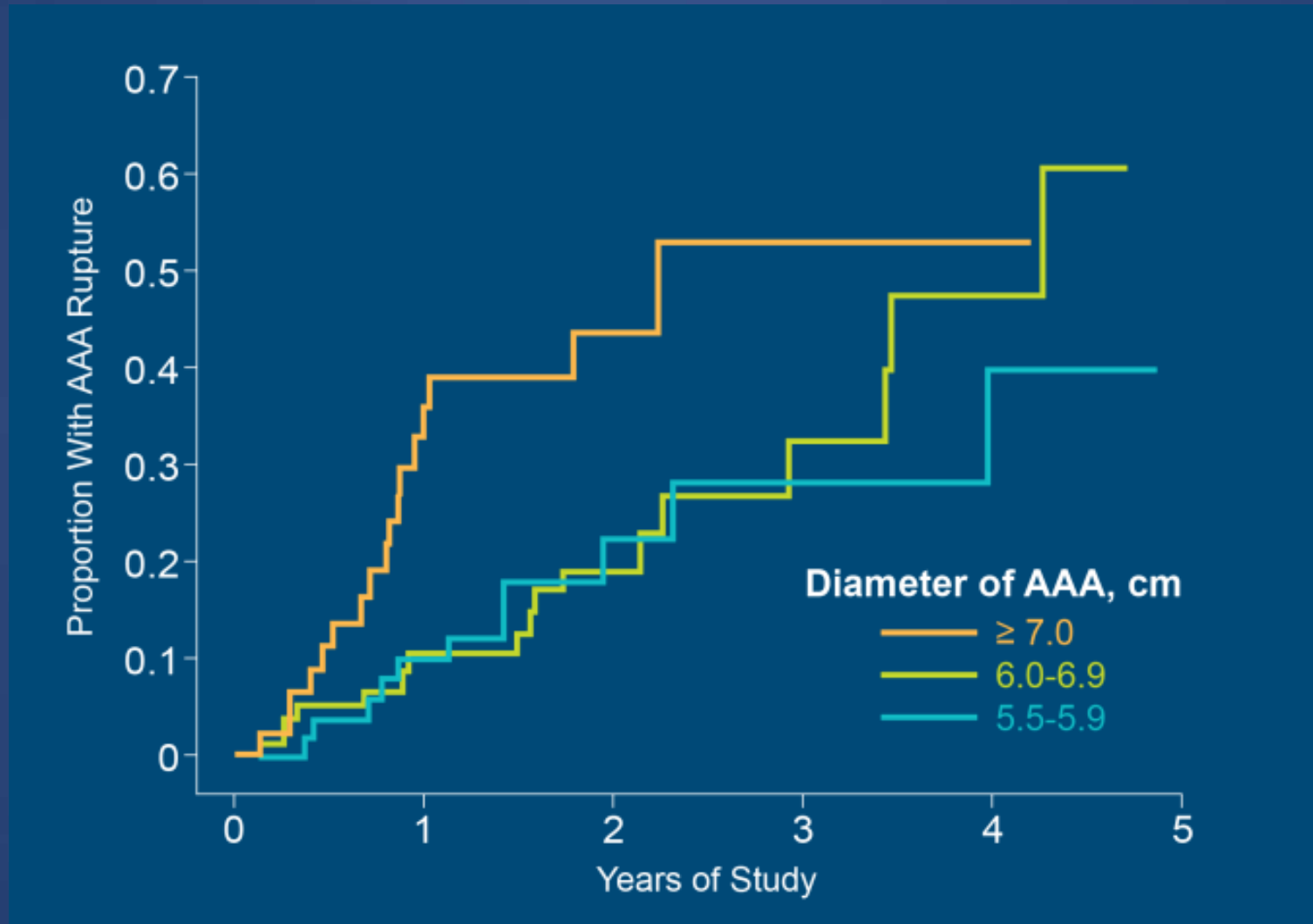


Endovascular treatment for Abdominal Aortic Aneurysm

Natural History



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

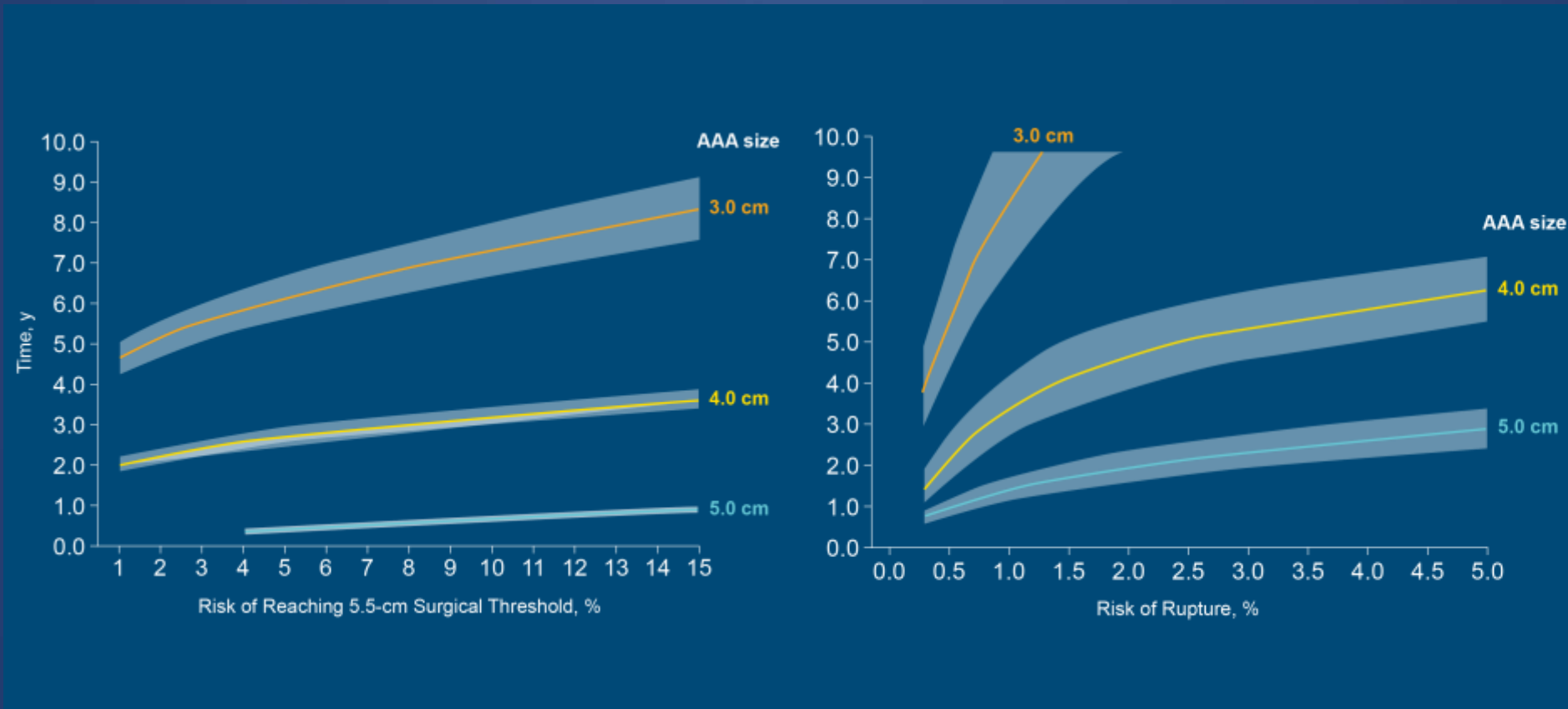
- Proportional to aneurysm size
- 1966, Szilagyi compared < 6 cm to > 6 cm
 - Follow up rupture rate: 43 % vs. 20%
 - 5-year survival: 6 % vs. 48%
- 1977, Darling analyzed AAA autopsy, pts., 25% ruptured
 - < 4 cm: 10%
 - 4-7 cm: 25%
 - 7-10 cm: 46%
 - >10 cm: 61%

473 consecutive AAA

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

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

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

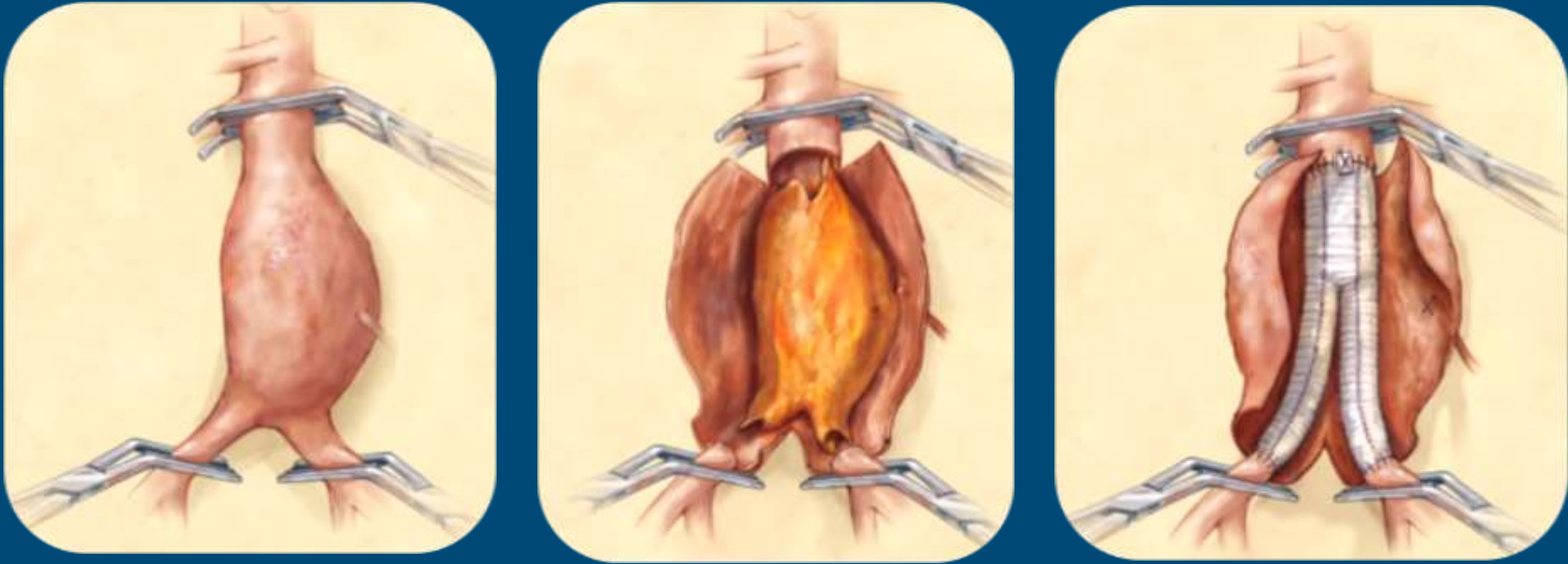
ENDOVASCULAR

First performed at 1987

Less invasive,
Through femoral vessels

Only certain types of AAA
can be repaired

Elective Open Repair AAA



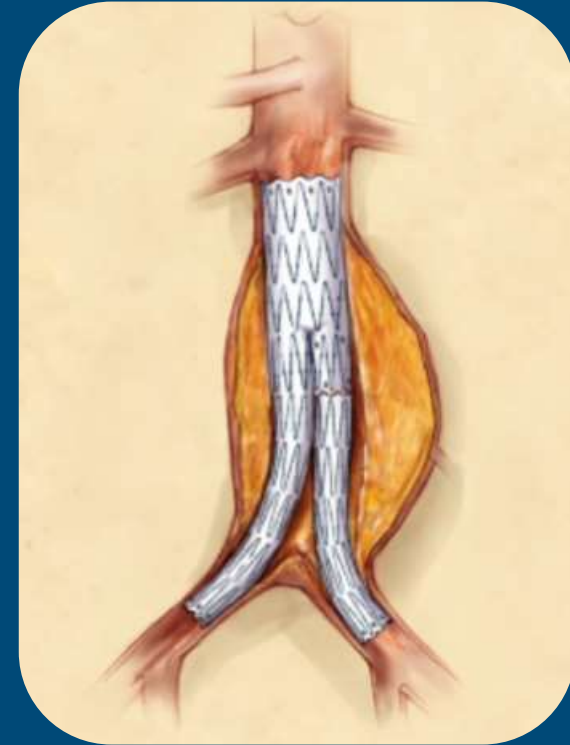
JAMA. 2009;302(18):2015

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



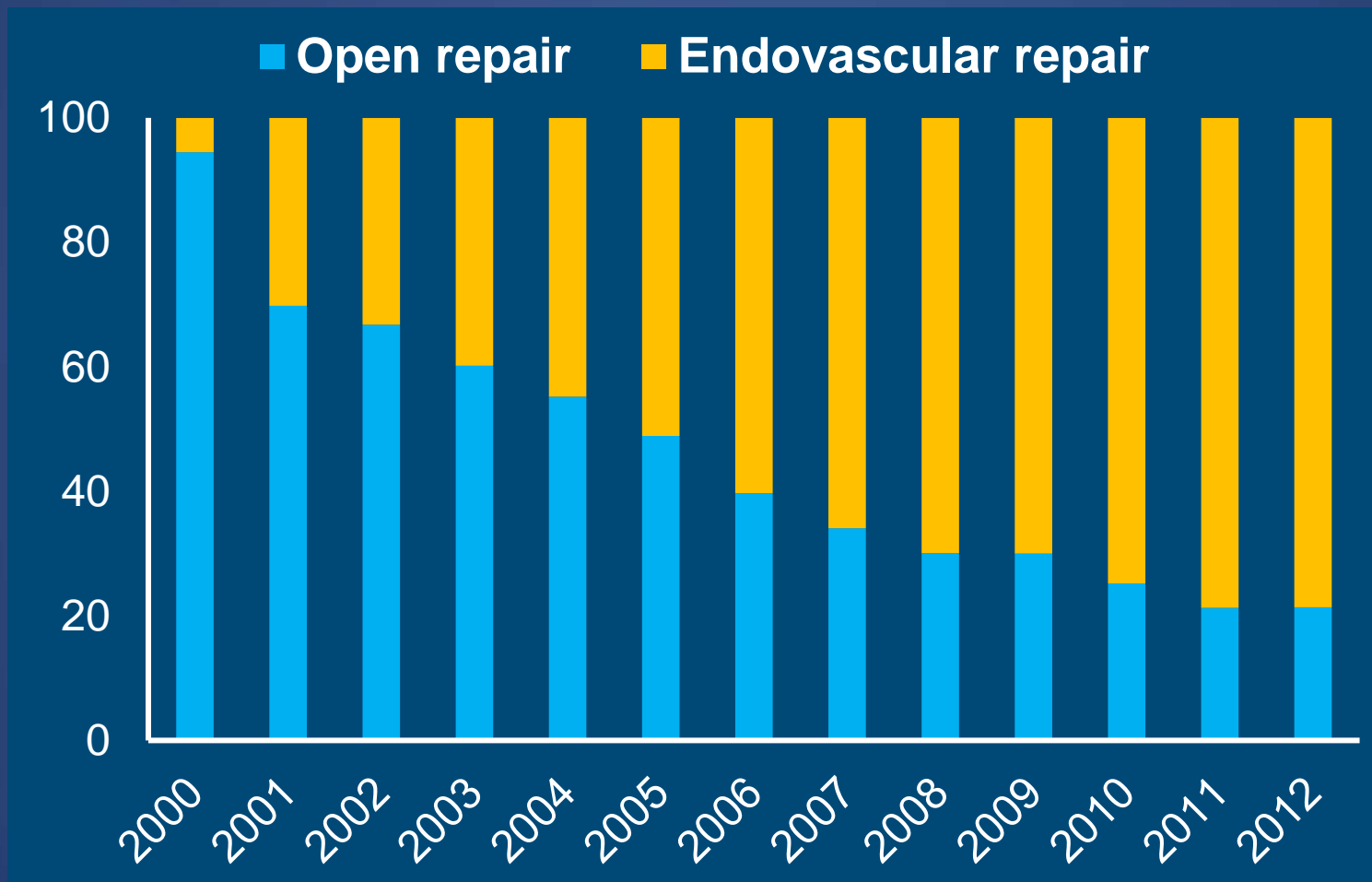
JAMA. 2009;302(18):2015

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%)

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%)

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

Technical Considerations

Device Description

Three Essential Components of endograft

1. **Delivery system**

Introducer sheath, Trocar, Deployment capsule and retractable cover

2. **Attachment system**

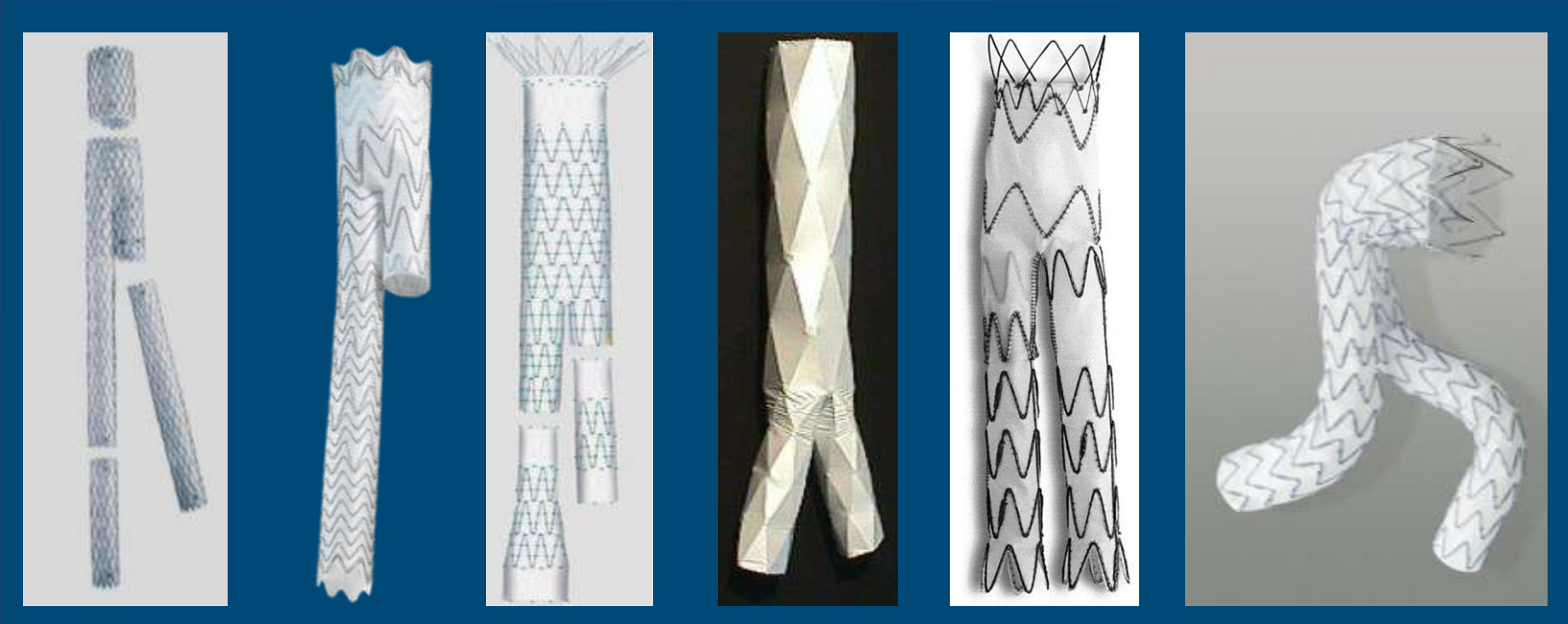
Stainless steel, Elgiloy, Tantalum or nitinol

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



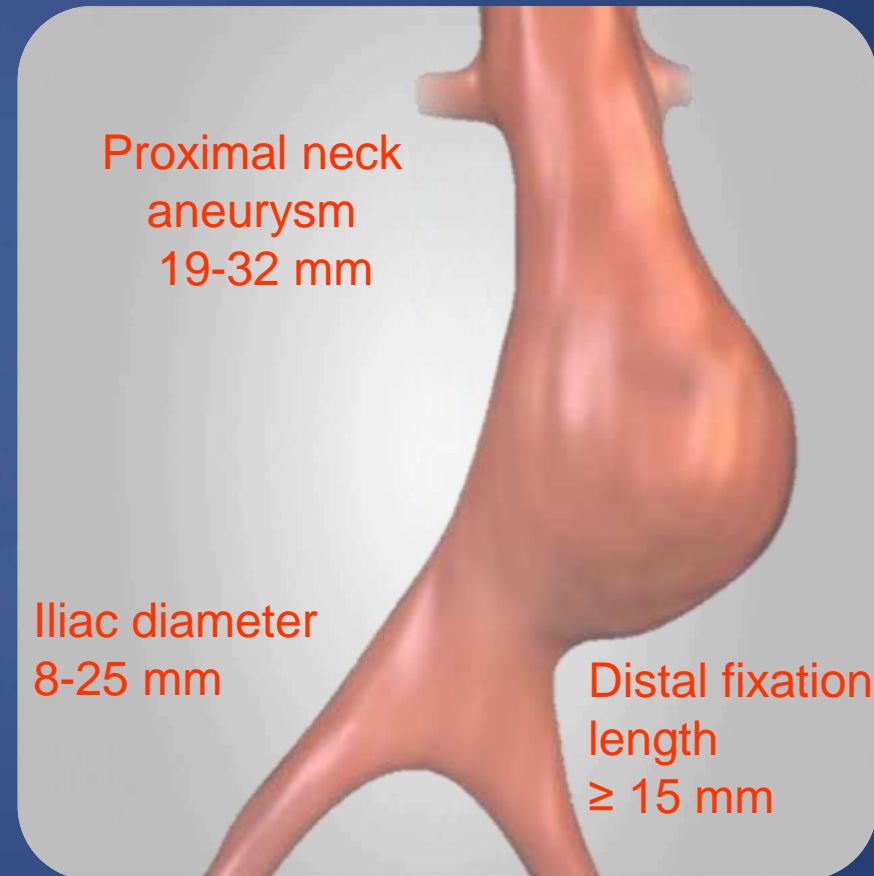
Ovation
Trivascular
14-F

Endurant II Stent Graft Indication

Iliac/femoral access



Aneurysm size

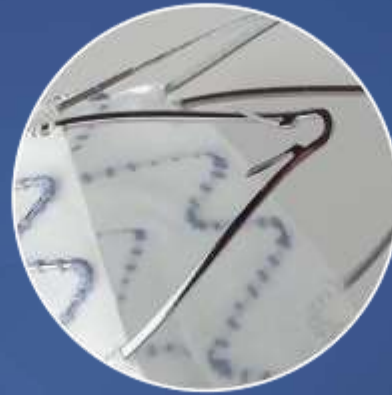


Endurant II Stent Graft Indication

- Proximal neck length ≥ 10 mm with non-significant calcification, and/or non-significant thrombus
- $\leq 60^\circ$ infrarenal angulation
 $\leq 45^\circ$ 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
- $\leq 75^\circ$ infrarenal angulation
 $\leq 60^\circ$ suprarenal angulation
- Vessel diameter approximately 10-20% smaller than Endurant Stent Graft diameter

Design Features

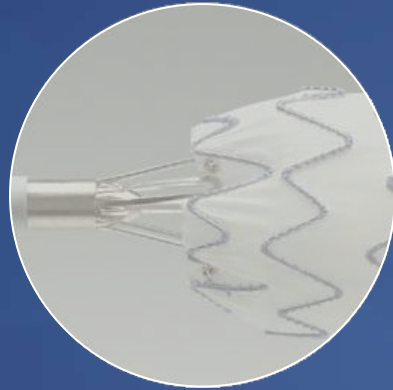


The M-shaped proximal stent designed to enhance wall apposition, minimize the risk of in-folding and provide a 5mm sealing zone.

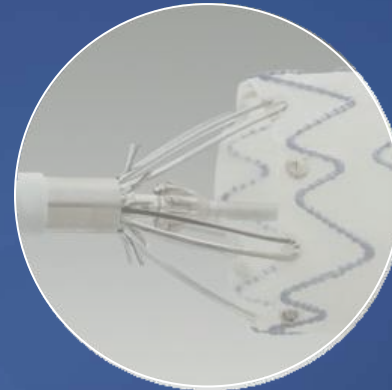
The suprarenal stent anchoring pins provide secure fixation.

Limb stent and stent spacing designed to prevent kinking.

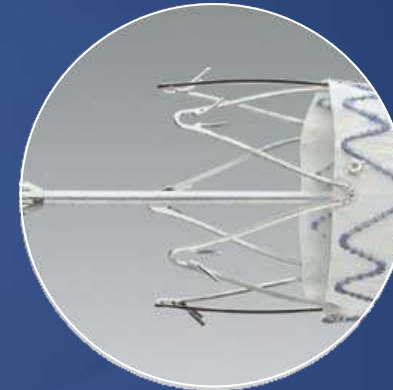
Design Features



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

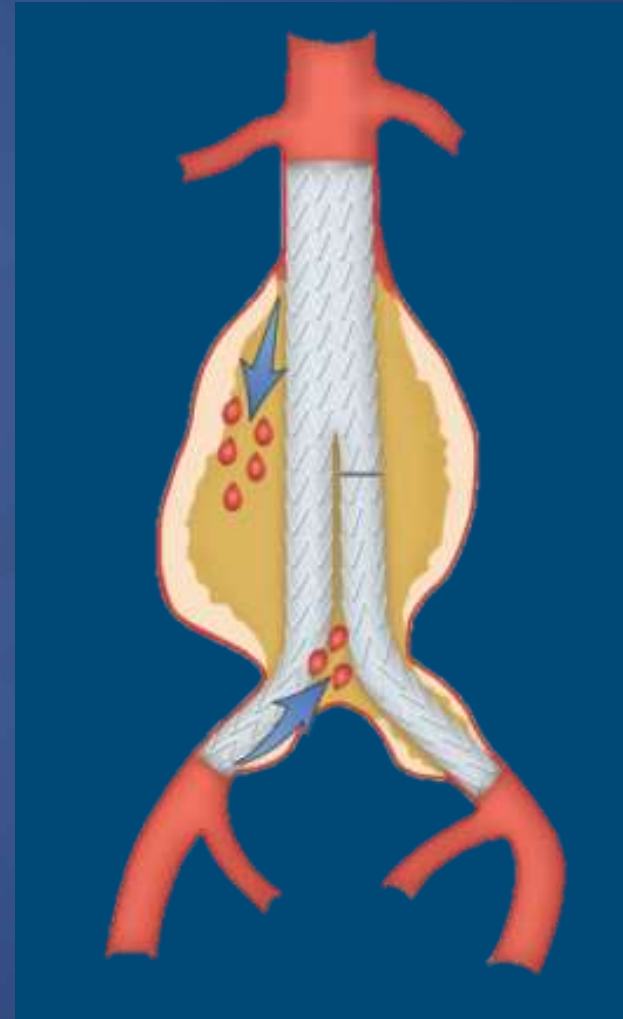
Endoleaks

- 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

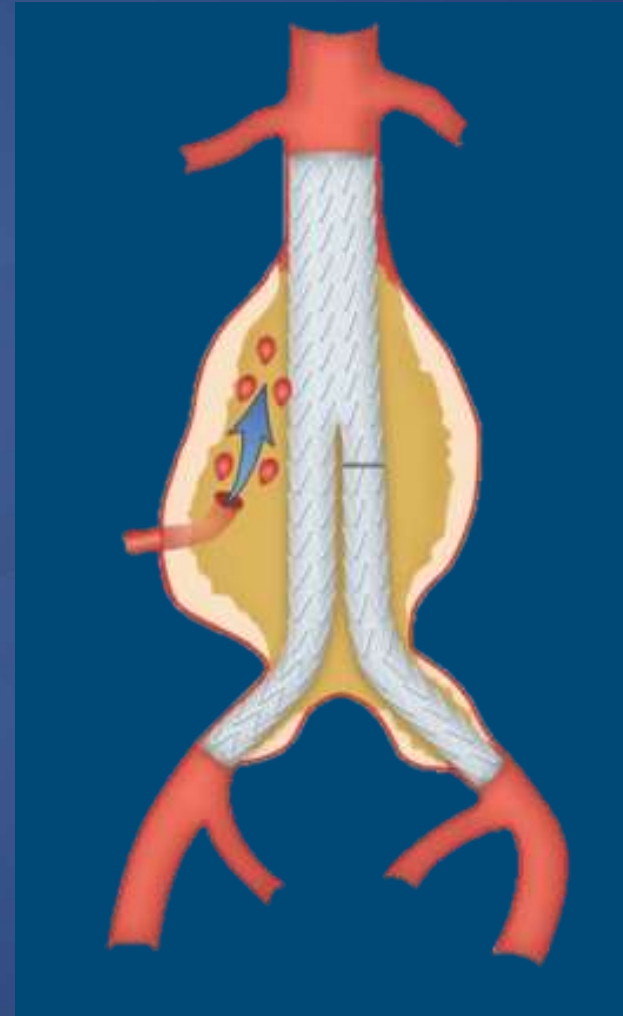
- **Type I:** Leak at graft attachment site
 - Ia: proximal attachment site
 - Ib: distal attachment site
- Treatment failures
- Treatment to prevent the risk of rupture



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

Classification of endoleaks

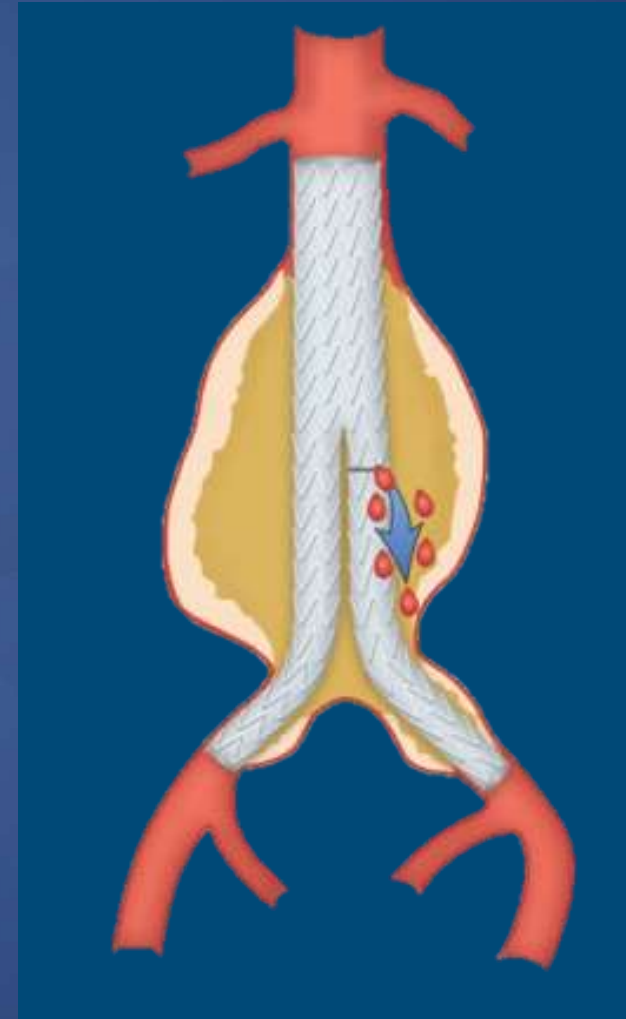
- **Type II:** Retrograde sac filling
 - Ila: single branch vessel
 - Ilb: multiple branch vessel
- Spontaneous seal in about 50% of cases
- Conservative management 'wait-and-watch'



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

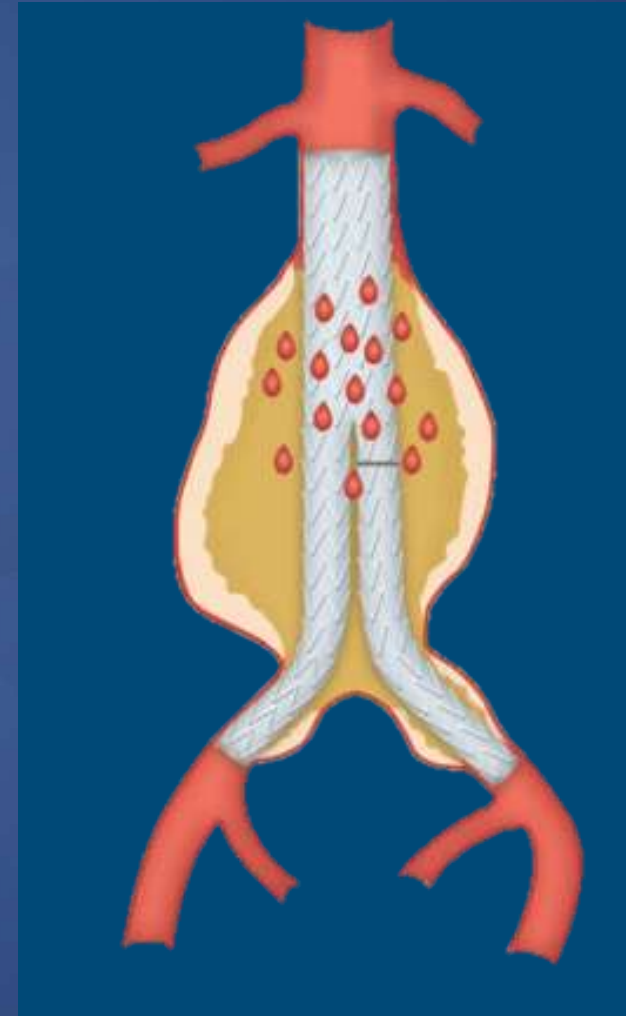
Classification of endoleaks

- **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



Classification of endoleaks

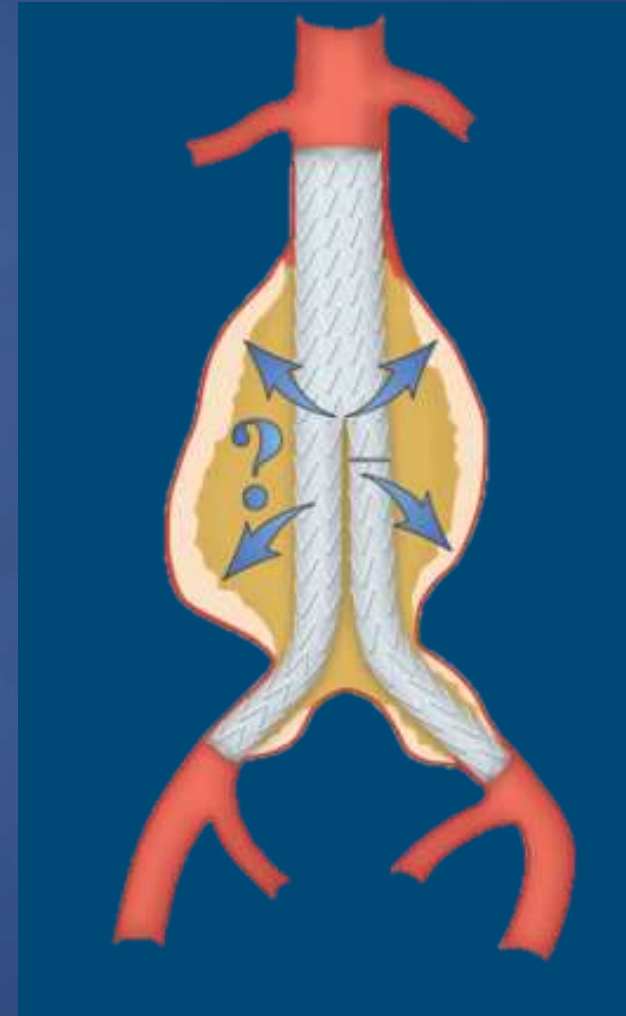
- **Type IV:**
Leak through graft fabric
- Indirect and benign course
- Treatment required in cases of aneurysmal expansion



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

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	<i>p</i> value
Endoleak	2.7	2.4-3.04	< 0.0001
Patient age \geq 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

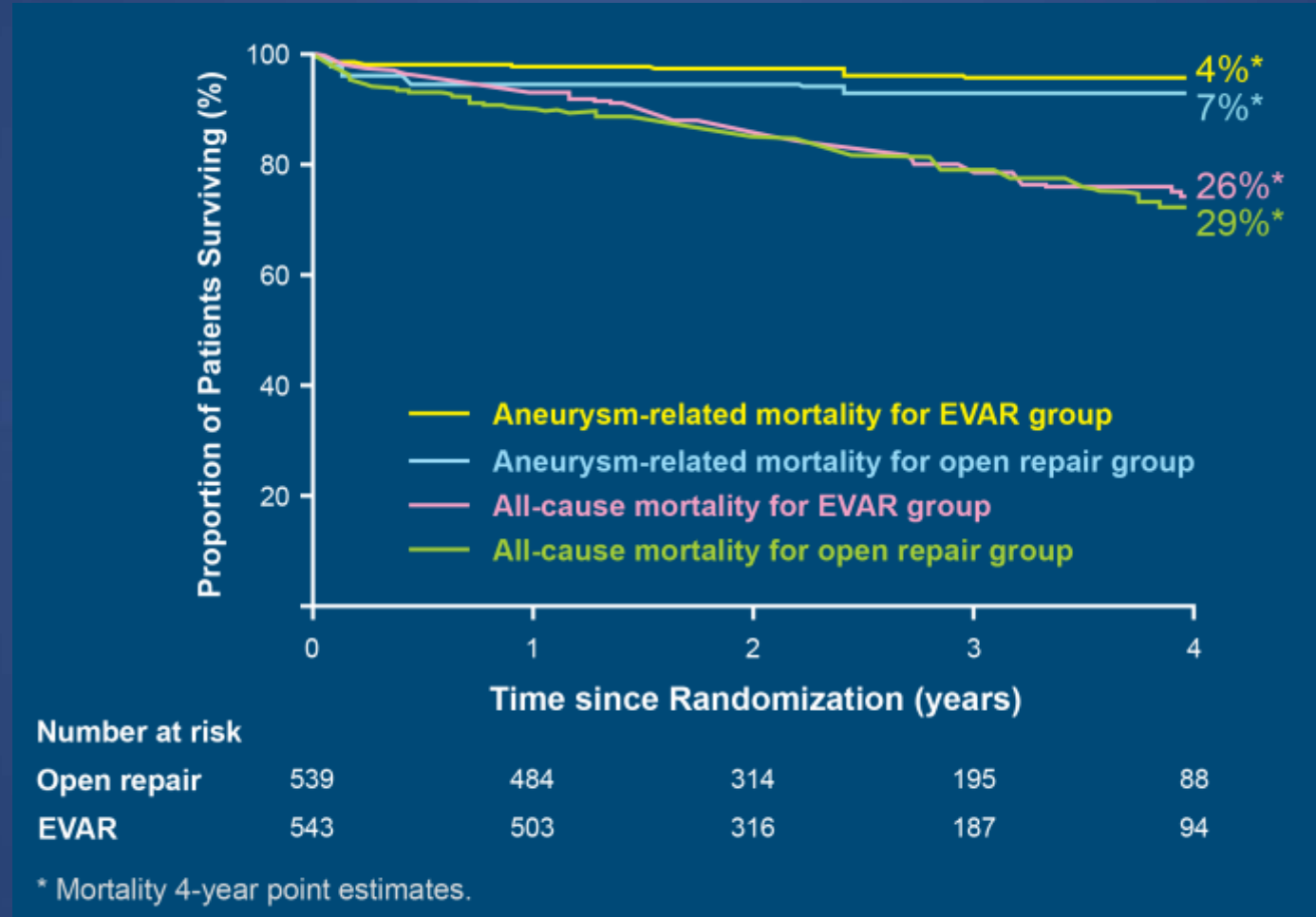
Circulation.
2011;123:2848

EVAR-1 Trial: Outcome

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

Lancet 2004;364:843

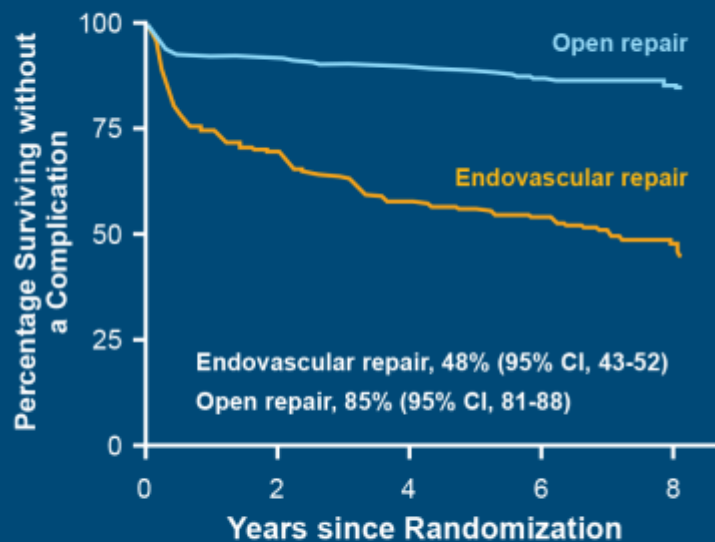
EVAR 1 Trial: Mortality Results



Lancet 2004;364:843

Long-term Outcomes of EVAR 1

Complication

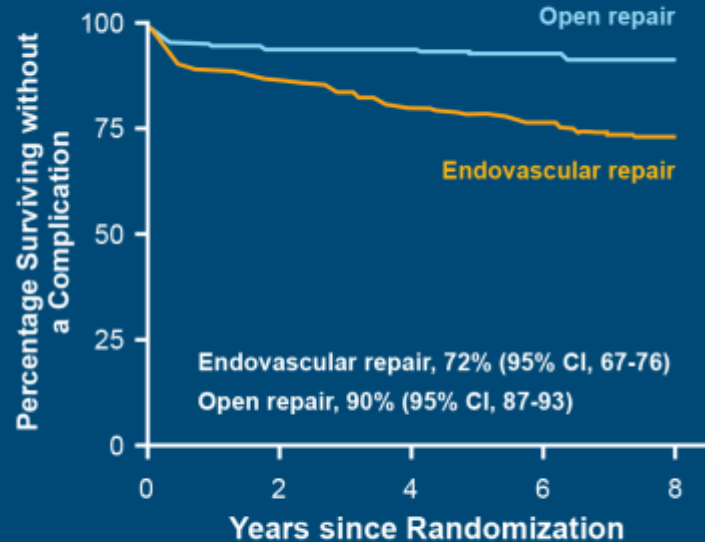


Number at risk

Endovascular repair	626	378	280	174	58
---------------------	-----	-----	-----	-----	----

Open repair	626	496	413	259	91
-------------	-----	-----	-----	-----	----

Reintervention



Number at risk

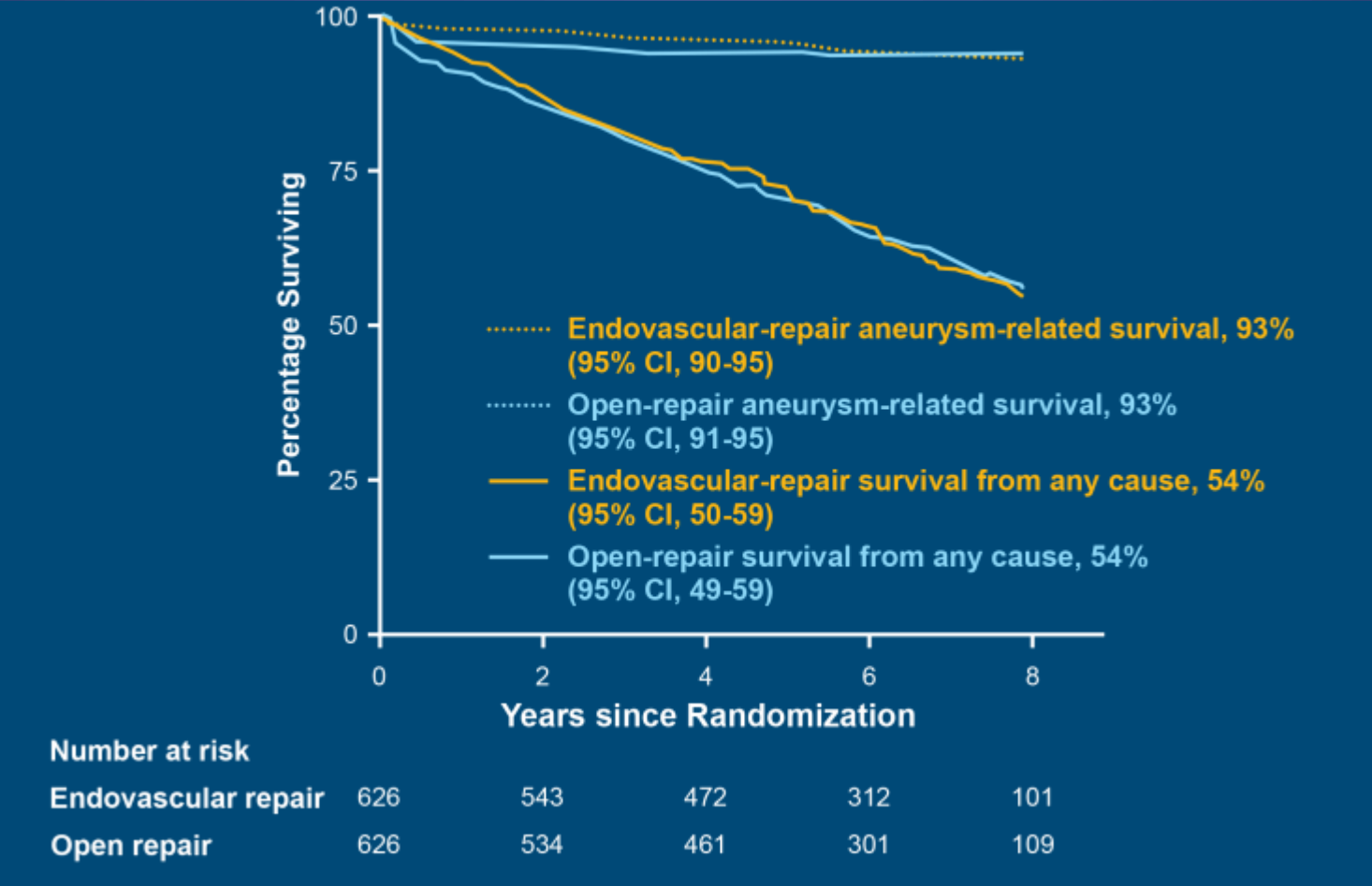
Endovascular repair	626	470	377	243	83
---------------------	-----	-----	-----	-----	----

Open repair	626	503	428	271	97
-------------	-----	-----	-----	-----	----

Lancet 2004;364:843

Long-term Outcomes of EVAR 1

Survivals



Lancet 2004;364:843

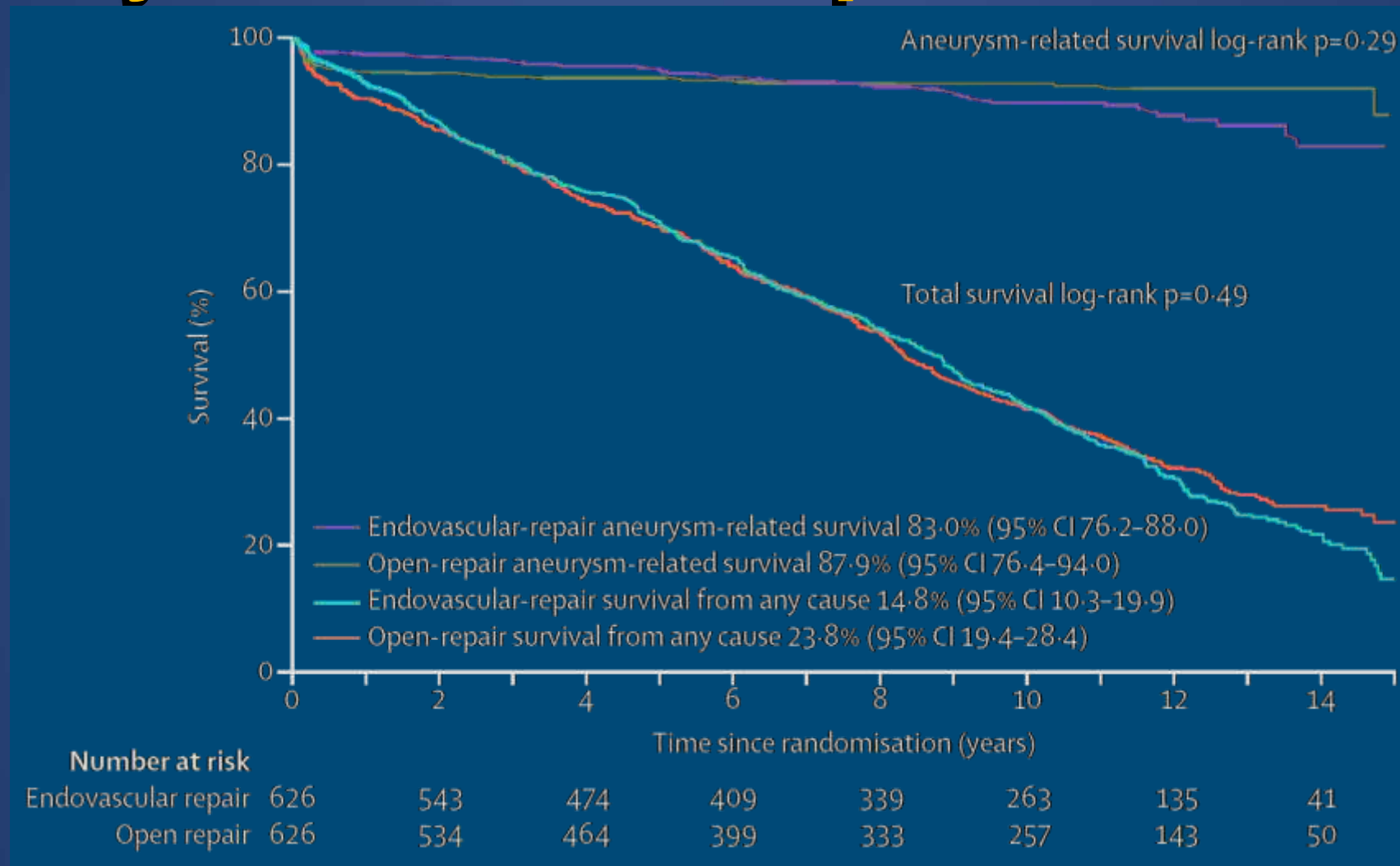
Long-term Outcomes of EVAR 1

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



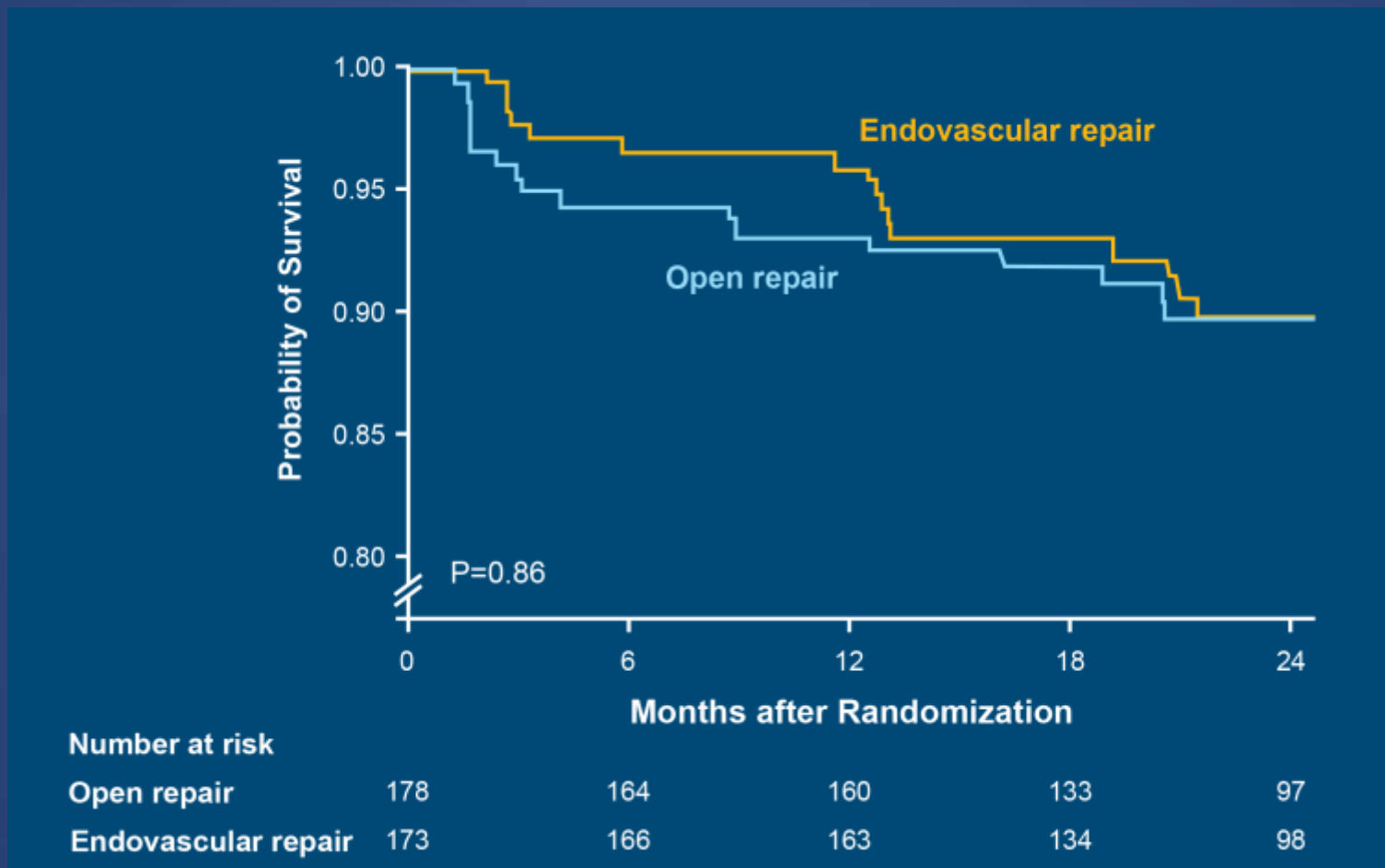
Lancet 2016; 388: 2366-74

DREAM Trial

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

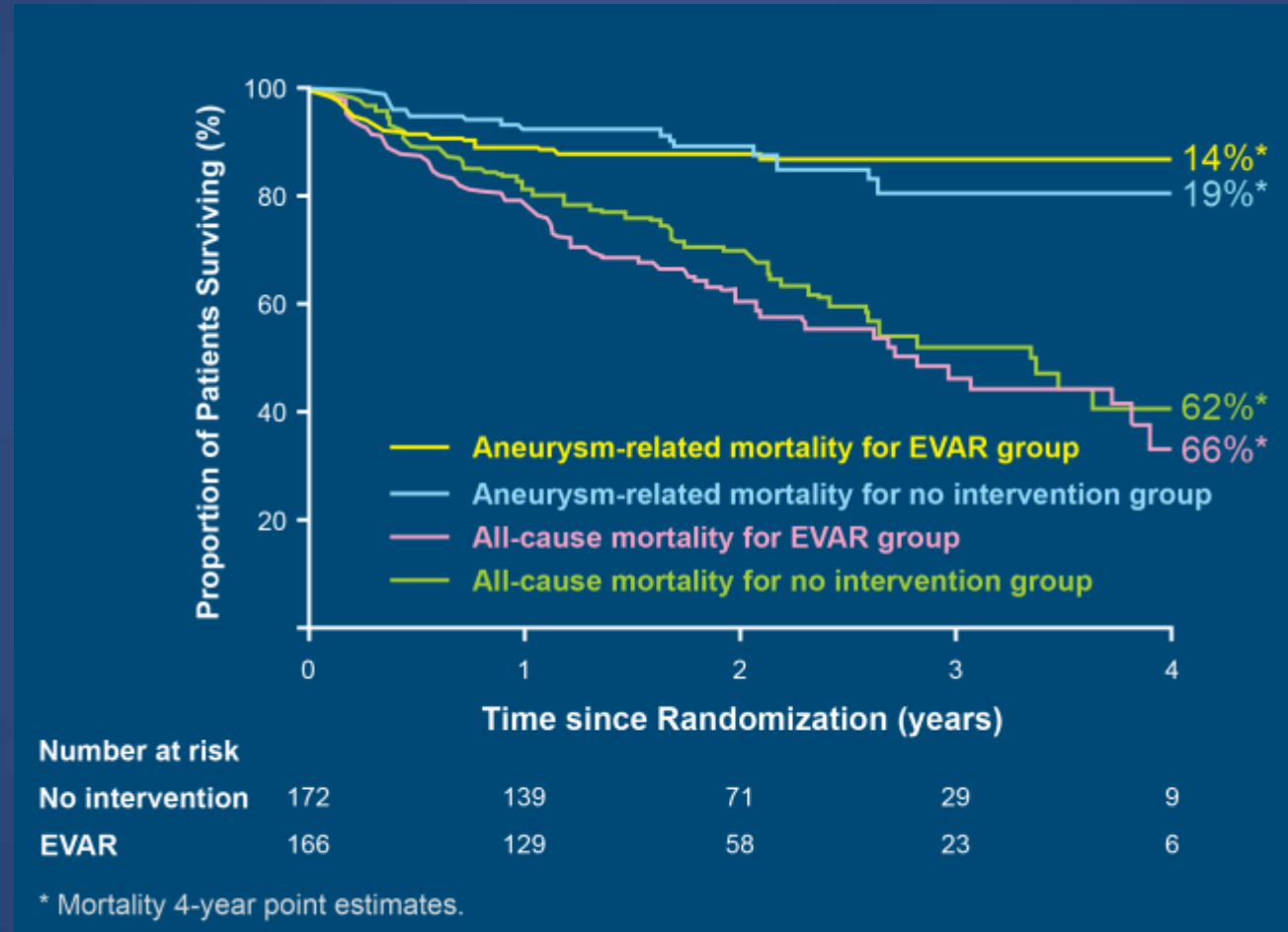
N Engl J Med 2004;351:1607

DREAM Trial: Mortality Results



N Engl J Med 2005;352:2398

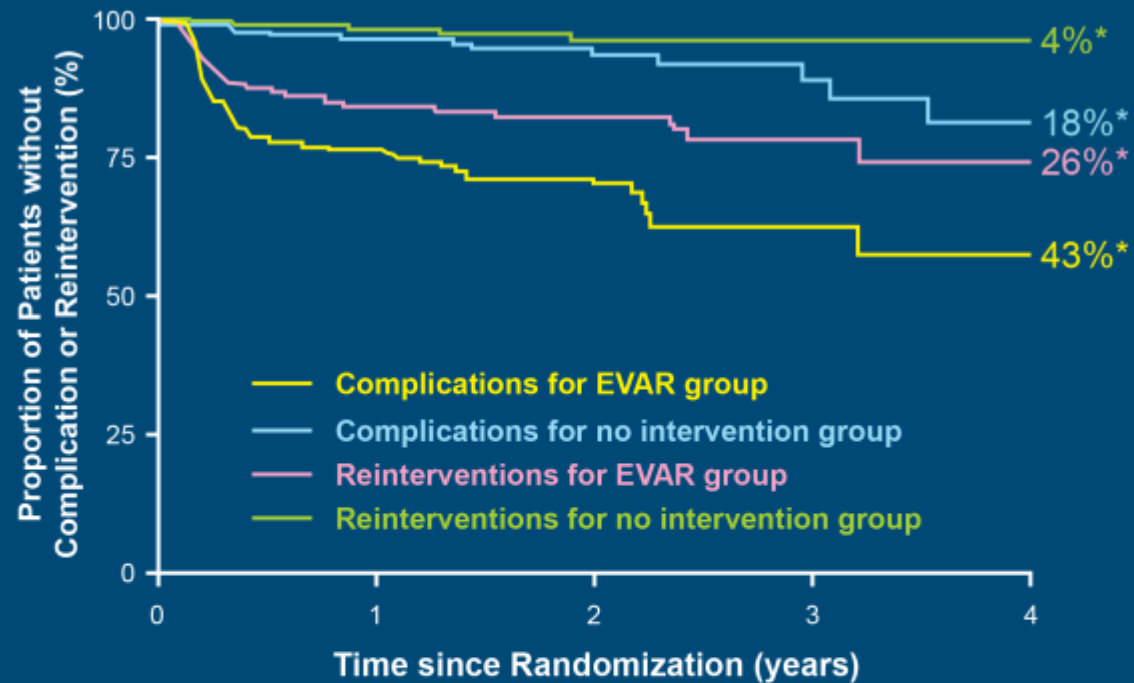
EVAR 2 Trial: Survival Curve



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.

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

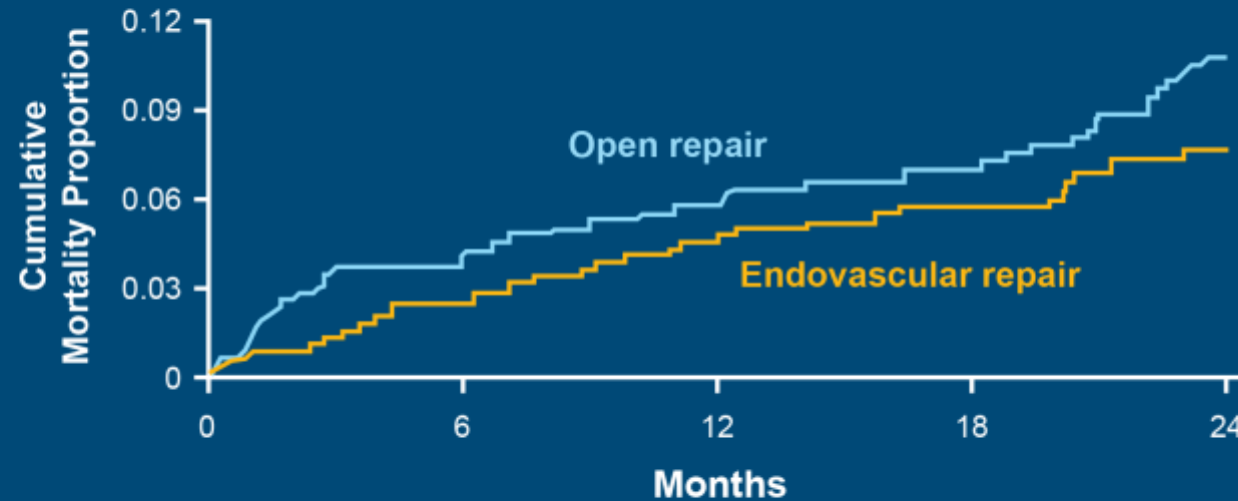
Outcomes of OVER Trial

	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)

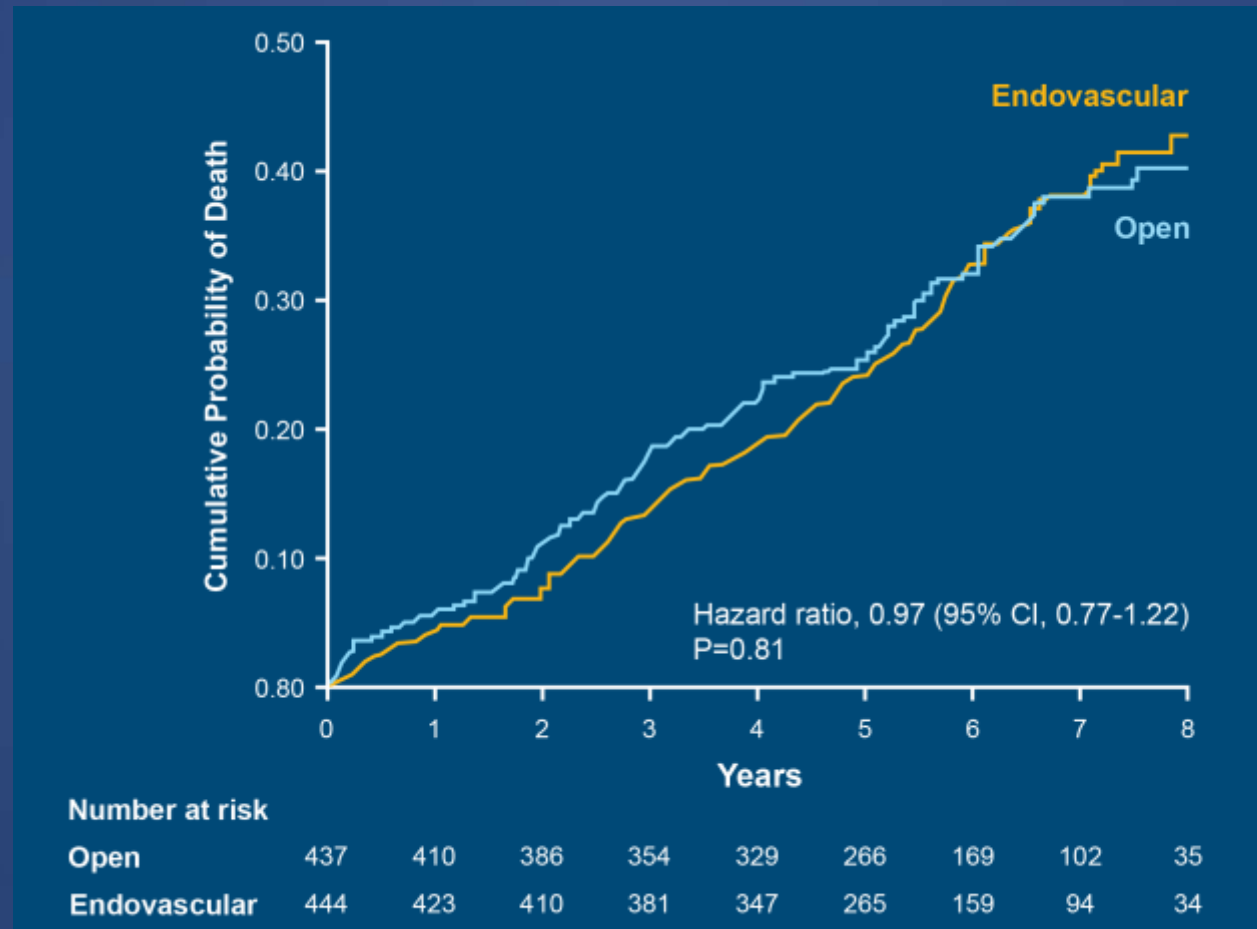
Mortality: Endovascular vs. Open Repair	HR	95% CI	P Value
At 2 Years	0.63	0.40-0.98	0.04
At 3 Years	0.72	0.51-1.00	0.05
At 8 Years ^a	0.97	0.77-1.22	0.81

^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.

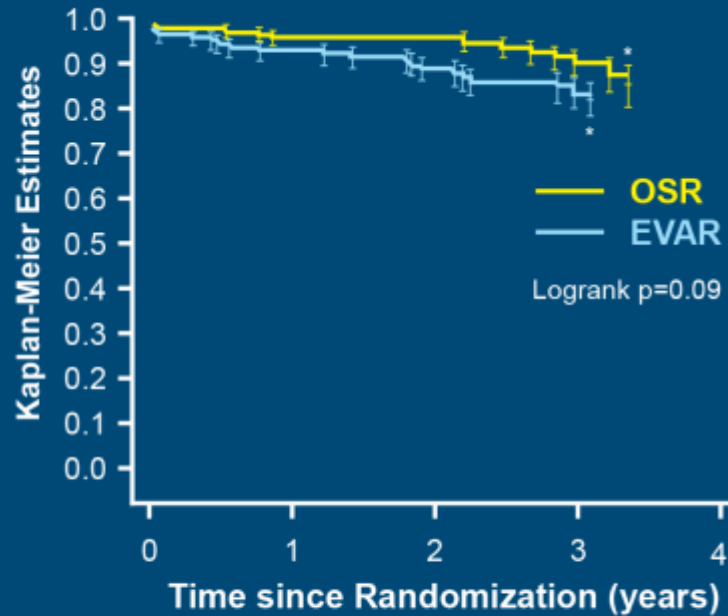
Median 3-Year Follow-up	Open Repair (n = 149)	EVAR (n = 150)	p Value
Death	8%	11.3%	NS
Major Adverse Events	4%	6.7%	NS
Reintervention	2.7%	16%	< 0.0001

**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

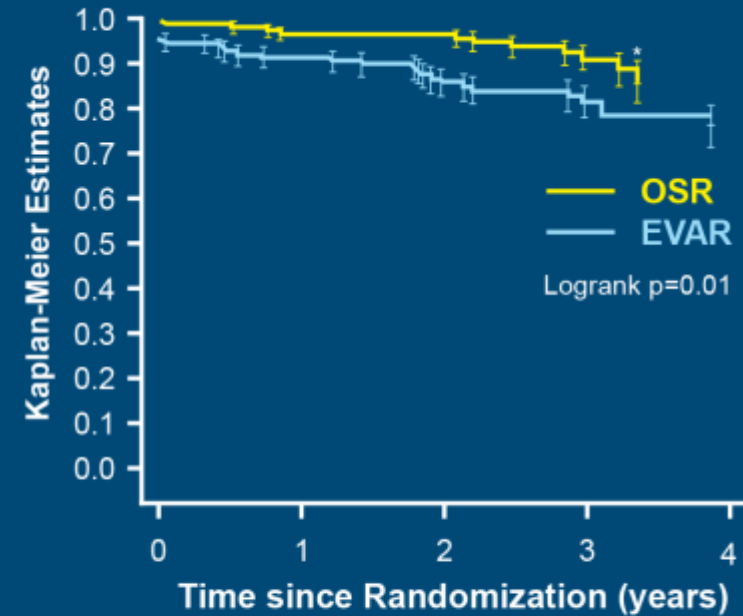
Death or Major Events



Number at risk	0	1	2	3	4
OSR	149	132	116	68	19
EVAR	150	129	103	71	26

* SED exceeds 10%

Death or Reintervention

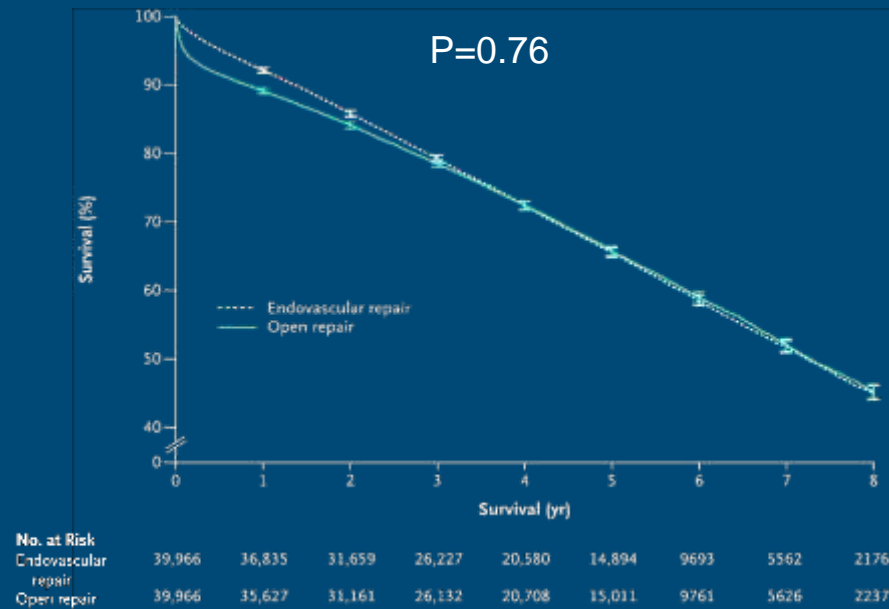


Number at risk	0	1	2	3	4
OSR	149	132	116	68	19
EVAR	150	128	103	71	25

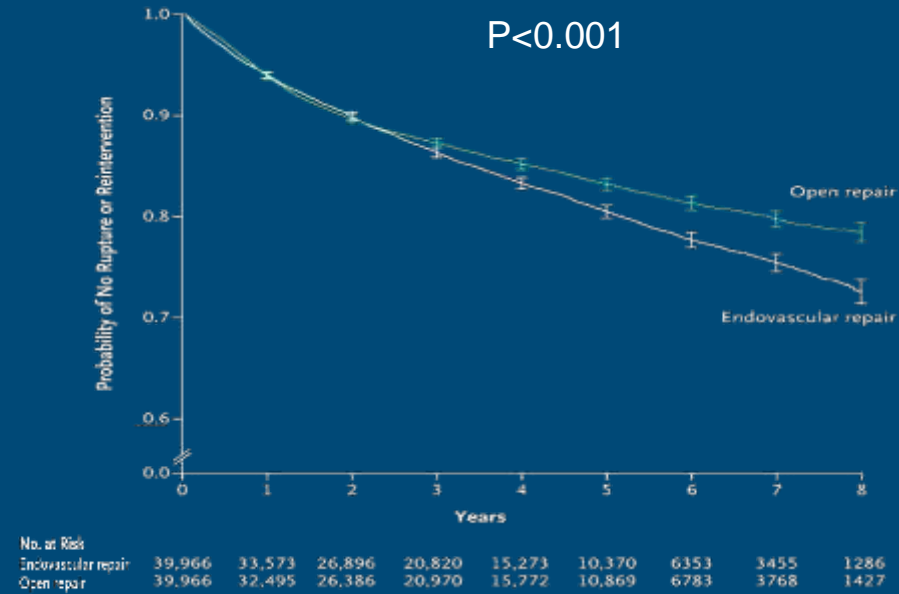
* SED exceeds 10%

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

Overall survival



Re-intervention or complication



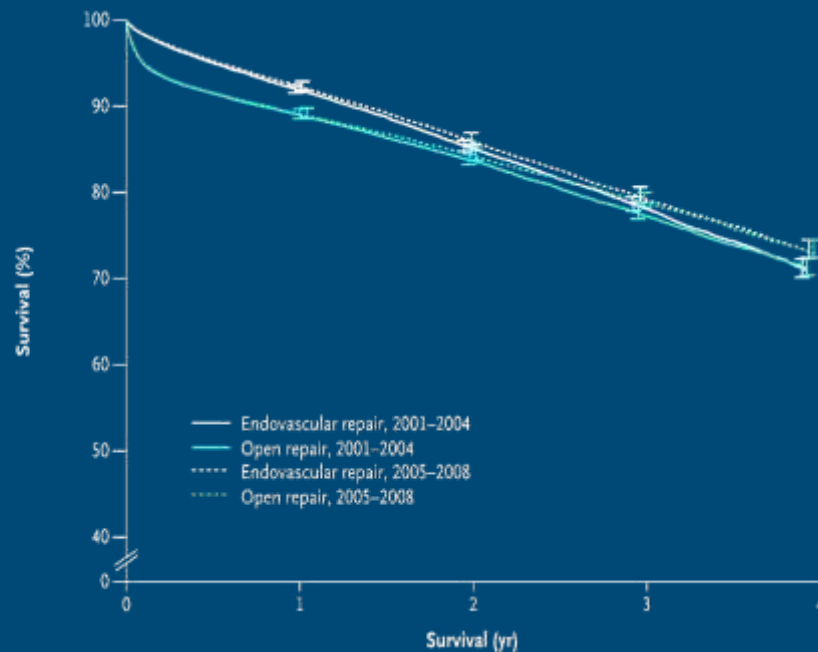
Similar long-term mortality rate, but higher risk of re-intervention or hospitalization for complication with

EVAR

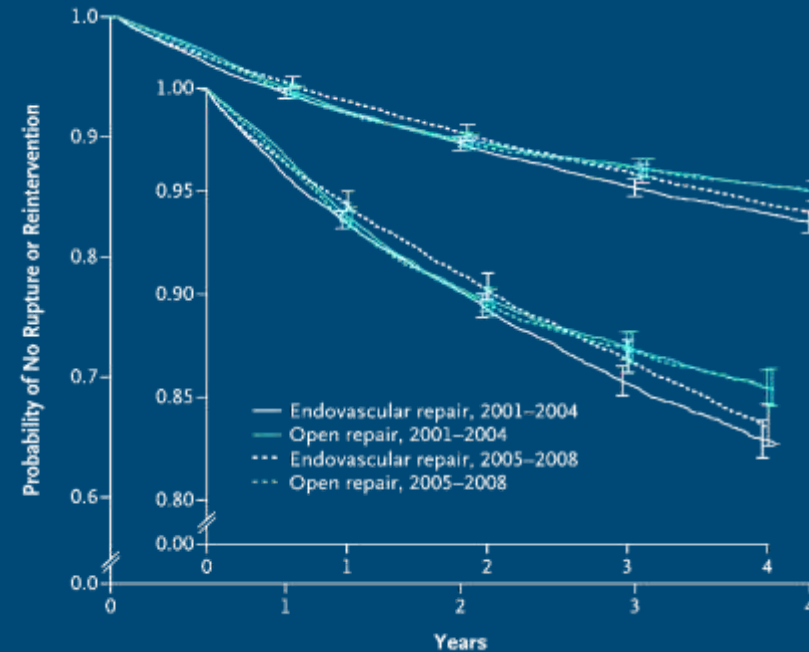
NEJM 2015;373:328

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

Overall survival

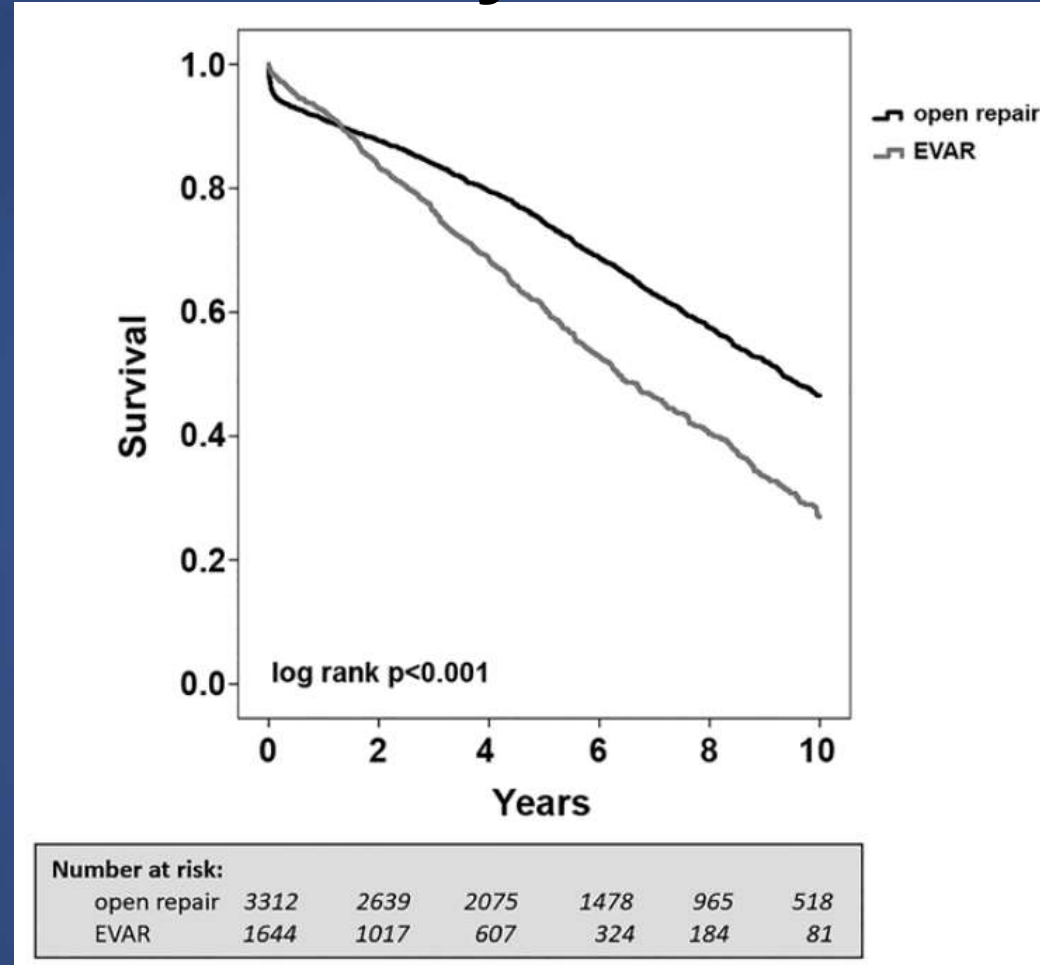


Re-intervention or complication



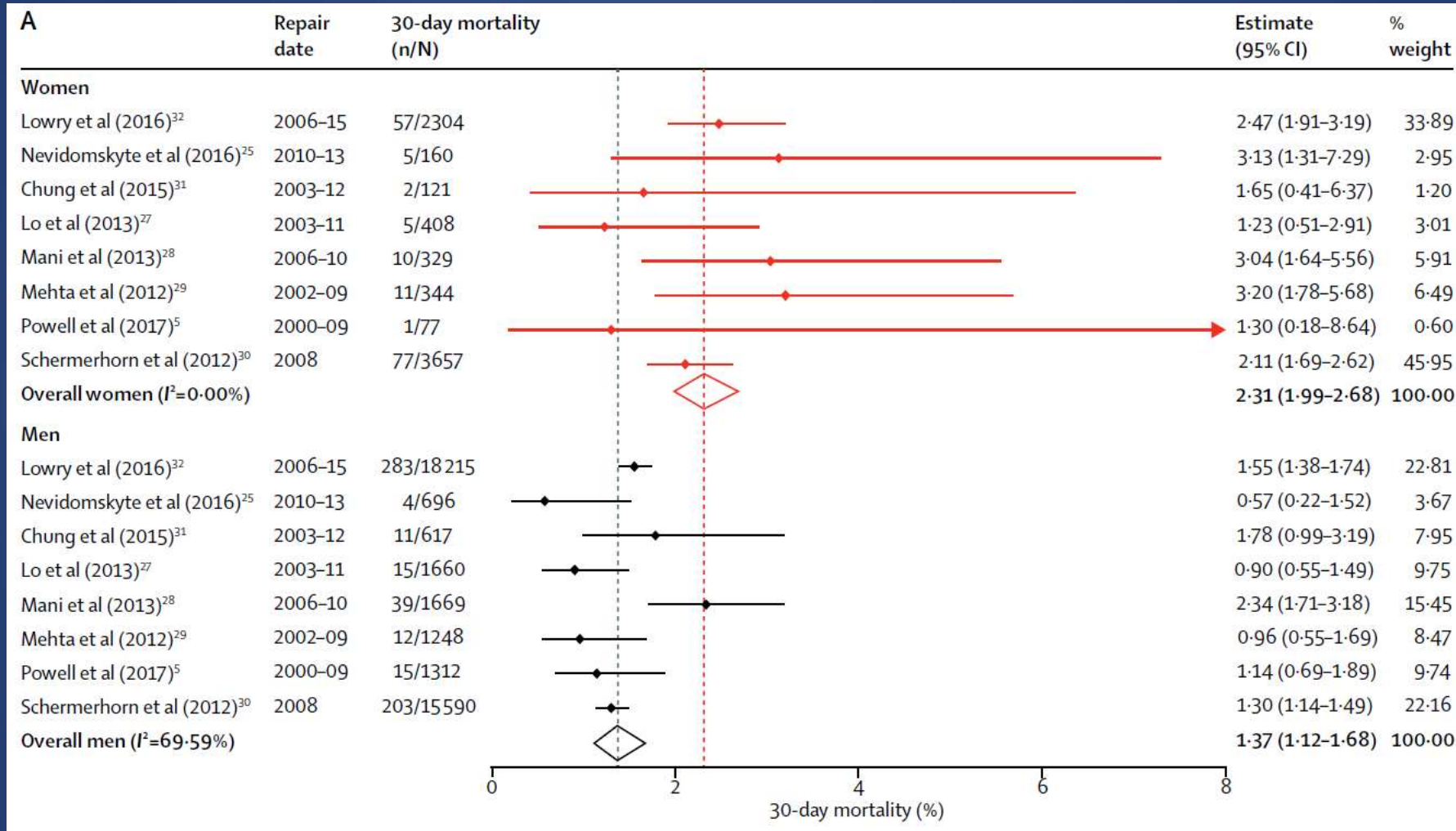
The outcomes of EVAR have been improving over time

Population based 10 year survival in Finland



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

Outcome for sex in EVAR

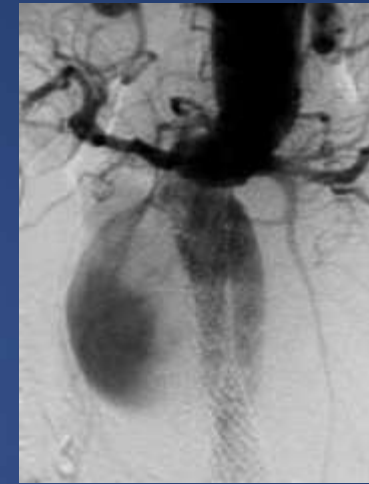


Higher 30-day mortality in women

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.)

ENDURANT EXCLUDER® TALENT AAA ZENITH®



20Fr



20.4Fr



22Fr



24Fr

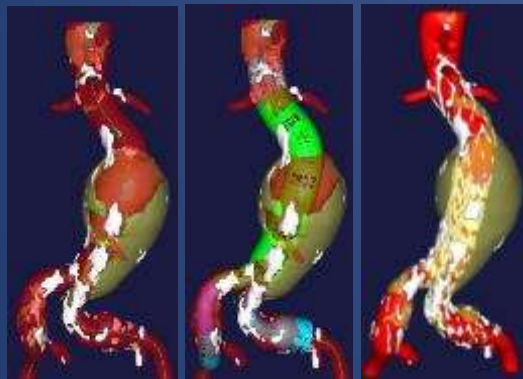


≈ 7mm access vessel required

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)	<i>P</i> 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**

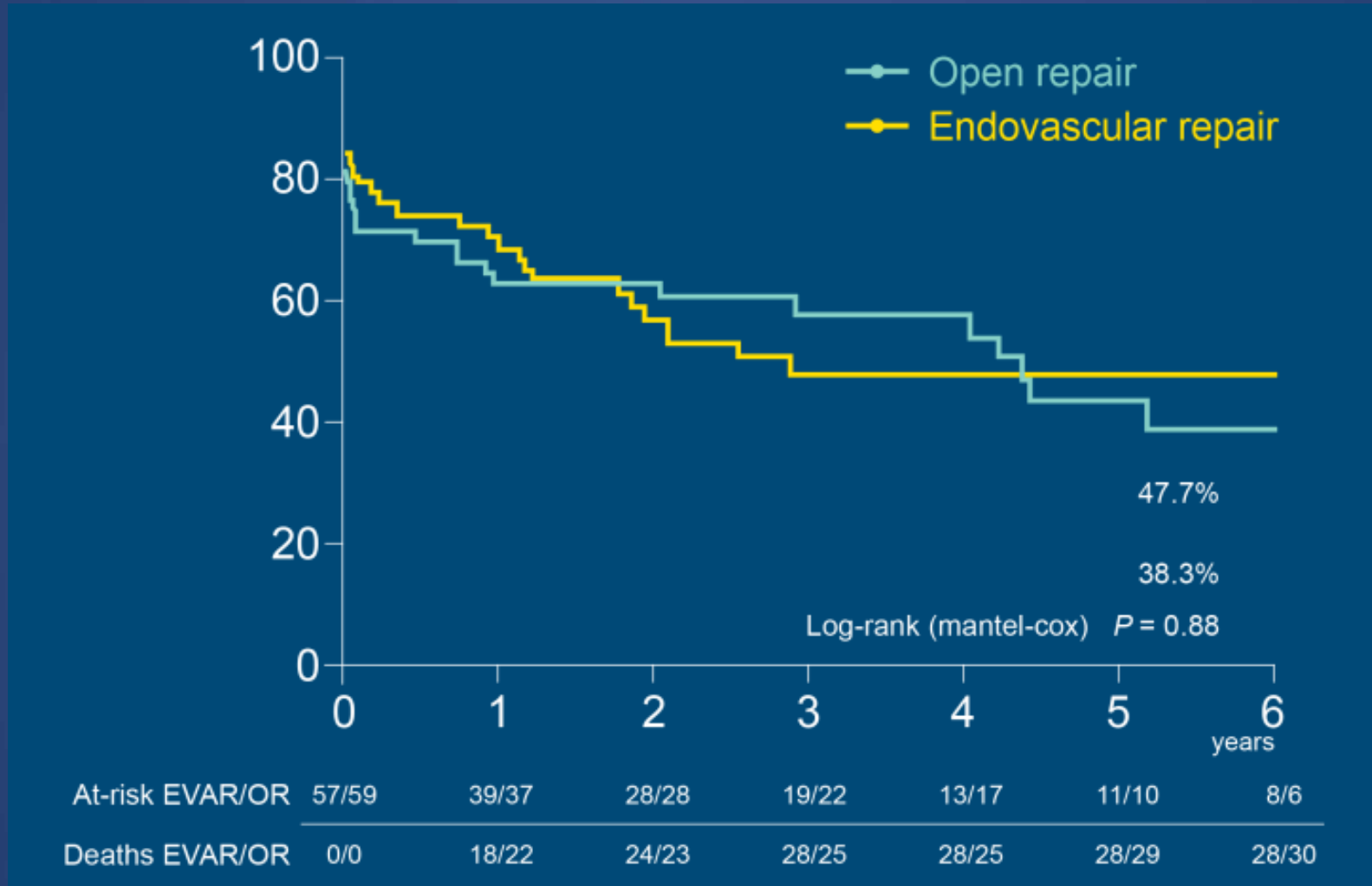
J Vasc Surg. 2011 Nov;54(5):1273

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



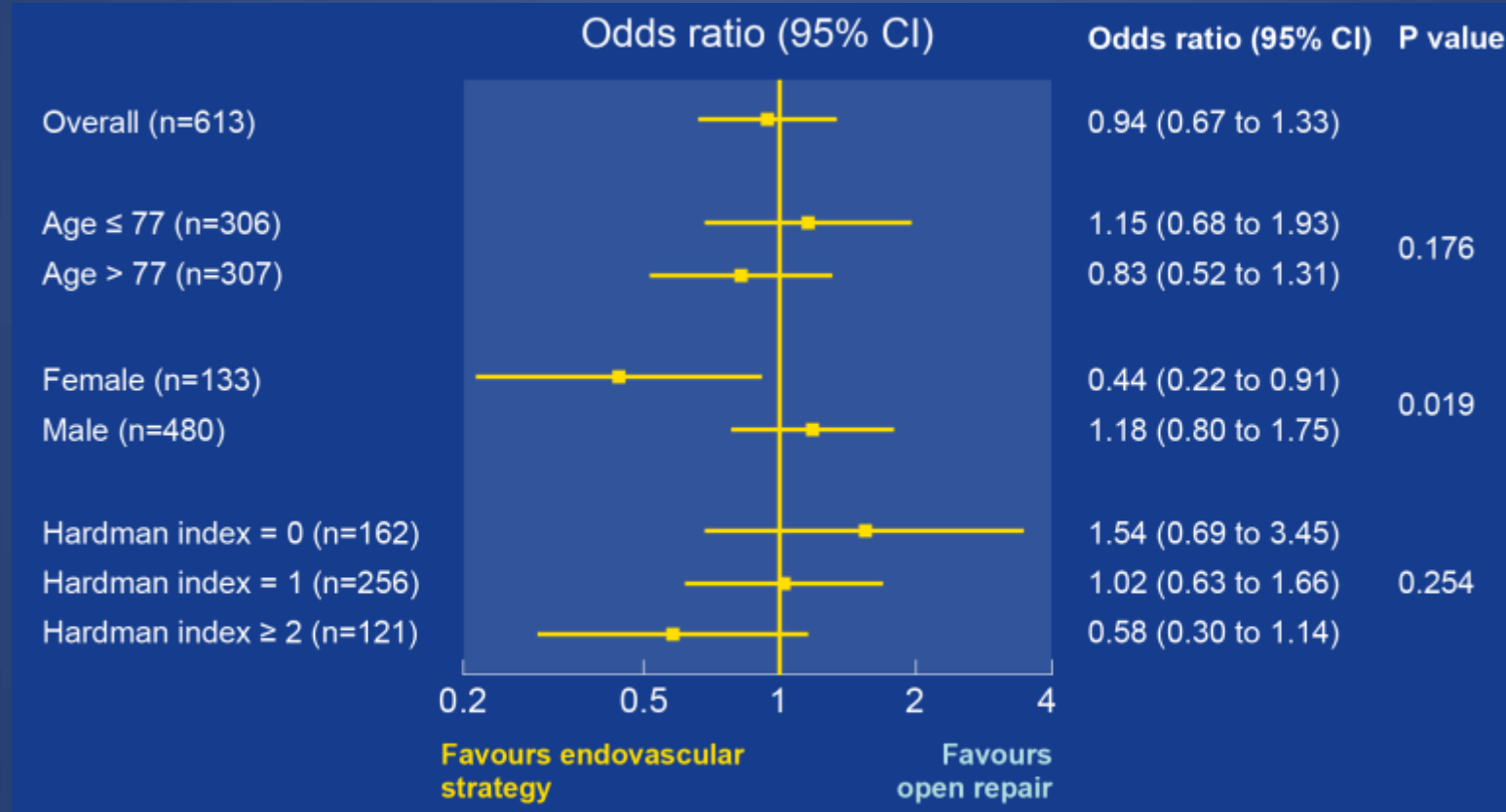
Ann Surg 2013;258: 248

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)

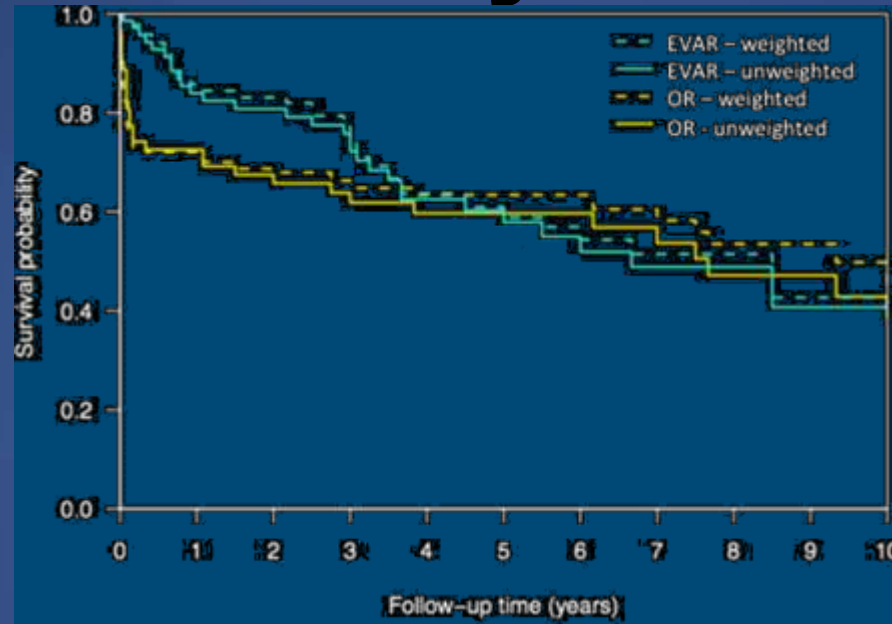
BMJ 2014;348:f7661

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

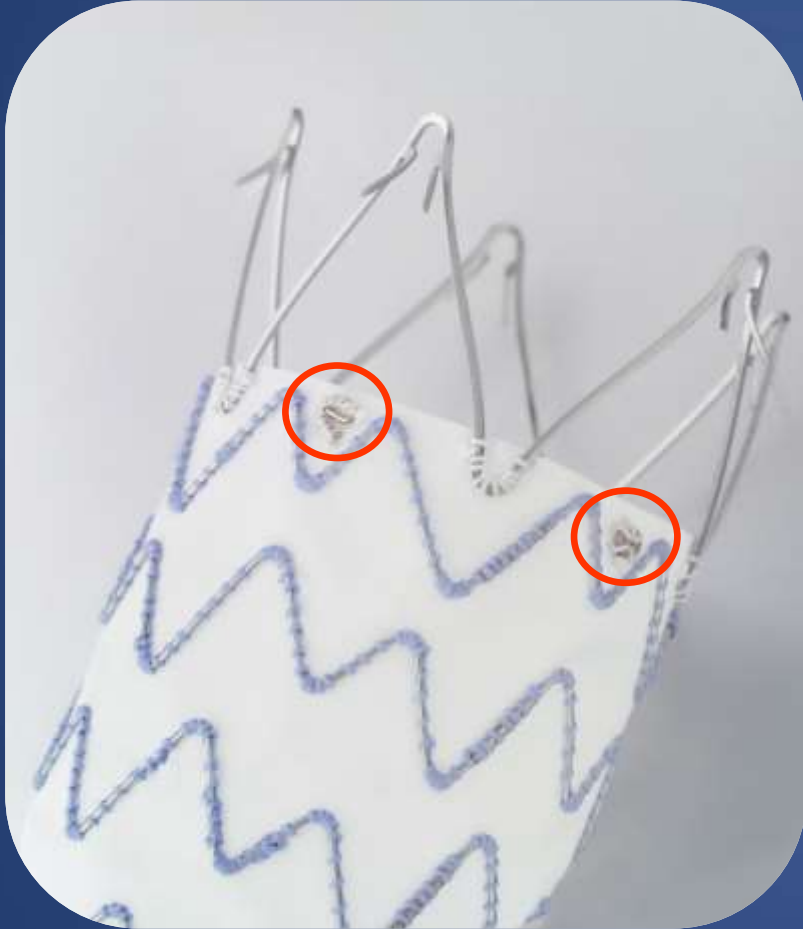
Circulation 2016;134:1822-1832

Procedure of EVAR

Match the proximal edge



Match the proximal edge

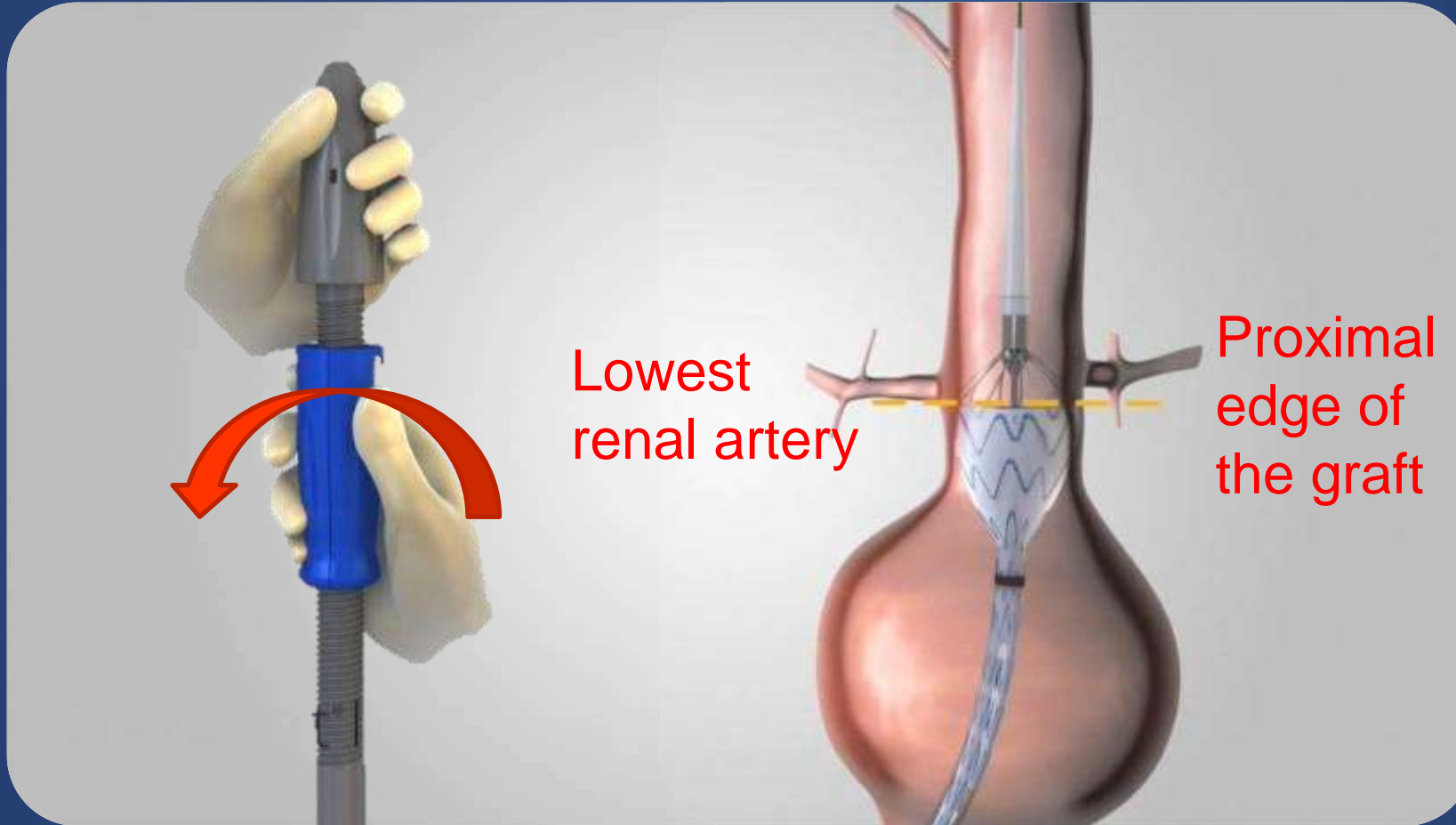


4 proximal radiopaque markers

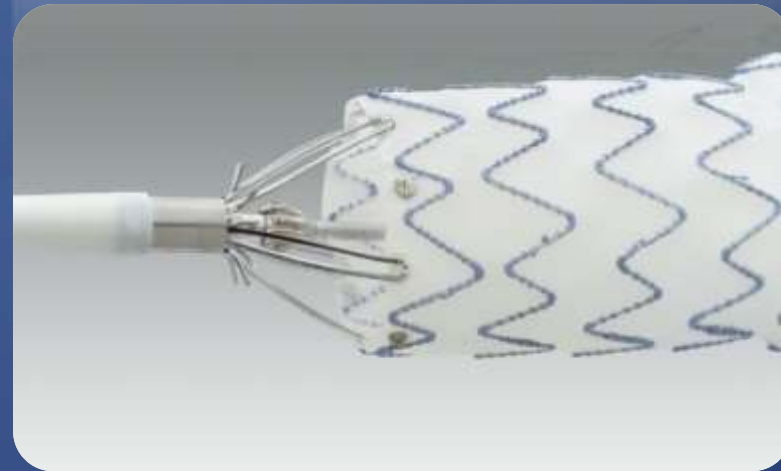
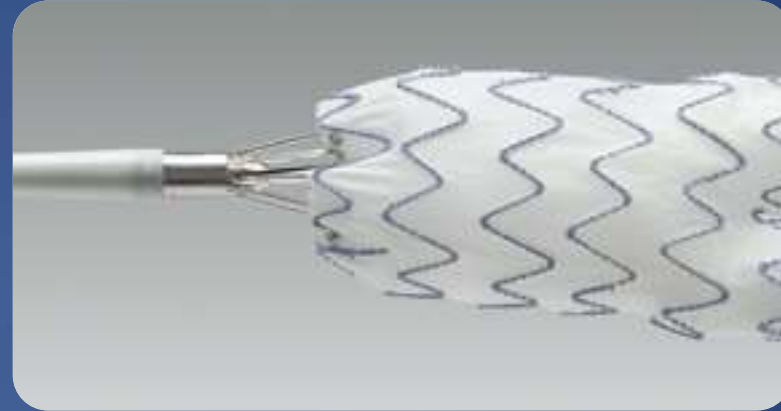
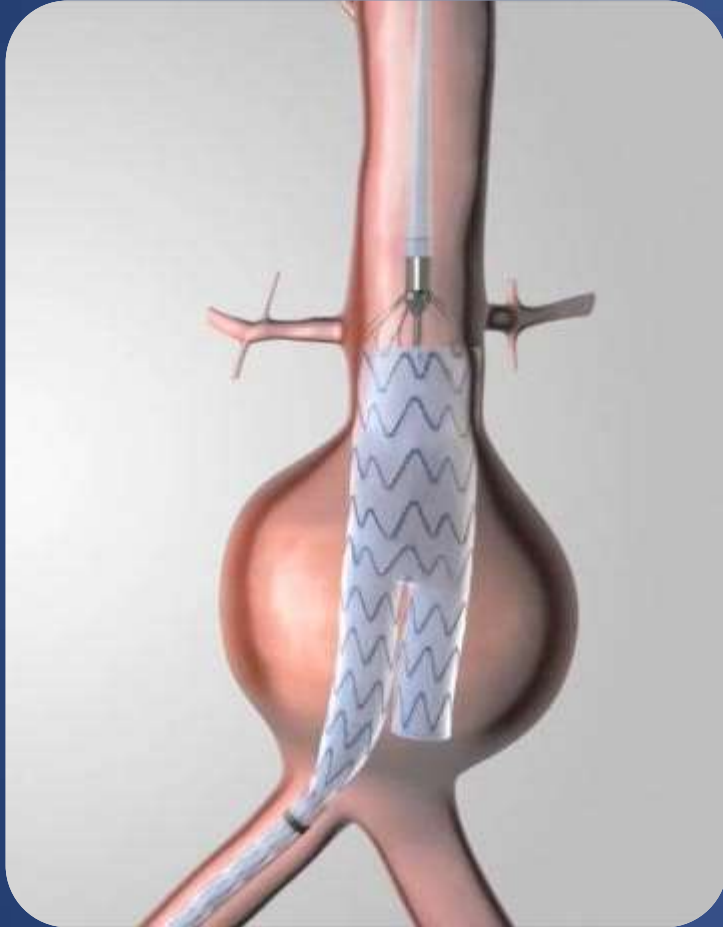


**Proximal edge of stent graft
1mm above proximal markers**

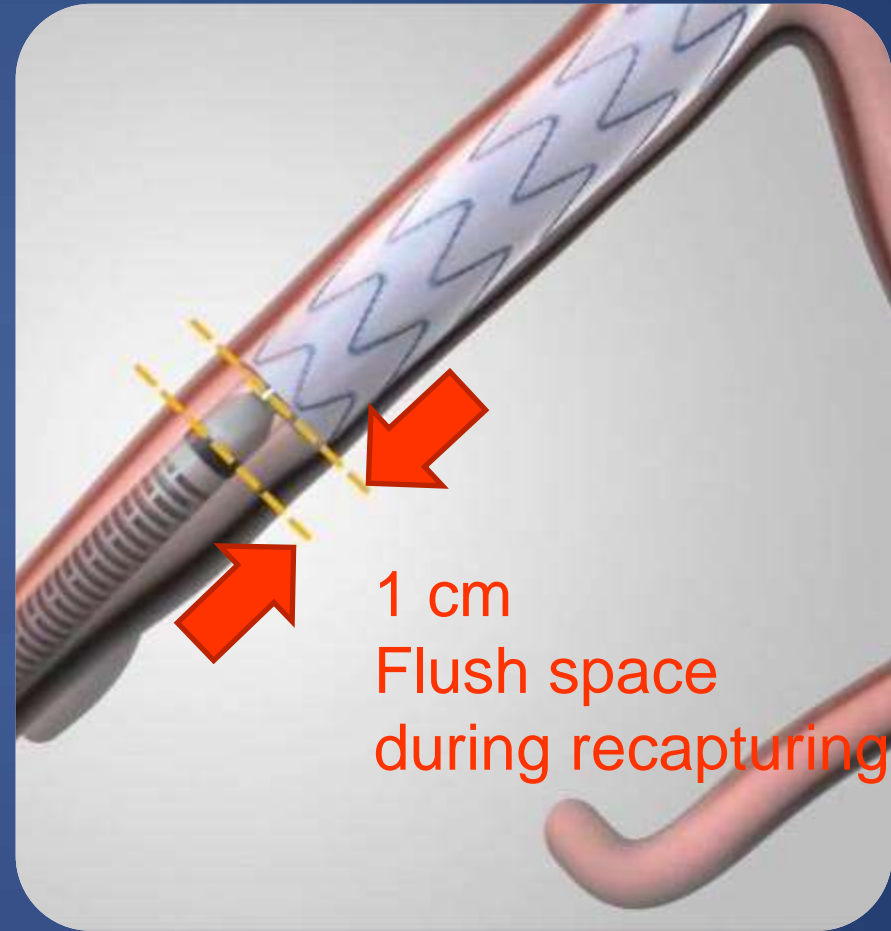
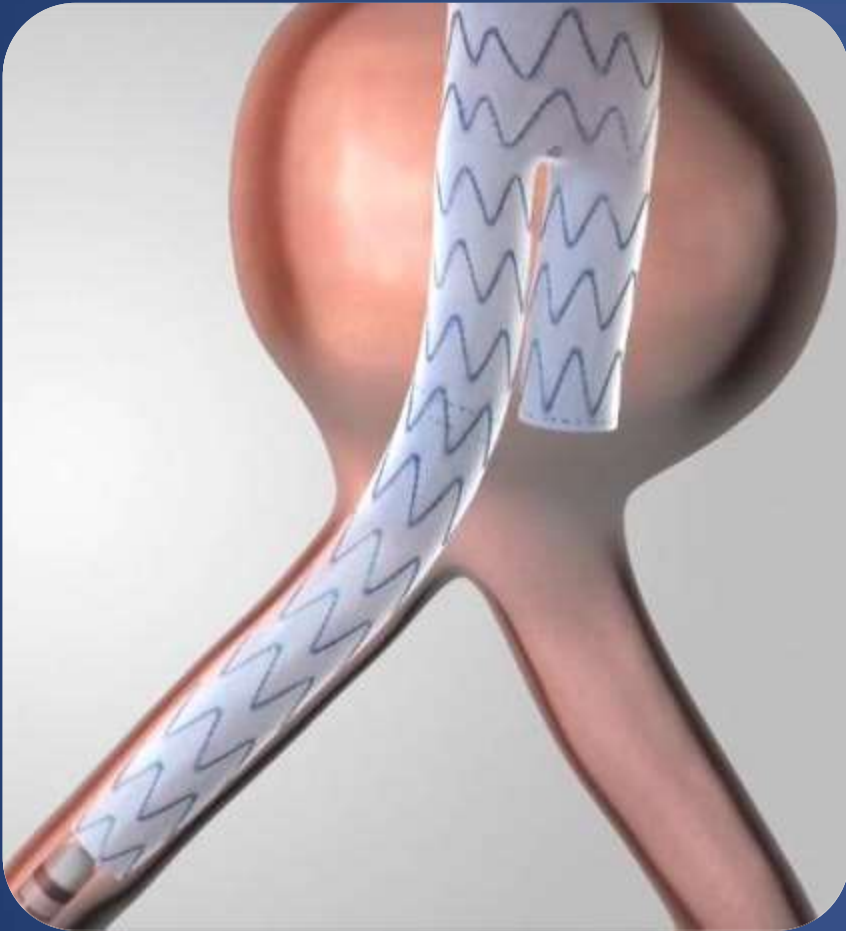
Match the proximal edge



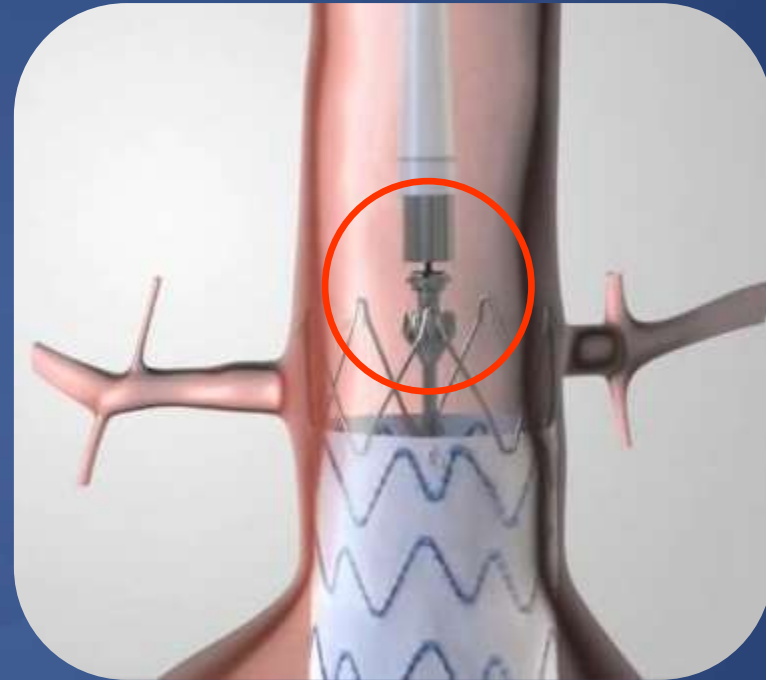
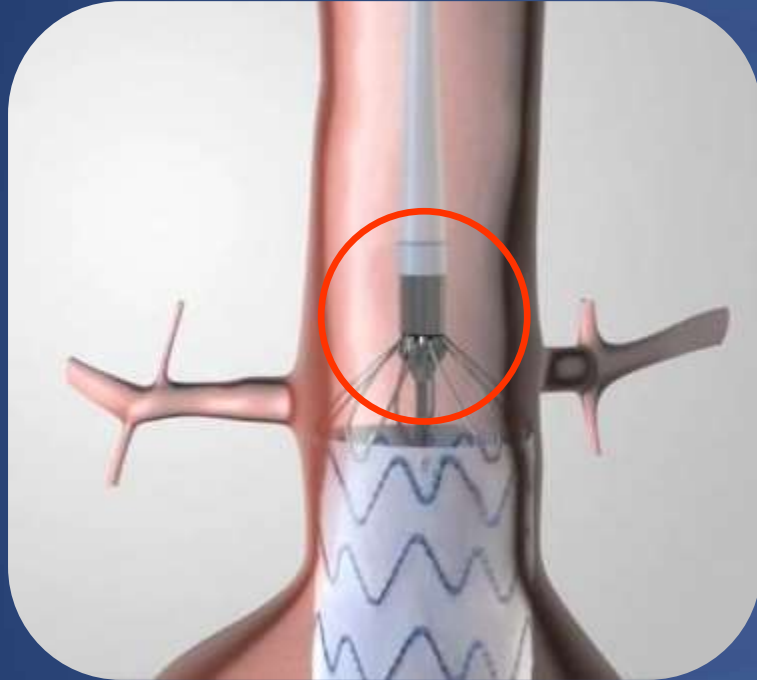
Deploy the stent



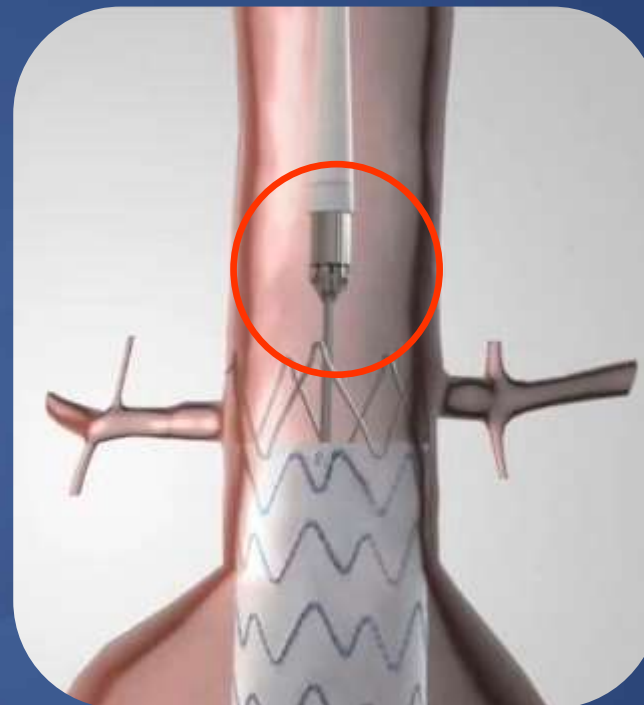
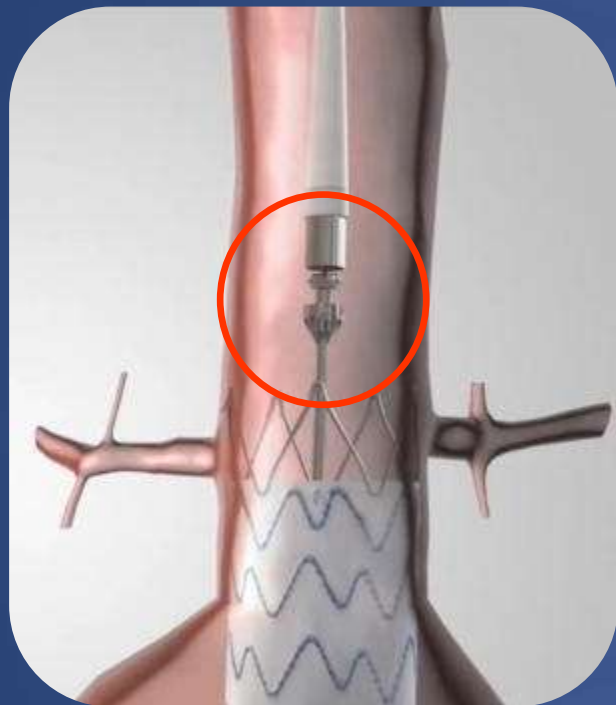
Deploy the ipsilateral limb stent



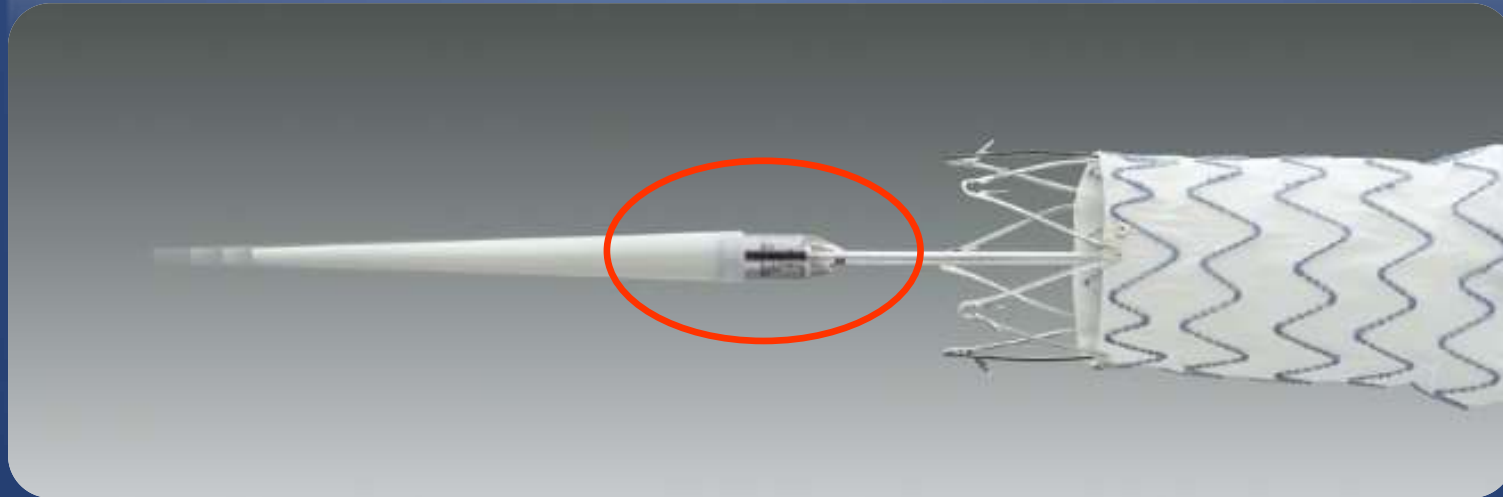
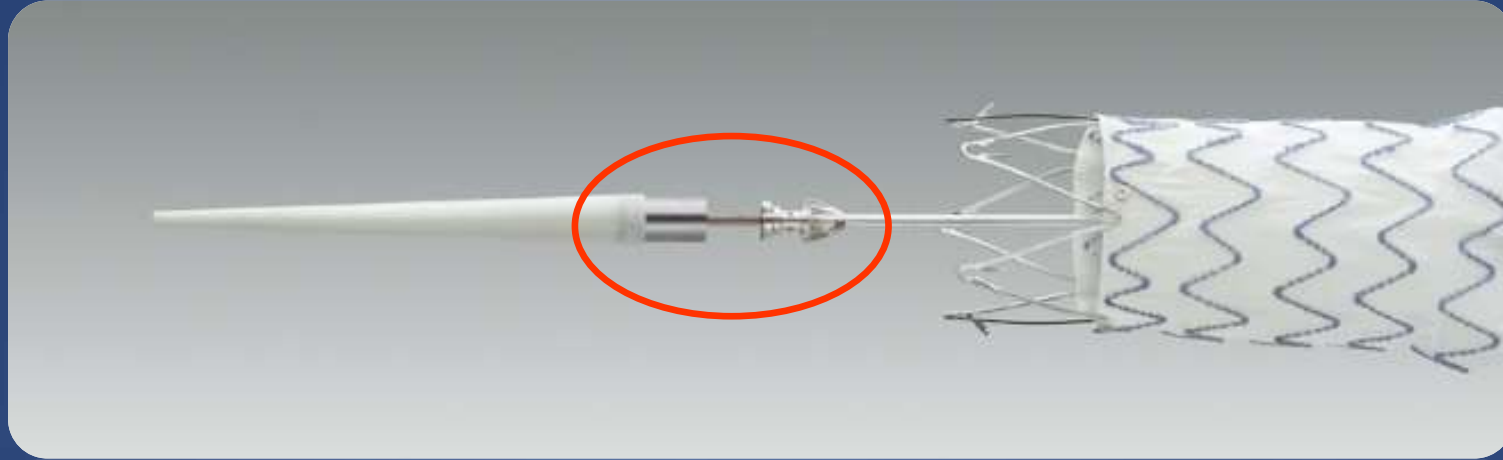
Release the suprarenal stent



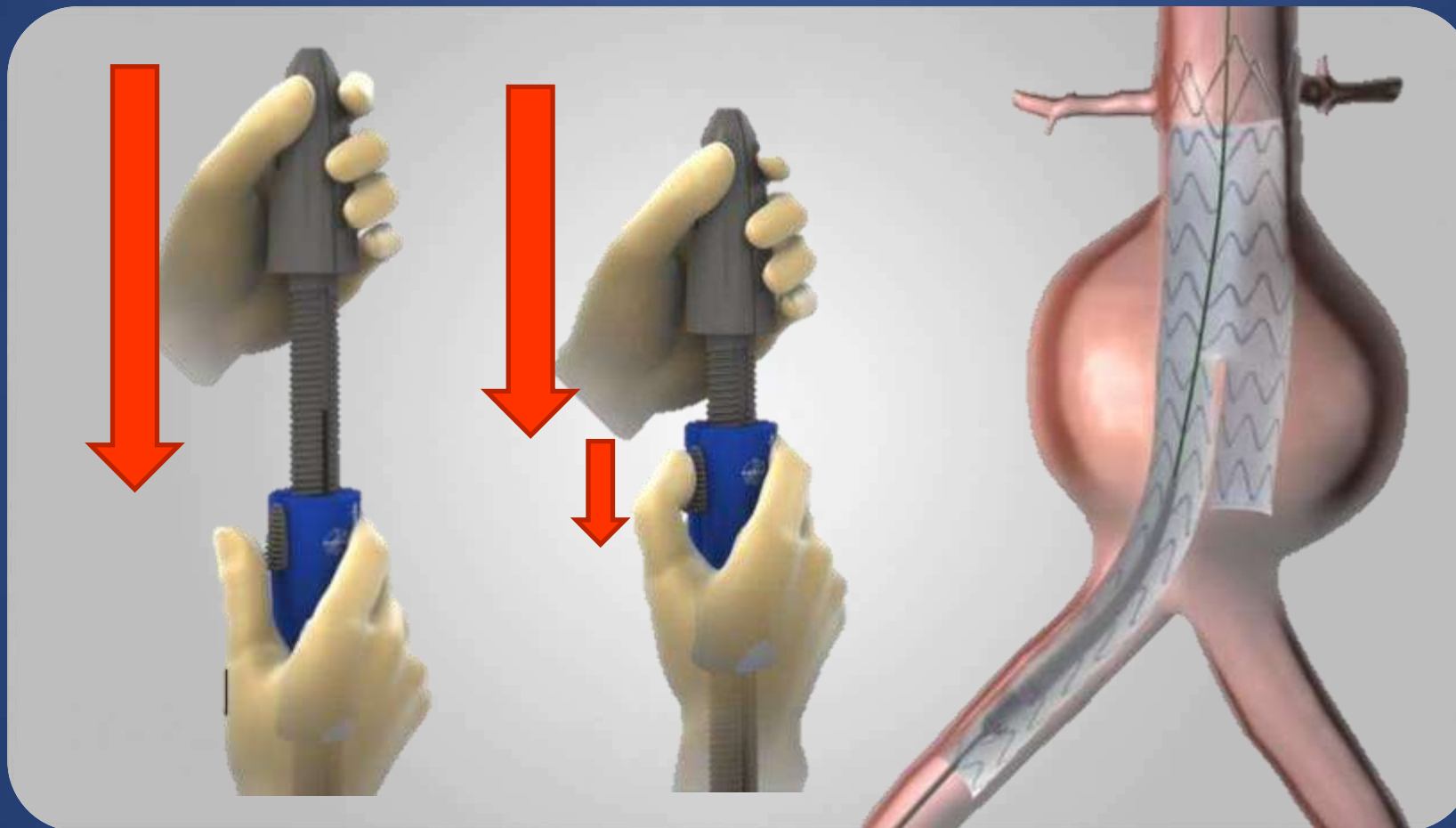
Recapturing the spindle



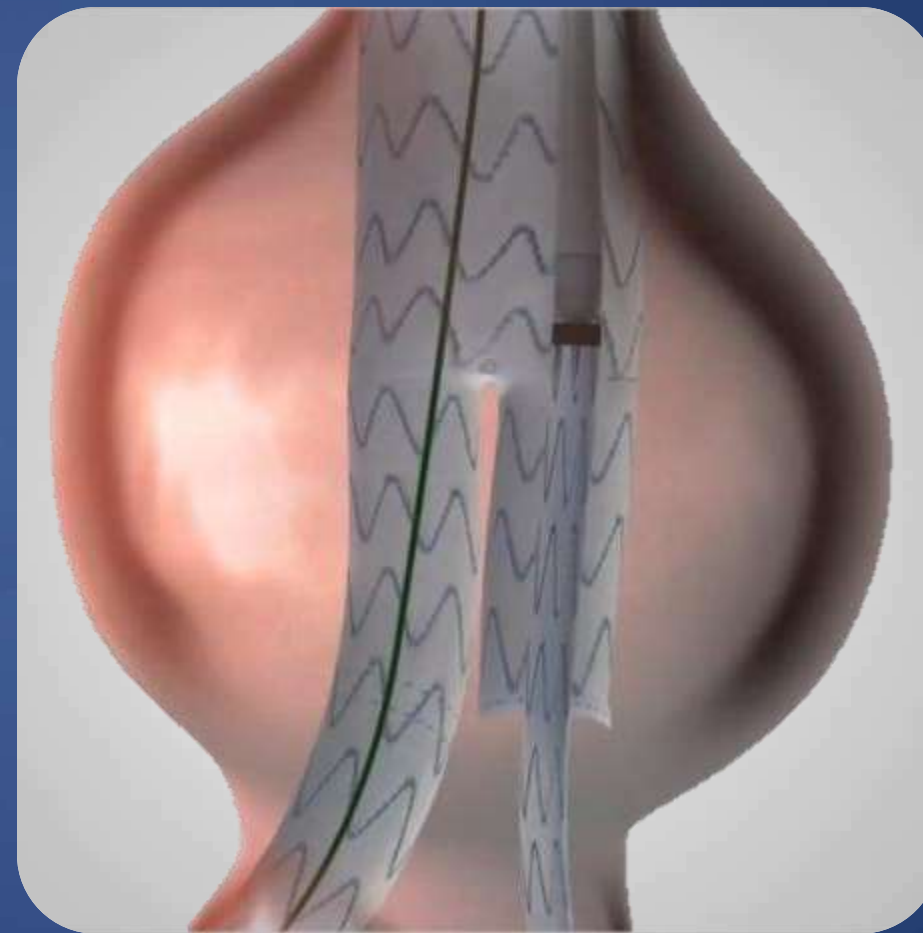
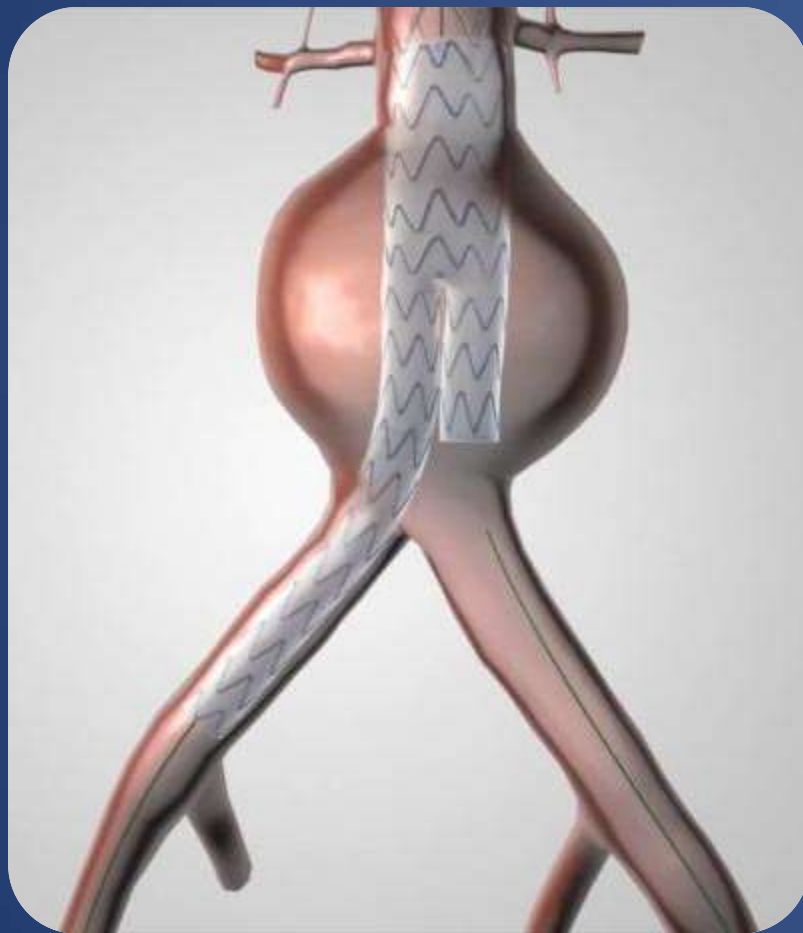
Recapturing the spindle



Deploy the ipsilateral limb stent



Deploy the contralateral limb stent



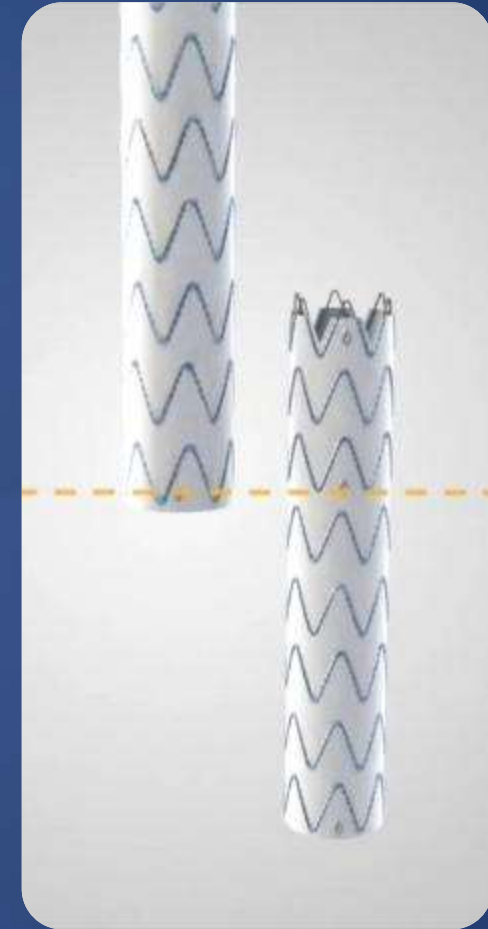
Deploy the contralateral limb stent



Flower Divider
Marker

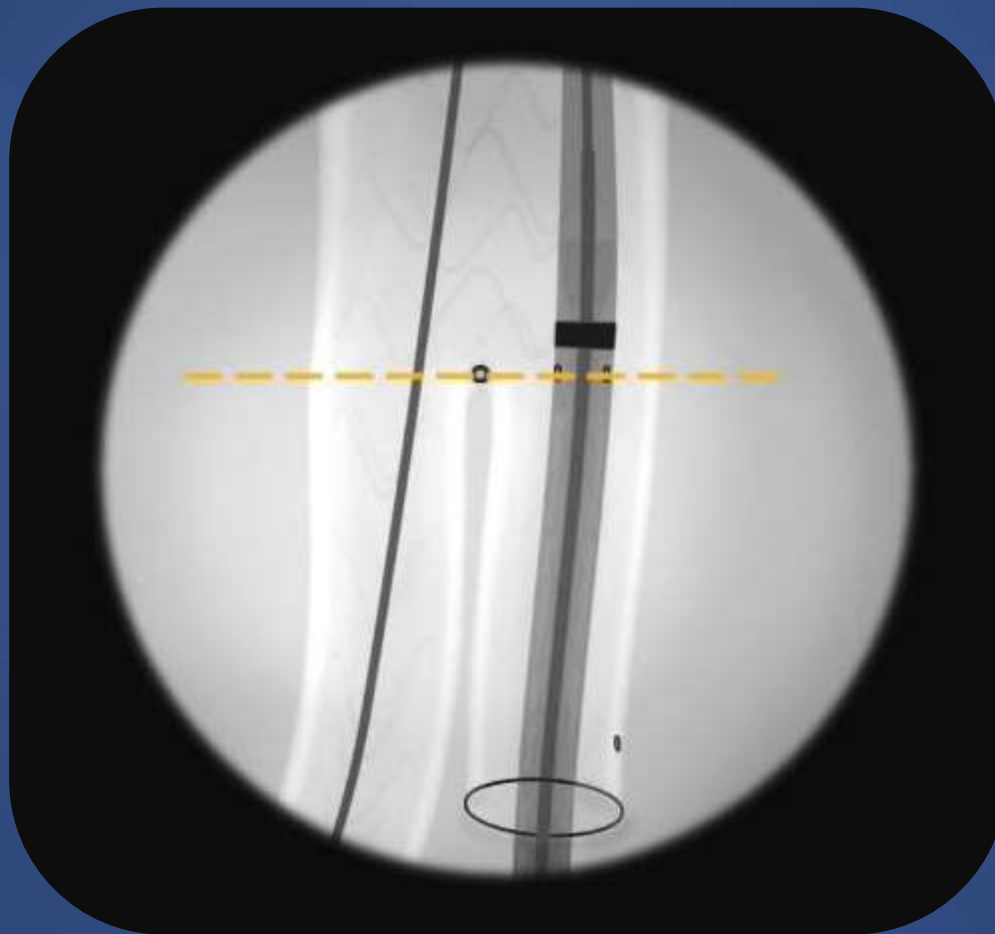


Contralateral
gate marker

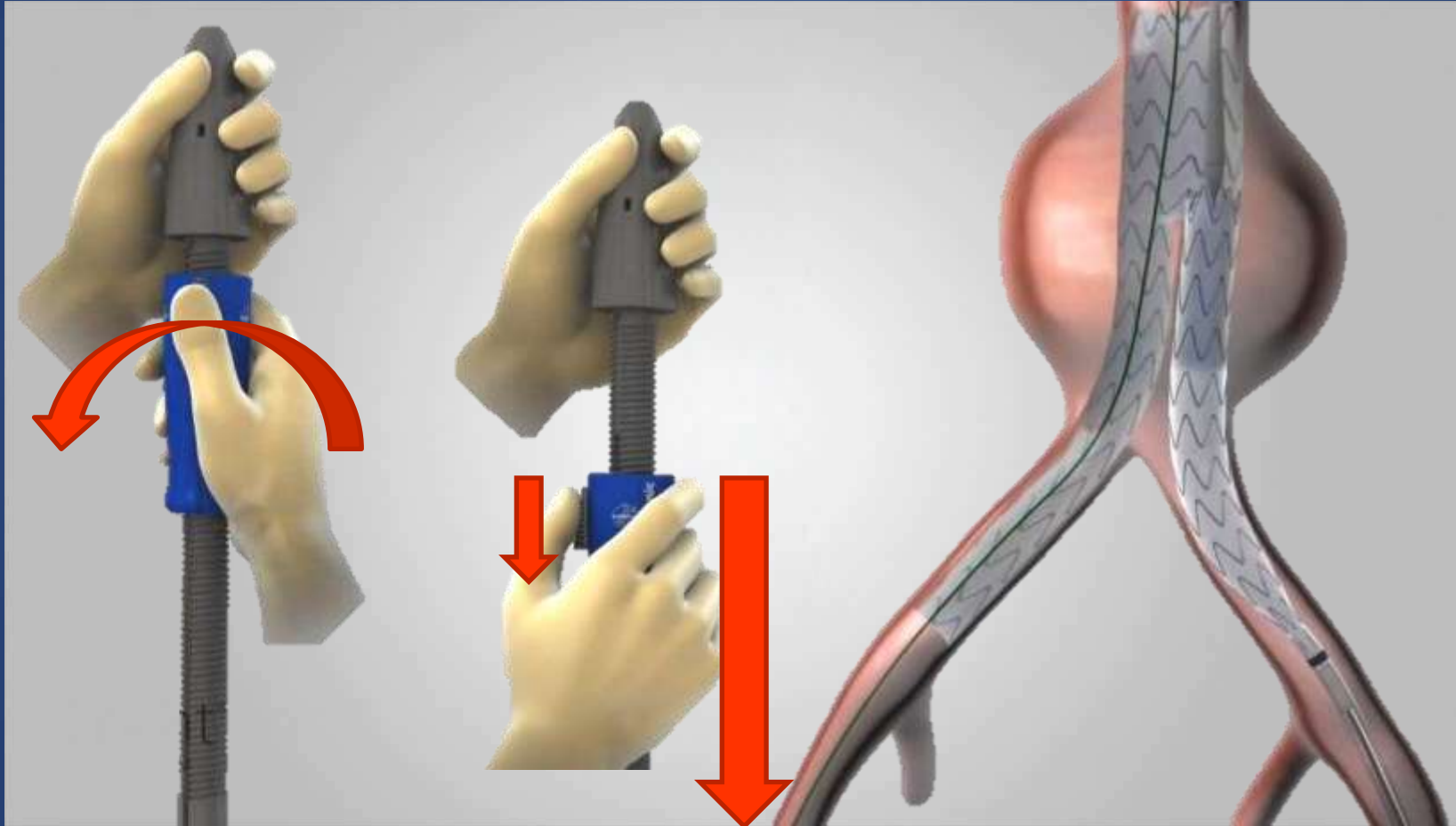


Overlap
marker

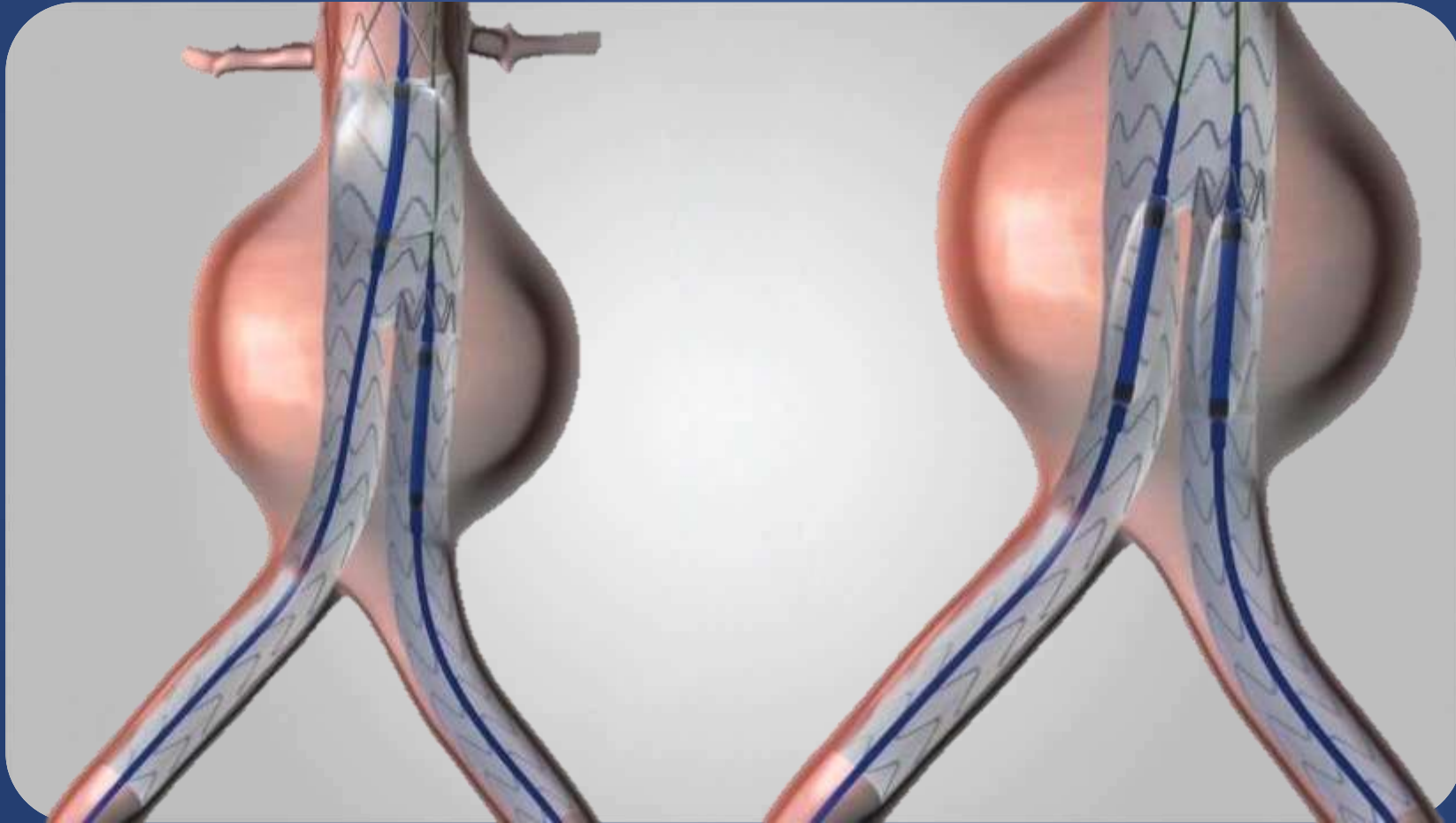
Deploy the contralateral limb stent



Deploy the contralateral limb stent



Ballooning the stent



Updated Guideline 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

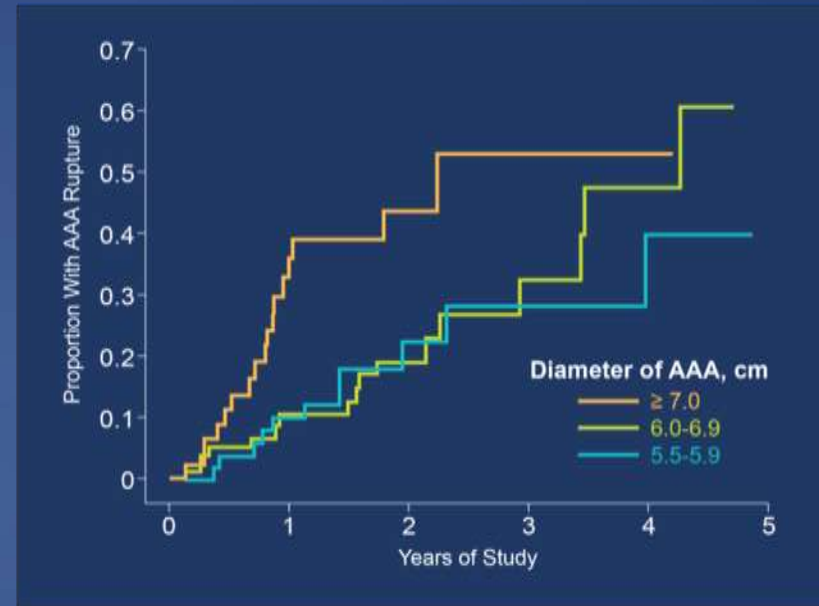
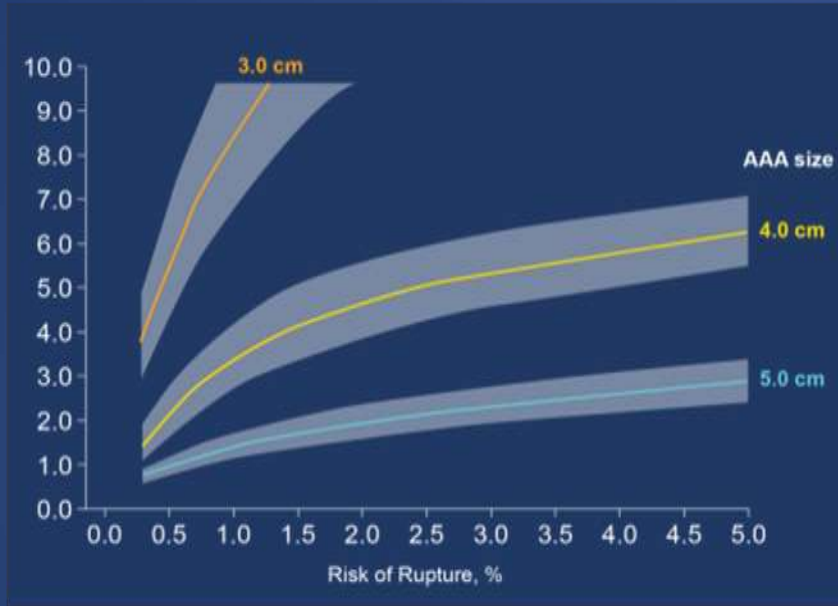


Table 1. Annual Risk of Rupture of Abdominal Aortic Aneurysms.*

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:
 - ① 흡연경험이 있는 65~75세 남성에는 초음파 복부대동맥류 검사를 1회 받도록 권고한다.
 - ② 흡연경험이 없는 65~75세 남성에는 전체가 아닌 임상 의사가 선별한 남성에게만 복부대동맥류 검사를 실시한다. 검사 대상의 선택 기준은 득실을 따져서 평가하고, 환자 기왕력과 가족력, 다른 위험인자도 고려한다
 - ③ 흡연경험이 있는 65~75세 여성에는 복부대동맥류 검사의 득실을 평가해야 할 근거 현재로서는 부족하다.
 - ④ 흡연경험이 없는 여성에게는 정기 검사가 불필요하다.

Size to treat? Small Aneurysm RCTs

UKSAT (4 – 5.5cm) (USG surveillance)

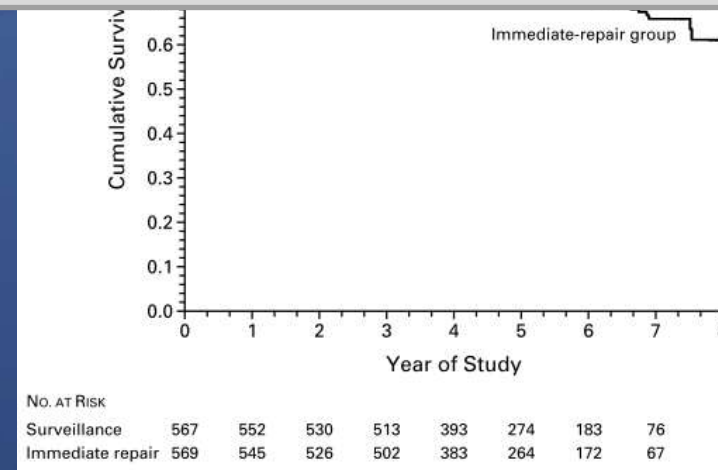
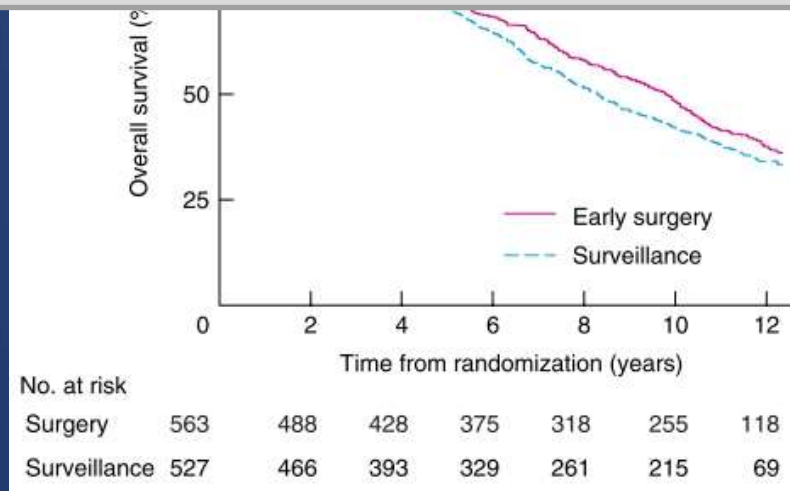
- 1090 randomized (17% female)
- Operative mortality of 5.8% in immediate repair group

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 <ul style="list-style-type: none"> • 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 symptomatic ruptured AAA, indicated.			
In case of symptomatic anatomically suitable either open or endovascular repair is recommended.			
AAA repair is indicated if: <ul style="list-style-type: none"> • AAA diameter exceeds 55 mm.^f • Aneurysm diameter exceeds 1 			
If a large aneurysm is anatomically suitable for EVAR, endovascular aortic repair is recommended in preference to open repair.			
If a large aneurysm is anatomically 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.

- 다음 -

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

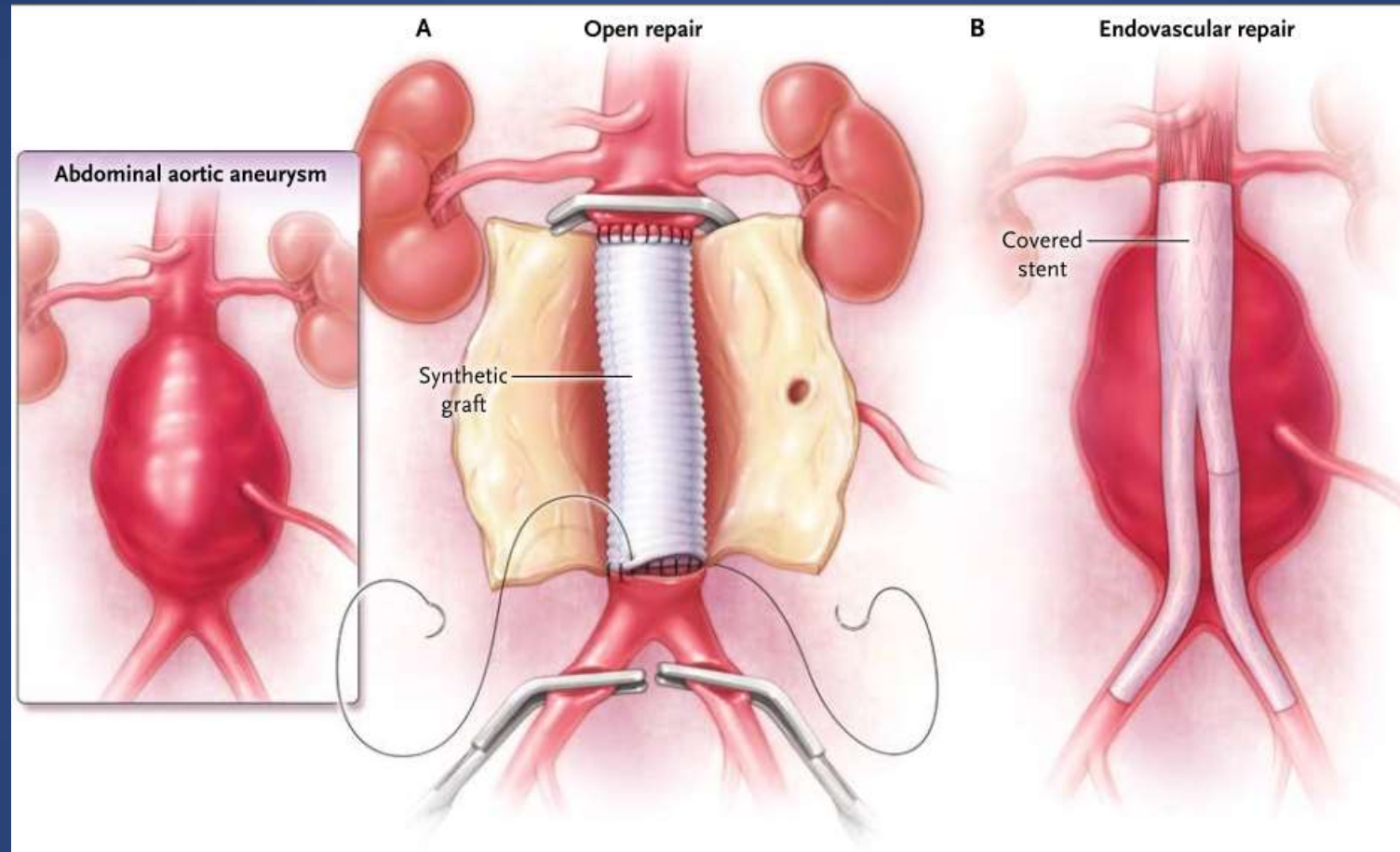
(1) 동(정)맥류 또는 가성 동(정)맥류의 경우 (Iliac artery, renal artery 등)

(2) 동(정)맥류 혹은 혈관 파열이 경우

Repair; Open or EVAR?

2005 Recommendations	2011 Focused Update Recommendations	Comments
<p>Class I</p> <p>Open repair of infrarenal AAA and/or common iliac aneurysms is indicated in patients who are good or average surgical candidates. <i>(Level of Evidence: B)</i></p> <p>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. <i>(Level of Evidence: B)</i></p>	<p>1. Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates (56,57). <i>(Level of Evidence: A)</i></p> <p>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). <i>(Level of Evidence: A)</i></p>	<p>Modified recommendation (endovascular repair incorporated from 2005 Class IIb recommendation [see below*]; level of evidence changed from B to A).</p> <p>Modified recommendation (level of evidence changed from B to A).</p>
<p>Class IIa</p> <p>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. <i>(Level of Evidence: B)</i></p>	<p>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. <i>(Level of Evidence: C)</i></p>	<p>Deleted recommendation (no longer current).</p> <p>New recommendation</p>
<p>Class IIb</p> <p>Endovascular repair of infrarenal aortic and/or common iliac aneurysms may be considered in patients at low or average surgical risk. <i>(Level of Evidence: B)</i></p>	<p>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). <i>(Level of Evidence: B)</i></p>	<p>Deleted recommendation (endovascular repair incorporated into 2011 Class I, #1 [see above*]).</p> <p>New recommendation</p>
<p>*Indicates merging of deleted 2005 Class IIb recommendation with the modified 2011 Class I, #1 recommendation.</p> <p>AAA indicates abdominal aortic aneurysm.</p>		

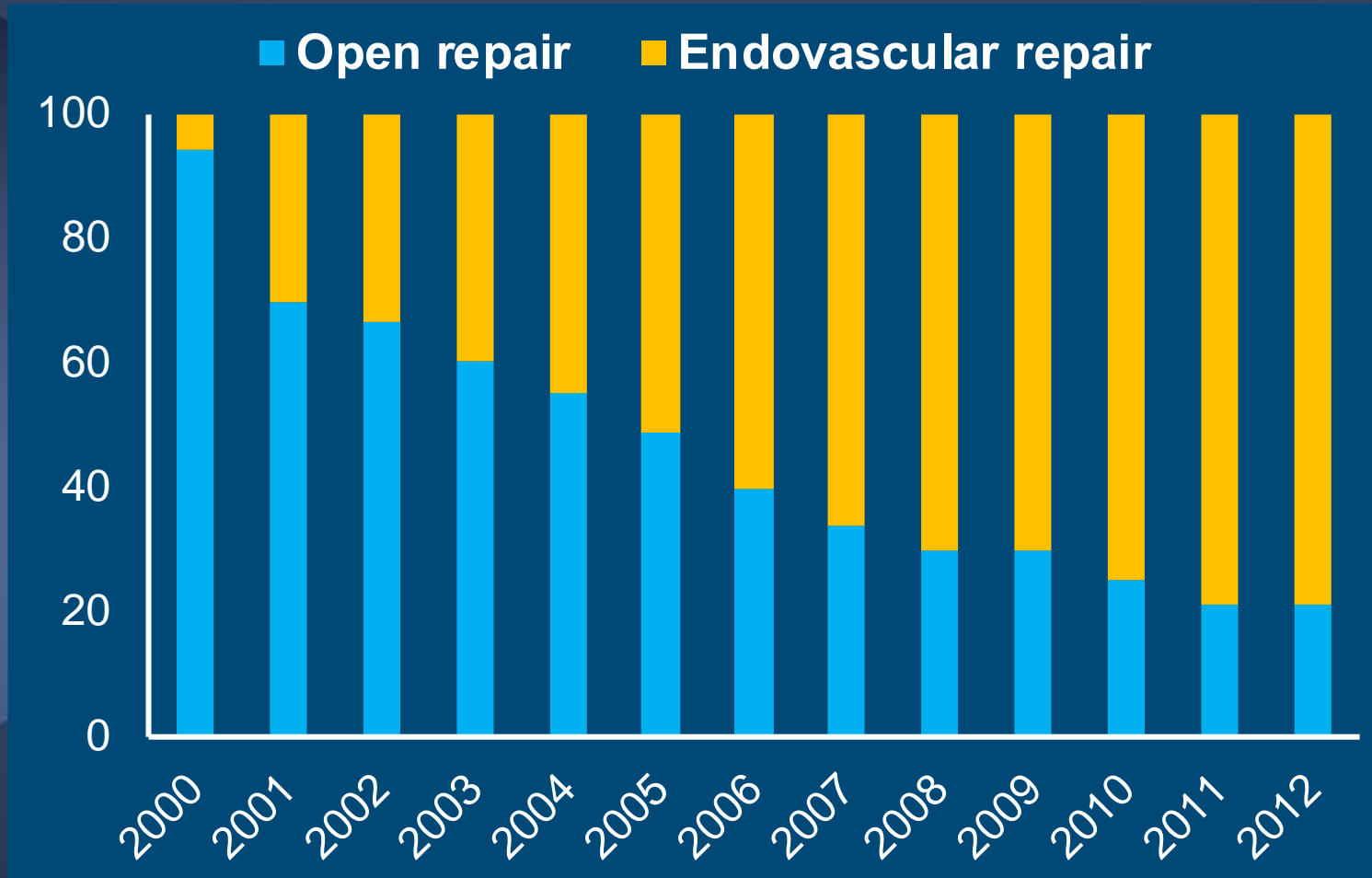
Same goal, completely different strategy



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

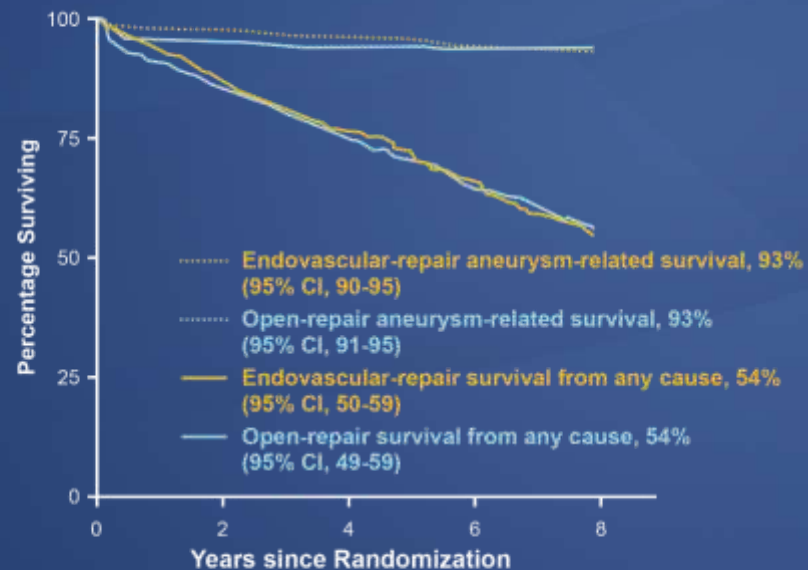


N Engl J Med 2014;371:2101-2108

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 ≥ 5.5 cm, fit for open or 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

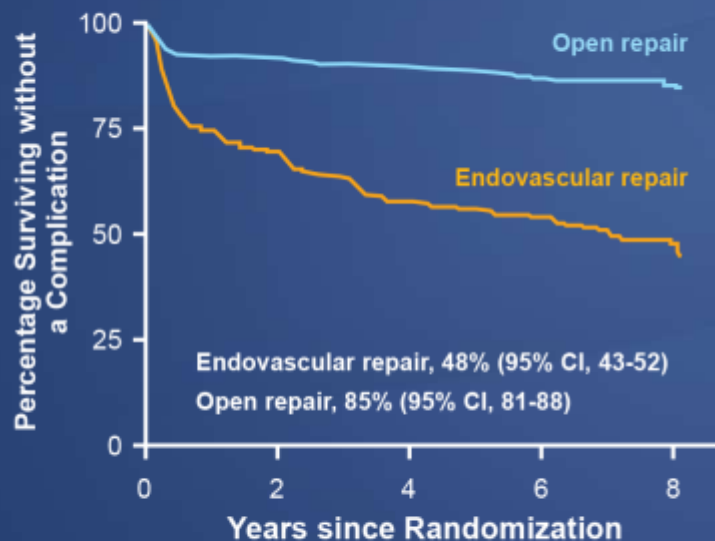
N Engl J Med 2010;362:1863-71

RCTs; Elective Open Repair vs. EVAR

Endovascular versus Open Repair of Abdominal Aortic Aneurysm

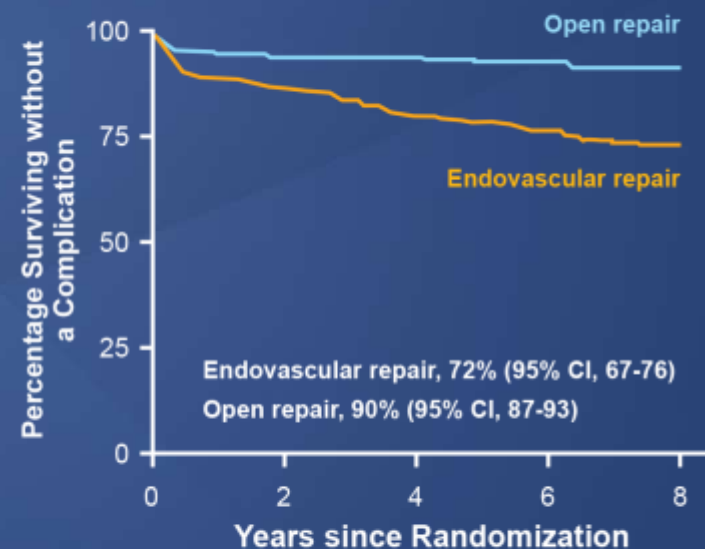
The United Kingdom EVAR Trial Investigators*

Graft-related Complication



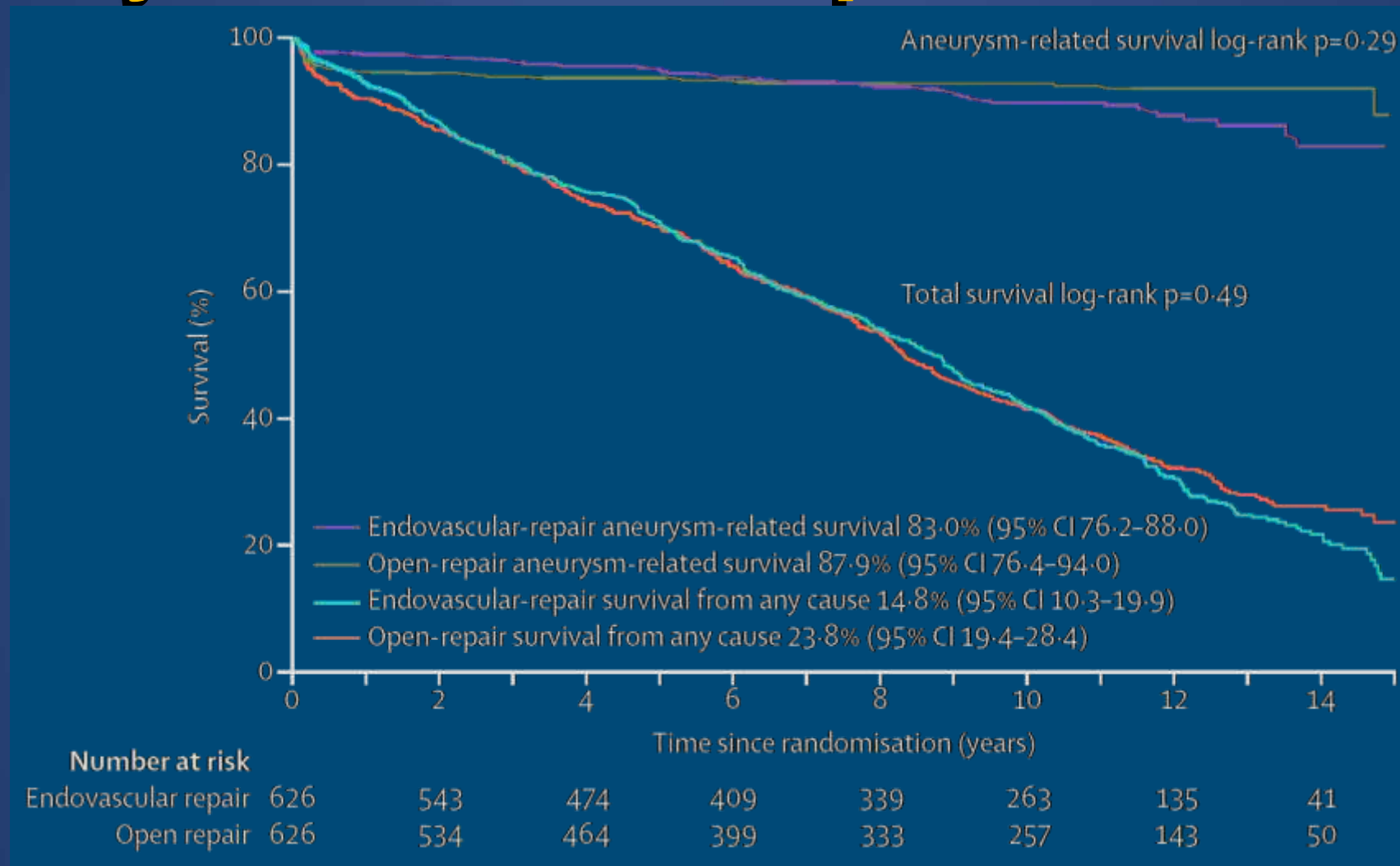
Number at risk	0	2	4	6	8
Endovascular repair	626	378	280	174	58
Open repair	626	496	413	259	91

Re-intervention



Number at risk	0	2	4	6	8
Endovascular repair	626	470	377	243	83
Open repair	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

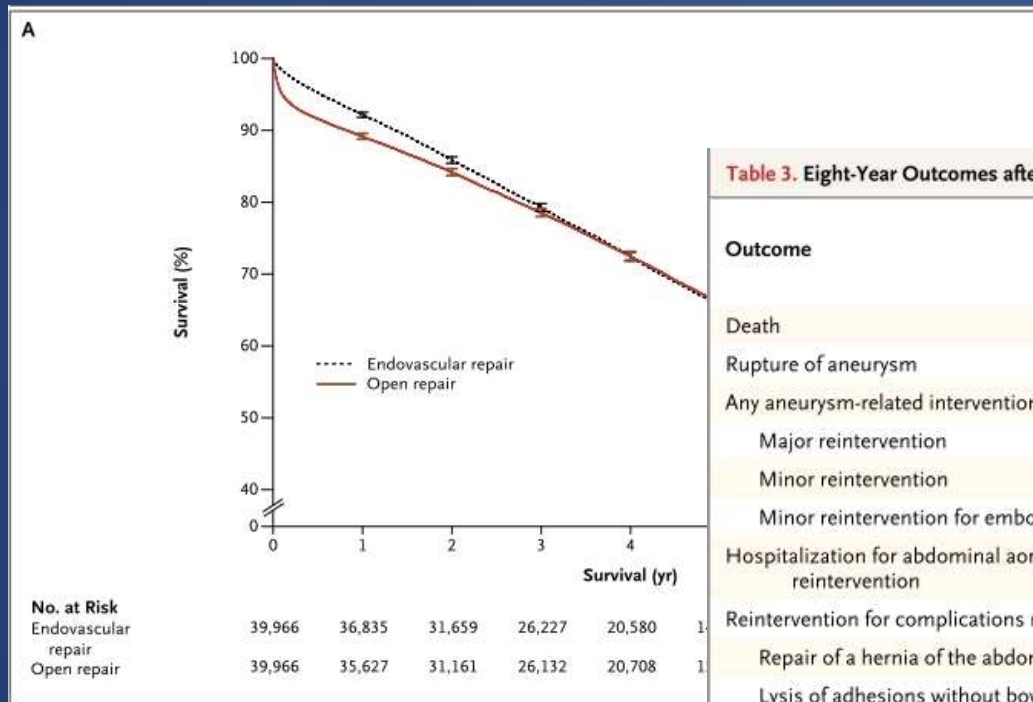
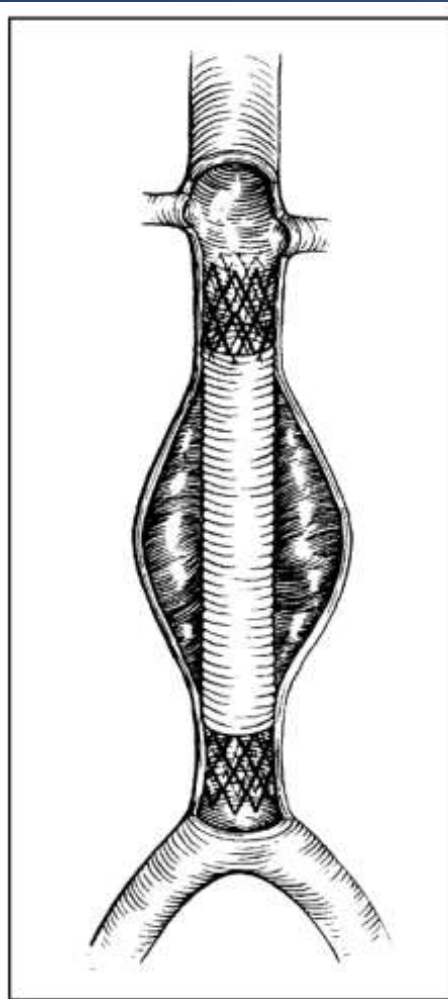


Table 3. Eight-Year Outcomes after Endovascular and Open Repair of Abdominal Aortic Aneurysm.

Outcome	Endovascular Repair (N = 39,966)	Open Repair (N = 39,966)	P Value
	<i>no. of patients (%)</i> *		
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

Maturation of EVAR



Now, EVAR is an ambulatory procedure

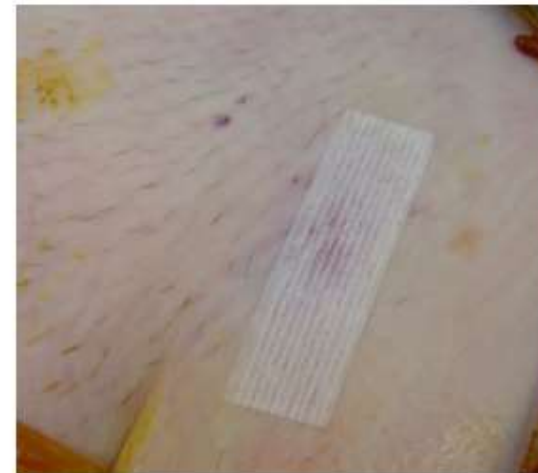


90% of
EVAR Cases

- **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

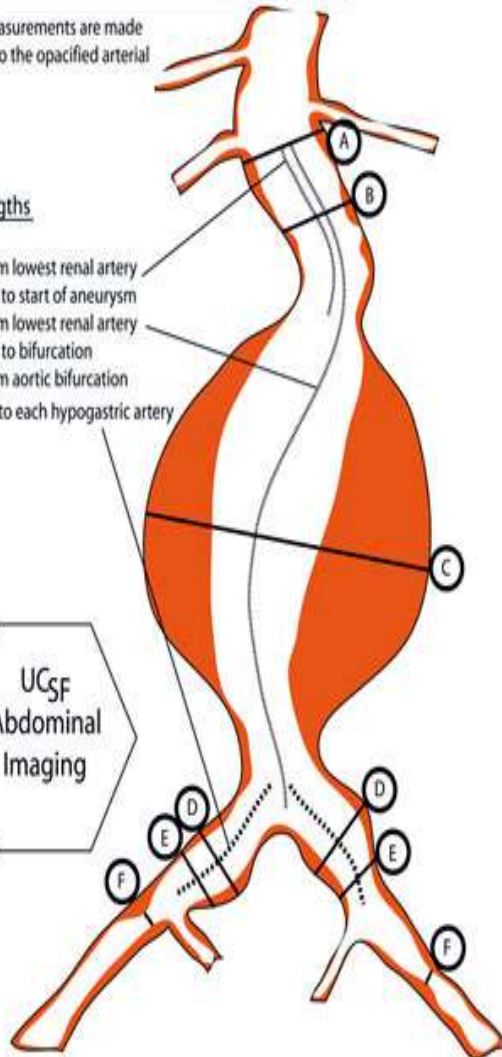
Pre-stentgraft AAA Measurement Guidelines

Note: All measurements are made orthogonal to the opacified arterial lumen

Lengths

- From lowest renal artery to start of aneurysm
- From lowest renal artery to bifurcation
- From aortic bifurcation to each hypogastric artery

UCSF
Abdominal
Imaging

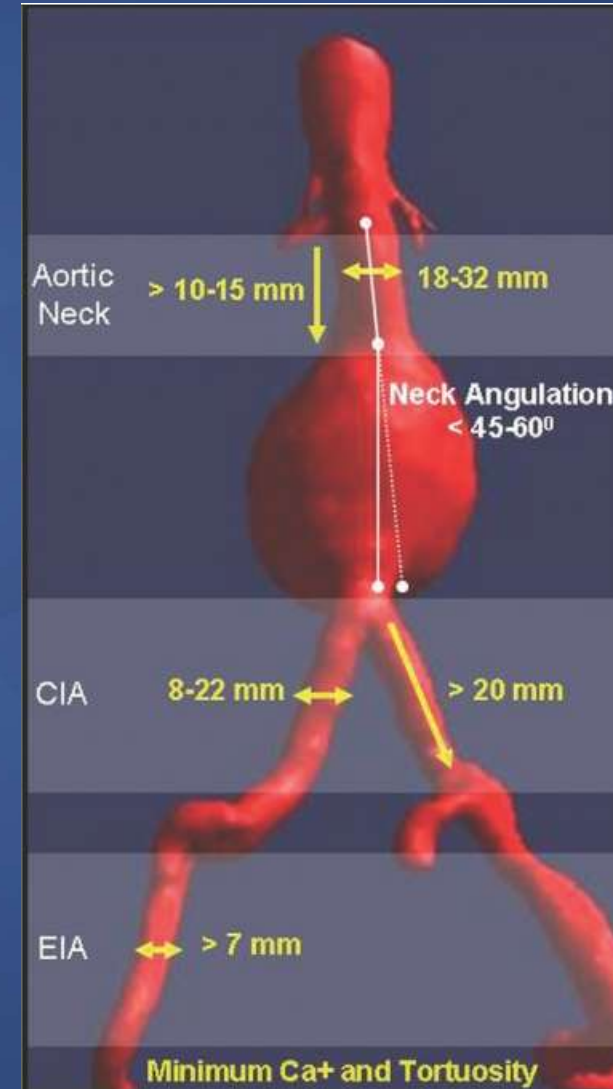


Diameters

- (A) Proximal neck diameter (outer diameter at lowest renal artery)
- (B) Proximal neck diameter 15mm below lowest renal artery (outer diameter)
- (C) Maximum aneurysm diameters (outer wall to outer wall, major & minor diameters)
- (D) Maximal outer diameter of each common iliac artery
- (E) Outer diameter of each common iliac artery 5 mm above the hypogastric
- (F) Narrowest inner diameter of each common or external iliac artery

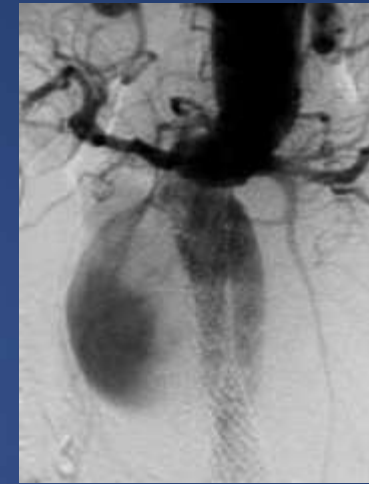
Angles

- Between immediate suprarenal neck and immediate infrarenal neck
- Between proximal neck and longitudinal axis of aneurysm



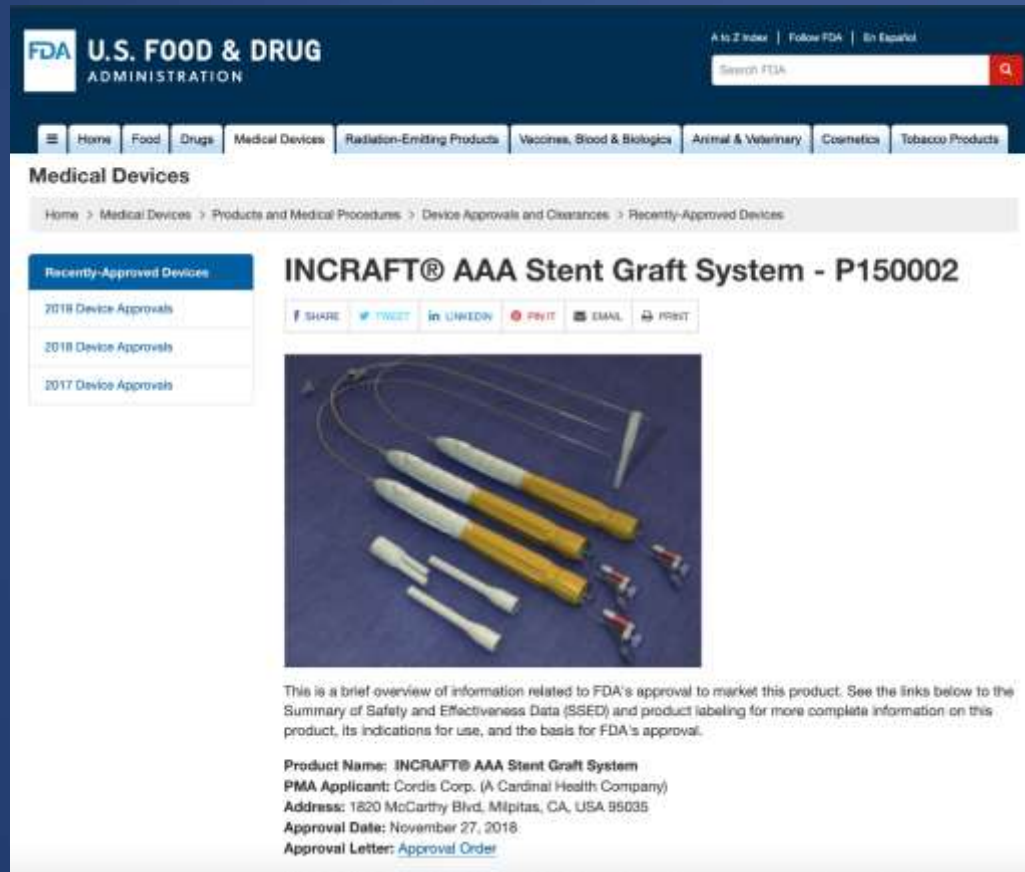


Aortic Endografts Current Limitations



- 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°**

US FDA Approval of the INCRAFT AAA Stent



The screenshot shows the FDA's website for the INCRAFT AAA Stent Graft System. The page title is "INCRAFT® AAA Stent Graft System - P150002". It includes a navigation menu with categories like Home, Food, Drugs, Medical Devices, etc. The main content area features a list of "Recently-Approved Devices" for the years 2018, 2018, and 2017. Below this is a section for the product, including a photograph of the device components and a brief overview of the FDA's approval. The product name is "INCRAFT® AAA Stent Graft System", the PMA applicant is "Cordis Corp. (A Cardinal Health Company)", the address is "1820 McCarthy Blvd, Milpitas, CA, USA 95035", the approval date is "November 27, 2018", and the approval letter is "Approval Order".

U.S. FOOD & DRUG ADMINISTRATION

Medical Devices

Home > Medical Devices > Products and Medical Procedures > Device Approvals and Clearances > Recently-Approved Devices

Recently-Approved Devices


2018 Device Approvals

2018 Device Approvals

2017 Device Approvals

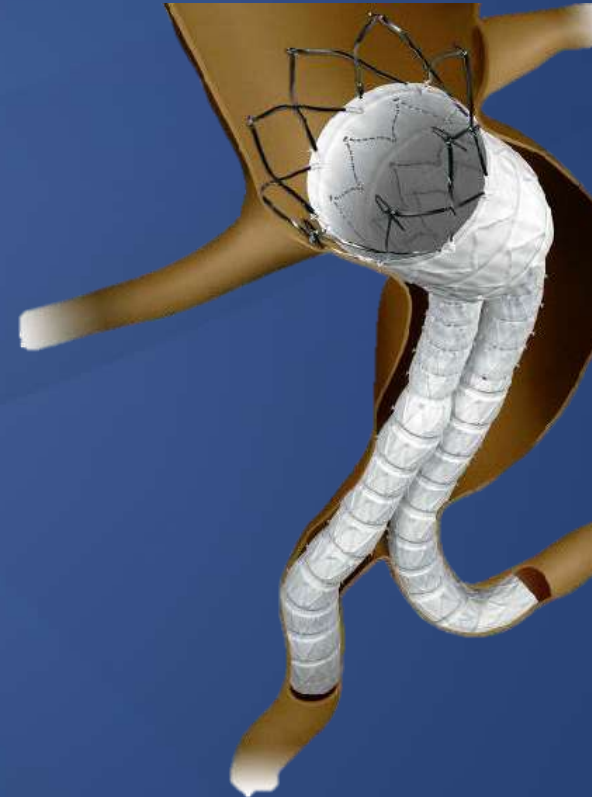
INCRAFT® AAA Stent Graft System - P150002

SHARE TWITTER LINKEDIN PINTEREST EMAIL PRINT



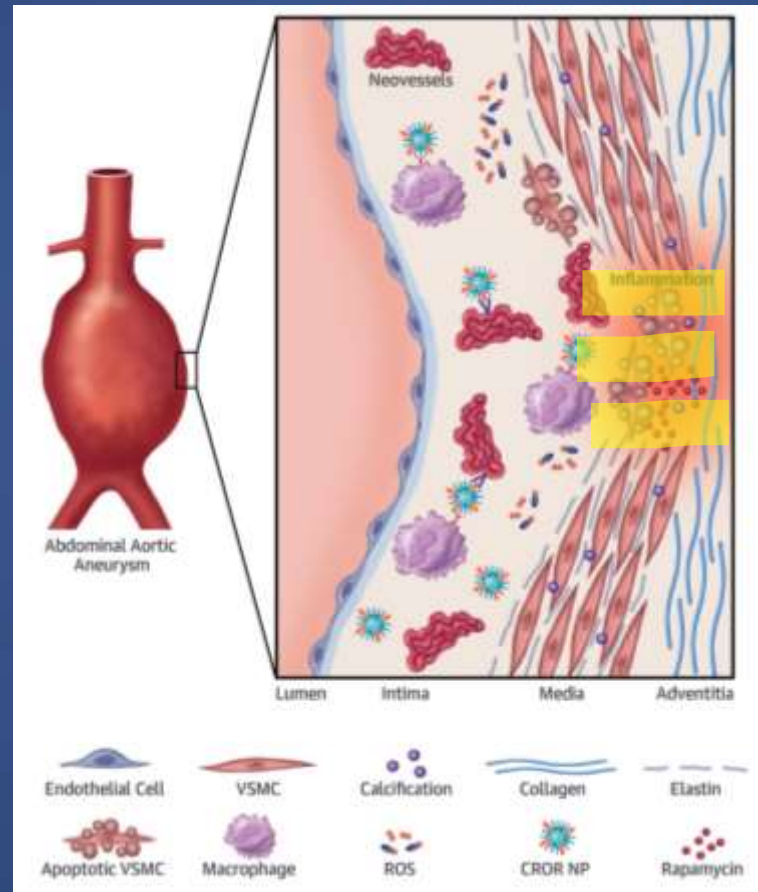
This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: INCRAFT® AAA Stent Graft System
PMA Applicant: Cordis Corp. (A Cardinal Health Company)
Address: 1820 McCarthy Blvd, Milpitas, CA, USA 95035
Approval Date: November 27, 2018
Approval Letter: [Approval Order](#)



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

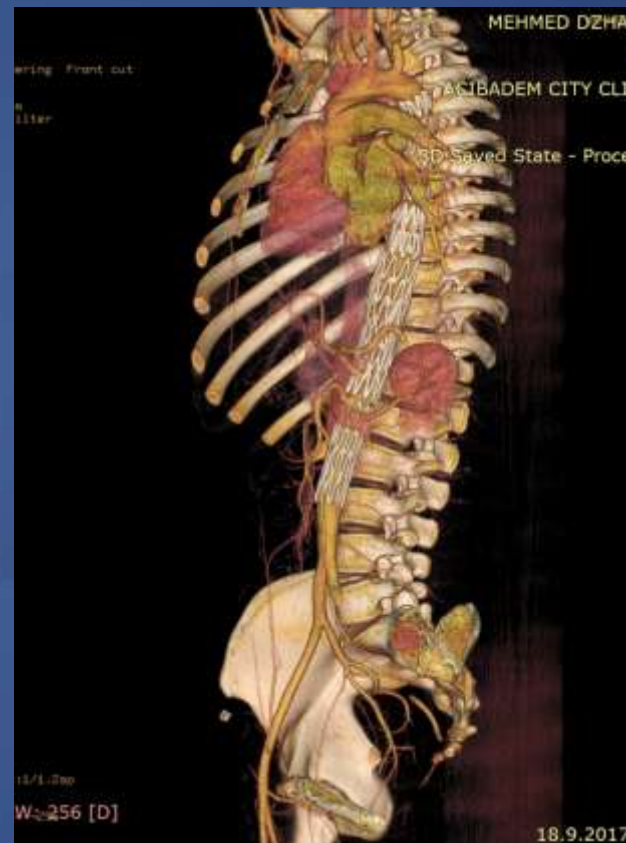
The role of noncovered stents for the treatment of malperfusion syndrome in type A and B aortic dissection

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

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



15yrs old



17 yrs old

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

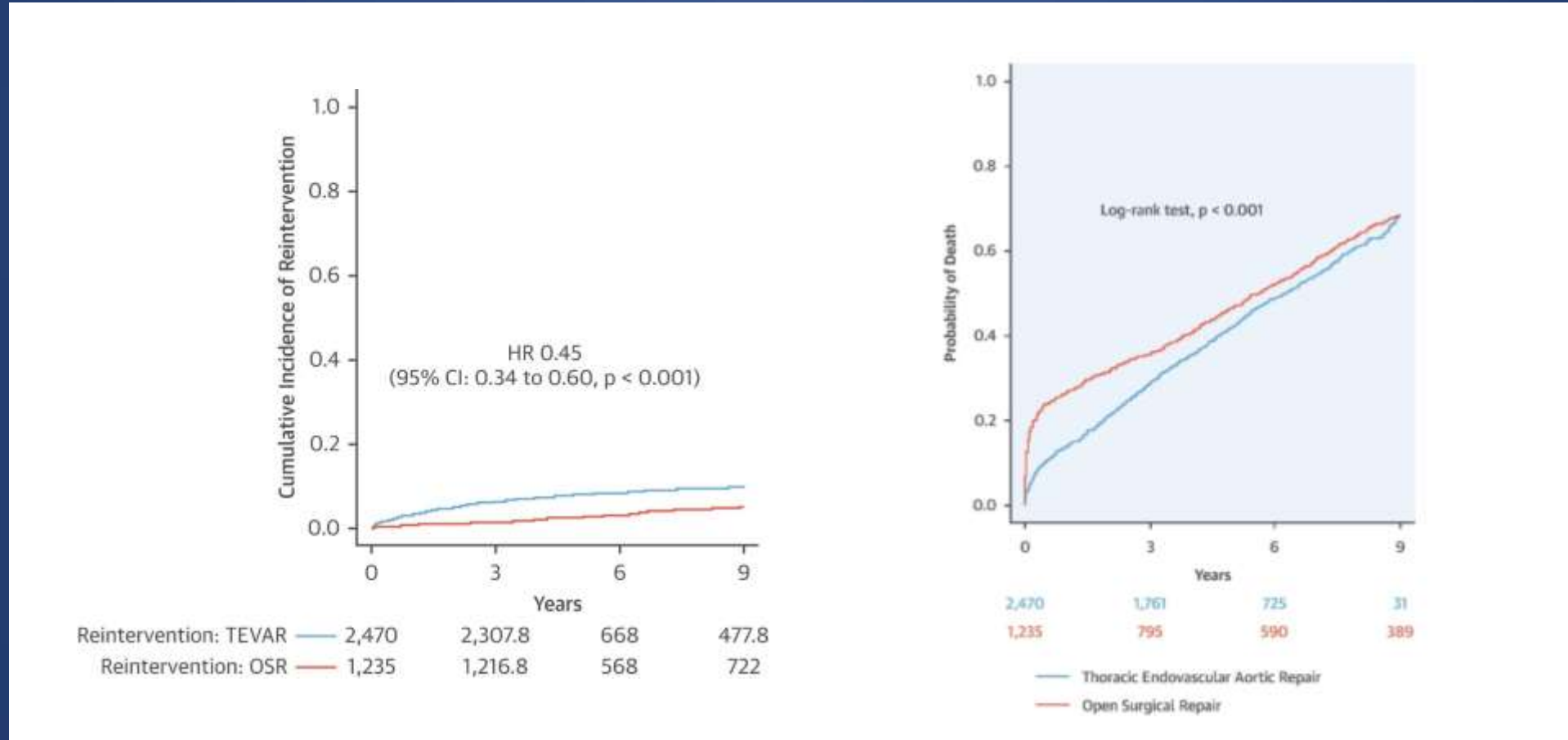
Changing Paradigms in Aortic Dissection

- 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

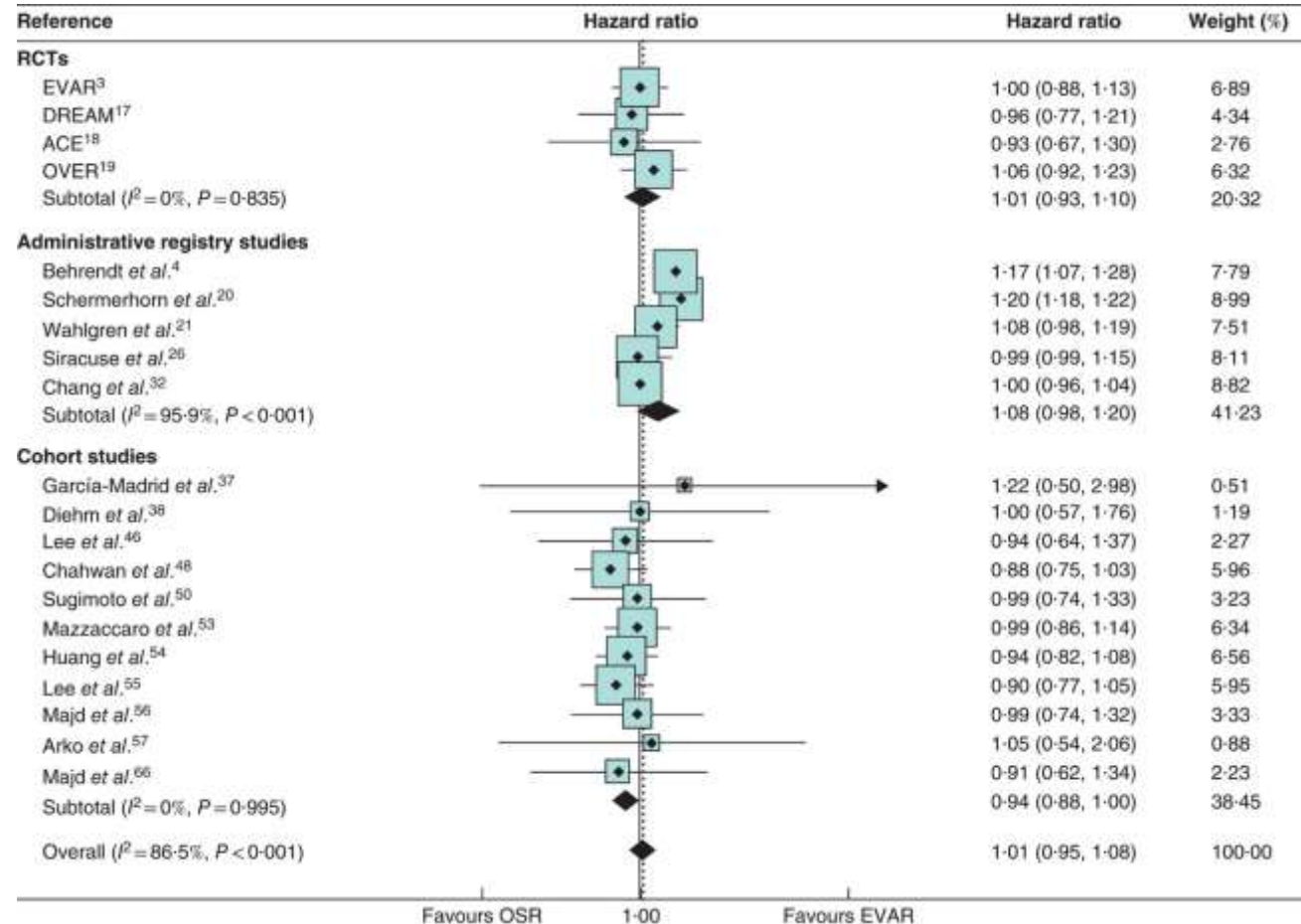
Ali Azizzadeh, Presentation at Controversies and Advances 2018

TEAVR vs OSR

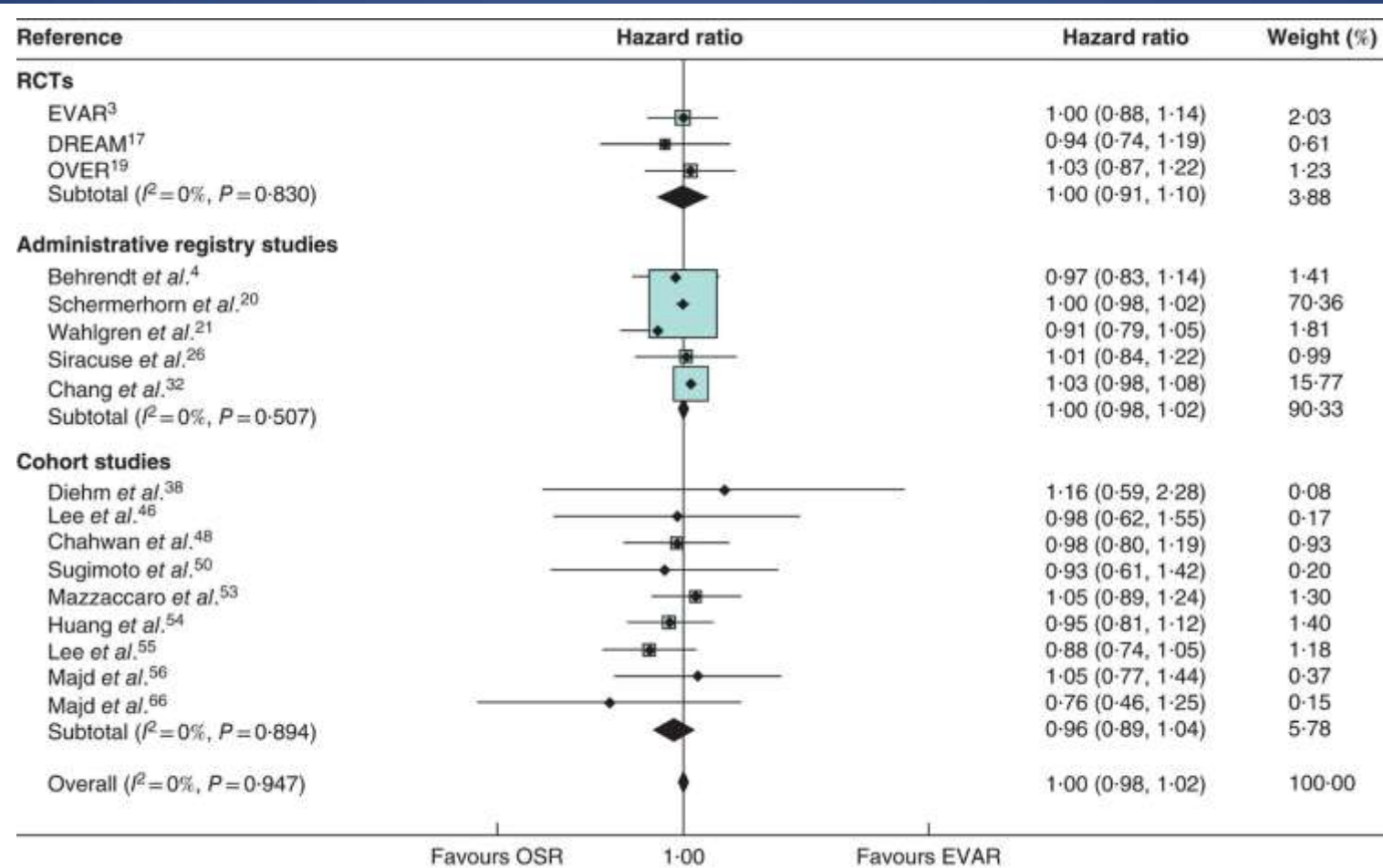
Reintervention & Mortality



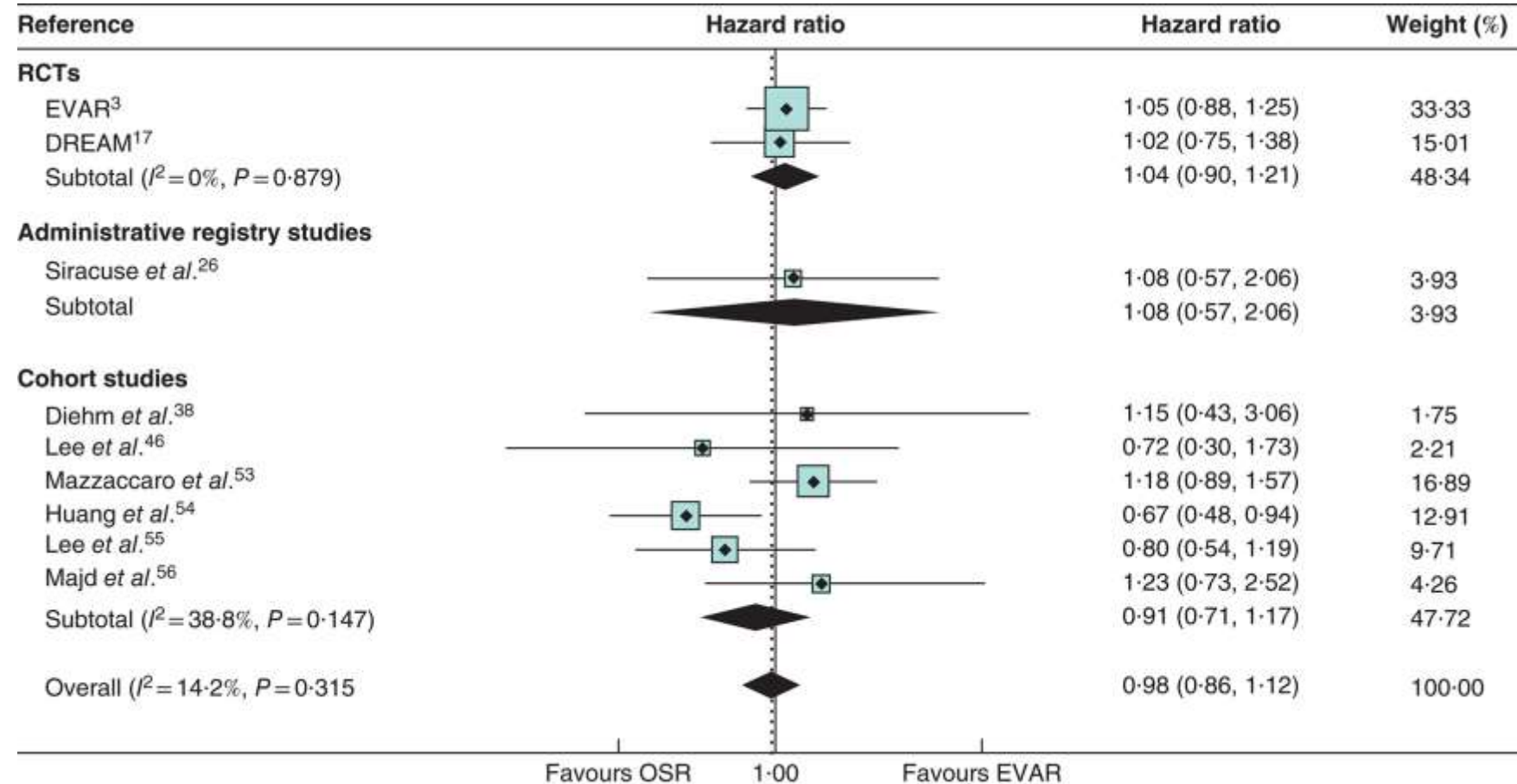
Meta-analysis of long-term survival (3 years)



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



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



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