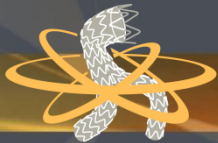


# Latest results of Endurant registries

## *The ENGAGE Registry*

Hence Verhagen, MD PhD  
*Erasmus University Medical Center*

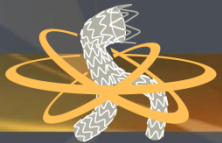
*On behalf of Engage Investigators*



ENGAGE

# Disclosures:

- Consultant for Medtronic

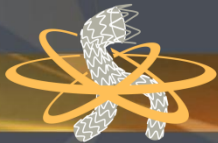


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# Global results of EVAR

- Well documented in the literature
  - DREAM
  - EVAR
  - OVER
  - ACE

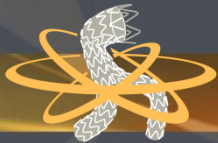
**Can these results be extrapolated to the general population ?**



# Global results of EVAR

- Well documented in the literature
  - Small studies
  - Centers of excellence

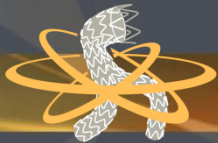
**Can these results be extrapolated to the general population ?**



# Global results of EVAR

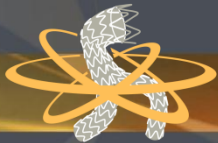
- With this in mind, a closely monitored registry may reveal much more reliable results of EVAR as
  - Real-world patients are included
  - From real-world practices

**Results may be better extrapolated to the general population**



# Study Purpose ENGAGE

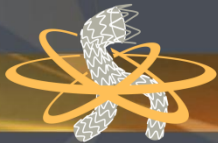
- To prospectively collect global ‘real life’ data on the Endurant stent graft system
  - Real world patients
    - Very limited inclusion/exclusion criteria
  - Real world practice
    - Limited procedural specifications
    - Patients are followed per institution standard practices
- To create a database that can be compared with other available stent graft data



# Materials and Methods

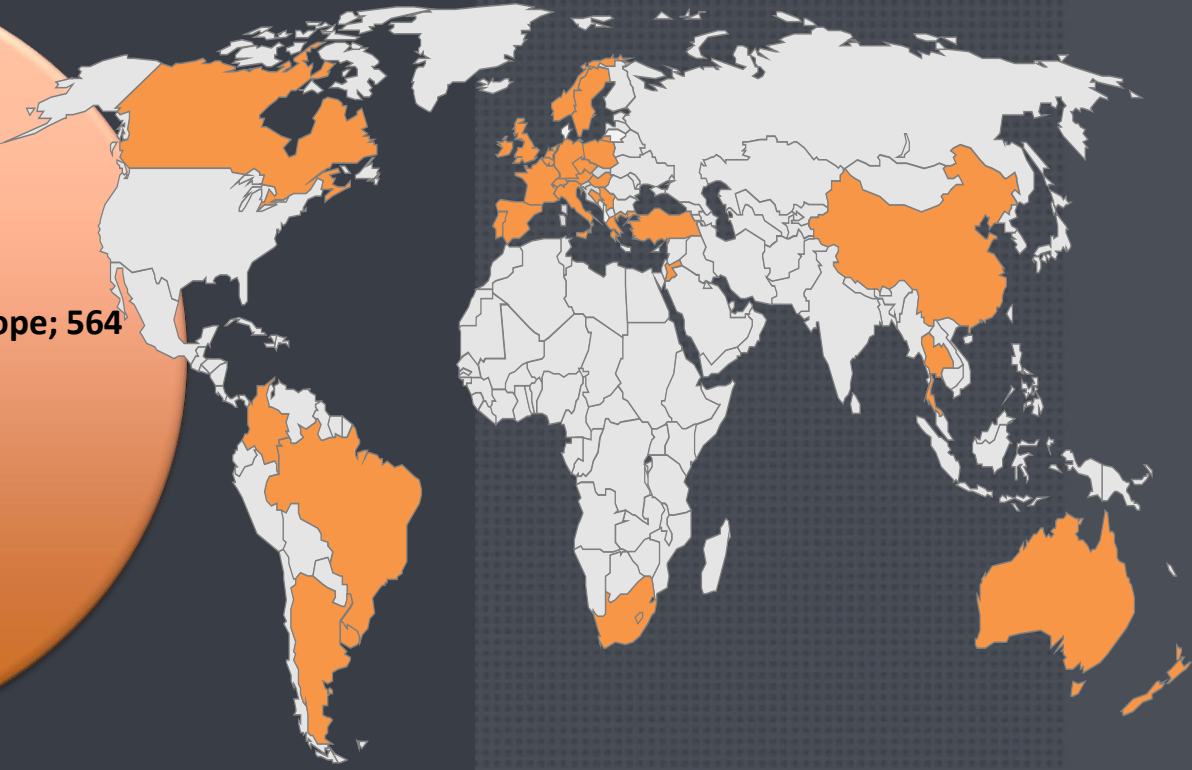
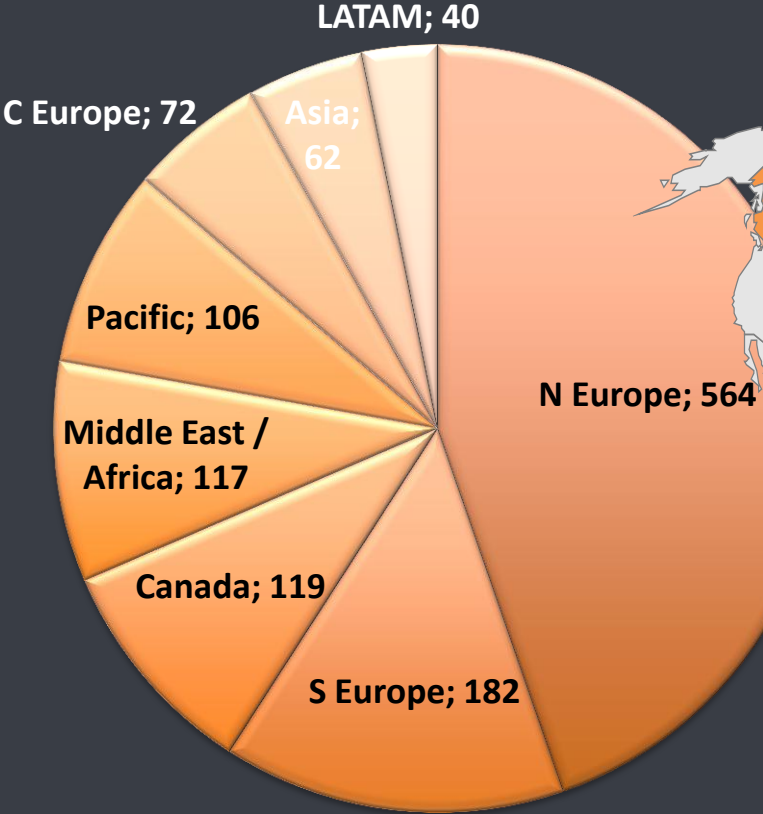
- Study Design
  - Prospective, Non Randomized, Multicenter, Closely Monitored, Single Arm Registry
    - 77 High Volume Centers Worldwide
  - Over 1200 subjects consecutively enrolled
    - First patient treated in March 2009
  - Long term Follow-up
    - 30 days, annual visits through 5 years

**Unprecedented Size and Scope**

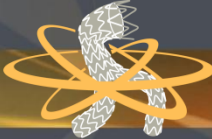


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# ENGAGE Enrollment Distribution



Total: 1262; 77 sites; 30 countries



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# ENGAGE Demographics

N = 1262 Patients

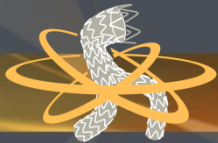
## Baseline Characteristics

Age (mean)	73.1 $\pm$ 8.1 years
Male Gender	89.6%

## Anatomic Characteristics

Max AAA Diameter (mean)	60.3 $\pm$ 11.7 mm
Neck Length (mean)	27.0 $\pm$ 12.4 mm
Infrarenal Neck Angle (mean)	30.3 $\pm$ 23.8°

**17.9% of Subjects Treated  
Outside of IFU Guidance**

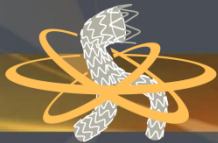
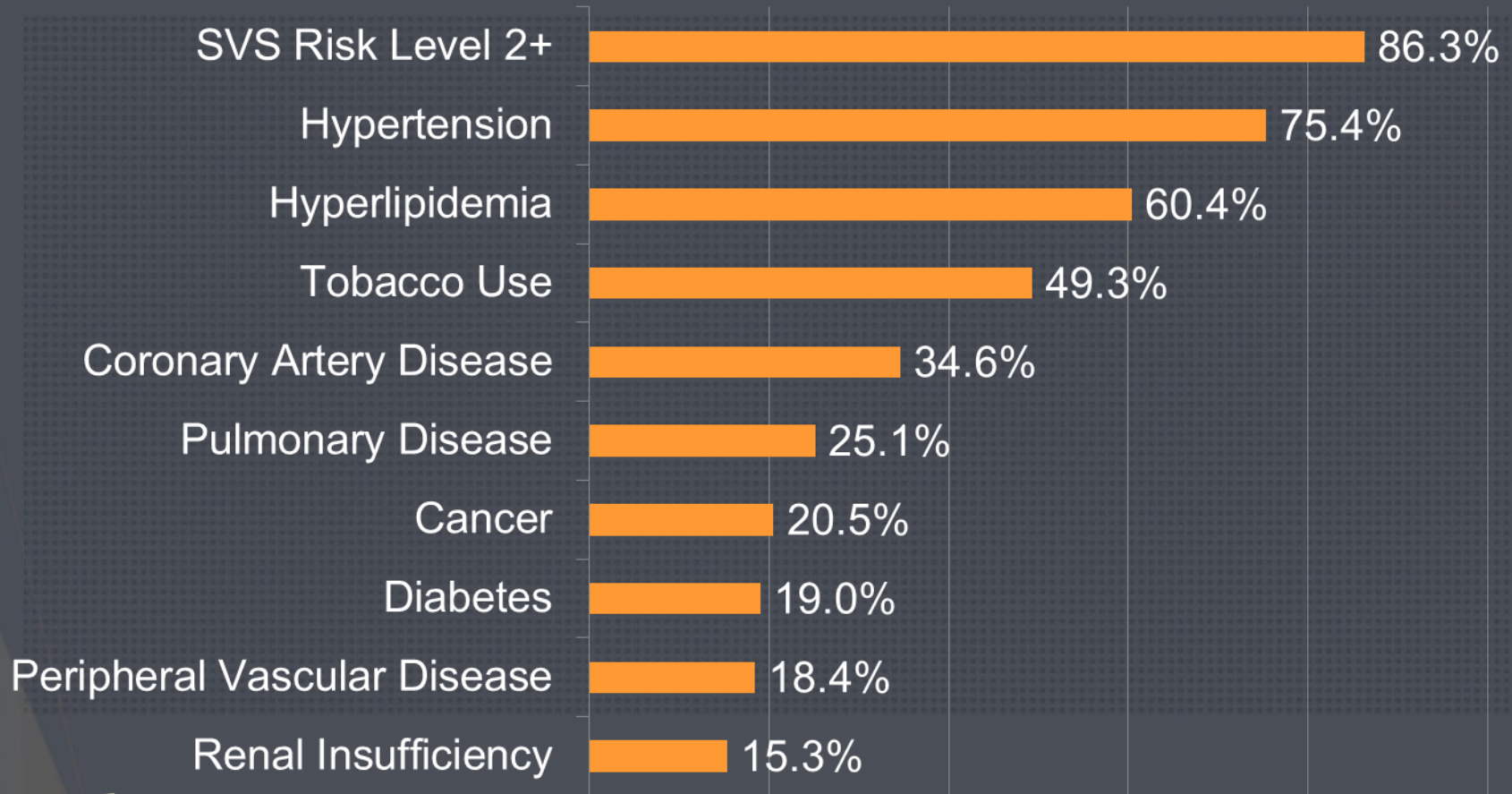


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# ENGAGE Demographics

N = 1262 Patients

## Baseline Risk Factors



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# ENGAGE Interim Analysis

Acute Procedural Data for first 1262 Patients Enrolled

## Baseline Characteristics

AAA Size > 50mm	88.1%
Proximal Neck	
Length $\leq$ 15 mm	19%
Length $\leq$ 10 mm	4.9%

## Procedural Data

Deployment Success	99.4%
Implant Duration (median)	90 min
General Anesthesia	62.3%
Length of Stay (median)	5 days



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# ENGAGE Interim Analysis

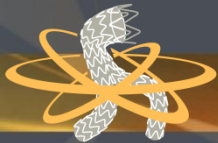
## 30 Day Follow-Up Data

### Safety Results

All Cause Mortality	1.3%
Major Adverse Events	4.1%

### Technical Results

Migration	0%
Occlusion	2%
Endoleak	
Type I	1.4%
Type III	0.2%
Type IV	0.1%

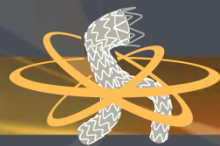


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# ENGAGE Interim Analysis (n=500)

## 1 Year Safety Results

All Cause Mortality	8.3%
Major Adverse Events	11.2%
Bowel Ischemia	0.4%
Myocardial Infarction	1.8%
Paraplegia	0%
Procedural Blood Loss $\geq$ 1000 ml	0.6%
Renal Failure	1.0%
Respiratory Failure	0.2%
Stroke	0.4%

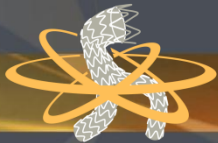


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# ENGAGE Interim Analysis (n=500)

## 1 Year Outcomes

–	Aneurysm Related Mortality	1.4%
–	Conversion	0.6%
–	Rupture	0.0%
–	Secondary Procedures	4.6%
–	Patency	97.5%



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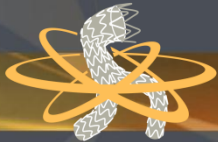
## ENGAGE Interim Analysis at 1 Year

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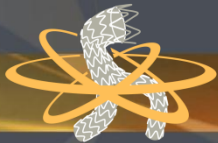
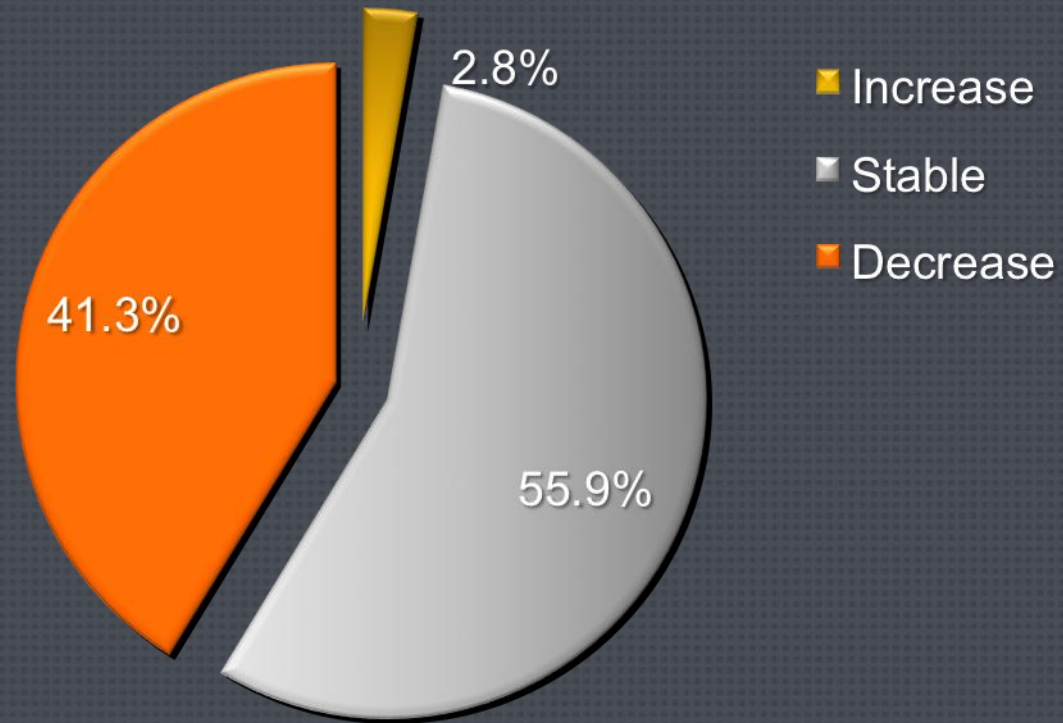
**Type I / III Endoleak at 1 Year      0.2%**

**Type II Endoleak at 1 Year              8%**

**Migration at 1 Year                          0%**



# ENGAGE Sac Changes at 1 Year



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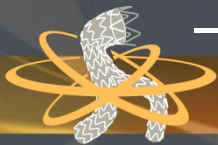
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# ENGAGE Interim Analysis

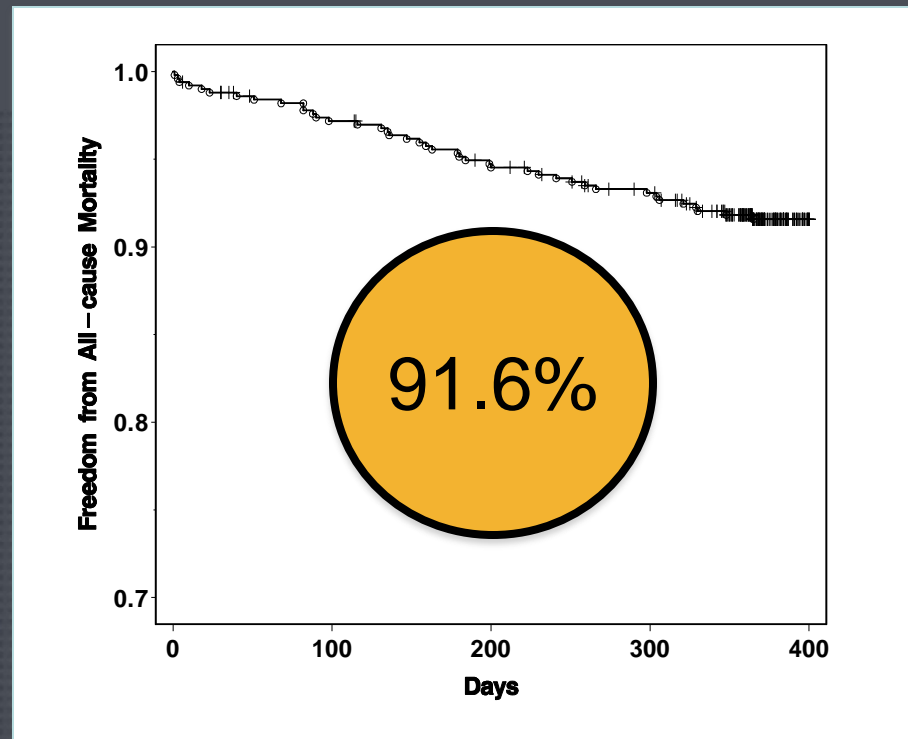
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## Serious Adverse Device Effects (0 – 365 Days)

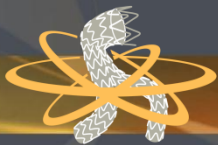
– Pulmonary Events	0%
– Bleeding >1000 ml	0.7%
– Cardiac Events	0%
– Renal Failure	0.7%
– Wound Events	0%
– Gastrointestinal Events	0%
– Vascular Events	1.3%
– Neurologic Events	0%
– Fever	0.7%



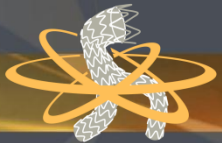
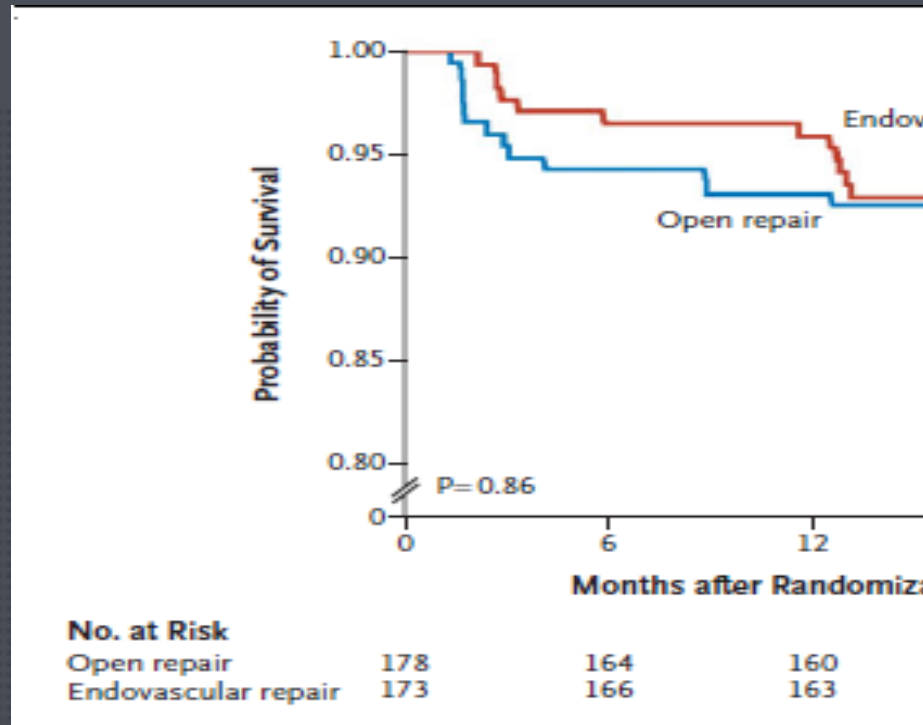
# Freedom from All-Cause Mortality



	0-30 days	31-365 days
No. at Risk <sup>1</sup>	500	490
No. of Events	6	35
No. Censored <sup>2</sup>	4	455
Kaplan-Meier Estimate <sup>3</sup>	0.988	0.916
Peto Standard Error	0.005	0.014

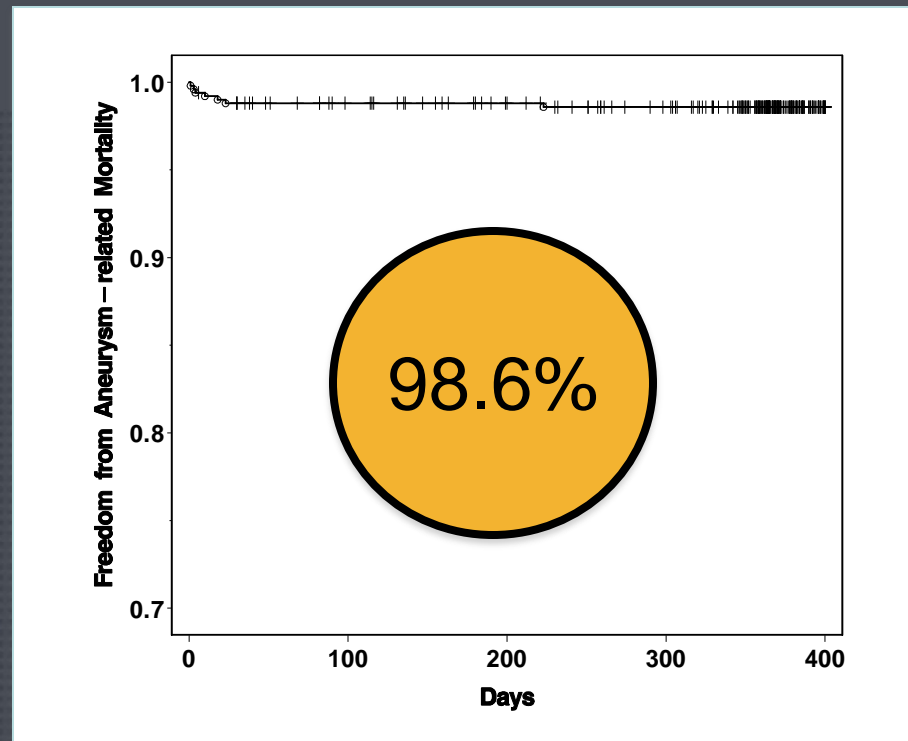


# Freedom from All-Cause Mortality

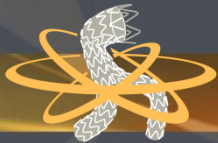


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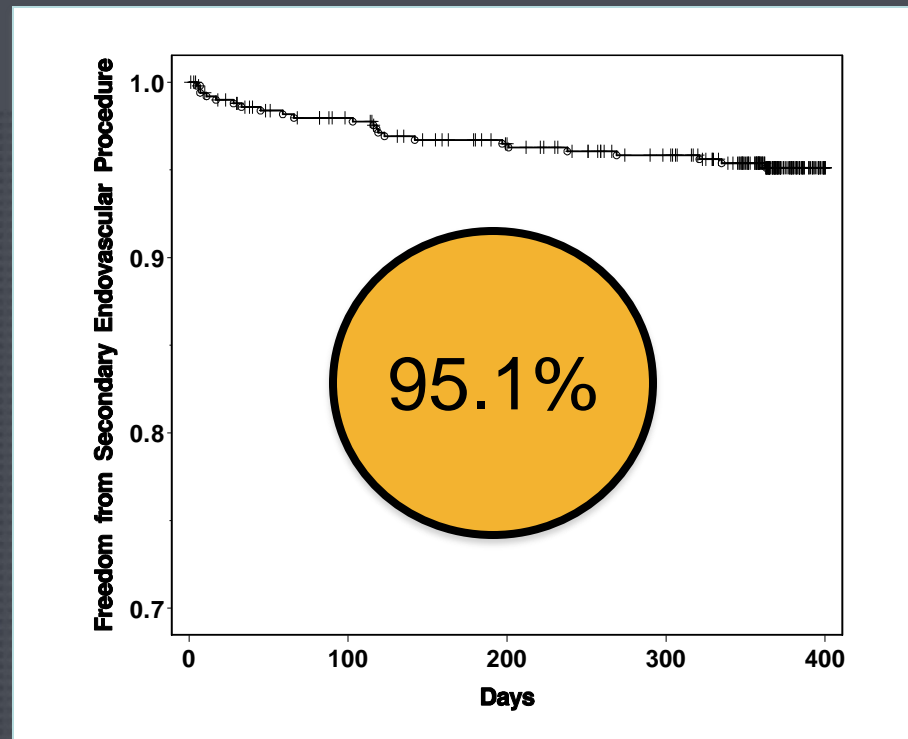
# Freedom from AAA-Related Mortality



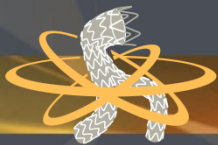
	0-30 days	31-365 days
No. at Risk <sup>1</sup>	500	490
No. of Events	6	1
No. Censored <sup>2</sup>	4	489
Kaplan-Meier Estimate <sup>3</sup>	0.988	0.986
Peto Standard Error	0.005	0.005



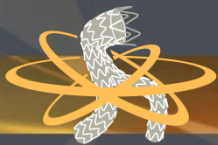
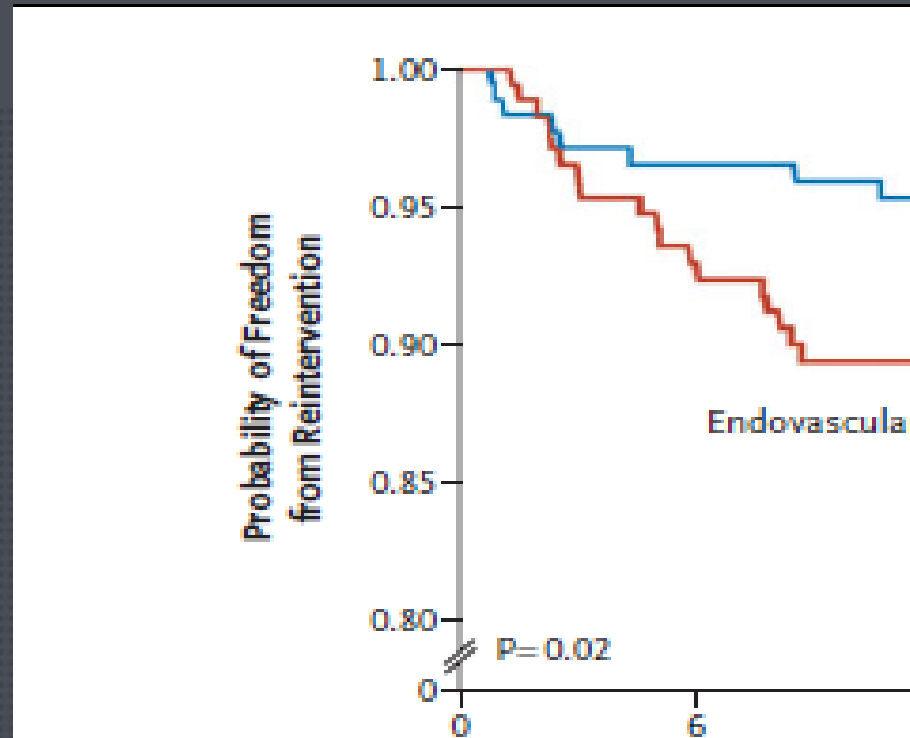
# Freedom from Secondary Interventions



	0-30 days	31-365 days
No. at Risk <sup>1</sup>	500	484
No. of Events	6	17
No. Censored <sup>2</sup>	10	467
Kaplan-Meier Estimate <sup>3</sup>	0.988	0.951
Peto Standard Error	0.005	0.011



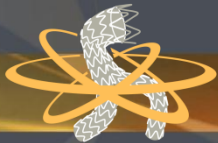
# Freedom from Secondary Interventions



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# Conclusion

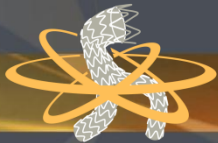
- ENGAGE is a well-monitored registry that supplies us with data on real-world outcome after EVAR in a global series of patients
- Results up to one year are exceptionally good
- long-term results have to be awaited



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# Conclusion

- In contrast to a randomized trial, ENGAGE is about real-world patients in a real-world practice
- It is debatable whether randomized trials should stay “the gold standard” for evaluating treatment results



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# Participating Sites

Teijink (NET), Catharina Hospital  
Lawlor (CAN), Victoria Hospital  
van Sterkenburg (NET), Alysis Zorggroep, Rijnstate Ziekenhuis  
Welten (NET), Atrium Hospital  
Peeters (BEL), Imelda Hospital  
Boeckler (DEU), Universitätsklinikum Heidelberg  
Mwipatayi (AUS), Royal Perth Hospital  
Papazoglou (GRC), Kianous Stavros Clinic  
Staszkiwicz (POL), Szpital Bielanski  
Verhagen (NET), Erasmus Medical Centre  
Goktay (TUR), Dokuz Eylül University  
Riambau (ESP), Hospital Clinic i Provincial de Barcelona  
Vermassen (BEL), Universitair Ziekenhuis Gent  
Rand (AUT), Krankenhaus Hietzing  
Bosiers (BEL), Sint Blasius Hospital  
Torsello (DEU), St Franziskus Hospital GmbH  
Vaquero Puerta (ESP), Hosp Clinico y Universitario de Valladolid  
Wolf (ISR), Sourasky Medical Center  
Fitridge (AUS), Queen Elizabeth Hospital  
Salmeron (ESP), Hospital Clinico Universitario San Cecilio  
Van Marle (SAF), Unitas Hospital  
Do/Schmidli (CHE), Inselspital, Universitatsspital Bern  
Hendriks (BEL), UZ Antwerpen  
Oguskurt (TUR), Adana Baskent University Hospital  
Becquemin (FRA), Hospital Henri Mondor  
Hill (NZL), Auckland City Hospital

Kritpracha (THA), Songklanagarind Hospital  
Punt (SAF), St Georges Hospital  
Kiskinis (GRC), Papageorgiou Hospital  
Novotny (CZE), Institut Klin a experimentalni mediciny  
Rose (GBR), Freeman Hospital  
Albuquerque e Castro (POR), Centro Hosp de Lisboa  
Choukroun (FRA), Hop Cardiologique du HautLeveque  
Gutowski (POL), Samodzielny Publ Szpital Kliniczny  
Haggart (NZL), Waikato DHB  
Numan (TUR), Memorial Hospital  
Cheng (HKG), Queen Mary Hosp  
De La Torra (ESP), Hosp Univ Central de Asturias  
Delle (SWE), Sodersjukhuset  
Dubenec (AUS), Royal Prince Alfred Hospital  
Bilkis (LIT), Vilnius University Hospital  
De Vries (NET), St. Antonius Hospital  
Grigg (AUS), Box Hill Hospital  
Grigg (AUS), Epworth Healthcare Eastern  
Hayes (GBR), Addenbrookes Hospital  
Hoffmann (DEU), Klinikum Solingen  
Midy (FRA), Hosp Pellegrin  
Palones (ESP), Hospital Universitario Dr. Peset  
Mc Williams (GBR), Royal Liverpool Univ Hosp  
Boyne (AUS), Royal Brisbane and Womens Hosp  
Matley (SAF), Kingsbury Hosp  
Mwipatayi (AUS), Hollywood Private Hospital



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