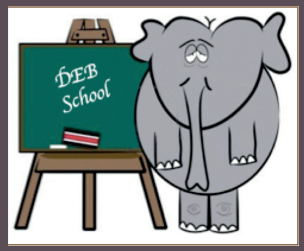
CRT17 CARDIOVASCULAR RESEARCH TECHNOLOGIES



BRS in STEMI: Rationale and Technique Differences Compared to Stable Lesions

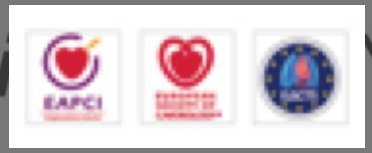
Bernardo Cortese, MD, FESC

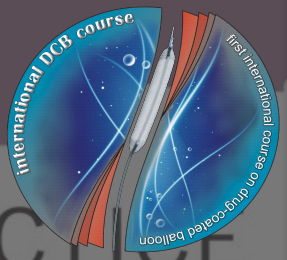
Intv' Cardiology, A.O. Fatebenefratelli MI

CNR-Fondazione Monasterio-Regione Toscana

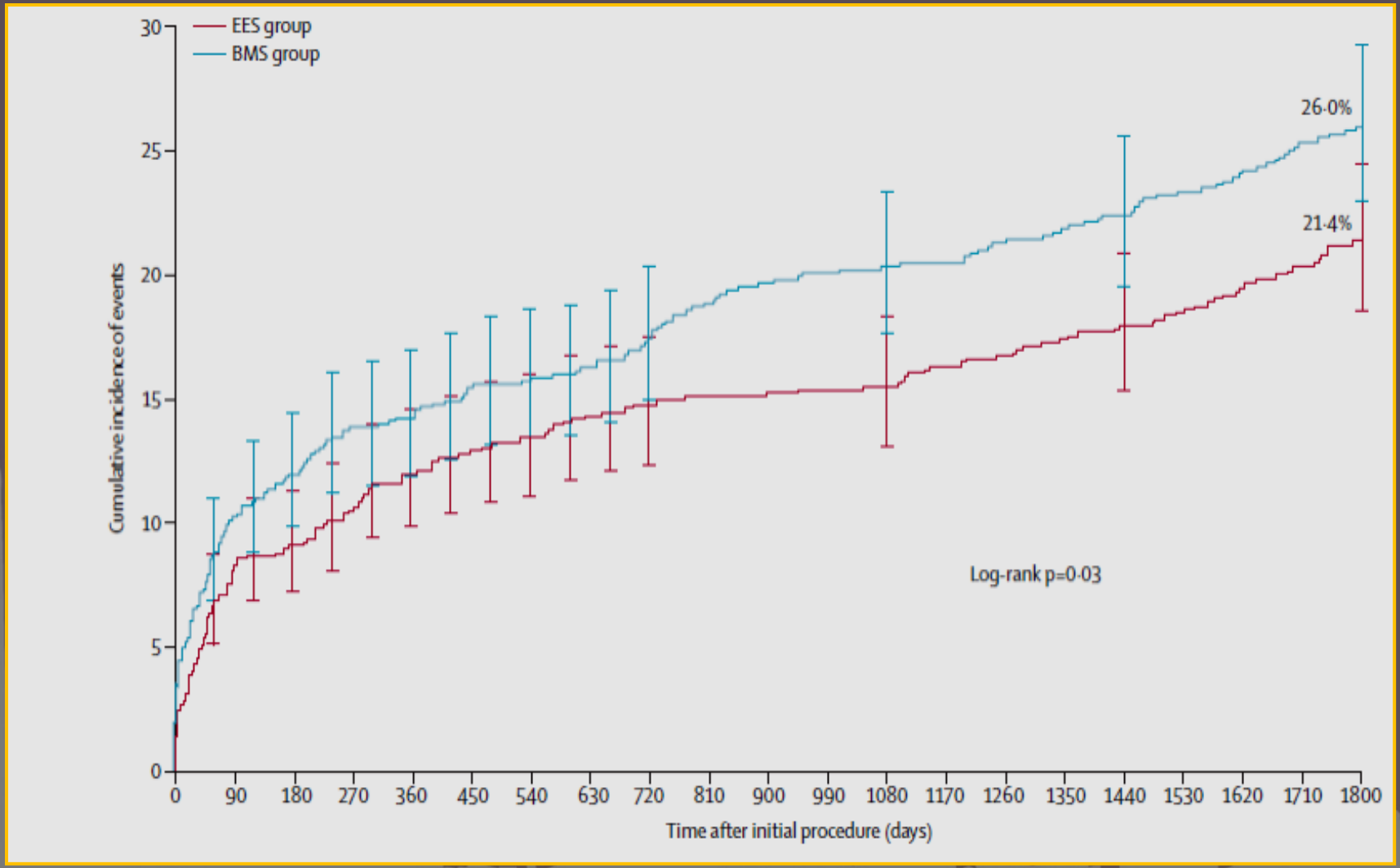
bcortese@gmail.com

bernardocortese.com



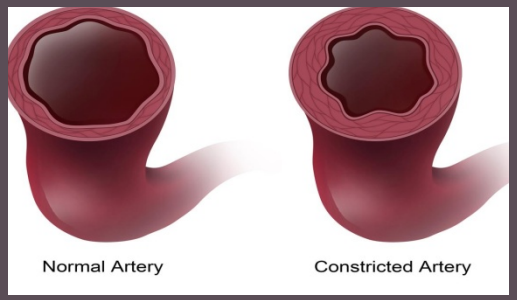


A YOUR PRACTICE



Sabatè M et al Lancet 2016 23; 387: 357-66

BRS and STEMI-open issues



Soft Plaque and Thrombus

Vasoconstriction

Distal embolization

Direct stenting

Difficult vessel/stent sizing

Slow/No-reflow

Malapposition

Worse Outcome

Is all of this affordable in the "PSP" era?

CRT17 CARDIOVASCULAR RESEARCH TECHNOLOGIES

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 **(2.5-3.75 mm)**
- Select appropriate scaffold for "best fit"

P POST-DILATE

OBJECTIVE

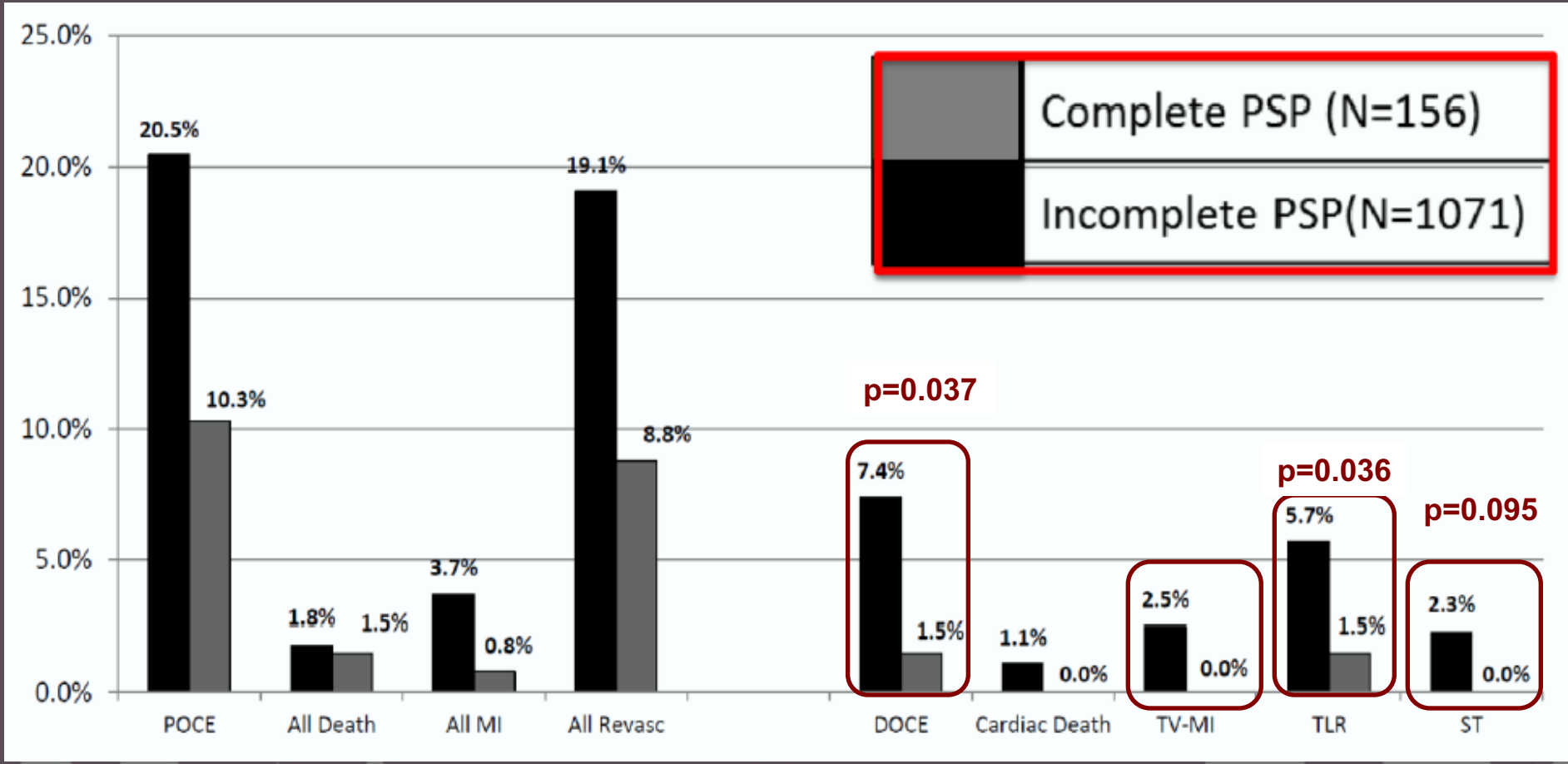
- Achieve **<10% final residual stenosis**
- Ensure full strut apposition

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.

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.

GHOST-EU "PSP" subanalysis



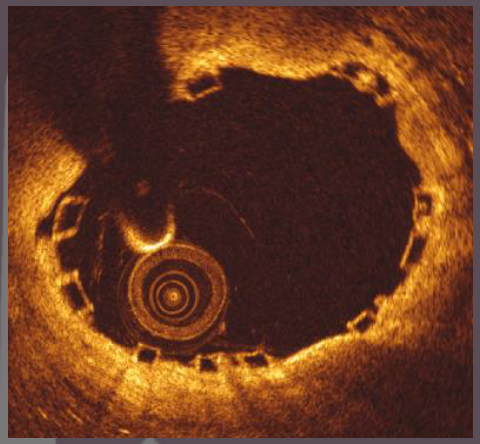
*Adjusted for multivariate propensity score model
Brugaletta S TCT 2016

iMPACT YOUR PRACTICE

First Generation BRS (CE Mark)

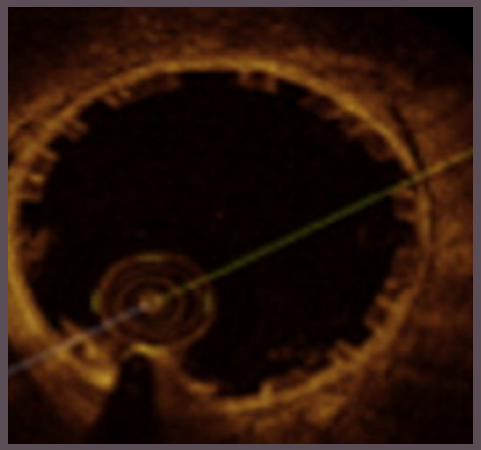
ABSORB BVS
Abbott Vascular

Poly-L-lactic acid
157 µn
Crossing profile ~1.5 mm
Absorption time 3 years
U.S. Japan and China approval



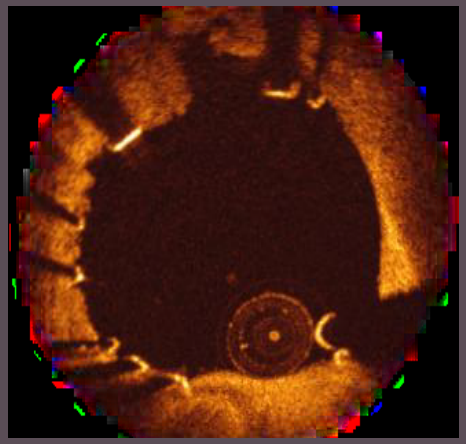
DESolve
Elixir

Poly-L-lactic acid
150 µn
Crossing profile ~1.5 mm
Absorption time: 2 years



MagMaris
Biotronik

Magnesium
150 µn
Crossing profile ~1.5 mm
Absorption time: 1 year



Rationale of BRS in STEMI

Patient Related Factors

1. Younger (vs. NSTEMI/stable CAD);
2. Less extensive and severe CAD (vs. NSTEMI/stable CAD);

"Culprit" Lesion Related Factors

1. Proximal segments localization;
2. Lipid-rich soft necrotic core of the vulnerable plaque;
3. Less calcific lesions

Device Related Factors

1. "Snow racket concept" (ABSORB BVS)

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BVS in STEMI patients: "Registro ABSORB Italiano" (RAI registry)

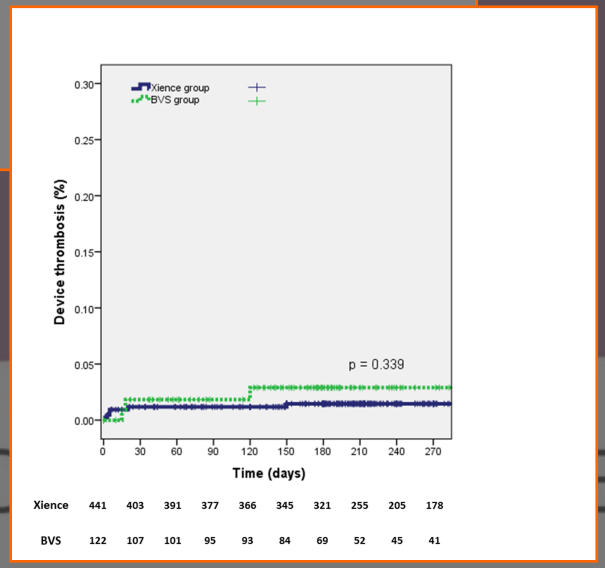
Table 4. In-hospital and midterm outcomes.

Patients, n (%)		Overall BVS n=74
In-hospital	Death	0
	Urgent CABG	0
	Q-wave MI	1 (1.3)
	TLR	1 (1.3)
	Definite/probable ST	1 (1.3)
Antiplatelet regimen at discharge	Cardioaspirin 100 mg/Clopidogrel 75 mg	39 (52.7)
	Cardioaspirin 100 mg/Ticagrelor 90 mg bid	24 (32.4)
	Cardioaspirin 100 mg/Prasugrel 10 mg	11 (14.9)
	Dual antiplatelet and warfarin	3 (4.1)
	Angiographic follow-up	5 (6.7)
6-month follow-up events	Death	0
	MI	2 (2.7)
	TVR	0
	TLR	3 (4.1)
	CABG	0
	Definite/probable ST	1 (1.3)

Ielasi/Cortese, Eurointervention '14

BVS vs EES in STEMI: results from the RAI registry (n=563 pts)

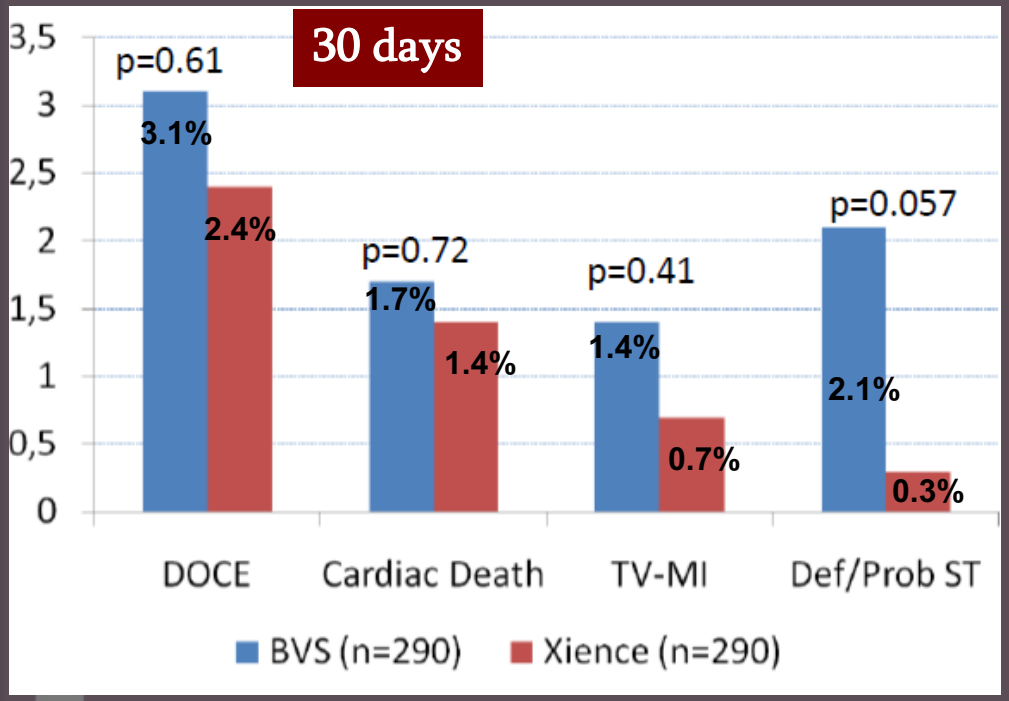
	BVS (n=122)	*EES (n=441)*	*p*
Procedural success	99.3%	97%	0.2
8-mo fup (*220 days, IQR-178-369*):			
POCE	4.9%	7%	0.4
Myocardial infarction	4.1%	2%	0.2
Death	0.8%	2%	0.4
TLR	4.1%		
Device thrombosis	2.5%		

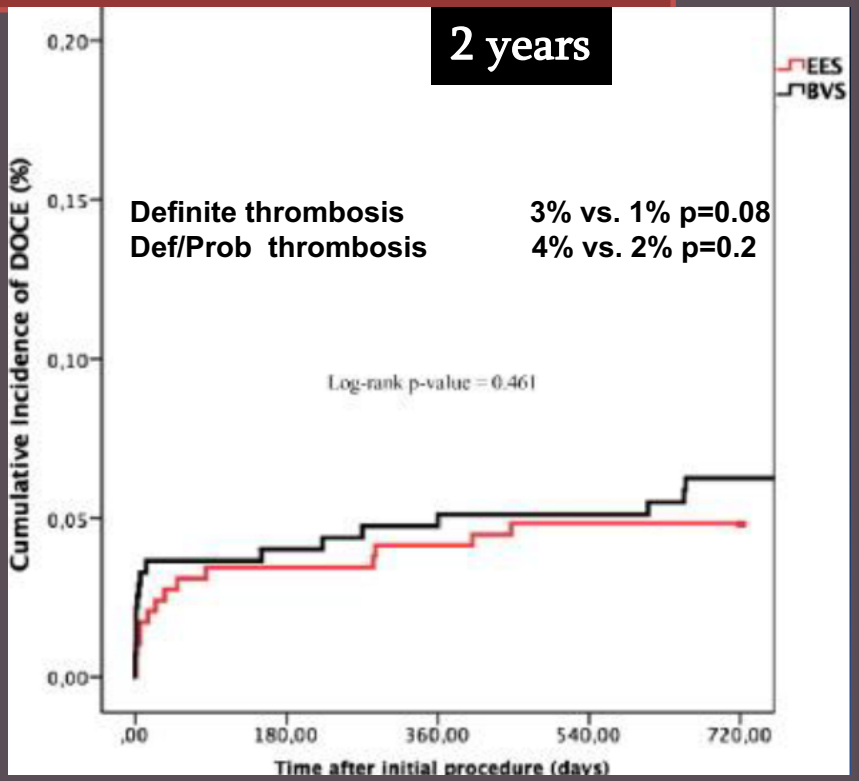


Cortese, AJC 2015

BVS in STEMI Propensity Match:

BVS EXAMINATION





Thrombus aspiration:	BVS vs. EES	75% vs. 69%	
Pre-dilatation:	BVS vs. EES	81% vs. 29%	p<0.001
Post-dilatation:	BVS vs. EES	36% vs. 11.8%	p<0.001
Final TIMI 3 flow:	BVS vs. EES	94.8% vs. 95.5%	
DAPT?/IC Imaging			

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Brugaletta et al, JACC Int 15

TROFI II

	Absorb N=95 (%)		EES N=96 (%)		p value
	6-month	2-year	6-month	2-year	6M 2Y
DOCE	1 (1.1)	3 (3.2)	0 (0)	3 (3.2)	0.31 0.97
Cardiac Death	0 (0)	1 (1.1)	0 (0)	0 (0)	NA 0.31
TV-MI	1 (1.1)	2 (2.1)	0 (0)	3 (3.2)	0.31 0.68
CI-TLR	1 (1.1)	2 (2.1)	0 (0)	1 (1.0)	0.31 0.55
All-cause Death	0 (0)	1 (1.1)	0 (0)	1 (1.0)	NA 0.99
Any MI	1 (0)	3 (3.2)	0 (0)	3 (3.2)	NA 0.99
All Revascularization	4 (4.2)	8 (8.4)	4 (4.2)	9 (9.5)	0.97 0.84

Sabatè M TCT 2016

BVS Implantation Technique:
All STEMIs are not Equal

	BVS STEMI First	BVS Prague-19	RAI BVS STEMI	Cortese BVS vs. EES	BVS EXAMINATION BVS EES BMS	TROFI II BVS vs. EES	EXAMINATION EES vs. BMS	COMFORTABLE AMI BES vs. BMS
TECHNICAL ASPECTS								
Thrombus Aspiration, %	78%	38%	43.2%	50% vs. 53%	75% vs. 69% vs. 68%	81% vs. 73%	66% vs. 64%	61% vs. 64%
Pre-dilatation, %	67%	85%	90.5%	94% vs. 60%	81% vs. 29% vs. 30.5%	56% vs. 51%	40% vs 42%	62% vs. 63%
Post-dilatation, %	20%	31%	93.2%	94% vs. 38%	36% vs. 11% vs. 10%	50% vs. 25%	16% vs. 14%	NA
Final TIMI 3 flow, %	92%	95%	98.6%	99% vs. 98%	95% vs. 95% vs. 95%	100% vs. 98%	92% vs. 94%	96% vs. 95%
Intracoronary imaging , %	100%	51.2%	2.7%	4.4% vs. 0.4%	NA	100%	NA	NA
RESULTS								
30 days def/prob thrombosis, %	0	2.5%	1.3%	0.9% vs. 0.2%	2.1% vs. 0.3% vs. 1.0%	1.1% vs. 0%	0.8% vs. 2.1%	only 1 year data
30 days DOCE, %	0	2.5%	2.7%	0.9% vs. 2.0%	3.1% vs. 2.4 vs. 2.8%	1.1% vs. 0%	2.7% vs. 5.1%	only 1 year data

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BVS STEMI STRATEGY-IT

STEMI with symptoms onset <12 hours, <75 y.o.

Original Studies

A Prospective Evaluation of a Standardized Strategy for the Use of a Polymeric Everolimus-Eluting Bioresorbable Scaffold in ST-Segment Elevation Myocardial Infarction: Rationale and Design of the BVS STEMI STRATEGY-IT Study

Alfonso Ielasi,[1*] MD, FESC, Attilio Varricchio,[2] MD, Gianluca Campo,[3] MD, PhD, Massimo Leoncini,[4] MD, Bernardo Cortese,[5] MD, Paolo Vicinelli,[6] MD, Salvatore Brugaletta,[7] MD, PhD, Fortunato Scotto di Uccio,[8] MD, Azeem Latib,[9] MD, and Maurizio Tespili,[1] MD

500 patients enrolled
-EuroPCR LBCT submitted

Catheter Cardiovasc Interv 2016

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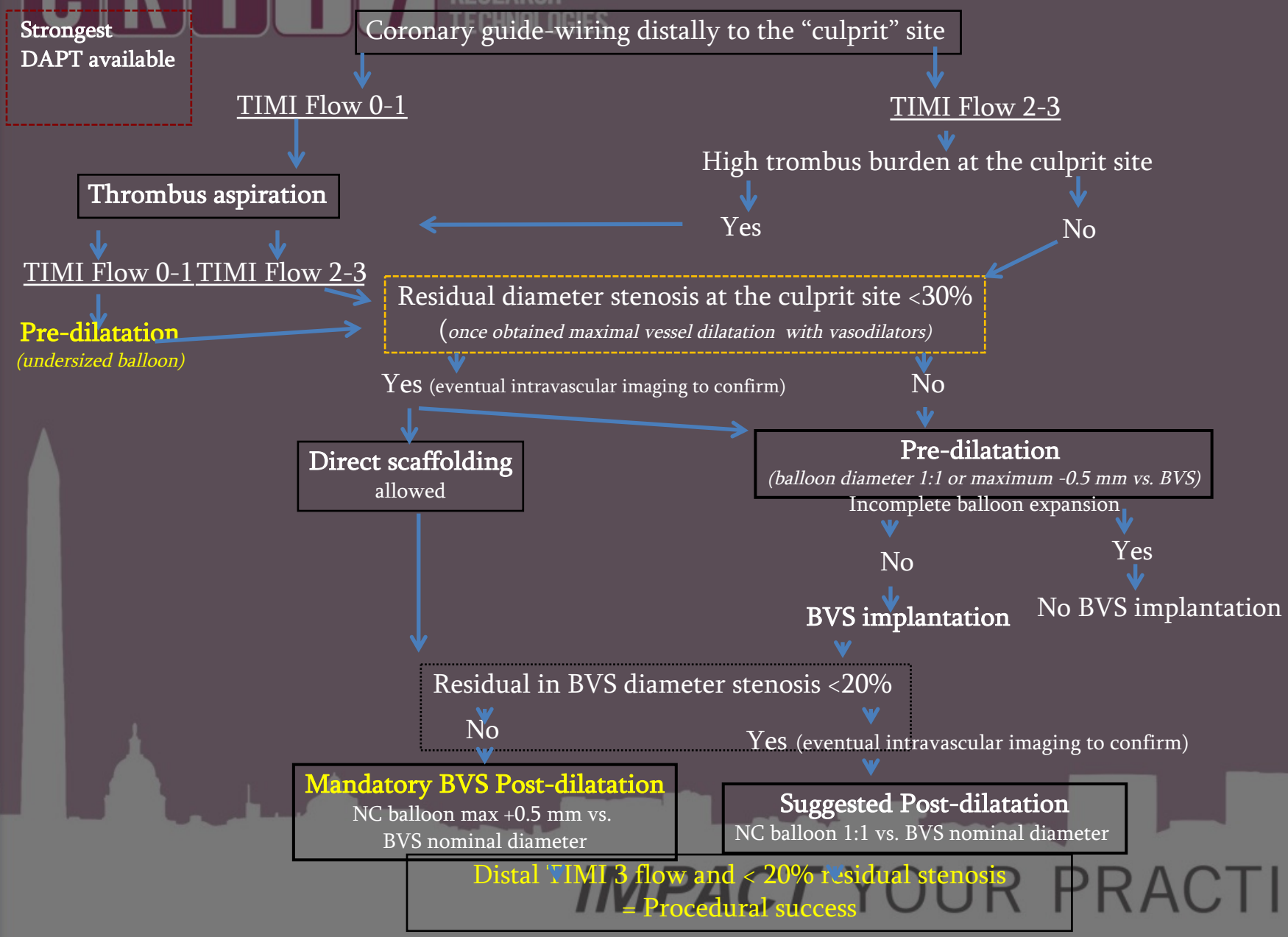
BVS STEMI STRATEGY-IT: the strategy



IMPACT YOUR PRACTICE

BVS STEMI STRATEGY-IT

-DAPT recommended at least 12 months

-after TCT ’16 possibly at least 24 months

-**Primary endpoint**: 30-d DOCE (cardiac death, target vessel myocardial infarction [TV-MI], ischemic driven TLR)

iMPACT YOUR PRACTICE

BRS in STEMI-CONCLUSIONS

- BVS is theoretically a good tool for PPCI (pts and lesions subsets, mechanical proprts)
- Evidence still limited
- Good implantation techniques is important, as for stable lesions
- BVS STEMI STRATEGY-IT study
- Mandatory *head-to-head* comparison BRS (implanted following optimal technique) vs. “best in class” DES