Morning Roundtable Forum: Meet the Experts over Breakfast: BRS and DES

Is BRS Safe?

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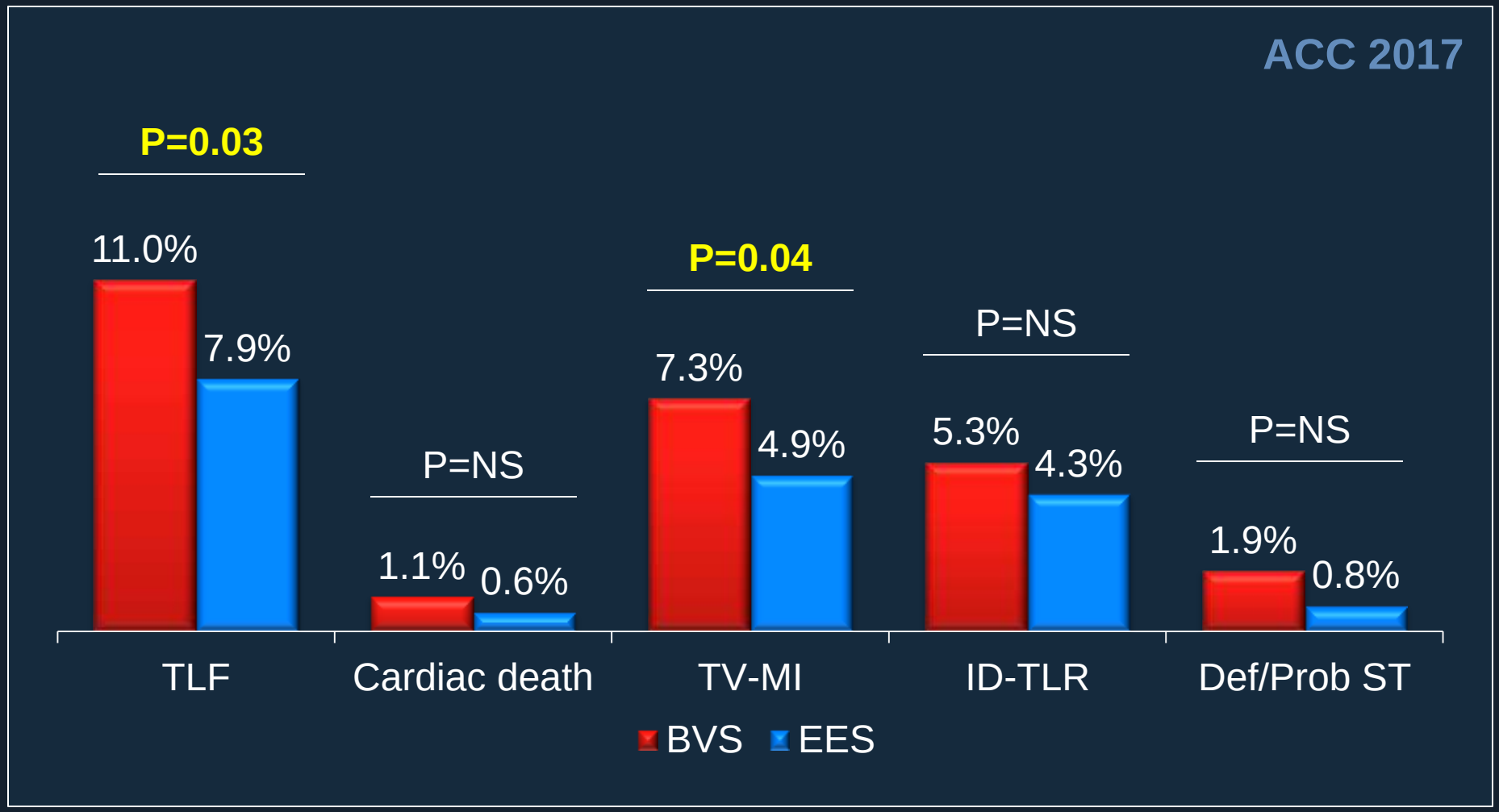
Disclosure Statement of Financial Interest

Within the past 12 months, I, **Davide Capodanno**, have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial relationship	Company
• **Speakers' honoraria**	None
• **Consulting**	Abbott Vascular (VHD branch)
• **Advisory Board**	None

ABSORB III - 2-Year Outcomes

2,008 patients with CAD undergoing PCI randomized 2:1 to BVS or EES



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Ellis SG. ACC 2017, Washington DC

Dear Cardiovascular Specialists and Interventional Cardiologists...

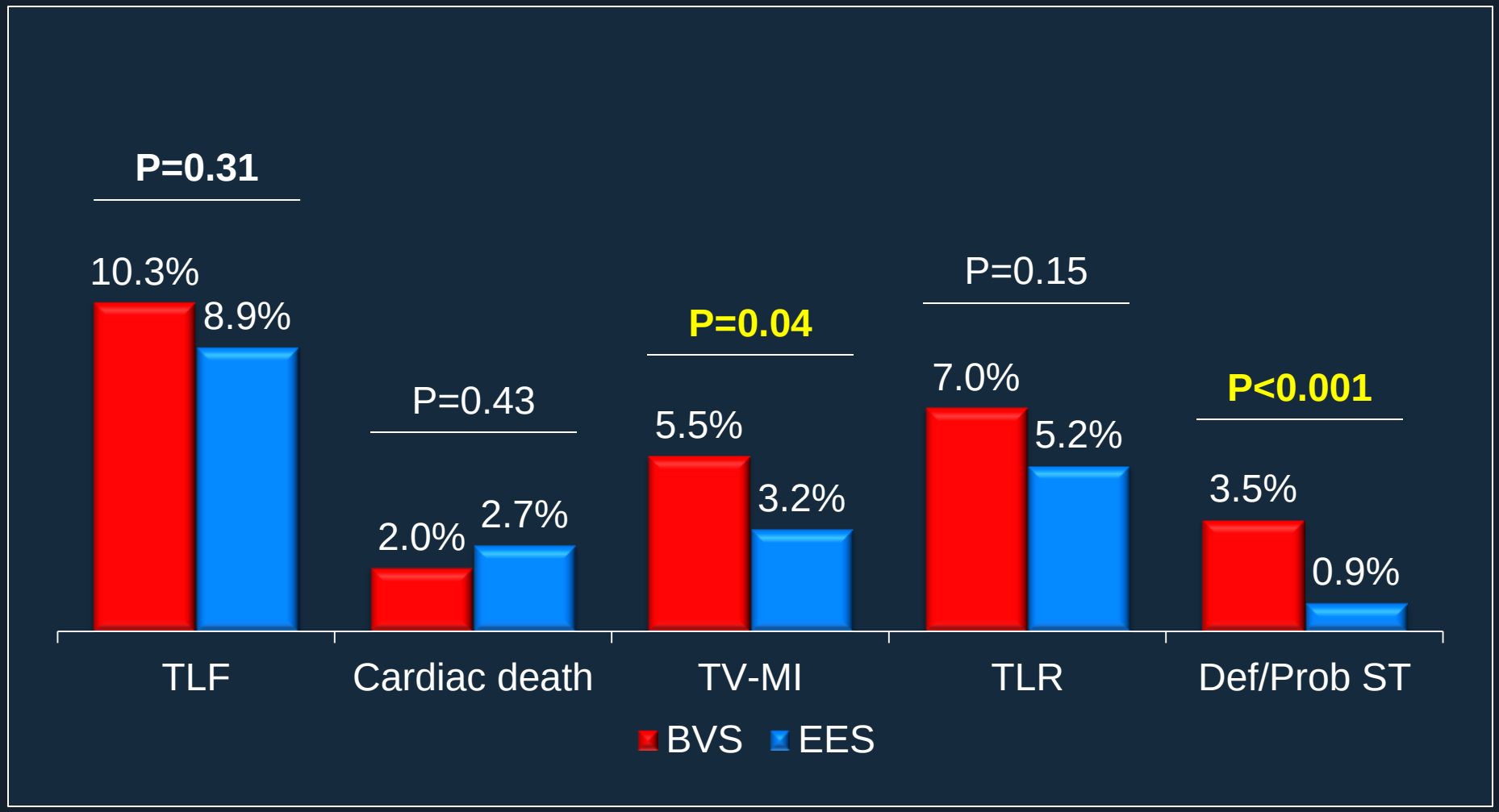
FDA letter to health care providers (March 18, 2017)

The FDA recommends that health care providers:

- Follow the instructions for target heart vessel selection (e.g., avoiding BVS use in small heart vessels) and optimal device implantation that are included in the BVS physician labeling.
- Advise patients experiencing any new cardiac symptoms such as irregular heartbeats, chest pain, or shortness of breath to seek clinical care. For more information about risks associated with the BVS, refer to the BVS physician labeling.
- Advise BVS patients to follow the recommendations for DAPT prescribed by their health care providers.
- Report any adverse events related to the BVS that come to your attention. If you suspect a problem with the BVS, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

AIDA – Interim 2-Year Outcomes

1,845 patients with CAD undergoing PCI randomized 1:1 to BVS or EES



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Wykrzykowska JJ, et al. N Engl J Med 2017 [ePub ahead of print]

Dear Cardiovascular Specialists and Interventional Cardiologists... / 2

Manufacturer Urgent Physician Advisory

★ "Effective May 31, 2017, the device will only be available for use in clinical registry setting until summer 2018 at which time the situation will be reassessed with the authorities. Note that sites not enrolling patients in a study will not receive shipments as of March 31st, 2017."

Abbott Vascular communication. March 31, 2017

Current Landscape of CE-Marked BRS

ABSORB GT1

Bioresorbable vascular scaffold (BVS)

PLLA, everolimus-eluting

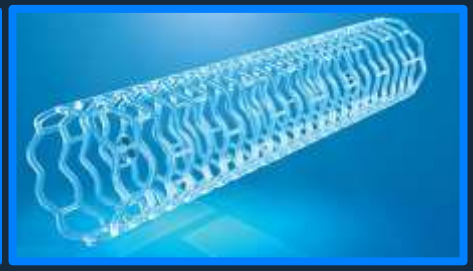
Strut thickness 150 μm, coat thickness 3 μm/side

Full mass loss at approximately 3 years

CE mark in October 2011

DESsolve

Bioresorbable coronary scaffold (BCS)



PLLA, novolimus-eluting

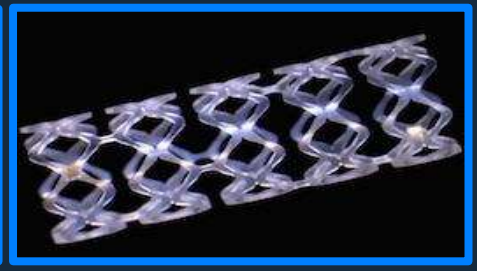
Strut thickness 150 μm, coat thickness <3 μm/side

Full mass loss at approximately 1 year

CE mark in May 2014

ART

Pure bioresorbable scaffold (PBS)



PDLLA, drug-free

Strut thickness 170 μm, uncoated

Full mass loss at approximately 1 year

CE mark in May 2015

Magmaris

Resorbable magnesium scaffold (BCS)

Mg, sirolimus-eluting

Strut thickness 150 μm, coat thickness 8 μm/side

Full mass loss at approximately 1 year

CE mark in June 2016

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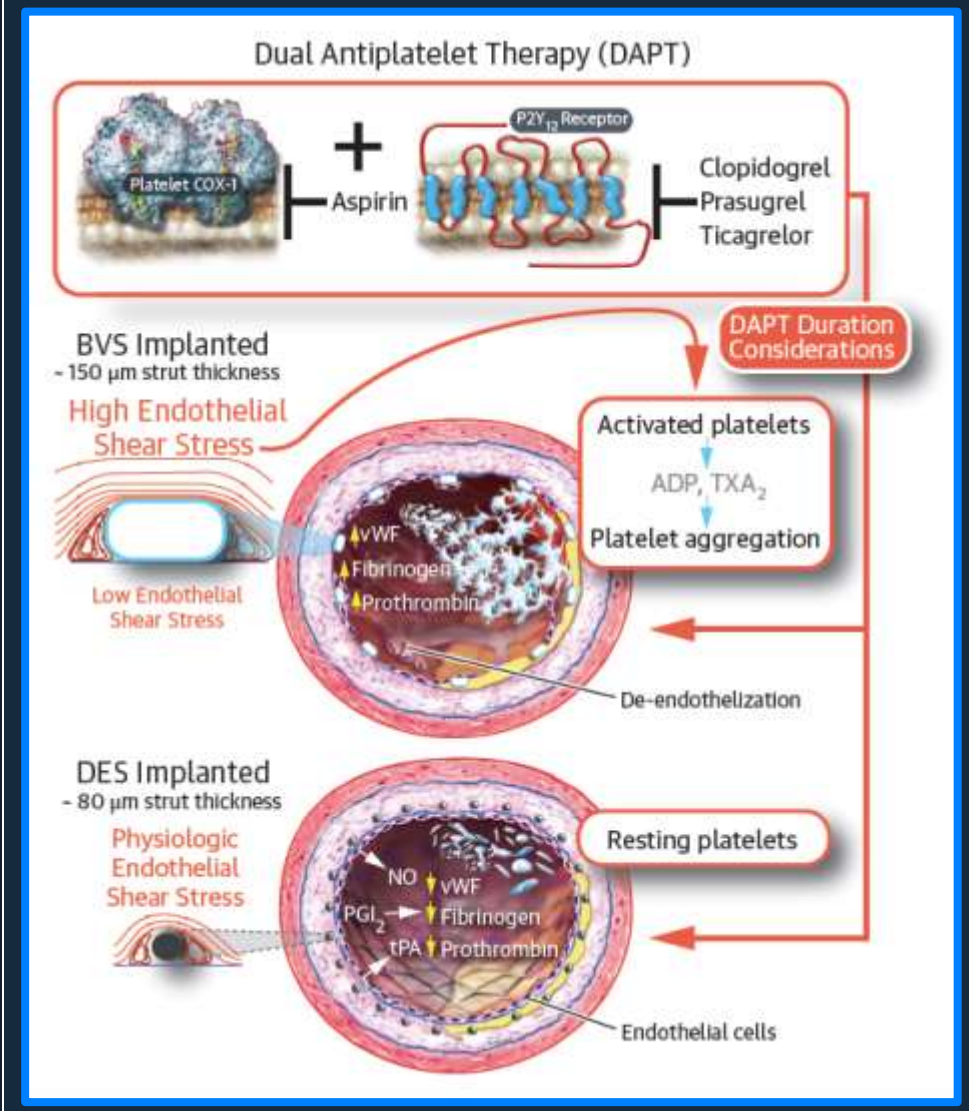
Capodanno D. Personal communication

Strut Thickness and Thrombogenicity



Bioresorbable scaffolds

① Thick, rectangular struts

② High endothelial shear stress (ESS) on top of struts

③ Recirculation zones with low ESS downstream of the strut

④ Platelet activation

Everolimus-eluting stents

① Thin, circular struts

② Physiologic ESS

③ Platelet quiescence on top of struts

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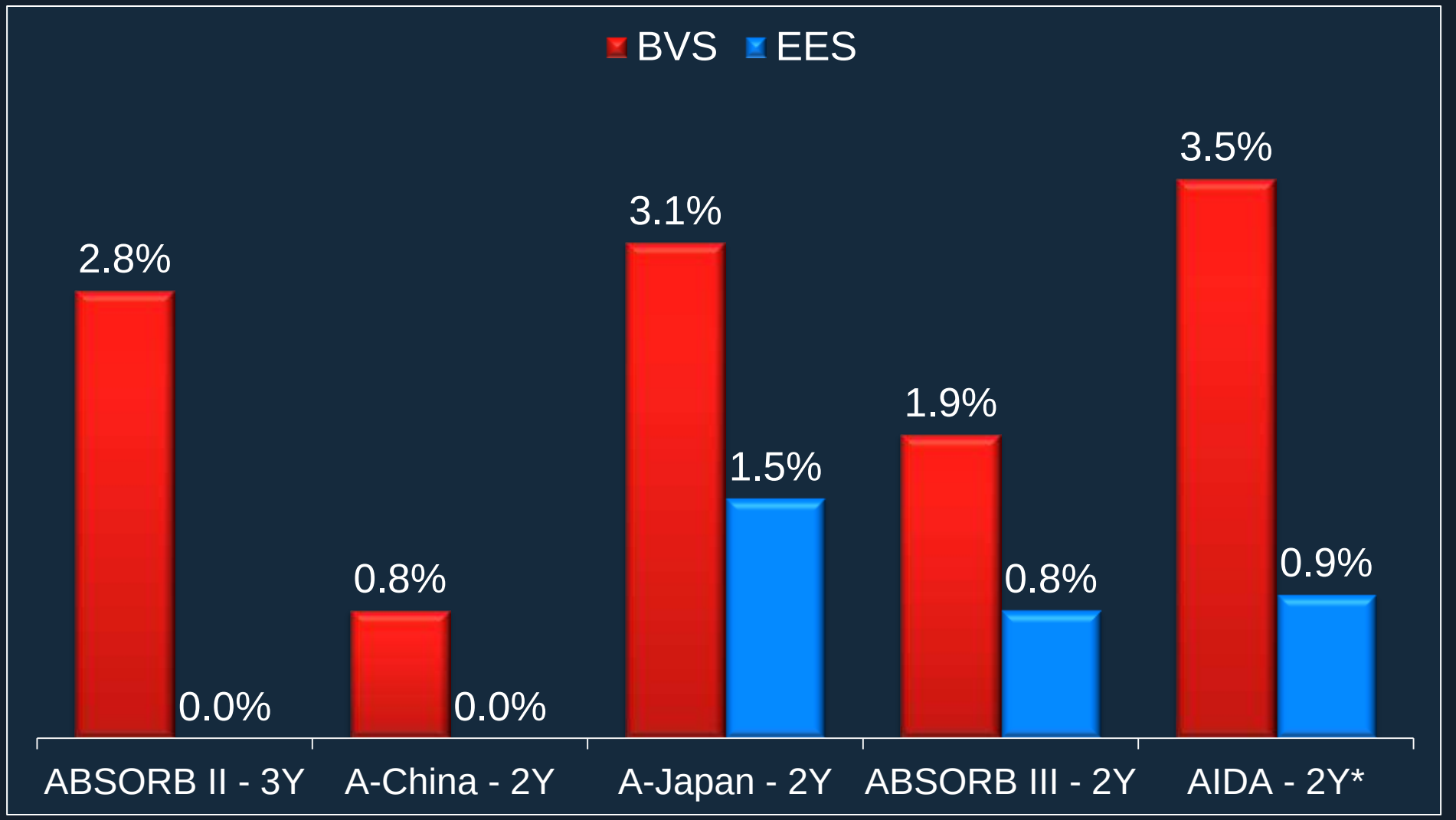
Capodanno D, Angiolillo DJ. J Am Coll Cardiol Intv 2017;10:425–37

BVS vs. EES Thrombosis (Absolute Risks)

Definite or probable thrombosis from 0 to 2-3 yrs in ABSORB RCTs



*Follow up of AIDA is incomplete (median 707 days)

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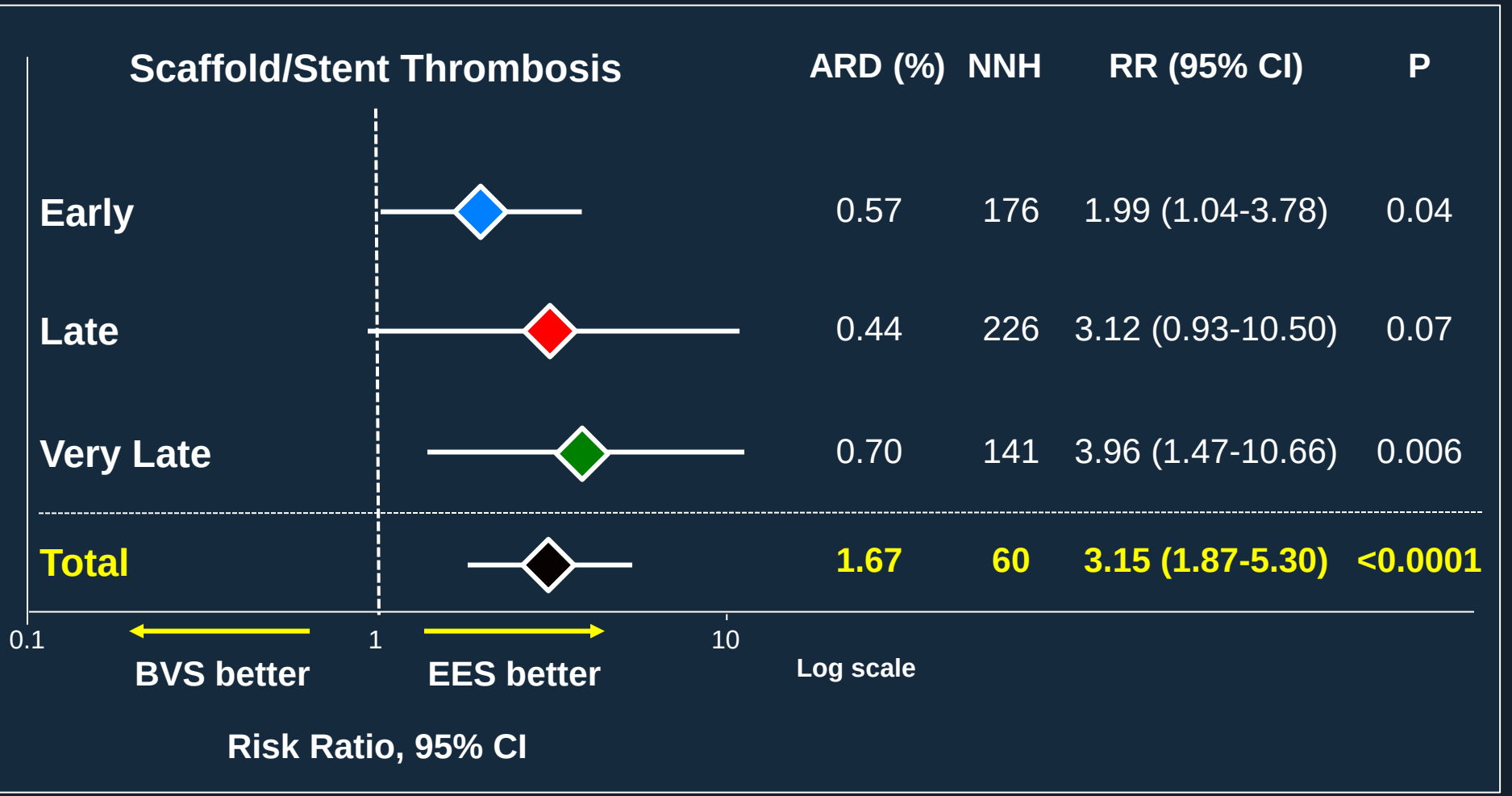
BVS vs. EES Thrombosis (Relative Risk)

Meta-analysis of 5,584 patients from 7 RCTs (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, EVERBIO II, TROFI II, AIDA)



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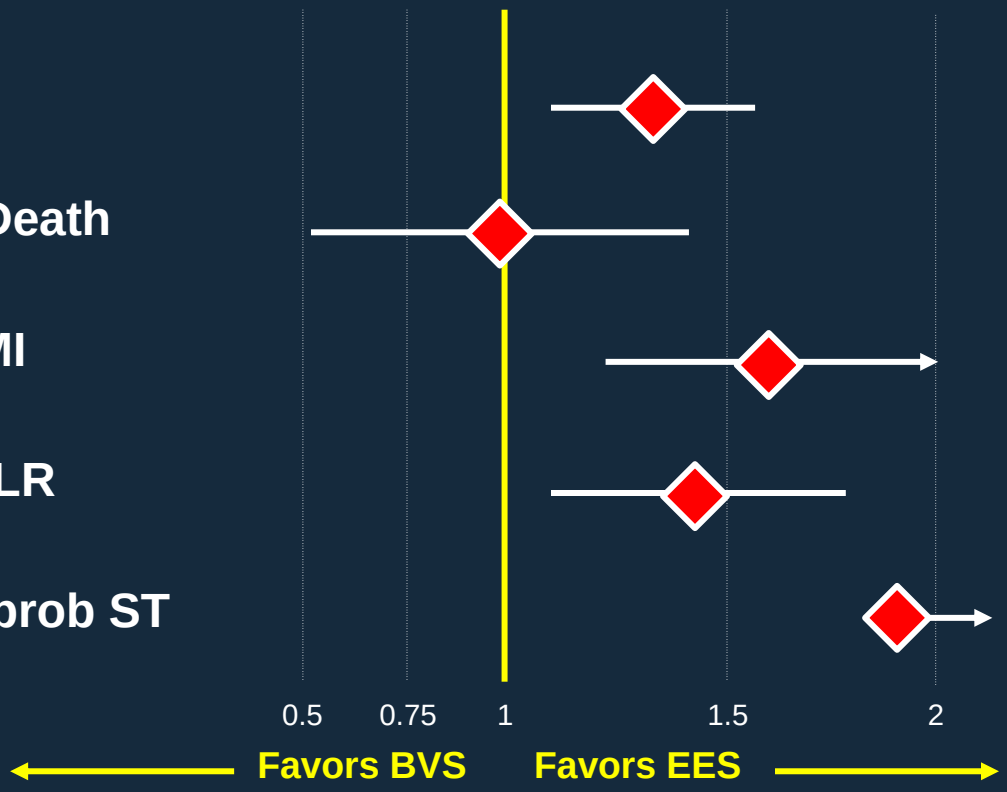
Sorrentino S, et al. J Am Coll Cardiol 2017 [ePub ahead of print]

Oucomes of BVS vs. EES (Relative Risks)

Meta-analysis of 5,584 patients from 7 RCTs (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, EVERBIO II, TROFI II, AIDA)

Median 2 years



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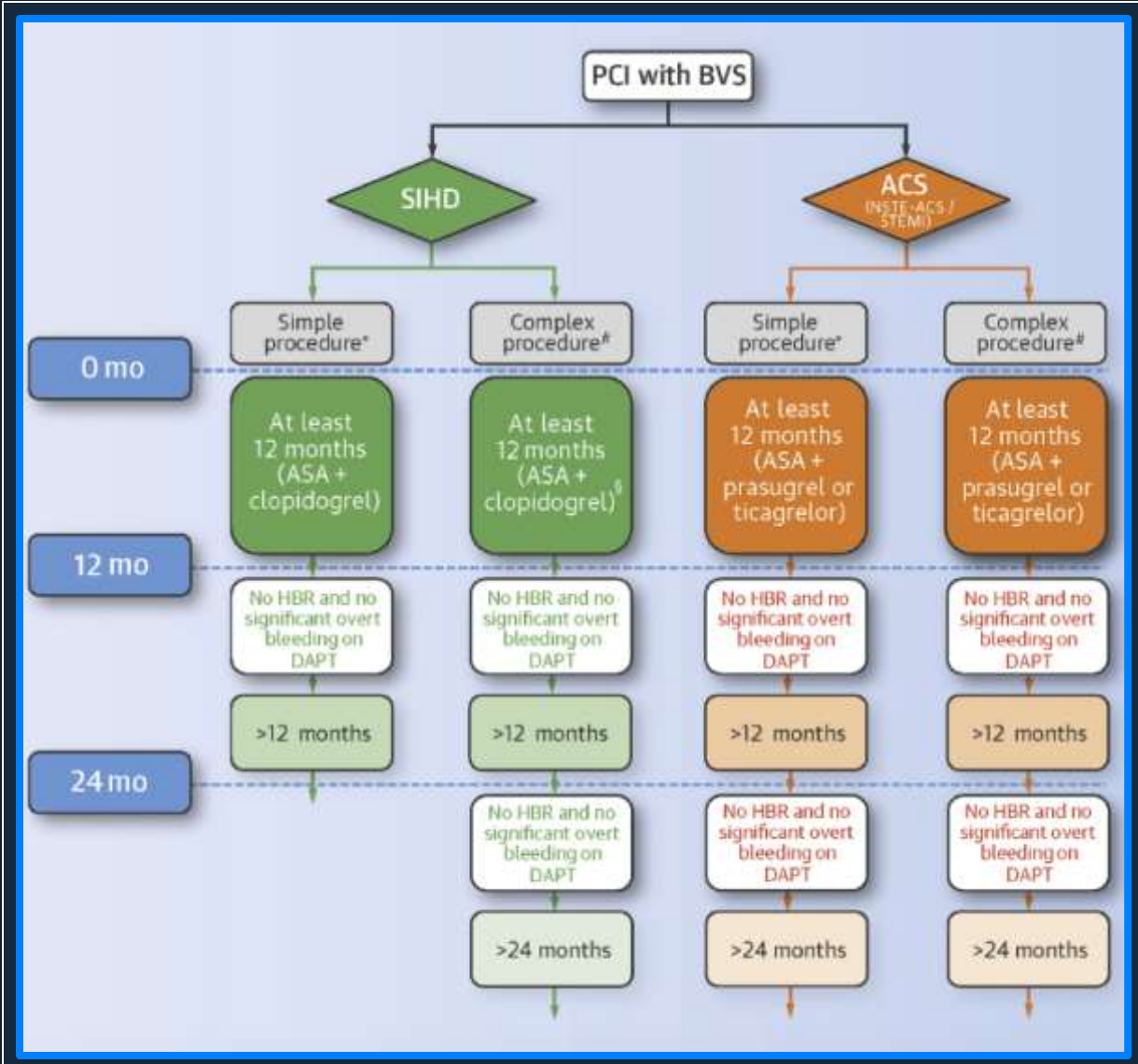
Sorrentino S, et al. J Am Coll Cardiol 2017 [ePub ahead of print]

DAPT duration After BVS Implantation



* Simple procedures include 1 BVS implanted in ACC/AHA A/B_1 lesions.

Complex procedures include 1 BVS implanted in ACC/AHA B_2/C lesions, >1 BVS implanted on lesions of any ACC/AHA type, or any other unfavorable clinical, angiographic and procedural characteristics.

§ Considerations on the use of aspirin in combination with prasugrel or ticagrelor for the initial 30 days, followed by switch to aspirin and clopidogrel, may prevail based on the individual risks of ischemia and bleeding.

Capodanno D, Angiolillo DJ. J Am Coll Cardiol Intv 2017;10:425–37

The Scaffold, the Lesion or the Doctor?

Get Ready for the Avalanche of PSP Analyses!

Prepare the vessel to be re-engineered

Pre-dilate using a 1:1 balloon-to-artery ratio using a non-compliant balloon (it can also help accurately size the vessel). Use plaque-modification devices if needed. Confirm full expansion of balloon and residual stenosis of 20-40% in 2 orthogonal views.

Size the vessel appropriately

Select the scaffold size for the best fit. Consider using intravascular ultrasound (IVUS), optical coherence tomography (OCT) or quantitative coronary angiography (QCA) to aid vessel sizing. **Note:** Absorb BVS is indicated for vessels with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm.

Post-dilate to embed the struts into the vessel wall

Dilate to high pressure with a non-compliant balloon up to 0.5 mm above nominal scaffold diameter. Verify <10% final residual stenosis in 2 orthogonal views, and ensure full strut apposition.

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Manufacturer Remarks on ABSORB III

① No statistically significant difference in TLF at 2 years in vessels ≥2.25 mm by QCA, consistent with IFUs

② No PSP in the 4 new scaffold thrombosis cases reported between 1 and 2 years

③ Only 8% of patients received full PSP, but they had event rates comparable to patients who received Xience EES

④ Blinded, Pooled, Interim results from ABSORB IV (4% of patients with vessels <2.25 mm by QCA, 84% of post-dilation in the BVS arm) suggest 0.4% ST at 30 days and 0.5% at 1 year

Abbott Vascular press release. March 18, 2017

Mechanisms Associated with LST and VLST and their Relation to Implantation Technique

Correctable	Uncertain	Not correctable
Malapposition Incomplete lesion coverage Underexpansion Acute disruption Overlap Acute recoil Uncovered struts Bifurcation	Late discontinuity Late recoil Restenosis	Peri-strut low intensity area Neoatherosclerosis

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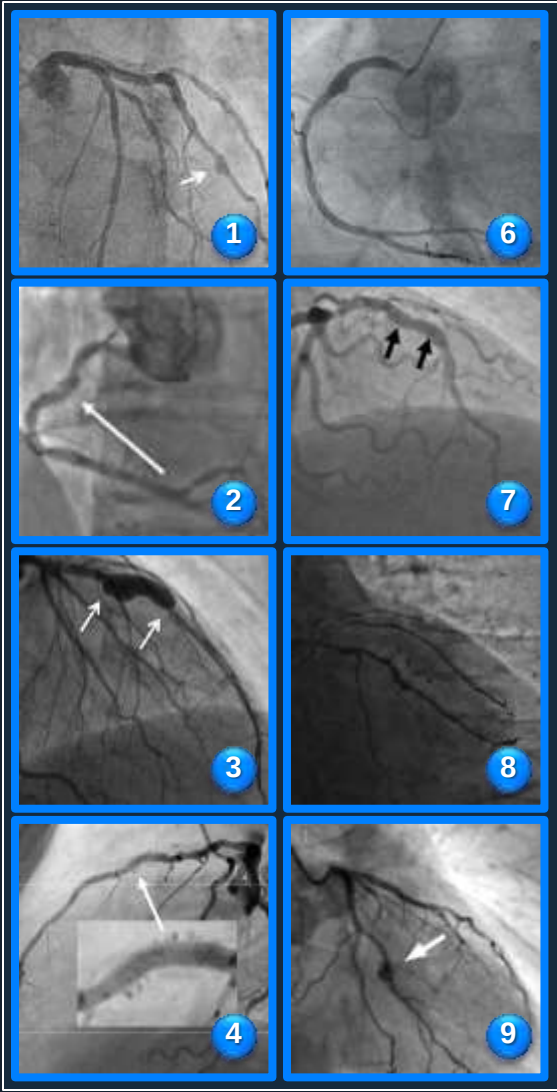
Yamaji K, et al. EuroIntervention 2017;12:1684-1687

Unknowns of BRS: Evaginations



PubMed search strategy: scaffol* [Title] AND aneur* [Title]

	Authors	Journal	Year
1	Chua SK, et al.	Catheter Cardiovasc Interv	2017
2	Patel A, et al.	Catheter Cardiovasc Interv	2017
3	Meincke F, et al.	JACC: Cardiovasc Interv	2017
4	Picard F, et al.	Can J Cardiol	2017
5	Paradies V, et al.	Coron Artery Dis	2016
6	O'Gallagher K, et al.	Eurointervention	2016
7	Timmers L, et al.	Eurointervention	2016
8	Cortese B, et al.	Int J Cardiol	2016
9	Varghese S, et al.	JACC: Cardiovasc Interv	2016
10	Lee WC, et al.	Int J Cardiol	2016
11	Gori T, et al.	Eur Heart J	2016
12	La Manna A, et al.	Can J Cardiol	2016
13	Nakatani S, et al.	Circulation	2015
14	Gargiulo G, et al.	JACC: Cardiovasc Interv	2015

BRS 2017: Expectations vs. Reality

Capodanno D, Personal Communication

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What's Next? Eyes on EuroPCR 2017

- ★ **Magmaris BRS**: Combined data of the BIOSOLVE-II and BIOSOLVE-III trials
- ★ **Aptitude BRS**: The RENASCENT II study
- ★ **DESsolve 120µm BRS**: 6-month clinical and imaging outcomes
- ★ **DESsolve BRS**: 4-year imaging and clinical outcomes
- ★ **Fantom BRS**: 1-year outcomes of the FANTOM II study
- ★ **MeRes 100**: 1-year clinical and multi-slice CT outcomes of the MERES - 1 study
- ★ **Absorb BRS**: 3-year clinical outcomes of ABSORB China
- ★ **Absorb BRS**: 3-year clinical and angiographic outcomes of ABSORB Japan
- ★ **Absorb BRS**: Clinical outcomes from the SCAAR registry
- ★ **And more...** GABI-R, RAI, Absorb UK, IT-DISAPPEARS, France Absorb

Is BRS safe? Closing Remarks

① First-generation BVS are associated with increased risk of TLF and target-vessel myocardial infarction at 2 years compared with second-generation everolimus-eluting stents. Device thrombosis is increased by 2-fold within 30 days, 3-fold between 30 days and 1 year and 4-fold beyond 1 year.

② Different implantation technique may translate into improved early and mid-term outcomes of first-generation BVS, but this is mostly based on PSP analyses that are post-hoc, underpowered and limited by selection bias.

③ All that we know about BRS safety is relevant to BVS. Beware of the promise of “second-generation scaffolds” that have not been tested in adequately sized randomized trials.

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