# Is EVAR Safe and Durable in Long- term?



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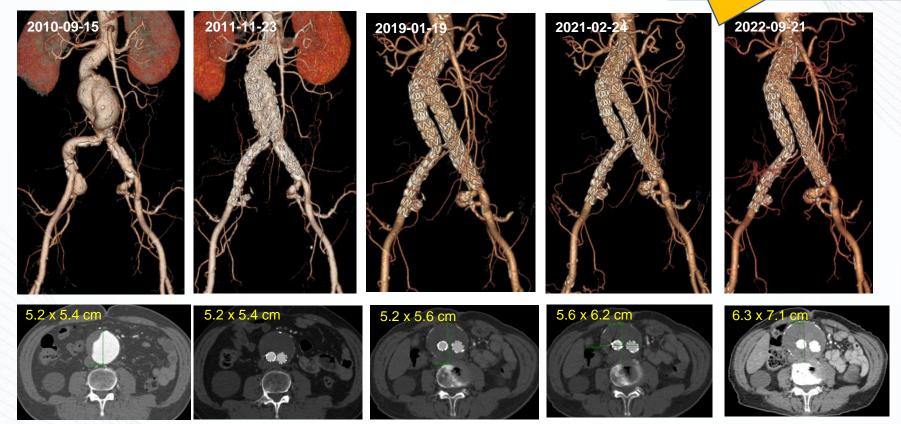
## **Disclosure**

- Consulting:
  - Genoss, S&G
- Research grants:
  - Medtronic, Cook Medical, Boston Scientific, Otsuka Korea, Dong-A ST, Samjin Pharm, Cordis
- Educational grants:
  - Medtronic, Cook Medical, Abbott, Cordis
- Proctoring:
  - Medtronic, Edwards



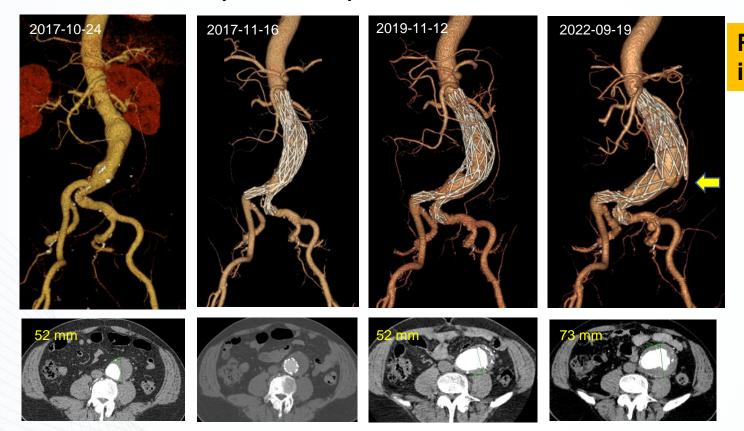
# M/66, S/P CABG: EVAR with Endurant & Rt IIA embolization (2010-10-26)

2021.03.24 Stent-graft reinforcement at Rt iliac limb



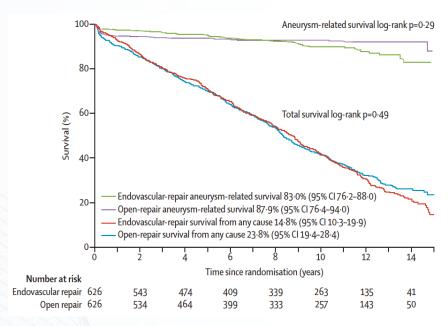


M/65, EVAR with AFX2 (2017-11-14)



Reintervention is needed!

## **EVAR-1: 15-years Follow-up**



	Endovascular repair (N=626)		Open repair (N=62	26)	Hazard ratio (95% CI	p value†		
	n/N (%)	Rate per 100 person-years	n/N (%)	Rate per 100 person-years	'			
Total mortality								
All patients	466/626 (74%)	9.3	444/626 (71%)	8.9	1.05 (0.92-1.19)	1.11 (0.97-1.27)	0.14	
0-6 months	26/626 (4%)	8.5	45/626 (7%)	15⋅0	0.57 (0.35-0.92)	0.61 (0.37-1.02)	0.06	
>6 months to 4 years	126/600 (21%)	6.7	116/581 (20%)	6-3	1.07 (0.83-1.38)	1.13 (0.87-1.47)	0.35	
>4–8 years	135/474 (28%)	8.3	129/464 (28%)	8-0	1.03 (0.81-1.31)	1.07 (0.83-1.37)	0.62	
>8 years	179/339 (53%)	14.9	154/333 (46%)	12-7	1.18 (0.95–1.47)	1.25 (1.00-1.56)	0.048	
Aneurysm-ı	related mo	rtality						
All patients	56/626 (9%)	1:1	45/626 (7%)	0.9	1.24 (0.84-1.83)	1-31 (0-86-1-99)	0.21	
0–6 months	14/626 (2%)	4.6	30/626 (5%)	10.0	0.46 (0.24-0.87)	0-47 (0-23-0-93)	0.031	
>6 months to 4 years	12/599 (2%)	0.6	8/581(1%)	0.4	1.48 (0.60-3.62)	1.46 (0.56-3.83)	0.44	
>4-8 years	14/474 (3%)	0.9	4/464 (1%)	0.2	3-46 (1-14-10-52)	3.11 (0.99-9.72)	0.05	
>8 years	16/339 (5%)	1.3	3/333 (1%)	0.2	5.50 (1.60-18.89)	5-82 (1-64-20-65)	0.0064	

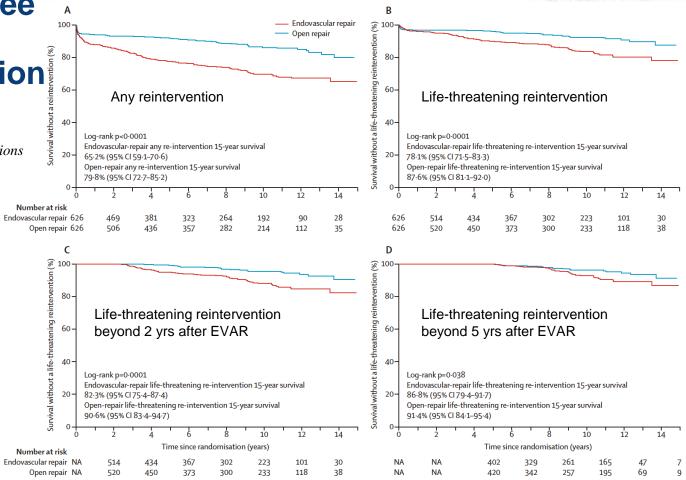
\*Hazard ratios adjusted for age, sex, maximum aneurysm diameter, forced expiratory volume in 1 s, log creatinine, statin use, body-mass index, smoking status, systolic blood pressure and total cholesterol; 77 individuals excluded due to missing data. †p value adjusted for covariates.

Patel R, Lancet 2016; 388: 2366

Survival free from reintervention

## Life-threatening reintervention:

- Conversion to open repair
- Reinterventions d/t graft infections
- Stent-graft extension



Patel R, Lancet 2016; 388: 2366



## All cause mortality

## **Aneurysm-related mortality**

Hazard Ratio

0.01

0.1

#### A All cause mortality - Any time

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> 0.0488 0.0674 DREAM 20178,18,19 0.1054 0.1356 OVER 20197,16,17 -0.0408 0.0804

Total (95% CI)

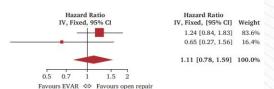
Heterogeneity:  $Chi^2 = 1.15$ , df = 2 (p = .56);  $I^2 = 0\%$ Test for overall effect: Z = 0.49 (p = .62)

**Hazard Ratio Hazard Ratio** IV, Fixed, [95% CI] Weight IV, Fixed, 95% CI 1.05 [0.92, 1.20] 51.3% 1.11 [0.85, 1.42] 12.7% 0.96 [0.82, 1.12] 36.0% 1.02 [0.93, 1.13] 100.0% A Aneurysm related mortality - Any time

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> 0.2151 0.1987 DREAM 20178,18,19 -0.4318 0.448

Total (95% CI)

Heterogeneity:  $Chi^2 = 1.74$ , df = 1 (p = .19);  $I^2 = 43\%$ Test for overall effect; Z = 0.60 (p = .55)



#### B All cause mortality - 0 to 6 months

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> -0.5621 0.2488 DREAM 20178,18,19 -0.5008 0.5161 OVER 20197,16,17 -0.2614 0.4023

Total (95% CI)

Heterogeneity:  $Chi^2 = 0.41$ , df = 2 (p = .82);  $I^2 = 0\%$ Test for overall effect: Z = 2.46 (p = .01)



Hazard Ratio

**Hazard Ratio** 

IV, Fixed, [95% CI] Weight

1.03 [0.81, 1.31] 61.7%

1.18 [0.87, 1.60] 38.3%

1.09 [0.90, 1.31] 100.0%

IV, Fixed, [95% CI] Weight

1.07 [0.83, 1.38] 52.5%

1.20 [0.80, 1.82] 20.0%

0.81 [0.57, 1.15] 27.4%

1.02 [0.84, 1.22] 100.0%

1 1.1 1.2

1.5 2

1.2

Favours EVAR ⇔ Favours open repair

Favours EVAR ⇔ Favours open repair

**Hazard Ratio** 

IV, Fixed, 95% CI

Favours EVAR ⇔ Favours open repair

**Hazard Ratio** 

IV. Fixed, 95% CI

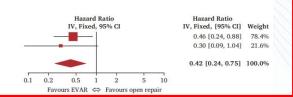
0.85

### B Aneurysm related mortality - 0 to 6 months

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> -0.7765 0.3319 DREAM 20178,18,19 -1.1969 0.6315

Total (95% CI)

Heterogeneity:  $Chi^2 = 0.35$ , df = 1 (p = .56);  $I^2 = 0\%$ Test for overall effect; Z = 2.95 (p = .003)



### C All cause mortality - 6 months to 4 years

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> 0.0677 0.1296 DREAM 20178,18,19 0.1863 0.21 OVER 20197,16,17 -0.2107 0.1793

#### Total (95% CI)

Heterogeneity:  $Chi^2 = 2.42$ , df = 2 (p = .30);  $I^2 = 17\%$ Test for overall effect: Z = 0.16 (p = .87)

### C Aneurysm related mortality - 6 months to 4 years

Study or Subgroup log [Hazard Ratio] EVAR-1 20165,13-15 -0.392 0.4607 DREAM 20178,18,19

#### Total (95% CI)

Test for overall effect: Z = 0.81 (p = .42)



100

0.71 [0.31, 1.63] 100.0%

## D All cause mortality - 4 to 8 years

Study or Subgroup log [Hazard Ratio] EVAR-1 20165,13-15 0.0296 0.1226 OVER 20197,16,17 0.1655 0.1555

Heterogeneity:  $Chi^2 = 0.47$ , df = 1 (p = .49);  $I^2 = 0\%$ Test for overall effect: Z = 0.85 (p = .40)

-0.0726 1.1378

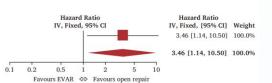
Heterogeneity:  $Chi^2 = 0.07$ , df = 1 (p = .79);  $I^2 = 0\%$ 

## D Aneurysm related mortality - 4 to 8 years

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> 1.2413 0.5665

## Total (95% CI)

Heterogeneity: Not applicable Test for overall effect: Z = 2.19 (p = .03)



10

#### E All cause mortality - > 8 years

Study or Subgroup log [Hazard Ratio] EVAR-1 2016 5,13-15 0.1655 0.1106 DREAM 20178,18,19 0 0.1893 OVER 20197,16,17 -0.0619 0.1221

#### Total (95% CI)

Heterogeneity:  $Chi^2 = 2.00$ , df = 2 (p = .37):  $I^2 = 0\%$ Test for overall effect: Z = 0.71 (p = .48)

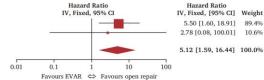
#### Hazard Ratio Hazard Ratio IV, Fixed, [95% CI] Weight IV, Fixed, 95% CI 1.18 [0.95, 1.47] 46.3% 1.00 [0.69, 1.45] 15.8% 0.94 [0.74, 1.19] 38.0% 1.05 [0.91, 1.22] 100.0% 1.1 1.2

### E Aneurysm related mortality -> 8 years

Study or Subgroup log [Hazard Ratio] EVAR-1 2016<sup>5,13-15</sup> 1.7047 0.63 DREAM 20178,18,19 1.0217 1.8284

#### Total (95% CI)

Heterogeneity:  $Chi^2 = 0.12$ , df = 1 (p = .72);  $I^2 = 0\%$ Test for overall effect: Z = 2.74 (p = .006)



## Antoniou GA, Eur J Vasc Endovasc Surg 2020;59:385

## 8-year Outcomes from ENGAGE OUS Registry

## ENGAGE Cohort

- 1263 real world subjects
- Enrollment from 2009-2011
- Endurant<sup>™</sup>
- Extended Follow Up (FU) Cohort
  - 390 subjects
  - 8 year follow up compliance:
    - 94% clinical FU, 83% imaging FU

Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181

Editor's Choice — Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry

Joep A.W. Teijink <sup>a,\*</sup>, Adam H. Power <sup>b</sup>, Dittmar Böckler <sup>c</sup>, Patrick Peeters <sup>d</sup>, Steven van Sterkenburg <sup>e</sup>, Lee H. Bouwman <sup>f</sup>, Hence J. Verhagen <sup>g</sup>, Marc Bosiers <sup>h</sup>, Vincente Riambau <sup>i</sup>, Jean-Pierre Becquemin <sup>j</sup>, Philippe Cuypers <sup>a</sup>, Marc van Sambeek <sup>a</sup>



1 Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.

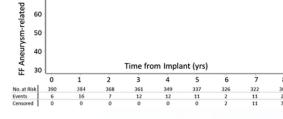
2. Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181



## 8-year Outcomes from ENGAGE OUS Registry

	ENGAGE cohort N = 1263	Extended cohort N = 390
Cumulative through time period	5 Yr	8 Yr
Secondary Endovascular Procedure	84.3% FF	75.8% FF
Aneurysm-related mortality <sup>1</sup>	97.8% FF	99.5% FF
At time period	5 Yr	8Yr
Type la Endoleak	1.6% (8/501)	3.4% (9/261)
Type II Endoleak	7.2% (36/501)	6.1% (16/261)
Type II Endoleak Type III Endoleak	7.2% (36/501) 0.4% (2/501)	6.1% (16/261) 0.8% (2/261)

Figure 1: ENGAGE Registry Extension FF from Aneurysm-Related Reinterventions through 8-







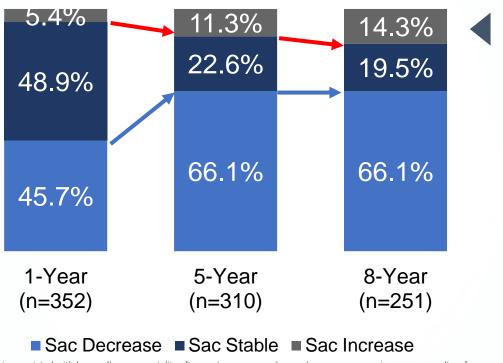
<sup>1</sup> Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.

<sup>2.</sup> Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181

 <sup>&</sup>lt;sup>1</sup> Determined by clinical event committee

## 8-year Outcomes from ENGAGE OUS Registry

## **Changes in Aneurysm Sac Dimensions after EVAR**



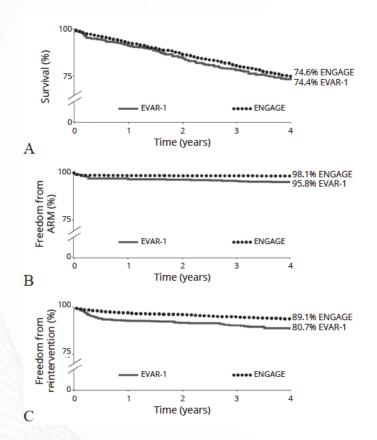
Over 97% (35/36) of patients wit h sac expansion at 8Y previously exhibited expanding or stable sacs

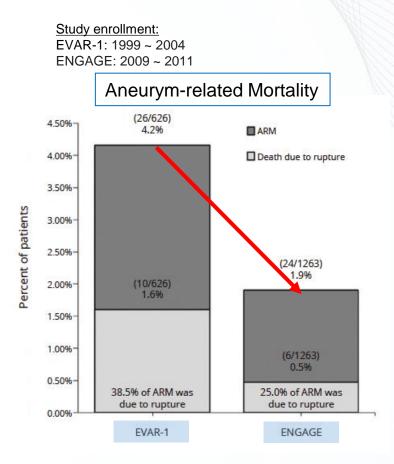
TCTAP

<sup>1</sup> Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presentation presented online at: ESVS 34th Annual Meeting. October 6, 2020.

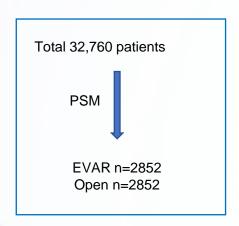
<sup>2.</sup> Teijink et al., Eur J Vasc Endovasc Surg. 2019;58(2):175-181

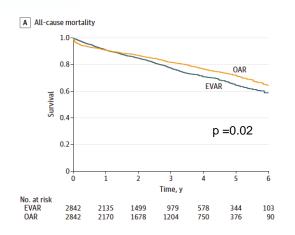
## **EVAR-1 RCT vs ENGAGE Registry EVAR Outcomes**

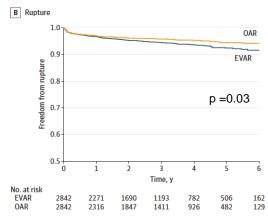


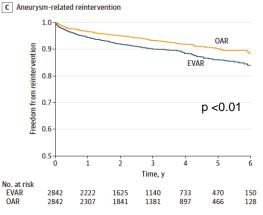


# **US Medicare data: Open Repair vs EVAR**



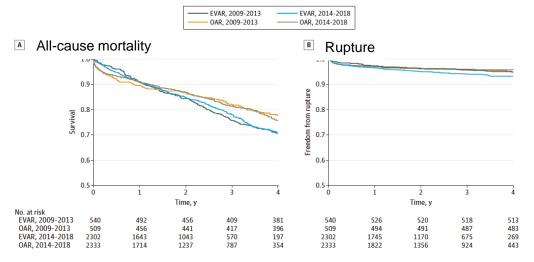


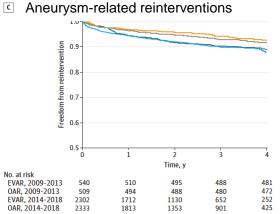




# **US Medicare data: Open Repair vs EVAR**

2009-2013 vs. 2014-2018





# Impact of IFU adherence on the Clinical Outcomes after EVAR

Vascular Quality Initiative Registry, N = 5,448 22.1% neck characteristics outside of the IFU

The association between device instructions for use adherence and outcomes after elective endovascular aortic abdominal aneurysm repair

Livia E. V. M. De Guerre, MD, ab Thomas F. X. O'Donnell, MD, Rens R. B. Varkevisser, BS, Nicholas J. Swerdlow, MD, Chun Li, MD, Kirsten Dansey, MD, Joost A. van Herwaarden, MD, Marc L. Schermerhorn, MD, and Virendra I. Patel, MD, MPH, Boston, MA: Utrecht, the Netherlands: and New York, NY

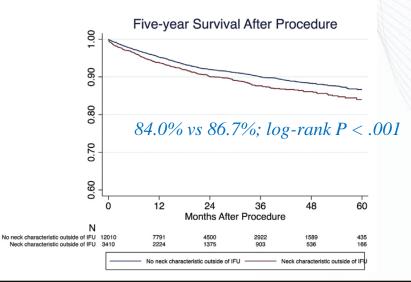
#### **ABSTRACT**

Objective: Aortic neck anatomy has a significant impact on the complexity of endovascular aortic aneurysm repair (EVAR), with concern that neck characteristics outside of the instructions for use (IFU) may result in worse outcomes. Therefore, this study determined the impact of neck characteristics outside of the IFU on perioperative and 1-year outcomes and mid-term survival after EVAR.

Methods: We identified all patients undergoing elective infrarenal EVAR from December 2014 to May 2020 in the Vascular Quality initiative database. Neck characteristics outside of the IFU were determined based the specific device IFU neck characteristics (neck diameter, length, and angulation,) Patients without 1-year follow-up were excluded for the 1-year outcomes analyses (n = 6138 [40%]). We used multivariable adjusted logistic regression and Cox proportional hazard models to identify the independent associations between neck characteristics outside of the IFU and our outcomes.

Results: Of the 15.448 patients identified, 22.1% had neck characteristics outside of the IFU, including 6.6% with a infrarenal angle, 6.8% with a neck length, 10.4% with a neck diameter, and 1.1% with a suprarenal angulation outside of the IFU. Of these, 2.4% had more than one neck characteristic outside of the IFU. Patients with neck characteristics outside of the IFU were more often female (27.9% vs 15.0%, P < .001) and were older (median age, 75 years vs 75 years, P < .001). EVAP patients with neck characteristics outside of the IFU had higher rates of type la endoleaks at completion (4.8% vs 2.5%, P < .001), perioperative mortality (1.2% vs 0.6%, P < .001), 1-year sac expansion (7.1% vs 5.3%, P = .017), and 1-year reinterventions (4.4% vs 3.2%; P = .003). In multivariable adjusted analyses, neck characteristics outside of the IFU were independently associated with type la completion endoleaks (OR, 1.6; 95% Cl. 1.5-2.0, P < .001), perioperative mortality (OR, 1.8; 95% Cl. 1.2-2.7, P = .005). 1-year sac expansion (OR, 1.4; 95% Cl. 1.0-1.8, P = .039). The unadjusted midterm survival was lower for patients with neck characteristics outside of the IFU than for patients without (5-year survival 84.0% vs 86.7%; log-rank P < .001). However, after adjustment, survival was similar for patients with neck characteristics outside of the IFU to those within (hazard ratio, 11, 95% Cl. 1.0-13, P = .20).

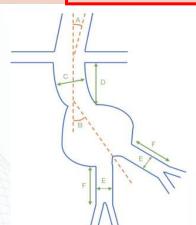
Conclusions: Neck characteristics outside of the IFU are independently associated with completion type Ia endoleaks, perioperative mortality. 1-year sac expansion, and 1-year reinterventions among patients undergoing elective EVAR. These results indicate that continued effort is needed to improve the proximal seal in patients with neck characteristics outside of the IFU undergoing EVAR. Also, in patients with severe hostile neck characteristics, alternative approaches such as open repair, use of a fenestrated or branched device, or endoanchors should be considered. (J Vasc Surg 2022;76:690-8.)

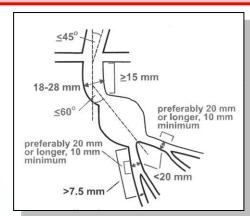


	OR	P value	95% CI
Endoleak (type Ia)	1.6	<.001	1.3-2.0
Perioperative mortality	1.8	.005	1.2-2.7
Reintervention during index hospitalization	1.9	.077	0.9-3.8
1-Year endoleak (type Ia)	1.0	.926	0.5-1.9
1-Year sac expansion	1.4	.025	1.0-1.8
1-Year reintervention	1.4	.039	1.0-1.9

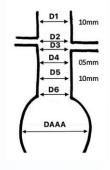
# Impact of Hostile Neck Components on Clinical Outcomes

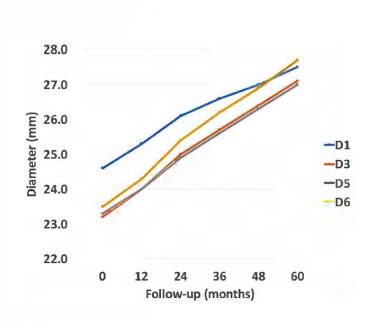
							1					
	Beta angulation outside IFU		Neck diameter larger than IFU		Neck length outside IFU		Alpha angulation outside IFU					
	OR	P value	95% CI	OR	P value	95% CI	OR	P value	95% CI	OR	P value	95% CI
Endoleak (type la)	2.0	<.001	1.5-2.7	1.5	.075	1.0-2.5	2.0	<.001	1.5-2.8	1.7	.097	.9-3.3
Perioperative mortality	1.8	.044	1.0-3.3	2.8	.007	1.3-6.0	1.2	.65	.5-2.6	.6	.65	.1-4.7
1-Year sac expansion	2.1	<.001	1.4-3.2	2.1	.017	1.1-3.7	1.2	.46	.7-2.0	.8	.69	.2-2.6
1-Year reintervention	2.1	.001	1.3-3.2	1.6	.19	.8-3.2	1.3	.35	.8-2.2	1.6	.37	.6-4.6

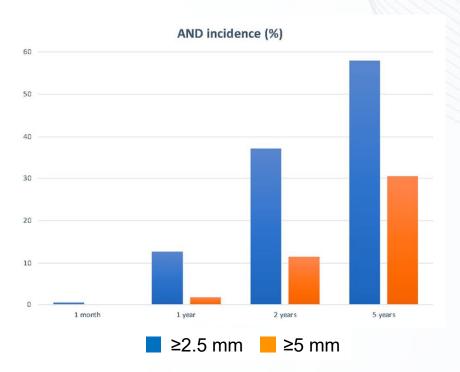




## **Proximal Aortic Neck Dilatation after EVAR**







Severance Hospital, Yonsei University & Gil Hospital, Gachon University (2000~2021)

Total number of patients	766		
Age (year)	71.0 ± 12.5		
Gender: Male (%)	691 (90.2)		
Diabetes mellitus (%)	169 (22.1)		
Hypertension (%)	541 (70.6)		
Dyslipidemia (%)	249 (32.6)		
Chronic kidney disease (%)	72 (9.4)		
Stroke (%)	82 (10.7)		
COPD (%)	40 (5.2)		
CHF (%)	20 (2.6)		
Coronary artery disease (%)	40 (5.2)		
Peripheral artery disease (%)	46 (6.0)		
Aterial fibrilariton (%)	12 (1.6)		
Smoking history	408 (53.3)		



Severance Hospital, Yonsei University & Gil Hospital, Gachon University

Total number of patients	766		
AAA diameter	58.99 ± 12.26 mm		
Aortic neck length	32.61 ± 15.74 mm		
Aortic neck diameter	22.09 ± 5.73 mm		
Proximal neck angle	46.17 ± 27.03 °		
Rt distal landing zone length	41.08 ± 13.94 mm		
Lt distal landing zone length	42.53 ± 15.07 mm		
Outside IFU	462 (60.3%)		
Neck length <10 mm	33 (4.3)		
Neck diameter >31	14 (1.8)		
Neck angle > 60	210 (27.4)		
Neck calcium>50%	82 (10.7)		
Neck thrombus>50%	189 (24.7)		
Reverse taper	135 (17.6)		

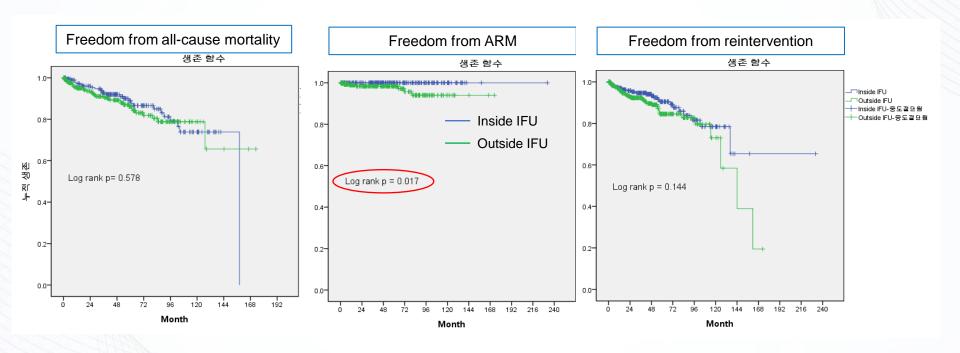
Severance Hospital, Yonsei University & Gil Hospital, Gachon University

Total number of patients	766		
Procedure time	68.26 ± 58.83 min		
Percutanous closure	726 (86.7)		
EVAR method			
Routine method	707 (92.3)		
Chimney method - Renal	27 (3.5)		
Sandwich method - IIA	25 (3.3)		
Iliac branched device - IIA	6 (0.8)		
Branch vessel embolization	209 (27.3)		
Device			
Medtronic Endurant	386 (46.3)		
Gore Excluder	185 (22.2)		
COOK Zenith	108 (13)		
Cordis Incraft	57 (6.8)		
Endologix AFX2	32 (3.8)		
S&G Seal	12 (1.4)		

Severance Hospital, Yonsei University & Gil Hospital, Gachon University

Total number of patients	542		
Follow up duration	45.8 ± 31.9 months		
AAA diameter	55.2 ± 16.8 mm		
Diameter increase (>5mm)	128 (23.6)		
Diameter stable	198 (36.5)		
Diameter decrease	216 (39.9)		
Endoleak	128 (23.5)		
Type 1	42 (7.7)		
Type 2	79 (11.7)		
Type 3	2 (0.3)		
Type 4	0 (0)		
Type 5	2 (0.3)		
Type 1 and 2	3 (0.4)		
Type 1, 4 and 5	1 (0.1)		
Complication of stent graft	12 (2.2)		
Migration	5 (0.7)		
Thrombotic occlusion	9 (1.3)		
Infection	2 (0.3)		

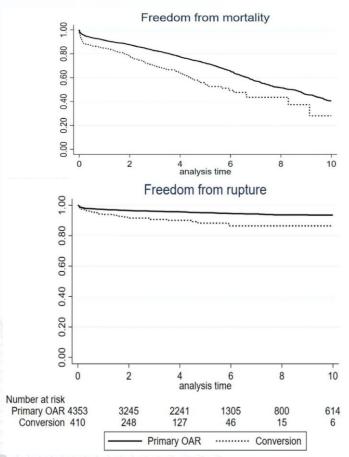
Severance Hospital, Yonsei University & Gil Hospital, Gachon University

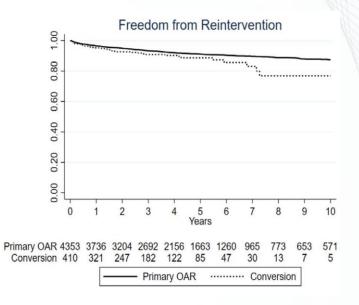


# Factors associated with Aneurysm-related Mortality

Aneurysm related mortality	OR	95% CI	Р
IFU	28847762.85	0	0.994
Neck_length	0	0	0.998
Neck_diameter	21.767	3.83 - 123.56	0.001
Neck_angle	1.051	0.20 - 5.46	0.953
Neck_calcium	0	0	0.997
Neck_thrombus	2.512	0. 56 - 11.35	0.231
Reverse taper	1.772	0.34 - 9.24	0.497
Endoleak_1st CT	0.497	0.06 - 4.48	0.533
Endoleak_Last CT	1.894	0.31 - 11.47	0.487

## **Open Conversion after EVAR vs. Primary Open Repair**



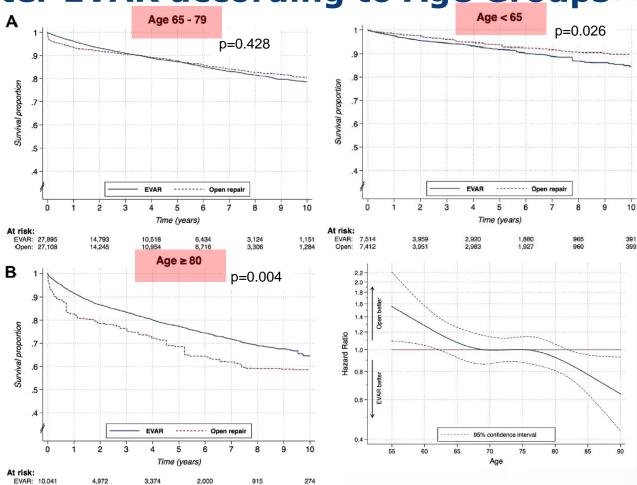


Elsayed N, J Vasc Surg 2022



Survival after EVAR according to Age Groups

Society of Vascular Surger y Vascular Quality Initiative (VQI) clinical registry



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# **Take Home Messages**

- Recent studies demonstrated that aneurysm-related mortality (ARM) during long-term follow-up is higher with EVAR than open repair despite reduced 30day mortality and perioperative morbidity after endovascular repair.
- Especially, non-adherence to IFU was associated with increased incidence of reinterventions and ARM after EVAR.
- Thus, EVAR should be primarily indicated for patients at old age or at high surgical risk after considering anatomical conditions according to IFU.
- Open repair should be considered for younger patients (below 65) as first-line therapy.
- Regular surveillance after EVAR is important to detect early unfavorable adverse changes of aneurysm sac and implants after EVAR.