

2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018



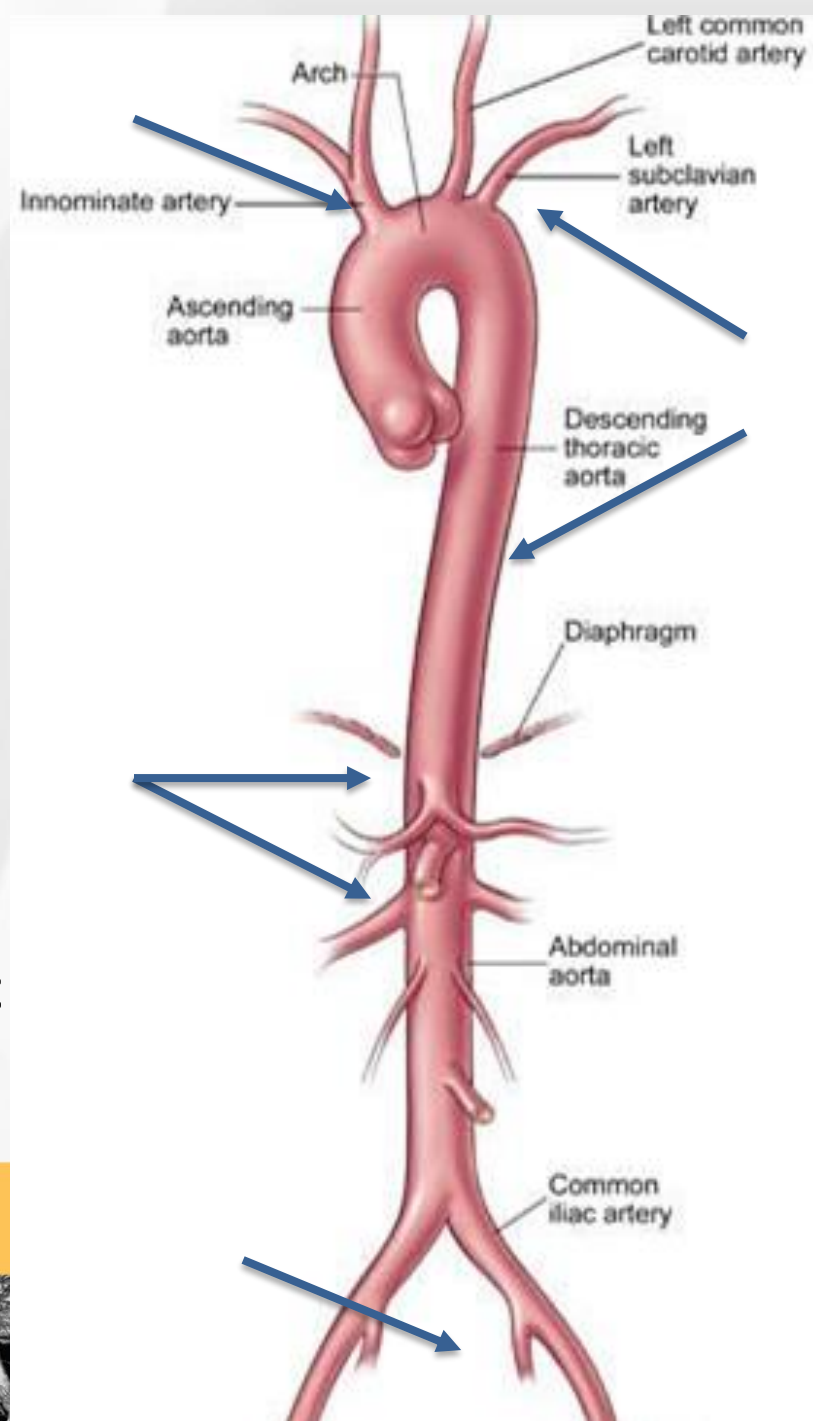
Animesh Rathore,
MD, RPVI
Sentara Vascular
Specialists

Debate 4:

**Complex endovascular aortic repair
will make open surgery obsolete**

Definition

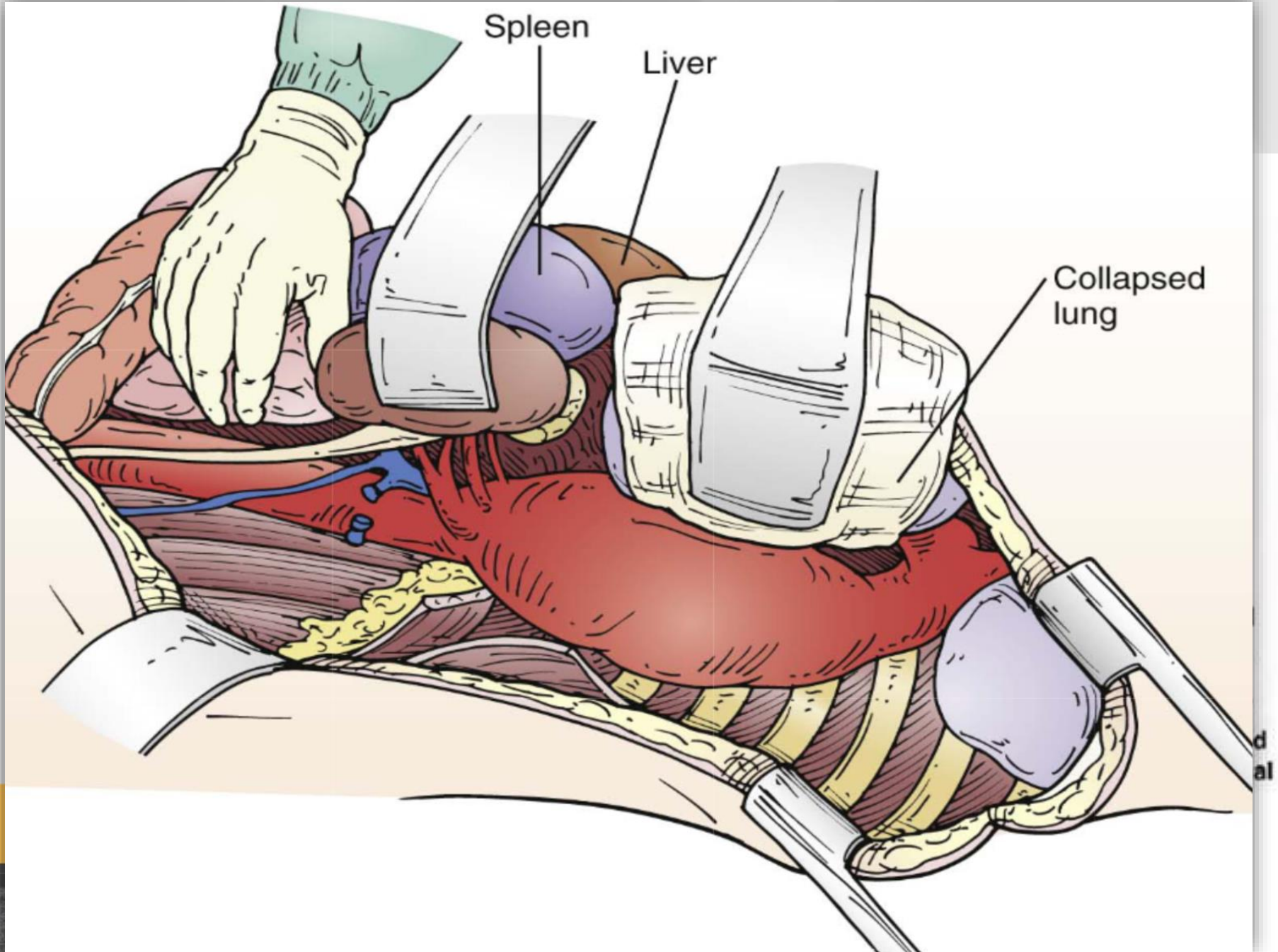
- Complex aortic pathology (aneurysms/dissection)
 - Involvement of thoracic and/or abdominal aorta involving visceral branches (celiac, SMA, renals)
 - Involvement of hypogastric arteries



Repair options

- Open repair
- Endovascular repair





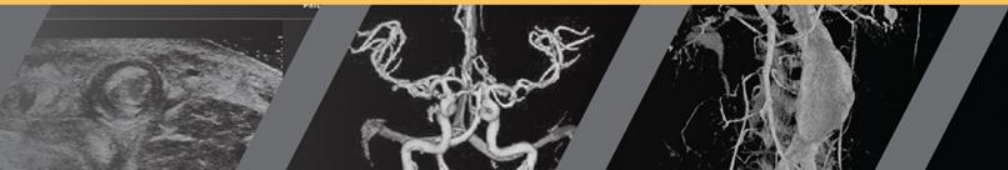
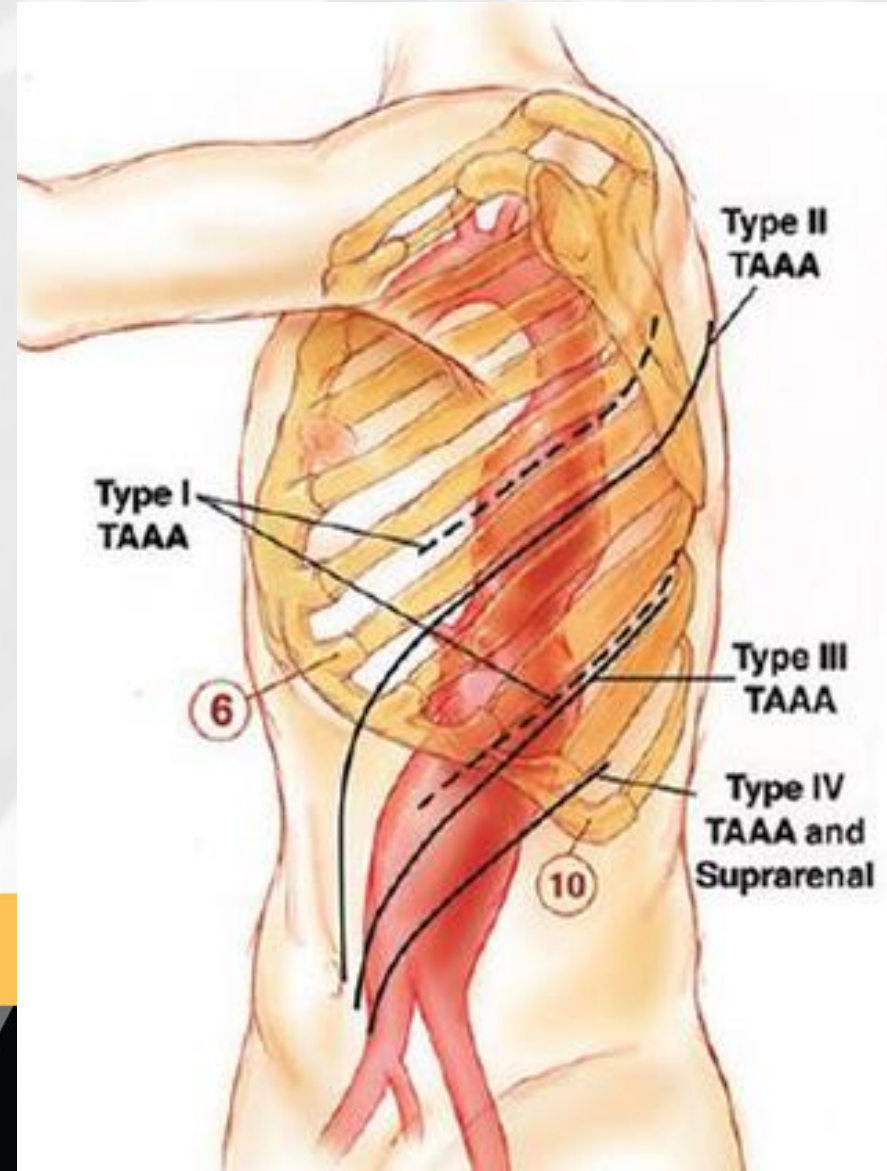


Thoraco-abdominal incision



Repair options : Open

- Higher risk, long duration, slow recovery
- “more fun” for the surgeon
- **Not so much for the patient!!**

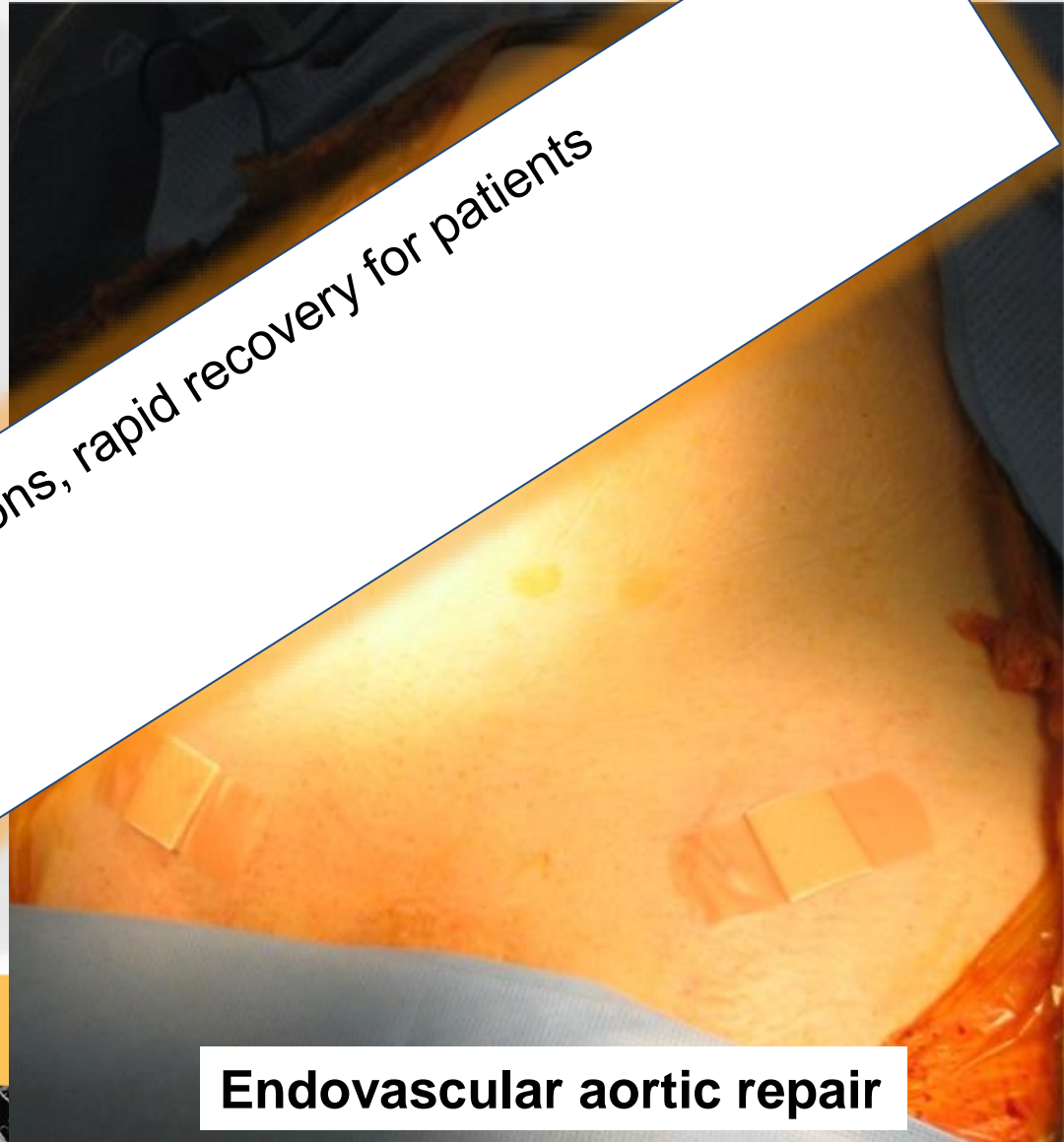


Repair options: Endovascular

- General or local anesthesia
- Percutaneous or limited groin incision (+/- brachial puncture)
- Spinal drainage
- Operative times 4 hours
- Hospital

- Lower operative risk, shorter operations, rapid recovery for patients
- "more fun" for the right surgeon
- **Patients love it!!!**

Endovascular aortic repair





I rest my case here...



Since this is a debate...

Lets talk evidence





EXCUSES



Myth #1

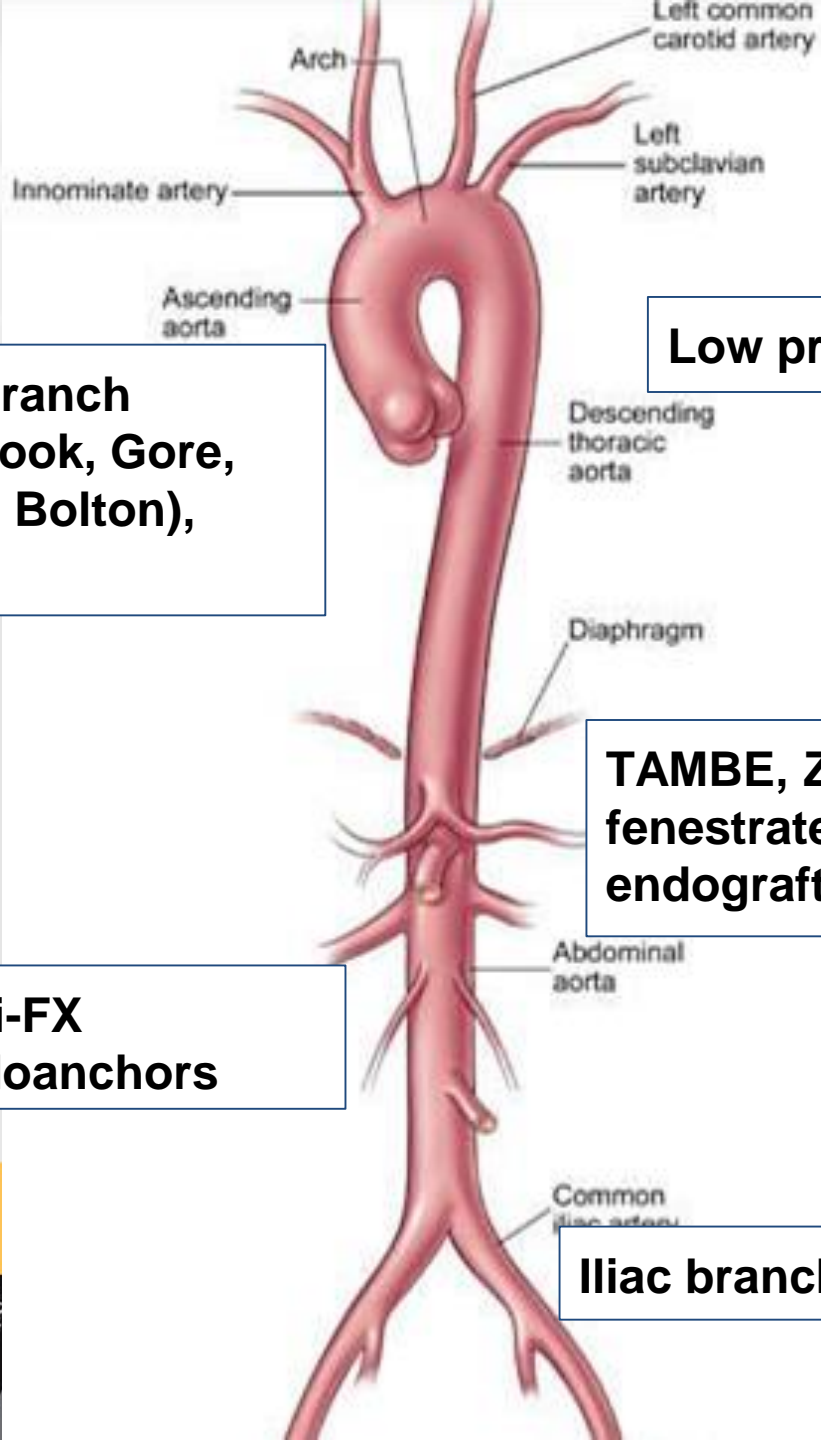
- Technology is not available
- Endovascular technology is available for only specific anatomy



Technology is available here!

	Patient specific design	Off the shelf
Currently approved	Zenith Fenestrated	Heli-FX Endoanchors Gore Iliac branch device
Under trial	Cook Fenestrated/Branched Endografts	TAMBE (Gore) Cook P branch Cook T branch Thoracic Branch Devices (Cook, Gore, Bolton, Medtronic)
Physician modified	In situ fenestration Back-table modification	Parallel branch endografts (Chimney, Snorkel, Periscopes)





Thoracic branch devices (Cook, Gore, Medtronic, Bolton), PMEGs

Low profile TEVAR

TAMBE, Z fen, Patient specific fenestrated/branched endografts, CHIMPS, PMEGs

Heli-FX endoanchors

Iliac branch endoprosthesis

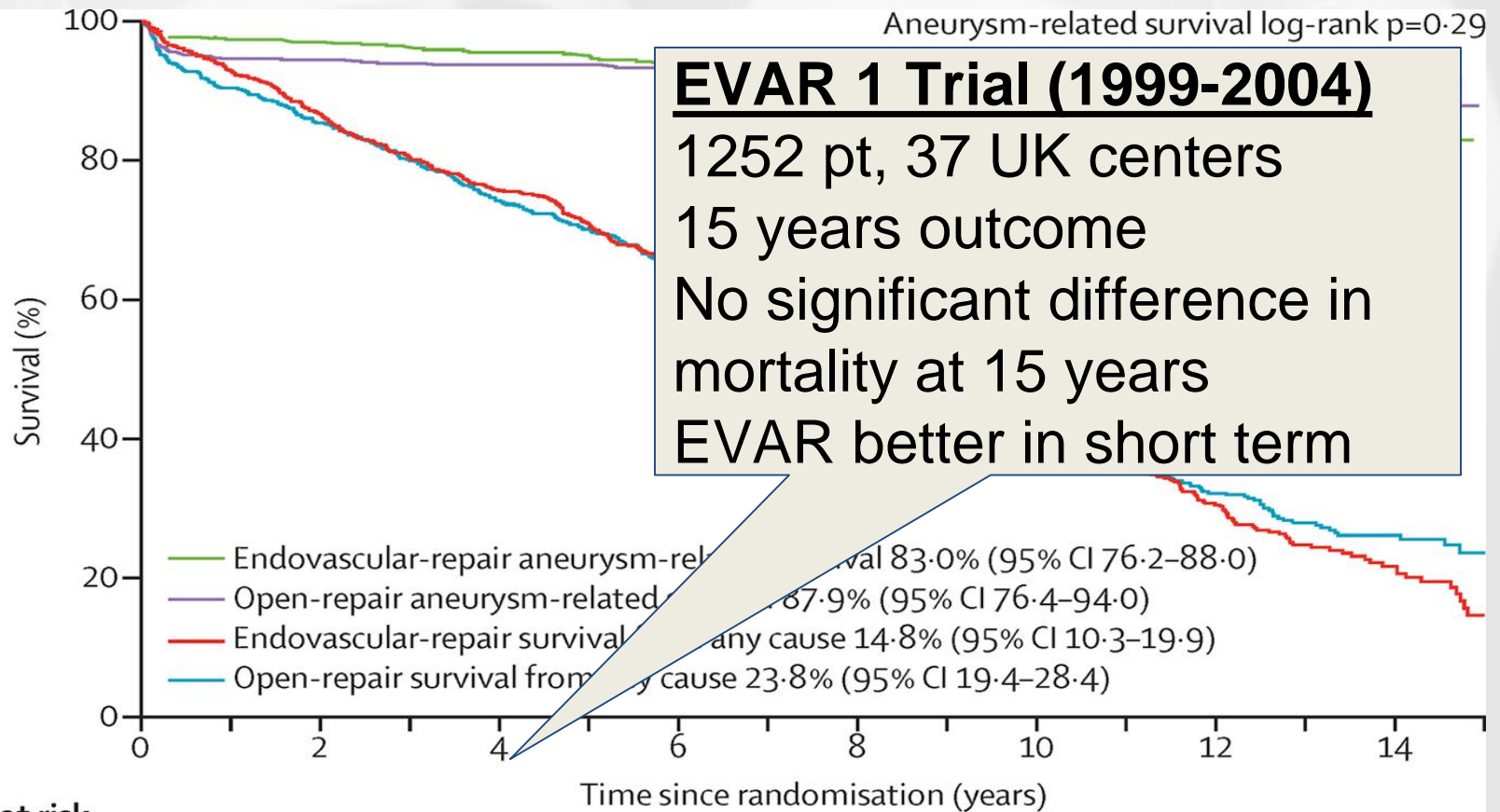


Myth #2

- Long term data favors open surgery



Long term clinical outcomes

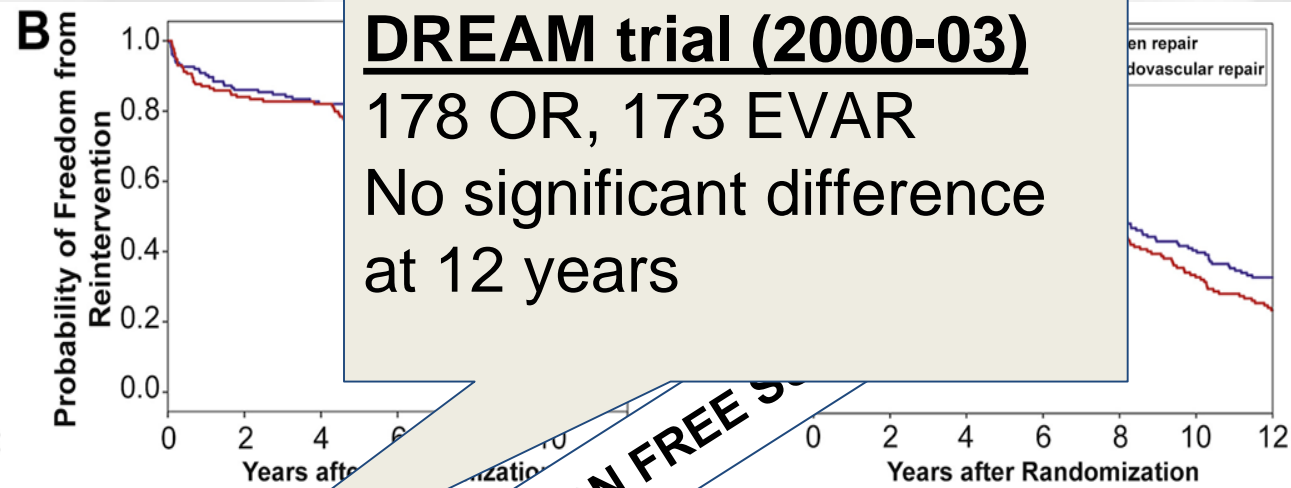
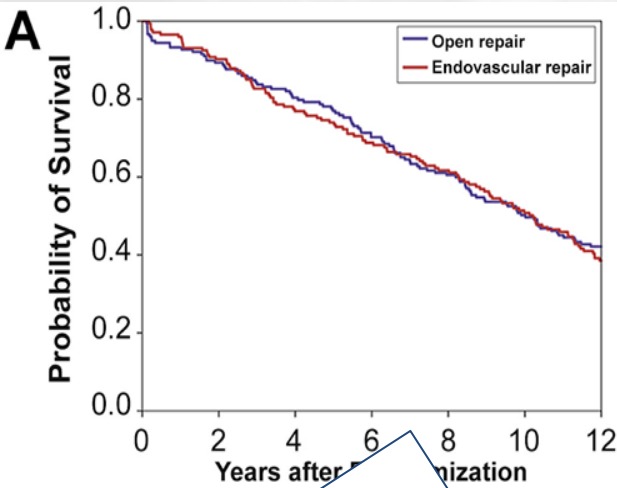


	Number at risk								
	0	2	4	6	8	10	12	14	15
Endovascular repair	626	543	474	409	339	263	135	41	
Open repair	626	534	464	399	333	257	143	50	

Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial Patel, Rajesh et al. The Lancet, Volume 388, Issue 10058, 2366 - 2374



Long term clinical outcomes



DREAM trial (2000-03)
 178 OR, 173 EVAR
 No significant difference
 at 12 years

SURVIVAL

NAR	OSR	178	159	106	88	72
	EVAR	173	156	103	83	63
Events	OSR	0	53	70	88	102
	EVAR	0	54	66	84	104
LFU	OSR	0	0	2	2	3
	EVAR	0	0	1	3	5

REINTERVENTION FREE SURVIVAL

NAR	OSR	178	140	95	42
	EVAR	173	137	88	42
Events	OSR	0	24	30	32
	EVAR	0	26	27	53
LFU	OSR	0	0	2	2
	EVAR	0	1	3	5

NAR	OSR	178	139	118	99	86	73	60
	EVAR	173	134	115	90	80	58	44
Events	OSR	0	39	60	77	90	103	115
	EVAR	0	39	58	83	93	112	126
LFU	OSR	0	0	0	2	2	2	3
	EVAR	0	0	0	1	3	5	5

Long-term survival and secondary procedures after open or endovascular repair of abdominal aortic aneurysms (DREAM TRIAL) *Journal of Vascular Surgery* 2017 66, 1379-1389 DOI: (10.1016/j.jvs.2017.05.122)



Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS(Gen Surg), and Alun H. Davies, DM, FRCS, *London, United Kingdom*

Background: Open repair is the gold standard management for juxtarenal aneurysms. Fenestrated endovascular aneurysm repair (FEVAR) is indicated for high-risk patients. The long-term outcomes of FEVAR are largely unknown, and there is no Level I comparative evidence. This systematic review and meta-analysis of case series compares elective juxtarenal aneurysm surgery by open repair and FEVAR.

Methods: A systematic literature search was conducted for all published studies on elective repair of juxtarenal aneurysms by FEVAR and open repair. The MEDLINE, EMBASE, and Cochrane databases were searched from 1947 to April 2013. The exclusion criteria were case series of <10 patients or ruptured aneurysms. The primary outcomes were perioperative mortality and postoperative renal insufficiency. The secondary outcomes were secondary reinterventions and long-term survival.

Results: We identified 35 case series with data on 2326 patients. Perioperative mortality was 4.1% in open repair and FEVAR case series (odds ratio for open repair with FEVAR, 1.059; 95% confidence interval, 0.642-1.747; $P = .822$). Postoperative renal insufficiency was not significantly different (odds ratio for open repair with FEVAR, 1.136; 95% confidence interval, 0.754-1.713; $P = .542$). FEVAR patients had higher rates of secondary reintervention, renal impairment during follow-up, and a lower long-term survival compared with open repair patients.

Conclusions: FEVAR and open repair have similar short-term outcomes but have diverging long-term outcomes that may be secondary to the selection bias of FEVAR being offered to high-risk patients. FEVAR is a favorable option in high-risk patients, and open repair remains viable as the gold standard. (J Vasc Surg 2015;61:242-55.)

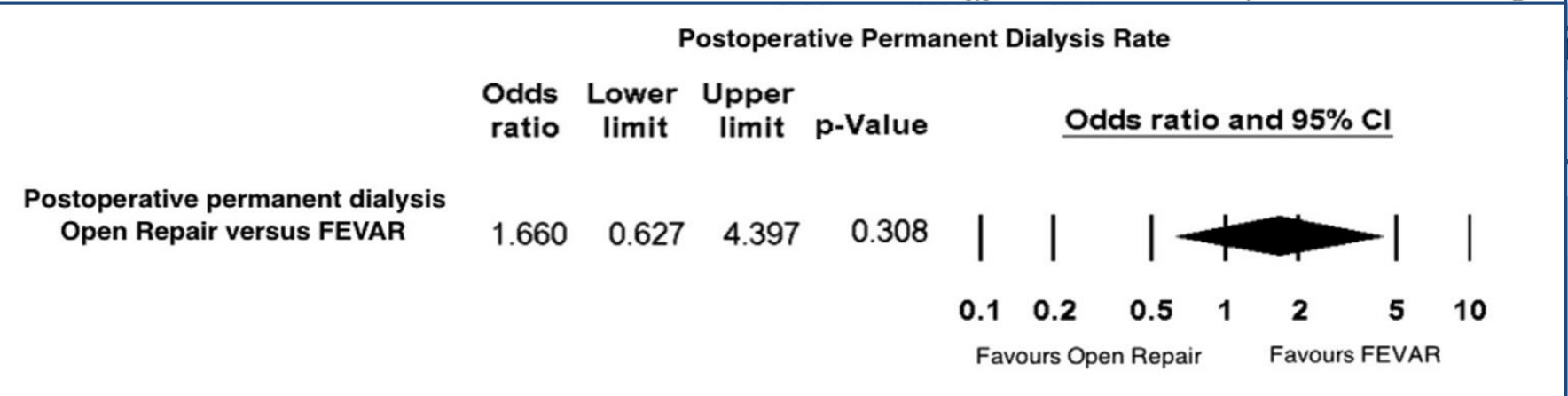
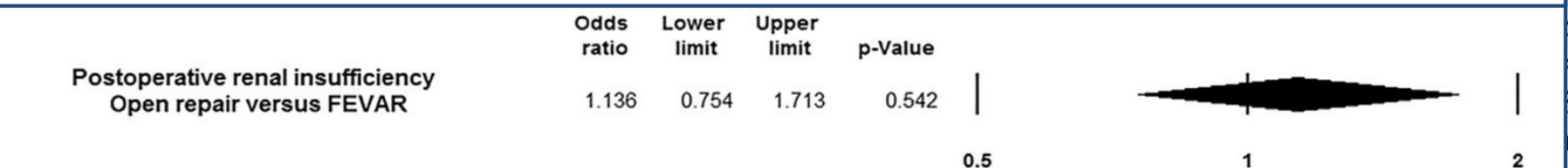
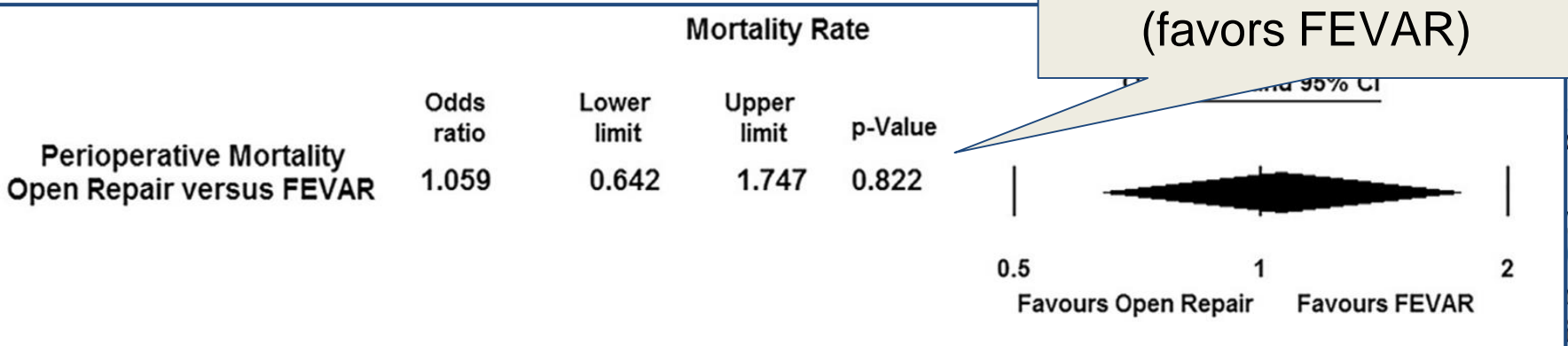


Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS, Alun H. Davies, DM, FRCS, London, United Kingdom

Metanalysis of 35 series comparing FEVAR (750) and Open repair (1575)

- published upto 2013
- similar short term mortality, AKI, dialysis (favours FEVAR)

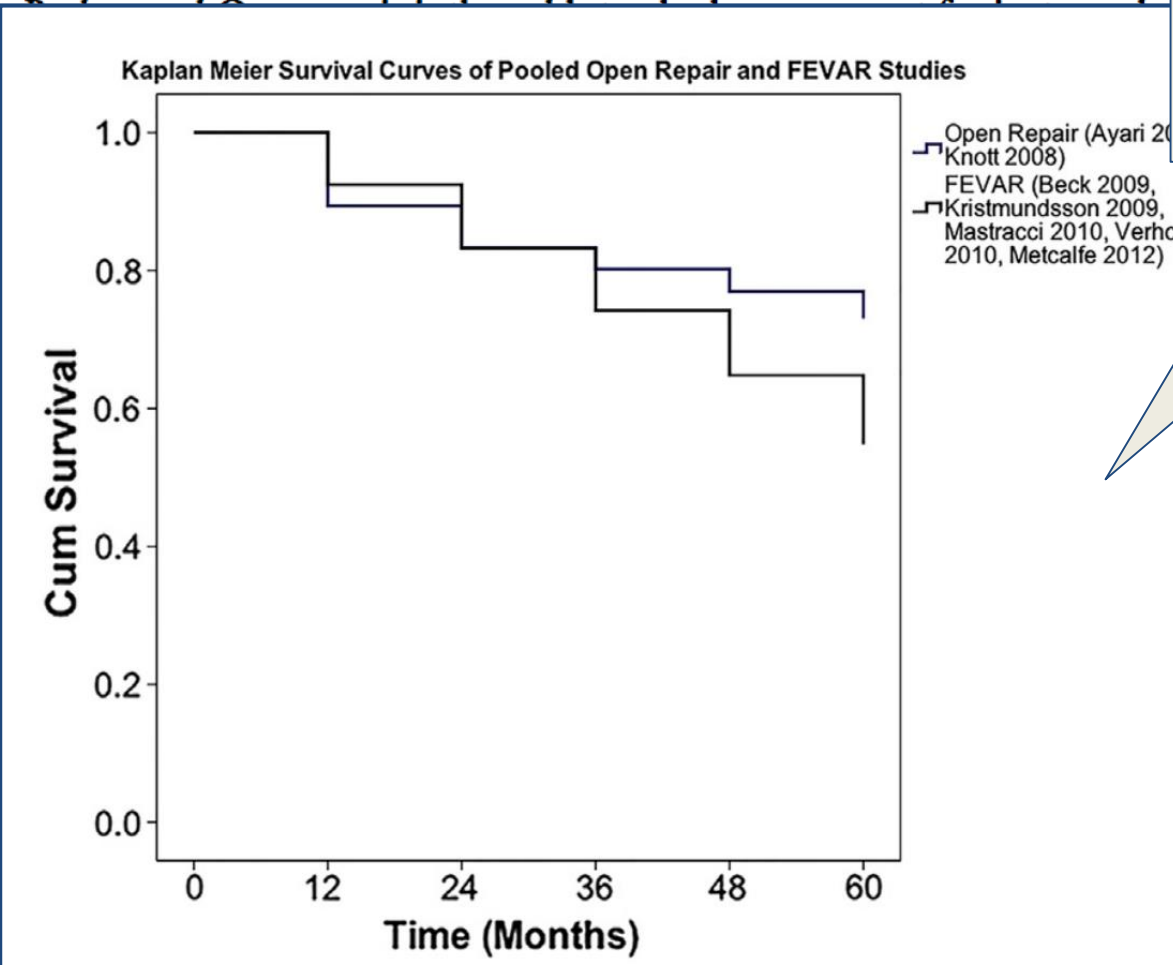


there is juxtarenal aneurysms by 2013. The perioperative mortality is similar. Postoperative renal insufficiency (OR = 1.136; 95% CI 0.754, 1.713), renal insufficiency (OR = 1.136; 95% CI 0.754, 1.713) that may be high-risk

Open repair versus fenestrated endovascular repair of juxtarenal aortic aneurysms

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS, Alun H. Davies, DM, FRCS, London, United Kingdom

- Metanalysis of 35 series comparing FEVAR (750) and Open repair (1575)**
- Similar survival at 5 years
 - Target vessel patency in FEVAR 95-98 % in long term
 - Type I and III endoleak 5.8 % and 3.2 %



... of juxtarenal aneurysms by ... from 1947 to April 2013. The ... outcomes were perioperative mortality ... interventions and long-term survival. ... mortality was 4.1% in open repair and ... ence interval, 0.642-1.747; $P = .822$). ... open repair with FEVAR, 1.136; 95% ... tes of secondary reintervention, renal ... en repair patients.

diverging long-term outcomes that may ... FEVAR is a favorable option in high-risk ... 5;61:242-55.)

Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones

Gustavo S. Oderich, MD,^a Mauricio Ribeiro MD, PhD,^{a,b} Jan Hoopes MD,^a Julia Chini,^a Thanila A. Macedo, MD,^d and Peter Gloviczki, M

ABSTRACT

Purpose: To investigate outcomes of manufactured fenestrated and branched endografts based on supraceliac sealing zones to treat pararenal aortic aneurysms (TAAAs).

Methods: A total of 127 patients (91 male; mean age, 75 ± 10 years) in a single-center study using manufactured F-BEVAR (November 2013–November 2016) with a supraceliac sealing zone in all patients with ≥ four vessels in 111 (89%). Follow-up included duplex ultrasound, and computed tomography imaging at discharge. Complications indicated by independent clinical event committee included mortality, myocardial infarction, stroke, paraplegia, acute kidney injury, respiratory failure, reintervention, and branch-related instability (occlusion, stenosis, dissection). Primary target vessel patency, sac aneurysm enlargement, and aneurysm rupture.

Results: There were 47 pararenal, 42 type IV, and 38 type I-III TAAAs with mean diameter of 59 ± 17 mm. A total of 496 renal-mesenteric arteries were incorporated by 352 fenestrations, 125 directional branches, and 19 celiac scallops, with a mean of 3.9 ± 0.5 vessels per patient. Technical success of target vessel incorporation was 99.6% (n = 493/496). There were no 30-day or in-hospital deaths, dialysis, ruptures or conversions to open surgical repair. Major adverse events occurred in 27 patients (21%). Paraplegia occurred in two patients (one type IV, one type II TAAAs). Follow-up was >30 days in all patients, >6 months in 79, and >12 months in 34. No patients were lost to follow-up. After a mean follow-up of 9.2 ± 7 months, 23 patients (18%) had reinterventions (15 aortic, 8 nonaortic), 4 renal artery stents were occluded, five patients had type Ia or III endoleaks, and none had aneurysm sac enlargement. Primary and secondary target vessel patency was 96% ± 1% and 98% ± 0.7% at 1 year. Freedom from any branch instability and any reintervention was 93% ± 2% and 93% ± 2% at 1 year, respectively. Patient survival was 96% ± 2% at 1 year for the entire cohort.

Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with supraceliac sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2017;65:1249-59.)

Mayo Clinic prospective study

127 patients (47 pararenal, 42 type IV, 38 type I-III) aneurysms repaired with patient specific endografts

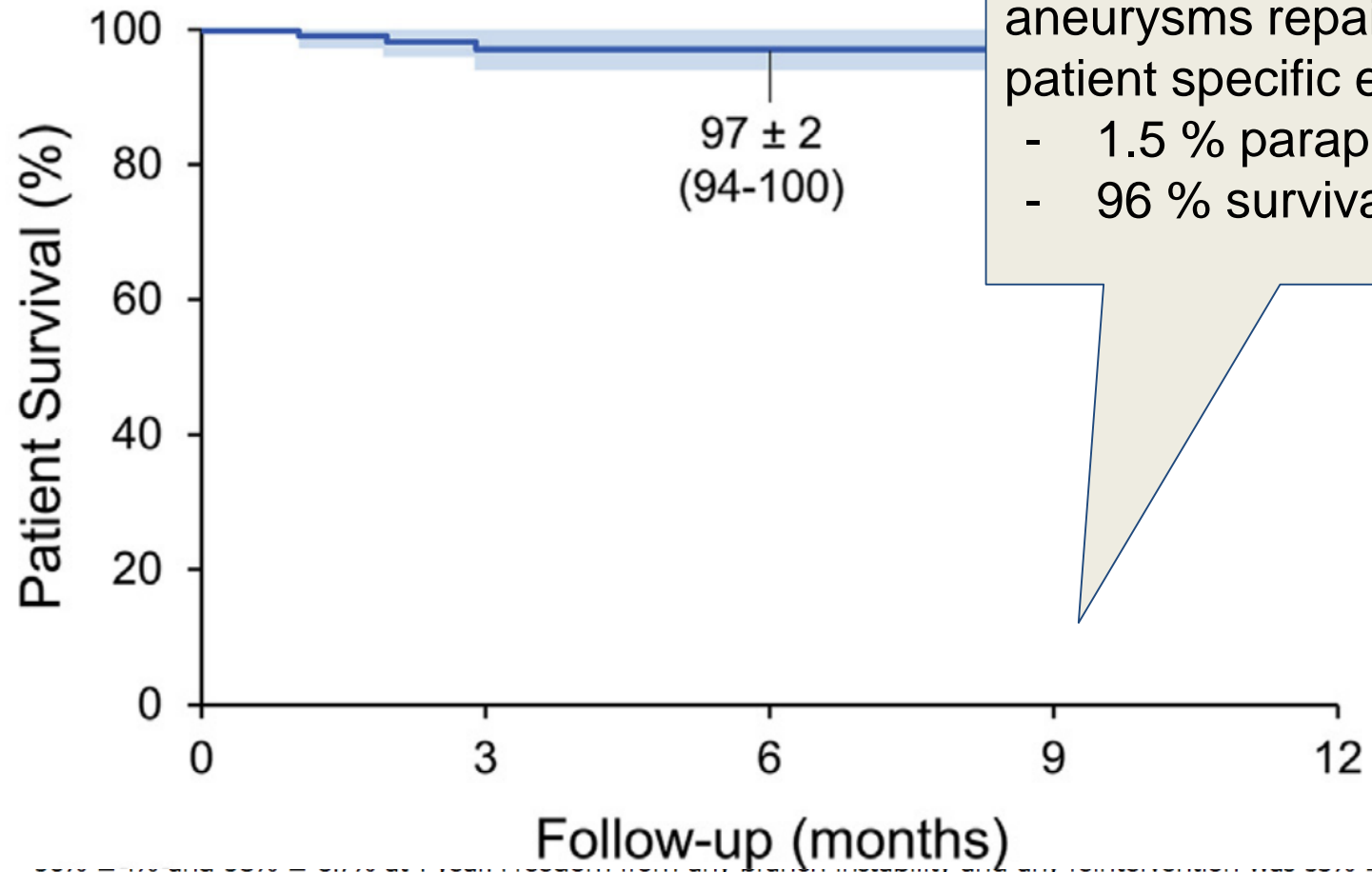
- 1.5 % paraplegia
- 96 % survival at 1 year

Prospective, nonrandomized study to evaluate repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on

Mayo Clinic prospective study

127 patients (47 pararenal, 42 type IV, 38 type I-III) aneurysms repaired with patient specific endografts

- 1.5 % paraplegia
- 96 % survival at 1 year



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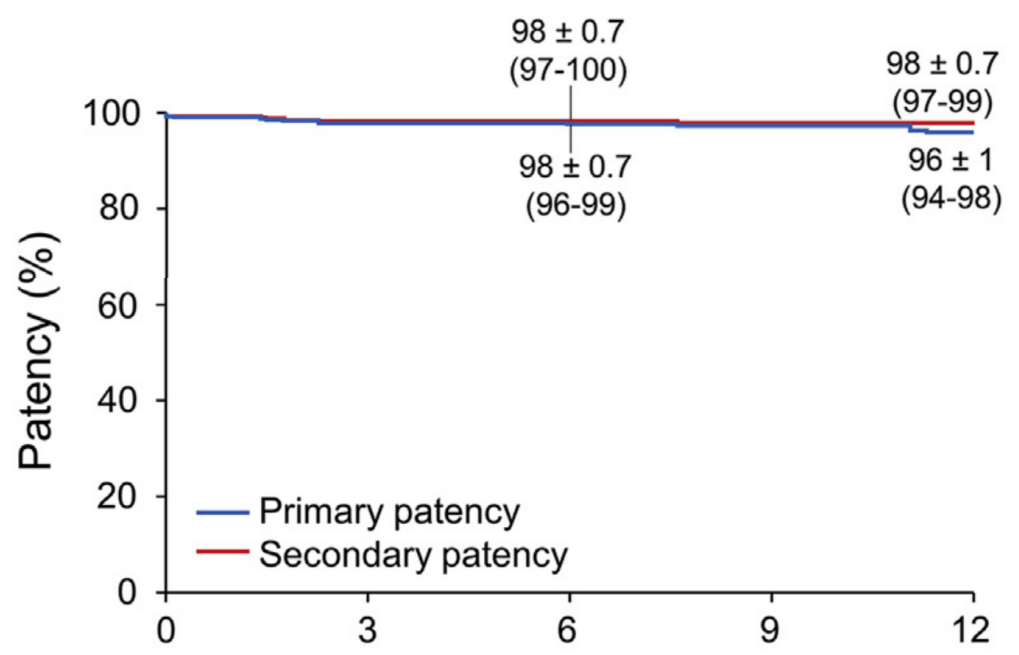
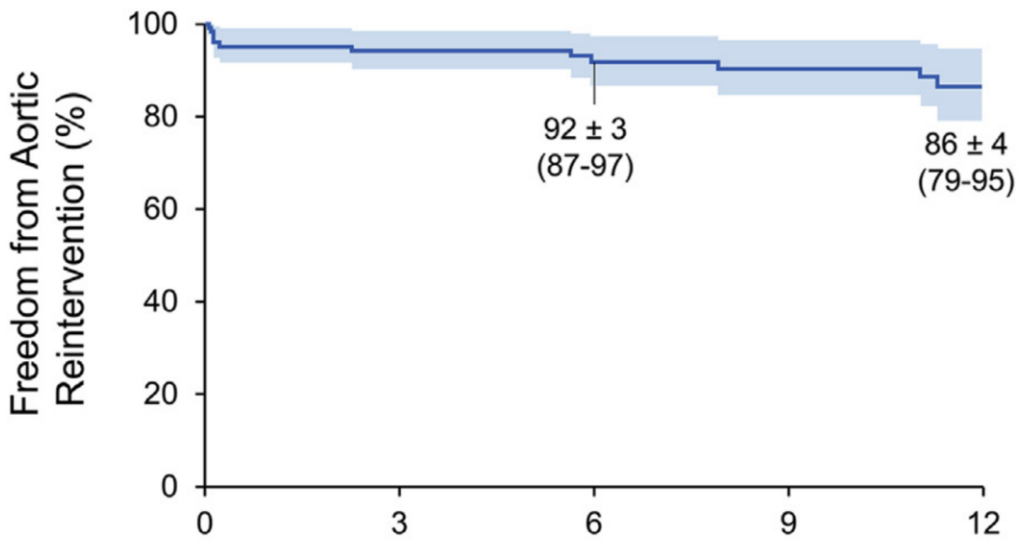
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Mayo Clinic prospective study

- Low reintervention
- Target vessel patency 98%
- 89% without renal dysfunction



d) were enrolled in this prospective, nonrandomized study. The study design was based on supraceliac coverage. The study design was based on supraceliac coverage. The study design was based on supraceliac coverage.

with mean diameter of 59 ± 17 mm. A total of 496 directional branches, and 19 celiac scallops, with a total incorporation was 99.6% ($n = 493/496$). There were no deaths or need for surgical repair. Major adverse events occurred in 10 patients (2.0%), including 1 type II TAAAs. Follow-up was >30 days in all patients. After a mean follow-up of 9.2 ± 3.1 months, 4 renal artery stents were occluded, five patients required reintervention. Primary and secondary target vessel patency was 98% and 96%, respectively, and any reintervention was 93% \pm 2% per year for the entire cohort.

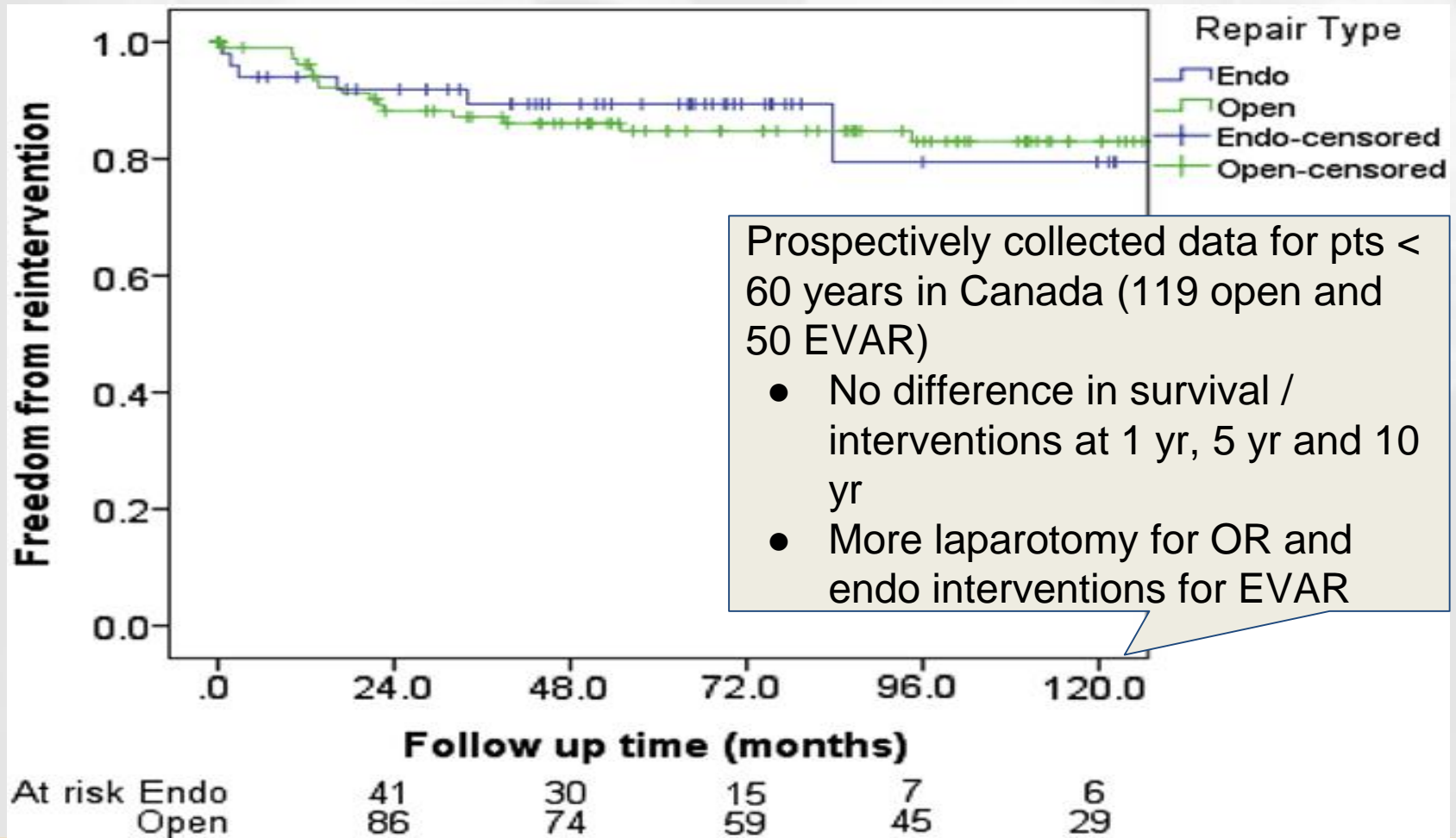
Conclusions: Endovascular repair of pararenal aortic aneurysms and TAAAs, using manufactured F-BEVAR with supraceliac sealing zones, is safe and efficacious. Long-term follow-up is needed to assess the impact of four-vessel designs on device-related complications and progression of aortic disease. (J Vasc Surg 2017;65:1249-59.)

Myth #3

Endovascular surgery only applicable for elderly patients with short term survival



EVAR for younger patients



Durability and survival are similar after elective endovascular and open repair of abdominal aortic aneurysms in younger patients Journal of Vascular Surgery 2015 61, 636-641 DOI: (10.1016/j.jvs.2014.10.012)

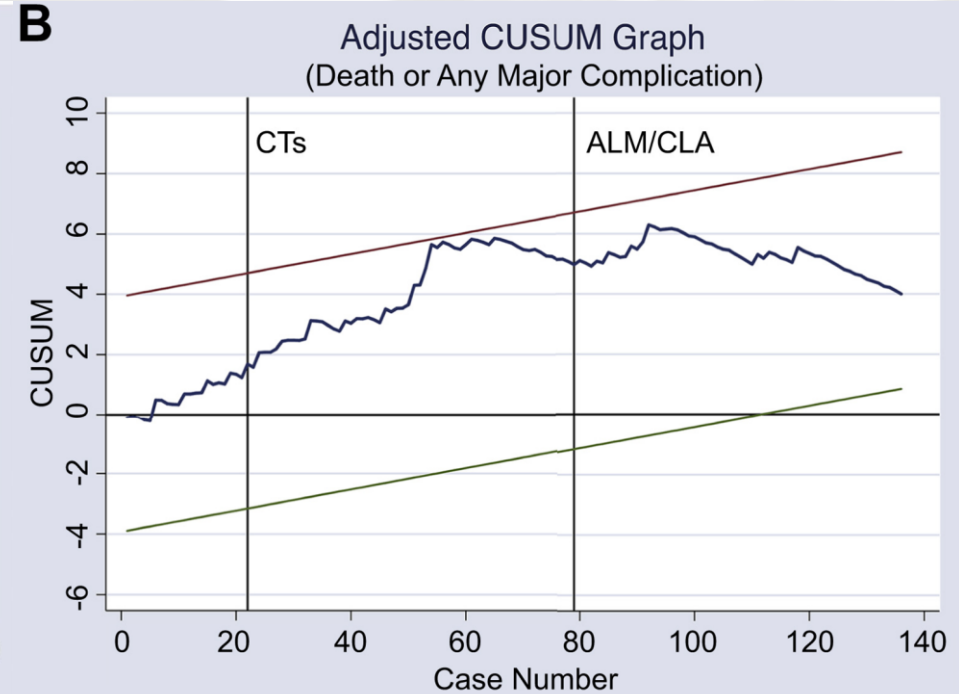
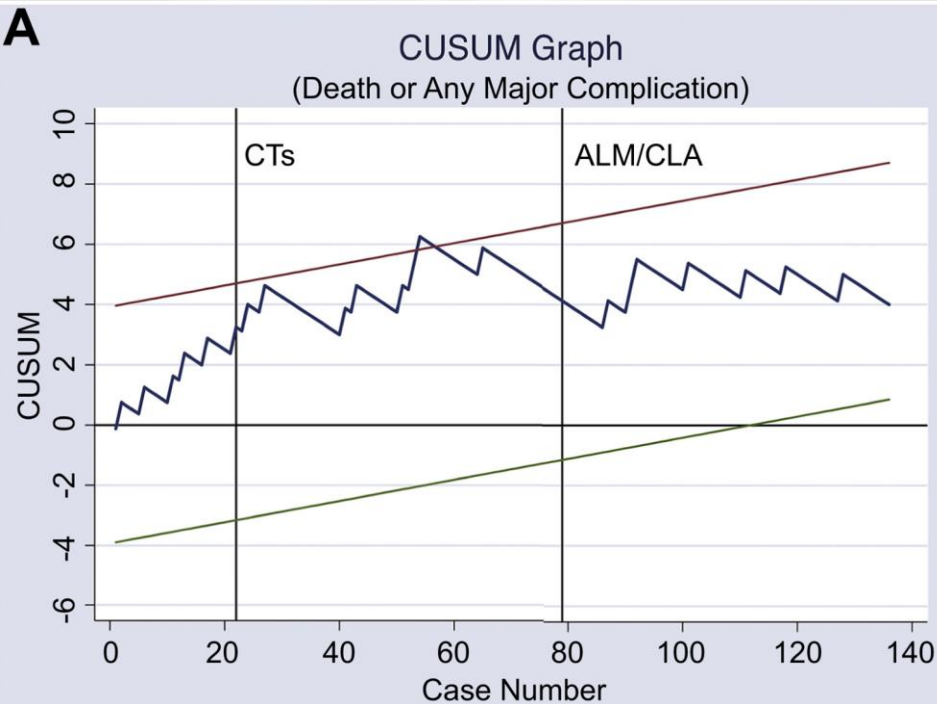


Myth #4

Endovascular surgery has a steep learning curve



Learning curve for FEVAR



Evaluation of the learning curve for fenestrated endovascular aneurysm repair *Journal of Vascular Surgery* 2016 64, 1219-1227 DOI: (10.1016/j.jvs.2016.04.049)



Aortic surgery in the US

Year	National cases				Open repair	Endovascular repair	Total
	OAR, No.	EVAR, No.	FEVAR/BREVAR, No.	Total, No.			
1998	42,213	N/A	N/A	42,213	2		
1999	42,415	N/A	N/A	42,415	2		
2000	42,872	2358	N/A	45,230	2		
2001	33,499	13,845	N/A	47,344	1		
2002	28,842	13,821	N/A	42,663	1		
2003	27,404	17,119	N/A	44,523	1		
2004	24,881	19,414	N/A	44,295	13,759	N/A	26,799 (61)
2005	21,485	21,332	N/A	42,817	10,369	N/A	22,158 (52)
2006	19,126	27,845	N/A	46,971	10,325	N/A	26,268 (56)
2007	15,895	29,769	N/A	45,664	8408	17,852	26,260 (58)
2008	16,253	34,888	N/A	51,141	8840	18,947	27,788 (54)
2009	14,389	32,403	N/A	46,792	834	18,711	27,055 (58)
2010	11,428	32,521	N/A	43,949	7128	17,776	24,904 (57)
2011	10,039	35,028	722	45,788	6055	19,876	26,400 (58)

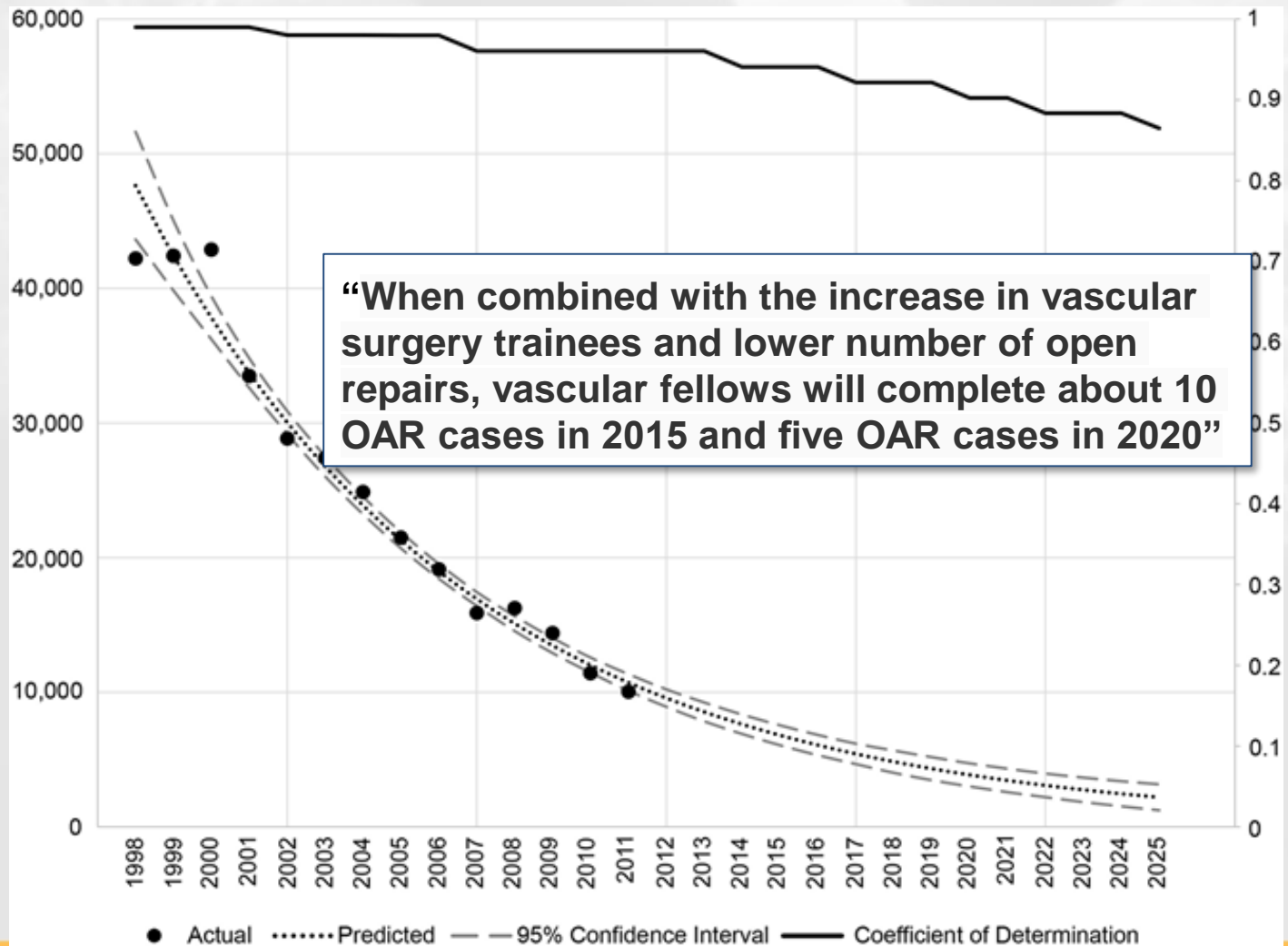
Decreasing OPEN REPAIR and increasing ENDO REPAIR

Year	OAR	95% Confidence interval	OAR	95% Confidence interval
2012	9570	8922-10,218	5356	4994-5719
2013	8541	7841-9241	4780	4389-5172
2014	7623	6903-8343	4267	3864-4670
2015	6805	6065-7545	3809	3394-4223
2020	3863	3006-4721	2162	1682-2642
2025	2200	1236-3163	1231	692-1770

Predicted shortfall in open aneurysm experience for vascular surgery trainees *Journal of Vascular Surgery* 2014 60, 945-949 DOI: (10.1016/j.jvs.2014.04.057)



Trends in open aortic repair



Predicted shortfall in open aneurysm experience for vascular surgery trainees *Journal of Vascular Surgery* 2014 60, 945-949 DOI: (10.1016/j.jvs.2014.04.057)



Myth #5

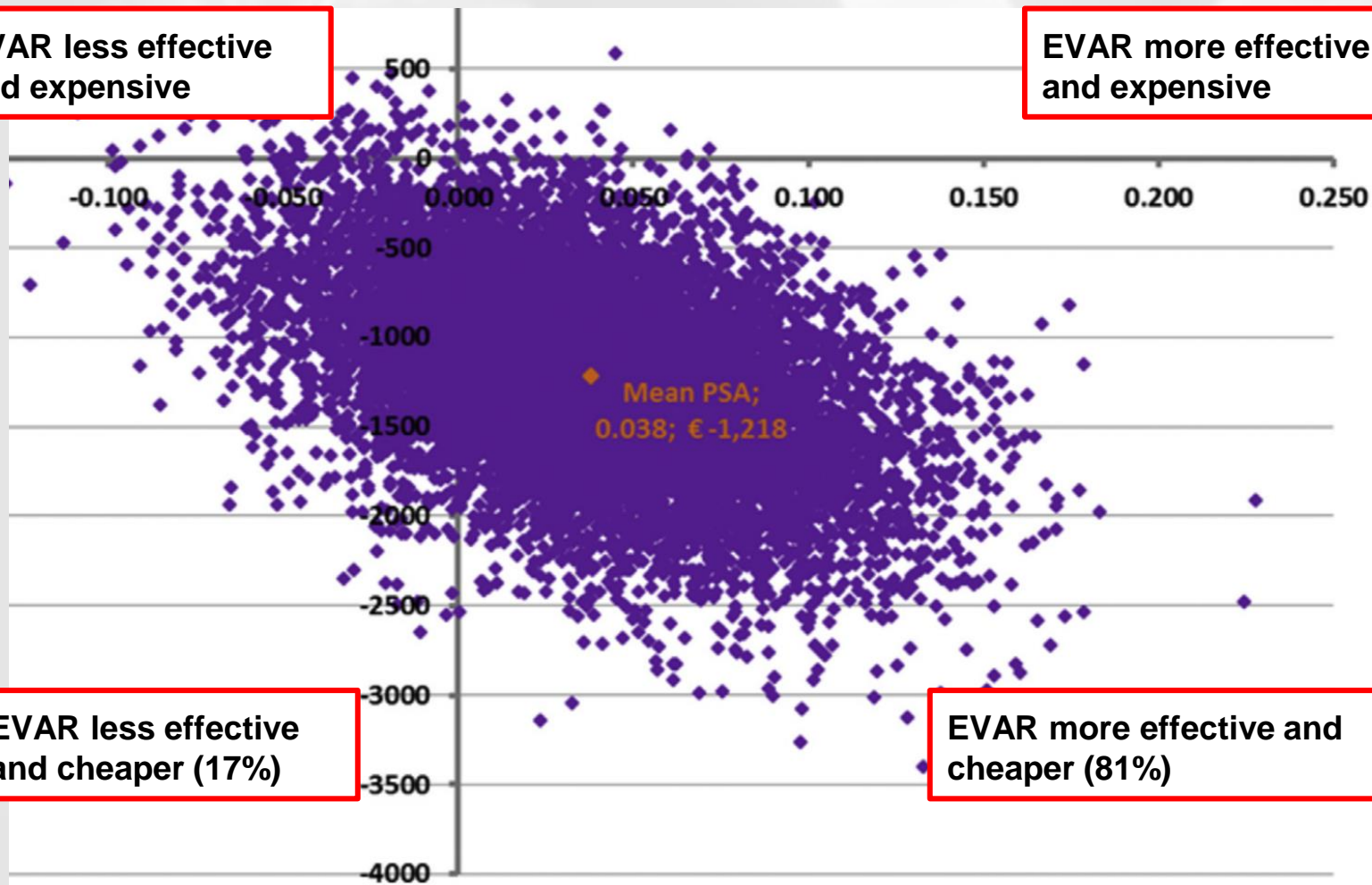
Endovascular repair is expensive



Cost effectiveness

EVAR less effective and expensive

EVAR more effective and expensive



EVAR less effective and cheaper (17%)

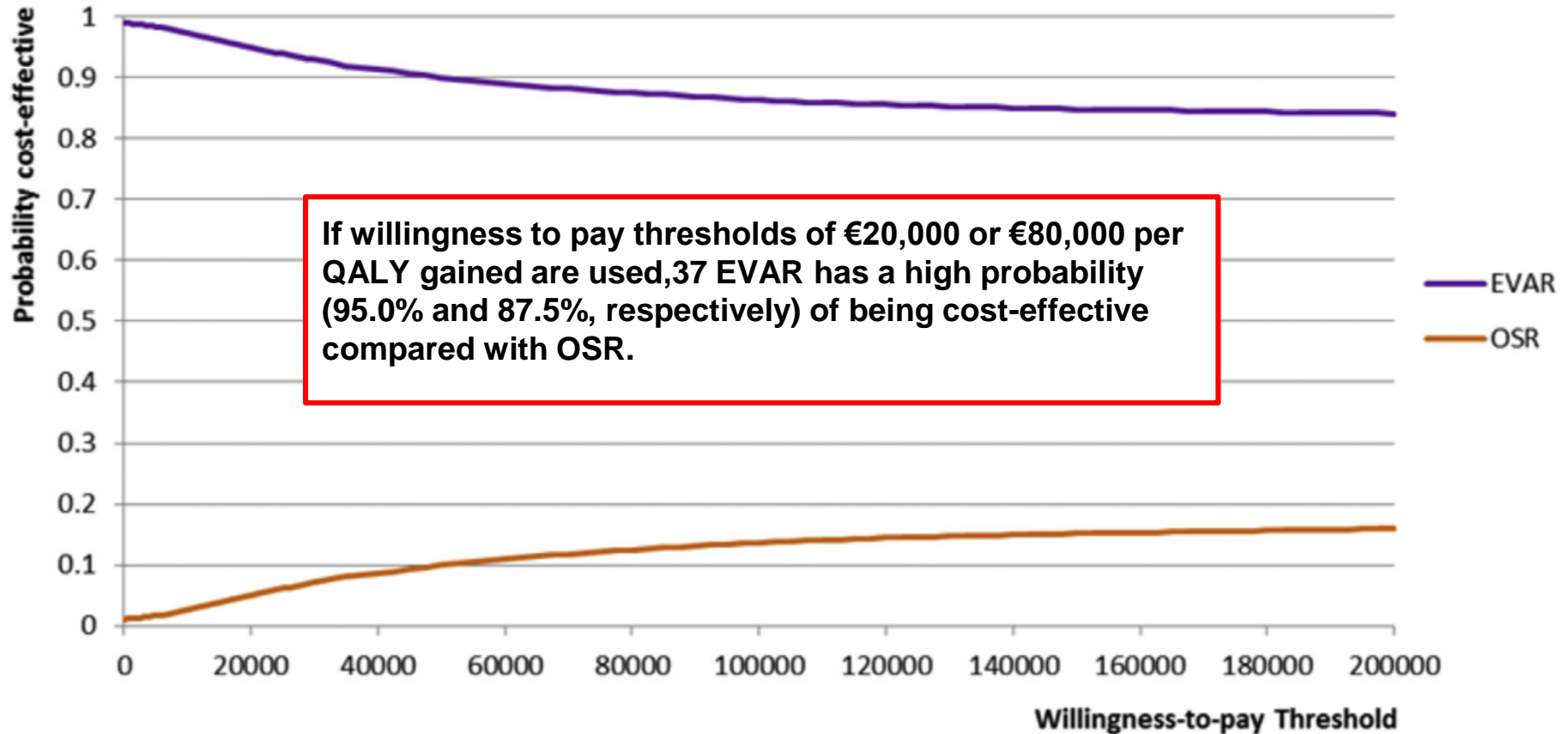
EVAR more effective and cheaper (81%)

Incremental effects (QALYs)



Cost effectiveness

Cost-effectiveness acceptability curve



Cost-effectiveness of Elective Endovascular Aneurysm Repair Versus Open Surgical Repair of Abdominal Aortic Aneurysms Burgers, L.T. et al. European Journal of Vascular and Endovascular Surgery , Volume 52 , Issue 1 , 29 - 40



Cost effectiveness

- Data remains unclear in US literature
- QALY added by EVAR not studied well so far in the US system.
- Similar outcomes for complex EVAR are not available

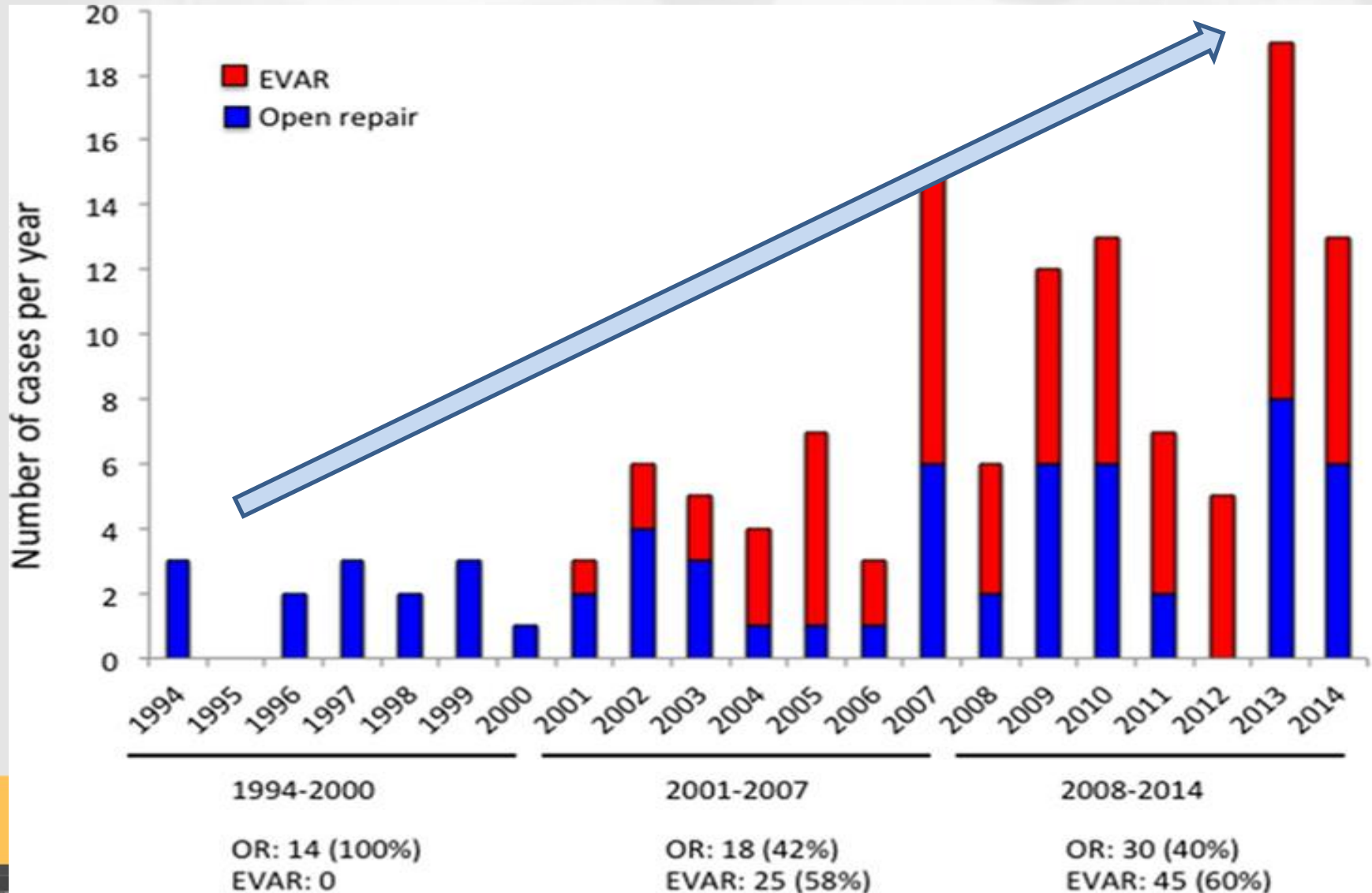


Myth #6

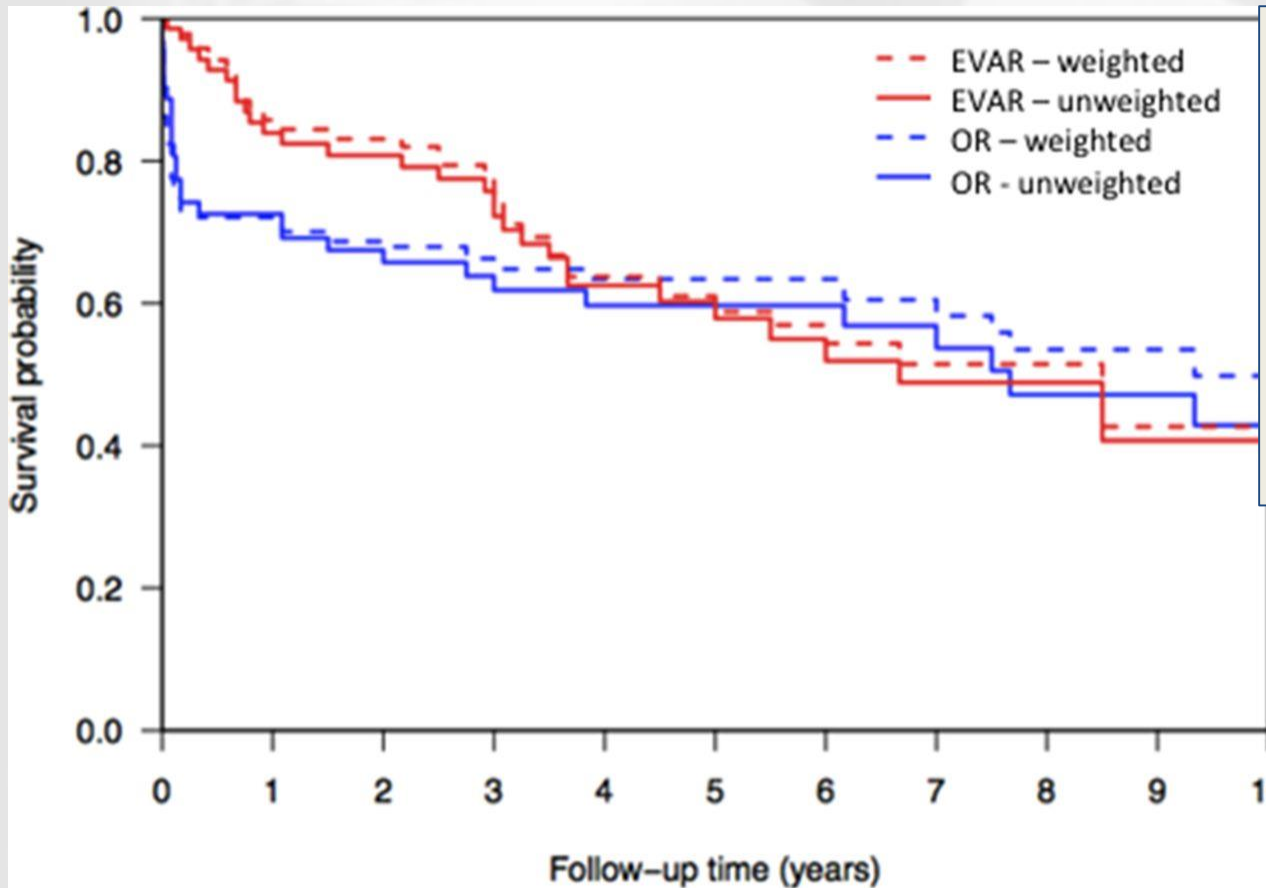
Endovascular surgery is not an options for infection, connective tissue disorders, vasculitis



Nationwide Study of the Treatment of Mycotic Abdominal Aortic Aneurysms Comparing Open and Endovascular Repair



EVAR for mycotic aneurysms



Paradigm shift in treatment of MAAA in Sweden
 EVAR was associated with improved short-term survival in comparison with OR, without higher associated incidence of serious infection-related complications or reoperations.

Propensity score weighted estimates of survival at respective time interval after surgery. Numbers within parenthesis indicate the 95% confidence interval.

	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	<0.001	0.110	0.687	0.782
Numbers at risk	113	100	52	15

Infections, CTD and Vasculitis

- Endovascular repair is being applied for challenging medical conditions worldwide
- Careful planning, staging and diligent follow up allows for safe outcome with these conditions



Conclusion

Complex EVAR is

- Available for all anatomy
- Safe, effective and durable
- Applicable for all patient population (young age, vasculitis etc)
- Comparable in cost
- **READY FOR PRIME TIME!!!**



**Complex endovascular
aortic repair will make the
open aortic surgery
obsolete**



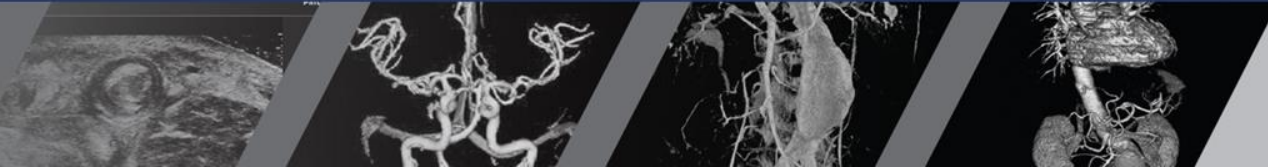
BRACE YOURSELVES



THE EXCUSES ARE COMING



THANK YOU



Outcomes

[http://www.jvascsurg.org/article/S0741-5214\(17\)30381-6/fulltext](http://www.jvascsurg.org/article/S0741-5214(17)30381-6/fulltext)

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