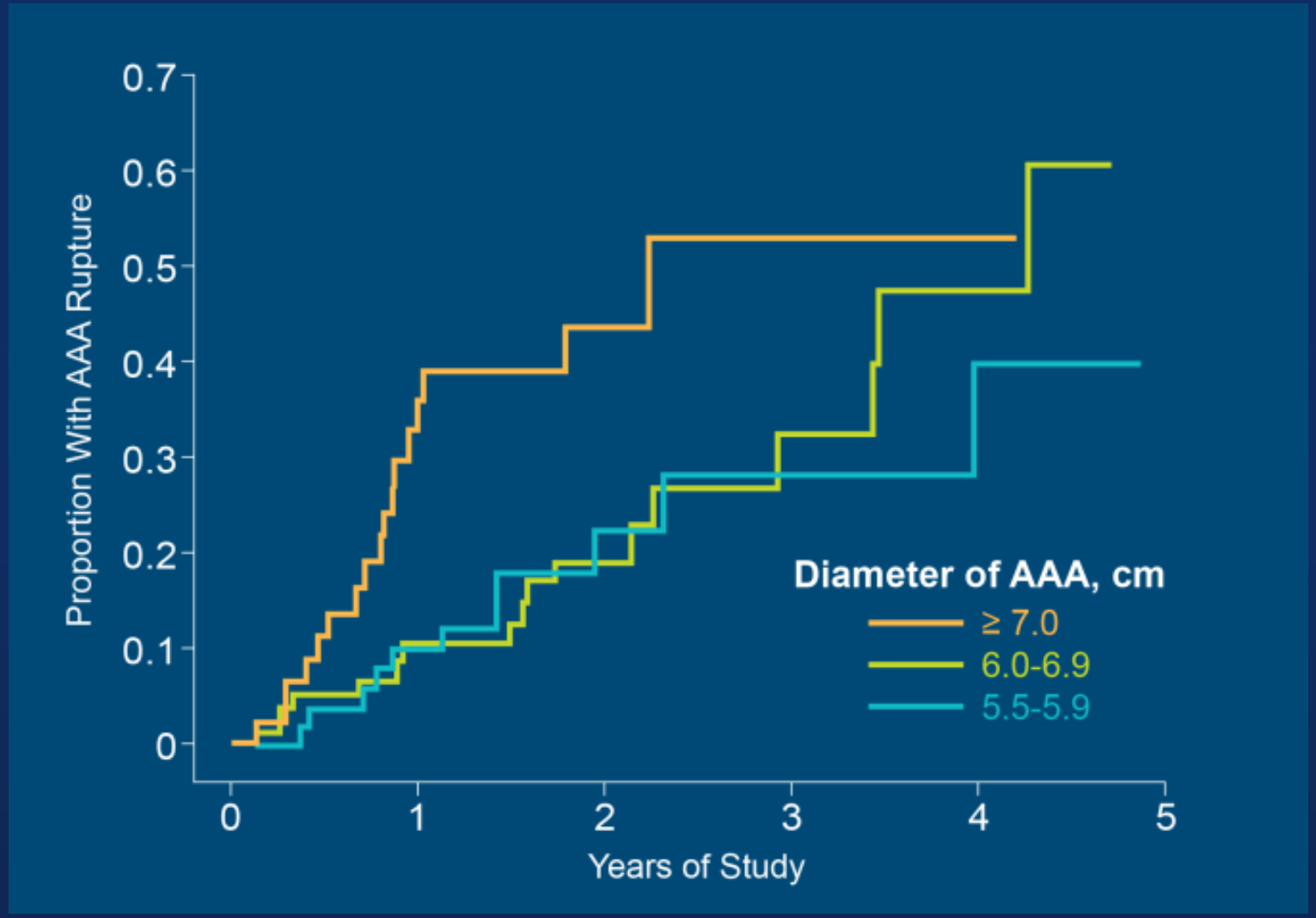
Endovascular treatment for Abdominal Aortic Aneurysm

Natural History



JAMA. 2012;307(15):1621-1628

Definition of Abdominal aortic aneurysm

- Segmental, full-thickness dilatation of abdominal aorta exceeding the normal vessel diameter by 50%
- Aneurysm diameter of 3.0 cm regarded as threshold
- Distinct degenerative process involving all layers of vessel wall
- Most common site of aneurysm: infrarenal (85%)
  - Infrarenal Aorta ; **1.4** ~ **3.0** cm
  - Average Aorta ; 2.0 cm

Eur Heart J 2014 Nov 1;35(41);2873

Risk for Rupture

- Proportional to aneurysm size

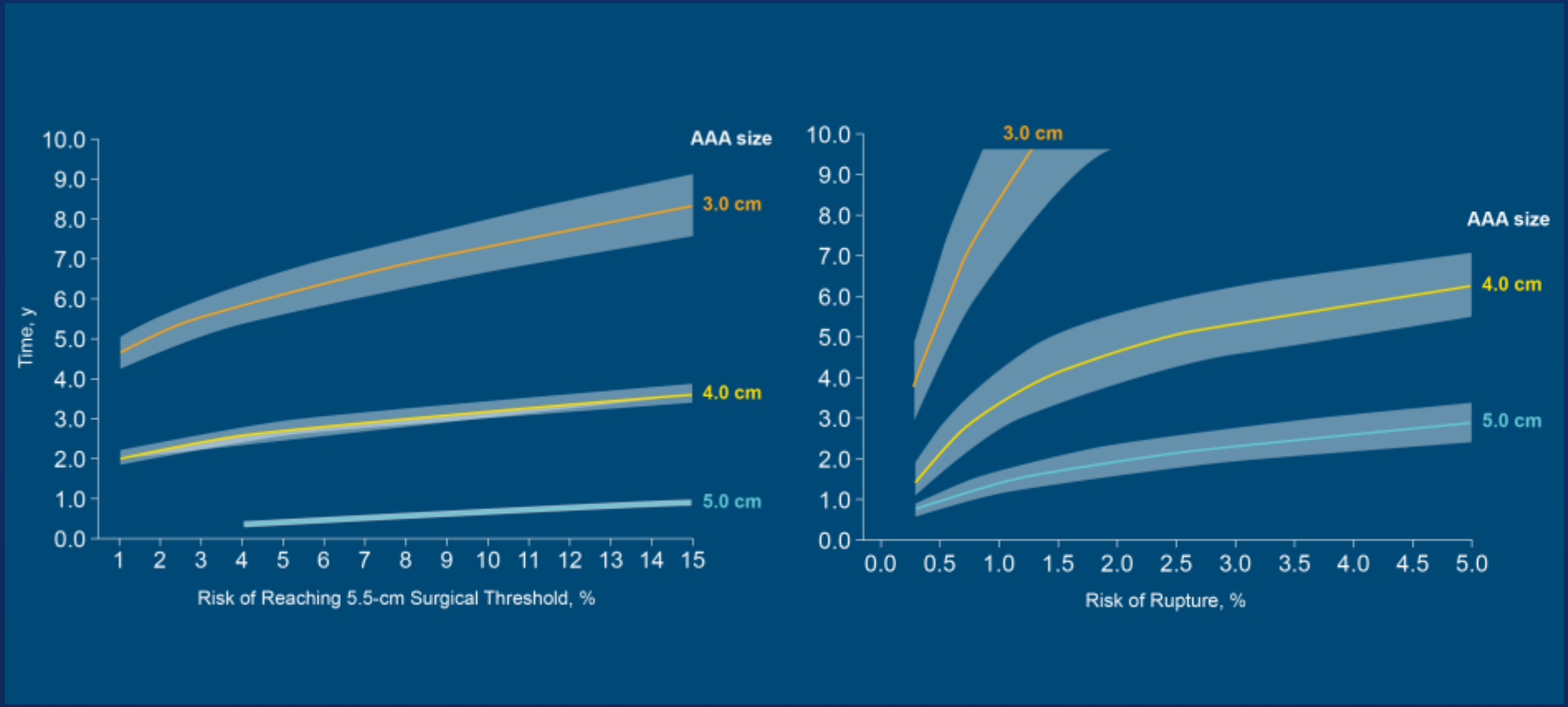
- 1966, Szilagyi compared < 6 cm to > 6 cm
  - Follow up rupture rate: 43 % vs. 20%
  - 5-year survival: 6 % vs. 48%

- 1977, Darling analyzed AAA autopsy, 473 consecutive AAA pts., 25% ruptured
  - < 4 cm: 10%
  - 4-7 cm: 25%
  - 7-10 cm: 46%
  - >10 cm: 61%

Risk for Rupture

	Annual	5-year
< 4 cm	0%	
4-5 cm	0.5-5%	2.5-25%
5-6 cm	3-15%	15-75%
6-7 cm	10-20%	50-100%
7-8 cm	20-40%	100%
>8 cm	30-50%	100%

Risk for Rupture



JAMA. 2013;309(8):806

Recommended intervals for Surveillance for small aneurysm

Country	Diameter, cm	Surveillance Interval, mo
England	3.0-4.4	12
	4.5-5.4	3
United States	2.5-2.9	50
	3.0-3.4	36
	3.5-4.4	12
	4.5-5.4	6
Norway	3.0-3.9	24
	4.0-4.5	12
	4.5-5.5	3-6

JAMA 2013;309:806

Guidelines for Repair of AAA

- Repair for males with AAA > 5.5 cm (IB)
- Repair for females with AAA > 5.0 cm (IB)
- Aneurysm growth exceeds 1 cm/year (IB)

- Large aneurysm suitable for EVAR, open or endovascular repair is recommended (IA)
- Large aneurysm unsuitable for EVAR, open aortic repair is recommended (IC)

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Surgical vs. Endovascular Repair

Open Repair

Endovascular Repair

AAA Repair Options

OPEN REPAIR

First performed at 1951

Now involves placement of Dacron or PTFE graft

2-4% operative death rate
5-10% complication rate

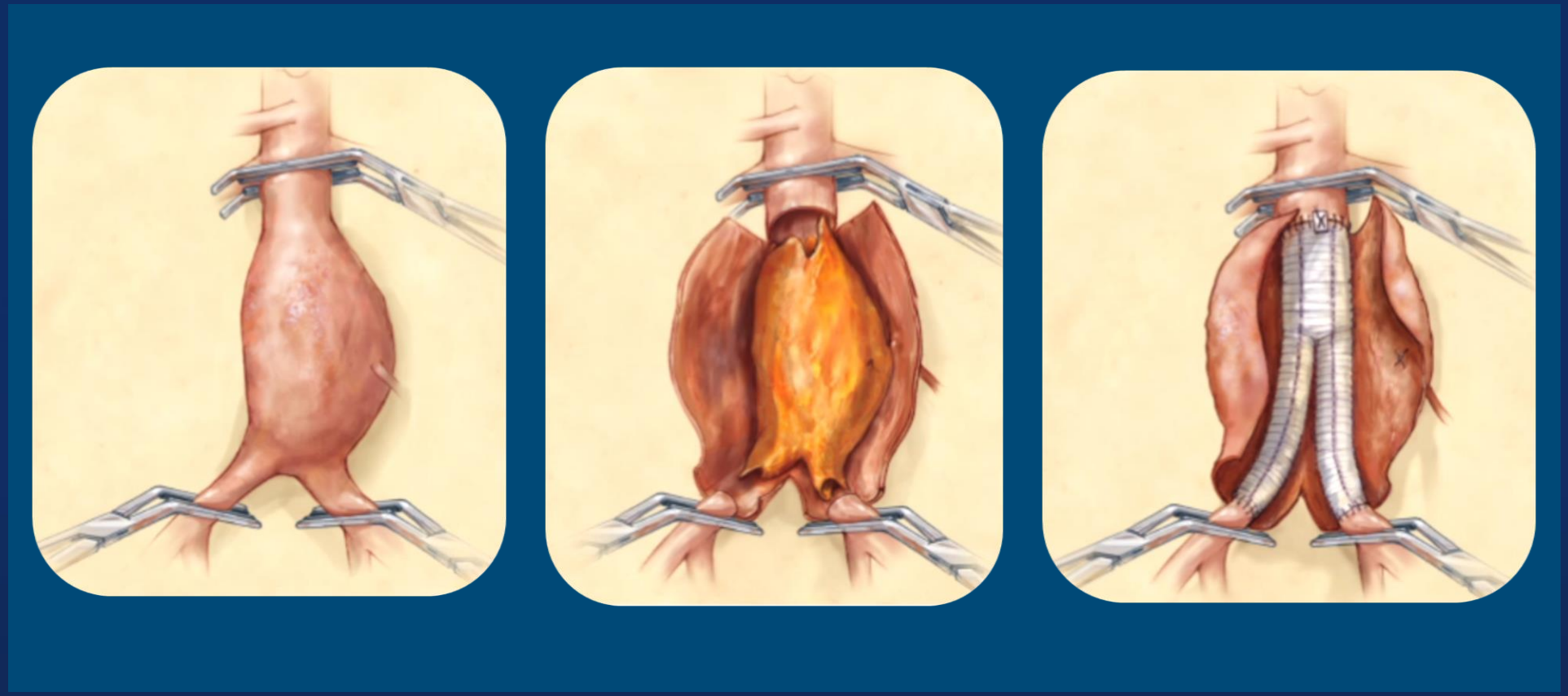
ENDOVASCULAR

First performed at 1987

Less invasive,
Through femoral vessels

Only certain types of AAA can be repaired

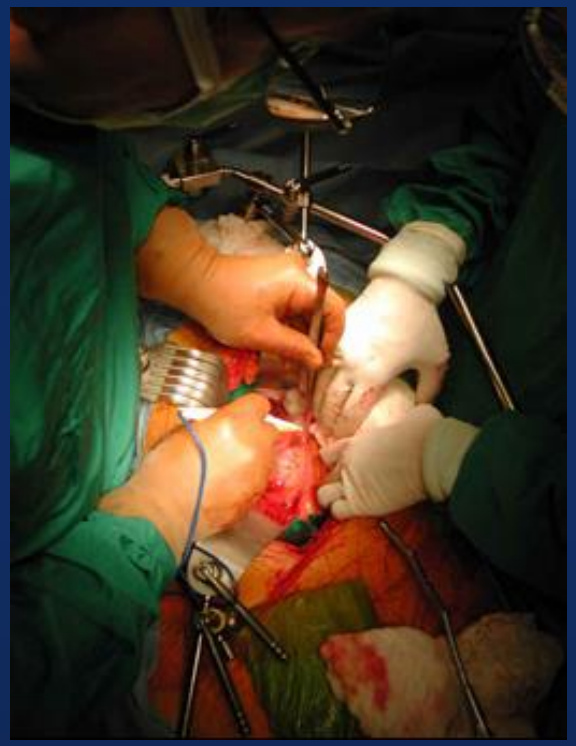
Elective Open Repair AAA



JAMA. 2009;302(18):2015

Elective Open Repair AAA

- Major surgical procedure
  - Mortality 2% to 5%
- Complications
  - Pseudoaneurysm
  - Erectile dysfunction
  - Aortoenteric fistula
  - Graft thrombosis
  - Graft infection
- Recovery period 6 weeks to 4 months



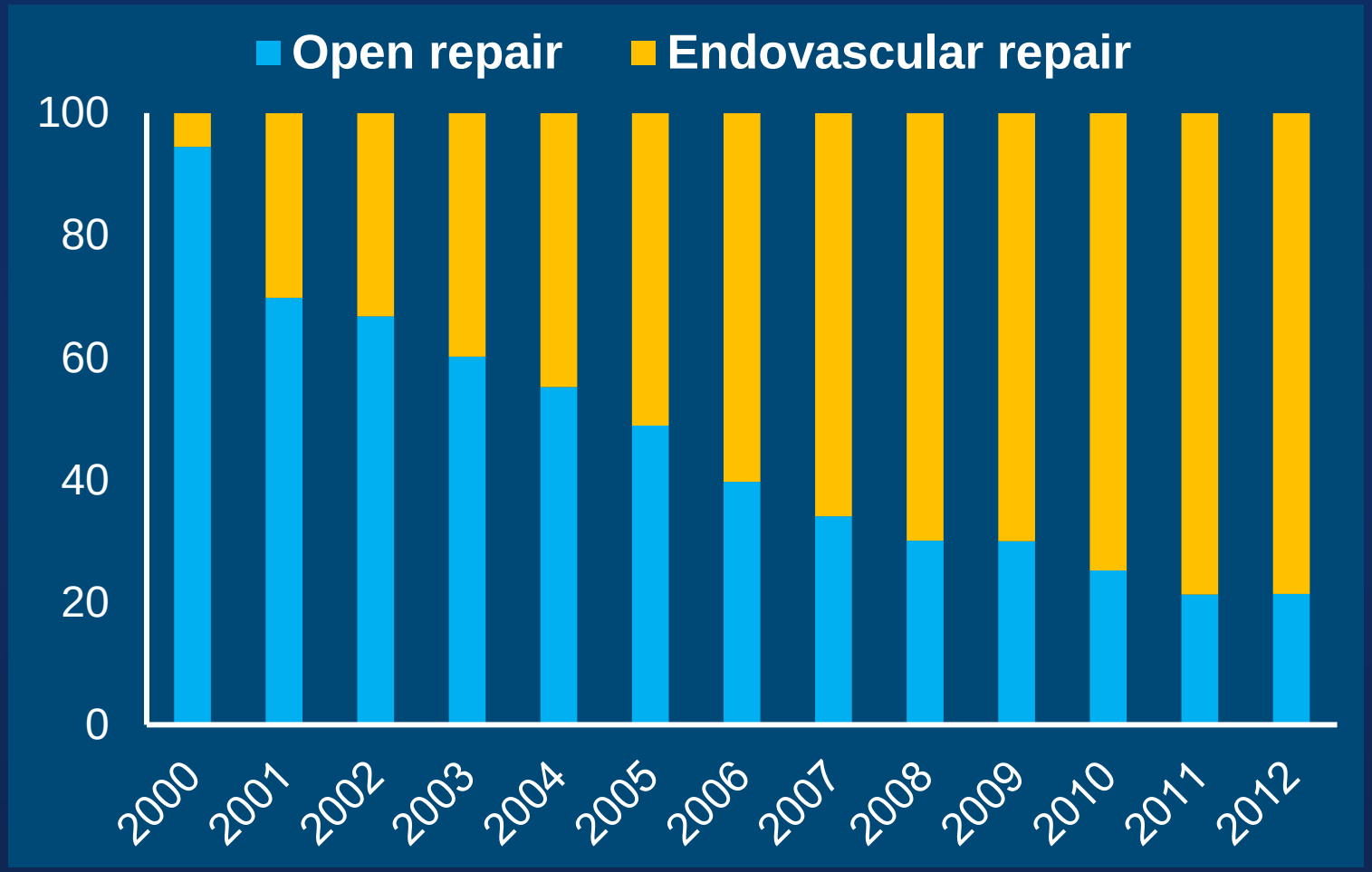
Endovascular Repair

JAMA. 2009;302(18):2015

EVAR, as an Alternative to OSR

- ✓ Avoidance of major abdominal surgery
- ✓ No cross-clamping of aorta
- ✓ Avoidance of surgery-specific complications (i.e. sexual dysfunction)
- ✓ Short LOS (1-3 days), no need for ICU
- ✓ Simple and Speedy recovery
- ✓ Rx for surgical high-risk patients.

Annual Proportion of EVAR and Open Repairs in US



N Engl J Med 2014;371:2101-2108

Proportion of EVAR

Intact AAA

Country	N patients	%EVAR (95% CI)
Hungary	849	27.8% (24.8%-30.8%)
Norway	2095	32.0% (30.0%-34.0%)
Denmark	2239	33.9% (31.9%-35.9%)
Finland	461	46.2% (41.7%-50.8%)
Switzerland	2174	50.3% (48.2%-52.4%)
New Zealand	1214	51.7% (48.9%-54.5%)
Iceland	76	53.9% (42.7%-65.2%)
Sweden	3893	56.8% (55.3%-58.4%)
Germany	12572	68.2% (67.4%-69.0%)
Australia	6306	73.7% (72.6%-74.8%)
United States	11819	79.4% (78.7%-80.2%)

Circulation 2016;134:1948-1958

Proportion of EVAR

Ruptured AAA

Country	N patients	%EVAR (95% CI)
Denmark	748	5.1% (3.5%- 6.7%)
Hungary	187	7.5% (3.7%-11.3%)
Finland	192	9.9% (5.7%-14.1%)
New Zealand	220	10.9% (6.8%-15.0%)
Norway	334	11.7% (8.2%-15.1%)
Iceland	21	19.0% (2.3%-35.8%)
Switzerland	342	24.9% (20.3%-29.4%)
Sweden	1038	29.3% (26.5%-32.1%)
Germany	1444	31.2% (28.8%-33.6%)
Australia	1444	39.8% (37.2%-42.3%)
United States	1075	51.8% (48.8%-54.8%)

Circulation 2016;134:1948-1958

Anatomic exclusion of EVAR

- Inadequate proximal landing zone
  too short, too wide, or too narrow neck
  severe angulation
- Inadequate distal landing zone
- Irregular calcification, plaque or thrombus

- Non-aneurysmal iliac length < 10mm
- Excessive tortuosity of vessel
- Too small, tortuous iliofemoral vessels.

Complications of EVAR

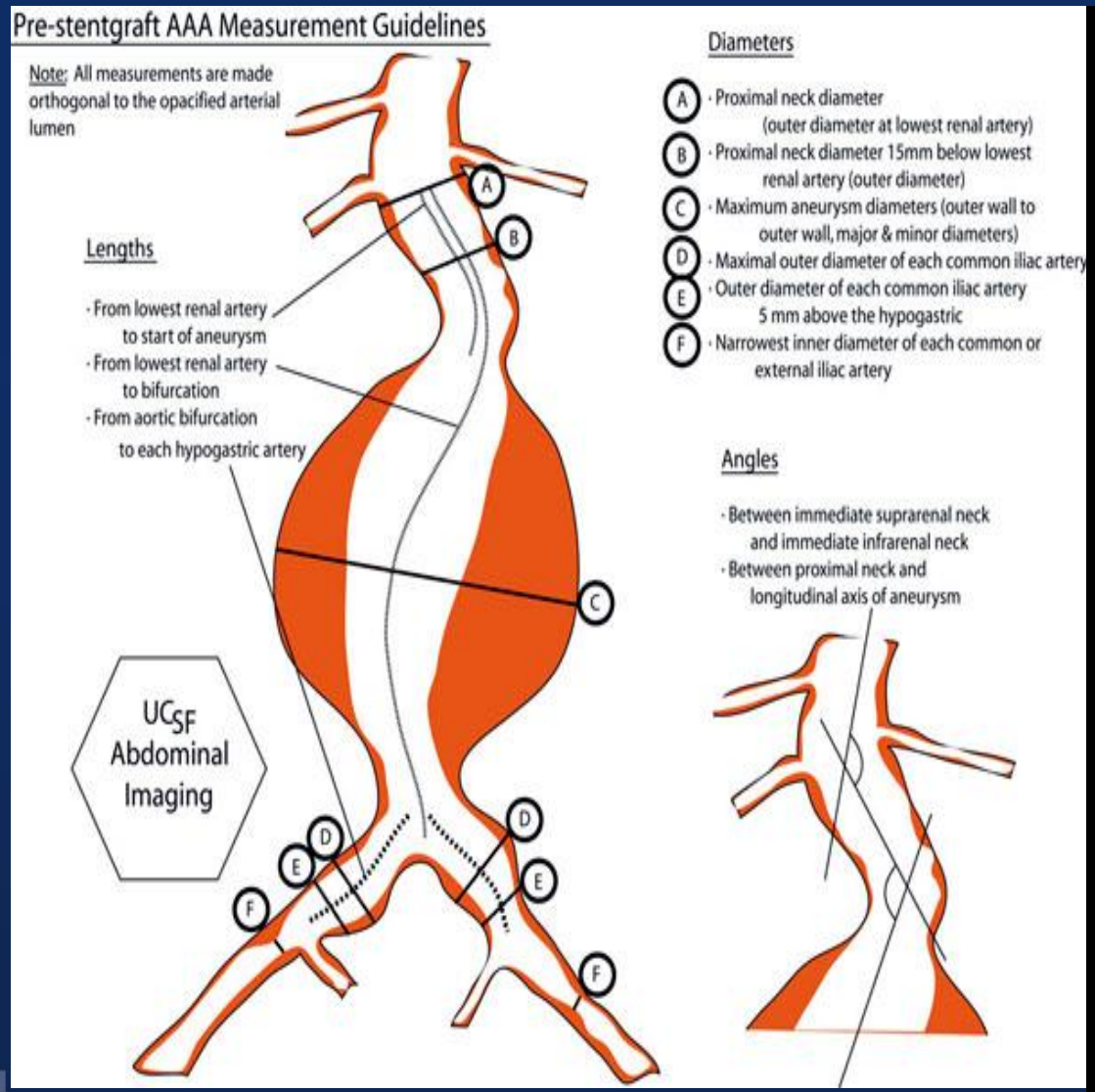
Early complication

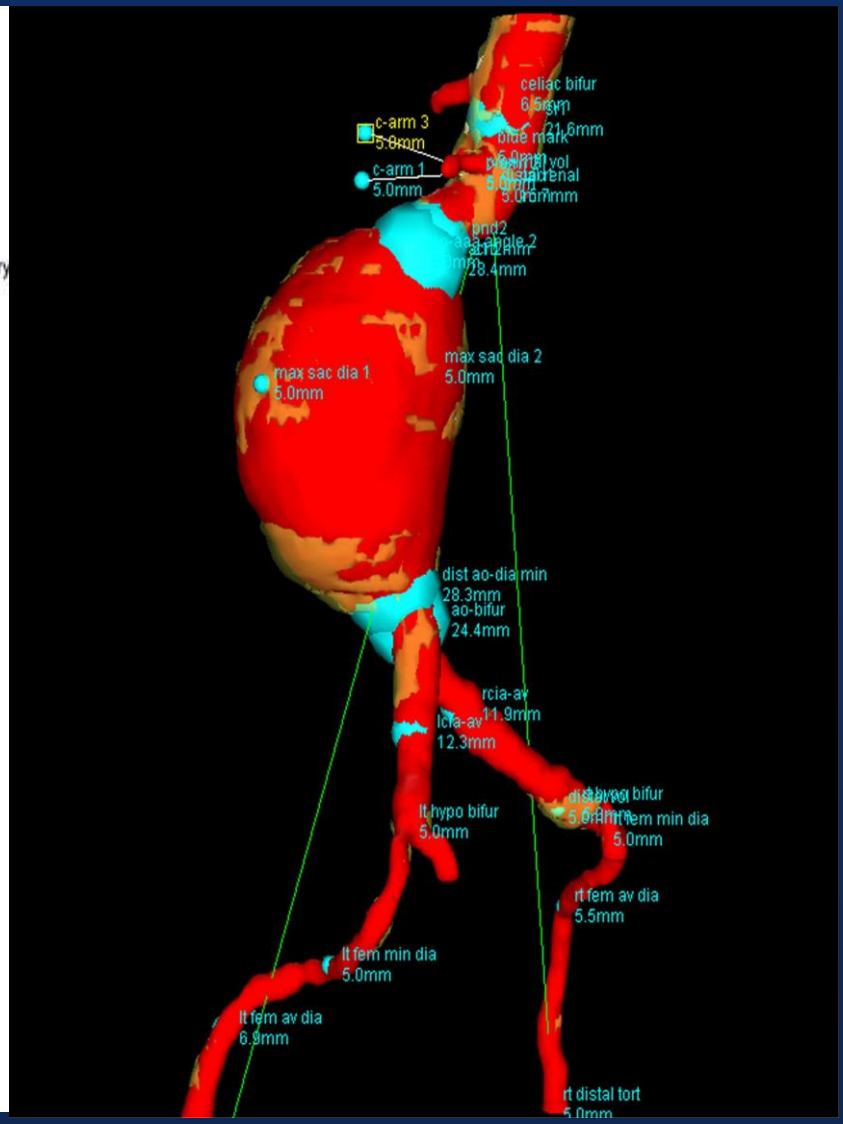
- Graft thrombosis
- Acute limb ischemia
- Bowel ischemia
- Embolization of renal and mesenteric vessel
- Paraplegia

Late complication

- Late graft thrombosis
- Aneurysm
- Endograft wear
- Infection
- Distal migration

Pre-Stent Graft Measurement Guidelines





Technical Considerations

Device Description

Three Essential Components of endograft

1. **Delivery system**
   Introducer sheath, Trocar, Deployment capsule and retractable cover

2. **Attachment system**
   Stainless steel, Elgiloy, Tantalum or nitinol

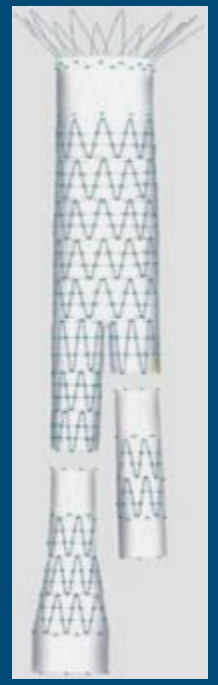
3. **The graft conduit**
   Polyester, PTFE (Polytetrafluoroethylene)

Company	Device	Body diameter	Outer diameter	Fixation location	Graft material	prox. bare-springs
Cook	Zenith	22-36	18F,20F, 22F	suprarenal	woven polyester	Yes
Vascutek Terumo	Anaconda	19.5-34	20F,23F	infrarenal	na	No
Endologix	Powerlink	25-28	21F	infrarenal	ePTFE	No
Medtronic	Endurant	23-36	18F,20F	suprarenal	woven polyester	Yes
Lombard Medical	Aorfix	24-31	22F	infrarenal	na	No
Gore	Excluder	23-31	20F,23F	infrarenal	ePTFE	No

FDA Approved EVAR Devices

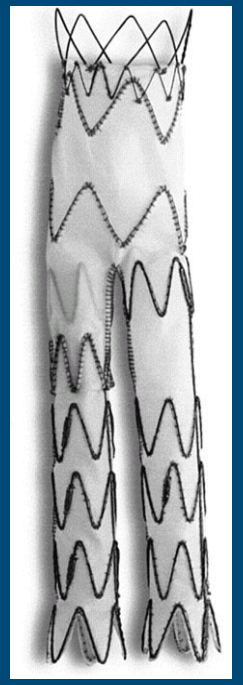
AneuRx

Excluder



Zenith

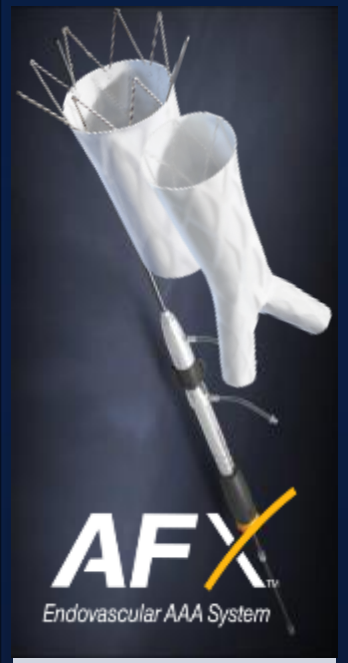
Endologix



Talent

Endurant II

All Current Generation EVAR Devices Can Be Used Via Percutaneous Approach!



AFX
Endologix
17& 19 F

Endurant II
Medtronic
18&20F

Excluder
WL Gore
18&20F

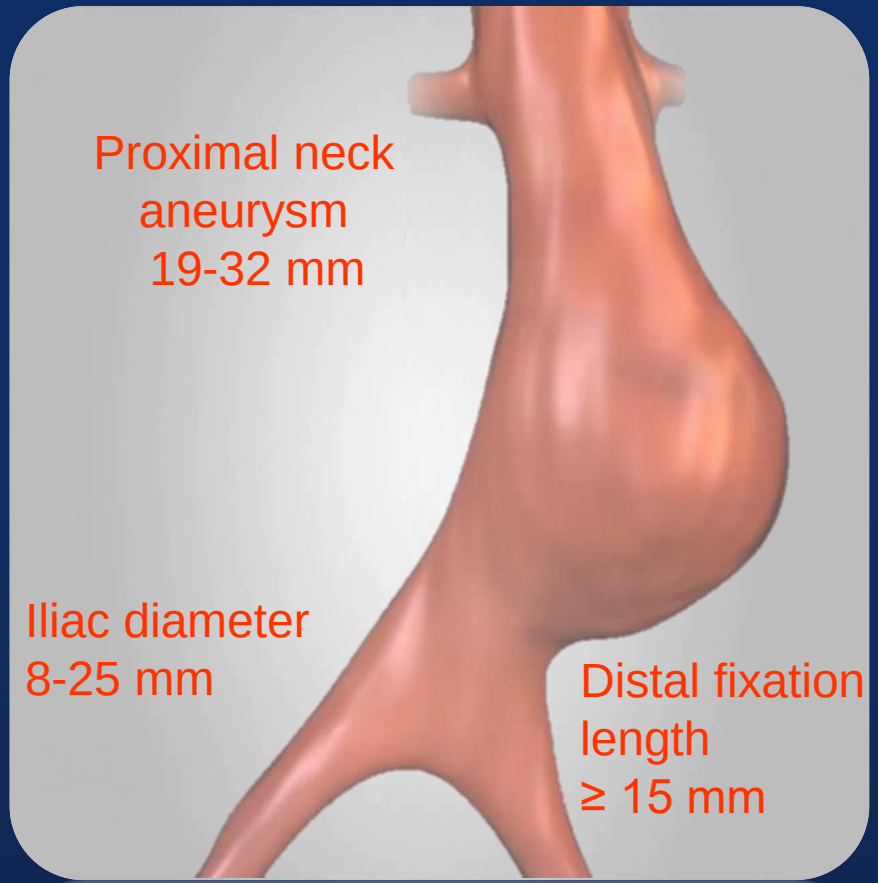
Zenith-Flex
Cook
18&22F

Ovation
Trivascular
14-F

Endurant II Stent Graft Indication

Iliac/femoral access

Aneurysm size



Endurant II Stent Graft Indication

- Proximal neck length ≥10 mm with non-significant calcification, and/or non-significant thrombus
- ≤ 60° infrarenal angulation ≤ 45° suprarenal angulation
- Vessel diameter approximately 10-20% smaller than Endurant Stent Graft diameter

- Proximal necks length ≥15 mm with non-significant calcification, and/or non-significant thrombus
- ≤75° infrarenal angulation ≤60° suprarenal angulation
- Vessel diameter approximately 10-20% smaller than Endurant Stent Graft diameter

Design Features

The M-shaped proximal stent designed to enhance wall apposition, minimize the risk of in-folding and provide
a 5mm sealing zone.

The suprarenal stent anchoring pins provide secure fixation.

Limb stent and stent spacing designed to prevent kinking.

Design Features

The tip sleeve covers the suprarenal pins to allow for positioning adjustments before tip release

Rotation of the back-end wheel provides slow and controlled release of the suprarenal stent with anchoring pins

You are in control at every step !

Complications of Endovascular Repair

- Arterial injury
  - Iliac, Suprarenal
- Embolization
  - Microembolization and renal failure
- Post Implant syndrome
  - Back pain, fever without infection
  - POD 0-7
  - Unknown etiology
  - Incidence up to 50%
- Graft Limb Thrombosis
  - Artery dissection
  - Endograft kinking in Iliac A.
  - Endograft kinking in Aneurysm Sac

Endoleaks

- Leak around proximal or distal attachment sites
  Coined by White, et al, 1996
  - Persistent flow in aneurysm sac
  - Incomplete exclusion

- Rates
  - 0 to 44%

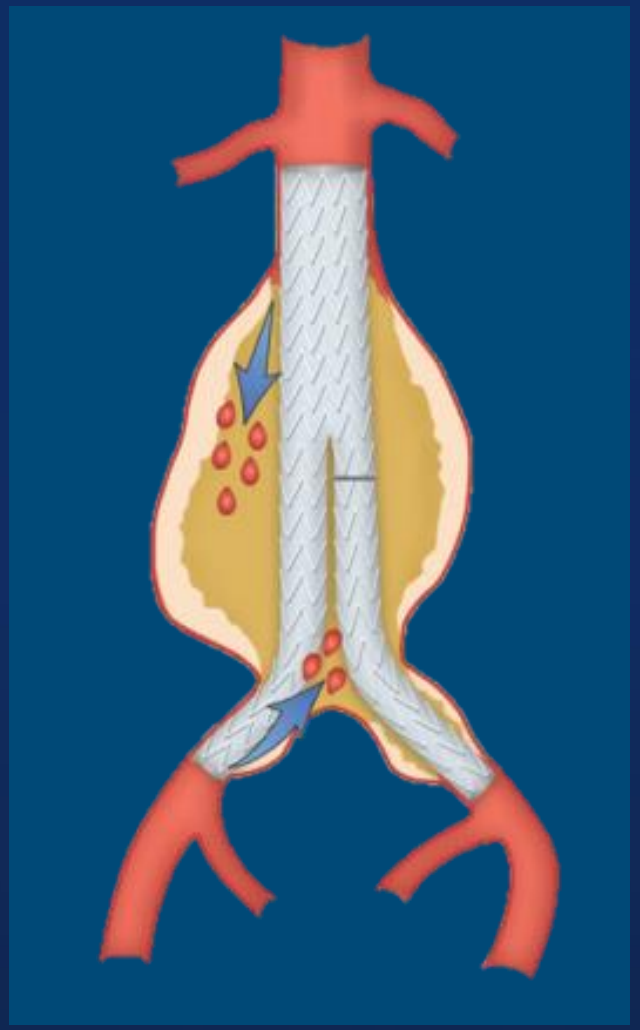
- Risks
  - Expansion
  - Rupture

Classification of endoleaks

- **Type I**: Leak at graft attachment site

  Ia: proximal attachment site
  Ib: distal attachment site

- Treatment failures
- Treatment to prevent the risk of rupture



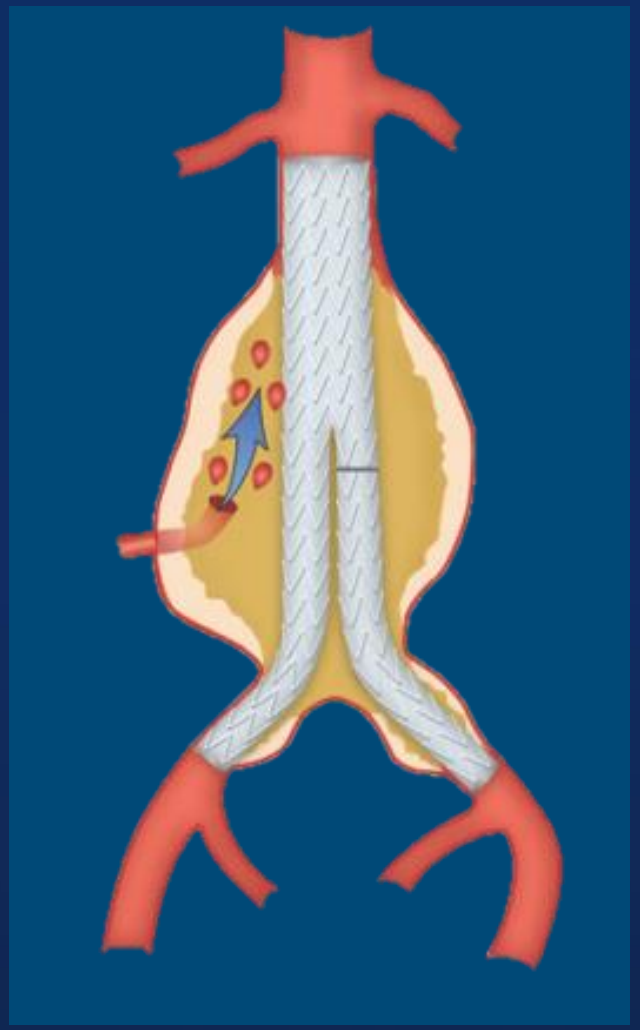
Eur Heart J 2014 Nov 1;35(41);2873

Classification of endoleaks

- **Type II**: Retrograde sac filling

  IIa: single branch vessel
  IIb: multiple branch vessel

- Spontaneous seal in about 50% of cases
- Conservative management ‘wait-and-watch’



Eur Heart J 2014 Nov 1;35(41);2873

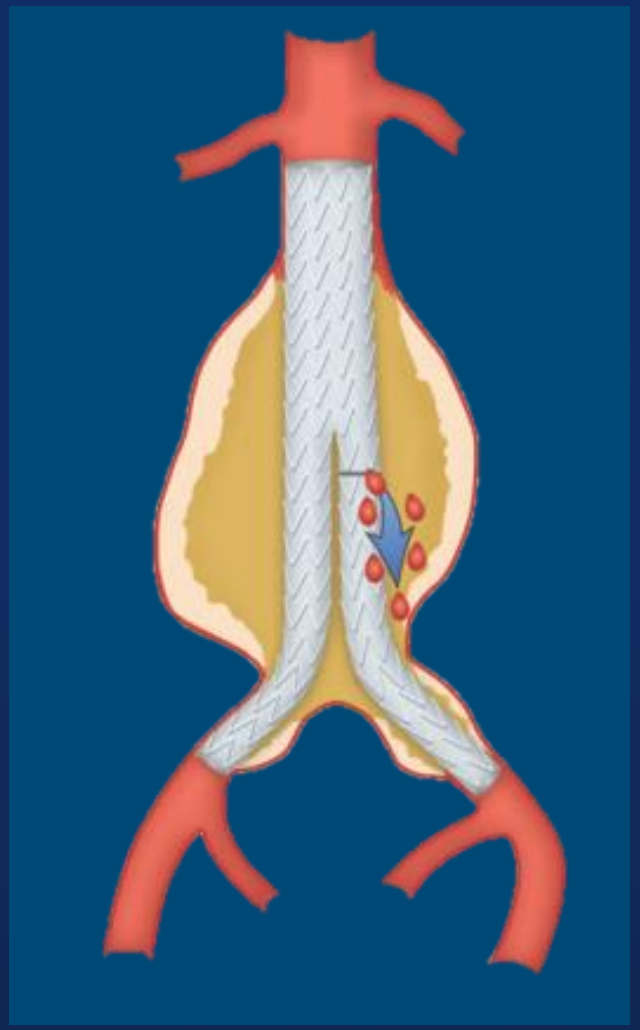
Classification of endoleaks

- **Type III**: Mechanical defect of stent

  IIIa: separation of the modular components

  IIIb: fractures or holes in the endograft

- Regarded as treatment failures
- Treatment to prevent the risk of rupture

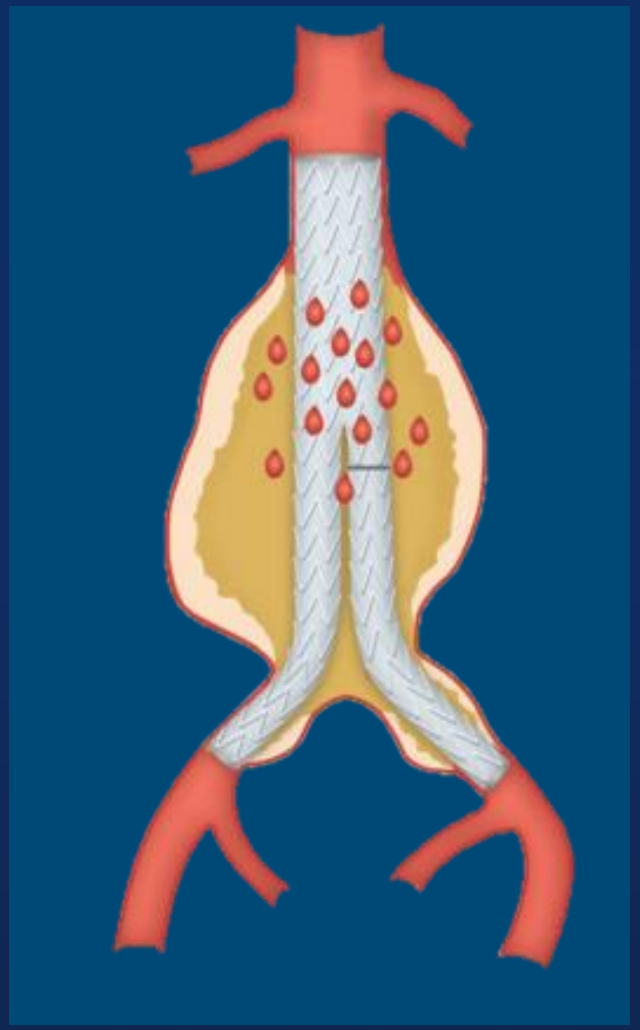


Eur Heart J 2014 Nov 1;35(41);2873

Classification of endoleaks

- **Type IV**:
  Leak through graft fabric

- Indirect and benign course
- Treatment required in cases of aneurysmal expansion



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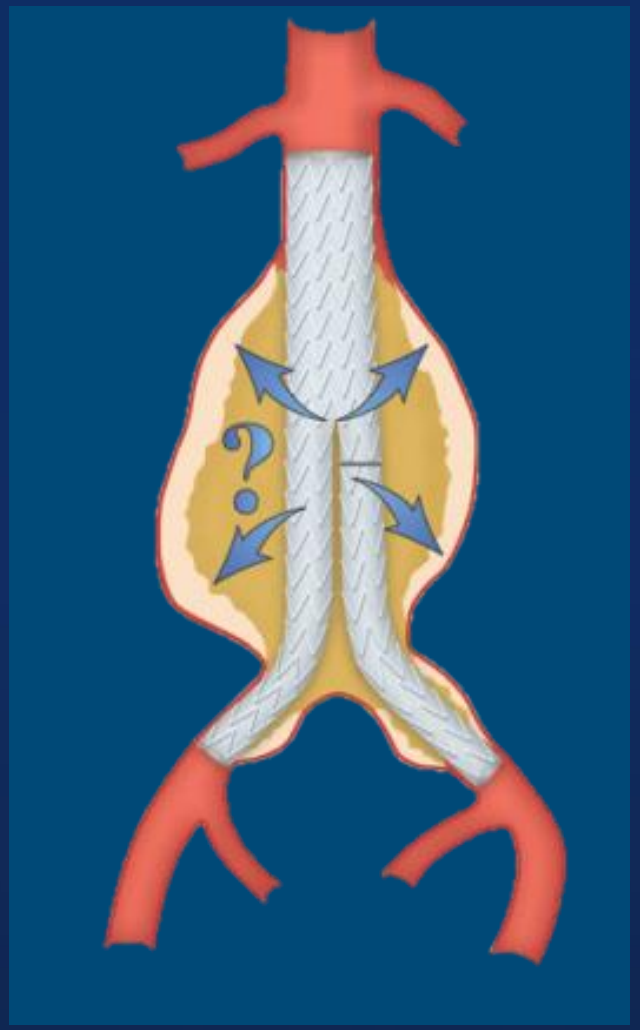
Classification of endoleaks

- **Type V**: Continued expansion without demonstrable leak

- Indirect and benign course
- Treatment required in cases of aneurysmal expansion



Eur Heart J 2014 Nov 1;35(41);2873

Independent Predictors of AAA Sac Enlargement After Repair

	HR	95% CI	*p* value
Endoleak	2.7	2.4-3.04	< 0.0001
Patient age ≥ 80	1.32	1.03-1.75	0.05
Aortic Neck Diameter > 32 mm	2.07	1.46-2.92	< 0.0001
Aortic neck angle > 60°	1.97	1.63-2.37	< 0.0001
Common iliac a diameter > 20 mm	1.46	1.21-1.76	< 0.0001

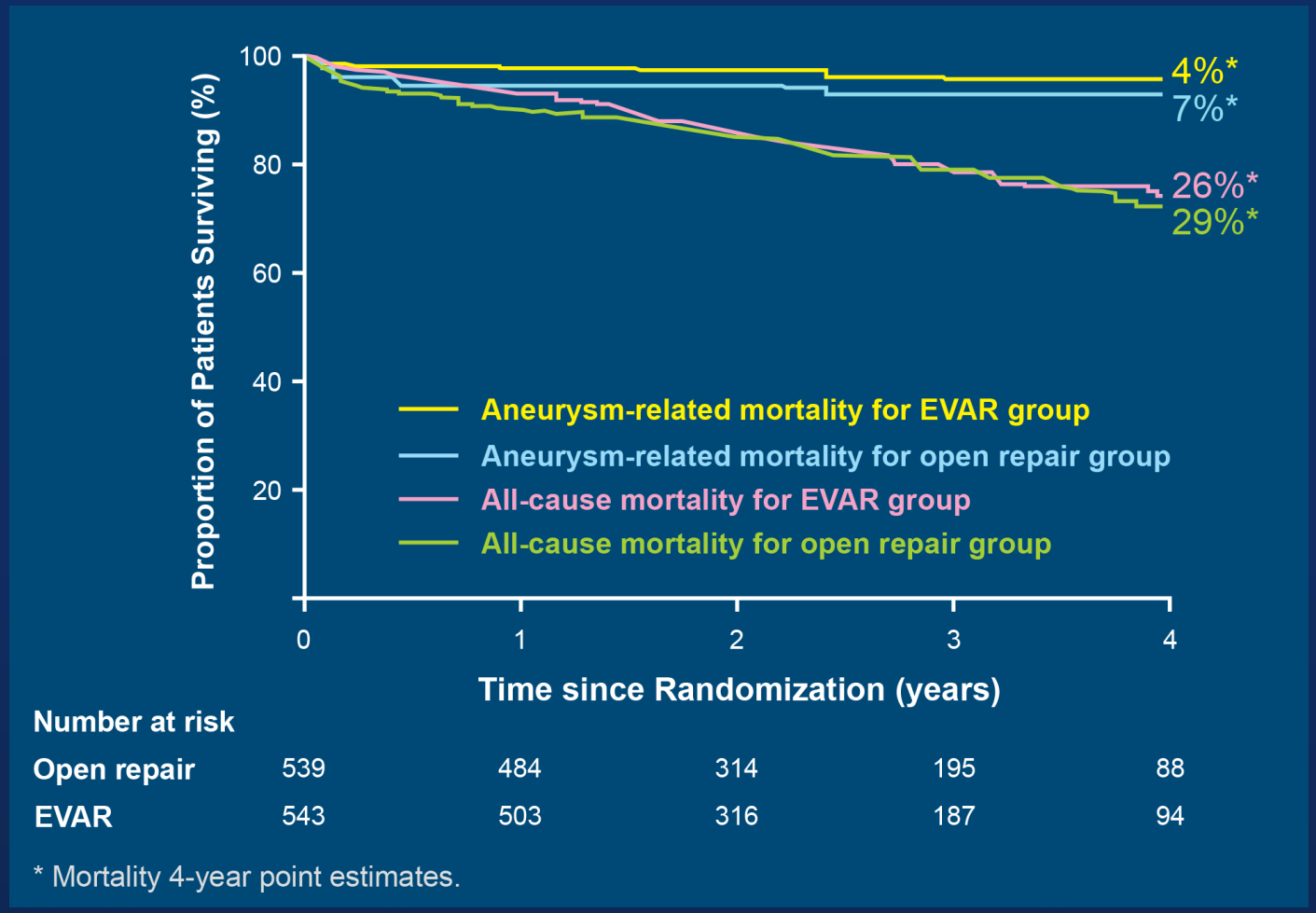
Circulation. 2011;123:2848

EVAR-1 Trial: Outcome

	EVAR	OPEN
30 Day Mortality	1.7 %	4.7 %
Secondary Interventions	9.8 %	5.8 %

Lancet 2004;364:843

EVAR 1 Trial: Mortality Results



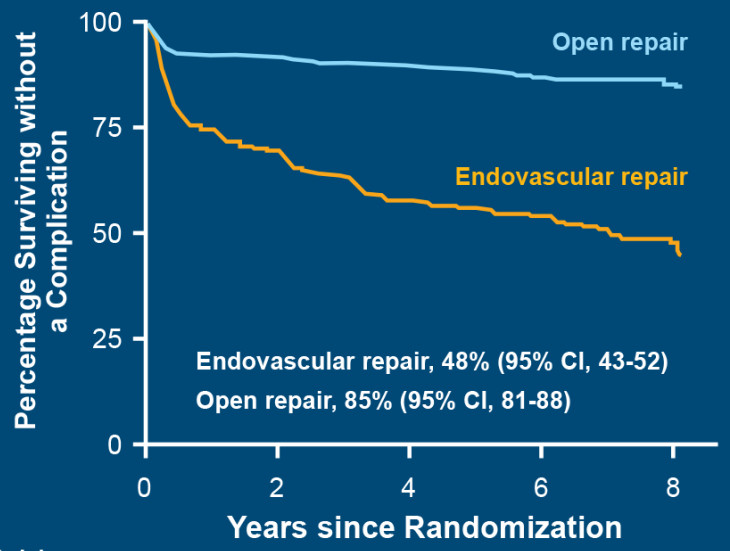
Number at risk					
Open repair	539	484	314	195	88
EVAR	543	503	316	187	94

* Mortality 4-year point estimates.

Lancet 2004;364:843

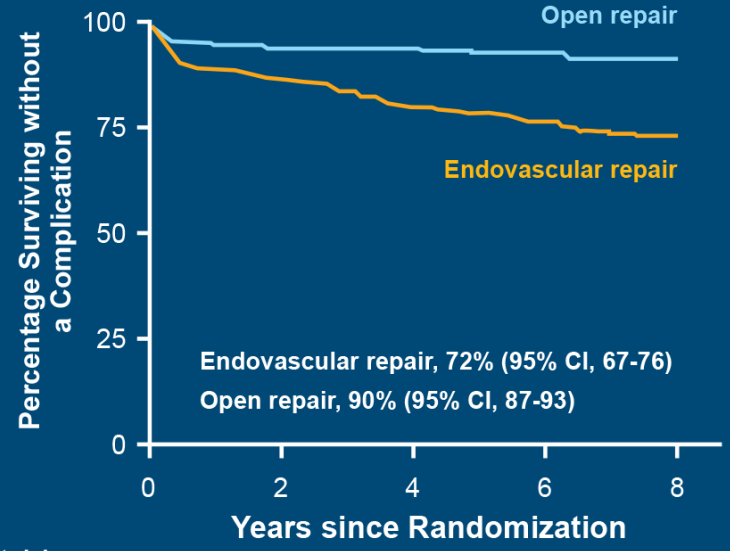
Long-term Outcomes of EVAR 1

Complication



Number at risk					
Endovascular repair	626	378	280	174	58
Open repai	626	496	413	259	91

Reintervention

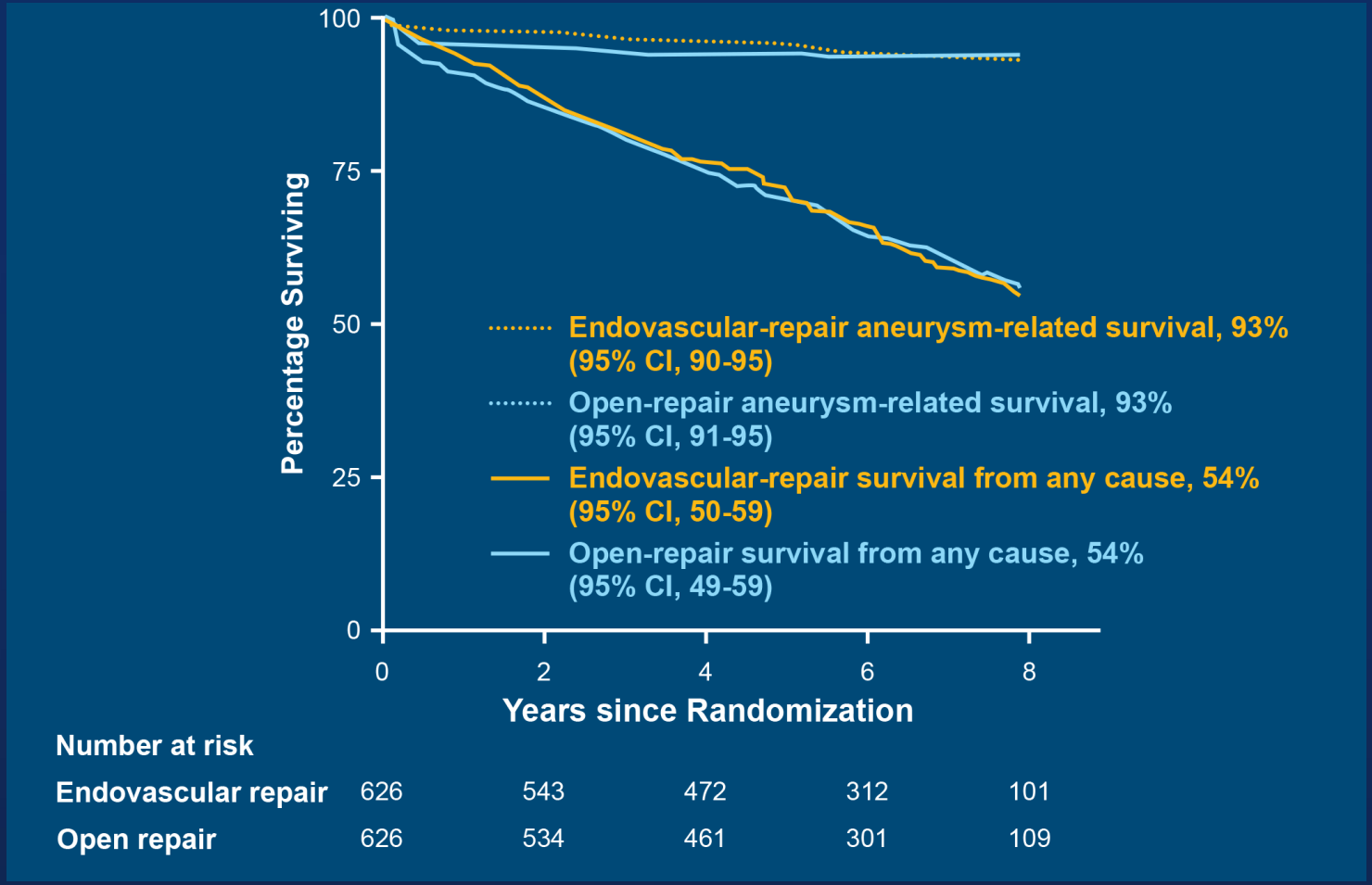


Number at risk					
Endovascular repair	626	470	377	243	83
Open repai	626	503	428	271	97

Lancet 2004;364:843

Long-term Outcomes of EVAR 1

Survivals



Lancet 2004;364:843

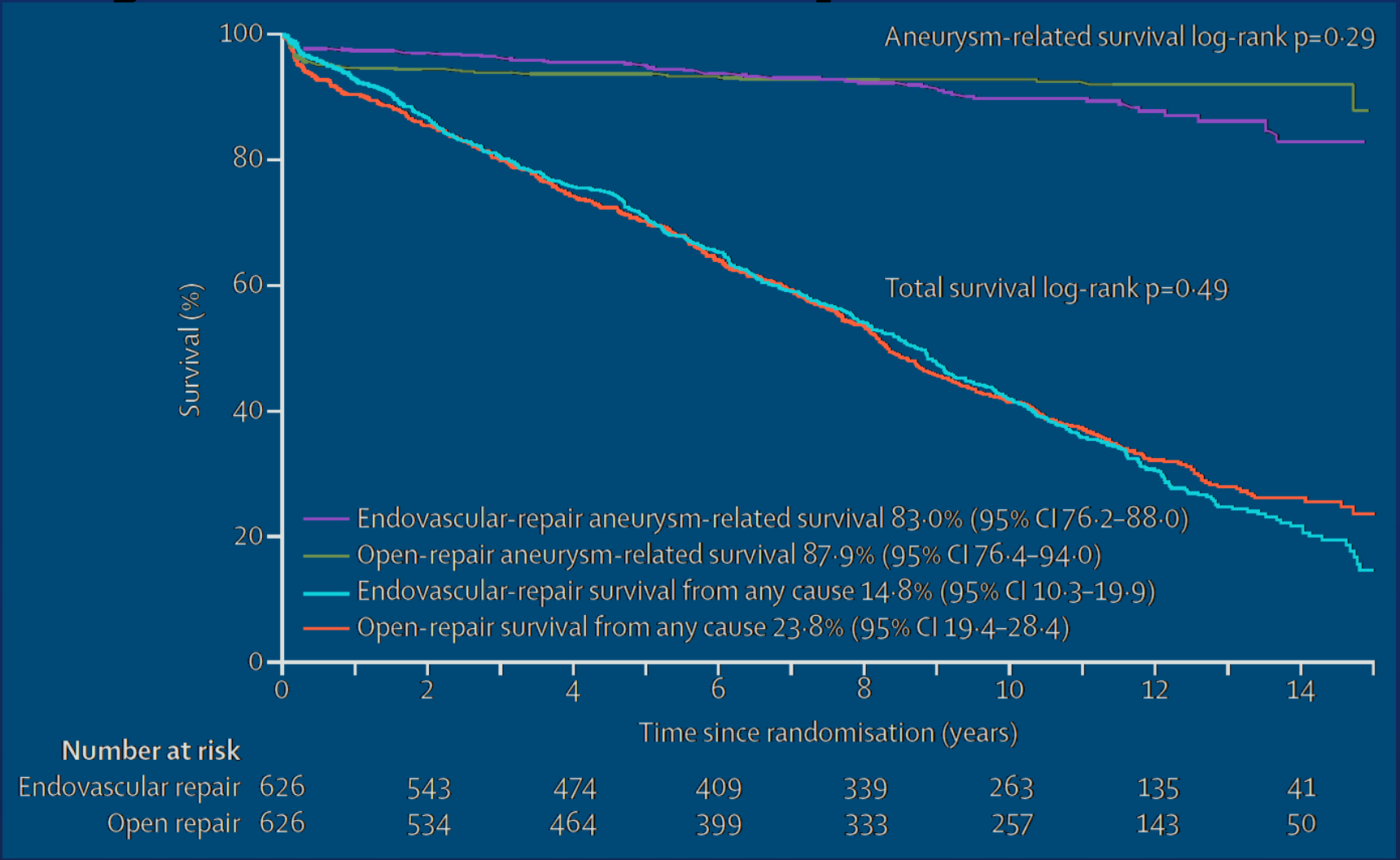
Long-term Outcomes of EVAR 1

Complication or Reintervention

	EVAR (n=626)	Open (n=626)	P value
Any death			
all patients	12.6(282)	2.5(78)	<0.001
Time since random			
0-6 mo	48.7(132)	15.6(45)	<0.001
> 6 mo – 4yr	9.0(114)	1.1(18)	<0.001
> 4yr	5.1(36)	1.4(15)	<0.001
Aneurysm related death			
all patients	5.1(145)	1.7(55)	<0.001
Time since random			
0-6 mo	22.9(66)	13.8(40)	0.007
> 6 mo – 4yr	3.4(55)	0.3(6)	<0.001
> 4yr	2.4(24)	0.8(9)	0.003

Lancet 2004;364:843

15 years follow-up of EVAR 1



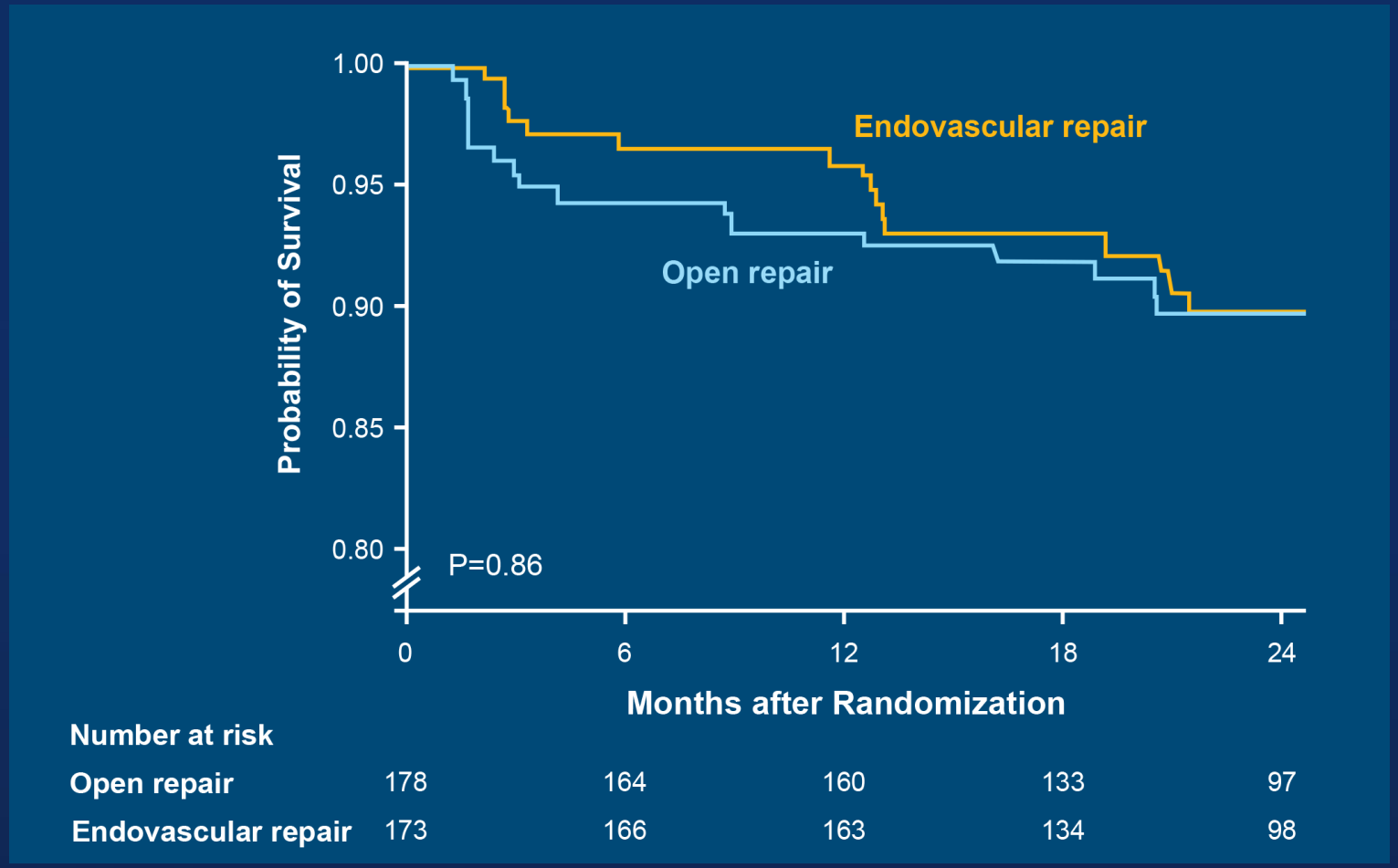
Lancet 2016; 388: 2366-74

DREAM Trial

	EVAR	OPEN
30 Day Mortality	1.2 %	4.6 %
Combined Op Mortality & Complications	4.7 %	9.8 %

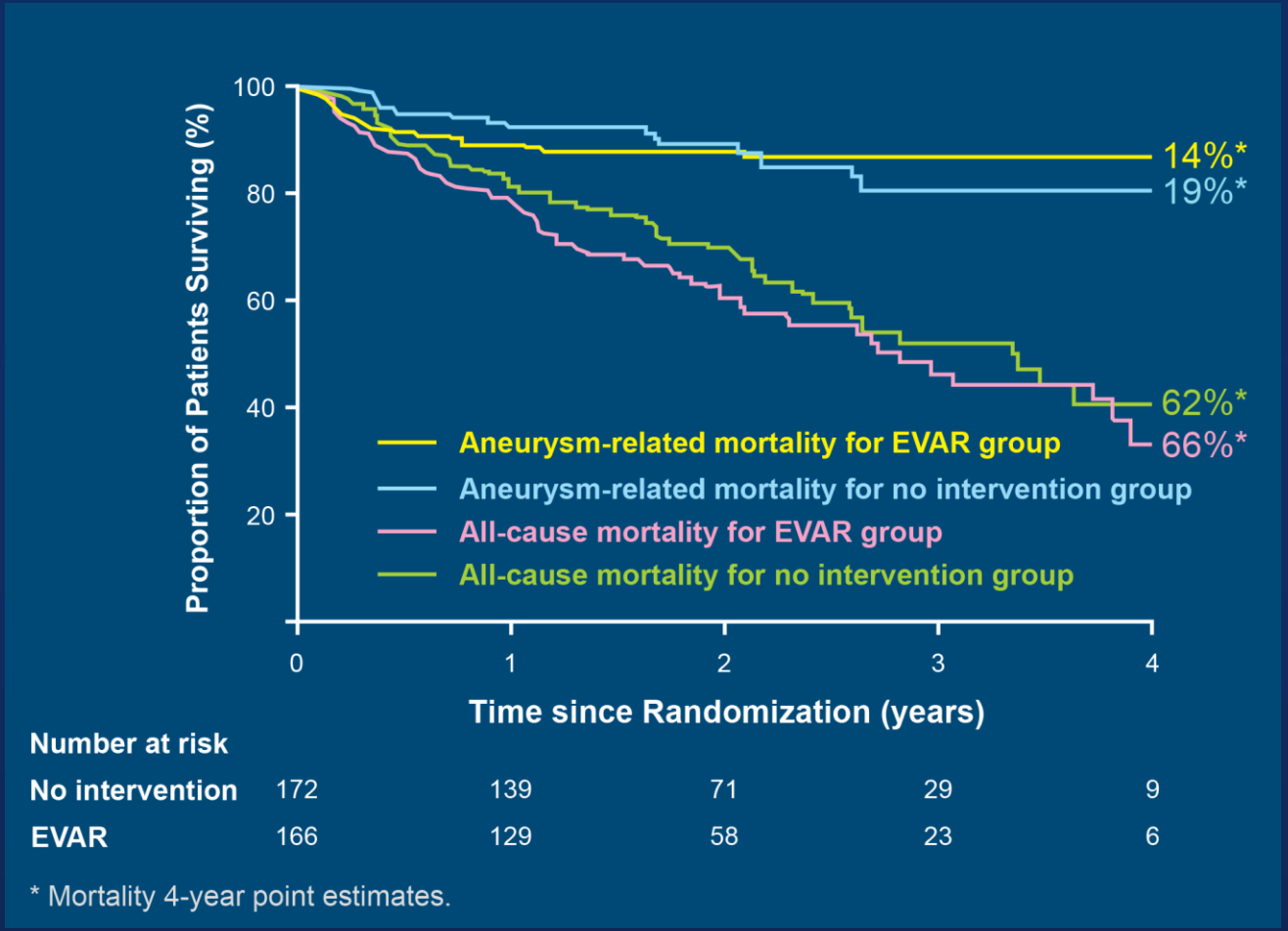
N Engl J Med 2004;351:1607

DREAM Trial: Mortality Results



N Engl J Med 2005;352:2398

EVAR 2 Trial: Survival Curve



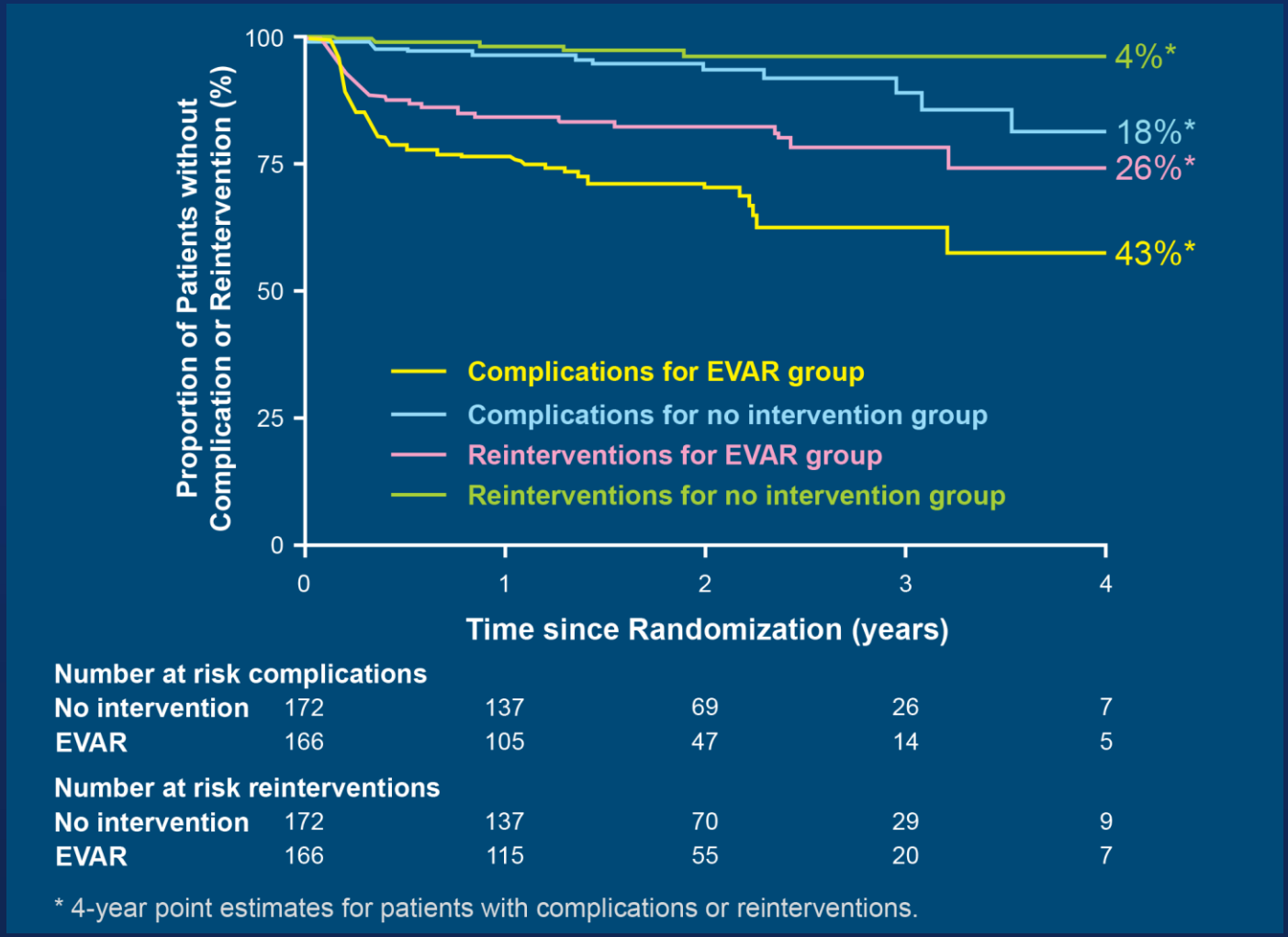
Number at risk					
No intervention	172	139	71	29	9
EVAR	166	129	58	23	6

* Mortality 4-year point estimates.

Lancet 2005;365:2187

EVAR 2 Trial

Complications and Reinterventions



Number at risk complications					
No intervention	172	137	69	26	7
EVAR	166	105	47	14	5
Number at risk reinterventions					
No intervention	172	137	70	29	9
EVAR	166	115	55	20	7

* 4-year point estimates for patients with complications or reinterventions.

Lancet 2005;365:2187

Small vs Large AAA

Clinical Outcomes following EVAR

	Small < 5.5 cm	Large > 5.5 cm
Type 1 Endoleak	1.4 %	6.4 %
Migration	4.4 %	13 %
Conversion	1.4 %	8.2 %
Aneurysm Related Death	1.5 %	6.1 %
Survival (24 months)	86 %	71 %

J Vasc Surg 2003;37:1206

Conclusions Regarding EVAR for Small vs Large AAA

- Outcomes of EVAR influenced by AAA size
- Differences important in choosing observation or repair
- It is important to balance risk for rupture with size dependent outcome: results of trials pending

J Vasc Surg 2003;37:1206

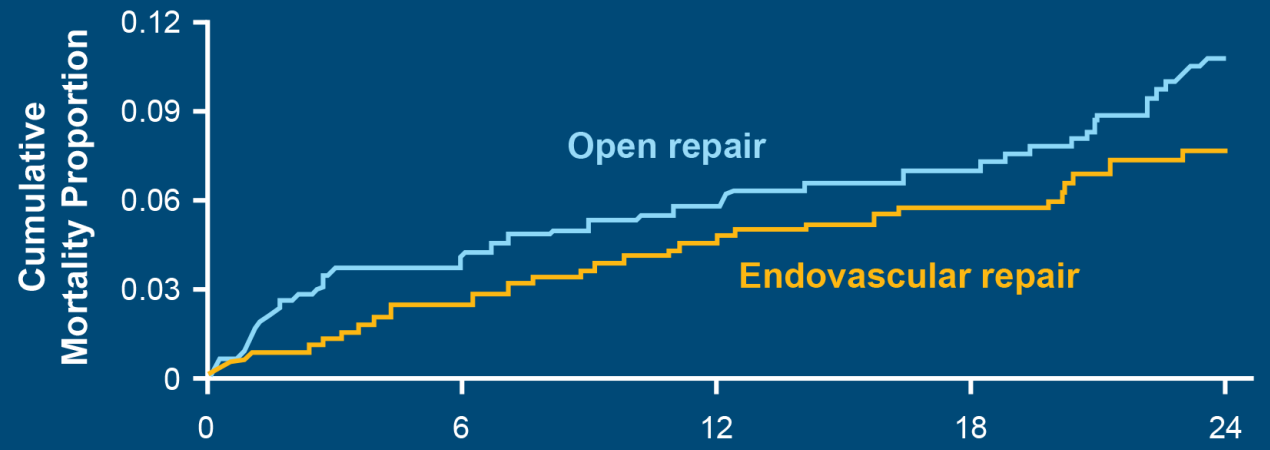
Outcomes of OVER Trial

	EVAR (n=444)	Open Repair (n=437)	P value
All cause mortality	31(7.0)	43(9.8)	0.13
Before AAA repair	2(0.5)	1(0.2)	>0.99
Within 30d after repair	1(0.2)	10(2.3)	0.006
Within 30d after repair or during hospitalization	2(0.5)	13(3.0)	0.004
- AAA diameter < 5.5cm	1(0.5)	5(2.6)	0.10
- AAA diameter >5.5cm	1(0.4)	8(3.2)	0.02
After 30d or hospitalization	27(6.1)	29(6.6)	0.74

JAMA. 2009;302(14):1535

Outcomes of OVER Trial

All-cause mortality at 2 years



Number at risk					
Open repair	437	420	396	363	310
Endovascular repair	444	433	411	371	326

hazard ratio,0.7;95% confidence interval, 0.4-1.1; log-rank *P=0.13*

JAMA. 2009;302(14):1535

Long-term Comparison of Endovascular and Open Repair of Abdominal Aortic Aneurysm (OVER trial)

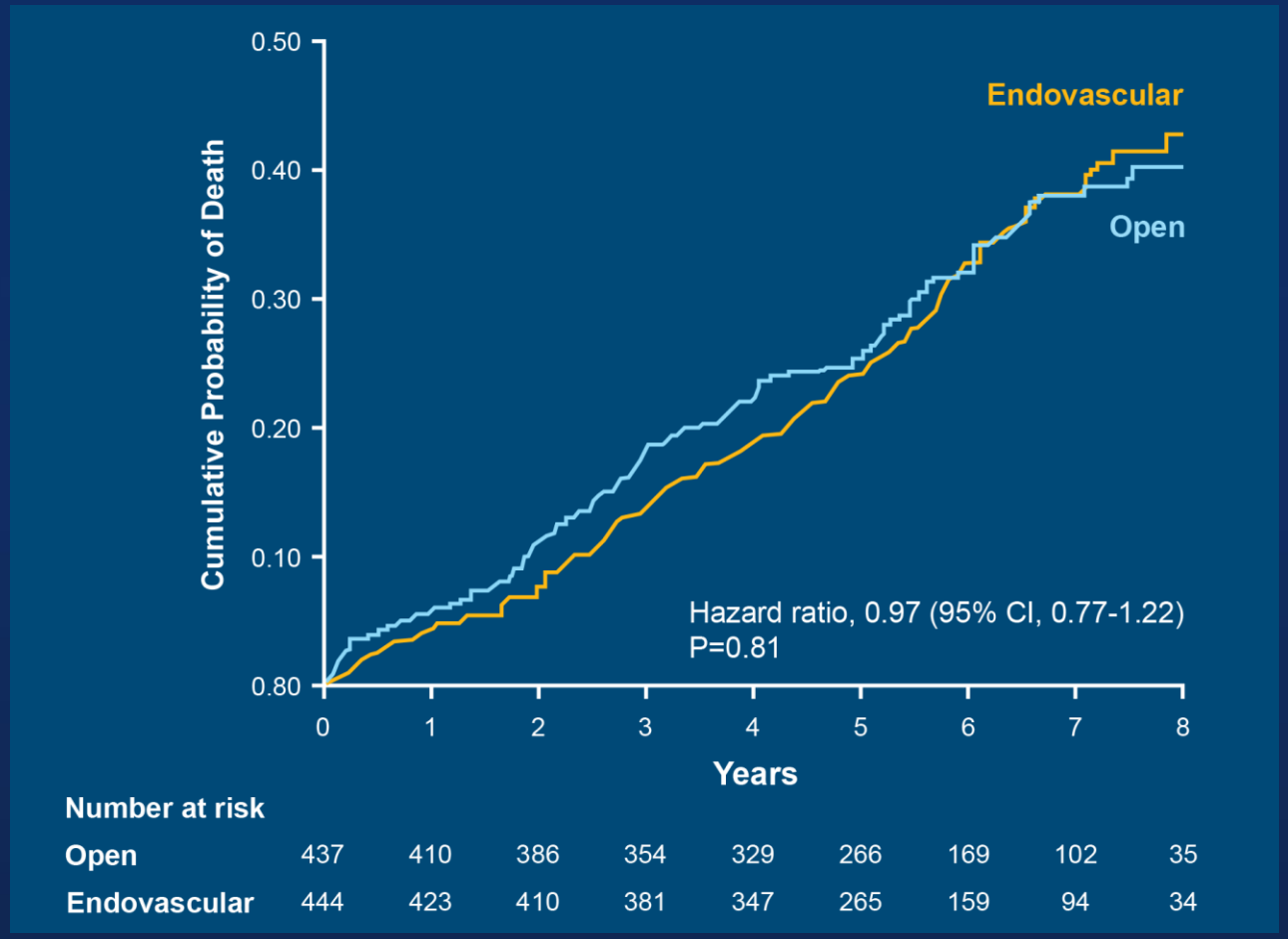
Mortality: Endovascular vs. Open Repair	HR	95% CI	*P* Value
At 2 Years	0.63	0.40-0.98	0.04
At 3 Years	0.72	0.51-1.00	0.05
At 8 Years[a]	0.97	0.77-1.22	0.81

[a] Kaplan-Meier estimate.

EVAR, Lower mortality through 3 years,
Long-term survival is similar

N Engl J Med. 2012;367:1988

Long-term Comparison of Endovascular and Open Repair of Abdominal Aortic Aneurysm (OVER trial)



N Engl J Med. 2012;367:1988

Open vs. Endovascular Stent Graft Repair of AAA: A Meta-analysis of Randomized Trials

Pooled data from 6 trials including 2,899 AAA patients treated either with EVAR (n = 1,470) or open surgery (n = 1,429)

At 30 days, all-cause mortality
Lower with EVAR (RR 0.35; 95% CI 0.19-0.64)

No difference at long-term follow-up (RR 0.99; 95% CI 0.85-1.15)

EVAR survival advantage,
Early and Intermediate follow-up
Similar mortality in the long term

JACC Intv. 2012;5:1071

A Randomized Controlled Trial of EVAR vs. Open Surgery for AAA in Low- to Moderate-Risk Patients

299 patients in the ACE trial
(Anévrysme de l'aorte abdominale: Chirurgie versus Endoprothèse) trial.

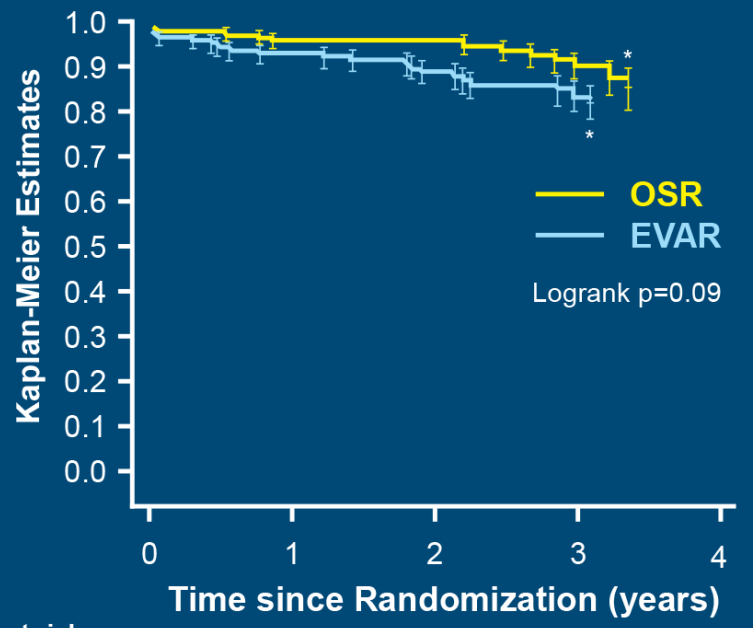
Median 3-Year Follow-up	Open Repair (n = 149)	EVAR (n = 150)	*p* Value
Death	8%	11.3%	NS
Major Adverse Events	4%	6.7%	NS
Reintervention	2.7%	16%	< 0.0001

Similar long-term mortality and complications.
Higher reintervention with EVAR

J Vasc Surg 2011;53:1167.

A Randomized Controlled Trial of EVAR vs. Open Surgery for AAA in Low- to Moderate-Risk Patients

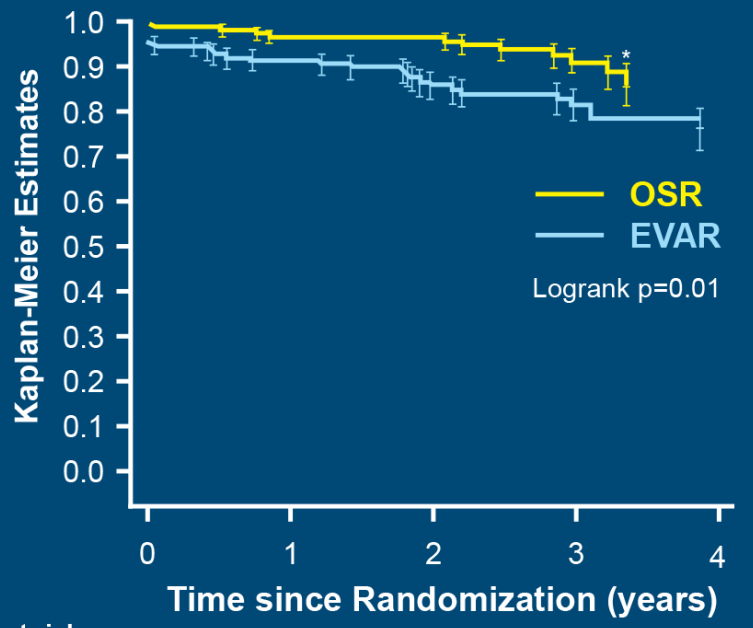
Death or Major Events



Number at risk					
OSR	149	132	116	68	19
EVAR	150	129	103	71	26

* SED exceeds 10%

Death or Reintervention



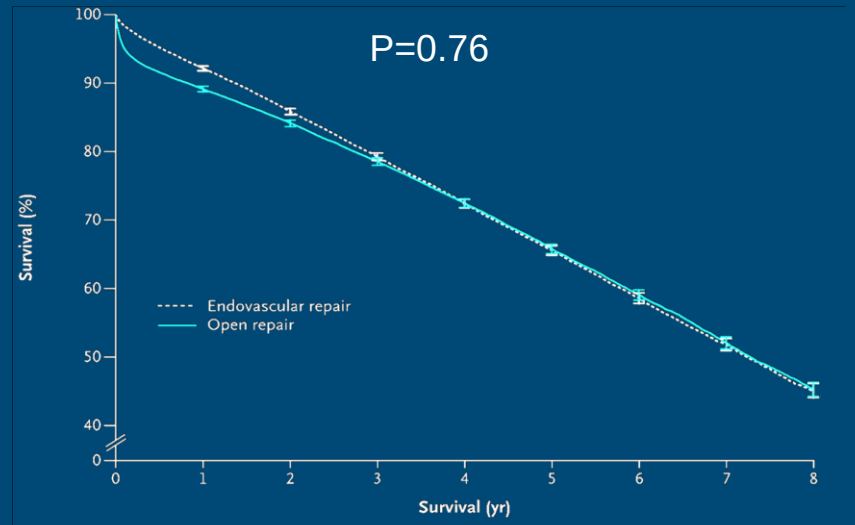
Number at risk					
OSR	149	132	116	68	19
EVAR	150	128	103	71	25

* SED exceeds 10%

J Vasc Surg 2011;53:1167

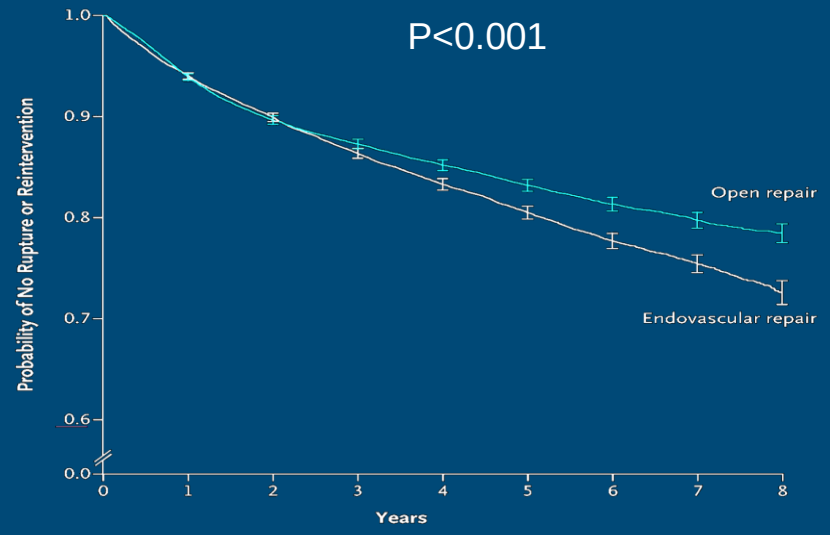
Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Overall survival



No. at Risk									
Endovascular repair	39,966	36,835	31,659	26,227	20,580	14,894	9693	5562	2176
Open repair	39,966	35,627	31,161	26,132	20,708	15,011	9761	5626	2237

Re-intervention or complication



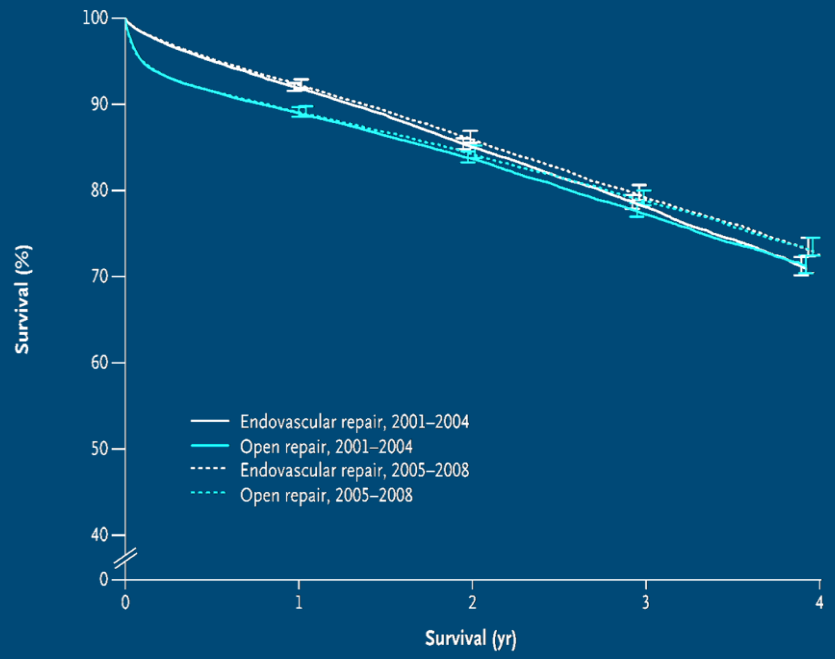
No. at Risk									
Endovascular repair	39,966	33,573	26,896	20,820	15,273	10,370	6353	3455	1286
Open repair	39,966	32,495	26,386	20,970	15,772	10,869	6783	3768	1427

Similar long-term mortality rate, but higher risk of re-intervention or hospitalization for complication with EVAR

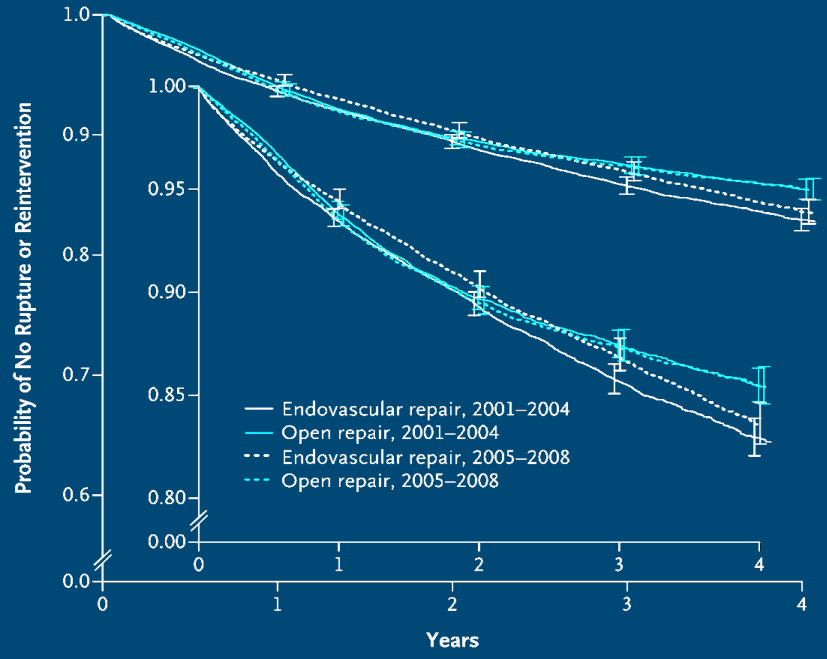
NEJM 2015;373:328

Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Overall survival



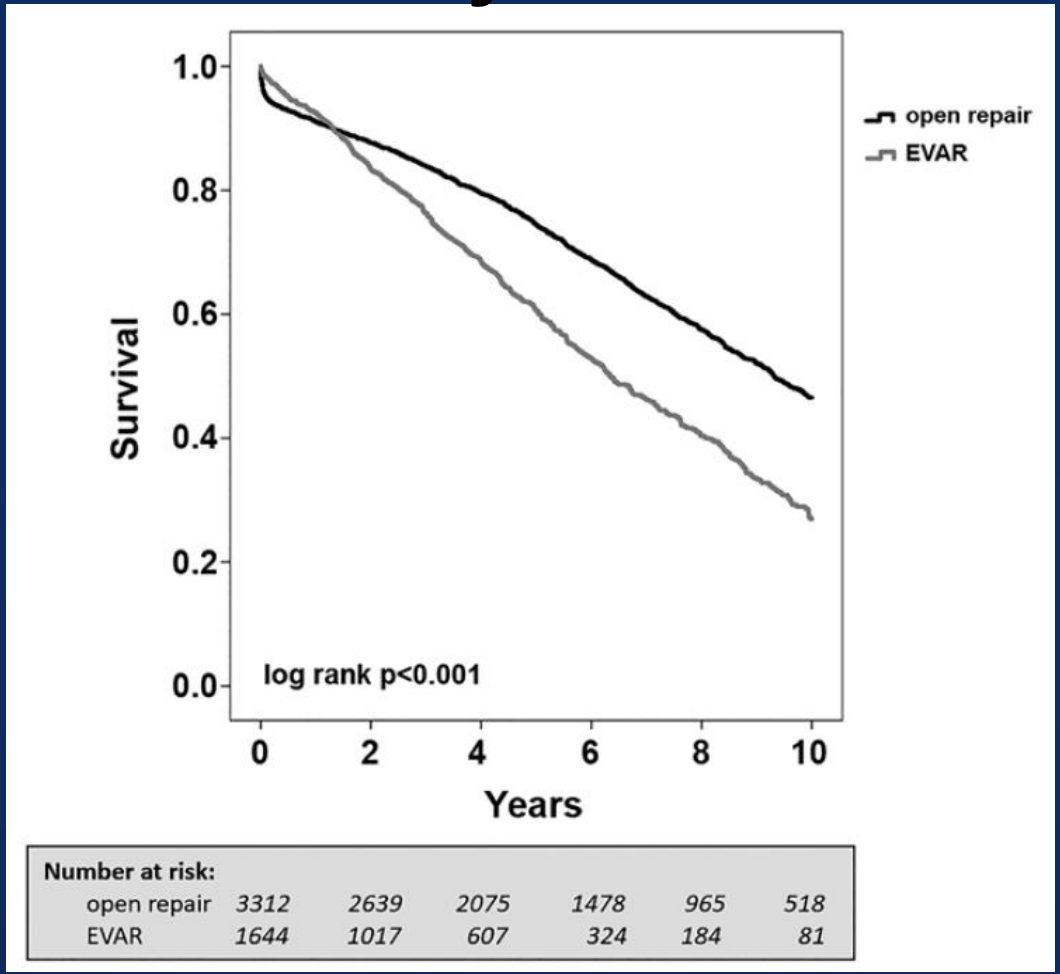
Re-intervention or complication



The outcomes of EVAR have been improving over time

NEJM 2015;373:328

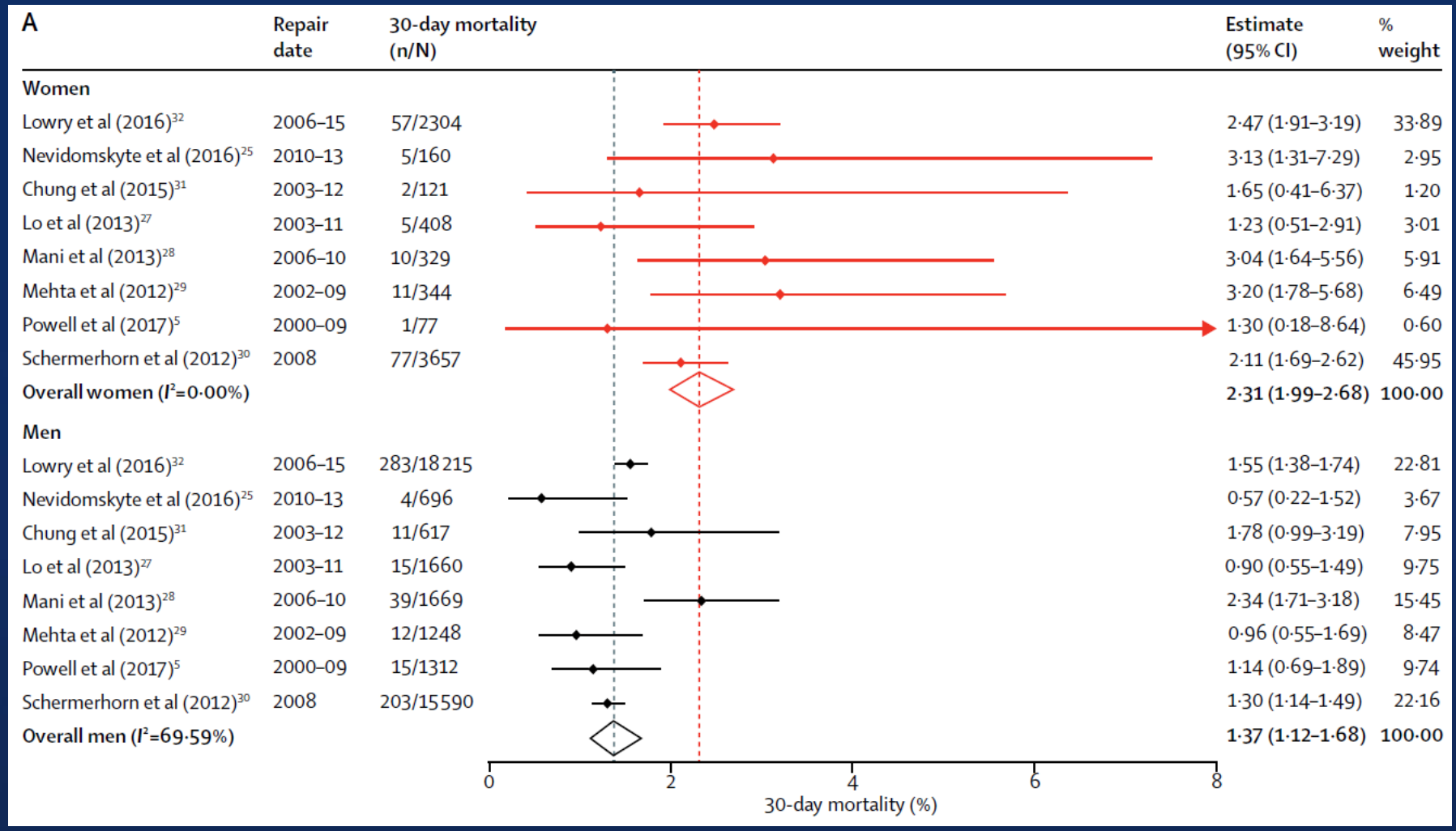
Population based 10 year survival in Finland



Higher 10-year mortality in EVAR,
BUT may have been exaggerated by patient selection

Circulation 2017;136:1726-1734

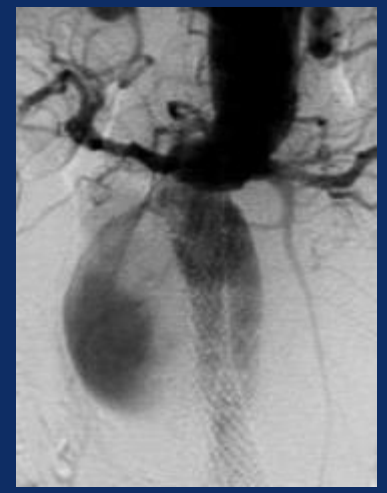
Outcome for sex in EVAR



Higher 30-day mortality in women

Lancet 2017;389: 2482-91

Aortic Endografts Current Limitations

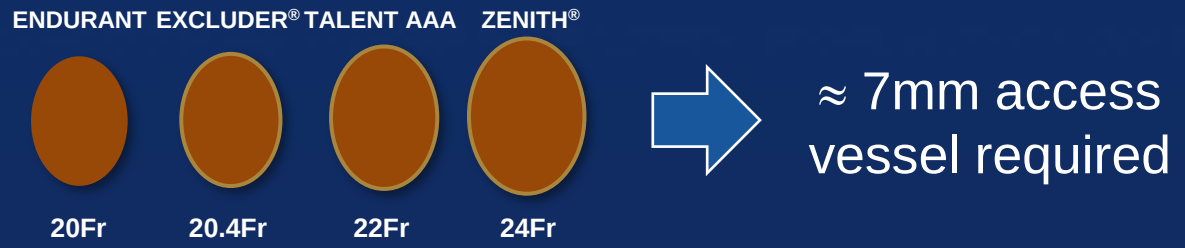


- Proximal neck diameters 18-32 mm
- Proximal neck lengths (supra and infra renal attachment) 5-15 mm
- Iliac artery size for delivery 6-9 mm
- Iliac artery attachment site diameter 8-20 mm
- Angle of neck to aneurysm <60°

Limitations of Current EVAR Devices

Access vessel morphology remain a limiting factor for EVAR application despite device improvements

Current delivery system profiles (O. D.)

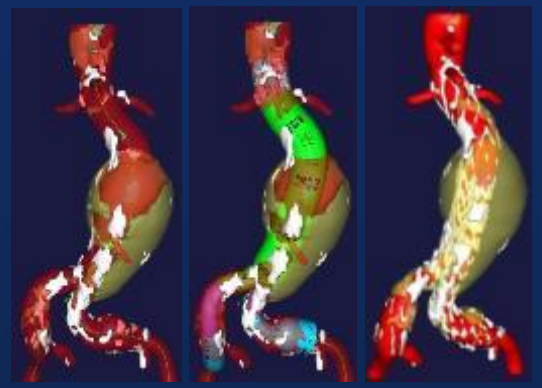


≈ 7mm access vessel required

6-19% of EVAR candidates are excluded due to small, tortuous and/or calcified access vessels

Eur J Vascular Endovascular Surgery 1999; 17:507
J Vascular Surgery, 2001; 34:1050
J Endovascular Therapy, 2004; 11:33

Limitations of Current EVAR Devices



Deployment accuracy remains a problem despite major advancements in imaging techniques:

- Proximal placement accuracy indicators

Event	EUROSTAR	DREAM	EVAR1
Unintentional Renal Artery Coverage		1.8%	
Acute Proximal Extension Utilization Rate	3.9%		2.8%

- Distal placement accuracy indicators

Event	EUROSTAR	DREAM	EVAR1
Unintentional Internal Iliac Artery Coverage		5.7%	
Acute Distal Extension Utilization Rate	22.2%		16.6%

N Engl J Med, 2004; 351:1607
Lancet, 2005; 365:2179
J Vascular Surgery, 2007; 45:79

Long-term Survival After Open vs EVAR of Intact AAA Among Medicare Beneficiaries

Retrospective analysis of 703 patients who received EVAR vs 3,826 who received surgery between 2003 and 2007.

2.6-Year Mean Follow-up, Open Repair vs. EVAR	Adjusted HR (95% CI)	*P* Value
All-Cause Mortality	1.24 (1.05-1.47)	0.01
AAA-Specific Mortality	4.37 (2.51-7.66)	< 0.001

Early survival advantage for EVAR persisted

JAMA. 2012;307:1621

Results of EVAR with General, Regional and Local/Monitored Anesthesia Care

Analysis of 6,009 procedures from the National Surgical Quality Improvement Program database.

General anesthesia

- Increased pulmonary morbidity
- Increases in length of stay of 10% and 20%
- Does not increase 30-day mortality

Less-invasive anesthetic techniques may limit postoperative complications decrease the overall costs of EVAR

J Vasc Surg. 2011 Nov;54(5):1273

Ruptured AAA

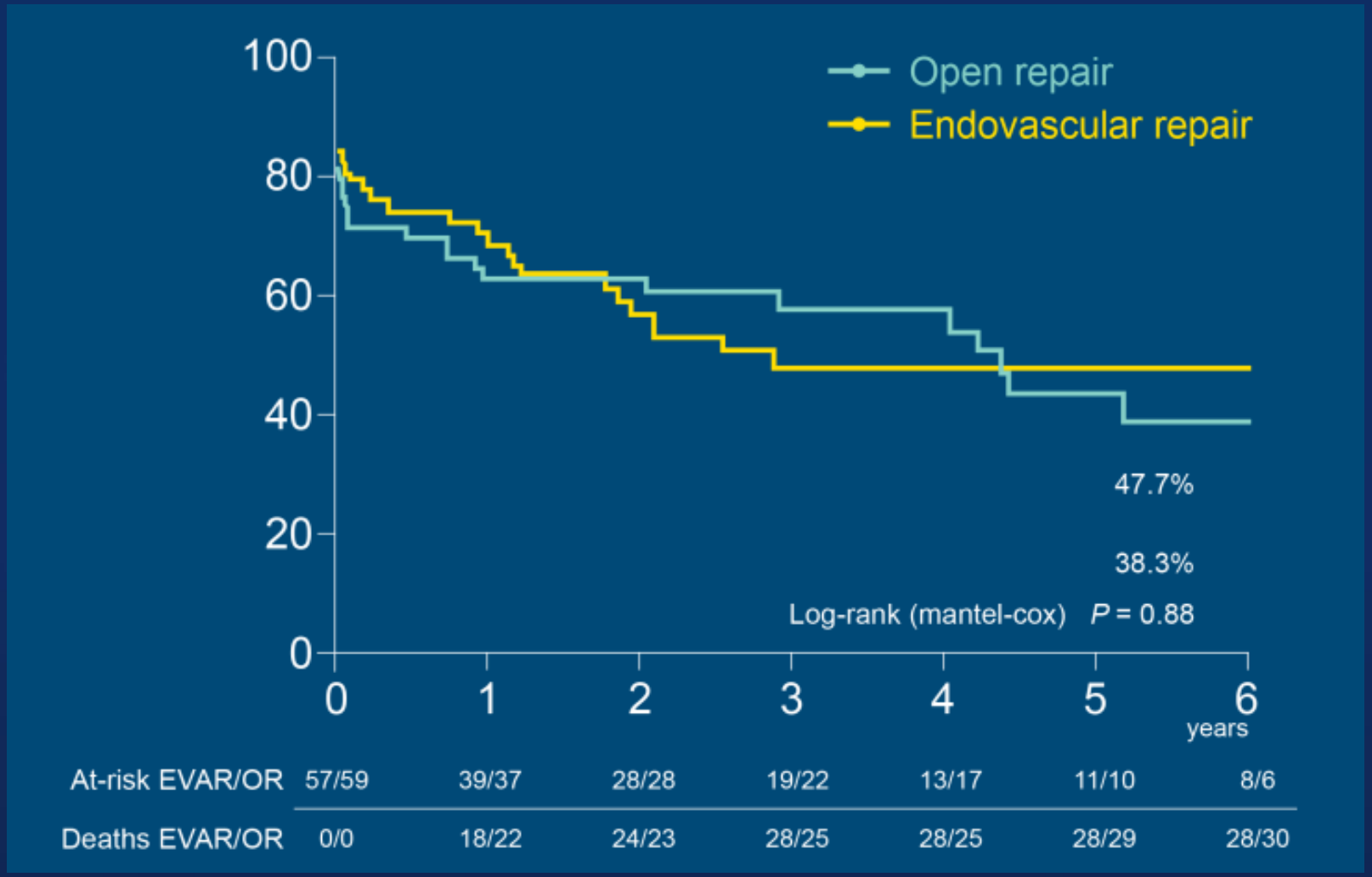
✓ With a RAAA of which 116 could be randomized.

- Primary endpoint
  Death and severe complications at 30 days.
  EVAR 42% vs OR 47%
  (ARR = 5.4%; 95% CI : −13% to +23%)

- The 30-day mortality
  EVAR 21% vs OR 25%
  (ARR = 4.4%; 95% CI:−11% to +20%)

Ann Surg 2013;258: 248

Ruptured AAA



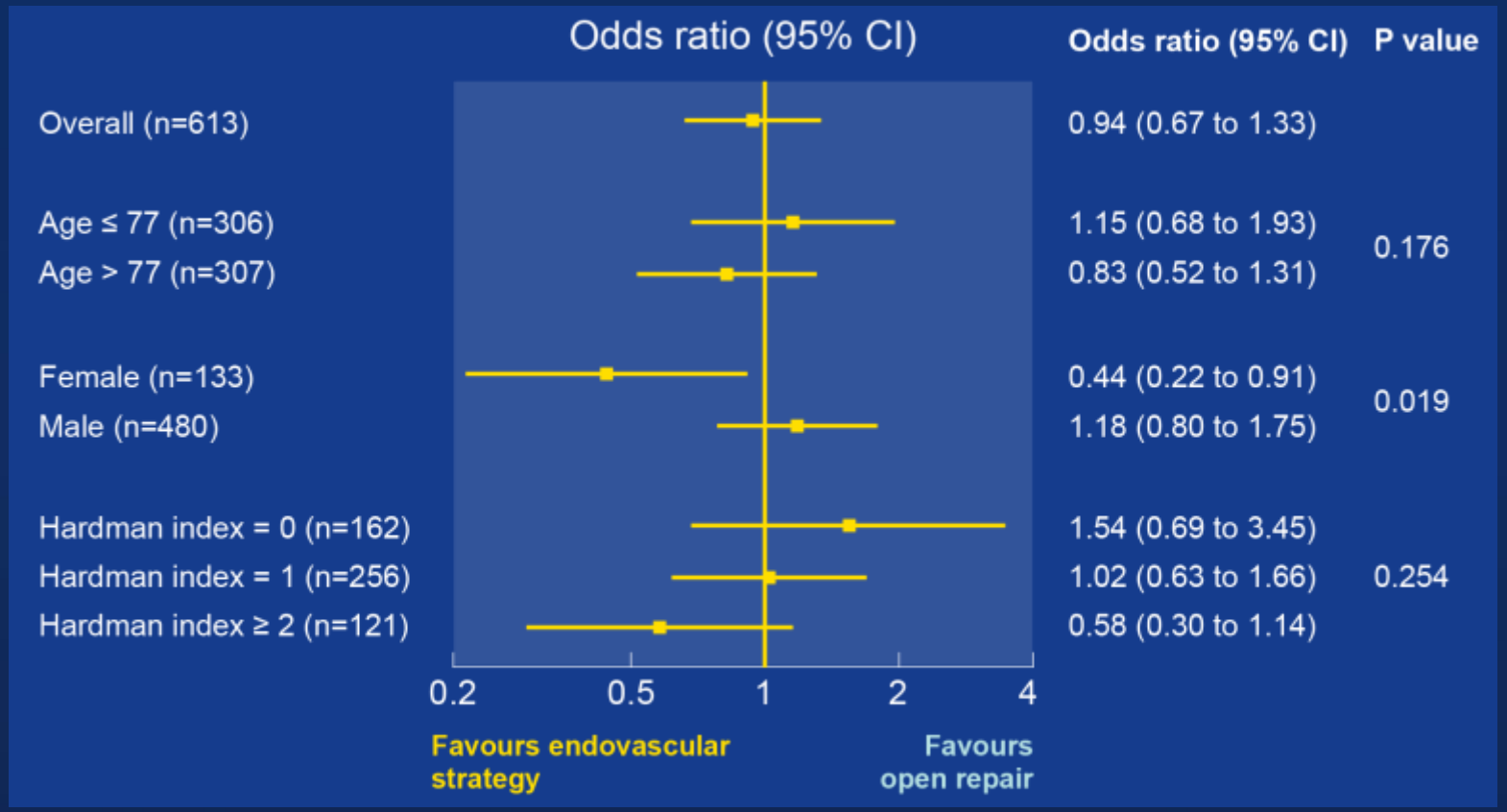
Ann Surg 2013;258: 248

IMPROVE randomized trial

- ✓ Now ongoing
- ✓ Suspected ruptured AAA
- ✓ EVAR versus OR
- 613 eligible patients
  with clinical diagnosis of ruptured aneurysm
- 316 patients were randomized to EVAR
  (275 confirmed, 174 anatomically suitable)
- 297 patients were randomized to Open Repair
  (261 confirmed)

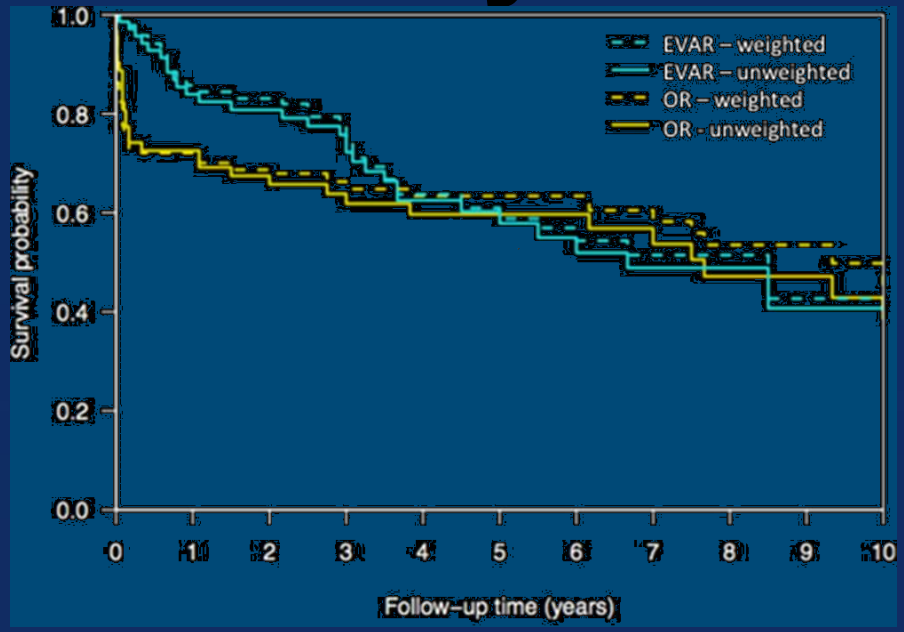
BMJ 2014;348:f7661

30 day mortality and subgroup analysis



BMJ 2014;348:f7661

EVAR for Mycotic AAA



	3-months	1-year	5-years	10-years
OR	72.8(65.9-80.5)	72.1(65.1-79.8)	63.4(55.5-72.5)	38.4(26.7-55.1)
EVAR	96.9(93.7-99.9)	85.8(79.4-92.6)	58.8(49.4-70.0)	42.7(31.8-57.2)
P-value	<0.001	0.110	0.687	0.782

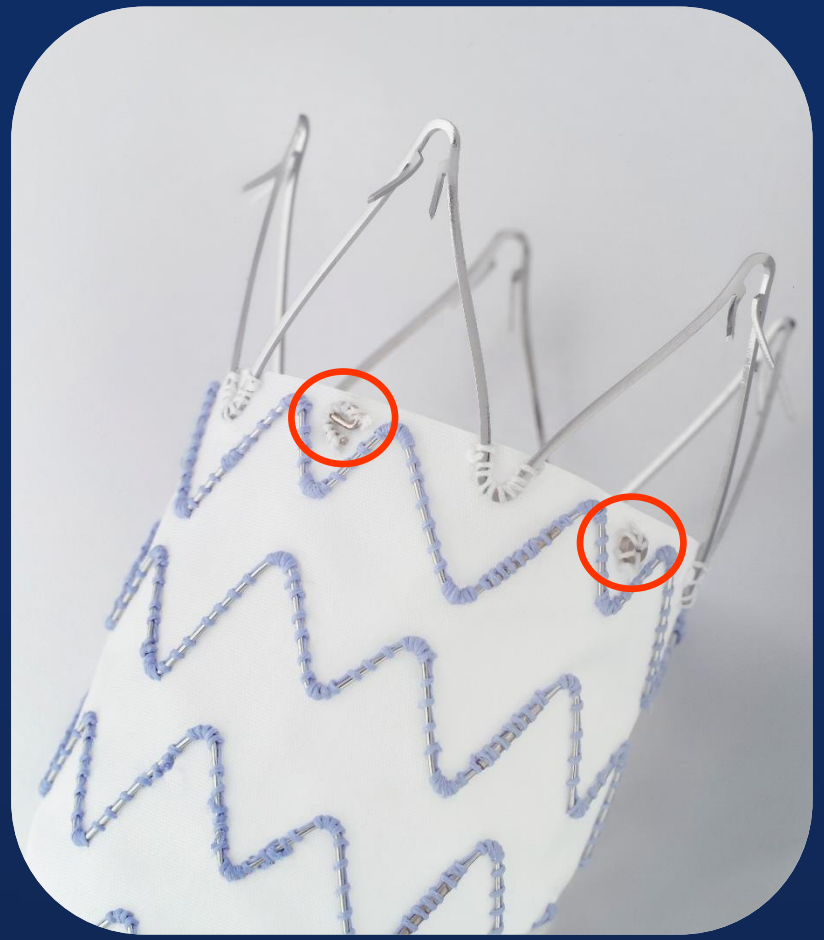
EVAR, Lower mortality for 3-months,
Long-term survival is similar

Circulation 2016;134:1822-1832

Procedure of EVAR

Match the proximal edge

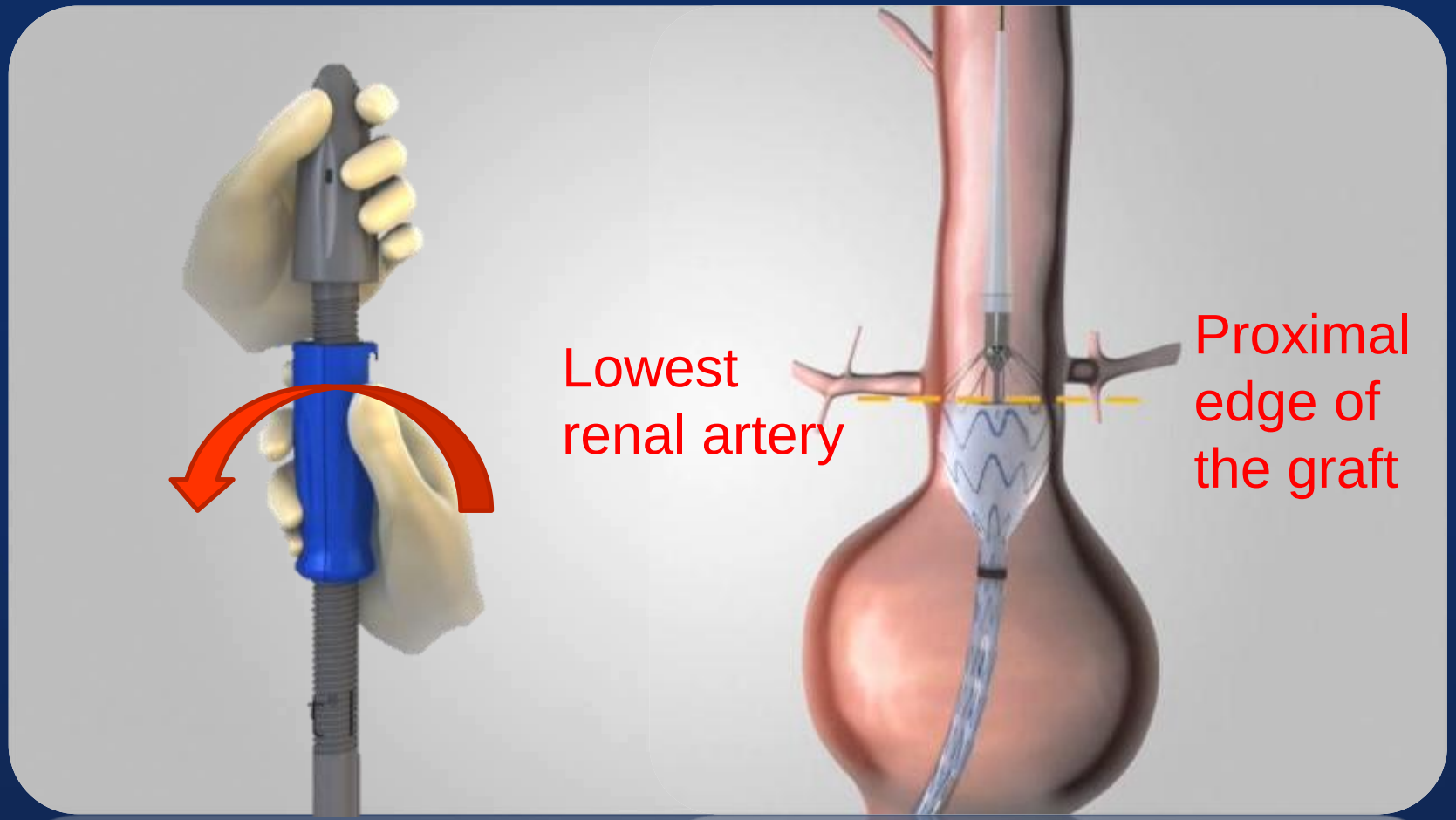
Match the proximal edge



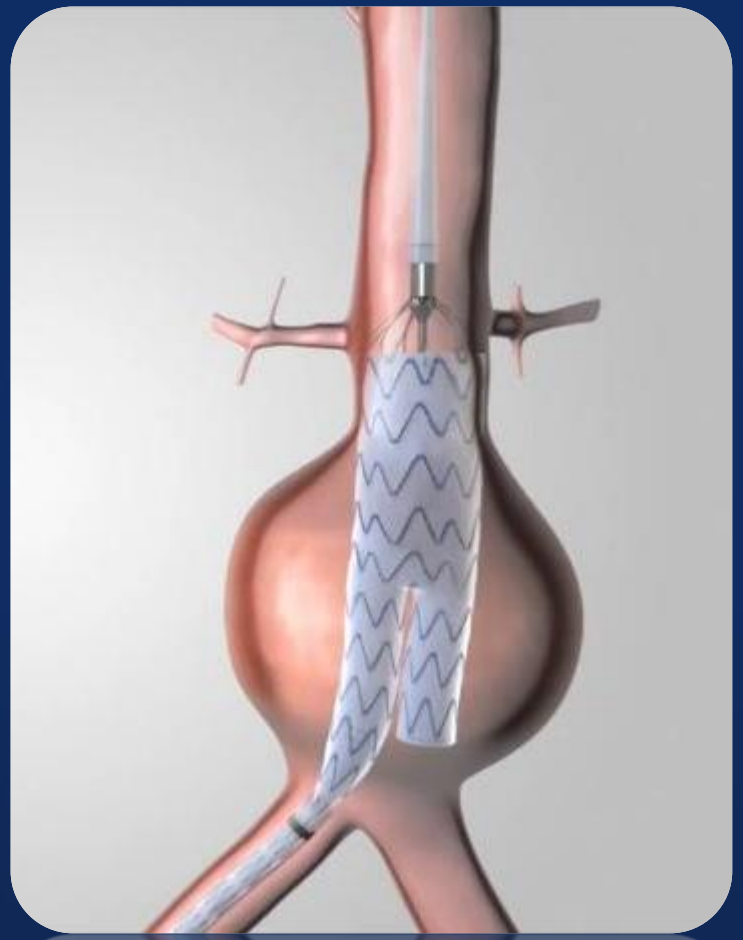
4 proximal radiopaque markers

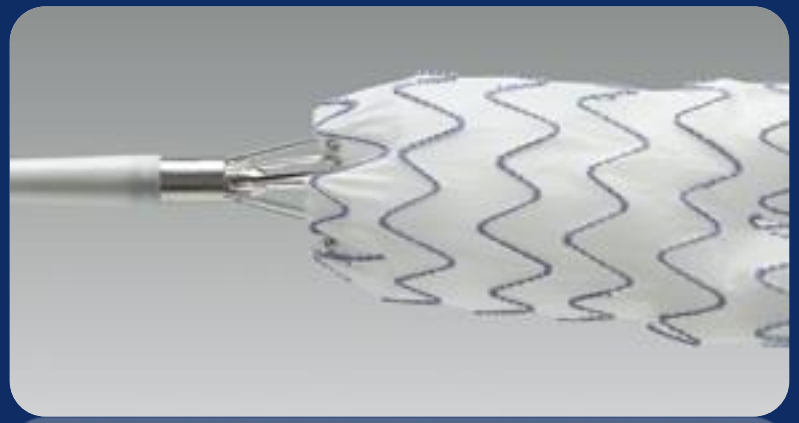
Proximal edge of stent graft
1mm above proximal markers

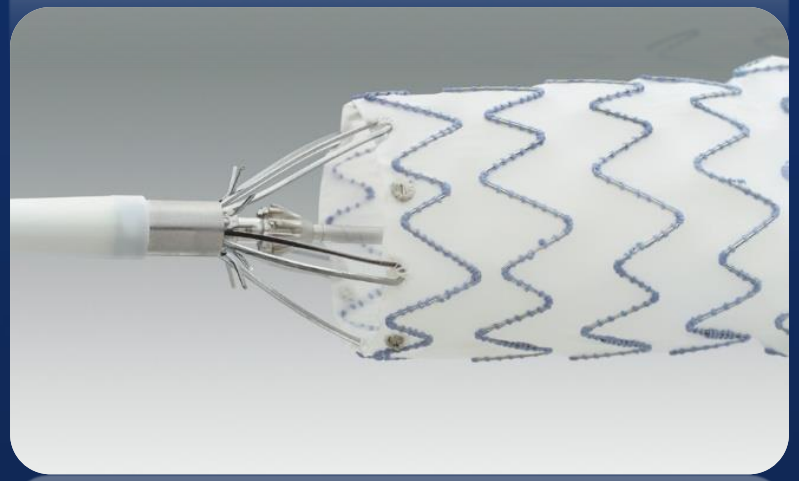
Match the proximal edge



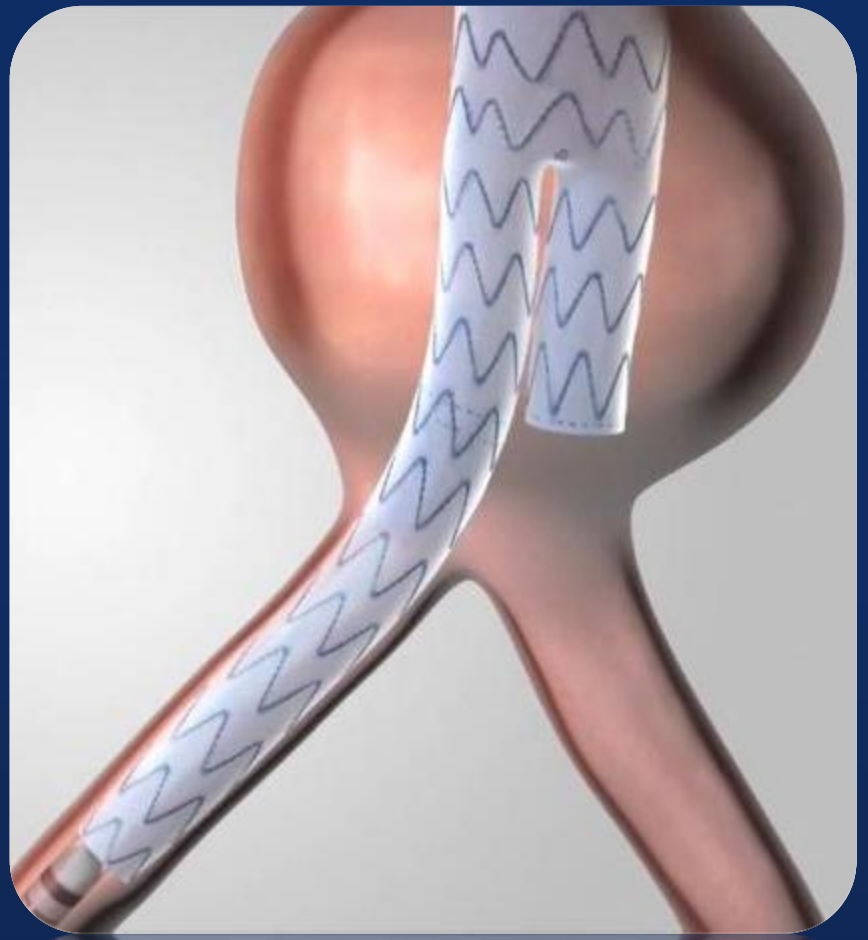
Deploy the stent

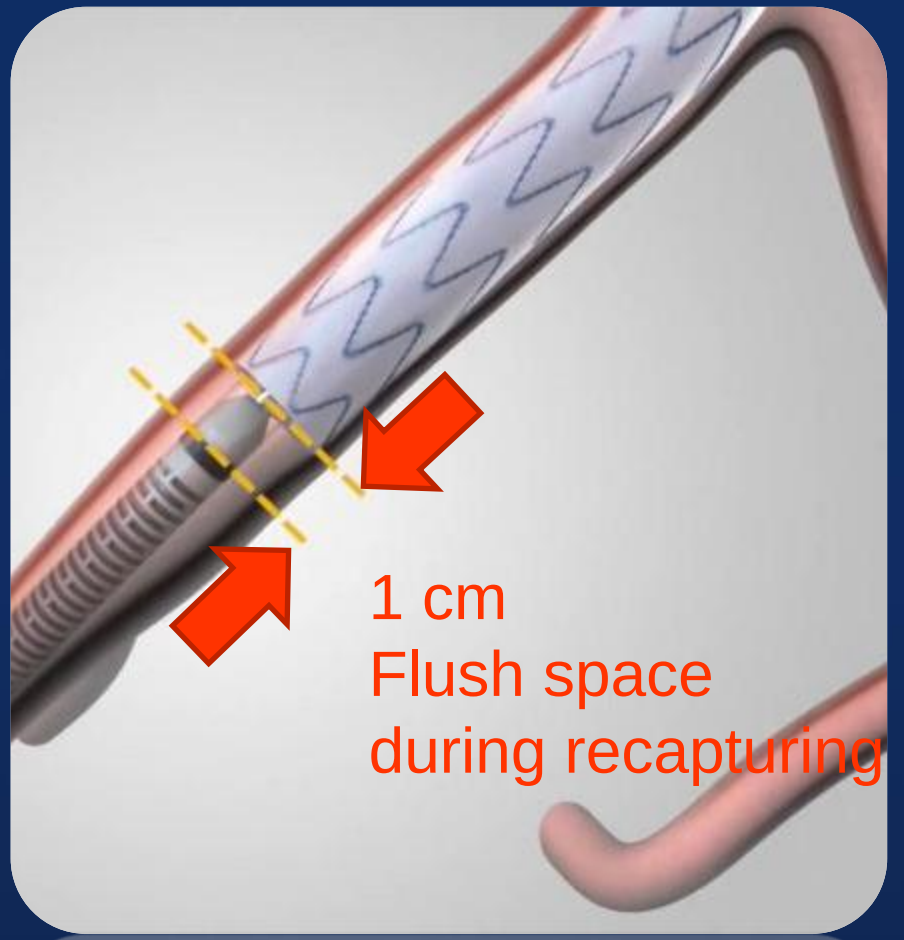




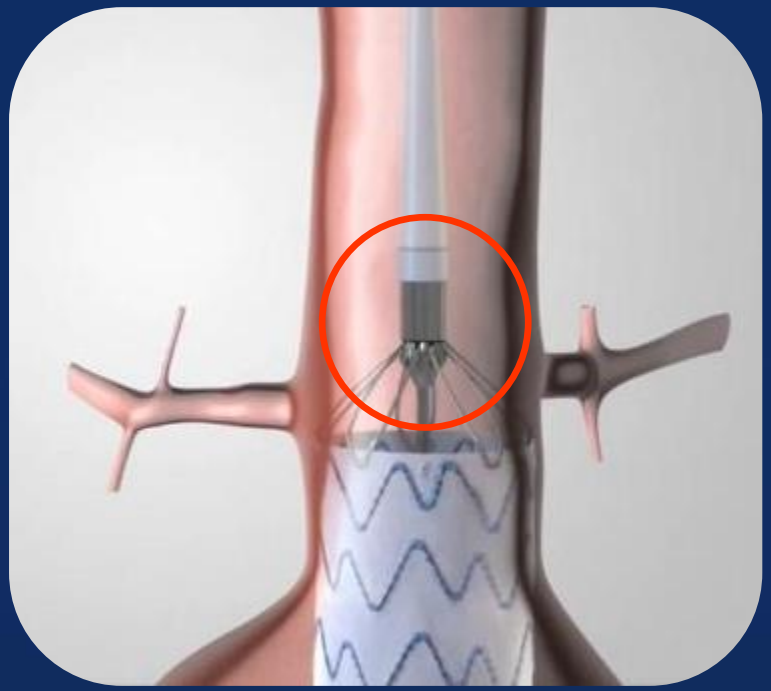


Deploy the ipsilateral limb stent

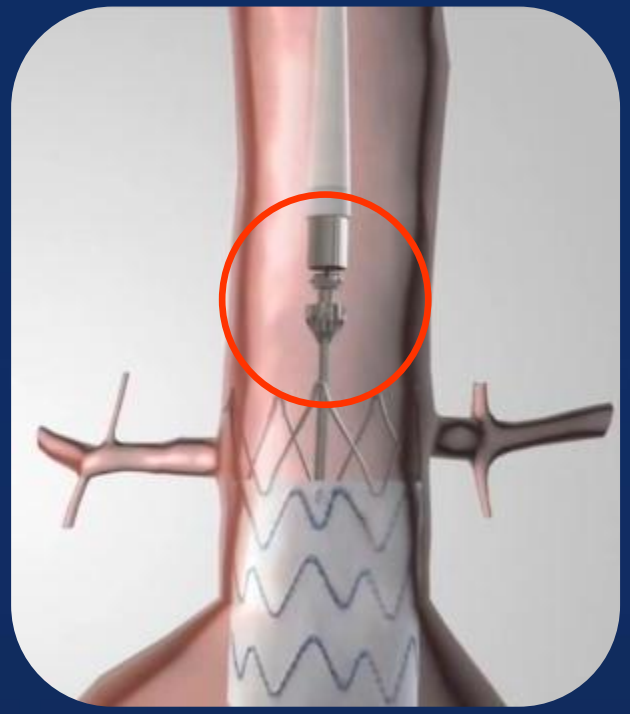


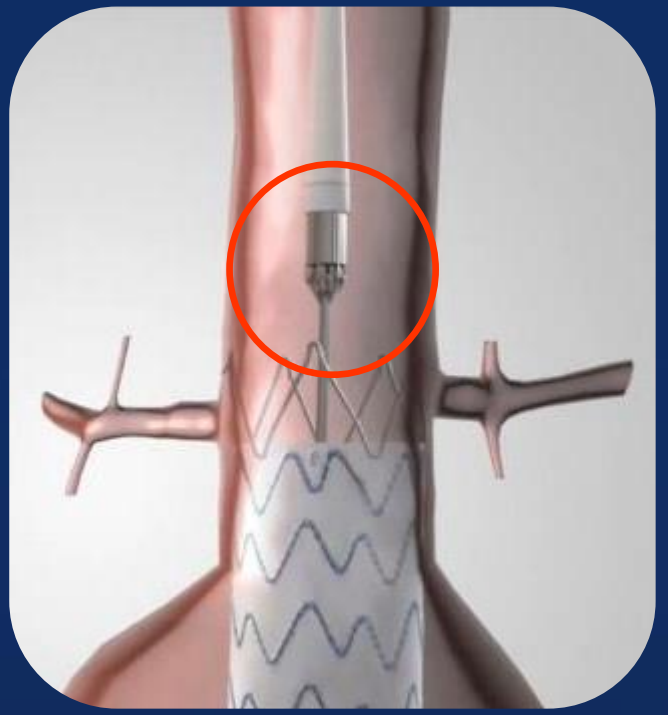


Release the suprarenal stent

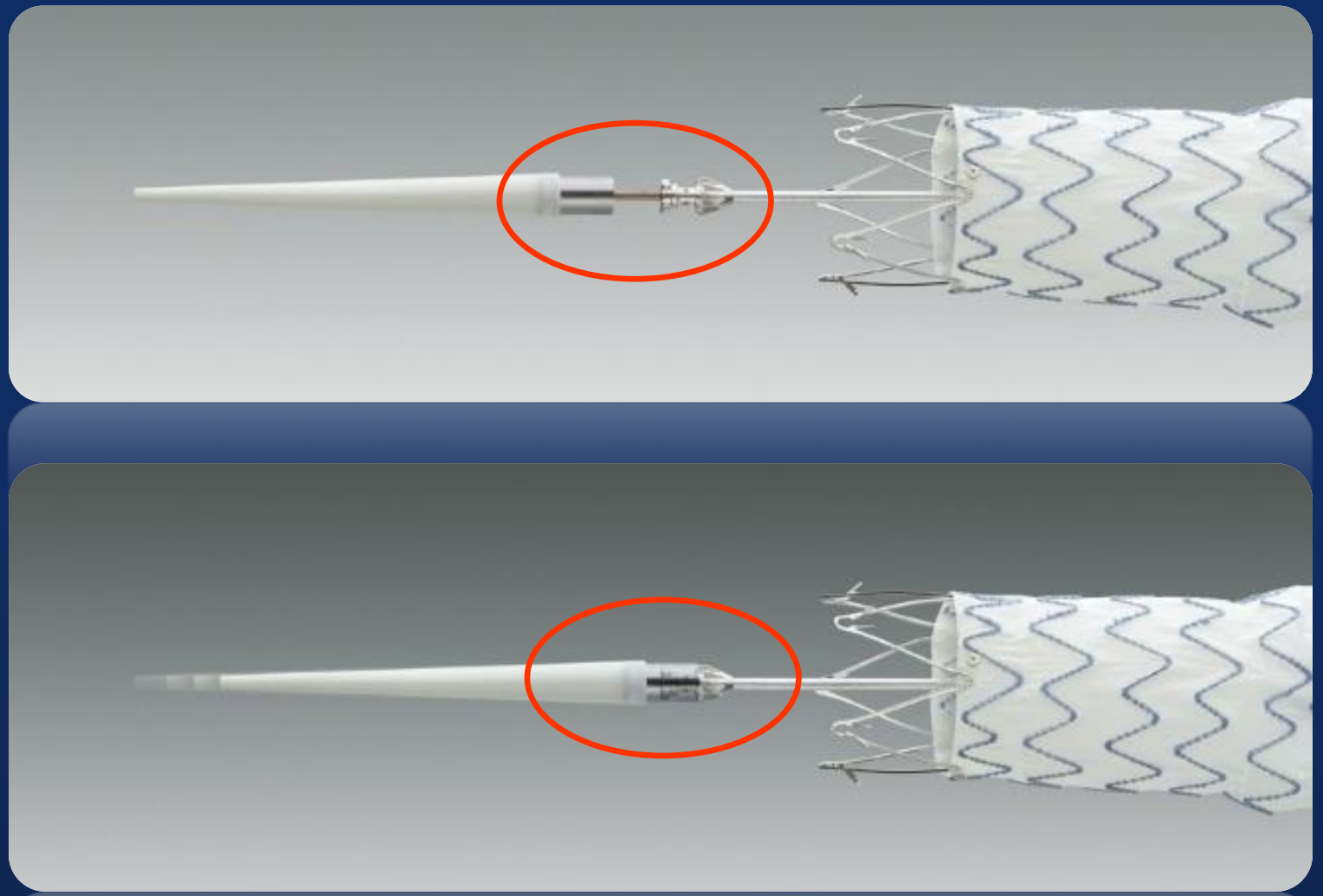


Recapturing the spindle

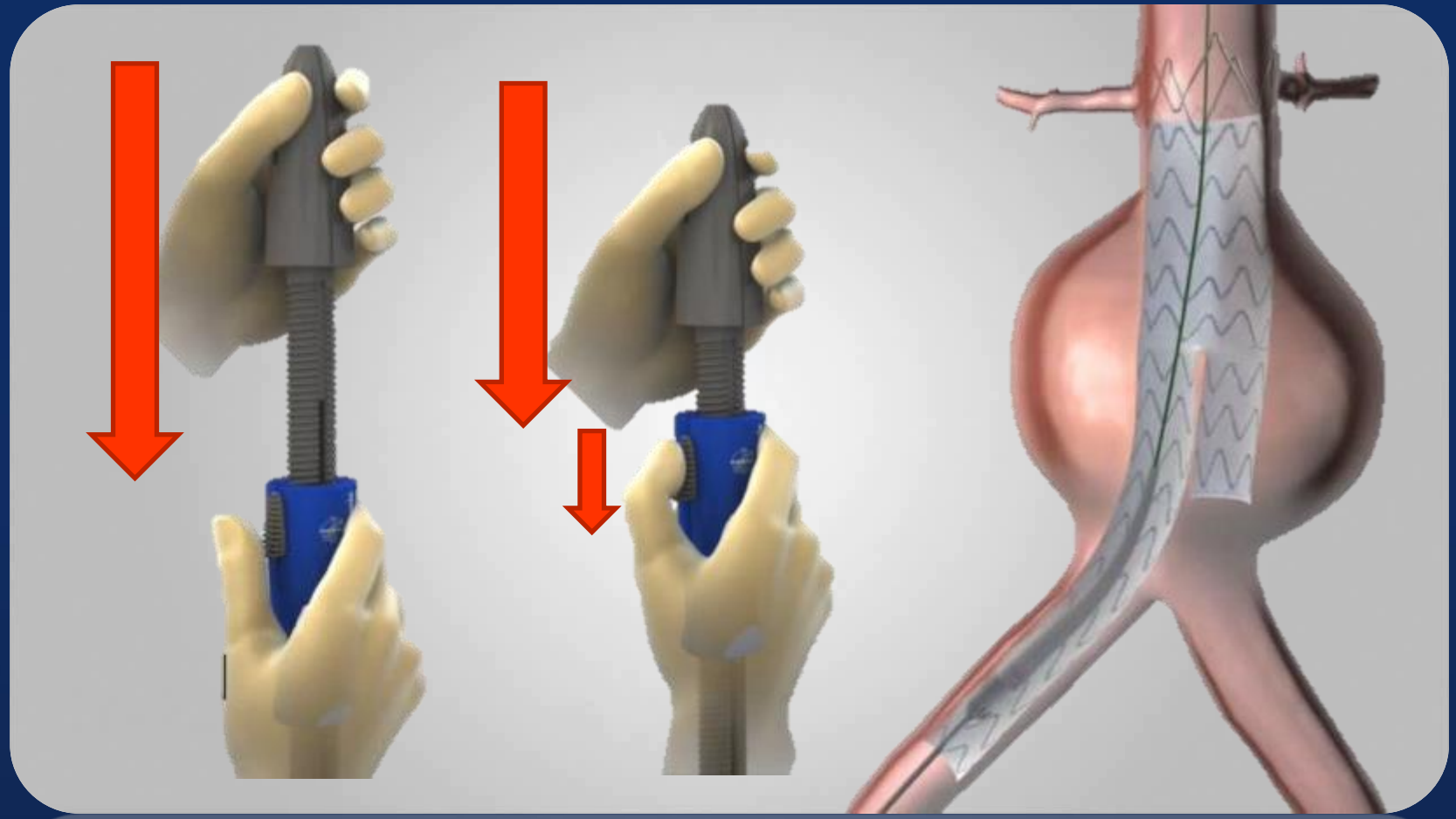




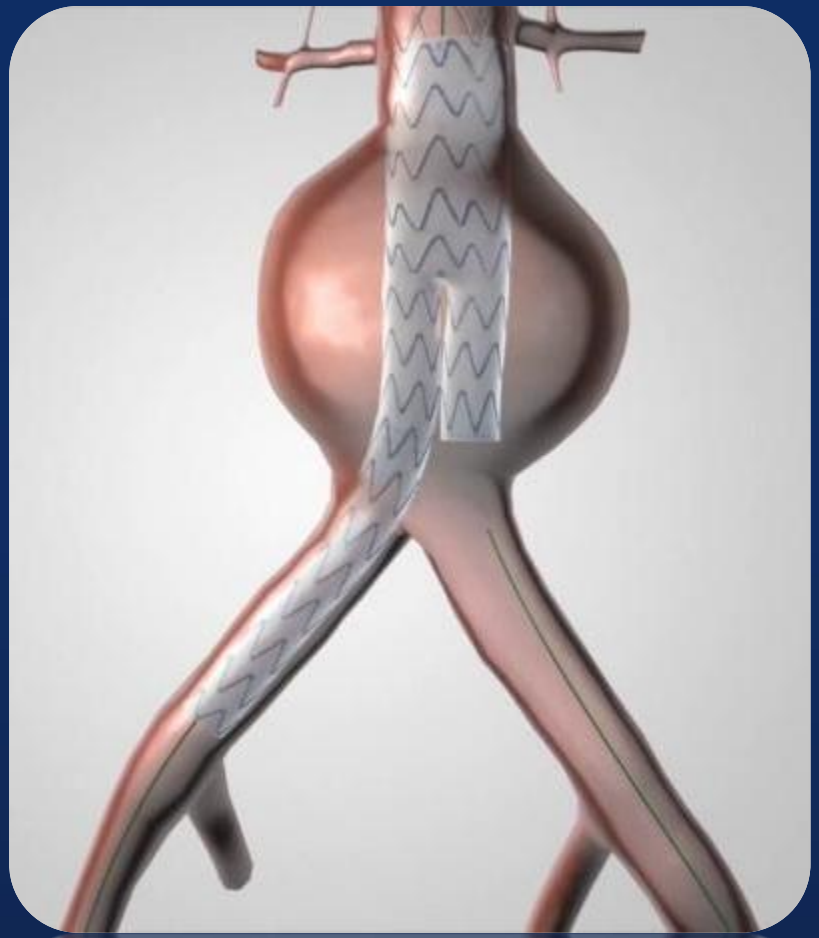
Recapturing the spindle

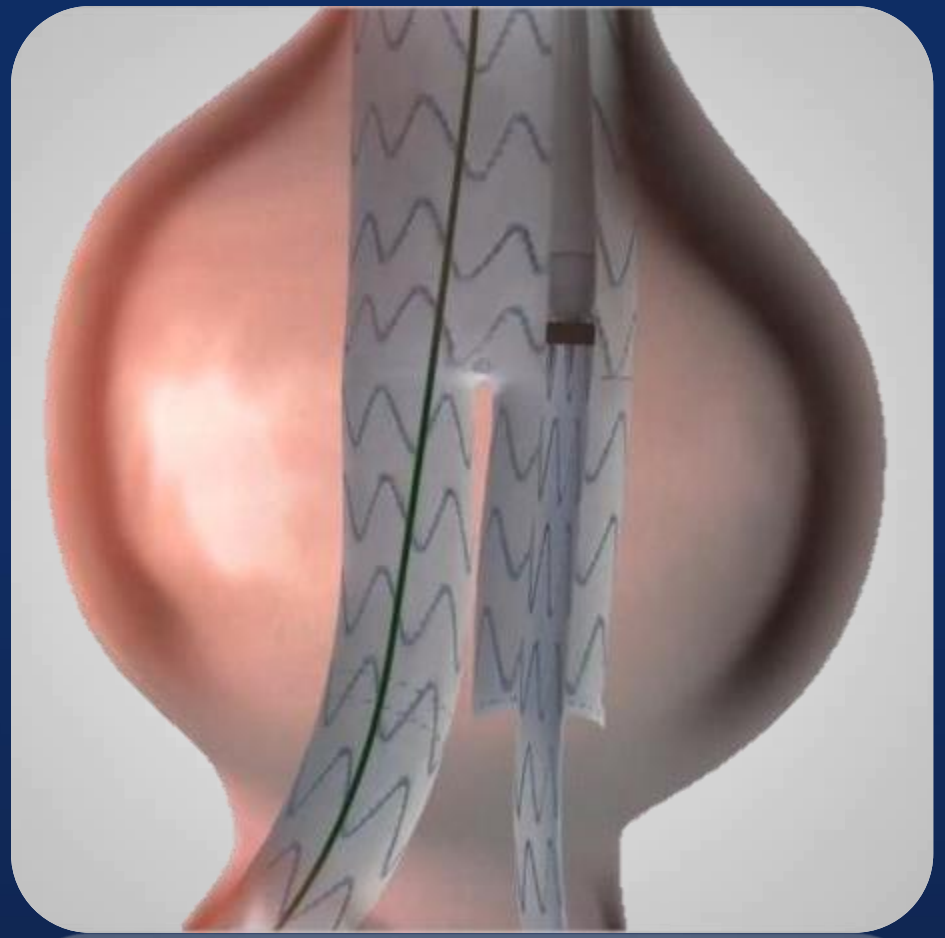


Deploy the ipsilateral limb stent



Deploy the contralateral limb stent

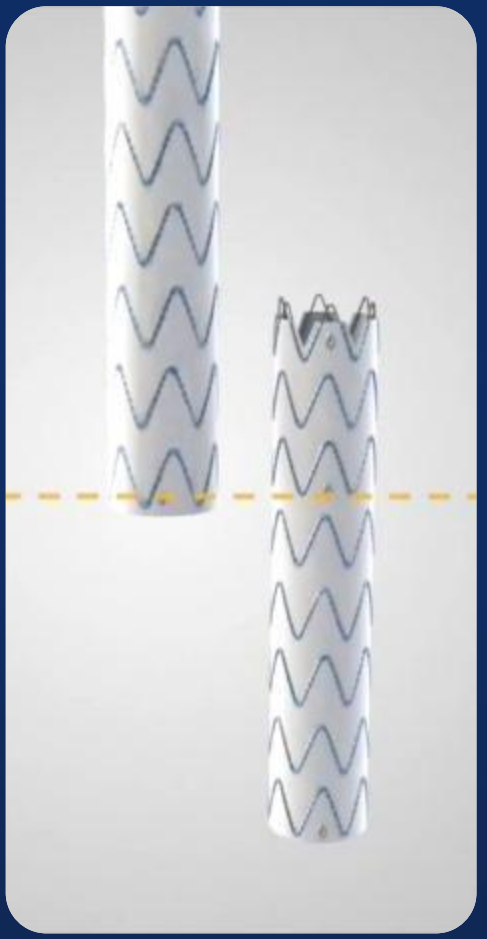




Deploy the contralateral limb stent

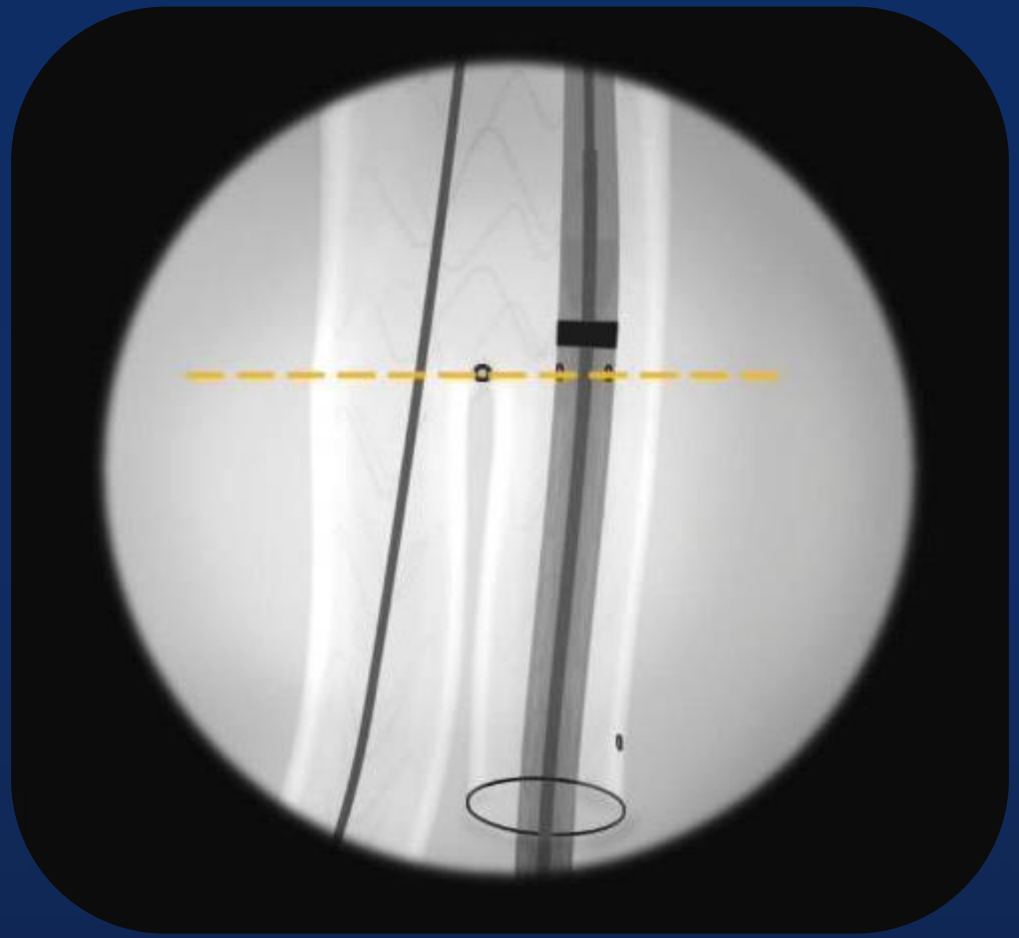
Flower Divider Marker

Contralateral gate marker

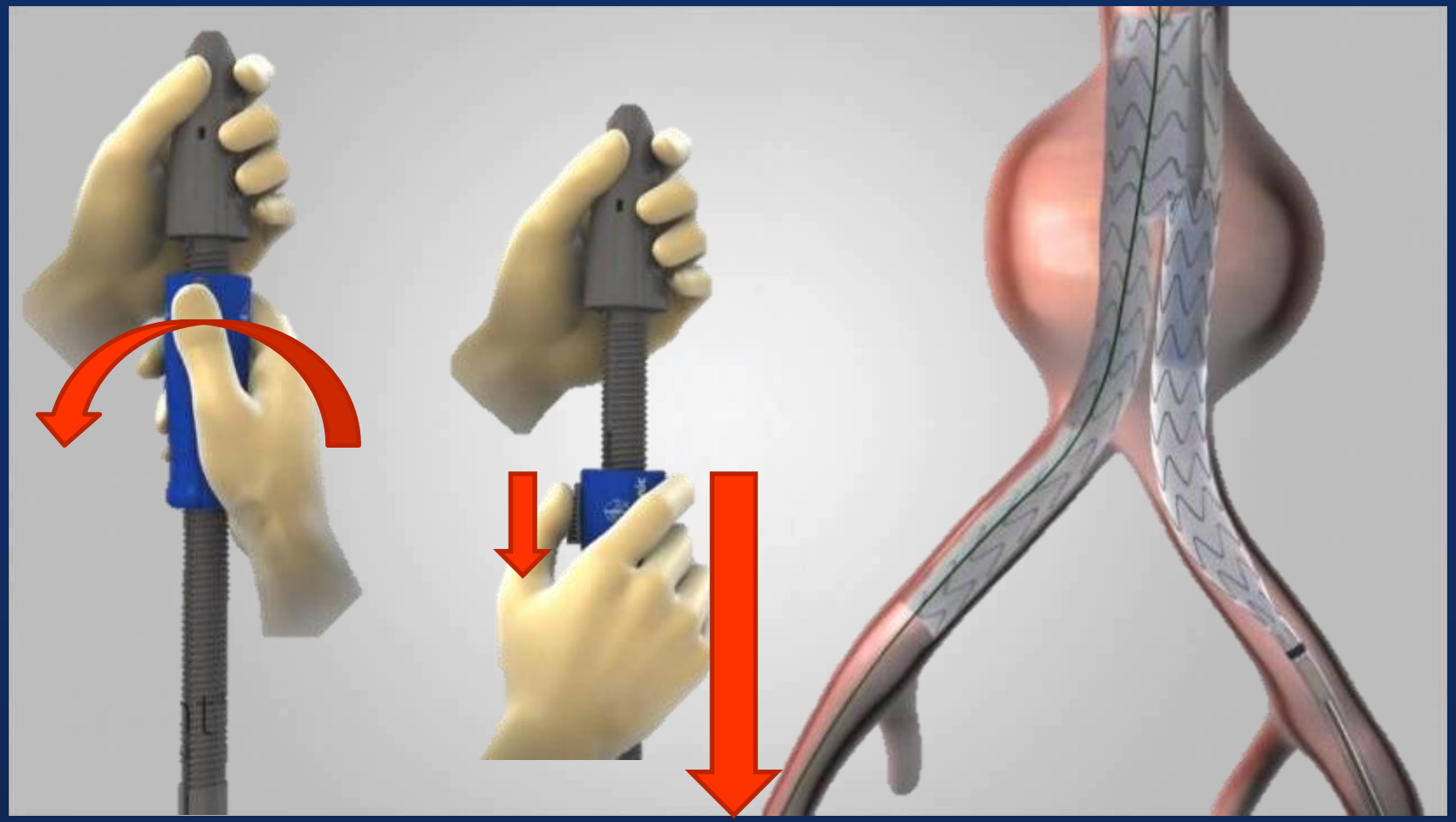


Overlap marker

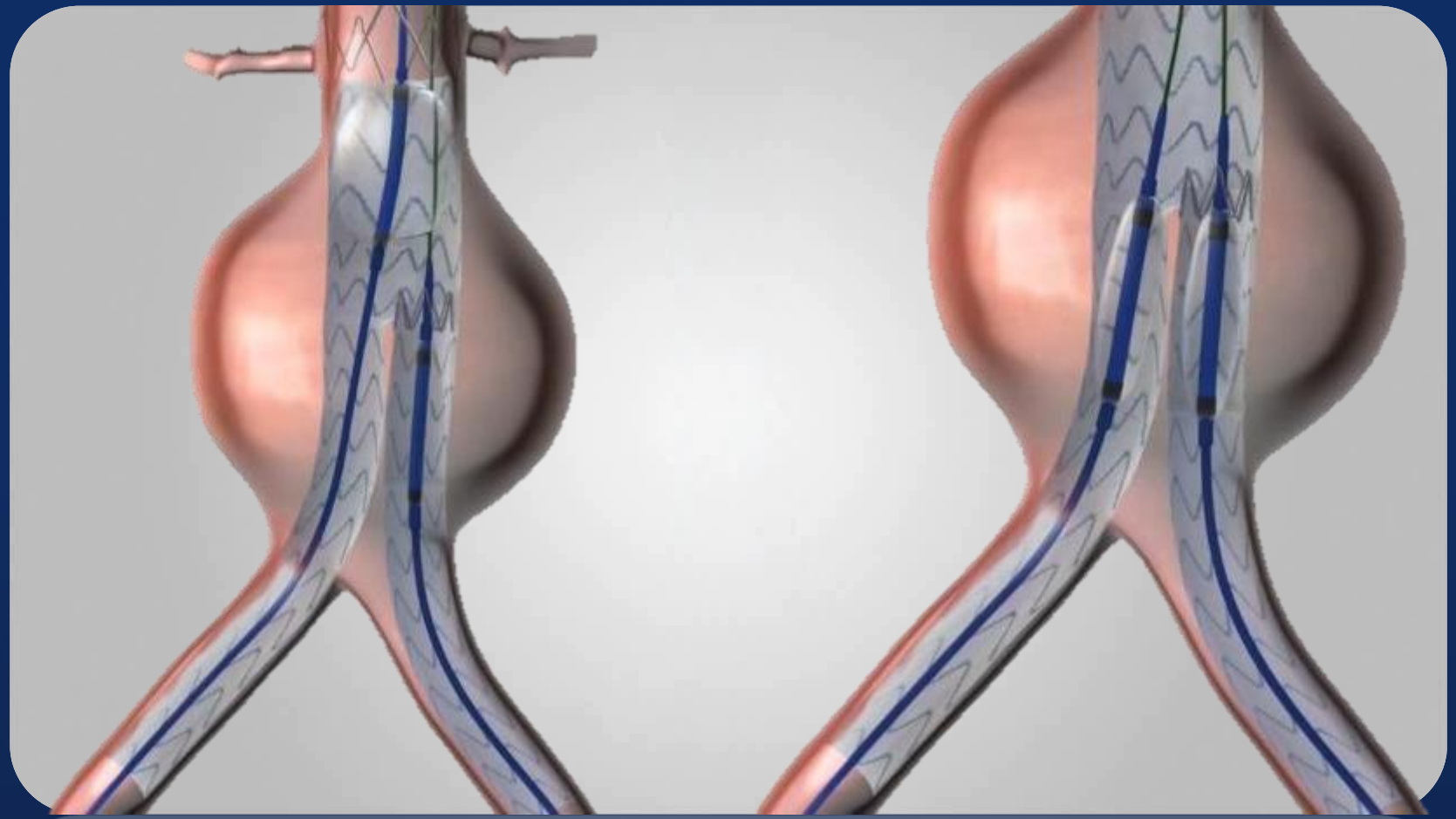
Deploy the contralateral limb stent



Deploy the contralateral limb stent



Ballooning the stent



Updated Guidline
EVAR

Asan Medical Center,
University of Ulsan College of Medicine, Seoul, Korea

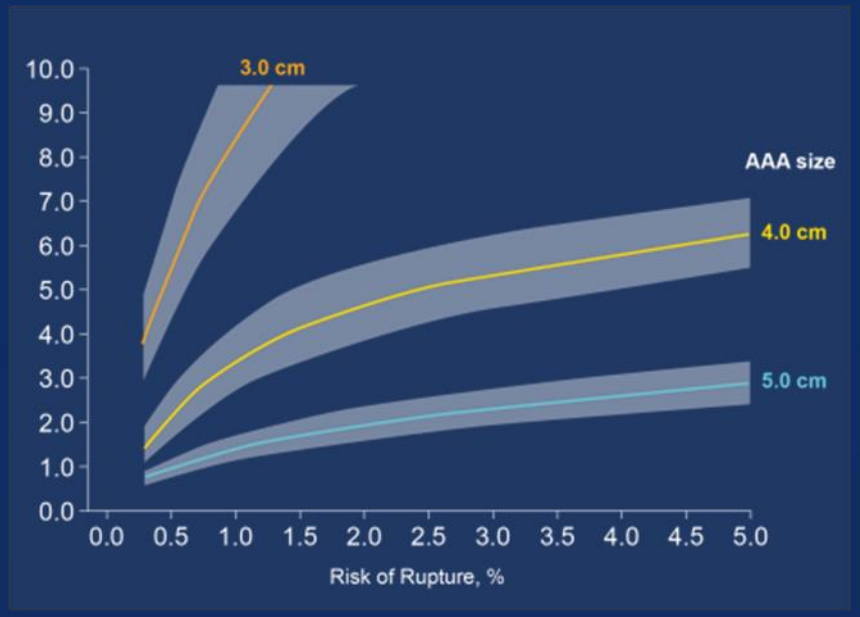
Guidelines for Repair of AAA

- Repair for males with AAA > 5.5 cm (IB)
- Repair for females with AAA > 5.0 cm (IB)
- Aneurysm growth exceeds 1 cm/year (IB)

- Large aneurysm suitable for EVAR, open or endovascular repair is recommended (IA)
- Large aneurysm unsuitable for EVAR, open aortic repair is recommended (IC)

Eur Heart J 2014 Nov 1;35(41);2873

Importance of AAA: Risk of Rupture



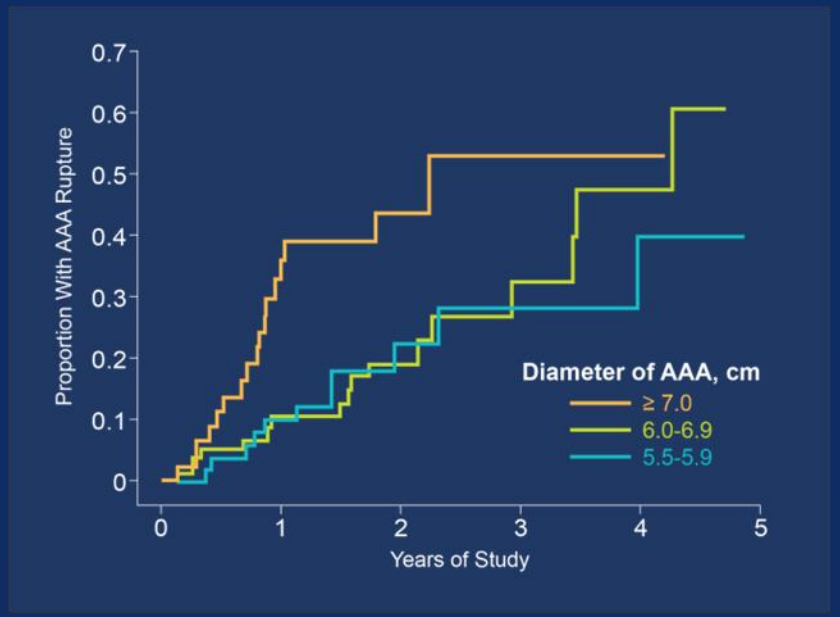


Table 1. Annual Risk of Rupture of Abdominal Aortic Aneurysms.*

Aneurysm Size	1-yr Incidence of Rupture
	%
<5.5 cm	≤1.0
5.5–5.9 cm	9.4
6.0–6.9 cm	10.2
≥7.0 cm	32.5

* Data are from Powell et al.,[33] Lederle et al.,[34] and Lederle et al.[35] The overwhelming majority of study participants were men.

JAMA. RESCAN trial 2013;309(8):806
NEJM. 2014; 371:2101-8.

National screening policy

- England, Sweden: one-time screening of all men 65 years of age or older

- U.S Preventive Services Task Force:

①흡연경험이 있는 65~75세 남성에는 초음파 복부대동맥류 검사를 1회 받도록 권고한다.

②흡연경험이 없는 65~75세 남성에는 전체가 아닌 임상의사가 선별한 남성에게만 복부대동맥류 검사를 실시한다. 검사 대상의 선택 기준은 득실을 따져서 평가하고, 환자 기왕력과 가족력, 다른 위험인자도 고려한다

③흡연경험이 있는 65~75세 여성에는 복부대동맥류 검사의 득실을 평가해야 할 근가 현재로서는 부족하다.

④흡연경험이 없는 여성에게는 정기 검사가 불필요하다.

Size to treat?
Small Aneurysm RCTs

UKSAT (4 – 5.5cm) (USG surveillance)

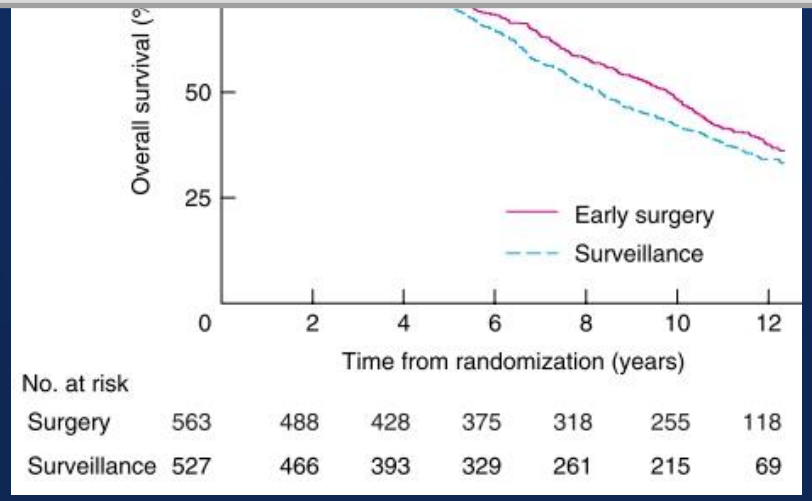
- 1090 randomized (17% female)
- Operative mortality of 5.8% in immediate repair group

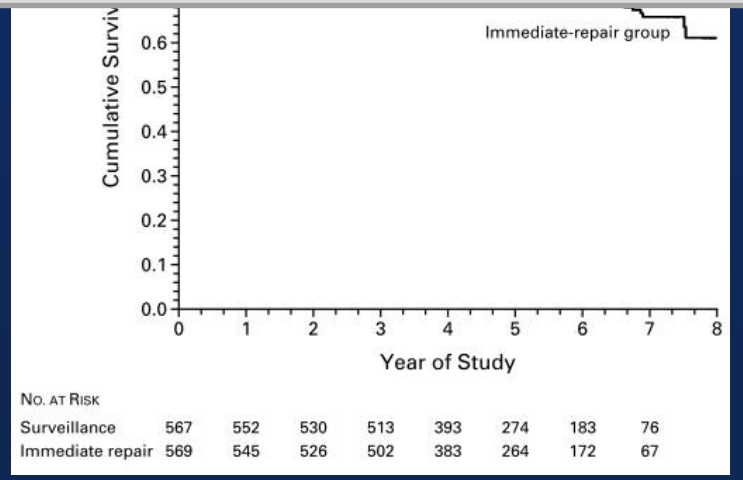
ADAM VA study (4 – 5.5cm) (CT scans)

- 1136 randomized (mean f/u 4.9 yrs)
- Operative mortality of 2.7% in immediate repair group

Treatment size should be **5.5cm for males** (<1% per year annual rupture rate for AAA <5.5cm in males)

Women rupture rate higher (4X) at same size; perhaps treat at 5 or even 4.5cm diameter





NEJM 2002, 9;346 (19), B J Surg 2007, 94(6)

Surveillance

Class I

2. **Patients with infrarenal or juxtarenal AAAs measuring 4.0 to 5.4 cm in diameter should be monitored by ultrasound or CT scans every 6 to 12 months to detect expansion.** ***(Level of Evidence: A)***

Class IIa

3. **In patients with AAAs smaller than 4.0 cm in diameter, monitoring by ultrasound examination every 2 to 3 years is reasonable.** ***(Level of Evidence: B)***

Recommendations	Class[a]	Level[b]	Ref.[c]
In patients with abdominal aortic diameter of 25–29 mm, new ultrasound imaging should be considered 4 years later.	IIa	B	367
In patients with small (30–55 mm) AAAs, the following time interval for imaging should be considered:[d] • every 3 years for AAA of 30–39 mm diameter. • every 2 years for AAA of 40–44 mm diameter. • every year for AAA >45 mm[e] diameter.	IIa	B	365

Indications for Aneurysm Repair

2014 ESC guideline

Recommendations	Class[a]	Level[b]	Ref.[c]
In patients with suspected rupture of AAA, immediate abdominal ultrasound or CT	I	C	
In case of rupture emergency repair			
In case of sympto ruptured AAA, u indicated.			
In case of sympto anatomically suita either open or en repair is recomm			
AAA repair is indic • AAA diam 55 mm.[f] • Aneurysm exceeds			
If a large aneurysm suitable for EVAR, endovascular aorti recommended in p acceptable surgical			
If a large aneurysm unsuitable for EVAR, open aortic repair is recommended.			
In patients with asymptomatic AAA who are unfit for open repair, EVAR, along with best medical treatment, may be considered.[g]	IIb	B	388,399

46 ((경피적 혈관내 스텐트 -이식 설치술)의 세부인정기준)

(경피적 혈관내 스텐트-이식 설치술)의 세부 인정기준은 다음과 같이함.

- 다 음 -

1. 적응증

가. 대동맥

(1) 대동맥류

① 흉부대동맥류 직경 5.5~6.0cm, 복부대동맥류 직경 5.0cm이상

② 4-5cm에서 6개월에 0.5cm이상 크기가 증가하거나 관련된 임상증상이 있는 경우

(2) 가성 동맥류 혹은 대동맥 파열

(3) 대동맥 박리증

① 최대 대동맥 직경이 4cm이상인 경우(급성)/또는 6cm이상인 경우(만성)

② 기준 이하의 직경이나

- 분지된 혈관의 허혈성 증후가 있는 경우
- 박리가 진행되는 경우
- Dynamic obstruction

나. 분지혈관

(1) 동(정)맥류 또는 가성 동(정)맥류의 경우 (Iliac artery, renal artery 등)

(2) 동정맥루 혹은 혈관 파열인 경우

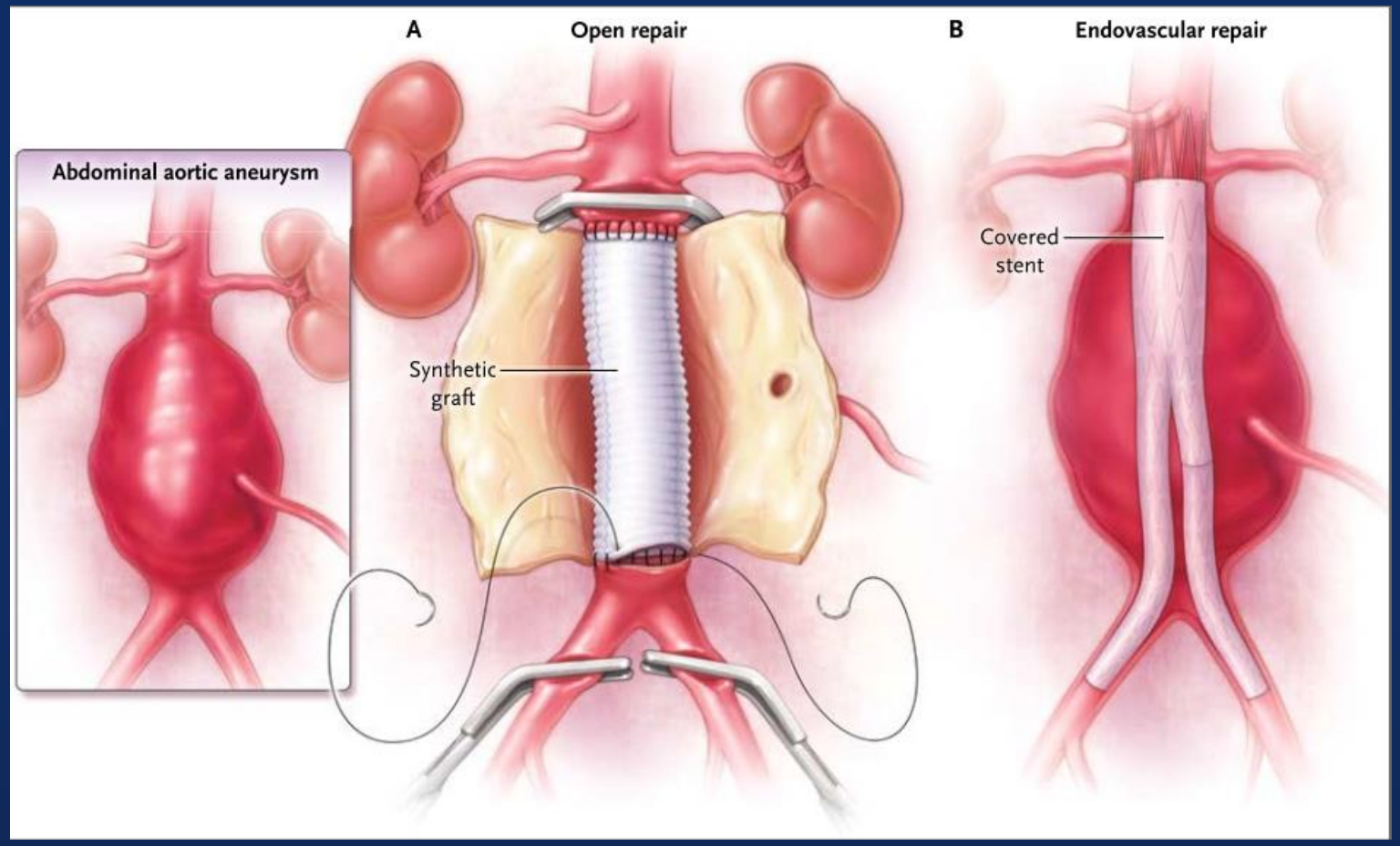
Repair; Open or EVAR?

2005 Recommendations	2011 Focused Update Recommendations	Comments
Class I		
Open repair of infrarenal AAA and/or common iliac aneurysms is indicated in patients who are good or average surgical candidates. *(Level of Evidence: B)*	1. Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates (56,57). (*Level of Evidence: A)*	Modified recommendation (endovascular repair incorporated from 2005 Class IIb recommendation [see below*]; level of evidence changed from B to A).
Periodic long-term surveillance imaging should be performed to monitor for an endoleak, to document shrinkage or stability of the excluded aneurysm sac, and to determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms. *(Level of Evidence: B)*	2. Periodic long-term surveillance imaging should be performed to monitor for endoleak, confirm graft position, document shrinkage or stability of the excluded aneurysm sac, and determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms (56,58). *(Level of Evidence: A)*	Modified recommendation (level of evidence changed from B to A).
Class IIa		
Endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complications from open operations because of cardiopulmonary or other associated diseases. *(Level of Evidence: B)*		Deleted recommendation (no longer current).
	1. Open aneurysm repair is reasonable to perform in patients who are good surgical candidates but who cannot comply with the periodic long-term surveillance required after endovascular repair. *(Level of Evidence: C)*	New recommendation
Class IIb		
Endovascular repair of infrarenal aortic and/or common iliac aneurysms may be considered in patients at low or average surgical risk. *(Level of Evidence: B)*		Deleted recommendation (endovascular repair incorporated into 2011 Class I, #1 [see above*]).
	1. Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness (59). *(Level of Evidence: B)*	New recommendation

*Indicates merging of deleted 2005 Class IIb recommendation with the modified 2011 Class I, #1 recommendation.

AAA indicates abdominal aortic aneurysm.

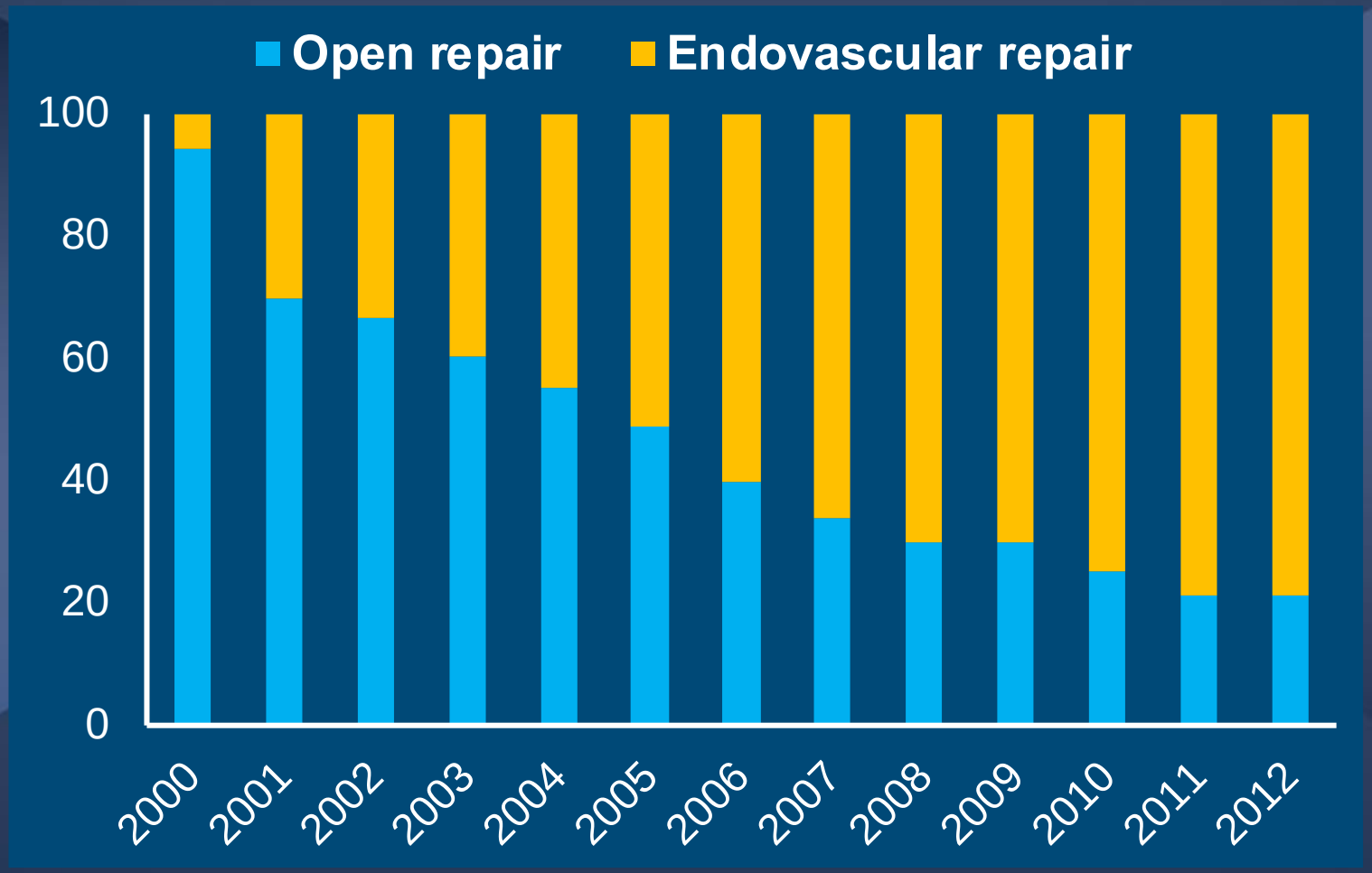
Same goal, completely different strategy



Open repair since 1950s
30-d mortality 4-5% for 20yrs
Hospital stay; 9 days
Full recovery weeks to months

Endovascular repair since 1987
30-d mortality ~1%
Hospital stay; 3 days
Full recovery days to weeks

Annual Proportion of EVAR and Open Repairs in US

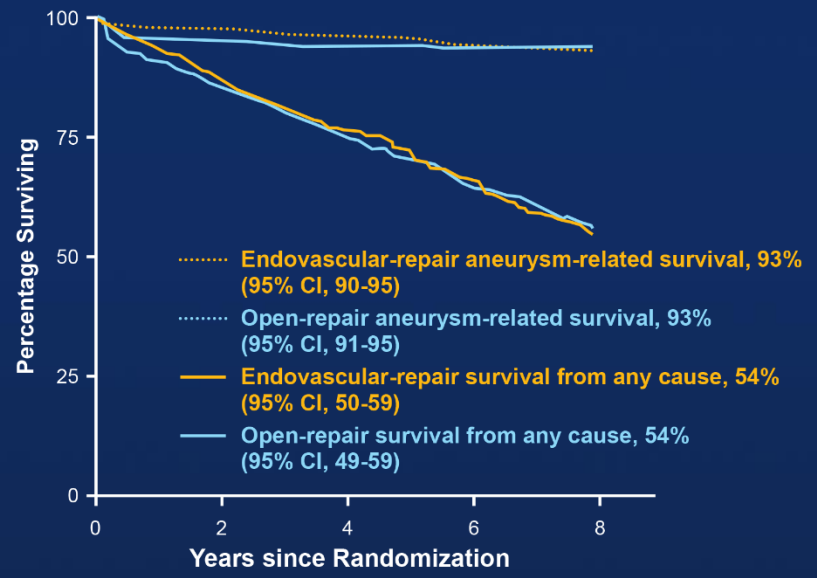


N Engl J Med 2014;371:2101-2108

RCTs; Elective Open Repair vs. EVAR

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

*EVAR trial participants**



Number at risk					
Endovascular repair	626	543	472	312	101
Open repair	626	534	461	301	109

- 1999-2004, 37 centers in UK 1252 patients aged ≥60, AAA ≥5.5cm, fit for open of EVAR
- Median FU 6 yrs
- EVAR significantly decreased perioperative
- No differences in all-cause and AAA-related mortality

Lancet 2004;364:843-48

Lancet 2005;365:2179-86

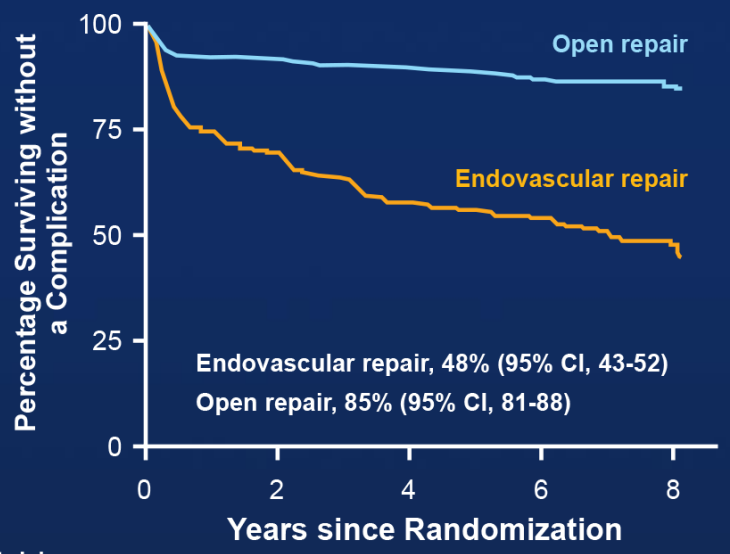
N Engl J Med 2010;362:1863-71

RCTs; Elective Open Repair vs. EVAR

Endovascular versus Open Repair of Abdominal Aortic Aneurysm

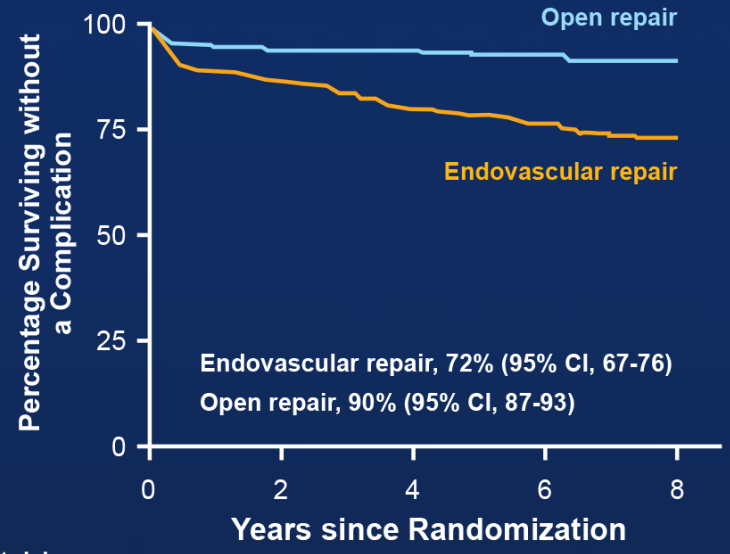
The United Kingdom EVAR Trial Investigators*

Graft-related Complication



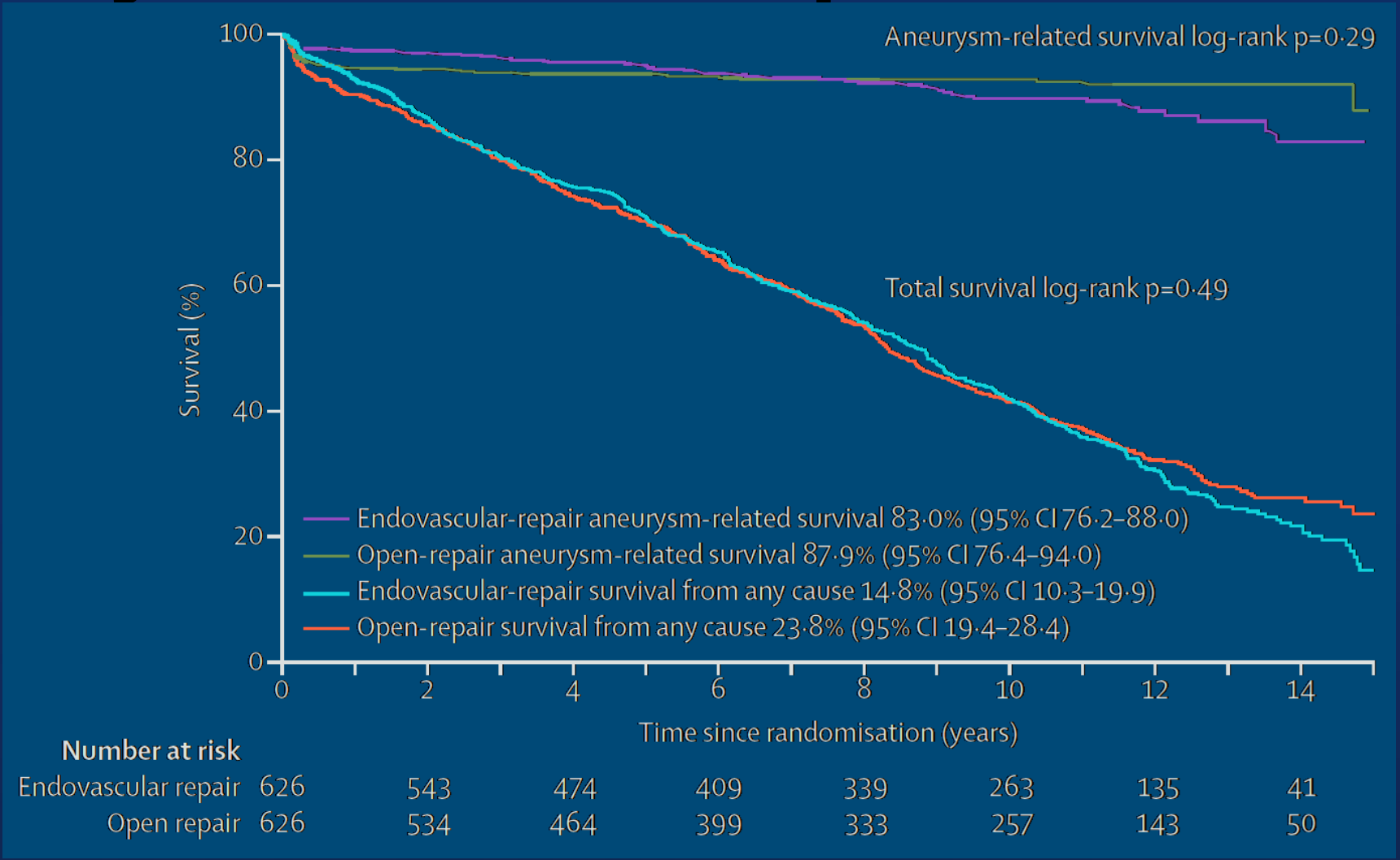
Number at risk					
Endovascular repair	626	378	280	174	58
Open repai	626	496	413	259	91

Re-intervention



Number at risk					
Endovascular repair	626	470	377	243	83
Open repai	626	503	428	271	97

15 years follow-up of EVAR 1



Lancet 2016; 388: 2366-74

RCTs; Elective Open Repair vs. EVAR

Trial	Short-term Death	Long-term Death
EVAR1 trial		
EVAR (n=626)	1.8% at 30d	23.1% at 4y
Open AAA (n=626)	4.3% at 30d	22.3% at 4y
DREAM trial		
EVAR (n=173)	1.2% at 30d	31.1% at 6y
Open AAA (n=178)	4.6% at 30d	30.1% at 6y
OVER trial		
EVAR (n=444)	0.5% at 30d	32.9% at 8y
Open AAA (n=437)	3.0% at 30d	33.4% at 8y

(1) Perioperative morbidity and mortality rates are significantly lower after EVAR
(2) Short-term survival advantage of EVAR diminishes during long-term FU, the long-term survival rates of patients are similar in both groups.
(3) Although the re-intervention rate after EVAR is higher than after open repair, most of these re-interventions are performed with catheter-based techniques, albeit at overall higher cost

Real World

39,966 matched cohorts of Medicare beneficiaries
From 2001 through 2008

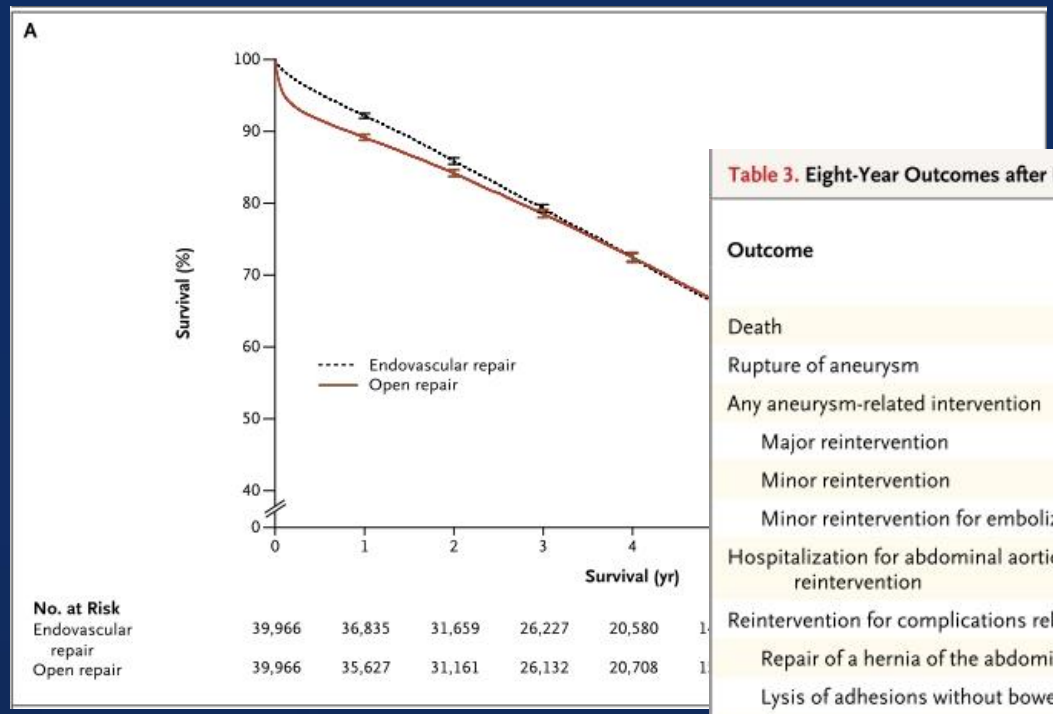
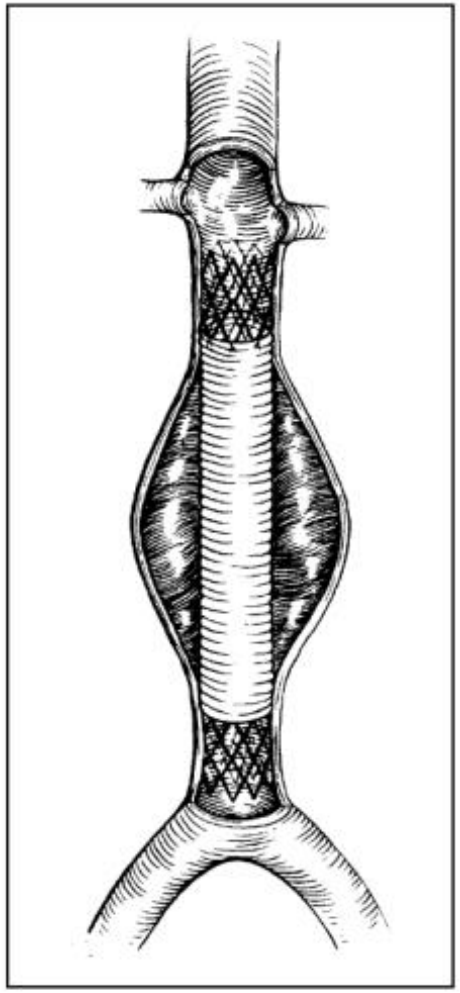


Table 3. Eight-Year Outcomes after Endovascular and Open Repair of Abdominal Aortic Aneurysm.

Outcome	Endovascular Repair (N=39,966)	Open Repair (N=39,966)	P Value
	*no. of patients (%)**		
Death	14,548 (54.9)	14,681 (54.7)	0.76
Rupture of aneurysm	962 (5.4)	353 (1.4)	<0.001
Any aneurysm-related intervention	4,165 (18.8)	754 (3.7)	<0.001
Major reintervention	392 (2.3)	186 (0.8)	<0.001
Minor reintervention	3,924 (17.5)	597 (3.1)	<0.001
Minor reintervention for embolization	1,857 (8.0)	161 (1.0)	<0.001
Hospitalization for abdominal aortic aneurysm without reintervention	233 (1.2)	55 (0.3)	<0.001
Reintervention for complications related to laparotomy	1,695 (8.2)	4,427 (17.7)	<0.001
Repair of a hernia of the abdominal wall	610 (2.7)	3,070 (11.2)	<0.001
Lysis of adhesions without bowel resection	238 (1.4)	654 (3.1)	<0.001
Bowel resection	1,035 (5.2)	1,199 (6.0)	0.008
Admission for bowel obstruction without surgery	3,510 (17.3)	4,805 (22.2)	<0.001
Aneurysm-related intervention or intervention for complications related to laparotomy	5,614 (25.1)	5,034 (20.6)	<0.001
Hospitalization related to aneurysm or for complications related to laparotomy, without intervention	3,710 (17.9)	4,846 (22.0)	<0.001
Reintervention or hospitalization without intervention for rupture, aneurysm, or complications related to laparotomy	6,279 (27.8)	5,355 (21.8)	<0.001

N Engl J Med 2015;373:328-38

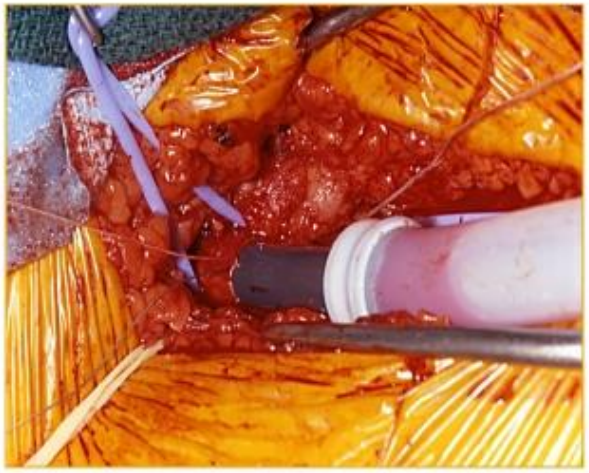
Maturation of EVAR



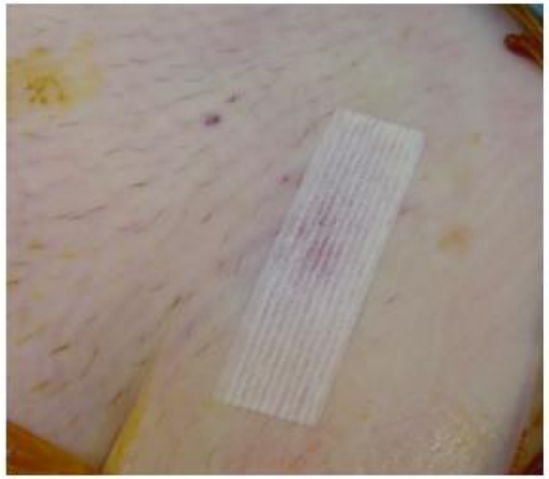
Now, EVAR is an ambulatory procedure

90% of EVAR Cases

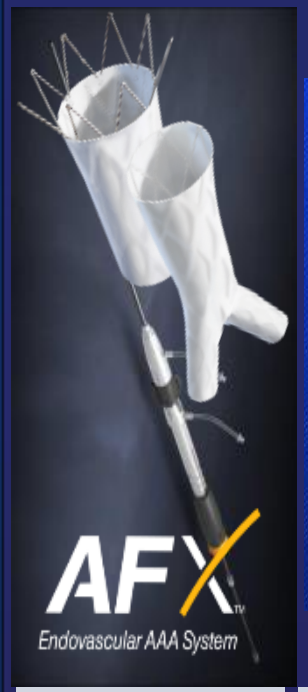
- Local Anesthesia



- No surgical incision



FDA approved
Current Generation EVAR Devices



AFX
Endologix
17F

Ovation iX
Endologix
14,15F

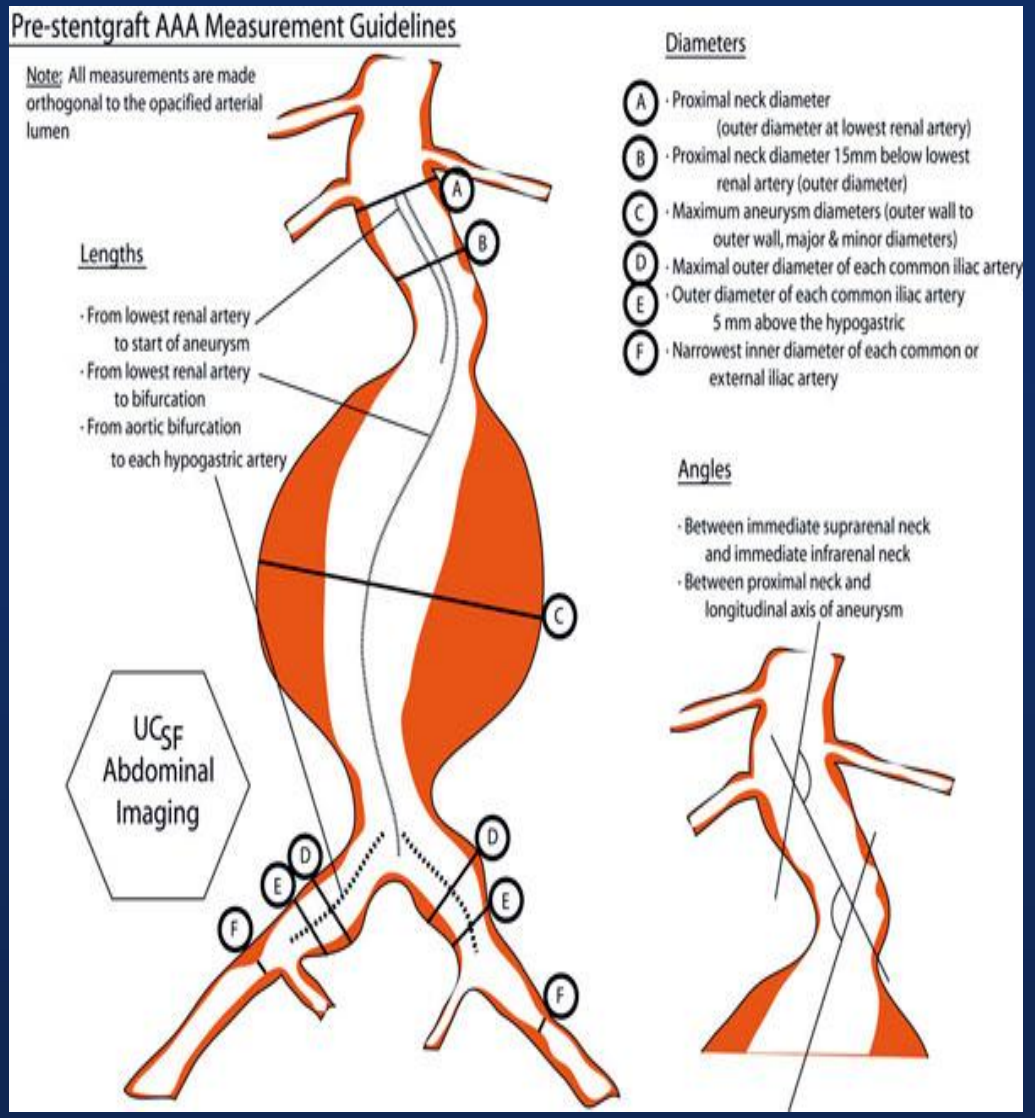
Endurant IIs
Medtronic
18,20F

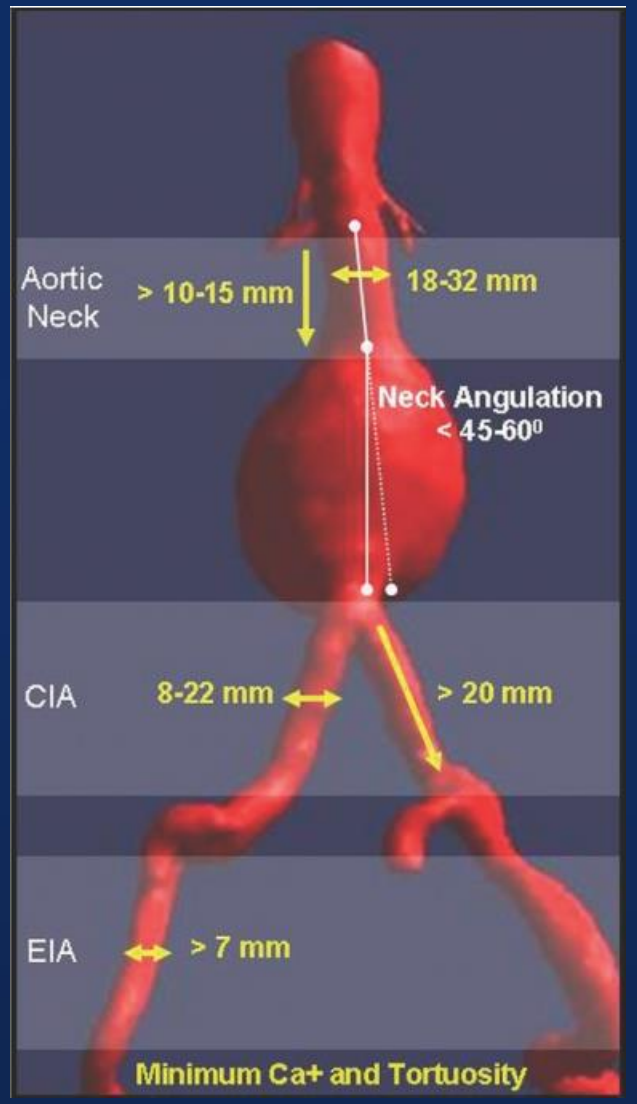
Excluder
Gore
16,18F

Zenith-Flex
Cook
20,22,24F

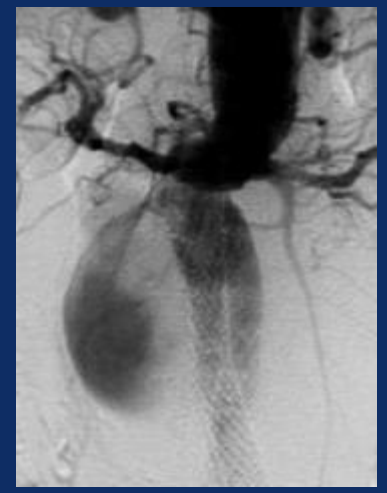
Aorfix
Lombard
22F

Planning is KEY
Comprehensive aortic assessment





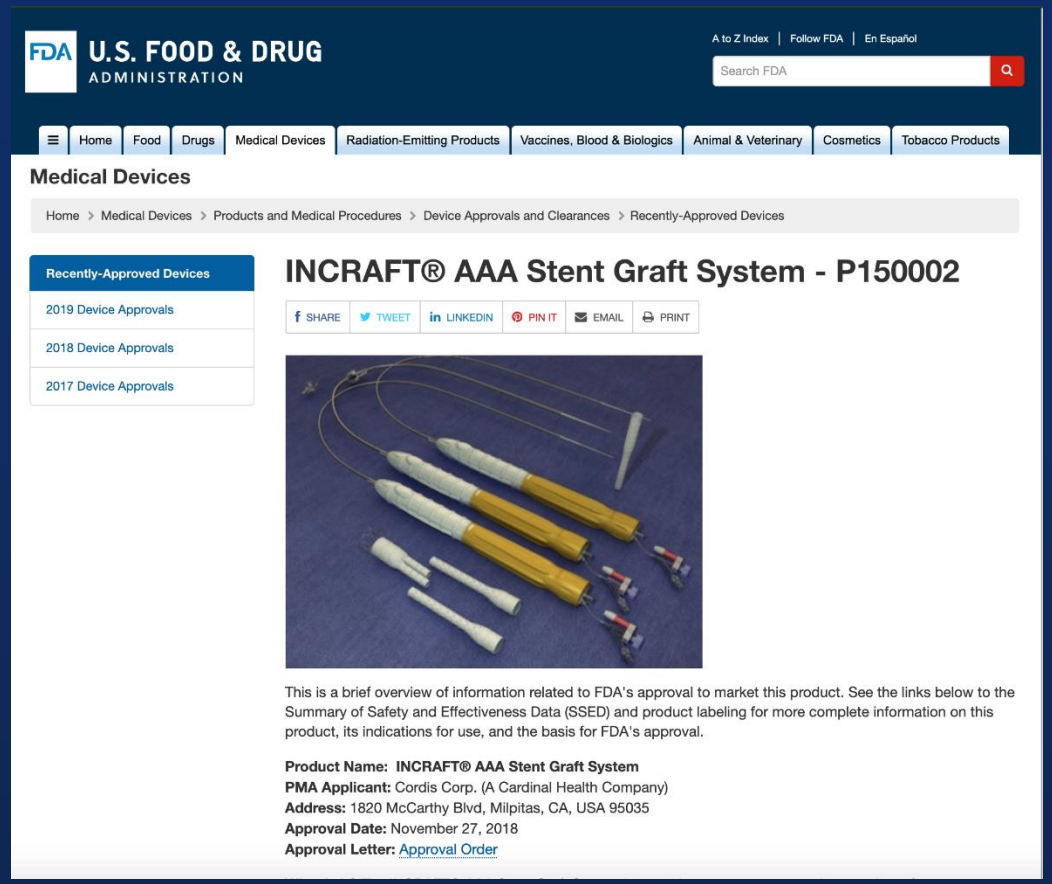
Aortic Endografts Current Limitations



- Proximal neck diameters 18-32 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
- Angle of neck to aneurysm <60°

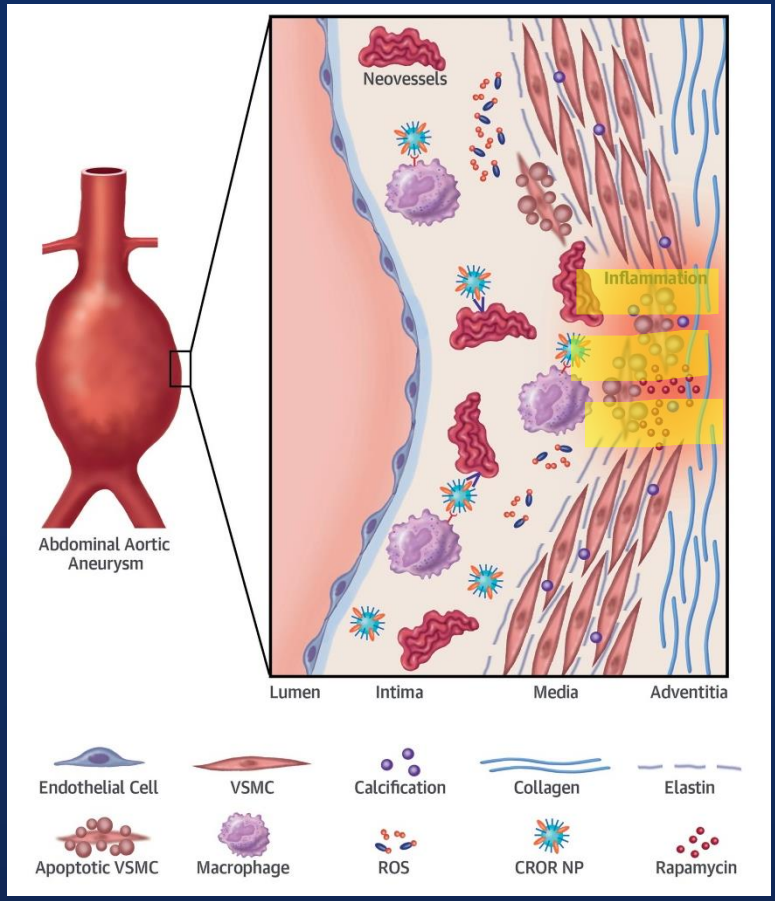
Circulation 2011;123:2848-2855

US FDA Approval of the INCRAFT AAA Stent



Approval Date : November 27, 2018

A Targeting Nanotherapy for Abdominal Aortic Aneurysms



Cheng J et al. J Am Coll Cardiol. 2018 Nov 27;72(21):2591-2605

Decision Making and Treatment Selection for Complex AAA

- Short necks and short seal zone…not a good long term solution (no real data)
- Fenestrated grafts provide an excellent seal…re-interventions necessary
- Long term follow up is imperative
- Low / Moderate risk patients should be considered for open repair at high volume centers
- Especially true for young patients given long term ARM with EVAR

Virendra I Patel, MD, MPH, TCT 2018

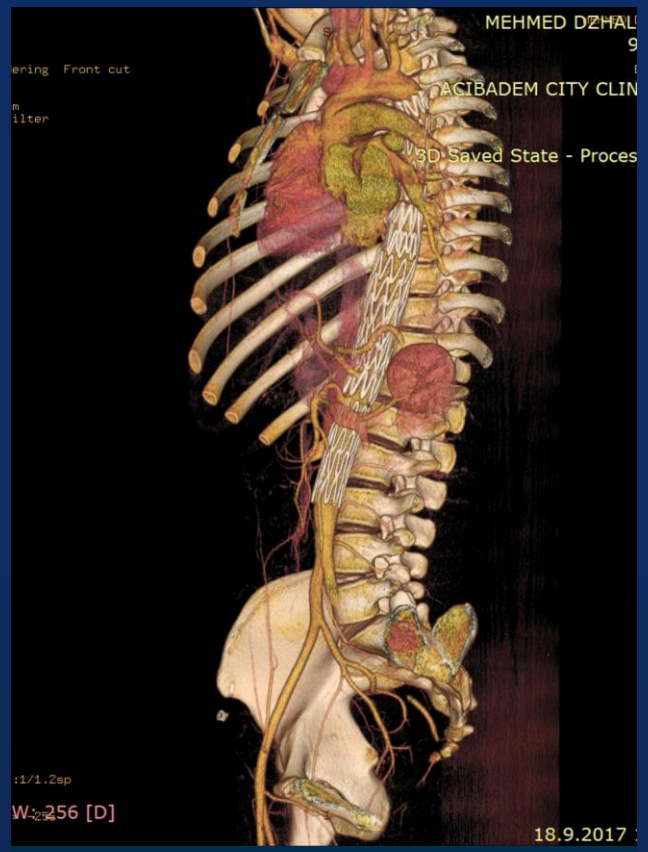
The role of noncovered stents for the treatment of malperfusion syndrome in type A and B aortic dissection

Aortic stents for AD. 1 year follow up:	
Clinical:	
Aorta related mortality	0%
Mortality 0% Late neurological complications	0%
Normal and normalized kidney function	38/38 (100%)
Device related outcomes:	
Device related failure	0%
Aortic stent thrombosis	0%
Side branch stent thrombosis	0%
Preserved covered side branches flow 98% 1. One renal artery arising from false lumen thrombosed	
Additional late procedures (more than 3 months after)	4/38

Zoran Stankov, MD, TCT 2018

First-in-man experience with endovascular tre atment of type B aortic dissection in children

15yrs old



17 yrs old

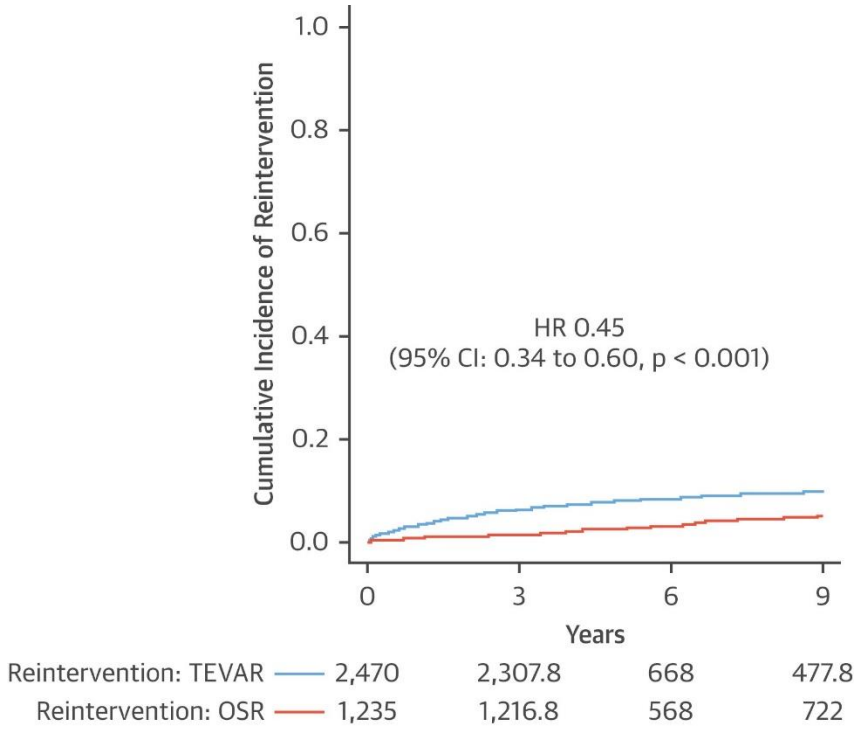
Ivo Petrov, MD, PhD, FESC, FACC, TCT 2018

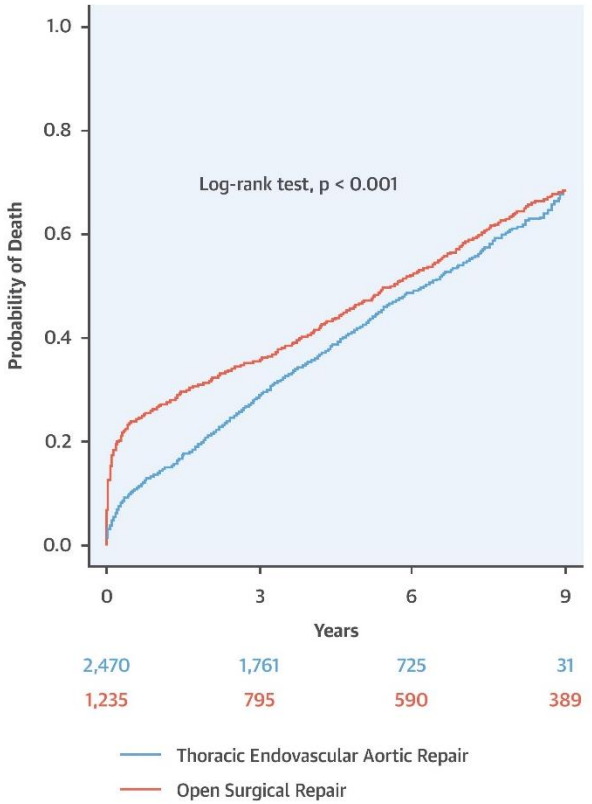
Changing Paradigms in Aortic Dissection

- Paradigm shift in therapy for TBAD
- All CTBAD should undergo TEVAR as first line therapy
- UTBAD patients with high risk criteria (2/3 of the cohort): TAD >44, FLD>22, Age >60 are candidates for OMT+TEVAR
- UTBAD patients with no high risk criteria (1/3 of the cohort): should be counseled about the risk/benefits of OMT vs. OMT+TEVAR

Ali Azizzadeh, Presenation at Controversies and Advances 2018

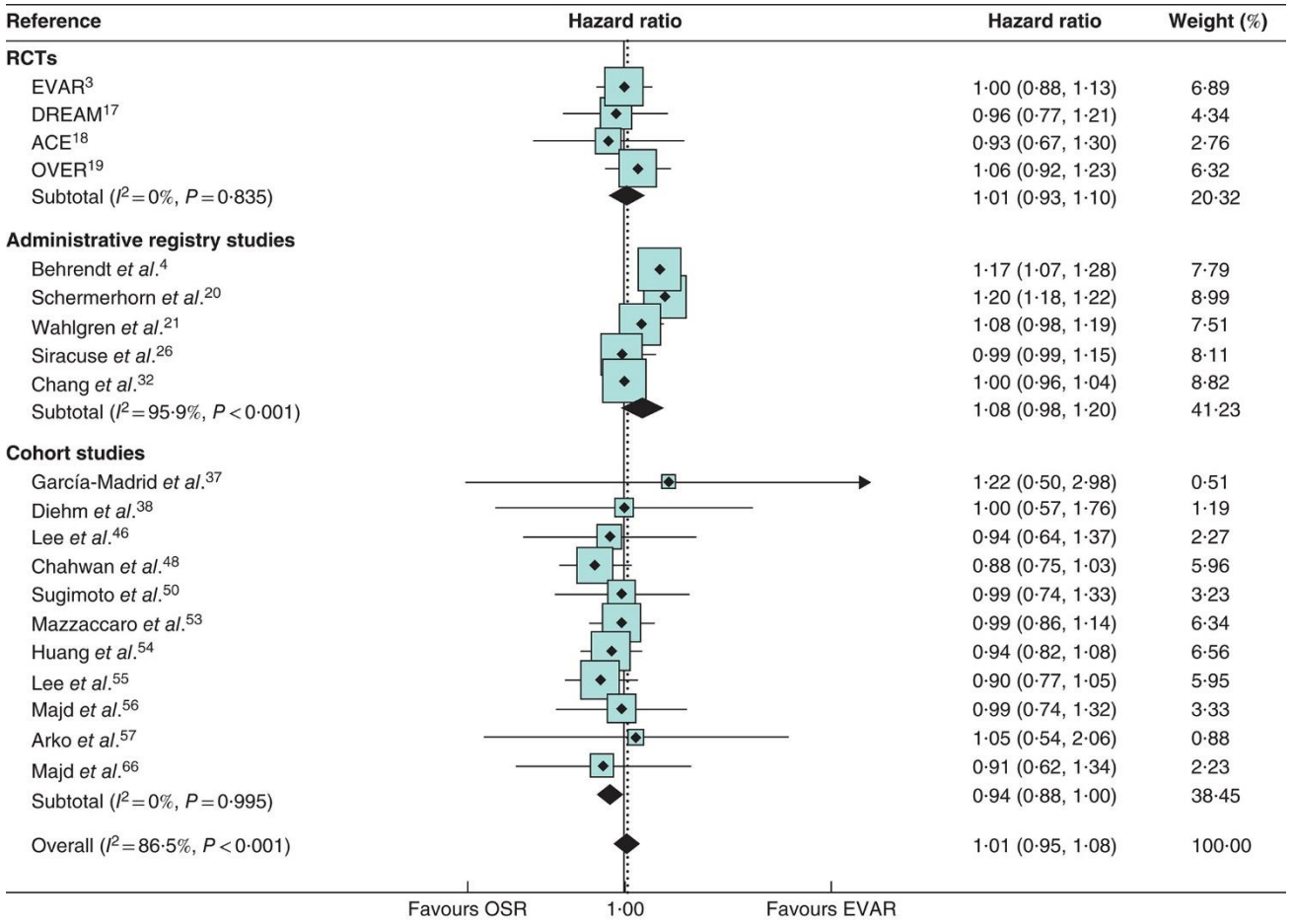
TEAVR vs OSR
Reintervention & Mortality





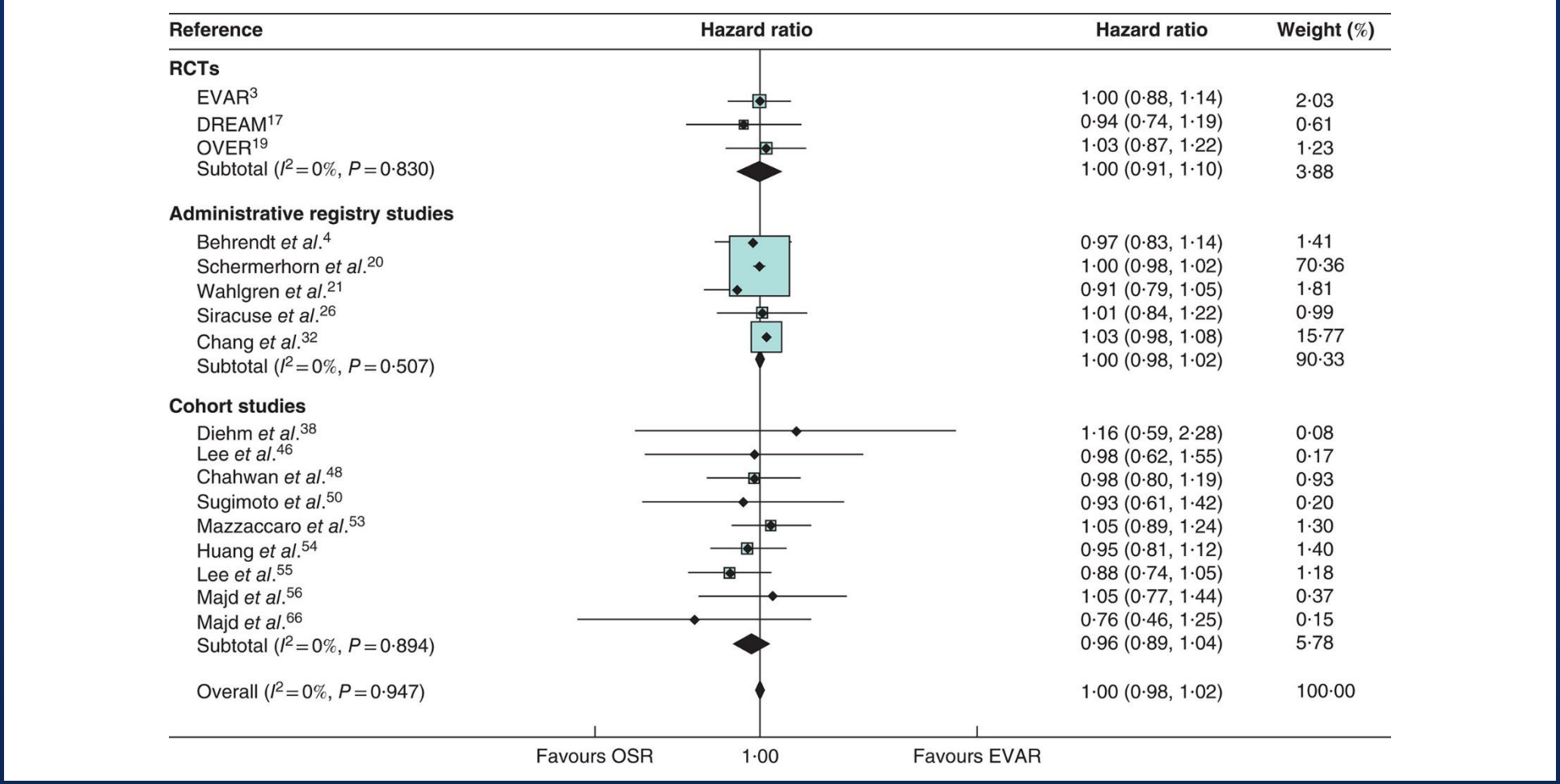
Chiu, P. et al. J Am Coll Cardiol. 2019;73(6):643-51.

Meta-analysis of long-term survival (3 years)



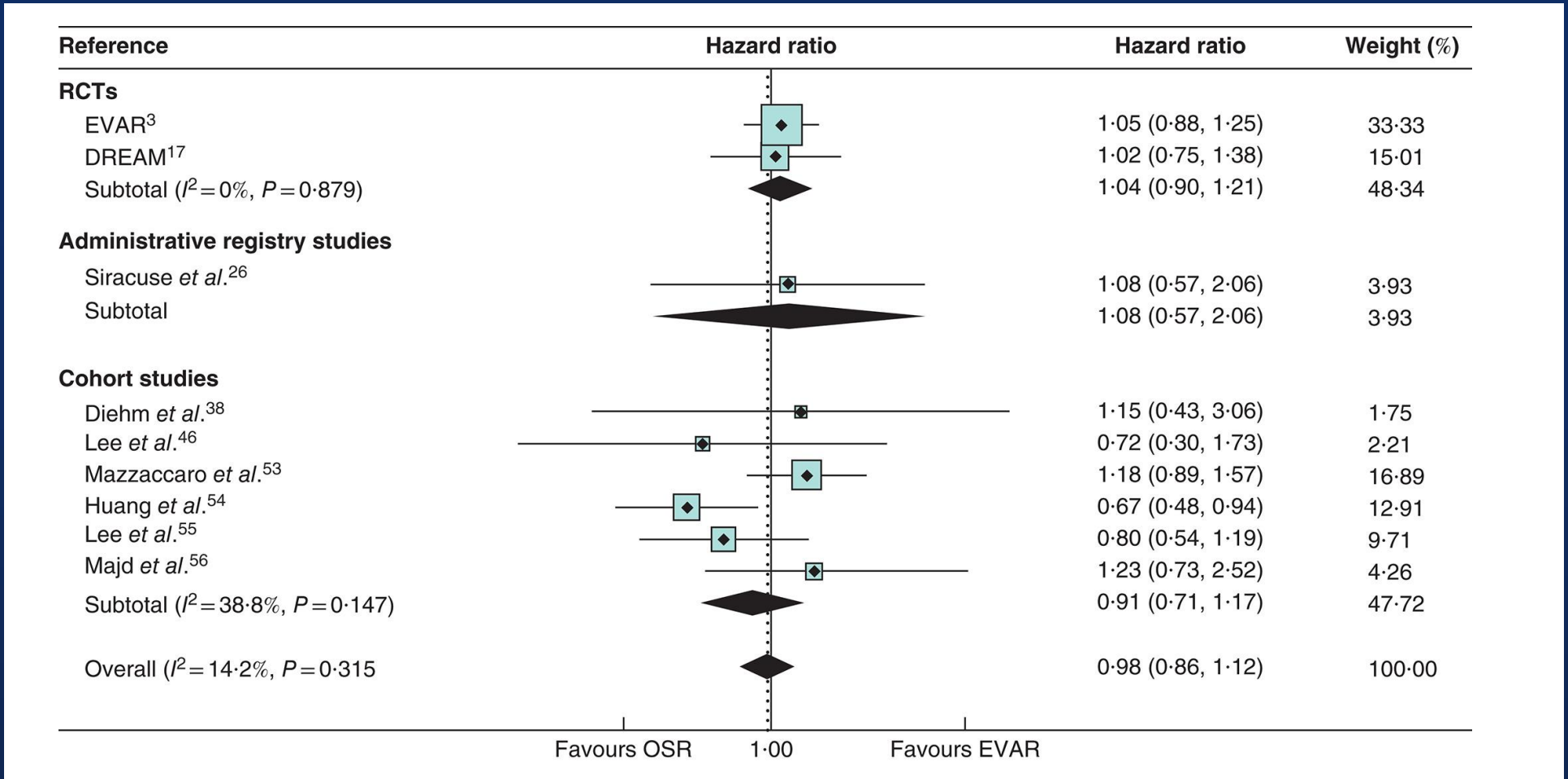
Bulder RMA et al. Br J Surg. 2019 Apr;106(5):523-533

Meta-analysis of long-term survival (5 years)



Bulder RMA et al. Br J Surg. 2019 Apr;106(5):523-533

Meta-analysis of long-term survival (10 years)



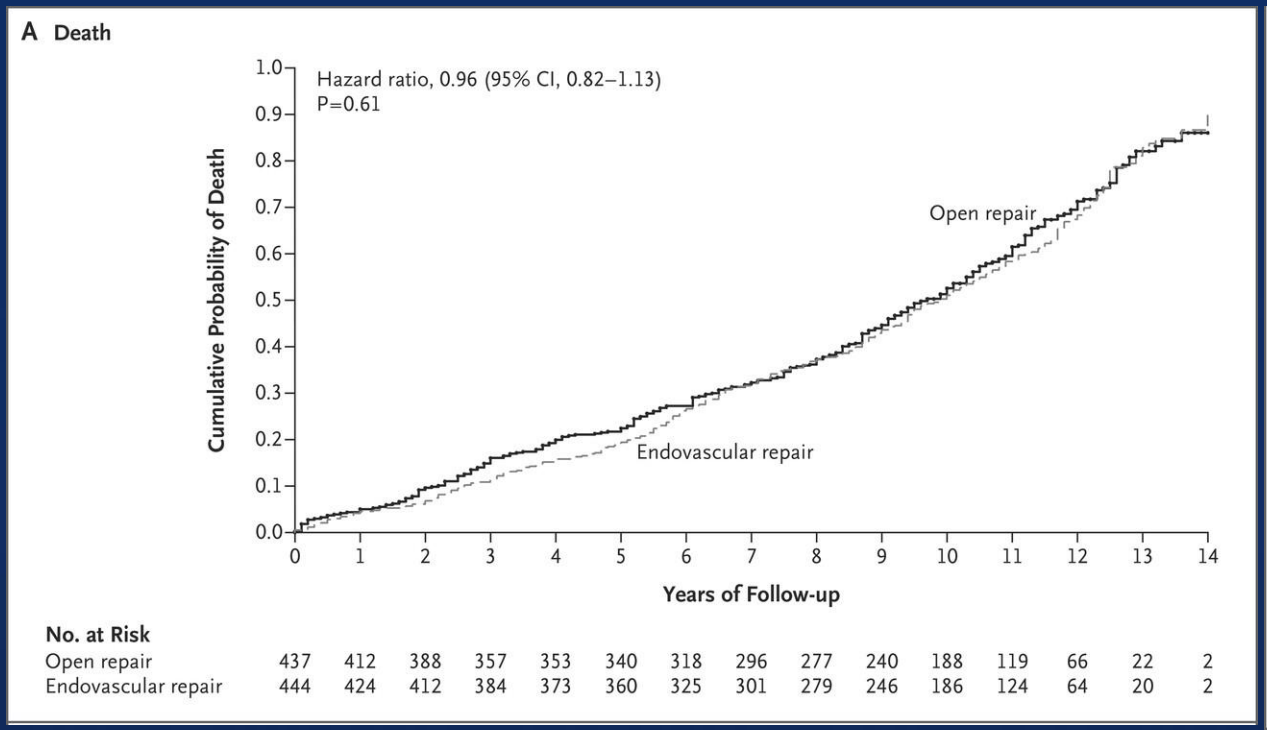
Bulder RMA et al. Br J Surg. 2019 Apr;106(5):523-533

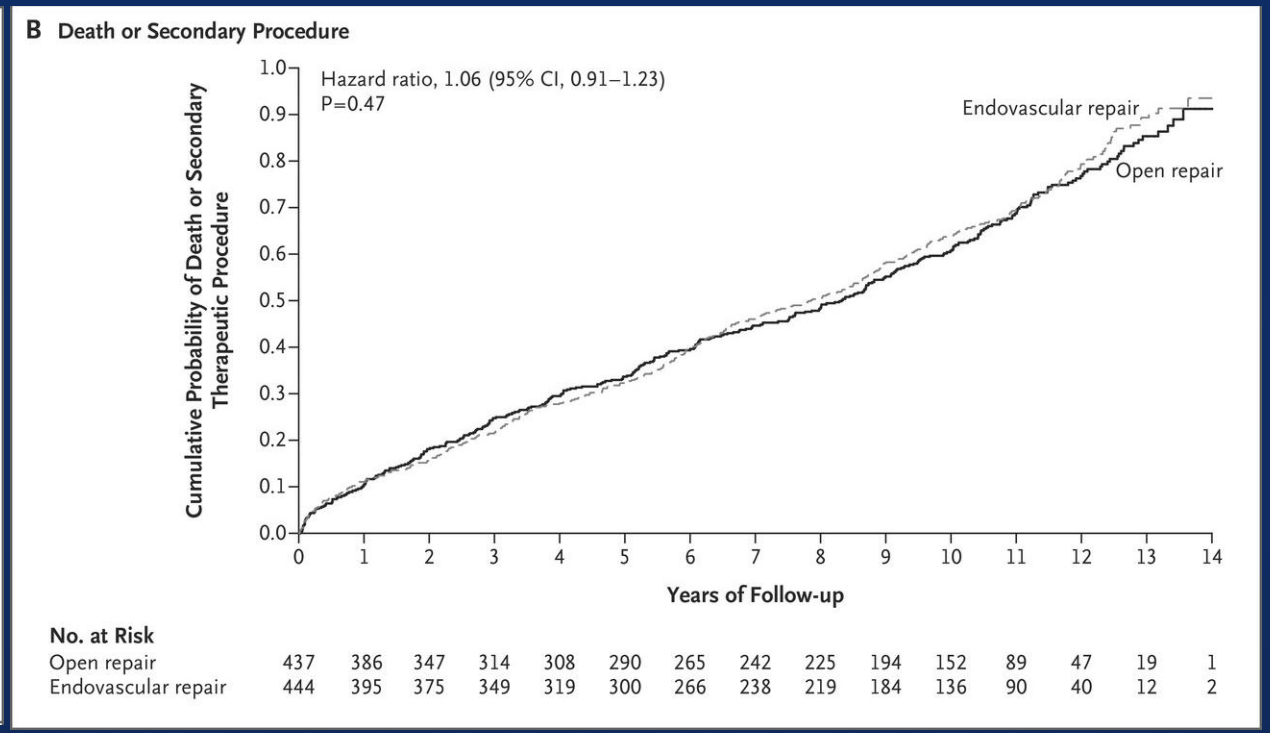
Meta-analysis of long-term survival after EVAR or OSR

	Relative survival ratio		
	3 years	5 years	10 years
EVAR	0·94 (0·92, 0·96)	0·91 (0·87, 0·94)	0·76 (0·67, 0·86)
OSR	0·96 (0·95, 0·98)	0·91 (0·88, 0·94)	0·76 (0·69, 0·85)

Bulder RMA et al. Br J Surg. 2019 Apr;106(5):523-533

Long-term survival after EVAR or OSR





Frank A. Lederle et al. N Engl J Med. 2019;380:2126-2135