Is EVAR Safe and Durable in Long-term?

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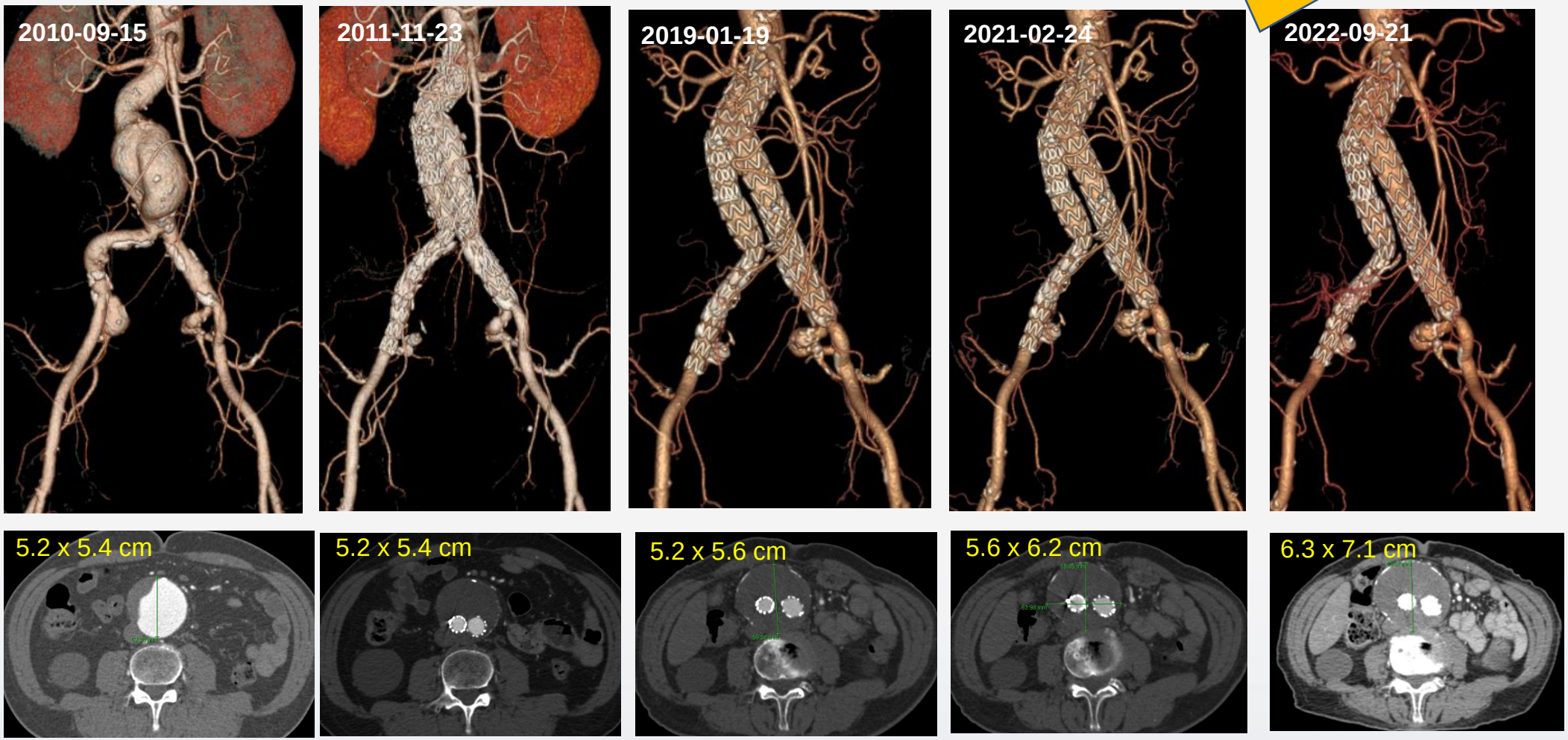
Disclosure

- 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

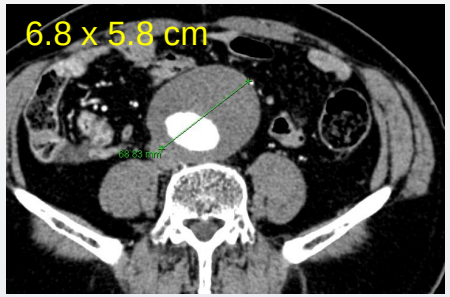
M/66, S/P CABG:
EVAR with Endurant & Rt IIA embolization (2010-10-26)

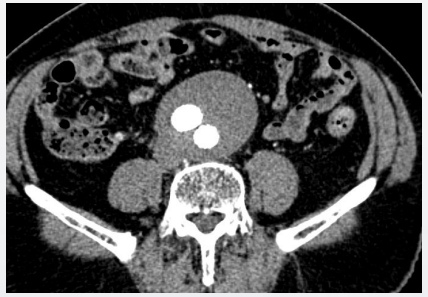
2021.03.24
Stent-graft reinforcement
at Rt iliac limb

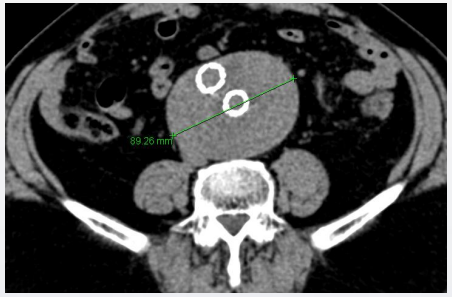


#5842569

M/75,
EVAR with Excluder (2016-10-11)







- **1st reintervention: 2019-10-16** Additional stent graft at Lt limb

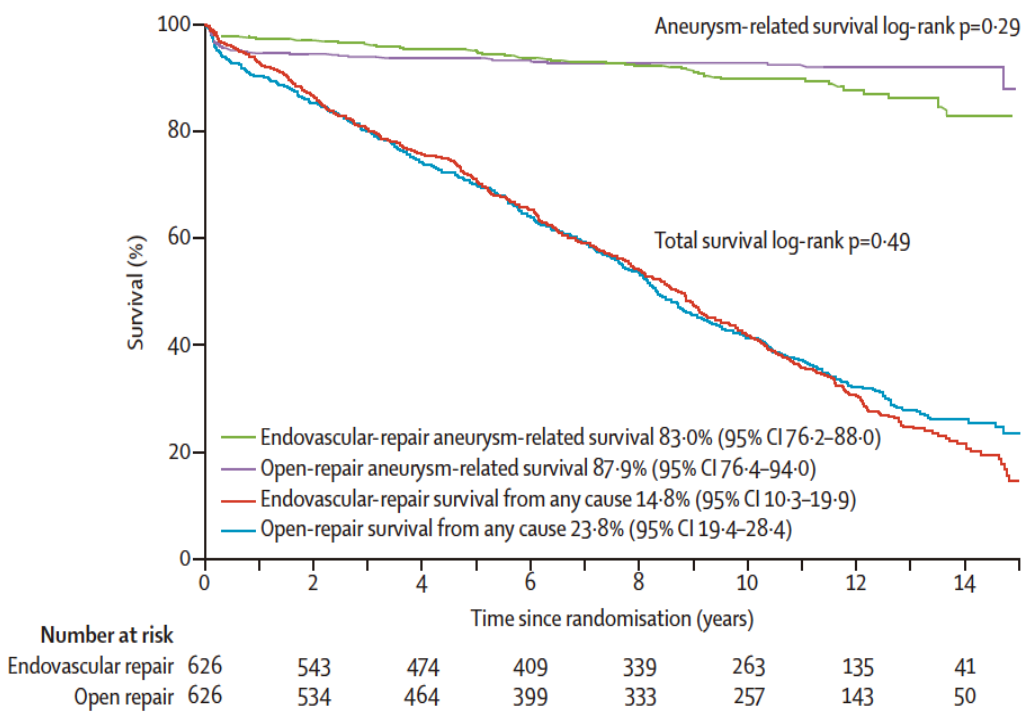
- AAA diameter increase with Type Ia endoleak
- **2nd reintervention: 2021-04-27**
  Aortic cuff at proximal main body
  Rt CIA-EIA (extension) with Rt IIA embolization

- 2022-09-19 CT:
  Further increase in AAA diameter
  --> 90mm.

3rd reintervention is needed!

#5583124

EVAR-1: 15-years Follow-up



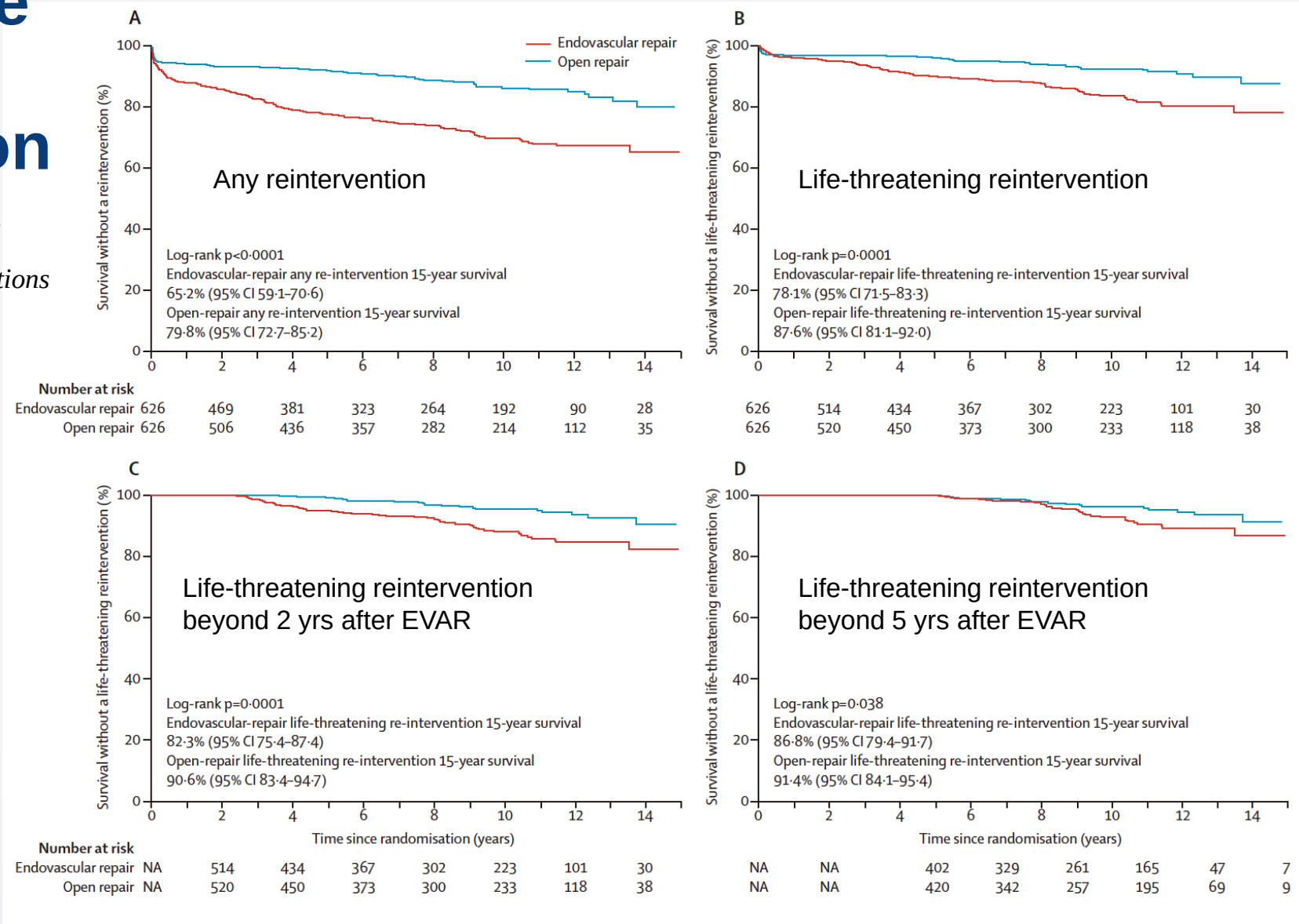
	Endovascular repair (N=626)		Open repair (N=626)		Hazard ratio (95% CI)		p value†
	n/N (%)	Rate per 100 person-years	n/N (%)	Rate per 100 person-years	Unadjusted	Adjusted*	
Total mortality							
All patients	466/626 (74%)	9·3	444/626 (71%)	8·9	1·05 (0·92–1·19)	1·11 (0·97–1·27)	0·14
0–6 months	26/626 (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-related mortality							
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

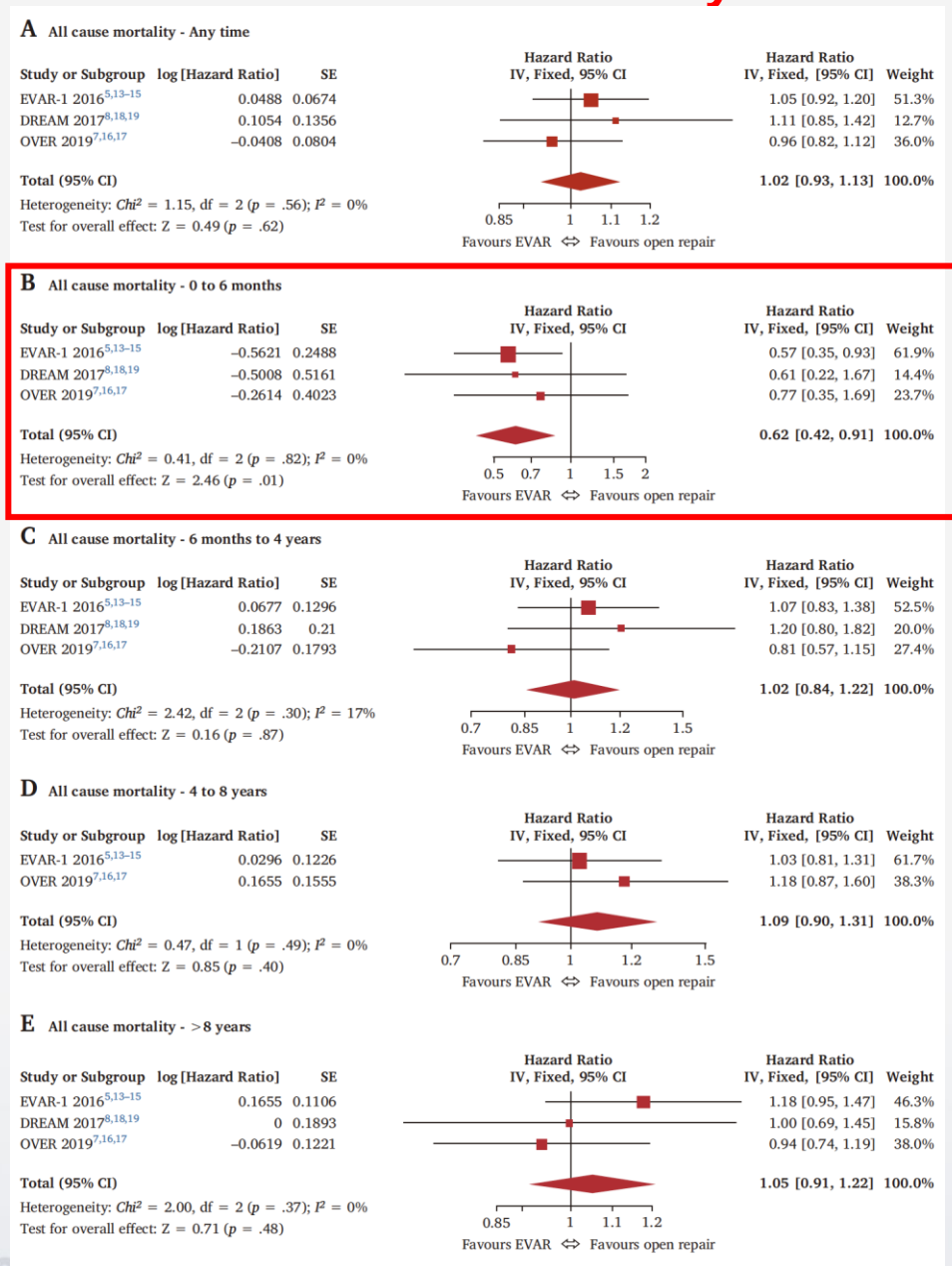
Survival free from reintervention

Life-threatening reintervention:
- *Conversion to open repair*
- *Reinterventions d/t graft infections*
- *Stent-graft extension*

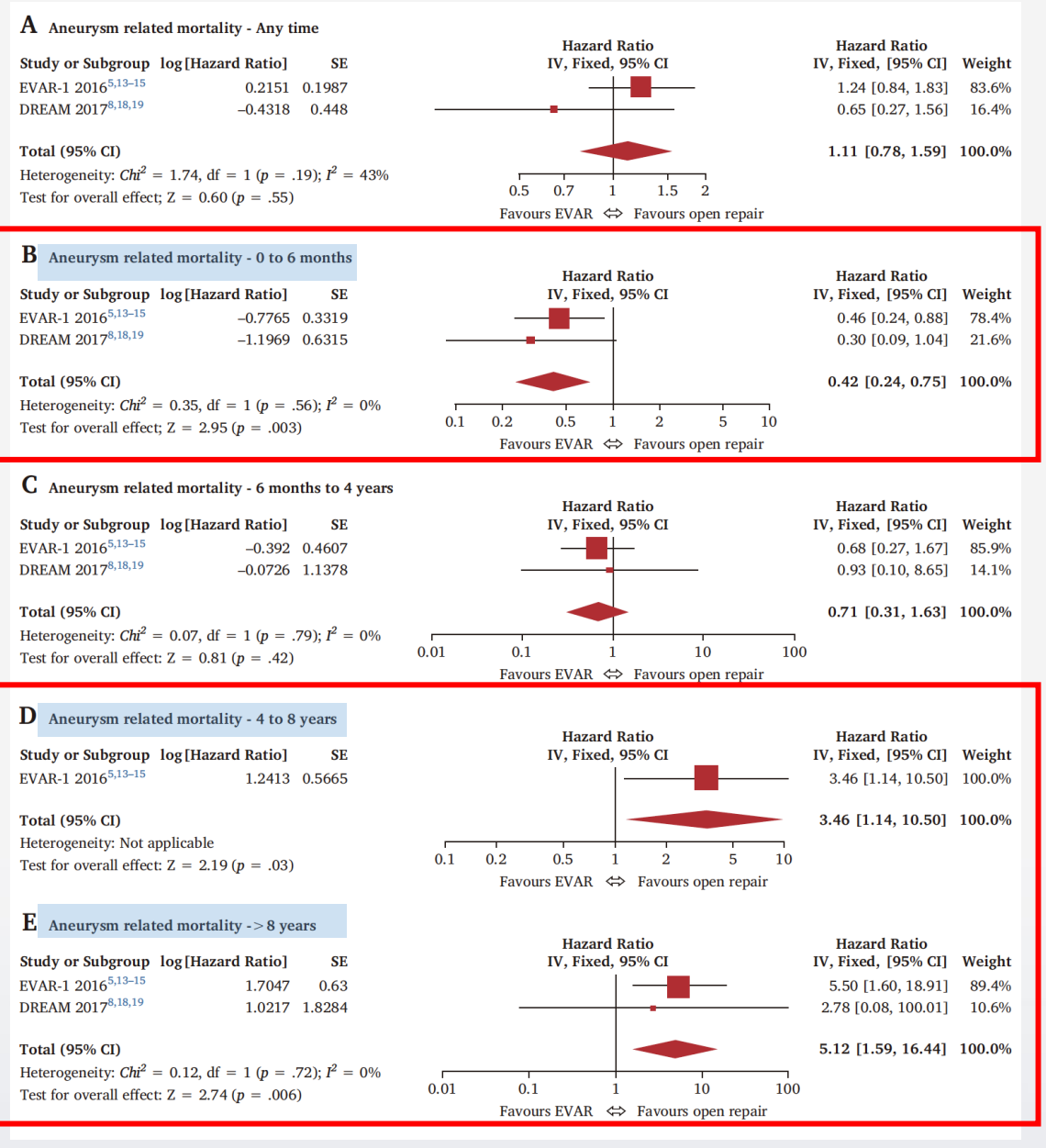


Patel R, Lancet 2016; 388: 2366

All cause mortality



Aneurysm-related mortality



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

Endurant™ stent graft natural selection global postmarket registry (ENGAGE registry)

A Large Contemporary EVAR Registry with A Single Manufacturer's Stent Graft

1,263 Patients

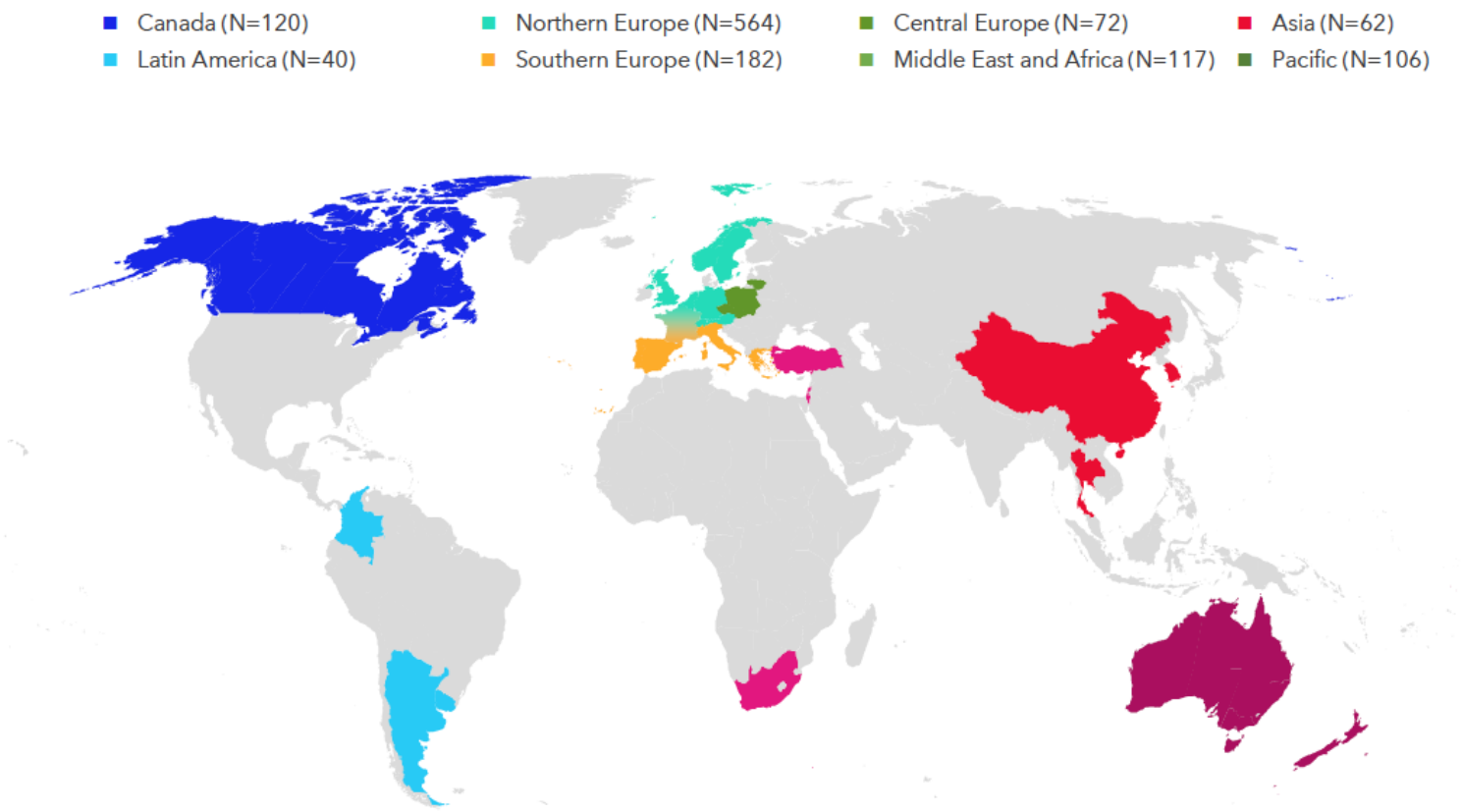
79 Sites

30 Countries

6 Continents

Real-world patients

Real-world practice

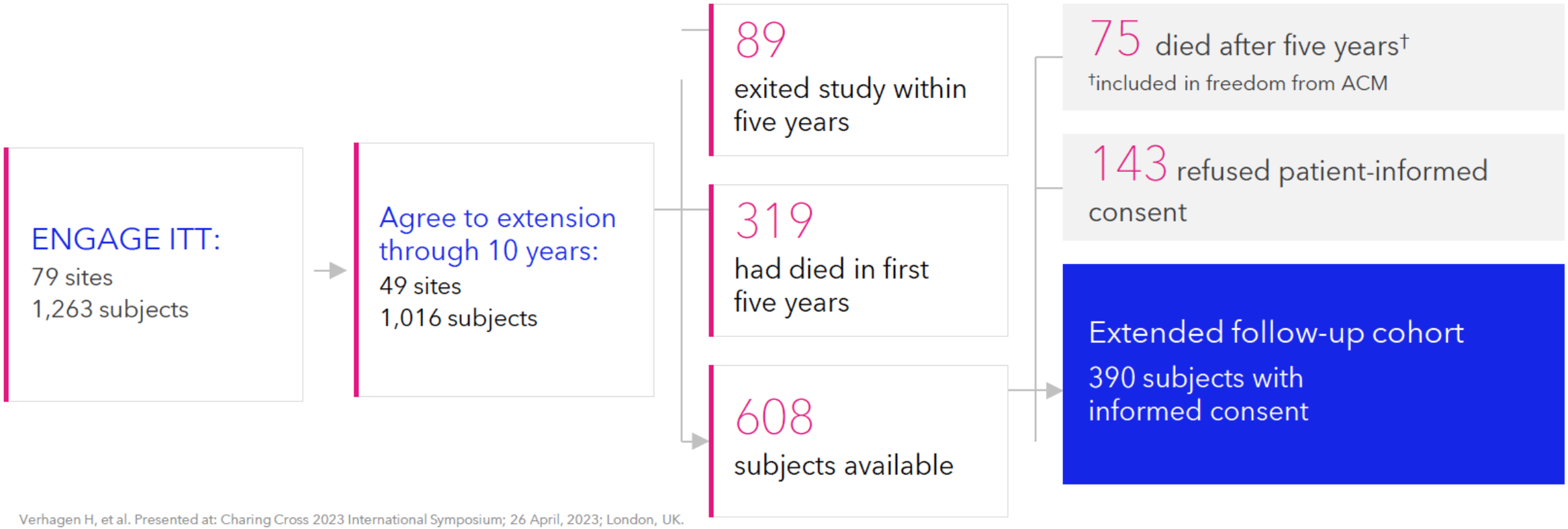


Verhagen H, presented at: Charing Cross 2023

Methods – Extended follow-up cohort

Ten-year follow up compliance

89.7% (244/272) clinical follow-up
68.3% (183/268) imaging follow-up



Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

Baseline characteristics

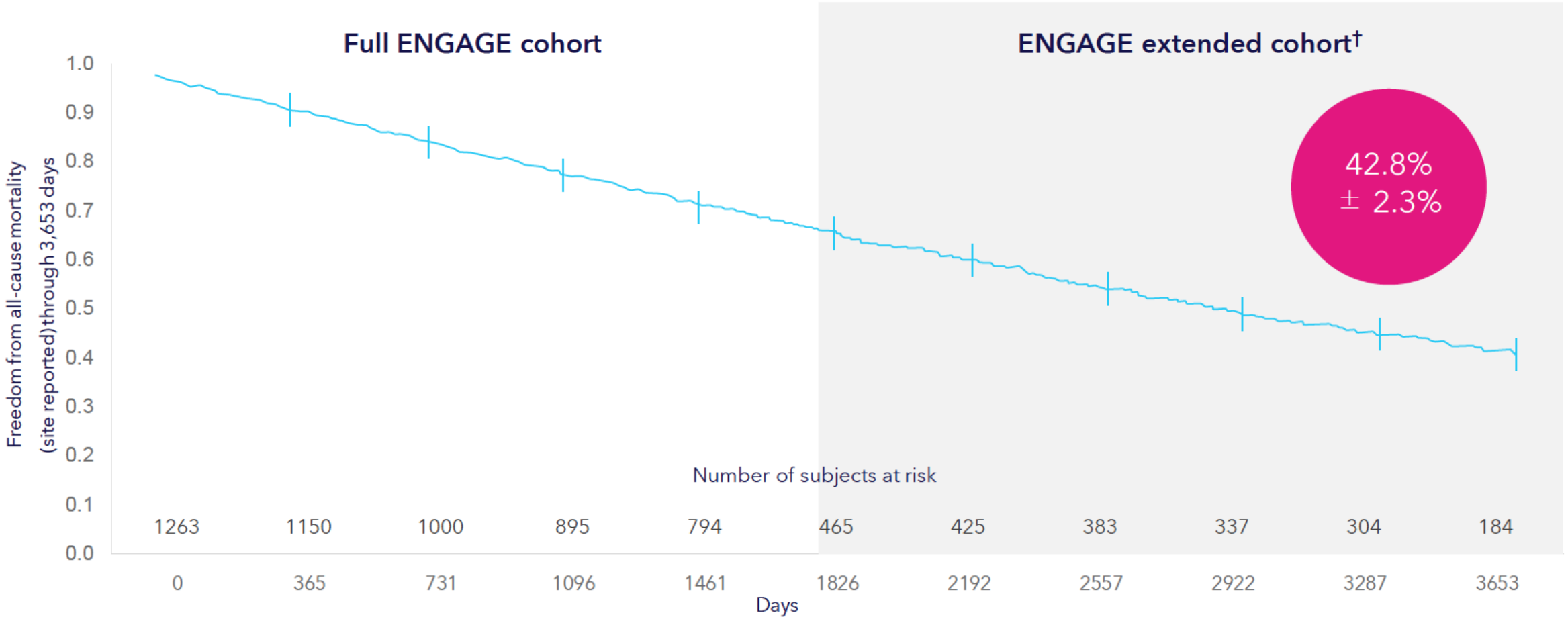
Baseline characteristics	Not extended	Extended follow-up cohort	P-value[1]
Age (years)	74.3 ± 8.1 (873)	70.4 ± 7.3 (390)	< 0.001
Female % (m/n)	11.8% (103/873)	7.7% (30/390)	0.028
Cardiac disease	55.6% (485/872)	49.5% (193/390)	0.044
Pulmonary disease	28.0% (241/860)	19.6% (75/382)	0.002
Renal insufficiency	17.4% (151/866)	11.4% (44/386)	0.007
Cerebral vascular accident (CVA)	6.3% (55/868)	3.1% (12/387)	0.019
Peripheral vascular disease	20.3% (175/860)	14.3% (55/385)	0.011
Procedural characteristics	**Not extended**	**Extended follow-up cohort**	**P-value[1]**
Volume of contrast (cc)	120.0 (10, 400)	100.0 (9, 355)	0.0012
Hospital stay (days)	5.0 (1, 69)	4.0 (1, 100)	< 0.0001

[1] P-value for categorical data calculated with chi-square p-value when cell frequency ≥ 5 or Fisher's p-value when cell frequency < 5; For continuous data, used t-test when n ≥ 30 or Wilcoxon rank sum test when n < 30.

Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

Freedom from all-cause mortality through 10 years

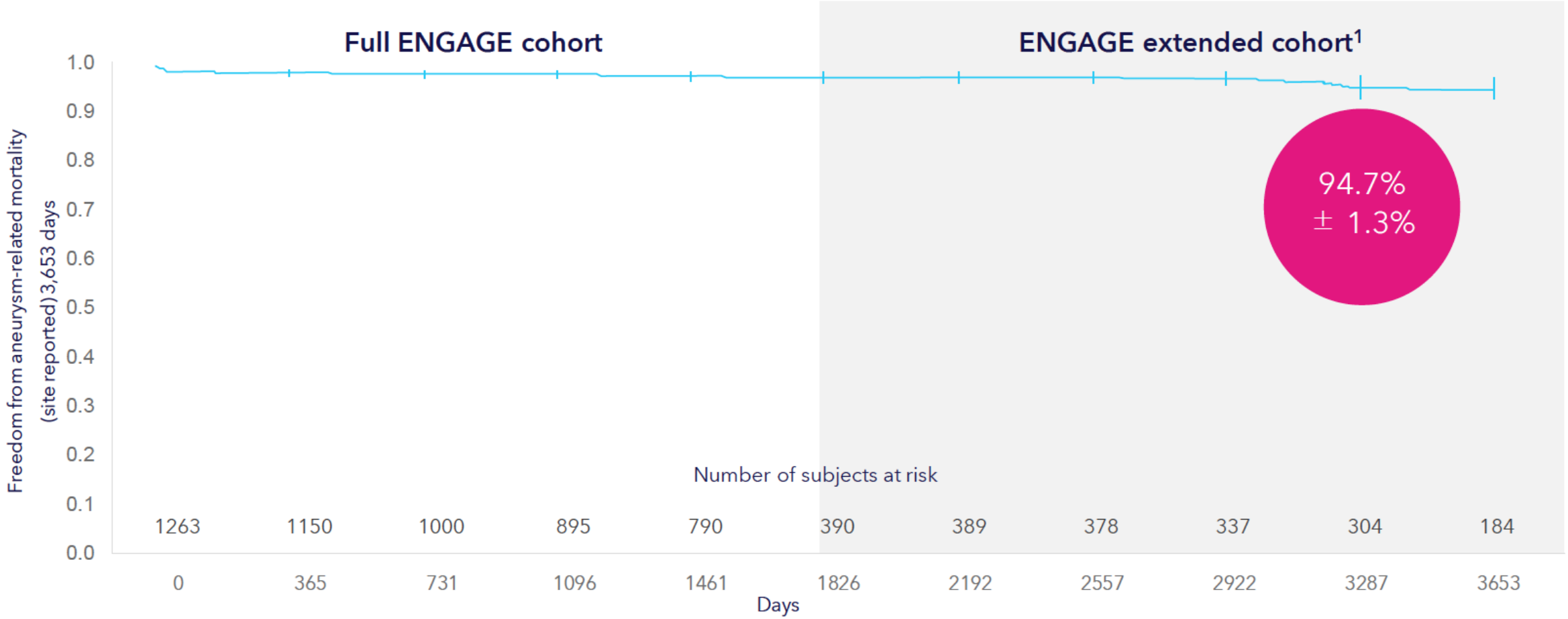


†465 subjects at risk at the beginning of year 6 includes the 390 of the Extended FU cohort as well 75 subjects who were from sites in the ENGAGE extension but died before reconsenting.
Number of subjects at risk are at the beginning of the interval. Survival estimates are made at end of the interval.

Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

Freedom from aneurysm-related mortality through 10 years

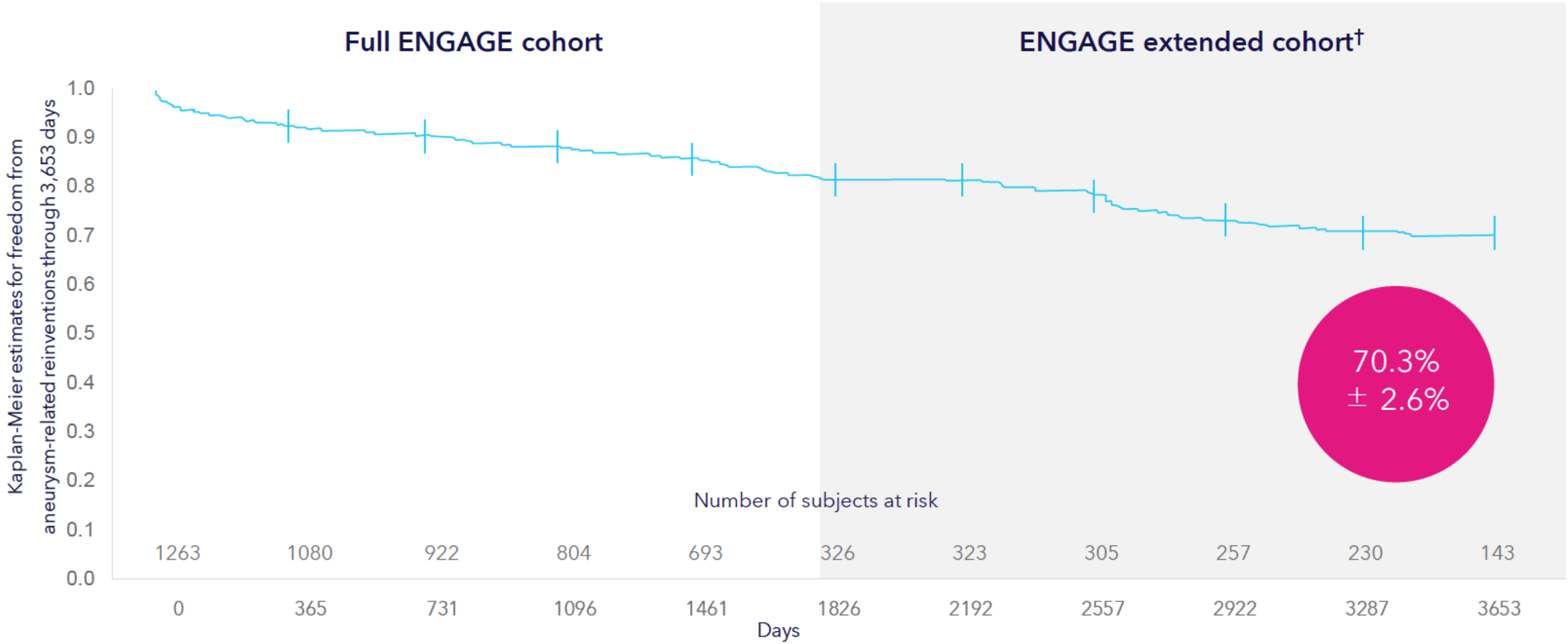


[1] Clinical events committee adjudicated.

Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

Freedom from aneurysm-related reintervention through 10 years

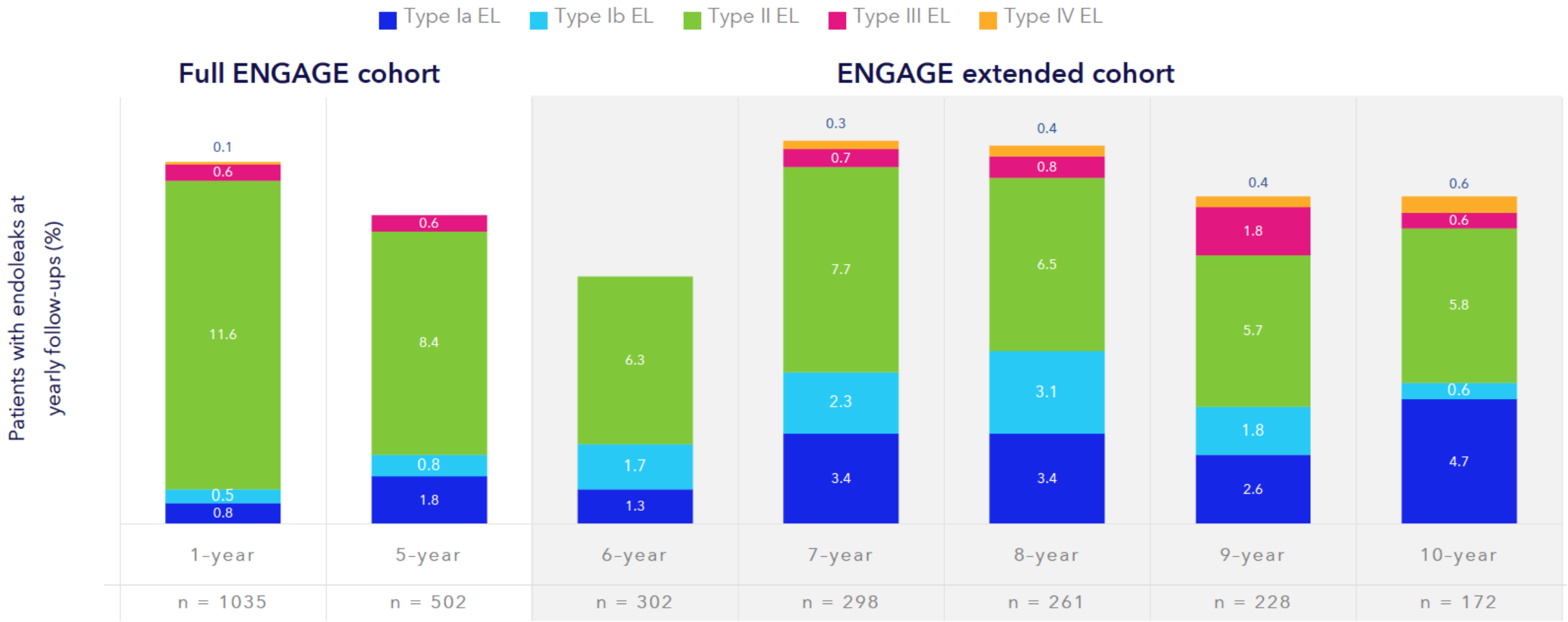


†Number of subjects at risk are at the beginning of the interval. Survival estimates are made at end of the interval. Aneurysm-related re-interventions are defined as all the secondary endovascular procedures (scheduled and unscheduled), secondary vascular procedures and conversions to open repair.

Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

Clinical events – Endoleaks



n = number of non-missing values. Individual subjects may have multiple endoleak types at each time point.

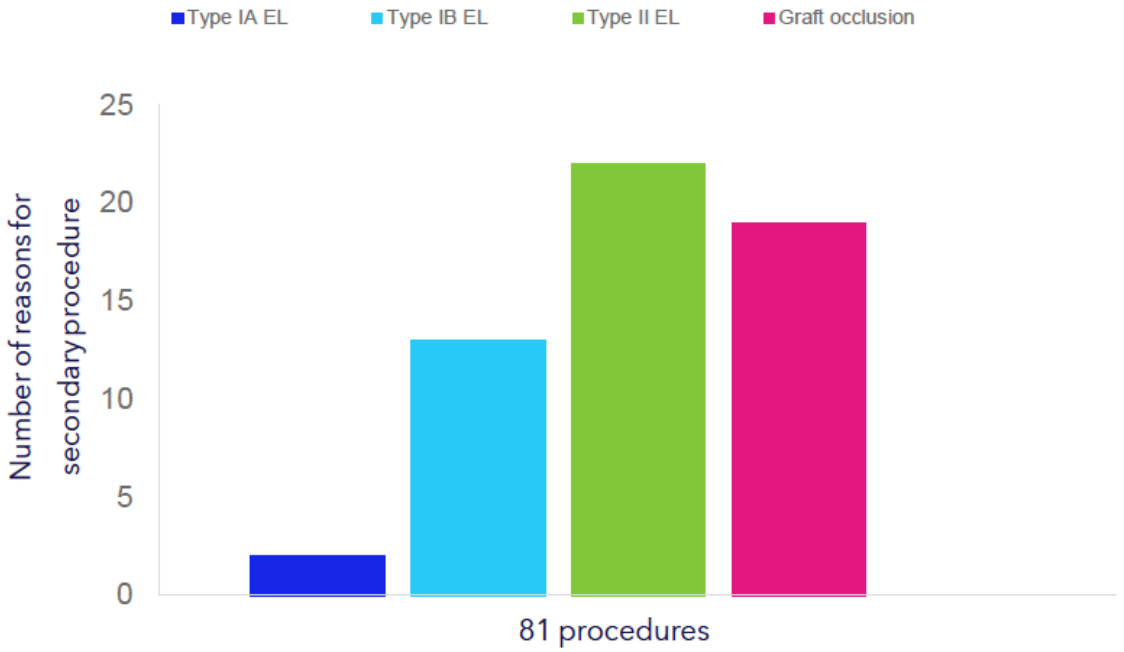
Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

Verhagen H, presented at: Charing Cross 2023

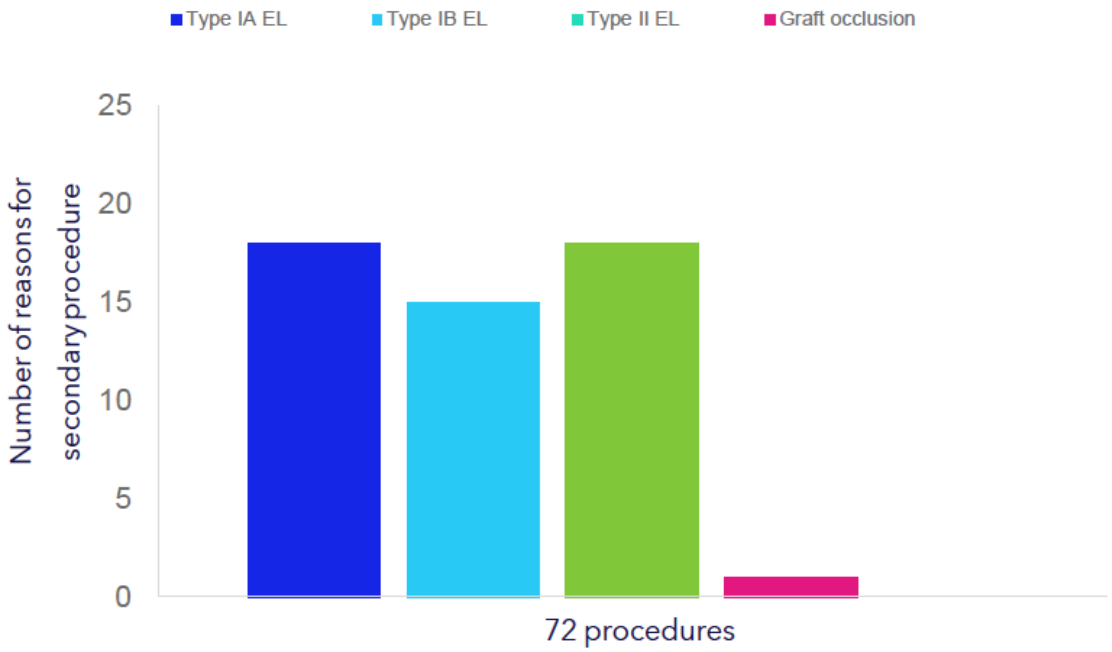
Reasons for reintervention – ENGAGE extended cohort

Late reinterventions appear related to aneurysm disease progression

Reasons for early reintervention (0–5 years)



Reasons for late reintervention (6–10 years)



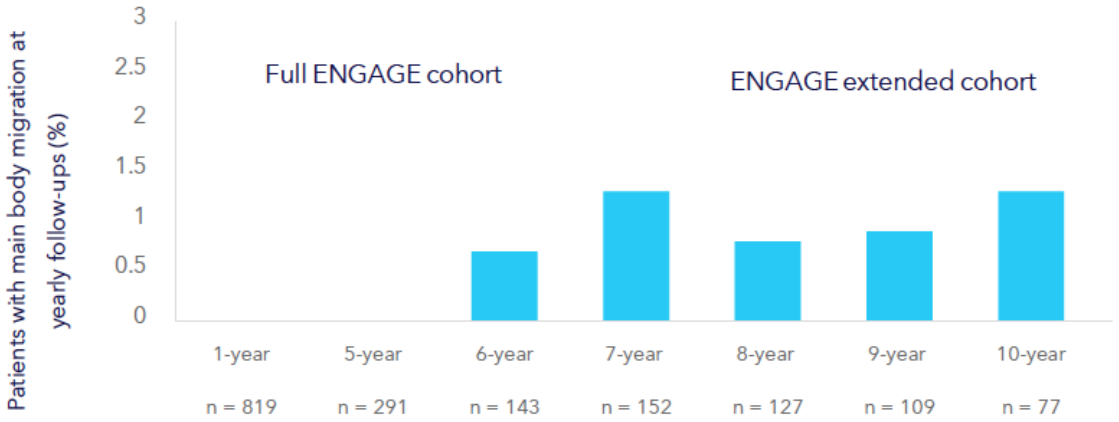
Note: A subject may have multiple reasons for the same secondary endovascular procedure, so the total number of all reasons can be more than the total number of procedures.

Verhagen H, et al. Presented at: Charing Cross 2023 International Symposium; 26 April, 2023; London, UK.

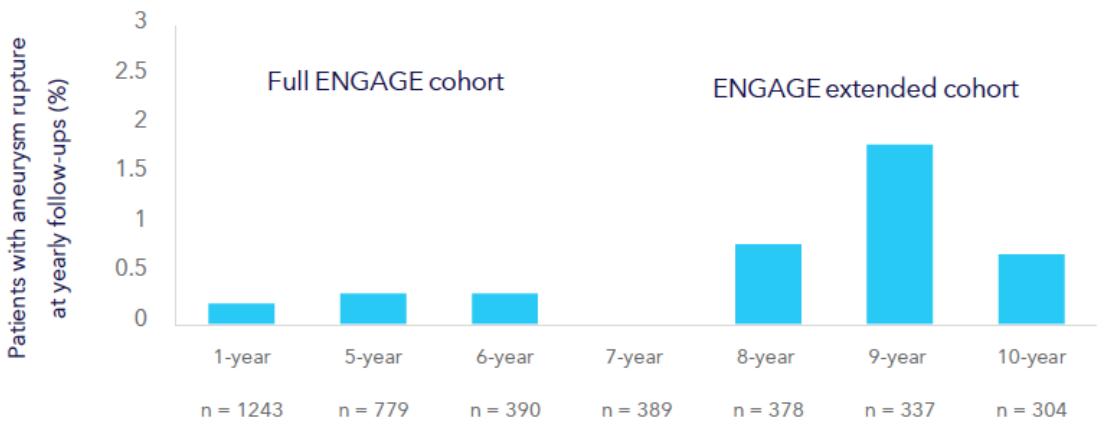
Verhagen H, presented at: Charing Cross 2023

Clinical events

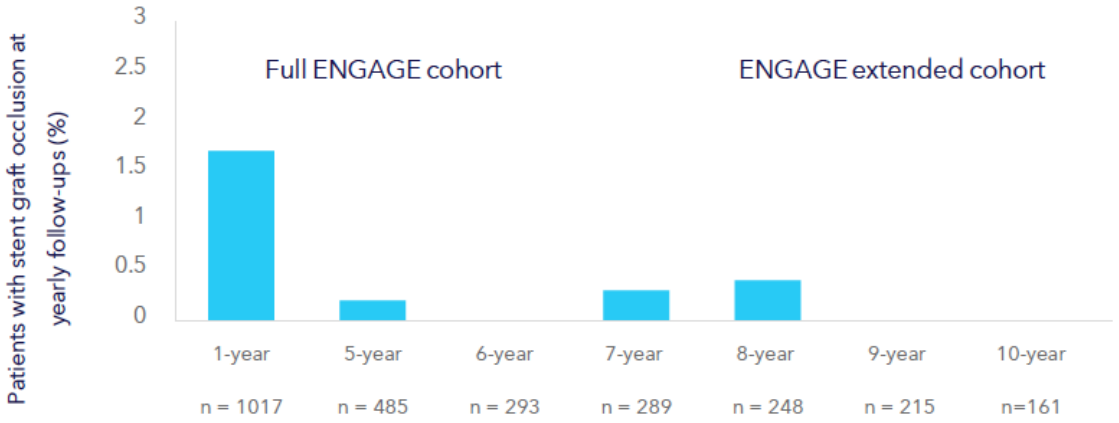
Main body migration[1]



Aneurysm rupture



Stent graft occlusion[1]



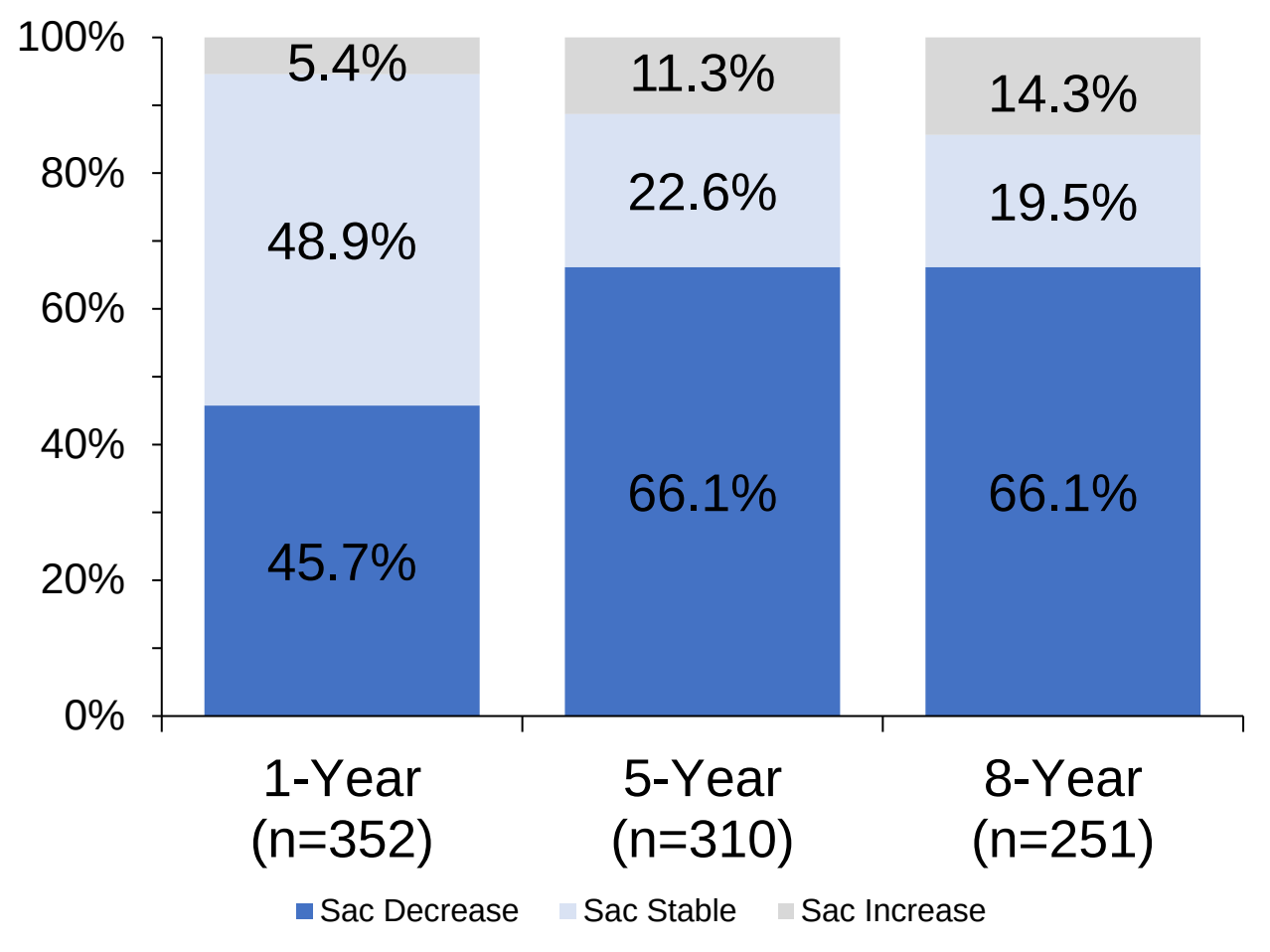
n = number of non-missing values.

All 12 patients with **late aneurysm** rupture (6–10 years) had endoleaks:

- EL type: Ia (3), Ib (4), III (4), unknown (1)
- Event result: Death (7) and resolved (5)

Verhagen H, presented at: Charing Cross 2023

Sac Regression



- 85.7% of patients had stable or decreasing sacs at 8 years
- Stable sacs may transition to increasing sacs with longer follow up
- Sustained 66% sac regression rate after 3 yrs

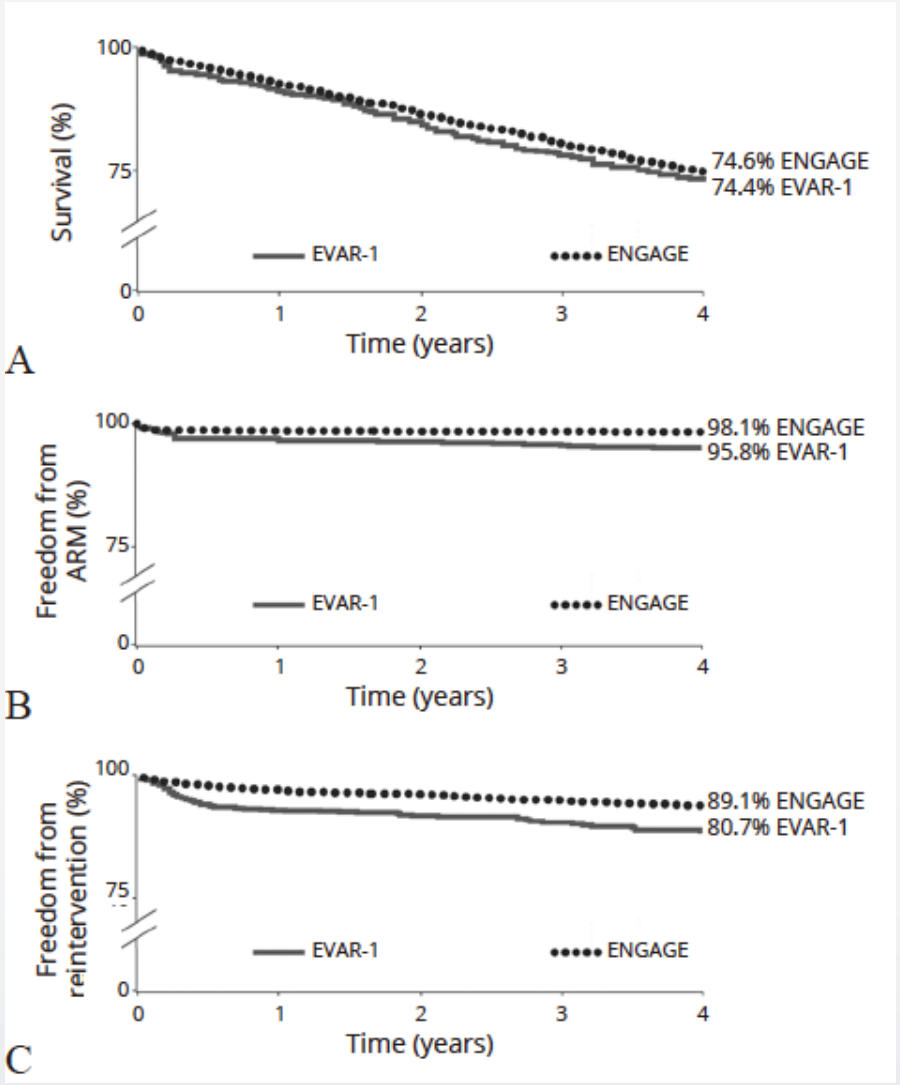
Key points:

- Endurant continues to deliver sac regression in all comer patients through 8Y
- Sac “stability” is not sufficient – the goal is sac regression

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

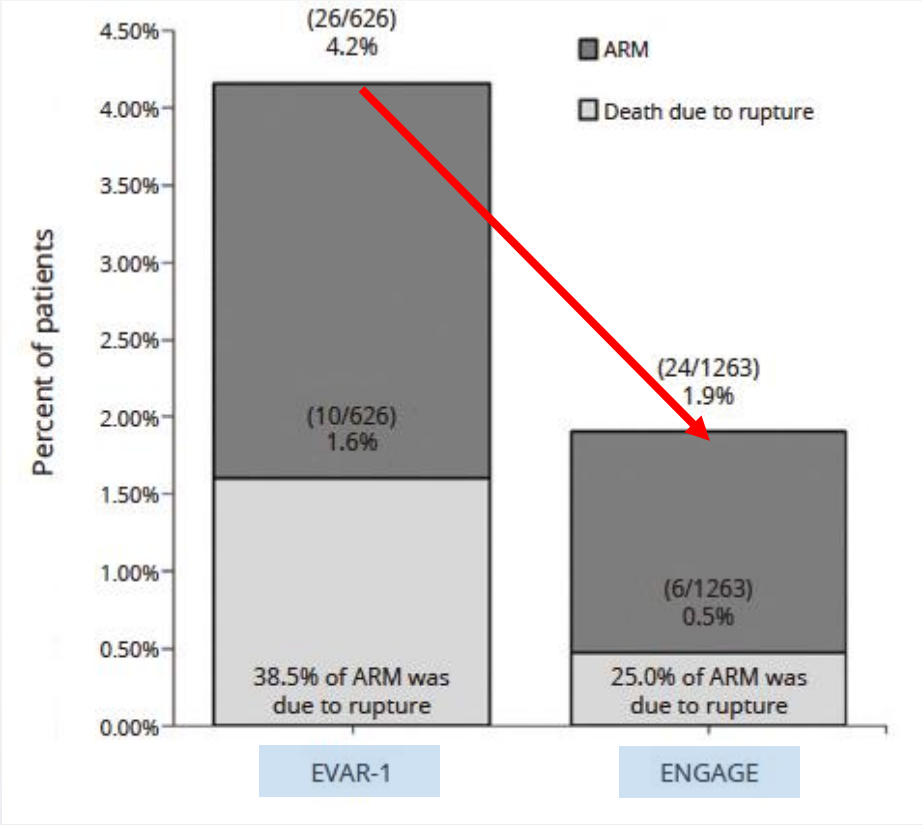
EVAR-1 RCT vs ENGAGE Registry EVAR Outcomes

EVAR-1 devices:
51% Zenith,
33% Talent,
7% Excluder,
4% AneuRx,
2% Quantum
or Teramed



Study enrollment:
EVAR-1: 1999 ~ 2004
ENGAGE: 2009 ~ 2011

Aneurysm-related Mortality



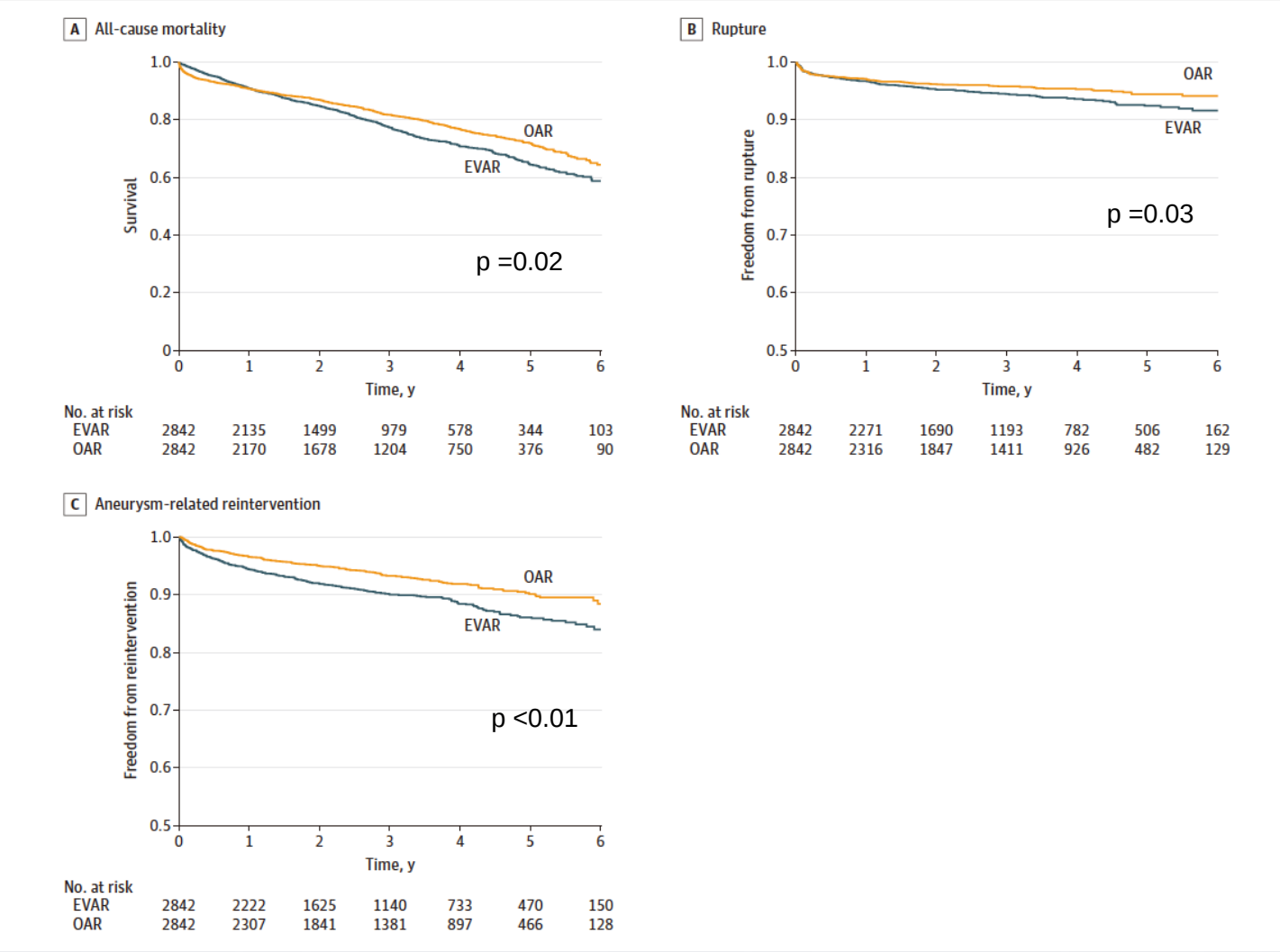
Böckler D, J Cardiovasc Surg 2020;61:604

US Medicare data: Open Repair vs EVAR

Total 32,760 patients
(2003~2018)

PSM

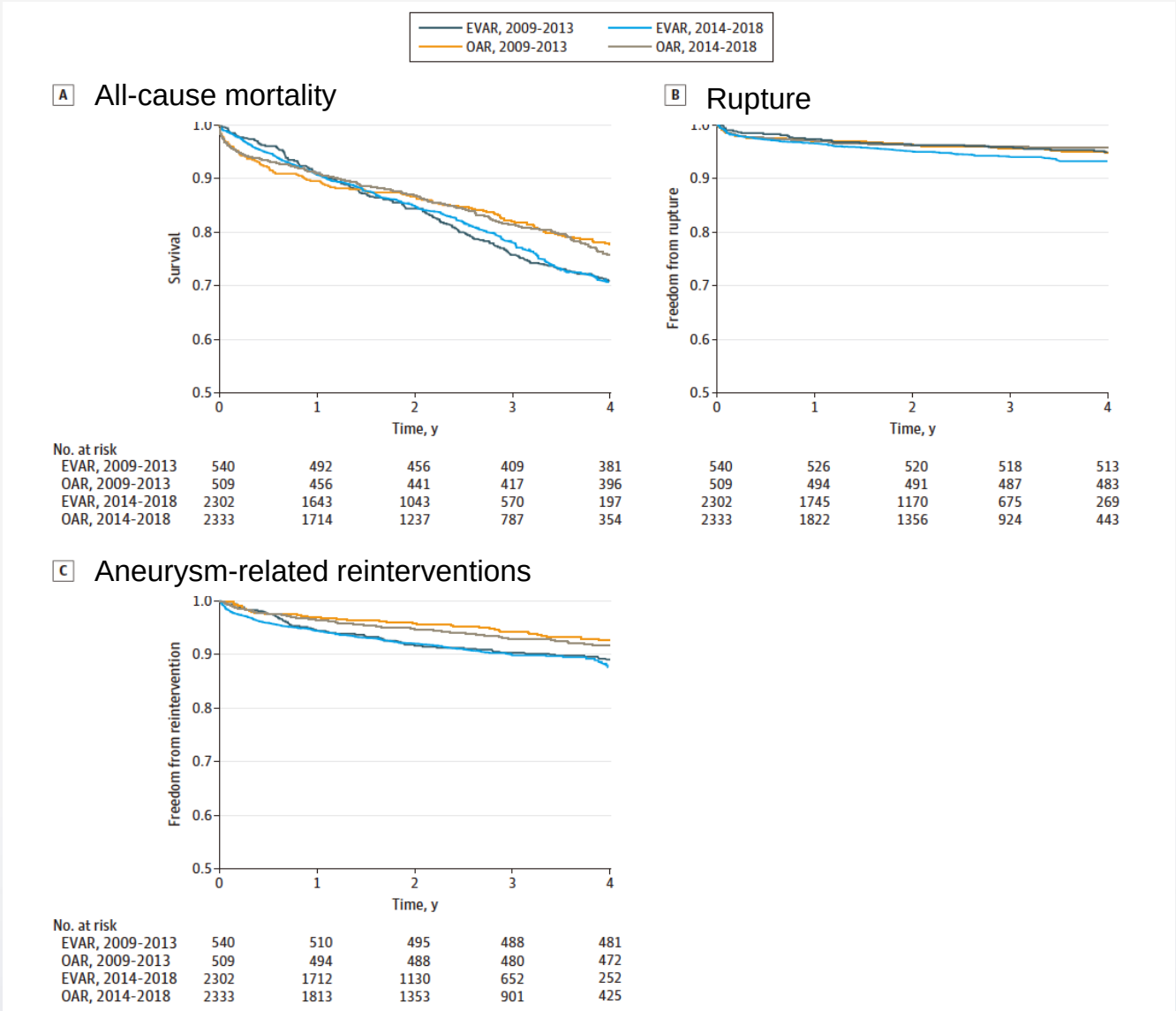
EVAR n=2852
Open n=2852



Yei K, JAMA Network Open 2022;5:e2212081

US Medicare data: Open Repair vs EVAR

Early phase (2009-2013)
vs.
Recent phase (2014-2018)



Yei K, JAMA Network Open 2022;5:e2212081

Impact of IFU adherence on the 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

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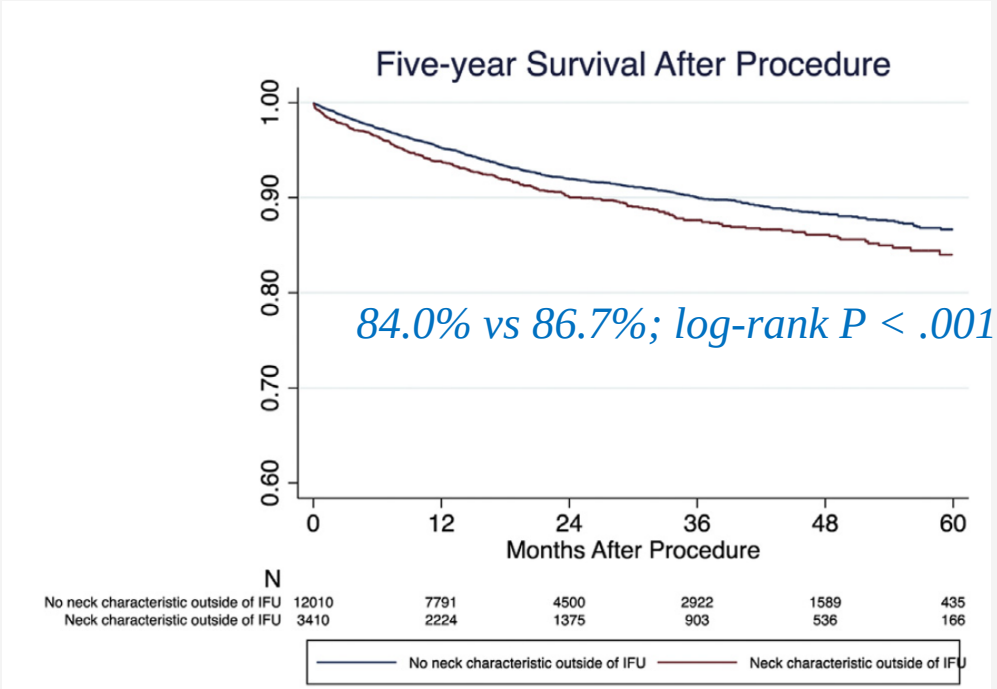
ABSTRACT

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 73 years; $P < .001$). EVAR patients with neck characteristics outside of the IFU had higher rates of type Ia 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%; $P = .03$). In multivariable adjusted analyses, neck characteristics outside of the IFU were independently associated with type Ia completion endoleaks (OR, 1.6; 95% CI, 1.3-2.0; $P < .001$), perioperative mortality (OR, 1.8; 95% CI, 1.2-2.7; $P = .005$), 1-year sac expansion (OR, 1.4; 95% CI, 1.0-1.8; $P = .025$), and 1-year reinterventions (OR, 1.4; 95% CI, 1.0-1.9; $P = .039$). 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, 1.1; 95% CI, 1.0-1.3; $P = .22$).

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.)

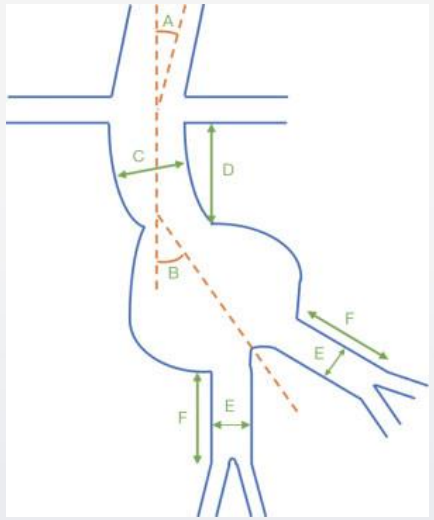


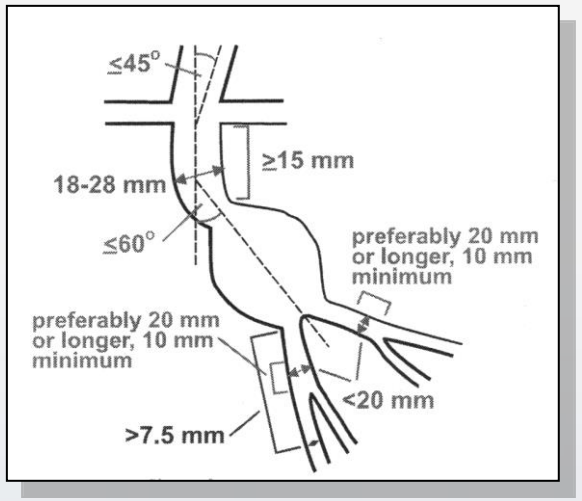
	OR	*P* value	95% CI
Endoleak (type Ia)	1.6	<.001	1.3-2.0
Perioperative mortality	1.8	.005	1.2-2.7
Reintervention during index hospitalization	1.9	.077	0.9-3.8
1-Year endoleak (type Ia)	1.0	.926	0.5-1.9
1-Year sac expansion	1.4	.025	1.0-1.8
1-Year reintervention	1.4	.039	1.0-1.9

De Guerre L, J Vasc Surg 2022;76:690

Impact of Hostile Neck Components on Clinical Outcomes

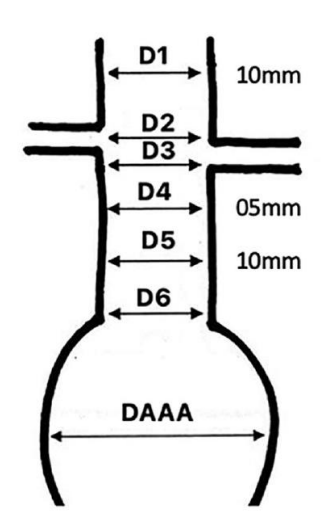
	Beta angulation outside IFU			Neck diameter larger than IFU			Neck length outside IFU			Alpha angulation outside IFU		
	OR	*P* value	95% CI	OR	*P* value	95% CI	OR	*P* value	95% CI	OR	*P* value	95% CI
Endoleak (type Ia)	2.0	<.001	1.5-2.7	1.5	.075	1.0-2.5	2.0	<.001	1.5-2.8	1.7	.097	.9-3.3
Perioperative 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

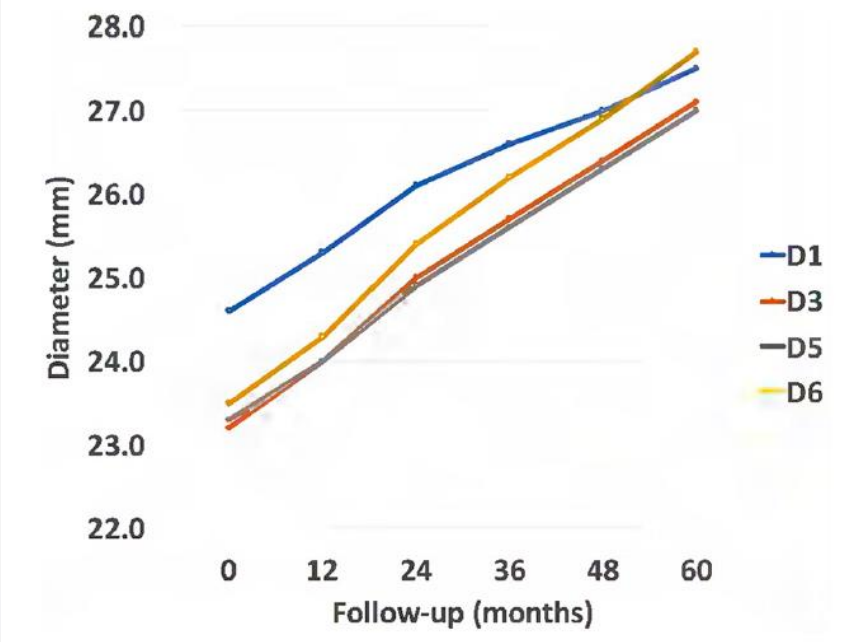




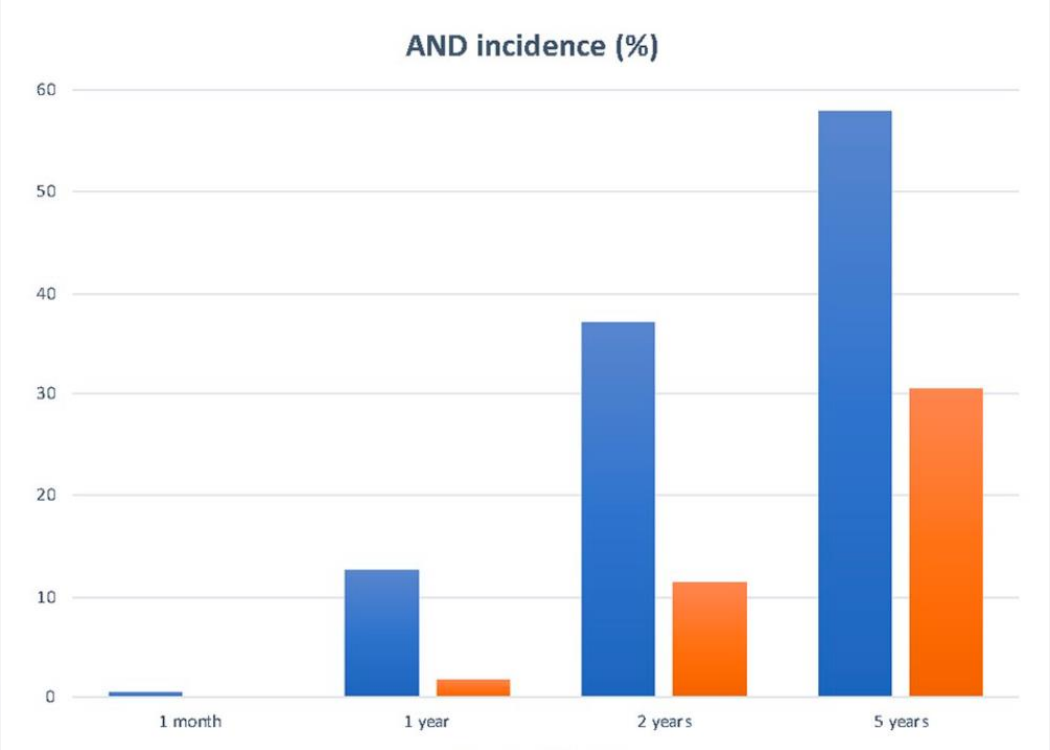
De Guerre L, J Vasc Surg 2022;76:690

Proximal Aortic Neck Dilatation after EVAR





Aortic neck dilatation



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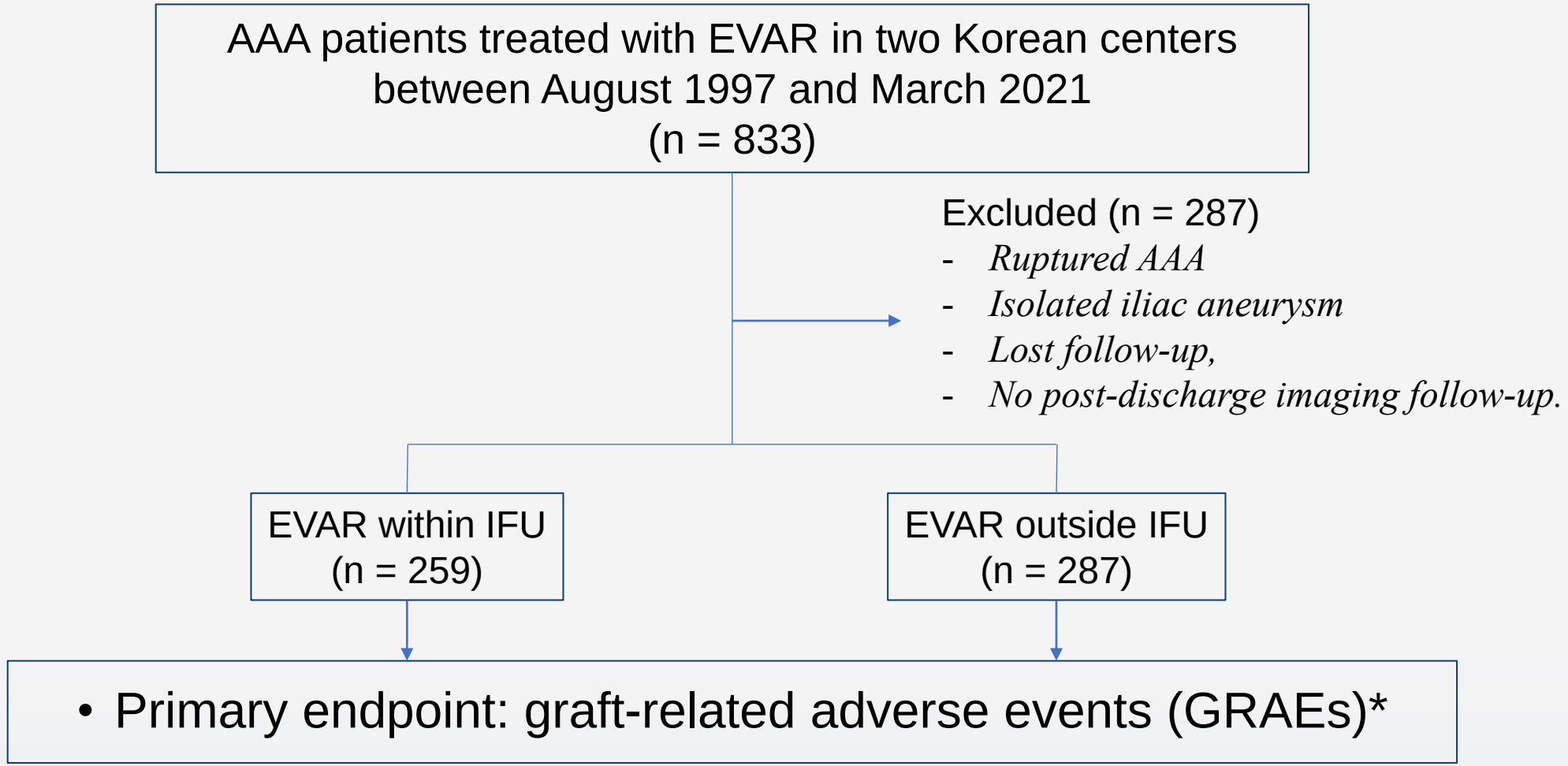
Study Design

- *Severance Hospital, Yonsei University, Seoul*
- *Gil Medical Center, Gachon University, Incheon*



**defined as a composite of the presence of type 1 or 3 endoleak, reintervention (included open conversion), aneurysm sac enlargement, aneurysm-related mortality, rupture, stent-graft migration, and stent thrombotic occlusion*

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Baseline Clinical and Anatomical Characteristics

	Total (n=546)	Within IFU (n=259)	Outside IFU (n=287)	p value
Clinical characteristics				
Age (years)	70.8±9.2	68.8±9.6	72.7±8.5	<0.001
Gender: male, n (%)	494 (90.6)	243 (93.8)	251 (87.8)	0.015
DM, n (%)	119 (21.8)	53 (20.5)	66 (23.0)	0.474
HTN, n (%)	389 (71.2)	196 (75.7)	193 (67.2)	0.030
CKD, n (%)	39 (7.1)	20 (7.7)	19 (6.6)	0.618
CAD, n (%)	218 (39.9)	103 (39.8)	115 (40.1)	0.943
PAD, n (%)	30 (5.5)	11 (4.2)	19 (6.6)	0.224
AF, n (%)	9 (1.6)	4 (1.5)	5 (1.7)	0.856
Smoke, n (%)	304 (60.0)	156 (64.2)	148 (56.1)	0.062
Anatomical characteristics				
AAA diameter (mm)	58.9±11.6	57.0±10.1	60.6±12.6	<0.001
Aortic neck length (mm)	32.0±15.6	32.3±13.7	31.7±17.2	0.68
Aortic neck diameter (mm)	22.3±6.2	21.4±3.0	23.0±7.9	0.003
Proximal neck angle (°)	45.7±27.3	31.9±16.5	57.9±29.1	<0.001
Right iliac length (mm)	40.7±13.7	40.9±11.8	40.5±15.3	0.751
Left iliac length (mm)	42.3±14.9	43.2±13.3	41.6±16.1	0.223

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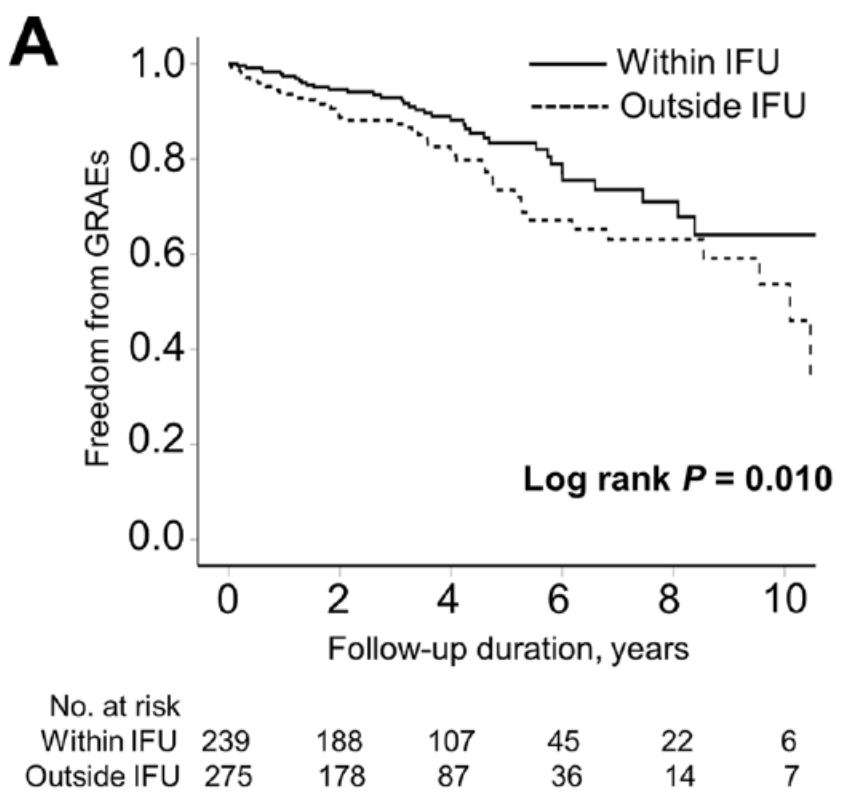
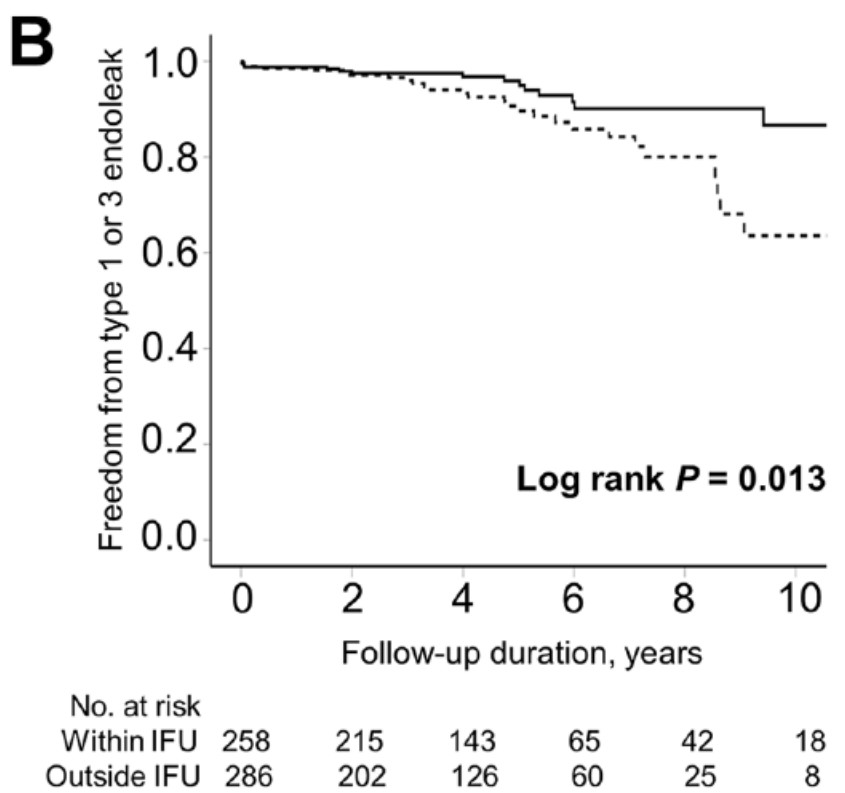
Comparison of Outcomes between within and outside IFU

(Median follow-up duration ~ 50 months)

Graft-related adverse events



Type 1 or 3 endoleak



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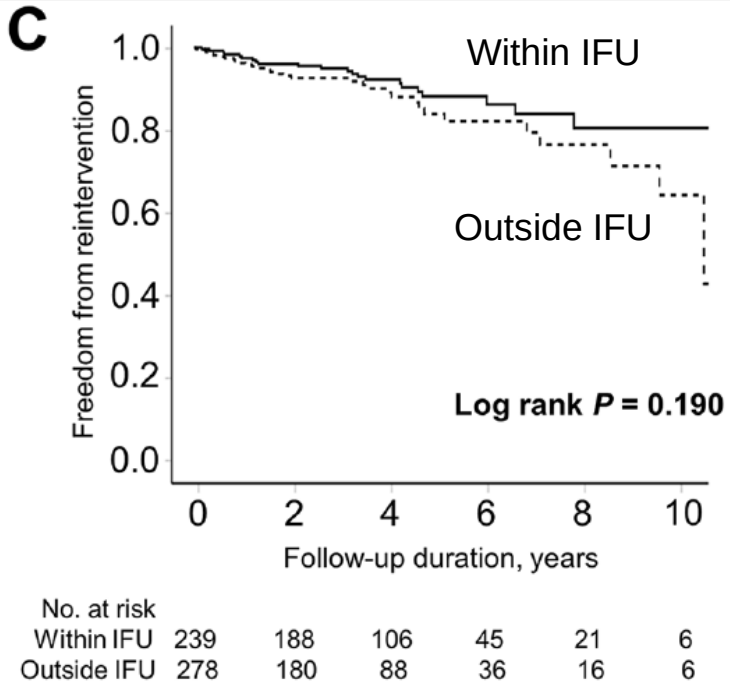
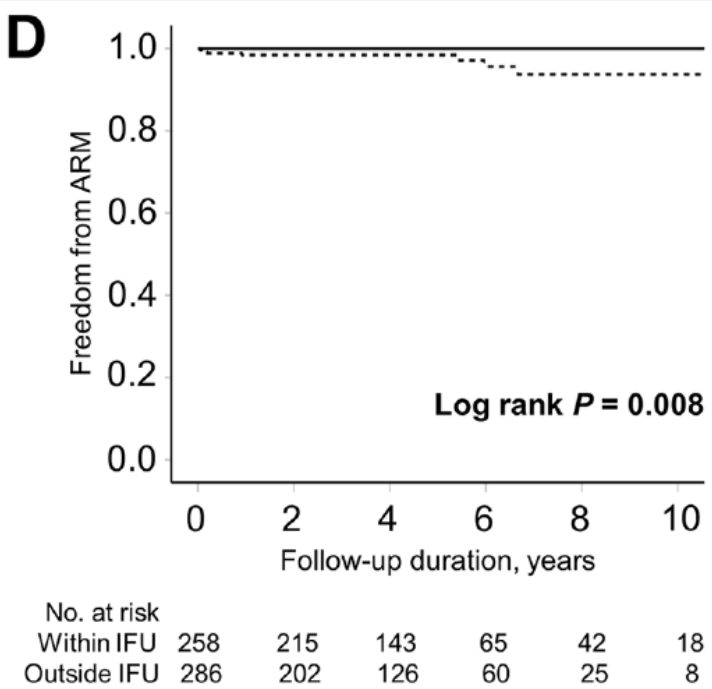
Outcomes between within and outside IFU

(Median follow-up duration ~ 50 months)

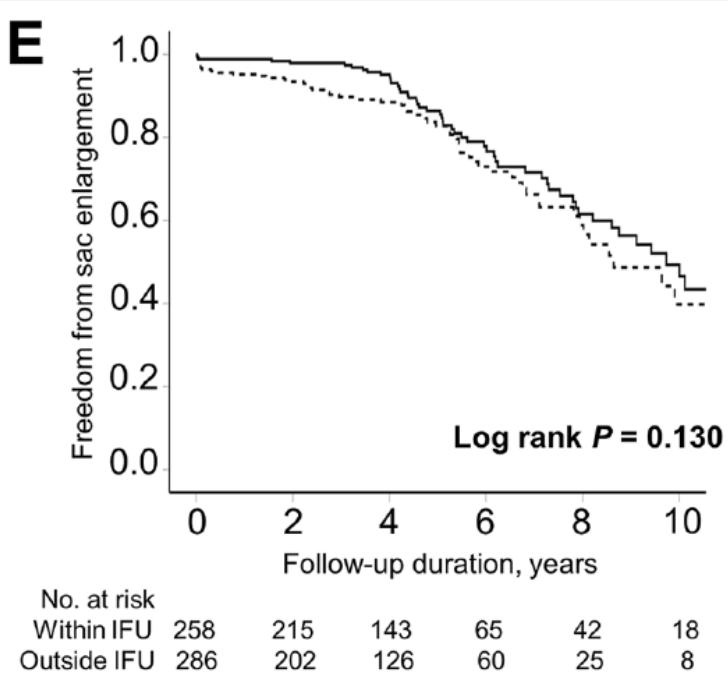
Reintervention



Aneurysm-related mortality



Sac enlargement



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Age-Matched and Sex-Matched Cox Proportional Hazards Regression Analysis in Primary Endpoint Component

	GRAEs		Type 1 or 3 endoleak		Reintervention		Aneurysm sac enlargement	
Variables	Adjusted HR (95% CI)	p value	Adjusted HR (95% CI)	p value	Adjusted HR (95% CI)	p value	Adjusted HR (95% CI)	p value
Neck length <10 mm	0.849 (0.266–2.710)	0.782	1.496 (0.338–6.630)	0.596	0.909 (0.219–3.765)	0.895	3.913 (1.908–8.026)	<0.001
Neck diameter >28 mm	1.976 (0.931–4.192)	0.076	2.051 (0.699–6.016)	0.191	1.968 (0.754–5.137)	0.167	1.562 (0.707–3.451)	0.271
Neck angle >60°	2.229 (1.418–3.503)	0.001	2.640 (1.343–5.189)	0.005	1.891 (1.055–3.388)	0.032	1.143 (0.731–1.785)	0.558
Neck calcium >50%	1.088 (0.491–2.410)	0.835	2.327 (0.856–6.326)	0.098	0.695 (0.212–2.272)	0.547	1.637 (0.830–3.226)	0.155
Neck thrombus >50%	0.692 (0.410–1.166)	0.167	0.538 (0.235–1.234)	0.144	0.634 (0.317–1.267)	0.197	0.739 (0.458–1.191)	0.214
Iliac length <15 mm	0.414 (0.097–1.766)	0.234	0.622 (0.078–4.984)	0.654	0.699 (0.158–3.086)	0.637	0.426 (0.100–1.819)	0.249

Abbreviations: CI, confidence interval; GRAEs, graft-related adverse events; HR, hazard ratio.

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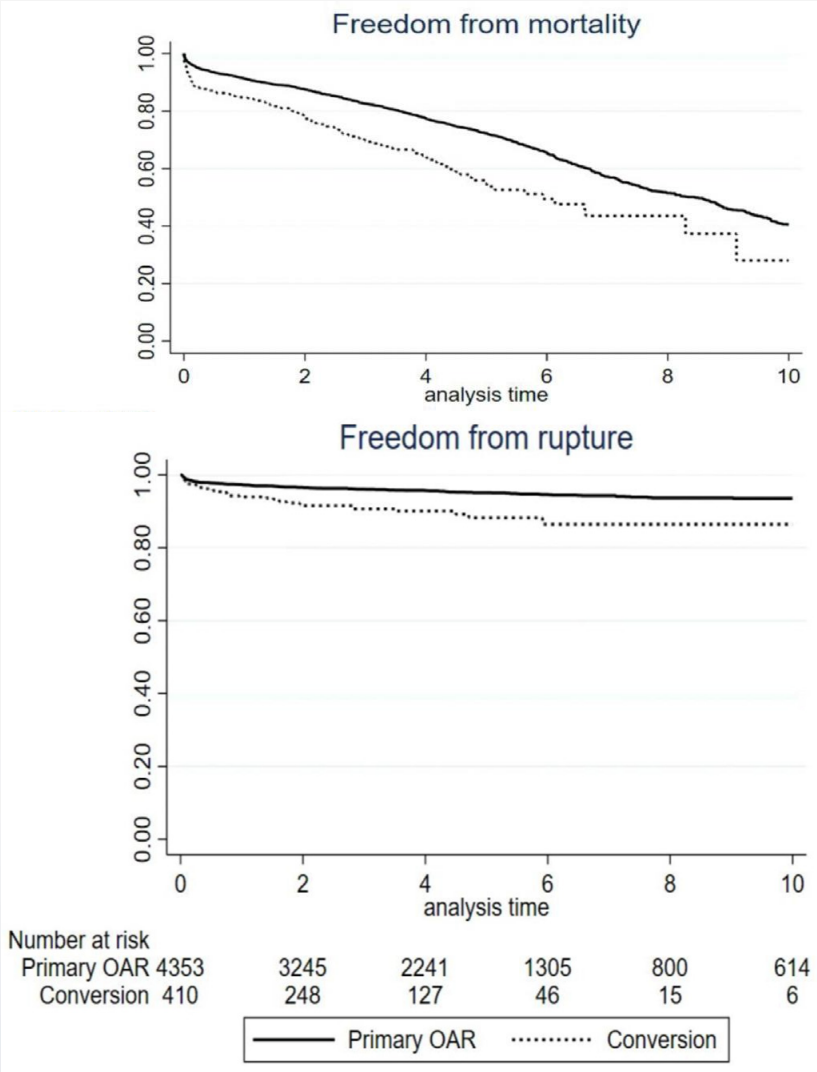
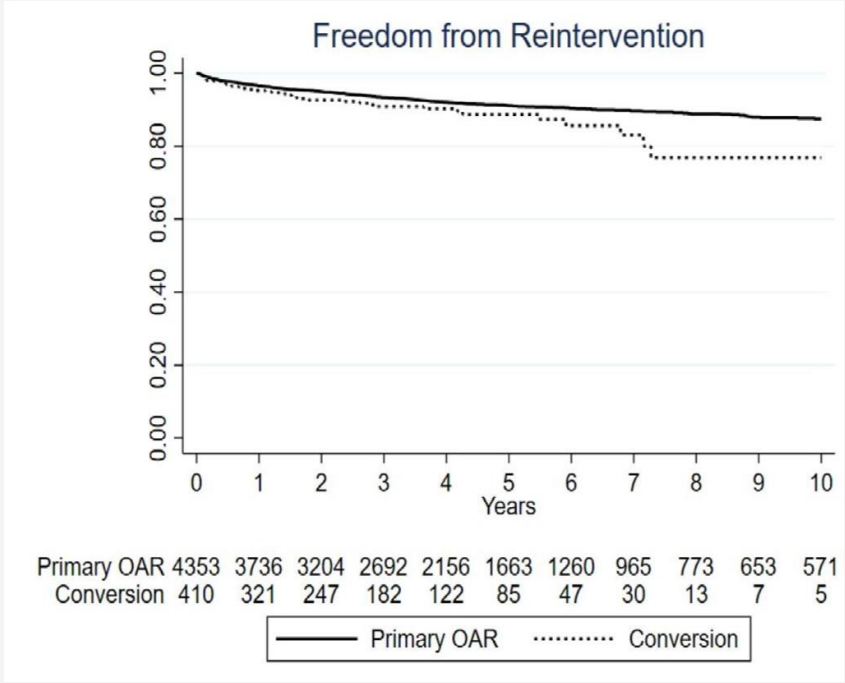
Open Conversion after EVAR vs. Primary Open Repair





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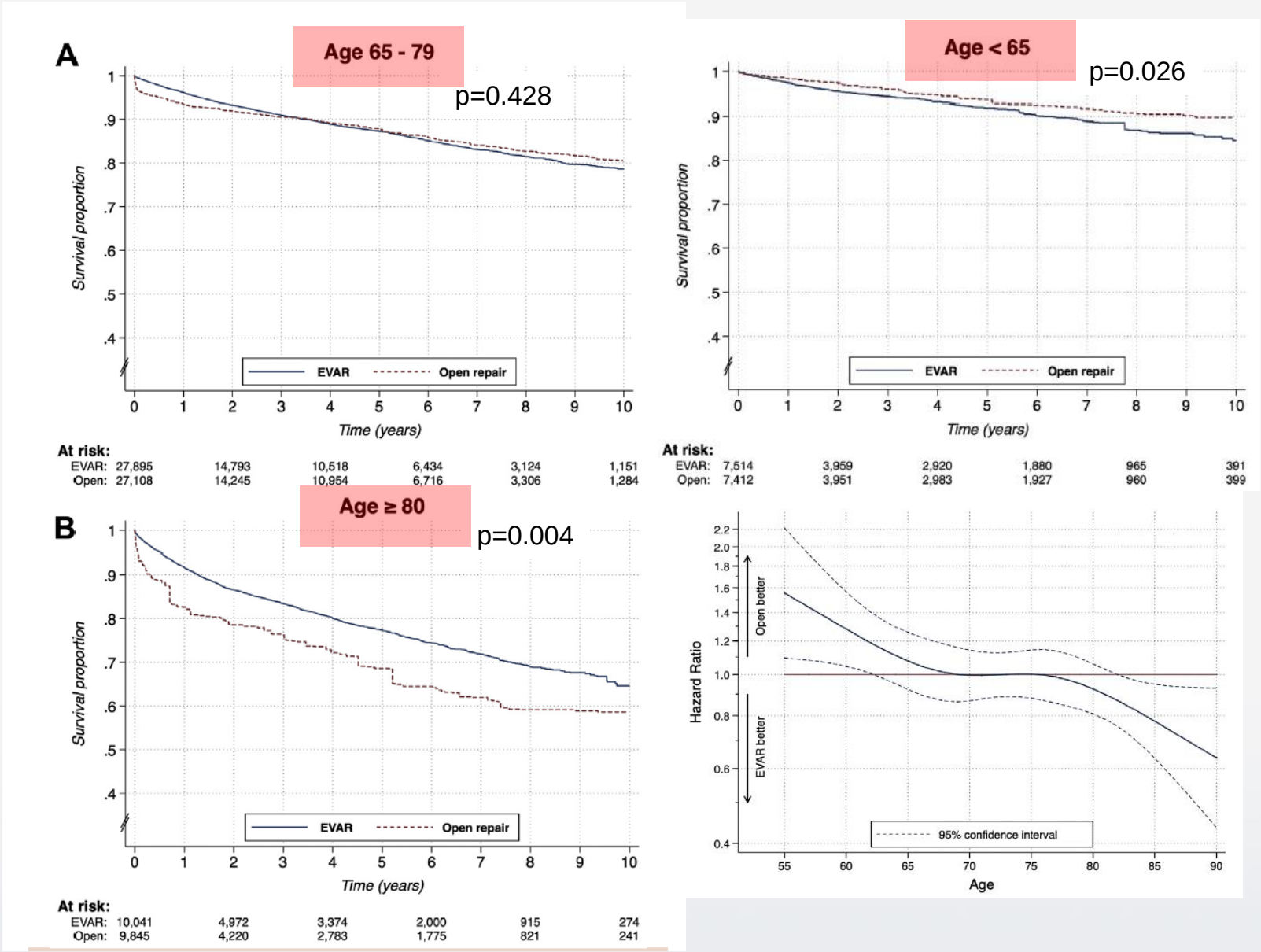
Survival after EVAR according to Age Groups

Society of Vascular Surgery Vascular Quality Initiative (VQI) clinical registry

N = 48,074



Varkevisser RR,
J Vasc Surg 2022;76:899

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 30-day mortality and perioperative morbidity after endovascular repair.
- Current generation EVAR devices appear to have improved clinical outcomes compared to old-generation devices
- However, non-adherence to IFU was associated with increased incidence of reinterventions and ARM after EVAR.
- Thus, EVAR should be primarily indicated for patients within IFU over 65 years and patients at high surgical risk.
- Open repair should be considered for younger patients (below 65 years) and patients outside IFU as first-line therapy.
- Regular surveillance after EVAR is important to detect early unfavorable adverse changes of aneurysm sac and implants after EVAR.