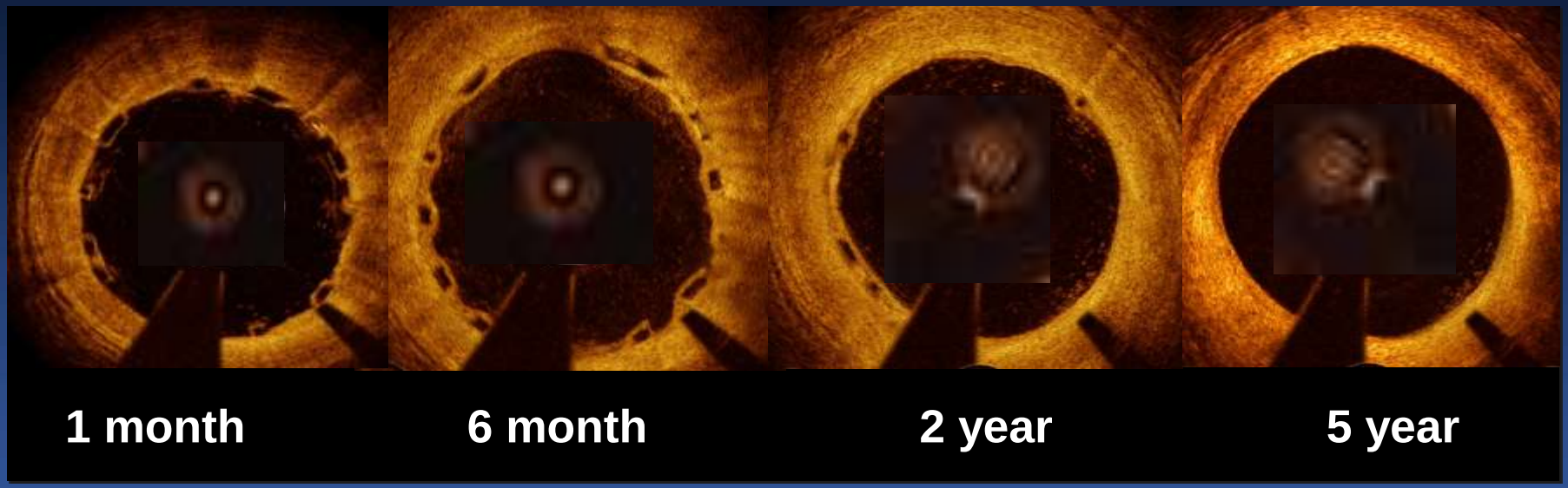
Future Perspective of BVS, Is It a Crisis or a Chance to Move Forward ?

1-Year Outcomes of IRIS-BVS Registry

Seung-Jung Park, MD, PhD

Professor of Medicine, University of Ulsan College of Medicine,
Heart Institute, Asan Medical Center, Seoul, Korea

BVS Concept Is Perfect !
Disappeared, Plaque Stabilization, and Lumen Enlargement



Clinical Evidences

REPARA[1]
GABI-R[2]
RAI[3]
IT-DISAPPEARS[4]
France ABSORB[5]
ABSORB III[8]
ABSORB Japan[9]
ABSORB China[10]
ABSORB-FIRST[11]
GHOST EU[12]
ABSORB II[13]
ASSURE[14]
PRAGUE-9[15]
ABSORB Extend[16]
TROFI II[6]
ESTROFA-BVS[7]
ABSORB Cohort B[17]

Short-term Efficacy and Safety of BVS is Comparable to 2nd Generation of DES.

[1.]Hernandez, F., REPARA, EuroPCR 2015; [2]Hamm, C., GABI-R, EuroPCR 2016; [3]Cortese, B., RAI, EuroPCR 2016; [4]Petronio A.S., IT-DISSAPEARS, EuroPCR 2016 [5]Koning C., France ABSORB, EuroPCR 2016; [6]Serruys, P.W.,TROFI II, ESC2015; [7]De La Torre Hernandez, J., ESTROFA BVS, EuroPCR 2015; [8]Kereiakes, D., ABSORB III, TCT 2015; [9]Kimura, T., ABSORB Japan, ESC 2015; [10]Gao, R., ABSORB China, TCT 2015; [11]Seth, A., ABSORB FIRST, TCT 2015; [12]Capadanno, D., GHOST-EU Propensity Matched Analysis, TCT 2015; [13]Chevalier, B., ABSORB II, TCT 2015; [14]Schwencke, C., ASSURE, TCT 2015; [15]Kocka V., PRAGUE-19, EuroPCR 2016 [16] C.J., ABSORB EXTEND, TCT AP 2015; [17]Serruys, P.W., ABSORB Cohort B, TCT 2015. Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands

1 Year Meta-Analysis Suggest Increased Risk of ST with Absorb

1-year outcomes with the Absorb bioresorbable scaffold in patients with coronary artery disease: a patient-level, pooled meta-analysis

Gregg W Stone, Rur
Xiaolu Su, Zhen Zh

Everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents: a meta-analysis of randomised controlled trials

Salvatore Cassese*, Robert A Byrne*,
Takeshi Kimura, Adnan Kastrati

SAFETY AND EFFICACY OUTCOMES OF BIORESORBABLE SCAFFOLD STENTS FOR TREATMENT OF ISCHEMIC CORONARY ARTERY DISEASE: A META-ANALYSIS OF RCTS

Poster Contributions
Poster Area, South Hall A1
Monday, April 04, 2016, 9:45 a.m.-10:30 a.m.

ACC.16

Session Title: Devices: Coronary Stents
Abstract Category: 7. ACC
Presentation Number: 12

Authors: Daniel Garcia,
Vascular Institute, New O

Review

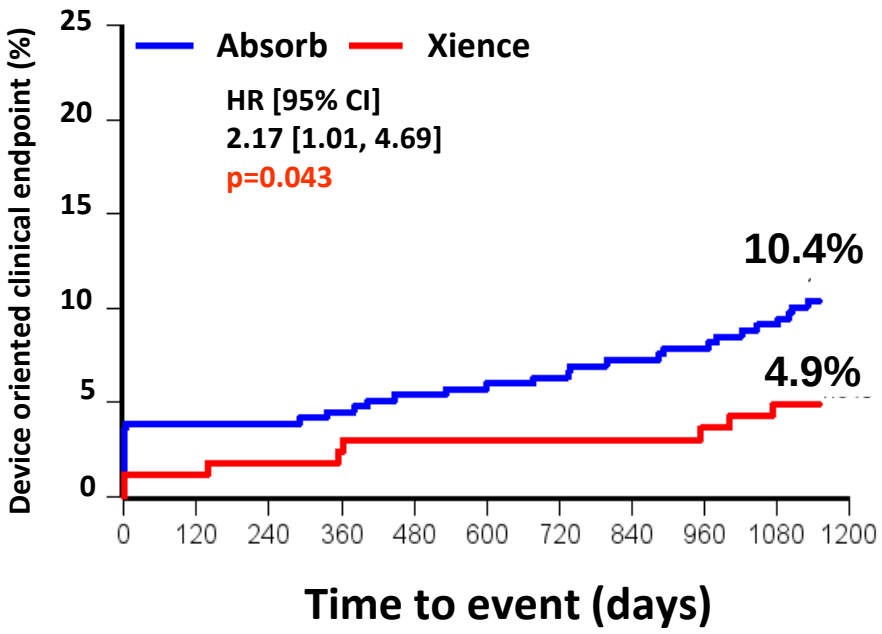
Safety and efficacy of everolimus-eluting bioresorbable vascular scaffolds versus durable polymer everolimus-eluting metallic stents assessed at 1-year follow-up: A systematic review and meta-analysis of studies☆

Bertrand N. Mukete [a,1], Liefke C. van der Heijden [b,1], Kenneth Tandjung [b], Hassan Baydoun [a], Kapil Yadav [a], Qusai A. Saleh [a], Carine J.M. Doggen [c], Nidal Abi Rafeh [a], Thierry H. Le Jemtel [a], Clemens von Birgelen [b,c,*]

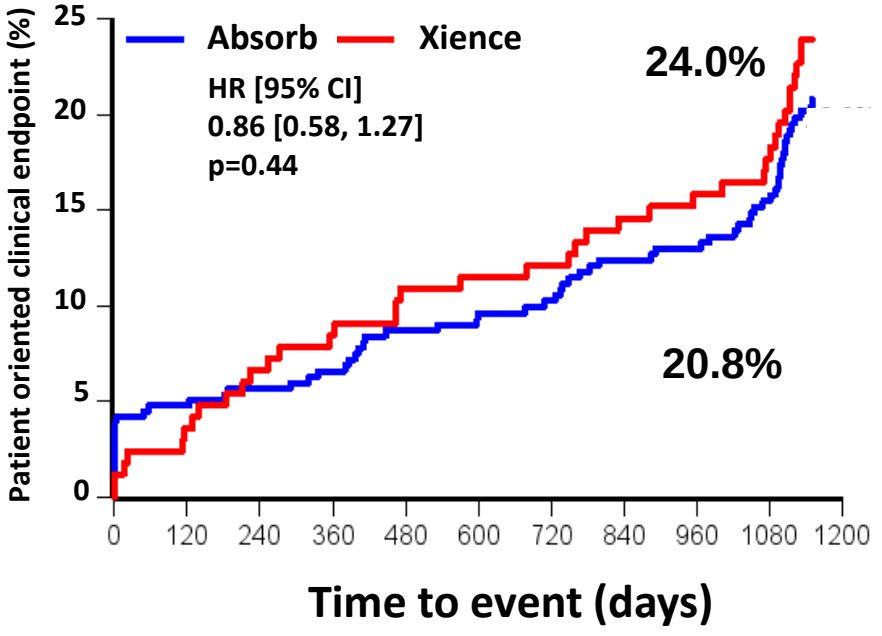
[1] Cassese S. et al. Lancet 2016 [2] Stone G. et al. Lancet 2016 [3] Kang SH. et al. J Am Coll Cardiol Interv 2016 [4] Yang Y. Et al. Int J Cardiol 2016 [5] Mukete B.N. et al. Am Coll Cardiol 2016 [6] Valencia-Serrano F et al., Am Coll Cardiol 2016 [7] Garcia D. et al., Am Coll Cardiol 2016 [8] Pandya B. et al. World J Cardiol 2016

ABSORB II, 3-year

Device-Oriented Composite Endpoints (Cardiac Death, TV-MI, CI-TLR)



Patient-Oriented Composite Endpoints (Any Death, Any-MI, Any Revascularization)



Patrick W Serruys et al, Lancet 2016; http://dx.doi.org/10.1016/S0140-6736(16)32050-5

ABSORB II, 3-year
Secondary Clinical Endpoints

	Absorb 325 patients	Xience 161 patients	Relative Risk	p value
Device-oriented composite endpoint [DOCE]	10.5%	5.0%	2·11 [1·00, 4·44]	0·04
Cardiac death	0.9%	1.9%	0·50 [0·10, 2·43]	0·40
Target vessel MI	7.1% (23)	1.2% (2)	5.70 [1.36, 23.87]	0.0061
Periprocedural MI (WHO)	3.9%(13)	1.2% (2)	3.22 [0.74, 14.11]	0.16
Spontaneous MI (WHO extended)	3.1% (10)	0% (0)	NC [NC]	0.06
Clinically indicated TLR	6.2%(20)	1.9% (3)	3.30 [1.00, 10.95]	0.036
Patient-oriented composite endpoint [POCE]	20.9%	24.2%	0·86 [0·61, 1·22]	0·40
All-cause death	2.5%	3.7%	0·66 [0·23, 1·87]	0·57
Any MI	8.3%	3.1%	2.68 [1.05, 6.82]	0.03
Any revascularization	15.1%	20.5%	0.74 [0.49, 1.10]	0.13

Patrick W Serruys et al, Lancet 2016; http://dx.doi.org/10.1016/S0140-6736(16)32050-5

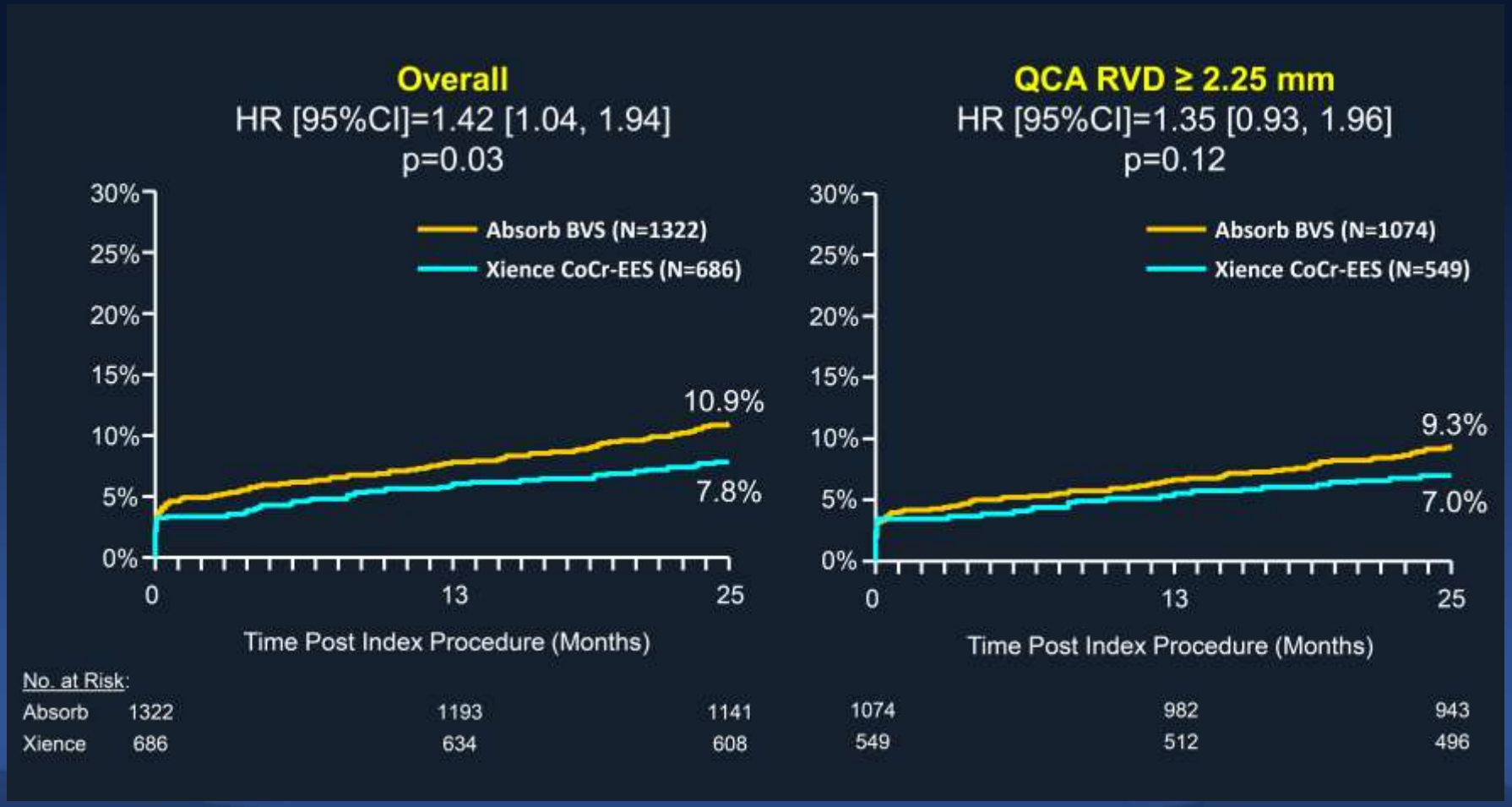
ABSORB II, 3-year
Scaffold or Stent Thrombosis

	Absorb 335 patients	Xience 166 patients	p value
Definite	**2·5% (8)**	**0·0% (0)**	**0·06**
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·0% (0)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19
Definite or probable	**2·8% (9/320)**	**0·0% (0/159)**	**0·03**
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·3% (1)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19

Patrick W Serruys et al, Lancet 2016; http://dx.doi.org/10.1016/S0140-6736(16)32050-5

Absorb III Trial, 2-year

Target-Vessel Failure
(Cardiac Death, TV-MI, ID-TLR)



Absorb III Trial, 1 to 2-year

Primary Endpoint and Stent thrombosis

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	3.7% (47)	2.5% (17)	3.2% (33)	1.9% (10)
Cardiac Death	0.5% (6)	0.4% (3)	0.4% (4)	0.2% (1)
TV-MI	1.3% (17)	0.7% (5)	1.3% (14)	0.4% (2)
ID-TLR	2.6% (33)	1.8% (12)	2.2% (23)	1.5% (8)
ST (Def/Prob)	0.3% (4)	0.0% (0)	0.4% (4)	0.0% (0)

P-value >0.05 for all comparisons

Stephen G. Ellis et al, ACC 2017

Absorb III Trial, 2-year

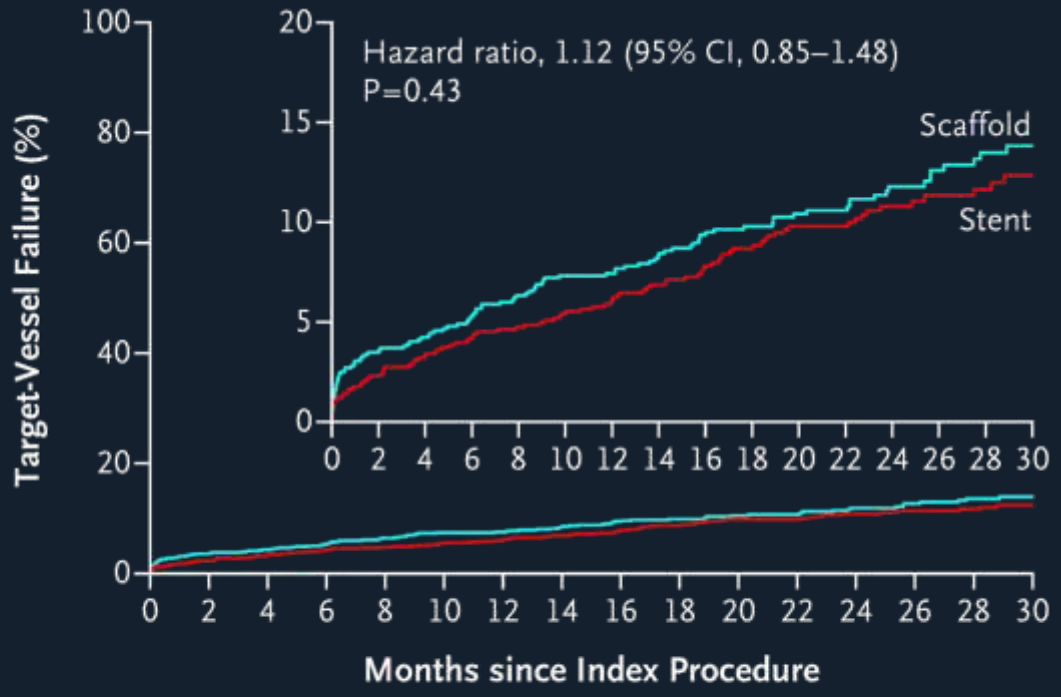
Primary Endpoint and Stent thrombosis

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	11.0% (143)*	7.9% (53)*	9.4% (99)	7.0% (38)
Cardiac Death	1.1% (14)	0.6% (4)	0.9% (10)	0.4% (2)
TV-MI	7.3% (95)**	4.9% (33)**	6.5% (68)	4.8% (26)
ID-TLR	5.3% (69)	4.3% (29)	4.1% (43)	3.0% (16)
ST (Def/Prob)	1.9% (24)	0.8% (5)	1.3% (13)	0.6% (3)

* P-value=0.03, ** P-value=0.04, P-value >0.05 for all other comparisons

AIDA Trial, 2-year

Device-Oriented Composite Endpoints
(Cardiac Death, TV-MI, TV-Revascularization)

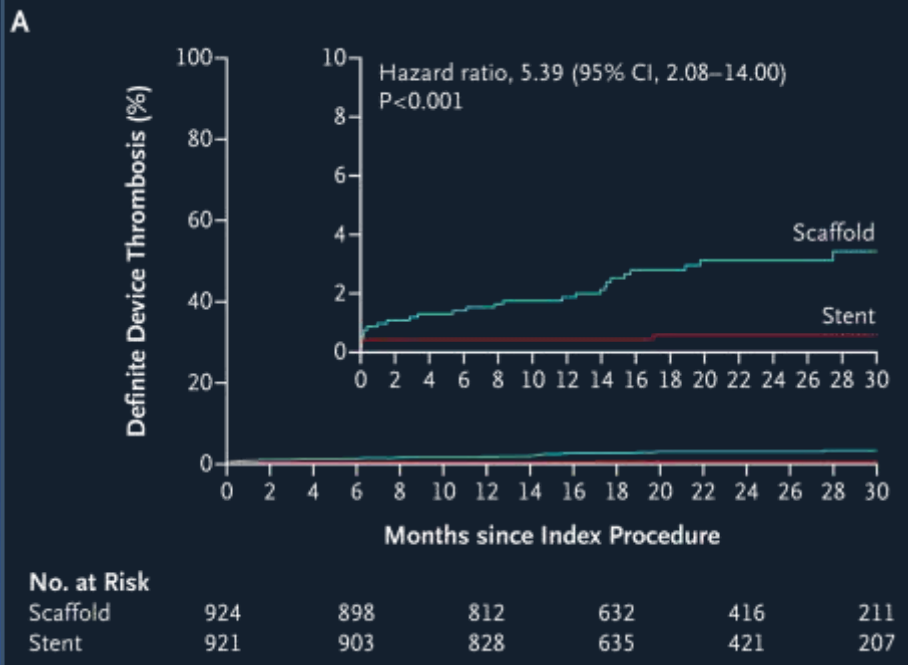


No. at Risk						
Scaffold	924	870	776	594	385	196
Stent	921	873	792	599	388	188

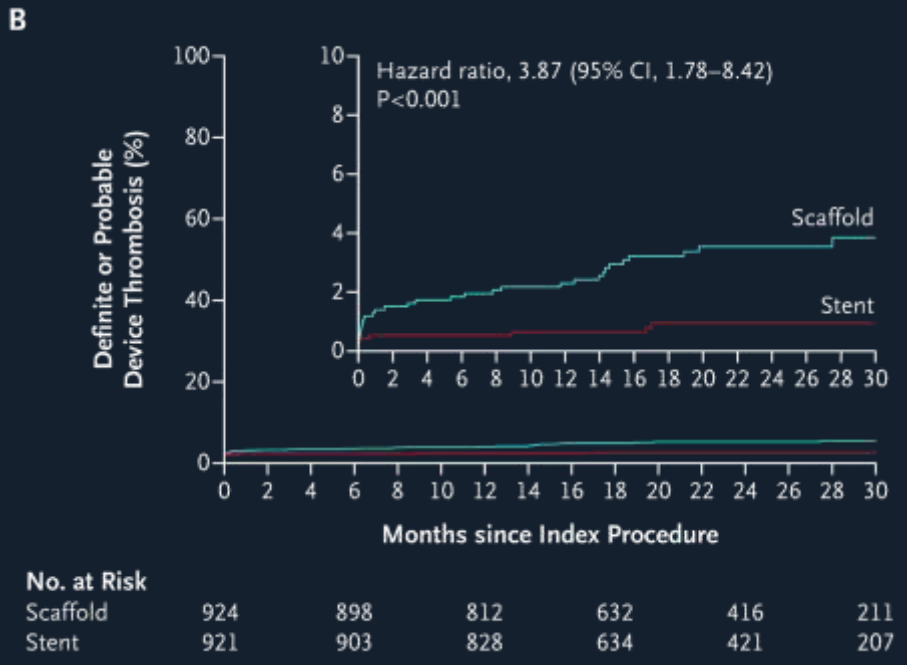
Joanna J. Wykrzykowska et al, NEJM 2017; March 29, 2017DOI: 10.1056/NEJMoa1614954

AIDA Trial, 2-year

Definite Device Thrombosis



Definite or Probable Device Thrombosis



Joanna J. Wykrzykowska et al, NEJM 2017; March 29, 2017DOI: 10.1056/NEJMoa1614954

AIDA Trial, 2-year
Scaffold or Stent Thrombosis

	Scaffold 924 patients	Stent 921 patients	HR	P Value
Definite	3.1% (27)	0.6% (5)	5.39 (2.08-14.00)	<0.001
Probable	0.4% (4)	0.4% (3)	1.32 (0.30-5.91)	0.71
Possible	0.4% (6)	0.4% (12)	0.50 (0.19-1.33)	0.15
Definite or probable	3.5% (31)	0.9% (8)	3.87 (1.78-8.42)	<0.001
Acute (0–1 day)	(3)	(3)	-	
Sub-acute (2–30 days)	(10)	(2)	-	
Late (31 days to 1 yr)	(8)	(1)	-	
Very late (>1 to 2 yr)	(9)	(2)	-	
Very late (>2 to 3 yr)	(1)	(0)	-	
Any device thrombosis	4.1% (37)	2.5% (20)	1.85 (1.08-3.19)	0.02

Joanna J. Wykrzykowska et al, NEJM 2017; March 29, 2017DOI: 10.1056/NEJMoa1614954

AIDA Trial, 2-year
Secondary Clinical Endpoint

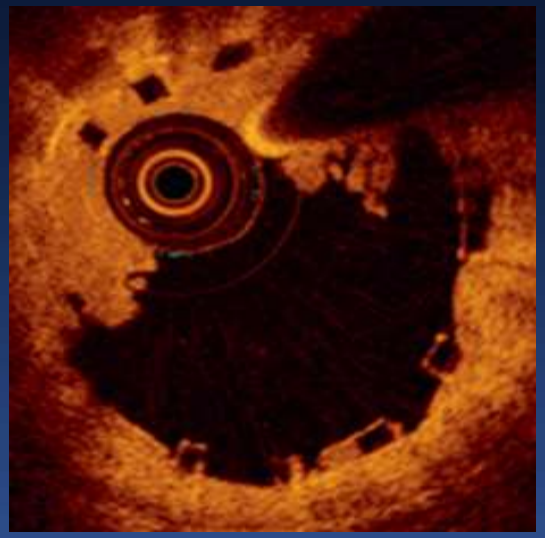
	Scaffold 924 patients	Stent 921 patients	Hazard Ratio	P value
Death from any cause	3.5% (32)	4.3% (43)	0.74 (0.47–1.17)	0.19
Cardiac death	2.0% (18)	2.7% (23)	0.78 (0.42–1.44)	0.43
All myocardial infarction	7.1% (62)	4.2% (41)	1.52 (1.02–2.25)	0.04
Target vessel	5.5%(48)	3.2% (30)	1.60 (1.01–2.53)	0.04
During index procedure	1.0% (9)	0.7% (6)	1.50 (0.53–4.20)	0.44
Not during index procedure	4.5% (39)	2.6% (24)	1.62 (0.98–2.70)	0.06
Death or myocardial infarction	9.6% (88)	8.1% (80)	1.10 (0.82–1.49)	0.52
Any revascularization	13.2%(115)	11.6% (103)	1.11 (0.85–1.45)	0.43
Target vessel	8.7% (76)	7.5% (65)	1.16 (0.84–1.62)	0.37
Target lesion	7.0% (60)	5.2% (45)	1.33 (0.90–1.96)	0.15
Device thrombosis	3.0% (26)	0.6% (5)	5.19 (1.99–13.50)	<0.001
Device stenosis	4.1% (35)	4.6% (40)	0.87 (0.55–1.36)	0.53

Joanna J. Wykrzykowska et al, NEJM 2017; March 29, 2017DOI: 10.1056/NEJMoa1614954

Main Issue

1. Rate of any death or cardiac death were not different.
2. Rate of Peri-MI and spontaneous MI were higher in BVS group at follow-up.
3. Scaffold VLST continues to occur at 1-3 years follow-up !

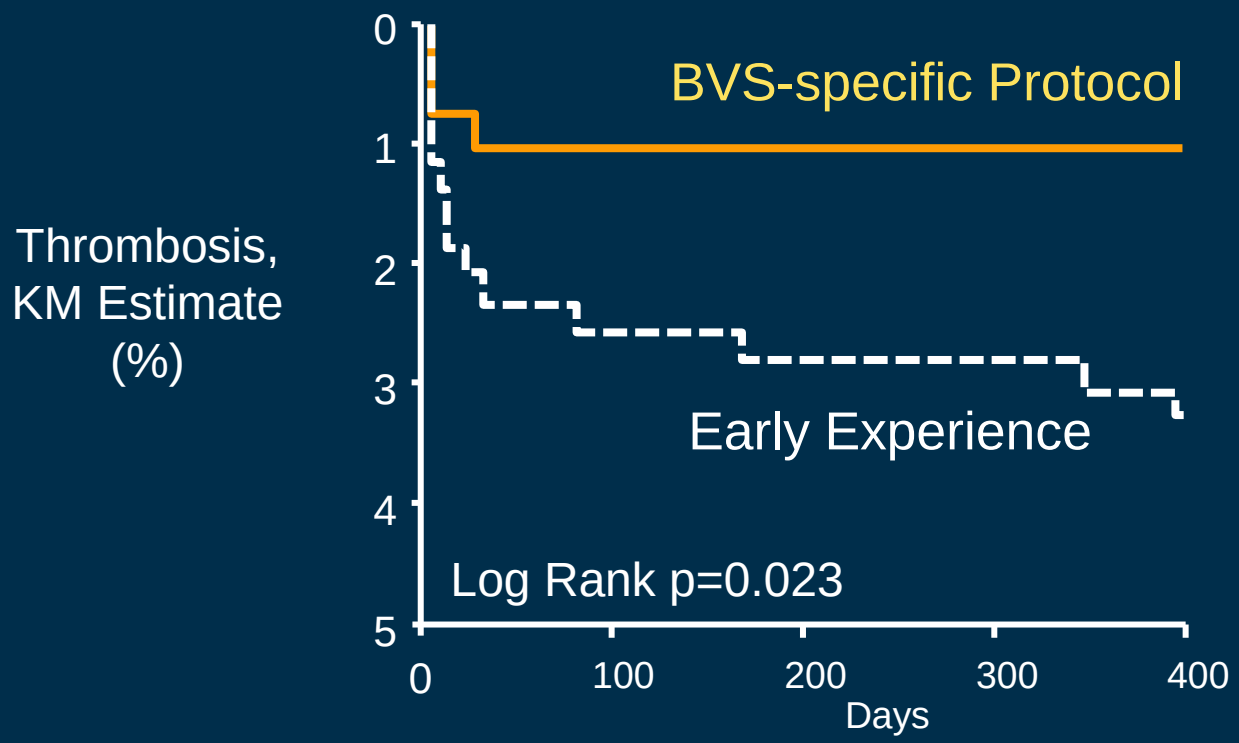
Main Issue Is,
Scaffold Thrombosis



We have to consider that Scaffold thrombosis is mainly related how to deploy the BVS (PSP) !

Why ?

BVS-Specific Protocol Reduced BVS Thrombosis



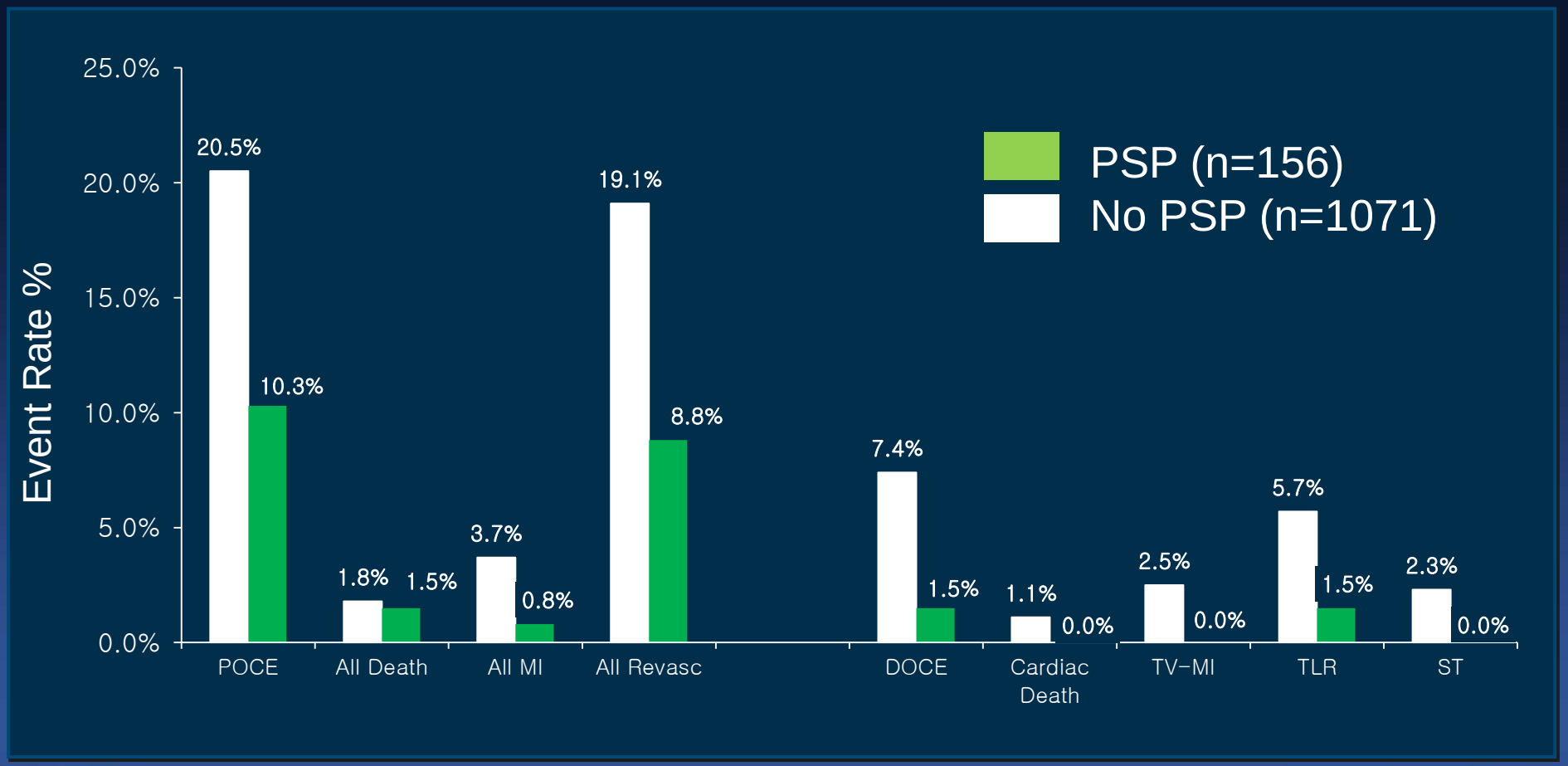
Patients					
Early Experience	369	369	369	369	369
Absorb–specific	292	292	281	217	155

Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31

BVS Specific Recommended Technique (PSP)

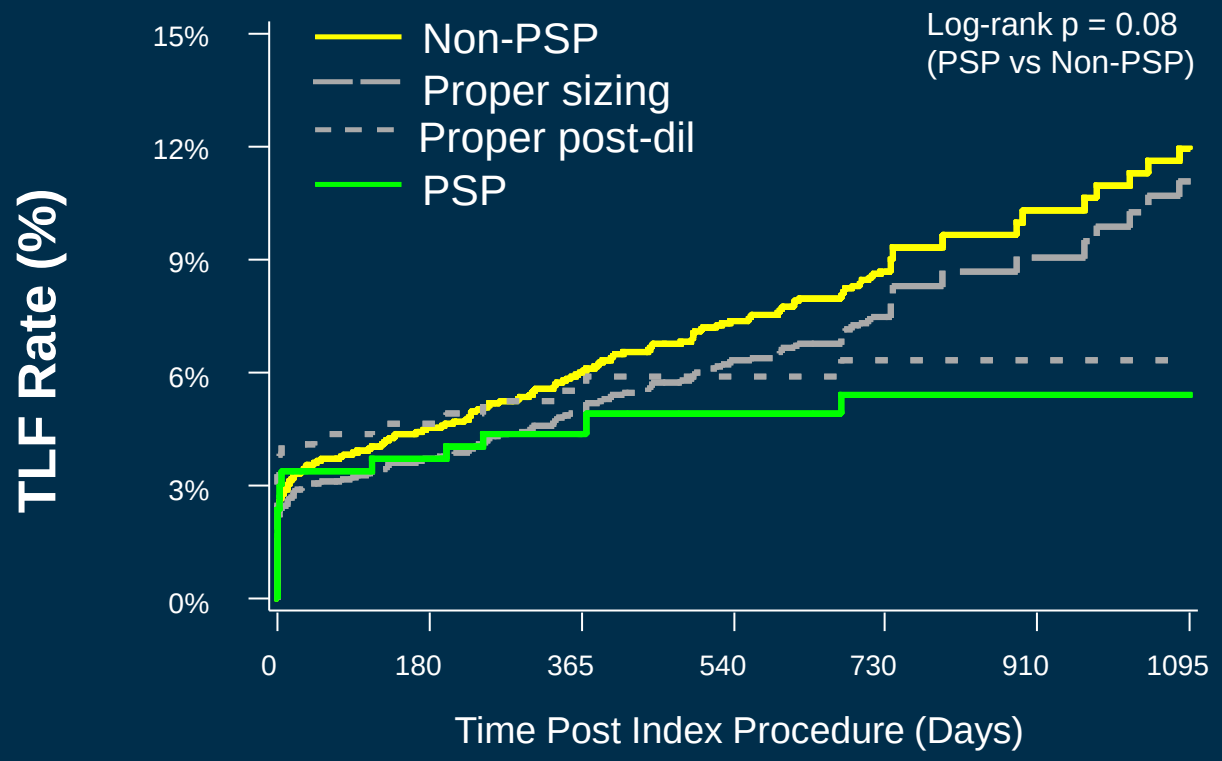
Puricel, S. et l. J Am Coll Cardiol. 2016; 67(8):921–31,
4 German and Swiss centers -BVS specific protocol

Significant Improvement of Outcomes
In GHOST-EU At 1 Year *With Completed PSP*



Brugaletta, S., GHOST-EU PSP Analysis, TCT 2016.

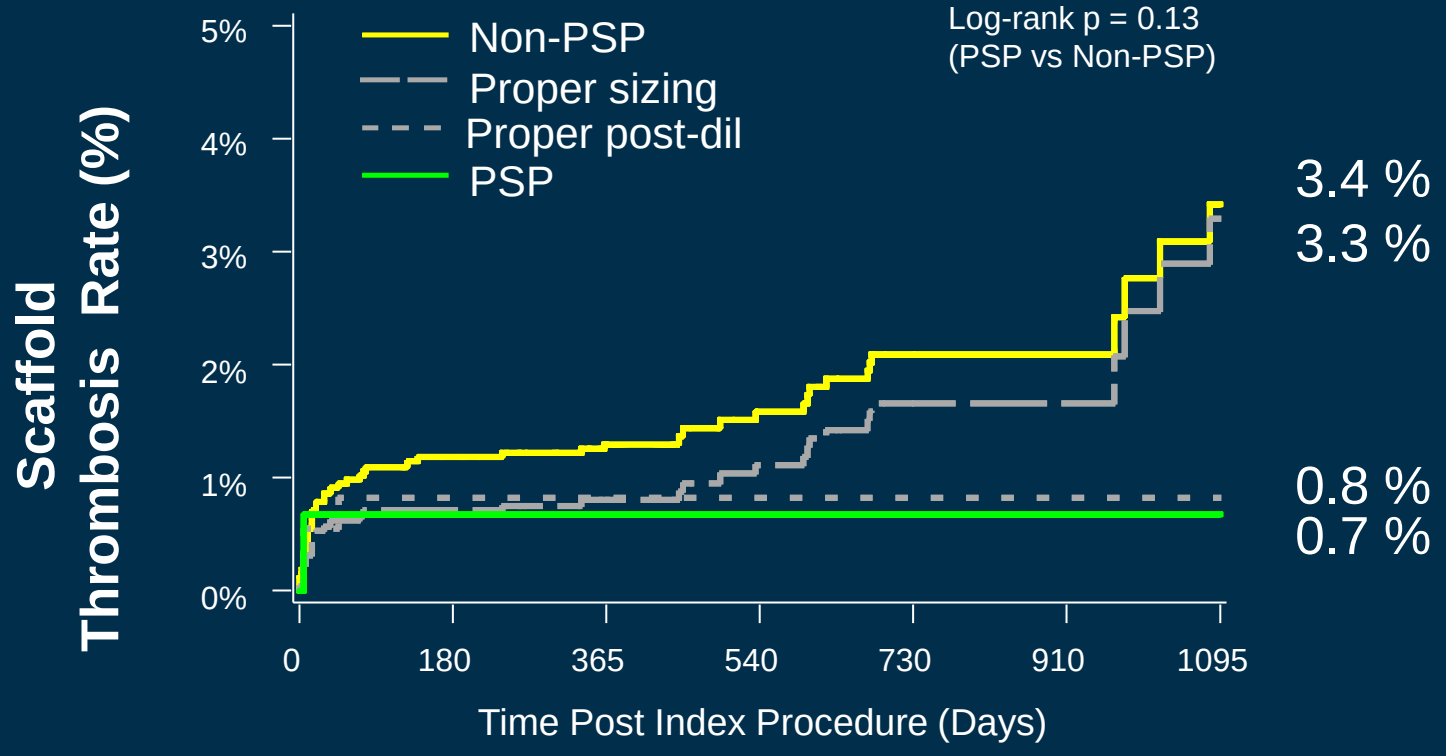
PSP Analysis - *TLF At 3-Years*
(Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2375	1289	268
Proper Sizing	2261	2125	1195	223
Proper post-dil	365	341	219	24
PSP	297	280	186	20

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

PSP Analysis – *Def/Prob ST At 3-Years* (Absorb Patients, As-Treated Population)



	0	365	730	1095
Non-PSP	2549	2483	1354	291
Proper Sizing	2261	2211	1247	238
Proper post-dil	365	357	227	26
PSP	297	290	192	21

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

PSP Use by Trial (As-Treated Population)

EXTEND	108/772	(14.0%)
ABSORB-II	21/324	(6.5%)
ABSORB-Japan	35/258	(13.6%)
ABSORB-China	32/237	(13.5%)
ABSORB-III	96/1224	(7.8%)

IRIS-BVS Registry

Design

- DESIGN: a multicenter, prospective, observational study
- OBJECTIVE: To compare the outcomes of BVS with other DES in “real world practice”.
- PRINCIPAL INVESTIGATOR
  Seung-Jung Park, MD, PhD,
  Asan Medical Center, Seoul, Korea
  Clinicaltrials.gov, Identifier: NCT02622100

Evaluation of Effectiveness and Safety of Absorb™ Stent in Real World Practice

IRIS – BVS Registry

All-Comer with Ischemic Heart Disease

PCI Patients With Absorb™ (N=1,000)

PCI Patients With Xience (N=1,000)

Clinical Follow-Up at 1-, 6-, and 12 months, and every other year upto 5 years

Participating Centers (N=12)

Country	Site	Investigator
Korea	Asan Medical center	Seung-Jung Park
Korea	Keimyung University Dongsan Medical Center	Seung Ho Hur
Korea	Korea University Guro Hospital	Seung Un Rha
Korea	The Catholic University of Korea, Daejeon ST. Mary's Hospital	Sung-Ho Her
Korea	Chungnam National University Hospital, Daejeon	Si Wan Choi
Korea	Kangwon National University Hospital	Bong-Ki Lee
Korea	Gangneung Asan Hospital, Gangneung	Sang-Sig Cheong,
Korea	Chonbuk National University Hosipital, Jeonju	Jei Keon Chae
Korea	Chonnam National University Hospital, Gwangju	Young-Keun Ahn
Korea	Bundang Cha Medical Center, Bundang	Sang Wook Lim
Korea	Hallym University Medical Center	Hyun Sook Kim

Primary End Point

Target-Vessel failure (TVF)

a composite clinical outcomes of

- Cardiac Death
- Myocardial Infarction
  - Periprocedural MI: CK-MB > 10 times UNL
  - Spontaneous MI: any cardiac enzyme elevation
- Target-Vessel Repeat revascularization

Baseline Characteristics

Variable	IRIS-BVS (N=352 patients)
Age	60.6 ± 10.0
Male	281 (79.8%)
BMI	25.1 ± 2.9
Current smoker	88 (25.0%)
Diabetes Mellitus	97 (27.6%)
Insulin-treated	8 (2.3%)
Hyperlipidemia	269 (76.4%)
Hypertension	194 (55.1%)
Family history of CAD	27 (7.7%)
History of PCI	28 (8.0%)
History of CABG	3 (0.9%)
History of renal disease	2 (0.6%)
Stable angina or silent ischemia	282 (80.1%)
ACS at presentation	70 (19.9%)
LVEF	62.8 ± 6.1
LVEF <40%	2 (0.7%)

Procedural Characteristics

	Patient-based (N=352)	Lesion-based (N=394)
Target vessel		
LMCA		3 (0.8%)
LAD		237 (60.2%)
LCX		110 (27.9%)
RCA		44 (11.2%)
Lesion type		
A		12 (3.0%)
B1		101 (25.6%)
B2		52 (13.2%)
C		229 (58.1%)
Moderate to severe calcification in QCA		45 (11.4%)
Chronic total occlusion	12 (3.4%)	5 (1.3%)
Bifurcated lesion	198 (56.2%)	206 (52.3%)
Thrombus present	1 (0.3%)	2 (0.5%)
Multi-vessel disease	101 (28.7%)	

Procedural Characteristics

	Patient-based (N=352)	Lesion-based (N=394)
PSP	**99%**	
Received both BVS and DES	60 (17.0%)	
Total number of scaffolds	1.5 ± 0.9	1.2 ± 0.4
Total scaffold length (mm)	30.6 ± 18.8	27.0 ± 12.1
Average scaffold diameter (mm)	3.3 ± 0.3	3.3 ± 0.3
Scaffold diameter (N=512)		
2.5 mm	27 (5.3%)	
3.0 mm	178 (34.8%)	
3.5 mm	307 (59.9%)	
Intravascular ultrasound use	327 (92.9%)	
Optical coherence tomography	41 (11.6%)	

Lesion Characteristics (AMC data)

Variable	QCA-based (N=275 lesion)	IVUS-based (N=247 lesion)
Lesion length (mm)	21.1 ± 11.6	24.4 ± 9.9
Long lesion (Lesion length >40 mm)	12 (5.4%)	9 (7.2%)
Proximal RVD (mm)	3.5 ± 0.5	4.4 ± 0.6
Distal RVD (mm)	2.6 ± 0.4	3.7 ± 0.6
Proximal RVD <2.5 mm	7 (2.5%)	0 (0.0%)
Distal RVD <2.5 mm	107 (38.9%)	6 (2.4%)
Interpolated normal reference (mm)	3.0 ± 0.4	
Minimal lumen diameter (mm)	1.2 ± 0.5	1.7 ± 0.3
Diameter Stenosis (%)	59.8 ± 15.3	
Minimal lumen area (mm^2)		2.4 ± 0.8
Proximal reference vessel area (mm^2)		15.7 ± 4.1
Distal reference vessel area (mm^2)		10.9 ± 3.9
Calcification observed in IVUS		209 (84.6%)
Plaque burden at MLA site (%)		78.4 ± 7.8

Procedural Characteristics (AMC data)

Variable	QCA-based (N= 211 lesion)
Pre-dilation using NS balloon	199 (94.3%)
Post-dilation using NC balloon	109 (99.1%)
Post-dilation, Pressure (atm)	19.5 ± 5.3
Final balloon diameter (mm)	3.6 ± 0.3
Final scaffold diameter (mm)	3.5 ± 1.9
Balloon to artery Ratio of proximal RV	1.06 ± 0.14
Balloon to artery Ratio of distal RV	1.37 ± 0.40
Mean Balloon to artery Ratio	1.22 ± 0.30
Mean inflation time (sec)	25 + 12
Absolute difference of final scaffold diameter compare to QCA proximal RVD (mm)	0.2 ± 0.5
Absolute difference of final scaffold diameter compare to QCA distal RVD (mm)	0.8 ± 1.9

Predictor of Scaffold Under Expansion
Univariate Logistic Regression

	MLA<5mm^2 (N=50)	MLA≥5mm^2 (N=180)	OR (95%CI)	P value
Age	61.5 ± 10.5	59.9 ± 9.8	1.01 (0.98 - 1.04)	0.33
Male	40 (80.0%)	147 (81.7%)	0.89 (0.40 - 1.97)	0.78
Hypertension	28 (56.0%)	98 (54.4%)	1.06 (0.56 - 2.00)	0.84
DM	13 (26.0%)	42 (23.3%)	1.15 (0.56 - 2.37)	0.69
Dyslipidemia	41 (82.0%)	139 (77.2%)	1.34 (0.60 - 2.99)	0.47
Smoking	12 (24.0%)	40 (22.2%)	1.10 (0.52 - 2.31)	0.79
History of PCI	4 (8.0%)	15 (8.3%)	0.95 (0.30 - 3.02)	0.94
History of CKD	0 (0.0%)	1 (0.6%)	--	0.99
ACS presentation	4 (8.0%)	15 (8.3%)	0.95 (0.30 -3.02)	0.94
Multi-vessel dis.	21 (42.0%)	75 (41.7%)	1.01 (0.53 - 1.91)	0.96
OCT use	6 (12.0%)	35 (19.4%)	0.56 (0.22 - 1.43)	0.22

Predictor of Scaffold Under Expansion
Univariate Logistic Regression

	MLA<5mm^2 (N=50)	MLA≥5mm^2 (N=180)	OR (95%CI)	P value
ACC/AHA B2/C lesion	36 (72.0%)	119 (66.1%)	1.16 (0.82 - 1.62)	0.38
Moderate to severe Calcification in QCA	5 (10.0%)	5 (2.8%)	3.88 (1.07 - 14.01)	0.038
Bifurcation lesion	40 (80.0%)	111 (61.7%)	2.48 (1.16 - 5.29)	0.018
Total Scaffold number (n)	1.2 ± 0.5	1.1 ± 0.4	1.87 (0.90 - 3.86)	0.09
Thrombus present	5 (10.0%)	15 (8.3%)	1.22 (0.42 - 3.54)	0.712
Plaque burden at MLA (%)	77.1 ± 7.6	78.9 ± 8.0	0.78 (0.69 - 0.88)	<0.001
Diameter stenosis in QCA (%)	61.1 ± 14.8	59.5 ± 15.4	0.98 (0.95-1.01)	0.13
Proximal RVD in QCA (mm)	3.3 ± 0.4	3.5 ± 0.5	0.16 (0.08-0.33)	<0.001
Distal RVD in QCA (mm)	2.3 ± 0.3	2.7 ± 0.4	0.05 (0.02-0.12)	<0.001

Predictor of Scaffold Under Expansion
Multivariate Logistic Regression

	MLA<5mm^2 (N=50)	MLA≥5mm^2 (N=180)	OR (95%CI)	P value
Distal RVD in QCA (mm)	2.3 ± 0.3	2.7 ± 0.4	0.04 (0.11 - 0.17)	<0.001
Proximal RVD in QCA (mm)	3.5 ± 0.5	3.3 ± 0.4	0.46 (0.19 - 1.00)	0.080
Moderate to severe Calcification in QCA	5 (10.0%)	5 (2.8%)	2.97 (0.59 - 14.84)	0.18
Plaque burden at MLA (%)	77.1 ± 7.6	78.9 ± 8.0	0.98 (0.93 – 1.04)	0.64
Bifurcation lesion	40 (80.0%)	111 (61.7%)	1.19 (0.42 – 3.35)	0.74

Result

IRIS-BVS, 1-year
Scaffold Thrombosis

	IRIS-BVS (N=352 patients)
Definite	
Acute (0-1 day)	0.0 %
Sub-acute (2-30 days)	0.0 %
Late (31-365 days)	0.0 %
Very late (>365 days)	0.0 %
Definite or probable	
Acute (0-1 day)	0.0 %
Sub-acute (2-30 days)	0.0 %
Late (31-365 days)	0.0 %
Very late (>365 days)	0.0 %

IRIS-BVS, 1-year
Clinical Endpoints

Variable	IRIS-BVS (N=352 patients)
Device-Oriented Endpoint	
Target-Vessel Failure	2 (0.45 %)
Cardiac Death	0 (0.0 %)
Myocardial infarction	2 (0.45 %)
Periprocedural MI (SCAI)	2 (0.45 %)
Spontaneous MI (SCAI)	0 (0.0 %)
Target-Vessel Revascularization	0 (0.0 %)
Patient-Oriented Endpoint	
Death from any cause	0 (0.0 %)
Cardiac Death	0 (0.0 %)
Non-Cardiac Death	0 (0.0 %)
Stroke	0 (0.0 %)

Absorb vs. Xience (EES)

Baseline Characteristics

	IRIS-BVS (N=352)	IRIS-PRIME (N=1380)	P value
Age (years)	60.6 ± 10.0	64.6 ± 10.0	<0.001
Male sex	281 (79.8%)	968 (70.1%)	<0.001
BMI, kg/m^2	25.1 ± 2.9	24.8 ± 3.0	0.053
Hypertension	195 (55.4%)	913 (66.2%)	<0.001
Diabetes mellitus	97 (27.6%)	514 (37.2%)	0.001
Hypercholesterolemia	269 (76.4%)	559 (40.5%)	<0.001
Current smoker	89 (25.3%)	371 (26.9%)	0.59
Previous PCI	27 (7.7%)	150 (10.9%)	0.095
Previous CABG	3 (0.9%)	33 (2.4%)	0.11
Chronic renal failure	2 (0.6%)	54 (3.9%)	0.003
LVEF, %	49.0 ± 26.5	46.2 ± 26.9	0.078
Stable angina or silent ischemia	70 (19.9%)	604 (43.8%)	<0.001
ACS presentation	60.6 ± 10.0	64.6 ± 10.0	<0.001

Lesion and Procedural Characteristics

	IRIS-BVS (N=352)	IRIS-PRIME (N=1380)	P value
Treated vessel			
LM	6 (1.7%)	49 (3.6%)	0.11
LAD	275 (78.1%)	938 (68.0%)	<0.001
LCX	85 (24.1%)	361 (26.2%)	0.48
RCA	108 (30.7%)	495 (35.9%)	0.078
Multi-vessel disease	101 (28.7%)	393 (28.5%)	0.98
Severe calcification	7 (2.0%)	187 (13.6%)	<0.001
Bifurcation	198 (56.2%)	709 (51.4%)	0.11
De novo lesion	350 (99.4%)	1323 (95.9%)	0.002
Lesion type B2/C	276 (78.4%)	1175 (85.1%)	0.003
Intracoronary Imaging	327 (92.9%)	706 (51.2%)	<0.001
Number of total stents	1.5 ± 0.9	1.6 ± 0.9	0.10
Average stent diameter, mm	3.3 ± 0.3	3.1 ± 0.4	<0.001
Total stent length, mm	30.6 ± 18.8	42.8 ± 26.6	<0.001

IRIS-BVS, 1-year
Scaffold or Stent Thrombosis

	IRIS-BVS (N=352)	IRIS-PRIME (N=1380)
Definite		
Acute (0-1 day)	0.0 %	1 (0.07 %)
Sub-acute (2-30 days)	0.0 %	0.0 %
Late (31-365 days)	0.0 %	0.0 %
Very late (>365 days)	0.0 %	0.0 %
Definite or probable		
Acute (0-1 day)	0.0 %	1 (0.07 %)
Sub-acute (2-30 days)	0.0 %	0.0 %
Late (31-365 days)	0.0 %	0.0 %
Very late (>365 days)	0.0 %	0.0 %

IRIS-BVS, 1-year
Clinical Endpoints

Variable	IRIS-BVS (N=352)	IRIS-PRIME (N=1380)	P value
Device-Oriented Endpoint			
Target-Vessel Failure	2 (0.06 %)	49 (3.6%)	0.062
Cardiac Death	0 (0.0 %)	16 (1.2 %)	0.12
Myocardial infarction	2 (0.06 %)	44 (3.2 %)	0.015
Periprocedural MI (SCAI)	2 (0.06 %)	25 (1.8 %)	0.093
Spontaneous MI (SCAI)	0 (0.0 %)	19 (1.4 %)	0.068
Target-Lesion Revascularization	0 (0.0 %)	21 (1.6 %)	0.28
Patient-Oriented Endpoint			
Death from any cause	0 (0.0 %)	21 (1.6 %)	0.11
Cardiac Death	0 (0.0 %)	16 (1.2 %)	0.12
Non-Cardiac Death	0 (0.0 %)	1 (1.0 %)	0.59
Stroke	0 (0.0 %)	13 (1.0 %)	0.22

Propensity Matching Analysis

Baseline Characteristics

PS matched	IRIS-BVS (N=352)	IRIS-EES (N=352)	P value
Age (years)	60.6 ± 10.0	61.8 ± 9.9	0.093
Male sex	281 (79.8%)	276 (78.4%)	0.71
BMI, kg/m^2	25.1 ± 2.9	24.8 ± 2.8	0.20
Hypertension	195 (55.4%)	210 (59.7%)	0.28
Diabetes mellitus	97 (27.6%)	110 (31.2%)	0.32
Hypercholesterolemia	269 (76.4%)	236 (67.0%)	0.007
Current smoker	89 (25.3%)	104 (29.5%)	0.23
Previous PCI	27 (7.7%)	33 (9.4%)	0.50
Previous CABG	3 (0.9%)	7 (2.0%)	0.33
Chronic renal failure	2 (0.6%)	4 (1.1%)	0.68
LVEF, %	49.0 ± 26.5	49.5 ± 25.1	0.80
Stable angina or silent ischemia	70 (19.9%)	92 (26.1%)	0.06
ACS presentation	60.6 ± 10.0	61.8 ± 9.9	0.093

Lesion and Procedural Characteristics

PS matched	IRIS-BVS (N=352)	IRIS-EES (N=352)	P value
Treated vessel			
LM	6 (1.7%)	8 (2.3%)	0.78
LAD	275 (78.1%)	257 (73.0%)	0.13
LCX	85 (24.1%)	47 (13.4%)	<0.001
RCA	108 (30.7%)	111 (31.5%)	0.87
Multi-vessel disease	101 (28.7%)	62 (17.6%)	0.001
Severe calcification	7 (2.0%)	7 (2.0%)	0.99
Bifurcation	198 (56.2%)	202 (57.4%)	0.81
De novo lesion	350 (99.4%)	350 (99.4%)	0.99
Lesion type B2/C	276 (78.4%)	288 (81.8%)	0.29
Intracoronary Imaging	327 (92.9%)	324 (92.0%)	0.77
Number of total stents	1.5 ± 0.9	1.3 ± 0.6	<0.001
Average stent diameter, mm	3.3 ± 0.3	3.3 ± 0.4	0.71
Total stent length, mm	30.6 ± 18.8	33.3 ± 18.7	0.06

IRIS-BVS, 1-year
Scaffold or Stent Thrombosis

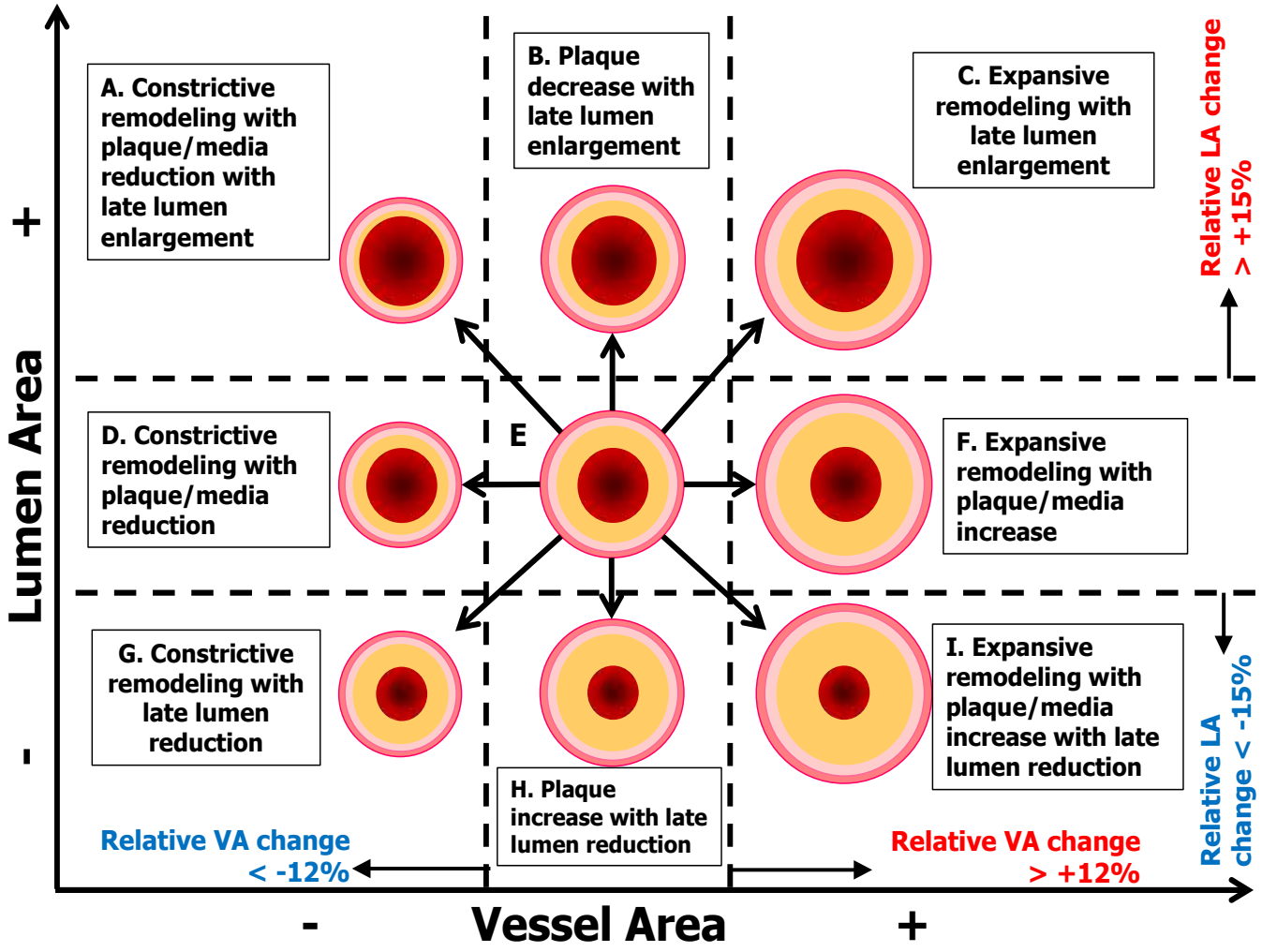
PS matched	IRIS-BVS (N=352)	IRIS-EES (N=352)
Definite		
Acute (0-1 day)	0 (0.0 %)	0 (0.0 %)
Sub-acute (2-30 days)	0 (0.0 %)	0 (0.0 %)
Late (31-365 days)	0 (0.0 %)	0 (0.0 %)
Very late (>365 days)	0 (0.0 %)	0 (0.0 %)
Definite or probable		
Acute (0-1 day)	0 (0.0 %)	0 (0.0 %)
Sub-acute (2-30 days)	0 (0.0 %)	0 (0.0 %)
Late (31-365 days)	0 (0.0 %)	0 (0.0 %)
Very late (>365 days)	0 (0.0 %)	0 (0.0 %)

IRIS-BVS, 1-year
Clinical Endpoints

PS matched	IRIS-BVS (N=352)	IRIS-EES (N=352)	P value
Device-Oriented Endpoint			
Target-Vessel Failure	2 (0.06 %)	6 (1.8 %)	0.88
Cardiac Death	0 (0.0 %)	3 (0.9 %)	0.41
Myocardial infarction	2 (0.06 %)	11 (3.1 %)	0.019
Periprocedural MI (SCAI)	2 (0.06 %)	9 (2.6 %)	0.033
Spontaneous MI (SCAI)	0 (0.0 %)	2 (0.06 %)	0.30
Target-Lesion Revascularization	0 (0.0 %)	3 (0.09 %)	0.68
Patient-Oriented Endpoint			
Death from any cause	0 (0.0 %)	5 (1.5 %)	0.35
Cardiac Death	0 (0.0 %)	3 (0.9 %)	0.063
Non-Cardiac Death	0 (0.0 %)	2 (0.06 %)	0.64
Stroke	0 (0.0 %)	1 (0.03 %)	0.47

Vascular Remodeling after BVS

Mean Lumen Area (LA) and Mean Vessel Area (VA) Change Over 3 Years

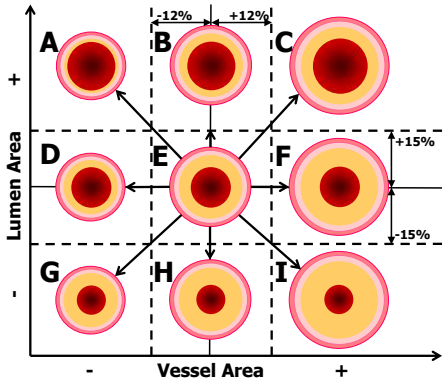


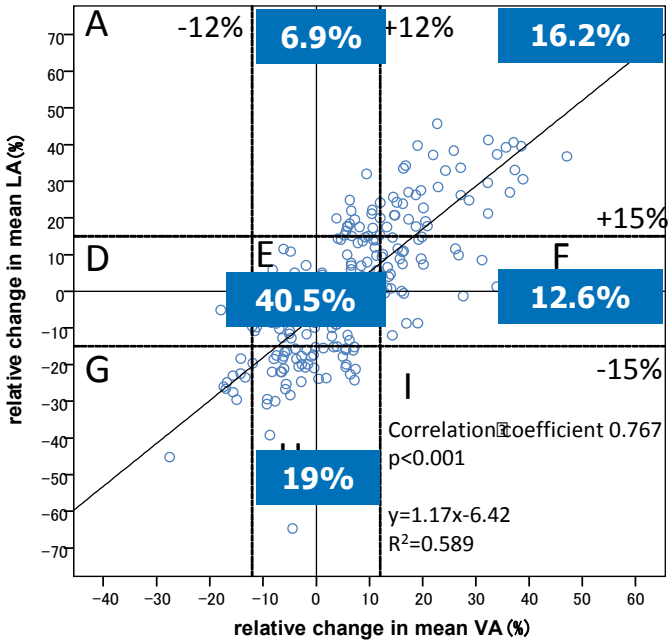
Van Mieghem, Serruys et al. *Int J Cardiovasc Imaging* 2005

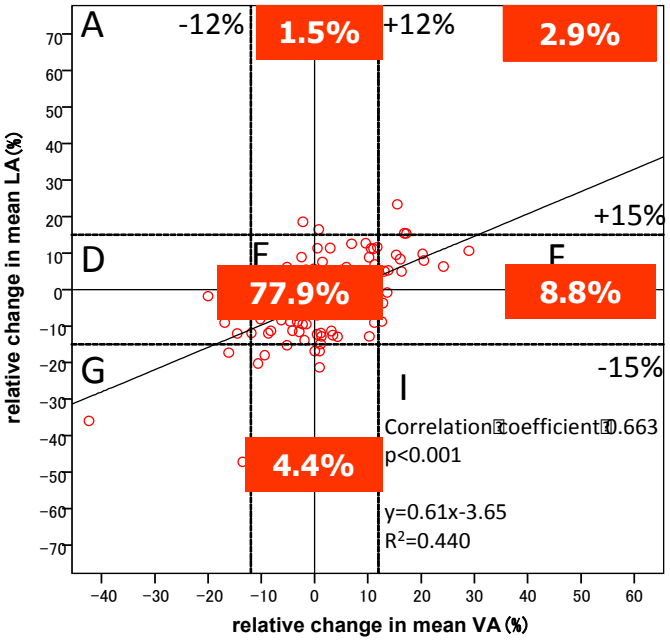
Mean Lumen Area (LA) and Mean Vessel Area (VA) Change Over 3 Years in ABSORB II

Absorb (n=237)

Xience (n=136)

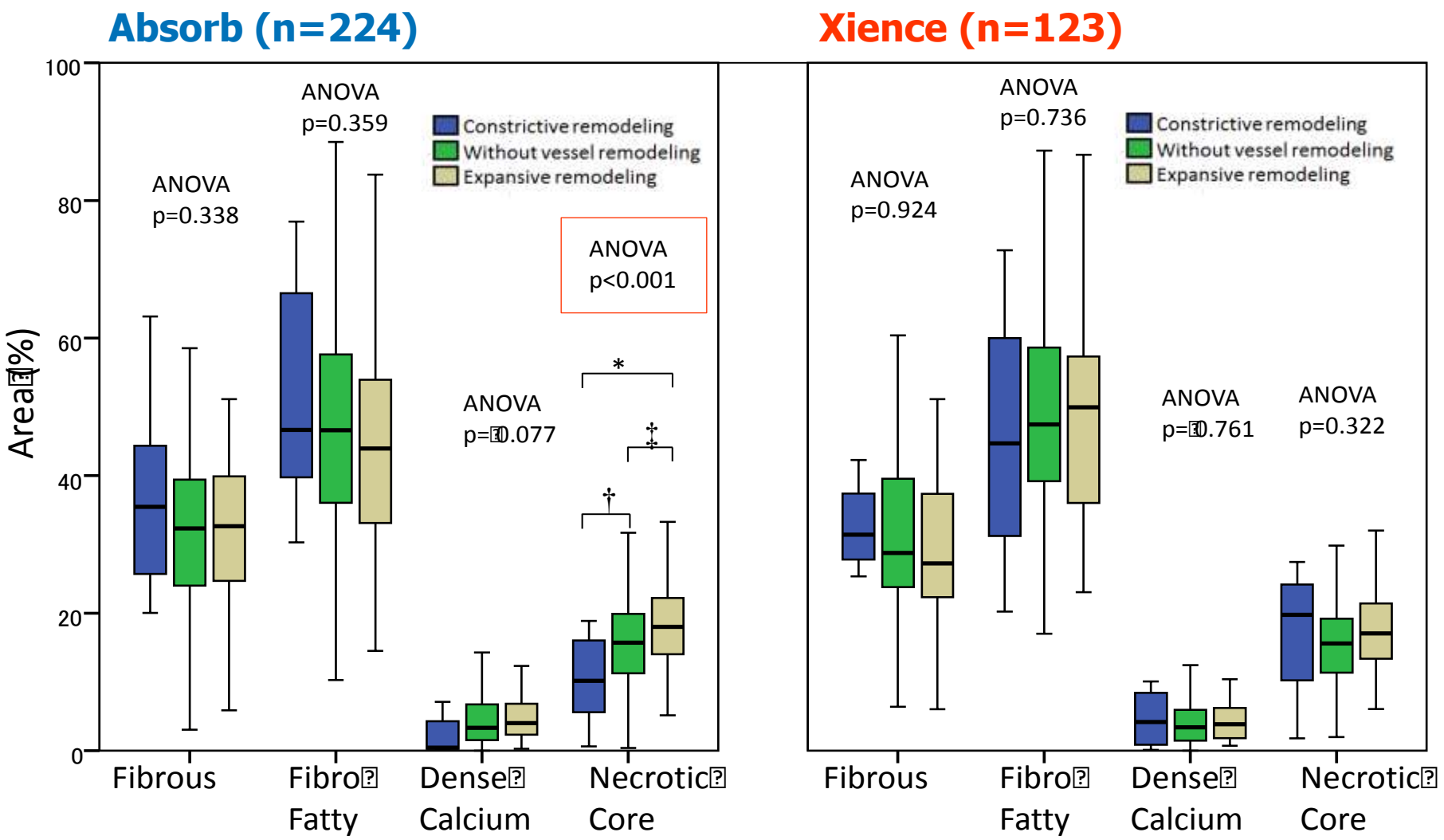




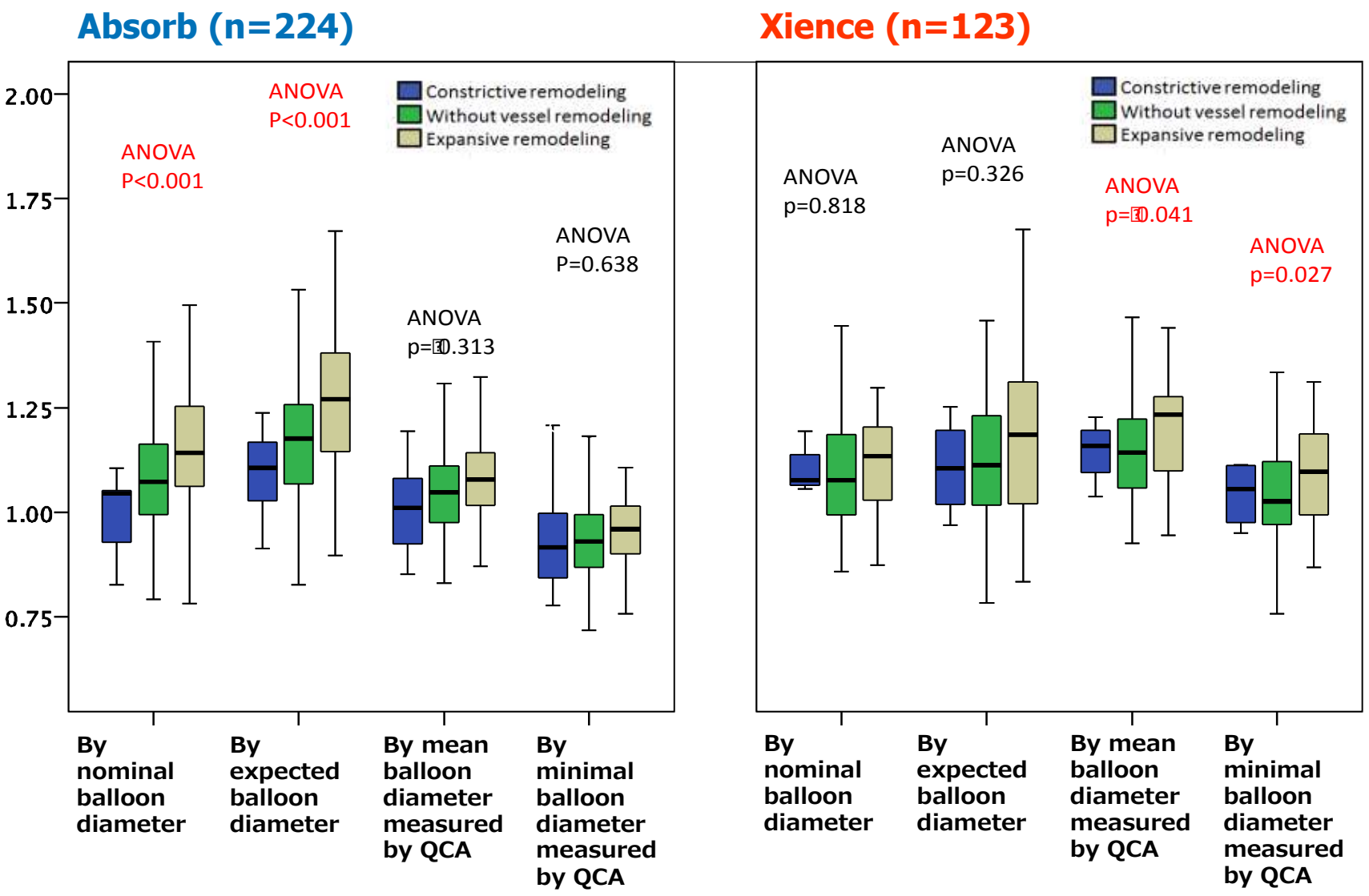


Courtesy of Patrick Serruys

Pre-procedural IVUS-VH and Vessel Remodeling over 3 years in ABSORB II



Various balloon-artery ratios and vessel remodeling



Independent Predictors for expansive remodeling over 3 years *Multivariate analysis from ABSORB II*

	Absorb		
	OR	[95% CI]	p value
Female	3.25	[1.35-7.81]	0.008
Expected balloon-artery ratio > 1.25	3.17	[1.23-8.14]	0.017
Post-procedural IVUS: expansion index ≥ 0.8	3.91	[1.49-10.22]	0.005
mean LDL cholesterol over 3 years (per mmol/L)	2.67	[1.38-5.17]	0.004
Pre-procedural IVUS-VH: necrotic core > 16.7%	2.5	[1.08-5.79]	0.033
Previous PCI	2.09	[0.90-4.86]	0.088
Post-procedural IVUS: asymmetry index > 0.3	1.65	[0.60-4.52]	0.334
Post-procedural IVUS: eccentricity index < 0.7	0.95	[0.35-2.57]	0.922
Pre-procedural IVUS: mean lumen area (per mm^2)	0.91	[0.54-1.55]	0.73
Pre-procedural IVUS: mean vessel area (per mm^2)	1	[0.81-1.23]	0.966

Independent Predictors for expansive remodeling over 3 years *Multivariate analysis from ABSORB II*

- Absorb implantation, female gender, expected balloon-artery ratio ≥ 1.25, expansion index ≥ 0.8, previous PCI, and higher mean level of LDL cholesterol (average over 3 years) were independent factors predicting expansive remodeling.

- Especially in the Absorb arm, pre-procedural greater proportion of necrotic core (> 16.5% in mean plaque area) was also an independent predictor for expansive remodeling.

Why
The Technique of PSP
Is so Important ?

Procedural Characteristics of AMC PSP

Variable	QCA-based (N= 211 lesion)
Pre-dilation using NS balloon	199 (94.3%)
Post-dilation using NC balloon	109 (99.1%)
Post-dilation, Pressure (atm)	19.5 ± 5.3
Final balloon diameter (mm)	3.6 ± 0.3
Final scaffold diameter (mm)	3.5 ± 1.9
Balloon to artery Ratio of proximal RV	1.06 ± 0.14
Balloon to artery Ratio of distal RV	1.37 ± 0.40
Mean Balloon to artery Ratio	1.22 ± 0.30
Mean inflation time (sec)	25 + 12
Absolute difference of final scaffold diameter compare to QCA proximal RVD (mm)	0.2 ± 0.5
Absolute difference of final scaffold diameter compare to QCA distal RVD (mm)	0.8 ± 1.9

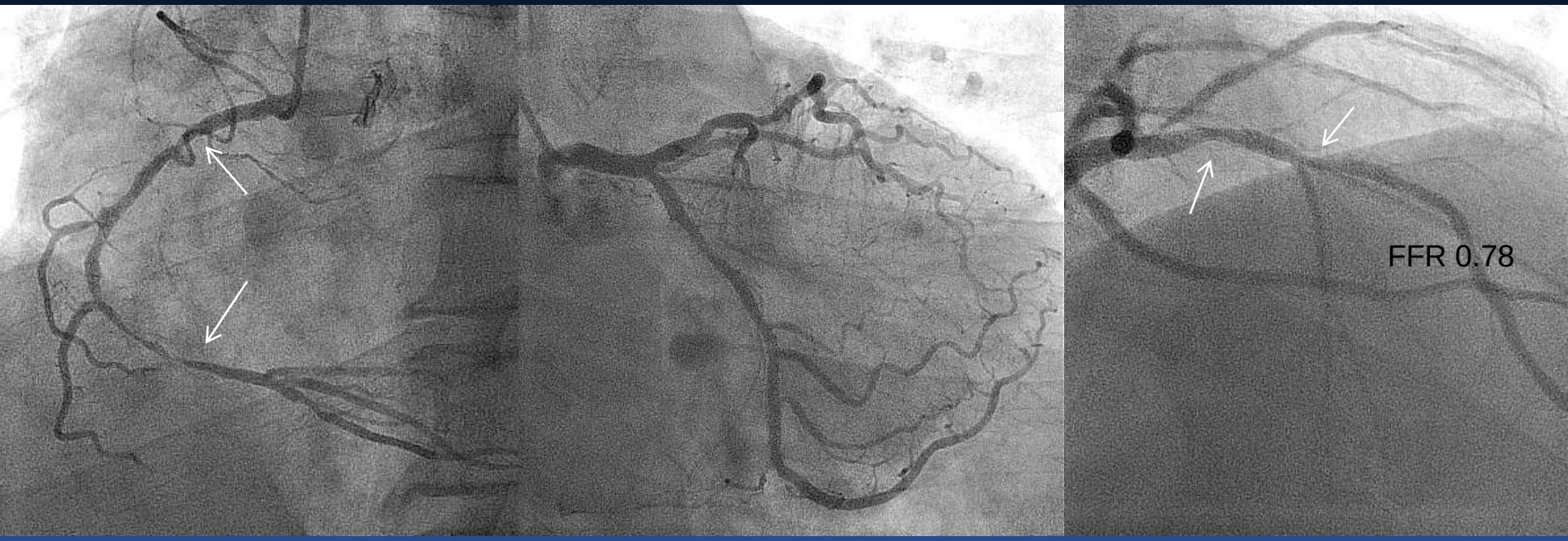
Why
The Technique of PSP
Is so Important ?

Large balloon to artery ratio and high pressure, long duration post-dilation can make a small absolute gain of final scaffold diameter.

0 % Scaffold Thrombosis

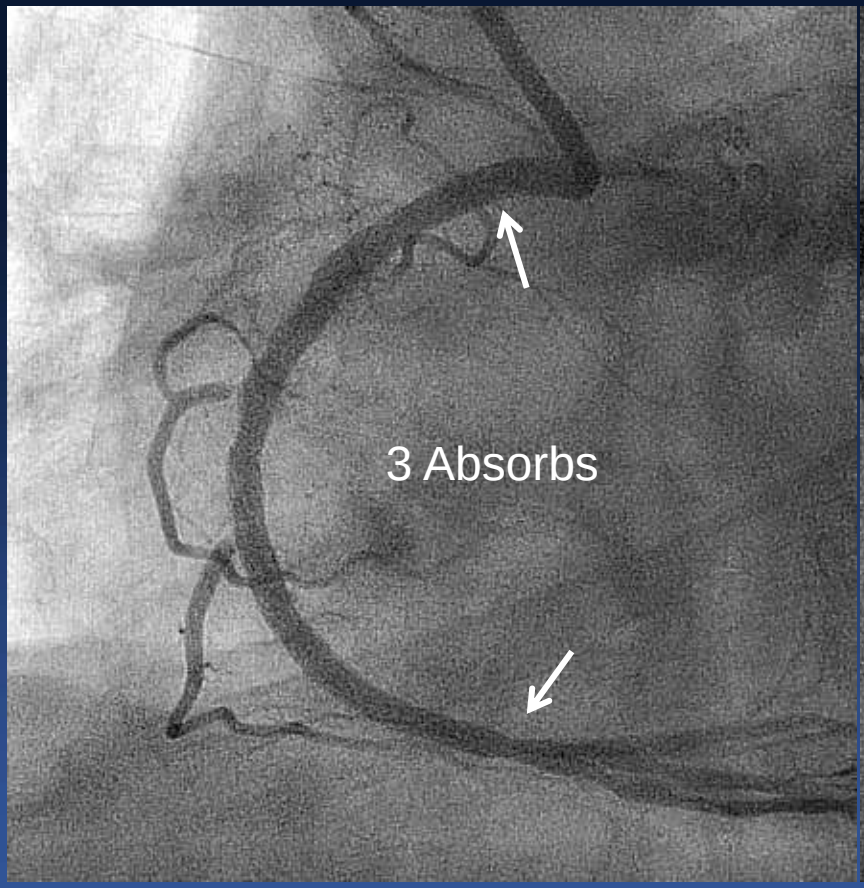
1. Big vessel >2.5 mm
2. BVS sizing by QCA - same size with proximal RVD
3. Balloon to artery ratio >1.2,
   (usually 0.5 mm bigger NC balloon)
4. Post-dilation with high pressure using NC balloon
   (mean 19 atm, 16~25), long duration >20 sec
5. Long lesion BVS implantation(>28 mm),
   imaging guided is mandatory
6. Triple antiplatelet therapy (DAPT+Cilostazol)
   for 6 months in selected cases.

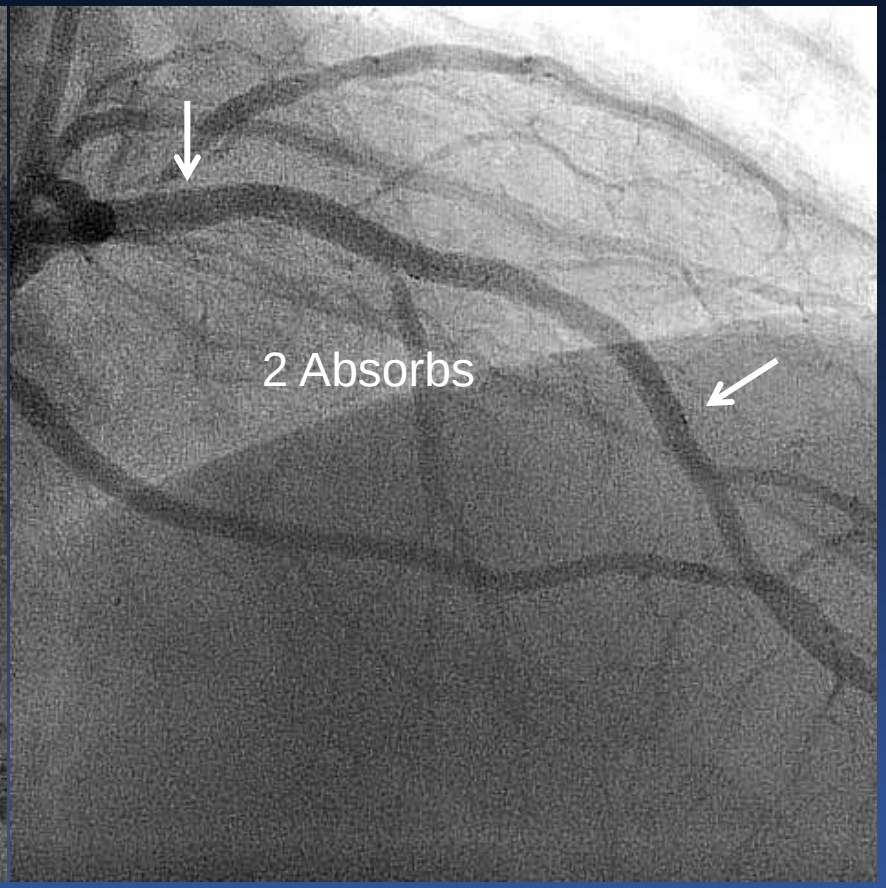
68 y/o male, Stable angina, 2-Vessel Disease, Diffuse Long in RCA, Tandem Lesions in LAD



Polymer Jacket !

5 ABSORBs in A Patient



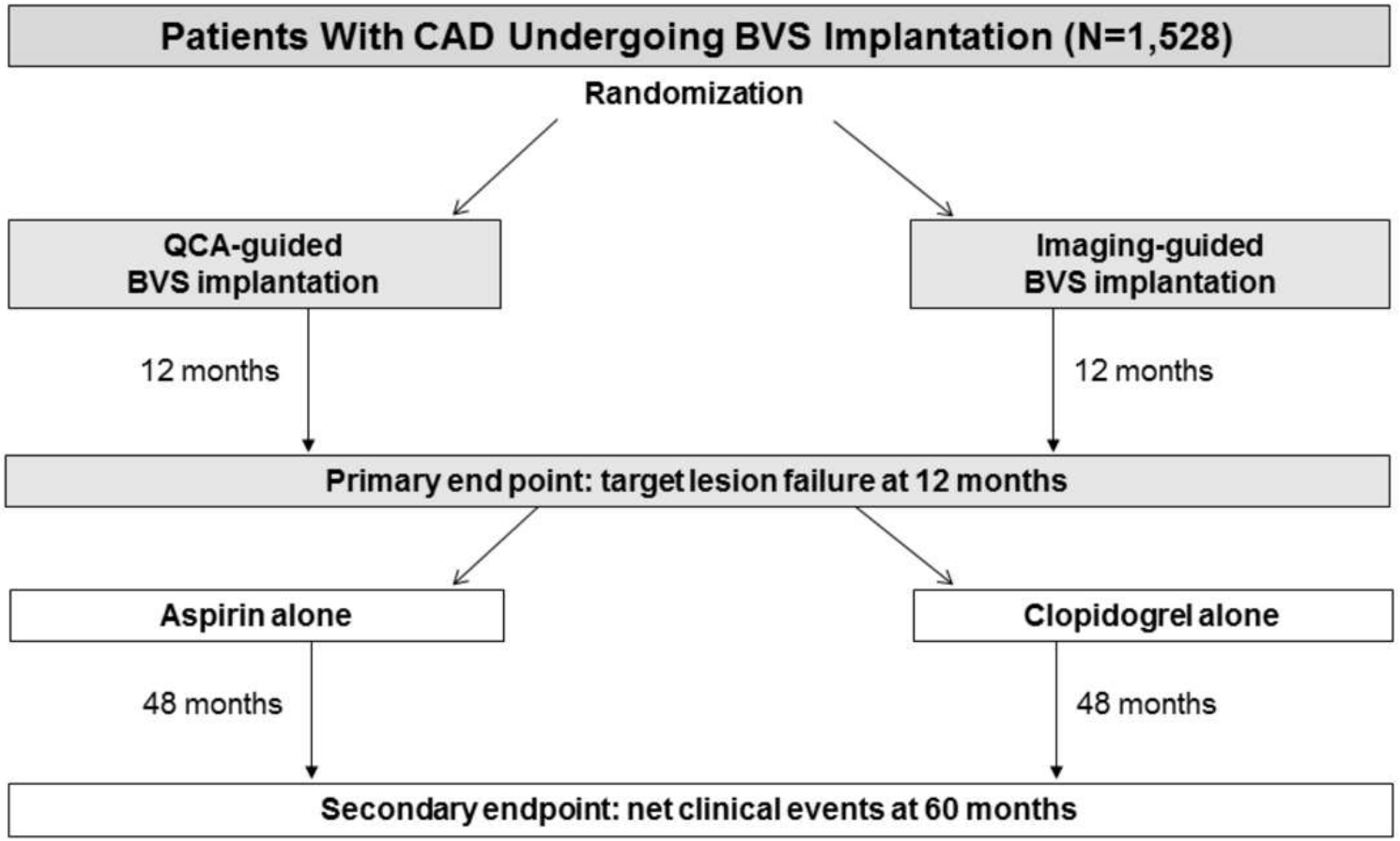


Unresolved Issues

1. Is Imaging guided BVS implantation mandatory ?
2. What are the results in complex long lesion compared to those of 2nd Generation DES ?
3. Is one year DAPT enough ?
4. Are the long term results really better with Absorb ?

QCA guided vs. Image guided

GUIDE-BVS

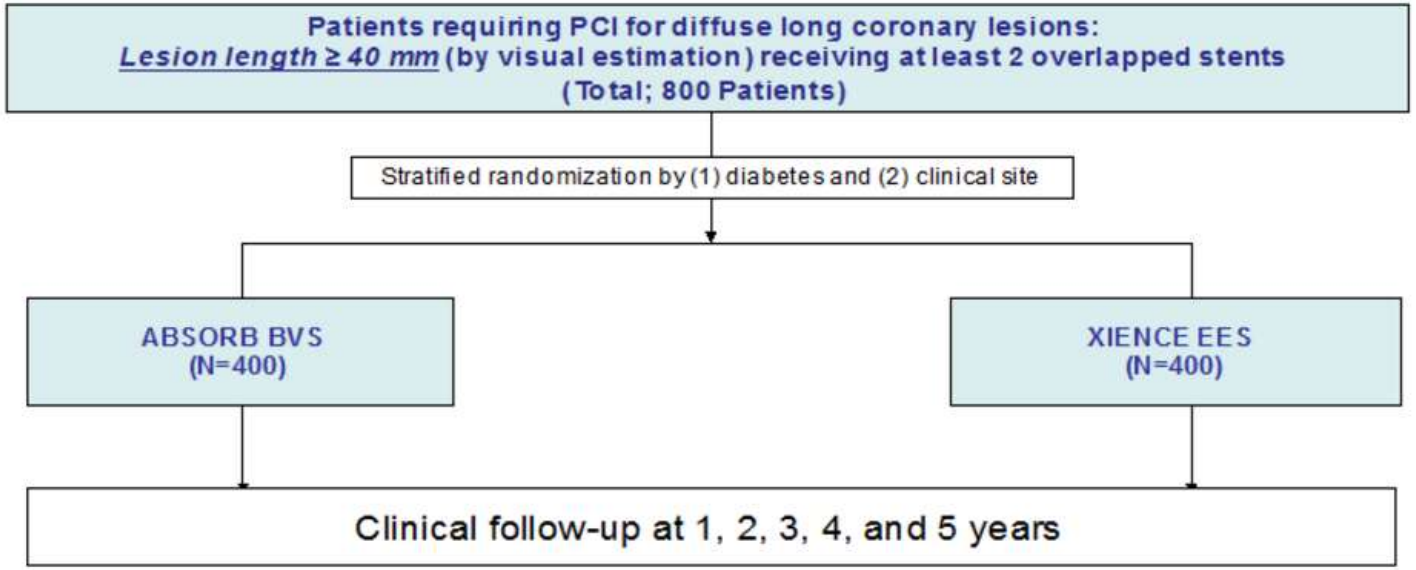


Target lesion failure: cardiac death, target vessel myocardial infarction, or ischemia-driven target lesion revascularization
Net clinical events: CVdeath, myocardial infarction, stroke, or clinically relevant bleeding

BVS for Long Lesion (>40mm)

Everolimus-Eluting Bioresorbable Scaffolds versus Everolimus-Eluting Metallic Stents for Diffuse Long Coronary Artery Disease

ABSORB-LONG Trial

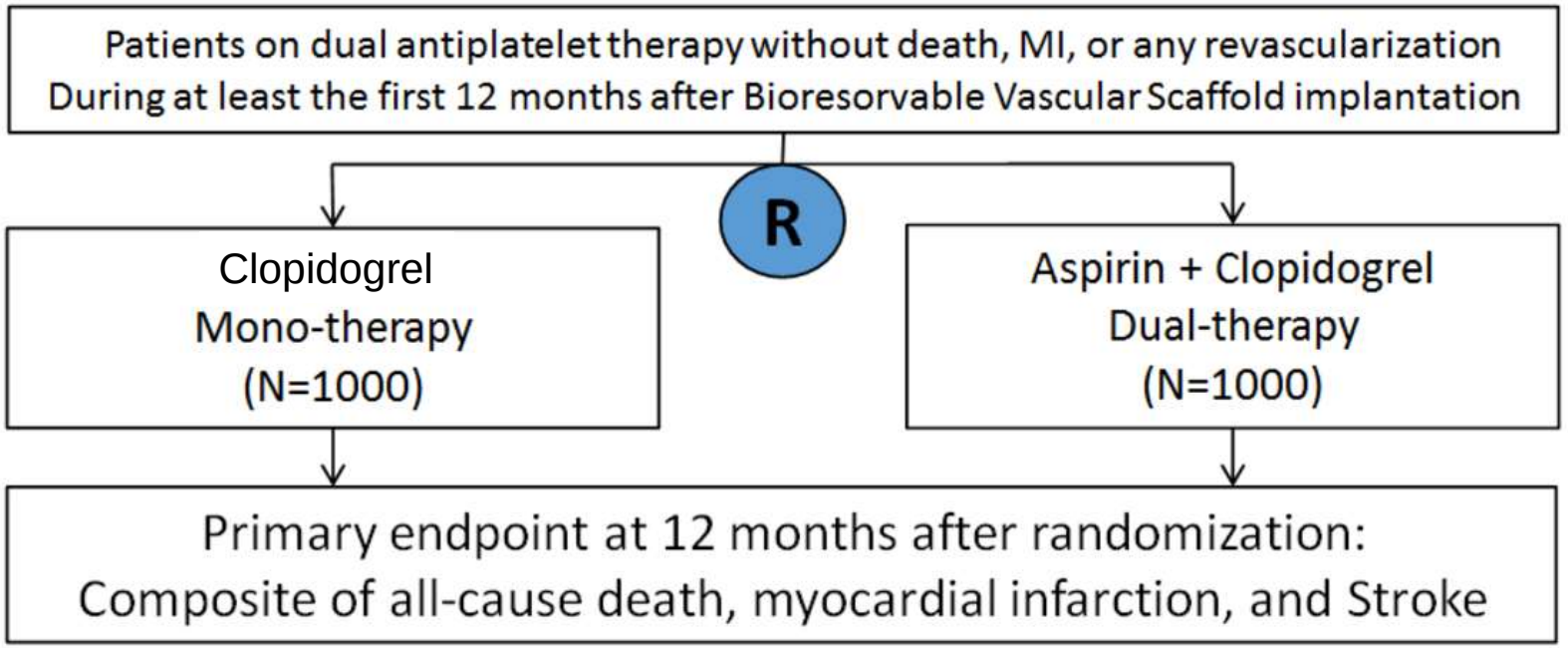


*Primary endpoint: target-lesion failure (composite of cardiac death, TV-MI, or ID-TLR) at 1 year

How Long DAPT ?

Optimal Duration of Antiplatelet Therapy after
Bioresorbable Vascular Scaffold Implantation
to Reduce Late Coronary Arterial Thrombotic Events

BVS-LATE trial



There are Concerns about BVS,
It's a Chance to Move Forward !

Thank You !!

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