# EVAR vs open repair has the standard shifted?

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# Conflict of Interest Statement

**Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.**

**Physician Name**

**L Garcia**

| **Company/Relationship** | |
|---|---|
| **BostonScientific** | **AdBoard (modest)** |
| **EV3** | **Research/AdBoard** |
| **Spectranetics** | **AdBoard (unpaid)** |
| **Pathway Medical** | **AdBoard (unpaid)** |
| **AngioSculpt** | **AdBoard (unpaid)** |
| **iDev Technologies** | **Research/AdBoard** |
| **Covidien** | **Consultant** |
| **Scion Cardiovascular** | **Board of Directors** |
| **Arsenal Medical** | **Equity shareholder** |
| **TissueGen Medical** | **Equity shareholder** |
| **Primacea** | **Equity shareholder** |
| **CVI Technologies** | **Equity shareholder** |

# Treatment Options for AAA

- Observation
  - high risk patients
  - Small Aneurysms
- Open Surgical Repair
- Endovascular Aortic Stent grafting

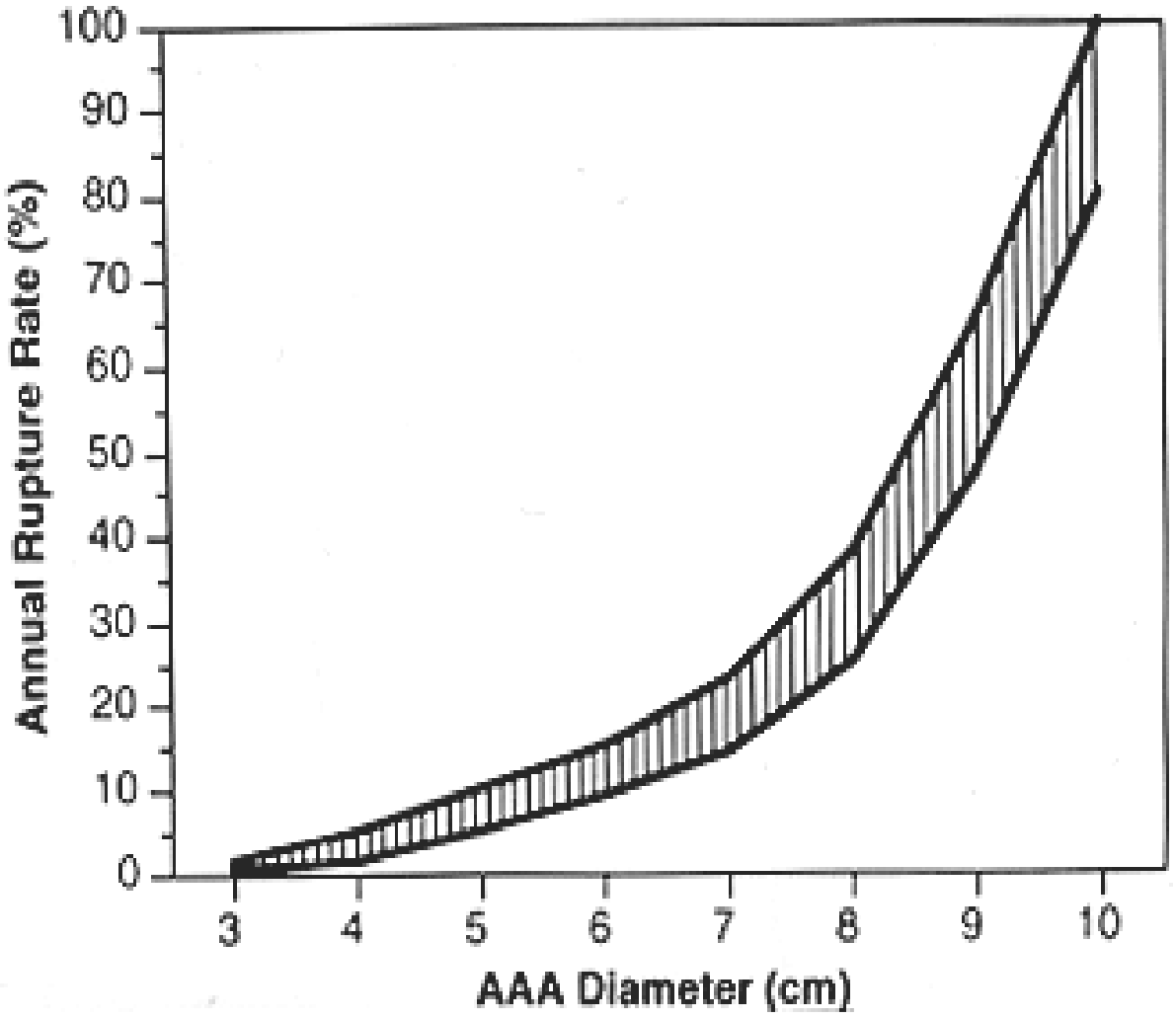
# Presentation of AAA

- 70-75% asymptomatic
  - 30-50% found on PE
  - Incidental finding on Xray
  - Men less than 5.5 cm in diameter
    - Risk of Rupture is 1% per year
- 20-25% symptomatic
  - Abdominal pain
  - Rupture 50-75% mortality

# Predicted Incidence of Aneurysm Rupture Within 5 Years After an Initial Screen (Chichester Data)

| *Initial diameter (mm)* | *Second measurement (mm)* | *Time after initial screen (years)* 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| *30* | *No measurement* | *0-2* | *0-4* | *0-7* | *1-1* | *1-7* |
| | *30* | *0-2* | *0-4* | *0-6* | *0-9* | *1-3* |
| | *35* | *0-3* | *0-7* | *1-1* | *1-6* | *2-4* |
| | *40* | *0-4* | *0-8* | *1-4* | *2-4* | *4-0* |
| *40* | *No measurement* | *0-8* | *1-7* | *3-0* | *4-8* | *7-5* |
| | *40* | *0-7* | *1-5* | *2-5* | *3-7* | *5-6* |
| | *45* | *0-9* | *2-0* | *3-4* | *5-4* | *8-7* |
| | *50* | *1-1* | *2-5* | *4-5* | *7-9* | *12-9* |
| *45* | *No measurement* | *1-4* | *3-1* | *5-4* | *8-8* | *13-1* |
| | *45* | *1-2* | *2-7* | *4-7* | *7-7* | *11-8* |
| | *50* | *1-6* | *3-6* | *6-4* | *10-5* | *15-9* |
| | *55* | *2-1* | *4-8* | *8-6* | *14-0* | *20-5* |
| *50* | *No measurement* | *2-5* | *6-0* | *11-1* | *18-3* | *26-9* |
| | *50* | *2-2* | *5-2* | *9-7* | *16-4* | *25-0* |
| | *55* | *2-8* | *6-8* | *12-8* | *21-4* | *31-3* |
| | *60* | *3-6* | *8-8* | *16-5* | *26-6* | *37-7* |

*Vardulaki et al, Br J Surg, 85:1674-1680, 1998.*

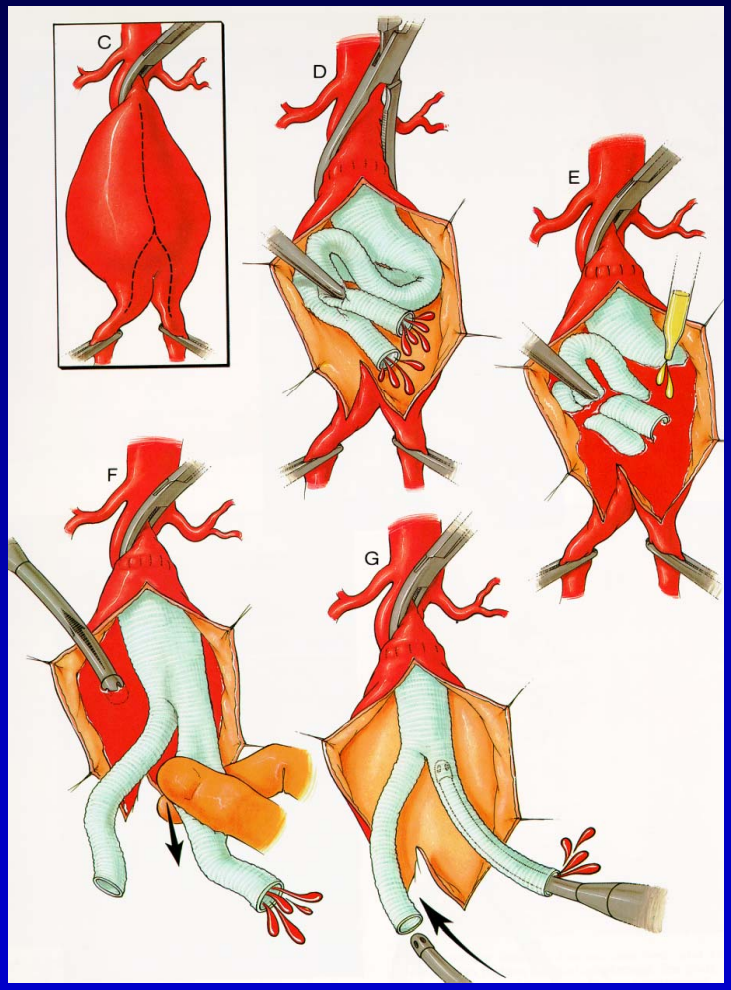

Annual Rupture Rate (%)
100
90
80
70
60
50
40
30
20
10
0
3
4
5
6
7
8
9
10
AAA Diameter (cm)

# Indications for Intervention of AAA

- European Small Aneurysm Trial and the VA Cooperative Trial
  - Men - 4.0 –5.5 cm asymptomatic AAA observation
    - 0.7 %/yr risk of rupture with observation
    - 62% repair rate due to expansion, onset of symptoms
  - Women
    - Repair AAA > 4.5 in good risk patients

# Conventional AAA repair

- Prox. And Distal Control
- Open the AAA sack
- Attach tube or bifurcated aortic graft



# Complications of AAA repair

- 2-4% operative mortality
- Morbidity
  - MI 3-16%
  - Renal failure 3-12%
    - Ureteral injury
  - GI colonic ischemia
  - Paraplegia
  - Emboli
  - Hemmorhage

# OPERATIVE MORBIDITY: *Elective Repair*

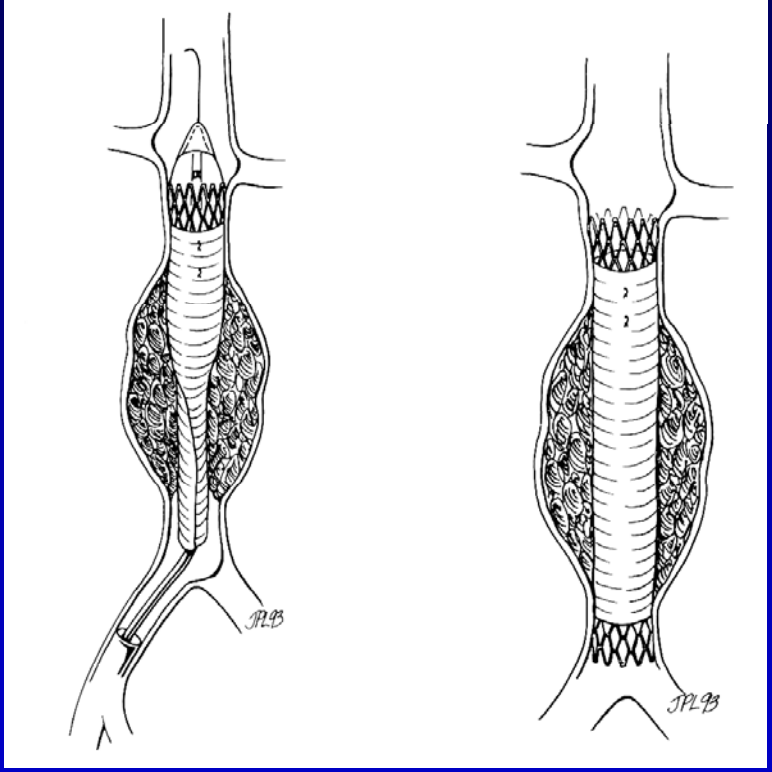
*(Johnston & Scobie -- Canadian Prospective Study)*

| | |
|---|---|
| • Cardiac event | 15.1% |
| • MI | 5.2% |
| • Respiratory failure | 8.4% |
| • Renal failure | 6.0% |
| • Stroke | 0.6% |
| • Ischemic colitis | 0.6% |
| • Prolonged ileus | 11.0% |
| • Limb ischemia | 3.5% |
| • Amputation | 1.2% |
| • Graft infection | 0.6% |

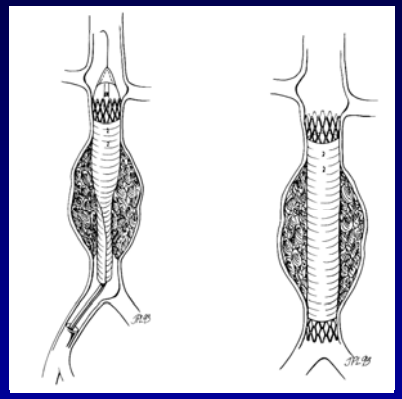
# Endoluminal Stent Grafting

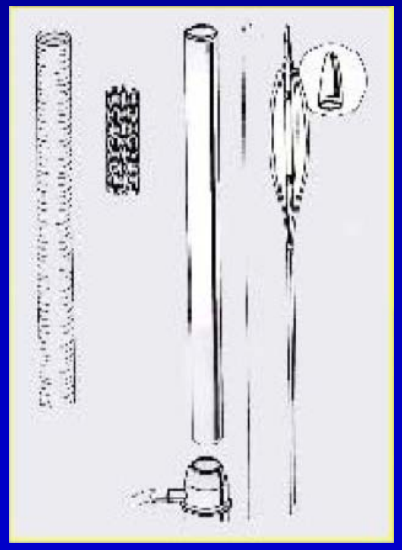
*Juan Carlos Parodi MD*

*"I foresee the day when patients with aneurysms will be treated under local anesthesia in the outpatient department"*
*--1978*



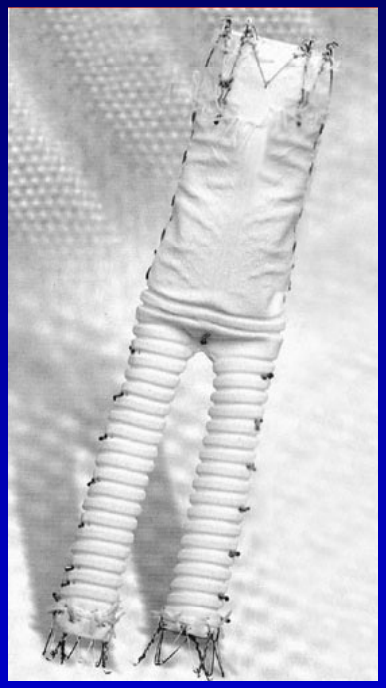
# First AAA Endograft Implant 1990



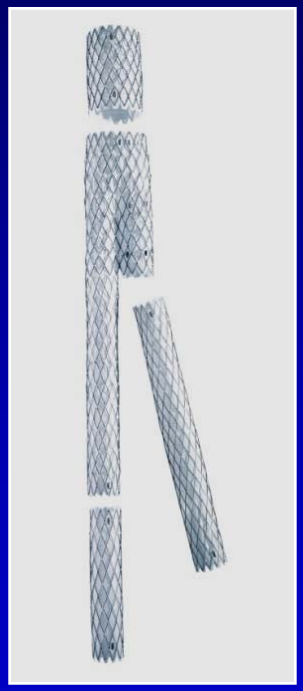


*Parodi JC, Palmaz JC and Barone HD Ann Vasc Surg 1991; 5: 491-499*

# FDA Approved EVAR Devices

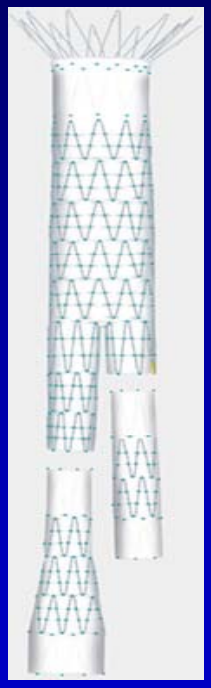


Ancure



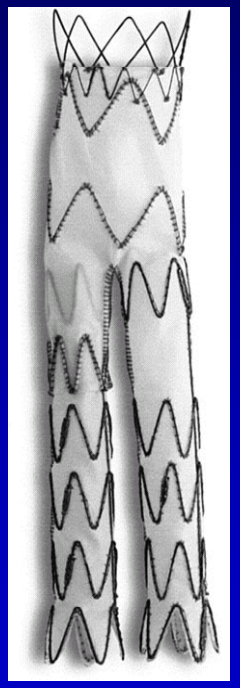
AneuRx

Excluder



Zenith

Endologix

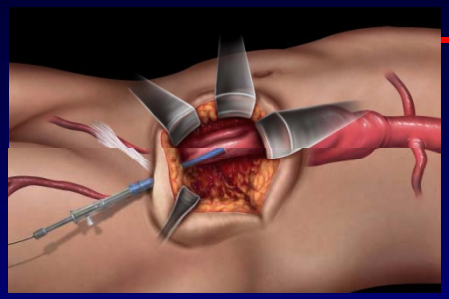


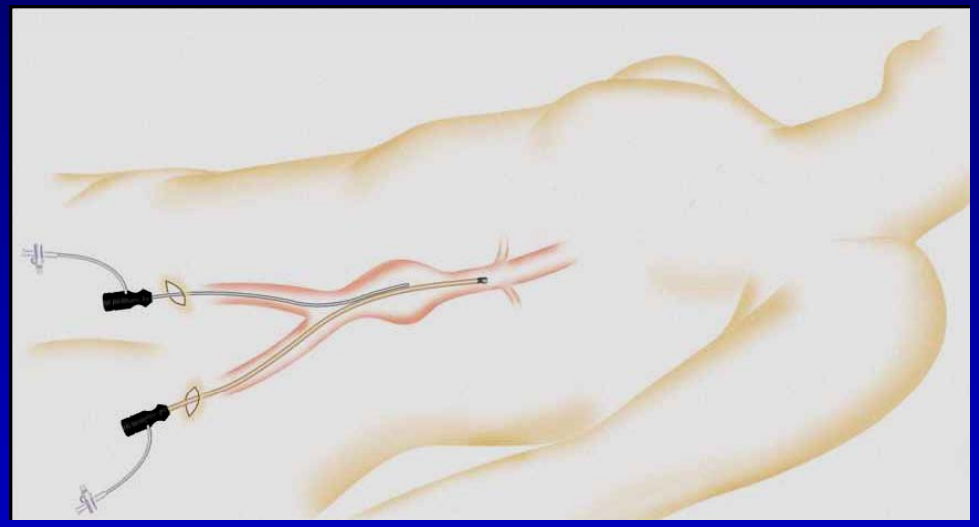
Talent

# EVAR - Profile and Anatomic Coverage of Current Devices

| | *Medtronic AneuRx* | *Medtronic Talent* | *Gore Excluder* | *Cook Zenith* | *Endologix Powerlink* |
|---|---|---|---|---|---|
| |  |  |  |  |  |
| *Profile (O.D.)* | *21/22Fr* | *22/23Fr* | *20/21Fr* | *21/24Fr* | *20/22Fr* |
| *Anatomic Coverage* | *≈50%* | *≈75%* | *≈60%* | *≈75%* | *≈40%* |

# *Endograft Implantation Technique*





Establish Vascular Access

# Aortic Endografts
# Current Limitations

- Proximal neck diameters
  - 18-32 mm (Talent—34 mm, Zenith—36 mm)
- Proximal neck lengths (supra and infra renal attachment)
  - 5-15 mm
- Iliac artery size for delivery
  - 6-9 mm
- Iliac artery attachment site diameter
  - 8-20 mm diameter
- Angle of neck to aneurysm <60°

# Complications of Endovascular AAA repair

- Endoleak: proximal
- distal
- AAA sac branches
- graft, hook, component
- Iliac and aortic dissection and rupture
- Migration
- Endograft limb thrombosis and modular component seperation
- Pelvic and lower extremity ischemia (microembolication)

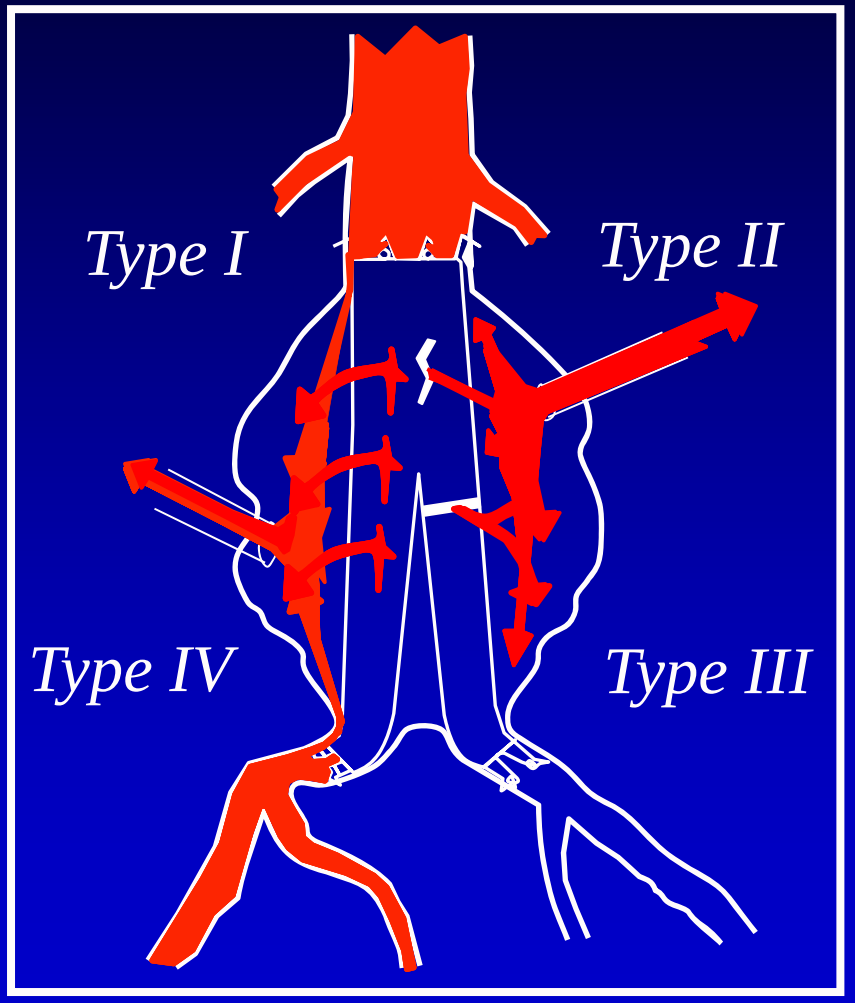
# Endoleak Classifications

Type I: Attachment seal failure

Type II: Collateral Branch Flow

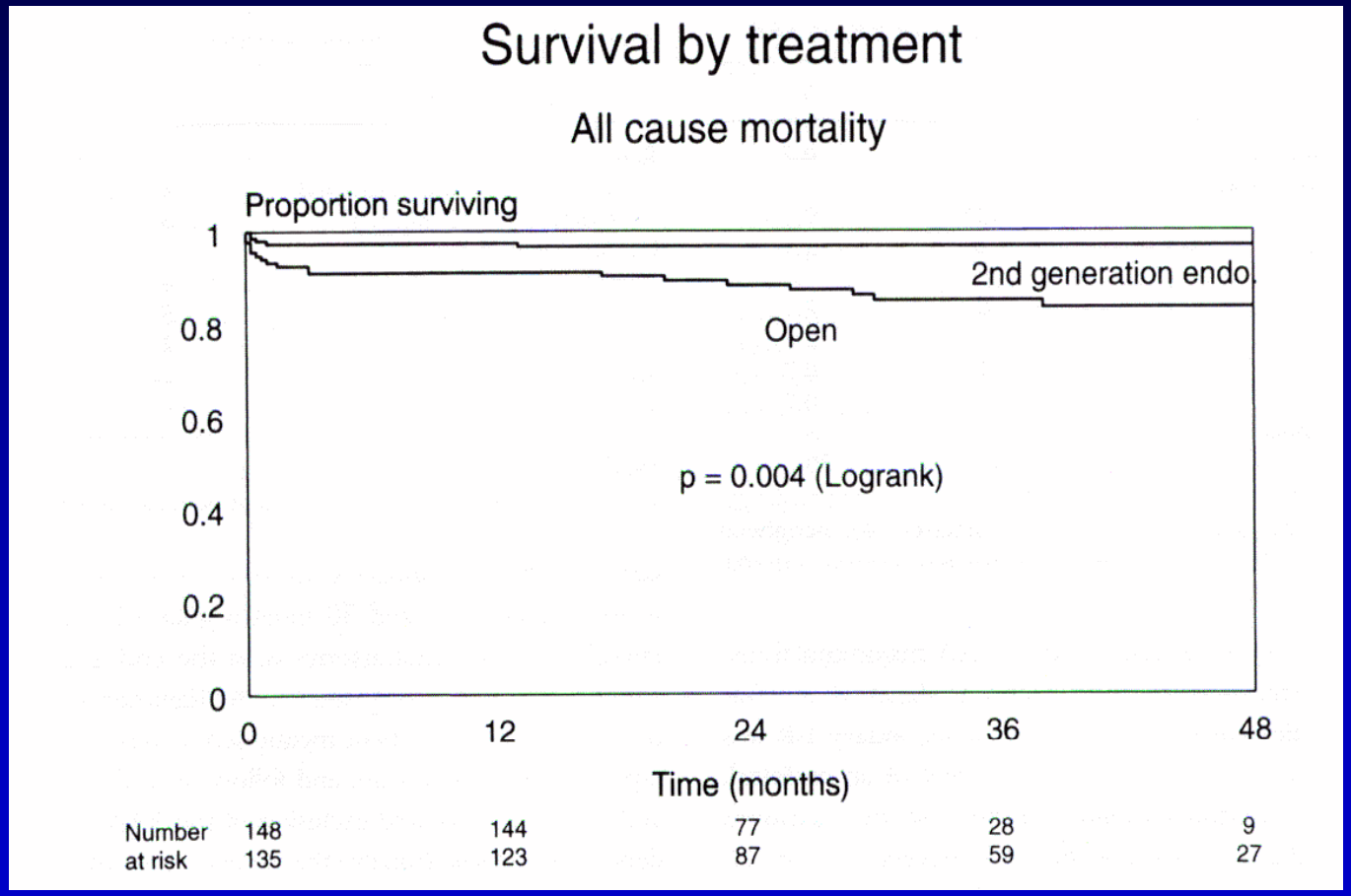
Type III: Fabric defect or modular disconnect

Type IV: Fabric porosity



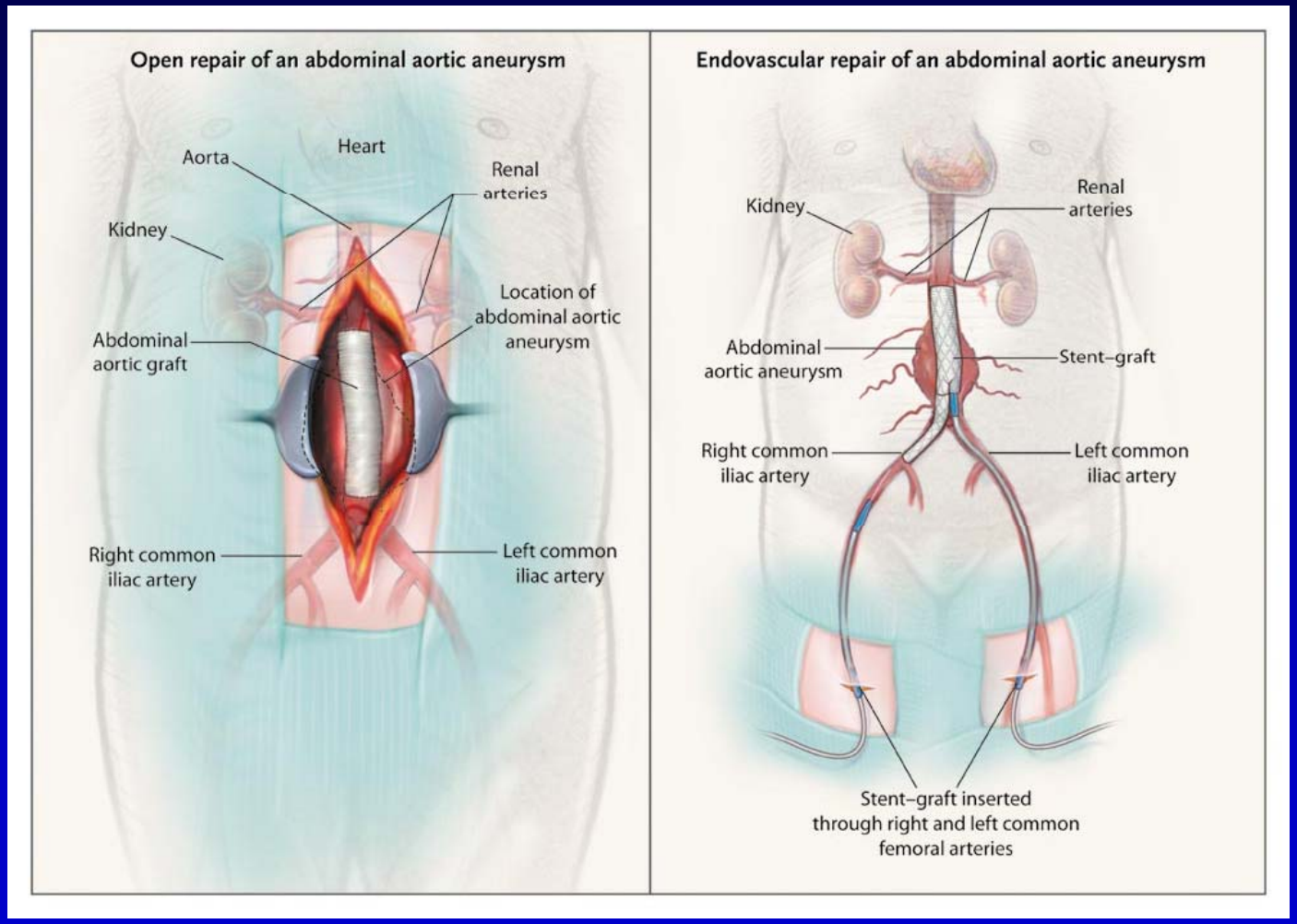

*White G et al J Endovas Surg 1998; 5: 305-309*

# Long Term Outcomes from AAA Repair




*May et al, JVS 2001; 33: s21-s26*

# *Open Versus Endovascular Repair of Infrarenal Abdominal Aortic Aneurysms*




# *EVAR Trial 1*

*National Health Service*
*Research & Development*
*Health Technology Assessment Programme*

*Greenhalgh RM et al Lancet 2005; 365: 2179-2186*

# EVAR-1 Trial

*Equipoise for patients fit for open repair*

*1082 randomisations to Dec 2003*

*Open repair*
*n=539*

*Endovascular repair*
*n=543*

*Endpoints :*

- *all-cause and aneurysm-related mortality*
- *30-day post operative mortality*

*Greenhalgh RM et al Lancet 2005; 365: 2179-2186*

# EVAR 1 - Endografts

- 272 (51%) Zenith
- 177 (33%) Talent
- 35 (7%) Excluder
- 19 (4%) Aneurx
- 15 (3%) others

*Second generation devices*

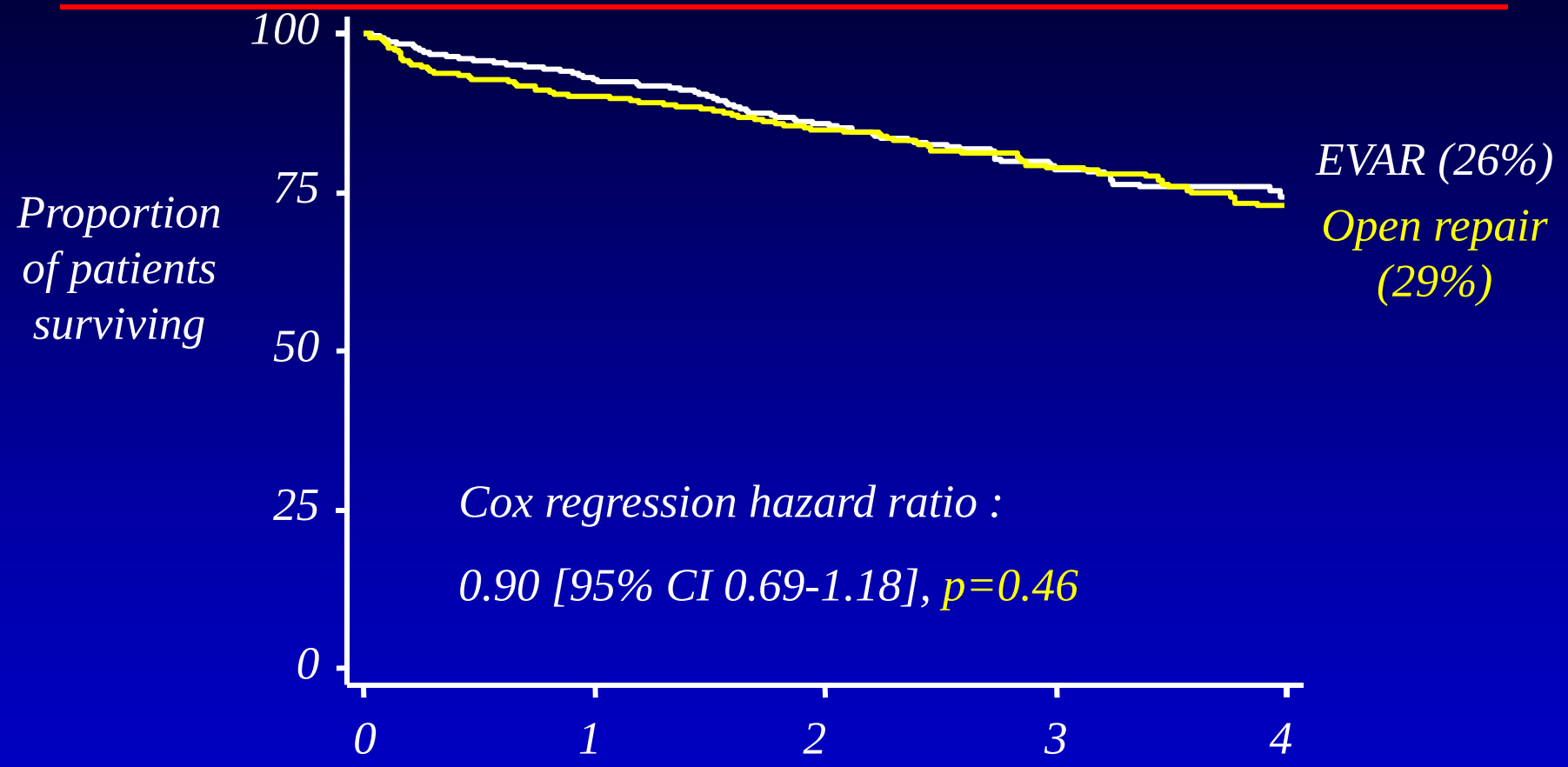
*Greenhalgh RM et al Lancet 2005; 365: 2179-2186*

# Operative Mortality

| | EVAR | Open repair | Crude hazard ratio [95% CI] (p-value) |
|---|---|---|---|
| 30-day mortality | 9/532 (1.7%) | 25/518 (4.8%) | 0.35 [0.16-0.77] p=0.009 |
| In-hospital mortality | 10/532 (1.9%) | 33/518 (6.4%) | 0.32 [0.16-0.64] p=0.001 |

Greenhalgh RM et al Lancet 2005; 365: 2179-2186

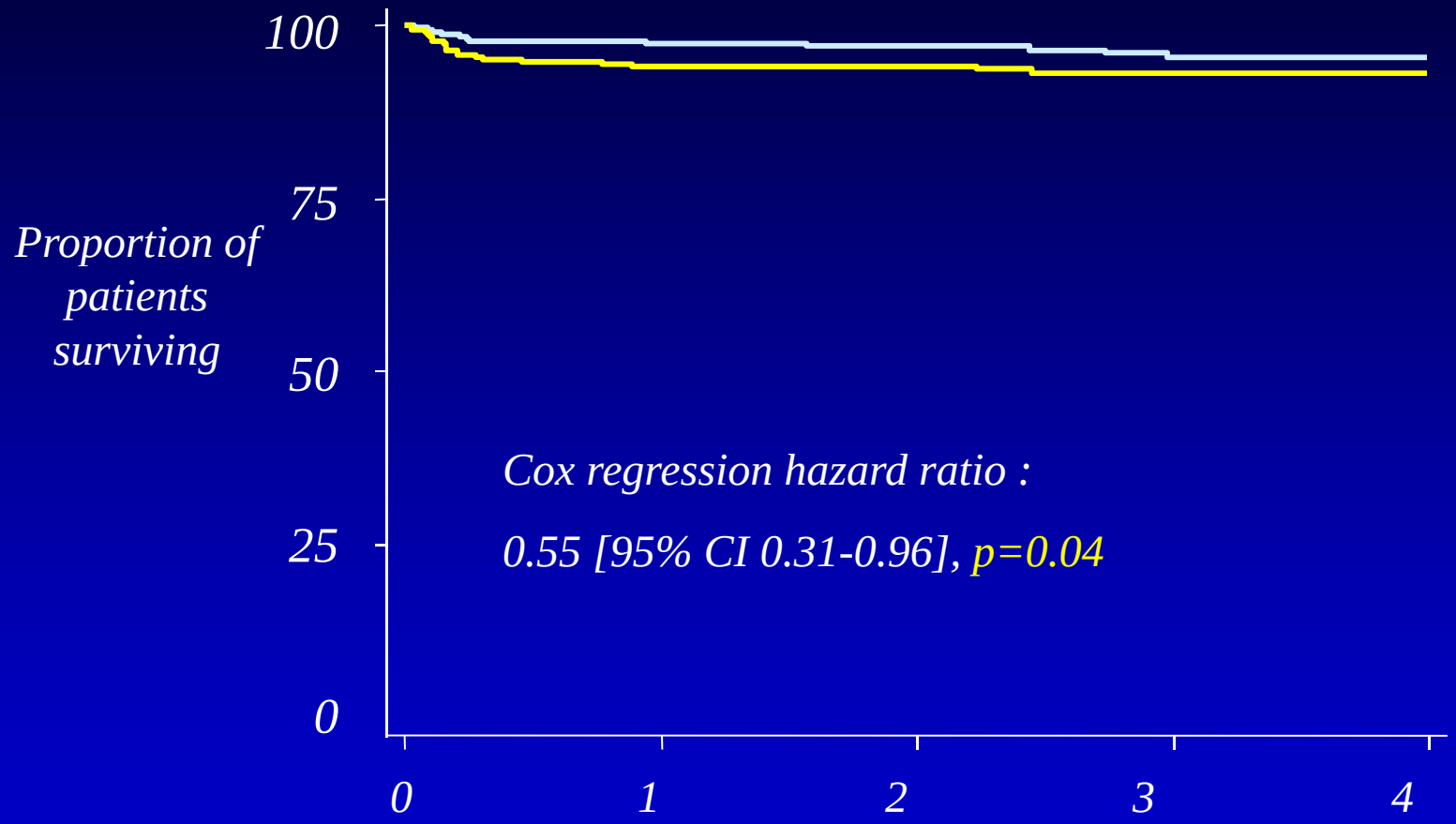
# All-cause Mortality




| Number at risk | | | | | |
|---|---|---|---|---|---|
| Open repair | 539 | 484 | 314 | 195 | 88 |
| EVAR | 543 | 503 | 316 | 187 | 94 |

Greenhalgh RM et al Lancet 2005; 365: 2179-2186

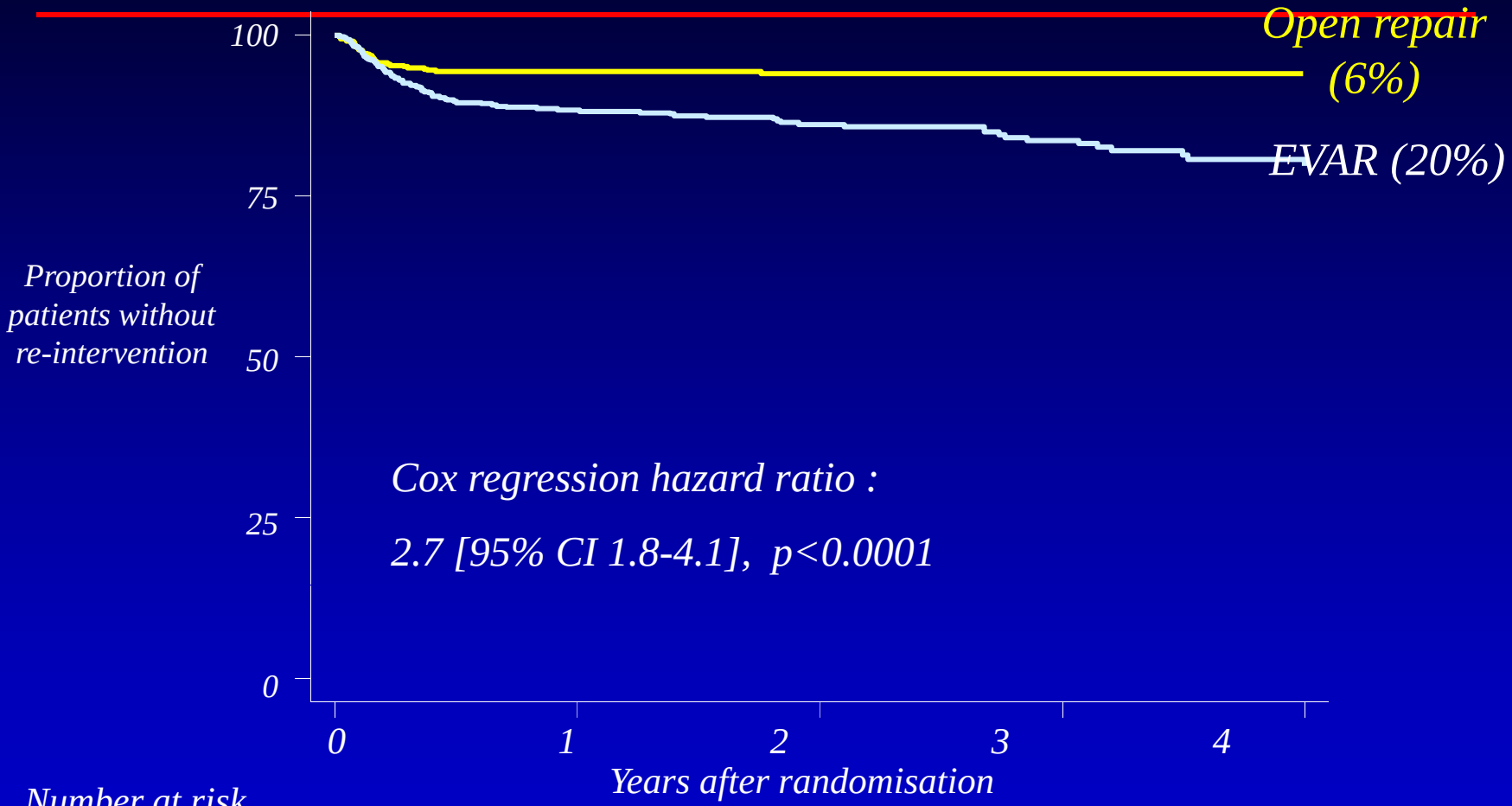
# Aneurysm-related Mortality




| Number at risk | | | | | |
|---|---|---|---|---|---|
| Open repair | 539 | 484 | 314 | 195 | 88 |
| EVAR | 543 | 503 | 316 | 187 | 94 |

Greenhalgh RM et al Lancet 2005; 365: 2179-2186

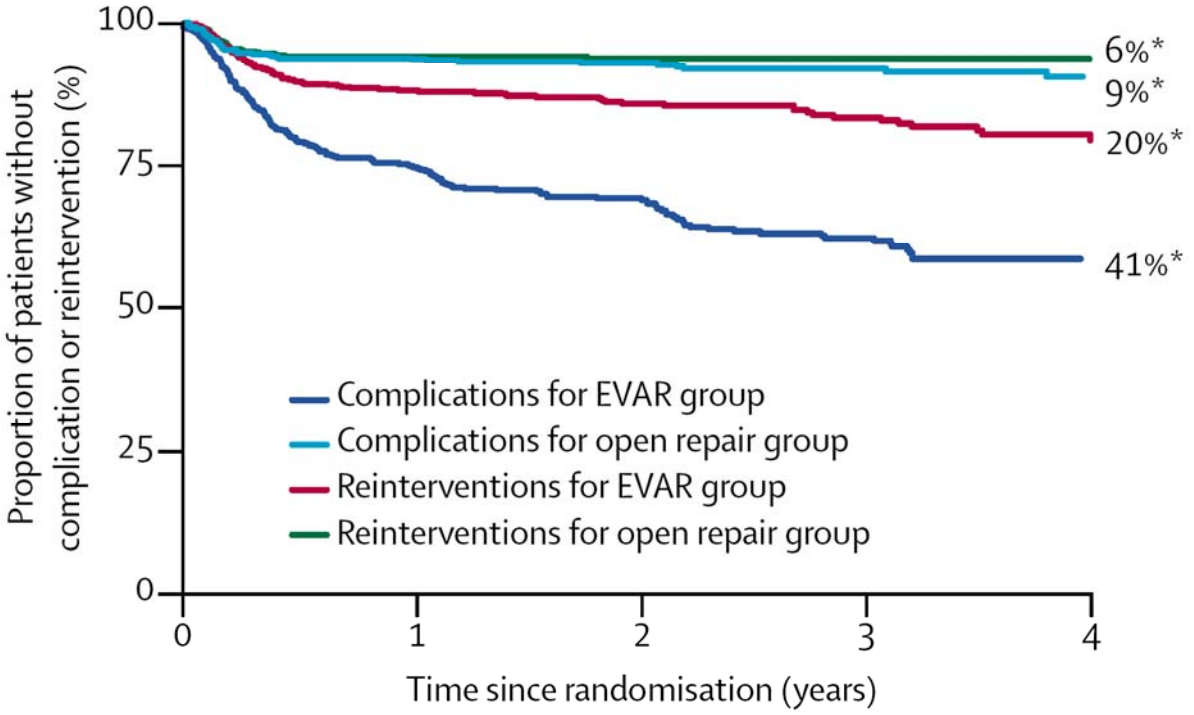
# Time to First Re-intervention




| Number at risk | | | | | |
|---|---|---|---|---|---|
| Open repair | 539 | 468 | 304 | 189 | 88 |
| EVAR | 543 | 450 | 278 | 168 | 80 |

Greenhalgh RM et al Lancet 2005; 365: 2179-2186

# EVAR-1 Trial




**Number at risk for complications**

| | | | | | |
|---|---|---|---|---|---|
| Open repair | 539 | 466 | 301 | 182 | 82 |
| EVAR | 543 | 386 | 235 | 134 | 67 |

**Number at risk for reinterventions**

| | | | | | |
|---|---|---|---|---|---|
| No intervention | 539 | 468 | 304 | 189 | 88 |
| EVAR | 543 | 450 | 278 | 168 | 80 |

*Greenhalgh RM et al Lancet 2005; 365: 2179-2186*

# *Cost-Benefit Analysis*

*Cost Differential $6,344 at 4 years*

| | EVAR (n=543) | Open repair (n=539) | Mean difference | SE of difference |
|---|---|---|---|---|
| **Primary hospital admission** | | | | |
| Main procedure | 7569 | 2811 | 4757 | 108 |
| Hospital stay | 3015 | 6304 | −3290 | 568 |
| Other | 235 | 89 | 146 | 34 |
| Total | 10 819 | 9204 | 1613 | 607 |
| **Secondary procedures, adverse events, scans** | | | | |
| Secondary AAA procedures | 1056 | 200 | 856 | 227 |
| Other adverse events | 294 | 359 | −65 | 169 |
| Outpatients/CT scan/ultrasound scan* | 1089 | 182 | 907 | 37 |
| Total | 2439 | 741 | 1698 | 631 |
| Total cost including 4-year follow up | 13 258 | 9945 | 3313 | 690 |

*Average number of outpatient follow-up appointments, CT and ultrasound scans estimated from a survey of trial centres.

***Table 6:* Estimated costs (UK£) over 4 years follow-up based on intention to treat**

*Greenhalgh RM et al Lancet 2005; 365: 2179-2186*

# DREAM Randomized Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

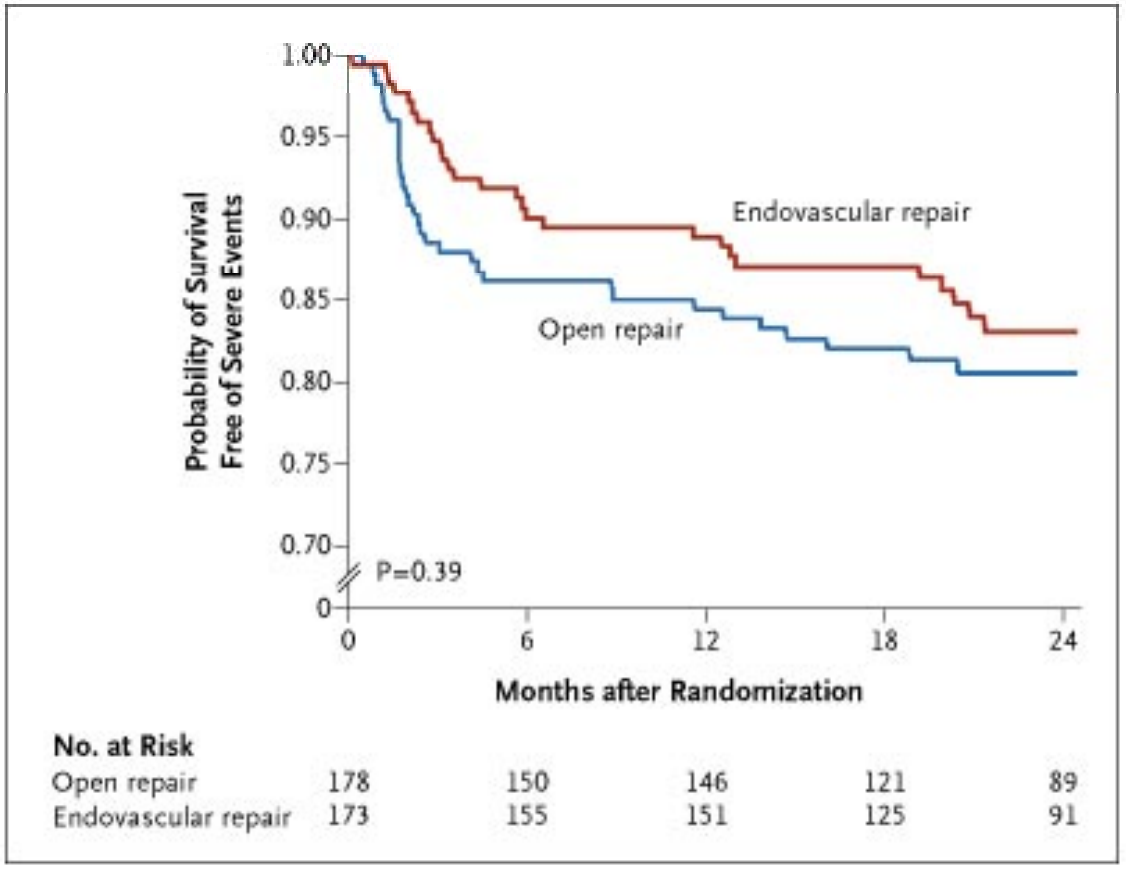
## Two-Year Outcomes after Conventional or Endovascular Repair of Abdominal Aortic Aneurysms

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*

*Blankensteijn, J. et al. N Engl J Med 2005; 352:2398-2405*

# *DREAM Randomized Trial*

*Kaplan-Meier Estimates of Event Free Survival among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair*




*Blankensteijn, J. et al. N Engl J Med 2005; 352:2398-2405*

# *DREAM Randomized Trial*

*Causes of Death after Open and Endovascular Repair of Abdominal Aortic Aneurysm*

**Table 2. Causes of Death after Open and Endovascular Repair of Abdominal Aortic Aneurysm.**

| Cause of Death | Before Surgery* | | In the Hospital† | | After Discharge | | Overall | |
|---|---|---|---|---|---|---|---|---|
| | Open Repair (N=178) | Endovascular Repair (N=173) | Open Repair (N=174) | Endovascular Repair (N=171) | Open Repair (N=166) | Endovascular Repair (N=169) | Open Repair (N=178) | Endovascular Repair (N=173) |
| | *number of patients* | | | | | | | |
| All causes | 1 | 1 | 8 | 2 | 9 | 17 | 18 | 20 |
| Cardiovascular causes | 0 | 0 | 2 | 1 | 3 | 6 | 5 | 7 |
| Myocardial infarction | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 2 |
| Cardiac arrest | 0 | 0 | 1 | 0 | 2 | 2 | 3 | 2 |
| Congestive heart failure | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 2 |
| Stroke | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| Aneurysm-related, noncardiovascular causes | 1 | 0 | 6‡ | 1§ | 1¶ | 1‖ | 8 | 2 |
| Cancer | 0 | 0 | 0 | 0 | 2 | 4 | 2 | 4 |
| Other | 0 | 1 | 0 | 0 | 1** | 4†† | 1 | 5 |
| Unknown | 0 | 0 | 0 | 0 | 2‡‡ | 2§§ | 2 | 2 |

* Two patients died before undergoing the assigned operation: one patient with preexistent pulmonary fibrosis assigned to undergo endovascular repair died from pneumonia 84 days after randomization, and one patient assigned to undergo open repair died from a ruptured abdominal aortic aneurysm.

† In-hospital data were reported previously.[2] All 10 in-hospital deaths were aneurysm-related by definition. None of the nine deaths from cardiovascular causes after discharge were aneurysm-related.

‡ The causes of death were as follows: infection of the prosthesis, anastomotic bleeding, ischemic bowel, intraoperative anaphylactic shock, multiorgan failure after repair of a burst abdomen, and progressive dementia and refusal to eat or drink leading to respiratory insufficiency and death.

§ The cause of death was bilateral pneumonia.

¶ The cause of death was peritonitis resulting from an iatrogenic bowel lesion during repeated operation to correct prosthetic malalignment.

‖ The cause of death was an infected endograft.

** The cause of death was pneumonia.

†† The causes of death were as follows: peritonitis, pulmonary embolism, respiratory insufficiency, and general deterioration related to old age.

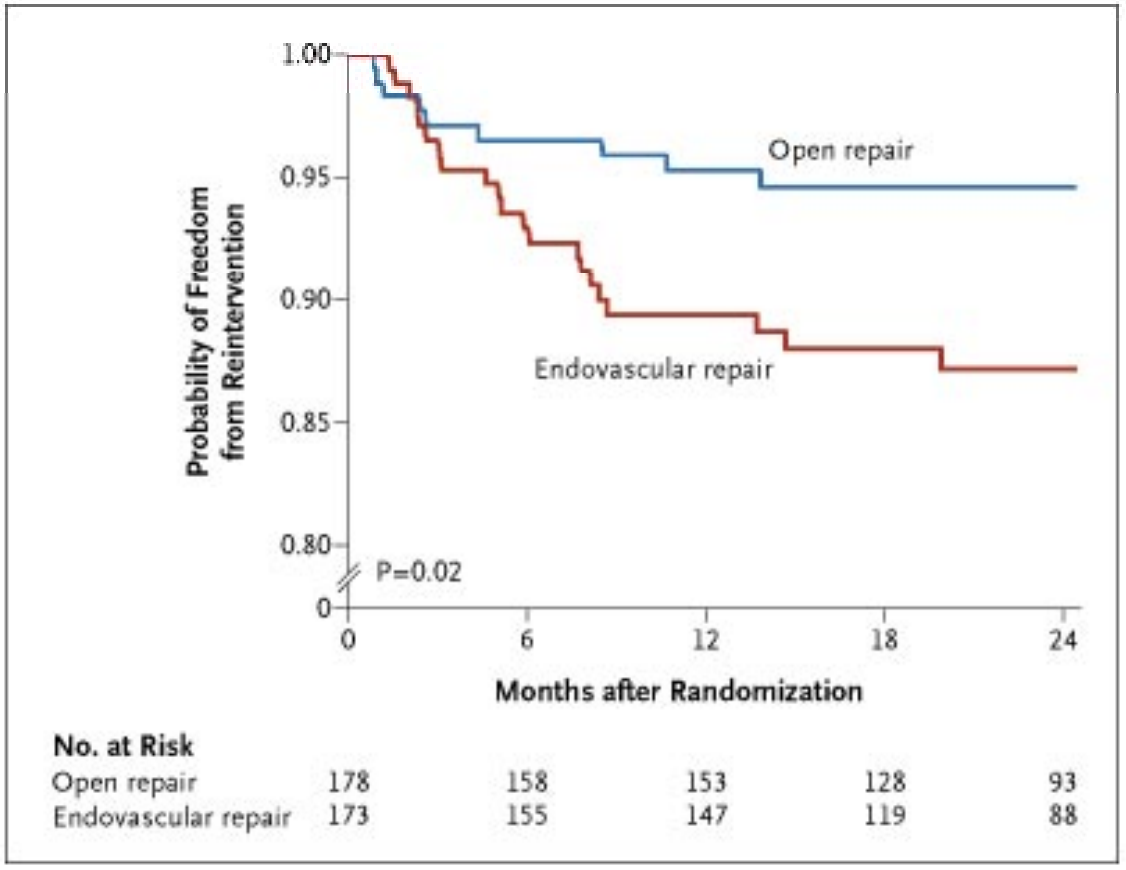
‡‡ No data were available on the cause of death.

§§ Both patients died suddenly, 33 and 41 months after the procedure. A ruptured aneurysm was considered a possible cause of death, but in neither patient was a postmortem examination performed. Both patients had evidence of a shrinking aneurysm sac on their last (24-month) follow-up computed tomographic scan.

*Blankensteijn, J. et al. N Engl J Med 2005; 352:2398-2405*

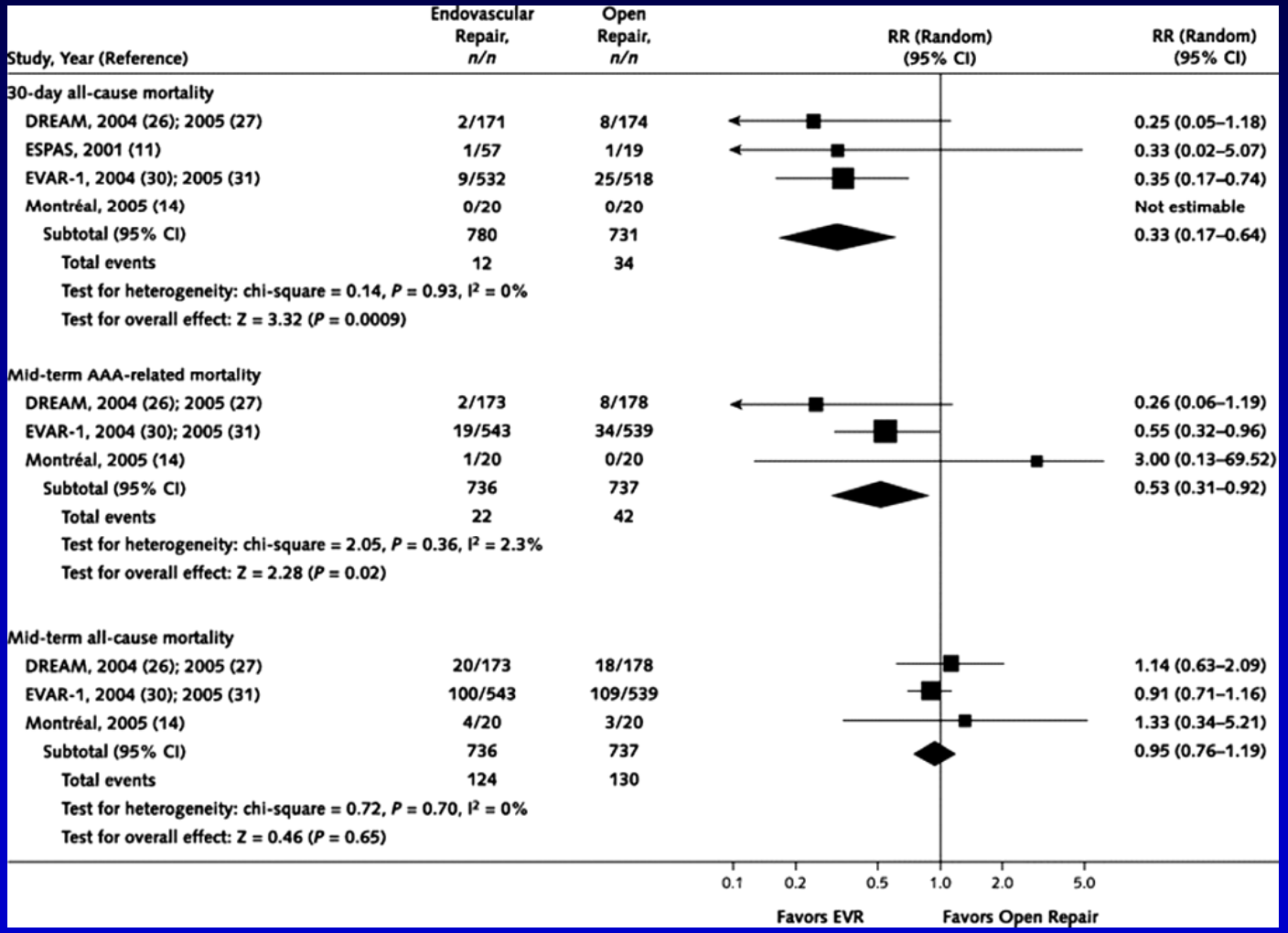
# *DREAM Randomized Trial*

*Kaplan-Meier Estimates of Freedom from Reintervention among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair*




*Blankensteijn, J. et al. N Engl J Med 2005; 352:2398-2405*

# *Randomized Trials Comparing Endovascular Repair with Open Repair*

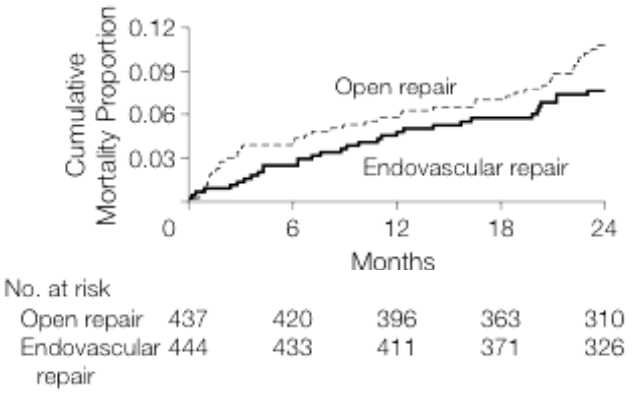



*Lederle, F. A. et. al. Ann Intern Med 2007;146:735-741*

# *OVER Randomized Trial*

*Outcomes after Open and Endovascular Repair of Abdominal Aortic Aneurysms*

**Figure 2.** Kaplan-Meier Curve of Cumulative Probabilities of Death From Time of Randomization




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 $P = .13$).

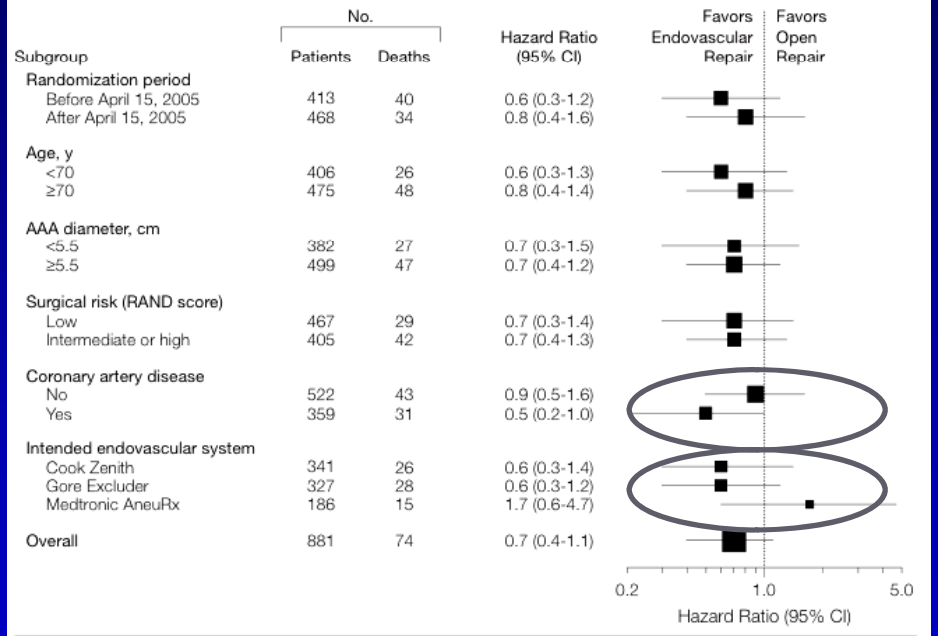
| Outcomes | No. (%) of Patients: Endovascular Repair (n = 444) | No. (%) of Patients: Open Repair (n = 437) | *P* Value |
|---|---|---|---|
| All-cause mortality | 31 (7.0) | 43 (9.8) | .13 |
| Before AAA repair | 2 (0.5) | 1 (0.2) | >.99 |
| Within 30 d after repair | 1 (0.2) | 10 (2.3) | .006 |
| Within 30 d after repair or during hospitalization | 2 (0.5) | 13 (3.0) | .004 |
| AAA diameter <5.5 cm | 1 (0.5) | 5 (2.6) | .10 |
| AAA diameter ≥5.5 cm | 1 (0.4) | 8 (3.2) | .02 |
| After 30 d or hospitalization | 27 (6.1) | 29 (6.6) | .74 |
| Cause of death | (n = 31) | (n = 43) | |
| AAA-related[a] | 6 (1.4) | 13 (3.0) | .10 |
| Cardiovascular | 9 (2.0) | 4 (0.9) | .26 |
| Cancer | 10 (2.3) | 15 (3.4) | >.99 |
| Other[b] | 5 (1.1) | 7 (1.6) | .54 |
| Unknown | 1 (0.2) | 4 (0.9) | .21 |

*Lederle FA et al JAMA 2009: 302(14):1535-1542*

# *OVER Randomized Trial*

*Outcomes after Open and Endovascular Repair of Abdominal Aortic Aneurysms*

**Figure 3.** Hazard Ratios for Death According to Baseline Characteristics




AAA indicates abdominal aortic aneurysm; CI, confidence interval. Size of the data markers is relative to the number of deaths in that subgroup. All $P > .10$ for interaction with treatment effect. For surgical risk (RAND score), see online eAppendix at http://www.jama.com.[5]

*Lederle FA et al JAMA 2009: 302(14):1535-1542*

# *Perioperative Outcomes after Endovascular Repair or Open Repair*

*CMS Database*

Table 2. Perioperative Outcomes after Endovascular Repair or Open Repair.*

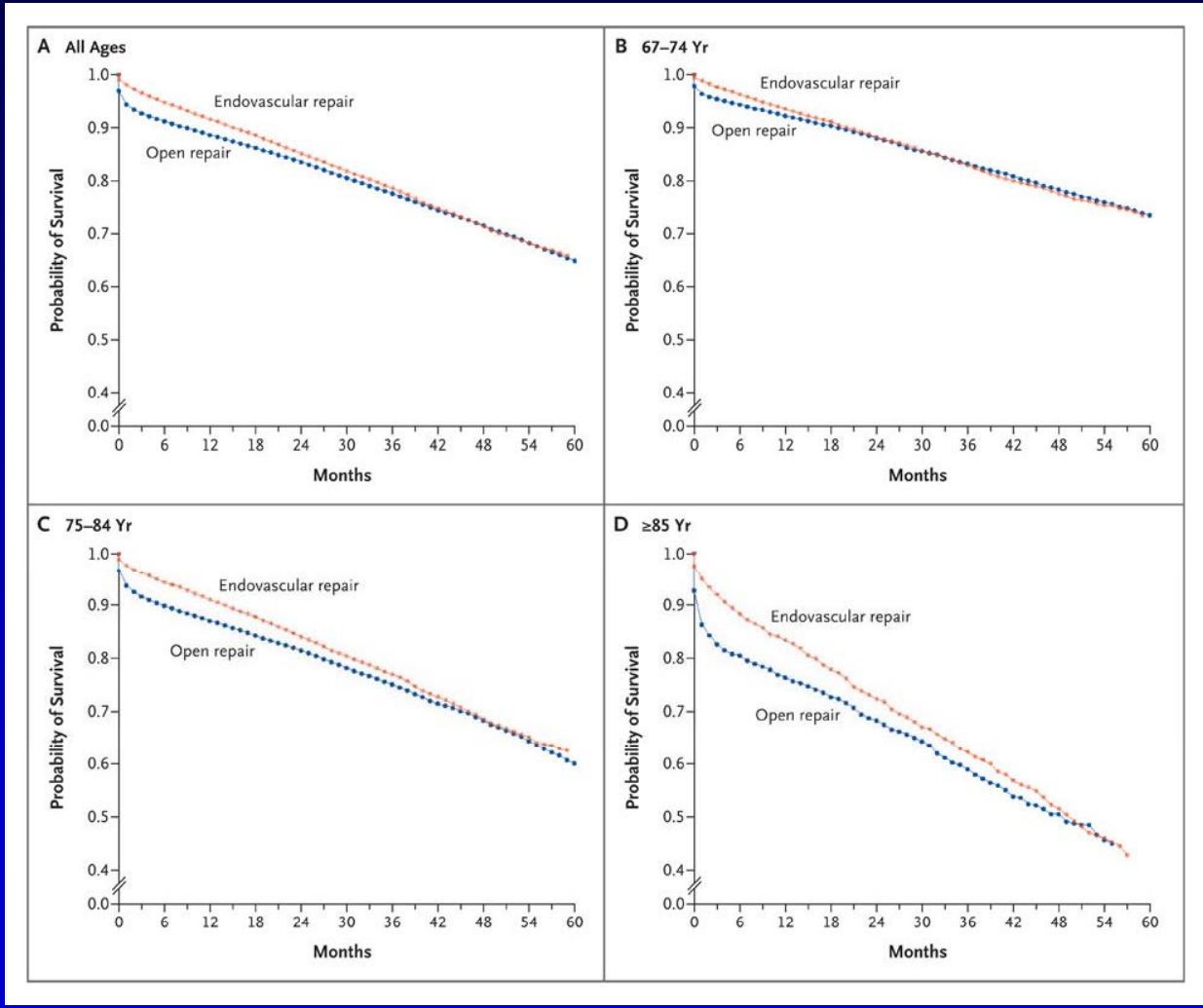
| Perioperative Outcome | Endovascular Repair (N=22,830) | Open Repair (N=22,830) | P Value | Relative Risk Associated with Open Repair (95% CI) |
|---|---|---|---|---|
| Death (% of patients) | | | | |
| All ages | 1.2 | 4.8 | <0.001 | 4.00 (3.51–4.56) |
| 67–69 yr | 0.4 | 2.5 | <0.001 | 6.21 (4.98–7.73) |
| 70–74 yr | 0.8 | 3.3 | <0.001 | 4.12 (3.51–4.84) |
| 75–79 yr | 1.3 | 4.8 | <0.001 | 3.69 (3.25–4.19) |
| 80–84 yr | 1.6 | 7.2 | <0.001 | 4.49 (4.02–5.02) |
| ≥85 yr | 2.7 | 11.2 | <0.001 | 4.14 (3.80–4.52) |
| Medical complications (% of patients) | | | | |
| Myocardial infarction | 7.0 | 9.4 | <0.001 | 1.34 (1.26–1.42) |
| Pneumonia | 9.3 | 17.4 | <0.001 | 1.89 (1.79–1.98) |
| Acute renal failure | 5.5 | 10.9 | <0.001 | 2.00 (1.87–2.14) |
| Renal failure requiring dialysis | 0.4 | 0.5 | 0.047 | 1.33 (1.00–1.75) |
| Deep-vein thrombosis or pulmonary embolism | 1.1 | 1.7 | <0.001 | 1.51 (1.29–1.76) |
| Surgical complications (% of patients) | | | | |
| Conversion to open repair | 1.6 | | | |
| Acute mesenteric ischemia | 1.0 | 2.1 | <0.001 | 2.19 (1.87–2.56) |
| Reintervention for bleeding | 0.8 | 1.2 | <0.001 | 1.50 (1.24–1.80) |
| Tracheostomy | 0.2 | 1.5 | <0.001 | 7.46 (5.48–10.14) |
| Thrombectomy | 0.4 | 0.2 | <0.001 | 0.50 (0.35–0.71) |
| Embolectomy | 1.3 | 1.7 | <0.001 | 1.29 (1.11–1.50) |
| Repair of infected graft or graft–enteric fistula | 0.01 | 0.09 | <0.001 | 7.00 (2.09–23.46) |
| Major amputation | 0.04 | 0.13 | 0.002 | 3.00 (1.47–6.14) |
| Complications related to laparotomy | | | | |
| Lysis of adhesions without resection | 0.1 | 1.2 | <0.001 | 13.05 (8.37–20.33) |
| Bowel resection | 0.6 | 1.3 | <0.001 | 2.17 (1.77–2.65) |
| Ileus or bowel obstruction without resection or lysis of adhesions | 5.1 | 16.7 | <0.001 | 3.25 (3.05–3.46) |
| Mean length of hospital stay (no. of days) | 3.4±4.7 | 9.3±8.1 | <0.001 | |
| Discharged home (% of survivors) | | | | |
| All ages | 94.5 | 81.6 | <0.001 | 0.87 (0.87–0.88) |
| 67–69 yr | 97.8 | 92.6 | <0.001 | 0.95 (0.95–0.95) |
| 70–74 yr | 96.8 | 88.7 | <0.001 | 0.92 (0.91–0.92) |
| 75–79 yr | 94.4 | 80.4 | <0.001 | 0.85 (0.84–0.86) |
| 80–84 yr | 90.6 | 67.7 | <0.001 | 0.75 (0.74–0.75) |
| ≥85 yr | 84.6 | 57.1 | <0.001 | 0.67 (0.66–0.68) |

* Plus–minus values are means ±SD.

*Death 1.2% vs. 4.8%*

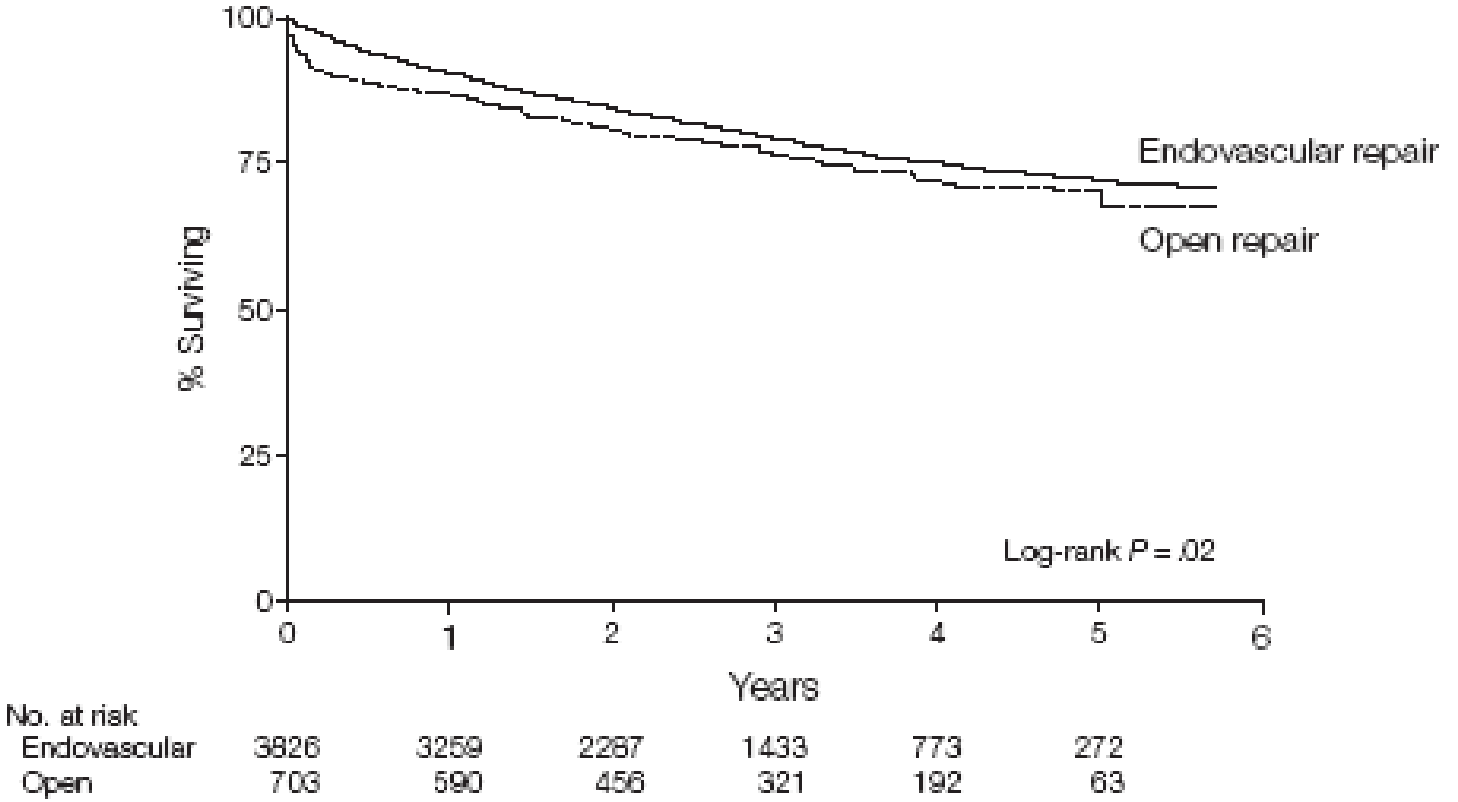
*Schermerhorn M et al. N Engl J Med 2008; 358: 464-474*

# *Survival with Endovascular Repair vs. Open Repair of Abdominal Aortic Aneurysms*




*Schermerhorn M et al. N Engl J Med 2008; 358: 464-474*

**Figure 2.** Survival After Open vs Endovascular Repair of Abdominal Aortic Aneurysm




| No. at risk | | | | | | |
|---|---|---|---|---|---|---|
| Endovascular | 3826 | 3259 | 2267 | 1433 | 773 | 272 |
| Open | 703 | 590 | 456 | 321 | 192 | 63 |

Median follow-up time was 2.8 years (interquartile range, 2.7 years) for open repair and 2.4 years (interquartile range, 1.3 years) for endovascular repair.

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# Conclusions

- Endograft therapy for AAA is here to stay
- Advancing technology will resolve problems:
  - Access
  - Attachment reliability
  - Endograft durability
  - Endoleak repair
  - Endograft accommodation to complex anatomy and changing morphology
  - Imaging reliability
- Percent of patients untreatable by this approach may approach zero in the future