ANGIOPLASY SUMMIT 2016
TCT ASIA PACIFIC

Seoul, Korea: 26-29 April 2016

Live Cases & Lecture Session II. BRS

Tips and Tricks to optimize acute and long-term BRS outcomes

Speaker – 12'

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Centro Cuore Columbus and
S. Raffaele Scientific Institute, Milan, Italy

No conflicts to disclose

General perspective regarding current BRS

Do not expect they may lower the risk of Thrombosis or Restenosis

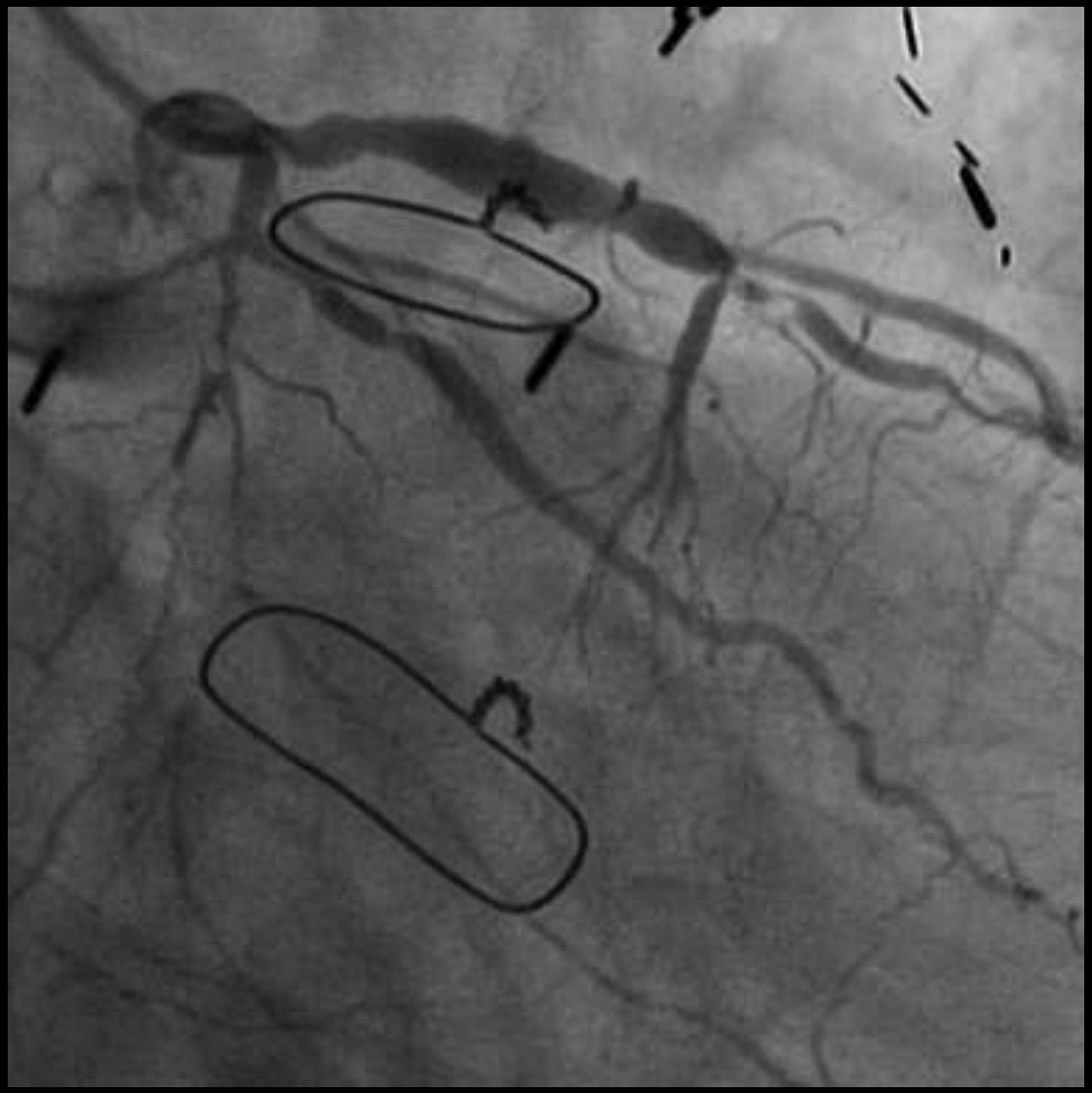
It is unlikely they will shorten the need for DAPT after 1 year unless you assume that DAPT needs to be continued long term following implantation of current DES

They will allow positive remodeling, maintain vessel reactivity and facilitate new procedures (PCI/CABG)

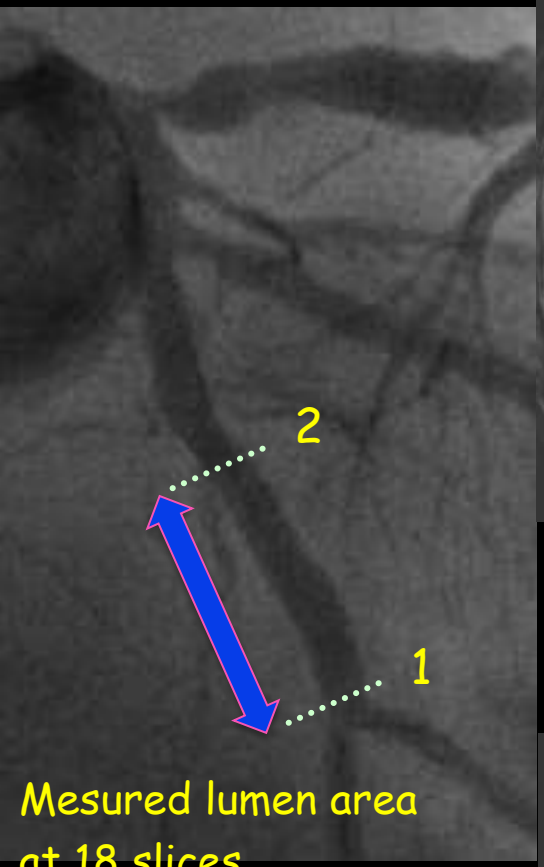
They allow easy evaluation by MSCT

They may lower the risk of very late Stent Thrombosis

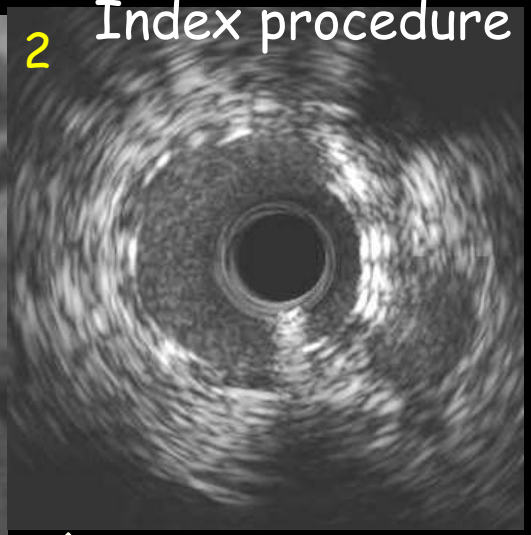
LCX CTO & IM stenosis



Lumen enlargement at CTO site

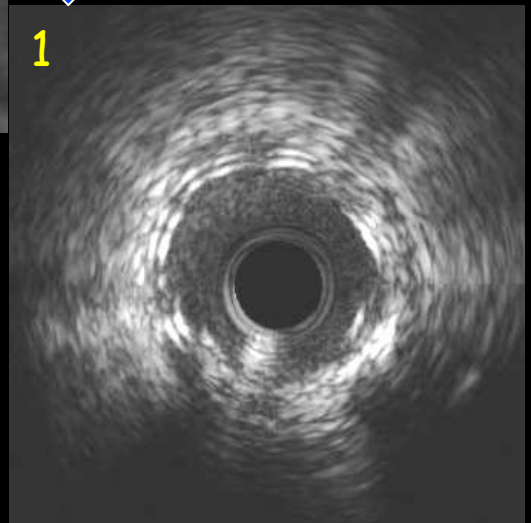


2 Index procedure

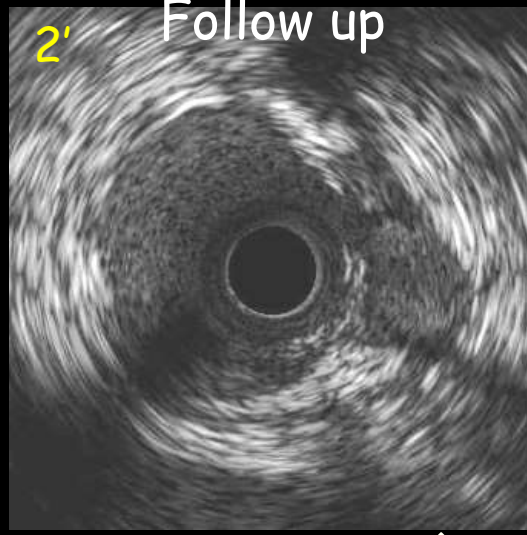


Mean lumen area
4.9 ± 0.2 mm²

1

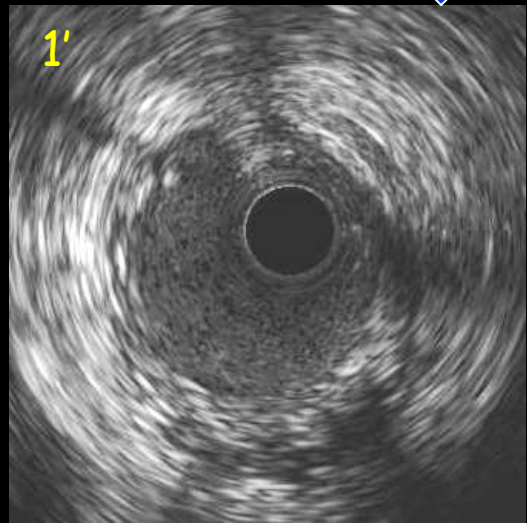


2′ Follow up

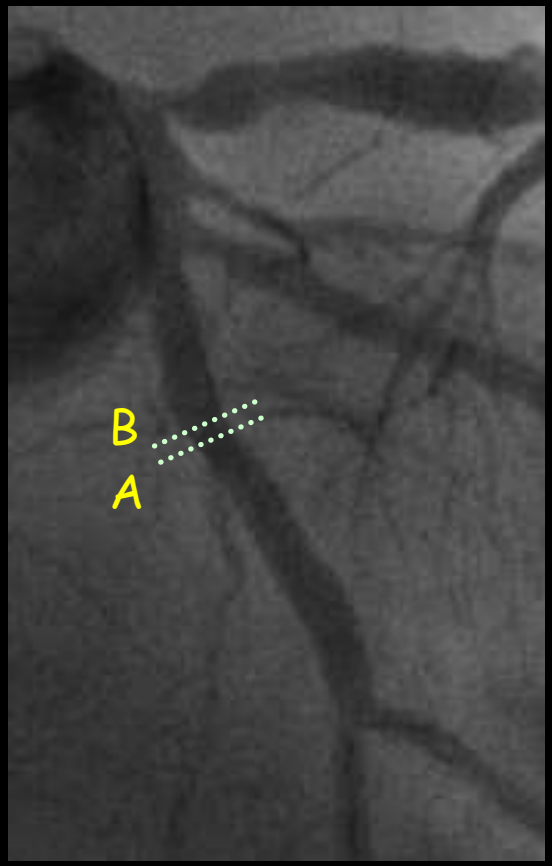


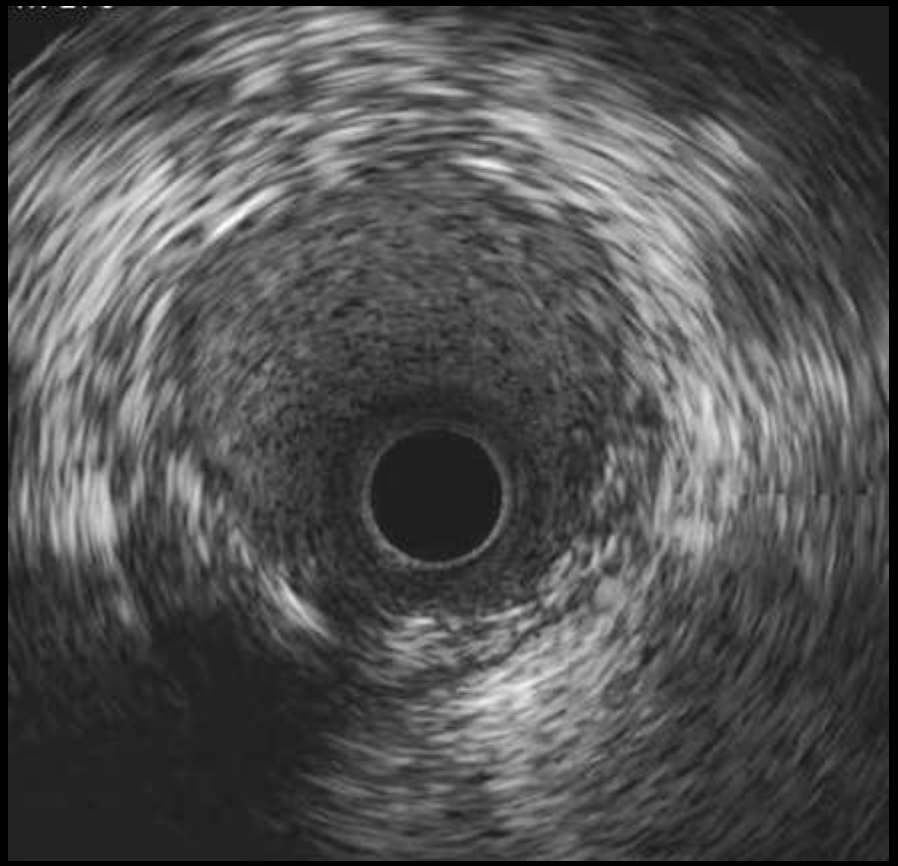
Mean lumen area
7.3 ± 0.9 mm²

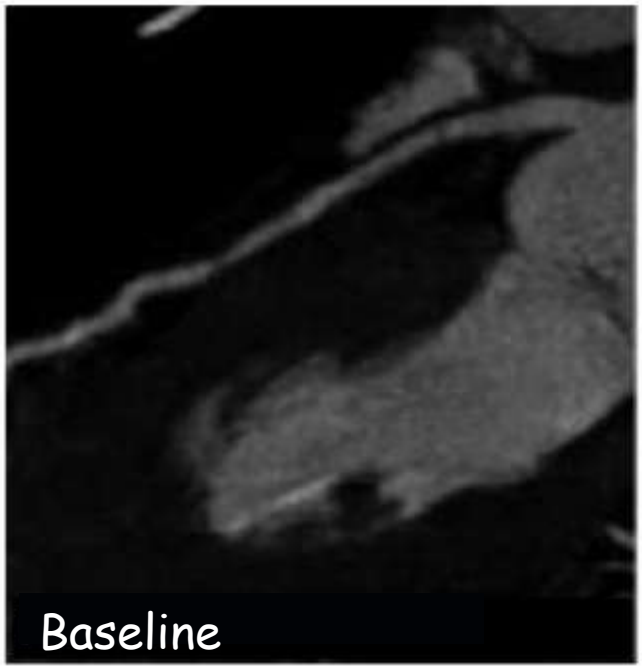
1′

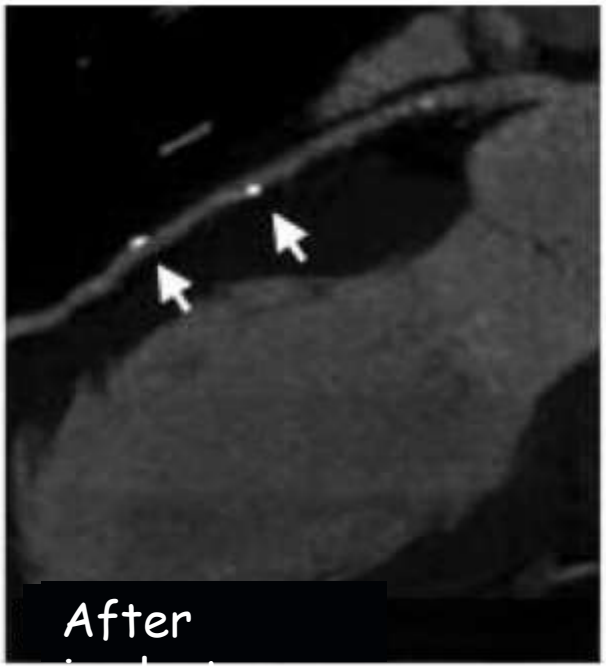


Pulsatile motion






Baseline


After implant


18 month FU

Lesion preparation

More important role for…

- BRS delivery
  - Larger crossing profile with bulky struts

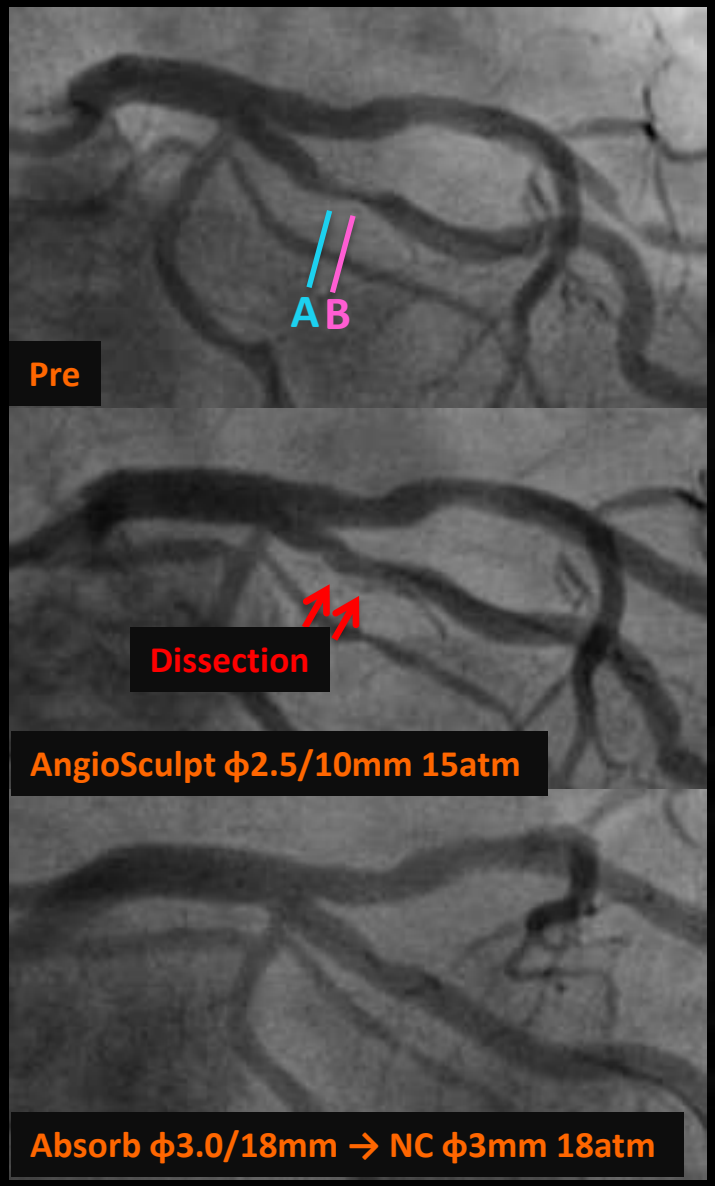
Ormiston et al. EuroIntervention 2015;11:60-67

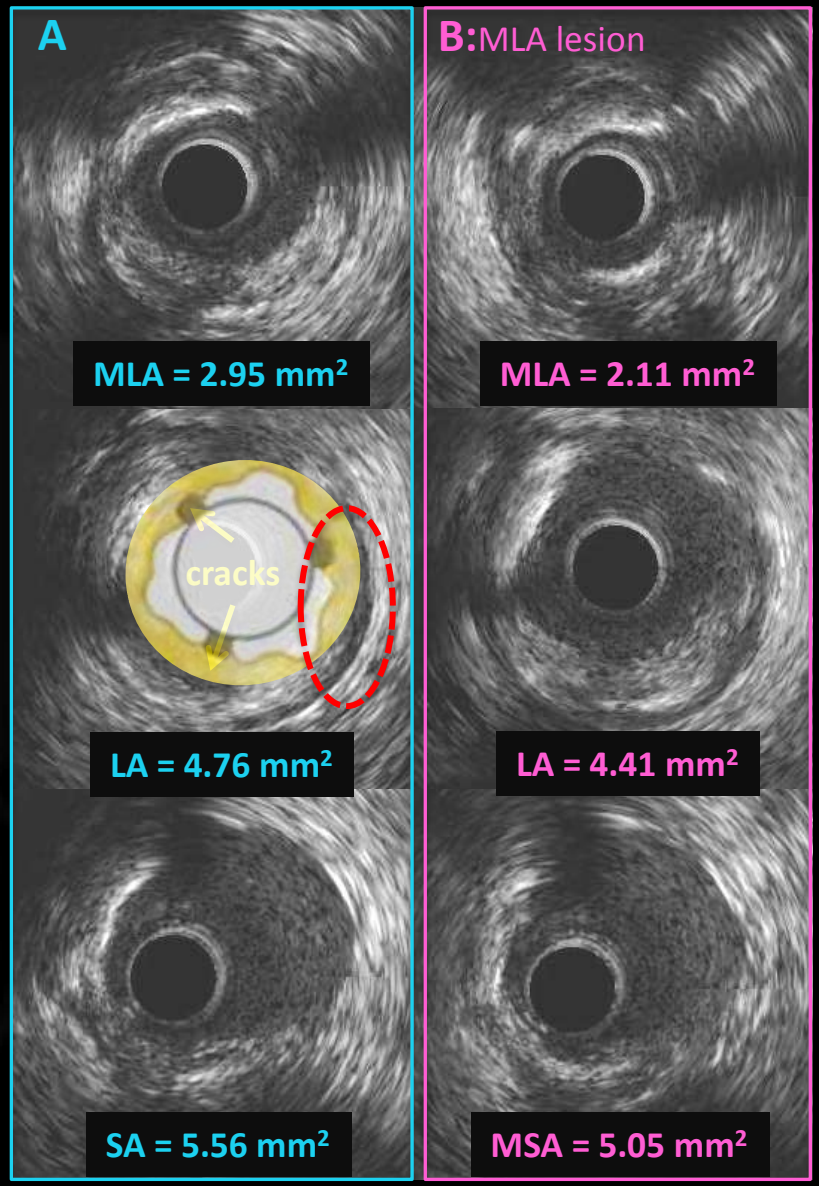
- Scaffold expansion
  - Less radial force and greater acute recoil
  - Inadequate lesion preparation may correlate with underexpansion

Brown et al. Cather Cardiovasc Interv 2014;84:37-45
Mattesini et al. J Am Coll Cardiol Intev 2014;7:741-750
Danzi et al. Cather Cardiovasc Interv 2015;

1:1 pre-dilatation with NC / Low threshold for debulking devices

Lesion preparation with Angiosculpt





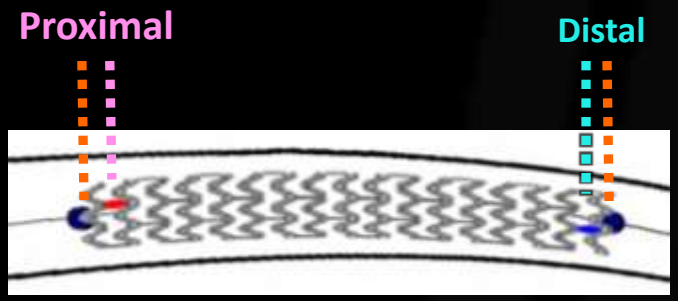
BRS deployment 1

- *Positioning / Minimize the overlap*
  - *Overlapping site (with bulky struts)* - Delayed neointimal coverage

Farooq et al. J Am Coll Cardiol Intev 2013; 6:523-532

- Greater thrombogenicity

Kolandaivelu et al. Circulation 2011;123:1400-9



	Expansion size	Balloon marker to scaffold marker (mm) Proximal	Distal
Absorb BRS ϕ2.5 or 3.0mm	Crimp	1.1	0.3
	2.5 mm	0.9	
	3.0 mm	0.9	
	3.5 mm	0.7	
Absorb BRS ϕ3.5mm	Crimp	1.4	0.3
	3.5 mm	1.1	
	4.0 mm	1.0	

It is important to know the marker position accurately

BRS deployment 2

- *Gentle deployment*

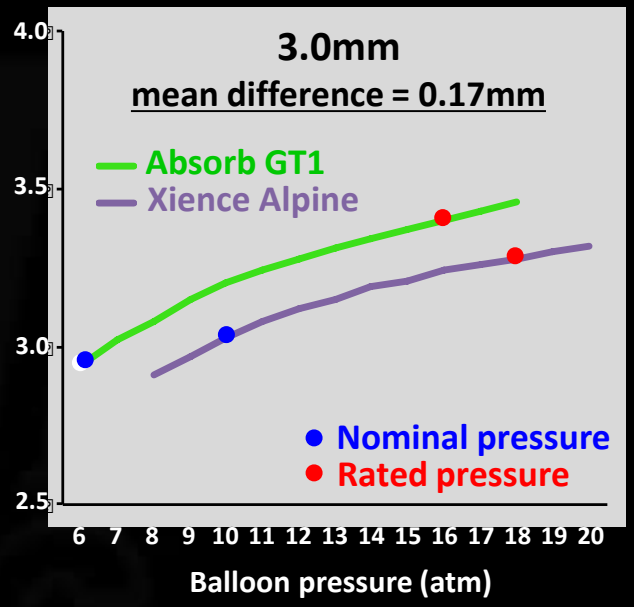
  - Very complaint delivery balloon

Kawamoto et al. Int J Cardiol 2016

Not recommended for use with high pressures

Unexpected balloon overexpansion/ elongation

→ Fracture, vessel injury



- ***Slow (2 atm per 5 sec) and long inflation (more than 30 seconds)***
- ***Avoid high-pressures with delivery balloon***

Post-dilatation

➢ *Importance of Post-dilatation*

- Acute lumen gain is lower for current BRS than metallic stents with similar pressures even in simplest lesion subset *Ellis et al. N Eng J Med 2015/Kimura et al. Eur Heart J 2015 Gao et al. J Am Coll Cardiol 2015/Serruys et al. Lancet 2015*
- High post-dilatation rates (over 90%) and pressures (over 20 atm) were associated with lower rates of ST *Caiazzo et al. Int J Cardiol 2015:201;129-136*

➢ *Risk with Overexpansion*

- Overexpansion might cause strut disconnection and a focal loss of mechanical support *Foin et al. Eurointerv2015; Sep, Epub*

➢ ***Non-oversized NC balloon with high-pressure (over 20 atm)***

➢ ***Balloon/Scaffold diameter 1:1, maximum +0.5mm***

Intravascular imaging

- *To assist Sizing*
  - *BRS requires more careful sizing* ✓ More difficult to correct after deployment

    - Undersize ⟶ Malapposition ➡ ✓ ST risk

    Lorenz et al. J Am Coll Cardiol 2015:66:1901-14
    Karanasos et al. Circ Cardiovasc Interv. 2015; 8:e002369

    - Oversize ⟶ Increased foot print ➡ ✓ Worse clinical outcomes
      ✓ Side branch occlusion

    Kawamoto et al. J Am Coll Cardiol Intev 2016;Feb
    Ishibashi et al. J Am Coll Cardiol Intev2015;8:1715-1726
    Muramatsu et al. J Am Coll Cardiol Intev2013:6;247-57

- *End of procedure*

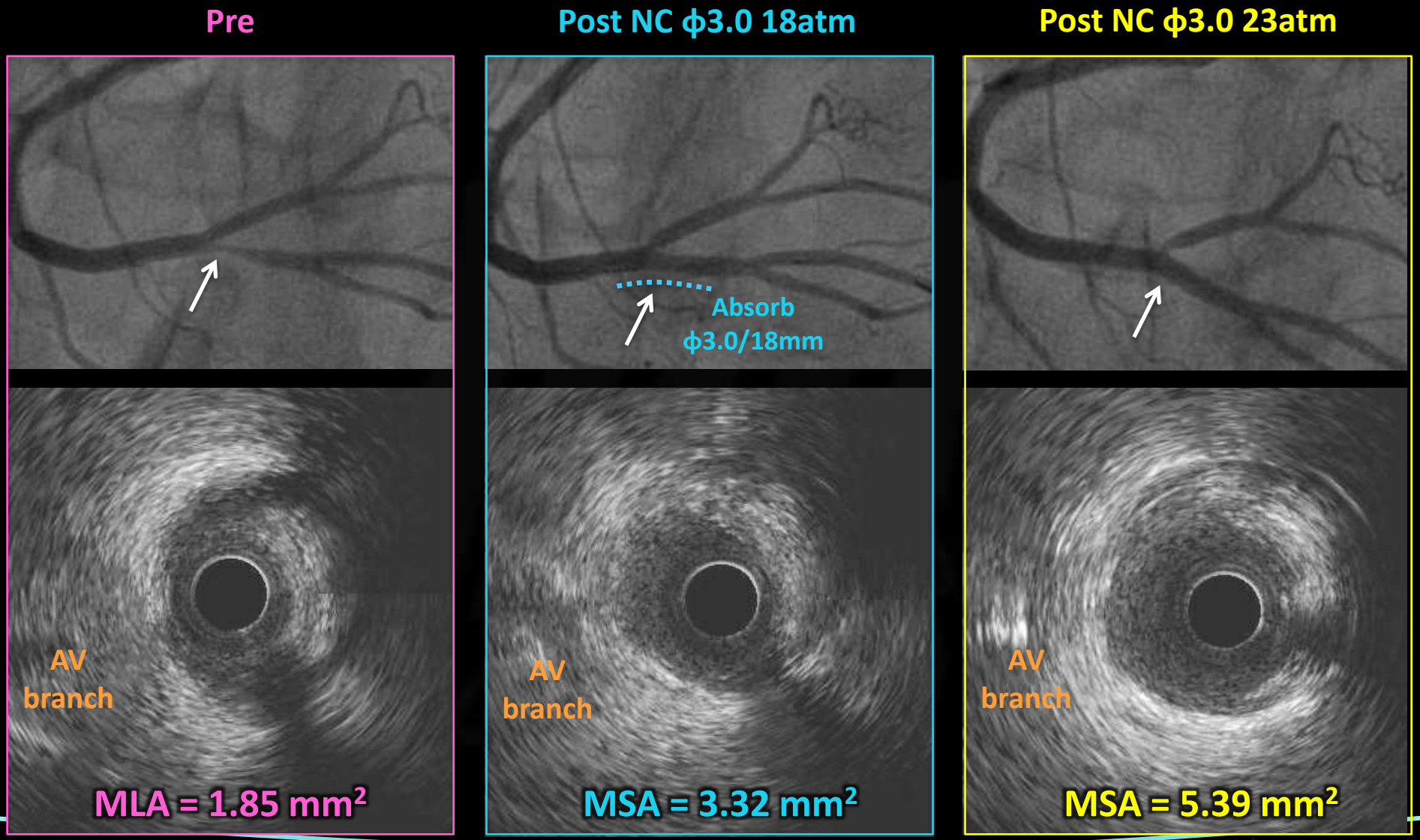
To detect… *-Underexpansion:* more common with BRS

-Edge injury: more common(?) due to the need for more aggressive pre- and post-dilatation

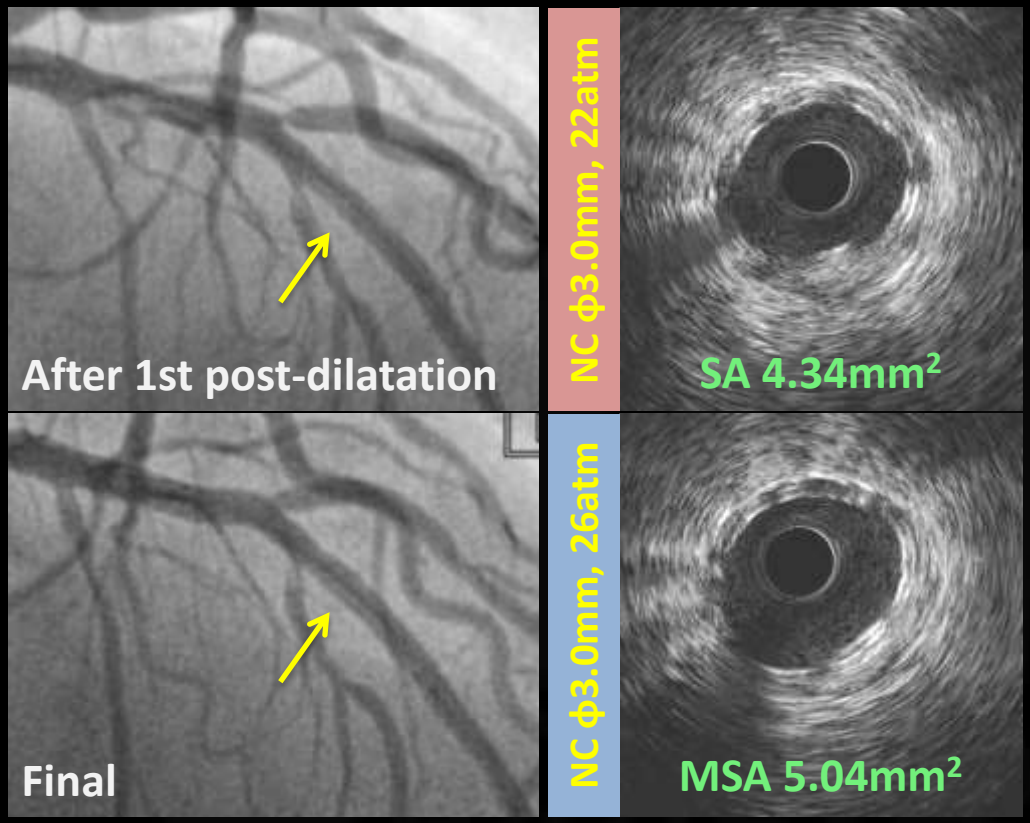
-Malapposition

Low threshold for Intravascular imaging especially at procedure end

IVUS images


Pre
Post NC ϕ3.0 18atm
Post NC ϕ3.0 23atm
Absorb
ϕ3.0/18mm
AV
branch
AV
branch
AV
branch
MLA = 1.85 mm²
MSA = 3.32 mm²
MSA = 5.39 mm²

Impact of Final IVUS and aggressive post-dilatation



Lumen diameter
2.10 x 2.58mm

Lumen diameter
2.28 x 2.78mm

BRS expansion should be evaluated even after high-pressure post-dilatation in a fibrous lesion.

Milan BVS experience

400 lesions in 264 patients with Absorb BRS

- **San Raffaele Scientific Institute**
- **EMO GVM Centro Cuore Columbus**
- **Milan, Italy**

Patients characteristics

	N=264 patients
Age (years)	63.5±10.5
Male, n (%)	236 (89.4%)
Hypertension, n (%)	167 (63.3%)
Dyslipidemia, n (%)	165 (62.5%)
Diabetes mellitus, n (%)	69 (26.1%)
Current smoker, n (%)	39 (14.8%)
Family history of CAD, n (%)	99 (37.5%)
Prior PCI, n (%)	116 (43.9%)
Prior CABG, n (%)	15 (5.7%)
Prior MI, n (%)	72 (27.3%)
eGFR<60, n (%)	49 (18.6%)
Ejection fraction (%)	55.2±8.7
SYNTAX score	17.1±10.4
Clinical presentation, n (%)	
Stable angina	228 (86.4%)
Unstable angina	31 (11.7%)
STMI/NSTEMI	5 (1.9%)

Lesion characteristics

Lesion	N=400 lesion, 264 Pt
Target vessel	
LAD	248 (62.0%)
LCX	79 (19.8%)
RCA	61 (15.3%)
LMT	10 (2.5%)
SVG	2 (0.5%)
No of target lesions per patient	1.5±0.8
No of target vessels per patient (1/2/3)	195 (73.9%)/63 (23.9%)/6 (2.2%)
ACC/AHA class B2orC	299 (74.8%)
Bifurcation, n (%)	187 (46.8%)
In-stent restenosis, n (%)	19 (4.8%)
Chronic total occlusion, n (%)	25 (6.3%)
Severe calcification	90 (22.5%)

	ABSORB III	Ghost EU
ACC/AHA class B2orC	68.7%	53.5%
Bifurcation, n (%)	exclusion	23.1%

Procedural characteristics

Lesion preparation	
Pre-dilatation, n (%)	389 (97.3%)
Scoring or Cutting balloon	61 (15.3%)
Rotablator, n (%)	19 (4.8%)
Scaffold implantation	
Total scaffold number	1.5±0.7
Total scaffold length (mm)	35.2±19.3
Average scaffold diameter, mm	3.05±0.35
Use of 2.5mm scaffold, n (%)	130 (32.5%)
Implantation pressure, atm	9.6±1.9
Total scaffold number per patient	2.3±1.3
Total scafflold length per patient, mm	53.2±32.5
Use of 2.5mm scaffold per patient, n(%)	116 (43.9%)
Post-dilation	
Post-dilation, n (%)	399 (99.8%)
Post-dilation pressure, atm	20.8±4.5
Post-dilation balloon/scaffold diameter ratio	1.04±0.08
Intravascular imaging	
Intravascular imaging use, n (%)	343 (85.8%)
Intravascular ultrasound, n (%)	328 (82.0%)
Optimal coherence tomography, n (%)	56 (14.0%)
Further intervention following imaging after post-dilation, n (%)	98 (24.5%)

	ABSORB III	Ghost EU
	20.5±7.2mm	32.6±23.0mm
	65.5%	49%
	11.2%	14.4%

EMO GVM CENTRO CUORE COLUMBUS s.r.l.

OSPEDALE SAN RAFFAELE

Clinical outcomes

median follow-up period of 544 (IQR 228 - 834) days

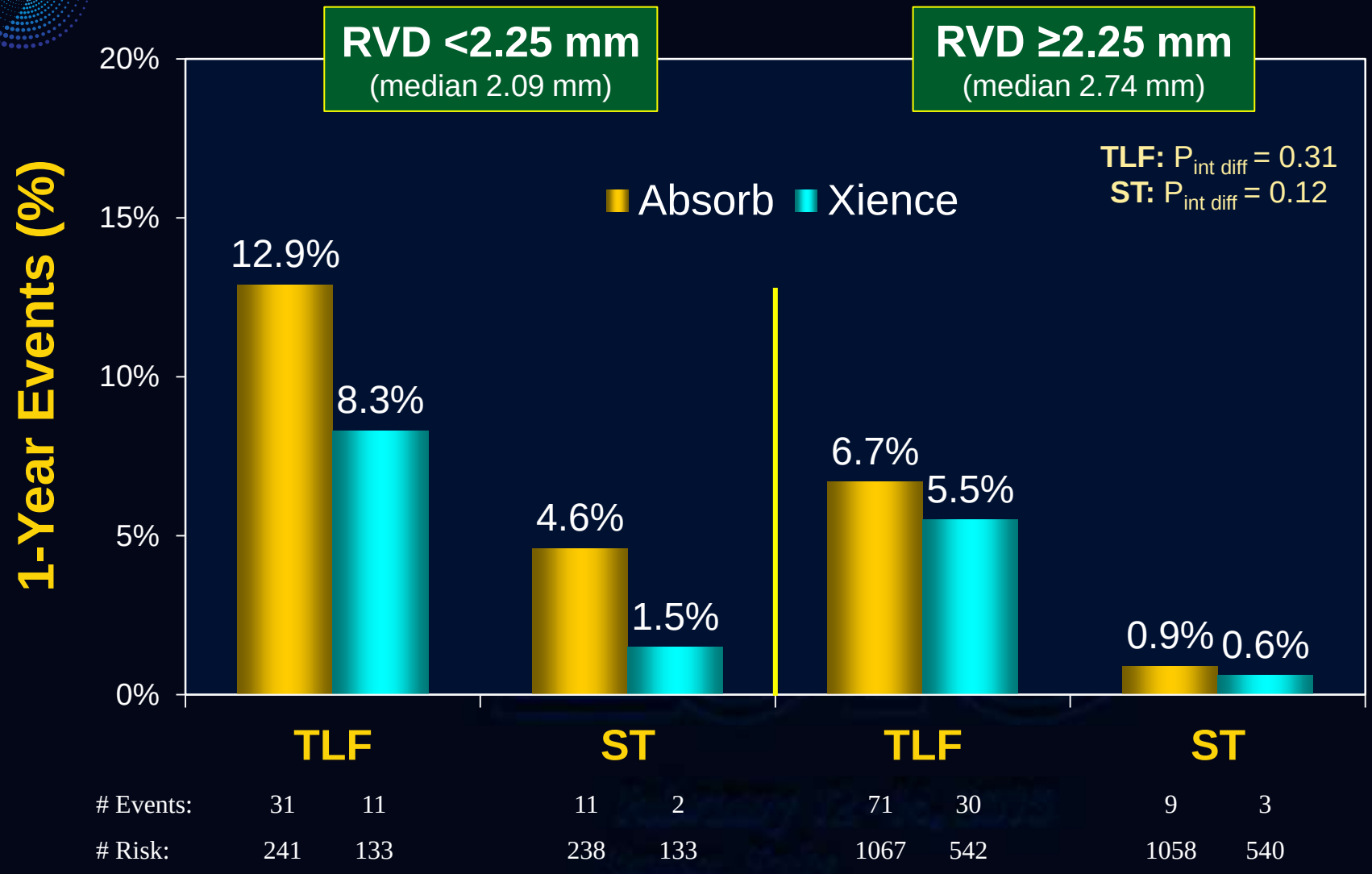
	1 year	ABSORB III	Ghost EU	2 year
Target lesion failure	17 (7.9%)	7.8%	4.4% at 6mo	22 (11.6%)
Cardiac death	3 (1.3%)			4 (2.0%)
Target vessel MI	4 (1.8%)			4 (1.8%)
TLR	14 (6.6%)			19 (10.4%)
Lesion complexity	Milan >>	ABSORB III	Ghost EU	
Optimal implantation	Milan >>	ABSORB III	Ghost EU	
All cause death	6 (2.8%)			7 (3.5%)
Any MI	5 (2.3%)			5 (2.3%)
TVR	17 (8.0%)			25 (13.8%)
Definite/probable ST	3 (1.2%) *			3 (1.2%)

Event rates are estimated using Kaplan-Meier analysis

*1 Acute ST (STEMI, day 0, on DAPT) 1 Subacute ST (day 3, BVS edge dissection)

1 Late ST (stable angina, day 146, the patient stopped clopidogrel at 2-month)

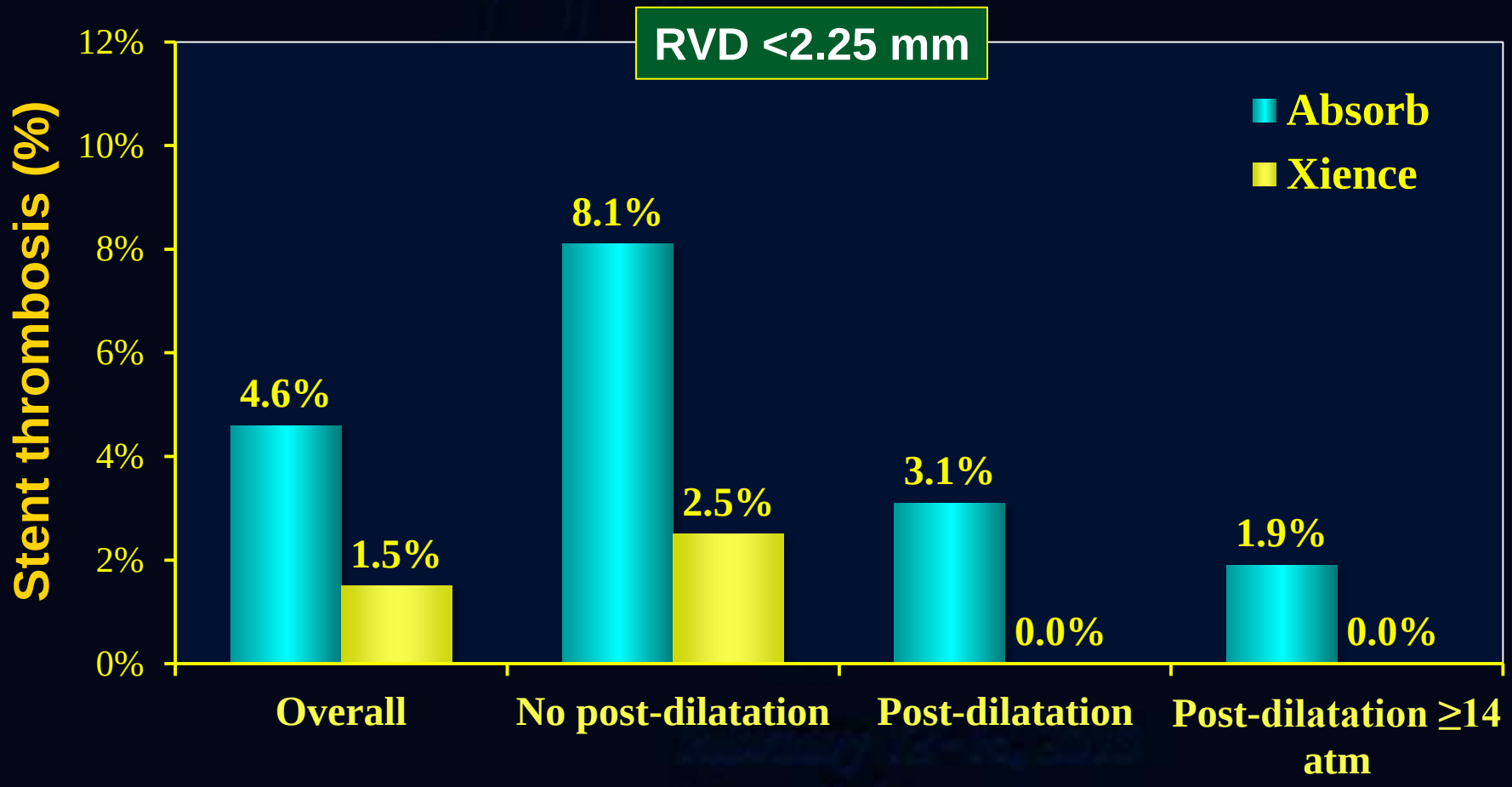
Outcomes by QCA RVD 2.25 mm



Median based on pooled Absorb and Xience

1-Year ST in Very Small Vessels

Impact of Post-Dilatation and Pressure



Absorb:	11 / 238	6/74	5 / 164	2 / 105
Xience:	2 / 133	2/79	0 / 54	0 / 36

2.5 mm Device Only*

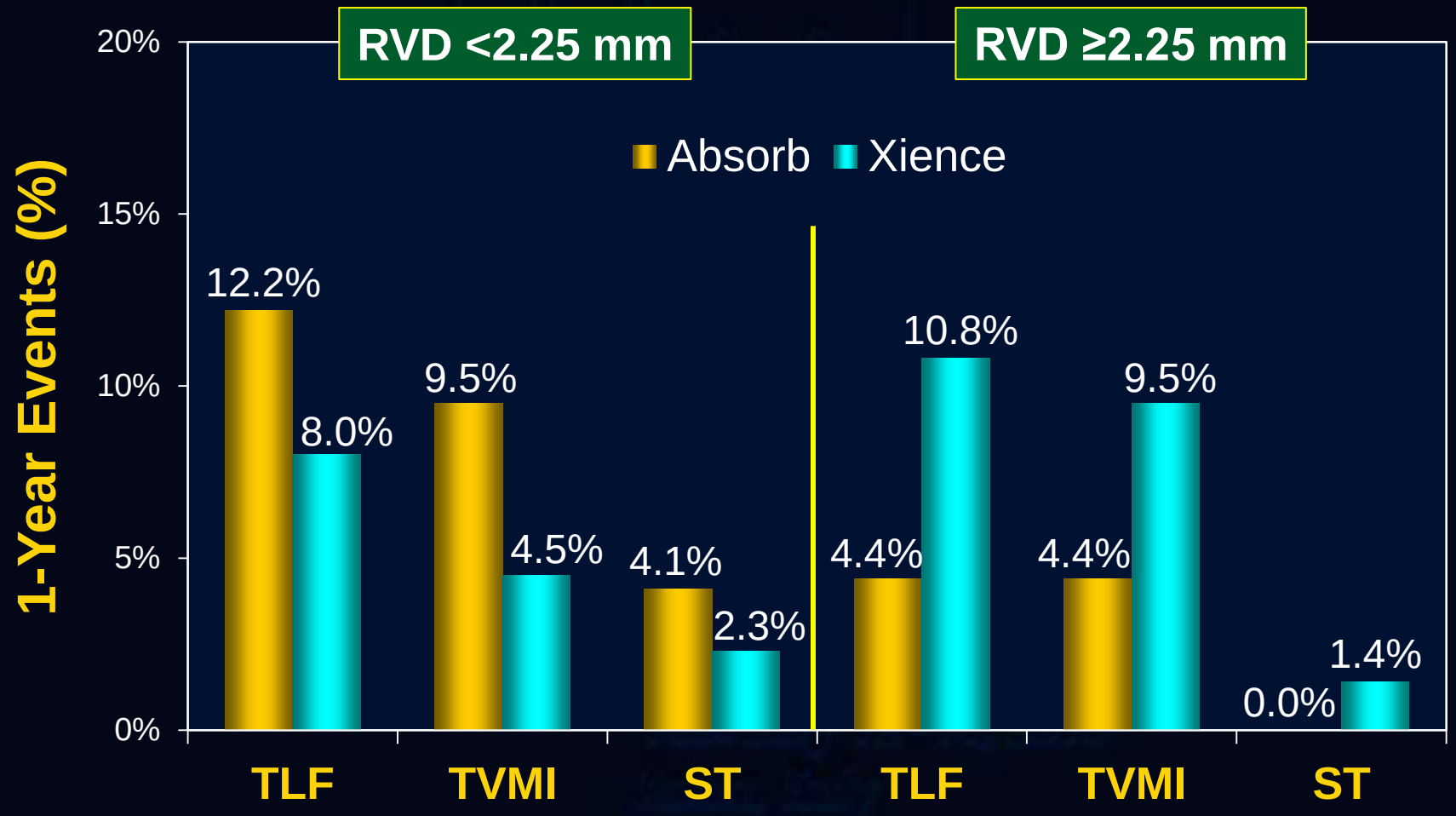
Target Lesion Failure

	Absorb N=285	Xience N=164	Relative Risk [95% CI]	p-value
TLF	8.5%	9.3%	0.91 [0.49, 1.69]	0.77
- Cardiac death	0.4%	0.6%	0.57 [0.04, 9.06]	1.00
- TV-MI	7.0%	6.8%	1.04 [0.51, 2.11]	0.92
- ID-TLR	4.2%	4.3%	0.98 [0.39, 2.43]	0.96

*As treated analysis

2.5 mm Device Treatment*

Events by QCA RVD



*As treated analysis

Ideal patient for BVS

- Diffuse disease of LAD requiring long stents

- Diffuse disease of any vessel 2.5 mm or larger requiring long stents

- Any lesion in a young patient

- Any lesion suitable for BVS