EVAR current indications and devices

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Abbott, Medtronic
• Consulting (non-compensated)	• Medtronic, Boston Scientific, Abbott, Phillips
• Major Stock Shareholder/Equity	• Primacea, TissueGen, Orchestra, R3 Vascular, Transit Medical, Syntervention, Cagent
• Royalty Income	• None
• Ownership/Founder	• Innovation Vascular Partners
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

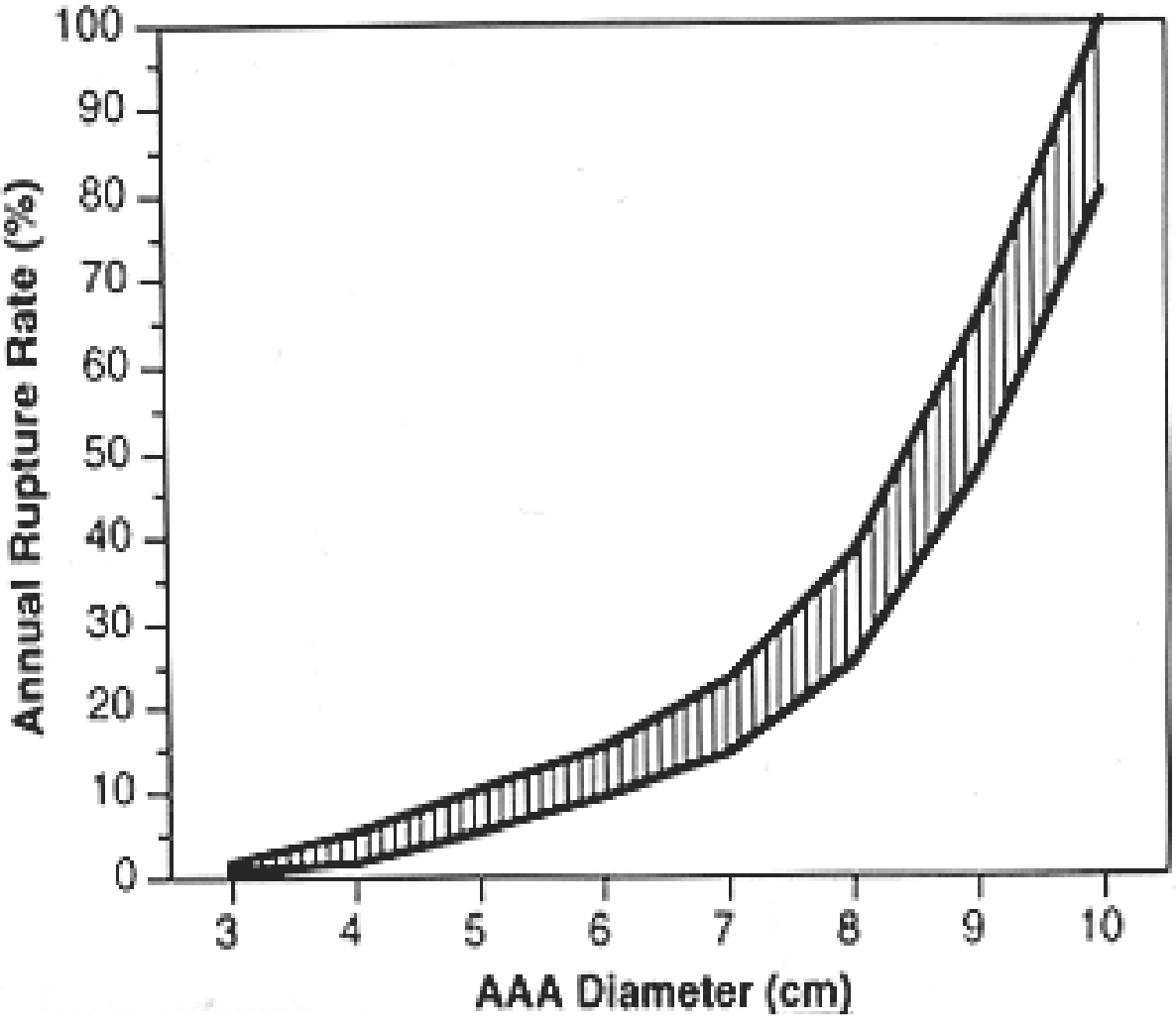
Presentation of AAA

- 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)

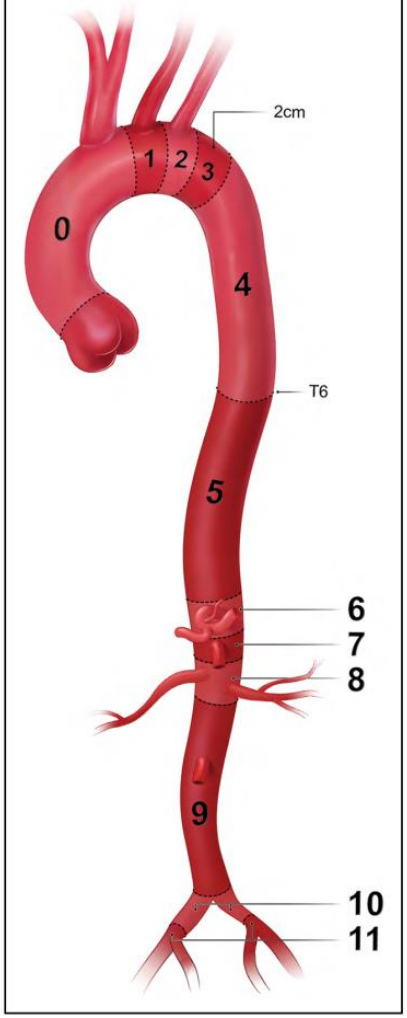
Initial diameter (mm)	*Second measurement (mm)*	*Time after initial screen (years)*				
		1	*2*	*3*	*4*	*5*
30	*No measurement*	*0-2*	*0-4*	*0-7*	*1-1*	*1-7*
	30	*0-2*	*0-4*	*0-6*	*0-9*	*1-3*
	35	*0-3*	*0-7*	*1-1*	*1-6*	*2-4*
	40	*0-4*	*0-8*	*1-4*	*2-4*	*4-0*
40	*No measurement*	*0-8*	*1-7*	*3-0*	*4-8*	*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)

- *Zone 6-7 require assessment and treatment with chimney or fenestration*
- *Zone 9 location of fabric standard EVAR*
- *Zone10 and 11 become important regarding anchoring and exclusion of endoleaks*

AHA 2022 guidelines



3. Classification of Aortic Anatomic Segments by 11 g Zones.
(involves the ascending to distal end of the origin of the ate artery); Zone 1 (involves the origin of the left common between the innominate and the left carotid); Zone 2 (involves in of the left subclavian; between the left carotid and the clavian); Zone 3 (involves the proximal descending thoracic own to the T4 vertebral body; the first 2 cm distal to the left ian); Zone 4 (the end of zone 3 to the mid-descending aorta – ne 5 (the mid-descending aorta to the celiac); Zone 6 (involves in of the celiac; the celiac to the superior mesenteric); Zone ves the origin of the superior mesenteric artery; the superior

Figure 19. Algorithm for Identifying Patients to Screen for Abdominal Aortic Aneurysm.
Colors correspond to Class of Recommendations in Table 2. AAA indicates abdominal aortic aneurysm.

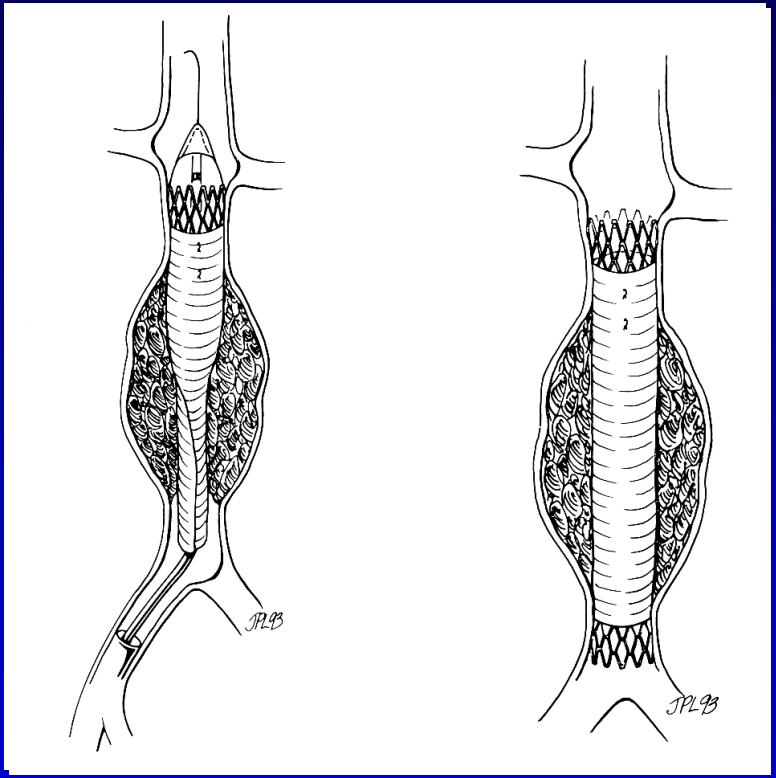
Medical therapy

- HTN
  - Target <130/80
  - Class 1 LOE B
- HLP
  - Target LDL under 70
  - Moderate/high dose statin
  - Class 1 LOE B
- Tobacco cessation
  - Class 1 LOE C
- Anti platelelet
  - ASA
  - Class 2b LOE C

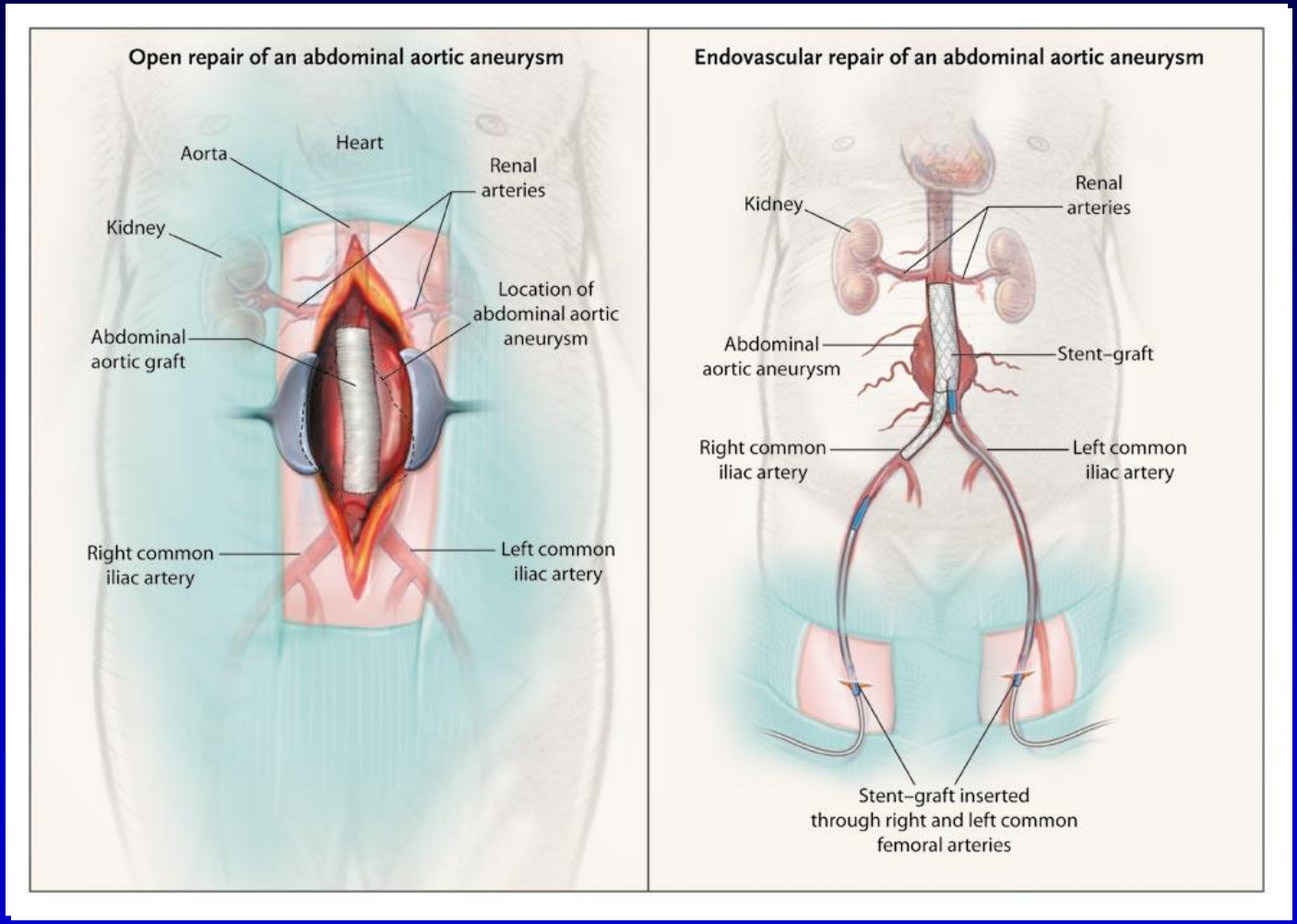
Endoluminal Stent Grafting

Juan Carlos Parodi MD

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



Open Versus Endovascular Repair of Infrarenal Abdominal Aortic Aneurysms



Characteristics of abdominal endovascular devices

Endograft	Materials graft/support	Suprarenal fixation	Active proximal fixation/hooks	Native aortic neck diameter (range in mm)	Native iliac diameter (range in mm)	Maximum bifurcated main body device/introducer sheath diameter (French, OD)	Potential advantages
AFX2 (Endologix)	PTFE/cobalt chromium alloy	Yes	No	18 to 32	10 to 23	17	Anatomic fixation at bifurcation, low profile
Alto (Endologix)	PTFE/nitinol*	Yes	Yes¶	16 to 30	8 to 25	15	Low profile, short aortic neck (7 mm below the lowest renal artery), short iliac seal zone (10 mm)
Aorfix (Lombard)	PTFE/nitinol	No	Yes	19 to 29	8 to 19	22	Flexibility, angulated neck
Endurant (Medtronic)	Polyester/electropolished nitinol	Yes	Yes	19 to 32	8 to 25	20	Indications include short (10 mm) aortic neck, angulated neck
Excluder (Gore)	PTFE/nitinol	No	Yes	19 to 32	10 to 18.5	20	C3 delivery system, ability to recapture and reposition body, delivery sheath with hemostatic seal
Incraft (Cordis; investigational device in the United States)	Polyester/nitinol	Yes	No	27 to 31	10 to 24	16	Ultra low profile
Terumo aortic	Polyester/nitinol	Yes	Yes (dual)Δ	17 to 32	8 to 20	19	Minimize modular disconnection; Detachable sheath; delivery system allows cranial or caudal adjustment; late repositioning
Zenith (Cook Medical)	Polyester/stainless steel	Yes	Yes	18 to 32	8 to 20	26	Spiral Z flexible limbs
Zenith fenestrated (Cook Medical)	Polyester/stainless steel	Yes	Yes	19 to 31	9 to 21	20	Juxtarenal aneurysm
Removed from US market◇							
Ovation (Endologix)	PTFE/nitinol	Yes	Yes	16 to 30	8 to 20	15	Low profile, proximal sealing ring

UptoDate 2023

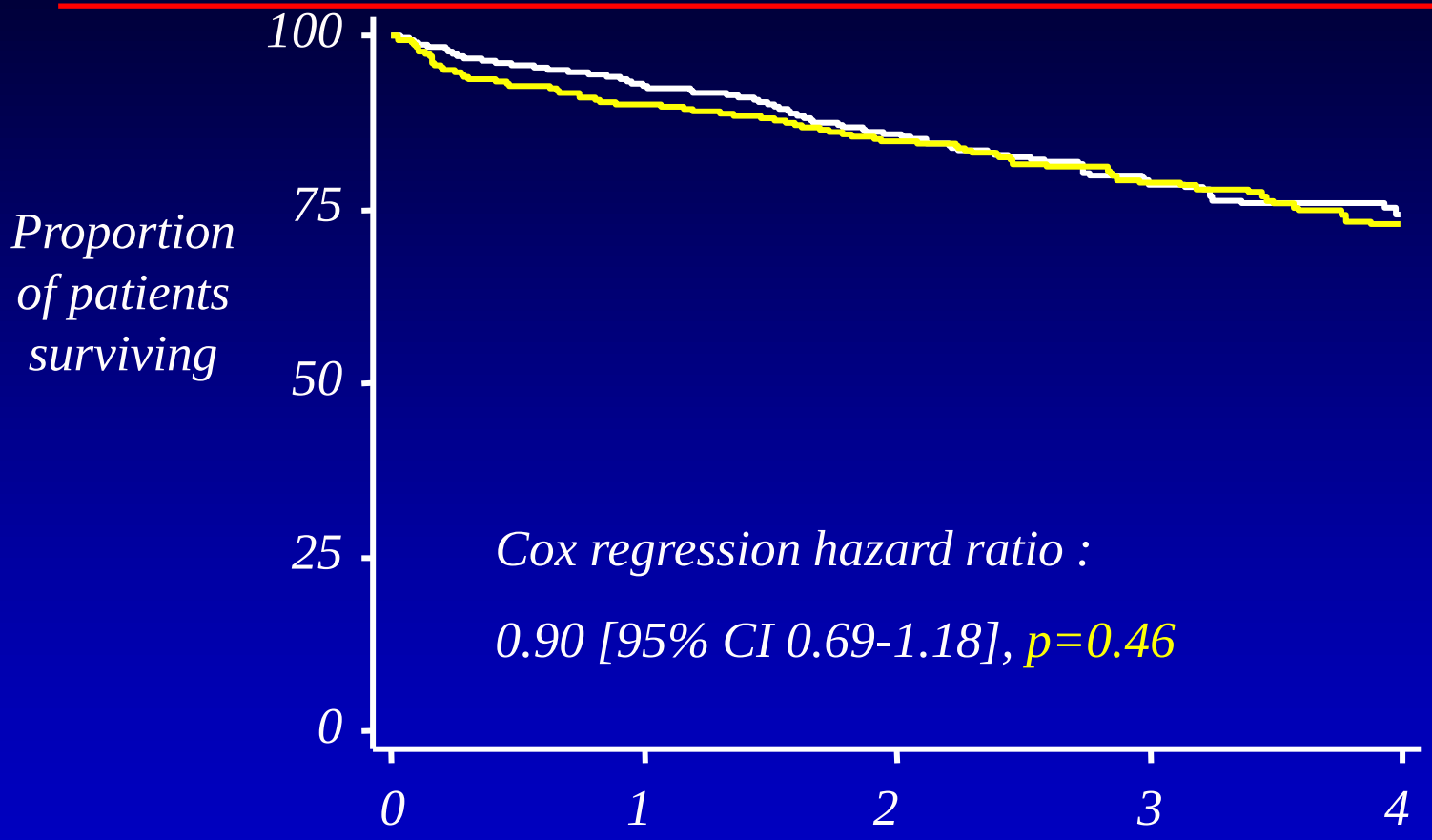
EVAR - Profile and Anatomic Coverage of Current Devices

	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%*

Open vs percutaneous

- DREAM
  - 331 patients (AAA>5CM)
  - Peri-operative mortality favored EVAR
  - Long-term no different
  - More EVAR long term reinterventions
- EVAR 1
  - 1252 patients (AAA>5cm)
  - Early EVAR benefit lost at 8 years post procedure (due to late secondary events in the EVAR group)
  - Some open repair complications were not counted
- OVER
  - VA cohort (AAA>5cm)
  - Early benefit of EVAR to open repair mortality
  - Long-term no differences

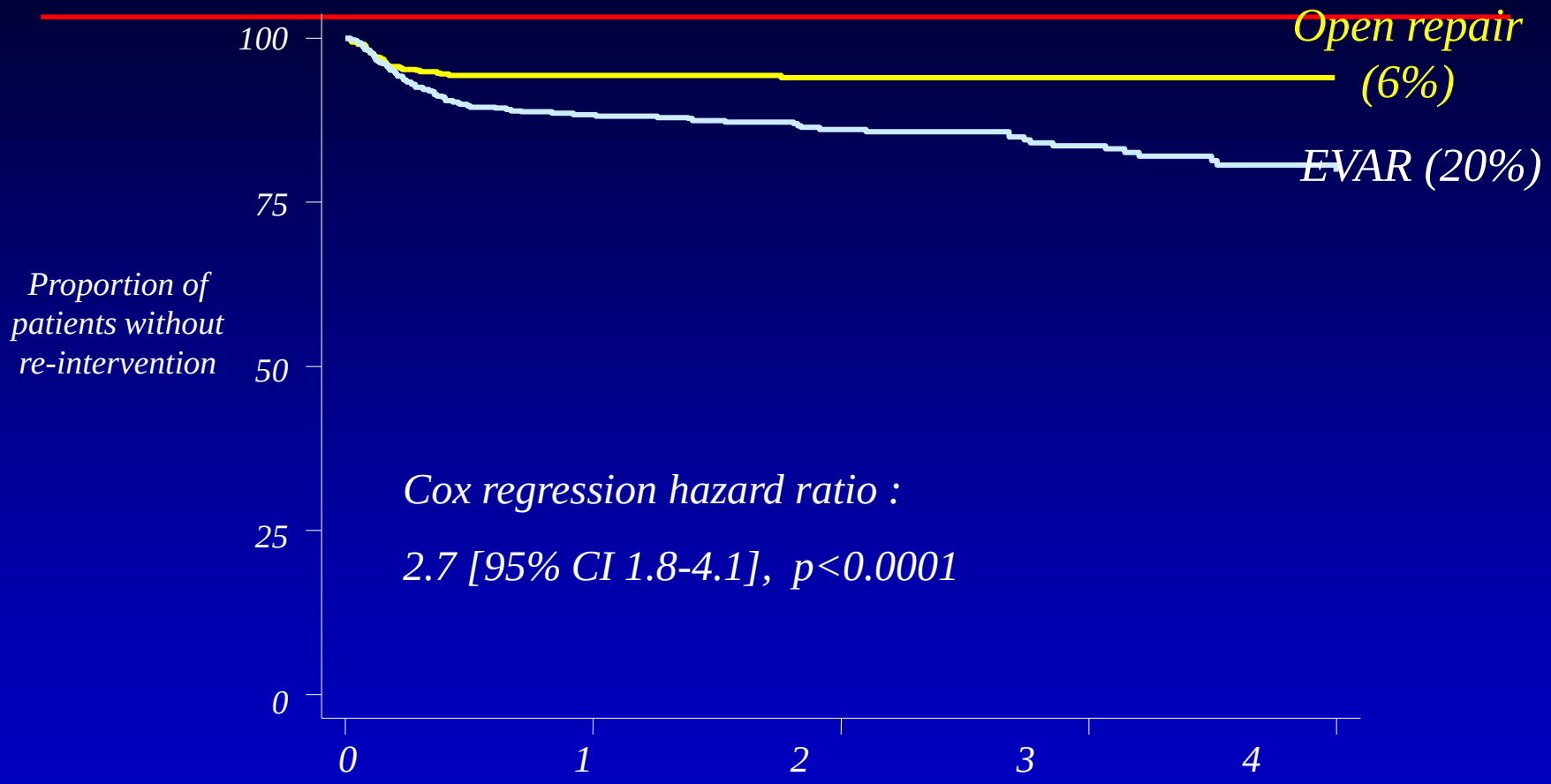
All-cause Mortality



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

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

DREAM Randomized Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

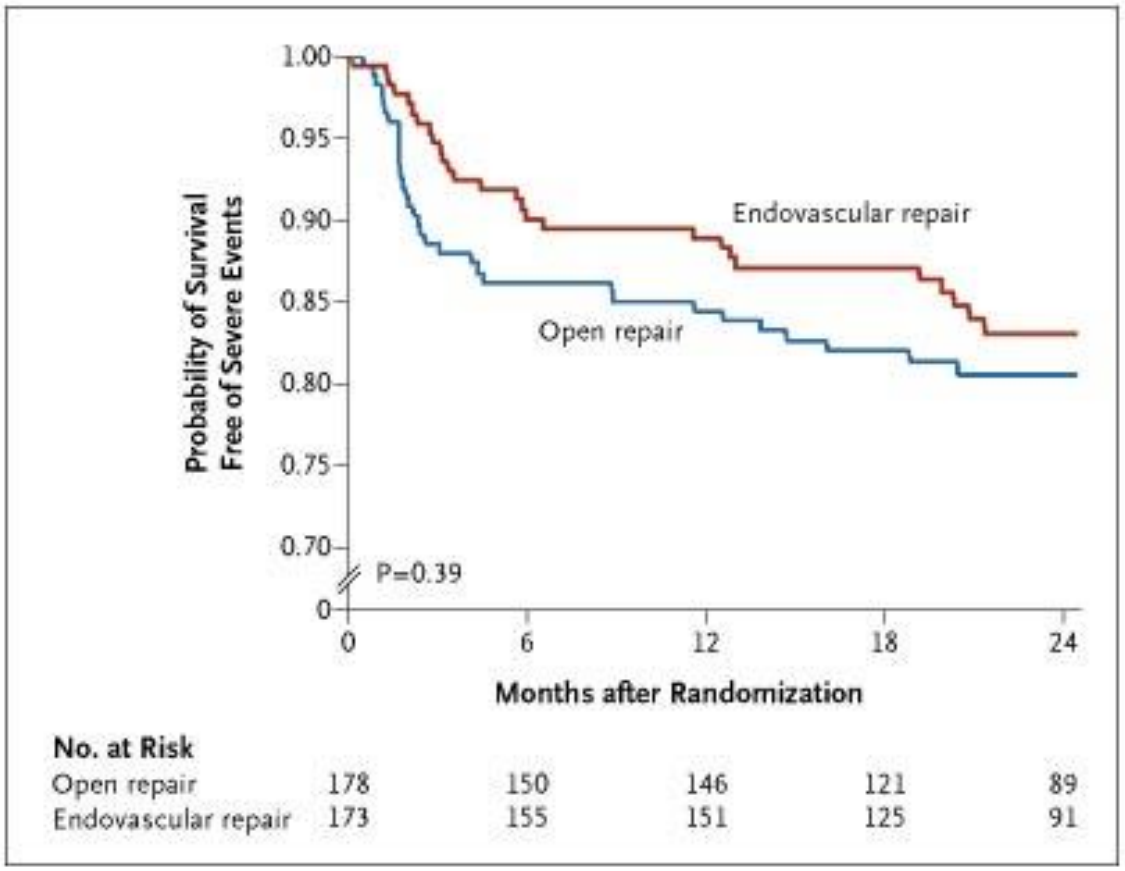
Two-Year Outcomes after Conventional or Endovascular Repair of Abdominal Aortic Aneurysms

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

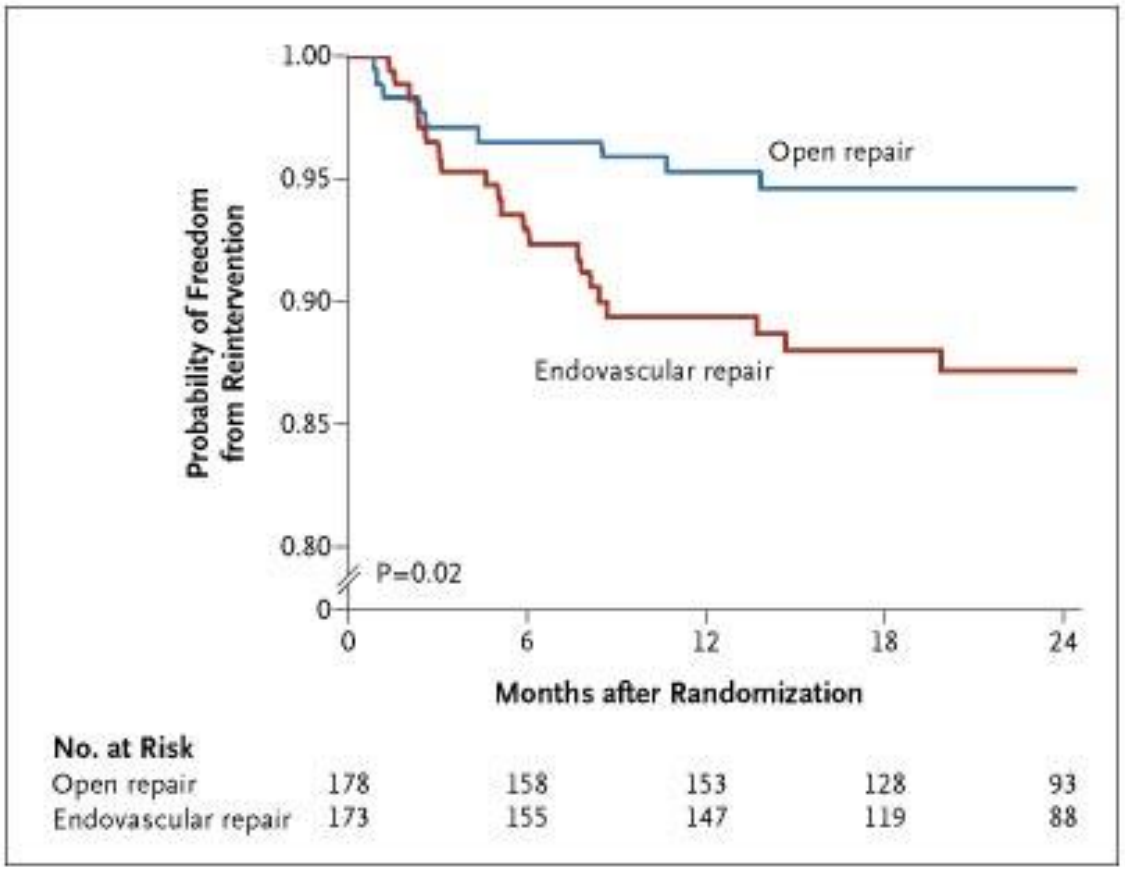
Kaplan-Meier Estimates of Event Free Survival among Patients Assigned to Undergo Open or Endovascular Aneurysm Repair



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

DREAM Randomized Trial

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

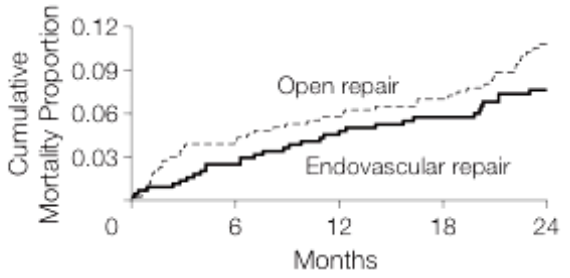


Blankensteijn, J. et al. N Engl J Med 2005; 352:2398-2405

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)	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

Perioperative Outcomes after Endovascular Repair or Open Repair

CMS Database

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

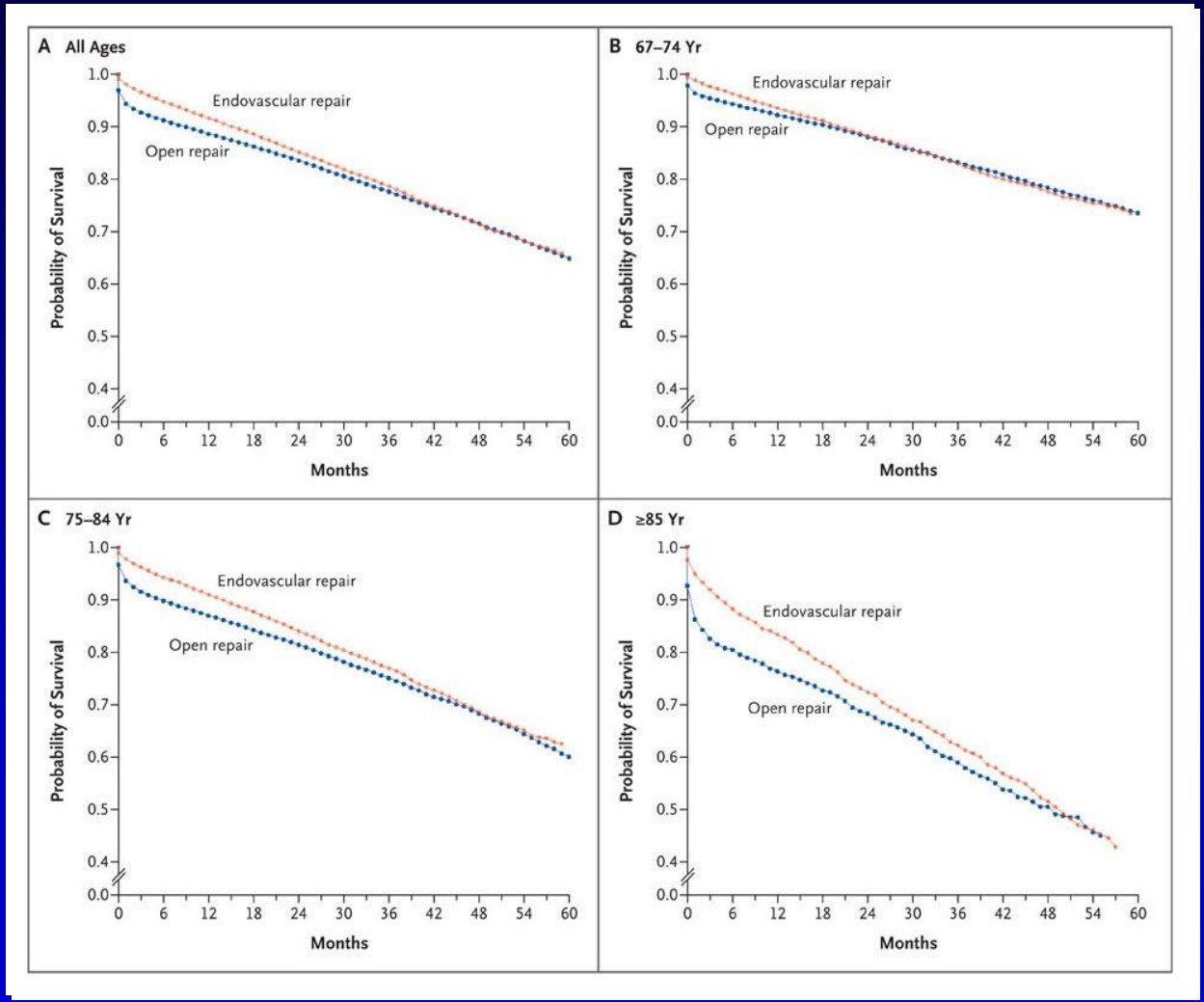
Perioperative Outcome	Endovascular Repair (N=22,830)	Open Repair (N=22,830)	P Value	Relative Risk Associated with Open Repair (95% CI)
Death (% of patients)				
All ages	1.2	4.8	<0.001	4.00 (3.51–4.56)
67–69 yr	0.4	2.5	<0.001	6.21 (4.98–7.73)
70–74 yr	0.8	3.3	<0.001	4.12 (3.51–4.84)
75–79 yr	1.3	4.8	<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%

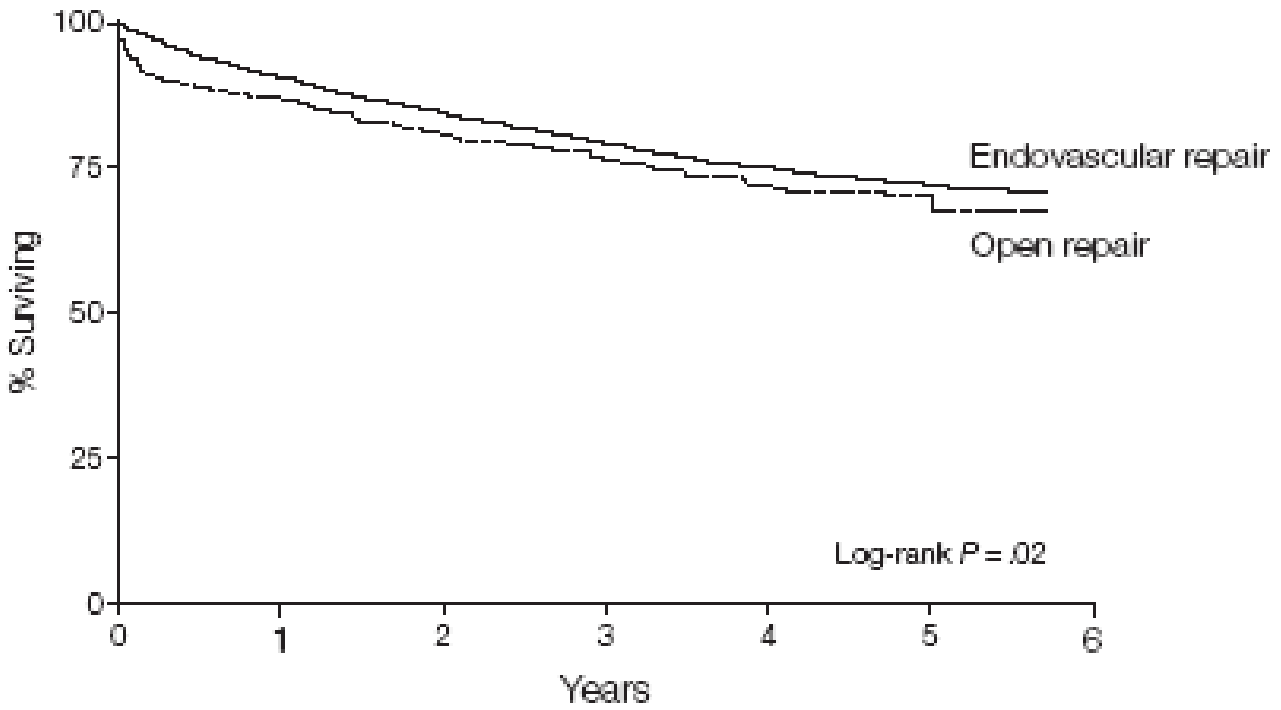
Schermerhorn M et al. N Engl J Med 2008; 358: 464-474

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	2287	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.

JAMA 2012, 307; 1621-28

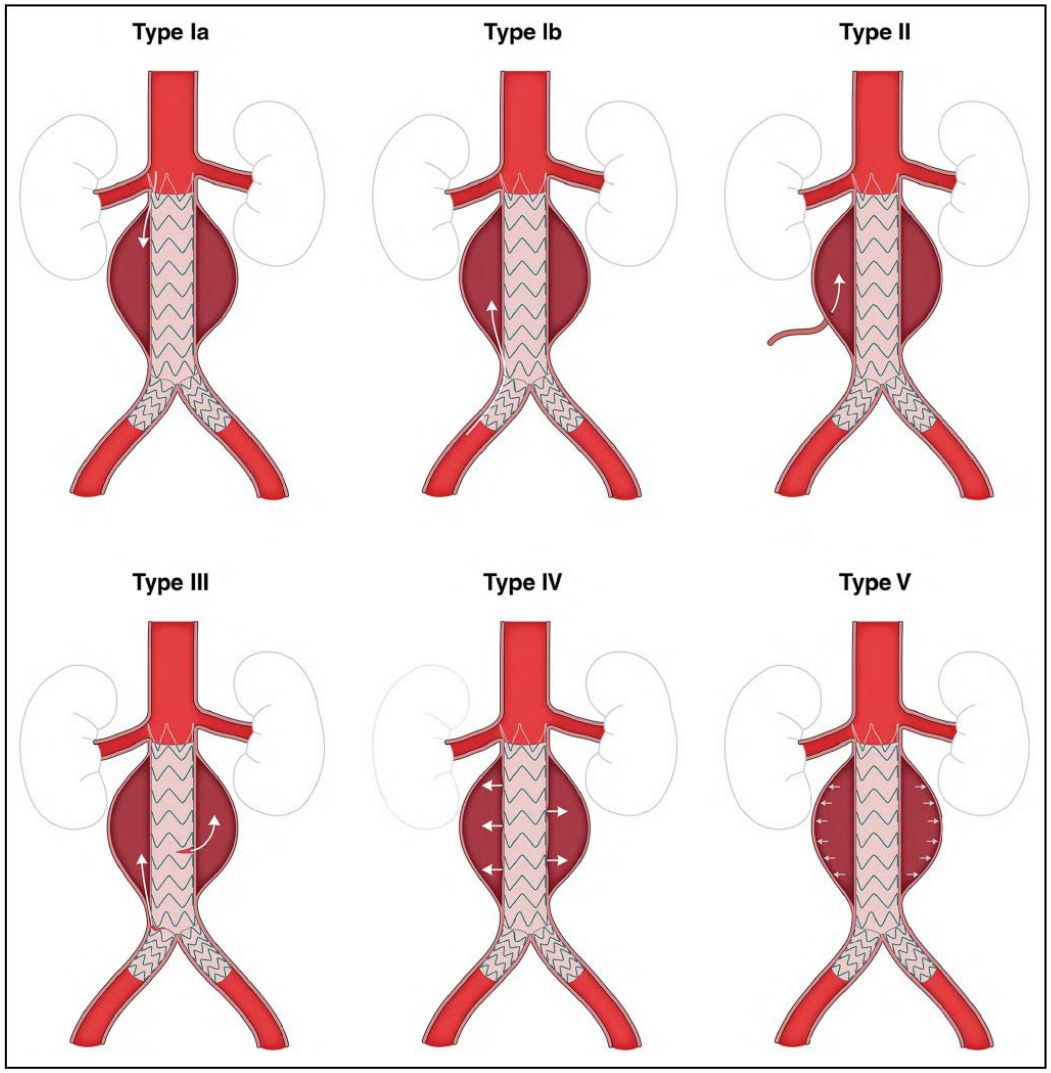


Figure 11. Classification of Endoleak Types.
Endoleaks are classified by 5 types: **Type Ia,** proximal attachment site endoleak; **Type Ib,** distal attachment site endoleak; **Type II,** backfilling of the aneurysm sac through branch vessels of the aorta; **Type III,** graft defect or component misalignment; **Type IV,** leakage through the graft wall attributable to endograft porosity; and **Type V,** caused by "endotension," possibly resulting from aortic pressure transmitted through the graft/thrombus to the aneurysm sac. Adapted from Rokosh et al.[2] Copyright 2021, with permission from Elsevier, Inc., and the Society for Vascular Surgery.

AHA 2022 guidelines

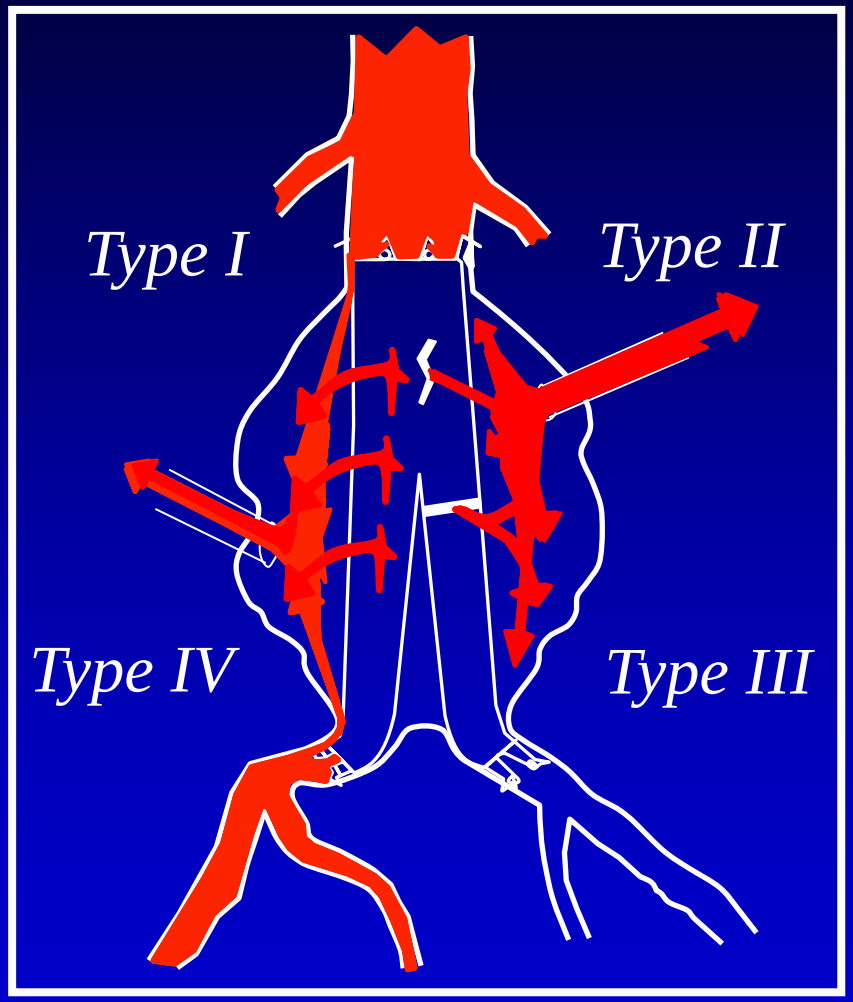
Endoleak Classifications

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

Conclusions

- EVAR remains the primary method of exclusion for AAA
- 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
- The long term outcomes remain the challenge and are best followed with strict adherence to serial surveillance of endografts