Morning Roundtable Forum: Meet the Experts over Breakfast

Contemporary Practice and Technical Aspects in Coronary Intervention with BRS
- *A European Perspective* -

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EXPERT REVIEW

Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective

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Tamburino C, et al. EuroIntervention. 2015;11:45-52

Frankfurt meeting, March 4, 2014

Informal collaboration of representatives from **14** European centers with a high volume of Absorb BVS procedures and representatives of the device manufacturer

- to explore different contemporary practices for the use of BVS
- to build a consensus on accepted technical approaches for BVS implantation
- to prepare a document summarizing the results of this joint effort

A survey-based and consensus approach in a data-free zone

- To get the most objective snapshot of different practices among the participating centers, a survey with **45** multiple choice questions was prepared and conducted in October 2014.
- The results of the survey served a basis for the technical advices provided in the document, and a source of information to highlight areas of controversy for further discussion by telephone conferences and e-mailing.

Covered topics

SECTION I

General implantation rules

- Evaluation of patient and lesion suitability
- Vessel sizing and scaffold selection
- Lesion preparation
- Scaffold implantation and optimization
- Intravascular imaging

SECTION II

Specific subsets and technical limitations

- Bifurcations
- Long lesions
- Thrombotic lesions
- Calcified lesions
- In-stent restenosis
- Post-treatment management

SECTION III

How to prevent and manage BVS complications

- Scaffold disruption
- Scaffold malapposition, restenosis, multiple inter-strut hollows
- Early scaffold thrombosis

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Tamburino C, et al. EuroIntervention. 2015;11:45-52

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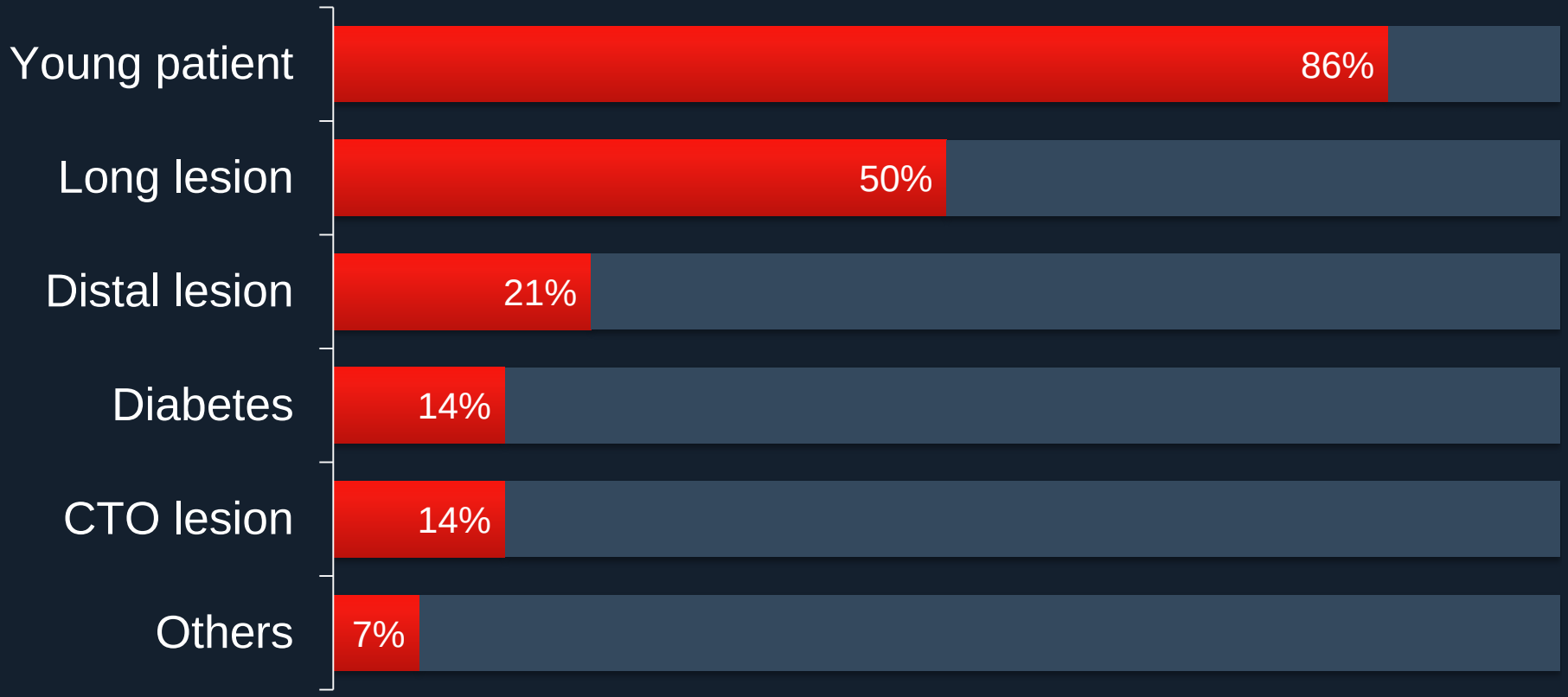
Evaluation of patient and lesion suitability

Question #7 - Which is the most frequent reason for choosing BVS in your centre? (multiple answers allowed)



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Tamburino C, et al. EuroIntervention. 2015;11:45-52

Practical Operating Protocol for New BVS users

01 **Sizing ± intravascular imaging guidance**
After i.c. nitrates, use intravascular imaging or the predilatation balloon for sizing

02 **Pre-dilation**
Predilate the lesion with whatever it takes until a ballon of nominal scaffold size is fully expanded at 10 atm within the lesion

03 **Implantation**
Implant the scaffold stepwise 2 atm every 5 seconds up to the maximum desired pressure, keeping the scaffold balloon inflated for at least 30 seconds

04 **Post-dilation**
Use short NC balloons, to at least of the nominal scaffold size and a maximum of nominal scaffold size +0.5 mm, making sure that full expansion is achieved

05 **Post-implantation intravascular Imaging guidance**
Non-compliant balloon post dilatation may be dropped if intracoronary imaging shows full strut apposition and complete scaffold expansion

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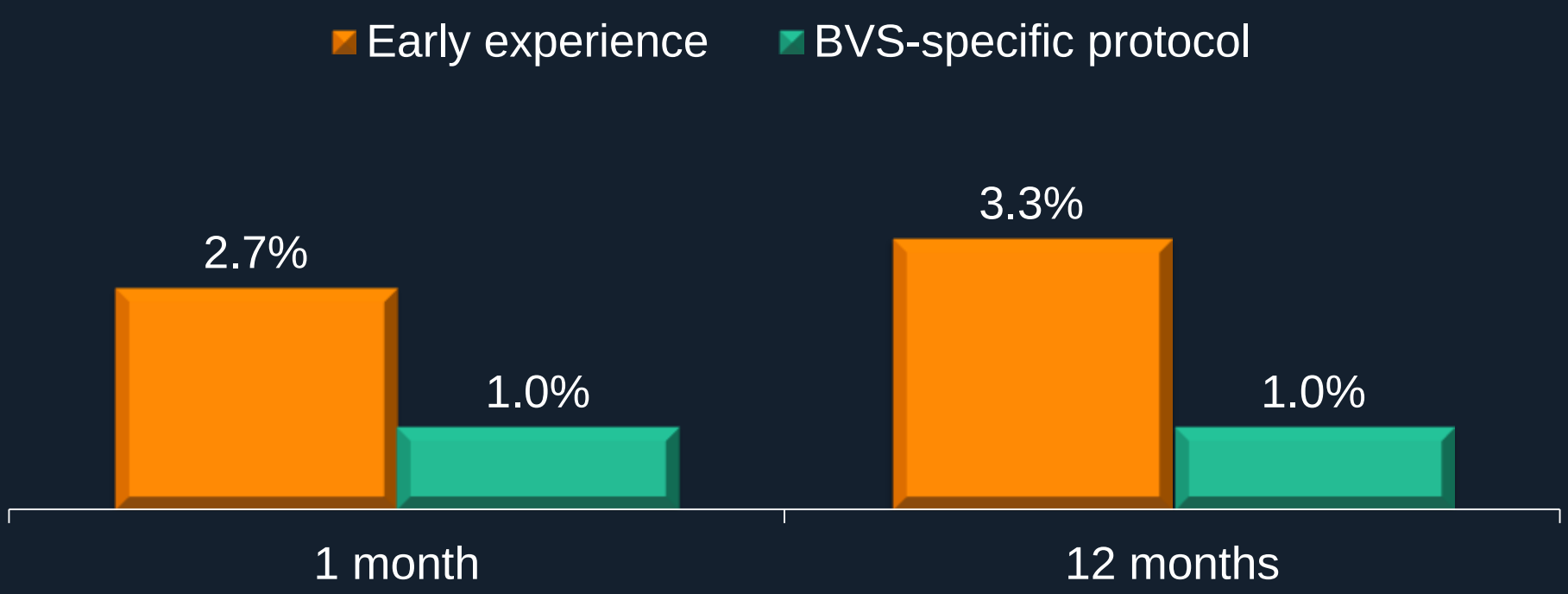
Tamburino C, et al. EuroIntervention. 2015;11:45-52 (adapted)

Impact of a BRS-specific implantation protocol

42 ScT in 1,305 patients from 4 German and Swiss centers



Adj. HR for a BVS-specific implantation strategy introduced in 2014
0.26 (0.08-0.90), P=0.035

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Puricel S, et al. J Am Coll Cardiol. 2016;67:921-31

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BVS and bifurcation lesions

- **Provisional stenting remains the default strategy**
  - SB fenestration and T-FKI with no or minimal protrusion of the SB balloon can be performed at low pressure if necessary
  - TAP is preferable for bailout SB stenting (easier with DES)
- **T stenting, when feasible, should be the preferred technique for elective double stenting**
  - A hybrid double-stenting strategy (BVS-MB and DES-SB) may be preferable to a two BVS strategy in case of true bifurcations with small SB and narrow bifurcation angle

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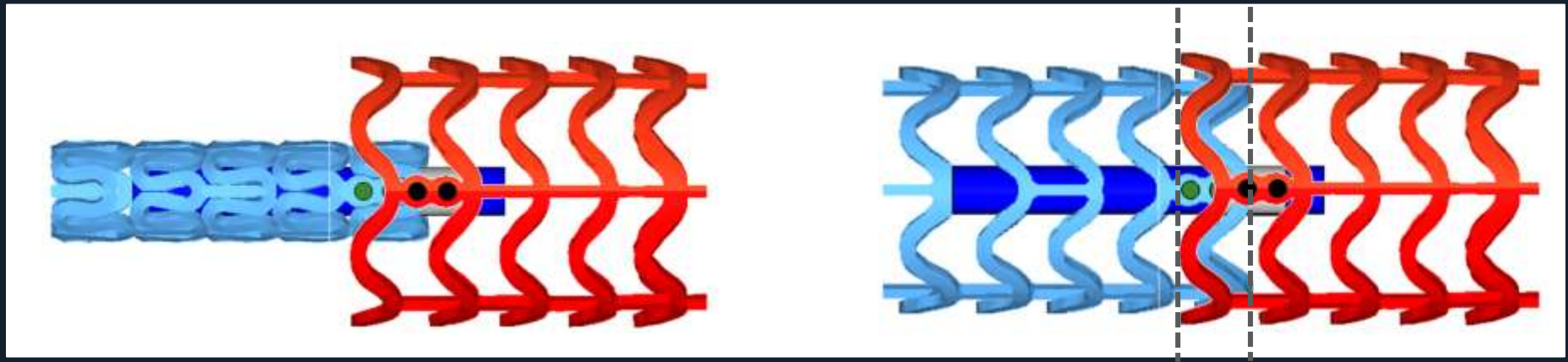
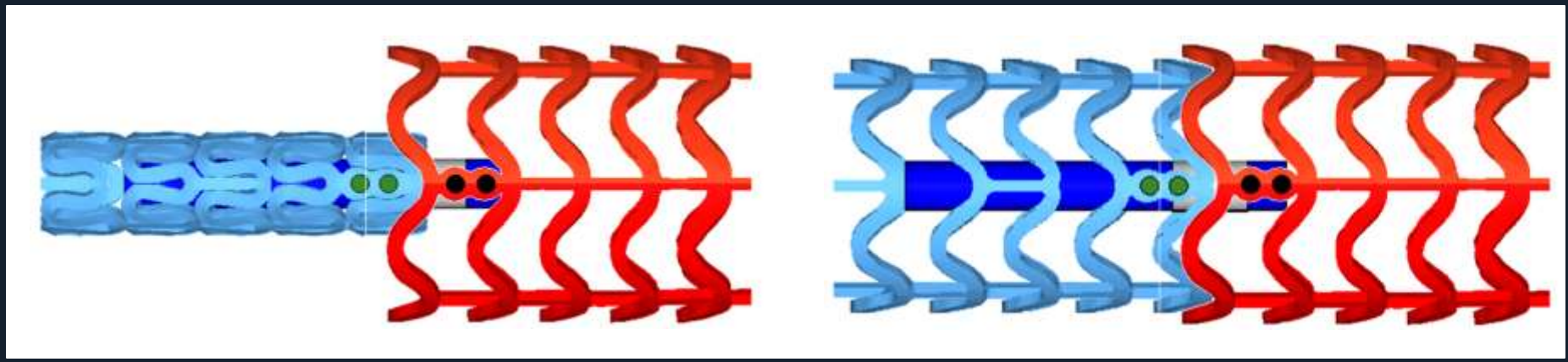
Tamburino C, et al. EuroIntervention. 2015;11:45-52

BVS and long lesions

'Marker to Marker' (~1 mm of overlap)



'Scaffold to scaffold' (no overlap)



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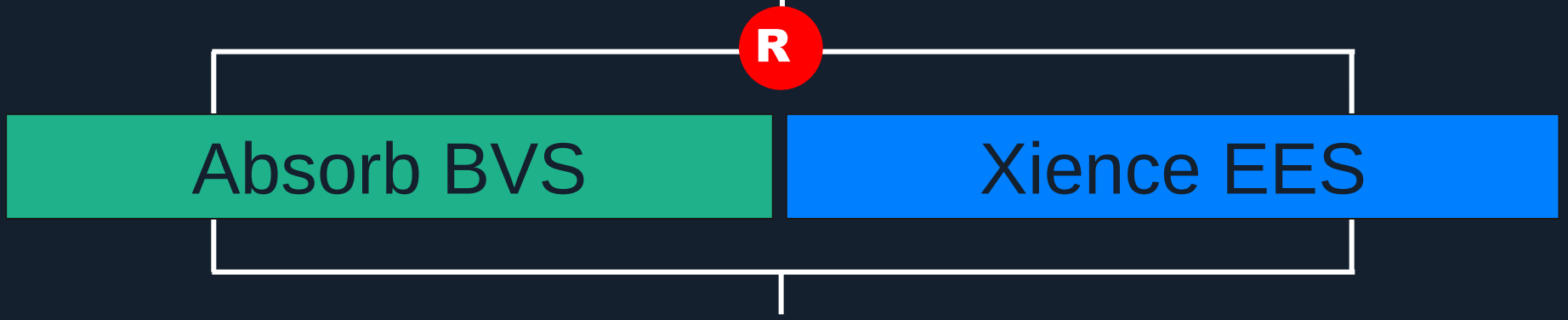
Tamburino C, et al. EuroIntervention. 2015;11:45-52

COMPARE ABSORB

2,100 pts at high risk of restenosis

Diabetes, MVD, length >28mm | RVD 2.25-2.75, CTO, bifurcation

Randomize 1:1, open label



Primary endpoint: 12-mo TLF (powered for BVS noninferiority)

Secondary endpoint: TLF between 1 and 5 years

NCT02486068

BVS and thrombotic lesions

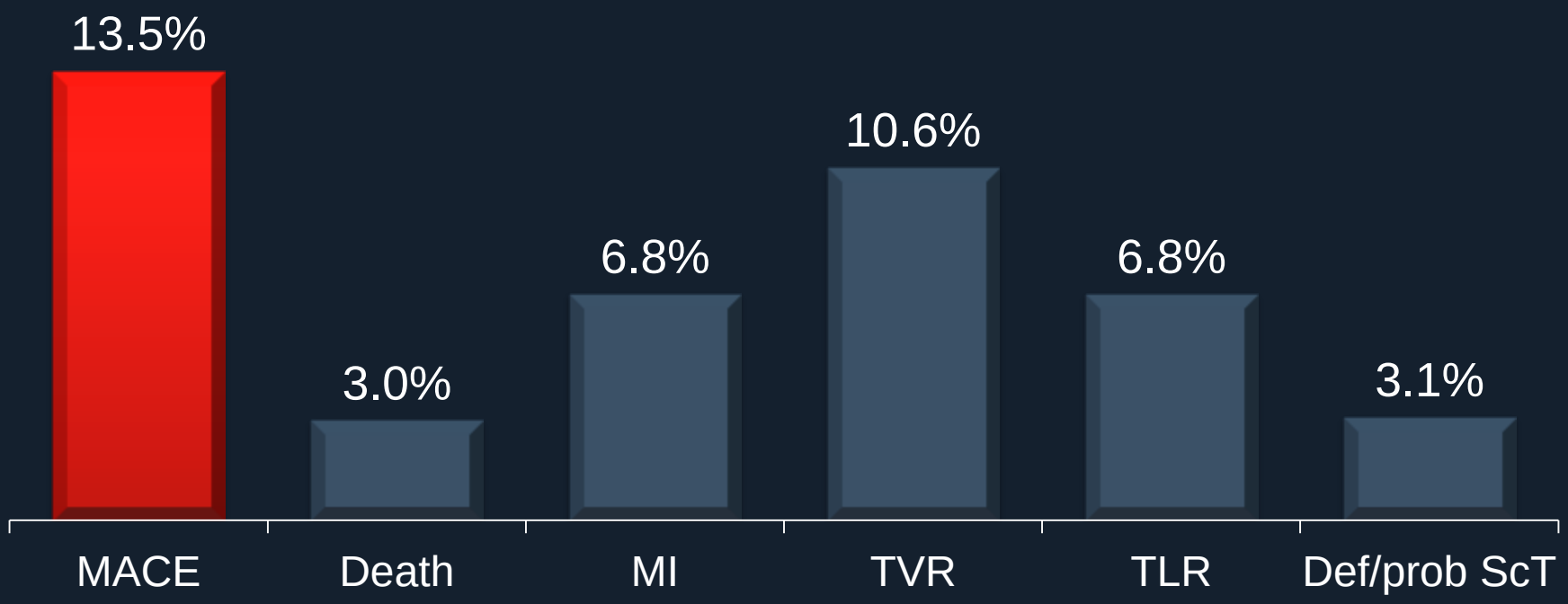
Theoretical advantages (vs. no supporting data)

- **Reduction in distal embolisation** due to the larger strut width, with a possible increased capacity to entrap thrombotic material between the scaffold and the vessel wall
- **Bioresorption and positive vessel remodelling** may offset the effect of device undersizing facilitated by acute phase vasoconstriction
- **Scaffolds may result in a neo-cap formation** acting as a protective layer shielding the underlying necrotic core

BVS and thrombotic lesions

133 patients undergoing BVS implantation for the treatment of thrombotic lesions in the setting of ACS (63% NSTE-ACS, 38% STEMI)

12-month clinical outcomes



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Gori T, et al. JACC Cardiovasc Interv. 2015;8:770-7

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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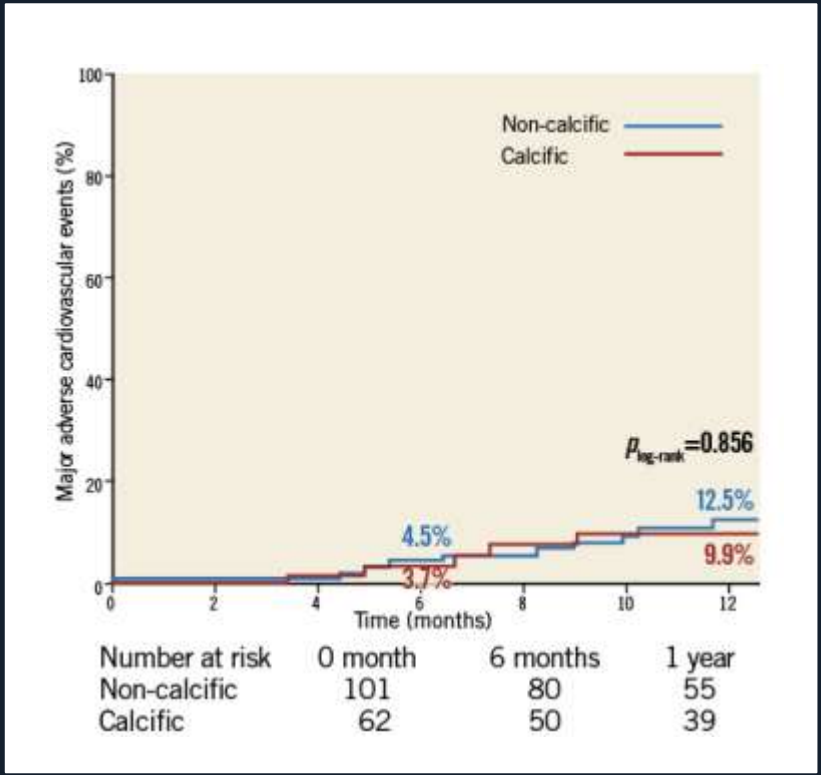
Stone GW, TCT 2015

BVS and calcified lesions

163 patients treated with BVS (62 with calcified lesions)

MACE at 14 months



	Calcified	Noncalcified	P
Acute gain, mm	1.86±0.63	1.83±0.60	0.73
Angiographic success	95.2%	98%	0.37
Periprocedural MI	13.1%	5%	0.07
Procedural success	**83.9%**	**94.1%**	**0.03**
Fluoroscopy time, min	**48±18**	**39±17**	**0.02**

"Not a free lunch!"

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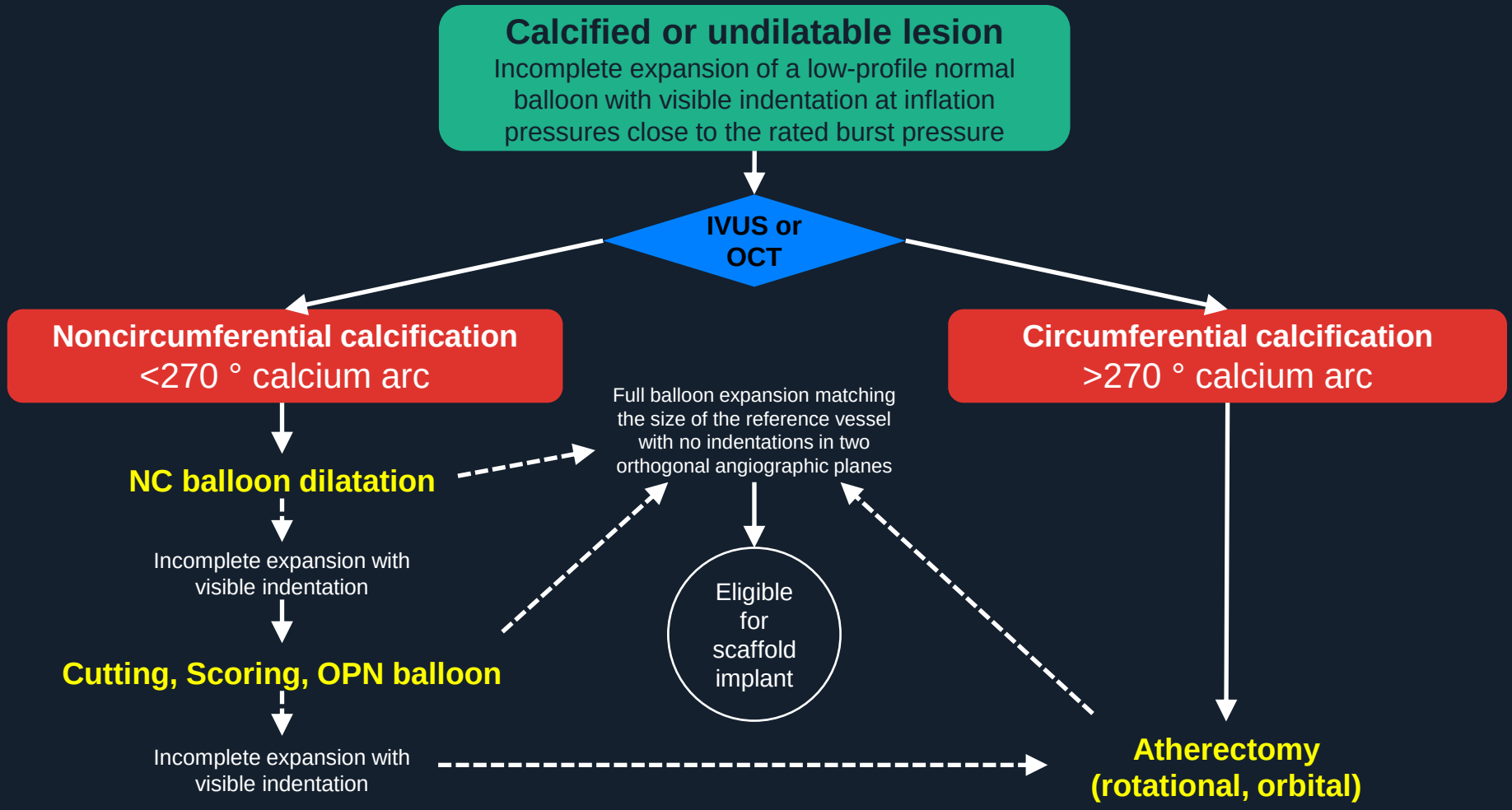
Panoulas V, et al. EuroIntervention 2016;11:1355-1362

BVS and calcified lesions



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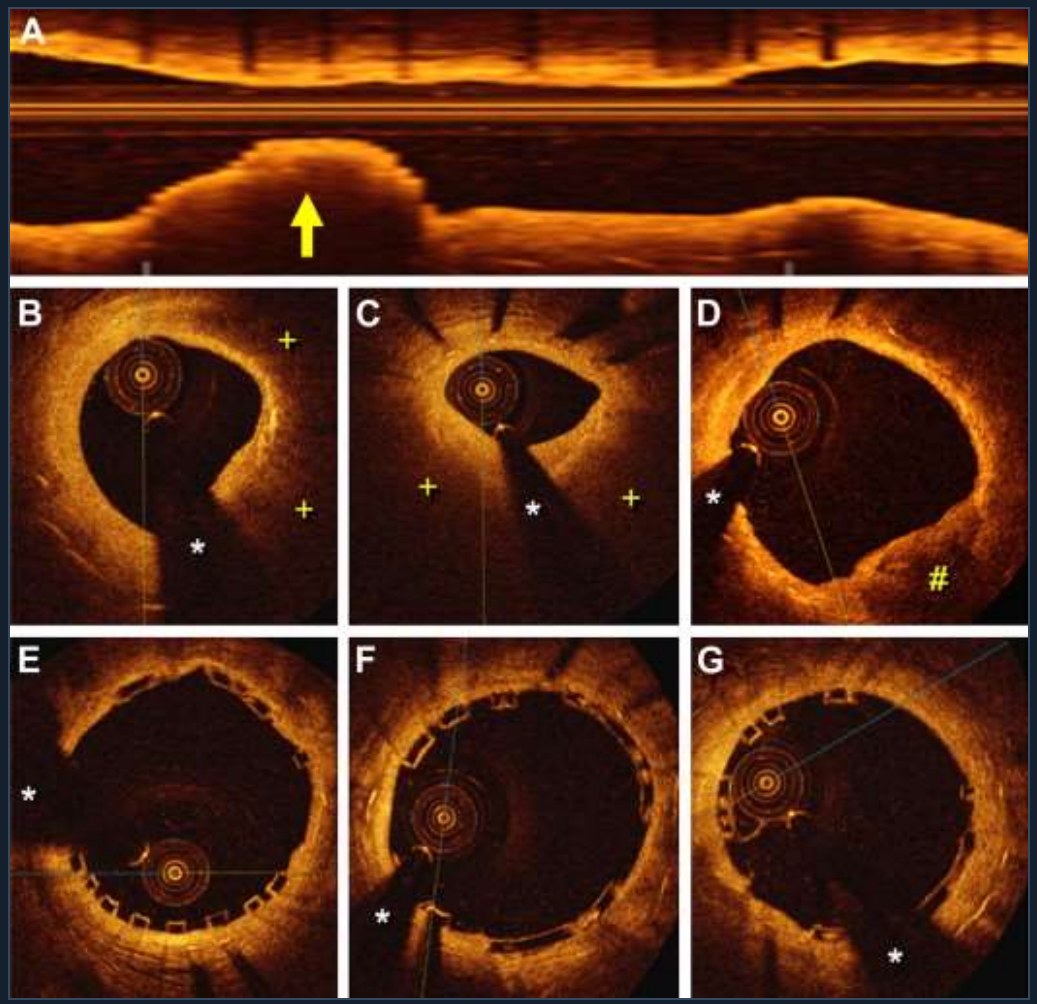
Capodanno D. EuroIntervention. 2016;11:1334-6

BVS and restenotic lesions



Rationale

The device should eventually disappear from the vessel wall, avoiding the presence of multiple stent layers (“onion skin”)

Unkowns

- Lumen crowding due to strut thickness
- Device flexibility that may affect access to restenotic lesions
- Questions regarding radial strength and recoil

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Alfonso F, et al. J Am Coll Cardiol 2014;63:2875

BVS and restenotic lesions

84 patients with ISR treated with BVS (DES 96%, BMS 4%)

	6 months N=65	1 year N=49
Death	1/65 (1.5%)	2/49 (4.1%)
Myocardial infarction	1/65 (1.5%)	1/49 (2.0%)
Target lesion revascularization	2/65% (3.1%)	6/49 (12.2%)
Target vessel revascularization	3/65 (4.6%)	9/49 (18.4%)
Scaffold thrombosis	0 (0%)	0 (0%)

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Jamshidi P, et al. EuroIntervention 2016;11:1479-1486

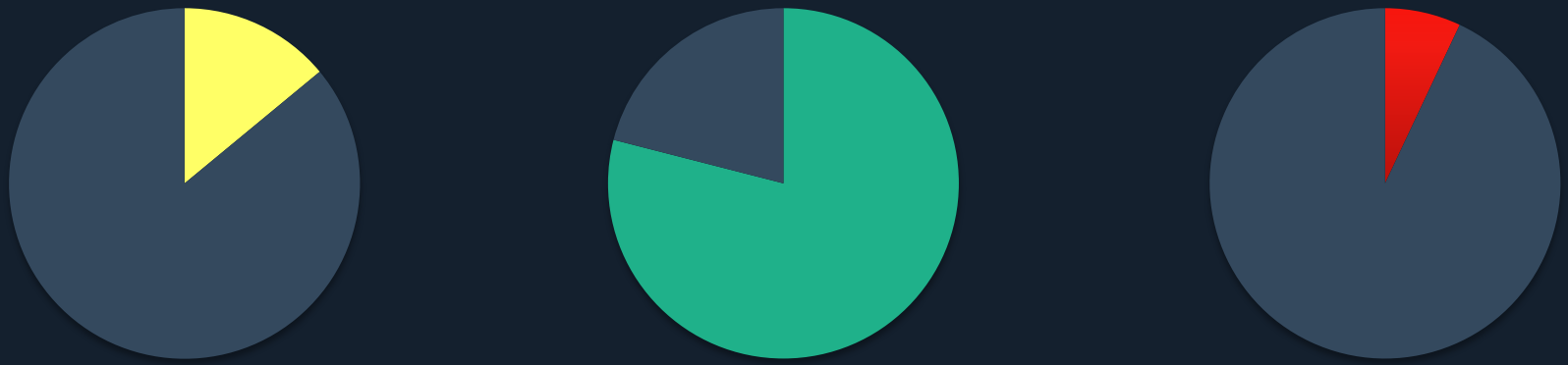
BVS and post-PCI management

Question #39 - How long do you recommend DAPT in stable angina patients treated with BVS?

14% 6 months

79% 12 months

7% >12 months



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Tamburino C, et al. EuroIntervention. 2015;11:45-52

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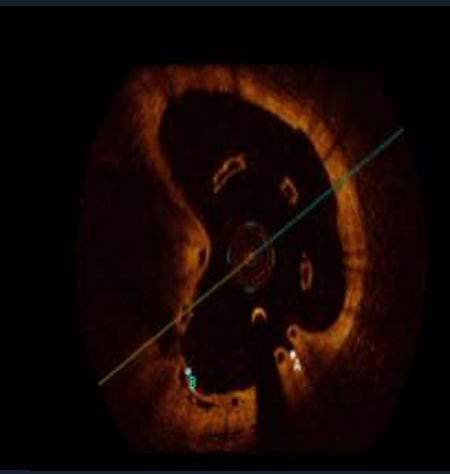
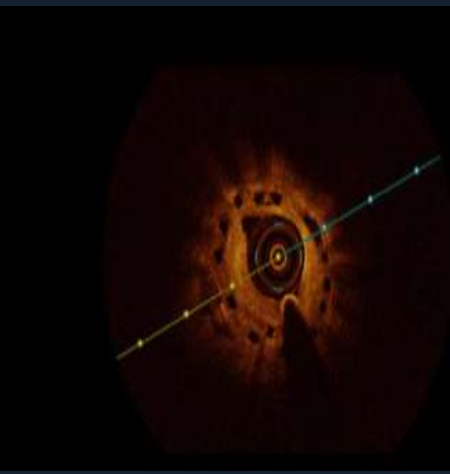
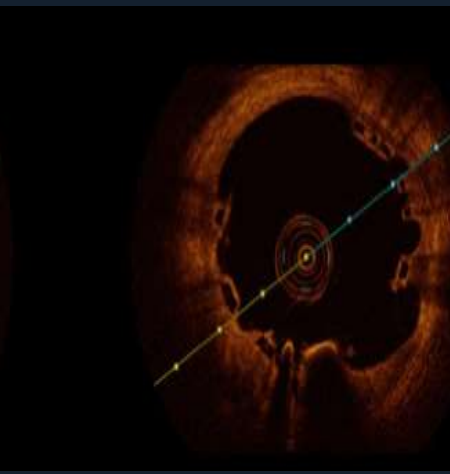
BRS failure: Knowledge gaps

Disruption Dismantling	Acute or acquired malapposition	Restenosis Neoatherosclerosis	Evaginations Hollows
			
To what extent can be tolerated? What is the fate of floating or embolized struts?	What is the incidence and effect of acute, persistent and late-acquired ISA?	Can we identify predictors? Which treatment strategy?	Cavities and peristrut contrast staining: are they innocent bystanders?

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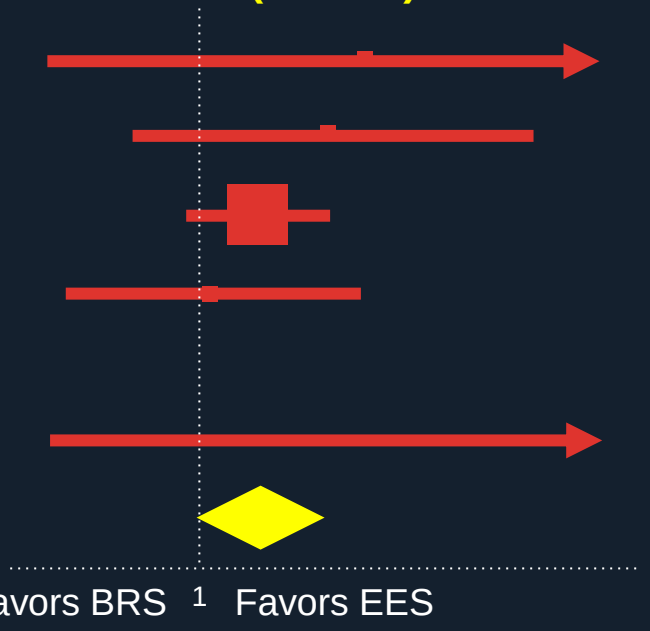
Definite or probable thrombosis in randomized trials of BRS versus EES

	BVS	EES	Fixed-effect OR	Fixed-effect OR BRS:EES
	n/N	n/N	(95% CI)	(95% CI)
ABSORB China	1/238	0/232	7.21 (0.14-363.23)	
ABSORB II	3/335	0/166	4.49 (0.04-49.92)	
ABSORB III	20/1301	5/675	1.89 (0.82-4.34)	
ABSORB Japan	4/262	2/133	1.02 (0.18-5.58)	
EVERBIO	0/78	0/80	Not estimable	
TROFI II	1/95	0/96	7.47 (0.15-376.35)	
Overall	**29/2309**	**7/1382**	**1.99 (1.00-3.98)**	



Heterogeneity: χ^2=1.90, df=4; p=0.75; **I**2=0%; Test for overall effect: **Z**=1.96; p=0.05
Random-effects odds ratio 1.99 (95% CI 1.00–3.98)

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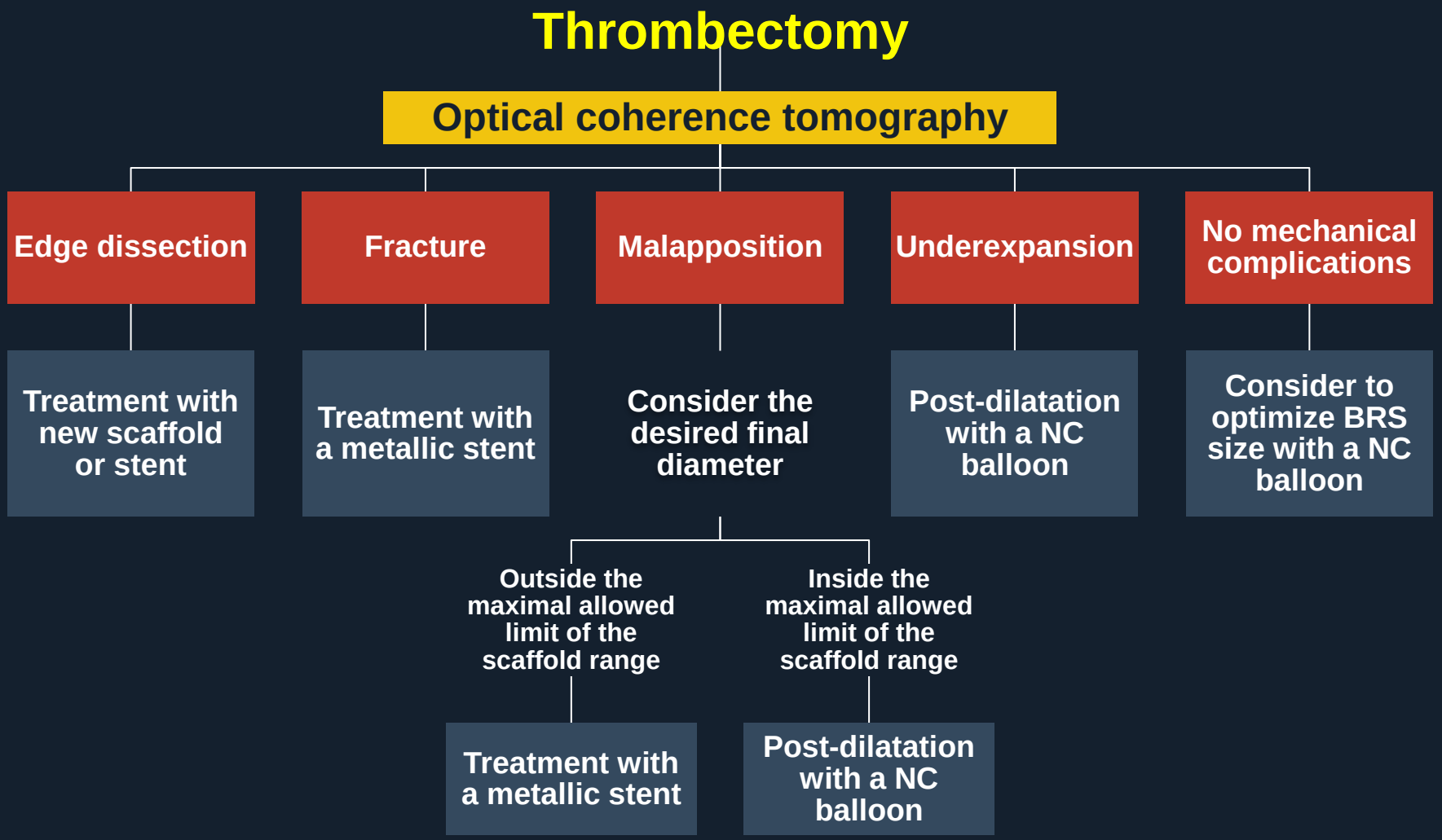
Cassese S, et al. Lancet. 2016;387:537-44

Management of early BRS thrombosis



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Contemporary practice and technical aspects in coronary intervention with BRS
- Closing remarks -

- Appraising the knowns and unknowns of a new technology is critical, particularly in the earlier phases of its introduction and implementation in daily practice.
- A standardised approach to optimal implantation techniques may have an impact on blunting the rates of early and late scaffold failure.
- The EIJ document aims at disseminating harmonized criteria for BVS use, and to provide education and practical advice in a field where evidence is rapidly accumulating.

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