HKSTENT @ TCTAP 2016 - Part I: STEMI Controversies

Should Bioresorbable Scaffolds (BRS) Be Used in STEMI?

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Disclosure 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**	Abbott Vascular, Aspen, AstraZeneca, Bayer, Cordis, Daiichi Sankyo, Eli-Lilly
• **Consulting**	Abbott Vascular, Stentys
• **Advisory Board**	AstraZeneca

STEMI and Bioresorbable Scaffolds

Premises, promises and doubts

DES ISSUES IN STEMI

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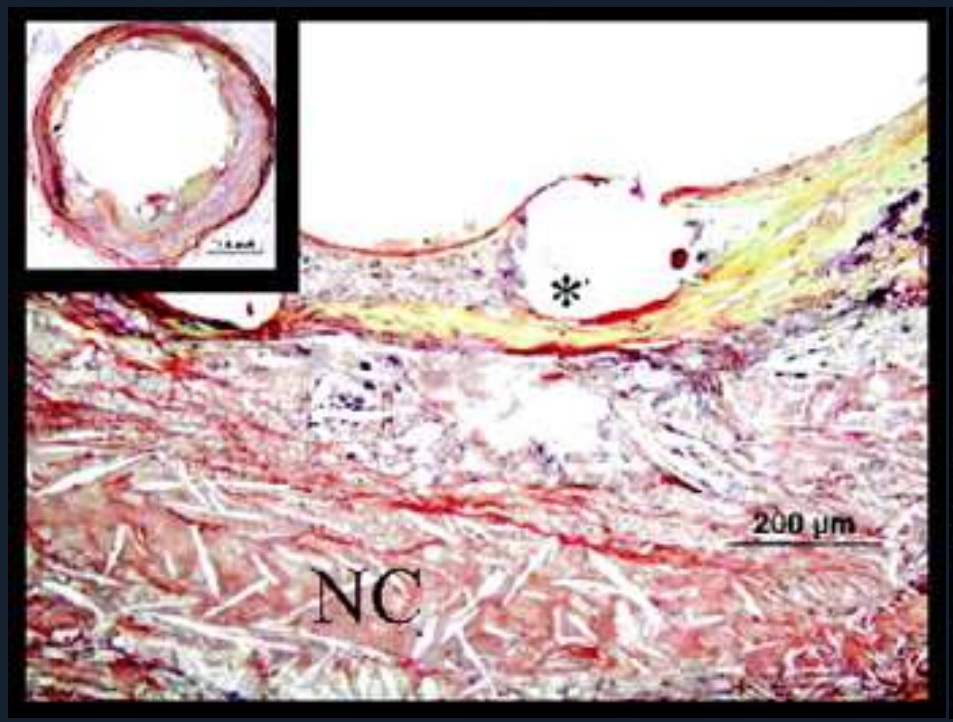
Necrotic Core and Arterial Healing

STEMI

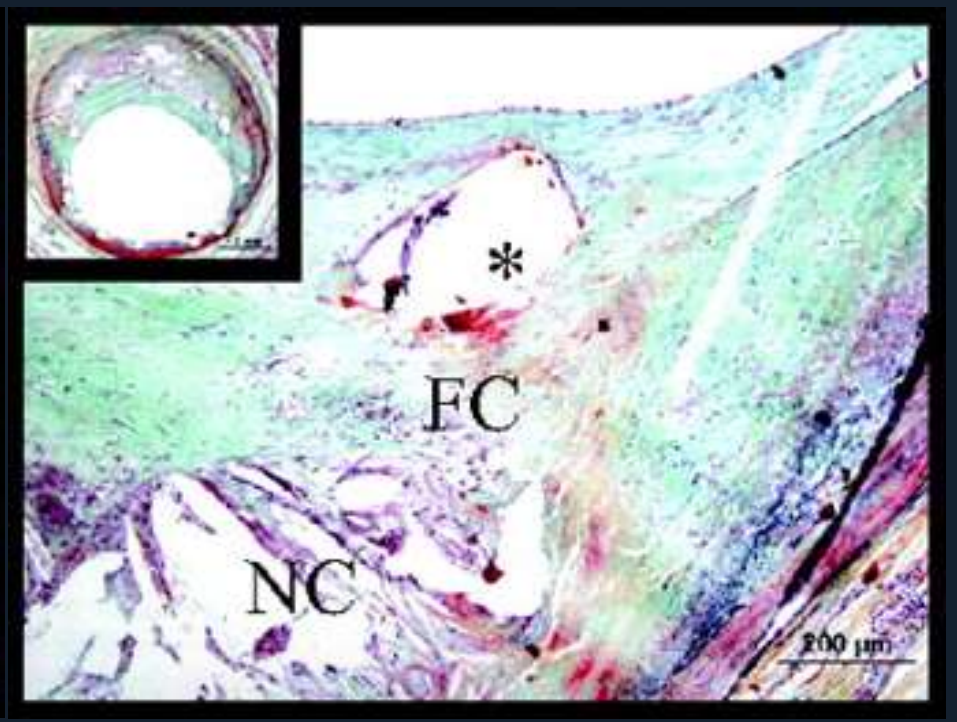
24 months, Cypher, very late ST



Necrotic core, minimal healing

Stable CAD

19 months, Cypher, noncardiac death



Thick-cap fibroatheroma

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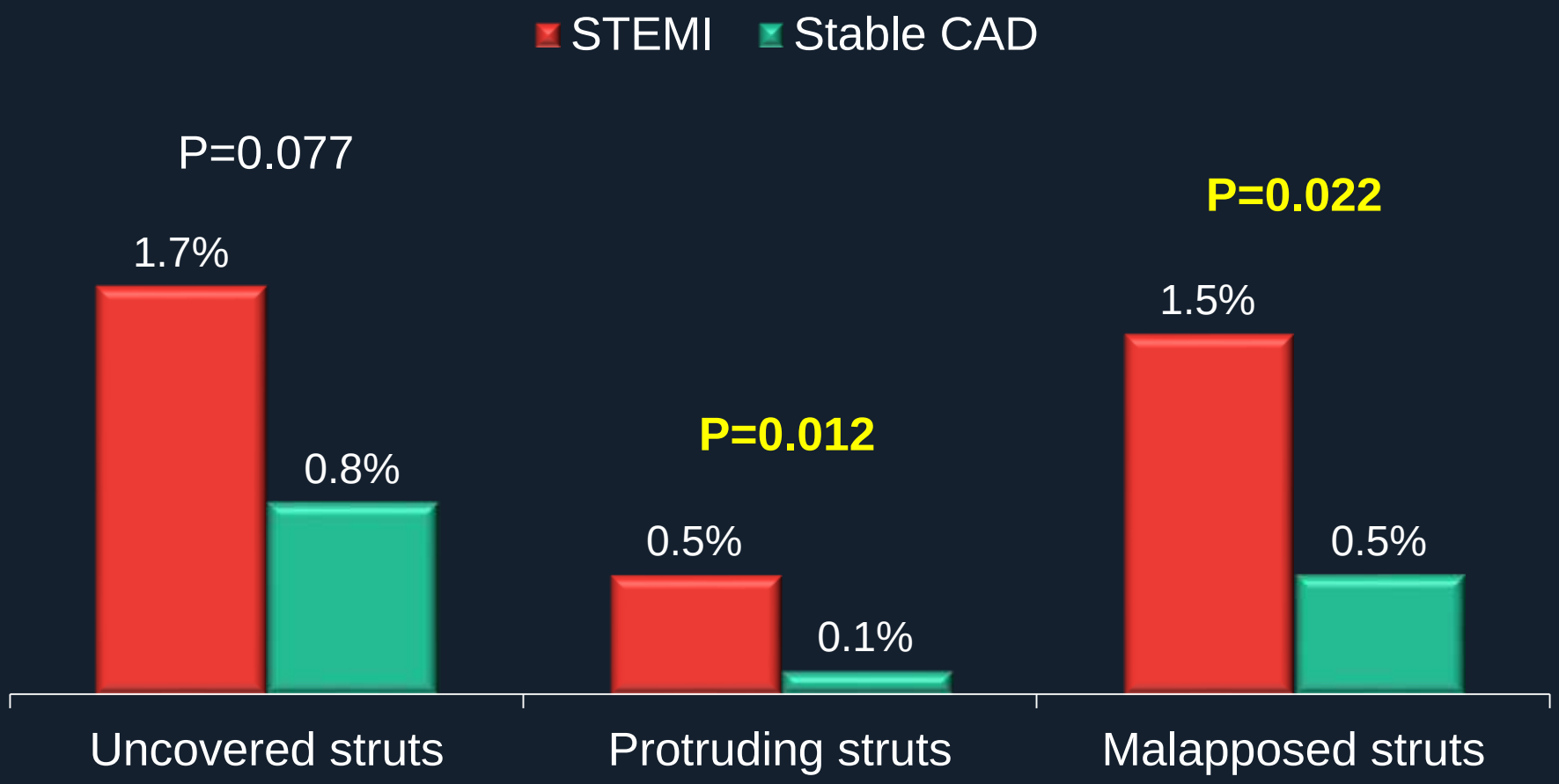
Nagazawa G, et al. Circulation. 2008;118:1138-45

Long-Term Strut Characteristics of DES

5-year OCT follow up in 88 patients with ACS and stable CAD



Raber L, et al. Int J Cardiol. 2014;173:259-67

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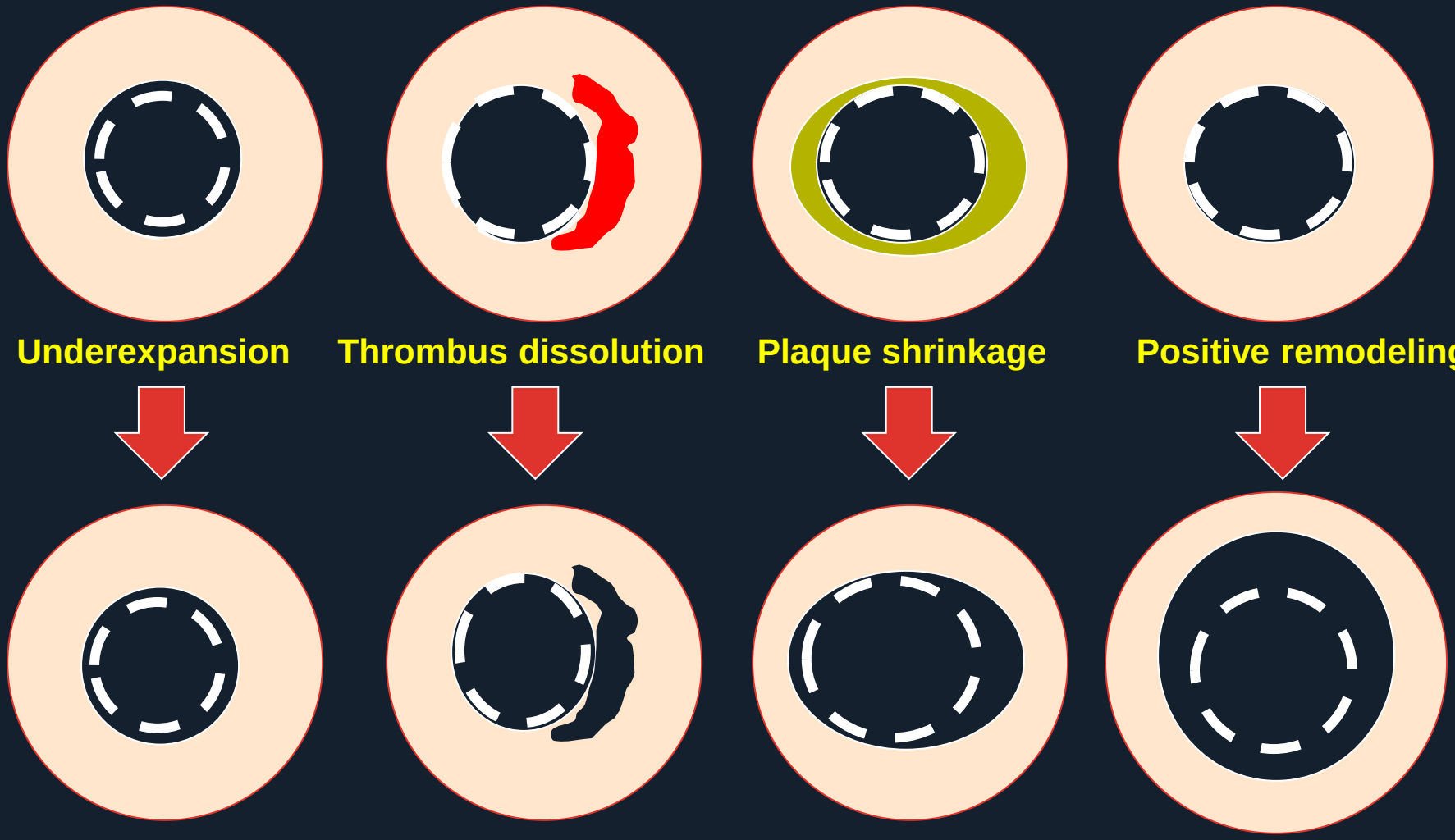
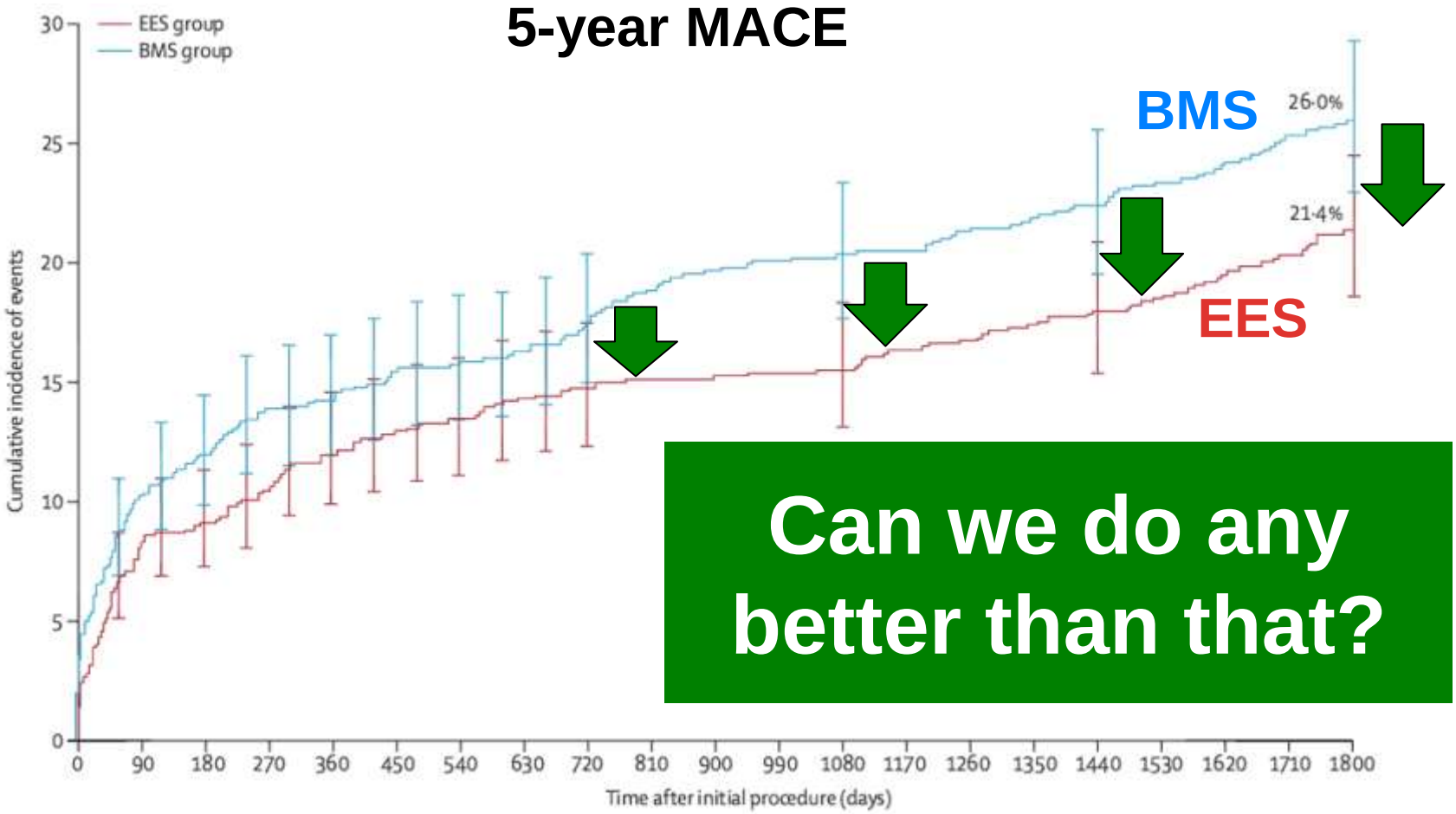
Mechanisms of Late Malapposition



EES: The DES Reference Standard

1498 patients randomly assigned to receive either EES (n=751) or BMS (n=747)



Can we do any better than that?

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Sabatè M, et al. Lancet. 2016;387:357-66

STEMI and Bioresorbable Scaffolds

Premises, promises and doubts

WHY BRS MIGHT BE A GOOD IDEA

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Rationale for BVS in STEMI

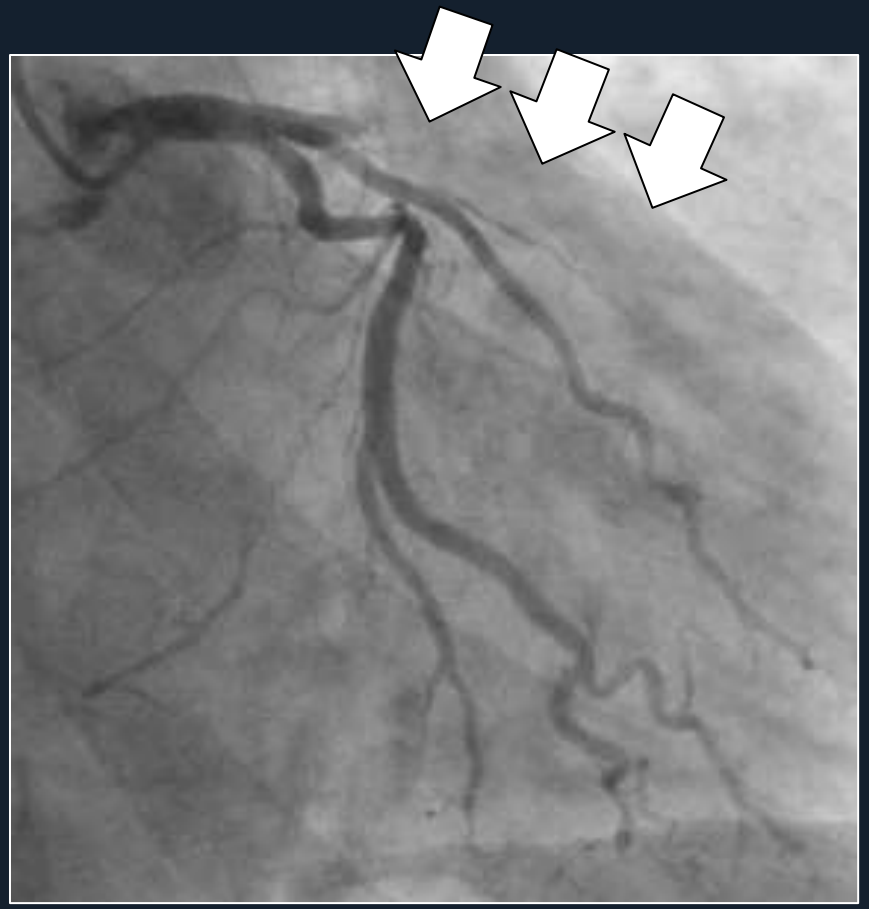
- Bioresorption and positive vessel remodelling may offset the effect of device undersizing facilitated by vasoconstriction
- Scaffolds may result in a neo-cap formation acting as a protective layer shielding the underlying necrotic core

Benefits of BVS Are Expected Proximally

Distance from the coronary ostium to the culprit lesion planimetred in 1,914 pts

75%

STEMI culprit lesions contained in the first 60 mm of a coronary artery



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Gibson CM, et al. J Thromb Thrombolysis. 2003;15:189-96

STEMI and Bioresorbable Scaffolds

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WHY BRS MIGHT NOT BE A GOOD IDEA

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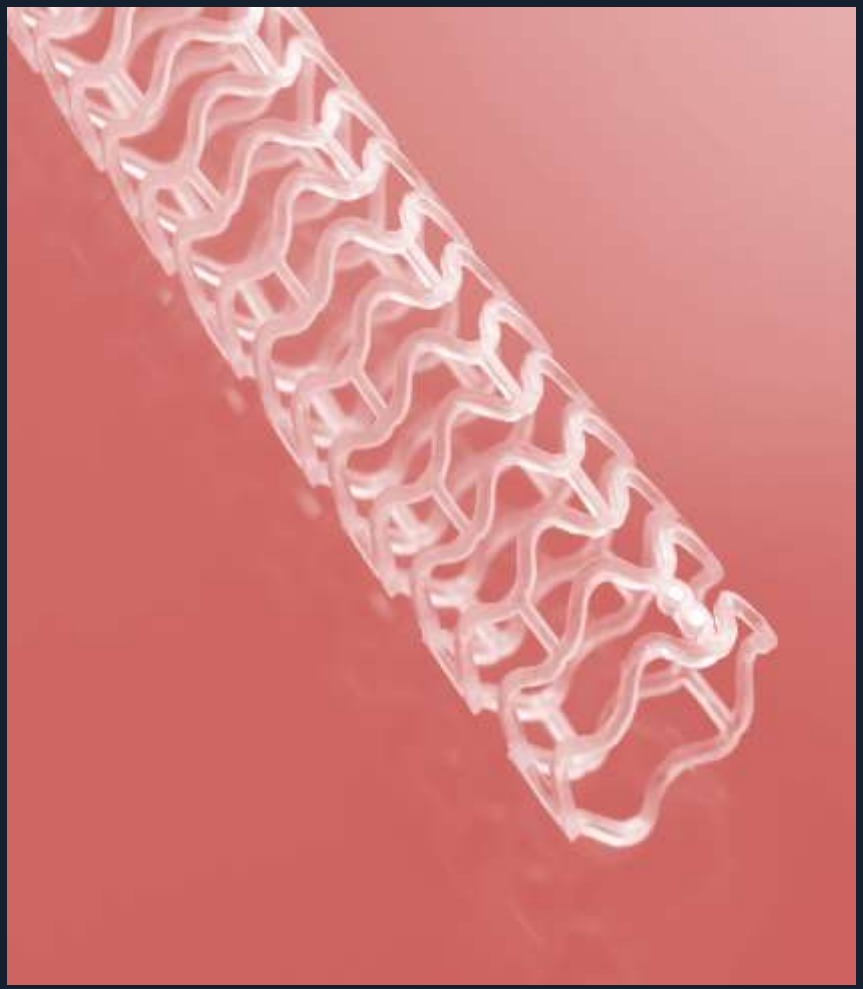
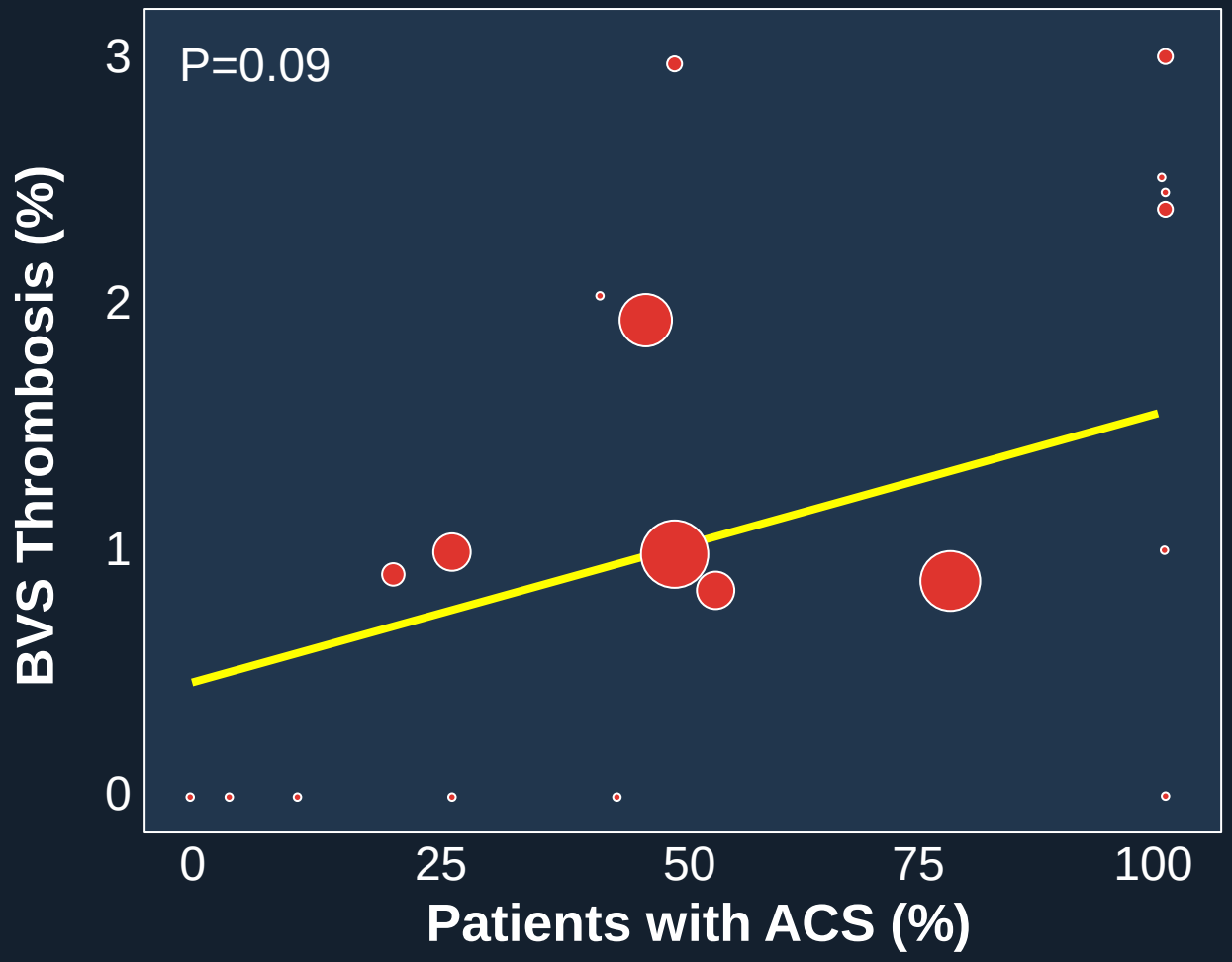
Rationale against BVS in STEMI

- Primary PCI is a time-sensitive and demanding procedure, where technical steps recommended for optimal BVS implantation might be overlooked
- Primary PCI is performed in a prothrombotic milieu, sometimes with poor platelet inhibition on board (a concern for early BVS thrombosis)



ACS and Early BVS Thrombosis

Meta-analysis of 10,510 patients from 26 studies



Lipinski MJ, et al. JACC Cardiovasc Interv. 2016;9:12-24

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Reasons for NOT implanting a BVS in STEMI

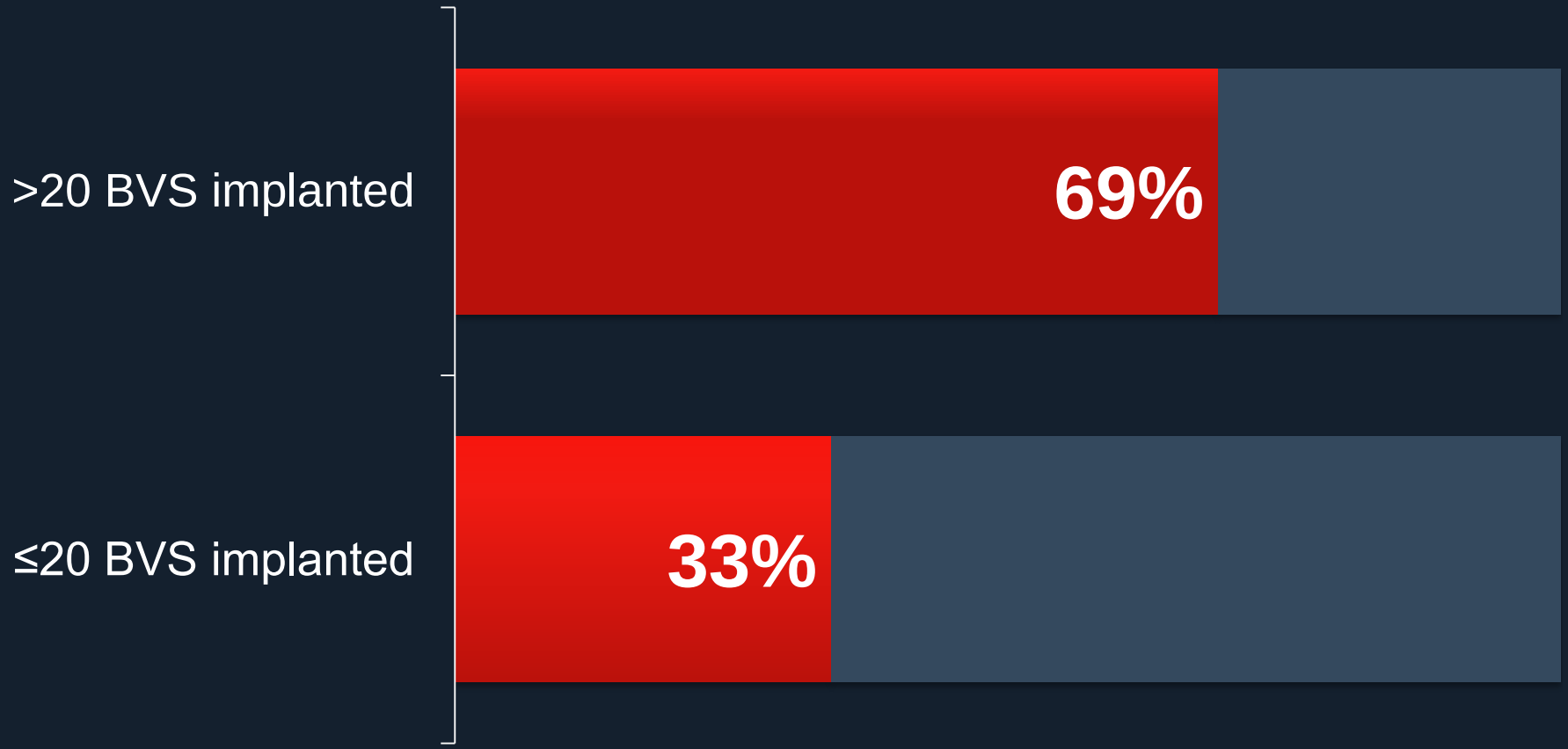
PRAGUE 19: 101 pts excluded from receiving BVS out of 142 consecutive pts with STEMI (71%) screened between December 2012 and August 2014

Exclusion criteria	Number of patients
Killip III-IV	24
Stent thrombosis	5
Poor compliance	8
Comorbidity with limited expected survival	3
Anticoagulation or contraindication to DAPT	4
Vessel diameter outside 2.3-3.7 range	30
Correct BVS size not in stock	14
Vessel calcification tortuosity	17
P-PCI without stent implantation	21

Kocka V, et al. Eur Heart J. 2014;35:787-94

"Do you use BVS in STEMI"?

Survey of 139 interventionalists from 23 countries



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Buccheri D, et al. Int J Cardiol. 2015;188:16-8

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BRS for STEMI: THE EVIDENCE BASE

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Single-Arm Registries of BVS in STEMI

Study	Journal	N	Follow up	MACE	Death	ScT
Kajiya et al	EIJ 2013	11	53±46 days	9%	9%	0%
Wiebe et al	CRC 2014	25	133±69 days	8%	4%	0%
STEMI First	EHJ 2014	49	30 days	0%	0%	0%
RAI	EIJ 2015	74	6 months	4.1%	0%	1.3%
Kochman et al	CJ 2015	23	229 [199-248] d	4.3%	0%	4.3%
Karanasos et al	HJC 2015	5	6 months	0%	0%	0%
Kochman et al	CCI 2015	12	12 months	8.3%	0%	0%
PRAGUE 19	Circ CI 2015	70	12 months	4.3%	2.9%	1.4%

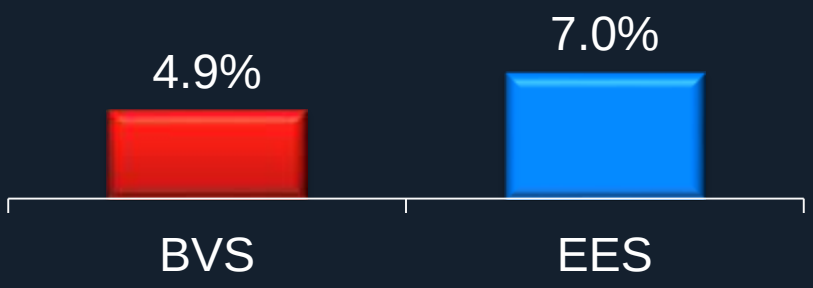
Dual-Arm Registries of BVS in STEMI

BVS-RAI[1]

135 patients treated with BVS vs.
470 patients treated with EES

220-day Death/MI/TLR

P=0.47

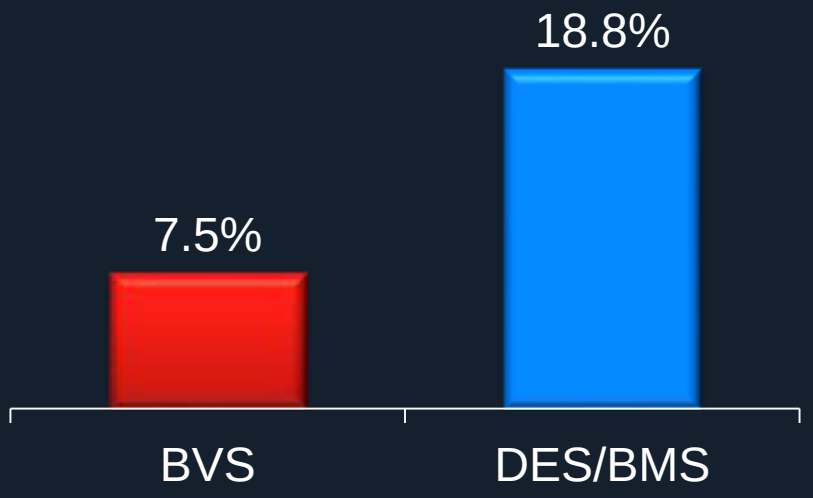


PRAGUE 19[2]

40 patients treated with BVS vs.
57 patients treated with DES/BMS

2-Year Death/MI/TVR

P=0.12



[1]Cortese B, et al. Am J Cardiol. 2015;116:705-10
[2]Tousek P, et al. Int J Cardiol. 2016;209:20-1

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BVS vs EES vs BMS (propensity-matched)

290 patients treated with BVS at 6 centers, matched with 290 patients treated with EES and 290 patients treated with BMS from EXAMINATION

	BVS	EES	BMS	BVS vs EES	BVS vs BMS
30-day					
TLF	3.1%	2.4%	2.8%	0.59	0.78
CV Death	1.7%	1.4%	1.7%	0.72	0.98
TV MI	1.4%	0.7%	0	0.22	0.31
TLR	1.0%	0.7%	1.0%	0.66	0.98
Def/prob ST	2.1%	0.3%	1.0%	**0.06**	0.32
1-year FU					
TLF	4.1%	4.1%	5.9%	0.99	0.31
CV Death	2.1%	2.1%	2.1%	0.91	0.53
TV MI	2.1%	1.4%	1.0%	0.58	0.20
TLR	1.7%	1.4%	3.4%	0.53	0.96
Def/prob ST	2.4%	1.4%	1.7%	0.95	0.85

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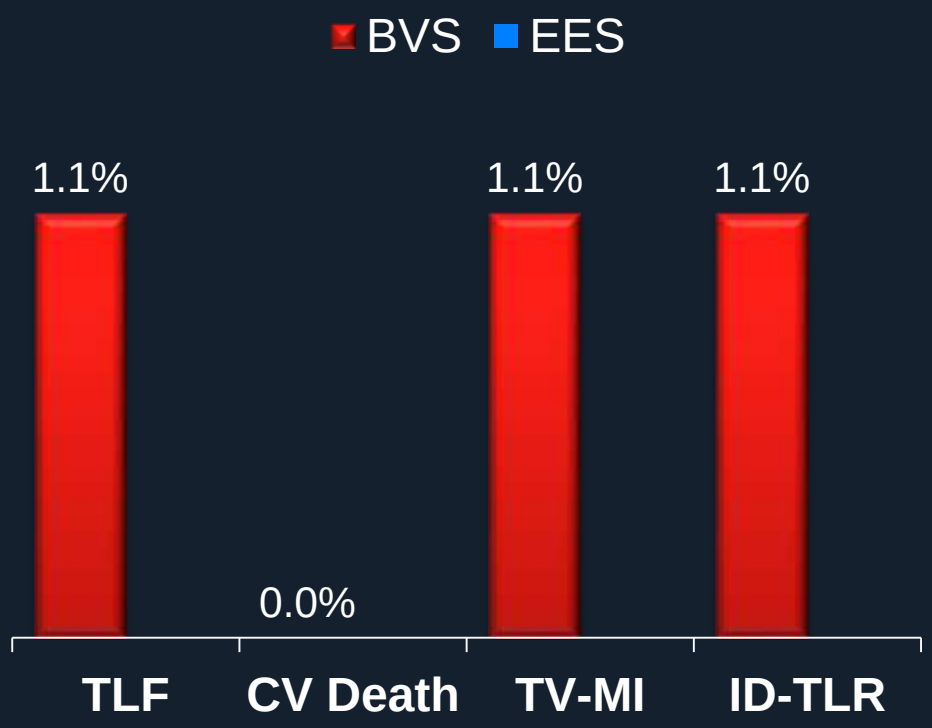
Brugaletta S, et al. JACC Cardiovasc Interv. 2015;8:189-97

BVS vs EES (Randomized)

TROFI 2: 191 patients with STEMI randomized to BVS or EES

6-month clinical outcomes



	BVS	EES	
6-mo QCA	**N=94**	**N=98**	
%DS (%)	17.3±7.4	14.5±9.3	**0.028**
ID-Late loss (mm)	0.17±0.24	0.08±0.28	**0.024**
IS-Late loss (mm)	0.14±0.28	0.06±0.29	0.09
6-mo OFDI	**N=84**	**N=87**	
Healing score (n)	1.74±2.39	2.80±4.44	0.053
Neointimal area (mm^2)	1.52±0.38	1.35±0.54	**0.018**
Coverage (mm)	0.11±0.03	0.09±0.05	**<0.001**

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Sabatè M, et al. Eur Heart J. 2016;37:229-40

HORIZONS ABSORB AMI

6,840 pts with STEMI undergoing primary PCI

Aspirin + oral $P2Y_{12}$ Inhibitor | IV Cangrelor + Infusion

Randomize 1:1:1, double blind, triple dummy

R

- Bivalirudin + 4 h post-PCI infusion (N=2,280)
- Bivalirudin, no infusion (N=2,280)
- Heparin, no infusion (N=2,280)

≈5,000 pts eligible for device randomization

Randomize 1:1, open label

R

1,840 pts not randomized (Xience EES)

- Xience EES
- Absorb BVS

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Stone GW, TCT 2015

Closing remarks

- Young STEMI patients with proximal culprit lesions may represent ideal candidates to vascular restoration therapy.
- However, the impact of implanting thick-strut devices in a prothrombotic environment is a major unknown, and scaffold thrombosis a key concern.
- In PRAGUE 19, less than one third of STEMI patients qualified for BVS implantation.
- Early real world outcomes of BVS in STEMI sound promising, but they lack scientific solidity. A large-scale randomized clinical trial has been launched to define the role of BVS in primary PCI.

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