The Next Step: BVS in Challenging Lesions

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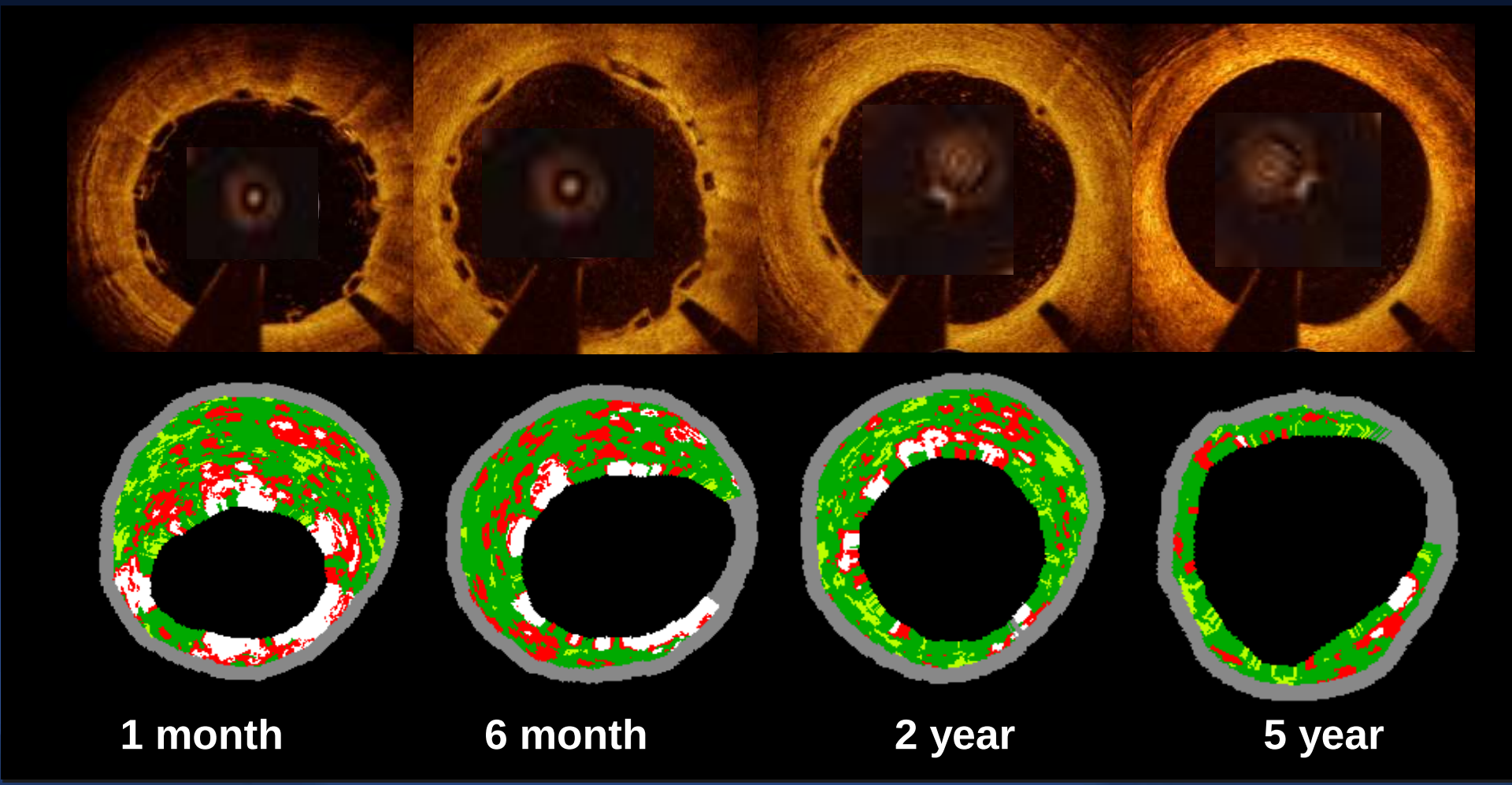
Totally Different Concept !

Do their Job and Disappear !

Plaque Stabilization and Lumen Enlargement



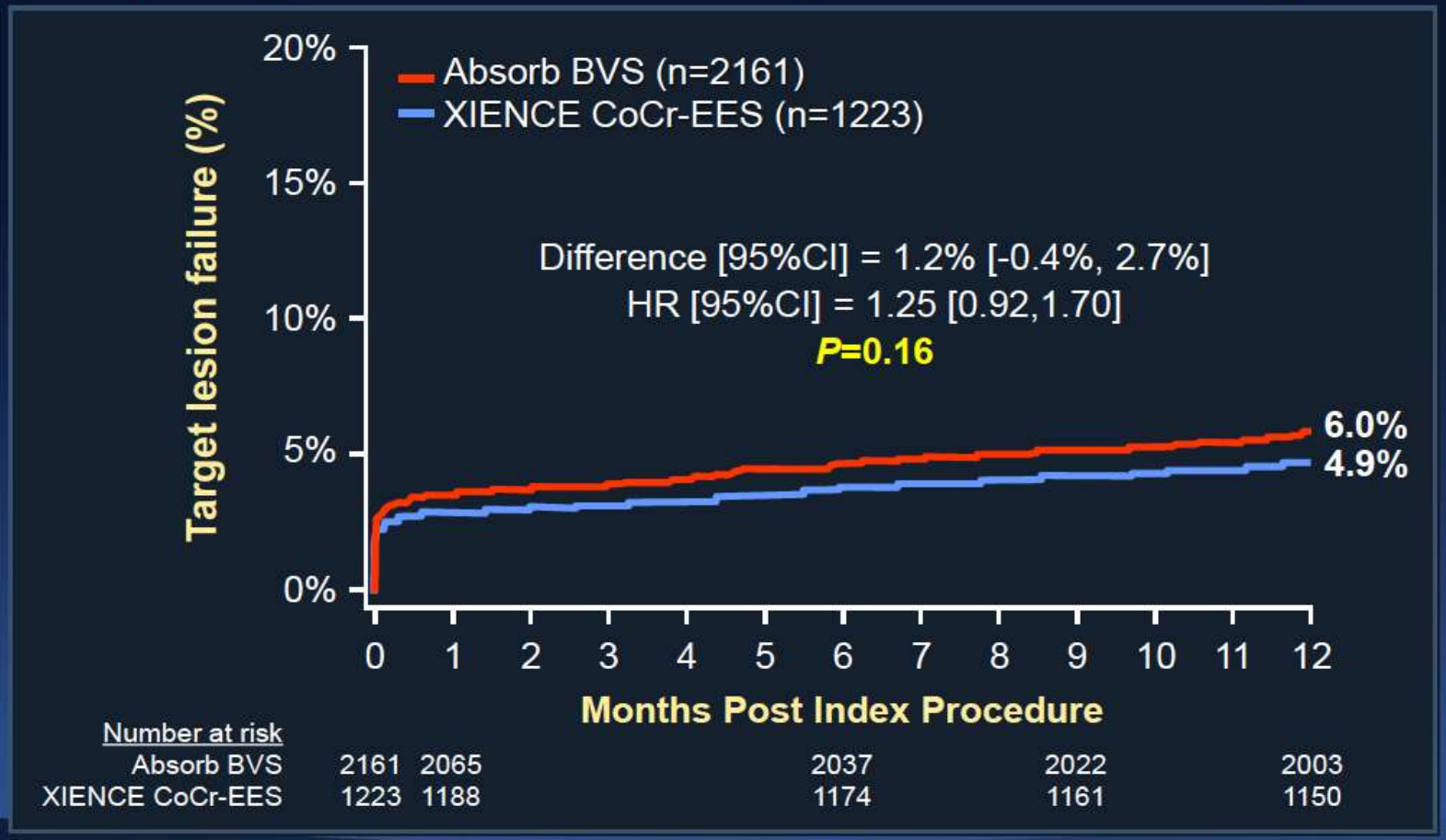
Potential Advantages of BRS

- Provides *transient* vessel scaffolding when needed, **“leaving nothing behind”**
- Local drug release inhibits restenosis
- Restores vessel to natural state with normal function and healing responses
- Reduces need for long term DAPT
- Eliminates source of inflammation/ irritation
- Reduces late events (esp. SAT)
- **Vessel free for future interventions; easy for re-PCI or CABG**

ABSORB 1-Year Meta-analysis

ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

DoCE (TLF): Cardiac Death, MI or ID-TLR (pooled)

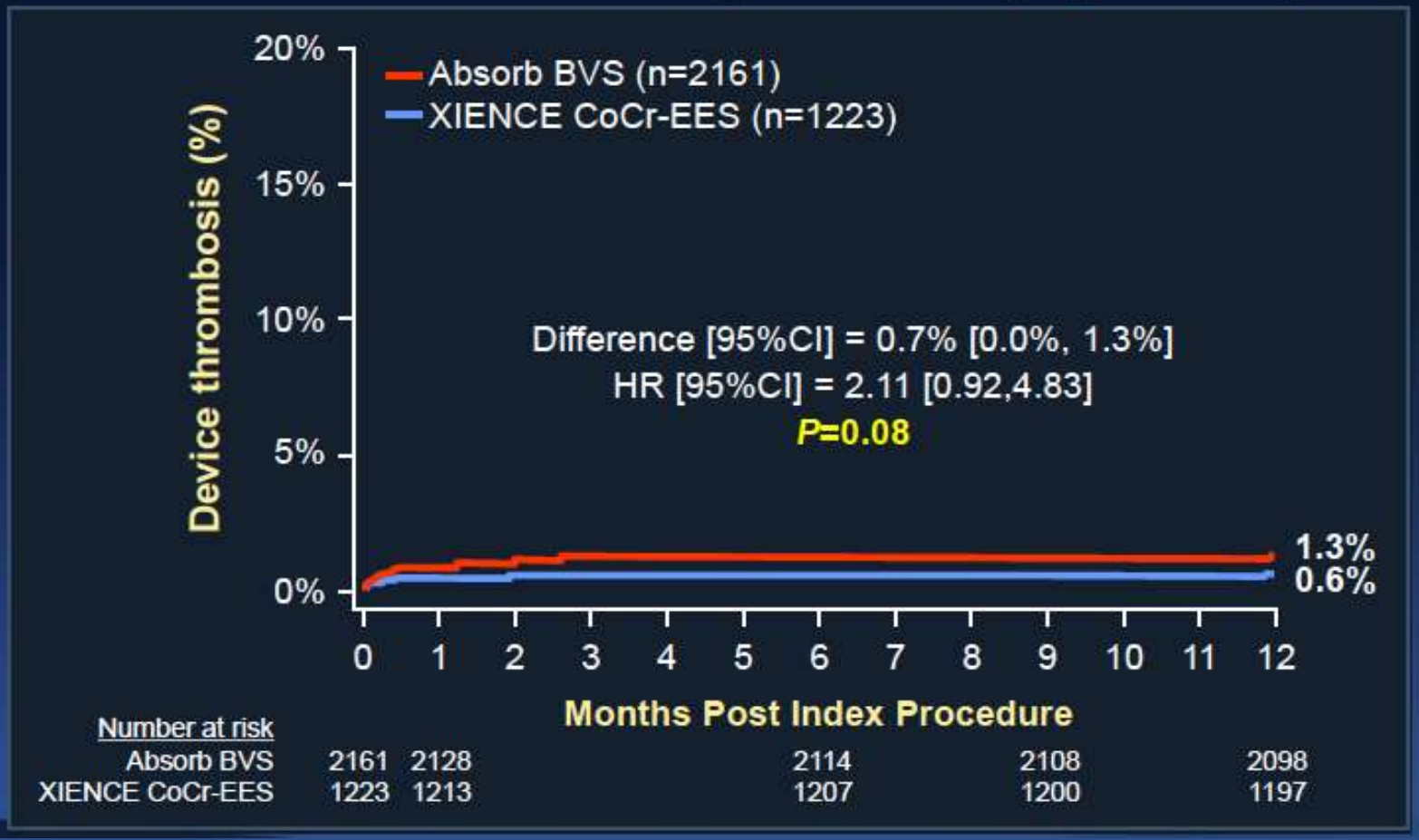


Lancet. 2016 Jan 25

ABSORB 1-Year Meta-analysis

ABSORB II, ABSORB III, ABSORB Japan, ABSORB China

Device Thrombosis (Def/Prob) (pooled)



Lancet. 2016 Jan 25

Clinical Evidences

REPARA[1]
GABI-R[2]
RAI[3]
IT-DISAPPEARS[4]
France ABSORB[5]
ABSORB III[8]
ABSORB Japan[9]
ABSORB China[10]
ABSORB-FIRST[11]
GHOST EU[12]
ABSORB II[13]
ASSURE[14]
PRAGUE-9[15]
ABSORB Extend[16]
TROFI II[6]
ESTROFA-BVS[7]
ABSORB Cohort B[17]

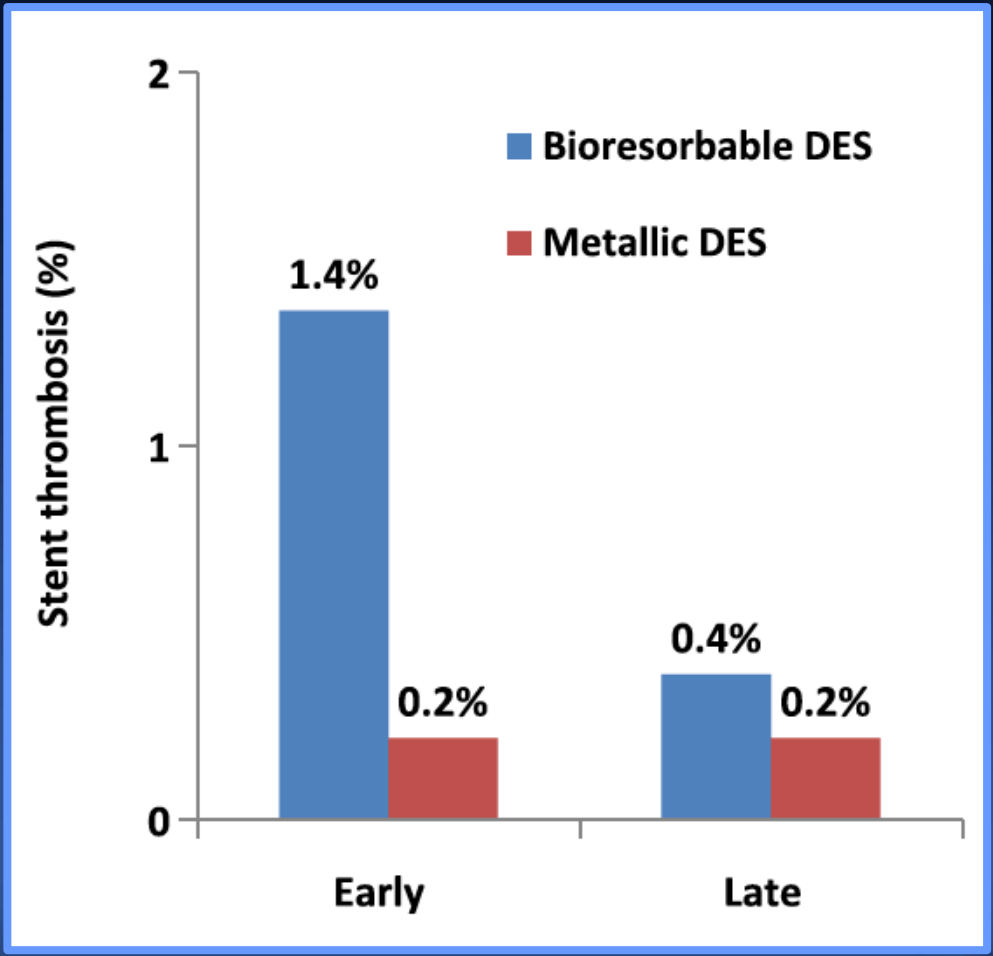
Efficacy and Safety of BVS is Comparable to 2nd Generation of DES.

[1]Hernandez, F., REPARA, EuroPCR 2015; [2]Hamm, C., GABI-R, EuroPCR 2016; [3]Cortese, B., RAI, EuroPCR 2016; [4]Petronio A.S., IT-DISSAPEARS, EuroPCR 2016 [5]Koning C., France ABSORB, EuroPCR 2016; [6]Serruys, P.W.,TROFI II, ESC2015; [7]De La Torre Hernandez, J., ESTROFA BVS, EuroPCR 2015; [8]Kereiakes, D., ABSORB III, TCT 2015; [9]Kimura, T., ABSORB Japan, ESC 2015; [10]Gao, R., ABSORB China, TCT 2015; [11]Seth, A., ABSORB FIRST, TCT 2015; [12]Capadanno, D., GHOST-EU Propensity Matched Analysis, TCT 2015; [13]Chevalier, B., ABSORB II, TCT 2015; [14]Schwencke, C., ASSURE, TCT 2015; [15]Kocka V., PRAGUE-19, EuroPCR 2016 [16] C.J., ABSORB EXTEND, TCT AP 2015; [17]Serruys, P.W., ABSORB Cohort B, TCT 2015. Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands

Bioresorbable Drug-Eluting Stents

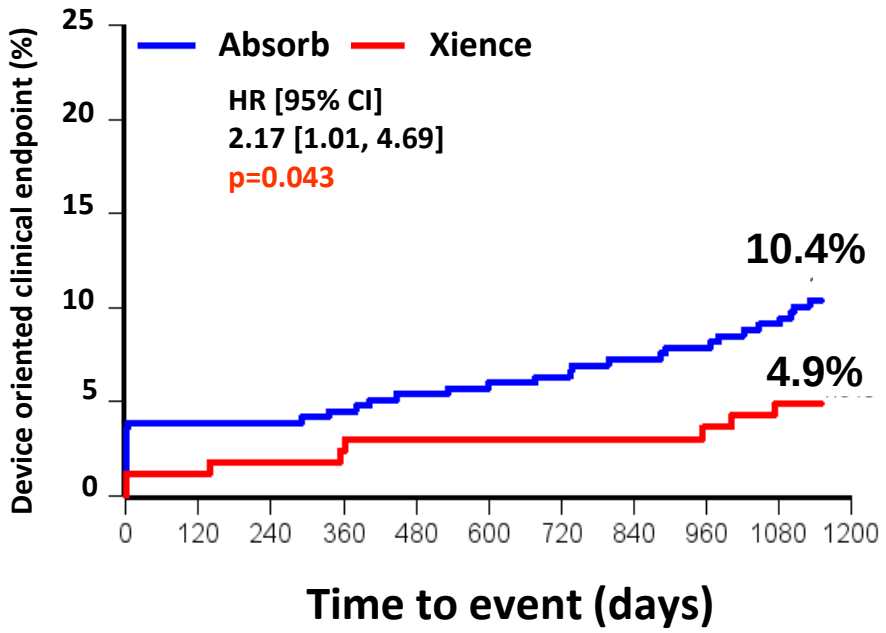
An Immature Technology in Need of Mature Application*

Robert A. Byrne, MB, BCh, PhD, Adnan Kastrati, MD

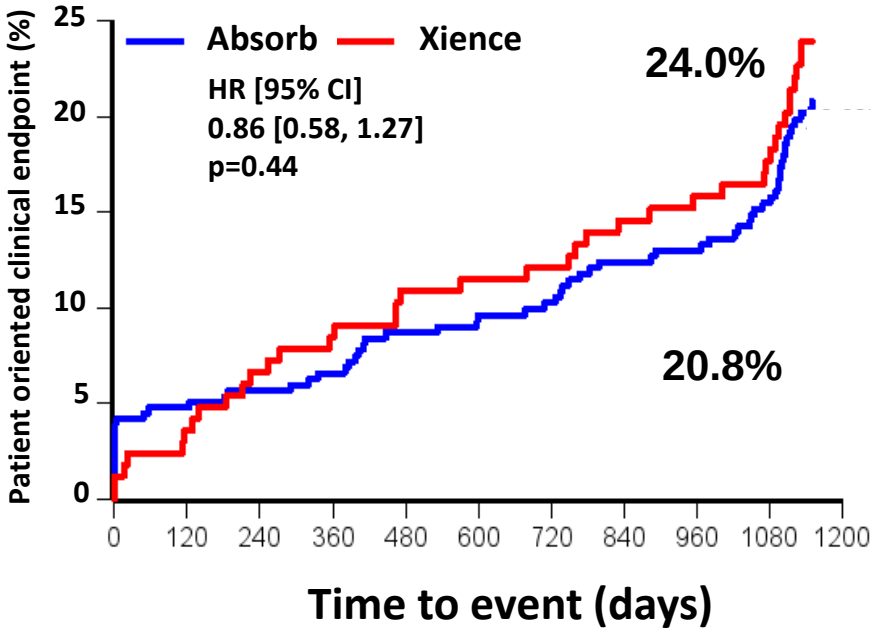


ABSORB II, 3-year

Device-Oriented Composite Endpoints (Cardiac Death, TV-MI, CI-TLR)



Patient-Oriented Composite Endpoints (Any Death, Any-MI, Any Revascularization)



Patrick W Serruys et al, Lancet 2016; http://dx.doi.org/10.1016/S0140-6736(16)32050-5

ABSORB II, 3-year
Scaffold or Stent Thrombosis

	Absorb 335 patients	Xience 166 patients	p value
Definite	2·5% (8)	0·0% (0)	0·06
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·0% (0)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19
Definite or probable	2·8% (9/320)	0·0% (0/159)	0·03
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·3% (1)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19

Patrick W Serruys et al, Lancet 2016; http://dx.doi.org/10.1016/S0140-6736(16)32050-5

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ASAN Medical Center

Revisited Camenzid's Curse for BVS??

TUESDAY

ESC Congress

2007 Oscar of the most viewed slide during cardiology meetings !

Do drug-eluting stents increase deaths?

TWO SEPARATE, independent meta-analyses, presented in Hot Line session I, suggest drug-eluting stents (DES) may increase death, Q-wave myocardial infarction (clinical surrogates of in-stent thrombosis) and cancer deaths, bringing the long-term safety of DES firmly into the spotlight. Discussant Salim Yusuf (McMaster University, Canada) hailed the data as one of the most important presentations to come out of this year's meeting.

"Six million people in the world have been implanted with DES, yet their long-term safety and efficacy is unknown," said Yusuf. "I've a feeling the data we're seeing today is only the tip of the iceberg. We need to encourage more public access to the data."

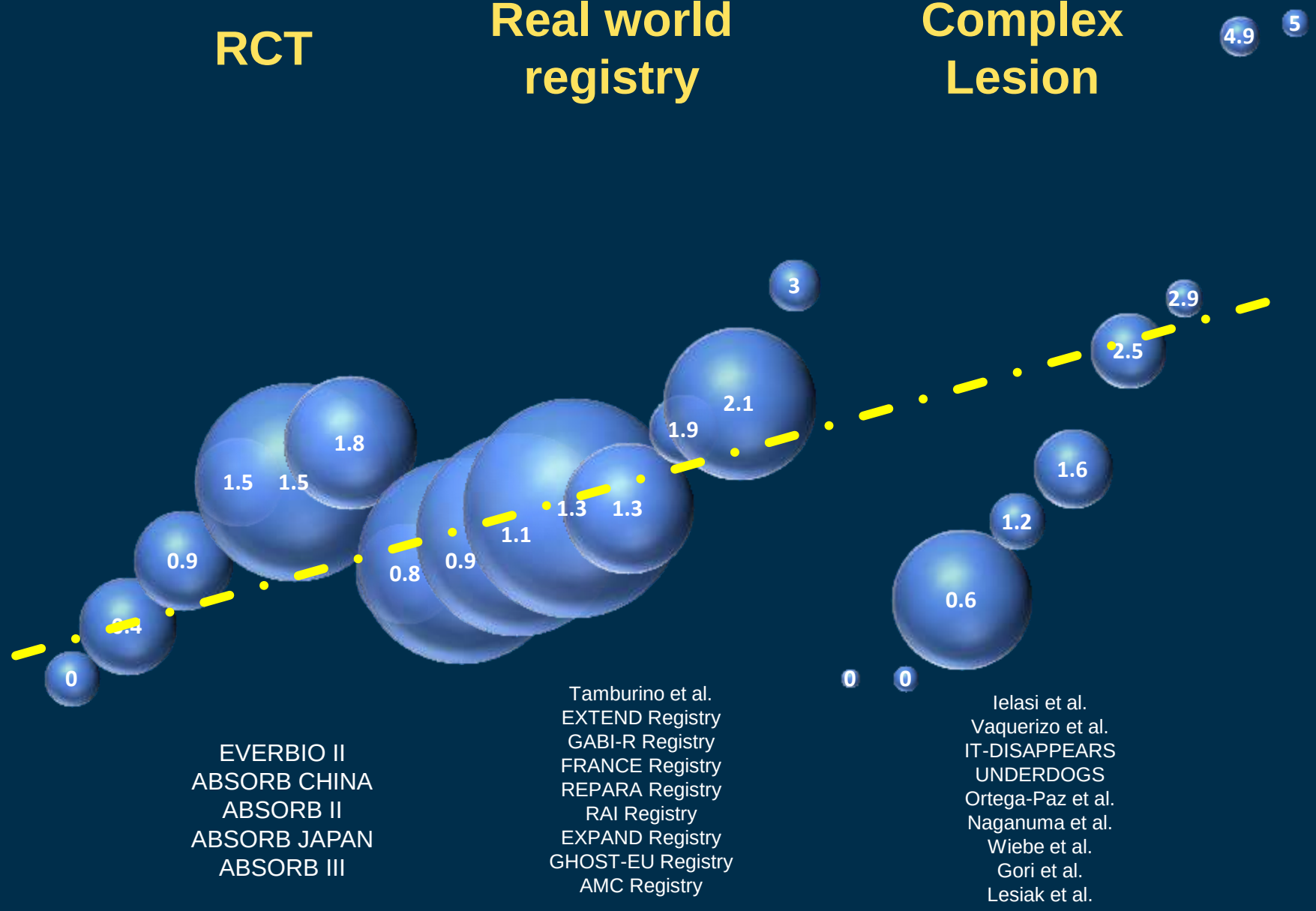
obtain this data from the manufacturer," said Nordmann. He speculated that the increase in cancer might be due to a rapid impairment of the immune system.

Yusuf widened the debate to include percutaneous coronary intervention (PCI). "The overuse of PCI is an insidious change in the culture of cardiology that needs to be reversed," he said. The use of PCI was established in MI, high-risk unstable angina and cardiogenic shock. However, its use in stable disease was a totally different question.

"There's no beneficial influence on mortality – PCI does nothing to prevent heart attack. All we are doing is providing short-term relief of chest pain. It's not re-stenosis that kills but the

Is Early and Late BVS Thrombosis the Real Achilles Heel ?

BVS Thrombosis Rate



BVS Story Changed after PSP

Recommended Technique

- **P** Pre-Dilation
- **S** Sizing Appropriately
- **P** Post-Dilation

Wright, RS, et al., Circulation. 2011; 123: 2022-2060. Wijns, W, et al., European Heart Journal. 2010; 31: 2501-2555.
Levine, GN, et al., Circulation. 2011; 124: 2574-2651. Steg, PG, et al., European Heart Journal. 2012; 33: 2569-2619.
O'Gara, PT, et al., Circulation. 2012; 127: e368-e425.

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PSP Use by Trial (As-Treated Population)

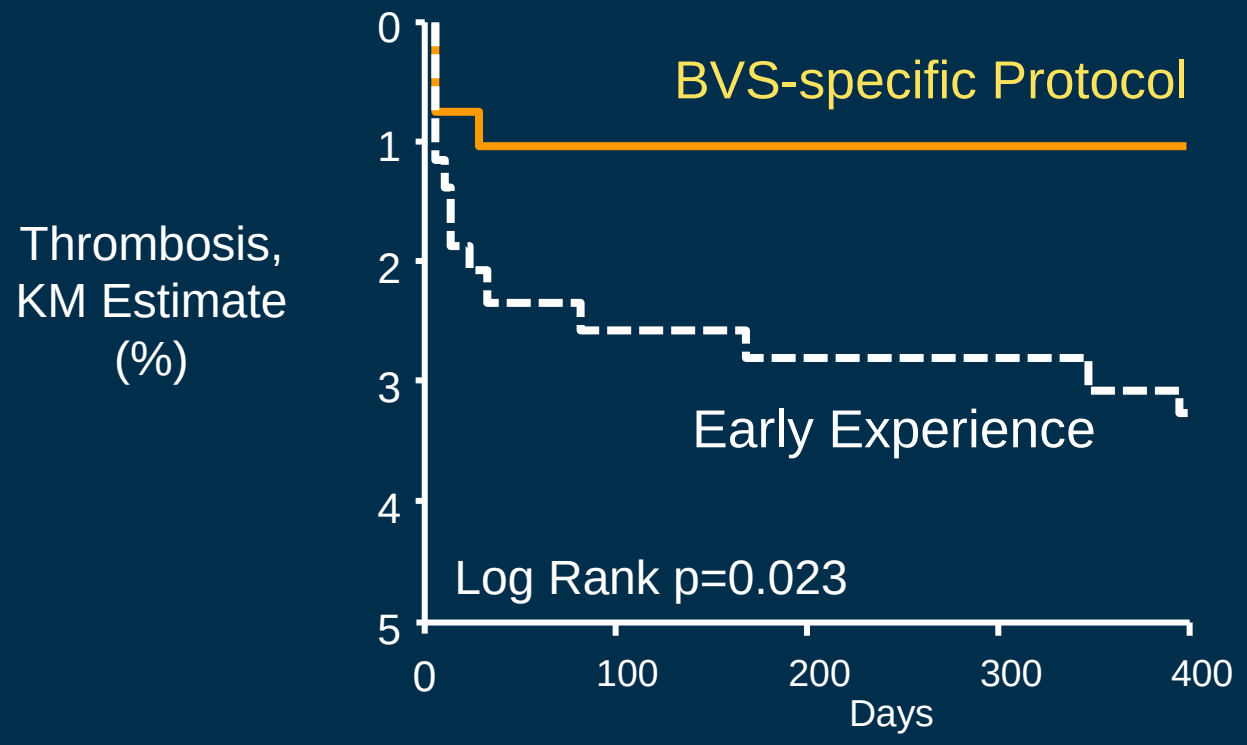
EXTEND	108/772	(14.0%)
ABSORB-II	21/324	(6.5%)
ABSORB-Japan	35/258	(13.6%)
ABSORB-China	32/237	(13.5%)
ABSORB-III	96/1224	(7.8%)

4 German and Swiss centers
BVS specific protocol

1. Pre-dilation with noncompliant balloon, 1:1 with the RVD.
2. Implantation of a BVS of the same size as the RVD at 10 to 12 atm.
3. Post-dilation with noncompliant balloons with a maximum of 0.5 mm larger at 14 to 16 atm.

Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31

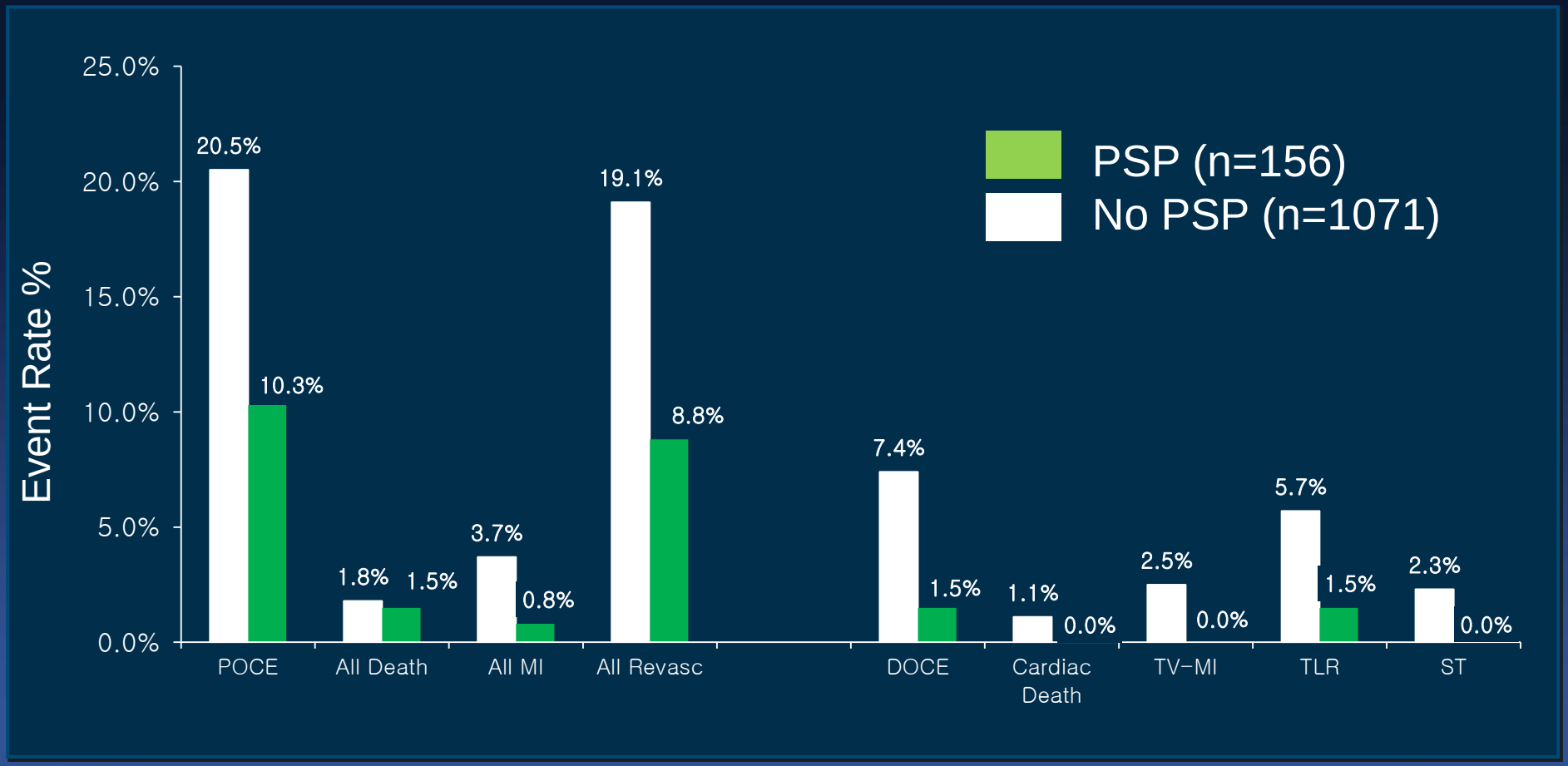
BVS Thrombosis Reduced with Improved PSP Technique !



Patients					
Early Experience	369	369	369	369	369
Absorb-specific	292	292	281	217	155

Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31

Significant Improvement of Outcomes
In GHOST-EU At 1 Year *With Completed PSP*



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

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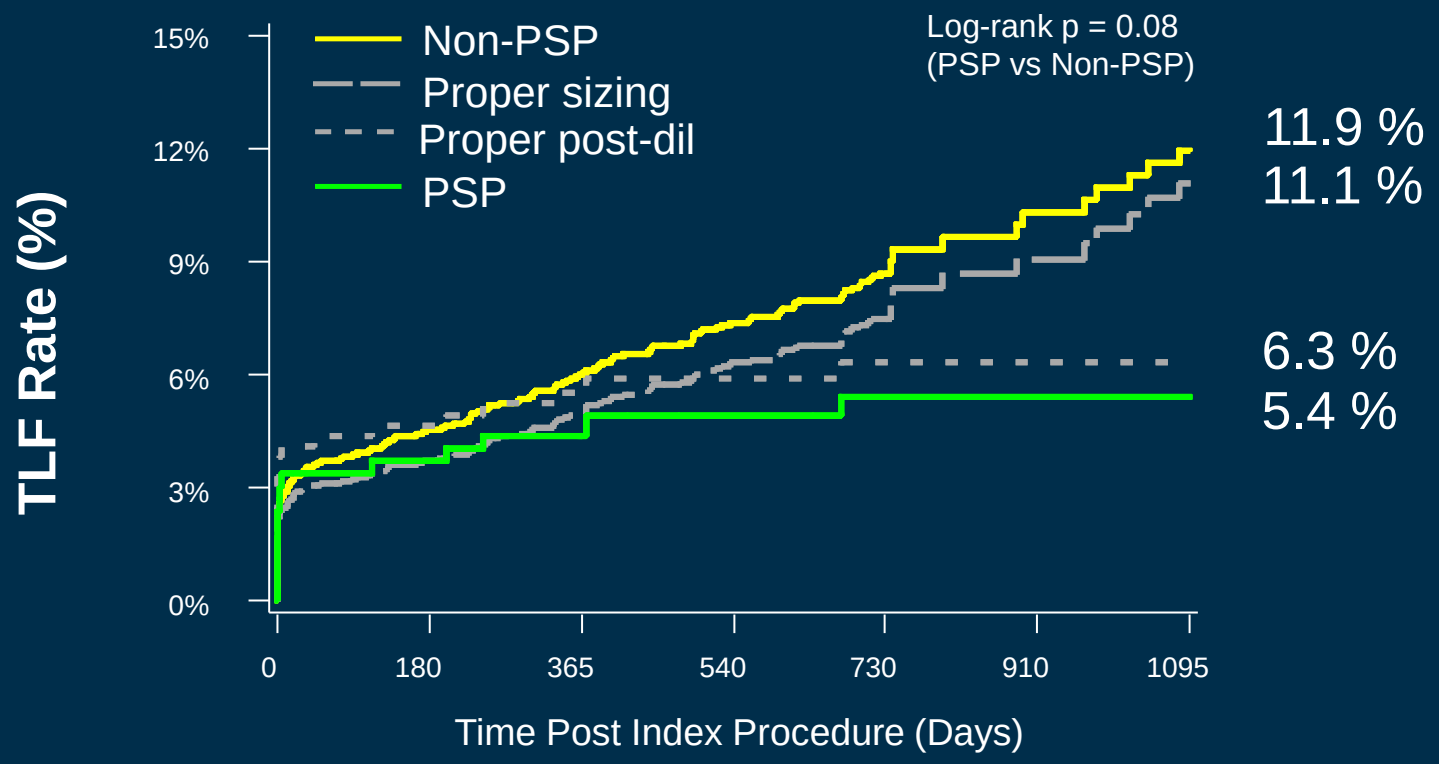
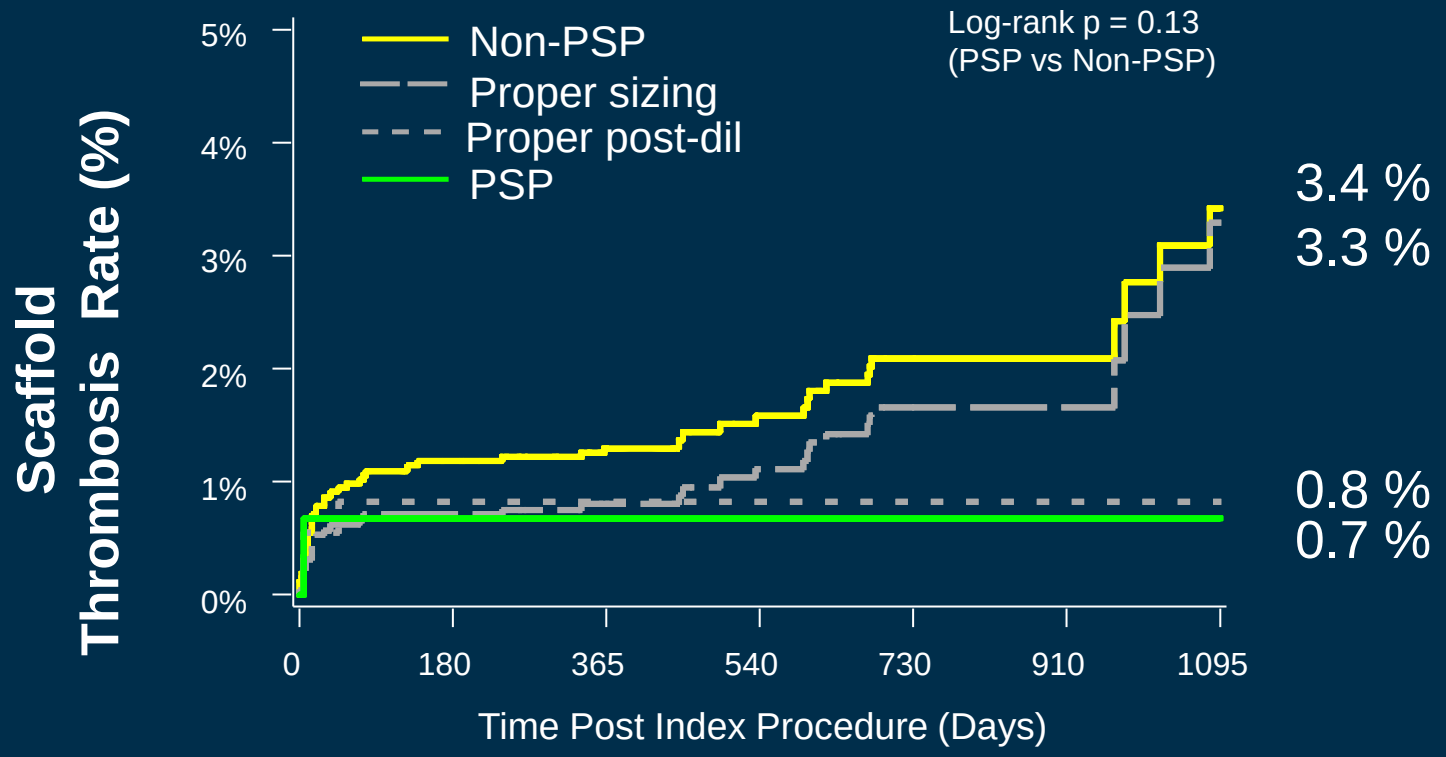
PSP Analysis - *TLF At 3-Years*
(Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2375	1289	268
Proper Sizing	2261	2125	1195	223
Proper post-dil	365	341	219	24
PSP	297	280	186	20

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

PSP Analysis – *Def/Prob ST At 3-Years*
(Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2483	1354	291
Proper Sizing	2261	2211	1247	238
Proper post-dil	365	357	227	26
PSP	297	290	192	21

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

Unresolved Mechanical Issues of BVS ; BVS Role in Daily PCI Practice

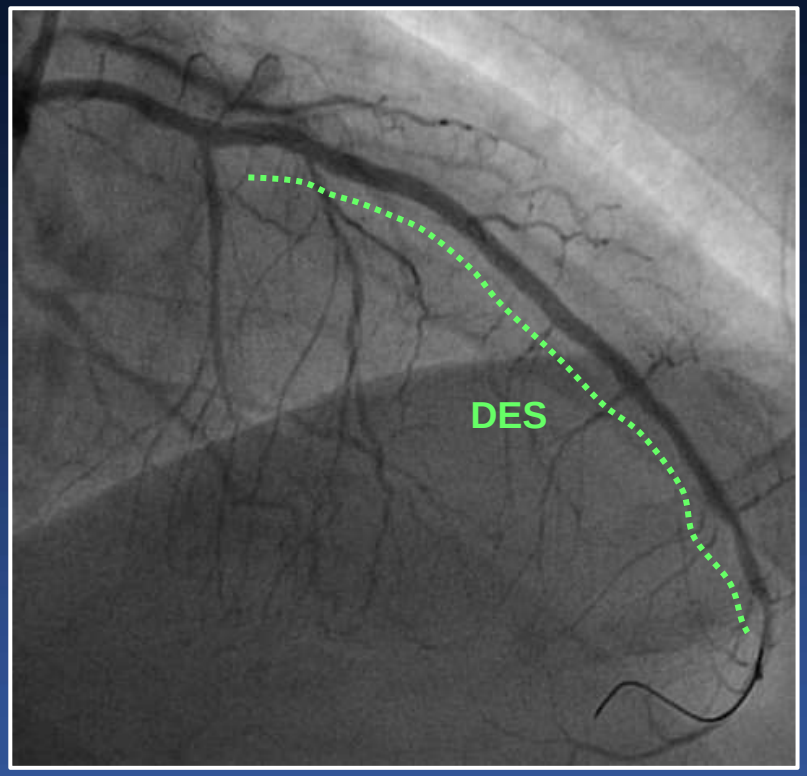
- Complex lesions; Calcified or tortuous, long lesion, bifurcation, left main
- Stretchability and fracture
- Overlapping
- Side branch
- Relatively high late loss

One Size Does Not Fit All in Contemporary PCI Practice

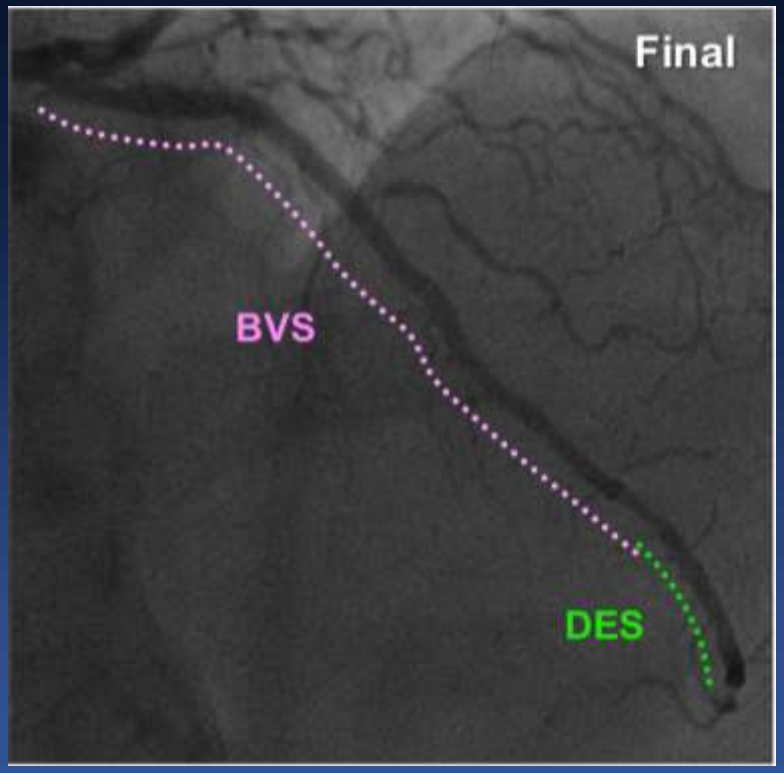
- **<u>Hybrid PCI with BVS in combination with Contemporary DES or DEB.</u>**
  1. Minimizing the length of permanent metallic caging may still be important for future advantages.
  2. Operators should fully understand the limitations of current BVS, and when to consider a hybrid strategy of BVS in combination with DES or drug-coated balloons.

BVS in Diffuse Long Lesion

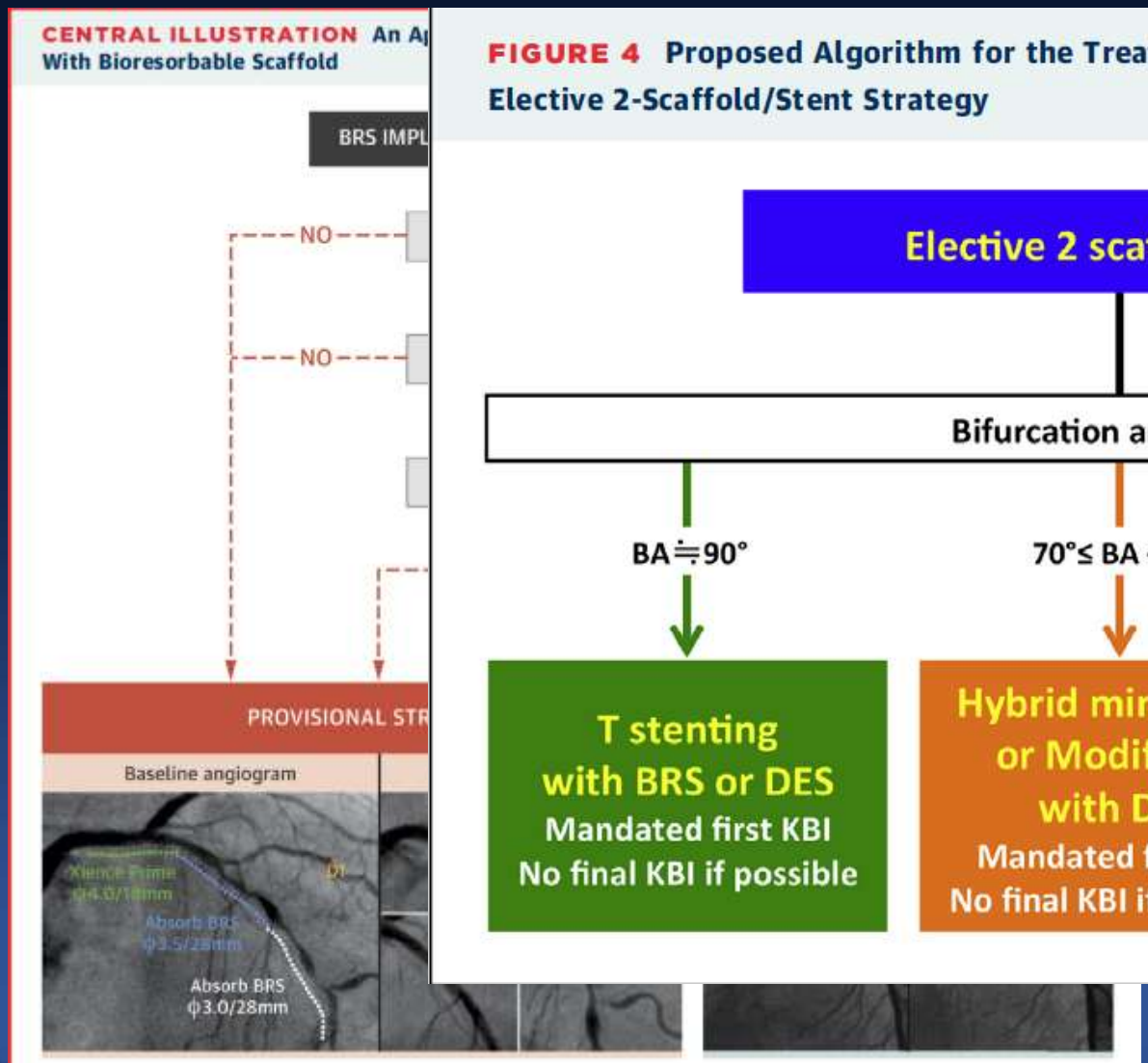
Full Metal Jacket



Hybrid DES/BVS Jacket

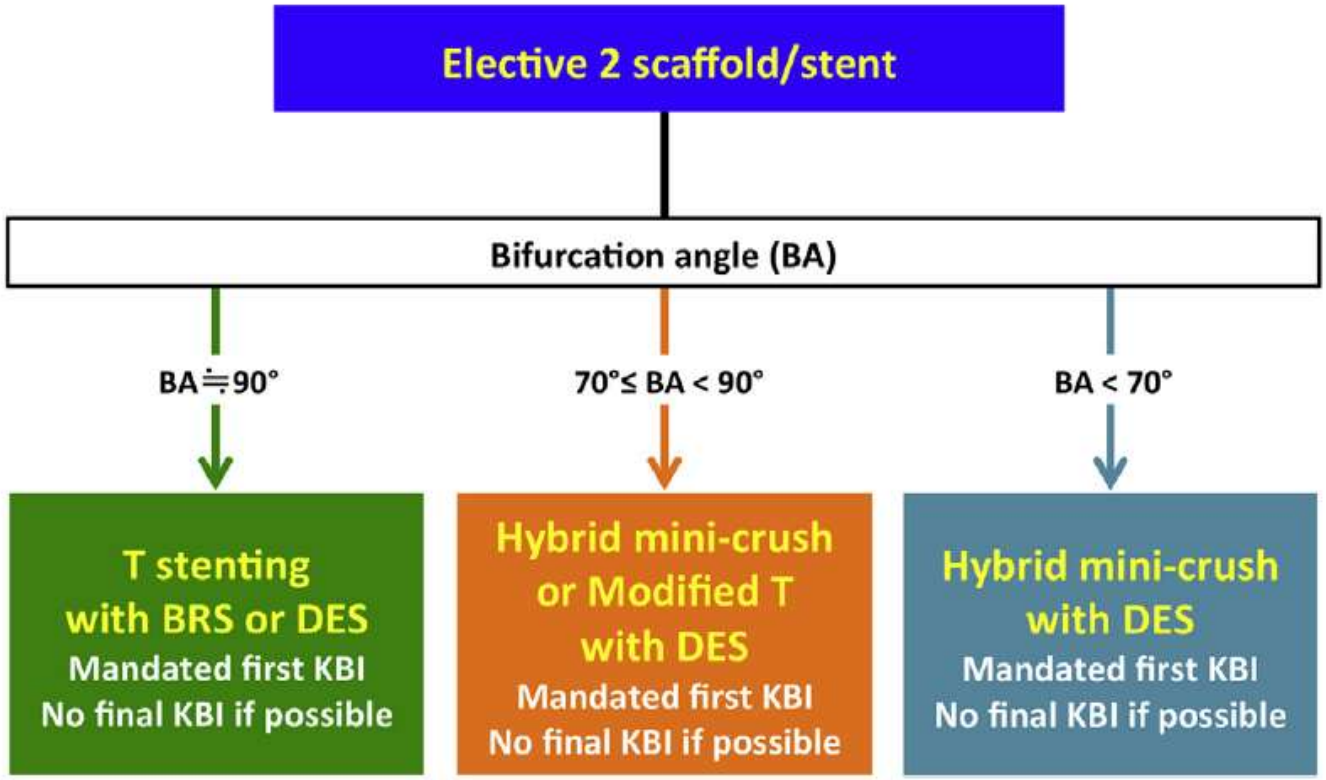


BVS in Bifurcation



Kawamoto, H. et al. J Am Coll Cardiol Intv. 2016;9(10):989-1000.

FIGURE 4 Proposed Algorithm for the Treatment of Coronary Bifurcations With Elective 2-Scaffold/Stent Strategy



Hybrid BVS in Complex Lesions

- **How to Do Hybrid BVS**

1. **Long lesion with proximal larger lumen diameter;** distal BVS and proximal DES
2. **Long lesion with distal small vessel diameter;** distal DCB and/or DES and proximal BVS
3. **Aorto-ostial long lesions;** DES for ostium and BVS for distal vessel.
4. **ISR lesions;** BVS could be a particularly attractive option due to the avoidance of adding another permanent metallic layer
5. **Left Main;** LM DES and LAD BVS overlap should be in the proximal LAD and not involving the ostium

Current Status and Future Perspective of BVS

1. BVS-Specific Implantation Protocol (PSP) is mandatory to achieve procedural success and fovourable clinical outcomes

2. Absorb is ready to be implanted in almost all patients, but not all patients/lesions.

Appropriate Use of BVS in Current Practice

- Do Not Stick One Device or One Strategy Too Much !!!
- You Can Choose Hybrid Strategy of BVS with DES or DCB!!!

Thank You !!

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