SESSION CONJUNTA TCT @SOLACI/SOCIME 2015

PERSPECTIVAS EN INTERVENCIONES CORONARIAS COMPLEJAS

NECESSIDADES NO SATISFECHAS EN CARDIOLOGIA INTERVENCIONISTA.PRESENTACION DEL CASO

Prof. Dr. EXPEDITO E. RIBEIRO

ASSOCIATE PROFESSOR CARDIOLOGY SCHOOL OF MEDICINE - UNIVERSTY OF SÃO PAULO
INTERVENTIONAL CARDIOLOGY OF INCOR-HCFMUSP
DIRECTOR OF INTERVENTIONAL CARDIOLOGY TOTALCOR / ALVORADA HOSPITAL
INTERVENTIONAL CARDIOLOGY OF THE GERMAN HOSP OSVALDO CRUZ

NO CONFLICT OF INTEREST RELATED TO THIS PRESENTATION

IN WHICH PATIENTS SHOULD I USE A BRS RATHER THAN ONE DES OF LAST GENERATION?

- EVERY PATIENT
- SOME PATIENTS
- NEVER

- THE ANSWER IS:

- WE DON'T KNOW YET

- WHY ?

POSSIBLES EXPLANATIONS

1ST. :NEW GENERATIONS OF DES ARE VERY GOOD

PROGESS WITH METALLIC DRUG-ELUTING STENTS

	Taxus	Cypher	BioMatrix Nobori	Endeavor	Yukon PC	Xience Promus	Resolute	Synergy	Orsiro	DESyne	Combo	Mistent	Ultimaster
Platform material	SS	SS	SS	CoCr	SS	CoCr PtCr	CoCr	PtCr	CoCr	CoCr	SS	CoCr	CoCr
Strut thickness (µm)	132	140	120	91	87	81	91	74	60	81	100	64	80
Polymer type	Durable	Durable	Biodegradable	Durable	Biodegradable	Durable	Durable	Biodegradable	Biodegradable	Biodegradable	Biodegradable	Biodegradable	Biodegradable
Polymer material	SIBS	PEVA/PBMA	PDLLA	MPC/LMA/HPMA/ 3-MPMA	PDLLA	PBMA/PVDF-HFP	PBMA/PHMA/ PVP/PVA	PLGA	PLLA	PLLA	PDLLA/PLGA	PLGA	PDLLA-PCL
Coating distribution	Circumferential	Circumferential	Abluminal	Circumferential	Circumferential	Circumferential	Circumferential	Abluminal	Circumferential	Circumferential	Abluminal	Circumferential	Abluminal
Polymer thickness (µm)	22	13	10	6	5	8	6	4	7	<3	5	10	15
Additional coating	-	-	-	-	-	-	-	-	Silicon carbide	-	Anti-CD34 Antibodies	-	-
Drug released	Paclitaxel	Sirolimus	Biolimus	Zotarolimus	Sirolimus	Everolimus	Zotarolimus	Everolimus	Sirolimus	Novolimus	Sirolimus	Sirolimus	Sirolimus

Stefanini, Taniwaki, Windecker. Heart 2014

RESEARCH

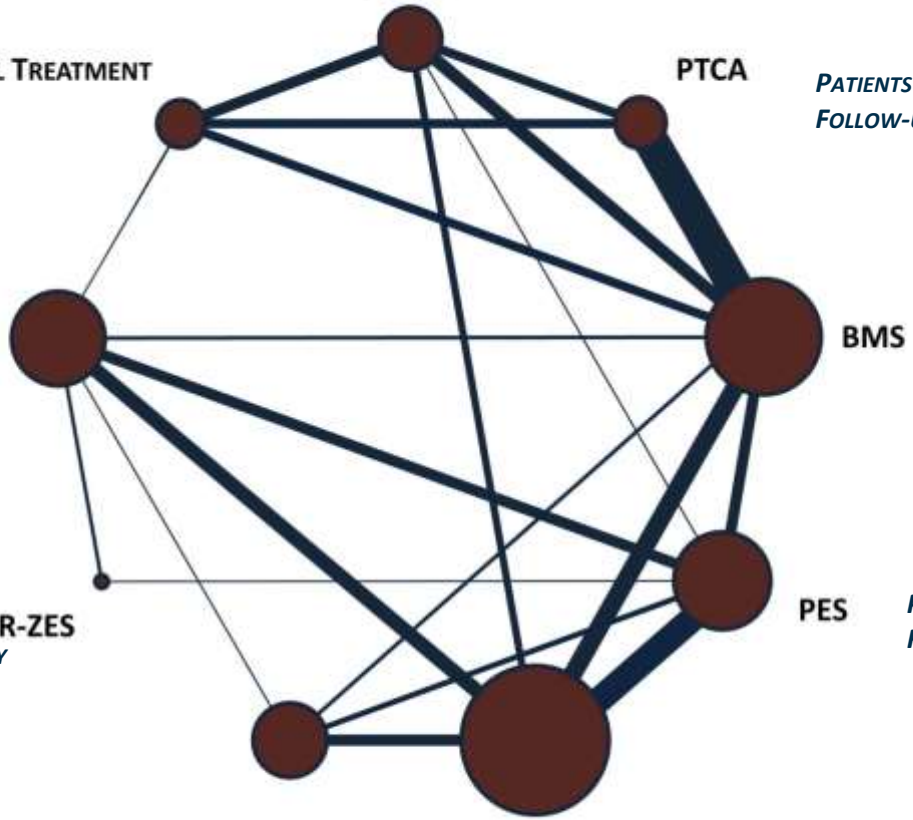
Revascularisation versus medical treatment in patients with stable coronary artery disease: network meta-analysis

Stephan Windecker, Stefan Stortecky, Giulio G Stefanini, Bruno R daCosta, Anne Wilhelmina Rutjes, Marcello Di Nisio, Maria G Siletta, Ausilia Maione, Fernando Alfonso, Peter M Clemmensen, Jean-Philippe Collet, Jochen Cremer, Volkmar Falk, Gerasimos Filippatos, Christian Hamm, Stuart Head, Arie Pieter Kappetein, Adnan Kastrati, Juhani Knuuti, Ulf Landmesser, Günther Laufer, Franz-Joseph Neumann, Dimitri Richter, Patrick Schauerte, Miguel Sousa Uva, David P Taggart, Lucia Torracca, Marco Valgimigli, William Wijns, Adam Witkowski, Philippe Kolh, Peter Juni

Revascularization versus Medical Therapy

A Network Meta-Analysis

100 RCTs - 93'553 patients randomized
Follow - Up of 262'090 Patient-years



Patients randomized 8,920
Follow-up 38,709 py

Patients randomized 6,846
Follow-up 30,628 py

Patients randomized 6,920
Follow-up 17,678 py

Patients randomized 14,802
Follow-up 25,096 py

Patients randomized 15,787
Follow-up 45,467 py

Patients randomized 2,035
Follow-up 3,134 py

Patients randomized 12,457
Follow-up 28,828 py

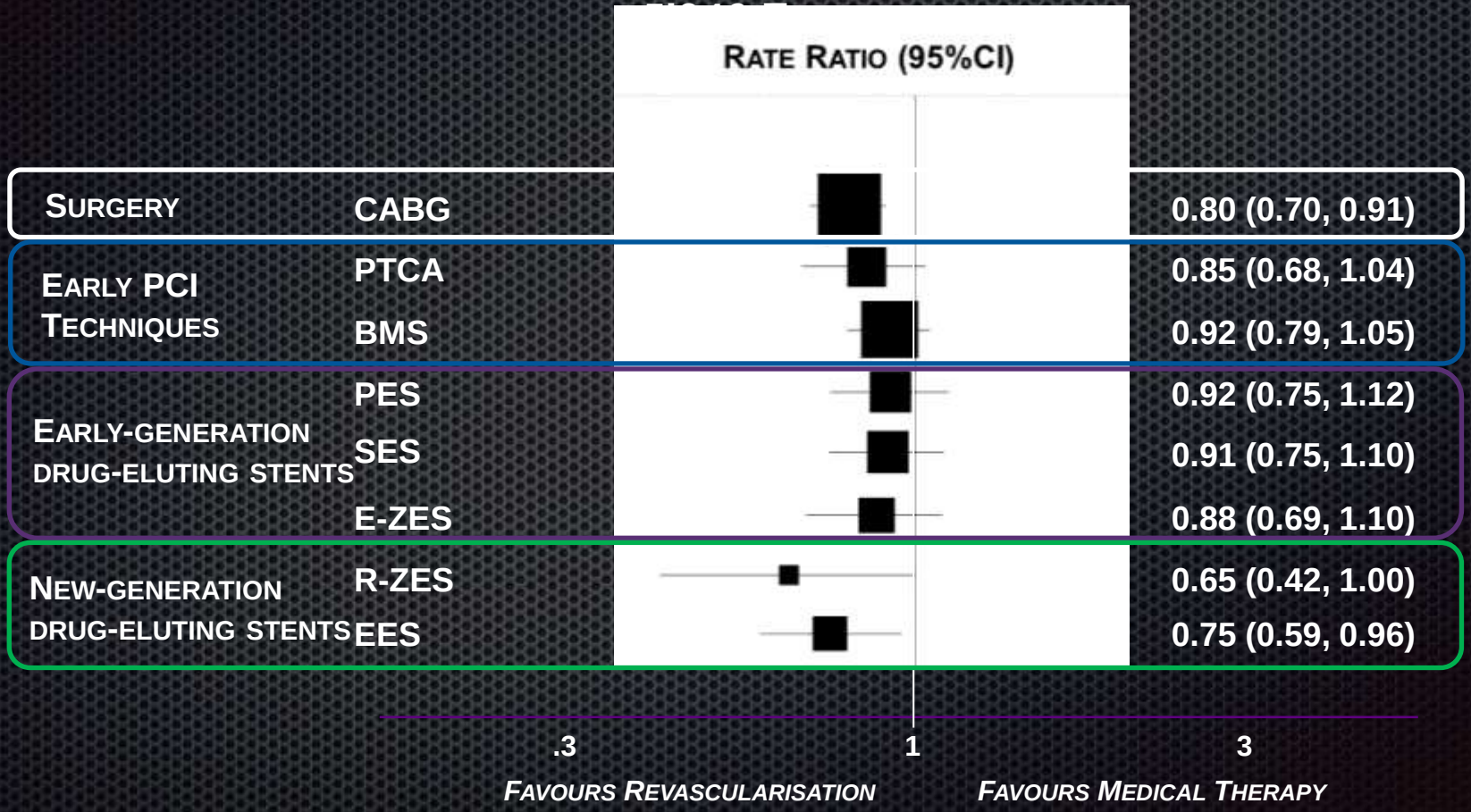
Patients randomized 9,187
Follow-up 27,384 py

Patients randomized 19,391
Follow-up 45,679 py

Windecker S et al. BMJ 2014

Revascularisation versus Medical Therapy in Stable CAD
A Network Meta-Analysis
Primary Endpoint: All-Cause Mortality

100 RCTs, 93'553 Randomized Patients, 262'090 patient-years of Follow-up,



Windecker S et al. *BMJ*

Revascularization versus Medical Therapy
A Network Meta-Analysis
Secondary Endpoint Repeat Revascularization

90'282 Randomized Patients, 234'693 patient-years of Follow-up
11'619 Events for the Analysis

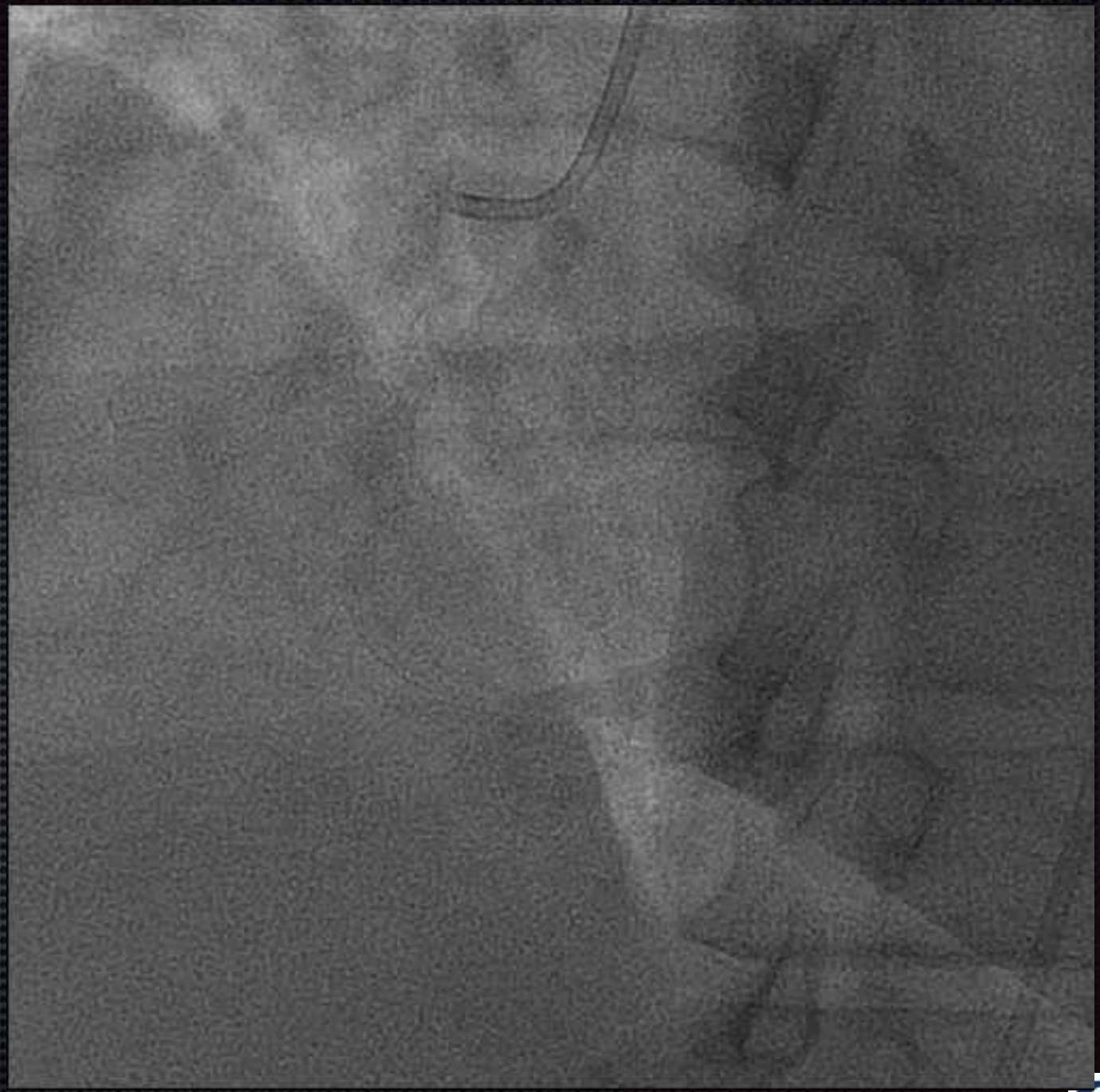
Windecker S et al. *BMJ* 2014

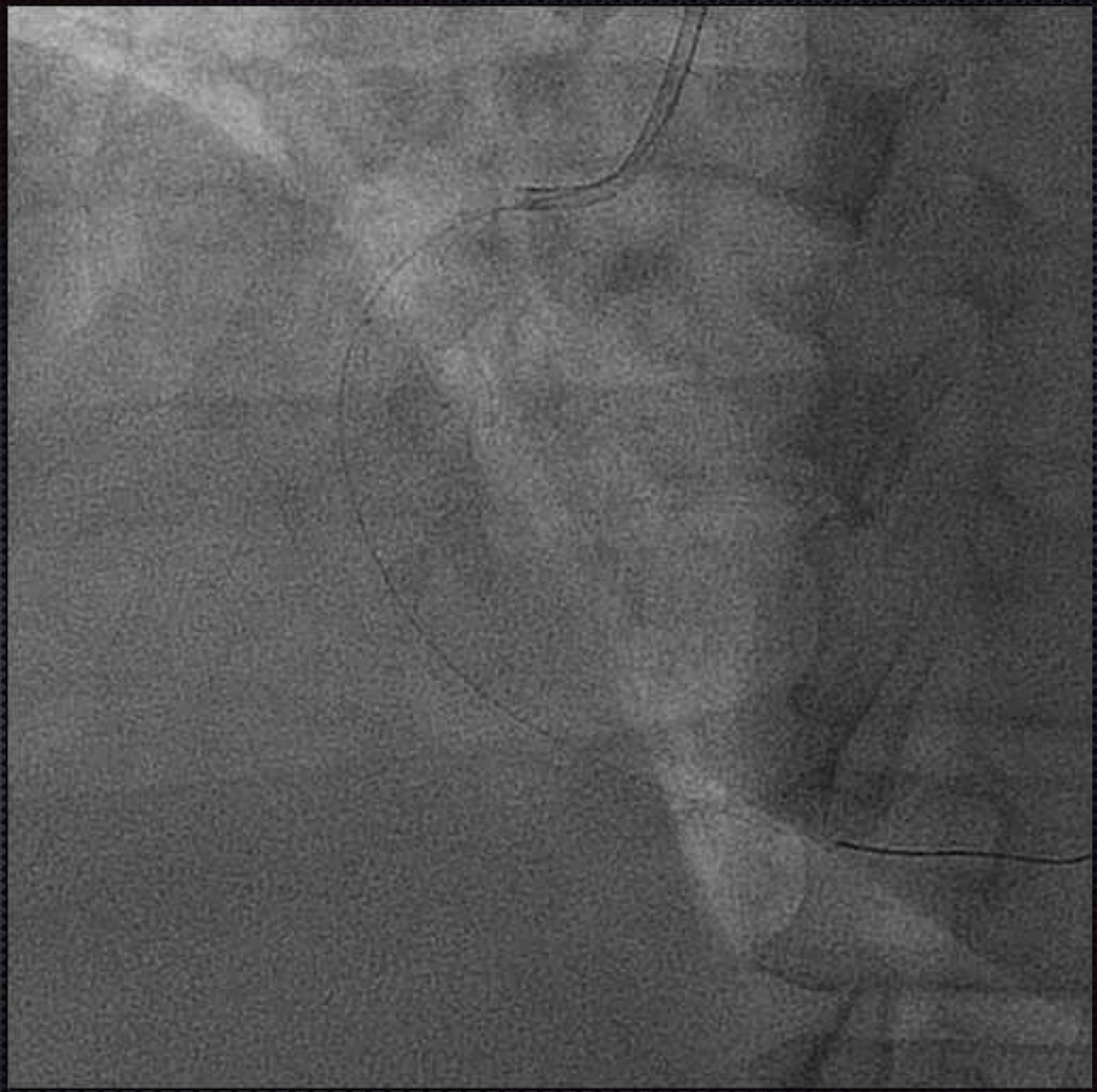
POSSIBLES EXPLANATIONS

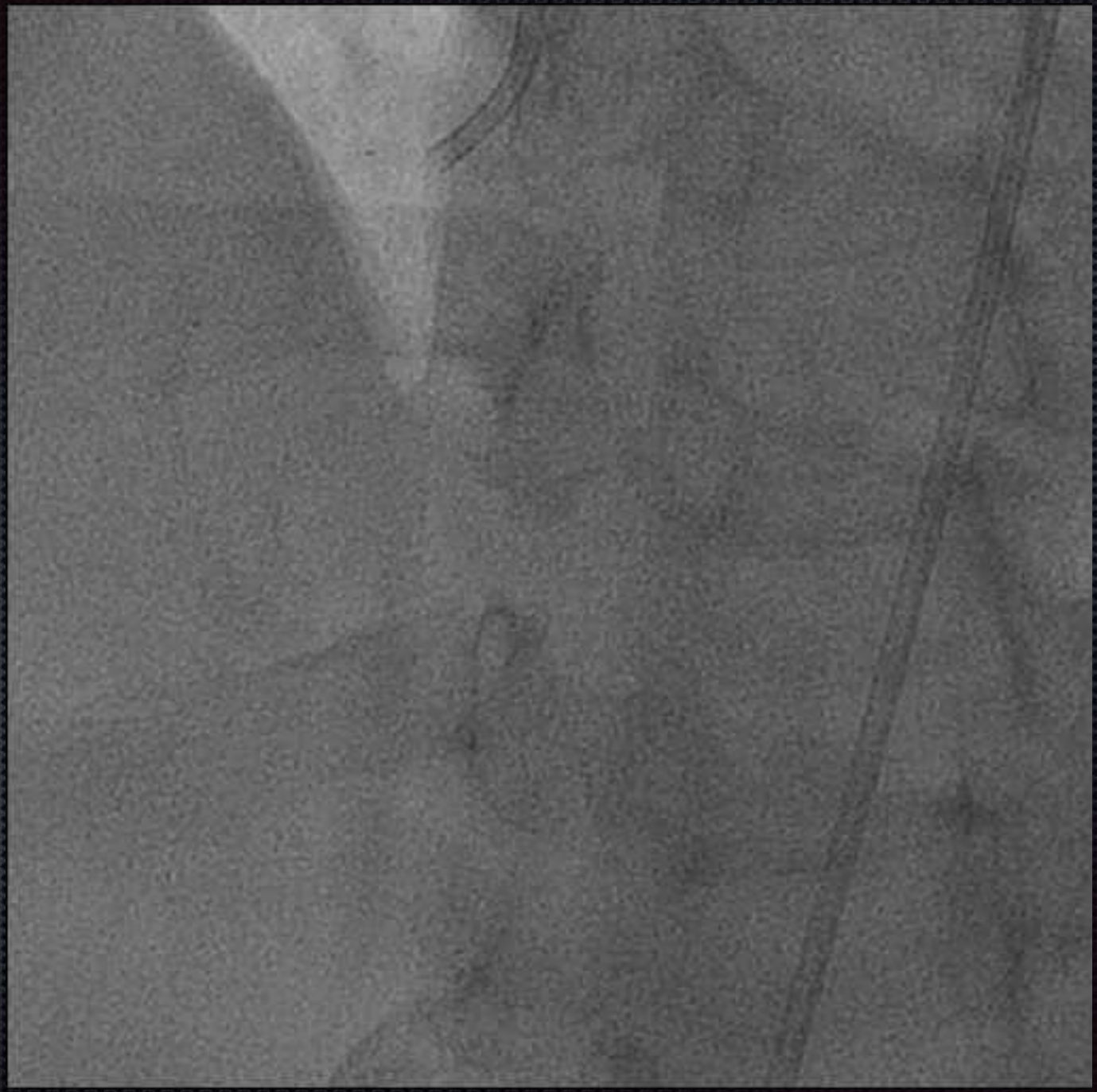
1ST. :NEW GENERATIONS OF DES ARE VERY GOOD

2ND. : TWO EXAMPLES OF UNMET NEEDS

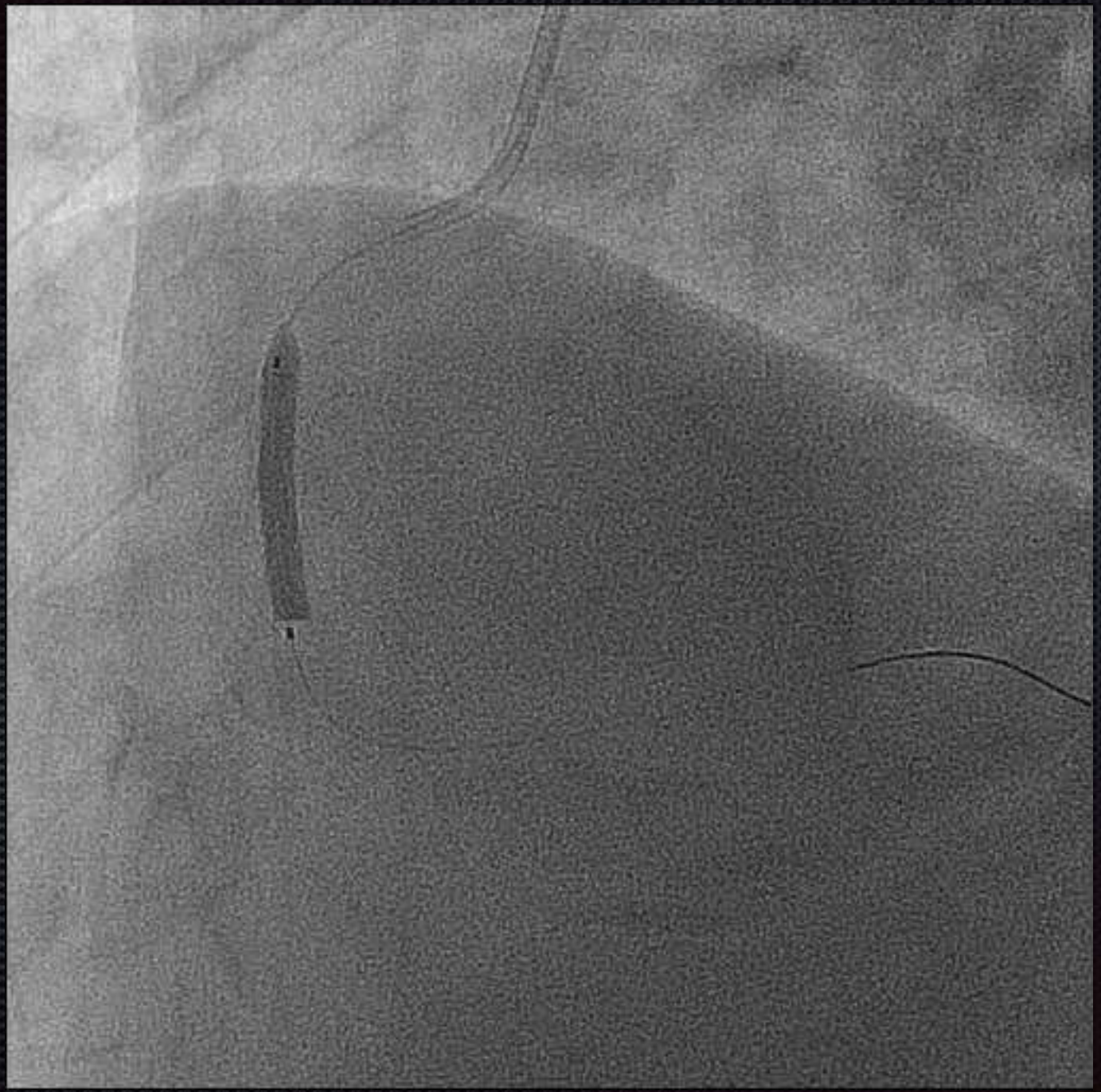
14 M
AFTER
ABSORB
W/O DAPT

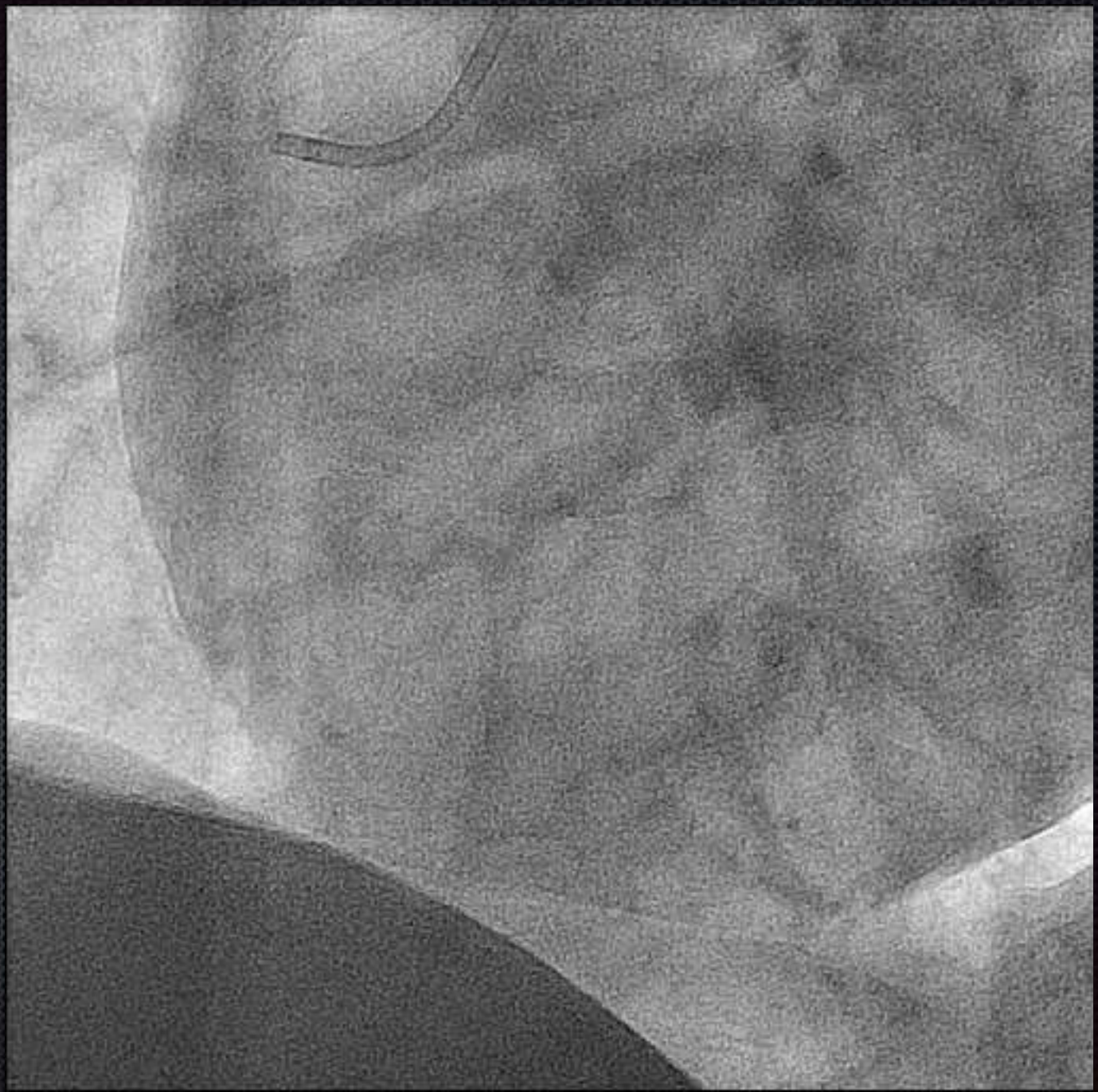




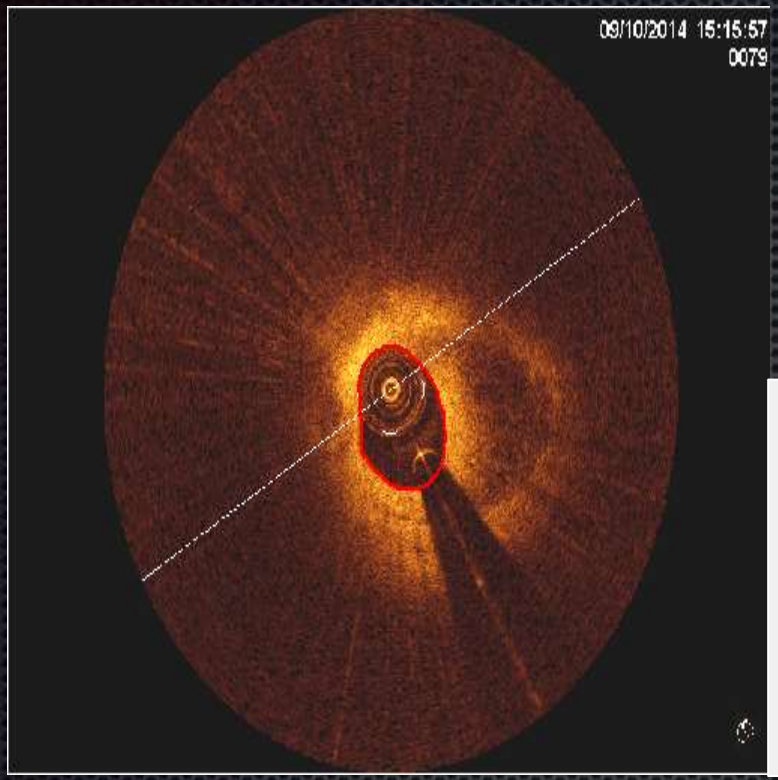


DREAMS 6 M AFTER





Area Luminal Mínima



	Lumen
Area	1.40
Average diameter	1.34
Largest diameter	1.56
Smallest diameter	1.14
Symmetry	0.73

POSSIBLES EXPLANATIONS

1ST. :NEW GENERATIONS OF DES ARE VERY GOOD

2ND. : TWO EXAMPLES OF UNMET NEEDS

3RD. : FINAL CONSIDERATIONS

TCT 2014 13 Sep 2014 - 17 Sep 2014 , Washington, DC - U.S.A
Plenary Session XII : Late-Breaking clinical Trials #2

ABSORB II : A Prospective, Randomized Trial of an Everolimus-Eluting Bioresorbable Scaffold Versus an Everolimus-Eluting Metallic Stent in Patients with Coronary Artery Disease

Patrick W. Serruys
Imperial College, London, UK
Erasmus University MC, Rotterdam, the Netherlands

ICPS, Bernard Chevalier
Massy, France
on behalf of the ABSORB II Investigators

Room: Level 3, Ballroom 11:00- 11:12, Sep 14st, 2014

ABSORB II Randomized Trial

Prospective, single blind, randomized 2:1 Absorb BVS vs EES
501 subjects at 46 European, Israeli, and New Zealand sites

Treatment of up to 2 de novo lesions in separate epicardial vessels

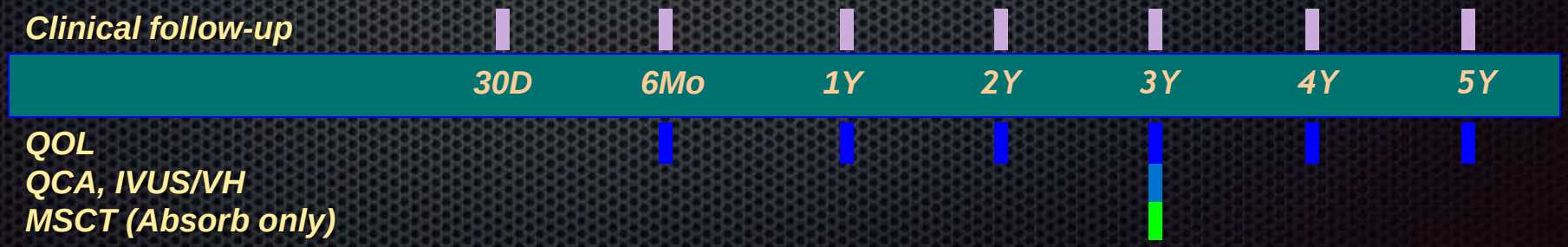
Lesion length ≤48 mm; Dmax 2.25 mm – 3.8 mm

Scaffold / stent diameters:	2.5, 3.0, 3.5 mm
Scaffold / stent lengths:	12 (3.5 mm dia), 18, 28 mm

Co-Primary Endpoints

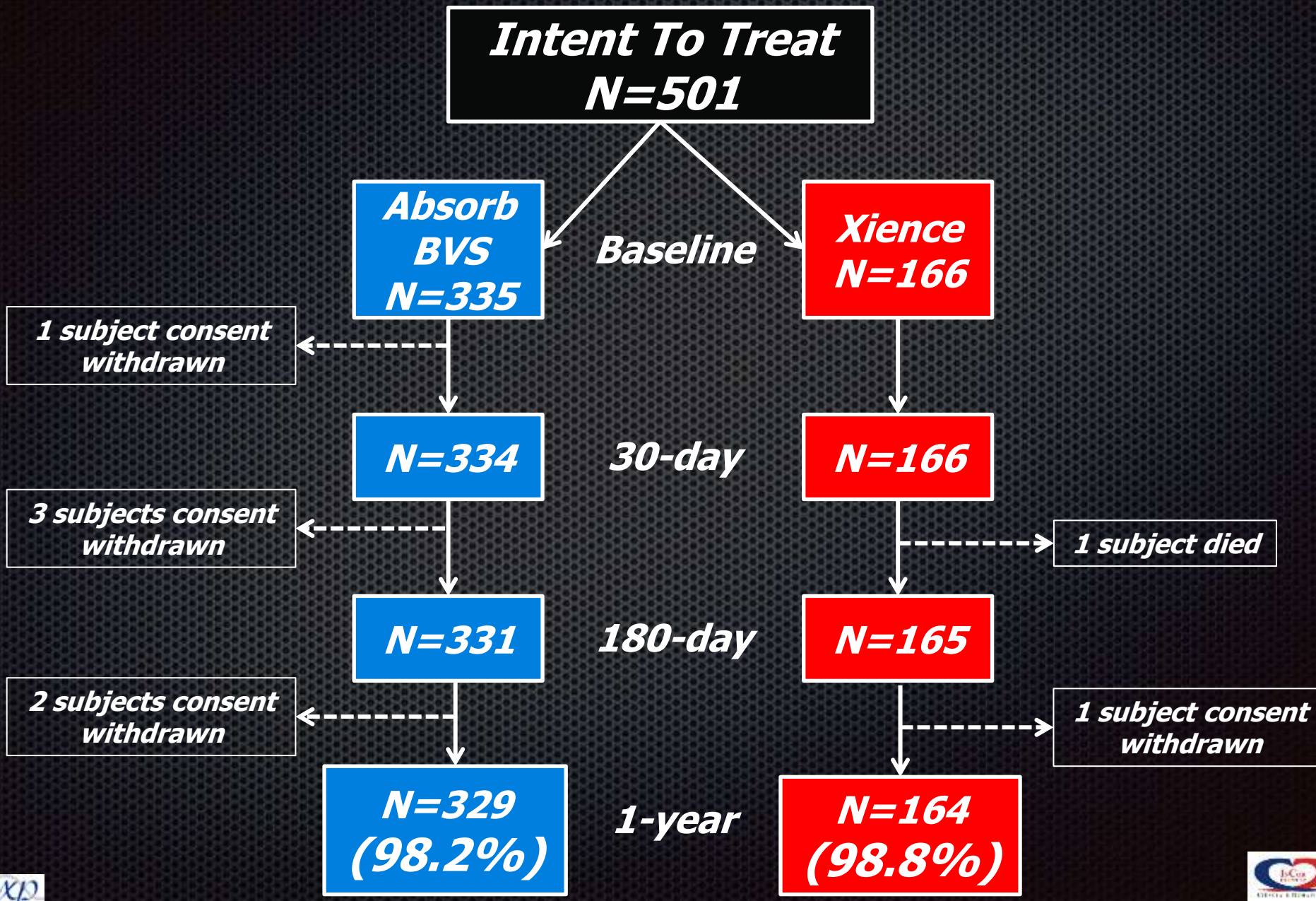
1) Nitro-induced vasomotion at 2 years by QCA (superiority)

2) Late loss at 2 years by QCA (non-inferiority to superiority)



Serruys PW et al. Lancet 2014

ABSORB II 1-Year Patient Flowchart



Clinical Outcomes

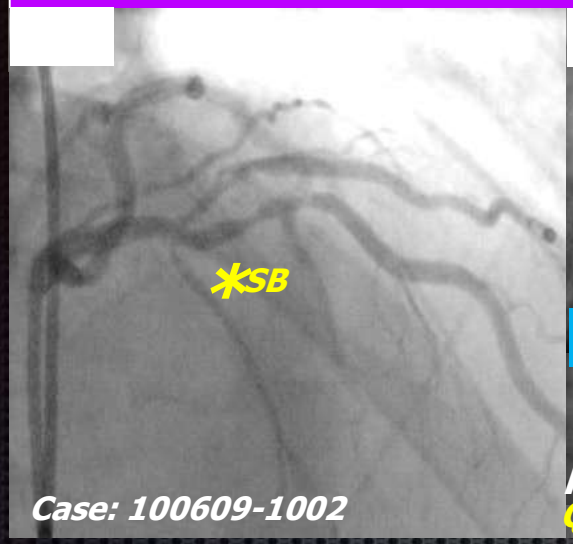
Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Composite of cardiac death, target vessel MI and clinically indicated target lesion revascularization (TLF, DoCE)	**4.8 %**	**3.0 %**	**0.35**
Cardiac death	0 %	0 %	1.00
Target vessel MI	4.2 %	1.2 %	0.07
Clinically indicated TLR	1.2 %	1.8 %	**0.69**
All TLR	1.2 %	1.8 %	**0.69**
Composite of all death, all MI and all revascularization (PoCE)	**7.3 %**	**9.1 %**	**0.47**
All death	0 %	0.6 %	0.33
All MI	4.5 %	1.2 %	0.06
All revascularization	3.6 %	7.3 %	0.08

Definite scaffold/stent thrombosis

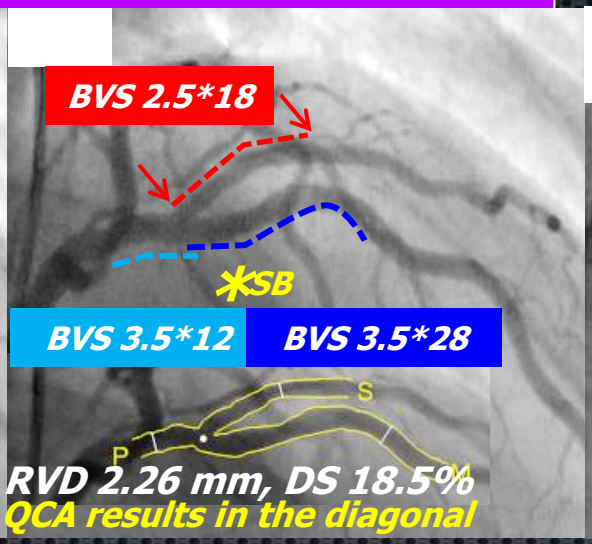
Cumulative incidence in percentage	Absorb 335 pts	Xience 166 pts	*p* value
Definite scaffold/stent thrombosis			
Acute (0-1 day)	**0.3 (1pt)**	0.0	NS
Sub-acute (2–30 days)	**0.3 (1pt)**	0.0	NS
Late (31–365 days)	0.0	0.0	NS
Probable scaffold/stent thrombosis			
Acute (0-1 day)	0.0	0.0	NS
Sub-acute (2–30 days)	0.0	0.0	NS
Late (31–365 days)	**0.3 (1pt)**	0.0	NS

Definite scaffold/stent thrombosis

Acute scaffold thrombosis at bifurcated

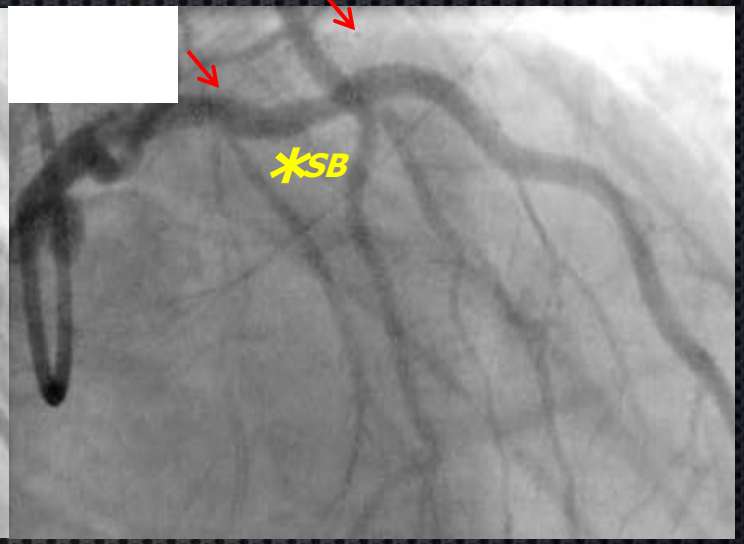


Case: 100609-1002

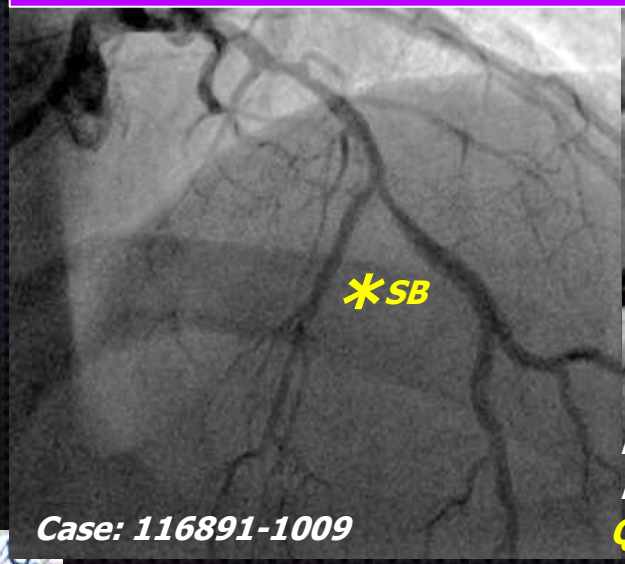


RVD 2.26 mm, DS 18.5%

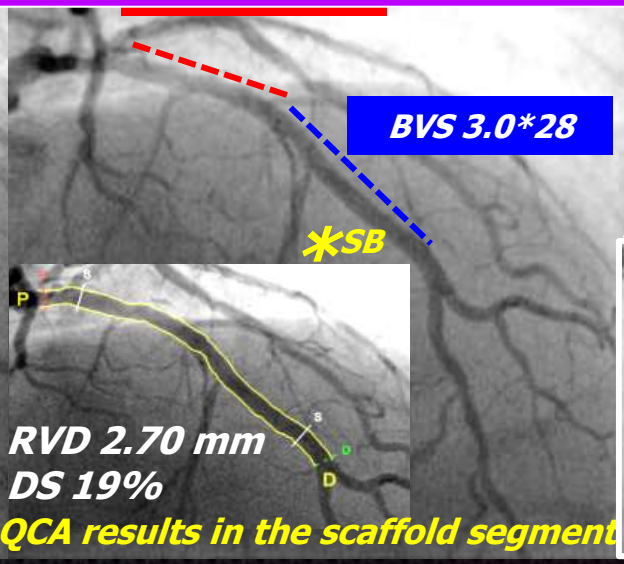
QCA results in the diagonal



Subacute scaffold thrombosis involving overlapping scaffolds



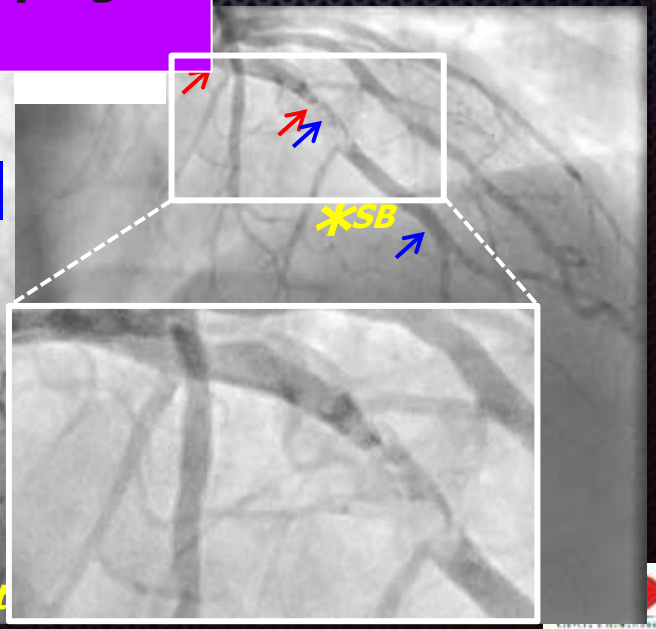
Case: 116891-1009



RVD 2.70 mm

DS 19%

QCA results in the scaffold segment



Comparison of Everolimus- and Biolimus-Eluting Coronary Stents with Everolimus-Eluting Bioresorbable Scaffold – The Randomized Controlled EVERBIO II Trial (NCT01711931)

Serban Puricel, Diego Arroyo, Noé Corpataux, Gérard Baeriswyl, Sonja Lehmann, Zacharenia Kallinikou, Olivier Müller, Jean-Christophe Stauffer, Mario Togni, Jean-Jacques Goy, Stéphane Cook

University & Hospital Fribourg, Switzerland

PRINCIPAL FEATURES OF THE 3 PLATFORMS

	EES PROMUS ELEMENT™	BES BIOMATRIX FLEX™	BVS ABSORB™
PLATFORM	Platinum Chromium	Stainless Steel	PLLA
strut thickness (um)	81	112	156
POLYMER			
polymer thickness (um)	7	10	6
	Durable fluoropolymer	Biodegradable PLLA	Biodegradable PLLA
DRUG	Everolimus	Biolimus A9	Everolimus
	1 ug/mm^2 - 87%, 90 days	15.6 ug/mm - 45%, 30 days	8.2 ug/mm - 80%, 30 days

Trial Design

Patients with stable CAD or ACS undergoing PCI

allocation ratio of 1:1:1 after lesion preparation

EES PROMUS ELEMENT™ (N=80)	BES BIOMATRIX FLEX™ (N=80)	BVS ABSORB™ (N=80)

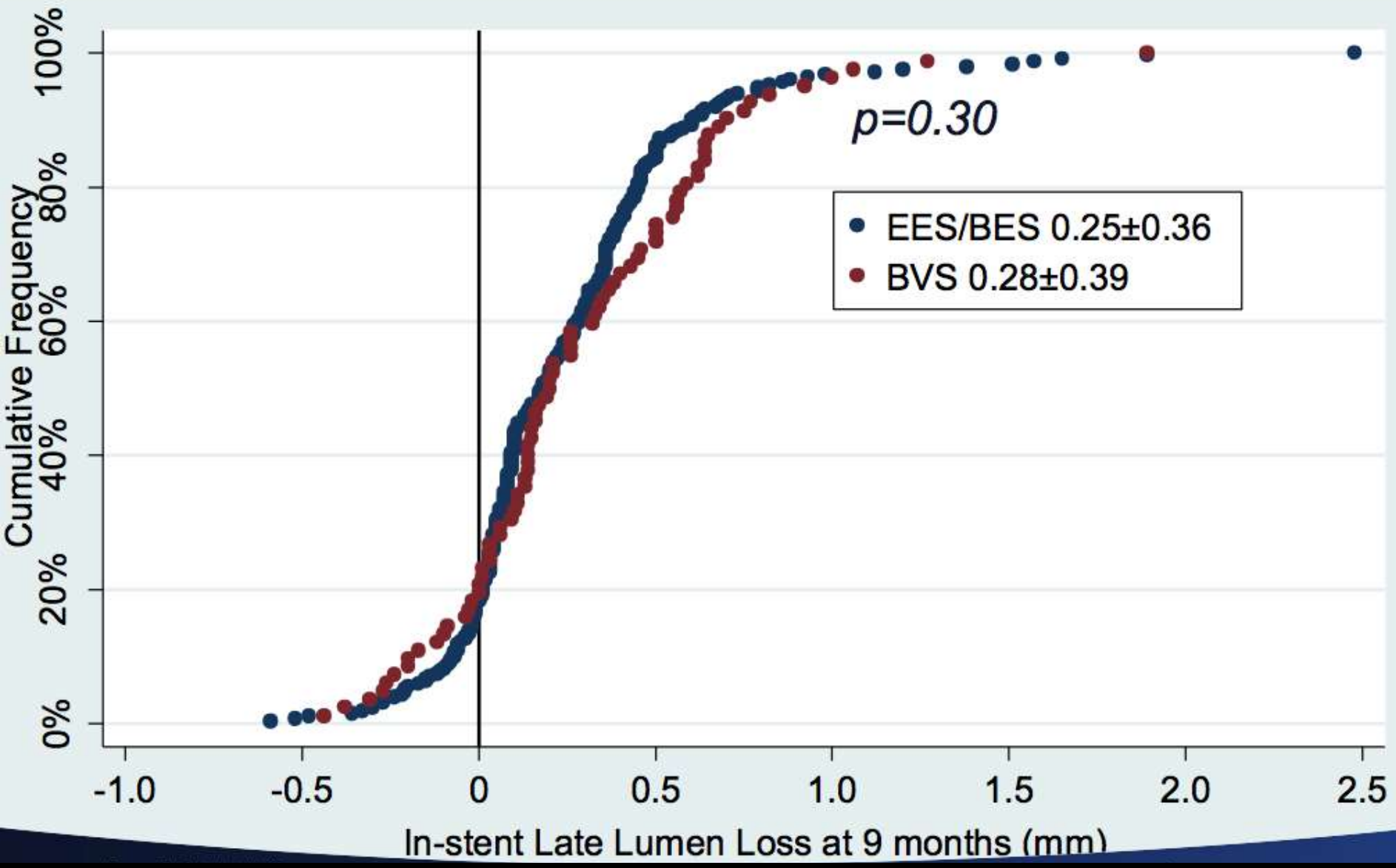
Clinical follow-up @ 1, 6, 9, 12 months, 2 & 5 y; Angio @ 9 months

Primary endpoint - in-stent late lumen loss (LLL) at 9 months

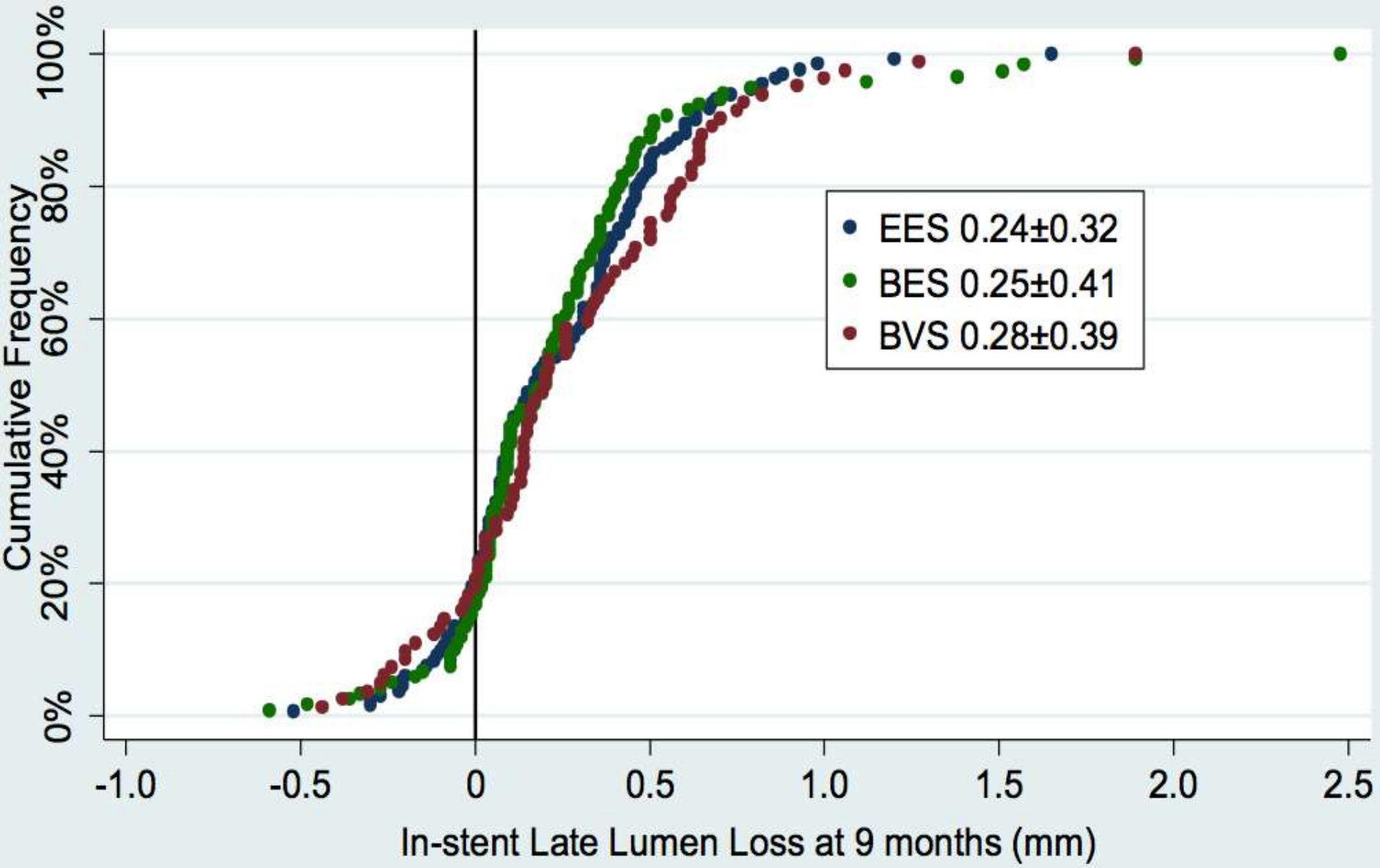
Secondary endpoints

- in-segment LLL
- patient-oriented MACE (death, myocardial infarction and target-vessel revascularization)
- device-oriented MACE (cardiac death, myocardial infarction and target-lesion revascularization), stent thrombosis according to ARC at 9-month follow-up.

PRIMARY ENDPOINT - IN-STENT LLL



PRIMARY ENDPOINT - IN-STENT LLL



CLINICAL OUTCOME AT 9 MONTHS

					p-value		
	EES	BES	EES&BES	BVS	EES	BES	EES/BES
	N=80	N=80	N=160	N=78	vs. BVS	vs. BVS	vs. BVS
Device-oriented MACE	11 (14)	4 (5)	15 (9)	9 (12)	0.68	0.14	0.6
Cardiac death, n(%)	0 (0)	0 (0)	0 (0)	1 (1)	0.49	0.49	0.33
MI of TV n(%)	0 (0)	0 (0)	0 (0)	0 (0)			
TLR, n(%)	11 (14)	4 (5)	15 (9)	8 (10)	0.5	0.21	0.83
clinically indicated, n(%	7 (9)	2 (3)	9 (6)	6 (8)	0.81	0.16	0.54
Patient-oriented MACE	26 (33)	15 (19)	41 (26)	21 (27)	0.44	0.22	0.83
All cause mortality, n(%)	3 (4)	0 (0)	3 (2)	1 (1)	0.62	0.49	1
Any MI, n(%)	1 (1)	0 (0)	1 (1)	1 (1)	1	0.49	0.55
Any Revasc., n(%)	24 (30)	15 (19)	39 (24)	19 (24)	0.43	0.39	0.99
TVR, n(%)	14 (18)	8 (10)	22 (14)	11 (14)	0.56	0.43	0.94
clinically indicated, n(%)	8 (10)	5 (6)	13 (8)	8 (10)	0.96	0.36	0.59
ST (definite/probable), n(%	0 (0)	0 (0)	0 (0)	0 (0)			
ST (possible), n(%)	0 (0)	0 (0)	0 (0)	1 (1)	0.49	0.49	0.33

ish-ahead-of-print February 2014

Early (before 6 months), late (6-12 months) and very late (after 12 months) angiographic scaffold restenosis in the ABSORB Cohort B trial

Shimpei Nakatani[1], MD; Yoshinobu Onuma[1]*, MD; Yuki Ishibashi[1], MD, PhD; Takashi Muramatsu[1], MD, PhD; Javaid Iqbal[1], MRCP, PhD; Yao-Jun Zhang[1], MD, PhD; Robert-Jan van Geuns[1], MD, PhD; John A. Ormiston[2], MBChB, PhD; Patrick W. Serruys[1], MD, PhD; on behalf of the ABSORB Cohort B investigators

1. Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands; 2. Auckland City Hospital, Auckland, New Zealand

GUEST EDITOR: Rafael Beyar, MD, DSc, MPH, Director; *Rambam Health Care Campus, Women's Division/Dr Phillip and Sara Gotlieb Chair, Department of Medicine and Biomedical Engineering, Technion, Israel*

Methods and results: The ABSORB Cohort B trial enrolled 101 patients with a maximum of two *de novo* coronary lesions. At the three-year imaging and clinical follow-up, there were six cases of in-segment binary restenosis: two early ISR (<6 months), one late ISR (6-12 months) and three very late ISR (>12 months). Three of these ISR cases seemed to be induced by anatomical or procedural factors. In the other three cases, intravascular imaging (IVUS/OCT) demonstrated that the main mechanism of restenosis was significant intra-scaffold tissue growth, while the structural circularity and diameter of the scaffold were not affected.

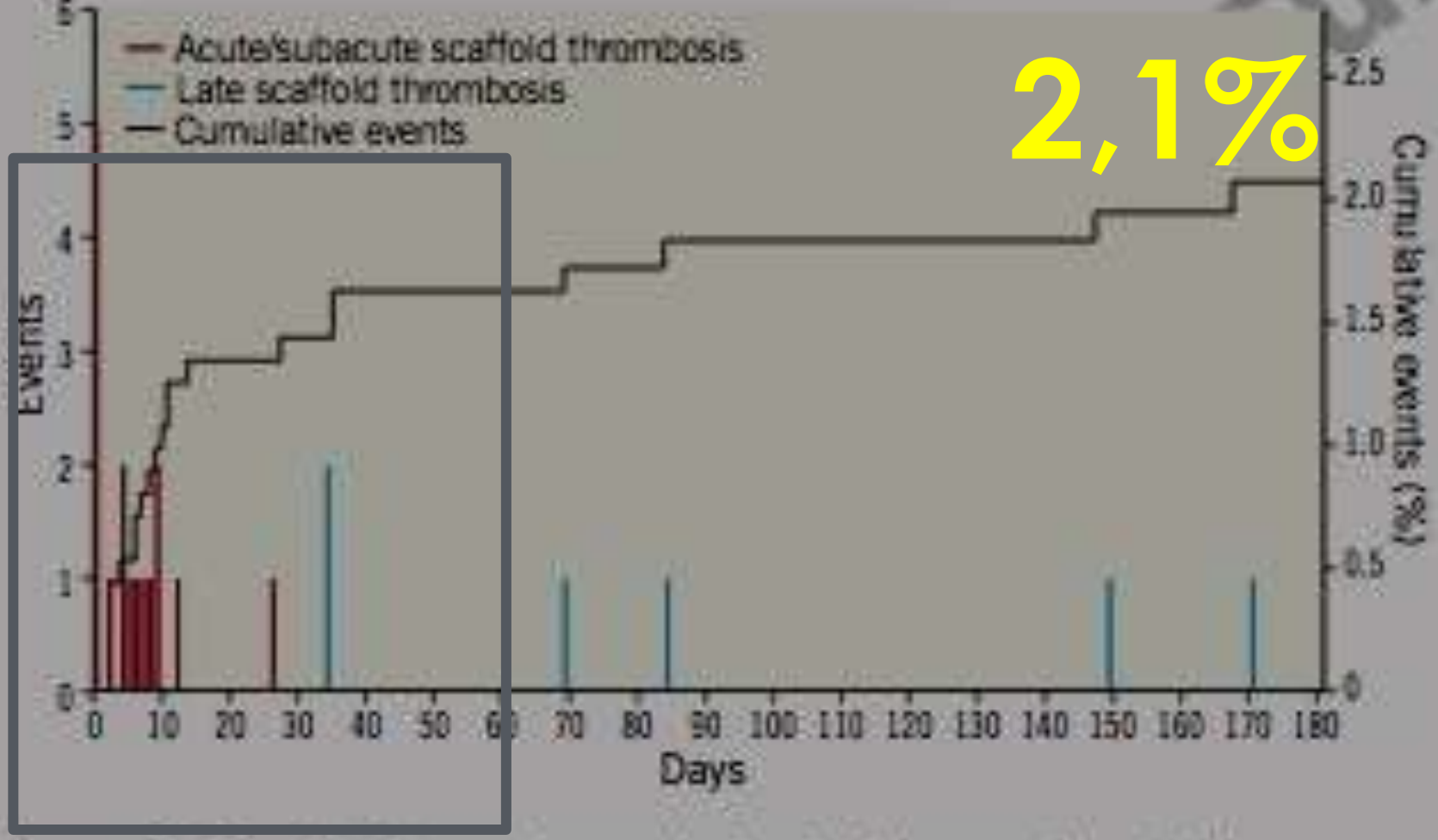
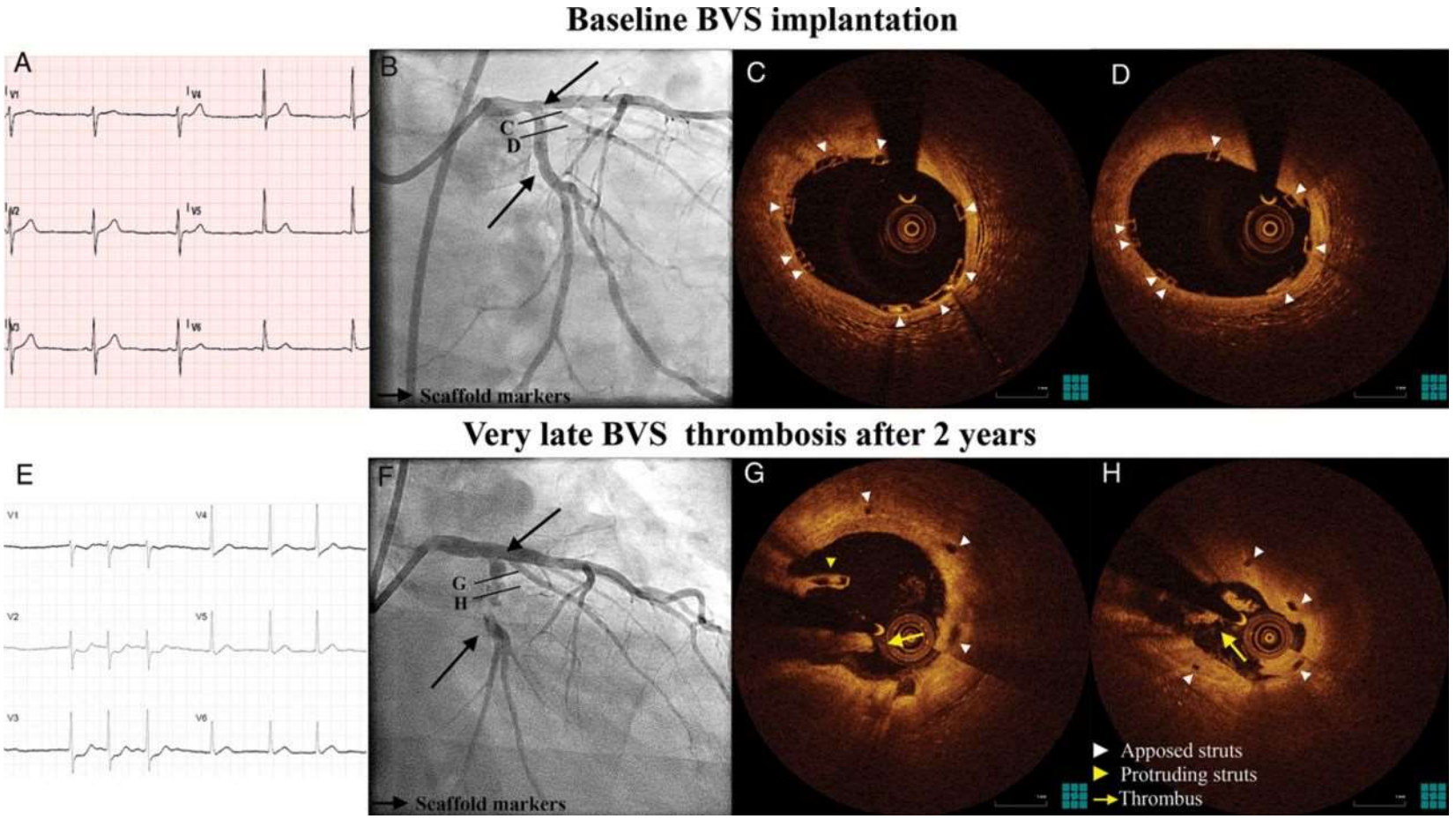


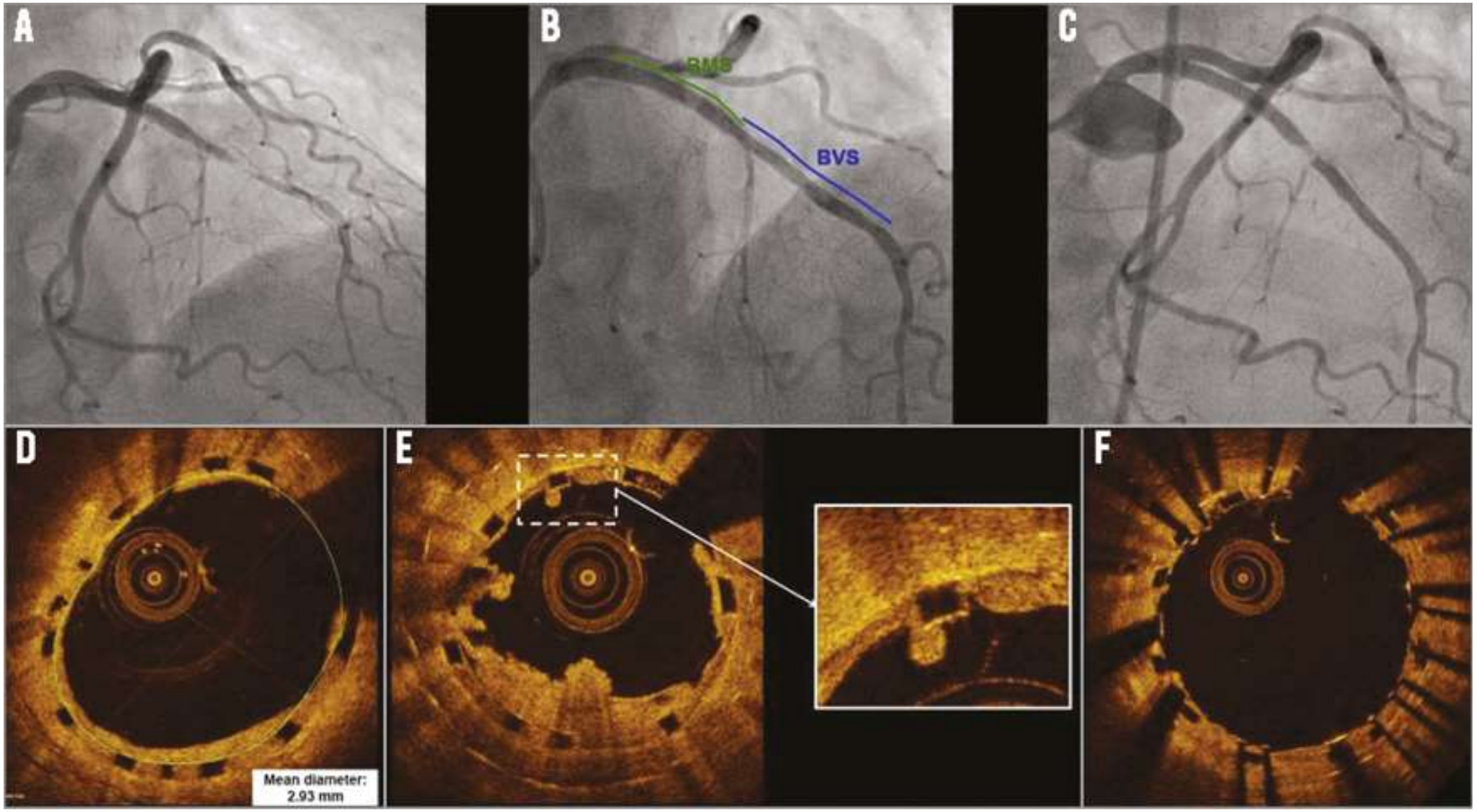
Figure 2. *Distribution and cumulative incidence of scaffold thrombosis up to six months.*



Antonios Karanasos et al. Eur Heart J 2014;35:1781

European Heart Journal

EuroIntervention



EuroIntervention 2015;11:e1-e2 published online e-article May 2015
Very late bioresorbable vascular scaffold thrombosis: a new clinical entity

UNMET NEEDS

- LIMITED DATA
- POOR DELIVERABILITY
- REQUIRE EXTENSIVE VESSEL PREPARATION
- POOR TENSILE STRENGTH
- LIMITED EXPANSILE RANGE
- POORLY VISUALISED
- COSTLY


grazzi
tanan
efcharisto
obrigada
havala
dekuji
paldies
spasibo
ThankYou
dakujem
MUITO OBRIGADO
kiitos
blagodarya
tack
Merci
dekui
gracias
dzieki
Danke
grazie
dank
koszi