Addressing the Risk of Neck Dilatation in Wide Necks: The Role of ESAR

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Disclosure

Speaker name: Apostolos Tassiopoulos

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s)

- ☐ I do not have any potential conflict of interest

Background

- **Hostile neck anatomy presents a significant challenge to successful EVAR**
- EVAR outside IFU is associated with increased risk of Type 1a endoleak (T1a EL) and increased re-interventions
- Patients with unfavorable neck anatomy have increased risk of developing 30-day morbidity and risk of aneurysm-related mortality within 1 year of initial treatment[1]
- ANCHOR registry = 1.4% T1a EL rate at 1 year with primary EndoAnchor use in hostile neck anatomy[2]

- [1] Antoniou et al. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. J Vasc Surg. 2013;57(2):527-38.
- [2] Jordan et al. Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy. J Vasc Surg. 2014;60(4):885-92.e2.

HOSTILE PROXIMAL NECK PREDICTS CHALLENGES

4.5x

Type I endoleaks 4.5x more likely at 1-year after endograft implantation in hostile proximal aortic neck anatomy (P = .010)

9x

Aneurysm-related mortality risk 9x greater in hostile neck anatomy at 1-year (P= .013)

Meta-Analysis of 7 major studies in EVAR by Antoniou et al[1] compared outcomes in hostile vs. friendly neck anatomies (total patients N = 1559)

Study	Sample Size	Endografts
Torsello et al, 2011	177	Endurant™
AbuRahma et al, 2010	238	AneuRx™, Excluder™*, Zenith™*, Talent™
Hoshina et al, 2010	129	Excluder™*, Zenith™*
Abbruzzese et al, 2008	565	AneuRx™, Excluder™*, Zenith™*
Choke et al, 2006	147	Talent™, Zenith™*, Excluder™*, AneuRx™
Fulton et al, 2006	84	AneuRx™
Fairman et al, 2004	219	Talent™

- [1] Antoniou GA et al. JVS. 2013;57(2):527-38.

DEFINITION OF WIDE NECK

There is no clear threshold definition for wide proximal AAA neck diameter

Emerging trend in literature - wider necks have greater risks

- Type Ia endoleaks
- Secondary procedures
- Rupture
- Mortality

This trend is consistent across varying neck diameters, follow-up periods, and devices

Study characteristics[1]

Study	Country	Single/ Multicenter	Study design	Recruitment period	Definition of large diameter
AbuRahma (2018)	USA	Single	Retrospective	2003-2015	>31 mm
Howard (2018) Oliveira (2018)	Australia The Netherlands	Multi Multi	Registry Registry	2011-2017 2009-2011	≥25 mm ≥30 mm
Oliveira (2017)	Portugal	Multi	Retrospective	2008-2012	≥30 mm
Kaladji (2015)	France	Multi	Retrospective	1998-2012	≥30 mm
Jim (2010)	USA	Multi	Registry	2002-2003	≥28 mm (stent graft ≥32 mm) ≥28 mm
McFarland (2019)[2]	USA	Single	Retrospective	2000-2016	≥29 mm
Gargiulo (2017)[3]	Italy / France	Multi	Retrospective	2009-2012	≥28 mm

EVAR OUTCOMES IN WIDE NECK ANATOMY

Metanalysis of 6 observational studies reporting on a total of 6602 patients (1616 with large and 4986 with small diameter neck)

6.7x more likely to have **Type Ia endoleak**	**10x** more likely to have **sac expansion**	**5x** more likely to have **aneurysm rupture**
n = 5922 patients P<0.001 95% CI: 4.39-10.20	n = 688 patients P=0.009 95% CI: 1.80-56.53	n = 1257 patients P=0.01 95% CI: 1.40-18.58

- survival (HR=1.55, 95% CI: 1.08-2.24; P=0.02).

Kouvelos et al. J Cardiovasc Surg 2019

NECK DILATATION

NECK DILATATION
LARGE DIAMETER NECKS

Data shows neck dilatation is common[1]

24.6%
of all EVAR patients had neck dilatation[1]

- Meta analysis*
- 12 articles (1998-2015)
- 8,550 pts

** Data point from subset of full metanalysis*

100%
of all wide necks (≥28mm) at 24m had neck dilatation[2]

- 3 European centers
- 2009-2012
- 118 pts
- ≥ 24m follow-up

Large diameter necks have worse outcomes[3]

6x
More likely Type Ia endoleak (p<0.001) in large diameter necks[3]

- 5.922 pts
- 95% CI

>10X
More likely sac expansion (p=0.009) in large diameter necks[3]

- 688 pts
- 95% CI

- Large diameter necks have worse outcomes
- Meta analysis; 6 studies; 6,602 pts

[1] Kouvelos. *J Endovasc Ther*. 2017;24(1):59-67
[2] Gargiulo M, et al. *J Vasc Surg.* 2017;66:1065-1072
[3] Kouvelos, et al., The Journal of Cardiovascular Surgery 2019 April;60(2):167-174

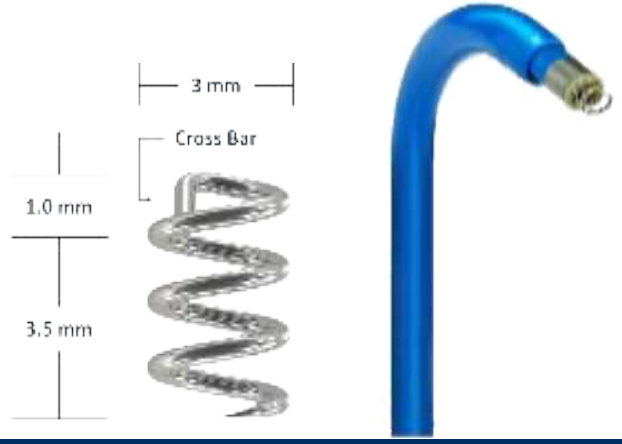
ENDOANCHORS PROVIDE RADIAL FIXATION

Unlike Open Repair, no endografts offer techniques for *radial fixation*

- *Yet, AAA is a dilating disease*

Heli-FX EndoAnchor System – *Facilitates EndoSuture Aneurysm Repair (ESAR)*

- Provides radial fixation[1,2]
- Increases proximal seal competency[3]



1: Melas et al. J Vasc Surg. 2012; 55(6):1726-33
2: Perdikides et al. J Endo Ther 2012; 19:707-715
3. Arko, et al., J Vasc Surg 2019;70:732-40

NECK DILATATION PREVENTIONS - ANCHOR

Predictors Of Aortic Neck Dilation Between The 1-month Post-operative And 12-month CT

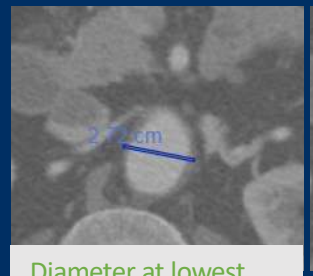
Aortic Level	Predictors of Dilatation at Specified Level	Coefficient*	Effect	P Value
Lowest renal	Endograft type	0.62 (0.12, 1.04)	*	.006
	Aortic aneurysm sac diameter	-0.04 (-0.07, 0.00)	Protective	.020
	Aortic diameter at lowest renal	0.16 (0.08, 0.24)	**Risk factor**	**<.001**
	Aortic neck length	-0.02 (-.04, 0.00)	**Protective**	**.021**
	Infrarenal Angulation	0.02 (0.00, 0.04)	Risk factor	.016
	Endograft oversizing	5.37 (2.34, 8.39)	**Risk factor**	**.001**
5mm distally	Aortic diameter at lowest renal	0.17 (0.07, 0.26)	Risk factor	.001
	Endograft oversizing	6.00 (2.68, 9.31)	Risk factor	.001
10mm distally	Aortic diameter at lowest renal	0.17 (0.04, 0.29)	Risk factor	.003
	Endograft oversizing	4.86 (0.13, 9.58)	Risk factor	.032
	Number of EndoAnchors placed	-0.29 (-0.55, -0.04)	**Protective**	**.037**
Suprarenal level	Suprarenal aortic diameter	0.08 (0.01, 0.16)	Risk factor	.021

NECK DILATATION PREVENTIONS - ANCHOR

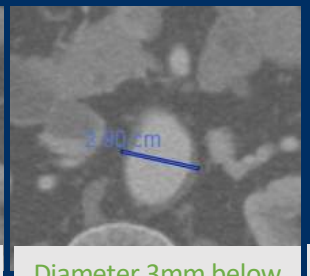
- Mechanism of endoanchor function

71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy

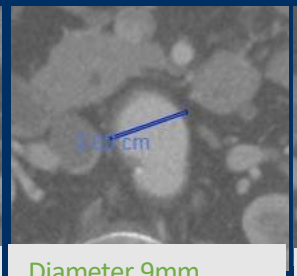
Pre Operative CTA



Diameter at lowest renal: **27mm**

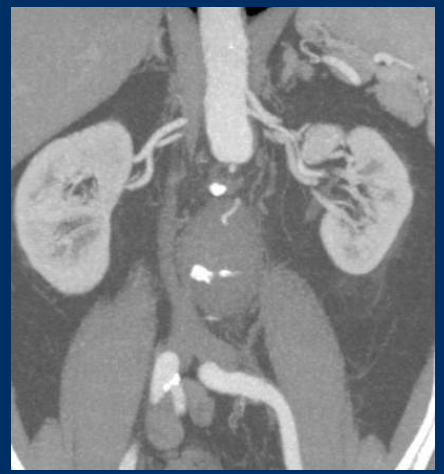


Diameter 3mm below renal: **29mm**



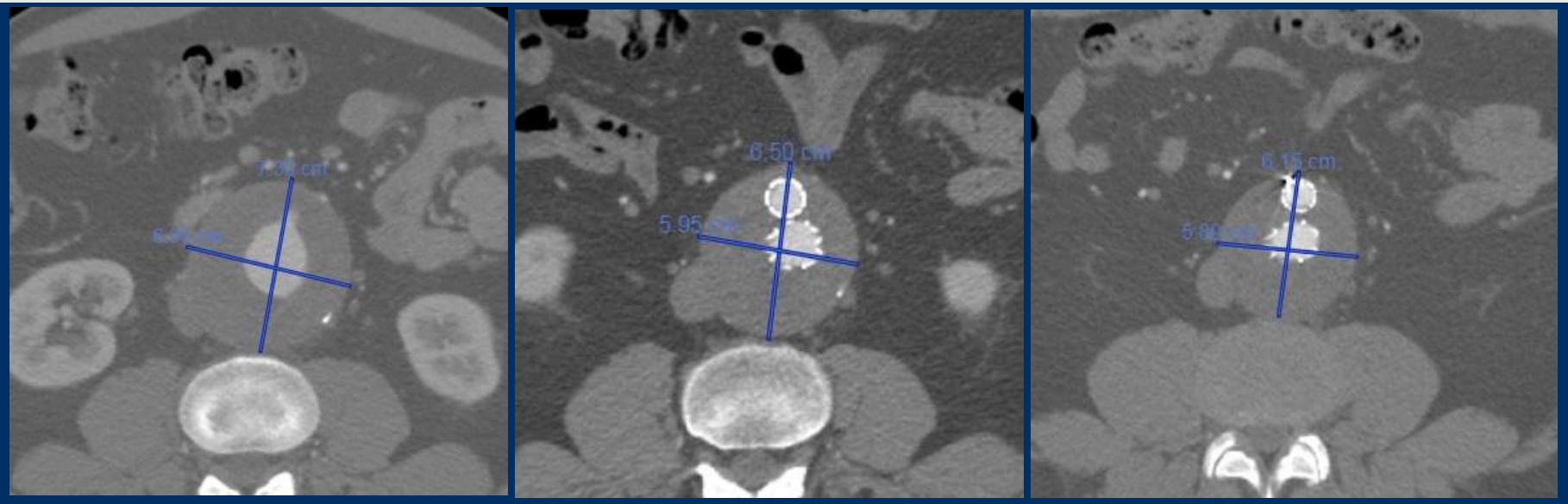
Diameter 9mm below renal: **30mm**

Diameter 15mm below renal:**36mm**



Short Conical Neck Bilateral Accessory Renals Angulation 39°

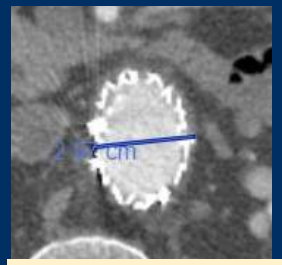
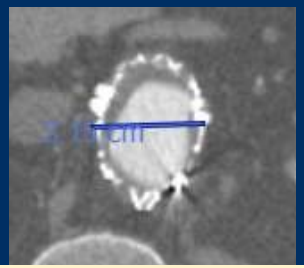
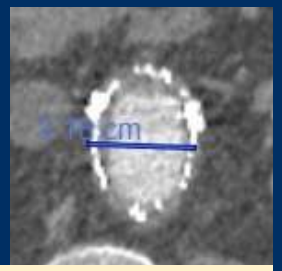
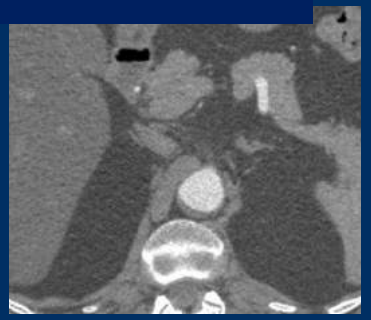
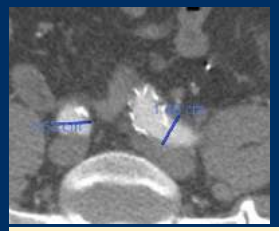
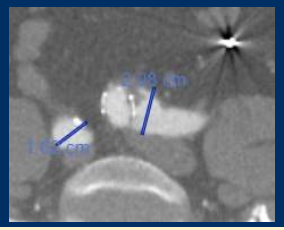
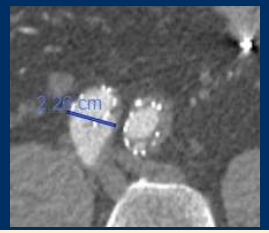
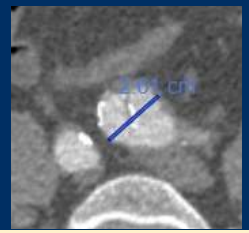
71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy



Pre Op 73mm x 67mm **1-year Post Op 65mm x 59mm** **3-year Post Op 61mm x 55mm**

Change on AAA sac Max Diameter

71 year old male with 7.3 cm AAA, short and conical neck and a concomitant malignancy

1 month	3 years	5 years	
			
29.7mm	31.5mm	31.8mm	
			
Rt Iliac: 15mm Lt Iliac: 14.5mm	Rt Iliac: 16.9mm Lt Iliac: 20.8mm	Rt Iliac: 22.6mm.	Lt Iliac: 26.1mm

Mid-Term Follow Up

Single Institution Prospectively Collected Data

- Inclusion criteria:
  - Standard EVAR with use of EndoAnchors at index procedure
  - Hostile Neck Anatomy

    Length < 15mm,

    Diameter > 28mm,

    Angulation > 60deg,

    Conical Neck (> 10% diameter increase)
- Exclusion criteria:
  - EVAR Revision
  - Associated fenestrated or snorkel/chimney technique
  - Absence of at least 1-year surveillance CTA

Methods

- Primary outcome
    - Maintenance of proximal seal zone integrity, defined as

        no neck dilation beyond nominal diameter of the endograft,

        no endograft migration,

        and no evidence of T1a EL
- Secondary outcomes
    - Aneurysm sac regression rates & extent
    - Aneurysm-related re-interventions
    - Aneurysm-related mortality

Results

	CTA at 1-year follow up (25)		CTA at Longest follow up (25)	
	Prophylactic	Intraoperative T1a EL	Prophylactic	Intraoperative T1a EL
# Sac Regression or Stability	6/7 (85.7%)	17/18 (94.4%)	7/7 (100%)	15/18 (83.3%)
Mean Sac Diameter Change (mm)	-11.8	-10.9	-11.5	-10.5
PSZ Failure	0	0	0	0
Aneurysm-related Reinterventions	0	2	2	3

- Median follow up 42 months (12-75 months)
- 96% sac regression or stability at 1 year, 88% at longest follow up
- No loss of PSZ integrity

Results

	CTA at 1-year follow up (25)		CTA at Longest follow up (25)	
	# patients	Cause - Intervention	# patients	Cause - Intervention
Sac Regression	23/25 (92%)	• DSZ degeneration without T1b EL	20/25 (80%)	• T3 EL – Re-lined limb
Sac Stability	1/25 (4%)	• No identified EL	2/25 (8%)	• T1b EL x2 – Limb Extensions • No Identified EL
Sac Growth	1/25 (4%)	• T2 EL – Coil Embolization	3/25 (12%)	• Persistent T2 EL – Sac Regressed • T2 EL – Coil Embolization • No Identified EL

- 19/25 (76%) with initial sac regression exhibited sustained sac regression

Conclusion

- EndoAnchors, used as an adjunct to EVAR, provide durable protection against PSZ failure in patients with hostile neck anatomy, and their use is associated with sustained aneurysm sac regression in 76% of patients
- They can protect against neck dilatation in patyients with wide neck anatomy
- Primary EndoAnchor use should be considered in patients with hostile neck anatomy if standard EVAR is preferred over open repair or other complex endovascular repair.

Thank You