SAMSUNG
삼성서울병원

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Endovascular Treatment of Symptomatic Abdominal Aortic Aneurysms

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- EVAR vs. Open repair
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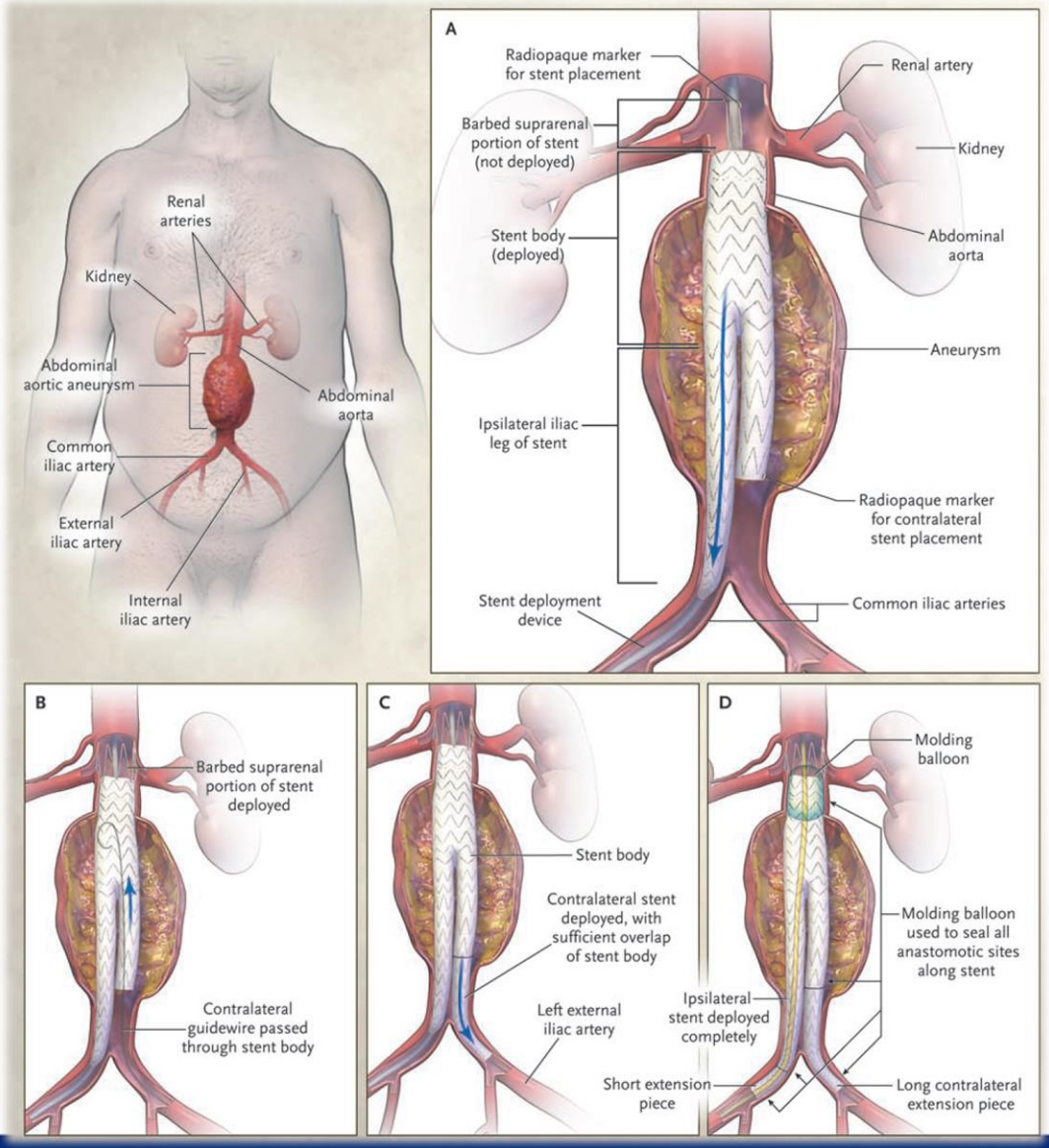
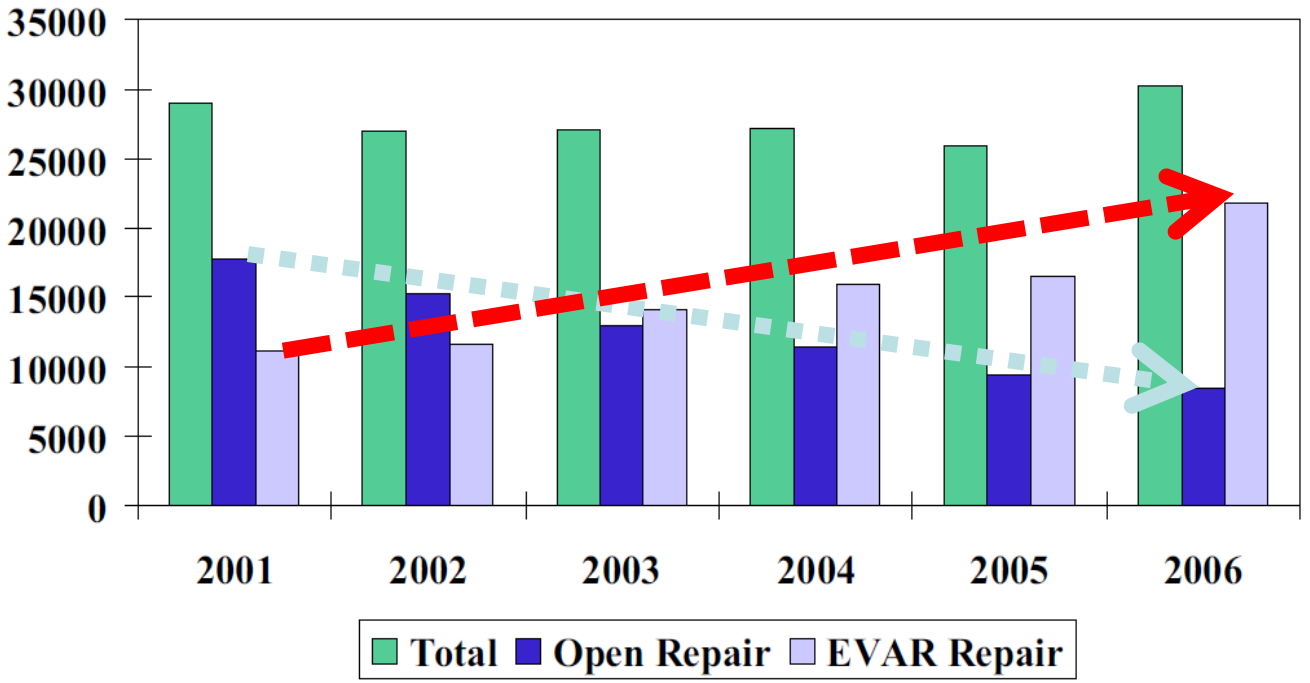
Endovascular Repair of AAA



Greenhalgh RM & Powell JT. NEJM 2008;358:494

Treatment Modality

- Surgical open repair – standard of care
- EVAR, since early 1990's, has received widespread acceptance for elective Tx of AAA



Schwarze ML, et al. J Vasc Surg 2009;50:722

EVAR vs. Open repair

- **4 RCT's**

	Country	Numb of Patients		Median F/U	Publication
		EVAR	OR		
EVAR-1	UK	626	626	6.0 y	NEJM 2010
DREAM	Dutch	173	178	6.4 y	NEJM 2010
OVER	USA	444	437	5.2 y	NEJM 2012
ACE	France	150	149	3.0 y	J Vasc Surg 2011

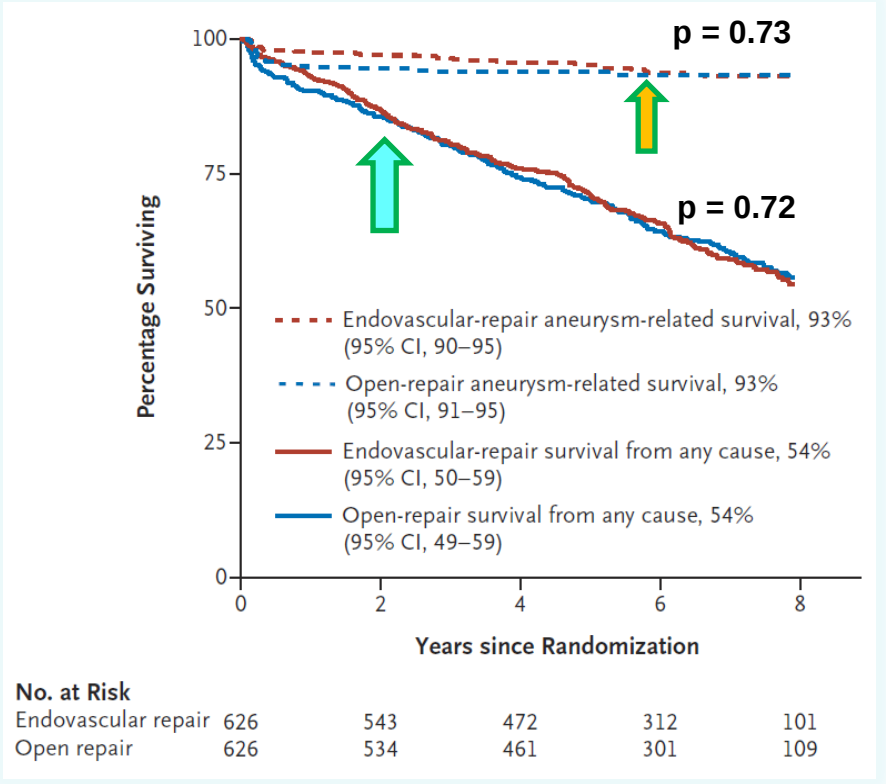
In-hospital Mortality

In-hospital Mortality	EVAR	Open Repair
EVAR-1	2.1%	6.2%
DREAM	1.2%	4.6%
OVER	0.5%	3%
ACE	1.3%	0.6%

EVAR is better than OR

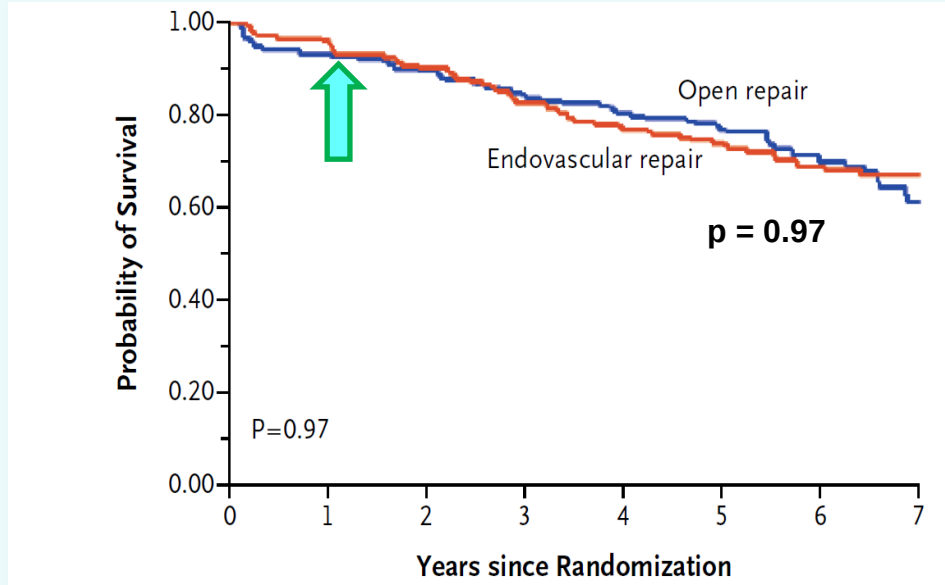
No Survival difference

EVAR-1



No. at Risk					
Endovascular repair	626	543	472	312	101
Open repair	626	534	461	301	109

DREAM



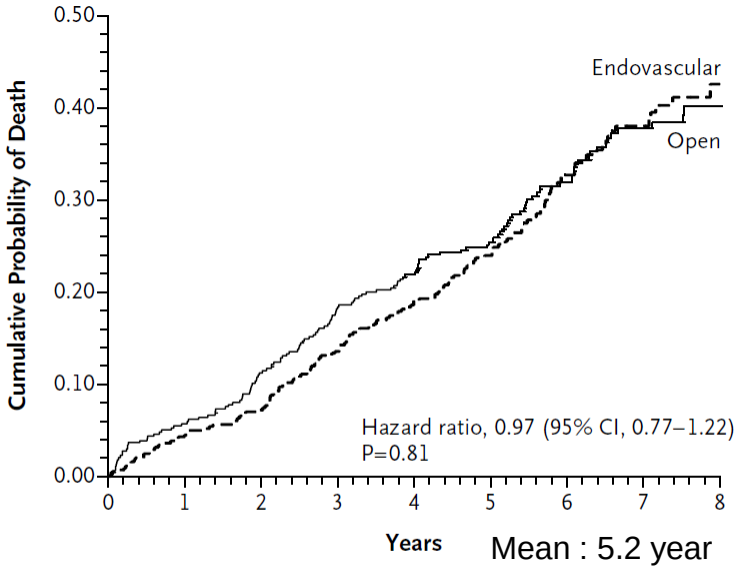
No. at Risk								
Open repair	178	166	159	150	143	137	88	36
Endovascular repair	173	166	156	143	133	128	83	39

De Bruin JL, et al. NEJM 2010;362:1881

UK EVAR investigators. NEJM 2010;362:1863

No Survival difference

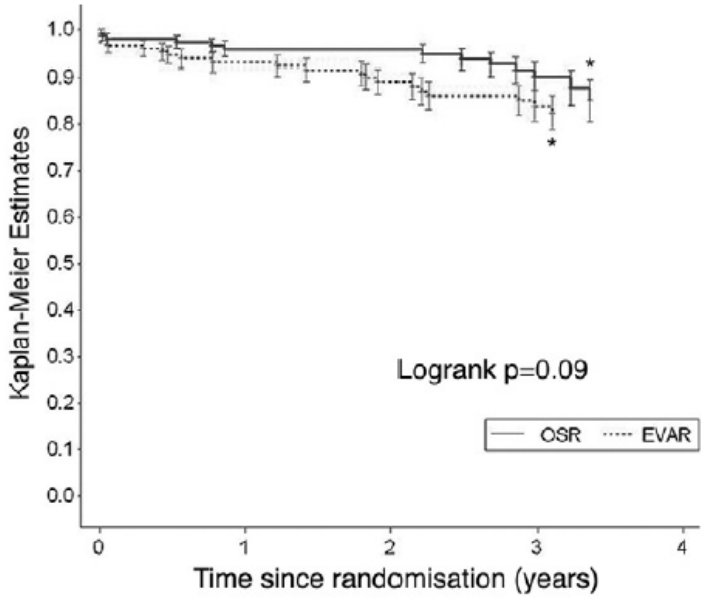
OVER



Mean : 5.2 year

No. at Risk									
Open	437	410	386	354	329	266	169	102	35
Endovascular	444	423	410	381	347	265	159	94	34

ACE



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

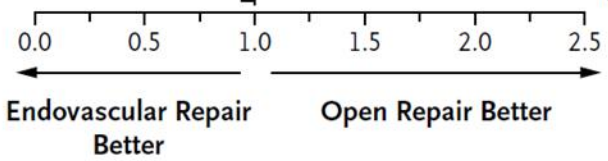
Lederle FA, et al. NEJM 2012;367:1988

Becquemin J, et al. J Vasc Surg 2011;53:1167

Hazard ratio for death

OVER

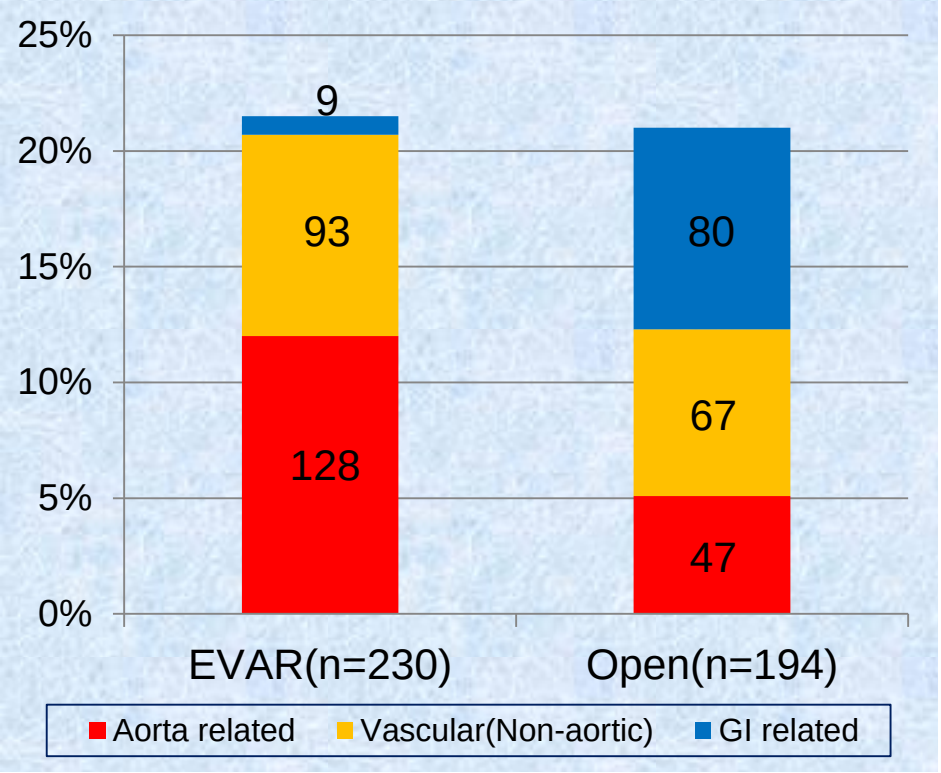
Subgroup	No. of Patients	No. of Deaths	Hazard Ratio (95% CI)	P Value for Interaction
Randomization period				0.05
Before April 15, 2005	413	170	1.18 (0.87–1.59)	
On or after April 15, 2005	468	122	0.75 (0.52–1.07)	
Age				0.006
<70 yr	406	94	0.65 (0.43–0.98)	
≥70 yr	475	198	1.31 (0.99–1.73)	
Abdominal aortic aneurysm diameter				0.75
<5.5 cm	382	120	0.93 (0.65–1.34)	
≥5.5 cm	499	172	1.00 (0.74–1.34)	
Surgical risk (RAND score)				0.08
Low	468	129	0.79 (0.56–1.12)	
Intermediate or high	404	157	1.19 (0.87–1.63)	
Coronary artery disease				0.60
No	522	170	1.02 (0.75–1.38)	
Yes	359	122	0.91 (0.64–1.29)	
Intended endovascular device				
Cook Zenith	341	104	0.97 (0.66–1.43)	
Gore Excluder	327	107	0.80 (0.55–1.18)	0.14
Medtronic AneuRx	186	69	1.49 (0.93–2.40)	0.06
All patients	881	292	0.97 (0.77–1.22)	



Lederle FA, et al. NEJM 2012;367:1988

Analysis for Re-Interventions

- 1986 procedures in 1908 patients
  - 1066 EVAR 1999-2009
  - 920 Open repair 1985-2009
- Mean F/U 27 months
- Secondary intervention
  - ✓ Vascular
    - Aorta and Non-aorta
  - ✓ Non vascular
    - GI related (incisional hernia)
- 21.3% Secondary intervention
  - 21.9% in EVAR
  - 21.2% in OR

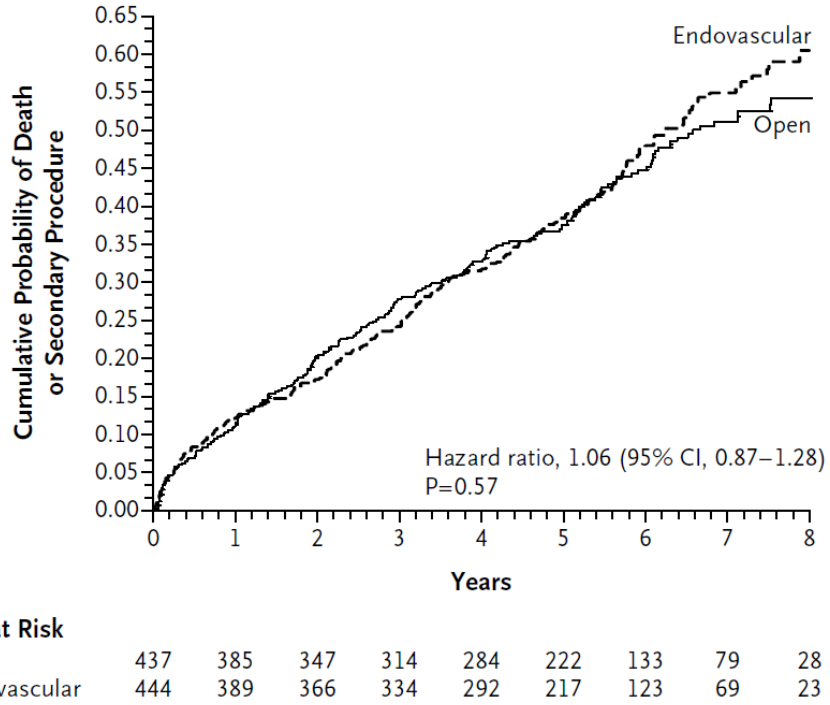


Quinney BE, et al . J Vasc Surg 2011;54:1592-8

Re-Interventions

Outcome	Endovascular Repair (N=444)	Open Repair (N=437)	P Value
All deaths — no. of patients (%)	146 (32.9)	146 (33.4)	0.81
Cause of death — no. of patients (%)			
Aneurysm-related cause	10 (2.3)	16 (3.7)	0.22
During hospitalization or within 30 days after repair	2 (0.5)	13 (3.0)	0.004
Cardiovascular cause not related to aneurysm	39 (8.8)	29 (6.6)	0.23
Cancer	39 (8.8)	48 (11.0)	0.27
Pneumonia or other infection	15 (3.4)	12 (2.8)	0.59
Chronic obstructive lung disease	5 (1.1)	13 (3.0)	0.05
Accident, homicide, or suicide	10 (2.3)	4 (0.9)	0.18
Other cause	15 (3.4)	9 (2.1)	0.23
Unknown cause	13 (2.9)	15 (3.4)	0.67
Aneurysm rupture	6 (1.4)	0	0.03
New or worsened claudication — no. of patients (%)	23 (5.2)	15 (3.4)	0.20
Secondary therapeutic procedures			
No. of patients (%)	98 (22.1)	78 (17.8)	0.12
No. of procedures	148	105	0.26
Hospitalizations after repair			
Total no. of hospitalizations	954	1040	0.08
Total no. of patients with one or more hospitalizations (%)	325 (73.2)	314 (71.9)	0.66
Hospitalizations related to aneurysm			
No. of hospitalizations	171	117	0.12
No. of patients (%)	95 (21.4)	78 (17.8)	0.19

OVER



Secondary therapeutic procedure included
- Incisional hernia repair
- laparotomy for bowel obstructions

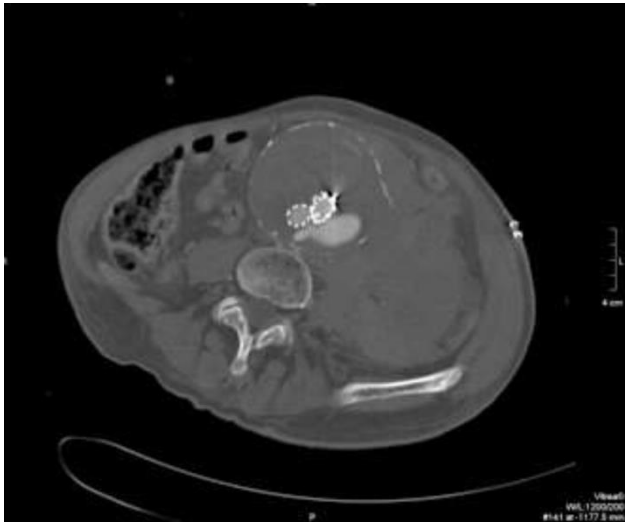
Lederle FA, et al. NEJM 2012;367:1988

Risk of aneurysmal rupture

- **Achilles' heel of EVAR**

EVAR-1 : 4.6% at 6 year f/u
DREAM : 1.7% at 6.4 year f/u
OVER : 1.4% at 5.2 year f/u
ACE : 2% at 3 year f/u

Higher mortality rate in ruptured patients



- Causes of rupture were identified by radiologists before ruptures in many of the patients
- Annual imaging follow up after EVAR is important to reduce the rupture

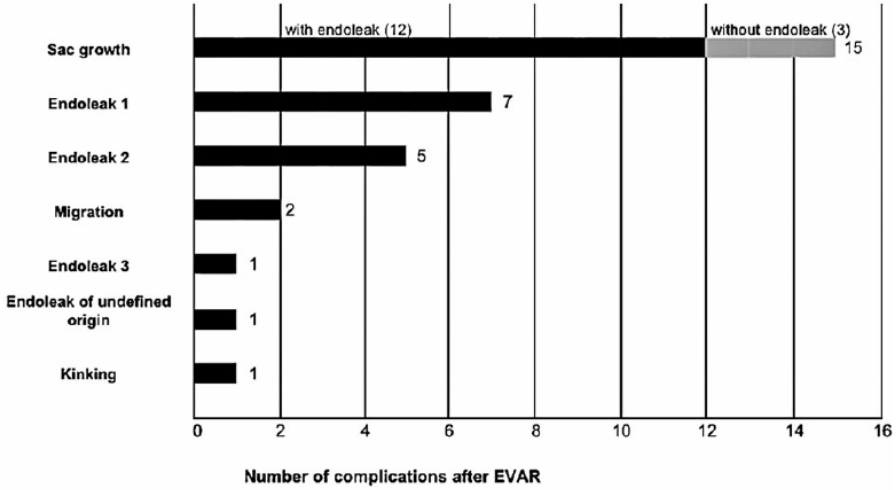
Wyss TR, Ann Surg 2010;805-12

Data from EVAR trials

EVAR 1 & 2 trial :
EVAR group : 848 patients
OR group : 594 patients

Follow up data

OR ⟶ **0 rupture**



EVAR ⟶ **27 ruptures**

5(18.5%) : perioperative ruptures
5(18.5%) : late rupture without prior complications
17(63%) : late rupture with prior complications

18(67%) died within 30 days of rupture

- 12 urgent procedure
  - 7 OR ⟶ 2 died
  - 5 EVAR modification ⟶ 1 died
- 15 died before intervention

Wyss TR, Ann Surg 2010;805-12

EVAR vs. Open Repair

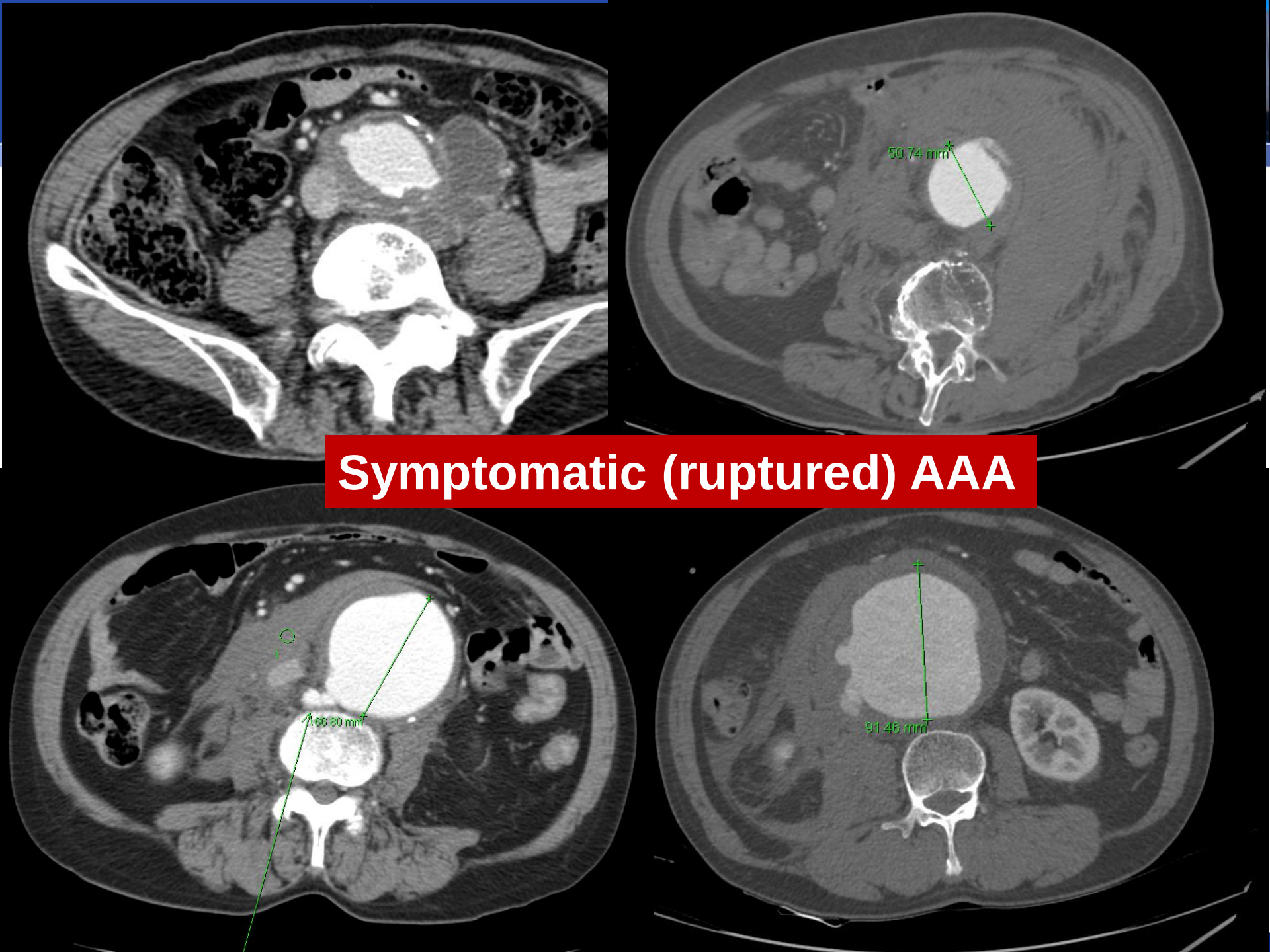
Early survival benefit in EVAR
& late equivalence in both group

Pros.

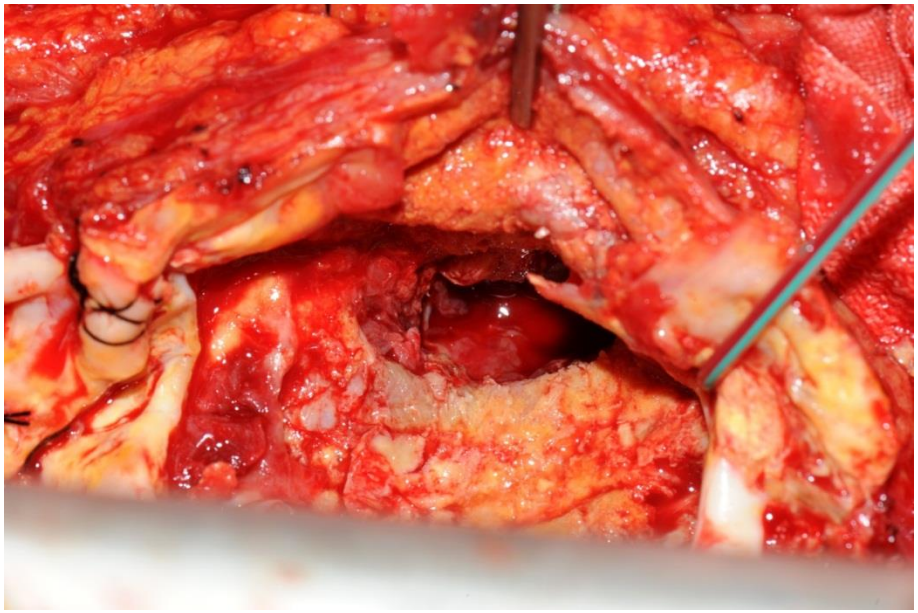
- **Less invasive**
- **Short procedure time**
- **Short ICU & hospital stay**
- **Less blood loss & transfusion**
- **Less GI related complications**

Cons.

- **Require long-term monitoring (contrast, radiation,…)**
- **Higher reintervention rate**
- **Higher rupture rate**
- **Higher cost**


50.74 mm
Symptomatic (ruptured) AAA
166.80 mm
91.46 mm

Open repair for ruptured AAA



- **Perioperative mortality**
  - ✓ **32 -53% in R-AAA repair**
  - ✓ **9.5-26% in S-AAA repair**
  - ✓ **3.5- 5% in E-AAA repair**

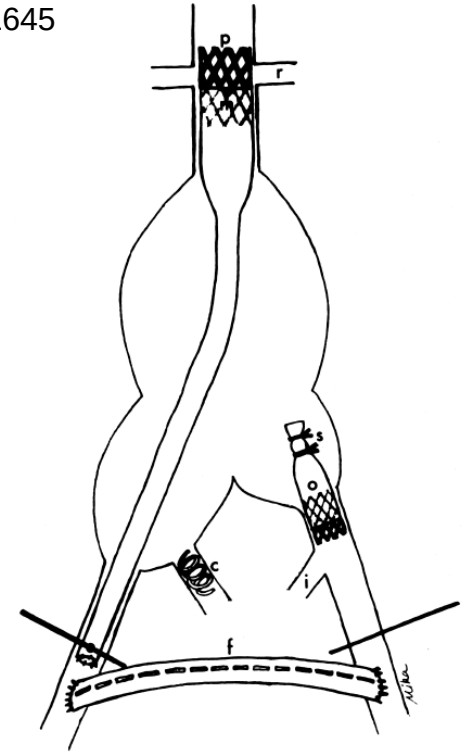
- **Symptomatic AAA without rupture : abdominal / back pain associated with aneurysmal tenderness → impending rupture**

EVAR for ruptured AAA

- **S.W. Yusuf 1994**
  - **First case of successful EVAR of a ruptured AAA**

Lancet 1994;344:1645

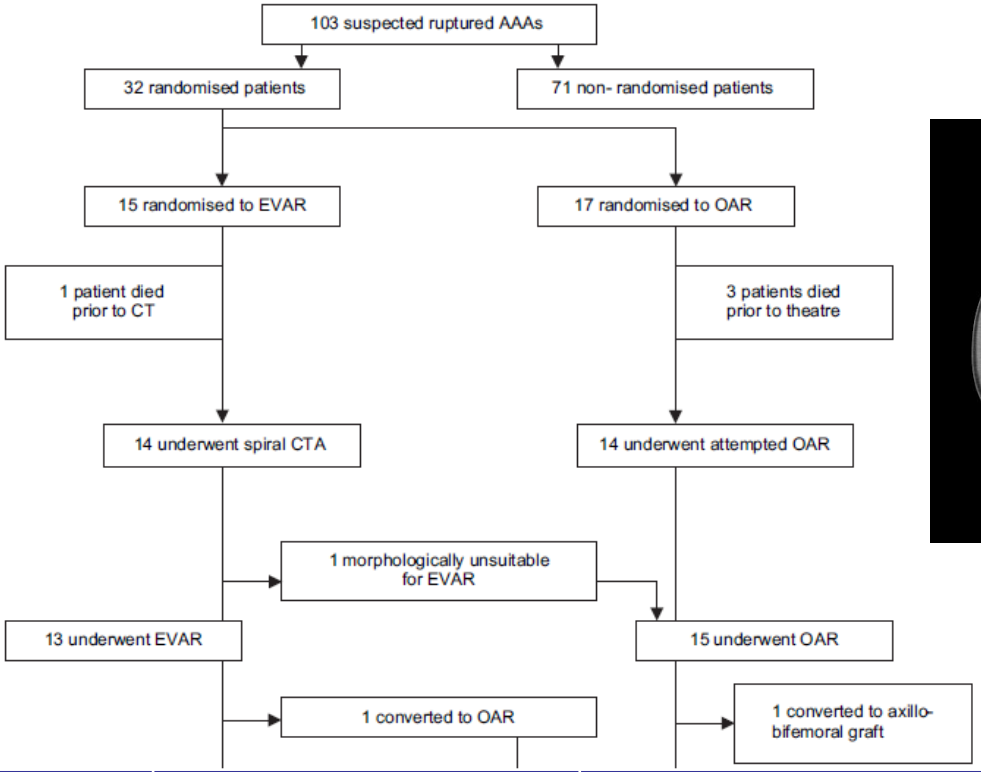
- **T. Ohki, FJ Veith 1999**
  - **12 ruptured AAA**
  - **Aorto-uniiliac (AUI) stent graft**
  - **16% mortality**

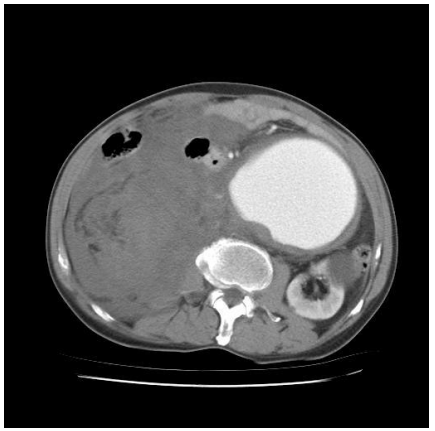


J Am Coll Surg 1999;189:102

EVAR vs. Open repair for r-AAA

Sep 2002-Dec 2004



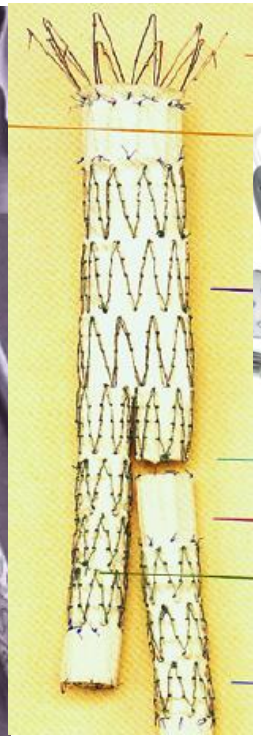


	EVAR(n=11)	OR(n=12)
30day mortality	53%	53%
Complications	77%	80%

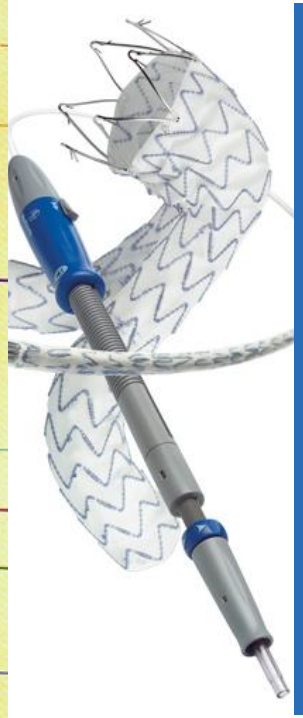
Hinchliffe RJ, Eur J Vasc Endovasc Surg 2006;32:506-13

FDA approved Endovascular Grafts

Excluder
Gore

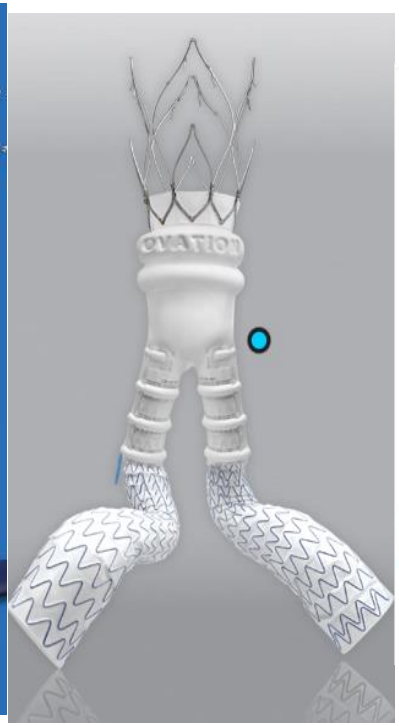


Zenith
Cook



Endurant
Medtronic

PowerLink
Endologix



Ovitation
Trivascular

Aortix
Lombard

EVAR vs. Open repair for r-AAA

Surgeon(s) City	No. RAAAs Treated by EVAR (+No. Not in Table 1)	EVAR Deaths/30-d EVAR Mortality (No./%)	No. RAAAs Treated by OR	OR Deaths/30-d OR Mortality (No./%)
Lachat, Mayer Zurich	111 (+61)	15/13.5	110	36/32.4
Malina, Holst Malmo, Sweden	111 (+56)	34/30.6	102	34/33.3
Mehta, Darling Albany	92 (+65)	16/17.4	84	34/40.5
Larzon Örebro, Sweden	62	8/12.9	52	21/40.4
Coppi, Gennai Modena, Italy*	56	18/32.1	101	44/43.6
Verhoeven Groningen	53 (+22)	9/17.0	135	39/28.9
Veith, Lipsitz, Gargiulo New York	45 (+7)	6/13.3	12	1/8.3
Van der Vliet, Blankensteijn Nijmegen	41 (+26)	7/17.1	59	31/52.5
Buth Eindhoven†	41 (+17)	12/29.3	27	12/44.4
Lee Gainesville, US	29 (+29)	3/10.3	43	7/16.3
Biasi, Deleo Milan	21 (+10)	5/23.8	33	16/48.5
Kasirajan Atlanta	11 (+11)	1/9.1	—	—
Cayne New York	7 (+7)	0/0	5	2/40
Total	680 (+311)	134/19.7%	763	277/36.3%

EVAR mean mortality = 17.4% ± 8.9%**	**Vs.**	OR mean mortality = 35.8% ± 12.4%**

Veith FJ, Ann Surg 2009;250:818-24

Changes in Abdominal Aortic Aneurysm Rupture and Short-Term Mortality, 1995–2008

A Retrospective Observational Study

Marc L. Schermerhorn, MD, Rodney P. Bensley, MD,* Kristina A. Giles, MD,* Rob Hurks, MD,* A. James O'Malley, PhD,† Philip Cotterill, PhD,‡ Elliot Chaikof, MD,* and Bruce E. Landon, MD, MBA†§*

338,278 patients : intact AAA
69,653 patients : ruptured AAA

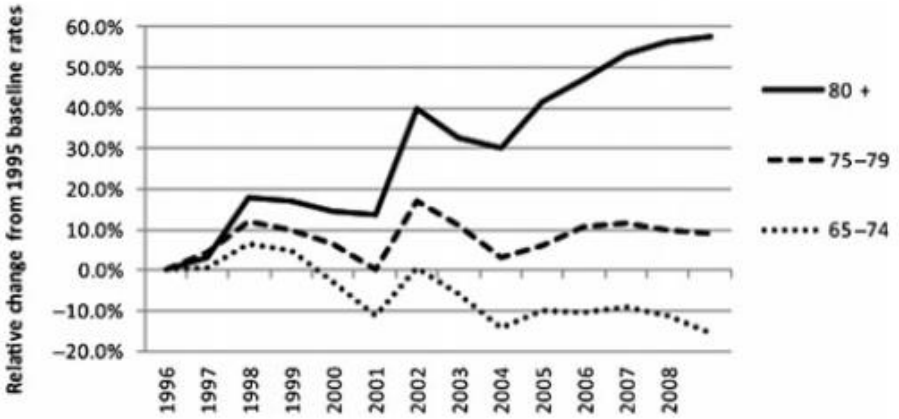


FIGURE 1. Changes in intact AAA repair rates subsequent to 1995 by age and year (sex adjusted).

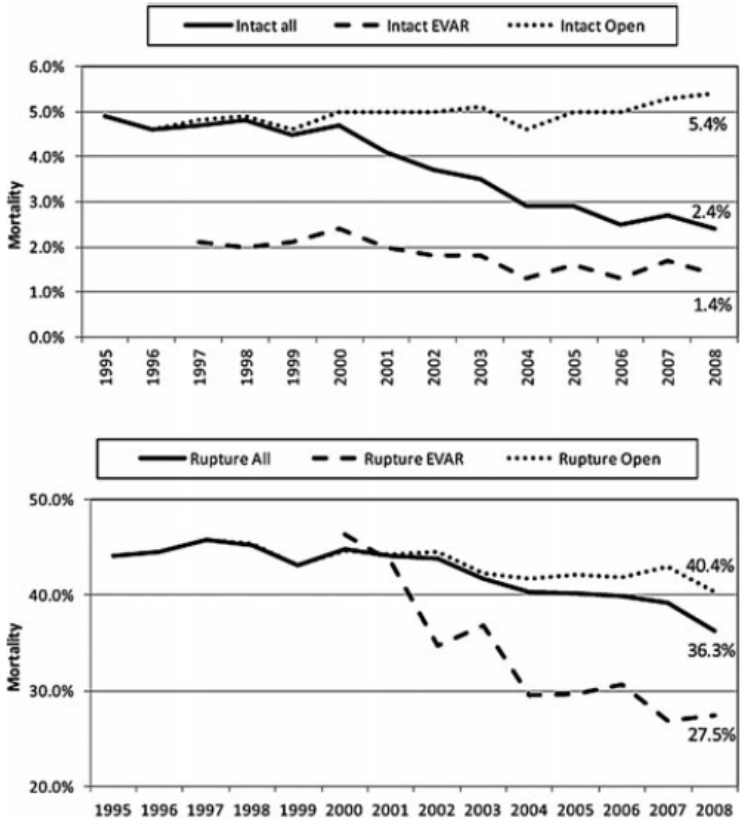
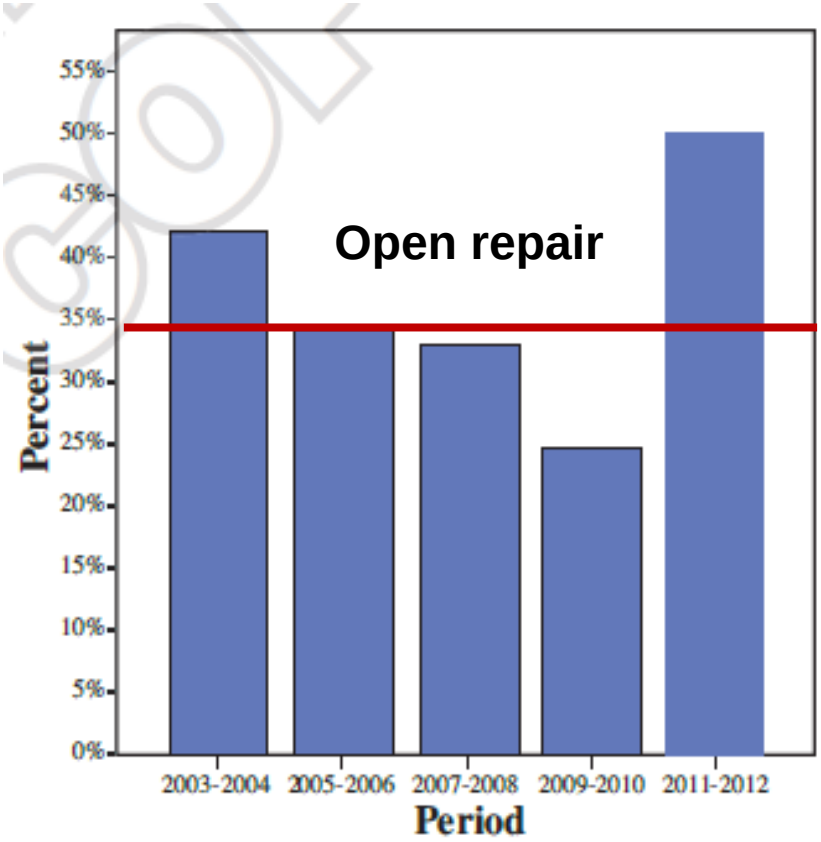
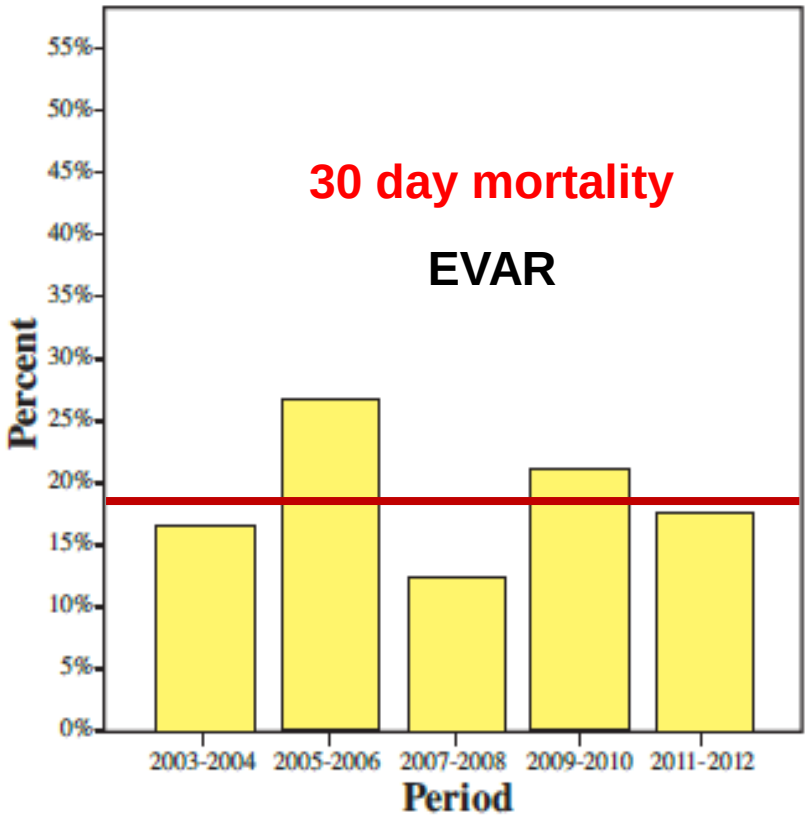


FIGURE 2. Operative mortality for EVAR, open repair, and total AAA repairs for US Medicare beneficiaries, 1995–2008. A, Intact AAA. B, Ruptured AAA.

Ann Surg 2012:256:651-8

Trend of management for r- AAA

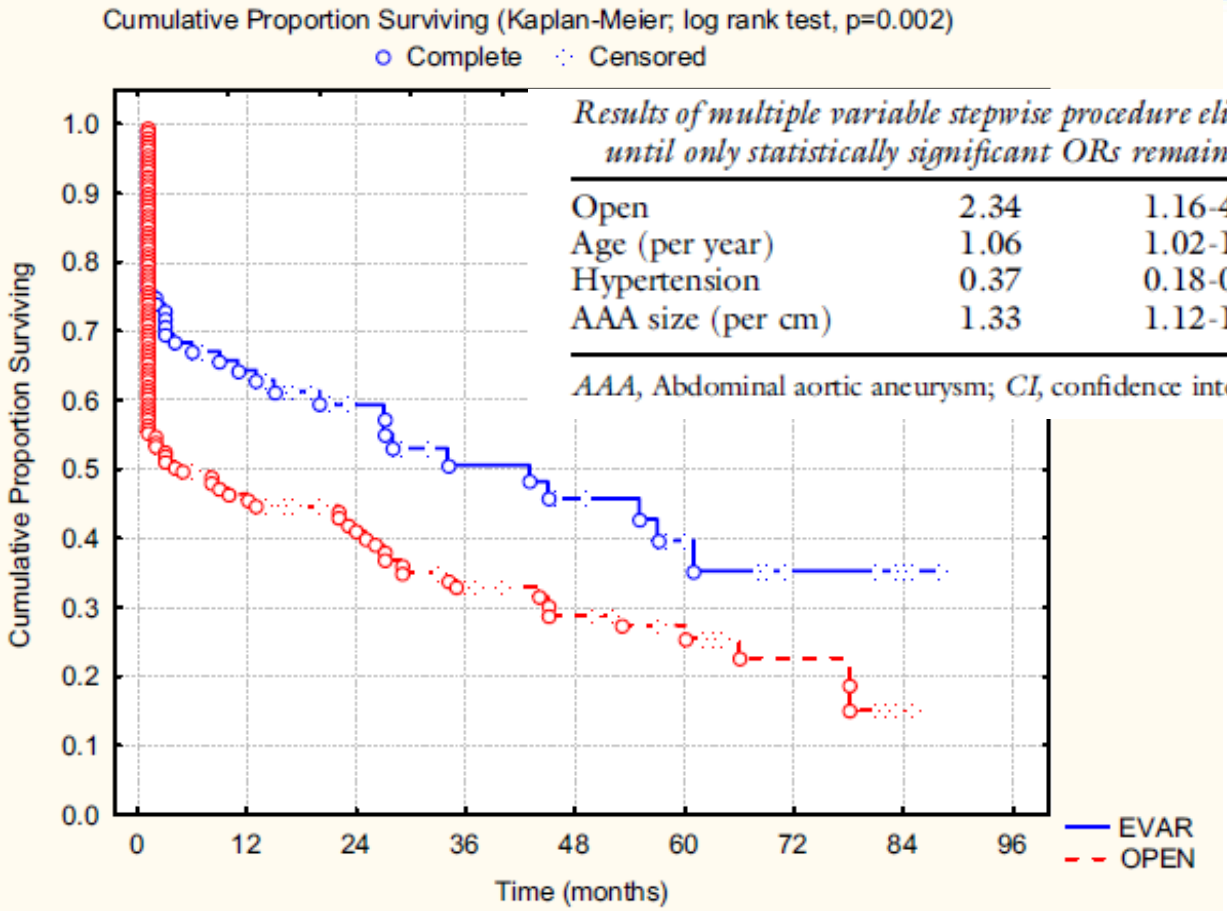




78 EVAR
236 OR
Netherlands

Defting D, J Cardiovasc Surg 2013;54:47-53

Trend of management for r- AAA



Results of multiple variable stepwise procedure eliminating variables until only statistically significant ORs remain

Open	2.34	1.16-4.70	.017
Age (per year)	1.06	1.02-1.10	.002
Hypertension	0.37	0.18-0.76	.01
AAA size (per cm)	1.33	1.12-1.59	.001

AAA, Abdominal aortic aneurysm; *CI*, confidence interval; *OR*, odds ratio.

120 EVAR
167 OR
Albany, NY

Mehta M, J Vasc Surg 2013;57:368-75

Hemodynamic status impacts outcomes of endovascular abdominal aortic aneurysm repair for rupture

Manish Mehta, MD, MPH, Philip S. K. Paty, MD, John Byrne, MCh, FRCSI(Gen), Sean P. Roddy, MD, John B. Taggert, MD, Yaron Sternbach, MD, Kathleen J. Ozsvath, MD, and R. Clement Darling III, MD, *Albany, New York*

Table II. Perioperative variables in hemodynamically (*Hd*) stable vs unstable patients

Variable[a]	*Hd-stable*	*Hd-unstable*	P
Patients	92 (68.0)	44 (32.0)	
Preoperative CT available	92 (100)	29.0 (64.0)	<.05
Aortic occlusion balloon	5.0 (5.0)	18.0 (41.0)	<.05
Blood loss ± SD, mL	363.0 ± 320 (50-2000)	744.0 ± 692 (50-2500)	<.01
ACS	4.0 (4.0)	13.0 (29.0)	<.01
Conversion to surgical repair	3.0 (3.0)	3.0 (7.0)	.21
Nonfatal complications	35.0 (38.0)	19.0 (42.0)	.13
Secondary interventions	23.0 (25.0)	10.0 (22.0)	.16

Table III. Abdominal compartment syndrome (*ACS*) and mortality difference in hemodynamically (*Hd*) stable vs unstable patients

Variable	*Hd-stable, No. (%)*	*Hd-unstable, No. (%)*	P
Patients	91 (67.0)	45 (33.0)	
ACS	4 (4.0)	13 (29.0)	<.01
30-day mortality	17 (18.0)	15 (33.0)	<.05

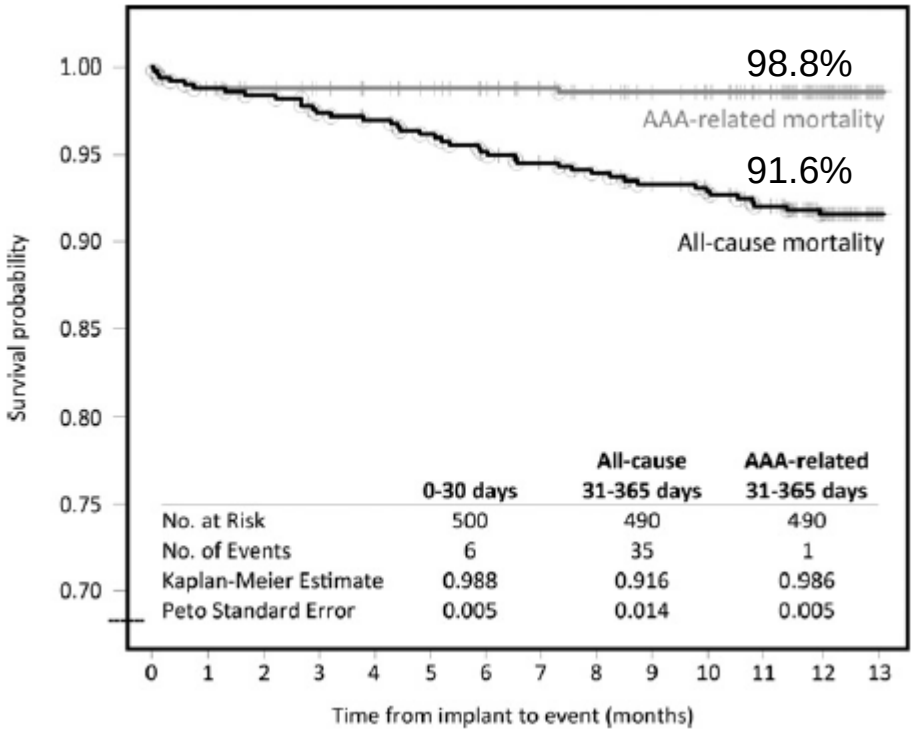
From 2001 to 2011
136 patients with r-AAA underwent EVAR

Mehta M, J Vasc Surg 2013 in press

ENGAGE registry

- 2009-2011
- 79 sites in 30 countries
- 1200 AAA patients
- Endurant
- 17.9% treated outside of IFU
- All patients at 30 day f/u
- 500 patients at 1 year f/u

- 1.4% type 1 Endoleak
- 9.9% type II Endoleak
- 0% Migration
- 0% Rupture
- 0.6% surgical conversion
- 4.9% secondary procedure



Stokmans RA, Eur J Vasc Endovasc Surgery 2012: 1-7

No Differences in Perioperative Outcome between Symptomatic and Asymptomatic AAAs after EVAR: An Analysis from the ENGAGE Registry

R.A. Stokmans [a,b], J.A.W. Teijink [a,b,*], P.W.M. Cuypers [a], V. Riambau [c], M.R.H.M. van Sambeek [a]

[a] Department of Vascular Surgery, Catharina Hospital, Michelangelolaan 2, P.O. Box 1350, 5602 ZA Eindhoven, The Netherlands
[b] Department of Epidemiology, Caphri Research School, Maastricht University, Maastricht, The Netherlands
[c] Division of Vascular Surgery, Thorax Institute, Hospital Clinic, University of Barcelona, Barcelona, Spain

Initial procedural data and evaluation (ITT analysis).

Variable	Asymptomatic AAA[a] $N = 1015$	Symptomatic AAA[a] $N = 185$	*P*-value	Adjusted *P*-value[b]
Duration of implant procedure (mins)	100.9 ± 45.3	95.0 ± 42.5	.097	.323
Type of anaesthesia				
General	64.5% (654/1014)	51.4% (95/185)	.001	.003
Spinal/Epidural	25.7% (261/1014)	34.6% (64/185)		
Local	9.8% (99/1014)	14.1% (26/185)		
Volume of contrast (mL)	130.2 ± 71.0	132.2 ± 66.3	.738	.858
Post-operative stay (days)	4.83 ± 5.29	4.37 ± 3.49	.253	.360
Time in ICU[c] (hours)	10.0 ± 45.9	10.6 ± 27.8	.861	.872
Admission to ICU[c]	33.4% (339/1015)	35.7% (66/185)	.547	.479
Evaluation				
Intra-operative mortality	0.0% (0/1015)	0.0% (0/185)	–	–
Technical success	98.9% (1004/1015)	100.0% (185/185)	.155	.163
Clinical success	97.3% (988/1015)	99.5% (184/185)	.079	.085

Major adverse events within 30 days (ITT analysis).

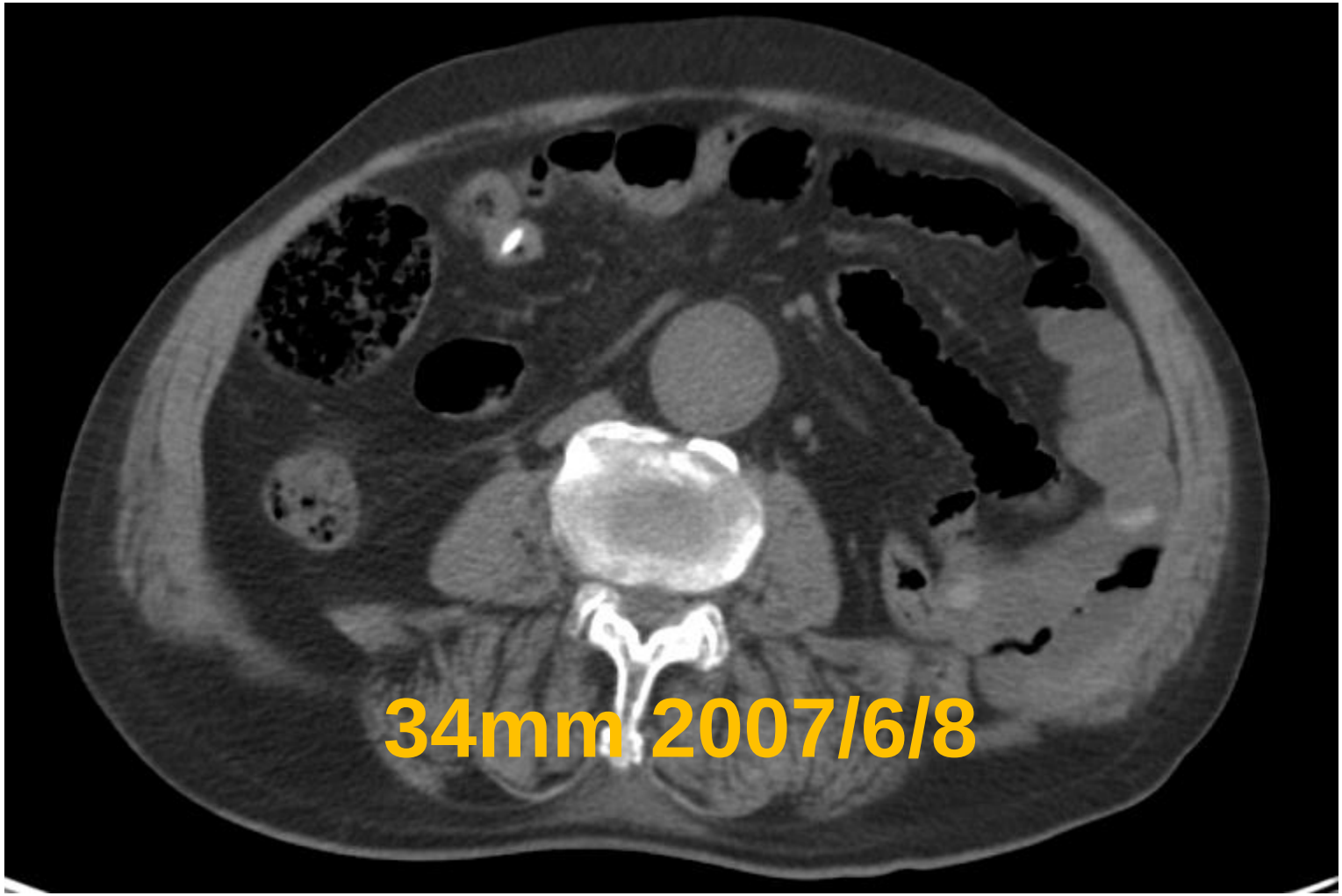
Variable	Asymptomatic AAA[a] $N = 1015$	Symptomatic AAA[a] $N = 185$	*P*-value	Adjusted *P*-value[b]
One or more (MAEs)	4.2% (43/1015)	3.2% (6/185)	.530	.572
All-cause Mortality	1.5% (15/1015)	0.5% (1/185)	.307	.316
Bowel ischemia	0.2% (2/1015)	0.5% (1/185)	.390	.378
Myocardial infarction	1.2% (12/1015)	1.1% (2/185)	.906	.975
Paraplegia	0.0% (0/1015)	0.0% (0/185)	–	–
Renal failure	0.3% (3/1015)	0.5% (1/185)	.068	.066
Respiratory failure	0.0% (0/1015)	0.0% (0/185)	.595	.484
Stroke	0.1% (1/1015)	0.5% (1/185)	–	–
Procedural blood loss ≥1000 mL	1.8% (18/1015)	0.0% (0/185)	.175	.191

Stokmans RA, Eur J Vasc Endovasc Surgery 2012: 667-3

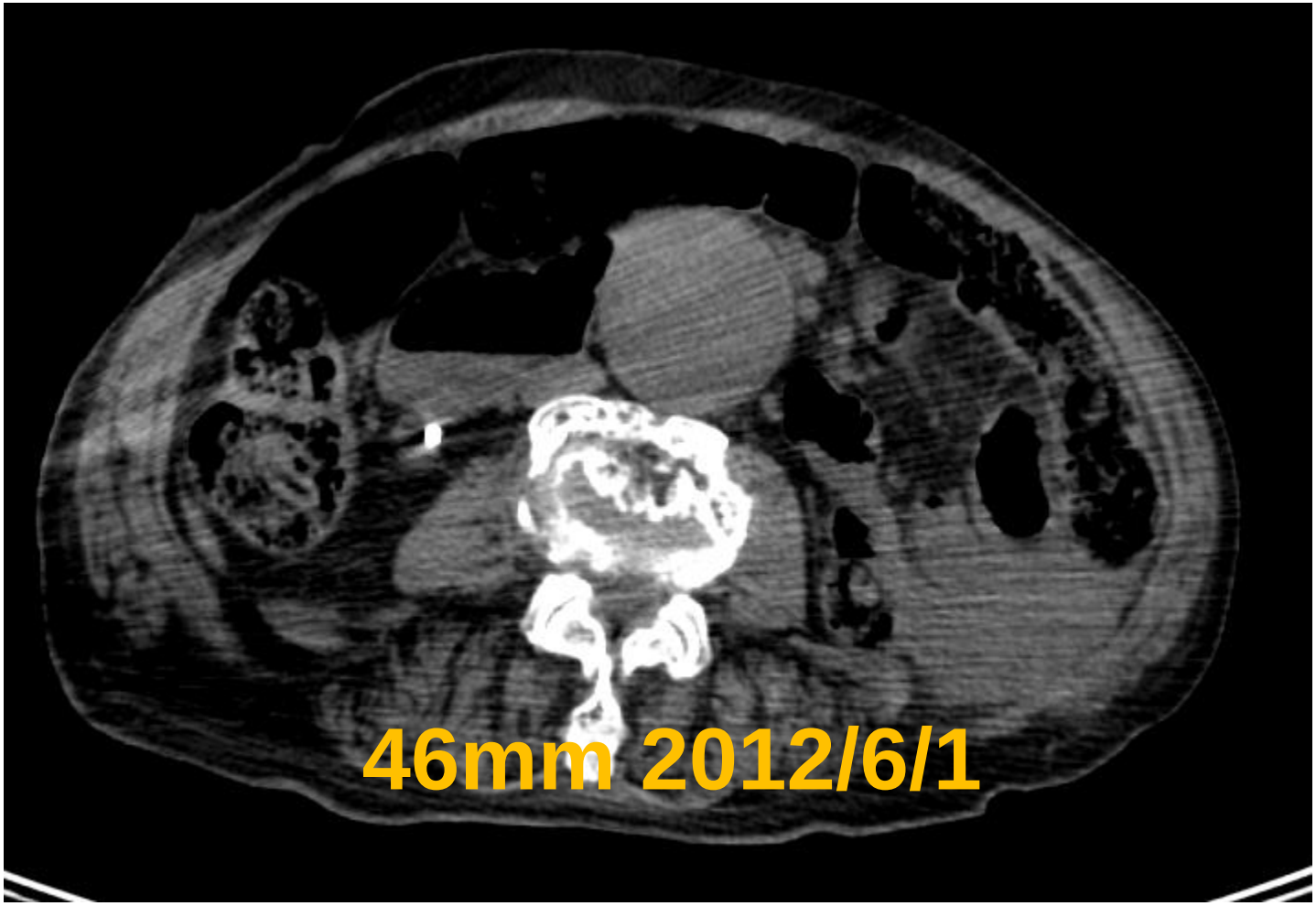
Case

- **M/82**
- **C.C : Abdominal pain, nausea, vomiting for 8 hours**
- **PHx.**
  - **Hypertension for 20 years**
  - **nephrectomy d/t malignacy of renal pelvis, Lt in April 2006**
  - **Hemodialysis since 2011.2**
  - **NSTEMI, stenting at m-RCA in July 2012**
- **BP : 120/77mmHg, HR 76min/min**

Previous CT



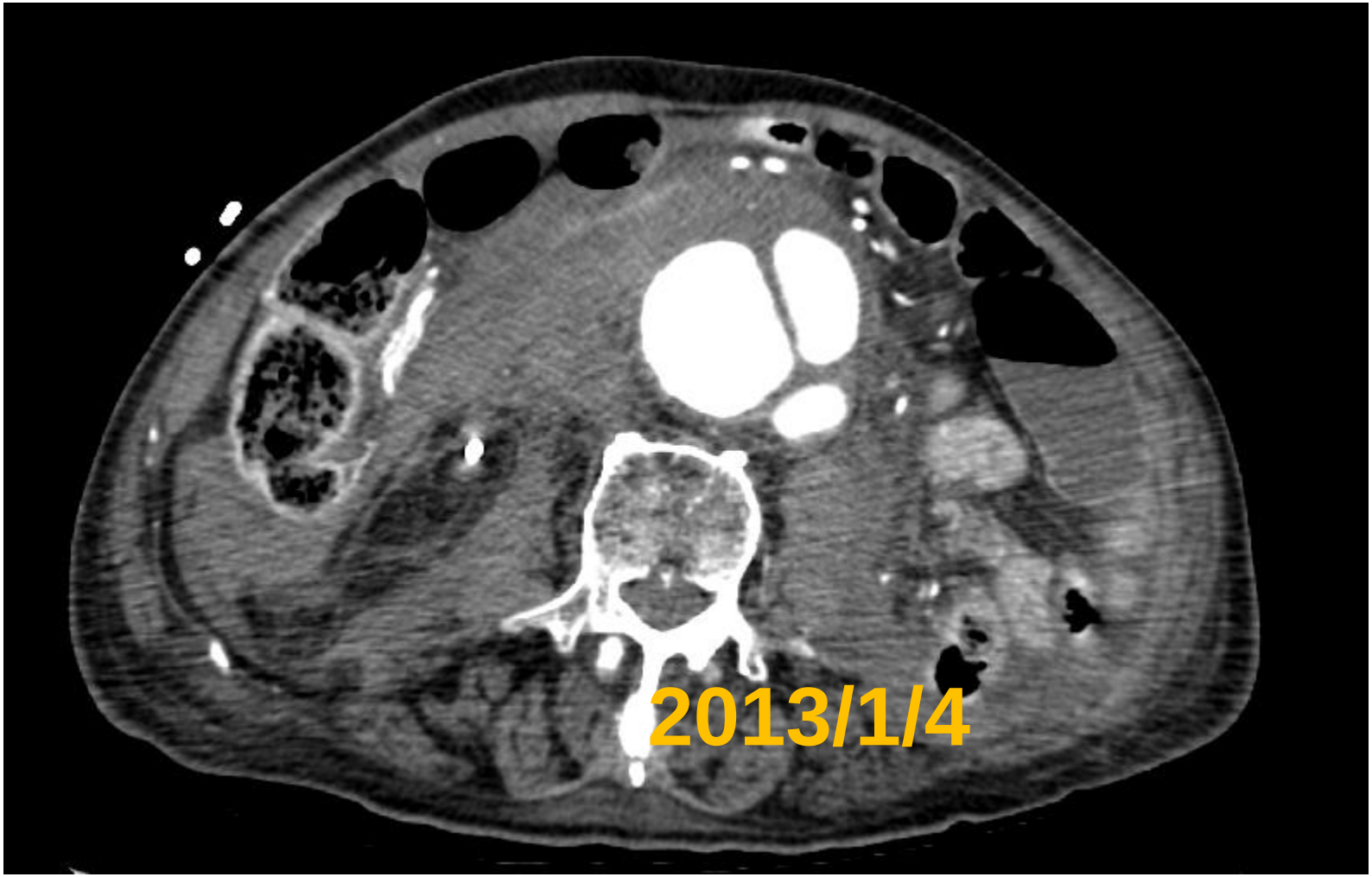
Previous CT



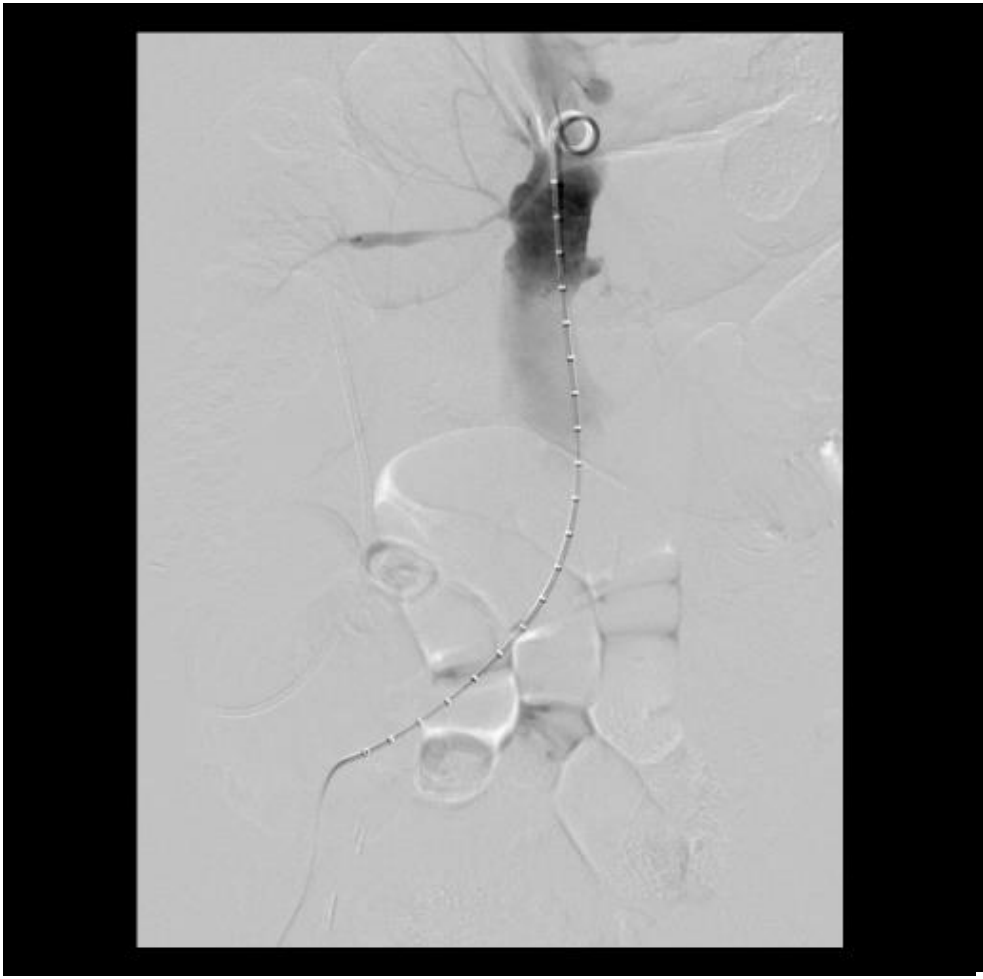
Previous CT

Ruptured AAA

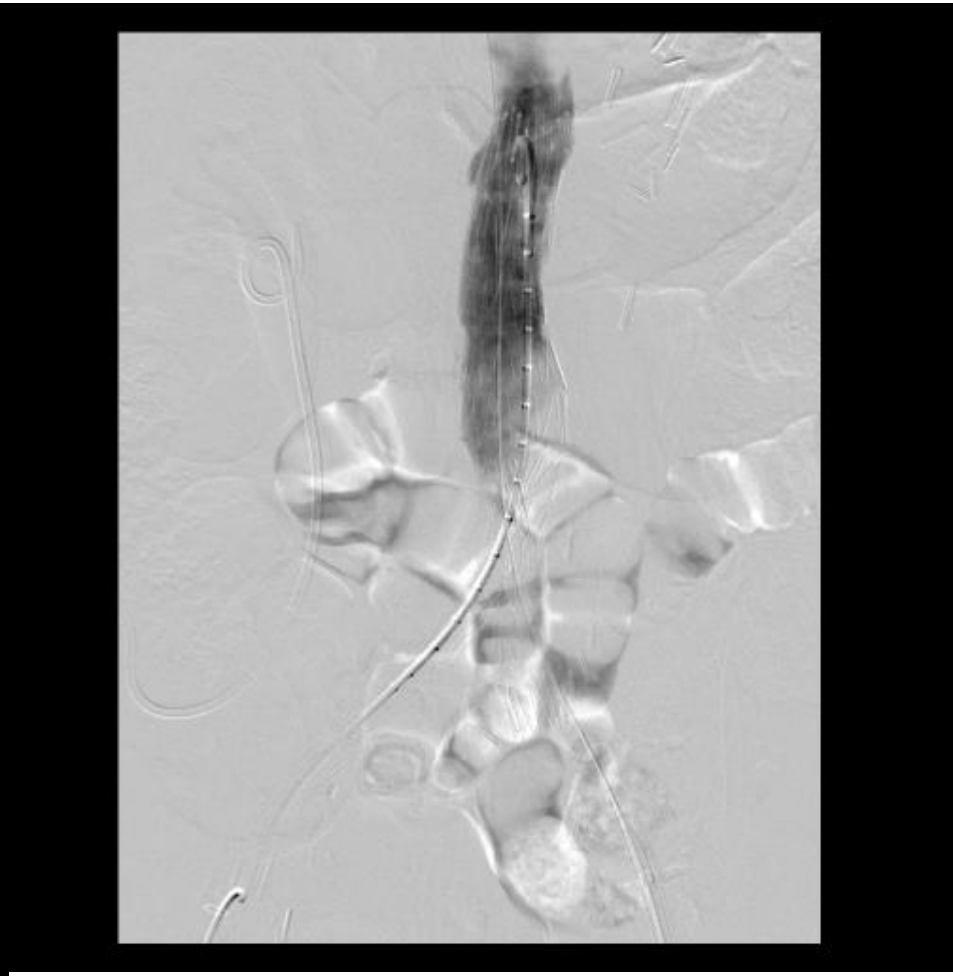
Ruptured AAA



Emergency EVAR

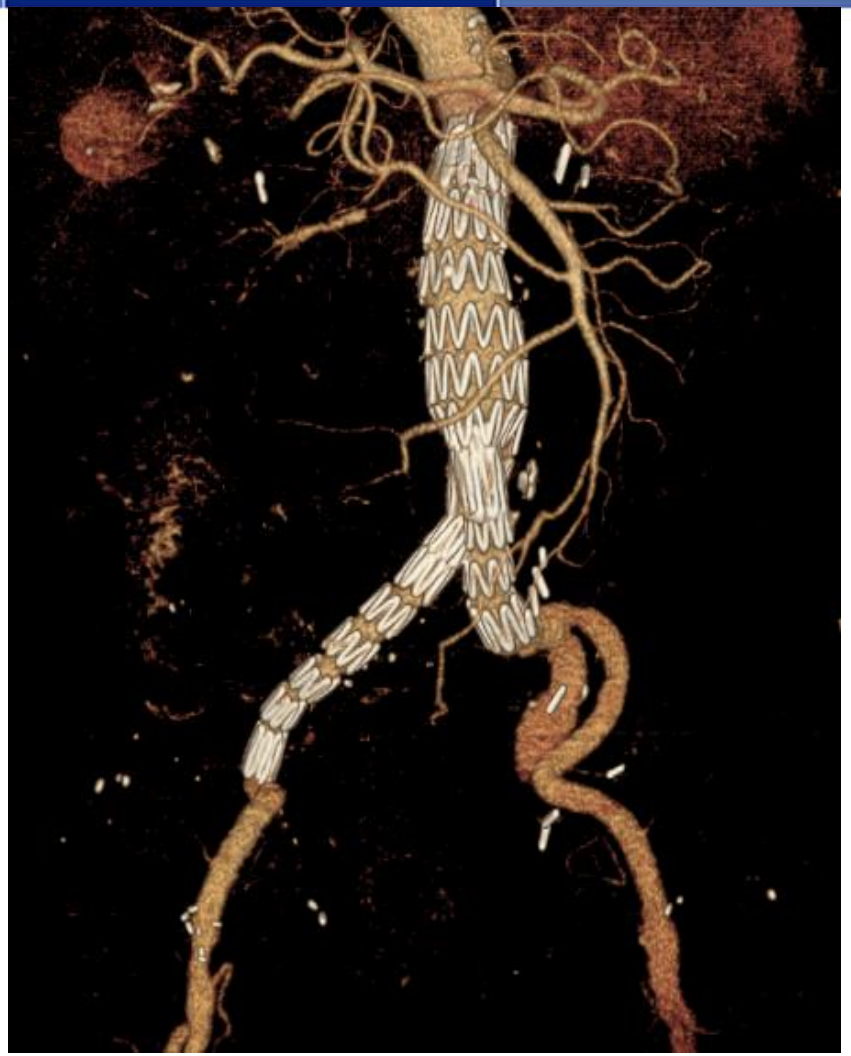


Baseline Angiogram



Post-EVAR

1 week F/U CTA



No endoleak

AJAX trial (preliminary data)

- **April 2004 –Feb 2011**
- **520 ruptured AAA**

  ➔395 evaluated with CT

  ➔155 suitable anatomy for EVAR

  (AUI with fem fem bypass)

  ➔116 randomized

  : 57 EVAR vs. 59 OR

  ➔ 30 day mortality

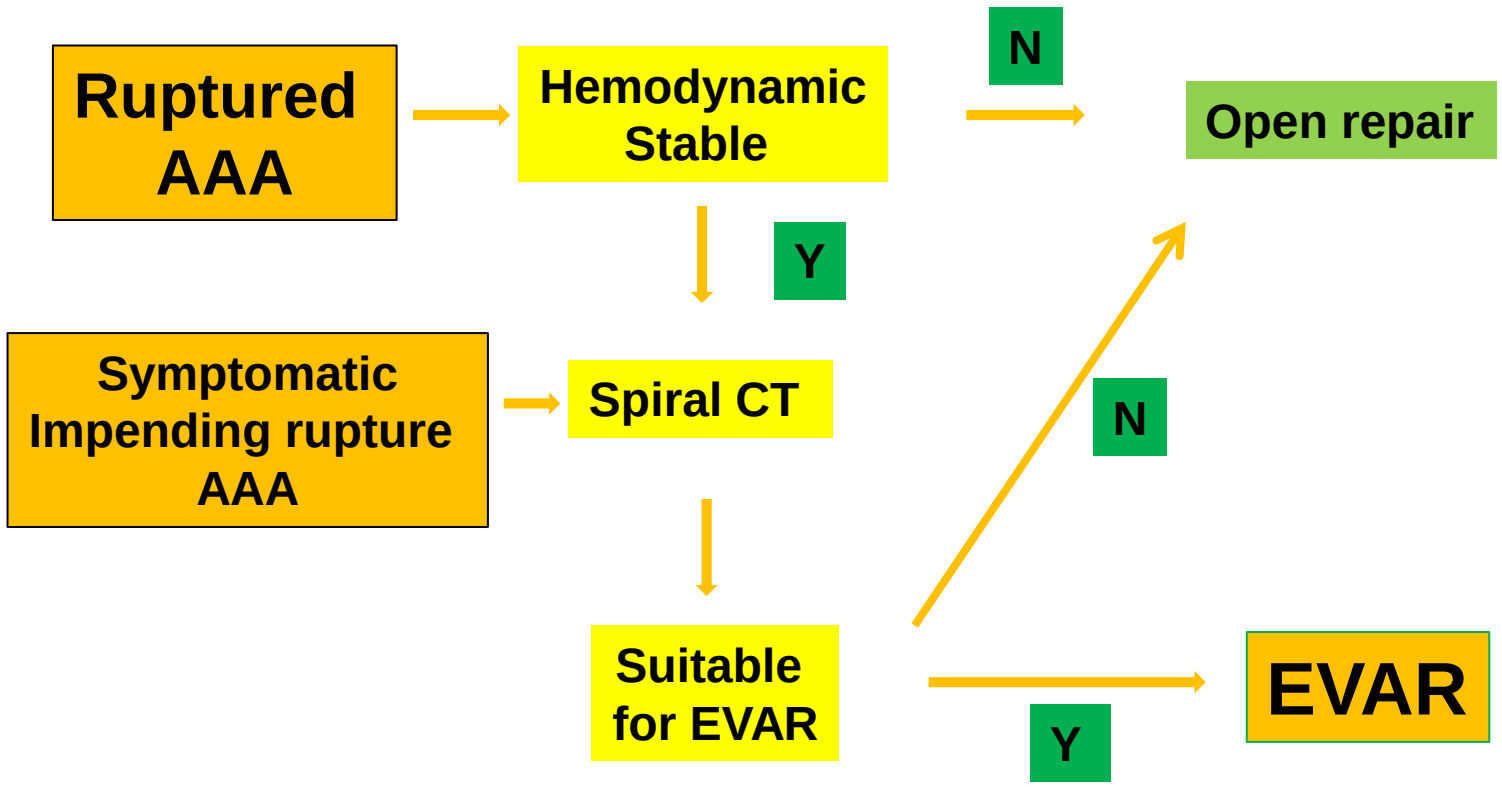
  : 21% EVAR vs. 25% OR

Ongoing RCT's for r-AAA

EVAR vs. open repair

- **ESCAR trial :**
  - **started at Jan 2008**
  - **total 160 patients**
- **IMPROVE trial :**
  - **start at Oct 2009**
  - **total 600 patients**

Management Algorithm for Rupture AAA



경청해주셔서 감사합니다