifically predictors with a differential effect to the extent that they exist. The results of this analysis will provide a clinical tool for the selection of patients best suited for endovascular or open repair and will assist clinicians in estimating

Beth Israel Deaconess Medical Center,* the Department of Health Care Policy, Harvard Medical School,† Centers for Medicare and Medicaid Services,‡ and the Department of Health Care Policy, Harvard Medical School.§

Competition of interest: none.
Presented at the Thirty-fifth New England Society for Vascular Surgery Annual Meeting, Newport, RI, October 4, 2008.

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0741-5214/$36.00
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doi:10.1016/j.jvs.2009.01.044

- Medicare database
- 2001-2004
- Propensity matched cohorts
  - OR 11,415 pts
  - EVAR 11,415 pts
- Overall periop. mortality
  - OR: 5.3%
  - EVAR: 1.8%

Giles JVS 2009

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OR vs EVAR

	Fit	Unfit
Younger		EVAR
Older	EVAR	

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OR vs EVAR

	Fit	Unfit
Younger		EVAR
Older	EVAR	EVAR? None?

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OR vs EVAR

	Fit	Unfit
Younger	OR? EVAR?	EVAR
Older	EVAR	EVAR? None?

OR vs EVAR

RCT Results: EVAR-1

Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial

Lancet 2005

EVAR trial participants*

- 1082 patients age ≥ 60, AAA ≥ 5.5cm, fit for open or EVAR
- Median f/u 2.9 yrs
  - EVAR significant decrease perioperative and AAA-related mortality
  - No advantage all cause mortality
  - EVAR high reintervention rate

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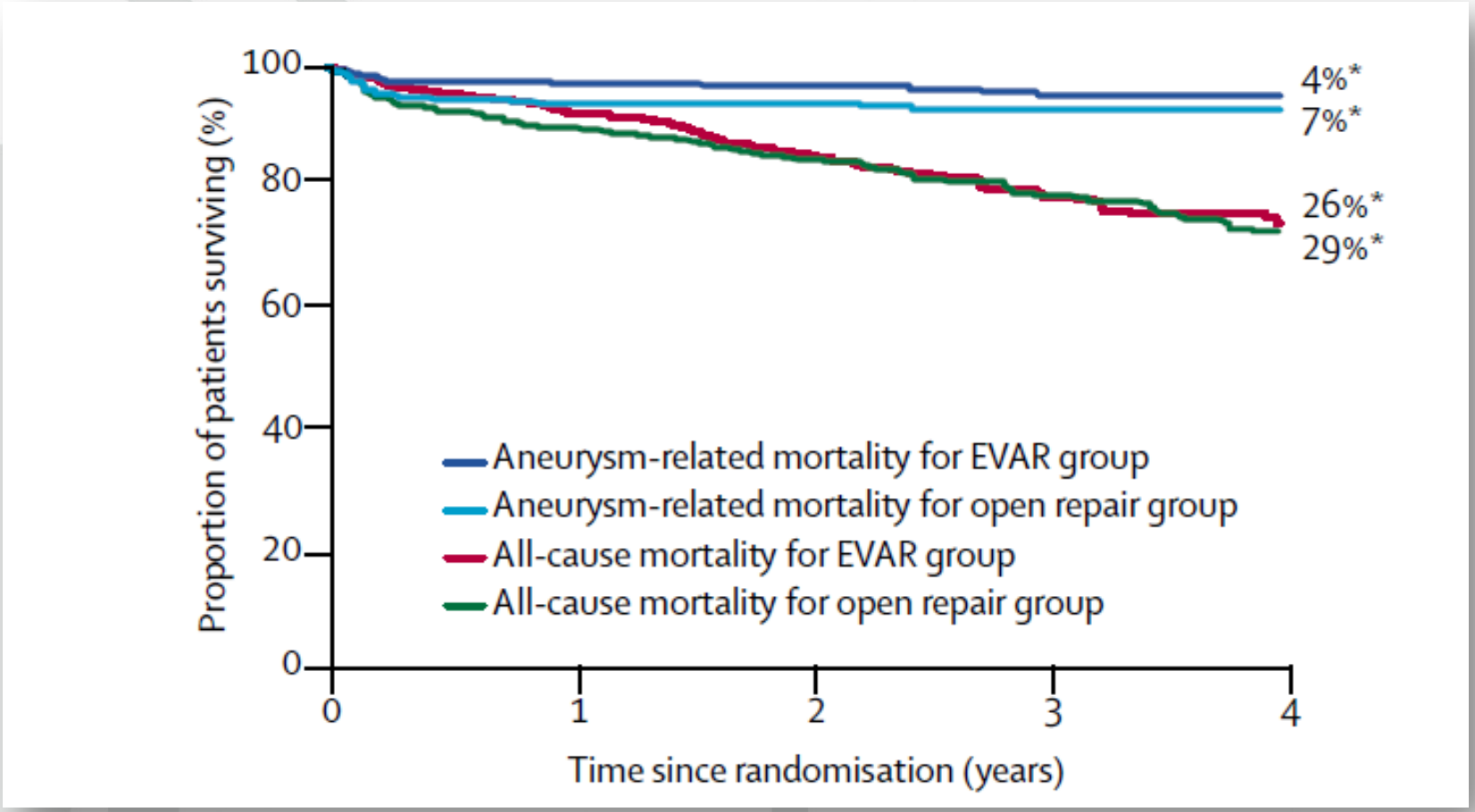
OR vs EVAR

Survival: EVAR-1



Lancet 2005

OR vs EVAR

RCT Results: DREAM

Two-Year Outcomes after Conventional or Endovascular Repair of Abdominal Aortic Aneurysms

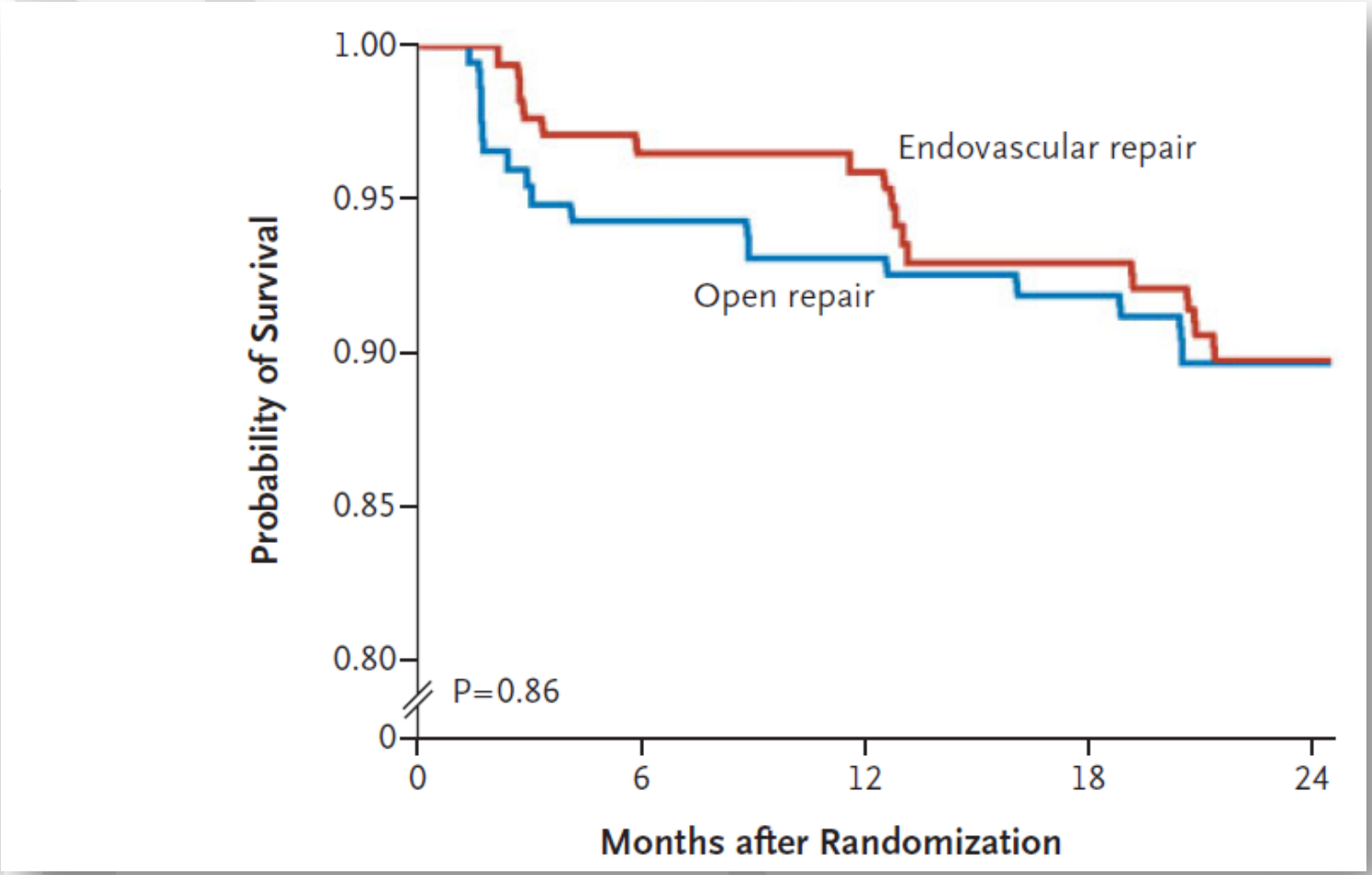
Jan D. Blankensteijn, M.D., Sjors E.C.A. de Jong, M.D., Monique Prinssen, M.D., Arie C. van der Ham, M.D., Jaap Buth, M.D., Steven M.M. van Sterkenburg, M.D., Hence J.M. Verhagen, M.D., Erik Buskens, M.D., and Diederick E. Grobbee, M.D., for the Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial Group*

- 351 patients, asymptomatic AAA eligible for repair
- Mean f/u 1.8 yrs
  - EVAR significant decrease perioperative mortality
  - Overall survival advantage lost after 1 year

NEJM 2005

OR vs EVAR

Survival: DREAM



NEJM 2005

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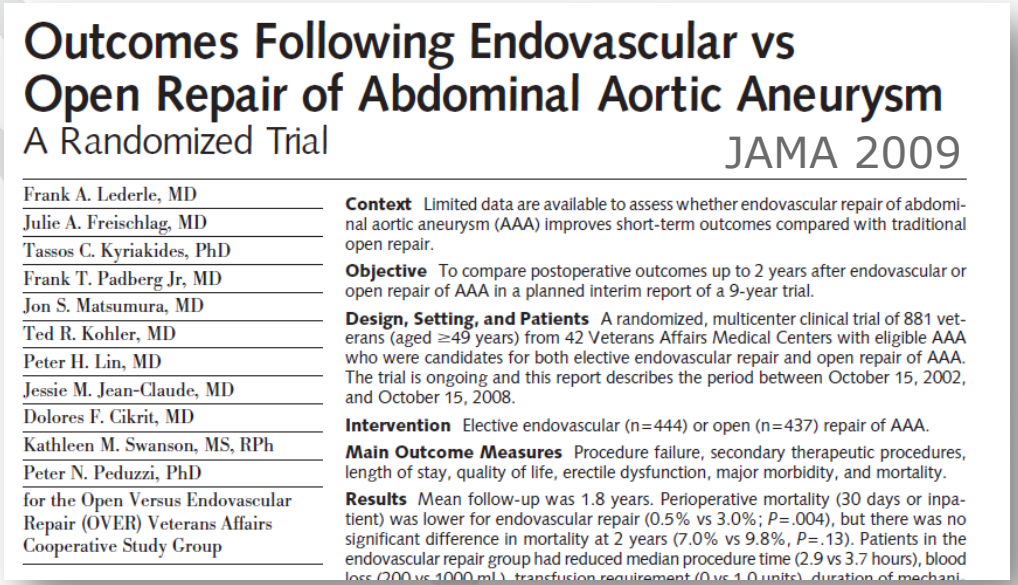
OR vs EVAR

RCT Results: OVER



Outcomes Following Endovascular vs Open Repair of Abdominal Aortic Aneurysm

A Randomized Trial

JAMA 2009

Frank A. Lederle, MD
Julie A. Freischlag, MD
Tassos C. Kyriakides, PhD
Frank T. Padberg Jr, MD
Jon S. Matsumura, MD
Ted R. Kohler, MD
Peter H. Lin, MD
Jessie M. Jean-Claude, MD
Dolores F. Cikrit, MD
Kathleen M. Swanson, MS, RPh
Peter N. Peduzzi, PhD
for the Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group

Context Limited data are available to assess whether endovascular repair of abdominal aortic aneurysm (AAA) improves short-term outcomes compared with traditional open repair.

Objective To compare postoperative outcomes up to 2 years after endovascular or open repair of AAA in a planned interim report of a 9-year trial.

Design, Setting, and Patients A randomized, multicenter clinical trial of 881 veterans (aged ≥49 years) from 42 Veterans Affairs Medical Centers with eligible AAA who were candidates for both elective endovascular repair and open repair of AAA. The trial is ongoing and this report describes the period between October 15, 2002, and October 15, 2008.

Intervention Elective endovascular (n=444) or open (n=437) repair of AAA.

Main Outcome Measures Procedure failure, secondary therapeutic procedures, length of stay, quality of life, erectile dysfunction, major morbidity, and mortality.

Results Mean follow-up was 1.8 years. Perioperative mortality (30 days or inpatient) was lower for endovascular repair (0.5% vs 3.0%; *P*=.004), but there was no significant difference in mortality at 2 years (7.0% vs 9.8%, *P*=.13). Patients in the endovascular repair group had reduced median procedure time (2.9 vs 3.7 hours), blood loss (200 vs 1000 mL), transfusion requirement (0 vs 1.0 units), duration of mechani

- 881 patients asymptomatic AAA eligible for repair open or EVAR (VA Hospitals)
- Mean f/u 1.8 yrs
  - EVAR significant decrease perioperative and AAA-related mortality
  - Mortality advantage persists at 2 yrs
  - No difference in reinterventions

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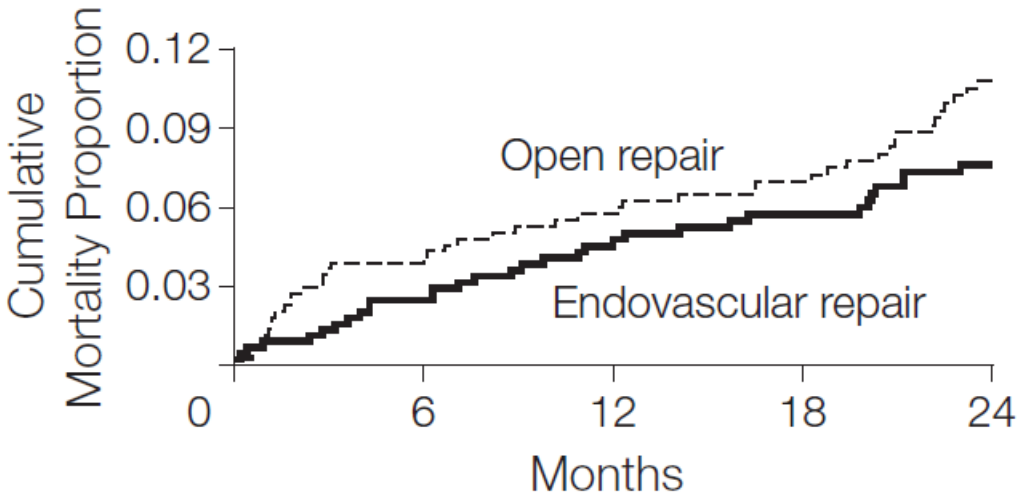
OR vs EVAR

Survival: OVER



No. at risk					
Open repair	437	420	396	363	310
Endovascular repair	444	433	411	371	326

There was no significant difference in cumulative mortality for open vs endovascular repair (hazard ratio, 0.7; 95% confidence interval, 0.4-1.1; log-rank $P=.13$).

JAMA 2009

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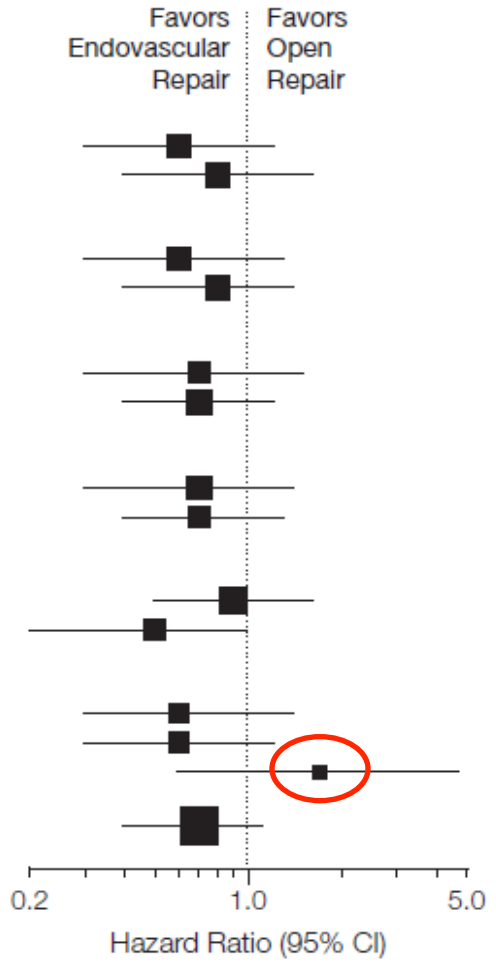
OR vs EVAR

Hazard Ratios for Mortality: OVER

Figure 3. Hazard Ratios for Death According to Baseline Characteristics

Subgroup	No. Patients	No. Deaths	Hazard Ratio (95% CI)
Randomization period			
Before April 15, 2005	413	40	0.6 (0.3-1.2)
After April 15, 2005	468	34	0.8 (0.4-1.6)
Age, y			
<70	406	26	0.6 (0.3-1.3)
≥70	475	48	0.8 (0.4-1.4)
AAA diameter, cm			
<5.5	382	27	0.7 (0.3-1.5)
≥5.5	499	47	0.7 (0.4-1.2)
Surgical risk (RAND score)			
Low	467	29	0.7 (0.3-1.4)
Intermediate or high	405	42	0.7 (0.4-1.3)
Coronary artery disease			
No	522	43	0.9 (0.5-1.6)
Yes	359	31	0.5 (0.2-1.0)
Intended endovascular system			
Cook Zenith	341	26	0.6 (0.3-1.4)
Gore Excluder	327	28	0.6 (0.3-1.2)
Medtronic AneuRx	186	15	1.7 (0.6-4.7)
Overall	881	74	0.7 (0.4-1.1)



JAMA 2009

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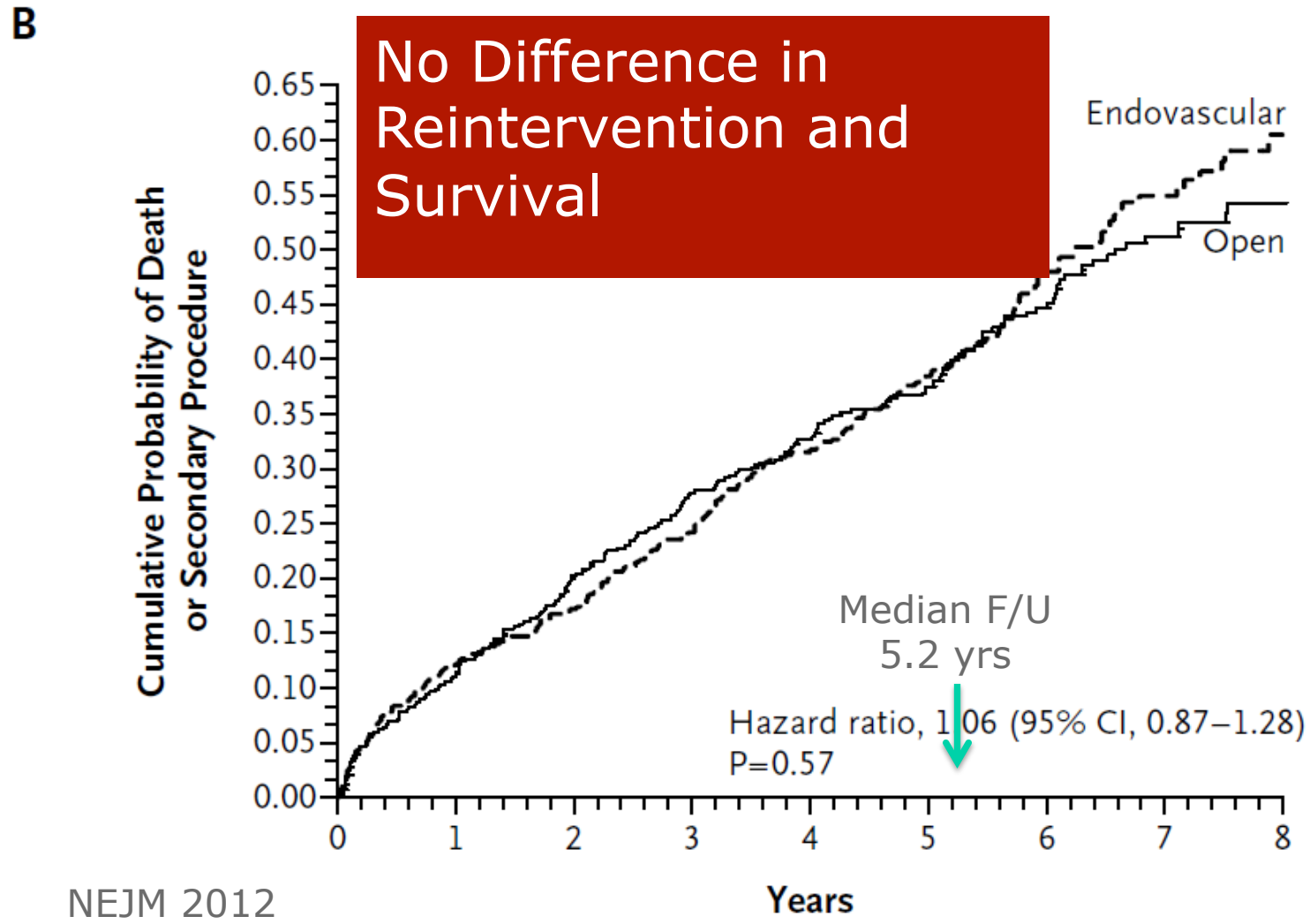
OR vs EVAR

Summary: RCT Results

Trial	Site	Enrollment Start	30-d Mortality Open	30-d Mortality EVAR	Reinter v Open	Reinter v EVAR
EVAR-1	UK	1999	6.2%	2.1%	9%	20%
DREAM	Netherlands Belgium	2000	4.6%	1.2%	5%	14%
OVER	USA (VA)	2002	2.3%	0.2%	12.5%	13.7%

OR vs EVAR

Long-Term Outcomes: OVER



NEJM 2012

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EVAR evidence

- the clinical effectiveness of EVAR and the comparison with OSR is well established

Meta-analysis

Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm

P. W. Stather[1], D. Sidloff[1], N. Dattani[1], E. Choke[1], M. J. Bown[1,2] and R. D. Sayers[1]

Conclusion: There is no long-term survival benefit for patients who have EVAR compared with open repair for AAA. There are also significantly higher risks of reintervention and aneurysm rupture after EVAR.

B J Surg, 2013

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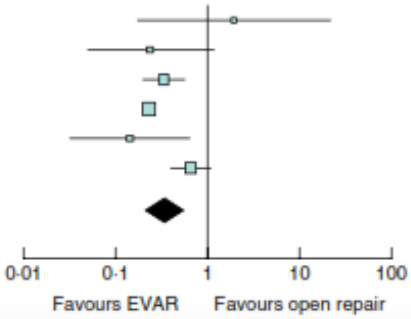
EVAR evidence: Mortality

30-day-mortality

ACE[33]	2 of 150	1 of 149	4·3	2·00 (0·18, 22·30)
DREAM[35]	2 of 173	8 of 178	8·6	0·25 (0·05, 1·19)
EVAR1[1,37]	22 of 614	58 of 602	24·0	0·35 (0·21, 0·58)
Medicare[9]	274 of 22 830	1096 of 22 830	29·7	0·24 (0·21, 0·28)
OVER[39]	2 of 444	13 of 437	9·1	0·15 (0·03, 0·66)
SweVasc[40]	20 of 855	99 of 2922	24·3	0·68 (0·42, 1·11)
Total	322 of 25 066	1275 of 27 118	100·0	0·36 (0·21, 0·61)

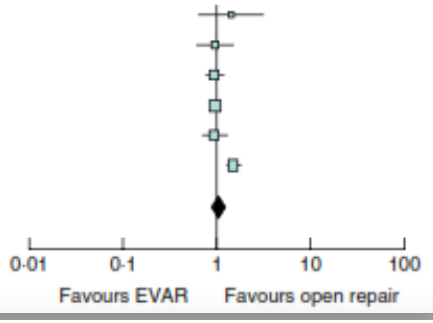
Heterogeneity: $\tau^2 = 0{\cdot}25$; $\chi^2 = 20{\cdot}93$, 5 d.f., $P < 0{\cdot}001$; $I^2 = 76\%$



≥4 year all cause mortality

ACE[33]	17 of 150	12 of 149	5·1	1·46 (0·67, 3·17)
DREAM[35]	58 of 173	60 of 178	11·1	0·99 (0·64, 1·54)
EVAR1[37]	260 of 626	264 of 626	19·3	0·97 (0·78, 1·22)
Medicare[9]	7922 of 22 830	7922 of 22 830	25·7	1·00 (0·96, 1·04)
OVER[39]	146 of 444	146 of 437	16·9	0·98 (0·74, 1·29)
SweVasc[40]	298 of 855	757 of 2922	22·0	1·53 (1·30, 1·80)
Total	8701 of 25 078	9161 of 27 142	100·0	1·11 (0·91, 1·35)

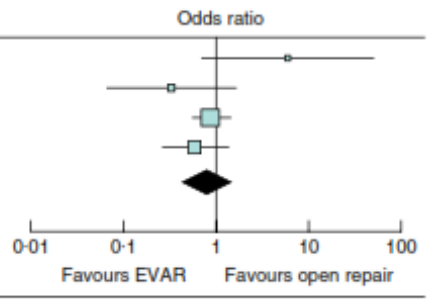
Heterogeneity: $\tau^2 = 0{\cdot}04$; $\chi^2 = 25{\cdot}82$, 5 d.f., $P < 0{\cdot}001$; $I^2 = 81\%$



Aneurysm-related mortality

Reference	EVAR	Open repair	Weight (%)	Odds ratio
ACE[33]	6 of 150	1 of 149	8·3	6·17 (0·73, 51·86)
DREAM[35]	2 of 173	6 of 178	13·1	0·34 (0·07, 1·68)
EVAR1[37]	36 of 626	40 of 626	46·6	0·89 (0·56, 1·42)
OVER[39]	10 of 444	16 of 437	32·0	0·61 (0·27, 1·35)
Total	54 of 1393	63 of 1390	100·0	0·81 (0·42, 1·58)

Heterogeneity: $\tau^2 = 0{\cdot}19$; $\chi^2 = 5{\cdot}33$, 3 d.f., $P = 0{\cdot}15$; $I^2 = 44\%$
Test for overall effect: $Z = 0{\cdot}61$, $P = 0{\cdot}54$



Stather et al B J Surg, 2013

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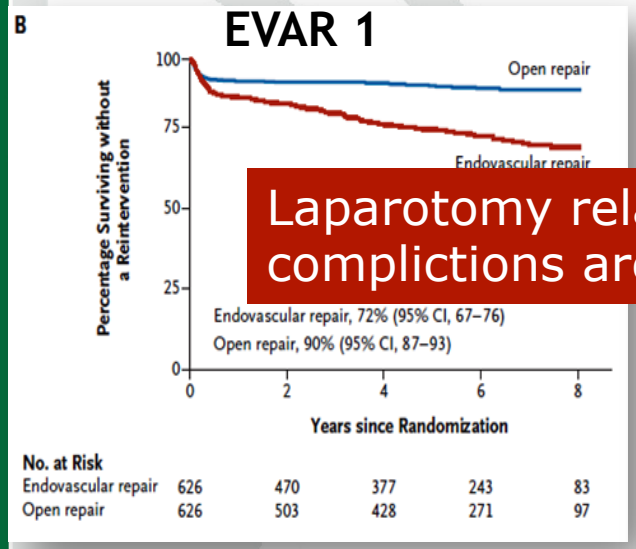
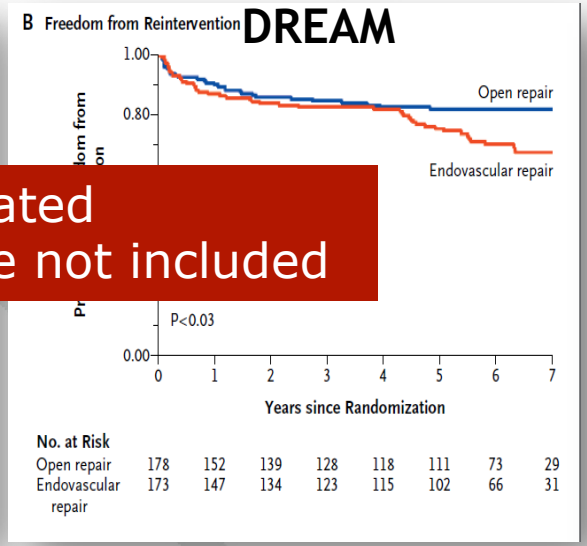
EVAR evidence: Reinterventions

EVAR reintervention rates worsen over time…

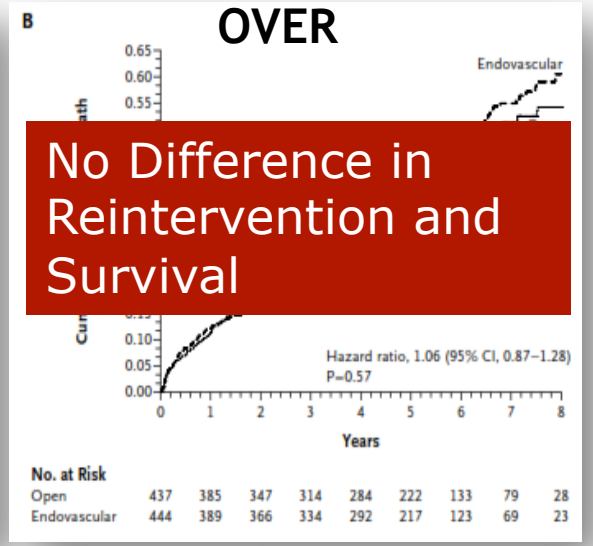


Laparotomy related complictions are not included

R.M. Greenhalgh *et al*. N Engl J Med 2010

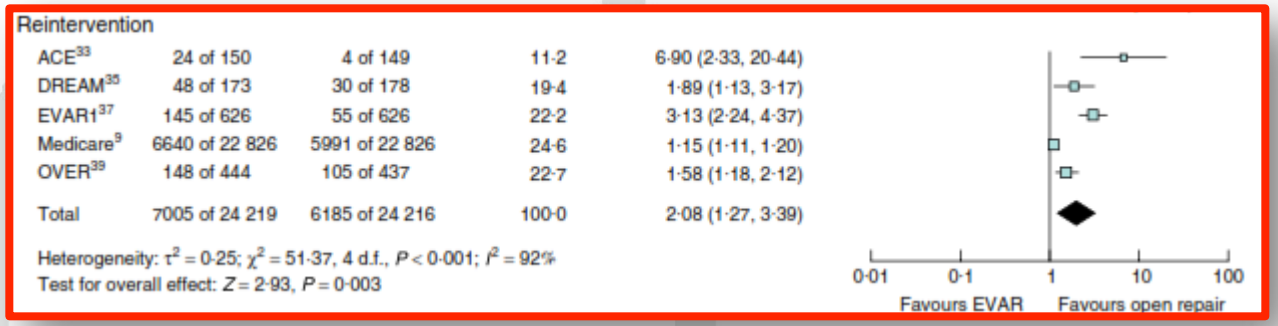


De Bruin *et al*. N Engl J Med 2010



No Difference in Reintervention and Survival

FA Lederle et al N Engl J Med 2012



Stather *et al B J Surg, 2013*

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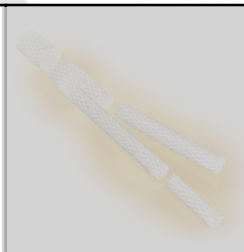
Involved Endografts in RCTs and major Registries

						
EVAR 1[1] (1999-2004)	X	X	X	X	X	
DREAM[2] (2000-2003)	X	X	X	X		
OVER[3] (2002-2008)	X	X		X		
ACE[4] (2003-2008)		X	X	X		X
EUROSTAR[5] (1996-2006)	X	X	X	X	X	X
LIFELINE[6] (1999-2004)	X	X				X

1. *R.M. Greenhalgh et al. N Engl J Med 2010*
2. *De Bruin et al. N Engl J Med 2010*
3. *Lederle et al. JAMA 2009*
4. *Becquemin et al. J Vasc Surg. 2011*
5. *Hobo et al, JVS 2006*
6. *Lifeline Registry of EVAR Publications Committee, JVS 2005*

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V Riambau. Current endografts for abdominal aortic stenting. In Matt Thompson, Marc Sappoval, Jon Matsumura, Rob Morgan: *Endovascular Intervention for Vascular Disease: Principles and Practice* Marcel Dekker Taylor and Francis Books Inc New Cork, 2008

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Newer Endografts