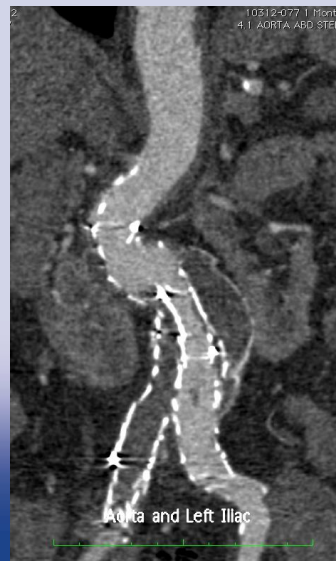


Does Flexible Stent Graft Increase the Risk of Limb Occlusion?

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On behalf of ENGAGE collaborators



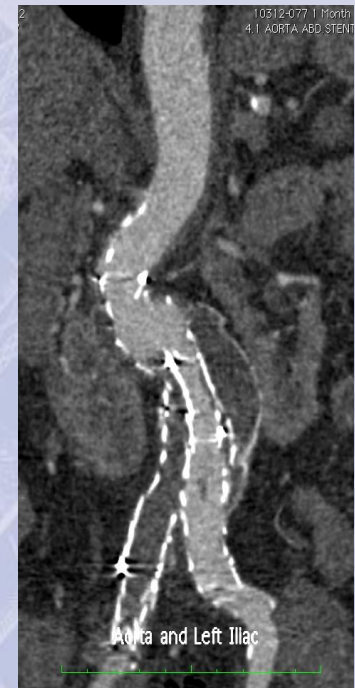
Disclosure

I do not have any potential conflict of interest

Background Limb Graft Occlusion

Reintervention and Rehospitalisation:
3rd cause

Related mortality:
0-0.6%



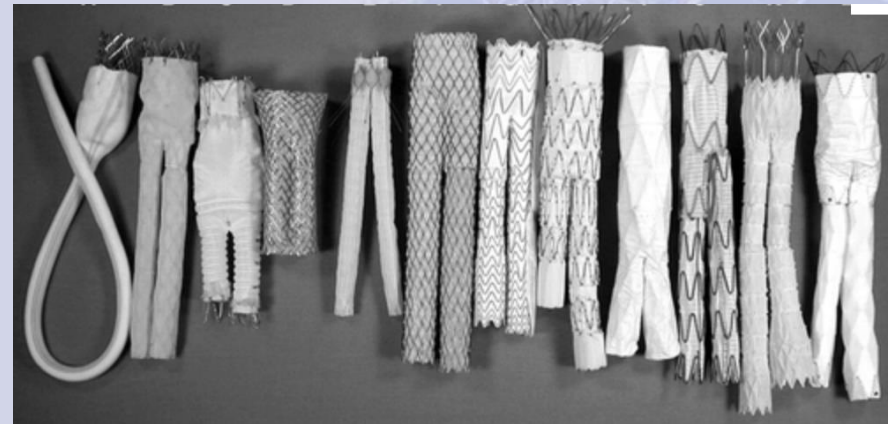
<i>Study (first author)</i>	<i>Year</i>	<i>No.</i>	<i>Endovascular devices used</i>	<i>Follow-up duration</i>	<i>Incidence of occlusion (%)</i>	<i>Occlusion-related mortality (%)</i>
Carroccio ²	2002	351	Mixed	20 months	3.7	0
Erzurum ⁴	2004	823	Mixed	24.2 months	2.7	0.12
Cochennec ⁵	2007	460	Mixed	22 months	7.2	3
Maleux ⁶	2008	288	Mixed	20 months	3.1	0
EVAR 1 ⁷	2010	624		2 years	3.2	Not stated
EVAR 2 ⁸	2010			2 years	2.2	Not stated
DREAM ⁹	2010			2 years	6.7 ^a	Not stated
Van Marrewijk (EUROSTAR) ¹⁰	2010			2 years	5	Not stated
Mehta, et al ¹¹	2010			2 years	1.4	0.05
Karthikesalingam ¹²	2010			2 years	1.1	Not stated
Conrad ¹³	2010			2 years	2.9	0
Abbruzzese ¹⁴	2010			2 years	6 ^b	0.35
Bos ¹⁵	2010			2 years	0	0
Maleux ¹⁶	2010			2 years	1.6	Not stated
BastosGoncalves ¹⁷	2010			5 years	1.4	0
Mertens ¹⁸	2010			66 months	5.6	Not stated
Sivamurthy ¹⁹	2010		Zenith	24 months	5.2	0
Jean-Baptiste ²⁰	2010	447	Zenith	24 months	1.8	0
Torsello ²¹	2010	45	Endurant ^c	30 days	2.2	0
Troisi ²²	2010	156	Endurant	9 months	1.9	0
Van Keulen ²³	2011	100	Endurant	1 year	3.0	1
Rouwet ²⁴	2011	80	Endurant	1 year	1.3	0
Stokmans ²⁵	2012	1151	Endurant	30 days	2.0	Not stated
Current study	2012	496	Endurant	1.7 years	4.0	0.6

**Reported incidence
 2002-2013:
 0%-7.2%
 (Mean: 3.3%)**

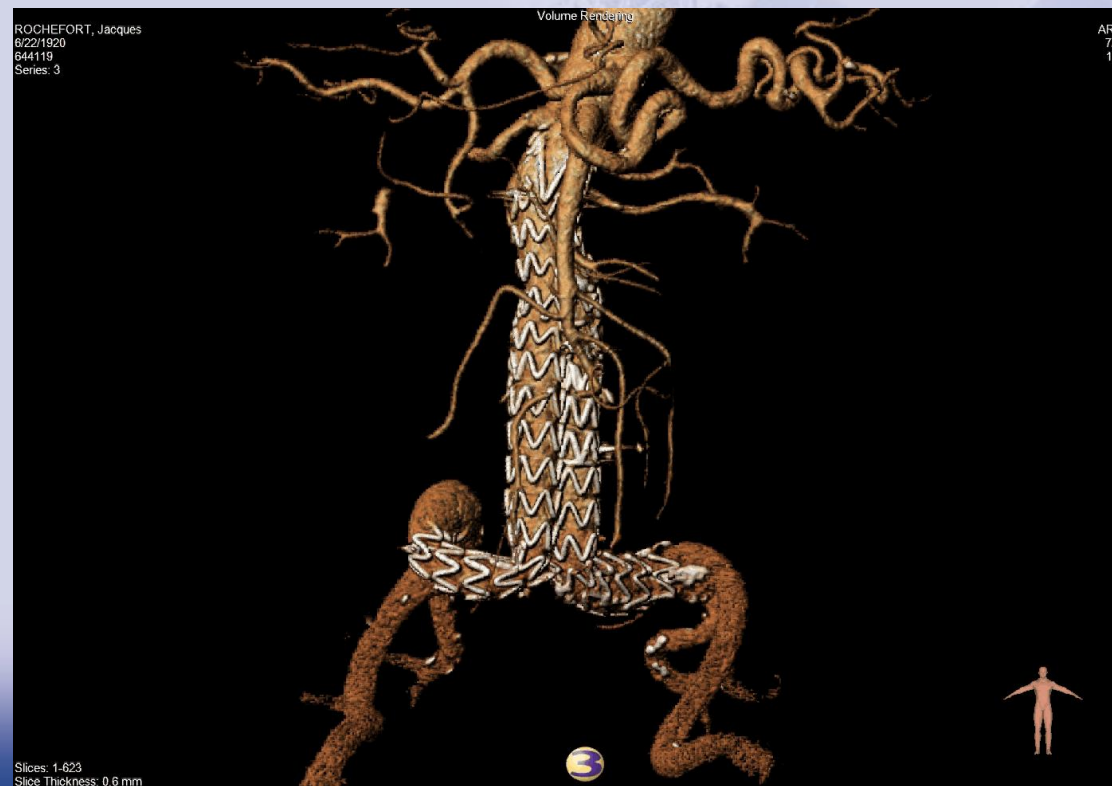
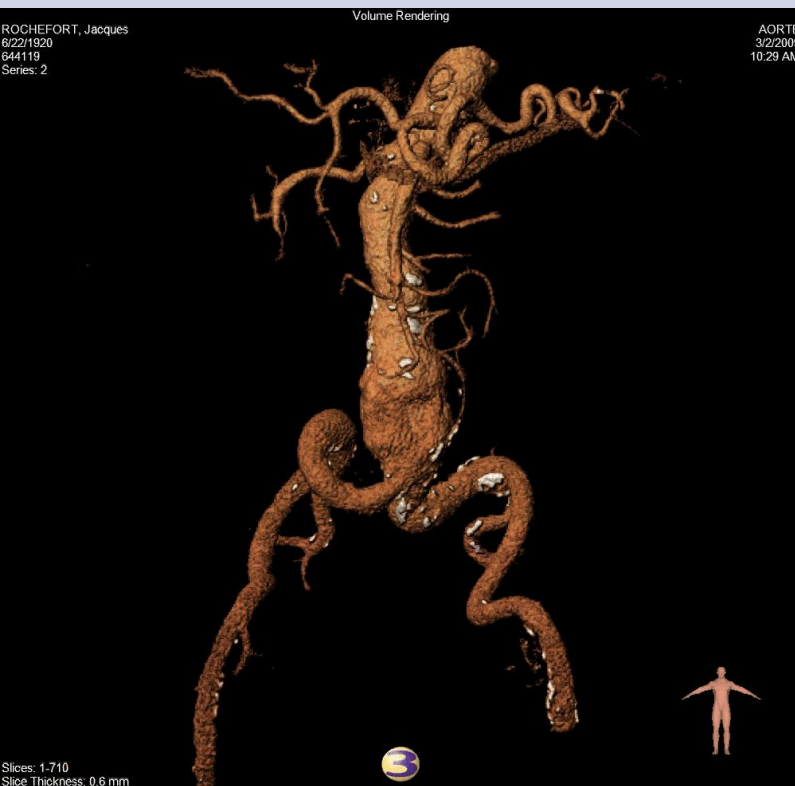
Background Limb Graft Occlusion

Stent-graft improvement since 1990:

- Lower profile
- Better flexibility
- More accurate placement
- Better anchoring
- Ease of use



Treat more complex anatomy: Broaden indication for EVAR



Could we treat tortuous, small, and/or
highly calcified iliac arteries **without**
compromising durable long-term
AAA repair?

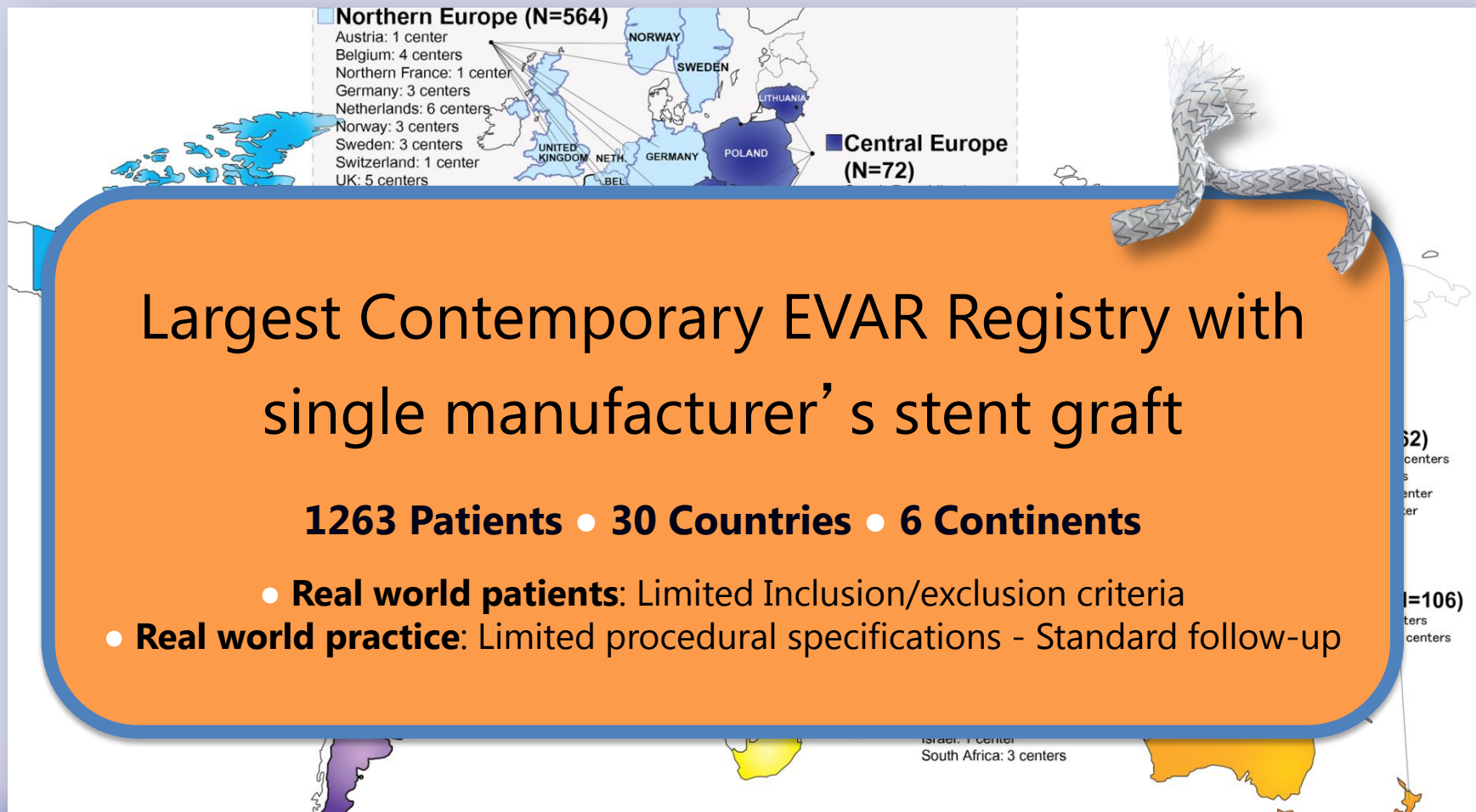
Aim of the study

Limb Graft Occlusion with New Generation of
Stent-Graft at 2 years:

Incidence?

Predictive factors?

Material: ENGAGE registry



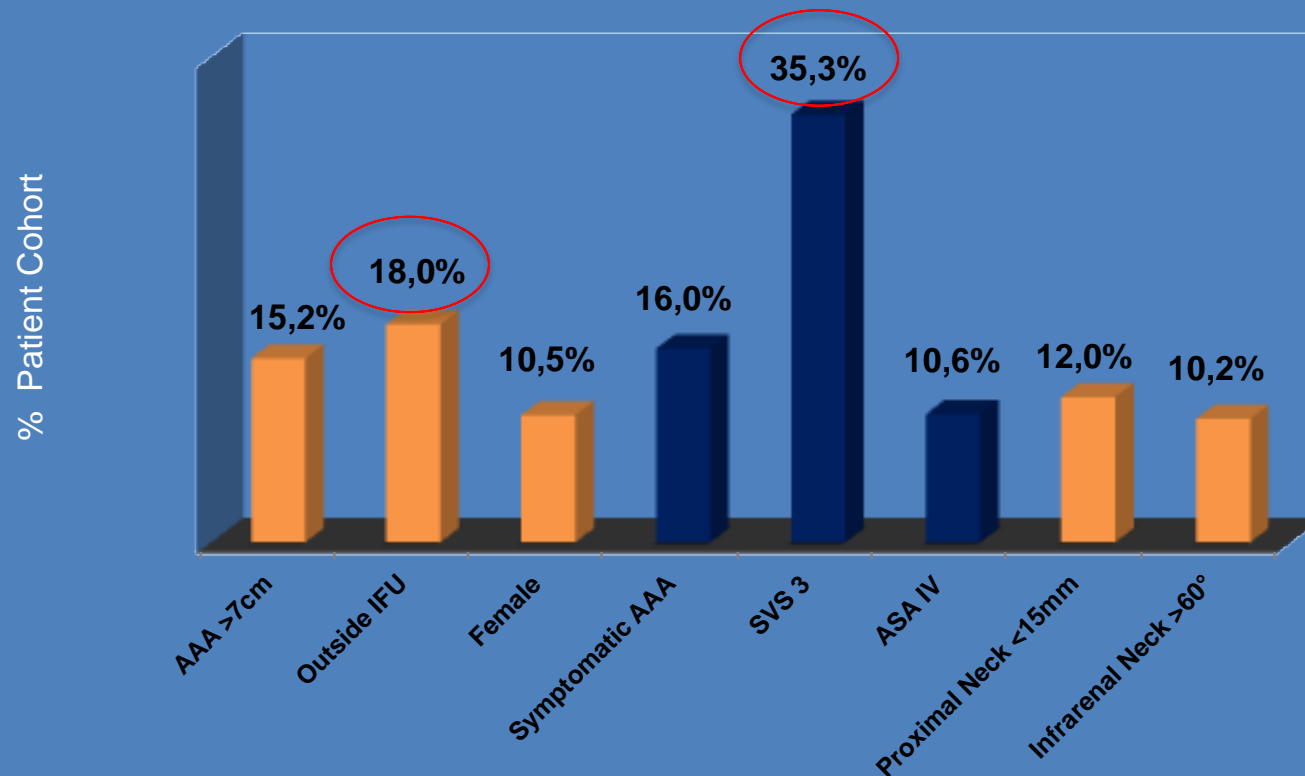
Largest Contemporary EVAR Registry with
single manufacturer's stent graft

1263 Patients • 30 Countries • 6 Continents

- **Real world patients:** Limited Inclusion/exclusion criteria
- **Real world practice:** Limited procedural specifications - Standard follow-up

Material: ENGAGE registry

Patient Baseline Characteristics n=1263



Methods: Clinical Data

- Demographics
- Anatomic characteristics
- Intra op events

The diagram illustrates the anatomical components of an aortic aneurysm for clinical data collection. It shows the proximal neck, the aneurysmal body, and the distal neck leading to the iliofemoral bypass grafts. Various measurement points are indicated with dashed lines connecting to data entry tables.

Requirements for Native Vessel:

L1	Length Prox. Neck:	≥ 10 mm
1	Diam. Prox. Neck:	20mm - 32mm
L3	Length Dist. Neck:	≥ 15 mm
3	Diam. Aortic Bifur:	≥ 22 mm
6r/6l	Access Vessels:	Ipsilateral ≥ 7,5 mm (22Fr) Contralateral ≥ 6 mm (18Fr)

Data Entry Tables:

- Proximal Neck:**

CT	Table pos.
Ø 1a	
Ø 1b	
- Aneurysm Body:**

CT	Table pos.
Ø 2a	
Ø 3	
Ø 4 r	
Ø 5 r	
Ø 6 r	
- Distal Neck:**

CT	Table pos.
L1	
L2	
L3 r	
L3 l	
- Access Vessels:**

CT	Table pos.
Ø 4 l	
Ø 5 l	
Ø 6 l	

Additional Fields:

- Total Length (mm):**

L2+L3 r =
L2+L3 l =
- Common Iliac Artery Length:**

CT	Table pos.
il.com.r	
il.com.l	

Please consider additional length according to the vessel tortuosity

Methods: Statistical analysis

Multivariate logistic regression model

Comparison of occluded vs. non occluded grafts

Classification And Regression Tree (“CART”) method

Strong tool for predictive modeling with a large number of covariates or higher order of interactions

Recursive partitioning

Statistical method to construct **binary decision trees**.

Results

Patients:

1143 bifurcated grafts

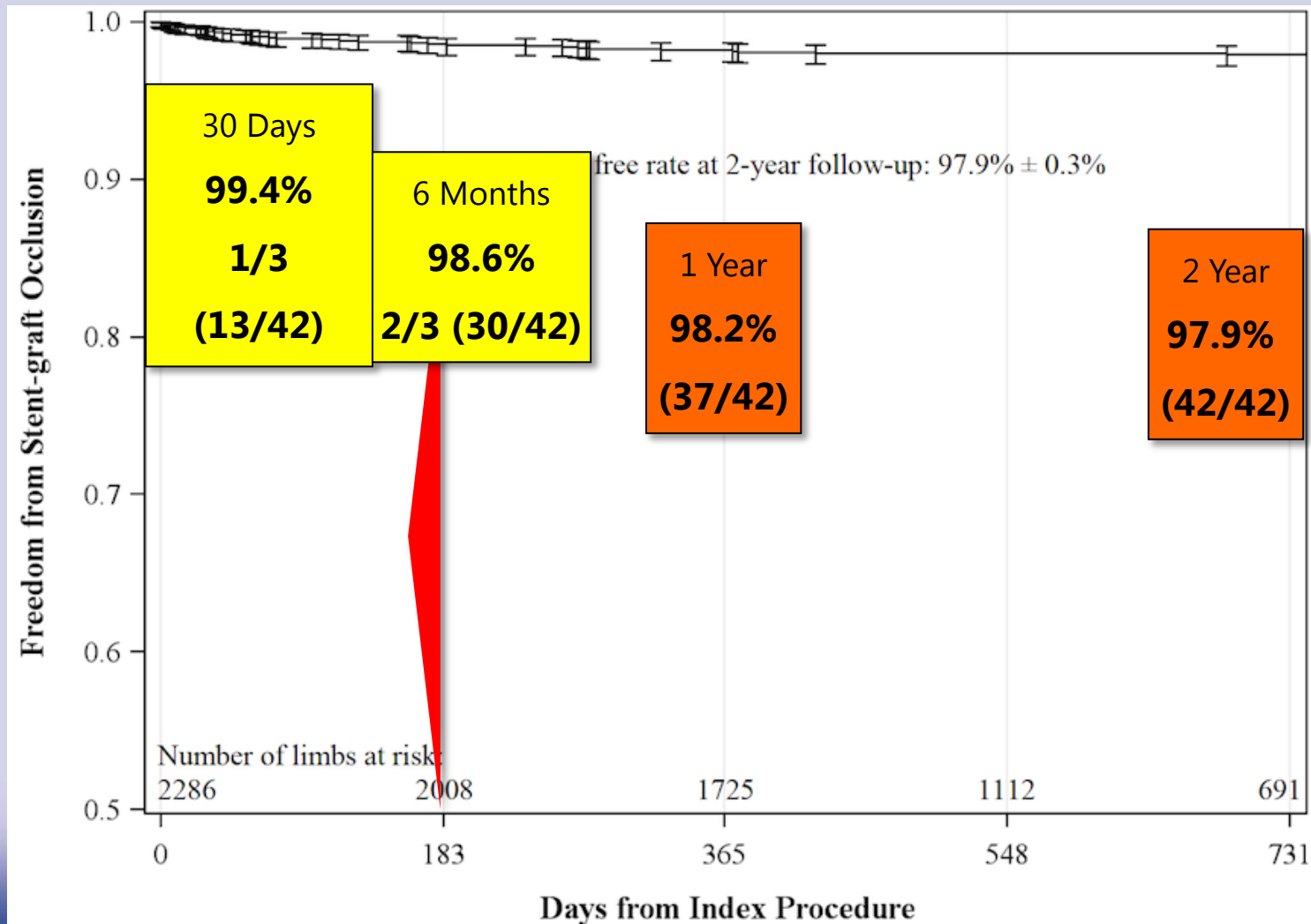
2286 limbs

Occlusion:

39 patients (3,4%)

42 limbs (1.8%)

Results



Results

Potential Predictors for Modeling

47 Covariates

- Demographic
- Medical Conditions
- Vessel Characteristics
- Stent-graft Events
- Index Procedure

"Key factors"

5 Predictors	G ²	% of Contribution	Cumulative Contribution
Stent graft landing into the external iliac artery	19.67	23.3%	23.3%
External iliac artery < 10 mm	14.19	16.8%	40.1%
Aneurysm diameter < 59 mm	10.92	12.9%	53.0%
Stent-graft kinking	10.34	12.2%	65.3%
Endoleak corrected	4.74	5.6%	70.9%

Results

Not significantly associated with limb occlusion:

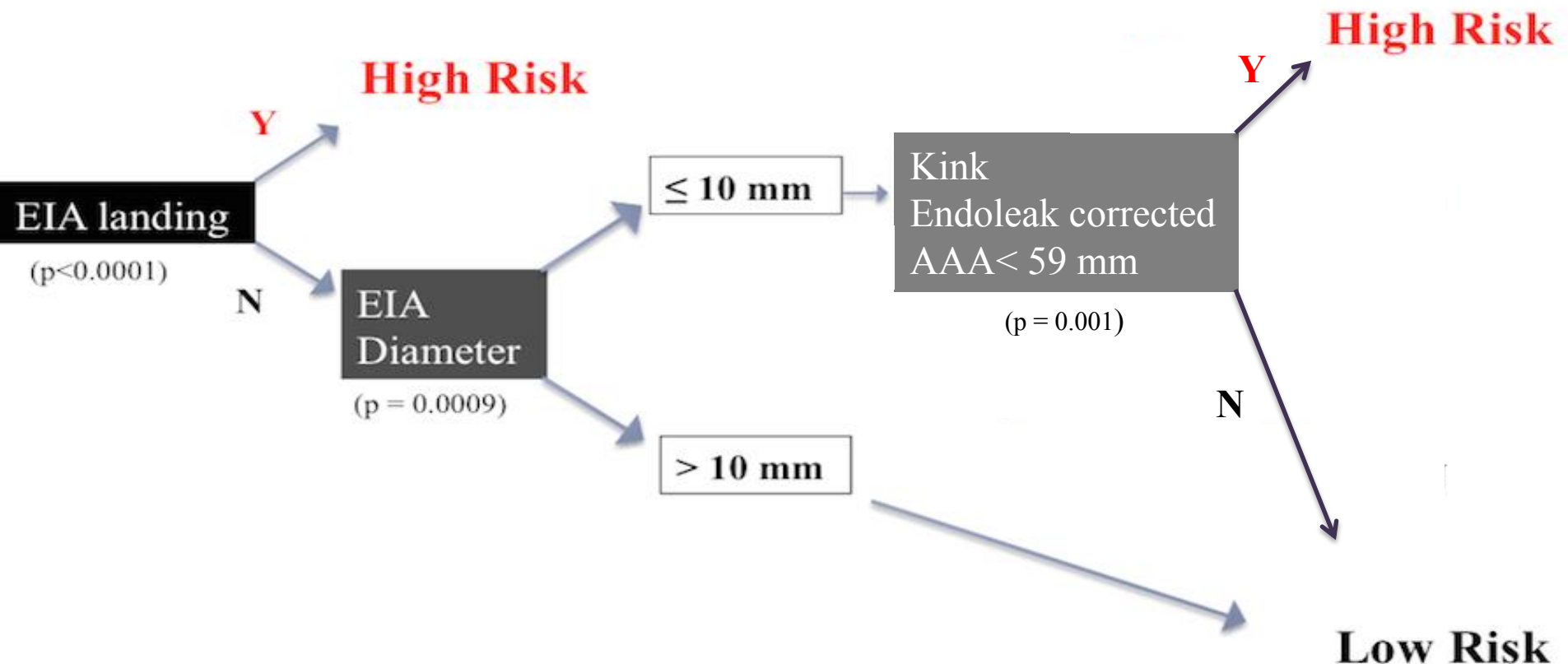
Distal diameter of the aorta

Iliac tortuosity

Common iliac artery diameter

Results

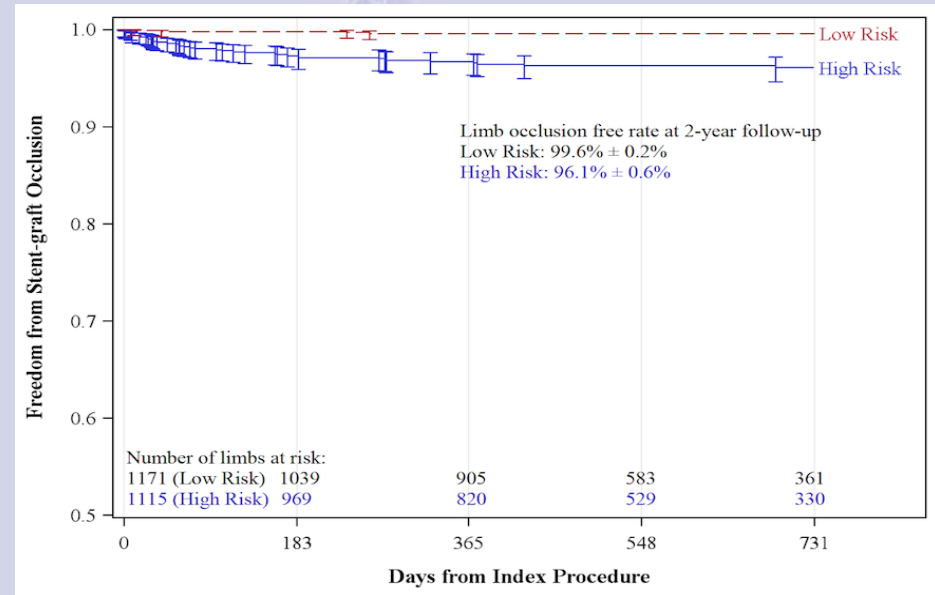
Predictors Chart based on weighted value of key predictors



Results:

Low Risk: 1171 limbs

High Risk: 1115 limbs



38/42 Occlusions in the High Risk group (p=0.0001)

Results:

Patient Group	Occlusion Rate (N = 1143)	Fisher's Exact Test	Odds Ratio (95% Confidence Interval)
At least one iliac artery of high risk	5.8% (37/636)	p < 0.0001	15.6 (3.7, 64.9)
Both iliac arteries are of low risk	0.4% (2/507)		

Having occlusion
with at least one side of high risk iliac artery is
15.6 times greater
than with both low risk iliac arteries

Conclusion

Conclusion

Smaller profile and greater flexibility

Low rate of limb occlusion:

Overall :	3.4%
Low Risk Patients :	0.4%
High Risk Patients:	5.8%

Conclusion

Limb occlusion

Early complication: **2/3 < 6 months**

High risk patients:

EIA landing

Small Access vessels <10 mm

+ Small AAA < 59 mm

Kink

Adjunct procedures

Cumulative
contribution

Conclusion

Decision tree based on very simple and accessible data

High risk patient:

Before procedure:	Choose the less risky option
During procedure:	If kinking: adjunctive stenting
After procedure:	Closer surveillance - 6 months