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OSPEDALE SAN RAFFAELE

BRS for Complex Lesions; Share the Experience

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Disclosure Statement of Financial Interest

I, [Alaide Chieffo], DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

MILAN EXPERIENCE

- Between May 2012 and August 2016, we treated 518 lesions in 340 patients with Absorb BVS in all-comer population in 2 centers

- Last follow-up at Nov-Dec 2016

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

Patients characteristics

	N=340
Age (years)	63.0±10.2
Male, n (%)	302 (88.8%)
Hypertension, n (%)	224 (65.9%)
Dyslipidemia, n (%)	209 (61.5%)
Diabetes mellitus, n (%)	87 (25.6%)
Insulin	20 (5.9%)
Current smoking, n (%)	51 (15.0%)
Family history of CAD, n (%)	129 (37.9%)
Prior PCI, n (%)	152 (44.7%)
Prior CABG, n (%)	17 (5.0%)
Prior MI, n (%)	93 (27.4%)
eGFR<60, n (%)	58 (17.1%)
Ejection fraction (%)	55.2±8.4
SYNTAX score	17.5±10.5
Clinical presentation, n (%)	
Stable angina	294 (86.5%)
Unstable angina	38 (11.2%)
STEMI/NSTEMI	8 (2.3%)

Lesion characteristics

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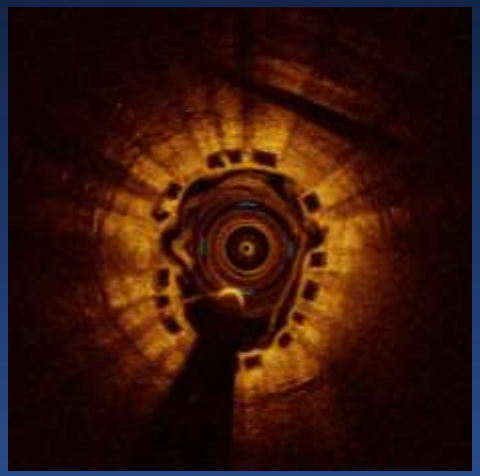
Lesion	N=518 lesion, 340 Pt
Target vessel	
LAD	311 (60.1%)
LCX	105 (20.2%)
RCA	84 (16.2%)
LMT	16 (3.1%)
SVG	2 (0.4%)
No of target lesions per patient	1.5±0.8
No of target vessels per patient (1/2/3)	250 (73.5%)/80 (23.5%)/ 10 (2.9%)
ACC/AHA class B2orC	394 (76.1%)
Bifurcation, n (%)	239 (46.1%)
In-stent restenosis, n (%)	20 (3.9%)
Chronic total occlusion, n (%)	32 (6.2%)
Severe calcification	117 (22.6%)

Procedural characteristics

Lesion preparation	
Pre-dilatation, n (%)	403 (97.1%)
Scoring or Cutting balloon, n (%)	85 (16.4%)
Rotablator, n (%)	19 (3.7%)
Laser, n (%)	5 (1.0%)
Scaffold implantation	
Total scaffold number per lesion	1.5±0.7
Total scaffold length per lesion, mm	35.3±19.4
Average scaffold diameter, mm	3.05±0.35
Use of 2.5mm scaffold per lesion, n (%)	171 (33.0%)
Implantation pressure, atm	9.4±1.7
Total scaffold number per patient	2.3±1.4
Total scaffold length per patient, mm	53.8±33.5
Use of 2.5mm scaffold per patient, n(%)	152 (44.7%)
Post-dilation	
Post-dilation, n (%)	517 (99.8%)
Post-dilation pressure, atm	21.0±4.3
Post-dilation balloon/scaffold diameter ratio	1.03±0.09
Intravascular imaging	
Intravascular imaging use, n (%)	446 (86.1%)
Intravascular ultrasound, n (%)	422 (81.5%)
Optimal coherence tomography, n (%)	76 (14.7%)
Further intervention based on imaging after post-dilation	122 (23.6%)

Intravascular imaging

- Angiographic assessment often underestimates vessel diameter in diffuse lesion
- When treating diffuse lesions with current BVS, Intravascular imaging should be important before deployment to confirm lumen/ vessel diameter



Clinical outcomes

Median F-U 706 days (IQR 355 - 1088): Clinical FU 98.5%

	1 year	*2 year*	*3 year*
Target lesion failure	21 (7.0%)	31 (12.1%)	34 (14.7%)
Cardiac death	3 (1.0%)	5 (2.0%)	5 (2.0%)
Target vessel MI	5 (1.6%)	6 (2.1%)	6 (2.1%)
TLR	18 (6.1%)	27 (10.6%)	30 (13.3%)
All cause death	6 (2.0%)	8 (3.0%)	8 (3.0%)
Any MI	6 (2.0%)	8 (3.0%)	8 (3.0%)
TVR	23 (7.7%)	36 (14.1%)	40 (17.4%)
TLR per lesion	21 (4.7%)	31 (8.1%)	35 (10.4%)
Definite/probable ST	4 (1.2%) *	4 (1.2%)	4 (1.2%)

Event rates are estimated using Kaplan-Meier analysis

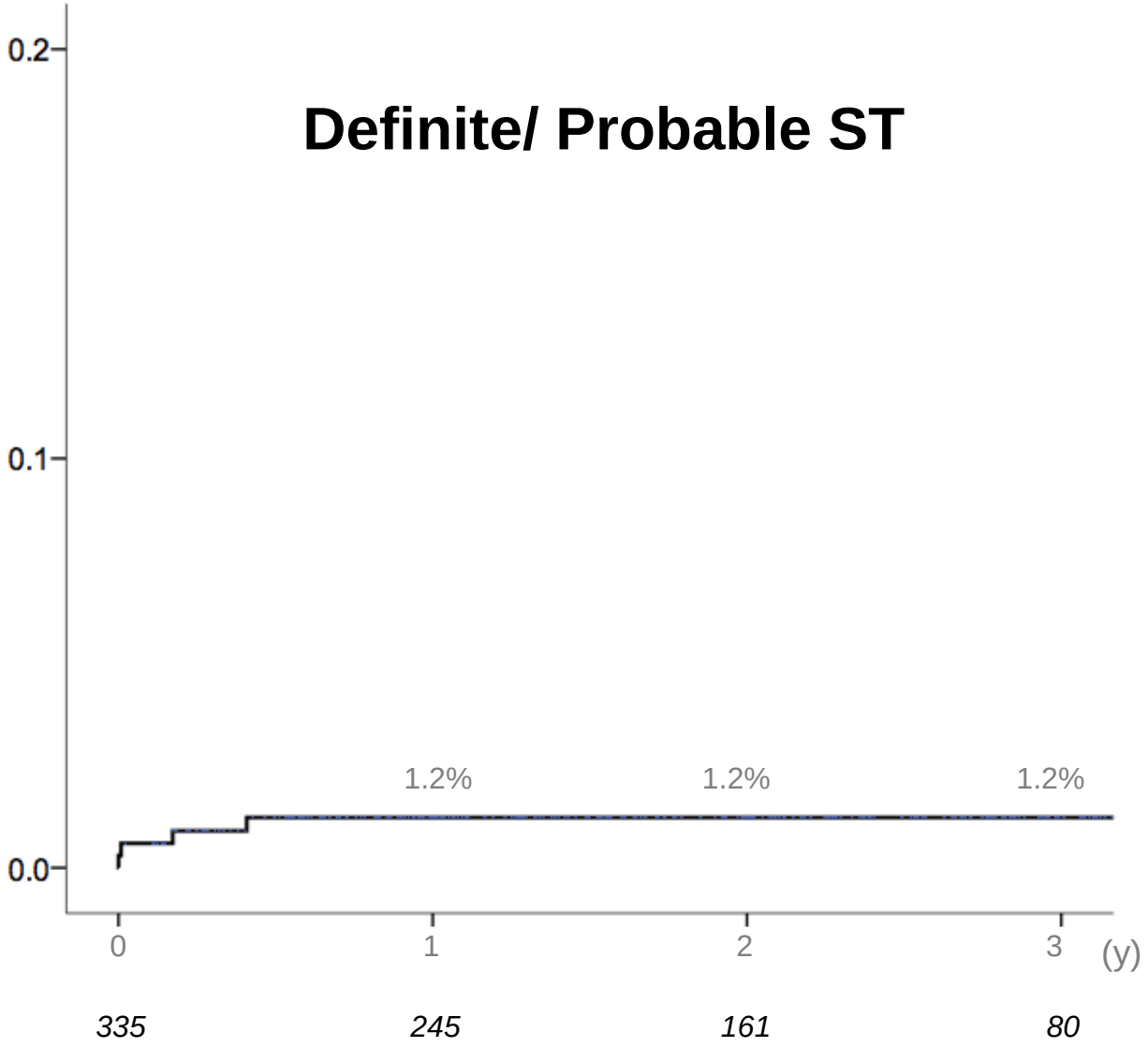
*1 Acute ST (BVS for STEMI, day 0) 1 Subacute ST (day 3, BVS edge dissection)

1 Late ST (day63, very small vessel with distal dissection)

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

Any DAPT cessation was recorded in 94 patients (27.6%) during f-u

Definite/ Probable ST



Full plastic jacket: **MILAN EXPERIENCE**

- ✓ Between May 2012 and Aug 2016
- ✓ All continuous stenting lesions were counted as 1 lesion
- ✓ Full plastic jacket was defined as continuous Absorb BVS implantation (without gap) more than 60mm length for main vessels

- ✓ 57 lesions (57 patients) were treated with FPJ

Baseline characteristics

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FPJ (total length ≥ 60 mm)	(n = 57)
Age, y	61.8 ± 10.2
Male, n (%)	54 (94.7%)
Hypertension, n (%)	46 (80.7%)
Dyslipidemia, n (%)	38 (66.7%)
DM, n (%)	26 (45.6%)
IDDM, n (%)	10 (17.5%)
current smoker, n (%)	11 (19.3%)
Family history of CAD, n (%)	16 (28.1%)
prior CABG, n (%)	1 (1.8%)
prior PCI, n (%)	25 (43.9%)
prior MI, n (%)	11 (19.3%)
CKD (GFR < 60) , n (%)	7 (12.3%)
EF, %	53.3 ± 9.9
Clinical presentation	
Stable angina/ Silent ischemia	48 (84.2%)
Unstable angina	9 (15.8%)
STEMI/ NSTEMI	0 (0%)

Lesion characteristics

FPJ (total length ≥ 60 mm)	(n = 57)
Treated vessel	
LAD	43 (75.4%)
LCX	2 (3.5%)
RCA	12 (21.1%)
ISR, n (%)	2 (3.5%)
CTO, n (%)	11 (19.3%)
Bifurcation, n (%)	44 (77.2%)
Severe calcification, n (%)	24 (42.1%)
Syntax score	24.1 ± 11.5

Procedural characteristics

FPJ (total length ≥ 60 mm)	(n = 57)
Pre-dilatation, n (%)	57 (100%)
Scoring balloon, n (%)	12 (21.1%)
Rotablator, n (%)	5 (8.8%)
Laser, n (%)	3 (5.3%)
Post-dilatation, n (%)	57 (100%)
BVS number	3.4 ± 0.6
Mean BVS diameter, mm	3.01 ± 0.21
Use of 2.5mm BVS, n (%)	37 (64.9%)
Total BVS length, mm	85.2 ± 15.3
Intravascular imaging, n (%)	52 (91.2%)
IVUS, n (%)	49 (86.0%)
OCT, n (%)	15 (26.3%)

Clinical outcomes at 1 year

Median follow-up period: 443 days [IQR 304–812]

FPJ (total length ≥ 60 mm)	(n = 57)
Periprocedural MI*	12 (21.1%)
1-year events (Kaplan–Meier analysis)	
TLF (Cardiac death, TV-MI, TLR)	7 (14.9%)
Cardiac death	1 (2.0%)
Target vessel MI	2 (4.3%)
TLR	6 (13.1%)
MACE (All cause death, TV-MI, TVR)	7 (14.9%)
All-cause Death	1 (2.0%)
TVR	6 (13.1%)
Scaffold thrombosis (definite and probable)	2 (4.3%)*

* 1 Late ST (day 63, very small vessel with distal dissection)
1 Late ST (day 146, the patient stopped clopidogrel at 2-months)

Periprocedural MI; CK ≥ 2xURL, in the absence of CK: CK-MB > 3xURL, in the absence of CK or CK-MB: troponin > 3xURL (same as ABSORB trial)

Case: 67 year-old Male

Hypertension/ Diabetes

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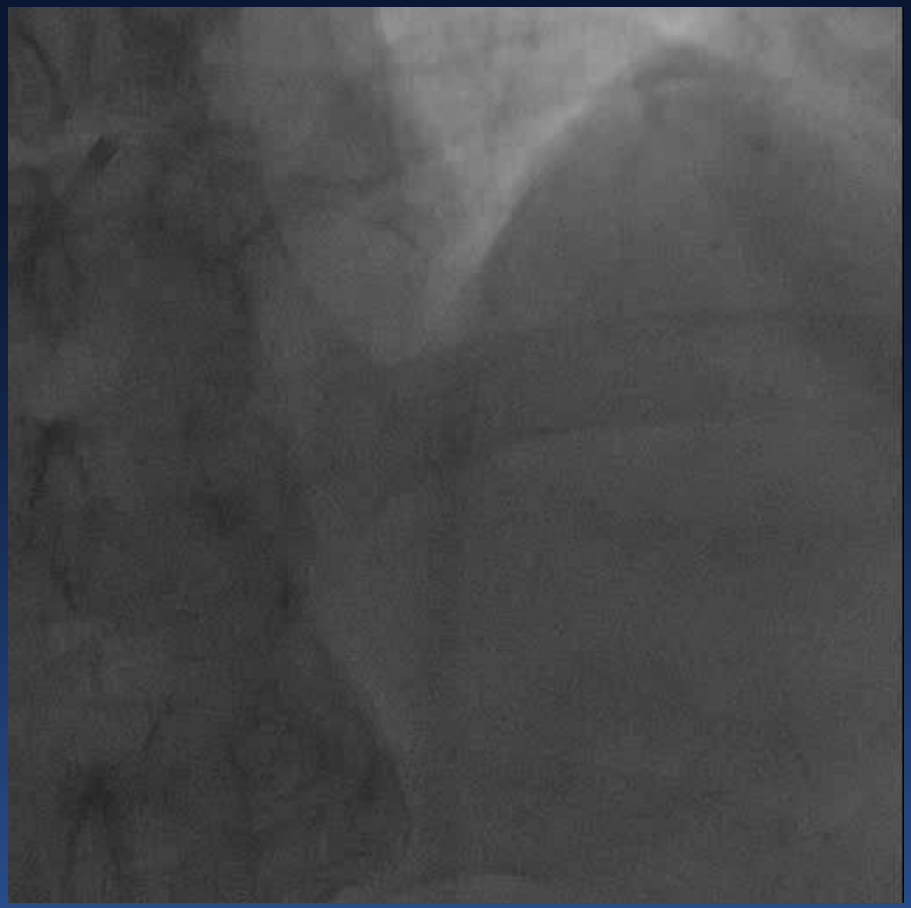
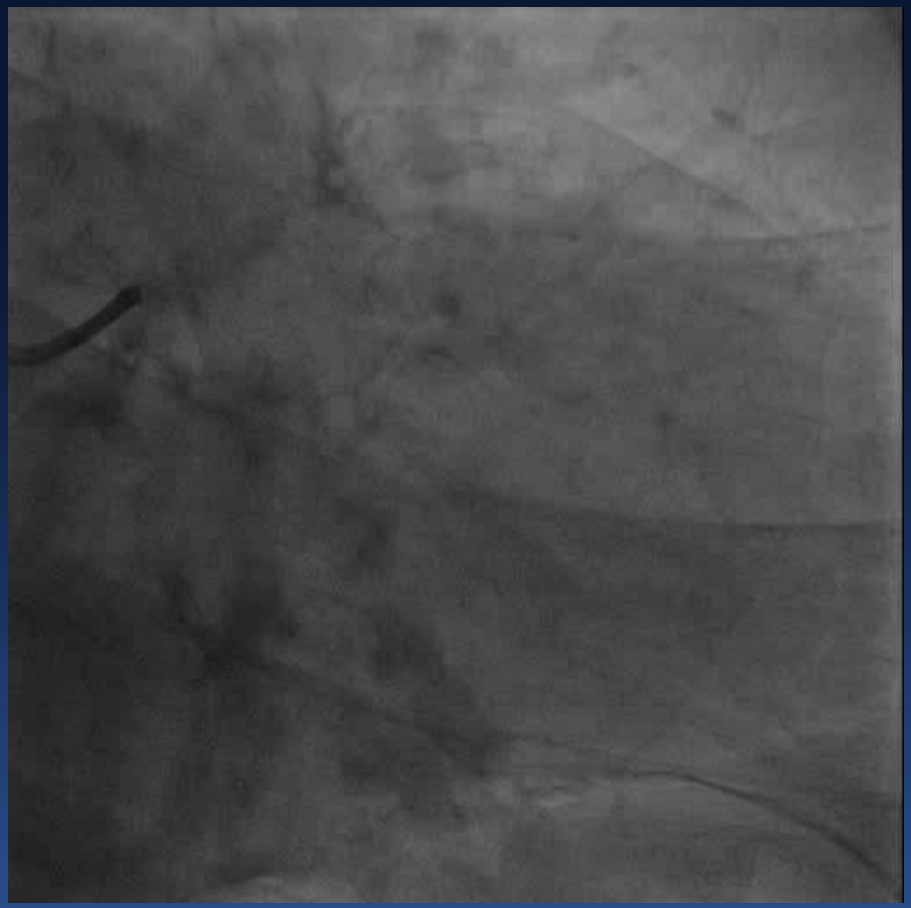
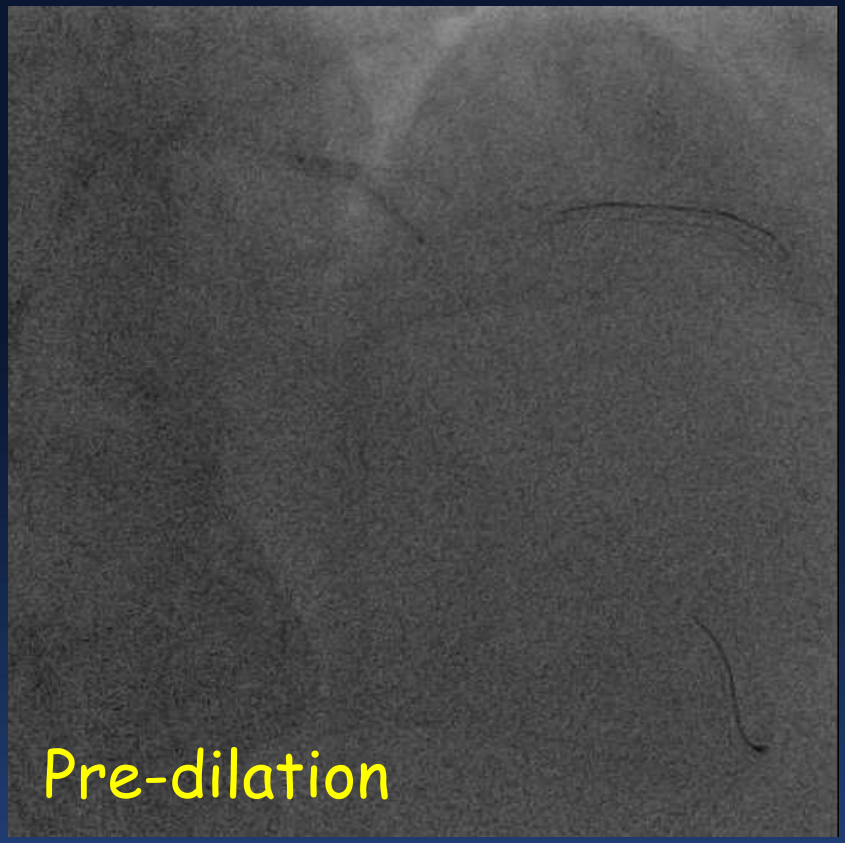
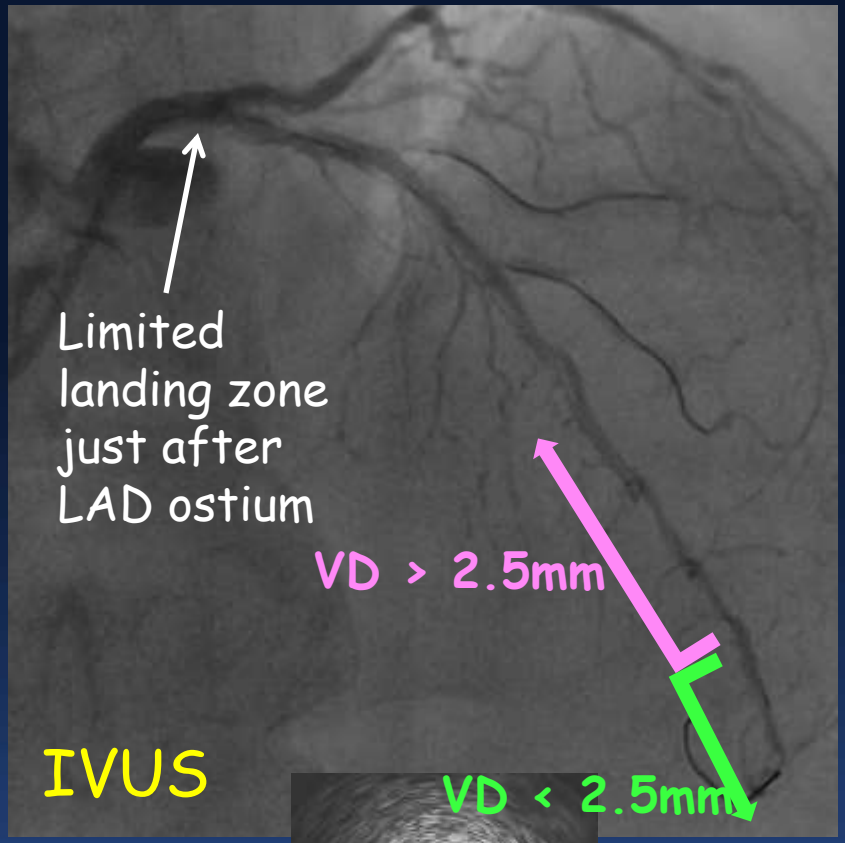
Baseline angiogram





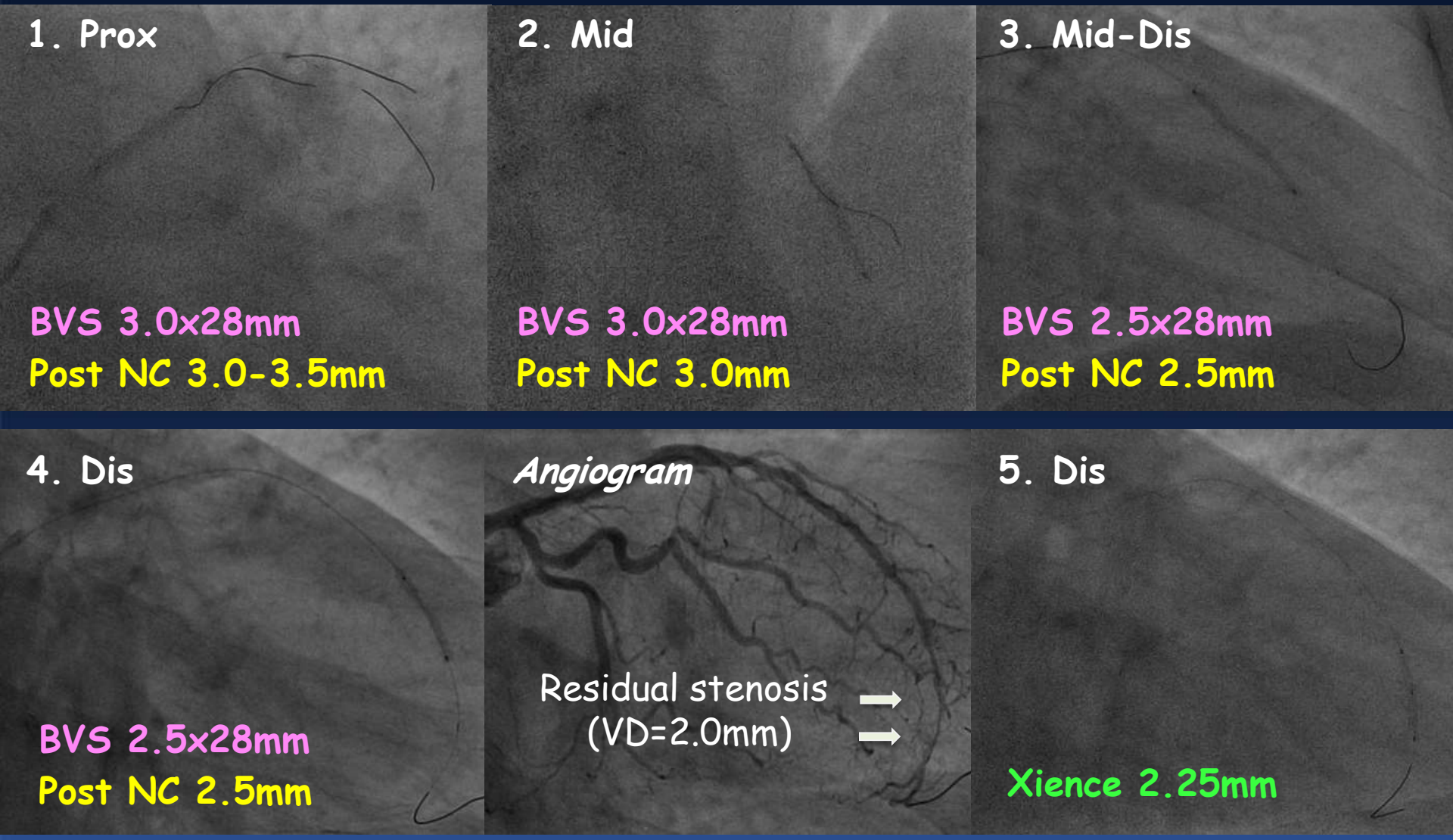
Pre-dilation/ IVUS for sizing



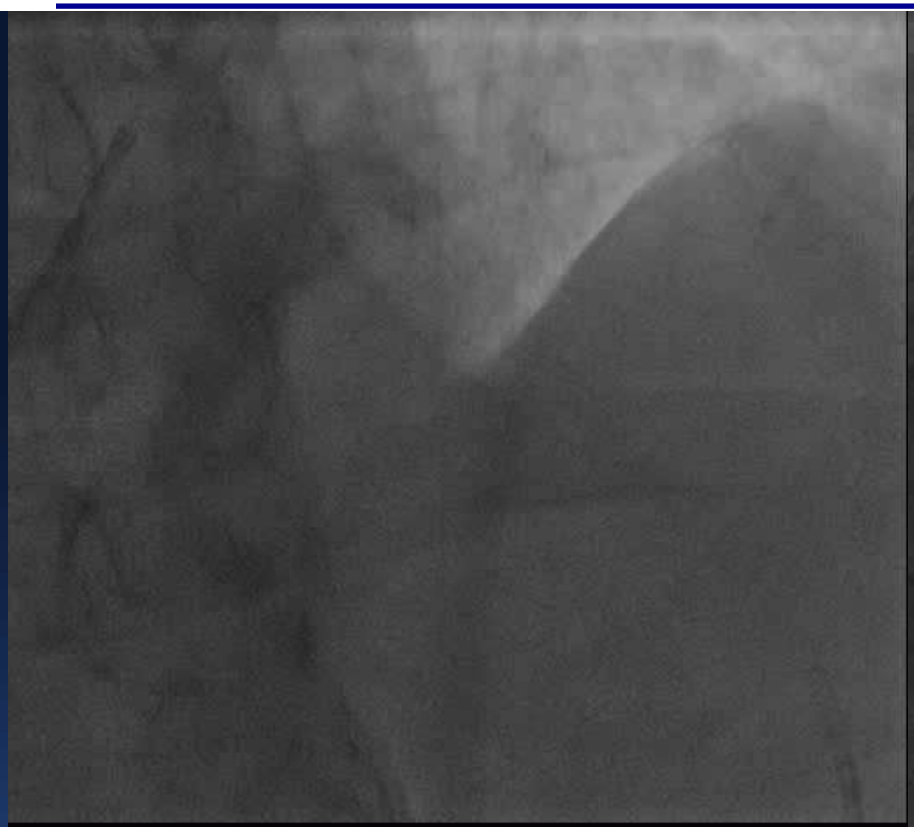


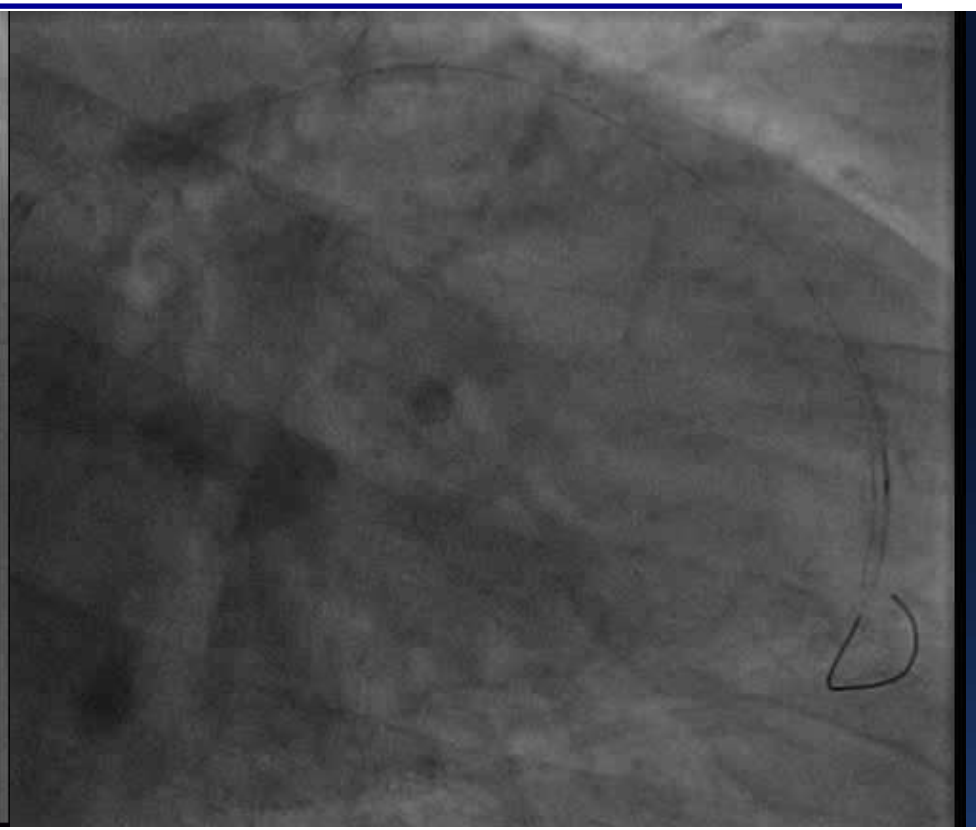
- LAD prox NC 3.0mm
- LAD prox-mid: Angiosculpt 2.5mm
- LAD dis: NC 2.0mm

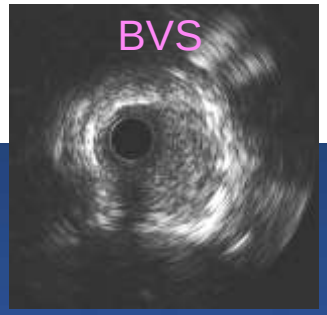
BVS implantation/ Post-dilation

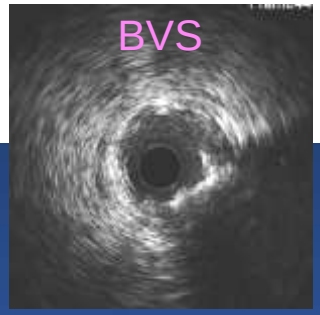


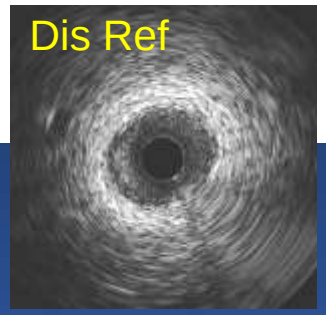
Final confirmation of IVUS/ Angio











Prox to Distal/ Distal to Prox

- In the majority of cases requiring multiple BVS in the same vessel, it is better to implant from distal to proximal, which avoids difficulties in crossing a second BVS through the first BVS and the risk of strut fracture and distortion when crossing.

- However, Implanting from proximal to distal should be reserved for cases of precise proximal positioning including a limited proximal landing zone, to avoid excessive overlap

In this case, multiple BVS were implanted prox to distal because of limited prox landing zone

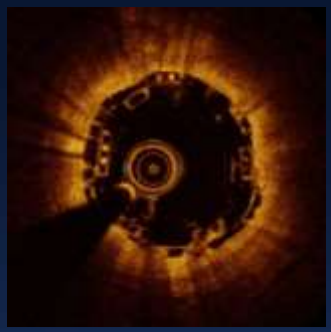
Post-dilation

- Especially when implanting proximal to distal, sufficient post-dilation of the proximal BVS should be done before crossing the second BVS distally, and delivery through the first BVS should be carefully done to avoid scaffold distortion

In this case, we did sufficient post-dilation whenever one BVS was implanted

Positioning/ Scaffold to scaffold

- Overlaping site seems be related to greater thrombogenicity and delayed neointimal coverage
- To minimize overlap with bulky struts, accurate positioning is important under understanding of marker position



		Scaffold edge to scaffold marker (mm)	
	Expansion size	Proximal	Distal
BVS 2.5 or 3.0mm	Crimp	1.1	0.3
	2.5 mm	0.9	
	3.0 mm	0.9	
	3.5 mm	0.7	
BVS 3.5mm	Crimp	1.4	0.3
	3.5 mm	1.1	
	4.0 mm	1.0	

Small diameter segment

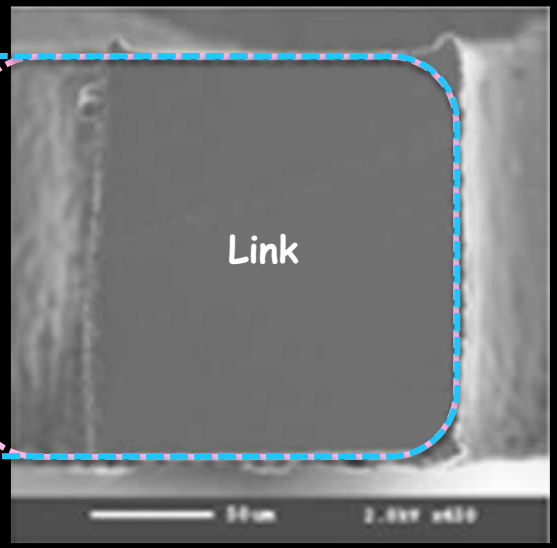
- Complex disease commonly involves small diameter segments, especially at the distal part of a lesion
- BVS must be avoided in segments with vessel diameter <2.5mm, and DES and/or DCB are valid options
- Angiographic assessment often underestimates true vessel diameter especially in diffuse disease. Intravascular imaging is helpful for sizing

In this case, according to IVUS guidance, we used DES for distal small distal segment

BVS have thicker and wider struts

2.5, 3.0mm BRS Hoop

3.5mm BRS Hoop

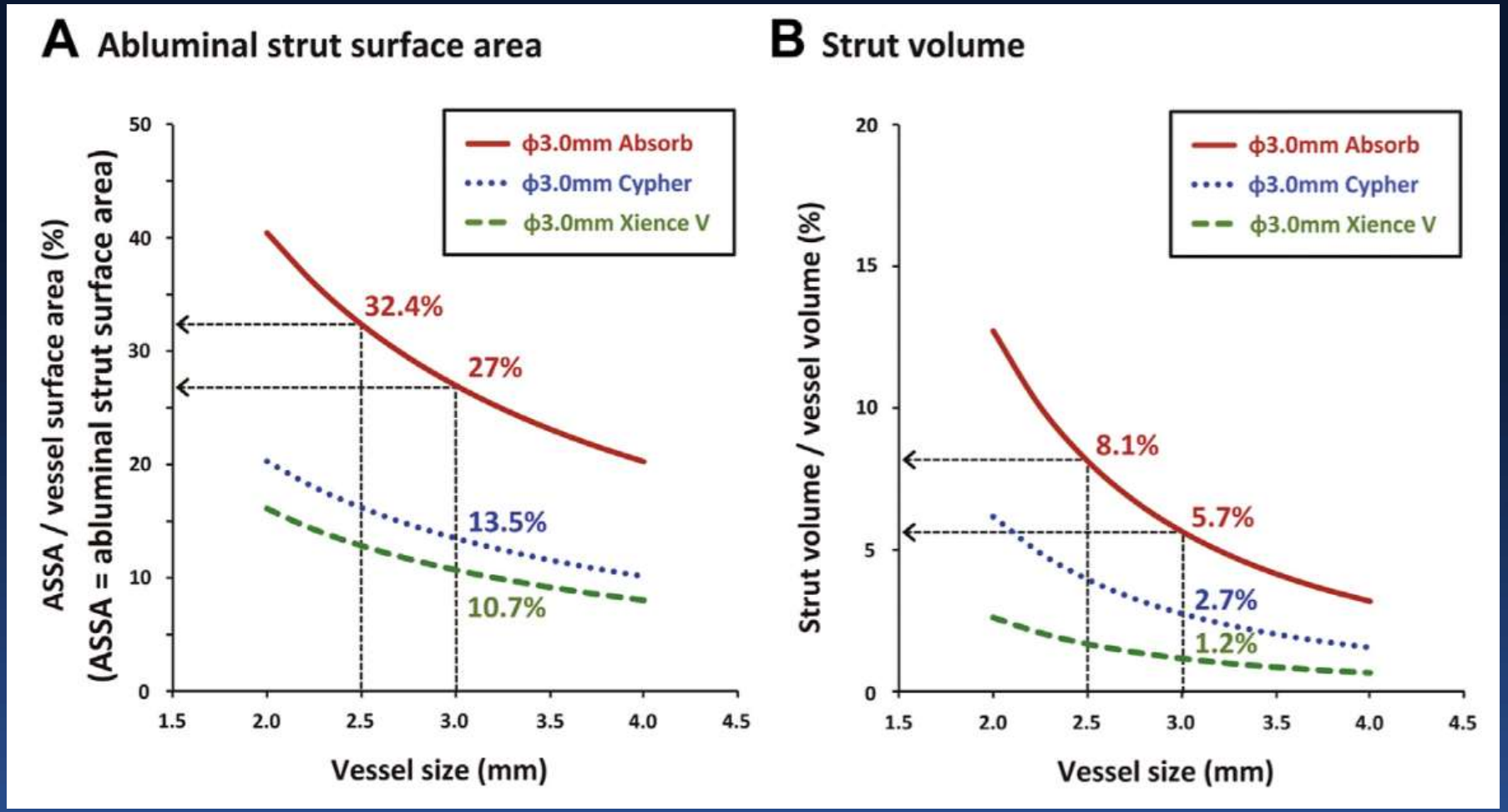


	Absorb BVS	Xience V
Strut thickness	157μm	81.3μm
Strut width (link)	140μm	81.3μm
Strut width (hoop)	2.5, 3.0mm; 190.5μm 3.5mm; 215.9μm	81.3μm
Vessel coverage (%)	2.5mm; 32% 3.0mm; 27% 3.5mm; 26%	10.7%

Macroscopic pictures; Absorb (Muramatsu et al. JACC intv 2013)
Xience V (Doostzadeh et al. Coronary Artery Disease 2010)

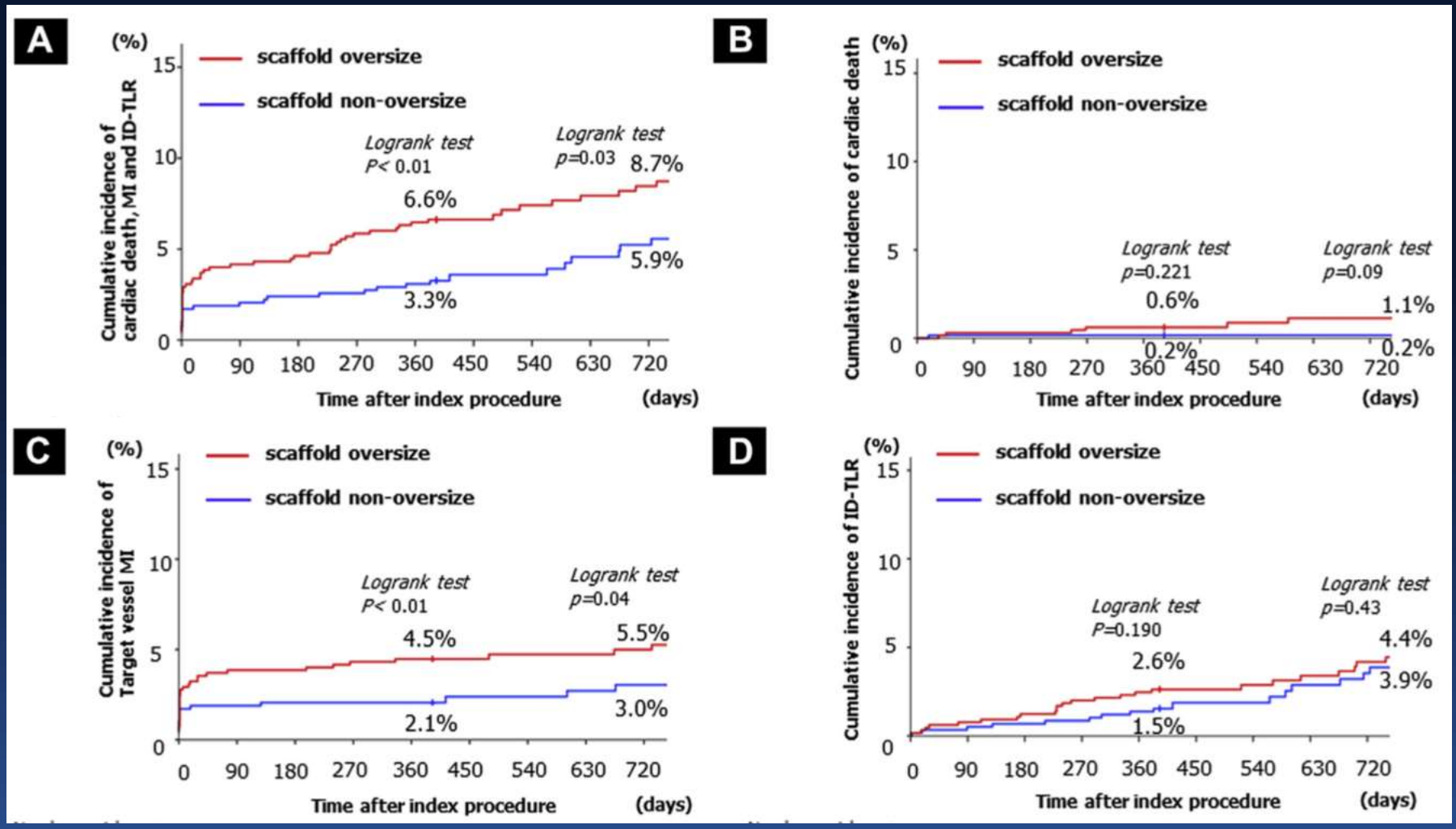
If BVS in small vessel,

Larger vessel coverage/ volume in the lumen



Kawamoto H, Colombo A et al. JACC Cardiovasc Interv 2016 9(3)299-300

Oversize is associated with adverse events



Ishibashi Y et al. JACC Cardiovasc Interv 2015 8(13)1715-26

Conclusions

Preliminary experience with BRS full plastic jacket in diffusely diseased vessels encouraging.

Careful lesion preparation , IVUS/OCT guidance postdilatation are essential in this kind of procedure

Larger numbers, longer clinical follow up is warranted