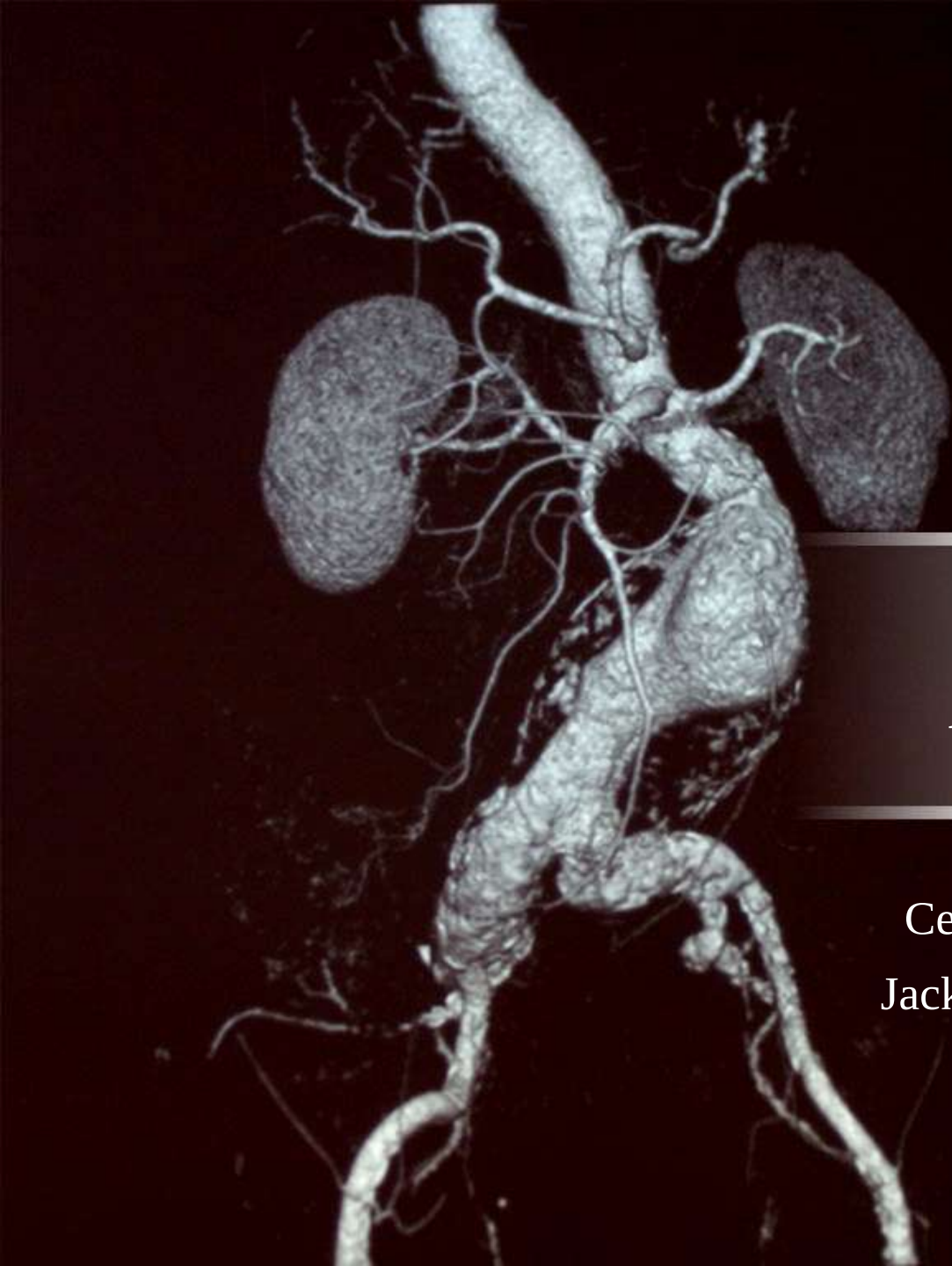


Endovascular Repair of Abdominal Aortic Aneurysms

Cesar E. Mendoza, M.D.

Jackson Memorial Hospital

Miami, Florida

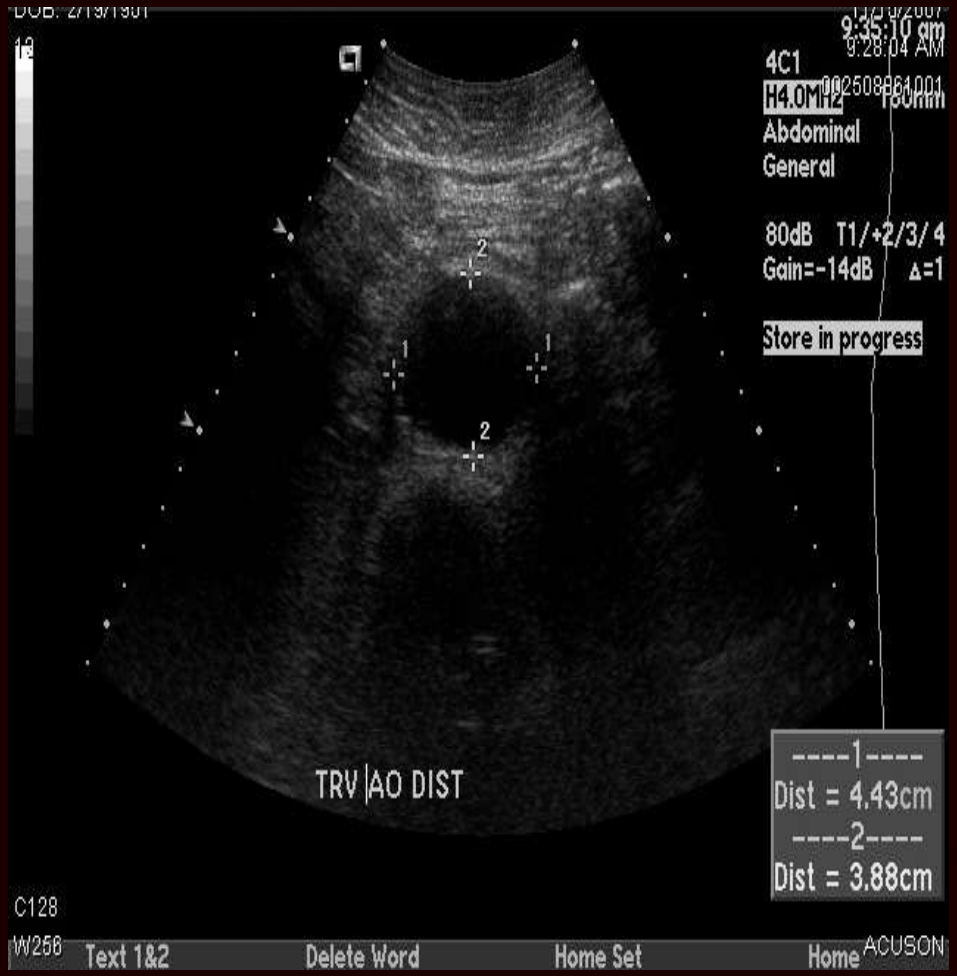
Disclosure

- Nothing to disclose.

Mr. X AAA

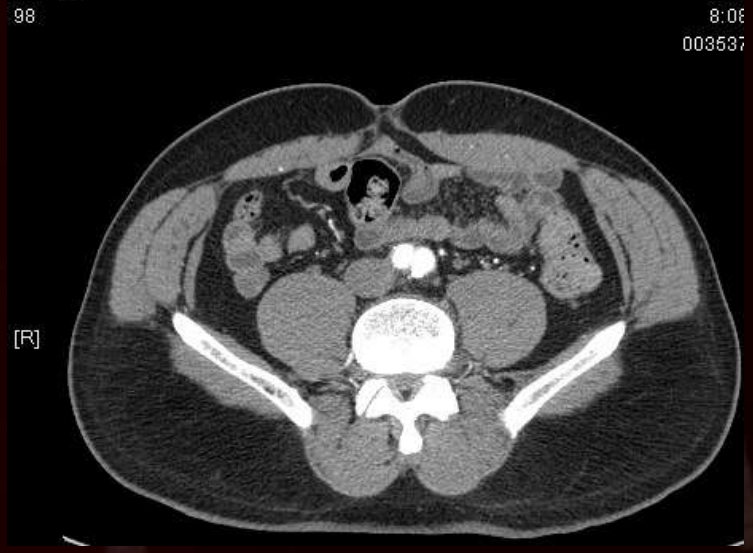
- Mr. X. Is a 70 year old male who presented to clinic referred by his primary doctor due to a rapid expanding AAA
- He has a history of HTN and dyslipidemia, which are well controlled
- He is a current heavy smoker with a 40 pack-year-history of smoking
- His family history is remarkable by the occurrence of a 3.5 cm AAA in his smoker sister

Mr. X Ultrasound 8/2008

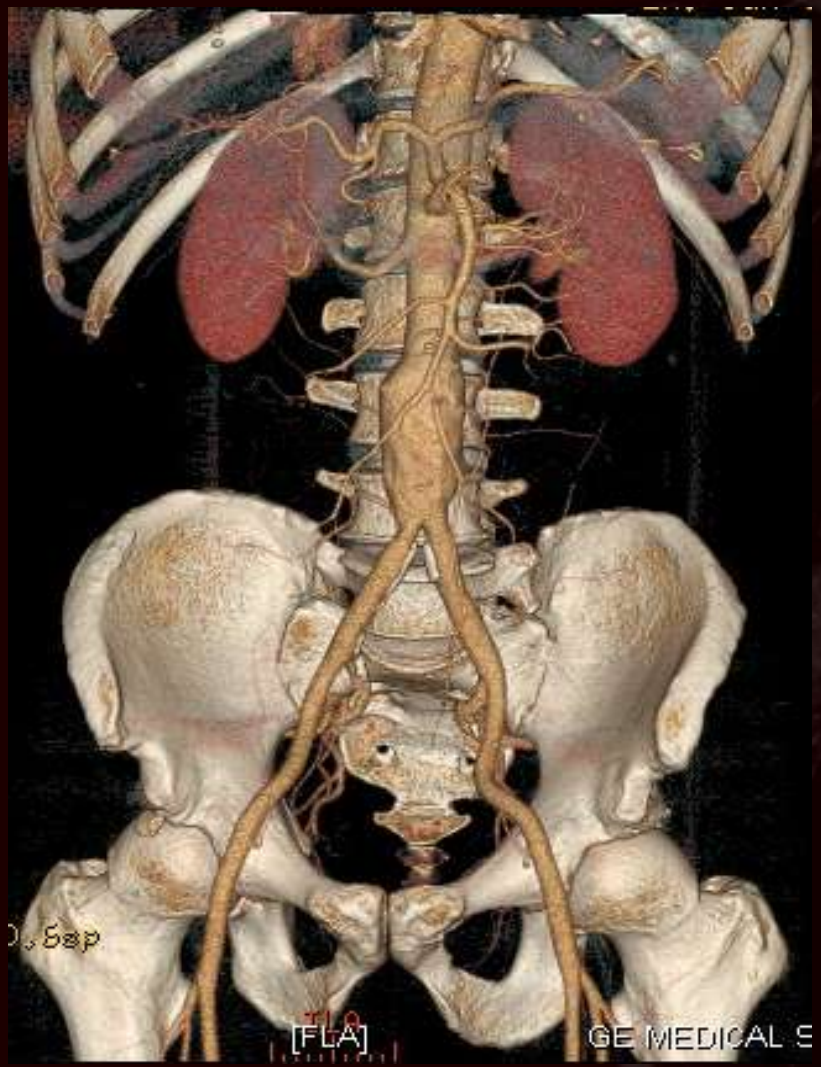


- Findings:
- Distal abdominal aortic aneurysm measuring 4.5 x 4.4 cm in AP and transverse dimensions, respectively
- Circumferential mural thrombus within aneurysm

Mr. X CTA 9/2009



Mr. X CTA 9/2009



Mr. X CTA 9/2009

- Findings/Impressions:
  - Infrarenal abdominal aortic aneurysm measuring 5.3 x 5.5 cm containing mural thrombus
  - No stenosis seen in common iliac, external iliac, common femoral, or superficial femoral arteries bilaterally

Clinical Problem

- Mr. X. Is a 70 year old male who presented to clinic with a rapid expanding (>0.5 cm/year) abdominal aortic aneurysm (AAA) measuring 5.5 cm in diameter.
- The recommended course of action is to be determined.
- It must be decided whether medical management, an open abdominal or endovascular repair is appropriate for Mr.E with regards to mortality and reintervention rates.
- Mr.E has 3 grandchildren and is keen to get back on his feet and spend as little time in hospital as possible.

Relevant Clinical Data

Growth rate of AAA

Initial size (cm)	Mean growth rate (cm/yr)	95% CI
3.0- 3.9	0.39	0.20-0.57
4.0-4.9	0.36	0.21-0.50
5.0-5.9	0.43	0.27-0.60
6.0-6.9	0.64	0.16-1.10

Risk of Rupture: Size Matters!

- 4.0-4.9 cm 1%/yr *
- 5.0-5.4 cm <5%/yr
- 5.5-5.9 cm 9.4%/yr
- 6.0-6.9 cm 10.2%/yr
- 6.5-6.9 cm 19%/yr
- 7.0 cm 33%/yr
- 8.0 cm 40%/yr

Most studies: AAA measured by maximum diameter

*UK Small Aneurysm Trial. Lancet. 1998;352:1649-1655.
*Lederle FA, et al. N Engl J Med. 2002;346:1437-1444..

Relevant Clinical Data

ACC/AHA Guidelines AAA repair

- Infrarenal/juxtarenal AAA ≥5.5 cm should undergo repair; 4.0-5.4 cm, ultrasound/CT scans every 6-12 mo
- Repair can be beneficial for infrarenal/juxtarenal AAAs 5.0-6.0 cm
- Repair probably indicated for suprarenal/type IV thoracoabdominal AA >5.5-6.0cm
- AAA <4.0cm, ultrasound every 2-3 years is reasonable
- Intervention not recommended asymptomatic infrarenal/ juxtarenal AAAs <5.0 cm (men) or <4.5 cm (women)

Class I
Class IIa
Class IIb
Class III

ACC/AHA Guidelines on PAD *Circulation* 2006;113:e463-465.

Additional Considerations for Repair

- Growth rate faster than 0.5 cm per year
- Infected/inflamed
- Ruptured
- Symptomatic

Mr. X Assessment

- No significant comorbidities
- Long life expectancy

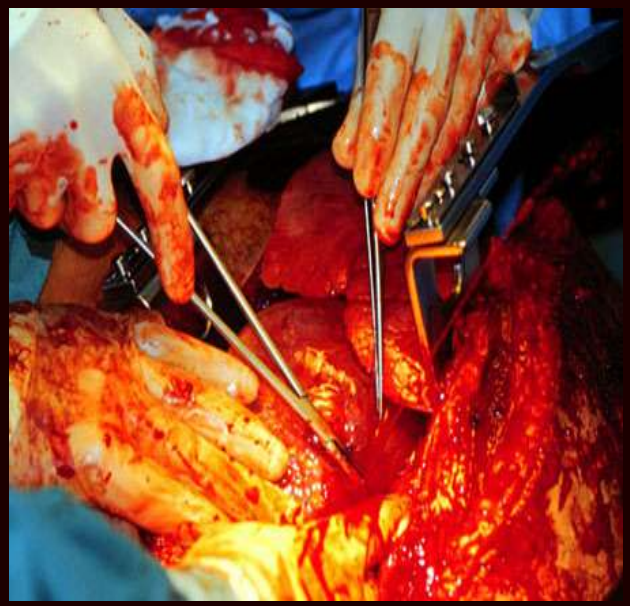
⇓

Fit

- Meets criteria for repair

Choosing the Right Repair Method

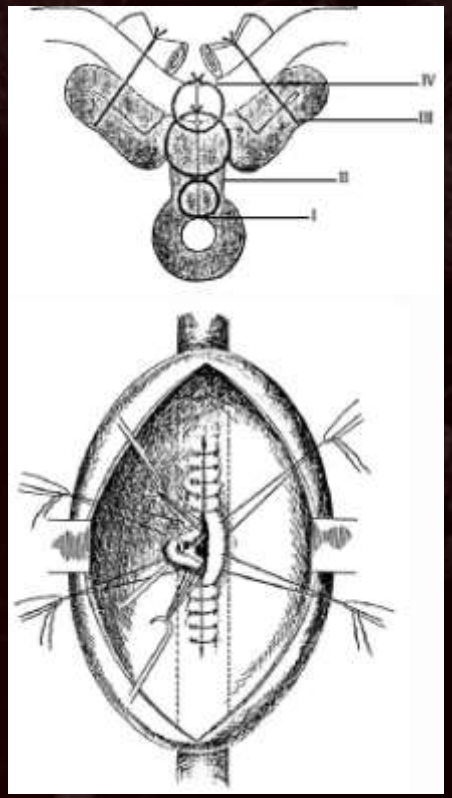
1. Operative risk of repair
2. Patient's life expectancy
3. Personal opinion of patient



Vs

ENDOANEURYSMORRHAPHY

- 1888: Rudolph Matas



Vascular Repair

- 1903: Alexis Carrel

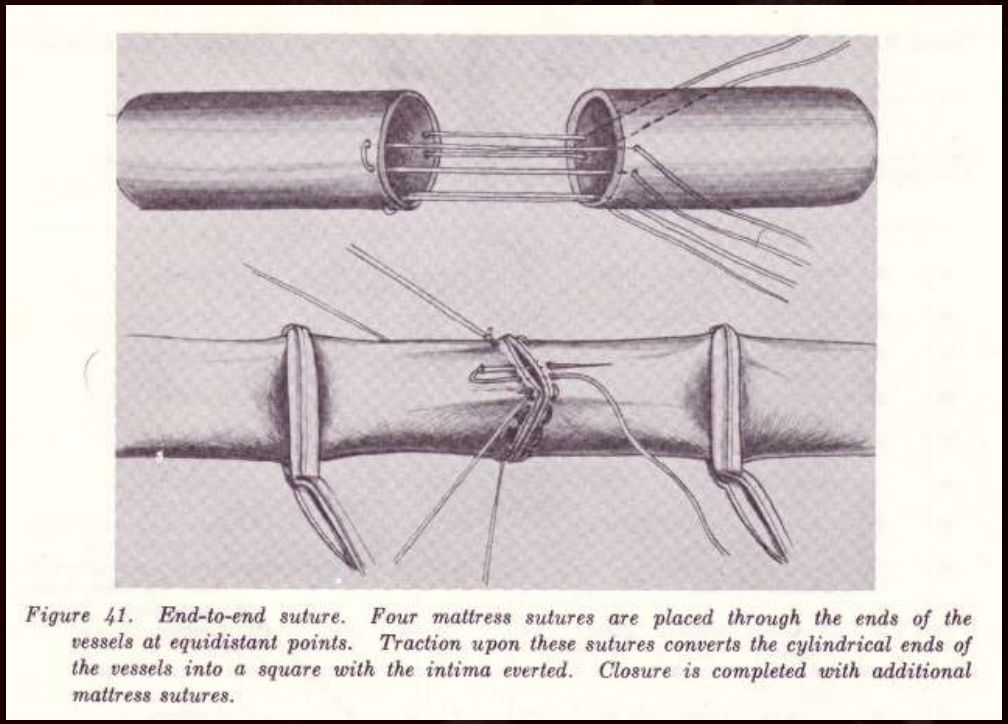
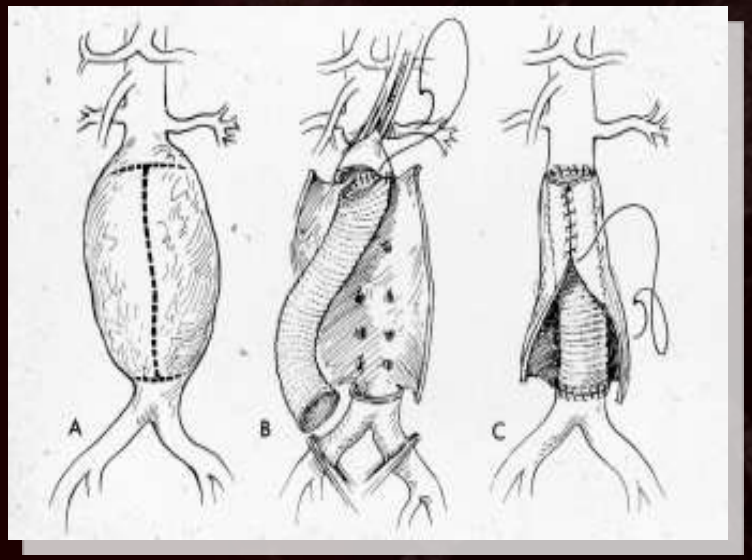


Figure 41. End-to-end suture. Four mattress sutures are placed through the ends of the vessels at equidistant points. Traction upon these sutures converts the cylindrical ends of the vessels into a square with the intima everted. Closure is completed with additional mattress sutures.

First Open AAA Repair

- 1951: Charles Dubost



Endovascular Repair

- 1990: Juan Parodi

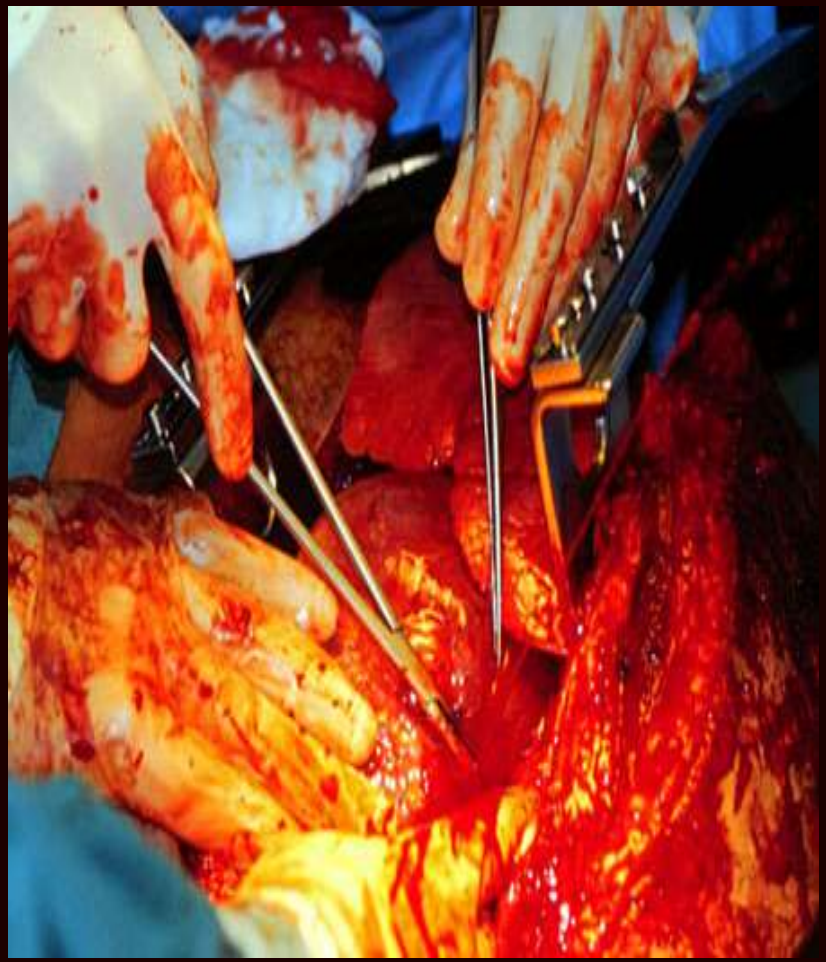
Original articles

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used. (*Ann Vasc Surg* 1991;5:491–489).

OPEN SURGICAL REPAIR (OSR)



Established procedure more than 60 years of experience

Excludes aneurysm and prevents sac growth

Reliable short term results

Proven, long term results

OSR Drawbacks

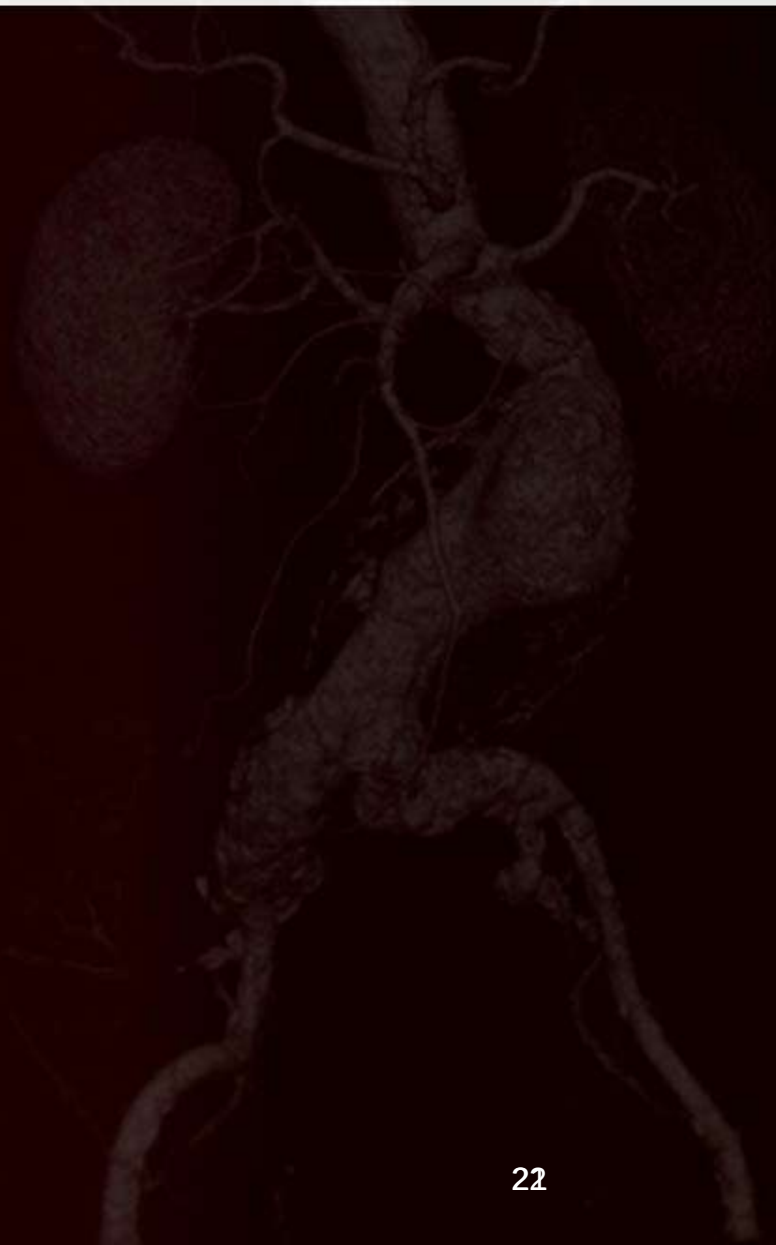
- Significant incision in the abdomen
- 30-90 minute cross-clamp
- Up to 4-hour procedure
- 1-2 days intensive care
- 5-10 days of hospitalization

OSR: Outcomes

- 4-7% perioperative mortality in population-based studies
- 15-30% significant morbidity; substantially higher in elderly patients with co-morbidity
- Recovery 2-3 months
- High risk patients often denied repair

OSR: Main Complications

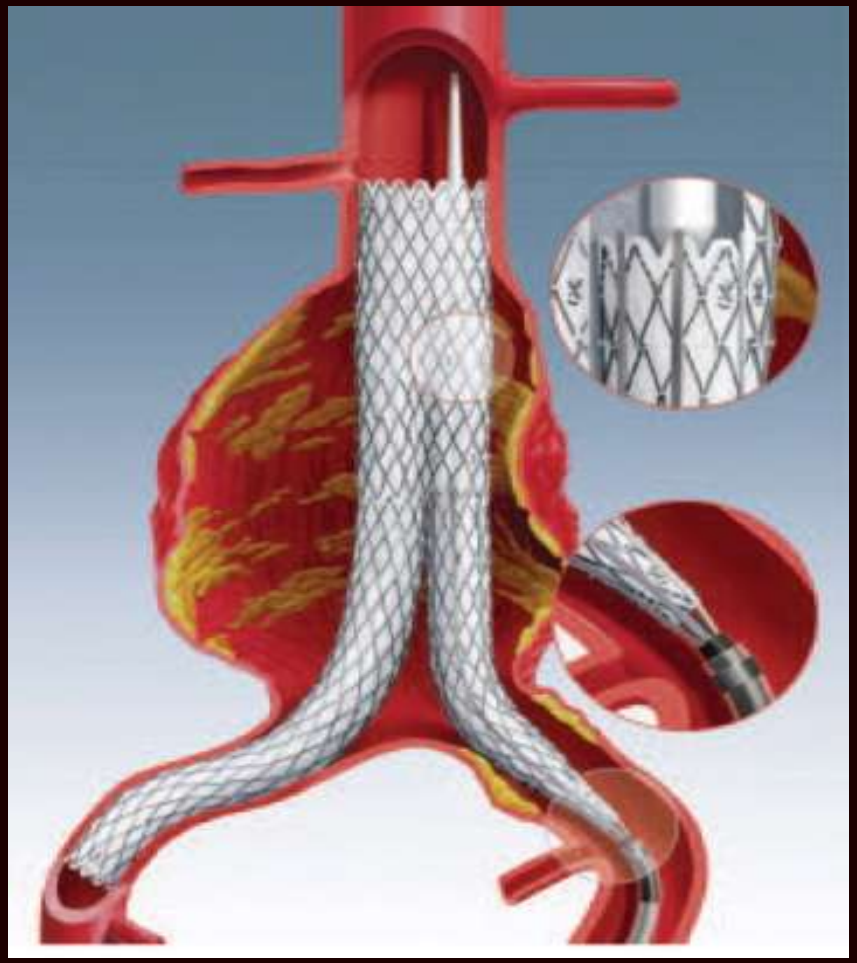
- Infection
- Hemorrhage
- Pseudoaneurysm
- Embolization
- Thrombosis
- Organ Failure
- Recurrent Aneurysm
- Collateral damage



Contraindications for OSR

- High anesthesia risk
- Morbid obesity
- Significant comorbidities
- Previous large abdominal surgery/hostile abdomen

Endovascular Aneurysm Repair



EVAR Benefits

- Less invasive: Avoids laparotomy
- Reduced frequency of postoperative complications
- Reduced risk of perioperative death
- Faster recovery
- Reduced hospitalization

EVAR Drawbacks

- Procedure-related complications
- Increased frequency of reinterventions
- More expensive

EVAR: Patient Selection

- **Patient selection has emerged as the most important factor related to successful EVAR**

- 3D reconstruction CT scan or angiography with a calibrated catheter necessary for assessment for EVAR eligibility

- Up to 37% of all patients may NOT be suitable candidates for EVAR of their infrarenal AAA

Eligibility Criteria

- Eligibility Criteria
  - Proximal Infrarenal Neck:
    - ≥15 mm length
    - <60° angle
    - < 29 mm maximum diameter, > 18 mm minimum diameter
  - Aortic bifurcation diameter ≥18 mm
  - Dispensable inferior mesenteric artery
  - Preservation of at least one hypogastric artery
  - Iliac seal zone of ≥15 mm length (≤18 mm diameter)
  - Femoral artery diameter ≥7 mm on at least one side (for access)

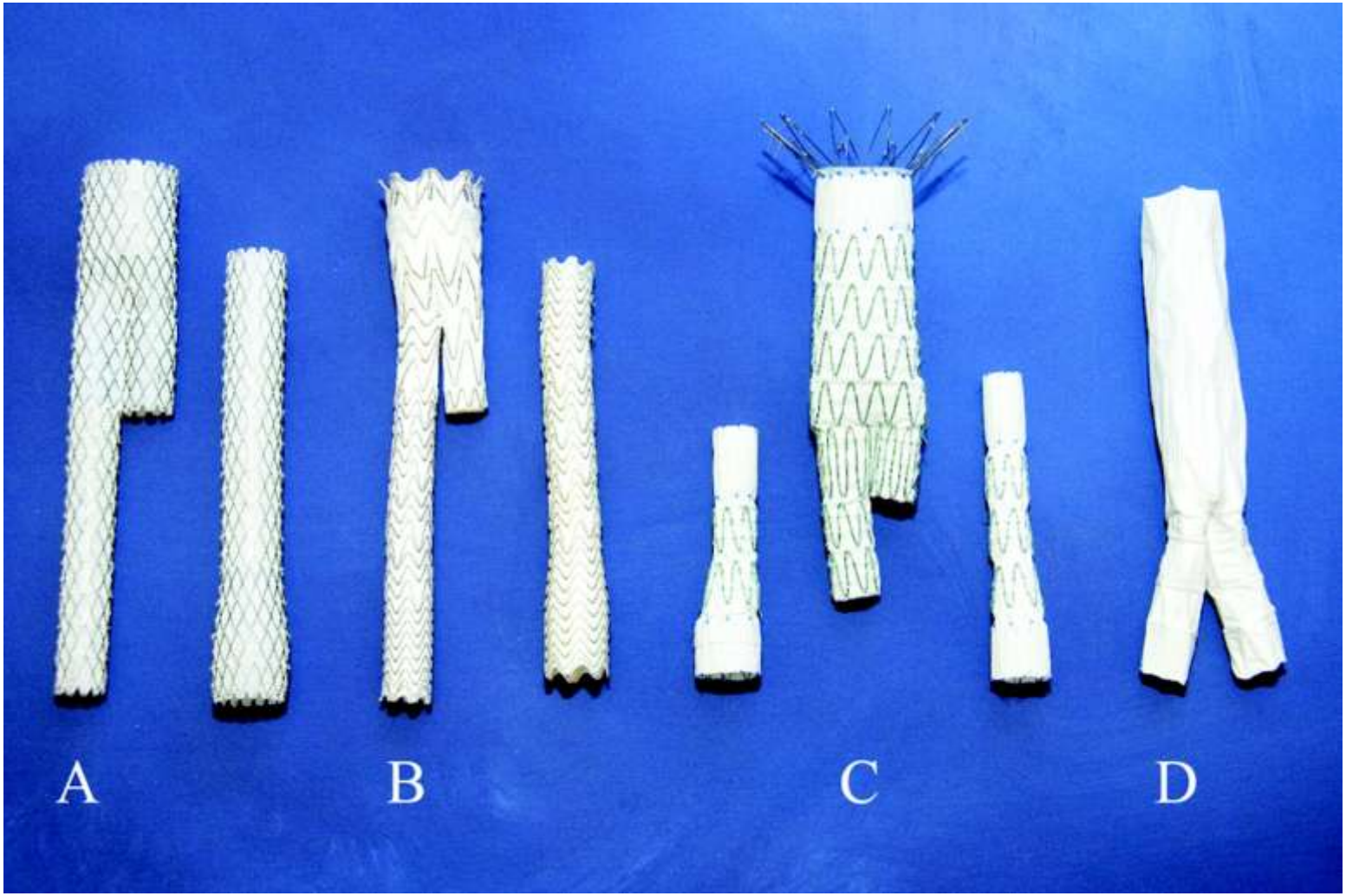
Anatomy Proximal Neck

Ileofemoral Anatomy

Proper Device Selection

- Graft: Modular vs unibody
- Flexibility – adaptability
- Fixation: Suprarenal vs infrarenal
- Experience with the device deployment
- Long term durability???

Figure 1. FDA-approved and currently marketed stent graft devices including (A) Medtronic, (B) Gore, (C) Cook, and (D) Endologix.



Eliason J L , Upchurch G R Circulation 2008;117:1738-1744

EVAR Complications

- **Deployment related**

Failed deployment

Bleeding

Hematoma

Lymphocele

Infection

Embolization

Perforation

Arterial rupture

Dissection

Device related

Structural failure

Post implant related

Endoleaks

Limb occlusion/stent-graft kink

Sac enlargement/proximal neck dilation

Stent migration

AAA rupture

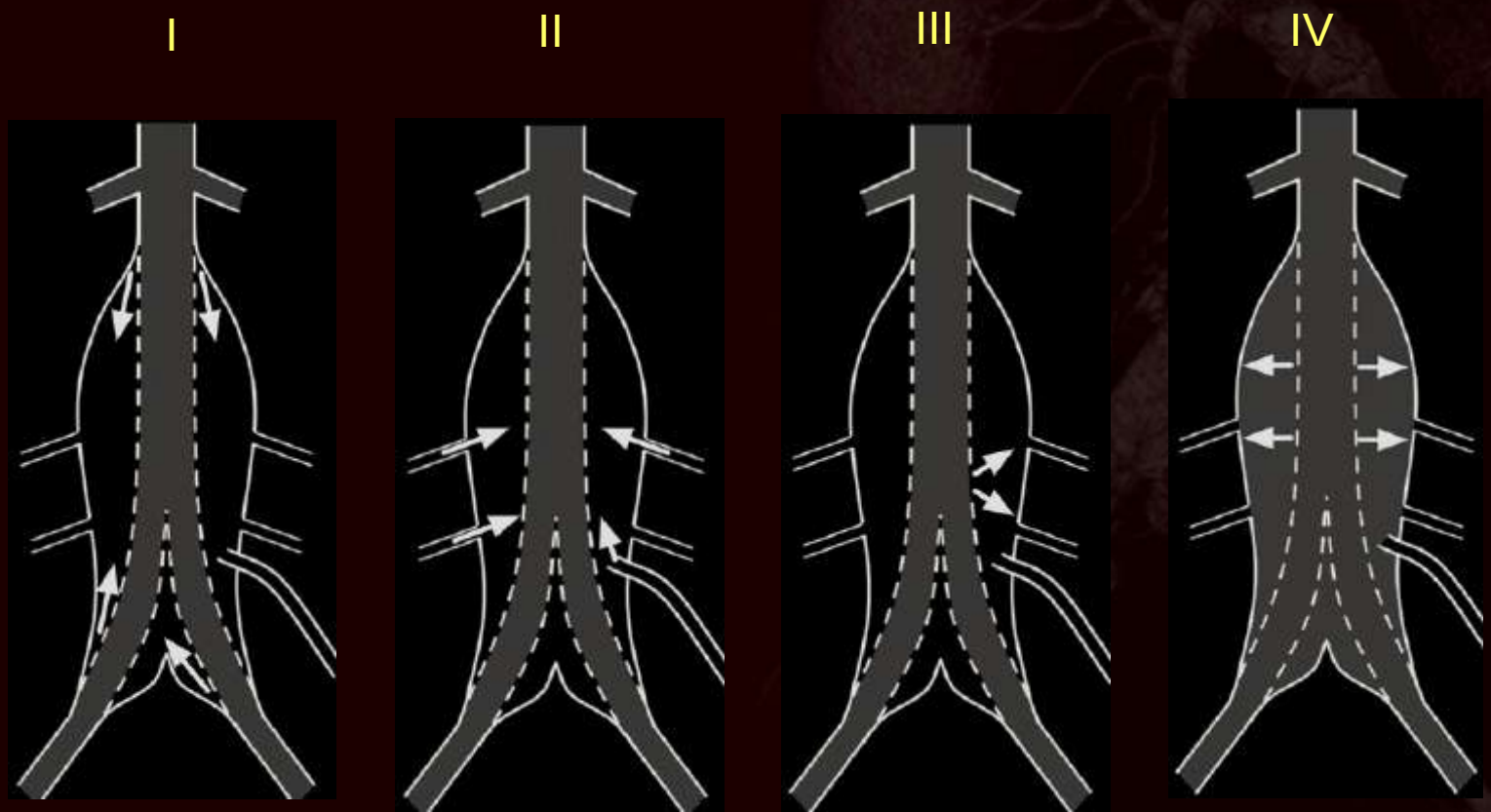
Infection

Buttock/leg claudication

EVAR Complications

- **Endoleak is the most common complications, greater than 20% - 30% in some studies.**
- An endoleak is define as persistent blood flow outside the wall of the stent into the aneurysmal sac.
- The endoleak exposes the weak aneurysm wall to continues flow that may lead to rupture.

Endoleaks



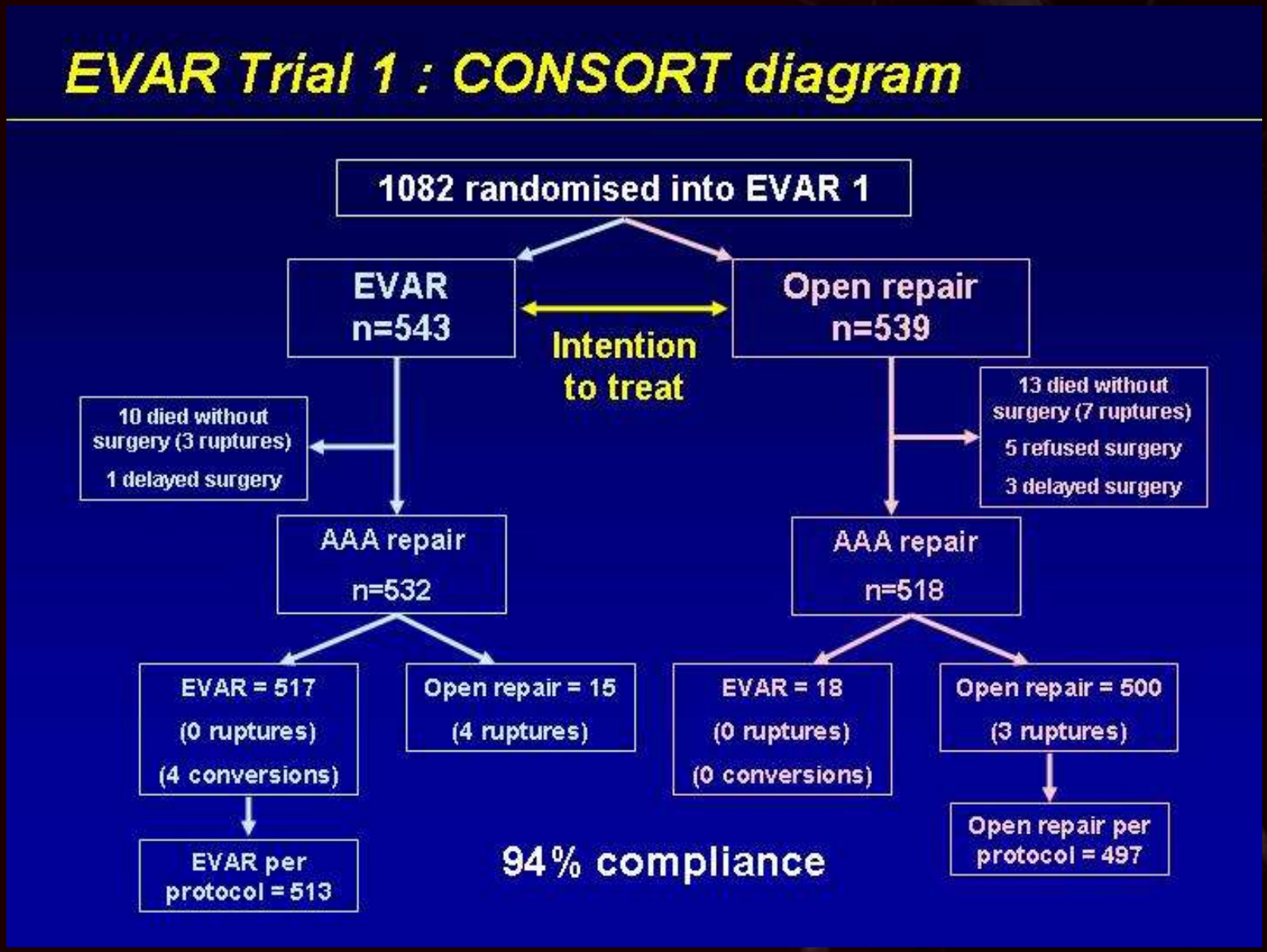
DREAM Trial

Major outcomes in DREAM

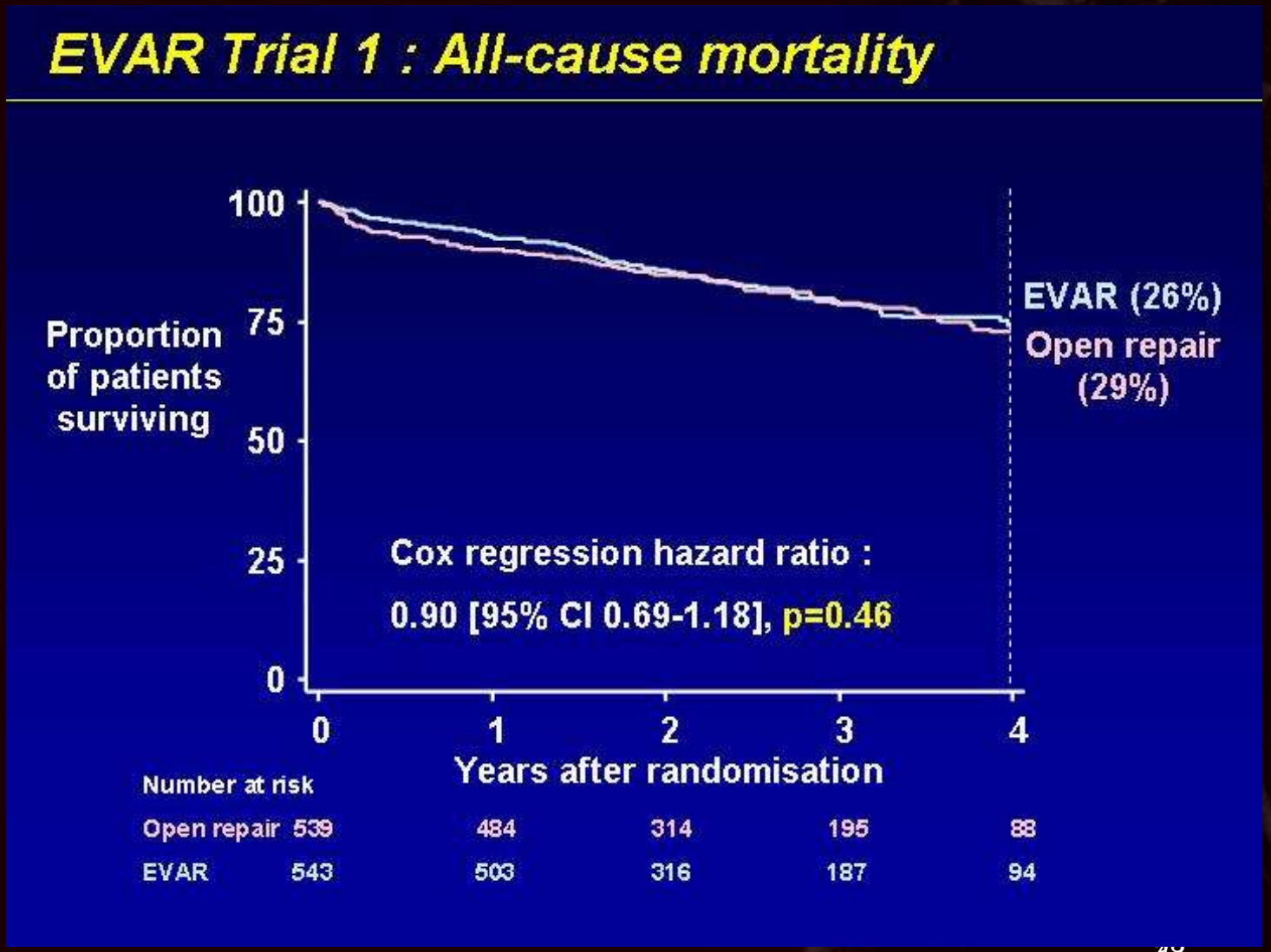
Outcome	Open repair (%)	Endovascular repair (%)	Relative risk (95% CI)
Operative mortality	4.6	1.2	3.9 (0.9-32.9)
Operative mortality and severe complications	9.8	4.7	2.1 (0.9-5.4)
Operative mortality and moderate or severe complications	23.6	18.1	1.3 (0.9-2.0)

Prinssen M et al. *N Engl J Med* 2004; 351:1607-1618.

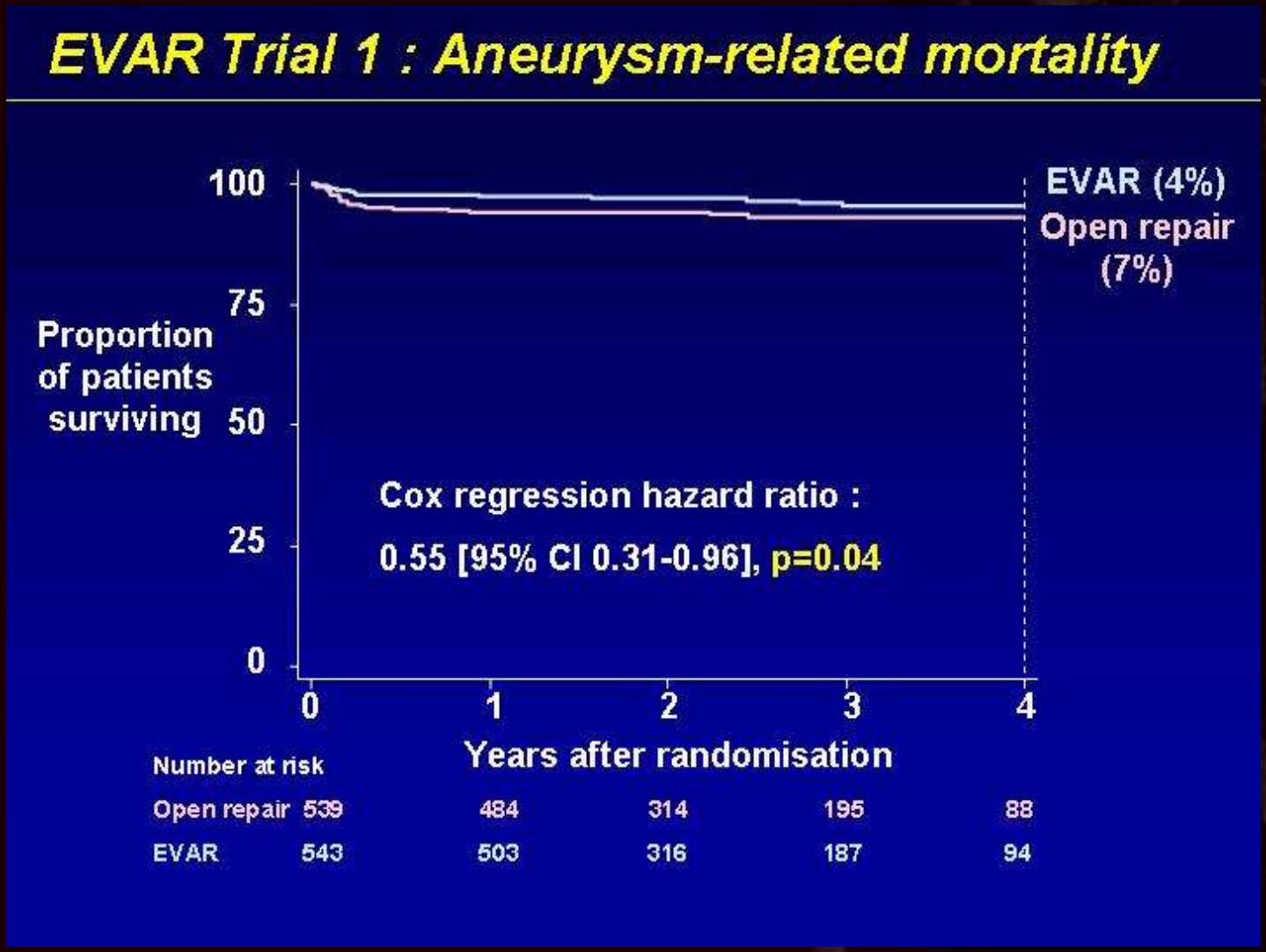
EVAR TRIAL 1


EVAR Trial 1 : CONSORT diagram
1082 randomised into EVAR 1
EVAR
n=543
Intention
to treat
Open repair
n=539
10 died without
surgery (3 ruptures)
1 delayed surgery
13 died without
surgery (7 ruptures)
5 refused surgery
3 delayed surgery
AAA repair
n=532
AAA repair
n=518
EVAR = 517
(0 ruptures)
(4 conversions)
Open repair = 15
(4 ruptures)
EVAR = 18
(0 ruptures)
(0 conversions)
Open repair = 500
(3 ruptures)
EVAR per
protocol = 513
94% compliance
Open repair per
protocol = 497

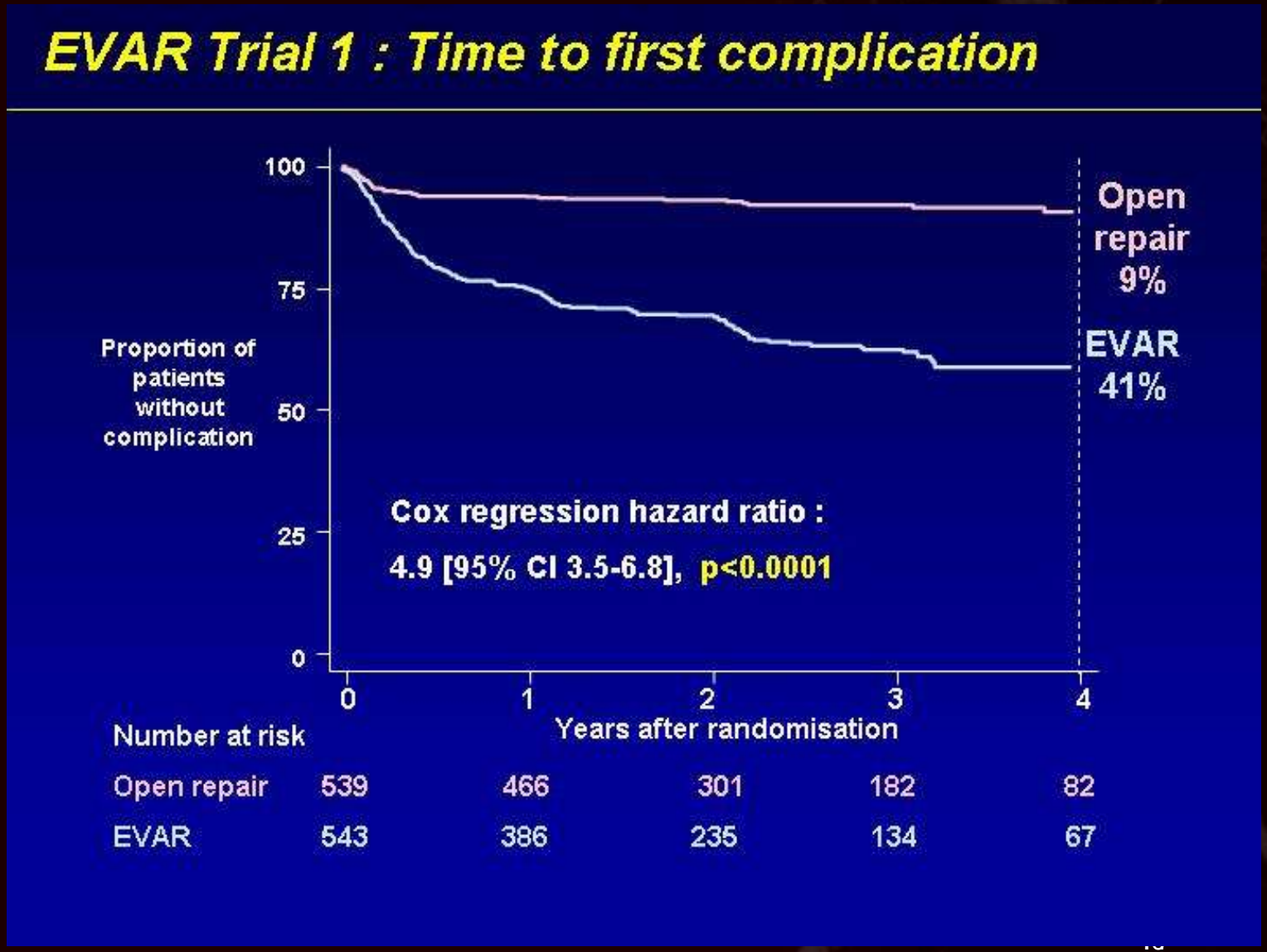
EVAR TRIAL 1


EVAR Trial 1 : All-cause mortality
Proportion of patients surviving
100
75
50
25
0
EVAR (26%)
Open repair (29%)
Cox regression hazard ratio :
0.90 [95% CI 0.69-1.18], p=0.46
0
1
2
3
4
Years after randomisation
Number at risk
Open repair 539 484 314 195 88
EVAR 543 503 316 187 94

EVAR TRIAL 1


EVAR Trial 1 : Aneurysm-related mortality
100
75
50
25
0
Proportion of patients surviving
EVAR (4%)
Open repair (7%)
Cox regression hazard ratio :
0.55 [95% CI 0.31-0.96], p=0.04
0
1
2
3
4
Years after randomisation
Number at risk
Open repair 539 484 314 195 88
EVAR 543 503 316 187 94

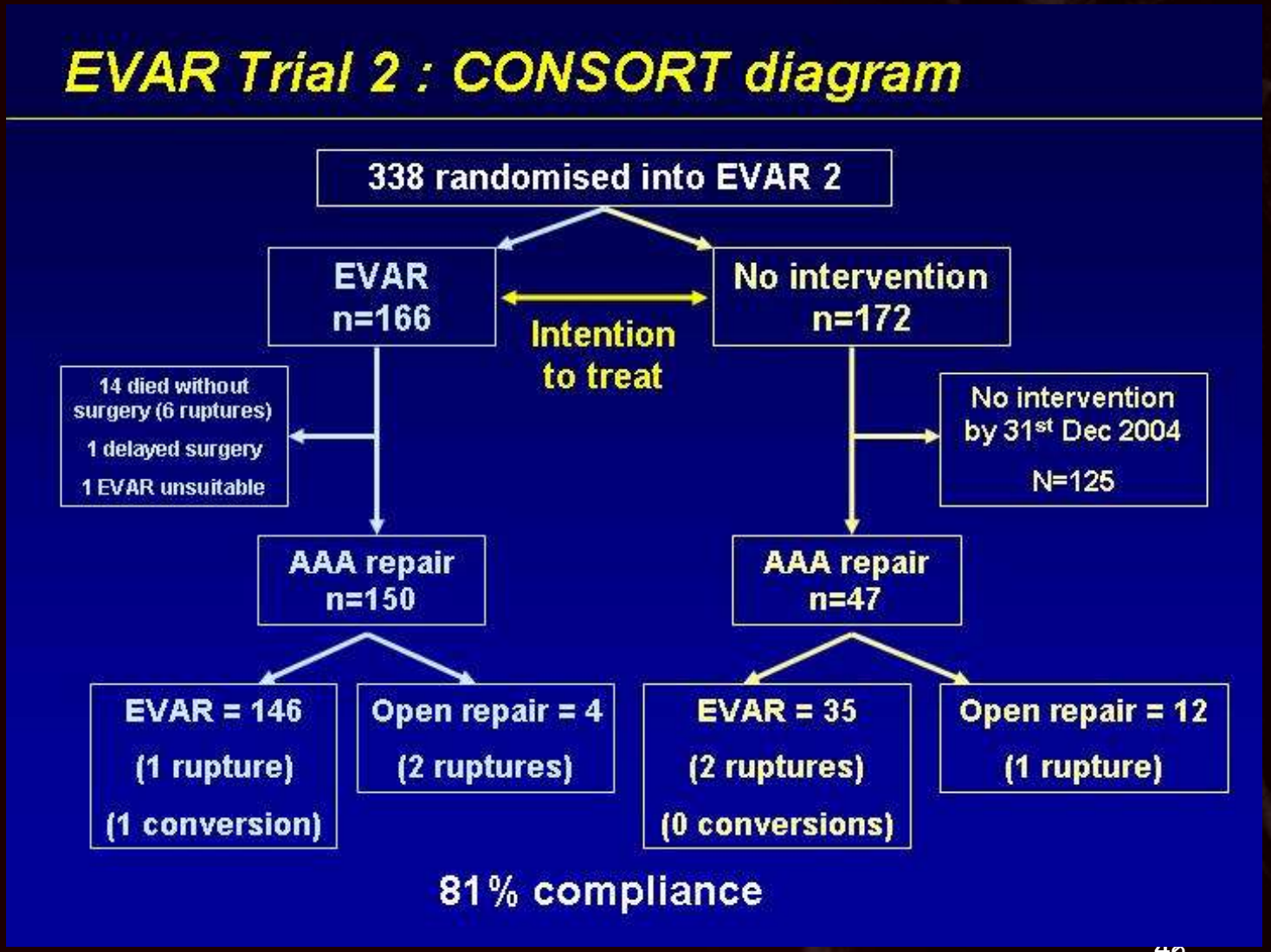
EVAR Trial


EVAR Trial 1 : Time to first complication
100
75
50
25
0
Proportion of patients without complication
Open repair 9%
EVAR 41%
Cox regression hazard ratio :
4.9 [95% CI 3.5-6.8], p<0.0001
0
1
2
3
4
Years after randomisation
Number at risk
Open repair 539 466 301 182 82
EVAR 543 386 235 134 67

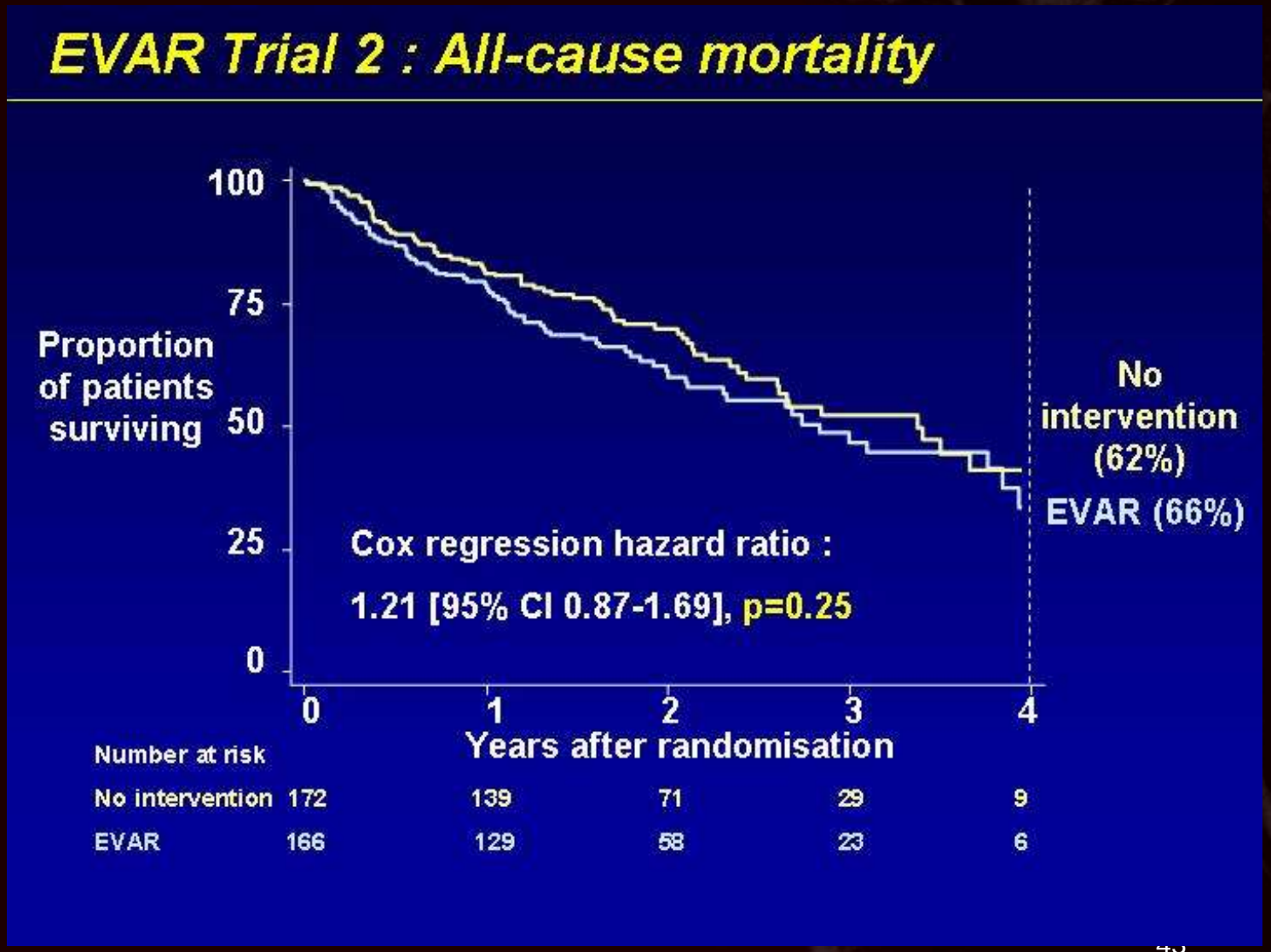
EVAR TRIAL 1


EVAR Trial 1 : Costs over 4 years
Cost (£)
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
EVAR group
£13,258
Open repair group
£9,946
Secondary interventions/ scanning
Other costs of primary admission
Hospital stay and ITU/HDU usage
Costs of primary procedure

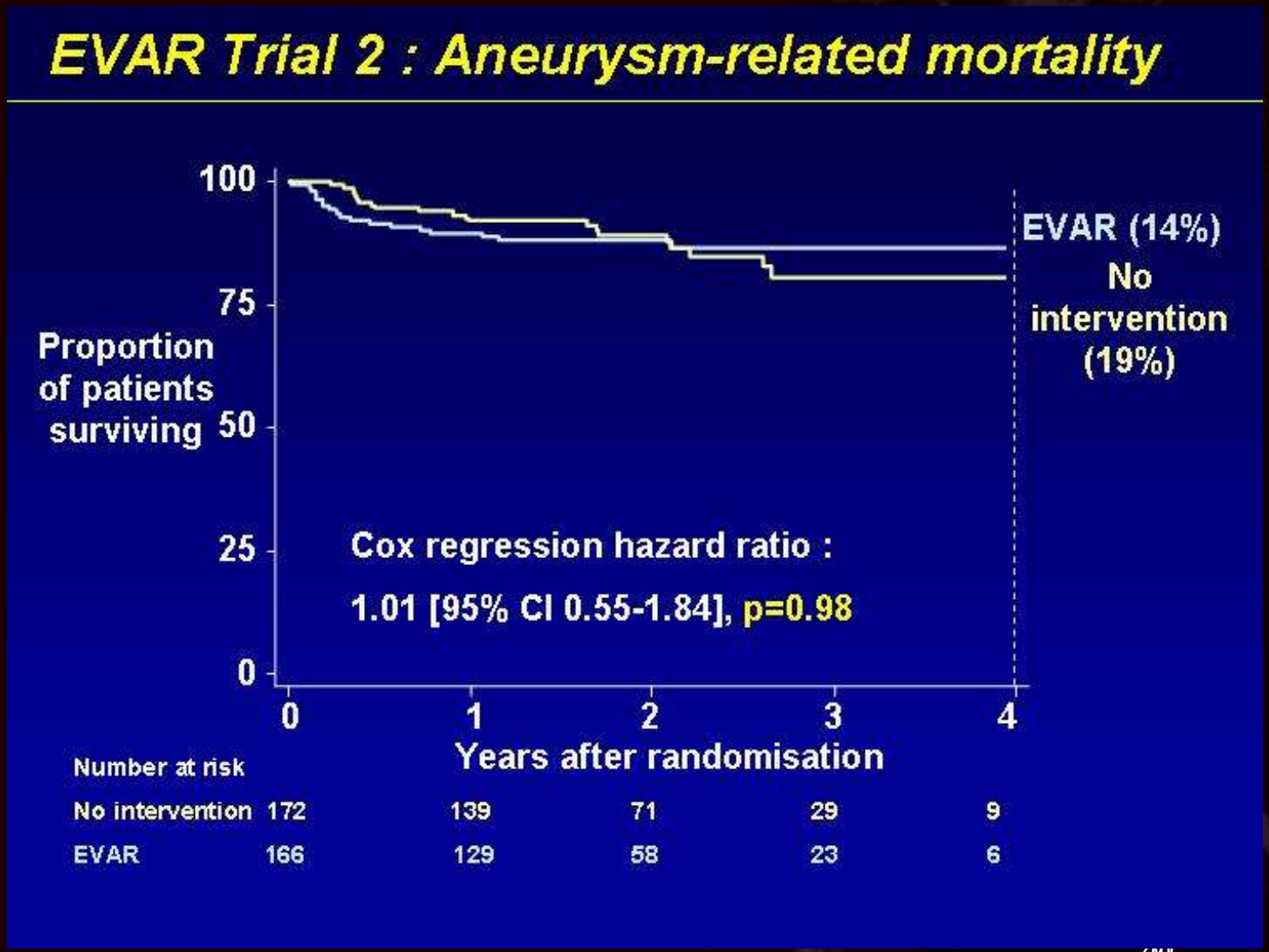
EVAR TRIAL 2


EVAR Trial 2 : CONSORT diagram
338 randomised into EVAR 2
EVAR
n=166
Intention
to treat
No intervention
n=172
14 died without
surgery (6 ruptures)
1 delayed surgery
1 EVAR unsuitable
No intervention
by 31st Dec 2004
N=125
AAA repair
n=150
AAA repair
n=47
EVAR = 146
(1 rupture)
(1 conversion)
Open repair = 4
(2 ruptures)
EVAR = 35
(2 ruptures)
(0 conversions)
Open repair = 12
(1 rupture)
81% compliance

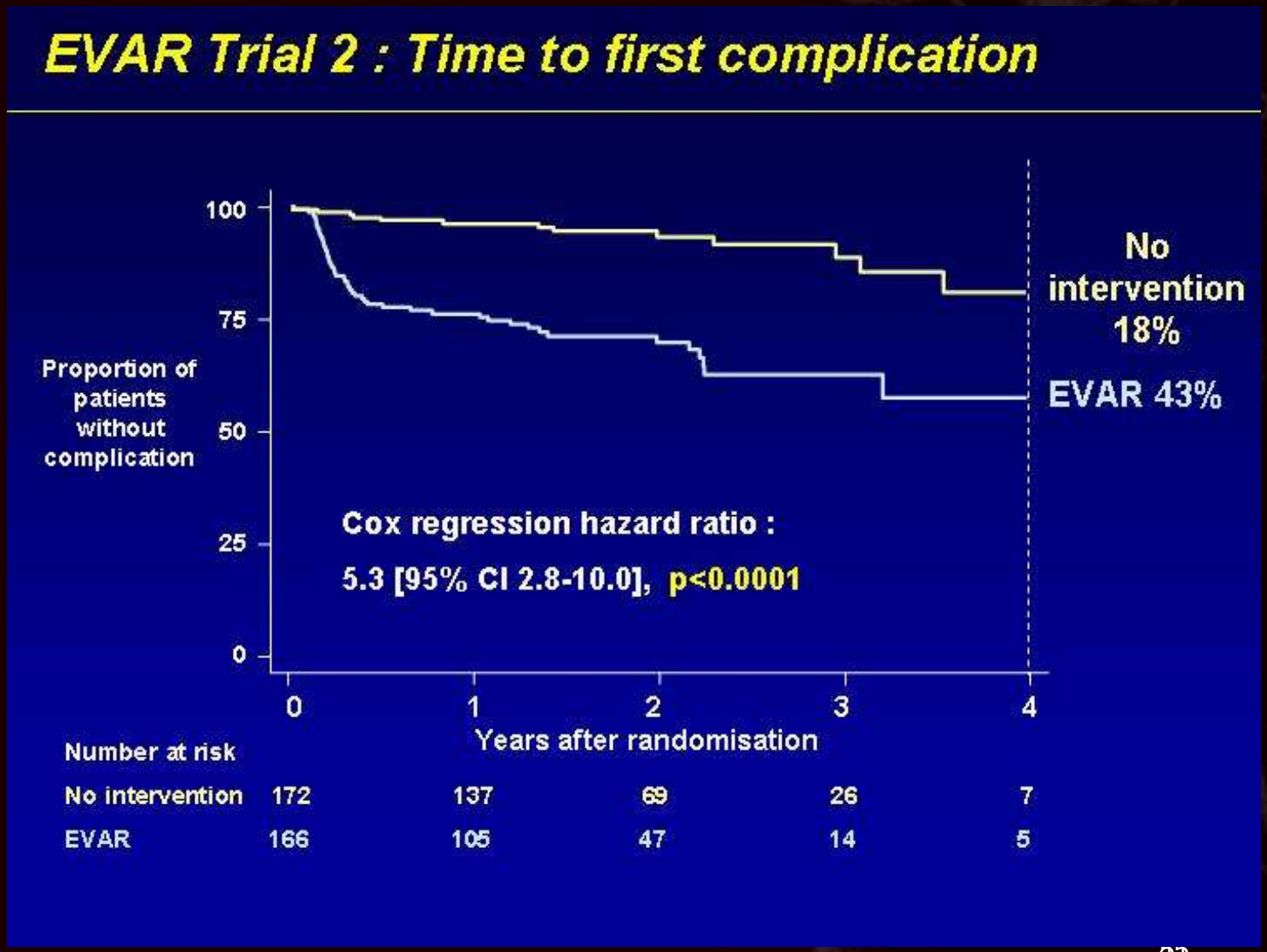
EVAR TRIAL 2


EVAR Trial 2 : All-cause mortality
100
75
50
25
0
Proportion of patients surviving
Cox regression hazard ratio :
1.21 [95% CI 0.87-1.69], p=0.25
No intervention (62%)
EVAR (66%)
0
1
2
3
4
Years after randomisation
Number at risk
No intervention 172 139 71 29 9
EVAR 166 129 58 23 6

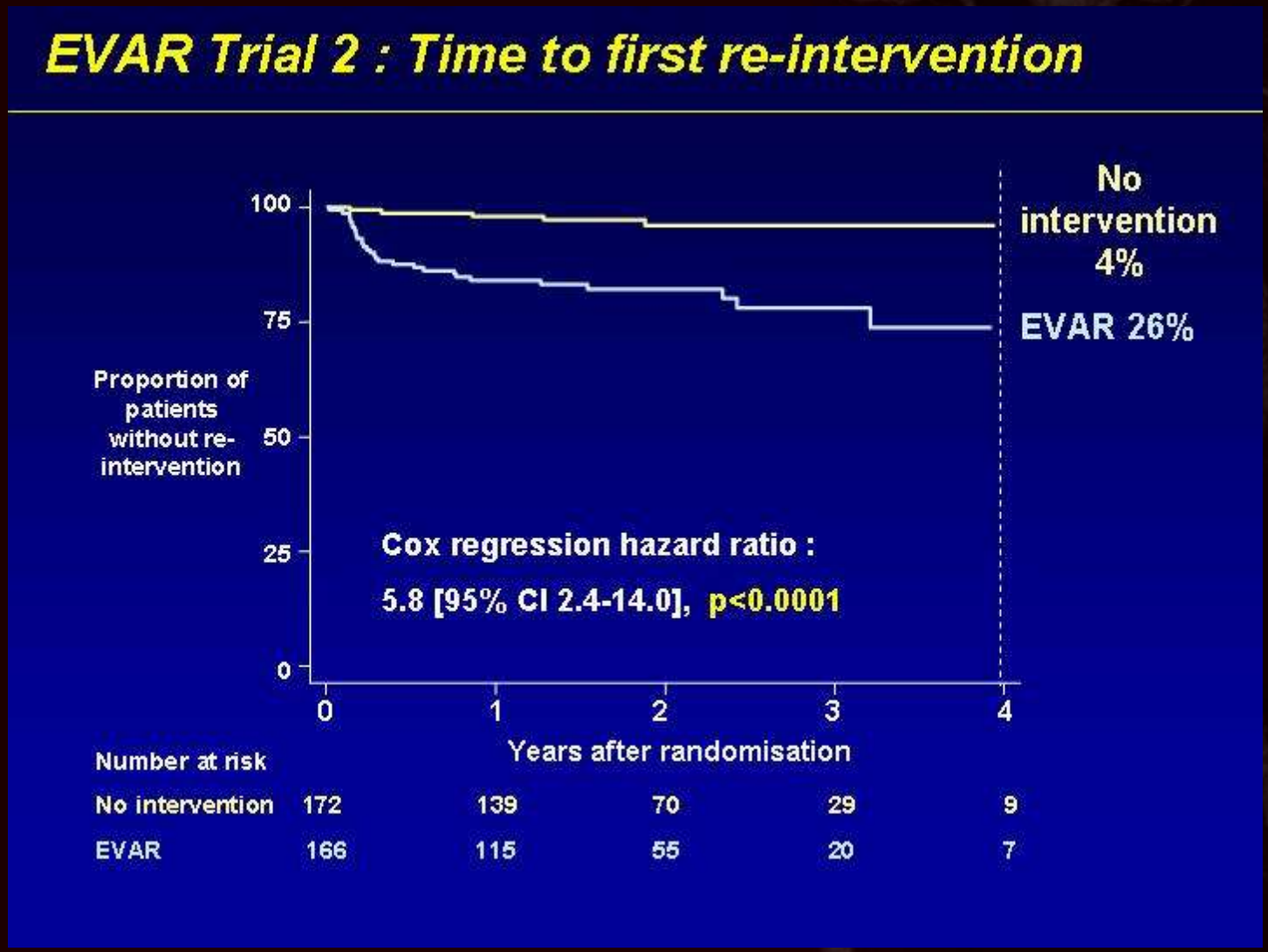
EVAR TRIAL 2


EVAR Trial 2 : Aneurysm-related mortality
100
75
50
25
0
Proportion of patients surviving
EVAR (14%)
No intervention (19%)
Cox regression hazard ratio :
1.01 [95% CI 0.55-1.84], p=0.98
0
1
2
3
4
Years after randomisation
Number at risk
No intervention 172 139 71 29 9
EVAR 166 129 58 23 6

EVAR TRIAL 2


EVAR Trial 2 : Time to first complication
100
75
50
25
0
Proportion of patients without complication
No intervention 18%
EVAR 43%
Cox regression hazard ratio :
5.3 [95% CI 2.8-10.0], p<0.0001
0
1
2
3
4
Years after randomisation
Number at risk
No intervention 172 137 69 26 7
EVAR 166 105 47 14 5

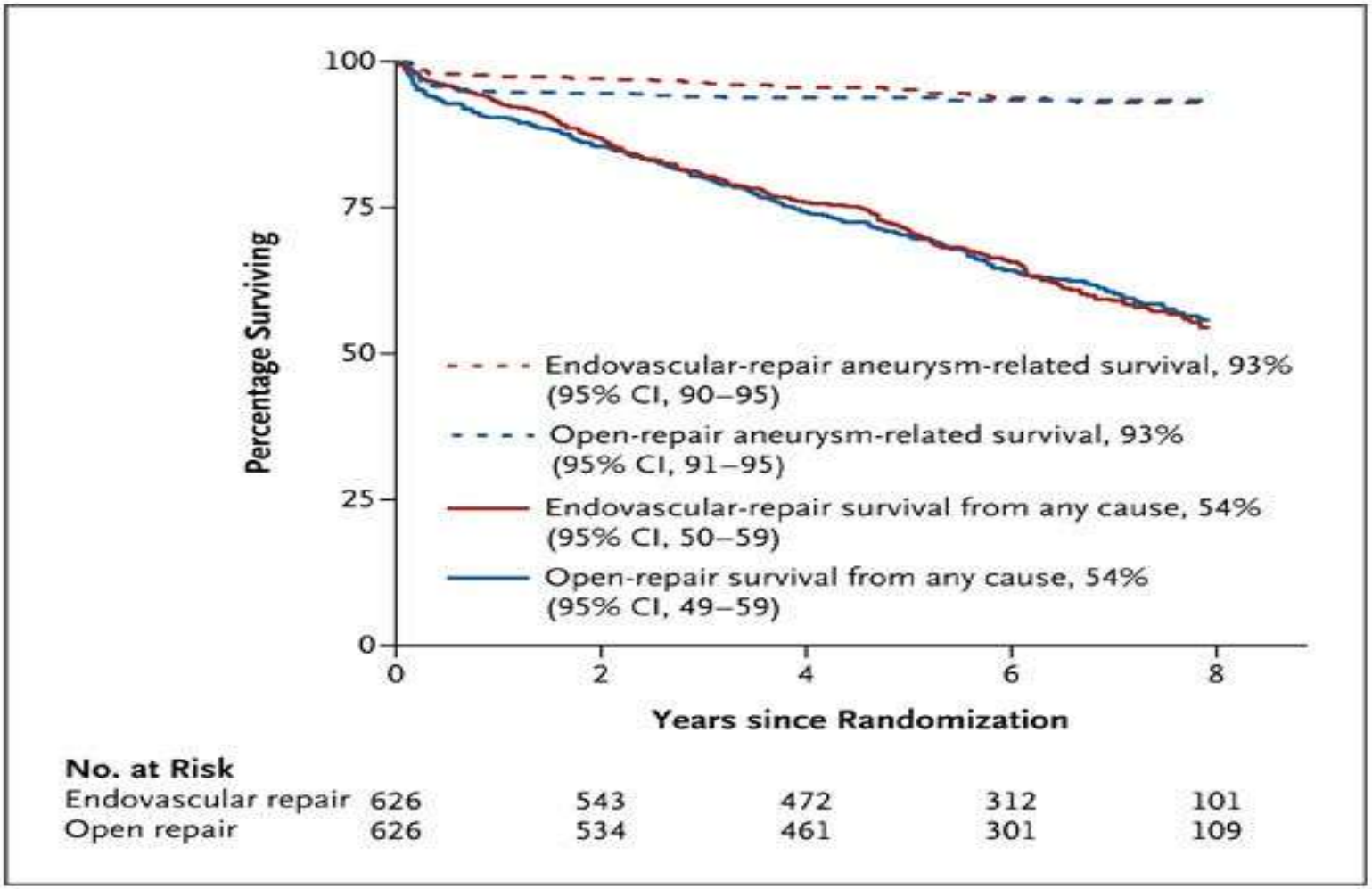
EVAR TRIAL 2


EVAR Trial 2 : Time to first re-intervention
100
75
50
25
0
Proportion of patients without re-intervention
No intervention 4%
EVAR 26%
Cox regression hazard ratio :
5.8 [95% CI 2.4-14.0], p<0.0001
0
1
2
3
4
Years after randomisation
Number at risk
No intervention 172 139 70 29 9
EVAR 166 115 55 20 7

EVAR TRIAL 2


EVAR Trial 2 : Costs over 4 years
Cost (£)
16,000
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
EVAR group
£13,632
No intervention group
£4,983
Secondary interventions/ scanning
Other costs of primary admission
Hospital stay and ITU/HDU usage
Costs of primary procedure

EVAR 1: 8-year Follow-up



OVER TRIAL

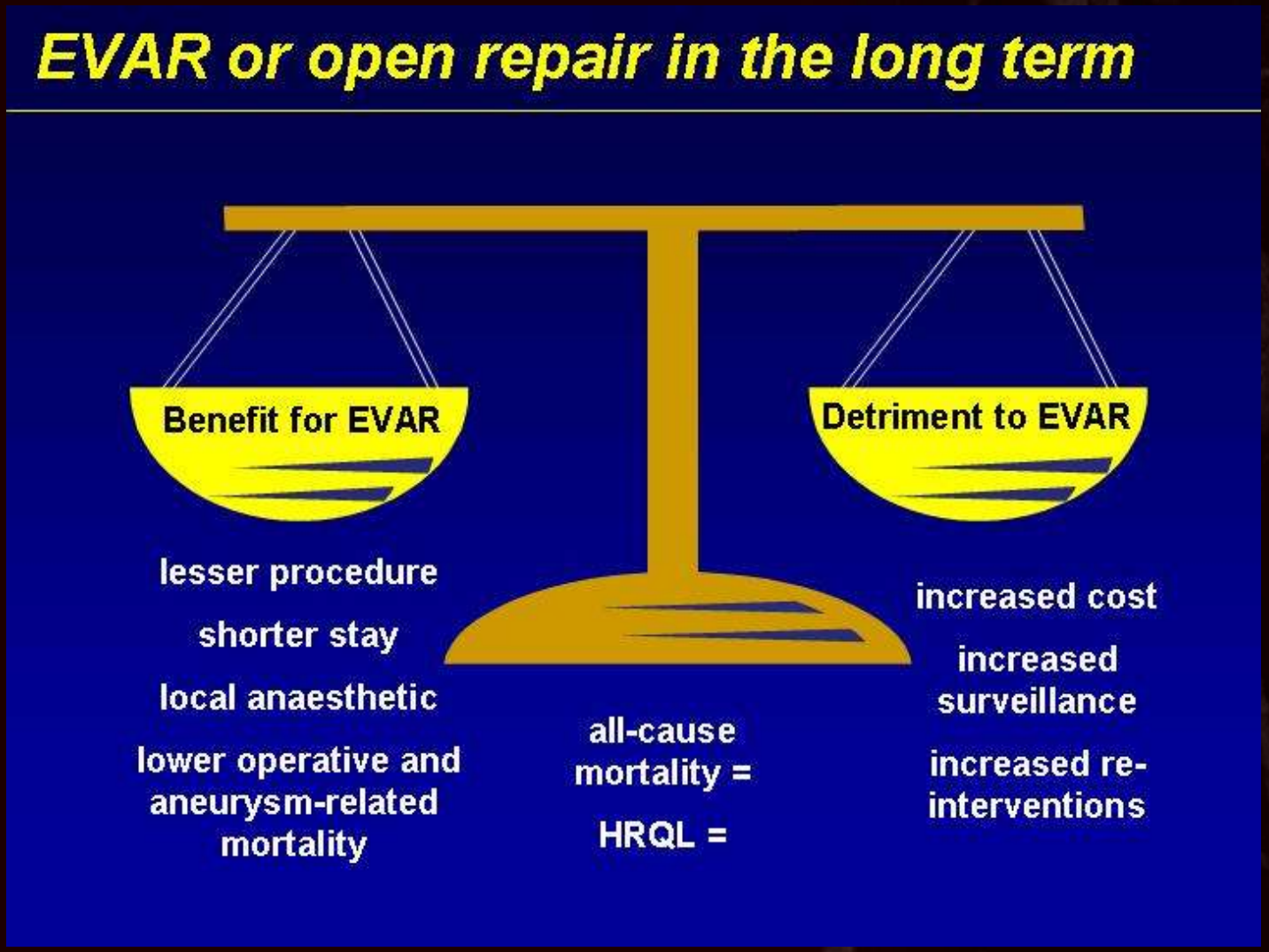
- 99.3% male
- Mean age: 70 years
- Current smoker: 41%
- Coronary artery disease: 41%
- AAA diameter < 5.5 cm: 43%
  ≥ 6.0 cm: 27%

- EVR system:
  Cook Zenith: 39%, Gore Excluder: 37%
  Medtronic Aneurx: 21%, Guidant/Endologix: 3%

OVERT Trial: Mortality within 30 days or inpatient

	EVR	Open
EVAR-1	2.1%	6.2%
DREAM	1.2%	4.6%
OVER	0.5%	3.0%

EVAR VS OPEN


EVAR or open repair in the long term
Benefit for EVAR
Detriment to EVAR
lesser procedure
shorter stay
local anaesthetic
lower operative and aneurysm-related mortality
all-cause mortality =
HRQL =
increased cost
increased surveillance
increased re-interventions

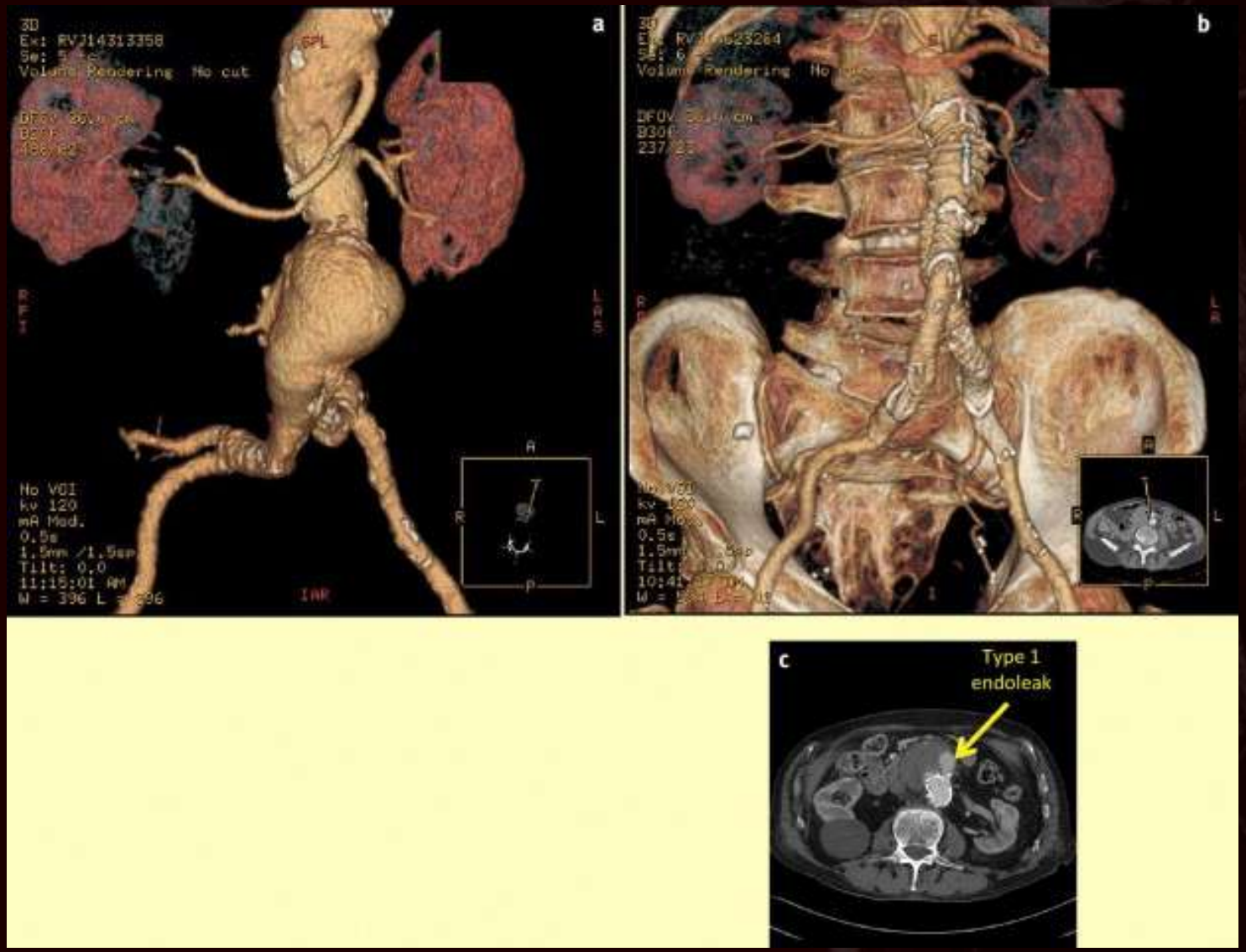
Ongoing Trials

- CAESAR (Comparison of Surveillance Versus Aortic Endografting for Small Aneurysm Repair)
- 740 patients
- Small AAA: 4.1 to 5.4 cm
- Zenith stent graft
- Primary end point: All cause mortality at 54 months.

Ongoing Trials

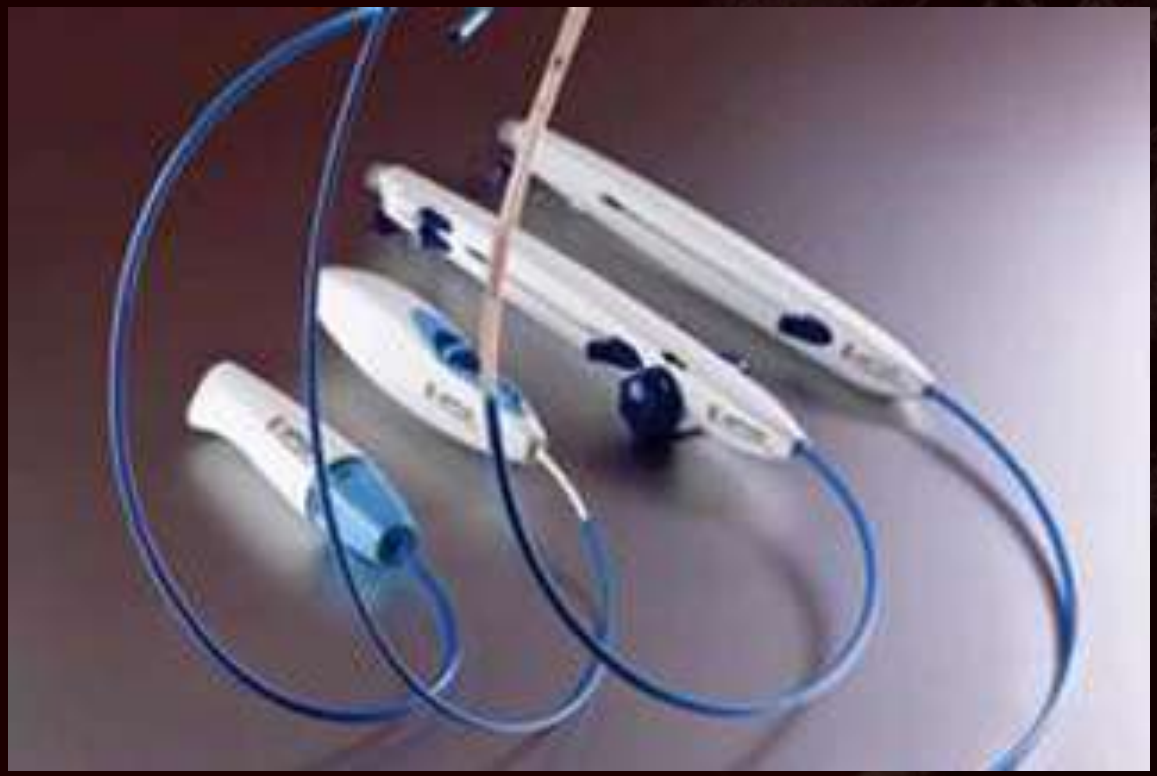
- PIVOTAL (Positive Impact of Endovascular Options for Treating Aneurysm Early)
- 1025 patients
- Small AAA: 4.1 to 5.4 cm
- AneuRx or Talent graft
- Primary end points: AAA rupture and AAA related deaths.

Complex Anatomy

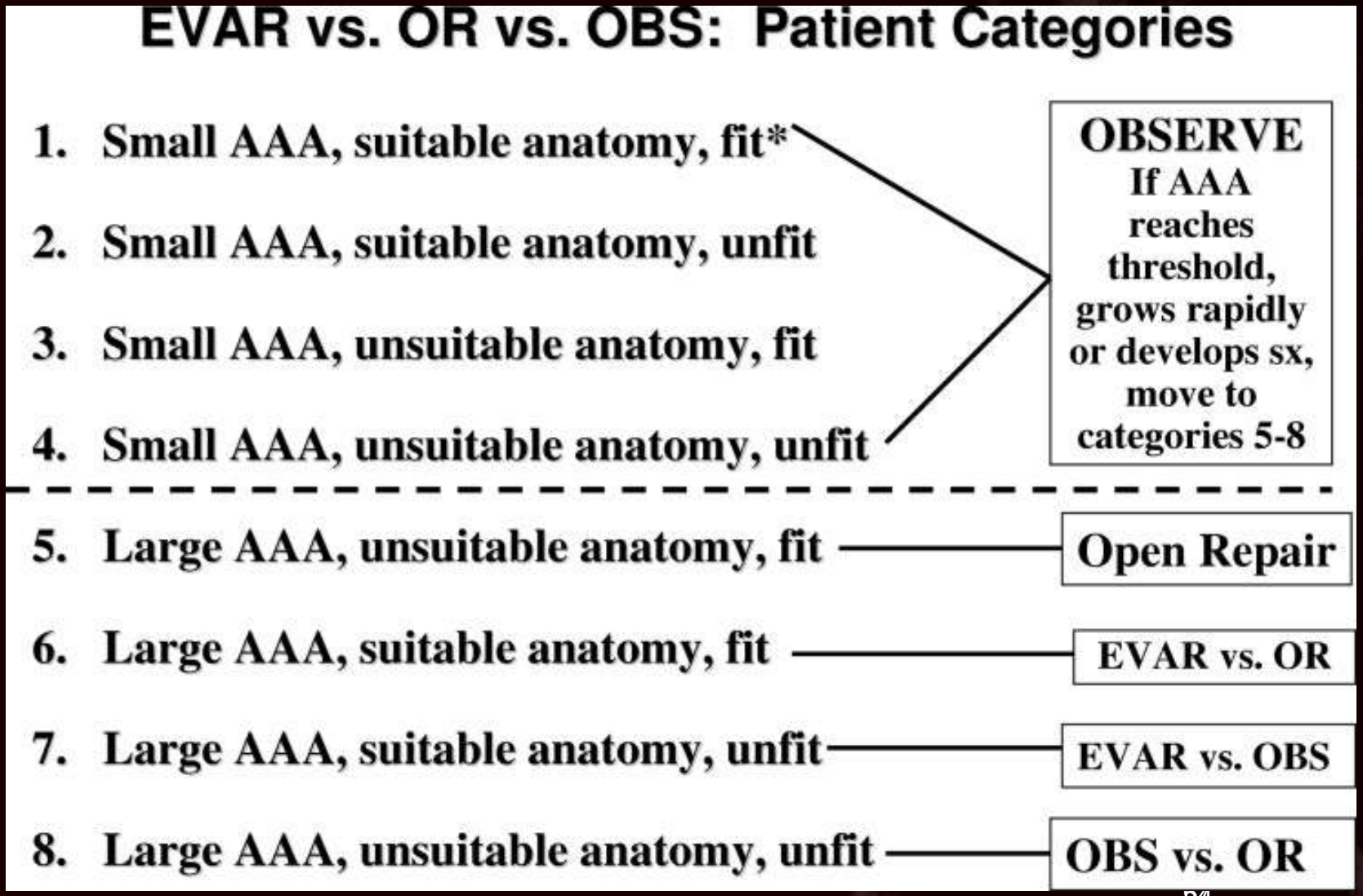


Preservation of Side Branches

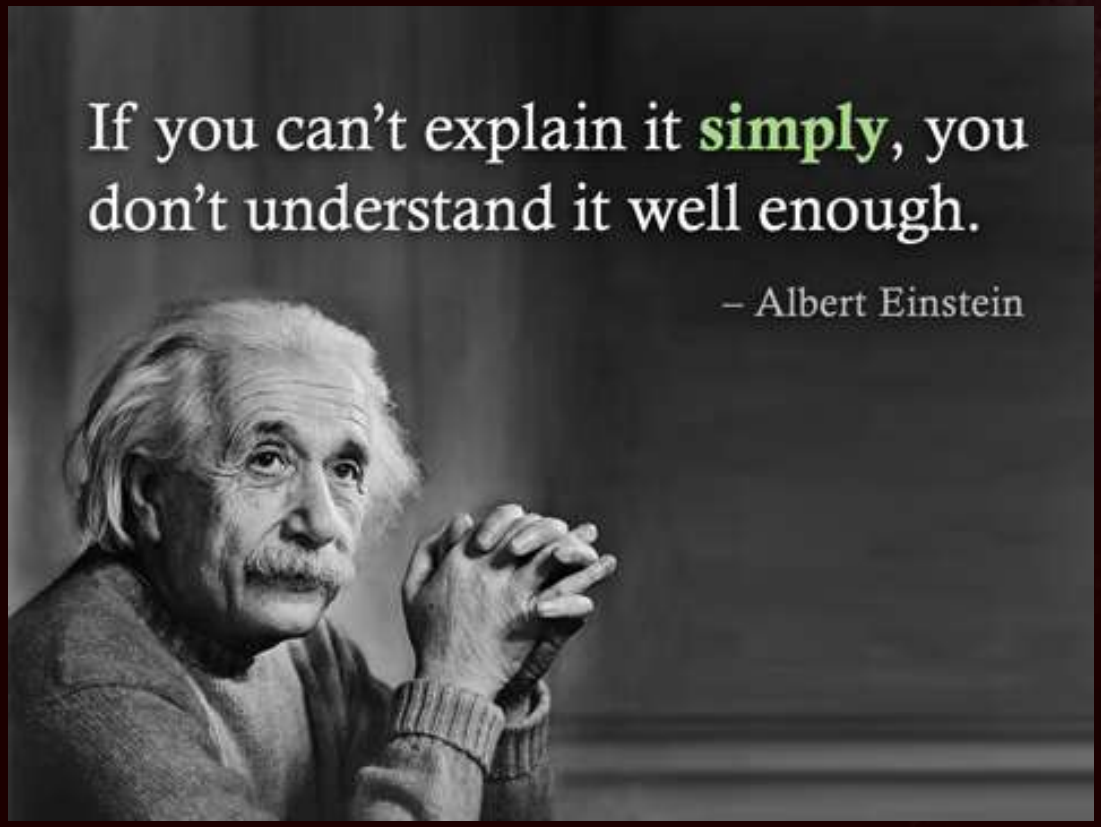
Lower Profile



Current Management



Thank You


If you can't explain it simply, you don't understand it well enough.
– Albert Einstein