Critical Issues 2021

How to Improve Durability

TM Mastracci
Honorary Associate Professor
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Disclosures

- Cook Medical: Proctoring and Consultation
- Philips Imaging: Medical Advisory Board
- CYDAR Medical: Chair, Medical Advisory Board and Consultation

How to improve durability at your centre:

1. Establish how good your durability is
2. Make it better

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What is the Durability at your Centre?

1

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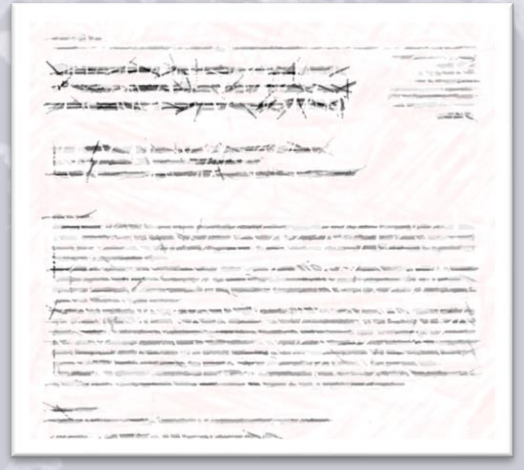
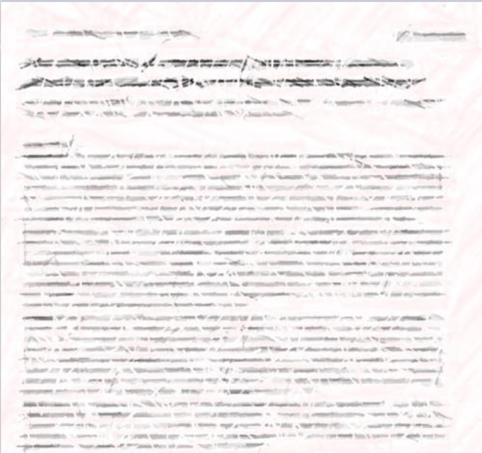
The Fallacy of Follow up

Survival analysis relies on the assumption that patients who are censored have the same survival prospects as those who continue to be followed.





Year of Public'n	2021	2021	2021	2021
Median f/u	27 m (IQR 13m)	3.7 y (IQR 1.7 – 5.3)	28.2 m(IQR 11.7 – 50.8)	26 (+/-20 months)
Time to event statistic	78% freedom from reintervention at **5 years**	70% freedom from reintervention for high complexity FEVAR at **10 years**	97.7% freedom from stent fracture at **60 months**	64% freedom from secondary intervention at **5 years**
Number at risk	21/221 = 9.5%	1/151 = 0.6%	60/286 = 21%	34/430 = 8%

Complications can be adjudicated differently

From the Society for Vascular Surgery

Poor concordance of contemporary performance measures in detecting complications in complex endovascular aortic repair

Check for updates

Katherine A. Giuliano, MD,[a] Rebecca Sorber, MD,[a] Caitlin W. Hicks, MD, MS,[a,b] Christopher J. Abularrage, MD,[a] Ying Wei Lum, MD, MPH,[a,c] and James H. Black III, MD,[a] Baltimore, Md

ABSTRACT

Background: The Agency for Healthcare Research and Quality Patient Safety Indicators (PSI) are quality improvement indicators used to determine hospital performance and, increasingly, to rank surgical programs. The American College of Surgeons National Surgical Quality Improvement Program and the Society for Vascular Surgery Vascular Quality Improvement databases are also frequently used to compare outcomes, but definitions of complications vary between the systems and the optimal system for tracking complications in complex endovascular repair remains unclear. Herein we assess the three outcome tracking systems and their ability to capture complications after fenestrated endovascular abdominal aortic aneurysm repair (FEVAR) and open aortic aneurysm repair in a large complex aortic program.

Methods: Demographic and operative data for patients undergoing repair of juxtarenal or pararenal aortic aneurysms between 2004 and 2018 via both open and FEVAR approaches at the Johns Hopkins Medical Institutions were compiled in a prospectively maintained retrospective database. Postoperative complications were defined according to a surgeon-defined system, the Society for Vascular Surgery Vascular Quality Initiative, the American College of Surgeons National Surgical Quality Improvement Program, and the Agency for Healthcare Research and Quality PSI data dictionaries and were compared between surgical approaches as well as eras before and after the introduction of FEVAR. Complication rates between the classification systems were compared using proportion testing and the strength of the correlation between the systems was evaluated with Spearman's rank test.

Results: Of 145 patients, 60 (41.4%) underwent FEVAR and 85 (58.6%) underwent open aortic aneurysm repair. The introduction of fenestrated technology was associated with a decrease in the overall number of complications from 37.2% to 20.6% by surgeon-defined classification system ($P = .036$). The VQI identified the most complications (39.9% of the entire cohort and 25% of FEVAR cases), followed by the NSQIP (29.0% and 33.3%, respectively) and PSI (4.1% and 5%). The two clinically focused databases were found to correlate well with a surgeon-designed classification system, as well as each other (Spearman $\rho \geq 0.735$) but not with PSI ($\rho < 0.23$). Proportion testing demonstrated the rate of complications identified by PSI to be significantly less than either VQI or NSQIP ($P < .001$). Specifically, PSI did not effectively identify renal complications (1.4% vs 9.0% by NSQIP and 27.3% by VQI definitions; $P < .001$).

Conclusions: The introduction of FEVAR is associated with an overall decrease in complications in this study. The clinically relevant VQI and NSQIP databases show good concordance in capturing complications; however, PSI did not correlate with either and captured significantly fewer complications. These data highlight the value of high scrutiny classification systems to track postoperative complications and suggest that PSI are insufficient to rank complex aortic programs with high levels of FEVAR use. (J Vasc Surg 2021;74:28-37.)

Keywords: Endovascular repair; Fenestrated endovascular aortic repair; Abdominal aortic aneurysm; Patient Safety Indicator

Table VI. Number of complications captured by each system for open complex aortic repair (*OAR*) and fenestrated endovascular abdominal aortic aneurysm repair (*FEVAR*) compared with the composite standard classification (the all-inclusive and most stringent version of each organ system definition)

	Composite		Surgeon designed		SVS-VQI		ACS-NSQIP		AHRQ-PSI	
	OAR (n = 85)	FEVAR (n = 60)	OAR	FEVAR	OAR	FEVAR	OAR	FEVAR	OAR	FEVAR
Patients with any complication	43	21	23 (53)	14 (67)	42 (98)	19 (90)	22 (51)	20 (95)	5 (12)	1 (5)
Total complications	67	33	35 (52)	21 (64)	57 (85)	31 (94)	32 (48)	29 (88)	2 (3)	1 (3)
Hemorrhagic	6	5	0 (0)	0 (0)	6 (100)	5 (100)	5 (100)	5 (100)	0 (0)	0 (0)
Cardiac	6	4	5 (83)	4 (100)	6 (100)	4 (100)	3 (50)	2 (50)	–	–
Respiratory	16	0	12 (75)	0 (100)	8 (50)	0 (100)	12 (75)	0 (100)	–	–
Renal	30	10	9 (30)	5 (50)	30 (100)	10 (100)	5 (17)	8 (80)	1 (3)	1 (10)
Wound	3	2	3 (100)	2 (100)	3 (100)	2 (100)	3 (100)	2 (100)	0 (0)	0 (0)
DVT/PE	1	0	1 (100)	0 (100)	–	–	1 (100)	0 (100)	1 (100)	0 (100)
Bowel ischemia	2	6	2 (100)	6 (100)	2 (100)	6 (100)	1 (100)	6 (100)	–	–
Neurologic	1	3	1 (100)	3 (100)	0 (0)	3 (100)	0 (0)	3 (100)	–	–
Extremity	2	0	2 (100)	0 (100)	2 (100)	0 (100)	2 (100)	0 (100)	–	–
UTI	1	2	1 (100)	2 (100)	–	–	1 (100)	2 (100)	–	–
Death	0	1	0 (100)	1 (100)	0 (100)	1 (100)	0 (100)	1 (100)	0 (100)	1 (100)

ACS-NSQIP, American College of Surgeons National Surgical Quality Improvement Program; *AHRQ-PSI*, Agency for Healthcare Research and Quality Patient Safety Indicators; *DVT*, deep vein thrombosis; *NC*, not captured; *PE*, pulmonary embolism; *SVS-VQI*, Society for Vascular Surgery Vascular Quality Initiative; *UTI*, urinary tract infection.
Values are number (%).

There may be variables we don't appreciate

- 256 patients undergoing FEVAR/BEVAR
- Functional status predicted 2 year mortality

From the Society for Vascular Surgery

Preoperative functional status predicts 2-year mortality in patients undergoing fenestrated/branched endovascular aneurysm repair

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ABSTRACT

Background: Fenestrated/branched endovascular aneurysm repair (F/BEVAR) is a minimally invasive alternative for patients at high risk of open repair of complex aortic aneurysms. Nearly all investigative study protocols evaluating F/BEVAR have required a predicted life expectancy of >2 years for study inclusion. However, accurate risk models for predicting 2-year survival in this patient population are lacking. We sought to identify the preoperative predictors of 2-year survival for patients undergoing F/BEVAR.

Methods: The prospectively collected data for all consecutive F/BEVAR procedures, performed in an institutional review board-approved registry and/or a physician-sponsored investigational device exemption (IDE) trial (IDE no. G130210), were reviewed (November 2010 to February 2019). We assessed 44 preoperative patient characteristics, including comorbidities, preoperative functional status, aneurysm morphologies, and repair techniques. Preoperative functional status was defined as totally dependent (any impairment in activities of daily living or residing in a skilled nursing facility), partially dependent (any impairment in instrumental activities of daily living), or independent (no impairment in activities of daily living or instrumental activities of daily living). Using the results of univariate analysis ($P < .2$), a Cox proportional hazards model was constructed to identify the independent predictors of 2-year all-cause mortality.

Results: For the 256 consecutive patients who had undergone F/BEVAR (6 common iliac [2.3%], 94 juxtarenal [41%], 35 pararenal [14%], 119 thoracoabdominal [47%], and 2 arch [0.8%] aneurysms), the 2-year mortality was 18%. On Cox modeling, the only independent preoperative predictor contributing to 2-year mortality was functional status (totally dependent: hazard ratio [HR], 5.4; 95% confidence interval [CI], 1.8-16; $P = .0024$; partially dependent: HR, 4.5; 95% CI, 2.4-8.7; $P < .0000019$). A history of an implanted anti-arrhythmic device was protective (HR, 0.4; 95% CI, 0.2-0.99; $P = .0495$). Factors such as age, congestive heart failure, chronic kidney disease, diabetes, chronic obstructive ... disease, aneurysm extent, and previous aortic ... (n = 176; 69%), partially dependent (n = 69; 27 ... respectively.

Conclusions: For patients undergoing F/BEVAR ... 2-year mortality, with totally dependent patien... pendently significant, perhaps reflecting the ... participating in an IDE trial. For the independen... survival after infrarenal EVAR. Therefore, for inde... BEVAR to low-risk patients. (J Vasc Surg 2021;74:383-95.)

Keywords: All-cause mortality; Complex aortic disease; F/BEVAR; Fenestrated/branched endovascular repair; Functional status

Preoperative functional status[a]				.0000099
Independent	177 (69)	157 (75)	19 (41)	
Partially dependent	69 (27)	46 (22)	23 (50)	
Dependent	10 (3.9)	6 (2.9)	4 (8.7)	

Flanagan, CP JVS 2021

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How can you improve durability at your Centre?

2

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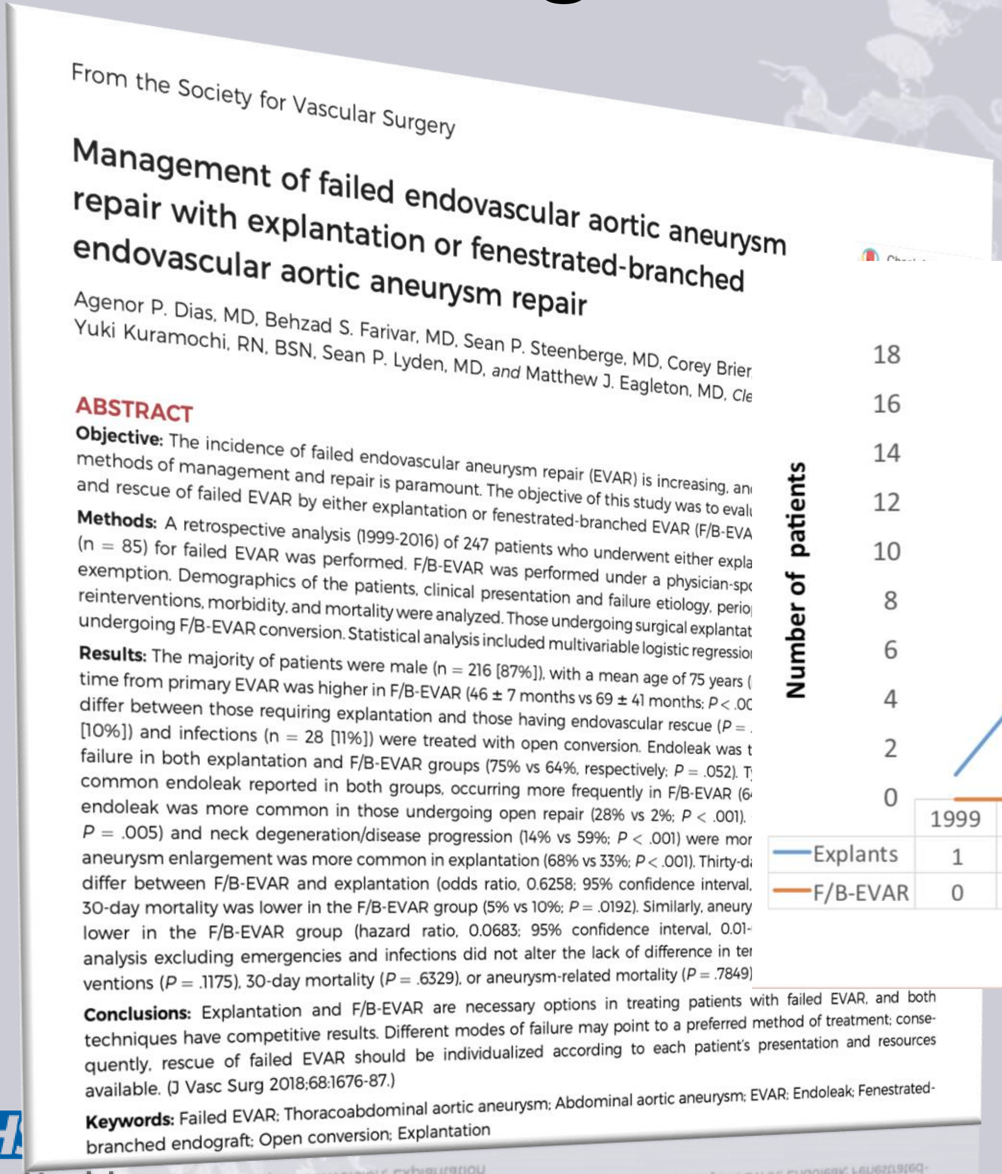
No Endograft Prevents Aortic Degeneration



From the Society for Vascular Surgery

Management of failed endovascular aortic aneurysm repair with explantation or fenestrated-branched endovascular aortic aneurysm repair

Agenor P. Dias, MD, Behzad S. Farivar, MD, Sean P. Steenberge, MD, Corey Brier, Yuki Kuramochi, RN, BSN, Sean P. Lyden, MD, *and* Matthew J. Eagleton, MD, *Cle*

ABSTRACT

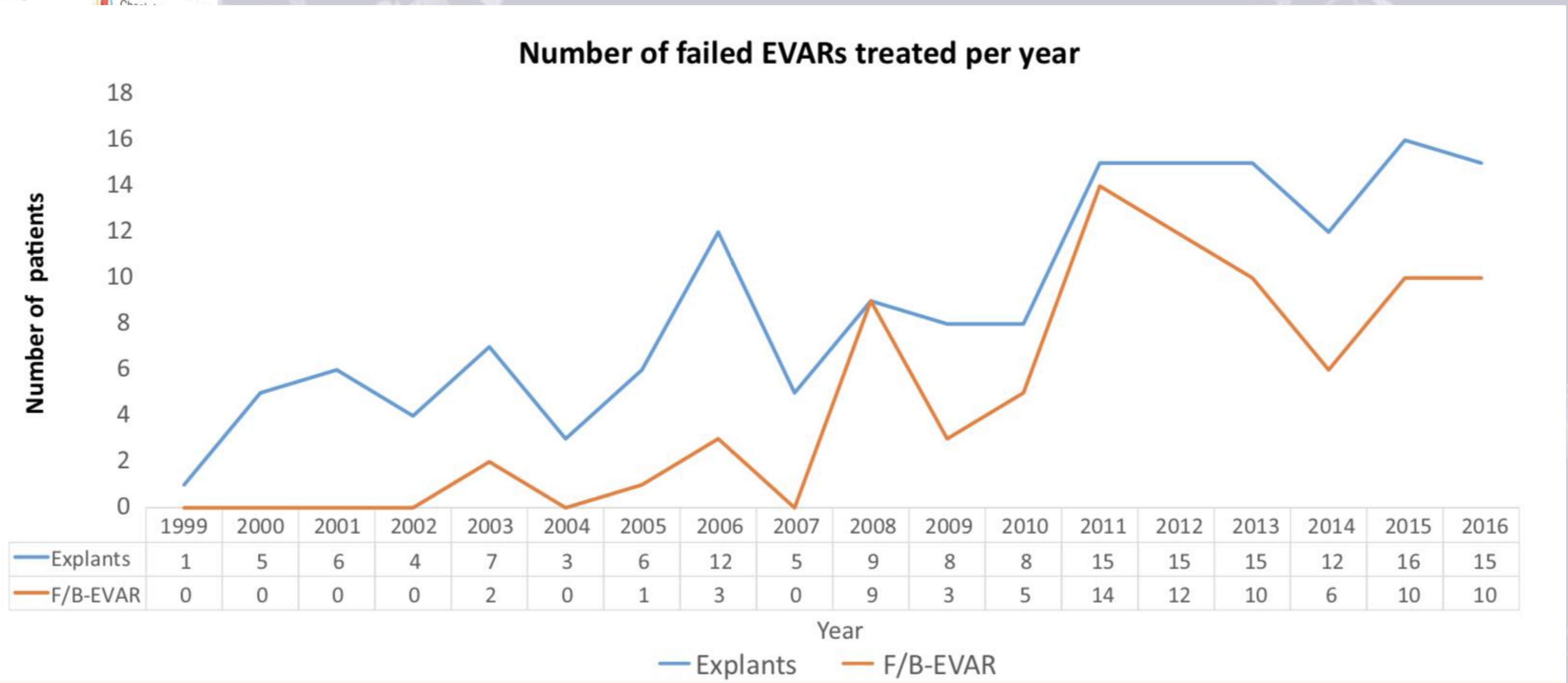
Objective: The incidence of failed endovascular aneurysm repair (EVAR) is increasing, an methods of management and repair is paramount. The objective of this study was to evalu and rescue of failed EVAR by either explantation or fenestrated-branched EVAR (F/B-EVA

Methods: A retrospective analysis (1999-2016) of 247 patients who underwent either expla (n = 85) for failed EVAR was performed. F/B-EVAR was performed under a physician-spo exemption. Demographics of the patients, clinical presentation and failure etiology, perio reinterventions, morbidity, and mortality were analyzed. Those undergoing surgical explantat undergoing F/B-EVAR conversion. Statistical analysis included multivariable logistic regressio

Results: The majority of patients were male (n = 216 [87%]), with a mean age of 75 years (time from primary EVAR was higher in F/B-EVAR (46 ± 7 months vs 69 ± 41 months; *P* < .00 differ between those requiring explantation and those having endovascular rescue (*P* = [10%]) and infections (n = 28 [11%]) were treated with open conversion. Endoleak was t failure in both explantation and F/B-EVAR groups (75% vs 64%, respectively; *P* = .052). T common endoleak reported in both groups, occurring more frequently in F/B-EVAR (6 endoleak was more common in those undergoing open repair (28% vs 2%; *P* < .001). *P* = .005) and neck degeneration/disease progression (14% vs 59%; *P* < .001) were mor aneurysm enlargement was more common in explantation (68% vs 33%; *P* < .001). Thirty-da differ between F/B-EVAR and explantation (odds ratio, 0.6258; 95% confidence interval, 30-day mortality was lower in the F/B-EVAR group (5% vs 10%; *P* = .0192). Similarly, aneury lower in the F/B-EVAR group (hazard ratio, 0.0683; 95% confidence interval, 0.01- analysis excluding emergencies and infections did not alter the lack of difference in ter ventions (*P* = .1175), 30-day mortality (*P* = .6329), or aneurysm-related mortality (*P* = .7849)

Conclusions: Explantation and F/B-EVAR are necessary options in treating patients with failed EVAR, and both techniques have competitive results. Different modes of failure may point to a preferred method of treatment; consequently, rescue of failed EVAR should be individualized according to each patient's presentation and resources available. (J Vasc Surg 2018;68:1676-87.)

Keywords: Failed EVAR; Thoracoabdominal aortic aneurysm; Abdominal aortic aneurysm; EVAR; Endoleak; Fenestrated-branched endograft; Open conversion; Explantation



Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Explants	1	5	6	4	7	3	6	12	5	9	8	8	15	15	15	12	16	15
F/B-EVAR	0	0	0	0	2	0	1	3	0	9	3	5	14	12	10	6	10	10

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A Dias, JVS 2018

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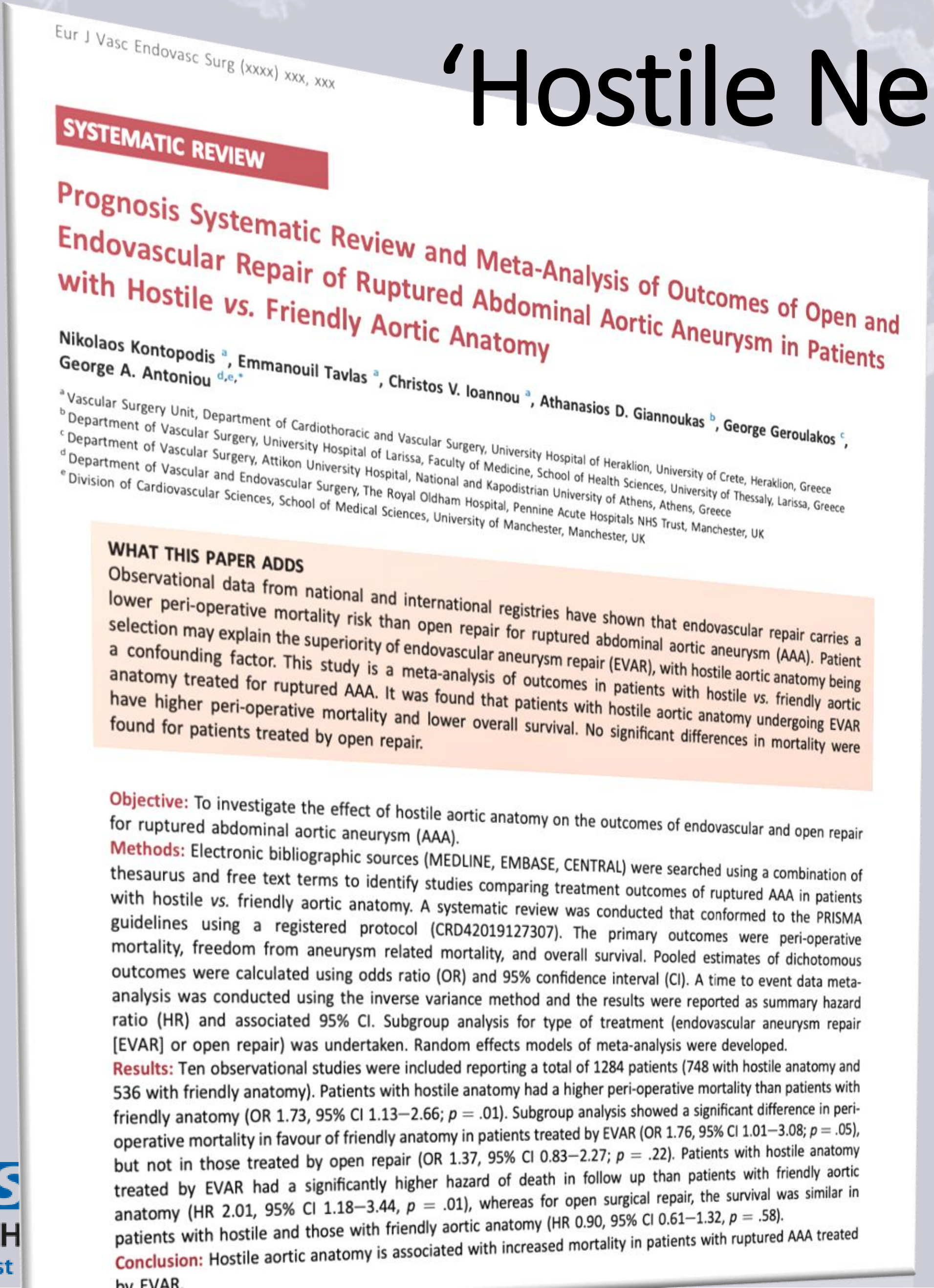
'Hostile Necks' predicts poor outcome



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SYSTEMATIC REVIEW

Prognosis Systematic Review and Meta-Analysis of Outcomes of Open and Endovascular Repair of Ruptured Abdominal Aortic Aneurysm in Patients with Hostile *vs.* Friendly Aortic Anatomy

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WHAT THIS PAPER ADDS

Observational data from national and international registries have shown that endovascular repair carries a lower peri-operative mortality risk than open repair for ruptured abdominal aortic aneurysm (AAA). Patient selection may explain the superiority of endovascular aneurysm repair (EVAR), with hostile aortic anatomy being a confounding factor. This study is a meta-analysis of outcomes in patients with hostile *vs.* friendly aortic anatomy treated for ruptured AAA. It was found that patients with hostile aortic anatomy undergoing EVAR have higher peri-operative mortality and lower overall survival. No significant differences in mortality were found for patients treated by open repair.

Objective: To investigate the effect of hostile aortic anatomy on the outcomes of endovascular and open repair for ruptured abdominal aortic aneurysm (AAA).
Methods: Electronic bibliographic sources (MEDLINE, EMBASE, CENTRAL) were searched using a combination of thesaurus and free text terms to identify studies comparing treatment outcomes of ruptured AAA in patients with hostile *vs.* friendly aortic anatomy. A systematic review was conducted that conformed to the PRISMA guidelines using a registered protocol (CRD42019127307). The primary outcomes were peri-operative mortality, freedom from aneurysm related mortality, and overall survival. Pooled estimates of dichotomous outcomes were calculated using odds ratio (OR) and 95% confidence interval (CI). A time to event data meta-analysis was conducted using the inverse variance method and the results were reported as summary hazard ratio (HR) and associated 95% CI. Subgroup analysis for type of treatment (endovascular aneurysm repair [EVAR] or open repair) was undertaken. Random effects models of meta-analysis were developed.
Results: Ten observational studies were included reporting a total of 1284 patients (748 with hostile anatomy and 536 with friendly anatomy). Patients with hostile anatomy had a higher peri-operative mortality than patients with friendly anatomy (OR 1.73, 95% CI 1.13–2.66; $p = .01$). Subgroup analysis showed a significant difference in peri-operative mortality in favour of friendly anatomy in patients treated by EVAR (OR 1.76, 95% CI 1.01–3.08; $p = .05$), but not in those treated by open repair (OR 1.37, 95% CI 0.83–2.27; $p = .22$). Patients with hostile anatomy treated by EVAR had a significantly higher hazard of death in follow up than patients with friendly aortic anatomy (HR 2.01, 95% CI 1.18–3.44, $p = .01$), whereas for open surgical repair, the survival was similar in patients with hostile and those with friendly aortic anatomy (HR 0.90, 95% CI 0.61–1.32, $p = .58$).
Conclusion: Hostile aortic anatomy is associated with increased mortality in patients with ruptured AAA treated by EVAR.

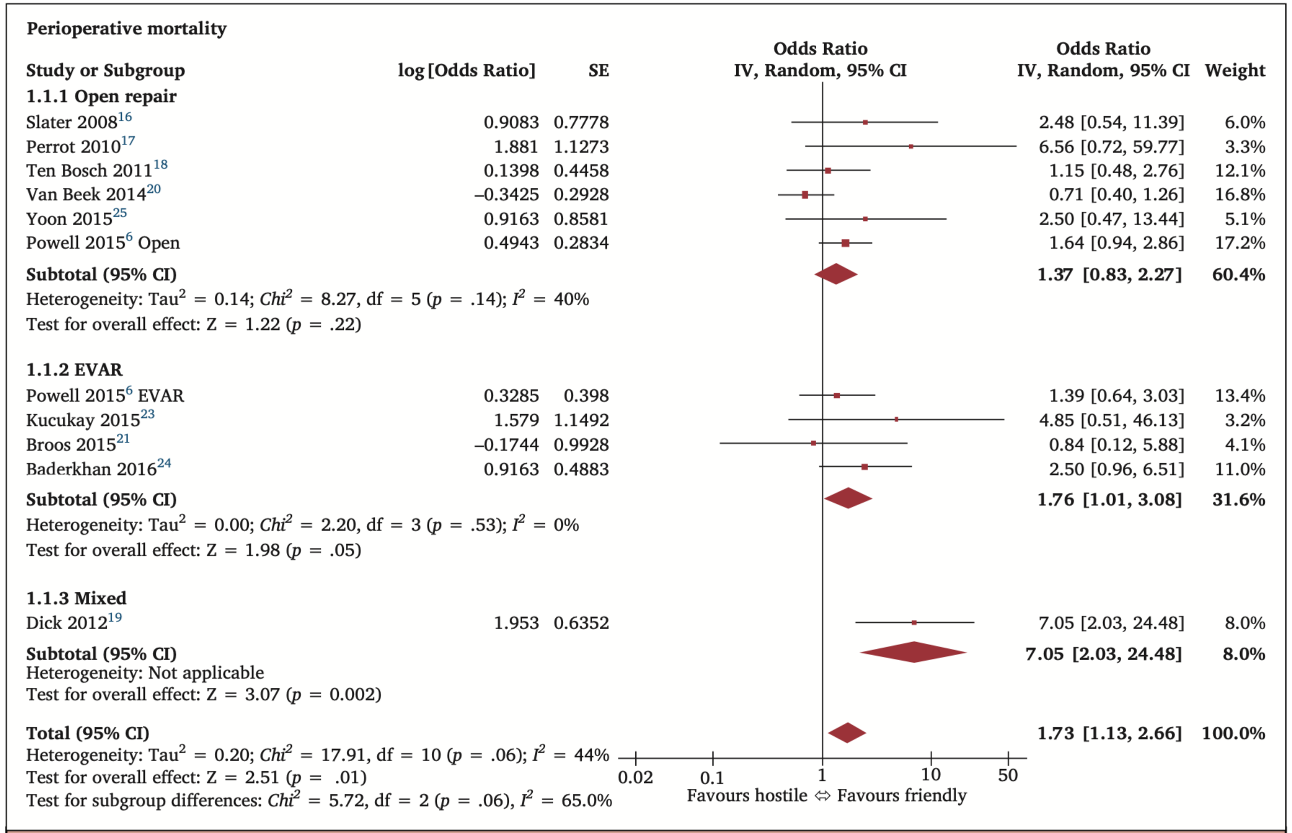

Figure 3. Forest plot of peri-operative mortality in patients with hostile *vs.* friendly aortic anatomy. The solid squares denote the odds ratios, the horizontal lines the 95% confidence intervals (CIs), and the diamonds the pooled estimates. IV = inverse variance; M–H = Mantel-Haenszel.

Kontopodis et al, 2020

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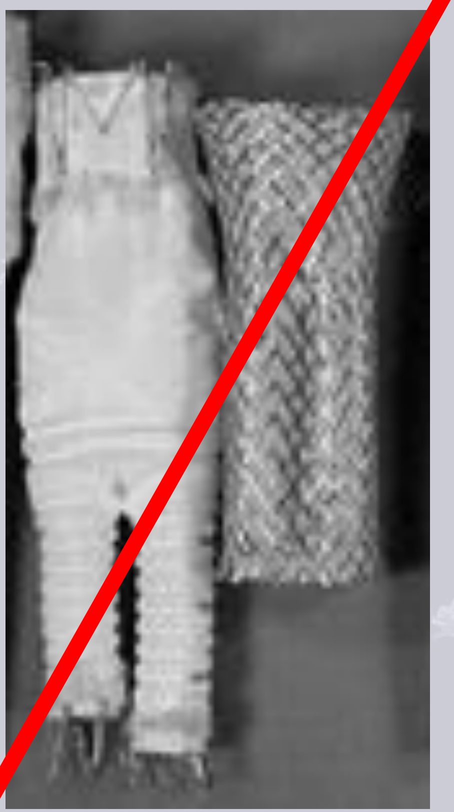

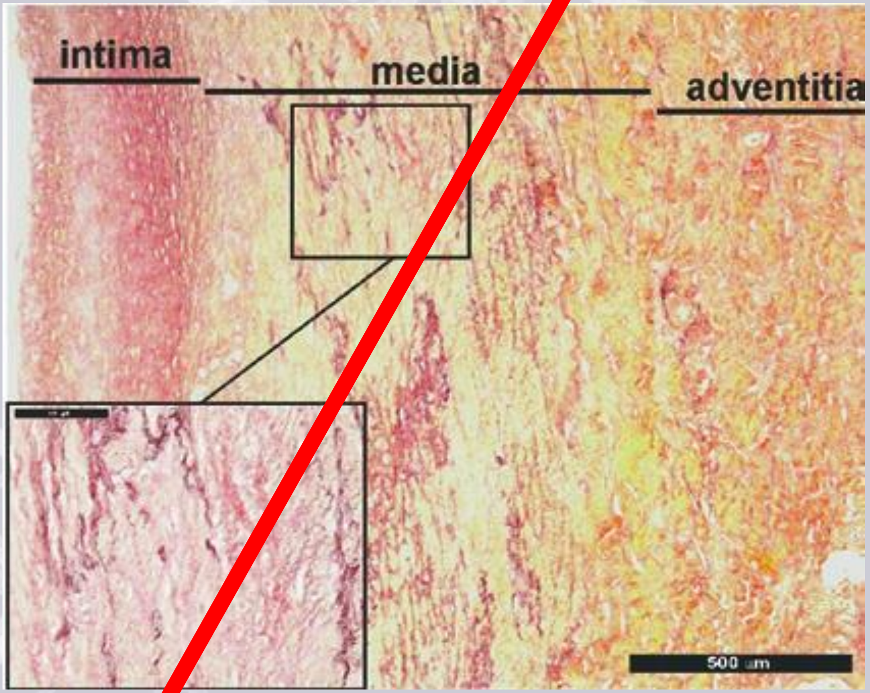
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Seal *Aggressively*

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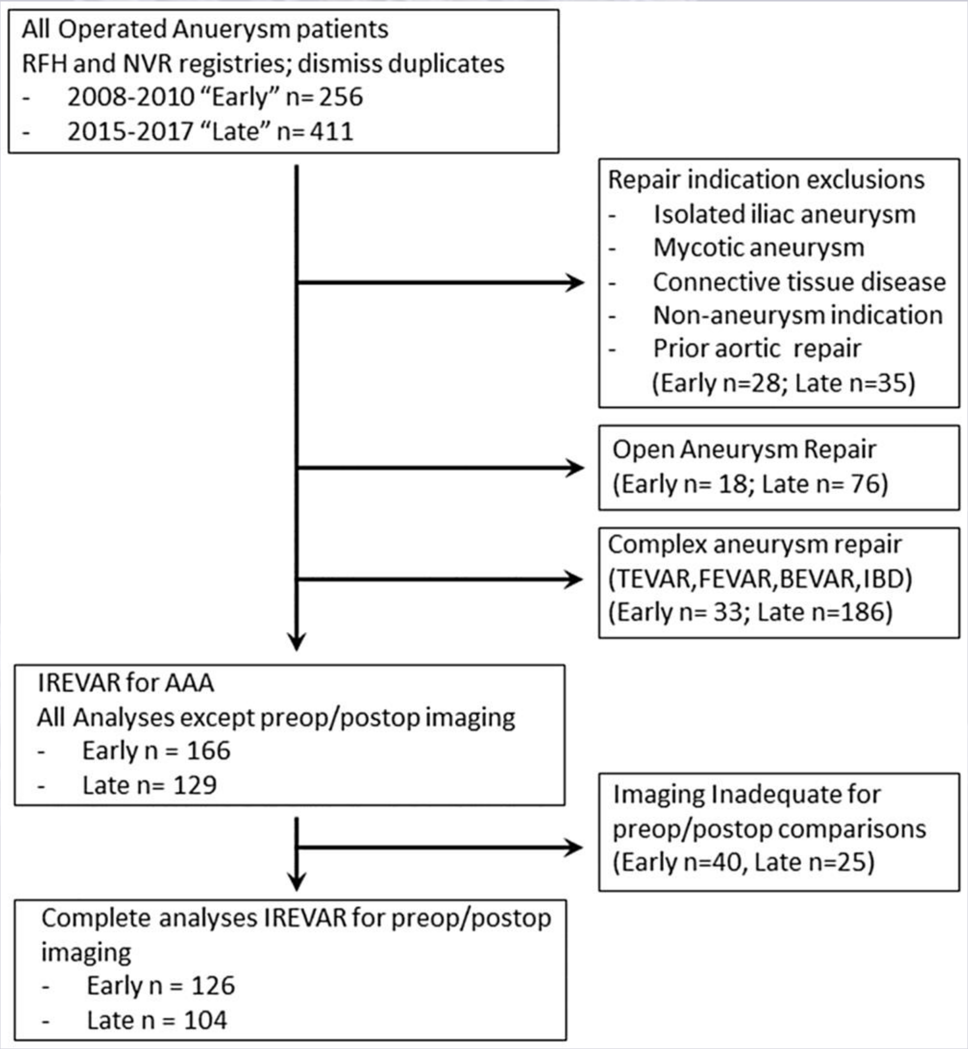
Experience from 1 Academic Teaching Centre

2008 – 2010
126 Patients



Witheford et al, 2021

2015 – 2017
104 Patients

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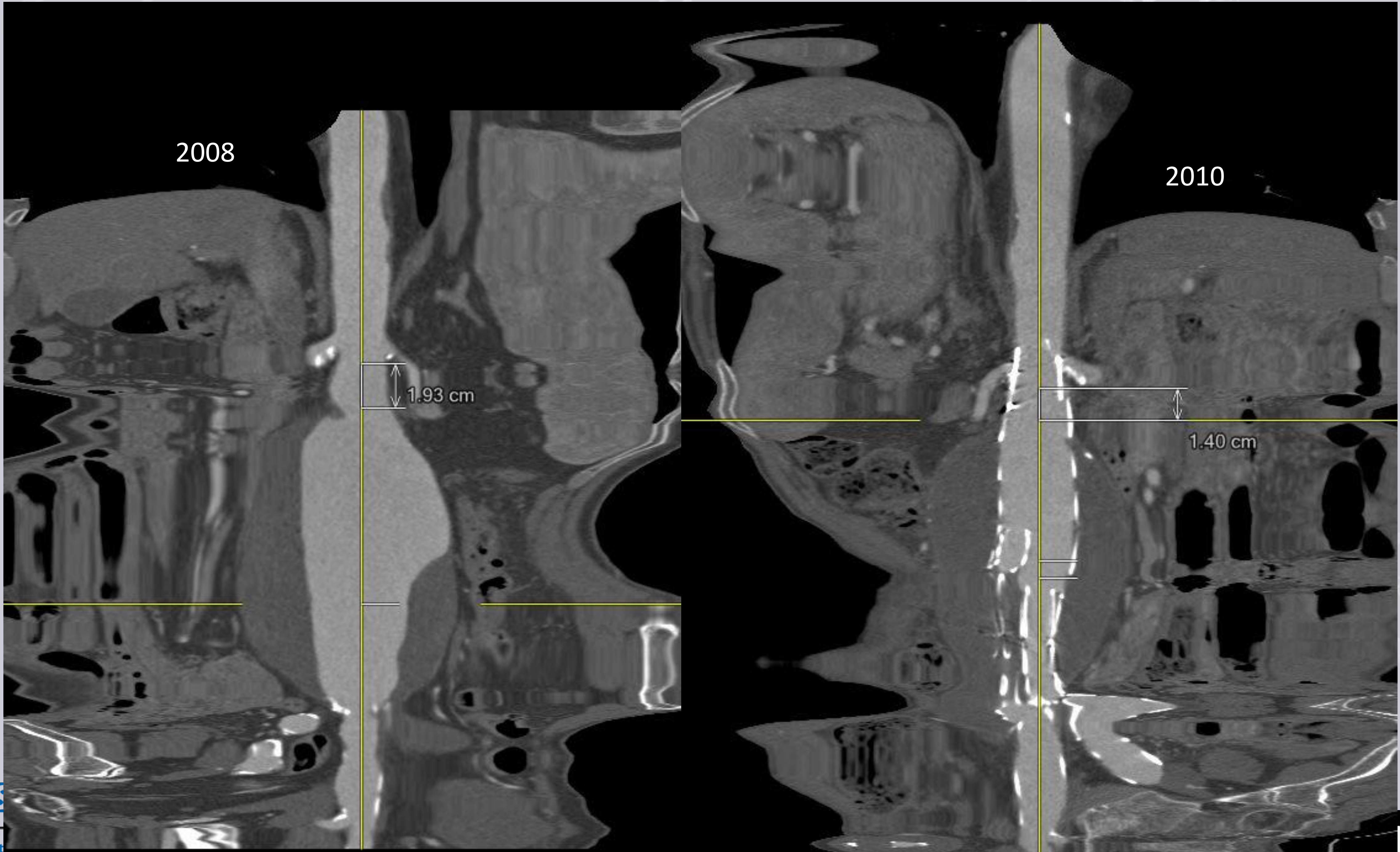
Modified Anatomic Severity Grading

Proximal: 13 points
Aneurysm: 9 points
Iliac: 18 points

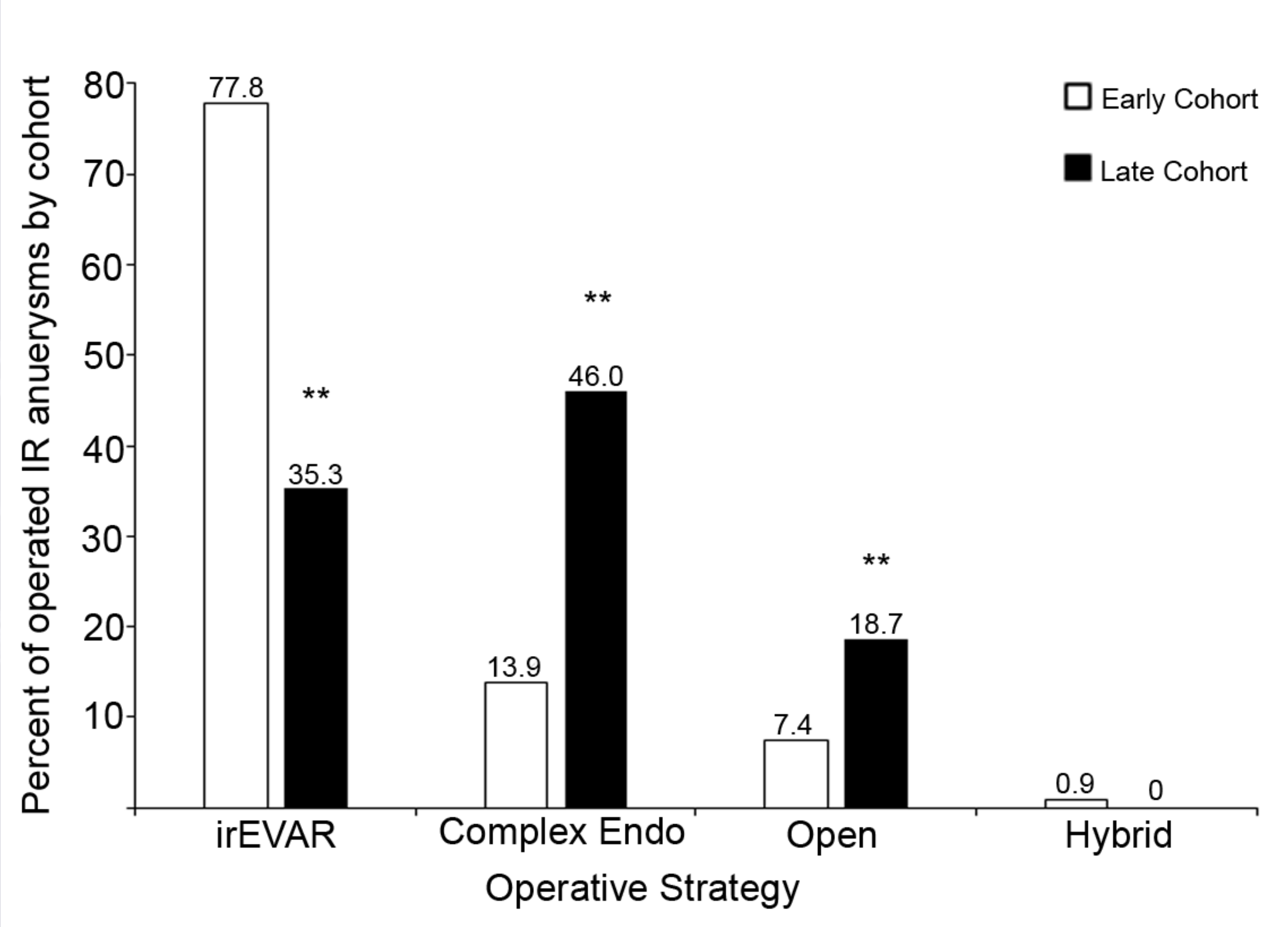
40 points

ATTRIBUTE				
PROXIMAL AORTA	Absent=0	Mild=1	Moderate = 2	Severe = 3
Aortic Diameter (celiac; cd)	cd<27mm	27≤cd<29mm	29≤cd≤31mm	cd≥31mm
Infrarenal Aortic diameter (d)	d<24mm	24≤d<26mm	26≤d<28mm	d≥28mm
Neck Length (L)	L≥25	15≤L<25	10≤L<15	L<10
Calcification	<25%	25-50%	>50%	-
Thrombus	<25%	25-50%	>50%	
ANEURYSM RELATED	Absent=0	Mild=1	Moderate = 2	Severe = 3
Aneurysm diameter (ad)	ad<5.4	5.5<ad<5.9	6<ad<6.5	ad>6.5
Aortic branch vessels	No vessels	1 lumbar/IMA	2 vessels, IMA d<4mm	2 vessels, IMA d>4 mm
Pelvic Perfusion	Patent bilateral IIA	Single IIA occlusion	Single IIA occlusion, contralateral IIA >50% stenosis	Bilateral IIA occlusions
ILIAC ARTERY	Absent=0	Mild=1	Moderate = 2	Severe = 3
Calcification	None	<25% vessel length	25-50% vessel length	>50% vessel length
Diameter (d)/ Occlusive disease	- d≥10 mm -No occlusive disease	- 8≤d<10 mm - No stenosis with d <7 or >3cm long	- 7≤d<8 mm - Focal stenosis with d <7mm, and < 3cm length	- d<7 mm - stenosis with d <7mm and > 3cm length - >1 focal stenosis
Sealing Length (L)	L>30 mm	20≤L<30 mm	10≤L<20 mm	L<10 mm
Sealing diameter (d)	D<12.5 mm	12.5≤d≤14.5 mm	14.5< d ≤17mm	d>17 mm

Modified from Chaikoff et al


2008
1.93 cm
2010
1.40 cm

Aggressive Approach to Sealing



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Demographics: No Difference

	Early Cohort n (%)			Late Cohort n, (%)			p
Mean Age at OR (years)	75.86			76.02			NS
Smoking Status	Never	Current	Former	Never	Current	Former	
	48 (28.7)	42 (25.1)	77 (46.1)	15(11.6)	35(27.1)	79(61.2)	0.001
Sex	Female	Male		Female	Male		
	17 (10.2)	150 (89.8)		12 (9.3)	117 (90.7)		NS
COPD	Absent	Present		Absent	Present		
	124 (74.3)	43 (25.7)		90 (69.8)	39 (30.2)		NS
Hypertension	45 (26.9)	122 (73.1)		29 (22.5)	100 (77.5)		NS
Dyslipidemia	78 (46.7)	89 (53.3)		56 (43.4)	73 (56.6)		NS
Diabetes Mellitus	128 (76.6)	38 (22.8)		103 (79.8)	26 (20.2)		NS
Ischemic heart Disease	76 (45.5)	91 (54.5)		69 (53.5)	60 (46.5)		NS
CHF	152 (91)	15 (9)		116 (89.9)	13 (10.1)		NS
Arrythmia	128 (76.6)	39 (23.4)		101 (78.3)	28 (21.7)		NS
PAOD	147 (88)	20 (12)		115 (89.1)	14 (10.9)		NS
TIA/CVA	141 (84.4)	26 (15.6)		113 (87.6)	16 (12.4)		NS
CKD	128 (76.6)	39 (23.4)		98 (76)	31 (24)		NS
Mean ASA Score at OR	2.74			2.85			NS

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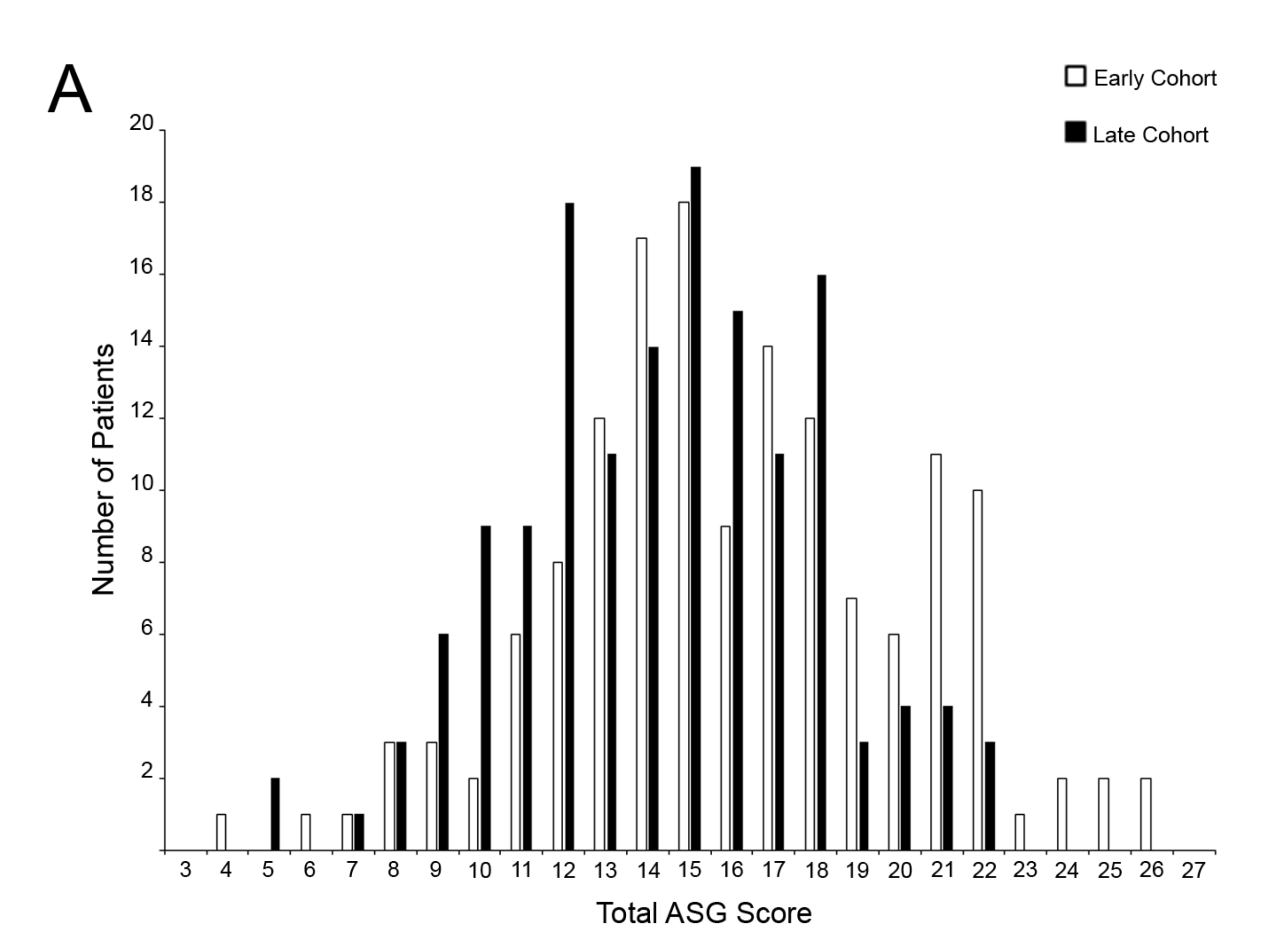
Anatomy Suitable for Infrarenal EVAR Changed

No difference in percentage differences of off IFU treatment between eras



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Anatomy Suitable for Infrarenal EVAR Changed

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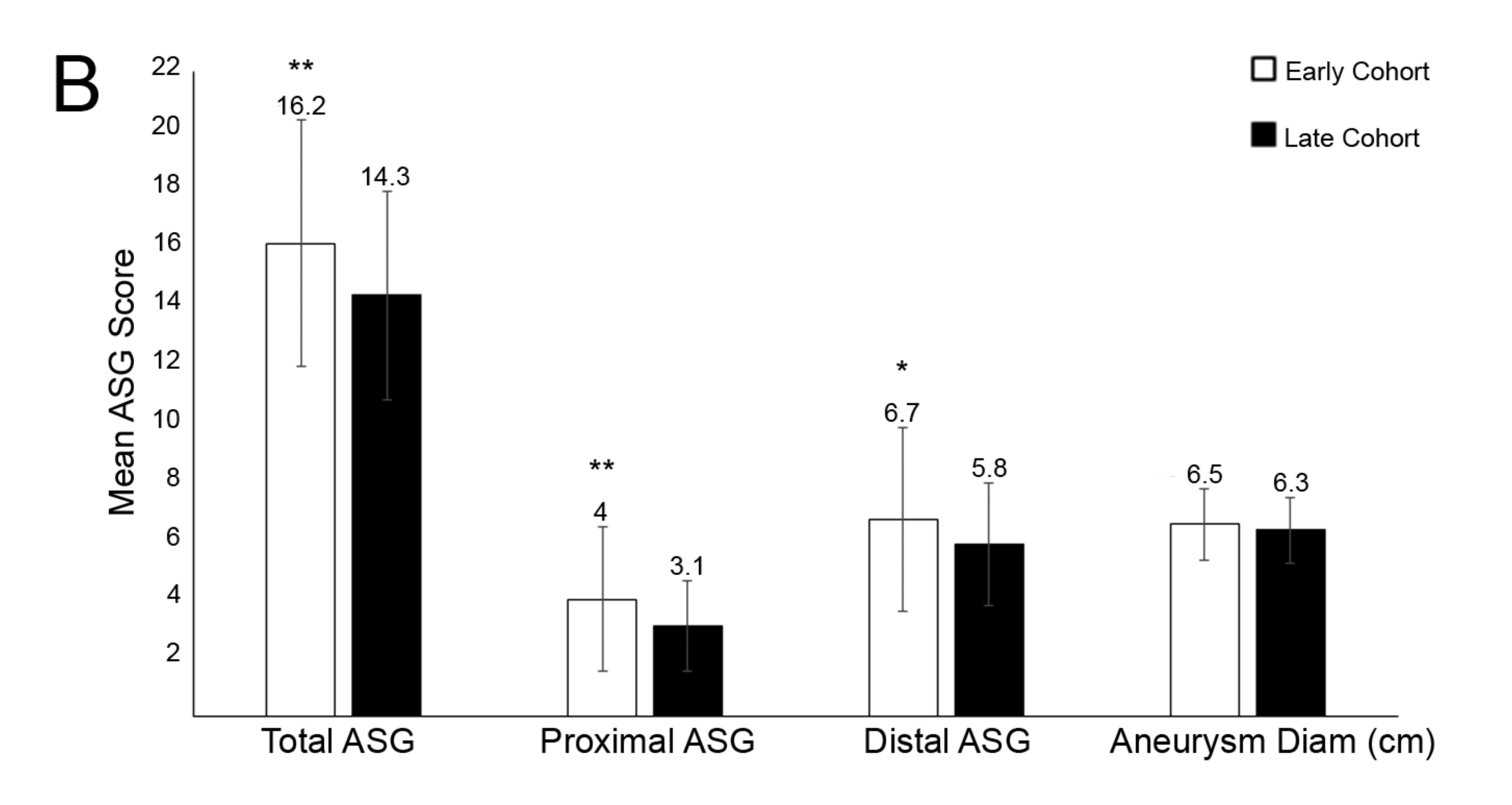

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Increasing Availability of FEVAR means IRAAA has longer Neck Length

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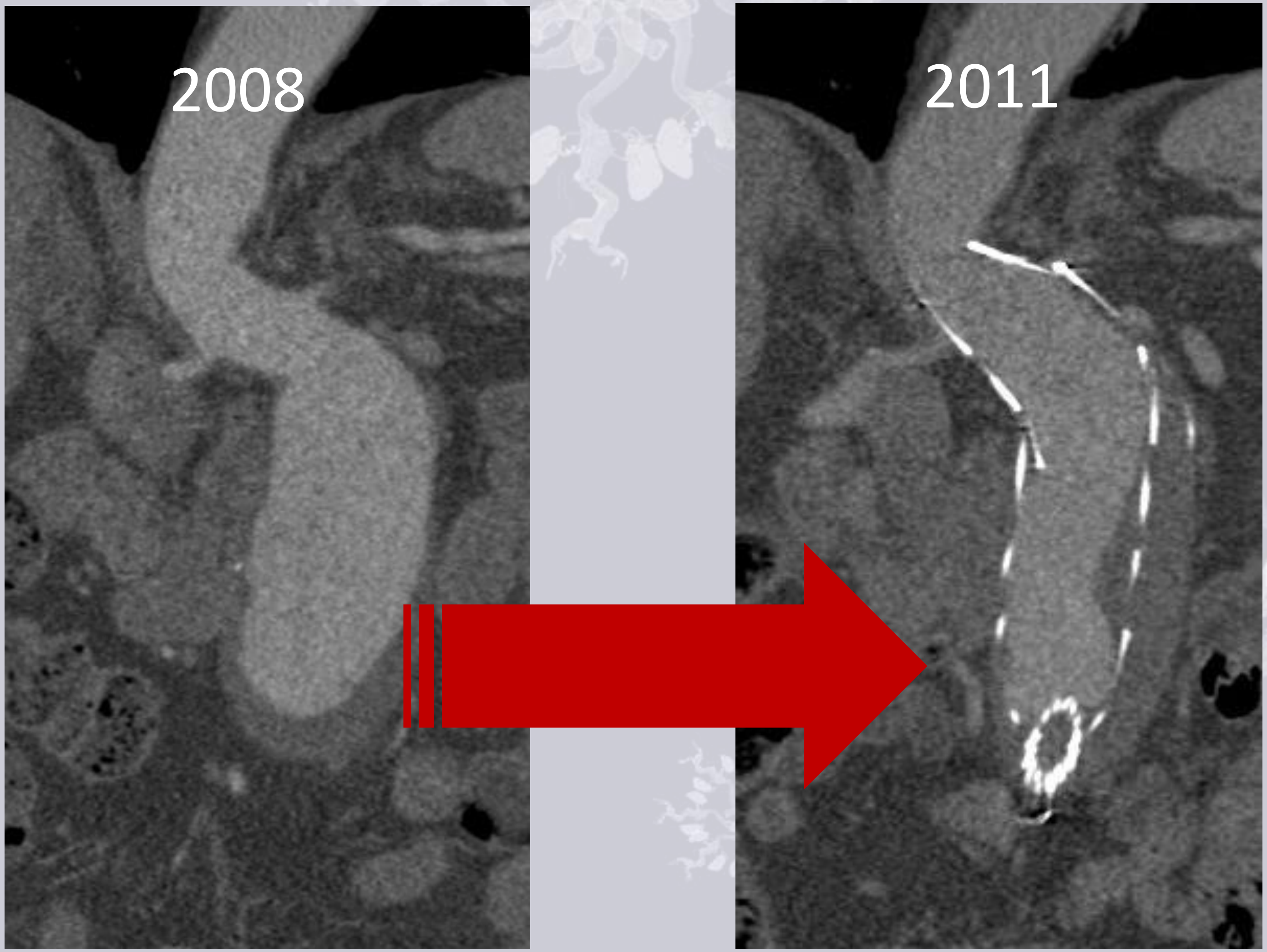
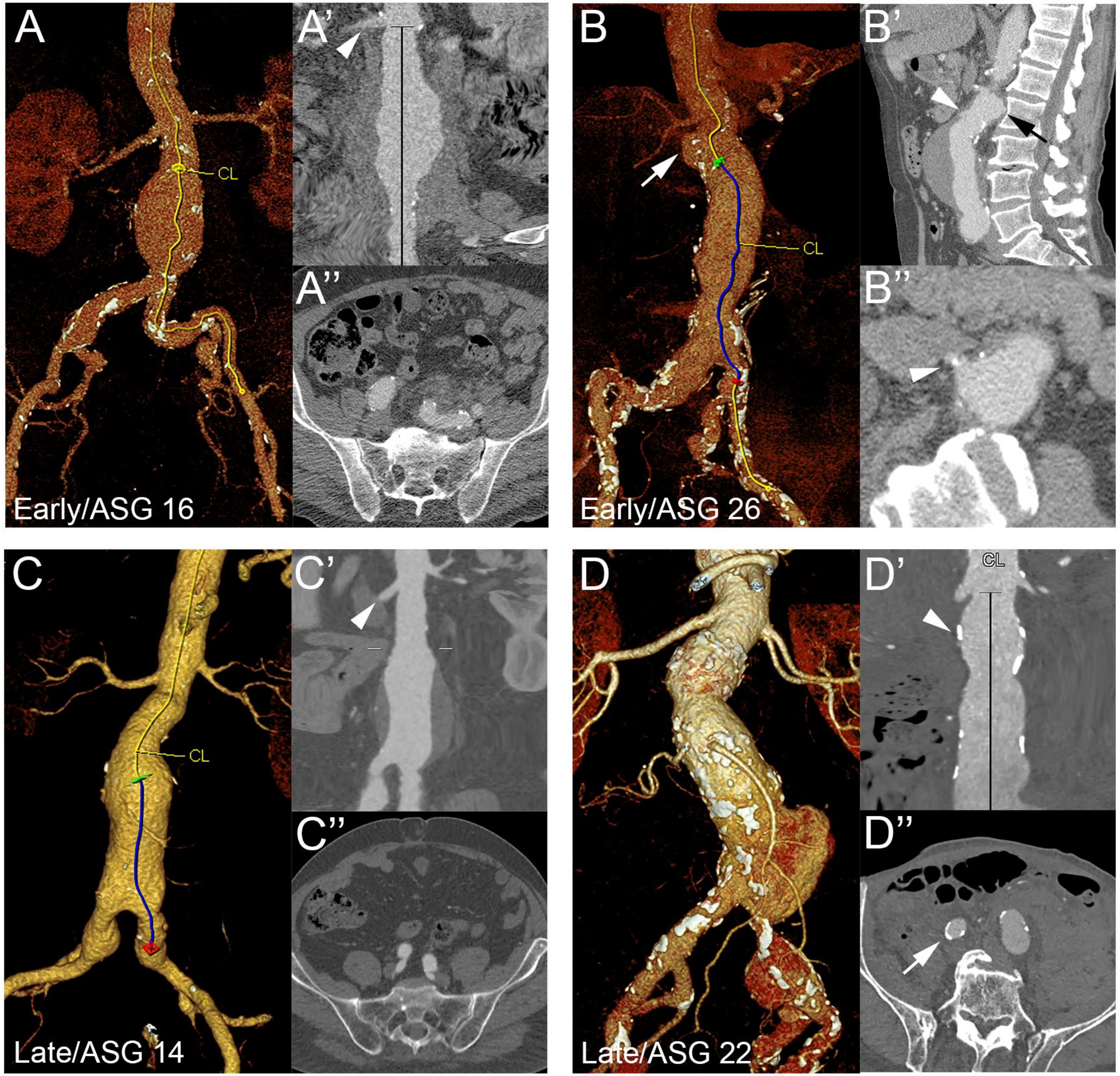
Being ‘On-IFU’ is not sufficient for durability



Anatomic Indiscretions were different



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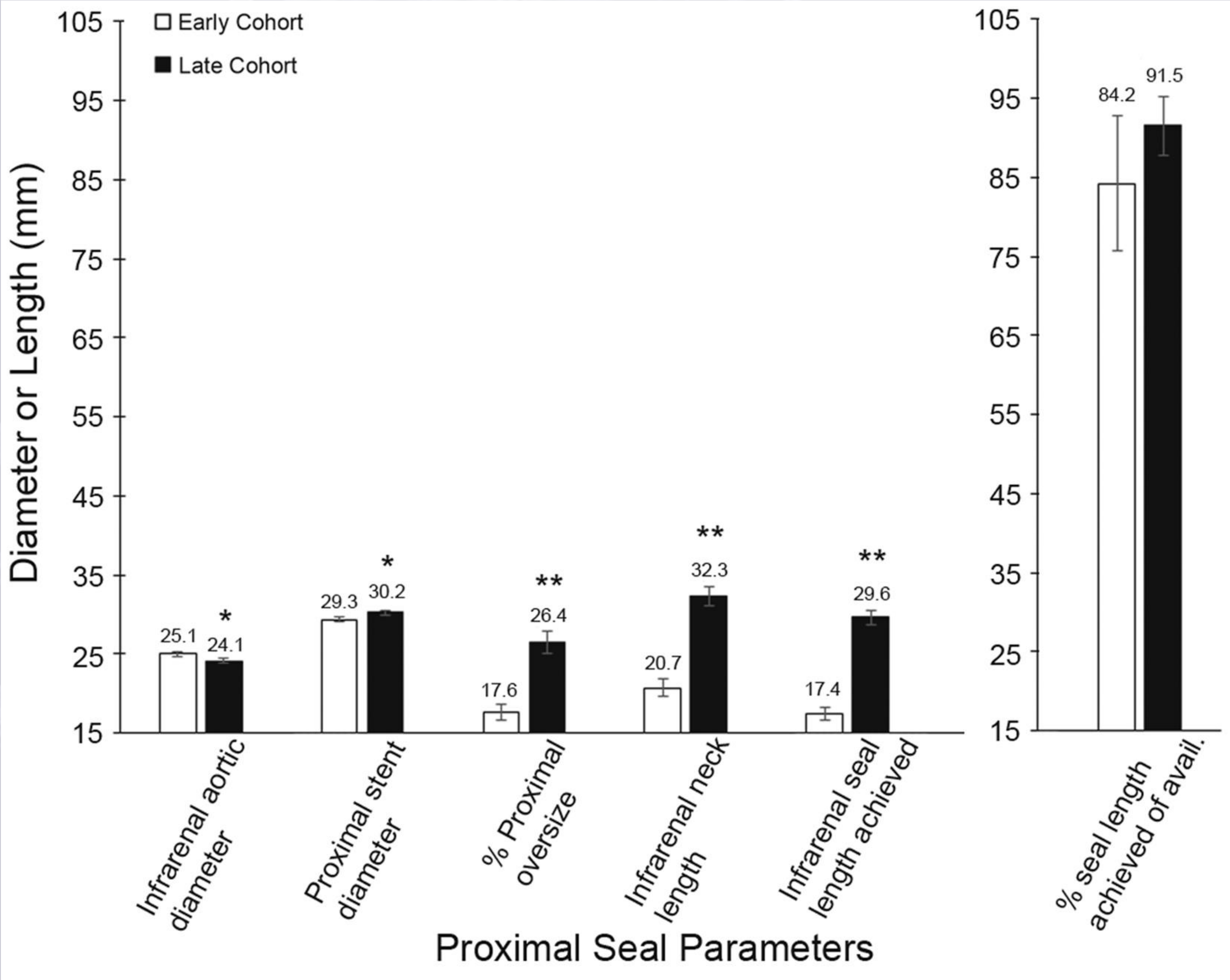
Technical Skill Was Equivalent



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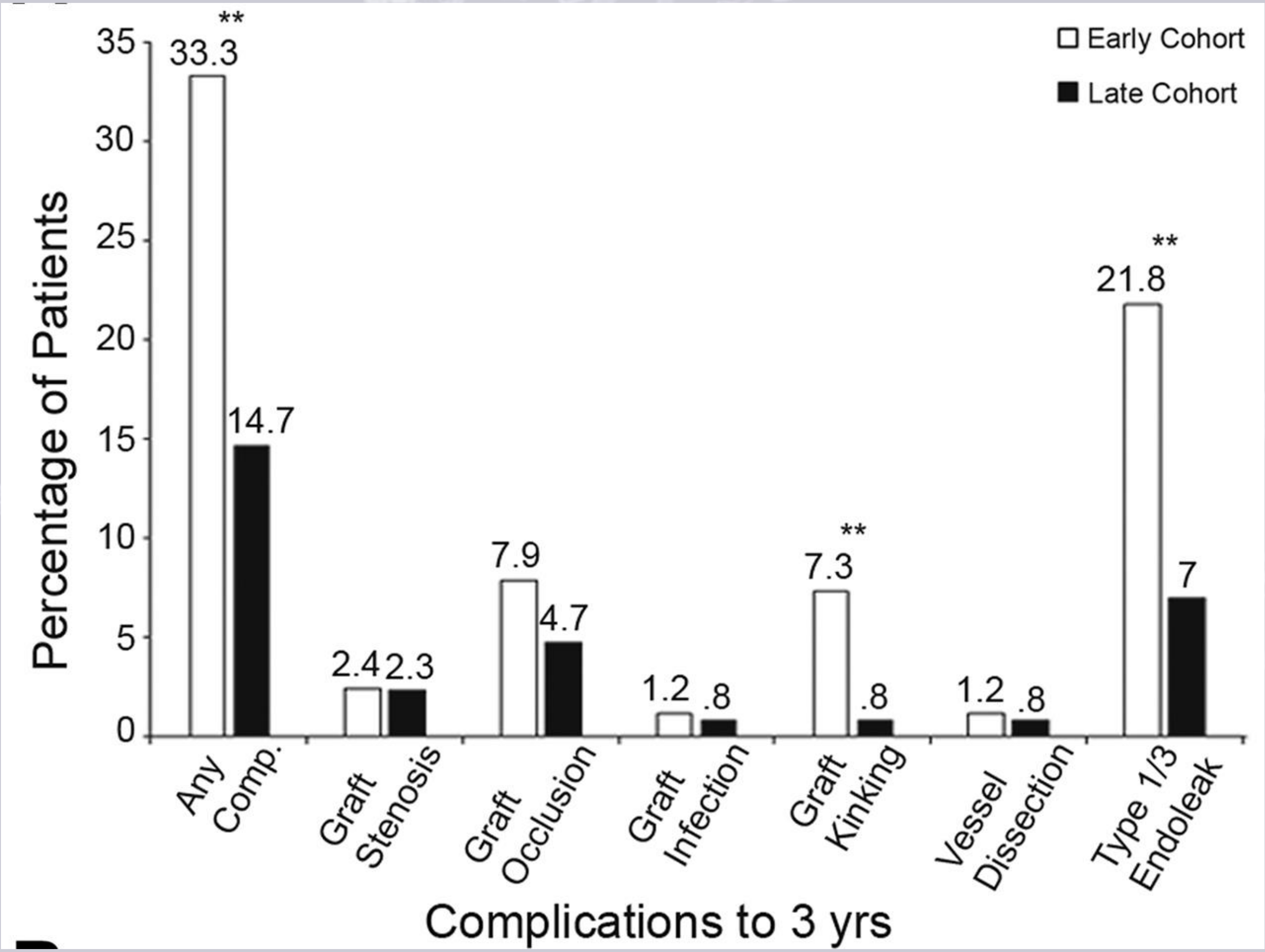
Complications over 3 years



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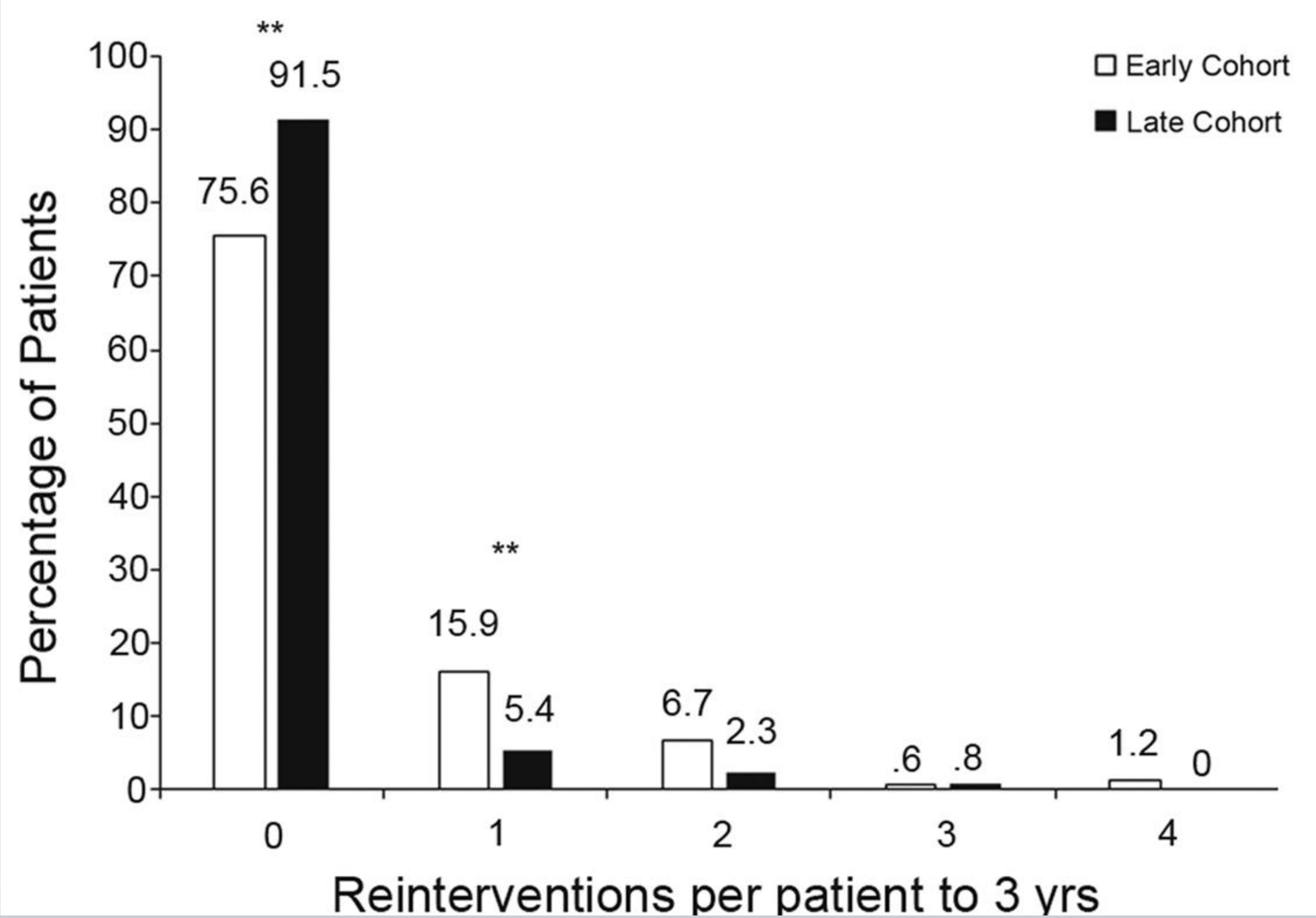
Reinterventions



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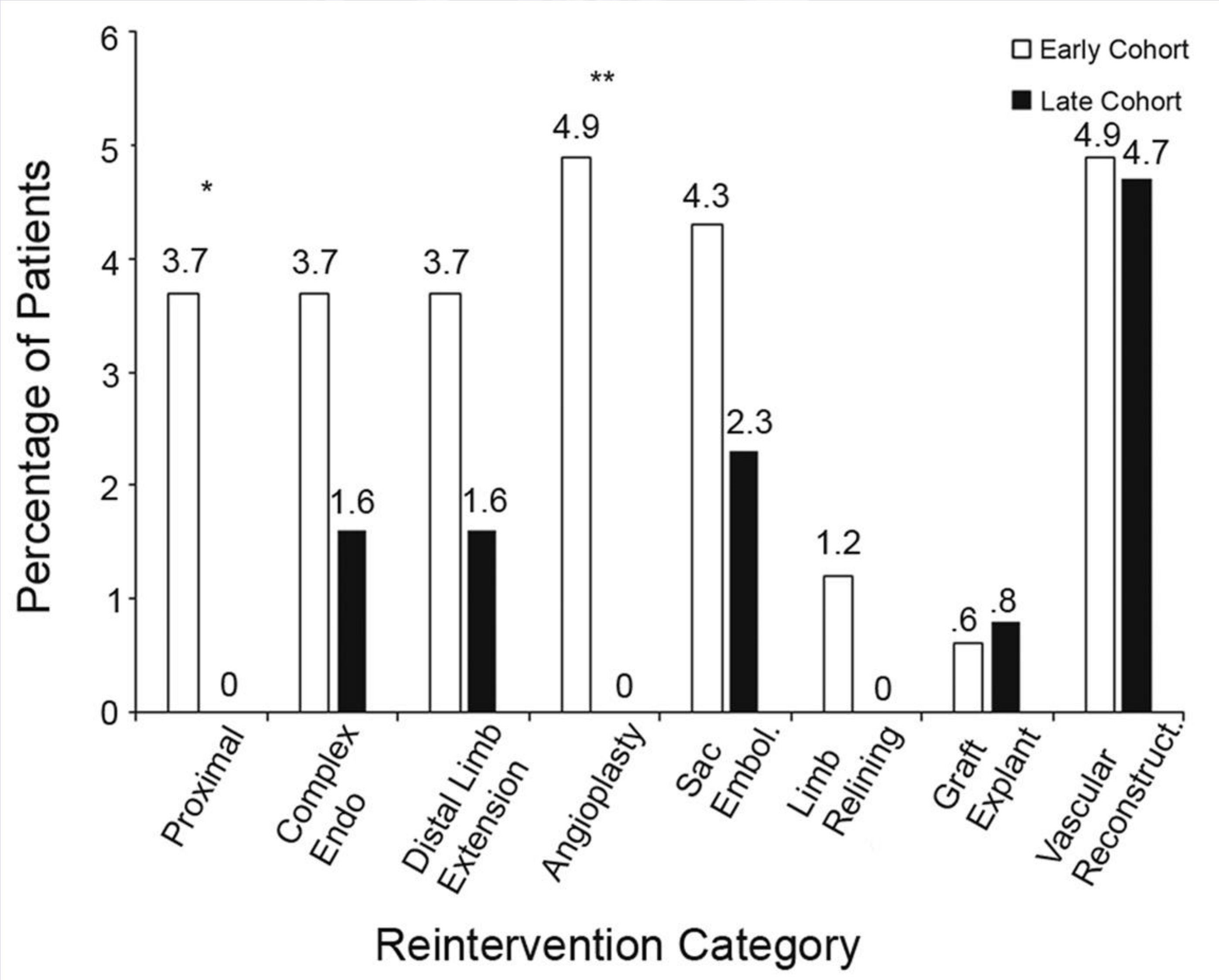
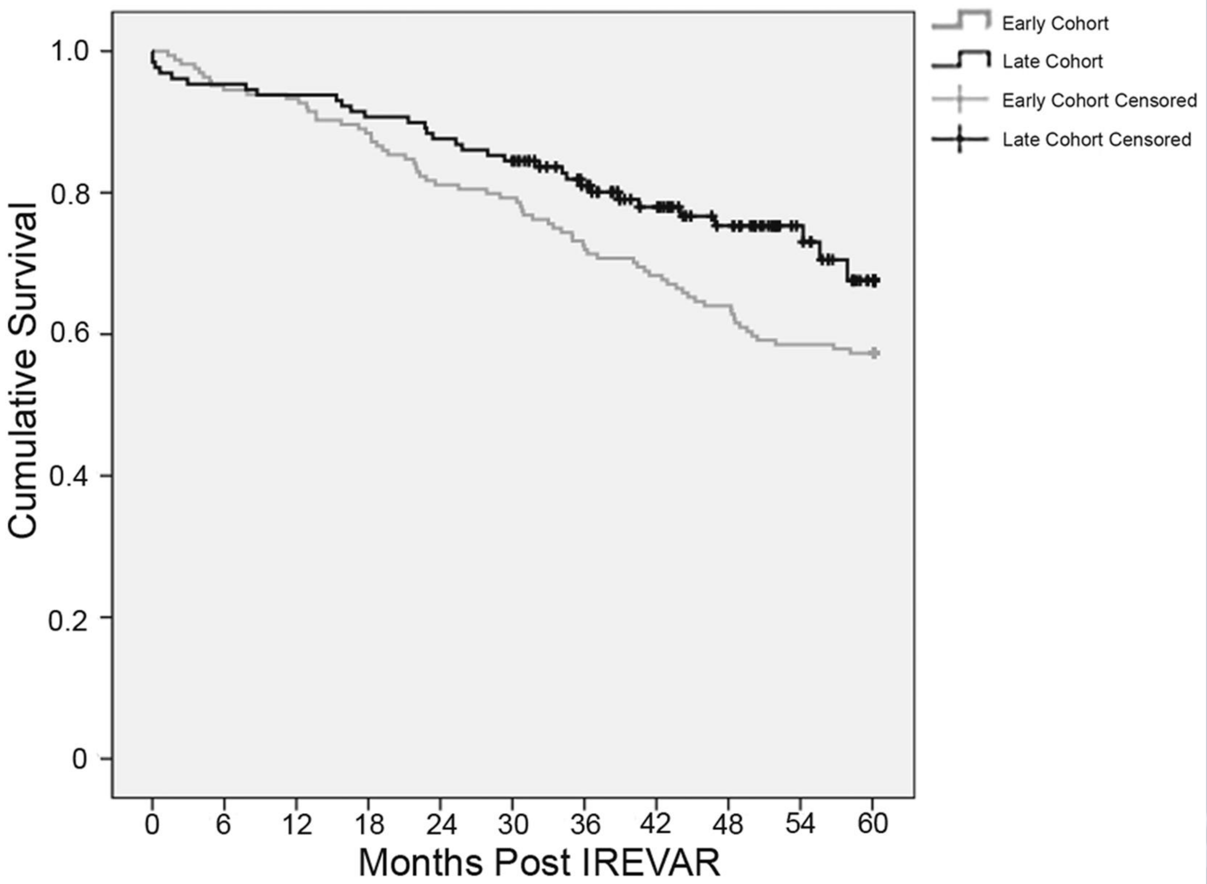
Reinterventions



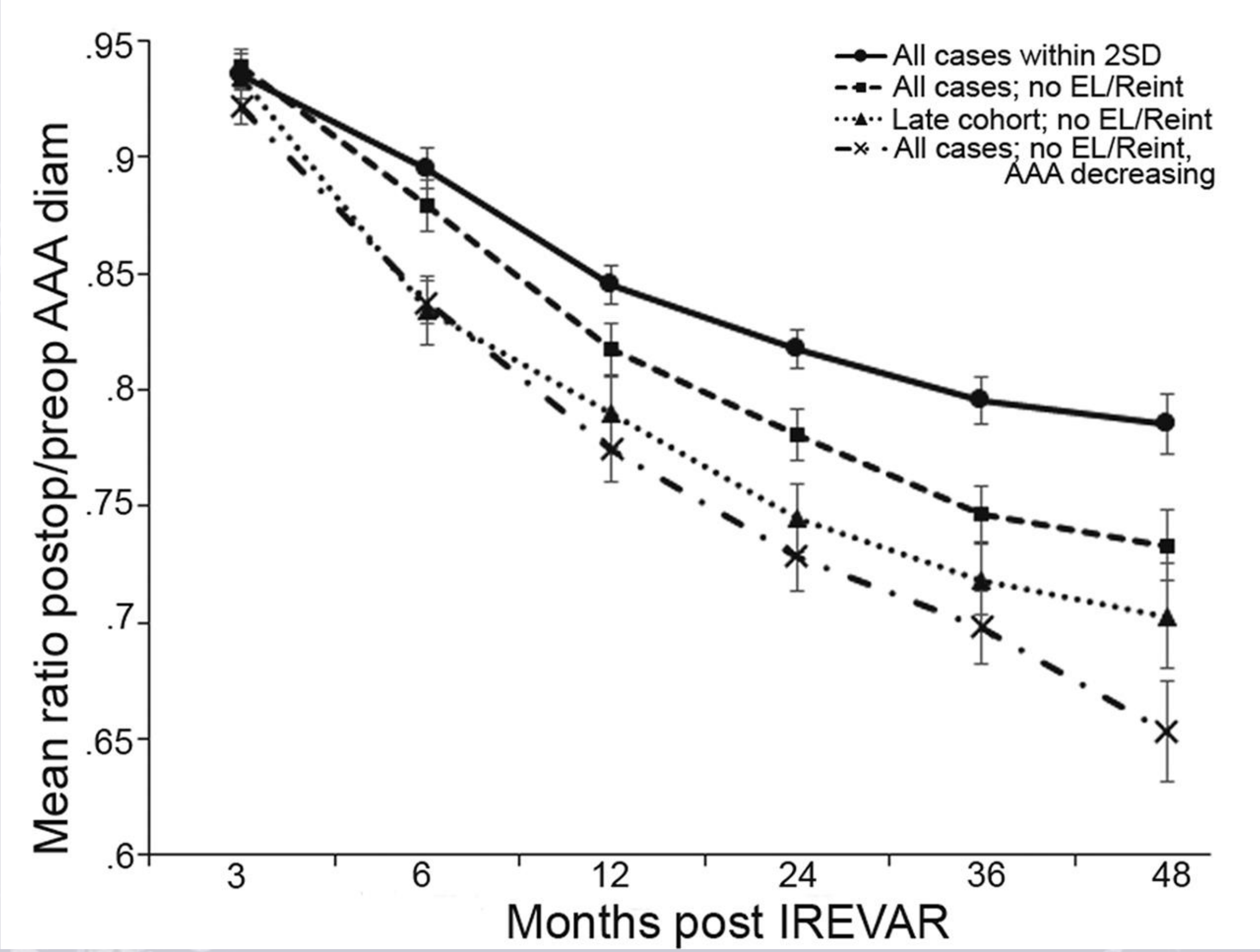
Witheford et al, 2021

Not just durability… These decisions impact survival



Early Cohort					
# at risk	152	133	117	104	93
# events	12	31	47	60	71
K-M estimate	.927	.811	.713	.634	.433
SE	.02	.031	.035	.038	.039
Late Cohort					
# at risk	121	113	90	53	23
# events	8	16	24	29	32
K-M estimate	.938	.876	.81	.753	.676
SE	.021	.029	.035	.041	.056

Track progress of the durable cases at your centre



Ratio of

$$\frac{\text{POST op diameter}}{\text{Pre op diameter}}$$

Witheford et al, 2021

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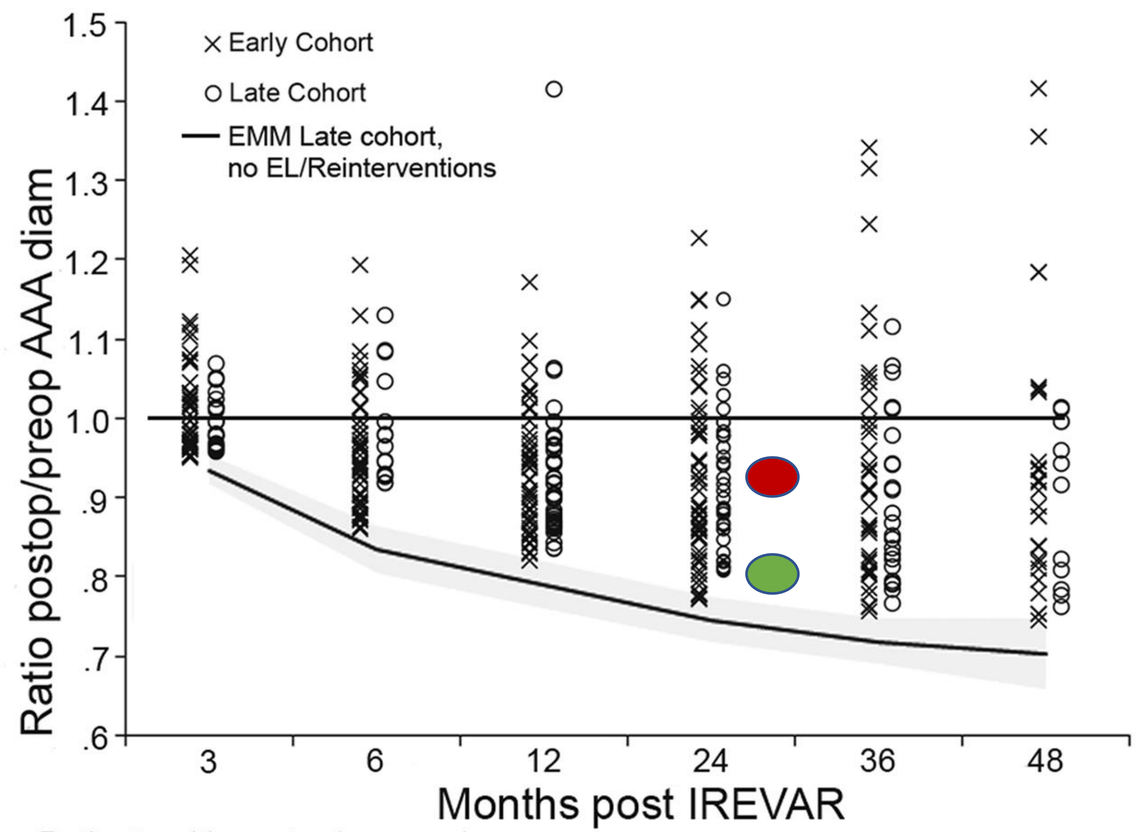
Can you predict the future?



Patients with postop/preop >1

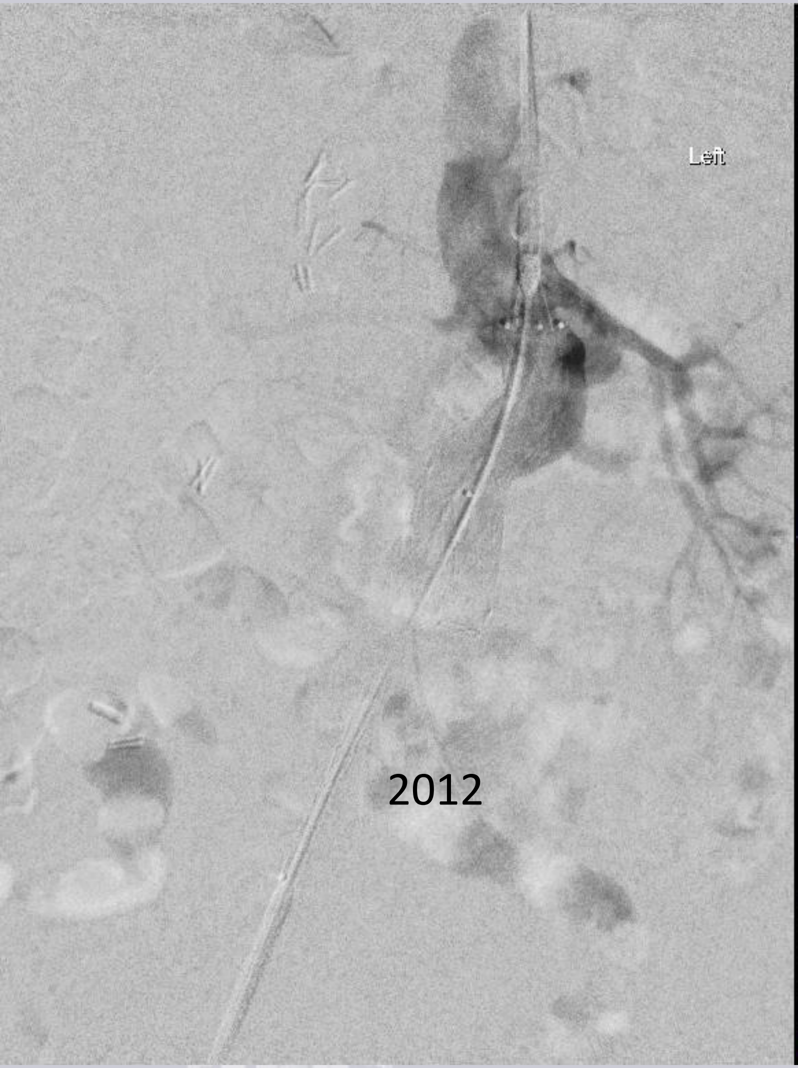
	3	6	12	24	36	48
Early n (%)	32 (19.4)	19 (11.5)	13 (7.9)	14 (8.5)	12 (7.3)	8 (4.8)
Late n(%)	20 (15.5)	6 (4.7)	7 (5.4)	7 (5.4)	5 (3.9)	4 (3.1)

Pre op: 63mm, 2 years post op: 59mm = 0.93

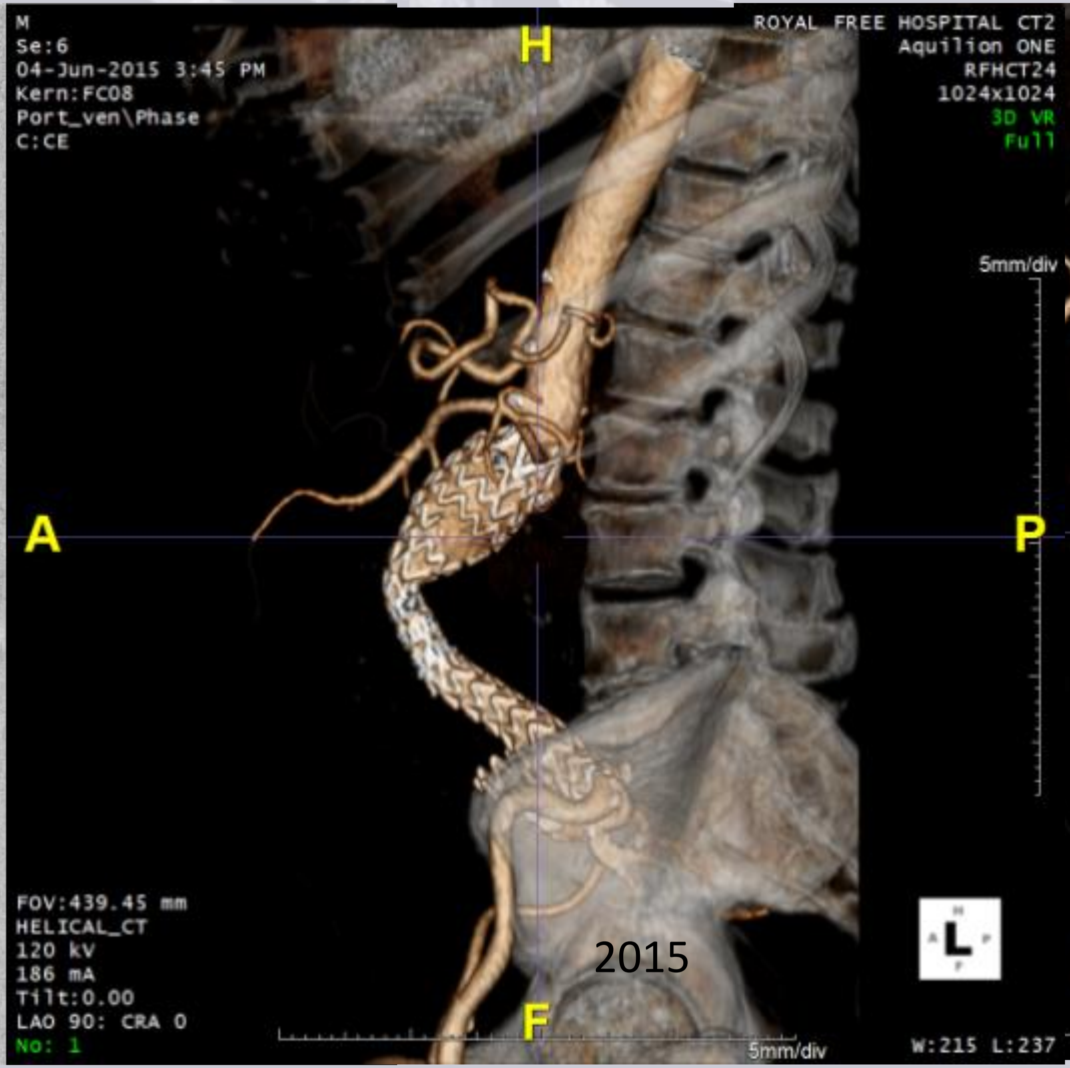
Pre op: 63mm, 2 years post op: 53mm = 0.84

Witheford et al, 2021

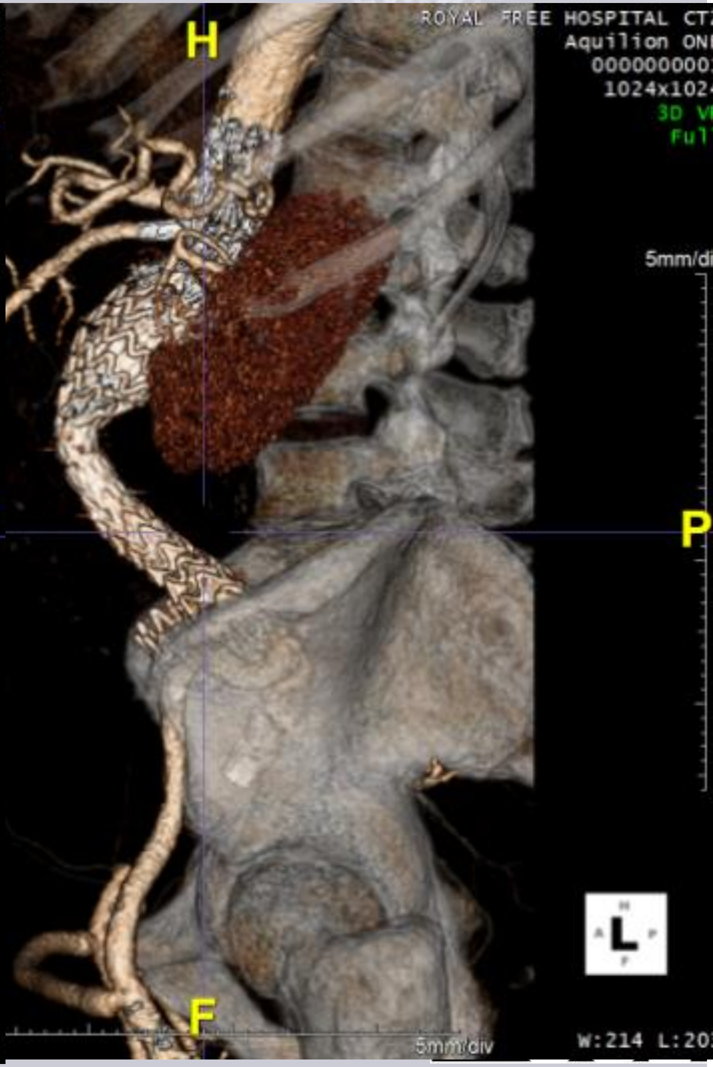
If you have to seal above the renals, COMMIT!



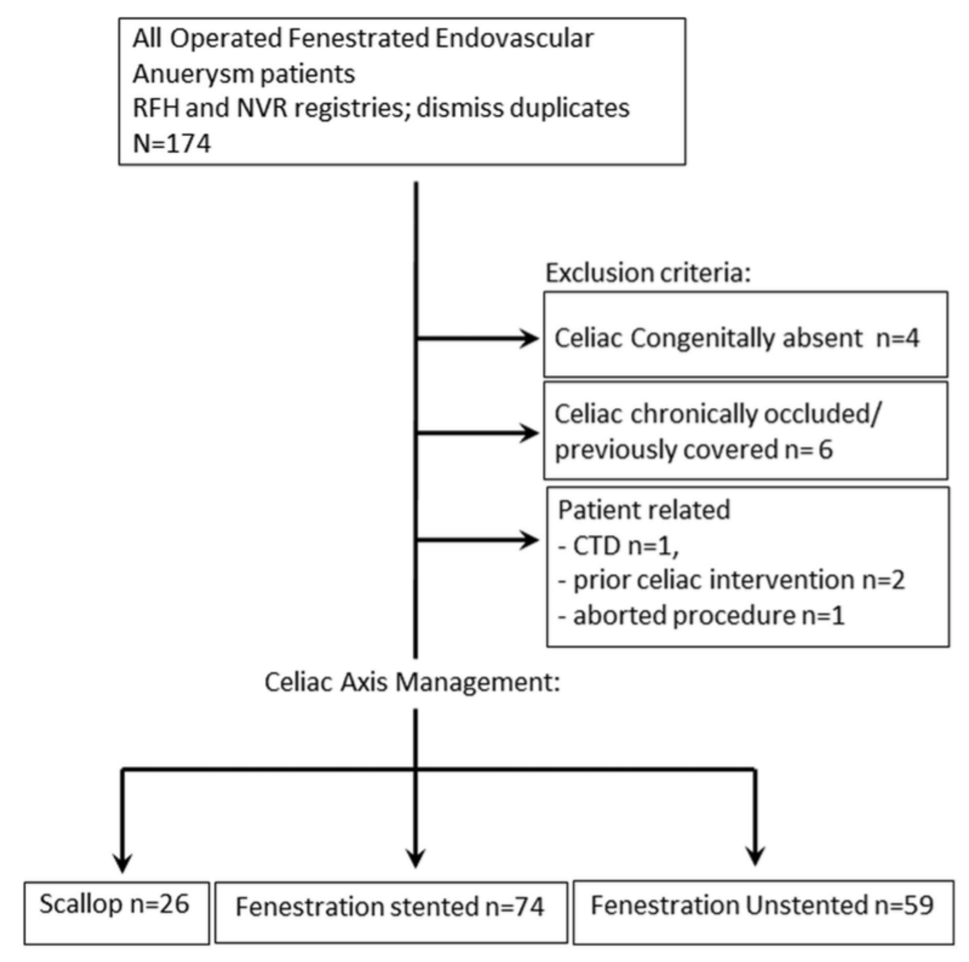
2012



2015



More evidence for aggressive sealing: The Celiac



- 159 Patients, Juxtarenal and group IV TAAA
- Similar technical success across three groups
- Type III endoleaks higher in the scallop group
- Celiac occlusion was clinically silent across all groups.
- Celiac Scallop design increased the risk of instability in the other branches (OR 0.43, P<0.01)

Witheford et al, Submitted EJVES 2021

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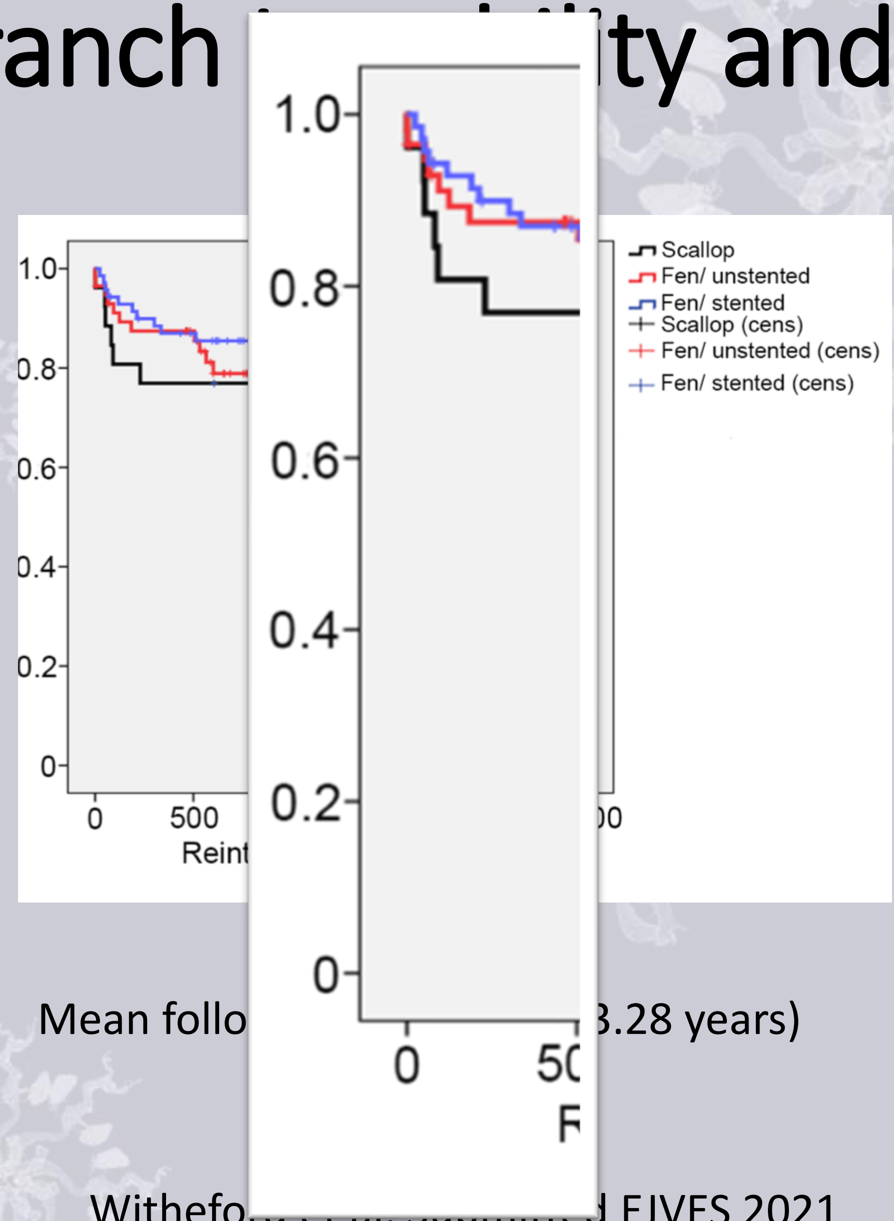
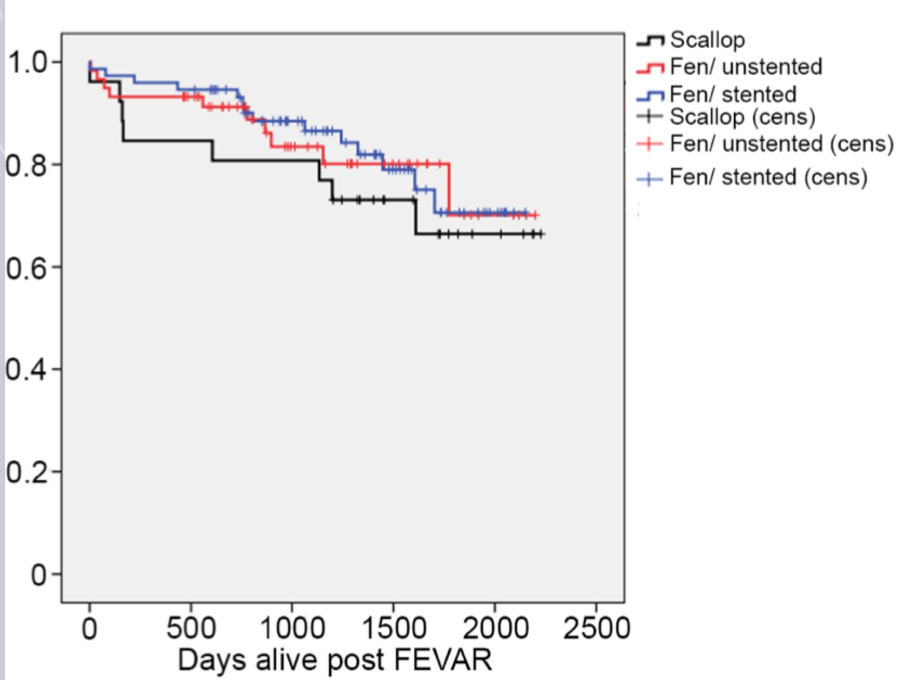
Branch ity and Including the Celiac



Mean follo 3.28 years)



Scallop				
# at risk	22	21	19	5
# events	6	5	7	8
KM estimate	.84	.81	.73	.66
SE	.07	.08	.09	.1
Fen/unstented				
# at risk	50	28	15	4
# events	4	8	9	10
KM estimate	.93	.84	.80	.7
SE	.03	.06	.06	.1
Fen/Stented				
# at risk	70	48	25	7
# events	4	8	12	14
KM estimate	.94	.89	.79	.71
SE	.03	.04	.06	.08

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Care
About Social Deprivation

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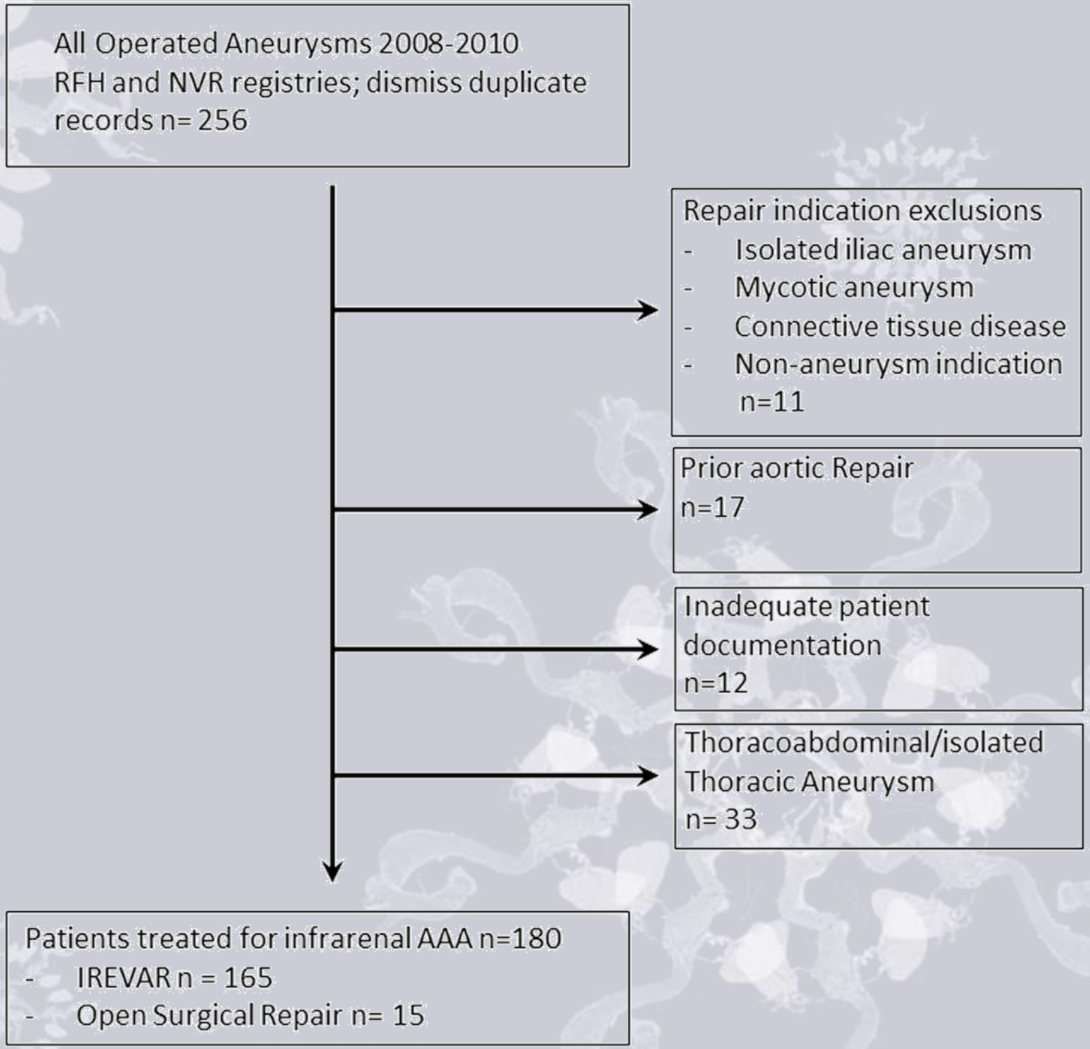
What about Deprivation?

- 2008-2010
- Tertiary referral centre
- 1.5 million catchment area



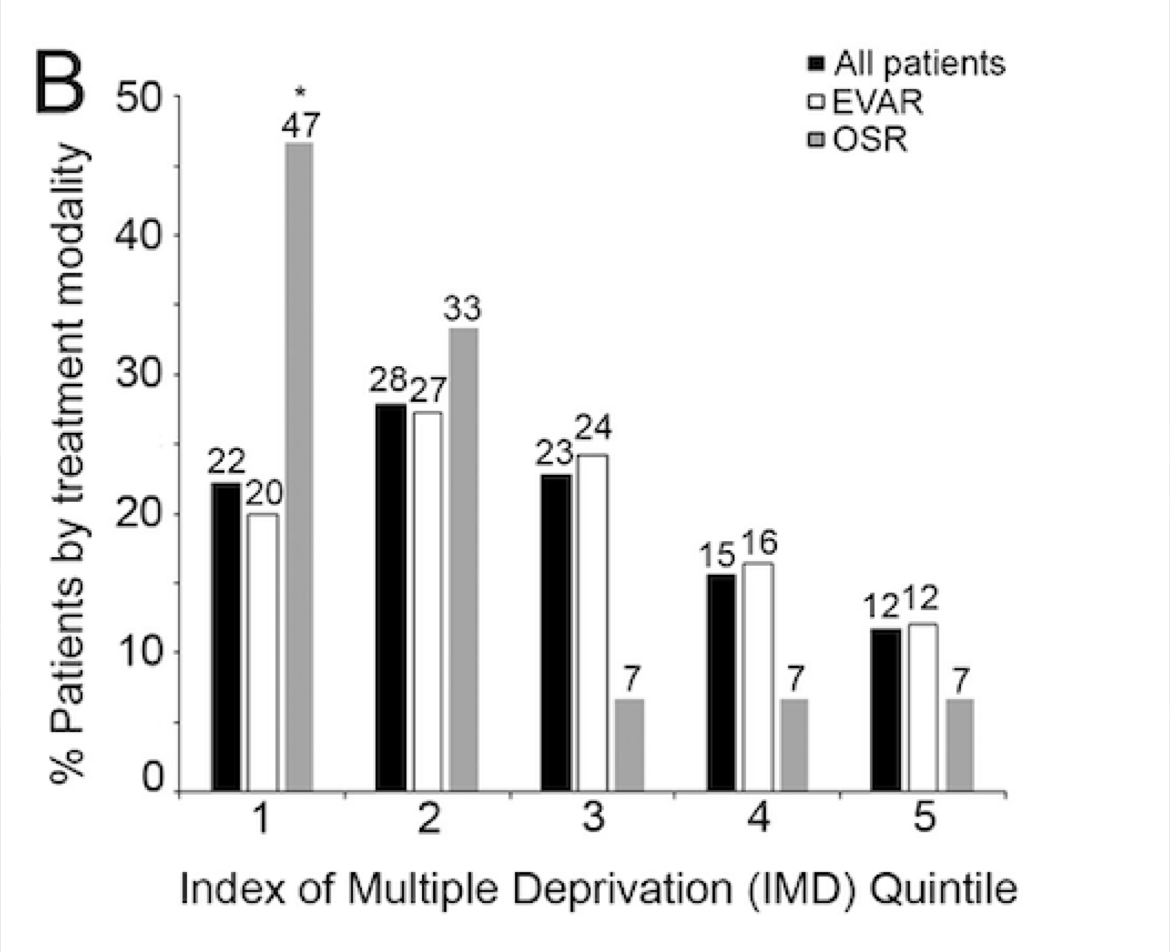
Witheford et al, submitted 2021

Social Deprivation Impact

No differences in

- their elective/emergent presentation
- perioperative outcomes
- clinical or imaging follow-up
- reintervention-free survival.

Disparities in Treatment Modality



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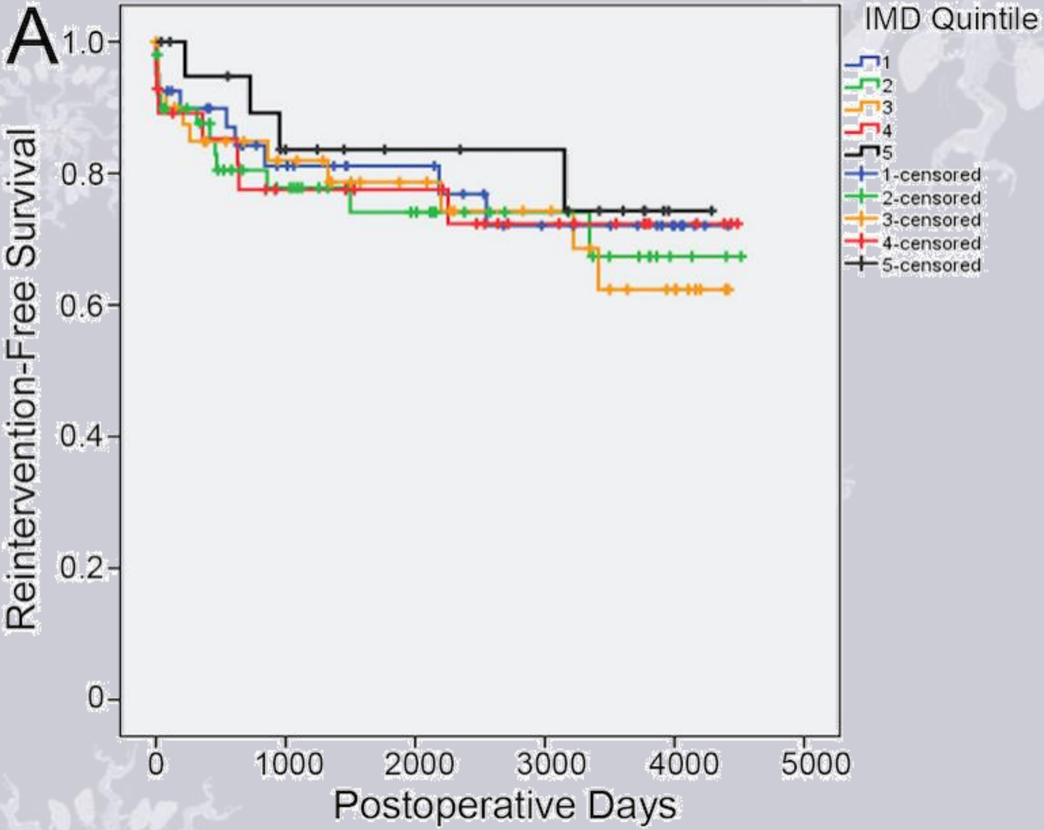
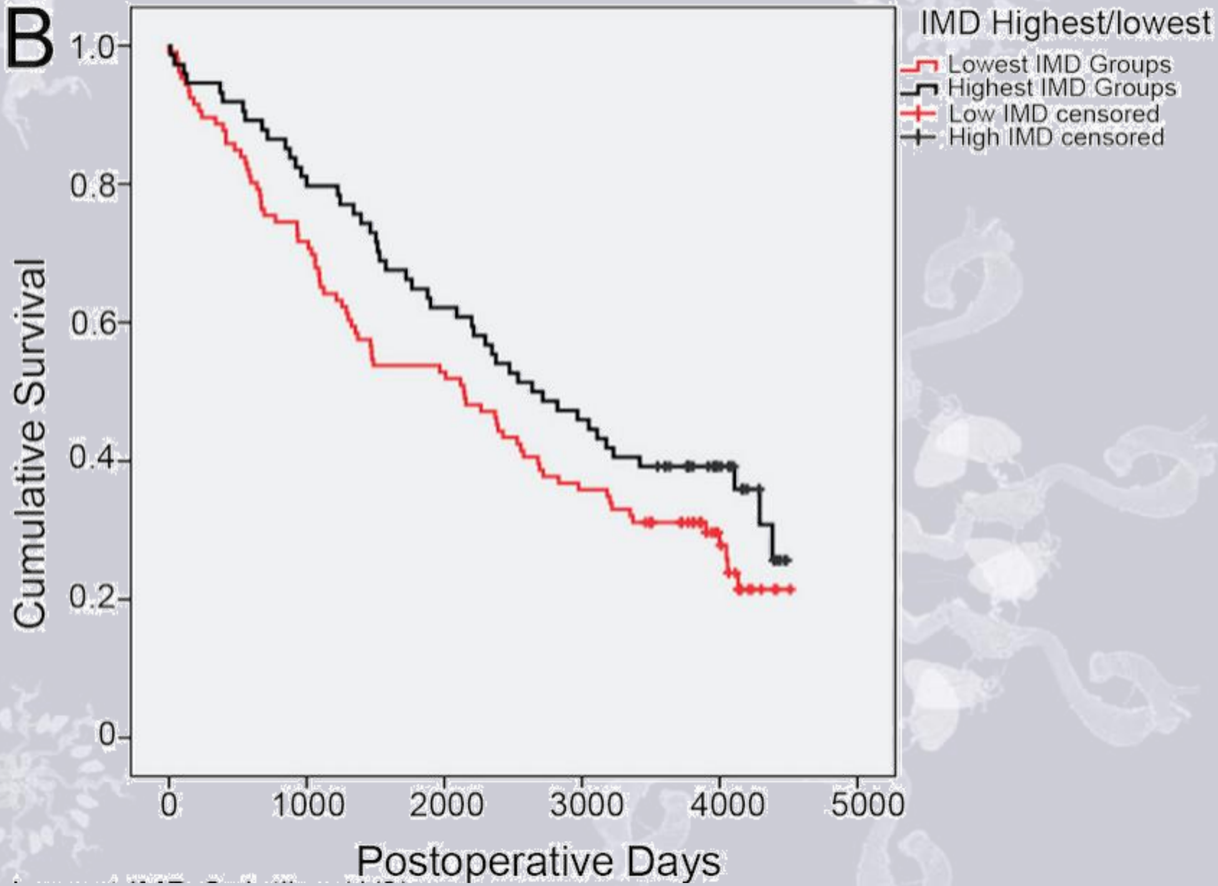
Impact of Social Deprivation on Outcome: Poorer All Cause Mortality Longterm





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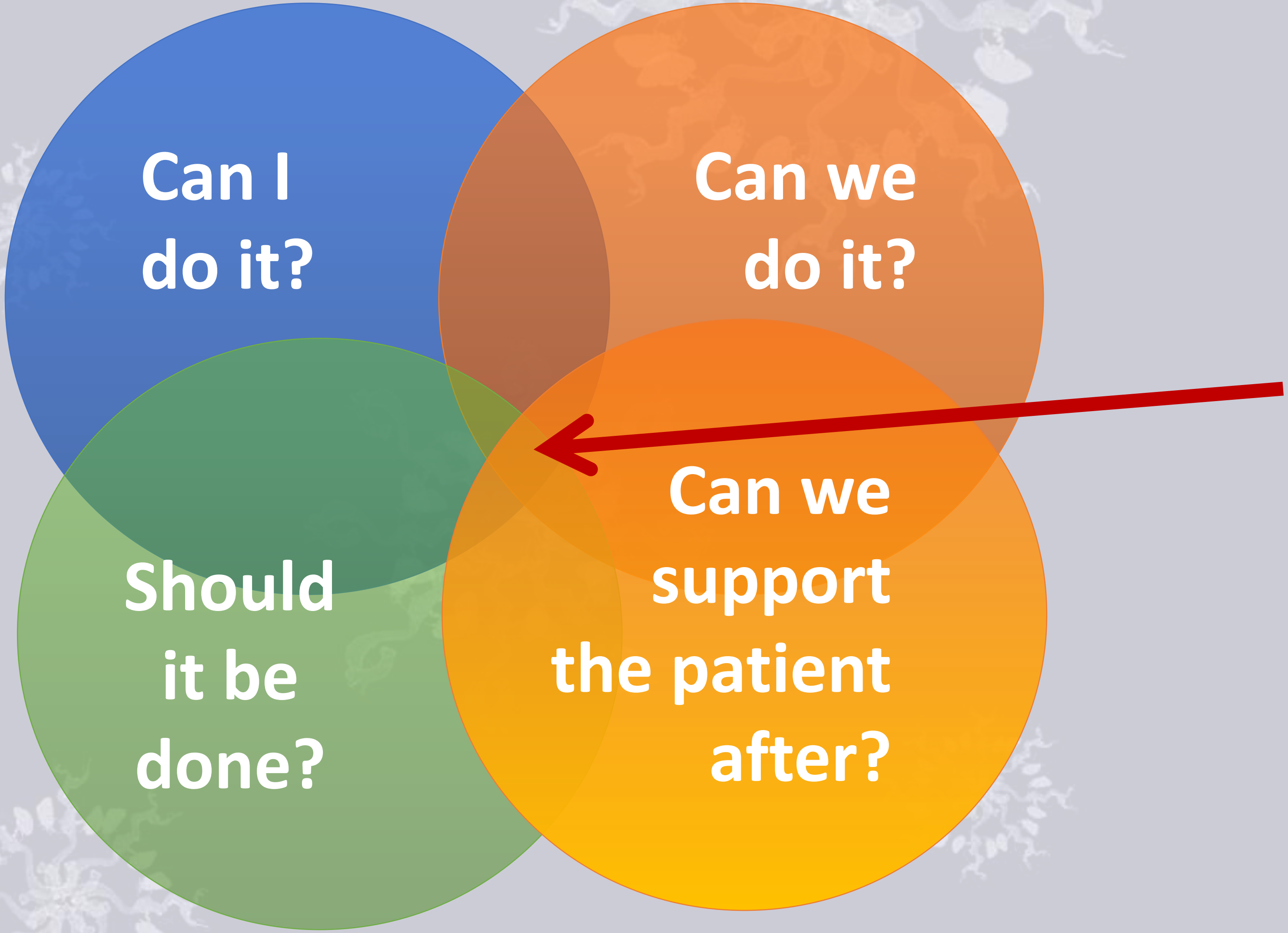
Improving Durability Requires Reflection



This is the centre where I want my aneurysm repaired!

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Happy Holidays….