IMPACT OF TECHNIQUE ON EARLY AND LATE OUTCOMES FOLLOWING BVS IMPLANTATION: ANALYSIS FROM THE ABSORB TRIALS

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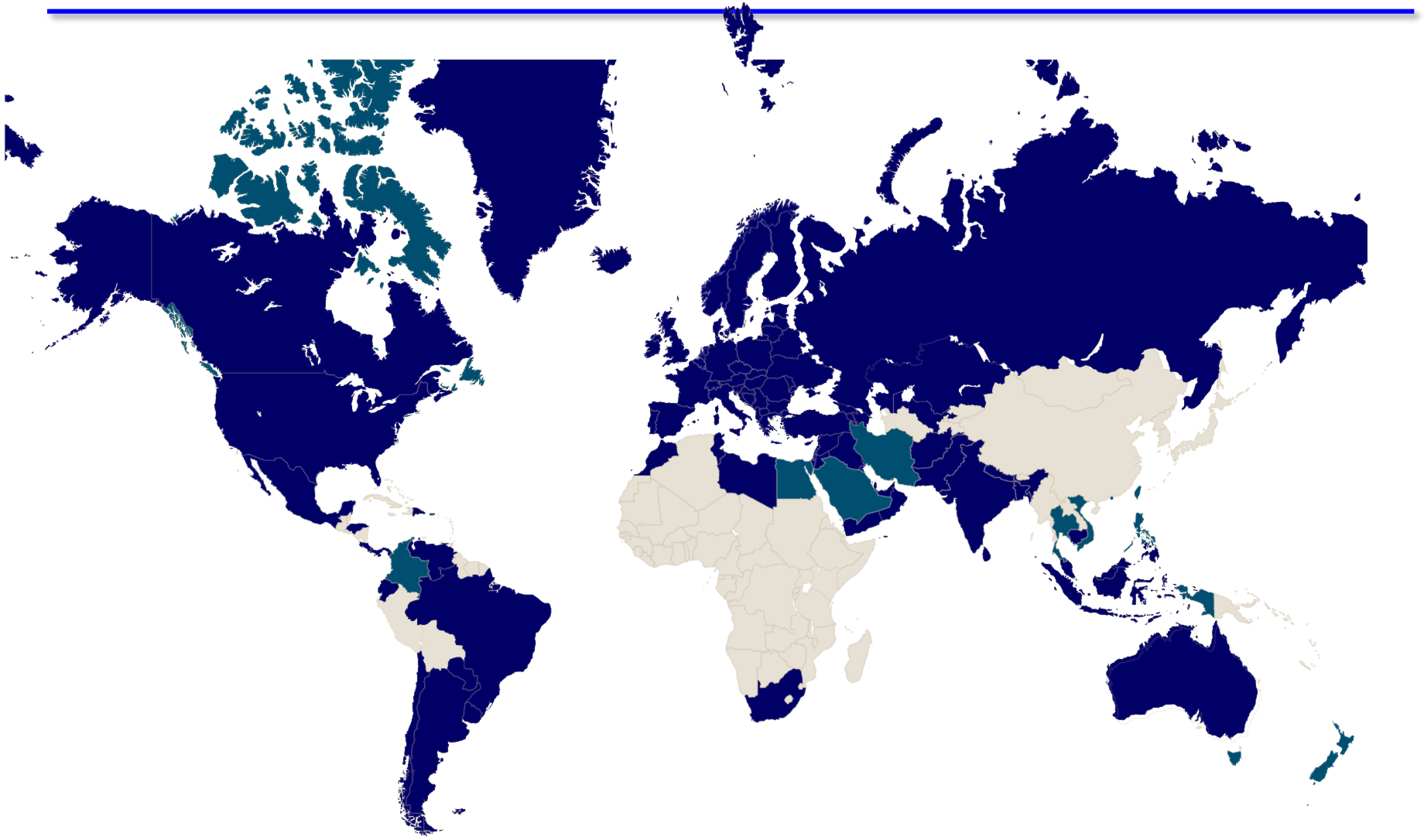
Absorb Worldwide Commercial Usage:

~200,000 patients treated to date
in over 100 countries



PSP OBJECTIVES

Optimal implantation technique is imperative for good clinical outcomes

P PREPARE THE LESION

OBJECTIVE
- Prepare lesion to receive scaffold
- Facilitate delivery
- Enable full expansion of pre-dilatation balloon to facilitate full scaffold expansion

S SIZE APPROPRIATELY

OBJECTIVE
- Accurately size the vessel
- Select appropriate scaffold for “best fit”

P POST-DILATE

OBJECTIVE
- Achieve **<10% final residual stenosis**
- Ensure full strut apposition

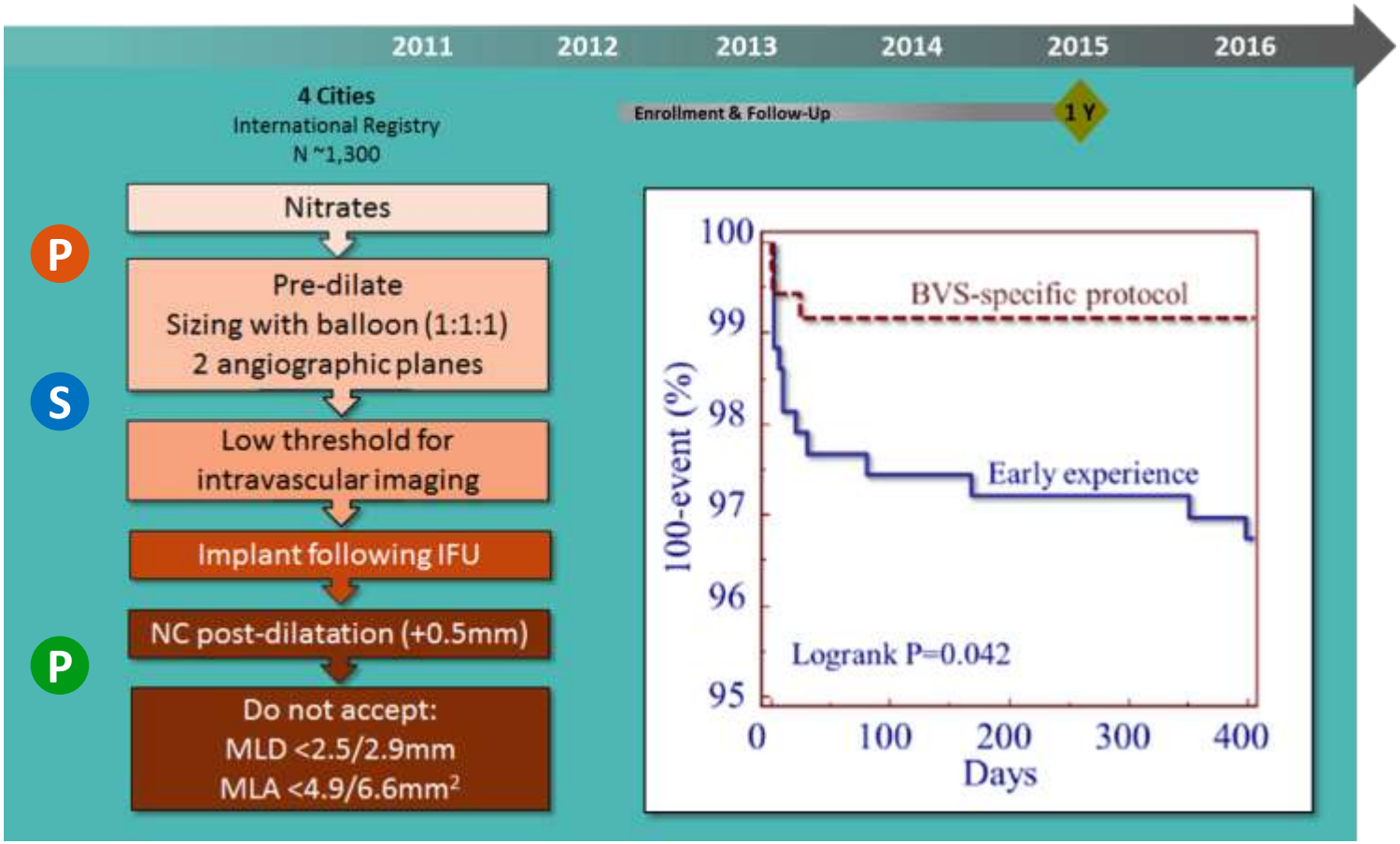
PRESCRIBE DAPT

In ABSORB III all patients were maintained on DAPT for a minimum of 12 months.
Risks versus benefits should be considered for each patient, including judgment regarding risk of antiplatelet therapy.
Antiplatelet therapy should be used per ACC/AHA guidelines, information from the ABSORB family of clinical trials, current literature on DES and scaffolds, and the specific needs of individual patients.

European Real World Registries: Impact of PSP use

4-CITIES REGISTRY LEARNING CURVE. A BVS-SPECIFIC STRATEGY CAN IMPROVE OUTCOMES

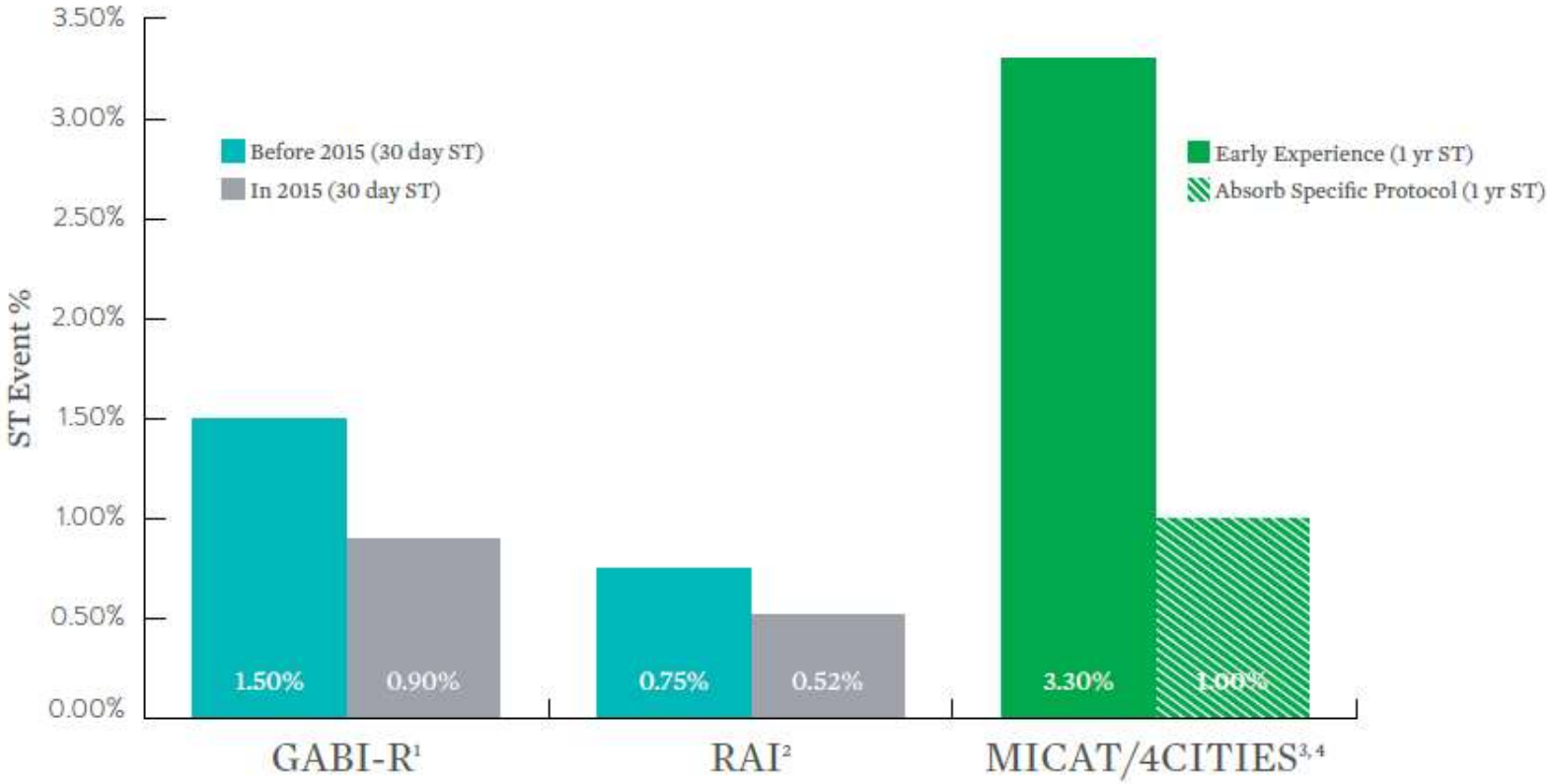
P PREPARE THE LESION **S** SIZE APPROPRIATELY **P** POST-DILATE



Adapted from Gori, T., EuroPCR 2015

REAL WORLD REGISTRIES. IMPLANTATION TECHNIQUE IS KEY DETERMINANT OF OUTCOMES

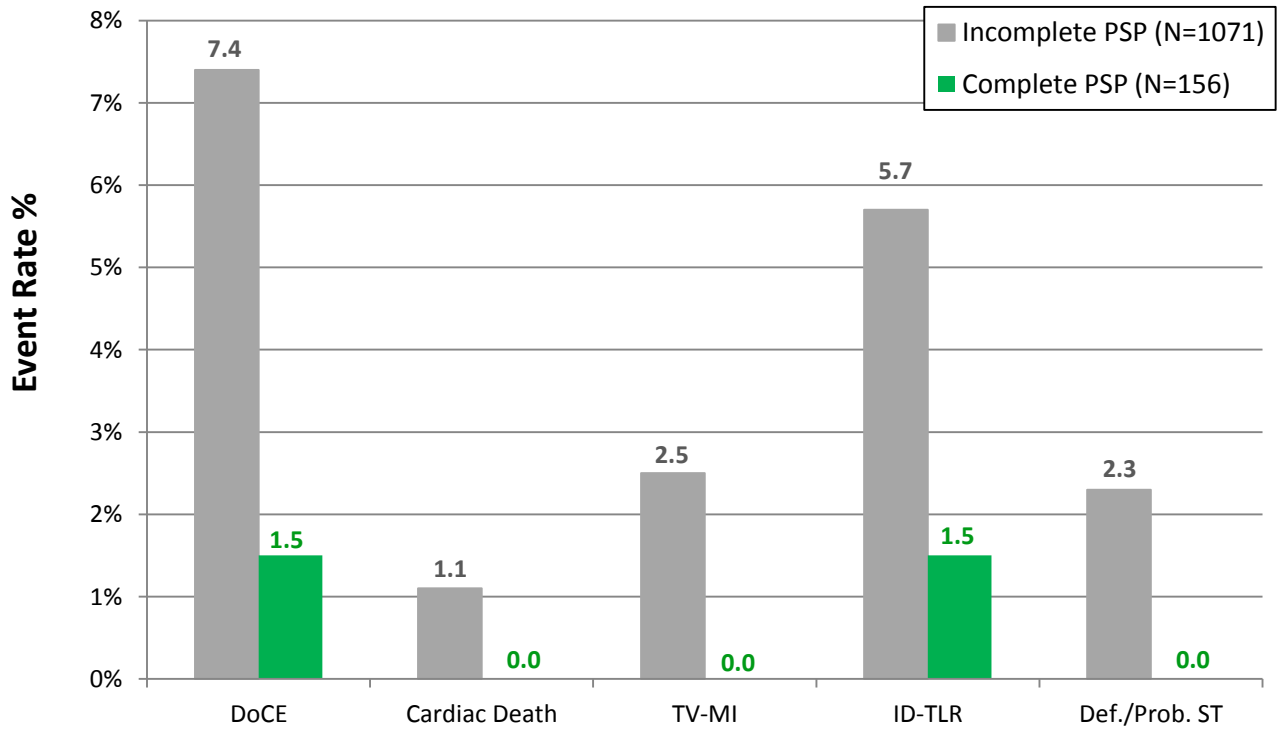
Improvement over time due to patient/lesion selection and improved technique



[1]Hamm, C. GABI-R, EuroPCR 2016. / [2]Cortese, B. RAI, EuroPCR 2016. /
[3]Puricell, S., et al. Bioresorbable Coronary Scaffold Thrombosis, J Am Coll Cardiol. 2016;67:921–31. / [4]Gori, T. 4 Cities Registry, EuroPCR 2015.

OPTIMAL IMPLANTATION TECHNIQUE IS IMPERATIVE FOR GOOD CLINICAL OUTCOMES

1-Year GHOST-EU Data Analysis: Complete PSP versus Incomplete PSP



Brugaletta, S., GHOST-EU PSP Analysis, TCT 2016.

BVS MILAN EXPERIENCE : A SERIES WITH SYSTEMATIC USE OF HIGH PRESSURE POST DILATATION AND NO VLST

Complex patients **264 patients, 400 lesions**	
SYNTAX score	17.1±10.4
ACC/AHA class B2 or C	299 (74.8%)
Bifurcation	187 (46.8%)
In-stent restenosis	19 (4.8%)
CTO	25 (6.3%)
Severe calcification	90 (22.5%)
Scaffold length (mm)	35.2±19.3
Scaffold length per patient (mm)	53.2±32.5
Scaffold overlap per lesion	116 (43.9%)

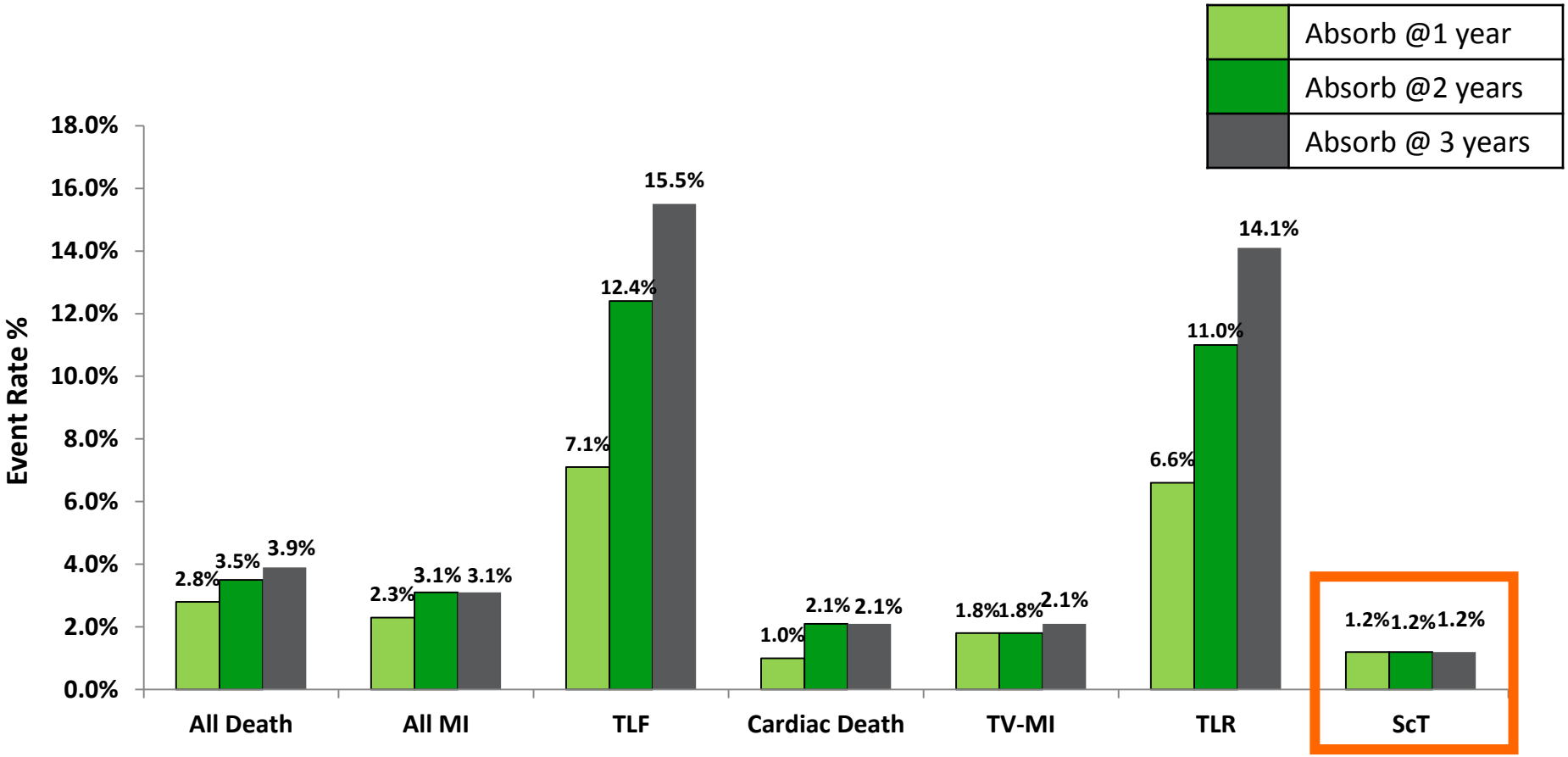
Proper PSP Compliance	
Lesion prep	
Pre-dilatation	389 (97.3%)
Scoring/Cutting balloon	61 (15.3%)
Rotablator	19 (4.8%)
Sizing	
Intravascular imaging	343 (85.8%)
Post-dilatation	
Post-dilatation	399 (99.8%)
Post-dilatation pressure	20.8±4.5atm
Balloon/scaffold ratio	1.04±0.08

Lesion complexity: Milan >> ABSORB III and GHOST EU

Optimal implantation: Milan >> ABSORB III and GHOST EU

Tanaka, A., et al. EuroIntervention. 2016: DOI: 10.4244/EIJ-D-16-00247.

BVS MILAN EXPERIENCE: A SERIES WITH SYSTEMATIC USE OF HIGH PRESSURE AND NO VLST



Lesion complexity: rates in Milan are much greater than ABSORB III and GHOST EU

Optimal implantation: rates in Milan are much greater than ABSORB III and GHOST EU

Latib, A., BVS Milan Experience, JIM 2017

Pooled ABSORB trial data: Impact of PSP use

Impact of Implantation Technique

- Implantation technique for Absorb BVS has evolved in recent years
- A growing body of evidence from ABSORB randomized trials and registries suggest that optimized implantation techniques may improve clinical outcomes
- Analysis based on pooled Absorb data was conducted to evaluate the impact of PSP, which stands for pre-dilatation, appropriate vessel sizing, and high pressure post-dilatation
- Pooled ABSORB data at 2 years: ABSORB EXTEND, ABSORB II, ABSORB Japan, ABSORB China, and ABSORB III

Data presented by Steve Ellis at ACC, Washington DC, March 2017.

PSP Analysis

- Definition of PSP components (must satisfy all the criteria below)
  - Pre-dilatation (performed in 99.9% of Absorb patients)
  - Sizing (vessel): 2.25mm ≤ QCA RVD ≤ 3.5mm
  - Post-dilatation:
    - Pressure ≥ 18 atm
    - Balloon diameter: Scaffold diameter > 1:1 and Balloon diameter ≤ Scaffold diameter + 0.5mm
- Full PSP: All three criteria met
- Not full PSP: any criteria not met

Data presented by Steve Ellis at ACC, Washington DC, March 2017.

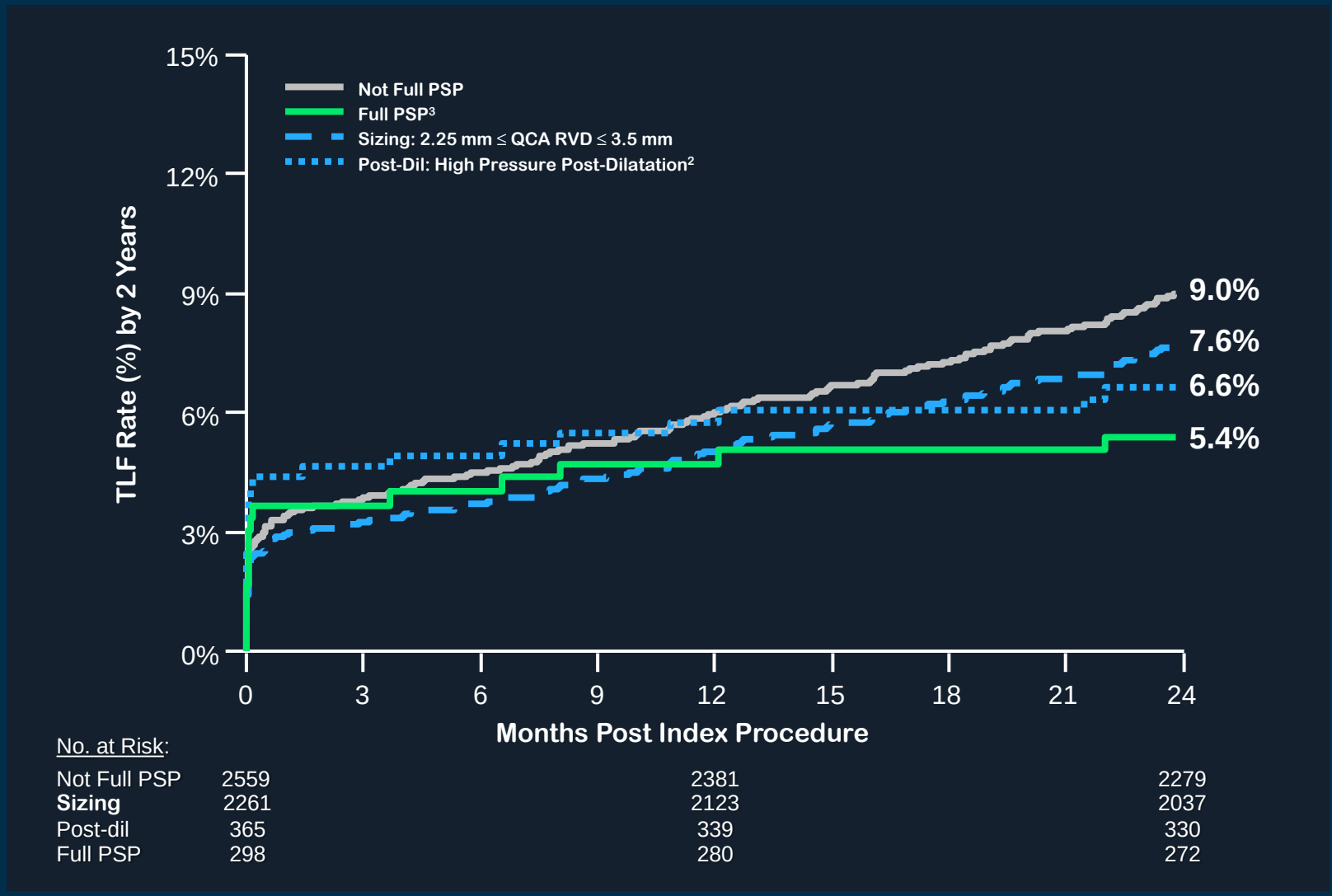
PSP Analysis
Pooled ABSORB Trials Absorb Arm[1]

Implantation Technique	Absorb (N=2870)
Pre-dilatation	99.9%
2.25 mm ≤ QCA RVD ≤ 3.5 MM	79.3%
High pressure Post-dilatation[2]	12.8%
Full PSP[3]	10.4%

1. Based on patient population treated with Absorb BVS in ABSORB II, ABSORB III, ABSORB China, ABSORB Japan and ABSORB EXTEND
2. Defined as post-dilatation balloon pressure ≥18 atm, post-dilatation balloon diameter > nominal scaffold diameter and post-dilatation balloon diameter ≤nominal scaffold diameter+0.5mm
3. Defined as patients with pre-dilatation, QCA RVD ≥2.25mm-≤3.5mm, and high pressure post-dilatation defined above in 2

Data presented by Steve Ellis at ACC, Washington DC, March 2017.

TLF by 2 Years
Pooled ABSORB Trials Absorb Arm[1]

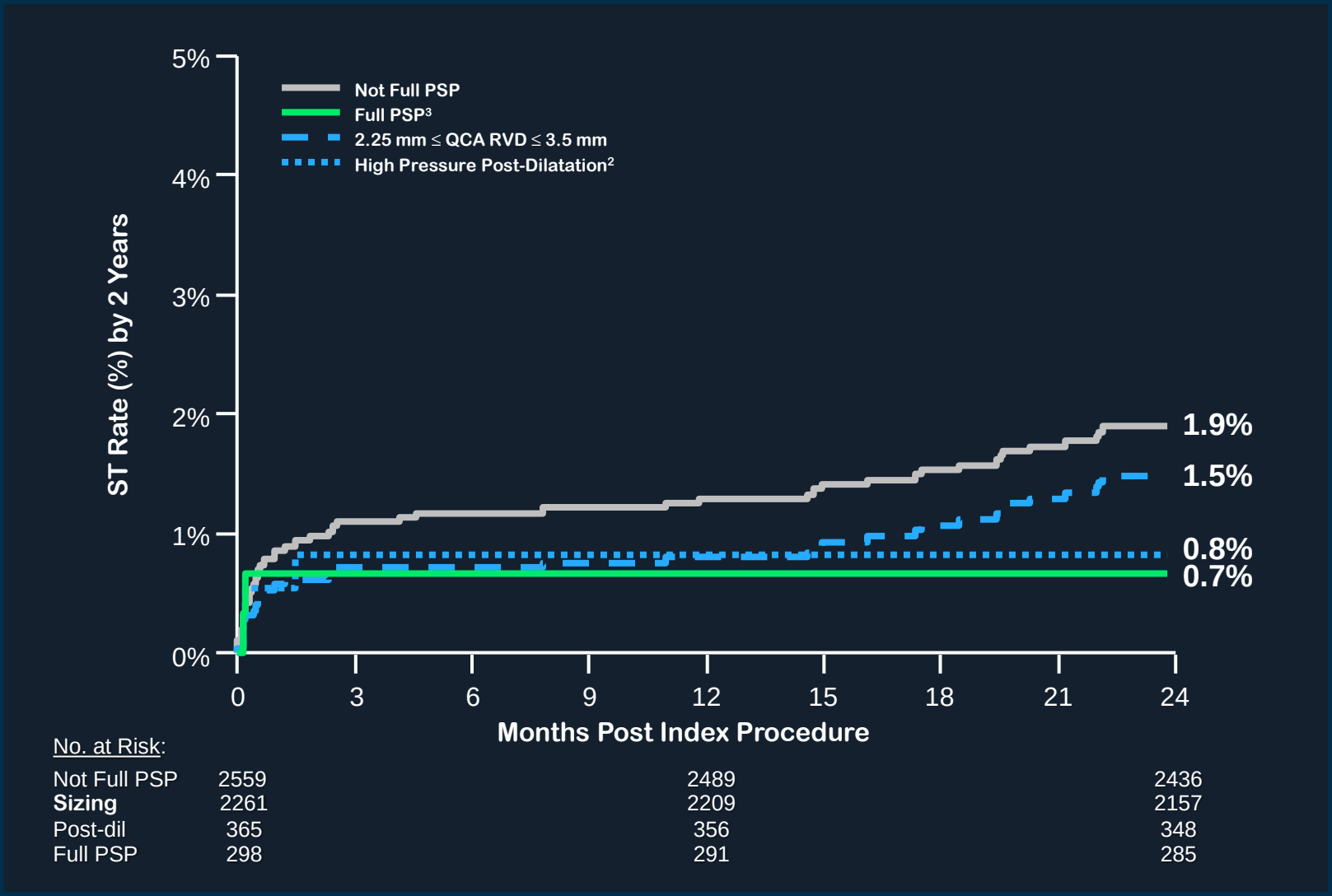


No. at Risk:

Not Full PSP	2559	2381	2279
Sizing	2261	2123	2037
Post-dil	365	339	330
Full PSP	298	280	272

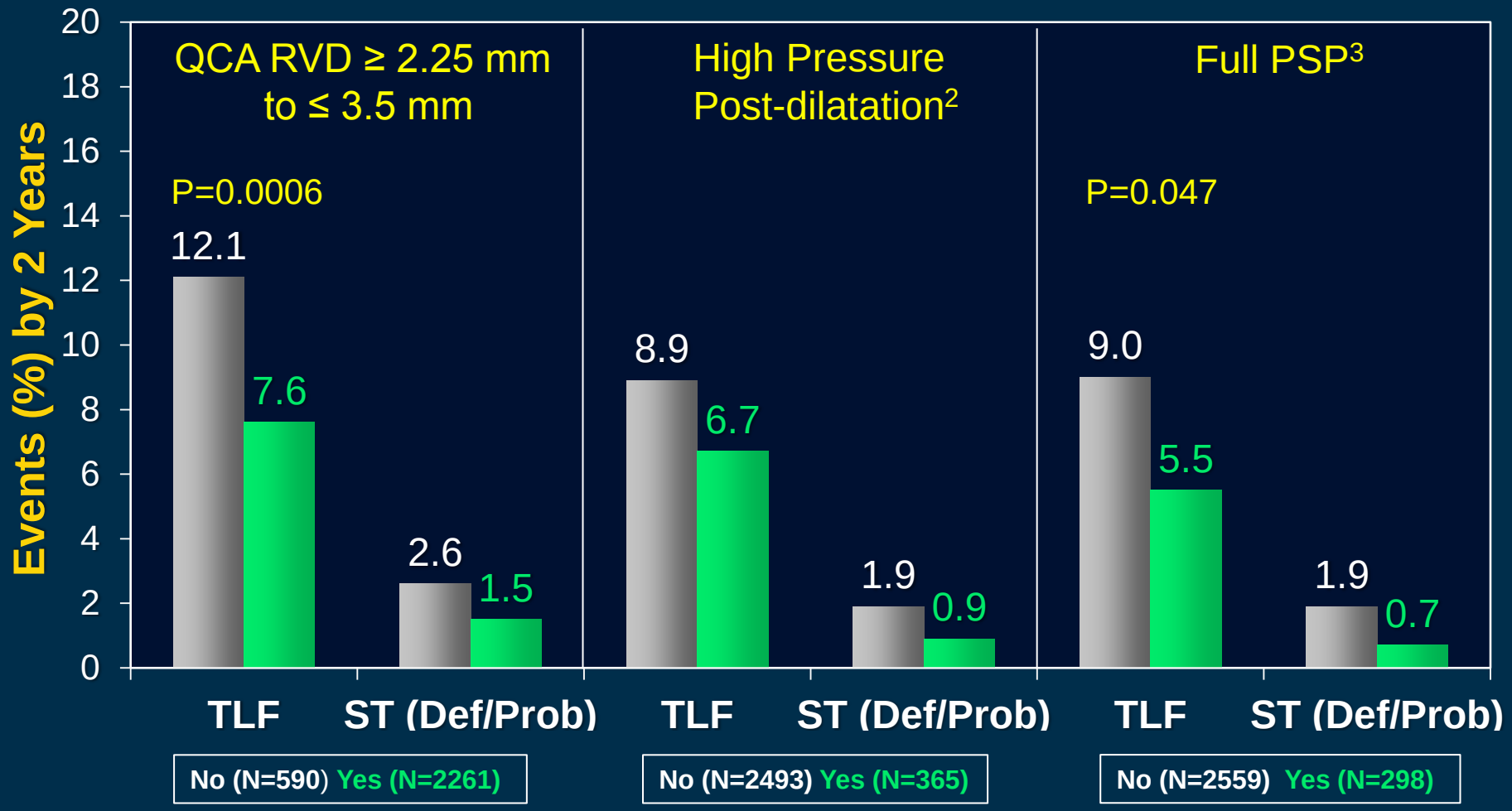
1. Based on patient population treated with Absorb BVS in ABSORB II, ABSORB III, ABSORB China, ABSORB Japan and ABSORB EXTEND
2. Defined as post-dilatation balloon pressure ≥18 atm, post-dilatation balloon diameter > nominal scaffold diameter and post-dilatation balloon diameter ≤nominal scaffold diameter+0.5mm
3. Defined as patients with pre-dilatation, QCA RVD ≥2.25mm-≤3.5mm, and high pressure post-dilatation defined above in 2.

Scaffold Thrombosis (Def/Prob) by 2 Years
Pooled ABSORB Trials Absorb Arm[1]



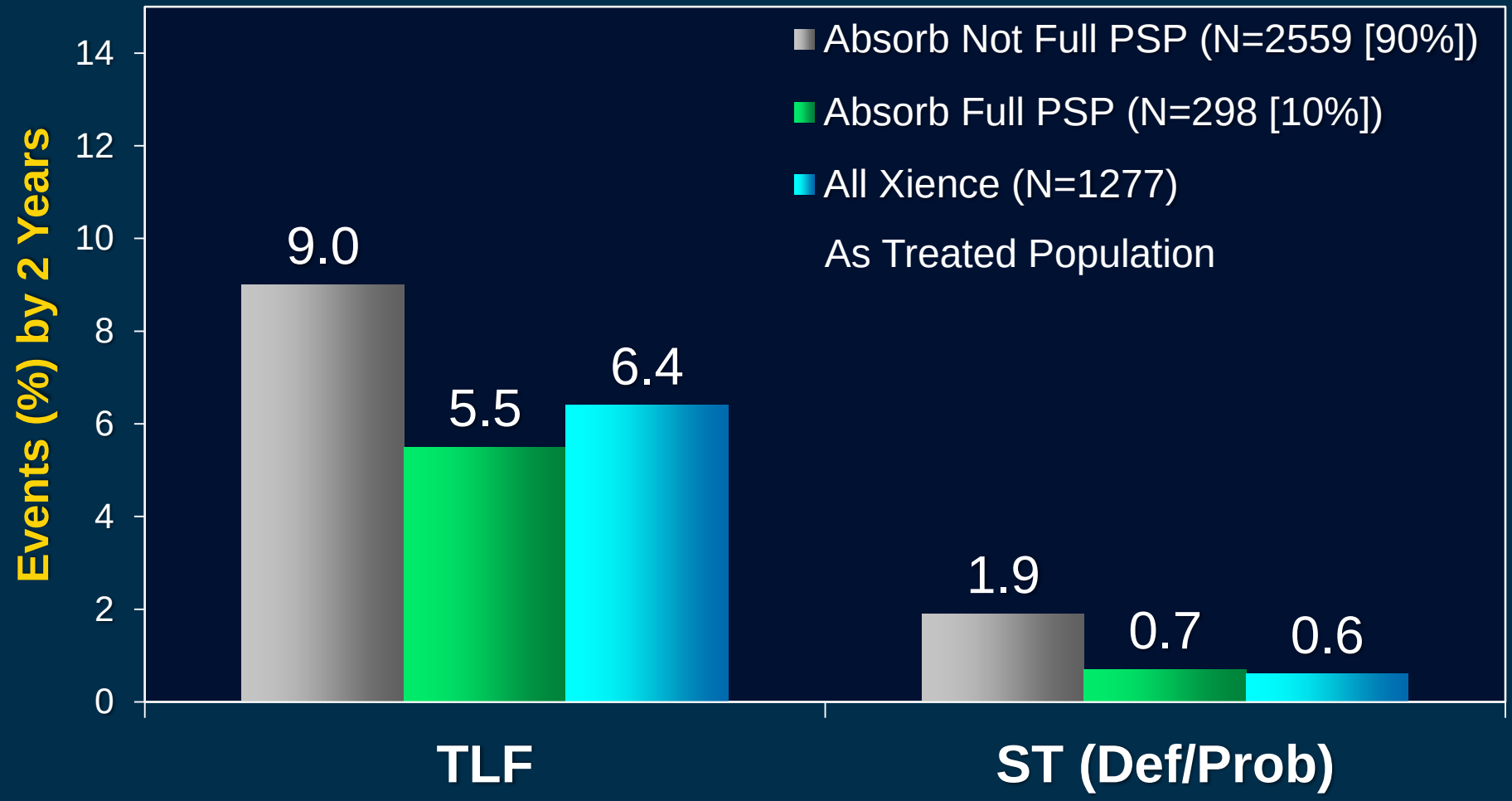
1. Based on patient population treated with Absorb BVS in ABSORB II, ABSORB III, ABSORB China, ABSORB Japan and ABSORB EXTEND
2. Defined as post-dilatation balloon pressure ≥18 atm, post-dilatation balloon diameter > nominal scaffold diameter and post-dilatation balloon diameter ≤nominal scaffold diameter+0.5mm
3. Defined as patients with pre-dilatation, QCA RVD ≥2.25mm-≤3.5mm, and high pressure post-dilatation defined above in 2.

Impact of Implantation Technique on Clinical Outcomes by 2 Years - Pooled ABSORB Trials Absorb Arm[1]



1. Based on patient population treated with Absorb BVS in ABSORB II, ABSORB III, ABSORB China, ABSORB Japan and ABSORB EXTEND
2. Defined as post-dilatation balloon pressure ≥18 atm, post-dilatation balloon diameter > nominal scaffold diameter and post-dilatation balloon diameter ≤nominal scaffold diameter+0.5mm
3. Defined as patients with pre-dilatation, QCA RVD ≥2.25mm-≤3.5mm, and high pressure post-dilatation defined above in 2.

Impact of Full PSP* on Clinical Outcomes by 2 Years Pooled ABSORB Trials As-Treated Population**



* Defined as patients with pre-dilatation, and QCA RVD ≥2.25mm-≤3.5mm, and post-dilatation performed at ≥18 atm, with post-dilatation balloon diameter > nominal scaffold diameter but ≤ nominal scaffold diameter + 0.5mm

** Pooled ABSORB II, ABSORB III, ABSORB China, ABSORB Japan and ABSORB EXTEND

Blinded, Pooled, Interim ABSORB IV Outcomes: Comparison to ABSORB III

ABSORB III: 2008 pts randomized 2:1 BVS:EES (1322:686)
ABSORB IV: 3000 pts being randomized 1:1 BVS:EES

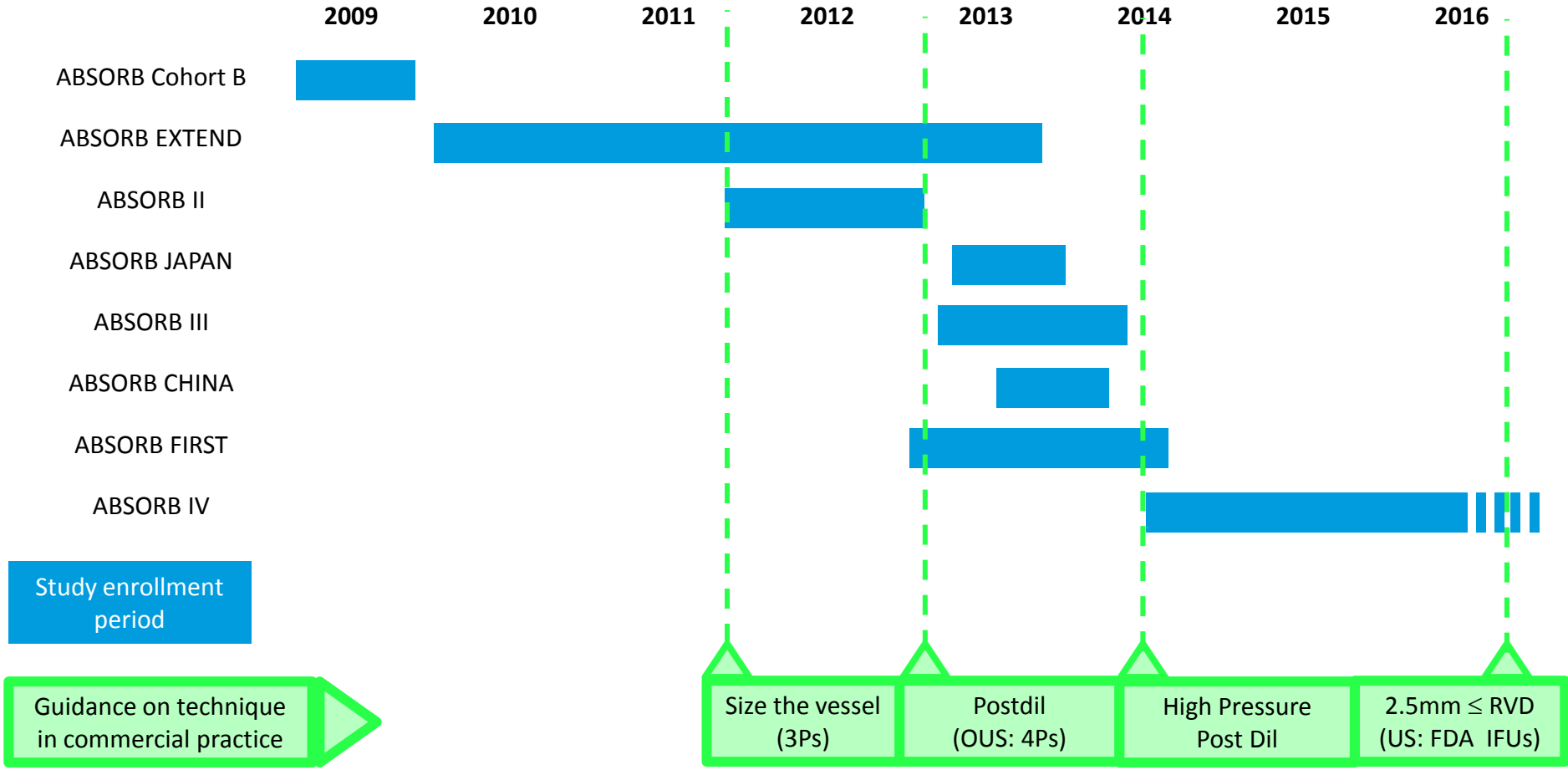
	ABSORB III Pooled (N=2008)[1]	ABSORB IV Pooled (N=2546)[2,3]
QCA RVD < 2.25 mm	19%	4%
Post-dilatation (BVS)	66%	84%
	Pooled Stent/Scaffold Thrombosis	
30 days	0.9%	0.4%
1 year	1.1%	0.5%

1. Assuming the observed event rates for each arm in ABSORB III, but adjusted for the 1:1 randomization ratio in ABSORB IV. The actual observed pooled ST rates in ABSORB III were 1.0% at 30 days and 1.3% at 1 year.
2. Based on February 15, 2017 data cut (N=2397 with 30-day FU and N=1415 with 1-year FU).
3. ABSORB IV includes ~25% non A-III like subjects (troponin+ ACS, 3 lesions treated, and planned staged procedures).

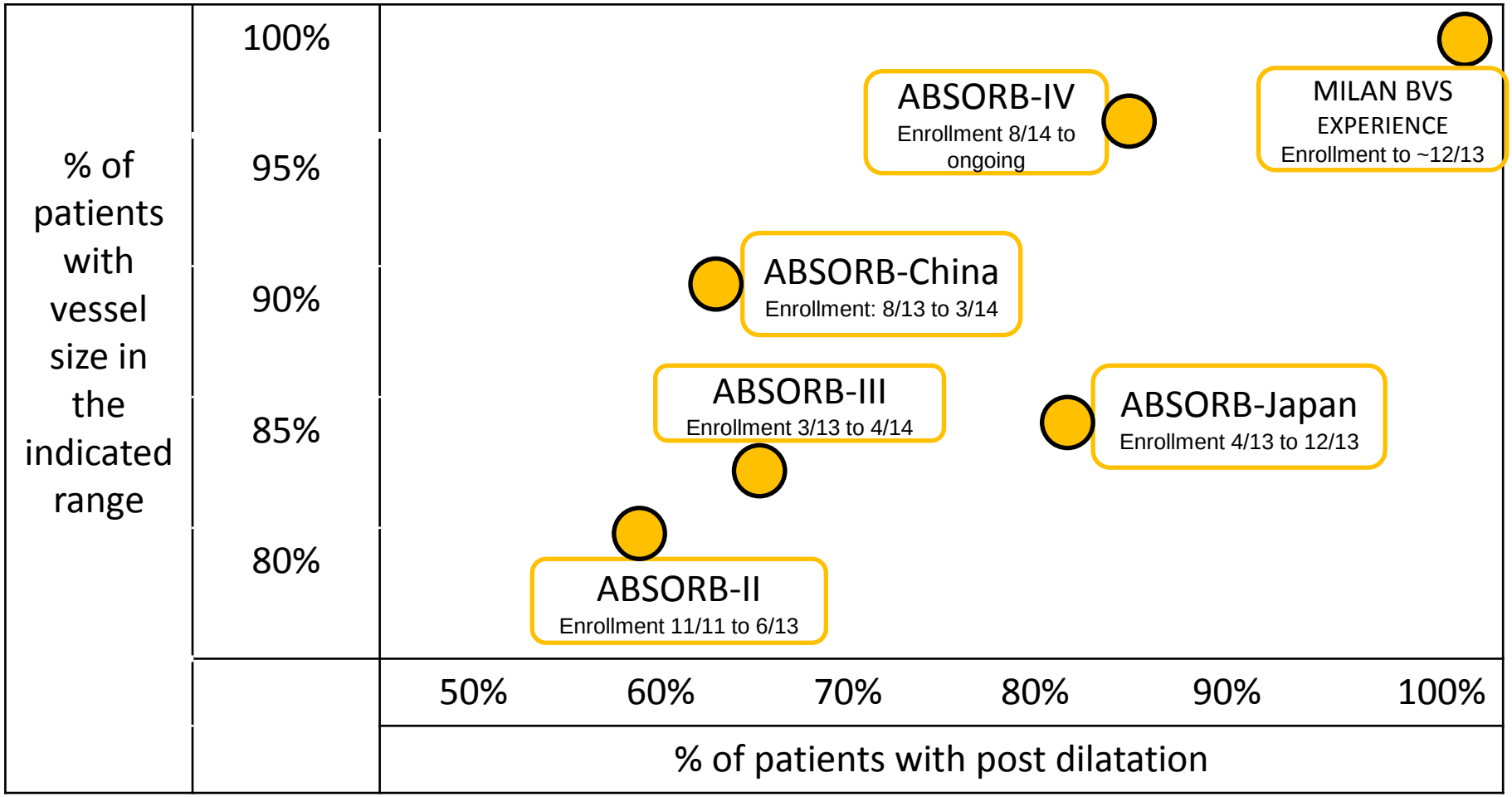
Data presented by Steve Ellis at ACC, Washington DC, March 2017.

OPTIMAL IMPLANTATION TECHNIQUE IS IMPERATIVE FOR GOOD CLINICAL OUTCOMES

IMPLANTATION GUIDANCE HAS EVOLVED DURING ENROLLMENT IN ABSORB TRIALS

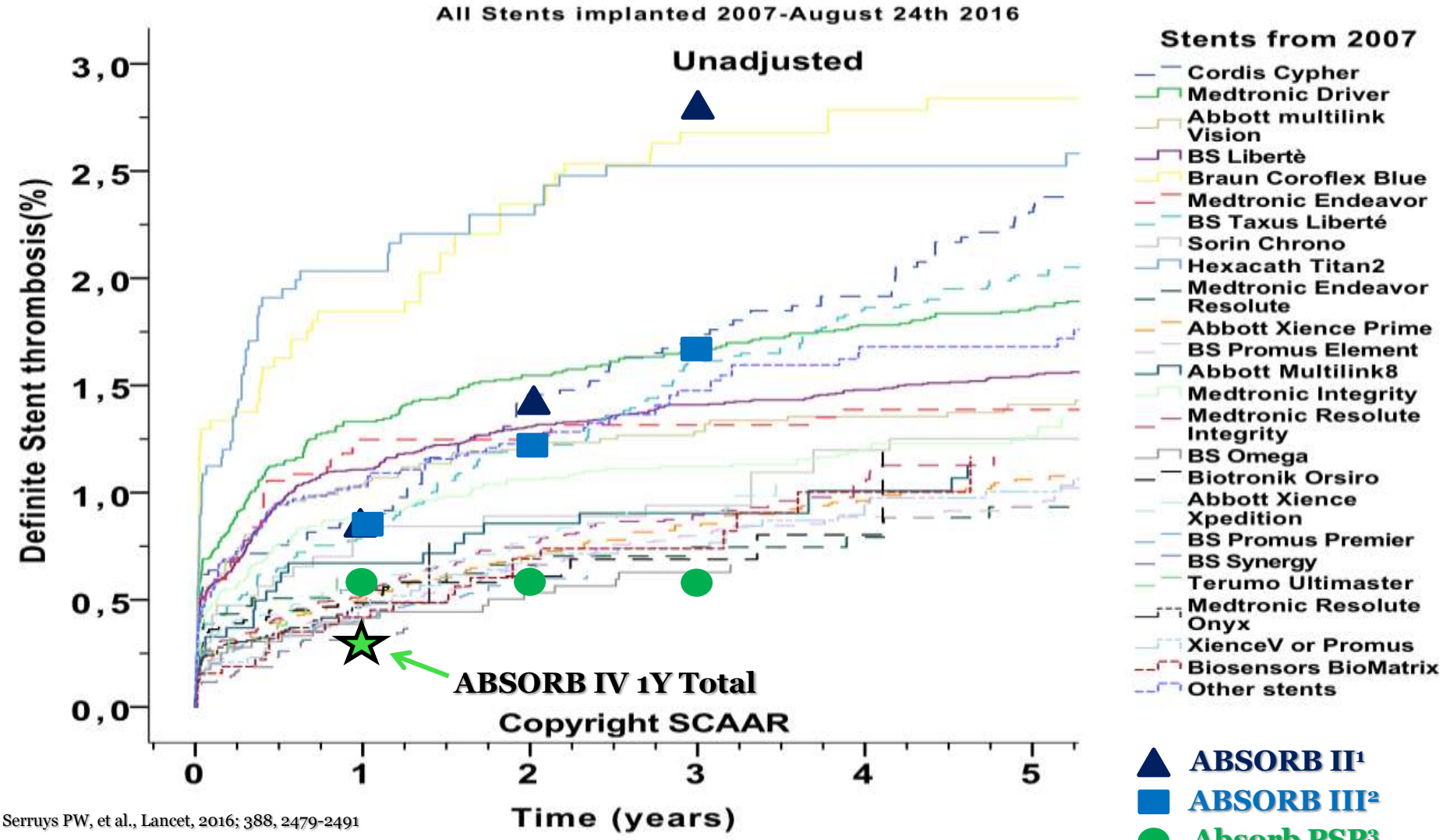


EVOLVING TECHNIQUE IN CLINICAL STUDIES[1]



1. Latib, BVS Milan Experience, JIM 2017, Kimura ABSORB Japan ESC 2016, Gao ABSORB China TCT 2016, Serruys ABSORB II TCT 2015, Stone ABSORB III TCT 2015

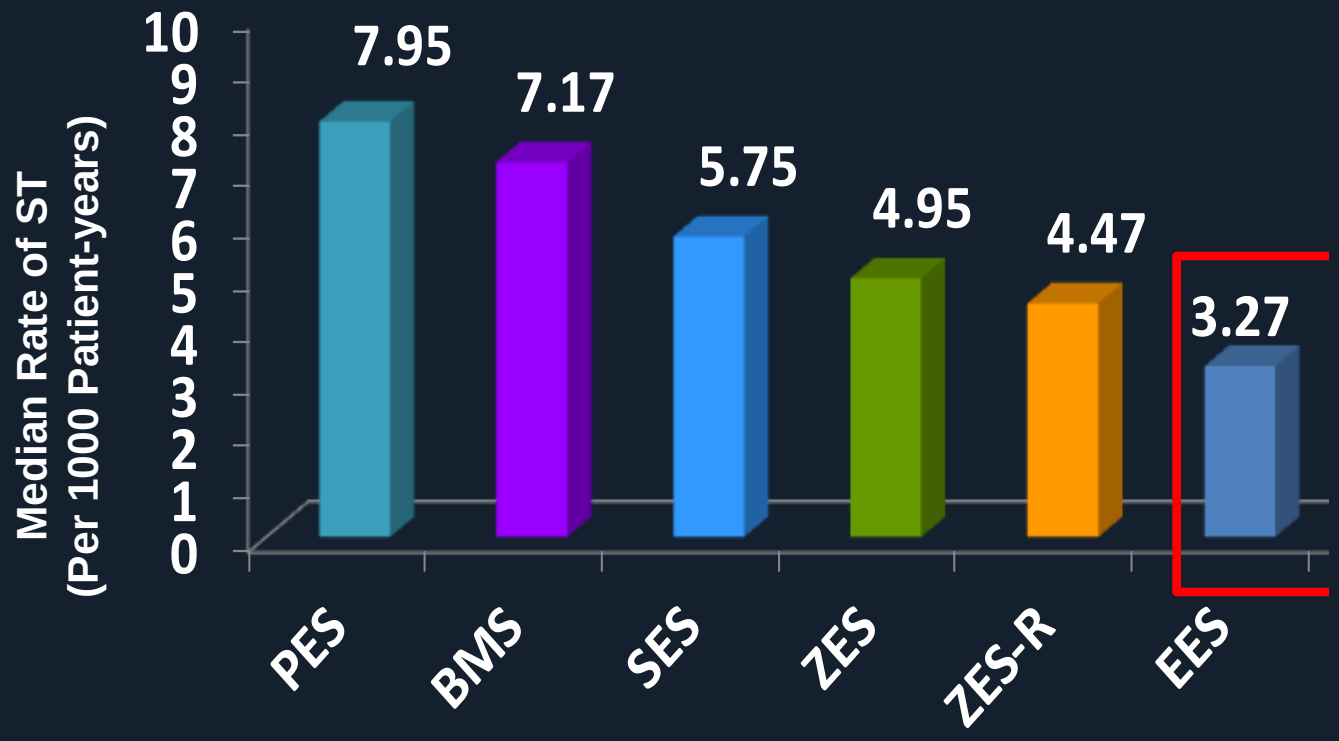
SCAAR REGISTRY: ST RATE OF CONTEMPORARY METALLIC STENTS



1. Serruys PW, et al., Lancet, 2016; 388, 2479-2491
2. Based on the appropriated sized group in ABSORB III and worst case scenario for 1-3 Y
3. Adapted from Rizik, D., ABSORB PSP Analysis, TCT 2016.

Stent Thrombosis

Median Rate per 1000 Patient-Years



Bangalore et al. *Circulation*. 2012;125:2873-2891

Pooled ABSORB PSP analysis (Ellis ACC 2017)

Data presented by Sripal Bangalore at ACC, Washington DC, March 2017.

Conclusions

- In an era where technique was not strongly considered, there were small differences between Absorb and Xience
- However the principle of PSP, in particular proper vessel sizing and high pressure post-dilatation, may minimize differences between Absorb and Xience, as shown by data from EU real world registries as well as pooled ABSORB trial analyses
- New insights regarding the impact of optimal technique on the early and late outcomes of Absorb BVS may emerge with the final 3-year data from ABSORB III, China and Japan, and when the ABSORB IV results become available

Thank you

Abbott
A Promise for Life