



# Is EVAS a proper choice in women?

**CACVS 2018**

Jan MM Heyligers, PhD, FEBVS

Consultant Vascular Surgeon

Elisabeth TweeSteden Hospital Tilburg

The Netherlands



# Disclosures

- Consultant for Endologix



# DEVASS = Dutch EVAS Study group

St. Antonius Hospital

Elisabeth TweeSteden Hospital

Rijnstate Hospital

Nieuwegein

Tilburg

Arnhem



# AAA women vs men

- Women have a twofold increased frequency of rupture
- Average aortic size at rupture is 5 mm smaller
- Higher rate of undiagnosed cardiovascular diseases



# AAA women vs men

- Smaller ileofemoral arteries
- More concomitant iliac aneurysms
- More challenging aortic neck



# AAA women vs men

- Smaller proportion eligible for EVAR
- Less likely to meet EVAR IFU
- Longer length of hospital stay after EVAR
- Higher re-admission rate



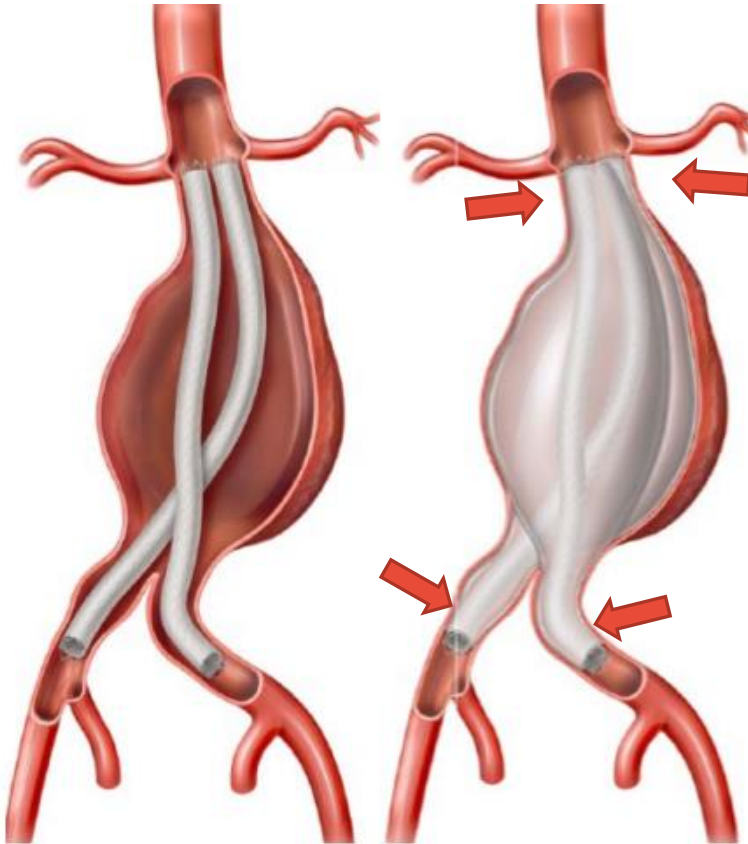
# AAA women vs men

- More major complications
- Higher mortality rate
- So, women and AAA is a challenging combination



# What was the primary motive of EVAS?

To overcome EVAR issues

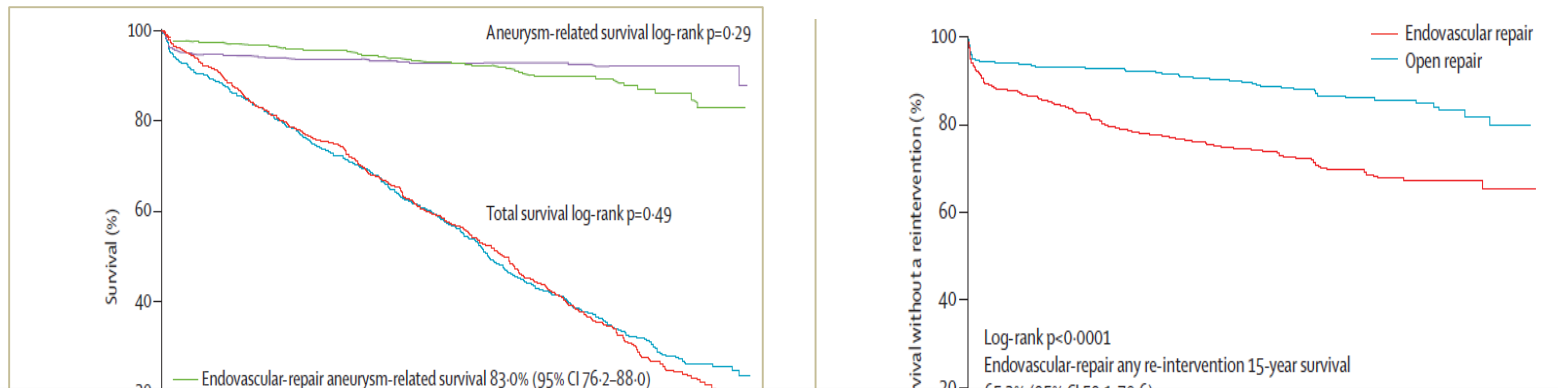


*EndoVascular Aneurysm Sealing System is an investigational device in the United States, limited by federal (or United States) law to investigational use only. The Nellix® EndoVascular Aneurysm Sealing System approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators\*

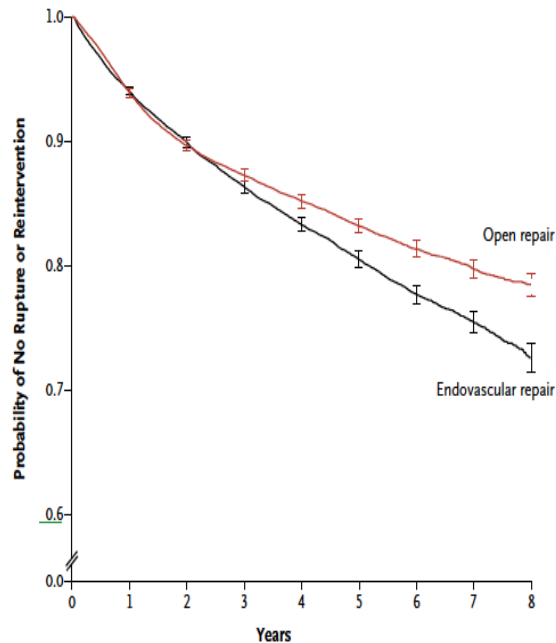


***“EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and prompt re-intervention if necessary.”***

ORIGINAL ARTICLE

## Long-Term Outcomes of Abdominal Aortic Aneurysm in the Medicare Population

Marc L. Schermerhorn, M.D., Dominique B. Buck, M.D.,  
A. James O'Malley, Ph.D., Thomas Curran, M.D., John C. McCallum, M.D.,  
Jeremy Darling, B.A., and Bruce E. Landon, M.D., M.B.A.



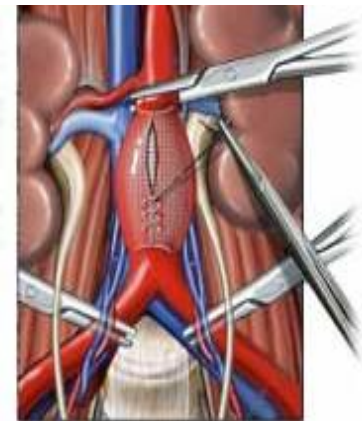
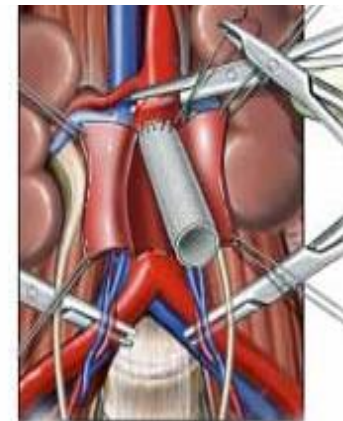
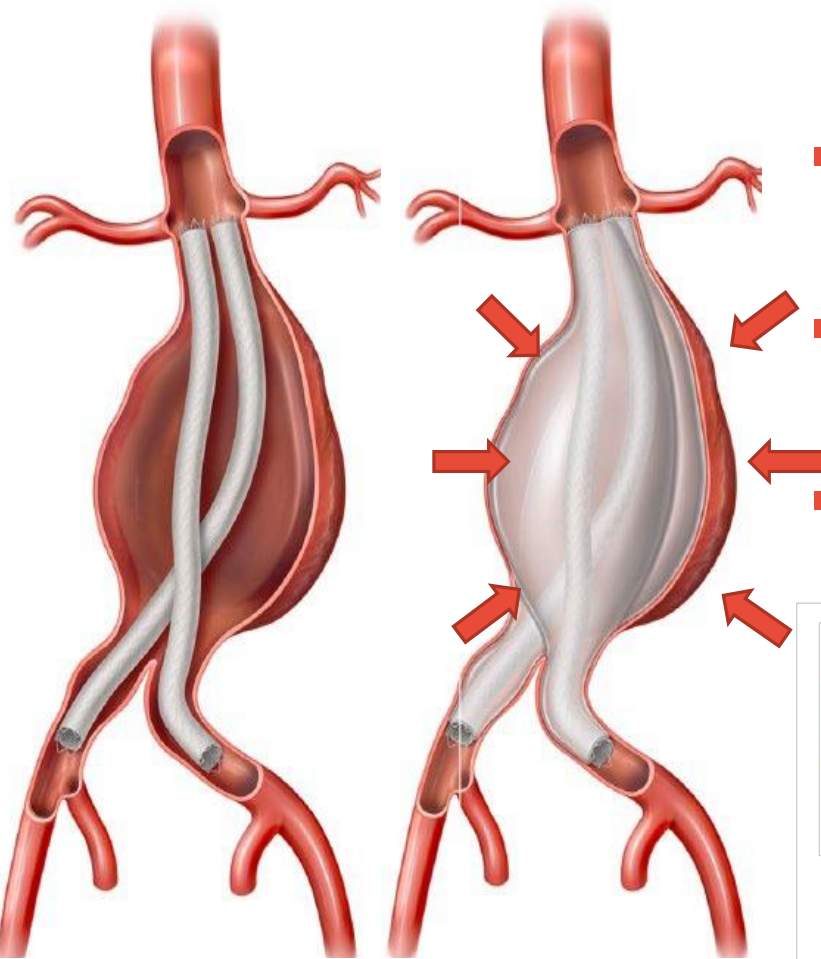
No. at Risk	0	1	2	3	4	5	6	7	8
Endovascular repair	39,966	33,573	26,896	20,820	15,273	10,370	6353	3455	1286
Open repair	39,966	32,495	26,386	20,970	15,772	10,869	6783	3768	1427

- Propensity-score matched cohorts of Medicare beneficiaries undergoing aneurysm repair
- 39,966 matched pairs of patients
- Early survival advantage for EVAR but significantly higher late rupture rate

N Engl J Med 2015;373:328-38

## Active aneurysm sac management

- Designed to mitigate endoleak of any type
- May prevent acute sac thrombosis – reduced Post Implant Syndrome
- Analogous to open surgical repair with sac ablation





# Baseline characteristics



Baseline characteristics	Frequency	Percent
Number	45	100
Age at procedure*	76	67-80
ASA class		
2	19	42.2
>2	25	55.6
Missing	1	2.2
Hypertension	31	68.9
Hyperlipidemia	34	75.6
Smoking, or history of smoking in last 10 years	26	57.8
Cardiac disease	14	31.1
Pulmonary disease	15	33.3
Creatinine value* (micromol/L)	73	64.75-87.75
Diabetes mellitus	6	13.3
Known peripheral arterial disease	10	22.2
Prior vascular intervention	7	15.6
Thrombo-embolic event in history	8	17.8
Other concomitant aneurysm	10	22.2
Within instructions for use 2013	13	28.9
Within instructions for use 2016	8	17.8
Symptomatic AAA	0	0



# Baseline characteristics



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# Anatomical characteristics

Anatomical characteristics	Median (*frequency)	IQR (*percent)
Infrarenal neck diameter	22.1	19-23.9
Infrarenal neck angle	22.6	11.6-32.5
Infrarenal neck length at 10% diameter increase	10.0	6.0-19.0
AAA lumen diameter	38.6	34.4-44
AAA outer diameter	56.0	52.6-58.1
Ratio AAA outer diameter to AAA lumen diameter	1.39	1.20-1.70
Infrarenal lumen volume	62.5	49.9-90.2
Right CIA lumen diameter	9.0	11.0-17.0
Right CIA outer diameter	13.6	8.0-10.1
Right EIA diameter 9-35mm	*31	*68.9
Left CIA lumen diameter	9.0	7.4-10.0
Left CIA outer diameter	13.2	11.0-17.0
Left EIA diameter 9-35mm	*32	*71.1



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Left CIA outer diameter	13.2	11.0-17.0



# Procedure characteristics



Procedure characteristics	Number/median	Percentage/IQR
<b>Anesthesia type</b>		
General	39	86.7
Local	1	2.2
Regional	2	4.4
Missing	3	6.7
<b>Access</b>		
Cutdown	43	95.6
Percutaneous	0	0
Missing	2	4.4
<b>Duration of hospital stay (days)</b>	4.0	3.0-6.5
<b>Number of days in ICU</b>	0	0-0
<b>Procedure time</b>	100.0	78.0-136.0
<b>Blood loss (mL)</b>	200.0	100.0-400.0
<b>Polymer volume</b>	54.0	43.5-85
<b>Secondary fill</b>	8	17.8
<b>Total fill volume</b>	56.5	43.5-82
<b>Polymer fill pressure</b>	199.0	188.0-205.0
<b>Procedural complication</b>		
Endoleak type IA	2	4.4
Endoleak type II	0	0
Endobag rupture	0	0
Conversion to open repair	0	0





# Procedure characteristics



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# Procedure characteristics



Procedure characteristics	Frequency	Percent
Normal	33	73.3
Unilateral		
Right	1	2.2
Left	1	2.2
Chimney	3	6.7
Distal extension	4	8.8
Unilateral Nellix with chimney	1	2.2
Nellix for CIAA	2	4.4



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<b>Nellix for CIAA</b>	2	4.4



# Clinical outcomes



# Reinterventions 0-12 Mo



Time to reintervention (months)	Indication for reintervention	Type of reintervention	Within IFU	Complication of reintervention
0	Migration pre-existing stent	Removal old kissing stent	No	-
0	Thrombus in proximal neck	Covered stent placement	No	-
0	Brachial artery occlusion after chimney	Venous patch brachial artery	No	-
11	IA Endoleak	Conversion to open repair	No	complicated by hemorrhage distal anastomosis, for which additional stitches were given. Complicated by kidney function deterioration (dialysis needed), atrial fibrillation, rectal bloodloss caused by bowel ischaemia, cardiac fluid overload, respiratory failure and urinary tract infection



# Reinterventions 12-24 Mo



Time to reintervention (months)	Indication for reintervention	Type of reintervention	Within IFU	Complication of reintervention
13	Stenosis	Relining	<b>YES</b>	Inguinal hematoma
14	IA Endoleak and migration	Relining iliac and Nellix in Nellix Chimney	No	-
25	IA Endoleak and migration	Conversion to open repair	No	Complicated by pneumonia, successfully treated by antibiotics
25	IA Endoleak	Nellix in Nellix Chimney	No	Renal insufficiency
25	IA Endoleak and migration	Conversion to open repair	<b>YES</b>	Death, Operation itself was uncomplicated, however, post-operatively the patient was in need of much inotropics and died due to limited cardiac reserves



# Endoleak



Time to endoleak (months)	Type of endoleak	Within IFU	Reintervention preformed
10	IA	No	Conversion to open repair performed
10	IA	No	None reported
12	IA	No	Relining iliac + Nellix in Nellix chimney.
23	IA	No	Conversion to open repair
23	IA	No	Nellix in Nellix chimney
24	IA	<b>YES</b>	Conversion to open repair



# Death characteristics



Time to death (months)	Within IFU	Description cause of death
0: 8 days	No	Post-operative decreased consciousness. Developed acute kidney insufficiency and unstable haemodynamics. Decrease in neurological functions and pneumonia. Medical treatment was stopped and a comfort treatment was given after which patient died.
1	No	Pneumonia/ decompensatio cordis. discharged, died at home. Refused treatment
1	No	Unknown
2	No	Autopsy : Probable cause of death, pulmonary embolus. Nellix system open.
6	No	Patient developed ventricular fibrillation during dialysis treatment
18	No	Unknown
25	<b>YES</b>	Patient underwent a conversion to open repair for a suspicion of endoleak and flinching. Operation itself was uncomplicated, however, post-operatively the patient was in need of inotropics and died due to limited cardiac reserves





# Re-interventions

- 0 - 12 Months: 4 (8,9%)
- 13 - 24 Months: 5 (11,1%)



# Conversion to open repair

- 0 - 12 Months: 1 (2,2%)
- 13 - 24 Months: 2 (4,4%)

# Endovascular re-intervention

- 0 - 12 Months: 2 (4,4%) = removal iliac stent; covered stent placement
- 13 - 24 Months: 3 (6,7%) = 2 NINA Chimney; relining



# Endoleak IA

- 0 - 12 Months: 3 (6,6%)
- 13 - 24 Months: 3 (6,6%)



# Endoleak II

- None reported

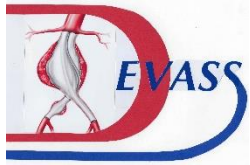


# Death

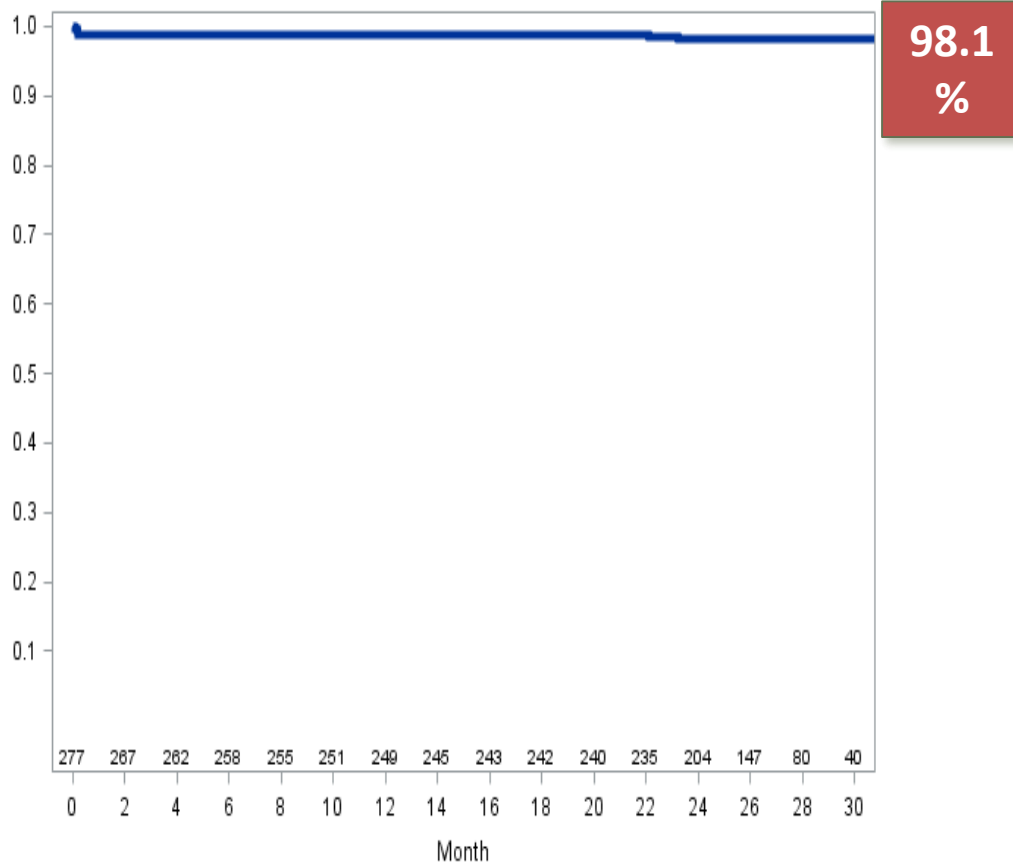
- 0 - 12 Months: 5 (11,1%) of which 1 ARM
- 13 - 25 Months: 2 (4,4%) of which 1 ARM



# Comparing these data with the EVAS Global data



# Freedom From All Persistent Endoleak @ 2 Years



All Endoleak	1.8% (5) (N = 277)
Type Ia	0.4% (1)
Type Ib	0.4% (1)
Type II	0.7% (2)
Type III	-
Type Unknown	0.4% (1)

Mean follow-up 25 mo (0-35 mo)

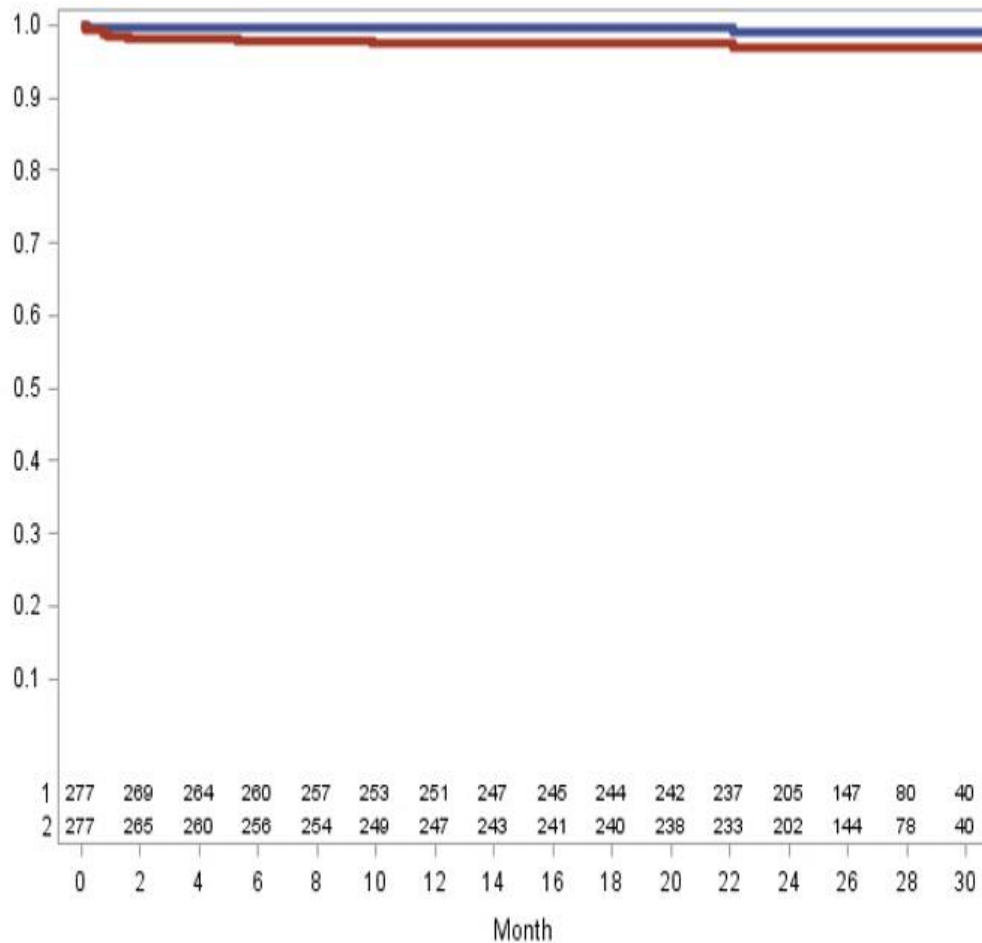




# Freedom from all persistent endoleaks after 2 years

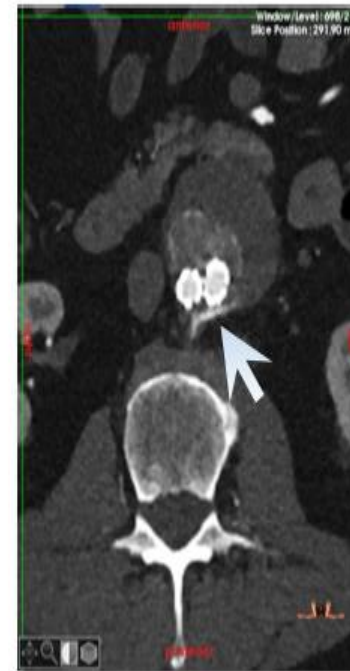
- 1 = 97,8%

# Freedom From Type II Endoleak

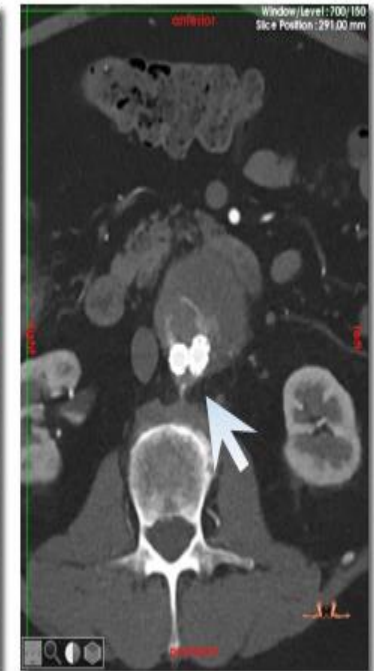


Persistence  
Incidence

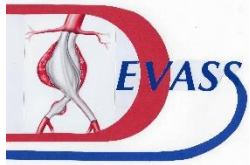
*Spontaneous Resolution of Type II Endoleak*



Low Volume  
0.1 – 0.4 mL

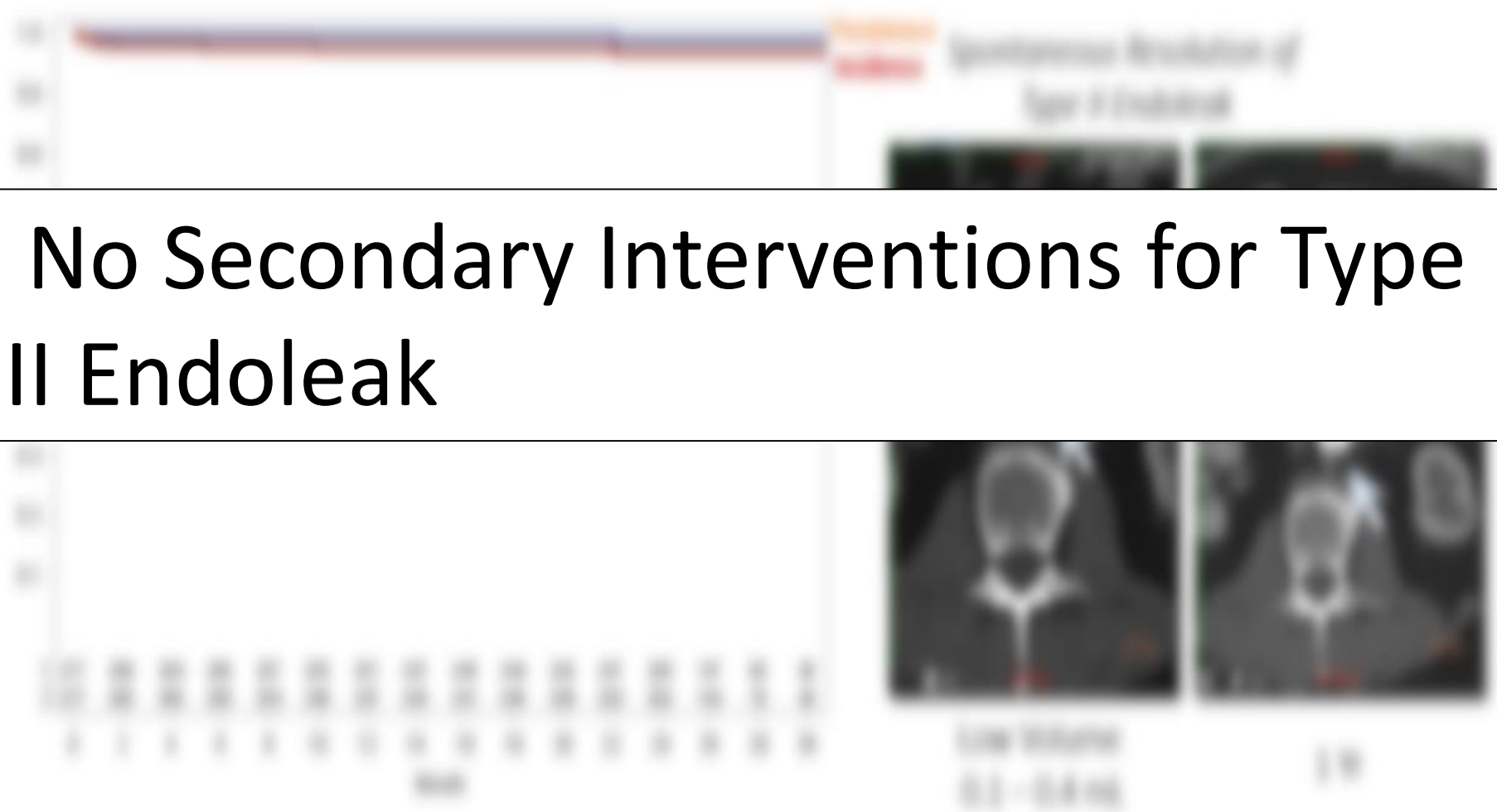


1 Yr



# Freedom From Type II Endoleak

No Secondary Interventions for Type II Endoleak

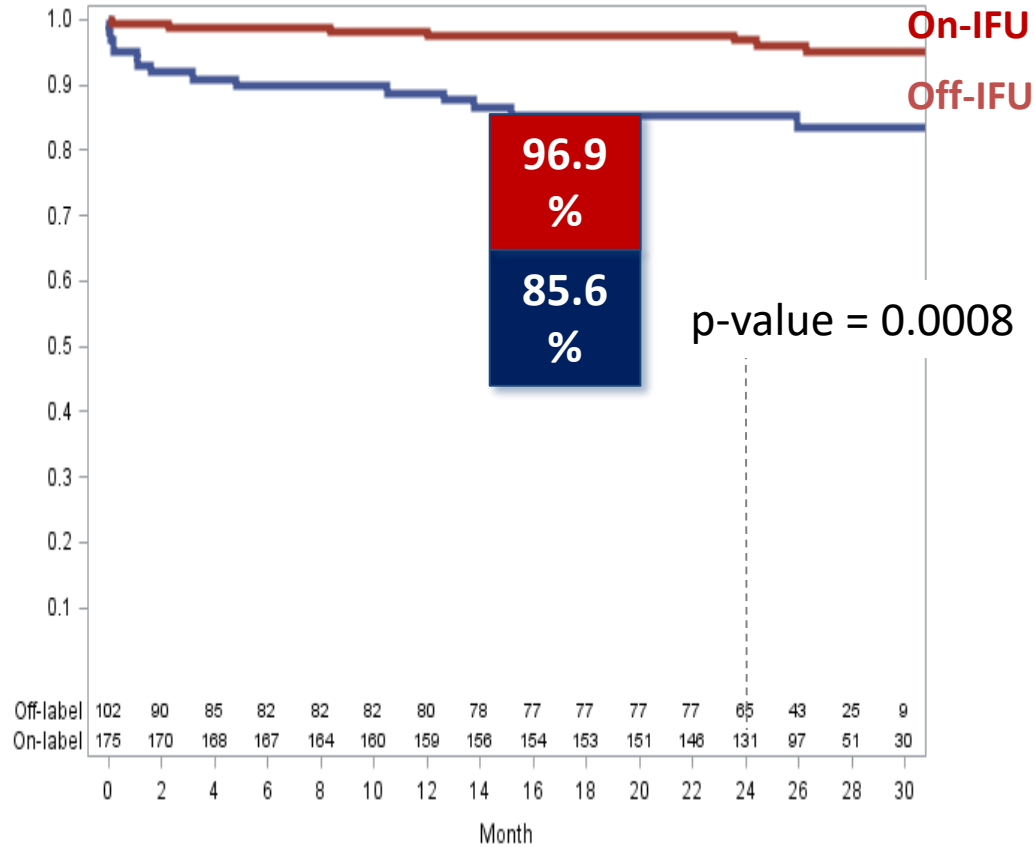




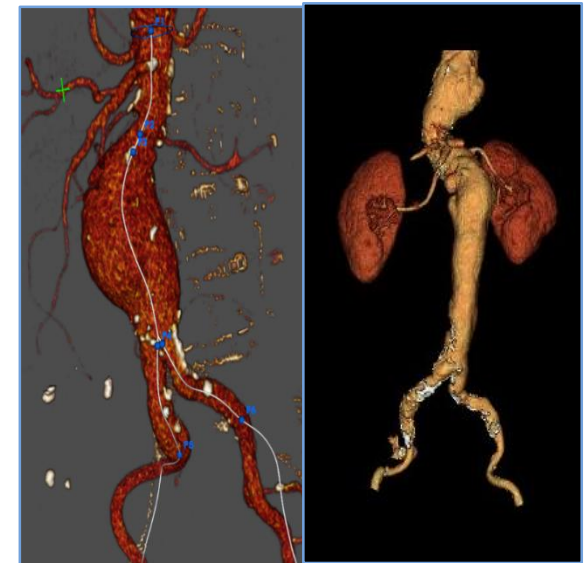
# Freedom from type II endoleak after 2 years

- 100%

# Freedom from Type Ia Endoleak: On and Off-IFU



## Complex Proximal Neck Anatomy



*Large proximal necks  
>28mm  
Thrombus-laden necks*

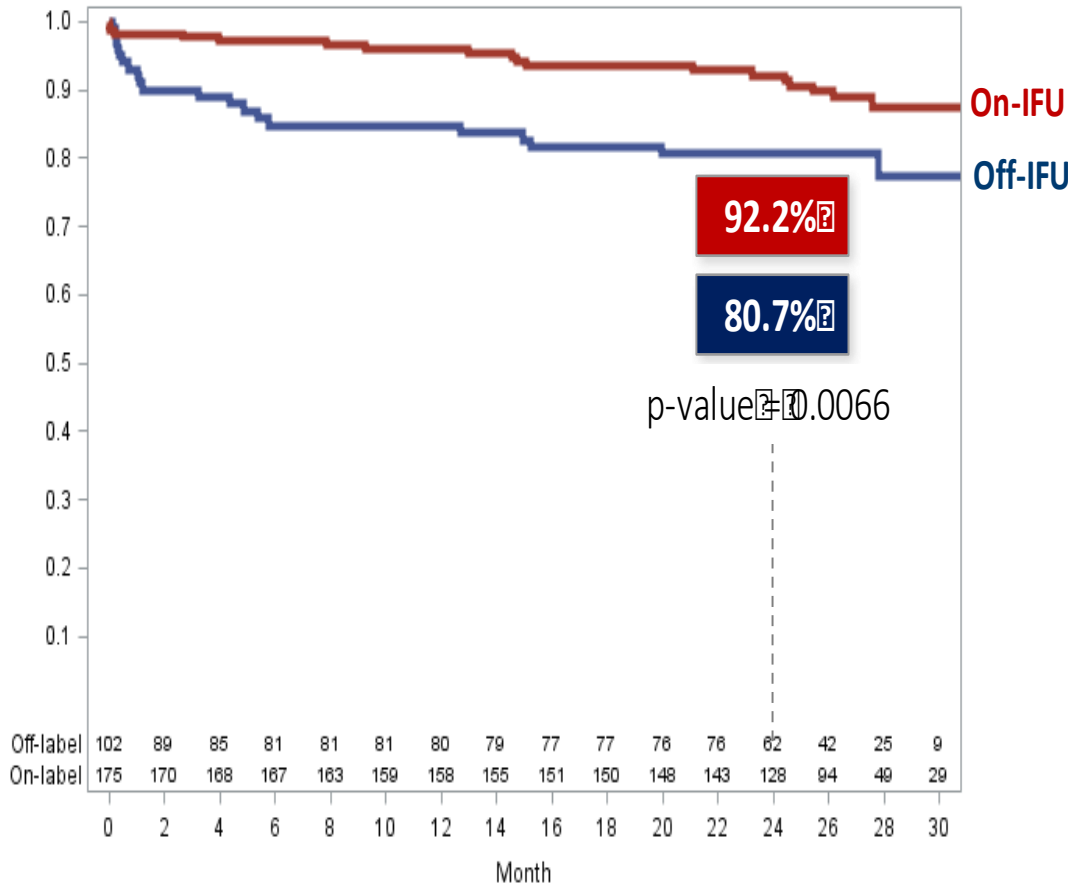
(based on original IFU)



# Freedom from type Ia Endoleak

- 6 = 86,7%
- Reminder: 71,1% outside IFU

# Freedom from Secondary Intervention: On- and Off-IFU



(based on original IFU)

Reason	(N=277)
Endoleak	20 (7.2%)
Occlusion	8 (2.9%)
Migration	3 (1.1%)
Other	13 (4.7%)

Mean follow-up  
25 months (0-35 )

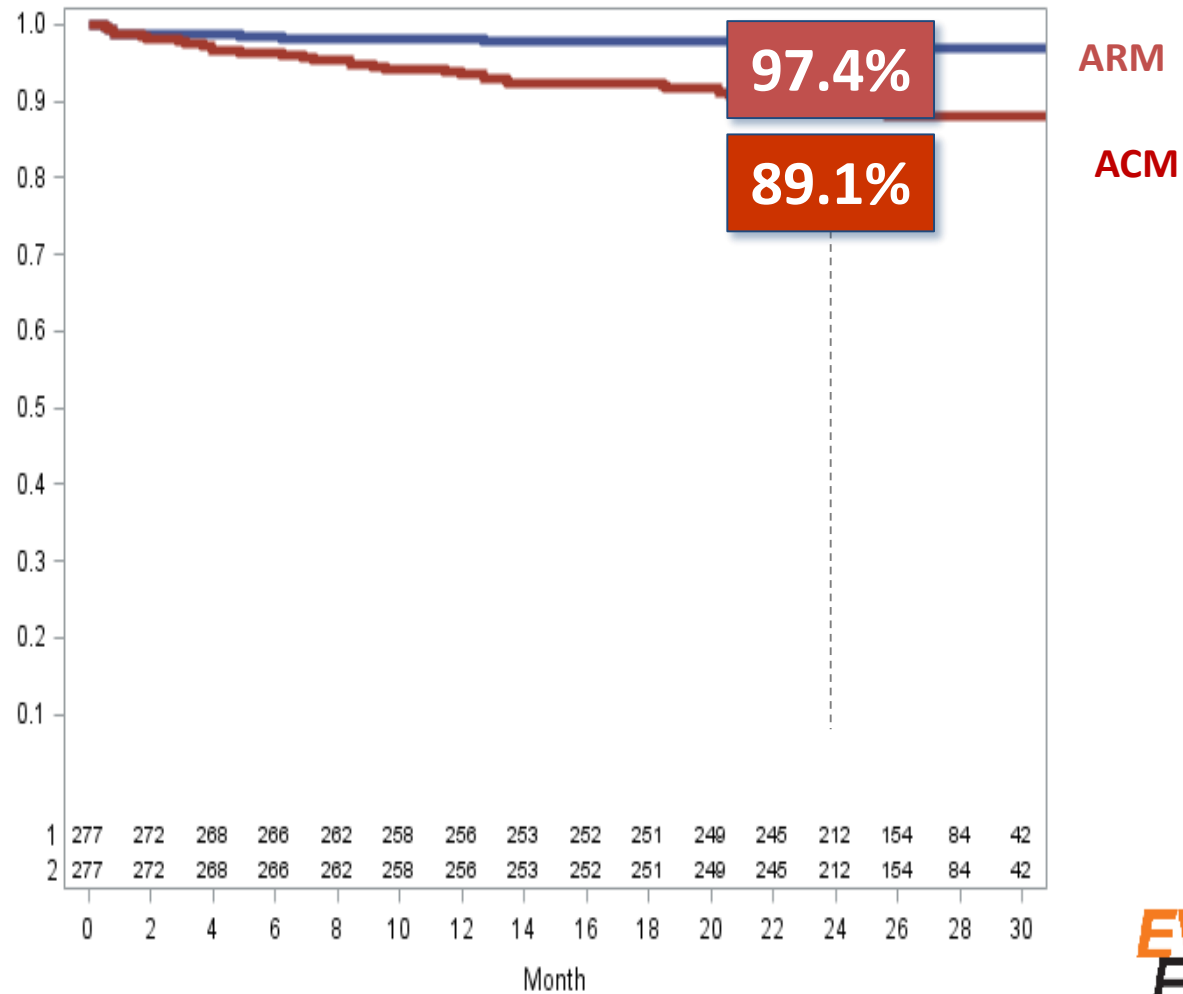


# Freedom from Secondary Interventions

- 9 = 80%



# Freedom from Mortality @ 2 Years





# Freedom from Mortality @ 2 Years

- ARM: 95,6%
- ACM: 84,4%



# Conclusions

- First cohort that focusses on women after EVAS
- Majority outside IFU (71,1%)
- Trend towards more secondary interventions?
- Trend towards higher mortality rate?



# Is EVAS a proper choice in women?

- Results appear to be in concordance with the results of EVAR in women in literature
- Not many women are within IFU
- EVAS can be offered to women

