

# How sac regression at 1 year affects all-cause mortality through 5 year: key insights from the ENGAGE registry

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# Disclosure

Speaker name:

Michel Reijnen

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



# Is EVAR undergoing a paradigm shift?

Sac dynamics have always been a robust indicator of EVAR durability but without distinction between stable and regressing aneurysms

What's wrong with stable sacs?



**NEW EVIDENCE** suggests there is a reason to differentiate.

Regressing sacs are linked to better long term outcomes



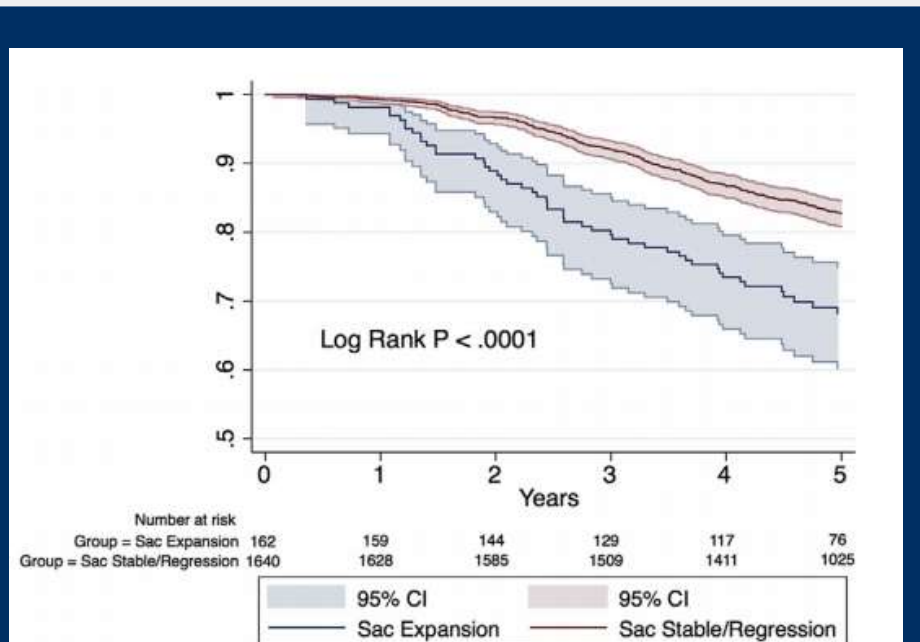
# Is EVAR undergoing a paradigm shift?

## *New evidence links sac shrinkage to better outcomes*

### 1-Yr Sac Dynamics Associated with 5-YR Mortality

#### VSGNE, 2003 – 2011

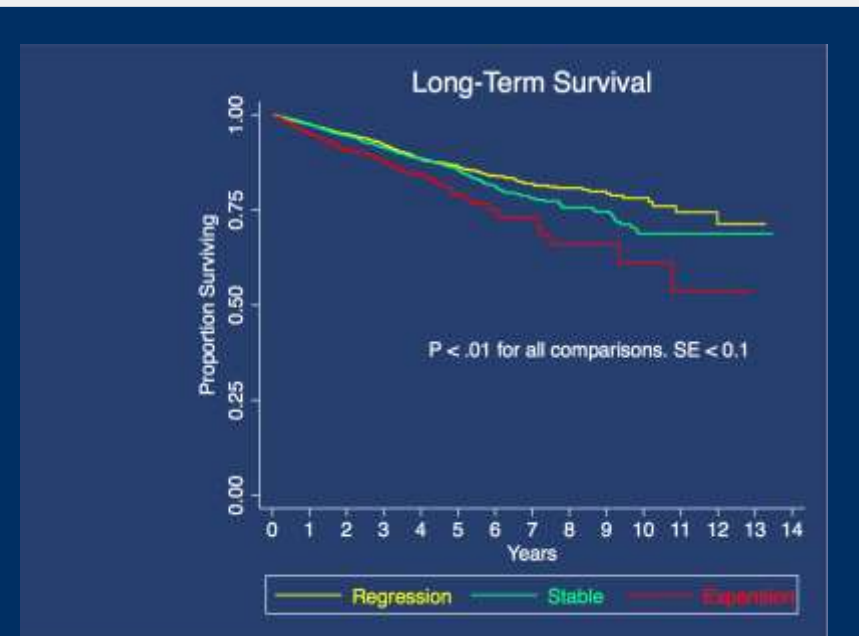
N=1,802 EVAR patients



### 1-Yr Sac Dynamics Associated with 5- and 10-Yr Mortality

#### VQI, 2003 – 2017

N=14,827 EVAR patients



# Is EVAR undergoing a paradigm shift? New evidence links sac shrinkage to better outcomes



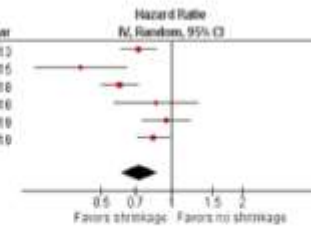
**17,096**

total subjects in 8 studies  
(8.518 patients with sac  
shrinkage & 8.578 patients  
without shrinkage)  
subjected to EVAR  
between 1997-2018<sup>2</sup>

## A All-Cause Mortality

Study or Subgroup	log(Hazard Ratio)	SE	Weight	Hazard Ratio		Year
				IV, Random, 95% CI	Year	
Clery	-0.22	0.09	20.2%	0.73	[0.61, 0.87]	2013
Soler	-0.89	0.23	10.0%	0.41	[0.26, 0.64]	2015
DeW	-0.5108	0.593	20.0%	0.60	[0.50, 0.72]	2018
Fujimura	-0.15	0.21	11.1%	0.86	[0.57, 1.30]	2018
Mizé	-0.05	0.12	17.7%	0.95	[0.75, 1.20]	2018
O'Donnell	-0.16	0.08	21.1%	0.84	[0.71, 0.99]	2018

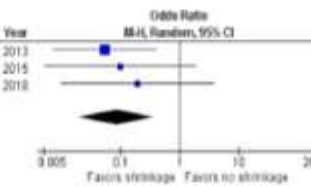
Total (95% CI) 100.0% 0.73 [0.60, 0.87]  
Heterogeneity: Tau<sup>2</sup> = 0.04, Chi<sup>2</sup> = 18.96, df = 5 (P = 0.002), I<sup>2</sup> = 73%  
Test for overall effect: Z = 3.40 (P = 0.0007)



## C Aneurysm Rupture

Study or Subgroup	Shrinkage		No shrinkage		Weight	Odds Ratio		Year
	Events	Total	Events	Total		M-H, Random, 95% CI	Year	
Clery	1	798	18	882	51.6%	0.05	[0.01, 0.41]	2013
Soler	0	102	4	95	24.6%	0.18	[0.01, 1.97]	2015
Langenberg	0	152	2	209	25.9%	0.19	[0.01, 3.77]	2018

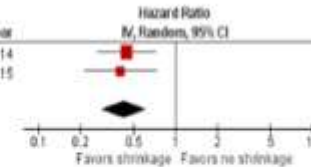
Total (95% CI) 100.0% 0.09 [0.02, 0.36]  
Total events: 1 23  
Heterogeneity: Tau<sup>2</sup> = 0.80, Chi<sup>2</sup> = 0.50, df = 2 (P = 0.78), I<sup>2</sup> = 0%  
Test for overall effect: Z = 2.12 (P = 0.0335)



## D Secondary Intervention

Study or Subgroup	log(Hazard Ratio)	SE	Weight	Hazard Ratio		Year
				IV, Random, 95% CI	Year	
Bacilio Gonçalves	-0.02	0.25	68.0%	0.44	[0.27, 0.72]	2014
Soler	-0.93	0.31	38.4%	0.39	[0.21, 0.72]	2015

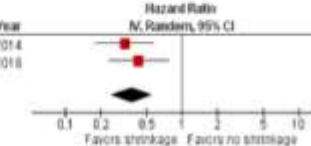
Total (95% CI) 100.0% 0.42 [0.29, 0.62]  
Heterogeneity: Tau<sup>2</sup> = 0.00, Chi<sup>2</sup> = 0.08, df = 1 (P = 0.78), I<sup>2</sup> = 0%  
Test for overall effect: Z = 4.44 (P < 0.00001)



## F Aneurysm-Related Complications

Study or Subgroup	log(Hazard Ratio)	SE	Weight	Hazard Ratio		Year
				IV, Random, 95% CI	Year	
Bacilio Gonçalves	-1.1332	0.2839	51.0%	0.31	[0.18, 0.57]	2014
Fujimura	-0.9557	0.3031	49.0%	0.42	[0.24, 0.77]	2018

Total (95% CI) 100.0% 0.37 [0.24, 0.56]  
Heterogeneity: Tau<sup>2</sup> = 0.00, Chi<sup>2</sup> = 0.44, df = 1 (P = 0.51), I<sup>2</sup> = 0%  
Test for overall effect: Z = 4.75 (P < 0.00001)



# ENGAGE Registry

**1263**

Patients

**30**

Countries

**6**

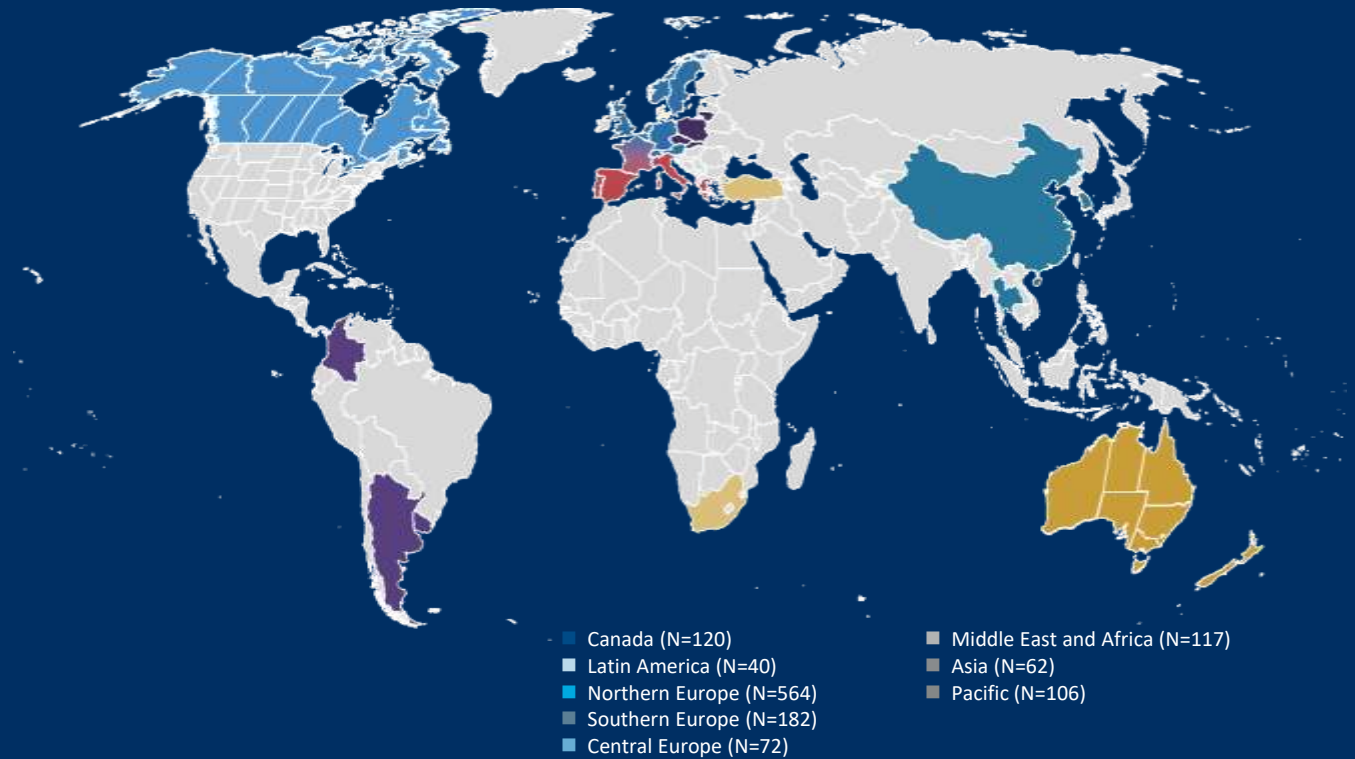
Continents

REAL WORLD PATIENTS:

Limited inclusion/  
exclusion criteria

REAL WORLD PRACTICE:

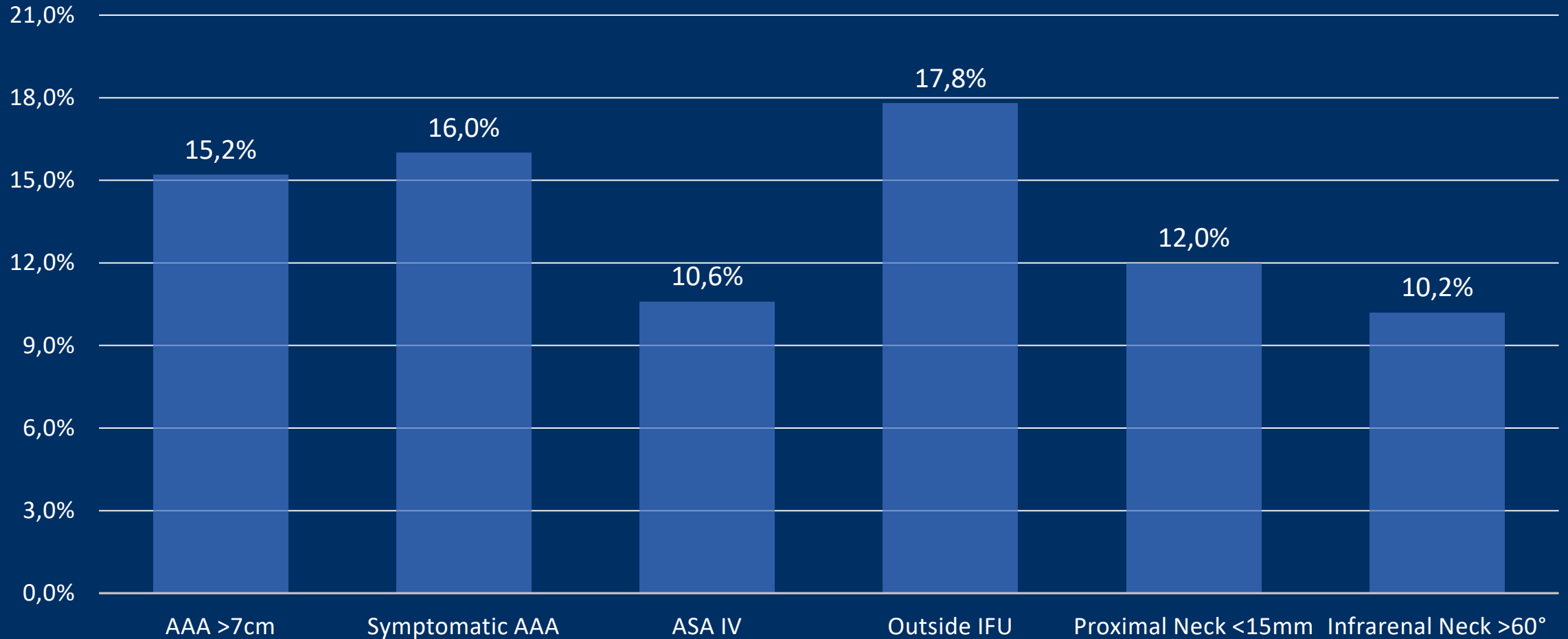
Limited procedural  
specifications -  
Standard follow-up



**> 20 publications and > 100 presentations** at major International/National conferences characterizing ENDURANT™ clinical outcomes

# ENGAGE Registry

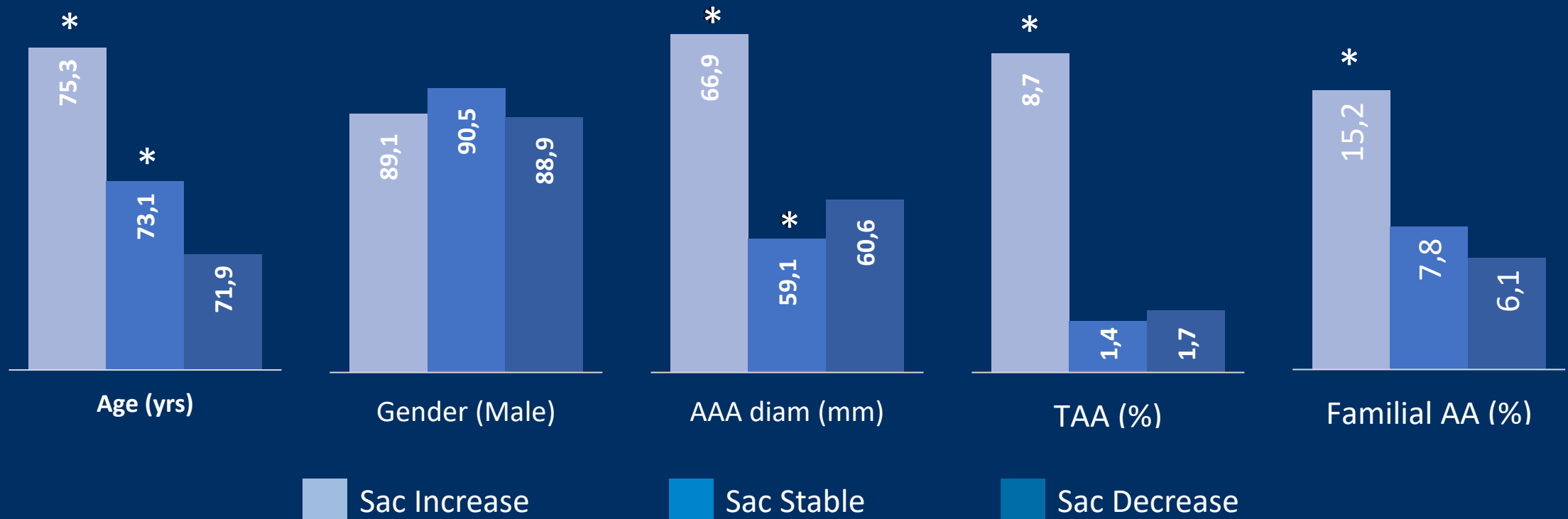
*challenging patient cohort*



# ENGAGE Registry

## Baseline Characteristics and sac dynamics

Other baseline characteristics were not statistically different between groups



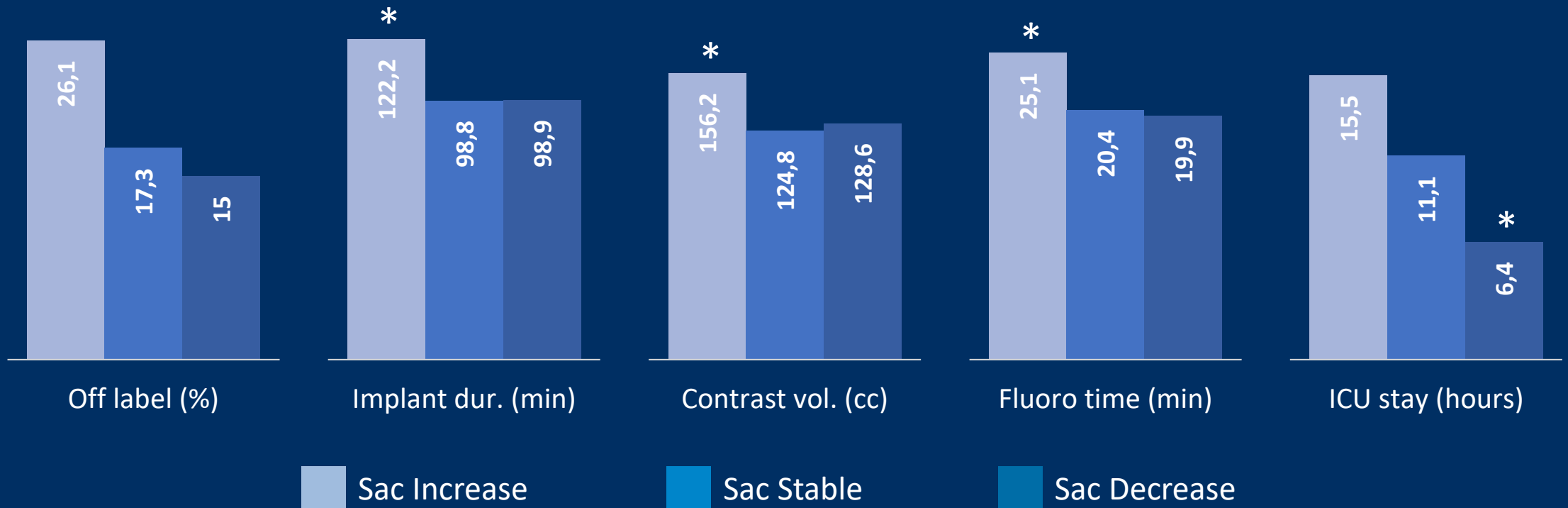
\* indicates  $p < 0.05$  compared to sac decrease group, note bars charts for different variables are not drawn to the same scale



# ENGAGE Registry

*Procedural data and sac dynamics*

Procedural differences observed despite similar baseline characteristics



\* indicates  $p < 0.05$  compared to sac decrease group, note bars charts for different variables are not drawn to the same scale

# ENGAGE Registry

## 5-years outcomes



Clinical  
follow-up  
compliance **>90%**  
at 5 Years  
(**>650 patients**)



Imaging  
follow-up  
compliance **>75%**  
at 5 Years  
(**> 500 patients**)

### SUMMARY OF RESULTS THROUGH 5 YEARS

**97.8%**

FF Aneurysm  
Related Mortality

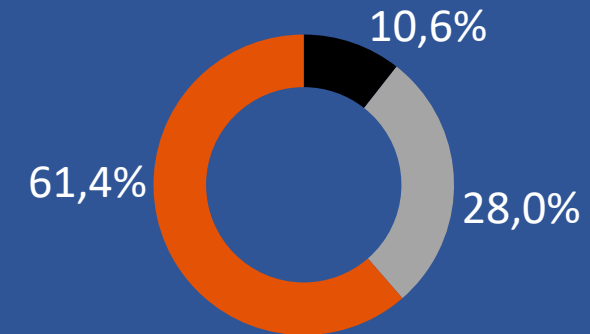
**98.6%**

FF Aneurysm  
Rupture

**84.3%**

FF Secondary  
Procedure

### SAC DYNAMICS AT 5 YEARS



5 Years

**61.4%** of AAA had sac diameter  
decrease at 5 years

■ Increase ■ Stable ■ Decrease

# US IDE trial

## CORE LAB

**99.3%**

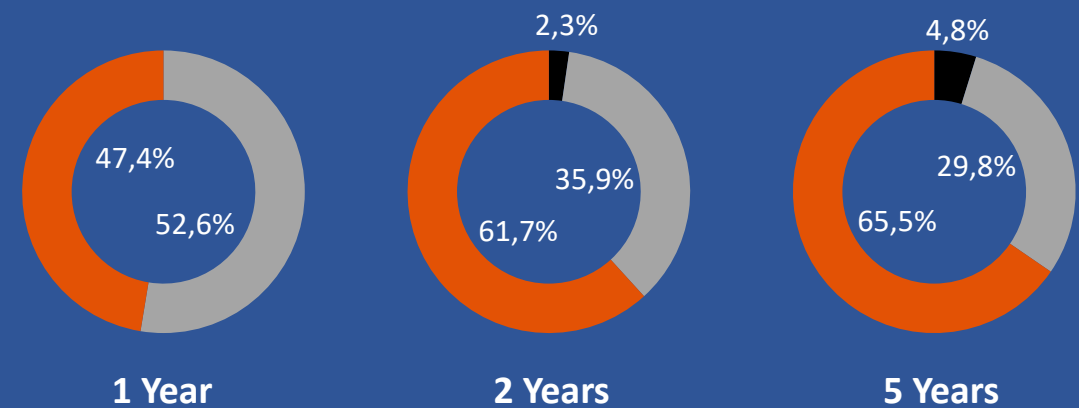
(149/150)

Successful  
delivery and  
deployment

## ENDOLEAKS

Core Lab	1 Year	2 Years	5 Years
Type I/III Endoleak	0%	0.8%	0%
Type II Endoleak	9.1%	9.1%	4.1%

## AAA SAC DYNAMICS



**65.5%** of AAAs decreased at 5 years

■ Increase ■ Stable ■ Decrease



No migrations



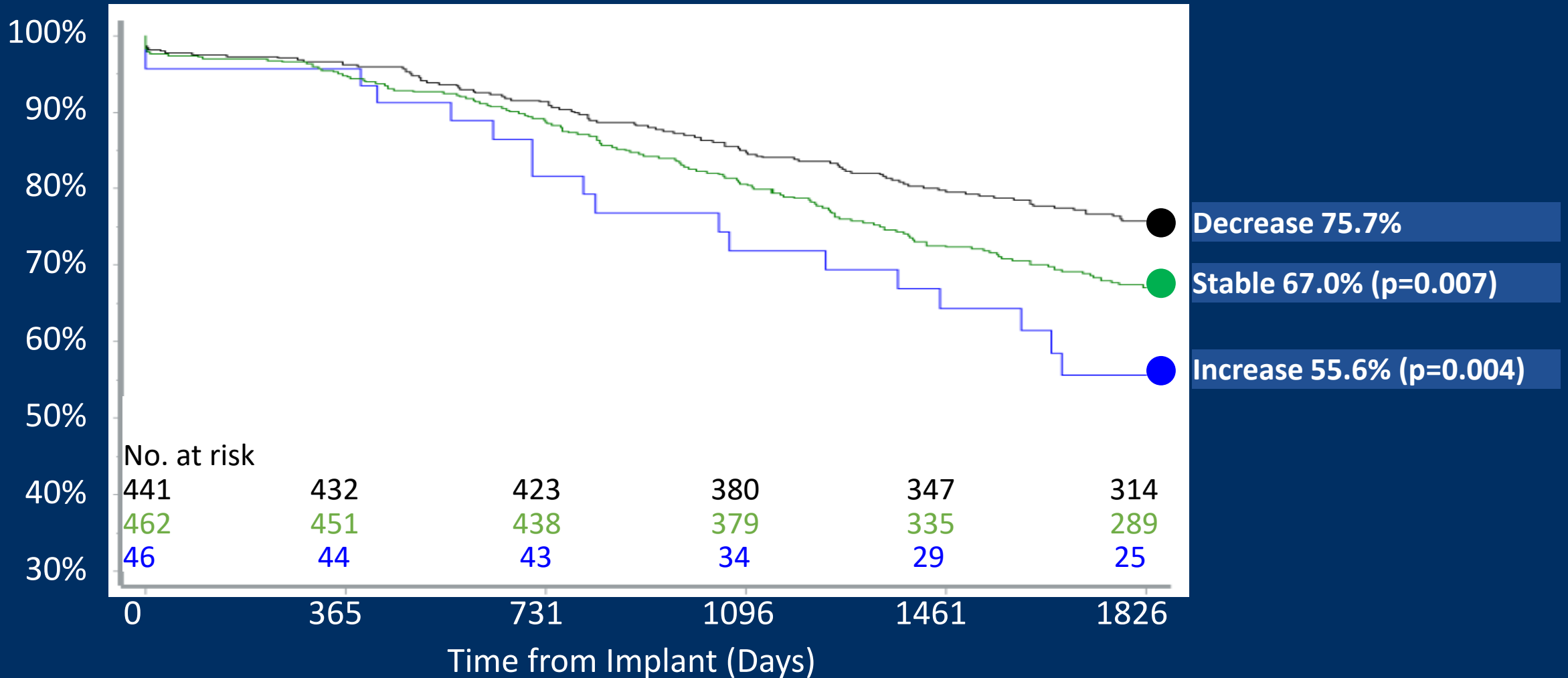
No fractures



No conversions

# ENGAGE Registry

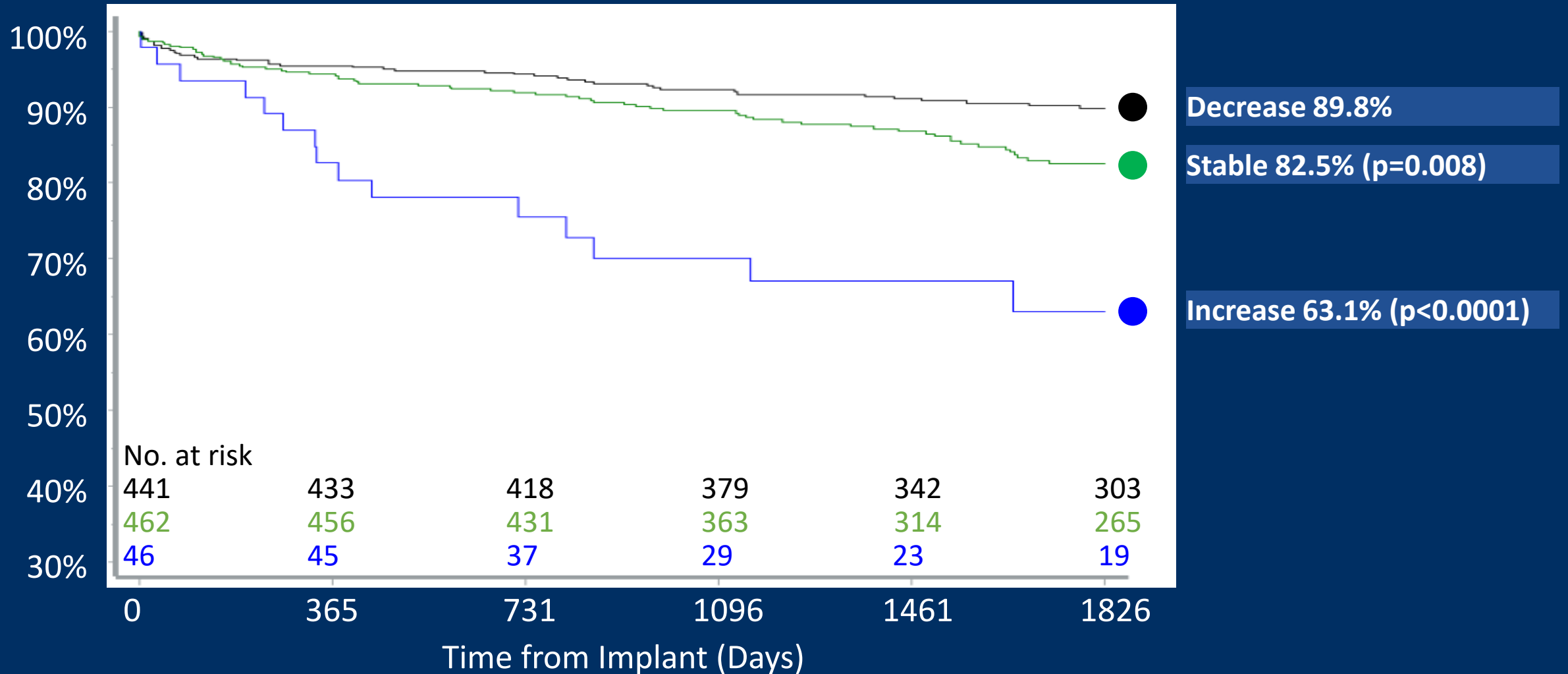
*Freedom from major adverse events*



p-values are for comparisons to the sac decrease group

# ENGAGE Registry

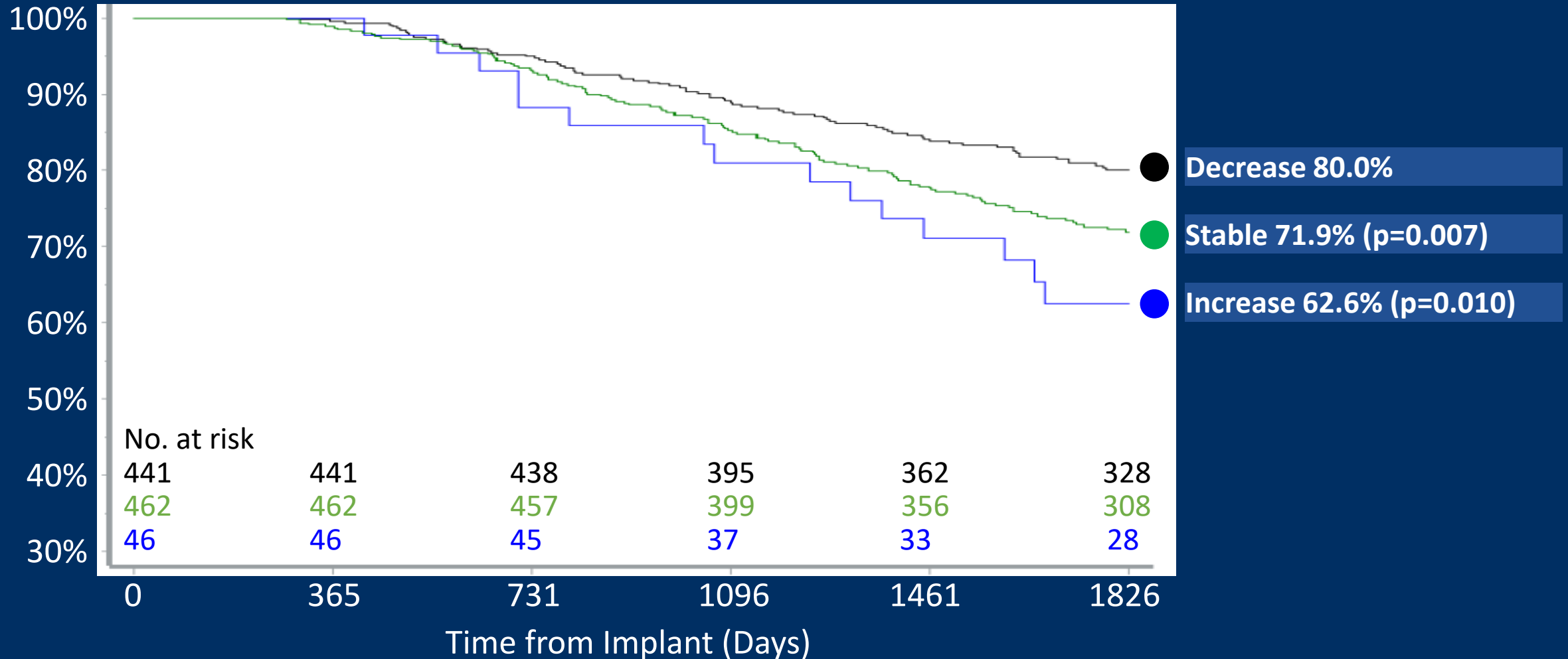
## *Freedom from secondary endovascular procedures*



p-values are for comparisons to the sac decrease group

# ENGAGE Registry

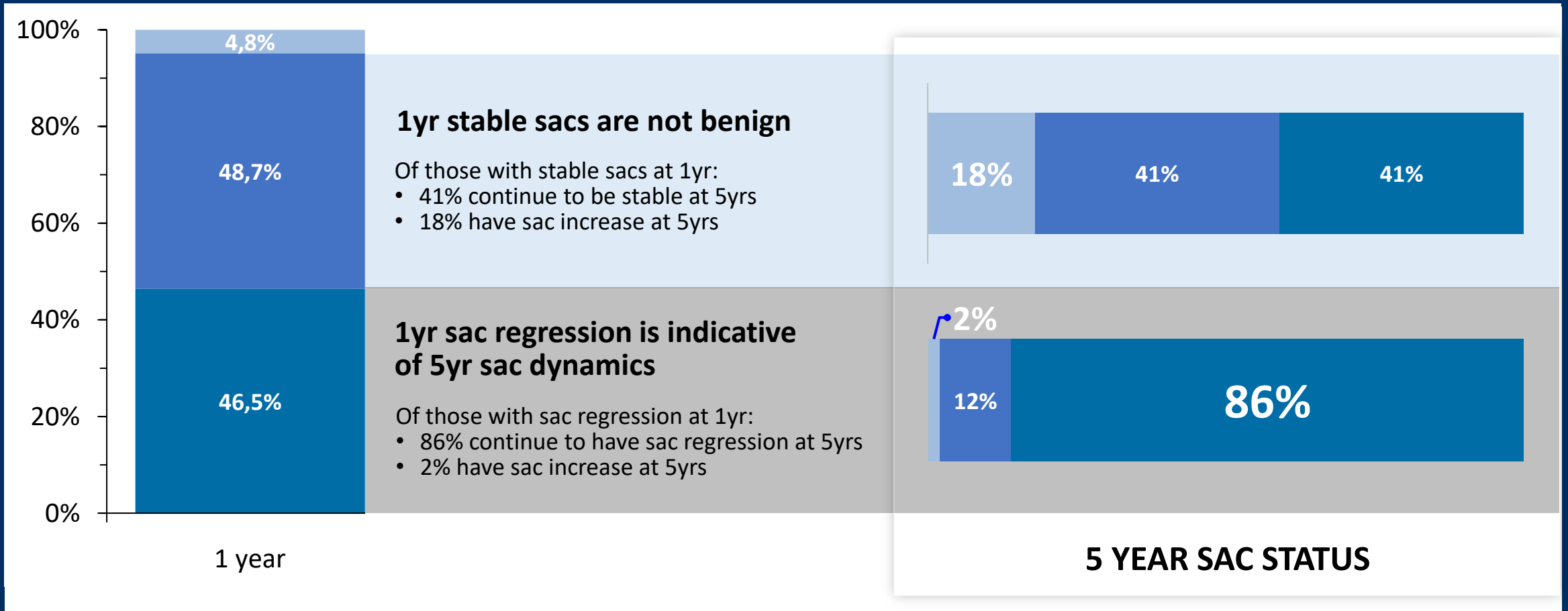
*Freedom from all cause mortality*



p-values are for comparisons to the sac decrease group

# ENGAGE Registry

5-years sac dynamics based on 1-year status



Sac Increase

Sac Stable

Sac Decrease

# Summary

- 1yr stable sacs are not always benign;
  - Major adverse events
  - Secondary endovascular interventions
  - All cause mortality
- 1yr sac regression is indicative of 5yr sac dynamics
- A paradigm shift is emerging and a shrinking aneurysm should be the goal of EVAR



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