



23RD INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES in aortic endografting 2019
LIVERPOOL UNITED KINGDOM **MAY 23-24**



Stop Bending the Rules:

Why you should avoid off-label EVAR!

Isabelle Van Herzeele

www.critical-issues-congress.com



Disclosure

Speaker name:

.....Isabelle Van Herzeele

- I have the following potential conflicts of interest to report:
 - Consulting
 - Employment in industry
 - Shareholder in a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest

I. EVIDENCE:

OFF-LABEL EVAR should be AVOIDED!!

- Selection

- Patient Co-morbidities

Recommendation 62	<i>ESVS AAA guidelines</i>	Class	Level
In patients with limited life expectancy, elective abdominal aortic aneurysm repair is not recommended .		III	B

Recommendation	<i>SVS AAA guidelines</i>	Class	Level
We suggest informing pts contemplating open aneurysm repair or EVAR of their VQI perioperative mortality risk score.		II weak	C

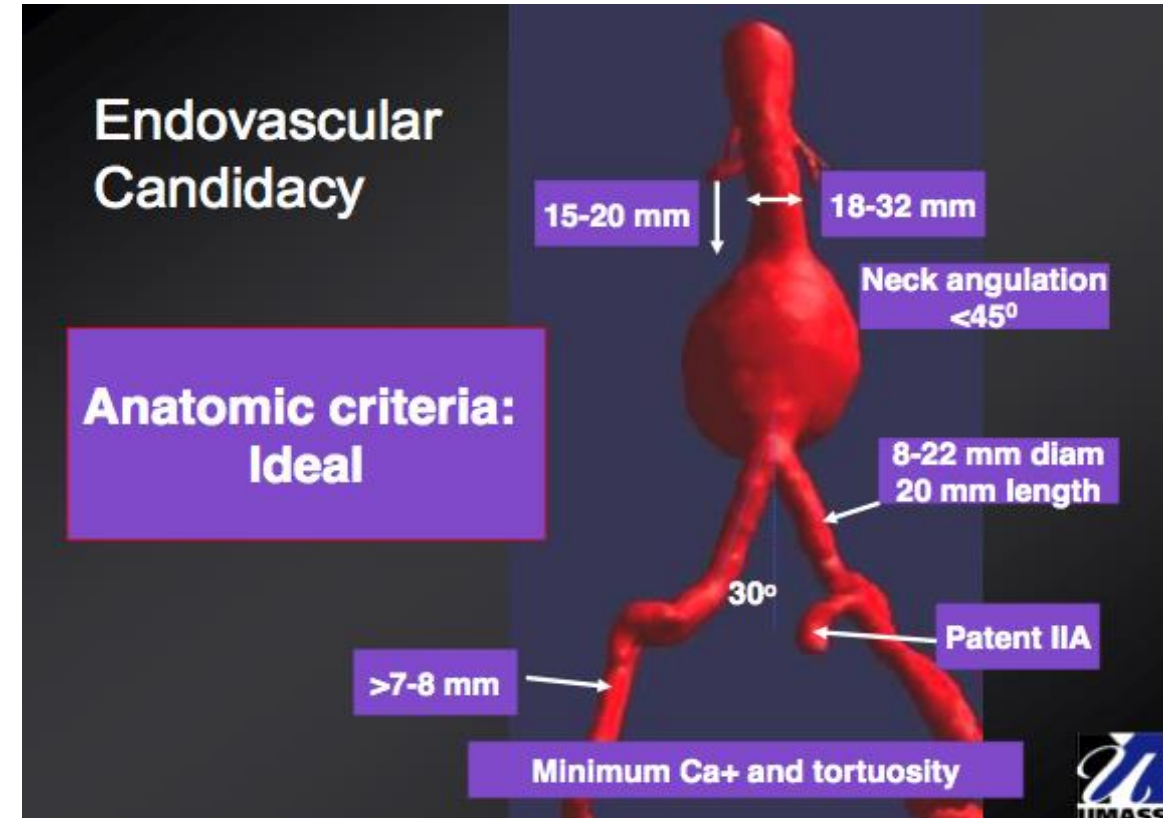
- Anatomical suitability

- **Operator/Centre** - higher annual caseload, lower operative mortality

OFF-LABEL EVAR should be AVOIDED!!

Selection

- Patient criteria
 - Co-morbidities
- Anatomical suitability
 - CTA ENTIRE AORTA
 - Diameter >54 mm (>50 in women)
 - Dedicated postprocessing software analysis
 - Sizing and planning
 - **Proximal landing zone**
 - Distal landing zone
 - Access

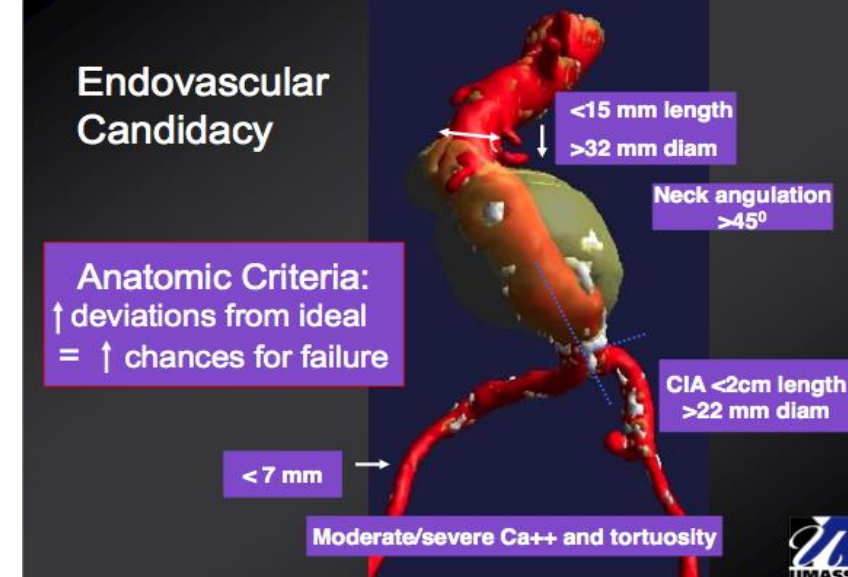


- Operator/Centre – higher annual caseload, lower operative mortality

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

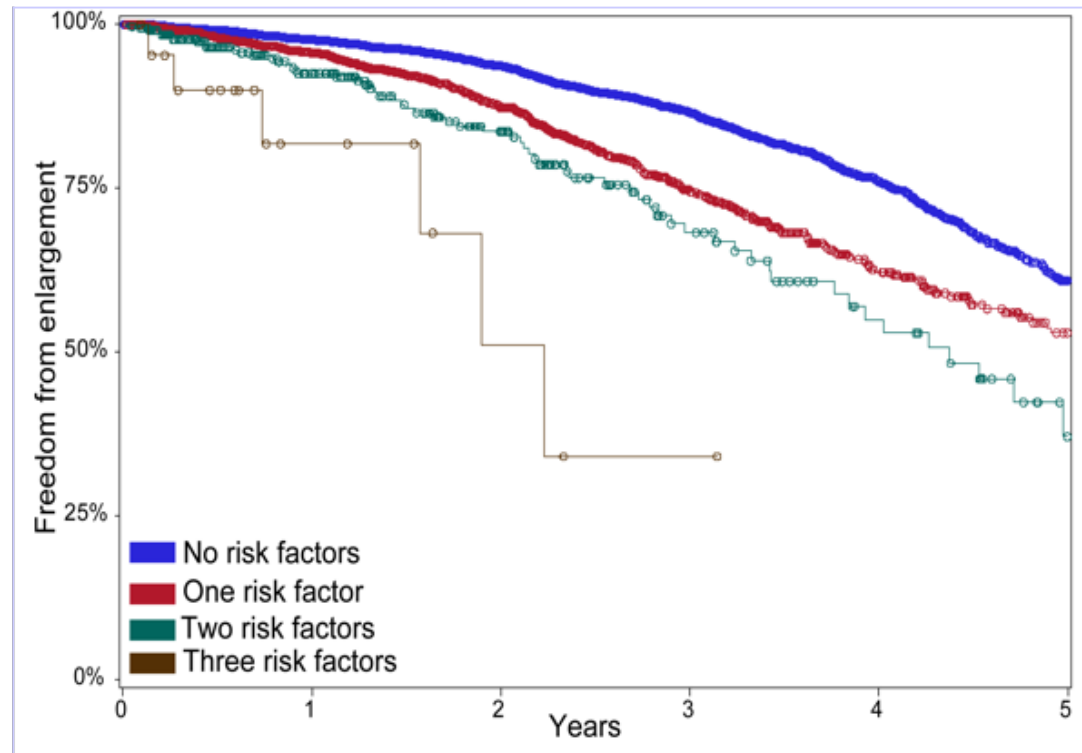
Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD
 Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

- N= 10 228 – 16% Females
- ⊖ AAA mean 54.8 mm (40.6% ≥ 55 mm)



Neck	Conservative IFU	Liberal IFU	Outside IFU
Length (mm)	>15 58%	>10 18%	<10 24%
Diameter (mm)	<28 91%	<32 6%	>32 3%
Angulation °	<45	<60	>60
	42%	69%	

Predictors of Sac Growth at 5 Years



Freedom from Sac Enlargement		
1 Yrs	3 Yrs	5 Yrs
97.7%	86.5%	60.9%
99.4%	74.4%	52.9%
92.5%	68.2%	37.1%
81.8%	34.1%	

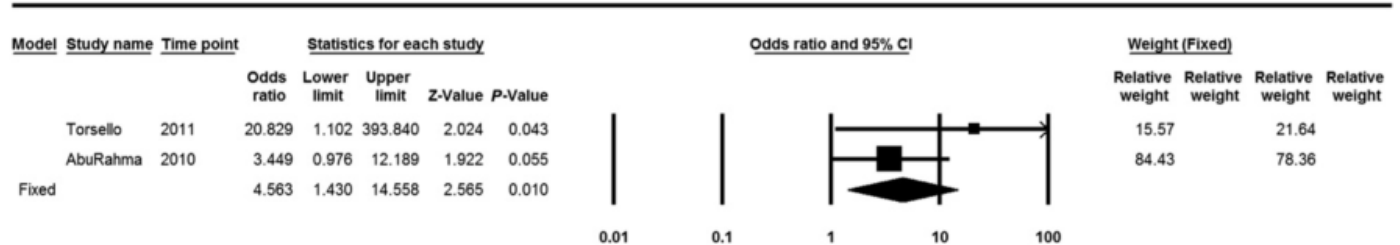
- Diameter neck at lowest renal > 28 mm
- Aortic neck angle > 60°
- Age > 80 years
- Either or both iliacs > 20 mm

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

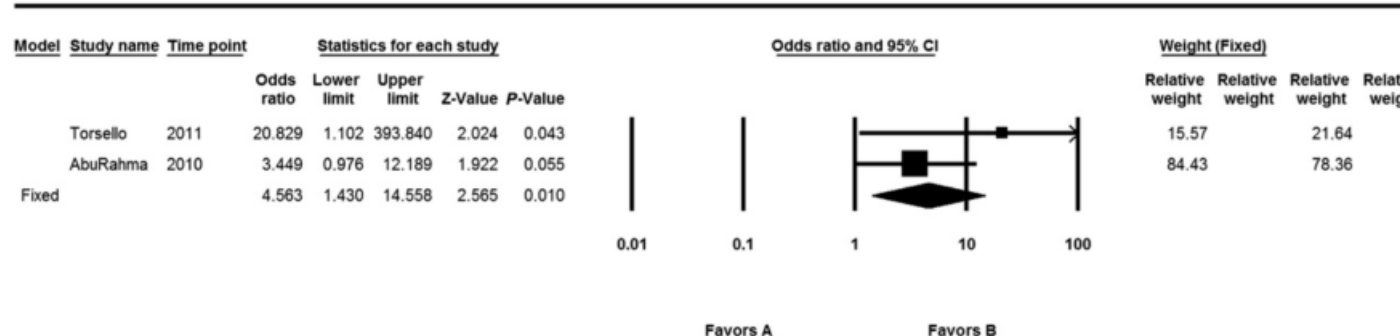
George A. Antoniou, MD, PhD,^a George S. Georgiadis, MD,^b Stavros A. Antoniou, MD,^c Ganesh Kuhan, MD, FRCS,^a and David Murray, MD, FRCS,^a Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany

J Vasc Surg 2013; 57: 527-38

7 studies with control group
 1559 pts: 845 FNA vs. 714 HNA
 Definition HNA varied



Type IA endoleak at 1 yr:
4.5 times higher



Aneurysm-related mortality
 at 1 yr:
9 times higher

Endovascular Aortic Aneurysm Repair in Patients with Hostile Neck Anatomy

Philip W. Stather, MRCS; John B. Wild, MRCS; Robert D. Sayers, MD, FRCS;
 Matthew J. Bown, MD, FRCS; and Edward Choke, FRCS, PhD

J Endovasc Ther 2013; 20: 623-37

16 studies

8920 FNA – 3039 HNA

30-day Early type IA endoleak

OR 2.92; 1.61-5.30, p<.001

Late type IA endoleak

OR 1.71; 1.31-2.23, p<.001

	Favorable/ Hostile Neck	Criteria for Hostile Neck Anatomy					
		Length, mm	Diameter, mm	Angulation, °	Thrombus	Taper	Other
Greenberg 2000 ²⁶	42/13	<10	N/A	N/A	N/A	N/A	N/A
Sternbergh 2002 ²⁴	71/10	N/A	N/A	>60	N/A	N/A	N/A
Dillavou 2003 ³⁰	115/91	<10	N/A	>60	>50%	>2-mm reverse	Focal bulge in neck >3 mm
→ Greenberg 2003 ²⁹	352/141	<15	>28	>60	N/A	N/A	Aortoiliac tortuosity (≥2 90° angulations), iliac diameter <8 mm, inability to preserve IIA
Fairman 2004 ²⁷	71/166	<15	>28	>45	>50%	N/A	N/A
Fulton 2006 ¹²	59/25	<15	>25	>45	N/A	N/A	N/A
→ Choke 2006 ³¹	87/60	<10	>28	>60	>50%	N/A	N/A
Leurs 2006 ²¹	2822/G2: 485, G3: 192	G2: 11–15; G3: ≤10	N/A	N/A	N/A	N/A	N/A
→ Hobo 2007 ⁹	4031/1152	N/A	N/A	>60	N/A	N/A	N/A
→ Abbruzzese 2008 ⁷	343/222	DS	DS	DS	DS	DS	N/A
→ AbuRahma 2009 ⁸	195/G2: 24, G3: 17	G2: 10–15; G3: <10	N/A	N/A	N/A	N/A	N/A
Georgiadis 2011 ²⁵	43/34	<12	N/A	>60	N/A	N/A	Iliac axis >60°
Hoshina 2011 ²⁸	80/49	<15	N/A	>60	N/A	N/A	N/A
Torsello 2011 ³³	121/56	<10	N/A	>60	N/A	N/A	N/A
→ AbuRahma 2011 ³⁴	89/149	<10	>28	>60	>50%	Reverse	>50% calcified neck
→ Stather 2012 ⁶	353/199	<15	>28	>60	>50%	Reverse	N/A

Outcome-based anatomic criteria for defining the hostile aortic neck

J Vasc Surg **2015**; 61: 1383-90

William D. Jordan Jr, MD,^a Kenneth Ouriel, MD,^b Manish Mehta, MD, MPH,^c David Varnagy, MD,^d William M. Moore Jr, MD,^c Frank R. Arko, MD,^f James Joye, DO,^g and Jean-Paul P. M. de Vries, MD,^h Birmingham, Ala; New York and Albany, NY; Orlando, Fla; West Columbia, SC; Charlotte, NC; Mountain View, Calif; and Nieuwegein, The Netherlands

100 with vs. 121 without type IA EL
Per 1 mm increase in neck diameter,
11% increased risk of developing type IA EL

Patients with large neck diameter have a higher risk of type IA endoleaks and aneurysm rupture after standard endovascular aneurysm repair

J Vasc Surg **2019**; 69: 783-91



Nelson F. G. Oliveira, MD,^{a,b} Frederico Bastos Gonçalves, MD, PhD,^{a,c} Klaas Ultee, MD, PhD,^a José Pedro Pinto, MD,^{a,d} Marie Josee van Rijn, MD, PhD,^a Sander Ten Raa, MD, PhD,^a Patrice Mwipatayi, MD, FCS, FRACS,^{e,f} Dittmar Böckler, MD, PhD,^g Sanne E. Hoeks, PhD,^h and Hence J. M. Verhagen, MD, PhD,^a Rotterdam, The Netherlands; Ponta Delgada, Lisbon, and Porto, Portugal; Perth, Australia; and Heidelberg, Germany

Large neck >30 mm
97 vs. 1160 pts
FU 48 months
OR 3.0 (1.0-9.3)

Infrarenal endovascular aneurysm repair with large device (34- to 36-mm) diameters is associated with higher risk of proximal fixation failure

J Vasc Surg **2019**; 69: 385-93



Graeme McFarland, MD, Kenneth Tran, BS, Whitt Virgin-Downey, BS, Michael D. Sgroi, MD, Venita Chandra, MD, Matthew W. Mell, MD, E. John Harris, MD, Ronald L. Dalman, MD, and Jason T. Lee, MD, Stanford, Calif

Proximal fixation failure (migration/EL IA)
108 vs. 392 pts
FU 34 months
24.1% vs. 6.1%

Conical neck is strongly associated with proximal failure in standard endovascular aneurysm repair

J Vasc Surg **2017**; 66: 1686-95



Georgios A. Pitoulis, MD, PhD,^a Andrés Reyes Valdivia, MD, FEBVS,^b Suteekhanit Hahtapornsawan, MD,^{c,d} Giovanni Torsello, MD, PhD,^c Apostolos G. Pitoulis, MD,^a Martin Austermann, MD,^c Claudio Gandarias, MD, PhD,^b and Konstantinos P. Donas, MD, PhD,^c Thessaloniki, Greece; Madrid, Spain; Münster, Germany; and Bangkok, Thailand

<15 mm neck + at least one HNF
156 pts - FU 25 months
Conical neck (>2 mm) = Strongest predictor of type IA EL (p<0.012)

Aortic Neck Anatomic Features and Predictors of Outcomes in Endovascular Repair of Abdominal Aortic Aneurysms Following vs Not Following Instructions for Use



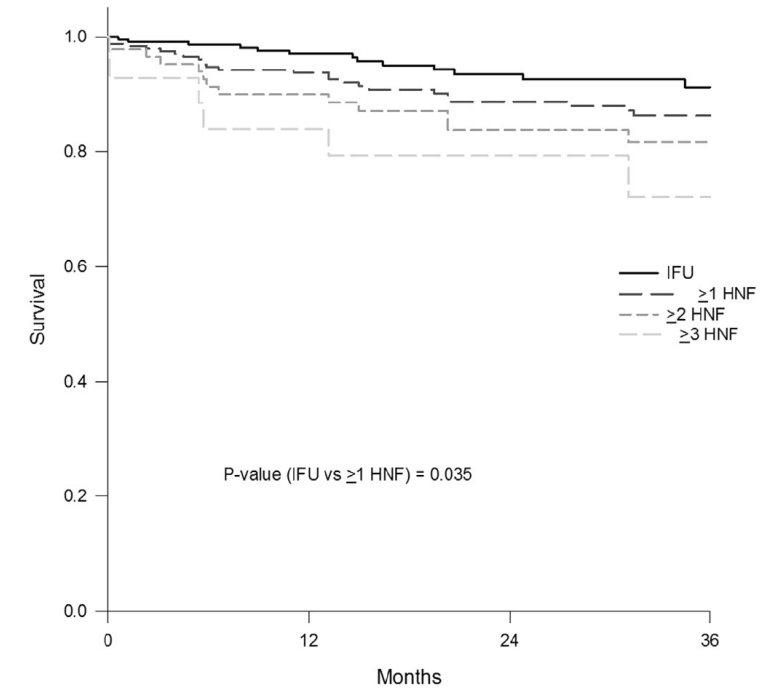
Ali F AbuRahma, MD, FACS, Michael Yacoub, MD, Albeir Y Mousa, MD, FACS, Shadi Abu-Halimah, MD, FACS, Stephen M Hass, MD, FACS, Jenna Kazil, MD, Zachary T AbuRahma, DO, Mohit Srivastava, MD, L Scott Dean, PhD, MBA, Patrick A Stone, MD, FACS

J Am Coll Surg 2016;222: 579-89

	Outside IFU N= 275/526	
	N	%
Neck angle >60°	49	18
Neck length < 10mm	35	13
Neck diameter >31mm	16	6
Neck calcium >49%	51	19
Neck trombus >49%	135	49
Reverse taper	133	48

Endoleak/intervention	IFU (n = 251)		Outside IFU (n = 275)		p Value
	n	%	n	%	
Early type I	18	7	50	18	0.0002
All early endoleak and type					
0	177	71	176	64	
1	18	7	50	18	
2	52	21	47	17	
4	4	2	2	0.7	
Aortic proximal cuff	13	5	43	16	0.0001
Proximal aortic stent	12	5	20	7	0.2324
All early intervention	25	10	66	24	< 0.0001
Late type I endoleak	5	2	14	6	0.0477
All late endoleak and type					
0	191	80	212	83	
1	5	2	14	6	
2	44	18	27	11	
3	0	-	1	0.4	
Late intervention	9	4	14	6	0.3529
Sac expansion	17	7	14	6	0.4716

IFU, instructions for use.

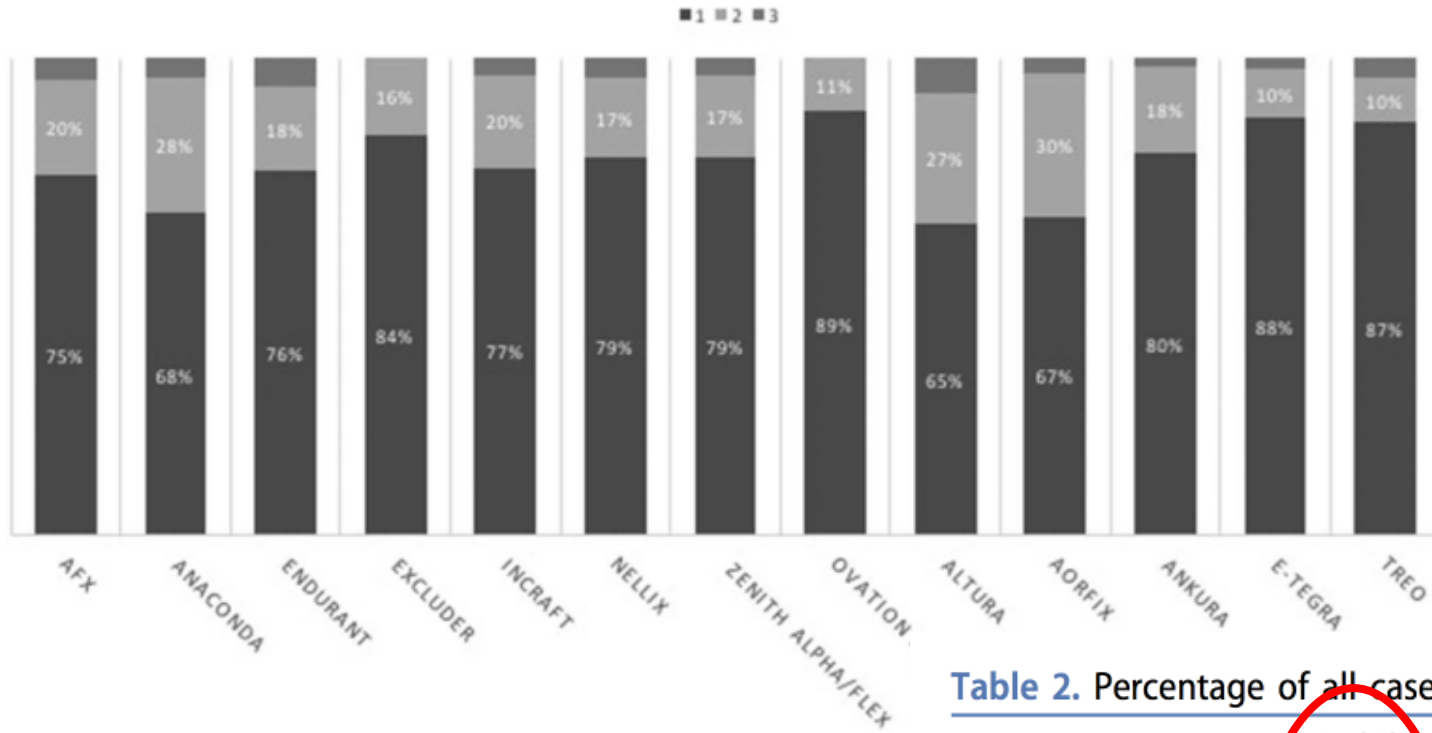


IFU			1+ HNF			2+ HNF			3+ HNF		
N	%	SE	N	%	SE	N	%	SE	N	%	SE
174	97	1.2	171	93.7	1.63	65	90	3.37	18	84	7.4
104	93.5	1.93	118	88.8	2.3	45	83.8	4.33	13	79.3	8.33
62	89.8	2.86	91	86.3	2.65	32	81.7	4.72	7	72.1	10.2

II. Why is OFF-LABEL EVAR being used?

- Difficult to say NO ...
 - Patient & relatives
 - Referring physician
- Other solutions: FEVAR, EVAR + adjuncts, OAR
 - Physiological reserves and fitness for surgery
 - Waiting time
 - Cost
 - Centre/operator – skills
 - Patient selection
 - Professional judgment >> IFU
 - Open/endo/imaging
 - Outcomes > renal and visceral vessels
- Fee for service
- Human nature...





Obstacles:

- Neck diameter
- Neck length
- Common iliac artery diameter

Table 2. Percentage of all cases deemed unsuitable by given AAA characteristics.

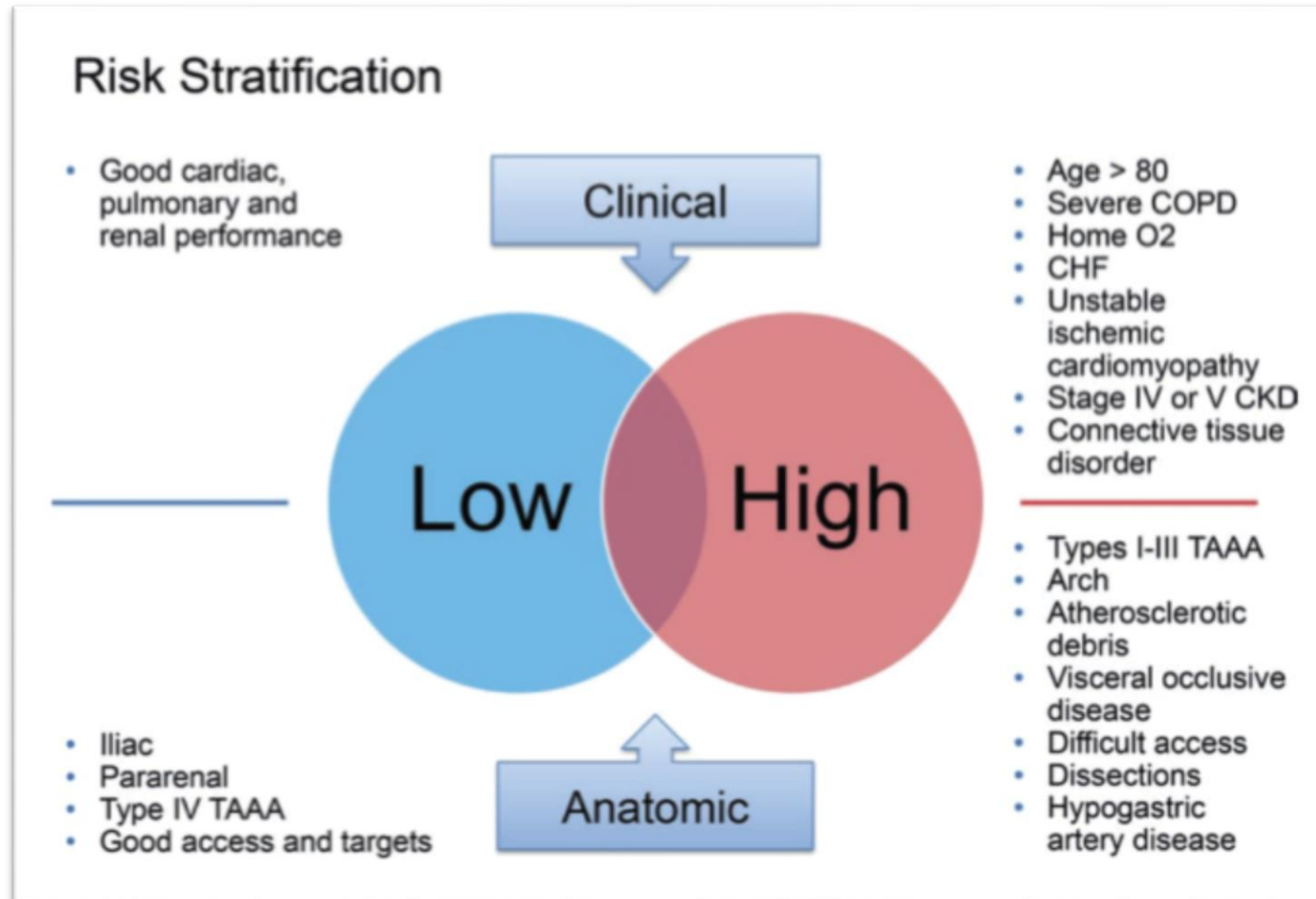
Stent-graft	Suitability rate	Neck diameter	Neck length	CIA diameter	CIA landing zone	α-angle	β-angle
Endurant II/lis	80.7%	2.3%	8.8%	0.6%	5.3%	1.2%	7.6%
Ovation iX	78.9%	15.2%	0.0%	0.0%	2.3%	0.0%	7.6%
Treo	74.9%	2.9%	9.4%	12.9%	2.3%	10.5%	2.3%
E-tegra	72.5%	2.3%	22.2%	0.6%	5.3%	0.0%	1.8%
AFX	62.6%	1.2%	22.2%	11.7%	5.3%	0.0%	6.4%
Ankura	62.6%	1.2%	22.2%	8.8%	5.3%	2.3%	6.4%
Nellix	60.2%	26.3%	8.8%	4.1%	0.0%	0.0%	6.4%
Excluder	57.9%	23.4%	22.2%	0.6%	2.3%	2.3%	0.0%
Anaconda	57.3%	9.9%	22.2%	13.5%	12.3%	0.0%	1.2%
Zenith Alpha/Flex	52.6%	1.2%	22.2%	18.7%	2.3%	9.4%	6.4%
Incraft	48.5%	9.9%	8.8%	36.8%	2.3%	2.3%	6.4%
Aorfix	42.7%	23.4%	22.2%	28.1%	5.3%	0.0%	0.0%
Altura	34.5%	26.3%	22.2%	33.3%	5.3%	0.0%	6.4%

Look for another solution...

- Patient's fitness
- Centre/operator dependent – learning curve

Tenorio ER et al.

J Cardiovasc Surg (Torino) 2019; 60(1): 23-34



Look for another solution...

- Type of treatment - Outcomes

Fenestrated endovascular aneurysm repair is associated with lower perioperative morbidity and mortality compared with open repair for complex abdominal aortic aneurysms

Rens R. B. Varkevisser, BS,^{a,b} Thomas F. X. O'Donnell, MD,^{a,c} Nicholas J. Swerdlow, MD,^a Patric Liang, MD,^a Chun Li, MD,^a Klaas H. J. Ultee, BS,^b Alexander B. Pothof, MS, MD,^a Livia E. V. M. De Guerre, MD,^a Hence J. M. Verhagen, MD, PhD,^b and Marc. L. Schermerhorn, MD,^a Boston, Mass; and Rotterdam, The Netherlands

J Vasc Surg 2018

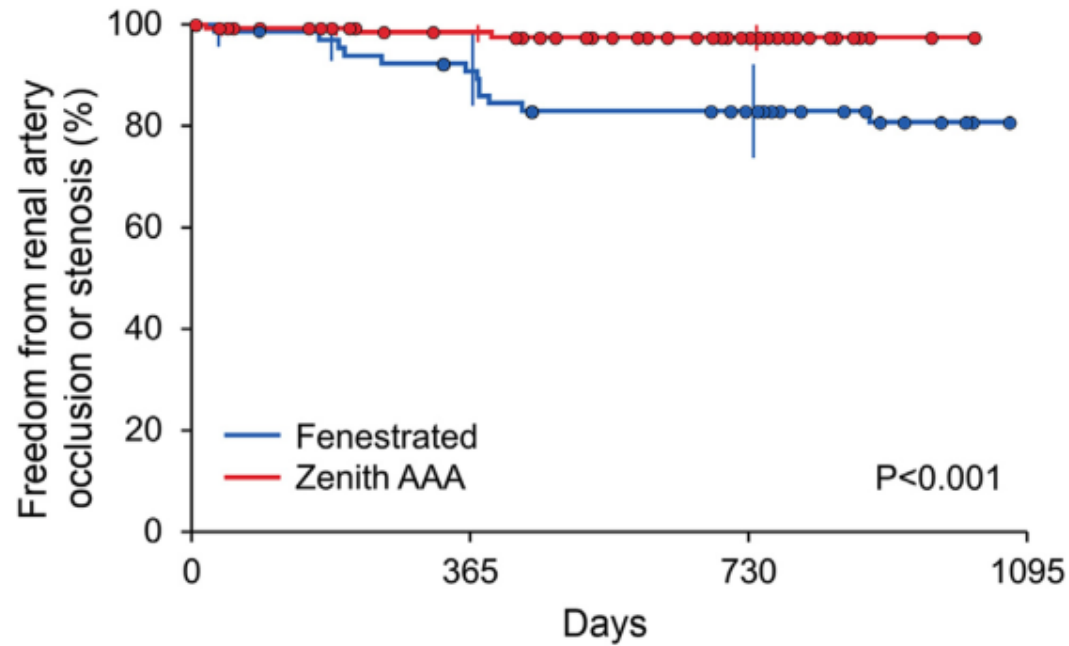
NSQIP
 Multicentre
 Retrospective
 N= 220 FEVAR
 N= 181 OR
 N= 6424 EVAR

	OR	95% CI	P value
30-Day mortality			
Procedure			
Zenith Fenestrated EVAR	Reference		
Open complex AAA repair ^a	4.9	1.4-18	.015
Infrarenal EVAR ^{a,b}	0.6	0.2-2.0	.42
Postoperative renal dysfunction			
Procedure			
Zenith Fenestrated EVAR	Reference		
Open complex AAA repair ^a	13	3.6-49	<.001
Infrarenal EVAR ^{a,b}	0.4	0.1-1.8	.24
Any complication			
Procedure			
Zenith Fenestrated EVAR	Reference		
Open complex AAA repair ^a	4.2	2.3-7.5	<.001
Infrarenal EVAR ^{a,b}	0.8	0.5-1.3	.35

Comparison of Renal Outcomes in Patients Treated by Zenith® Fenestrated and Zenith® Abdominal Aortic Aneurysm Stent grafts in US Prospective Pivotal Trials

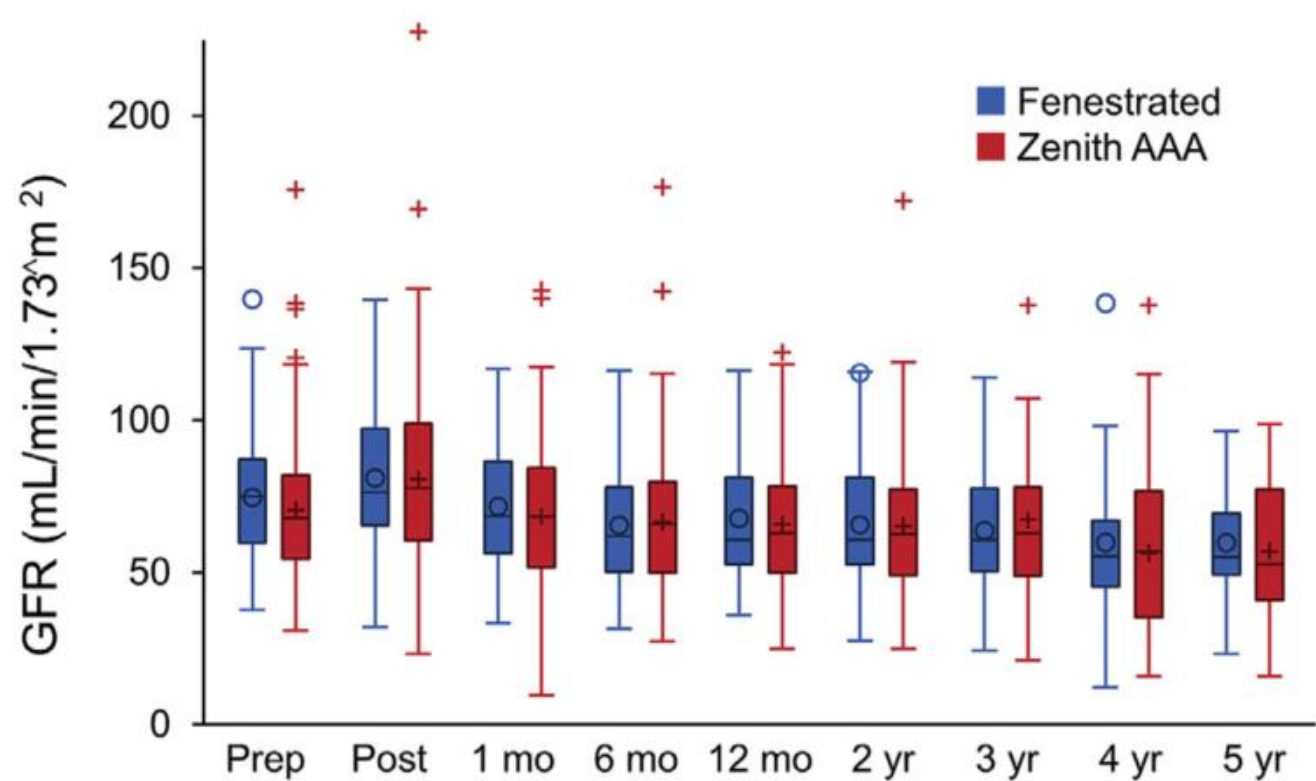
Eur J Vasc Endovasc Surg 2017; 53(5): 648-55

L.R. de Souza ^{a,b}, G.S. Oderich ^{a,*}, M.A. Farber ^c, S. Haulon ^d, P.V. Banga ^{a,e}, A.H. Pereira ^b, P. Gloviczki ^a, S.C. Textor ^f, F. Jia ^g, on behalf of the Zenith Fenestrated and the Zenith Infrarenal Stent grafts Trial Investigators



At risk	67	58	48	24
Events	0	6	11	12
At risk	134	117	86	33
Events	0	2	3	3

12/67 vs. 3/134



Take the risk – convert later? FEVAR or OAR...

Fenestrated Stent-Grafts for Salvage of Prior Endovascular Abdominal Aortic Aneurysm Repair

EJVES 2013

A. Katsargyris ^a, O. Yazar ^{a,b}, K. Oikonomou ^a, F. Bekkema ^c, I. Tielliu ^c, E.L.G. Verhoeven ^{a,b,*}

^a Department of Vascular and Endovascular Surgery, Klinikum Nürnberg, Germany

^b Department of Vascular Surgery, University Hospital Leuven, Belgium

^c Department of Surgery, Division of Vascular Surgery, University Medical Center Groningen, University of Groningen, The Netherlands

N=26 – type IA endoleak/migration

Technical success 92.3%

Catheterization difficulties 42.3%; 4/26 reinterventions

Complementary Role of Fenestrated/ Branched Endografting and the Chimney Technique in the Treatment of Pararenal Aneurysms After Open Abdominal Aortic Repair

Andrés Reyes, MD¹, Konstantinos P. Donas, MD, PhD², Georgios Pitoulis, MD, PhD³, Martin Austermann, MD, PhD², Claudio Gandarias, MD, PhD¹, and Giovanni Torsello, MD, PhD²

Journal of Endovascular Therapy
1-7
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DOI: 10.1177/1526602816647363
www.jevt.org
SAGE

N= 34 pts – technical success 97% - 1/34 died

11% transient weakness lower limbs

3 renal deterioration

8 reinterventions – 18.2%

Increasing use of open conversion for late complications after endovascular aortic aneurysm repair J Vasc Surg 2018

Abhisekh Mohapatra, MD, Darve Robinson, BA, Othman Malak, MD, Michael C. Madigan, MD, Efthimios D. Avgerinos, MD, Rabih A. Chaer, MD, Michael J. Singh, MD, and Michel S. Makaroun, MD, Pittsburgh, Pa

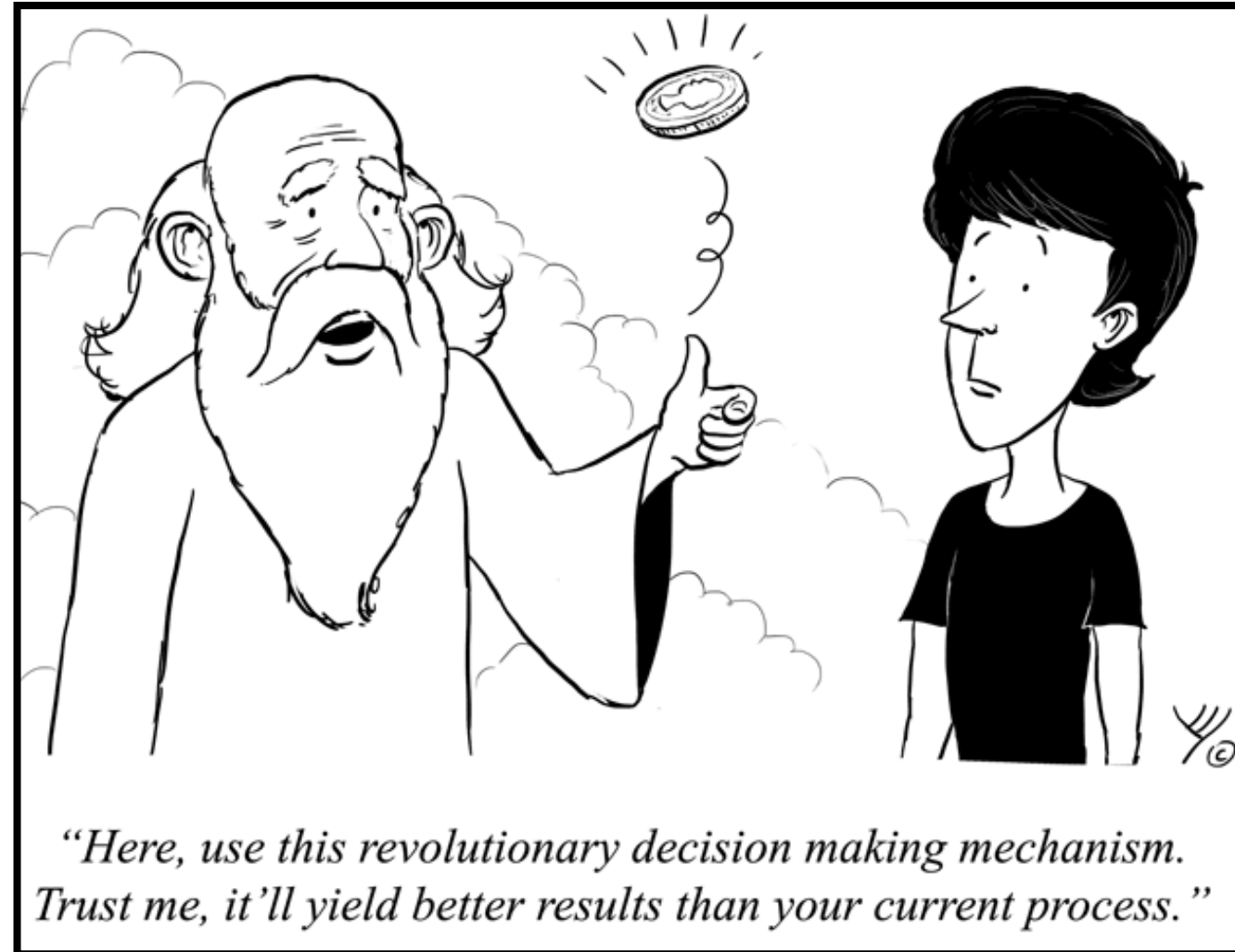
N= 102 pts – 2002-2017

30d mortality

- 65 Elective 6.2%
 - 28 pts graft-preserving – 3.6%
 - 37 Explantation (partial or complete)– 8.1%
- 20 Ruptures 40%
- 15 Infections 40%

III. *How can OFF-LABEL EVAR use be minimized?*

- Network & centralization
- Training of team
 - Knowledge
 - Technical & non-technical skills
- Multi-disciplinary meeting
 - ***DURABILITY***
 - Case selection
 - Type of treatment
 - Personalized Surveillance
- Quality control - registry
- R&D



Network: Resources and caseload

Recommendation 2, 3, 4 - ESVS Guidelines	Class	Level
<p>It is recommended that centres or networks of collaborating centres treating patients with abdominal aortic aneurysms can offer both endovascular and open aortic surgery at all times.</p>	I	B
<p>Abdominal aortic aneurysm repair should only be considered in centres with a minimum yearly caseload of 30 repairs.</p>	IIa	C
<p>Abdominal aortic aneurysm repair should not be performed in centres with a yearly case load <20.</p>	III	B
Recommendation 94 - ESVS Guidelines		
<p>Centralization to specialized high volume centres that can offer both complex open and complex endovascular repair for treatment of juxtarenal abdominal aortic aneurysm is recommended.</p>	I	C
Recommendation - SVS Guidelines		
<p>We suggest that elective OSR for AAA be performed at centers with an annual volume of at least 10 open aortic operations of any type and a documented perioperative mortality of 5% or less.</p>	II (weak)	C

Center and operator experience - Training

The Benefits of EVAR Planning Using a 3D Workstation **CME**

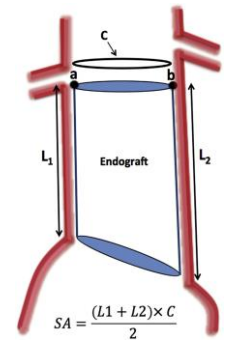
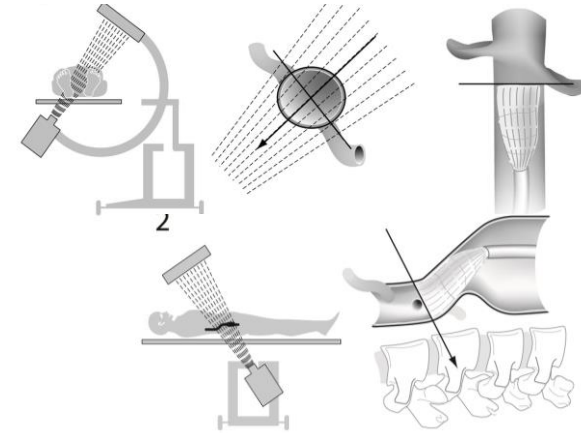
J. Sobocinski, H. Chenorhokian, B. Maurel, M. Midulla, A. Hertault, M. Le Roux, R. Azzaoui, S. Haulon*

Eur J Vasc Endovasc Surg 2013; 46(4): 418-23

WHAT THIS PAPER ADDS

In order to enhance the midterm results of EVAR, and especially the occurrence of type 1 endoleaks, this study shows that endovascular therapists should always perform endograft sizing utilizing 3D workstations.

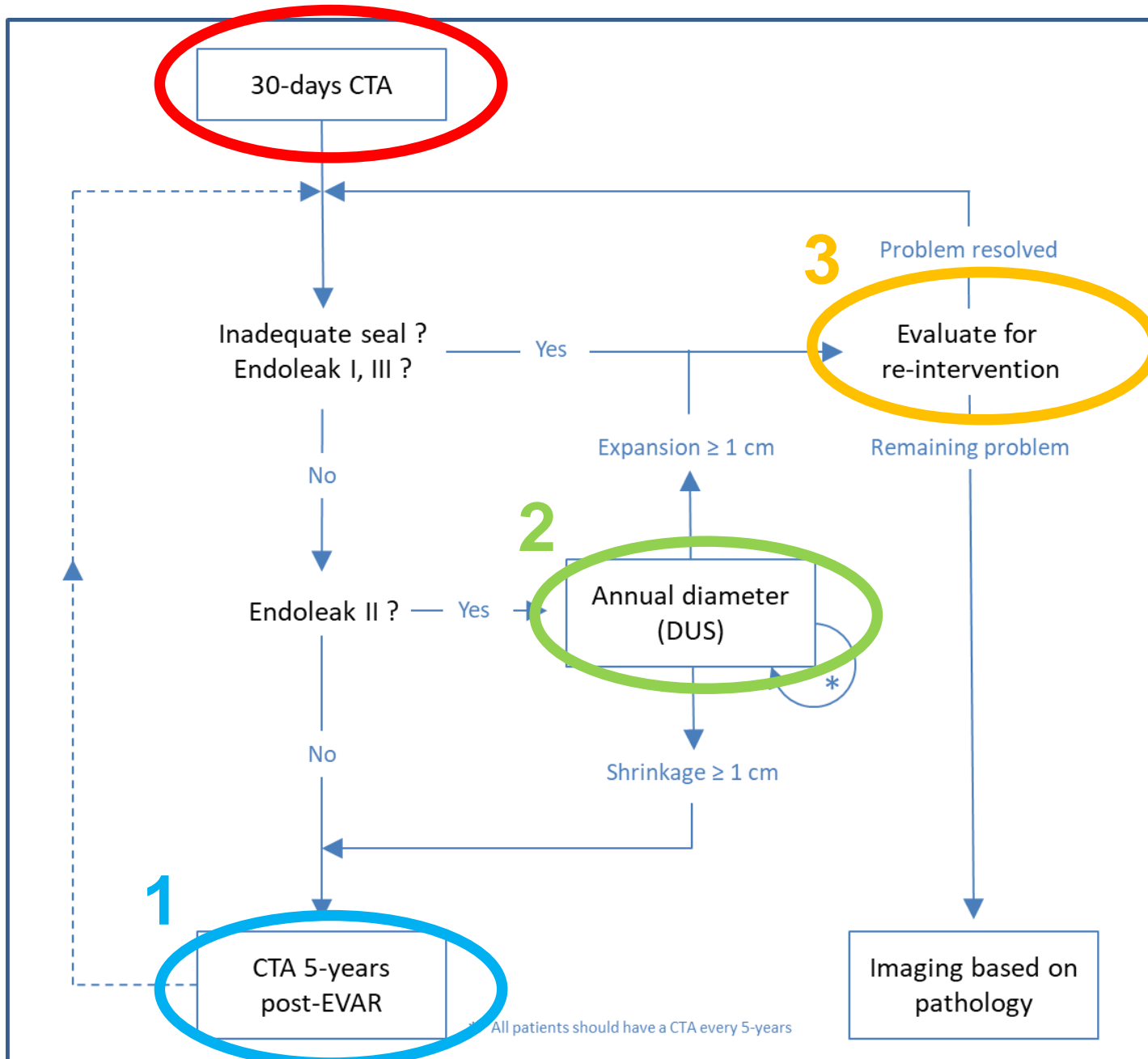
- Patient selection
- Sizing and Planning
- Choice and familiarity with stent-graft
- Patient specific rehearsal
- Peri-operative Imaging: Fusion, ...
- Quality of deployment
 - Elimination of parallax
 - Fabric is placed 2-3 mm below lowest renal



Acceptable (score 1 or 2)

- Partial renal artery coverage \leq 2 mm OR
- \leq 2-4 mm distal to the renal artery orifice

Unacceptable (score 3 or 4)



MDT:

- Selection
- Treatment
- Surveillance

Quality control

Recommendation 1	Class	Level
Centres performing aortic surgery are recommended to enter cases in a validated prospective registry to allow for monitoring of changes in practice and outcomes.	I	C
Recommendation 57	Class	Level
For newer generation of stent grafts based on existing platforms, such as low-profile devices, long-term follow-up and evaluation of the durability in prospective registries is recommended .	I	C

The Safety of Device Registries for Endovascular Abdominal Aortic Aneurysm Repair: Systematic Review and Meta-regression

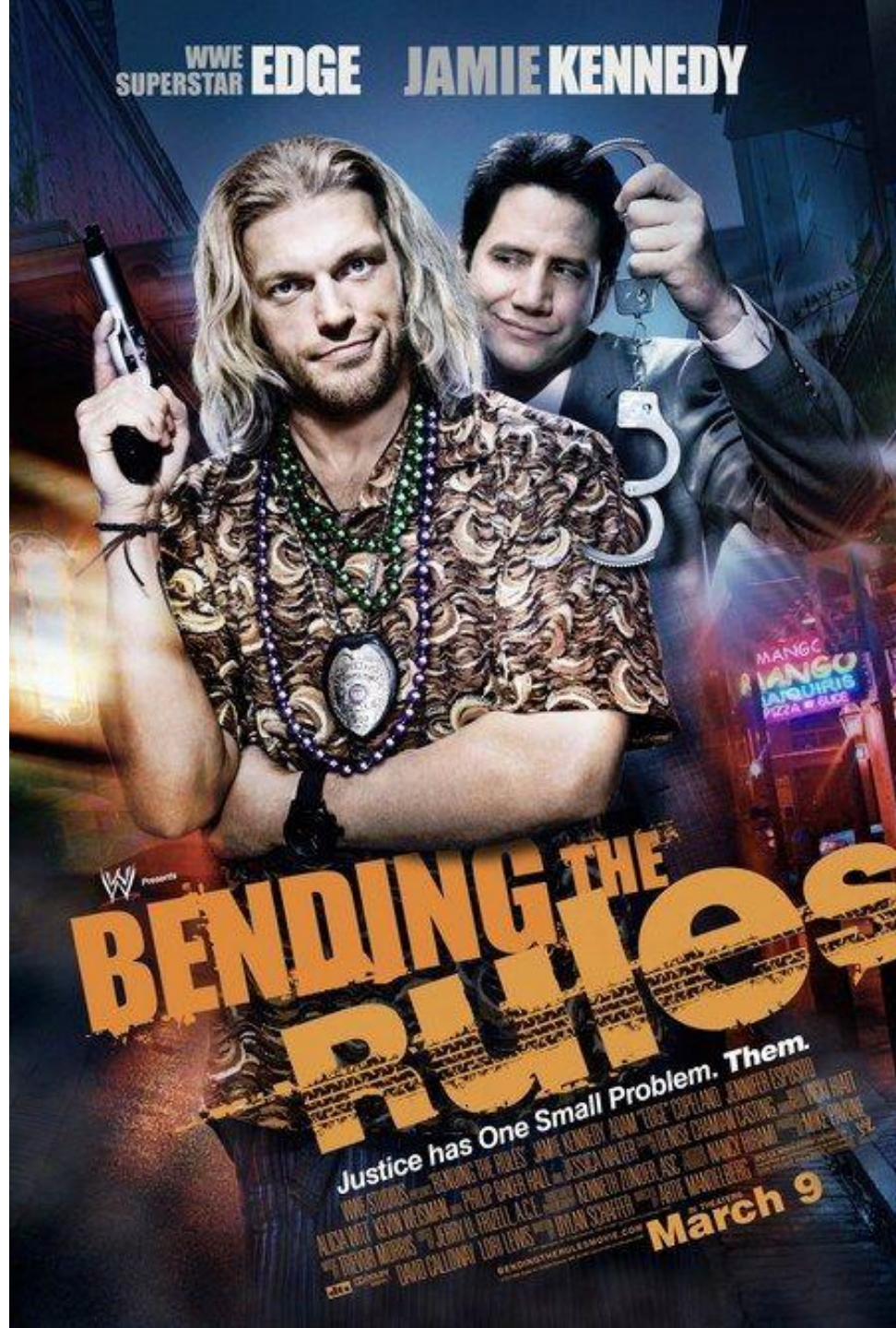
Fran Kent ^a, Graeme K. Ambler ^{a,b}, David C. Bosanquet ^a, Christopher P. Twine ^{a,b,*}, on behalf of BSET (British Society for Endovascular Therapy)

Conclusions: Five hundred and twenty-five patients need to be entered into a registry to demonstrate non-inferiority to previous stent grafts. Almost all previous publications have captured lower patient numbers. With performance varying between devices, and new devices being introduced regularly, there is an urgent need to capture higher quality long-term data on EVAR stent grafts.

EJVES 2018; 55:177-83

Cumulative endoleak: N 525 pts

Reintervention rate: N 492 pts



Patients and healthcare have just one small problem...

