Un update clinico in tema di BVS

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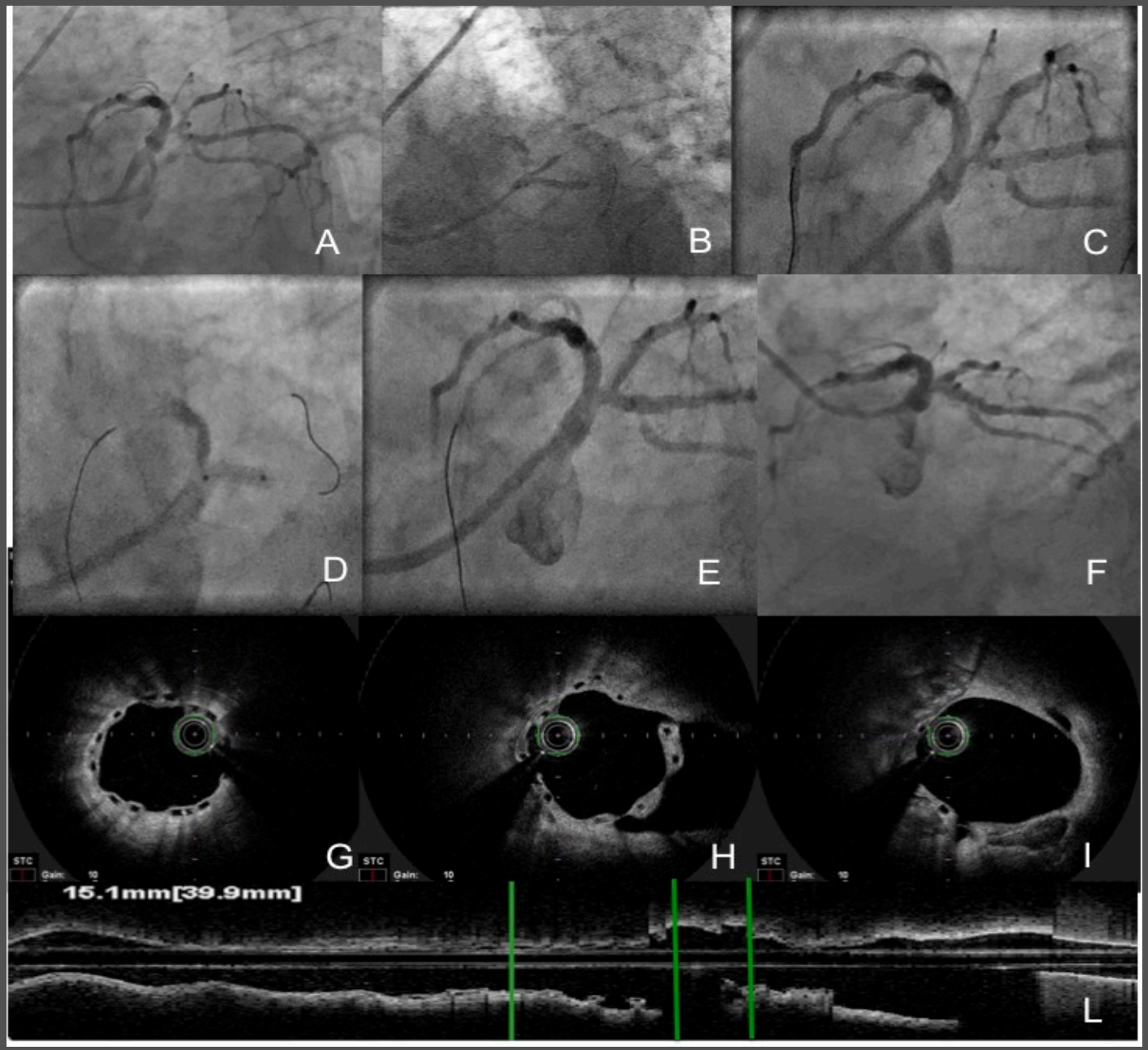
SESSIONE EMODINAMICA

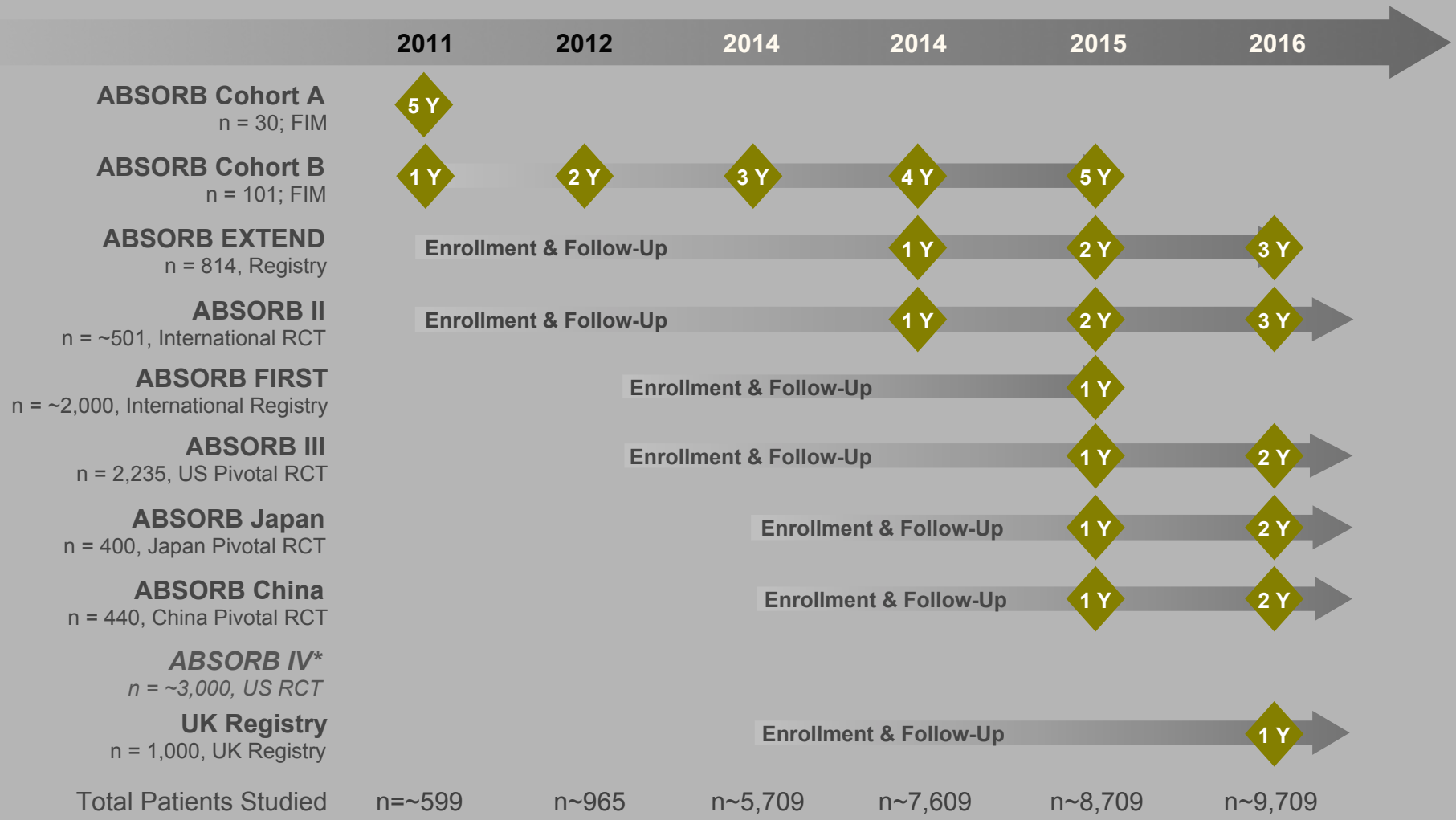
TERAPIA DI RIPARAZIONE VASCOLARE CON STENT RIASSORBIBILE ABSORBTM BVS

M. De Benedictis - A. Rognoni

14.00	Update clinico in tema di BVS	**B. Cortese**
14.20	"Registro ABSORB Italiano" (RAI registry)	**G . Steffenino**
14.40	Due anni di follow-up: esperienza di Castelfranco Veneto	**C. Cernetti**


A
B
C
D
E
F
G
H
I
STC
Gain: 10
STC
Gain: 10
STC
Gain: 10
15.1mm[39.9mm]
L

The ABSORB Clinical Trial Program



Each trial *n* reflects total patients. Data as of January 2014
*ABSORB IV trial is in the planning stage and subject to change

Absorb Clinical Update

ABSORB II – Trial Design

Prospective, Multi-Center, Randomized Clinical Trial
2:1 Randomization Absorb versus XIENCE
n =501 patients

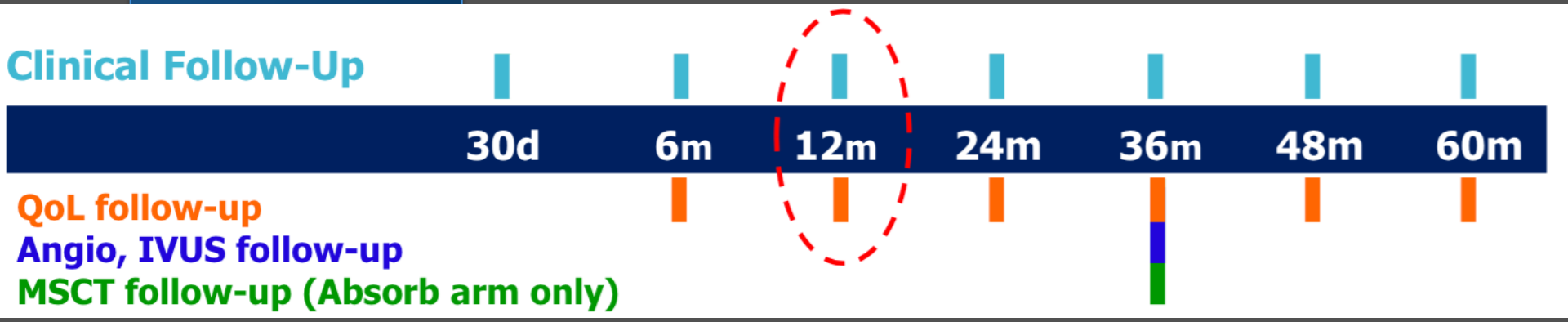
- Absorb n = 335
- XIENCE n = 166

Co-primary Endpoints

- Vasomotion (change in Mean Lumen Diameter at 3 years (superiority)
- LLL (non-inferiority, reflex to superiority)

Treatment

- Up to 2 *de novo* lesions in different epicardial vessels
  Planned overlapping allowed in lesions ≤48 mm



Absorb Clinical Update

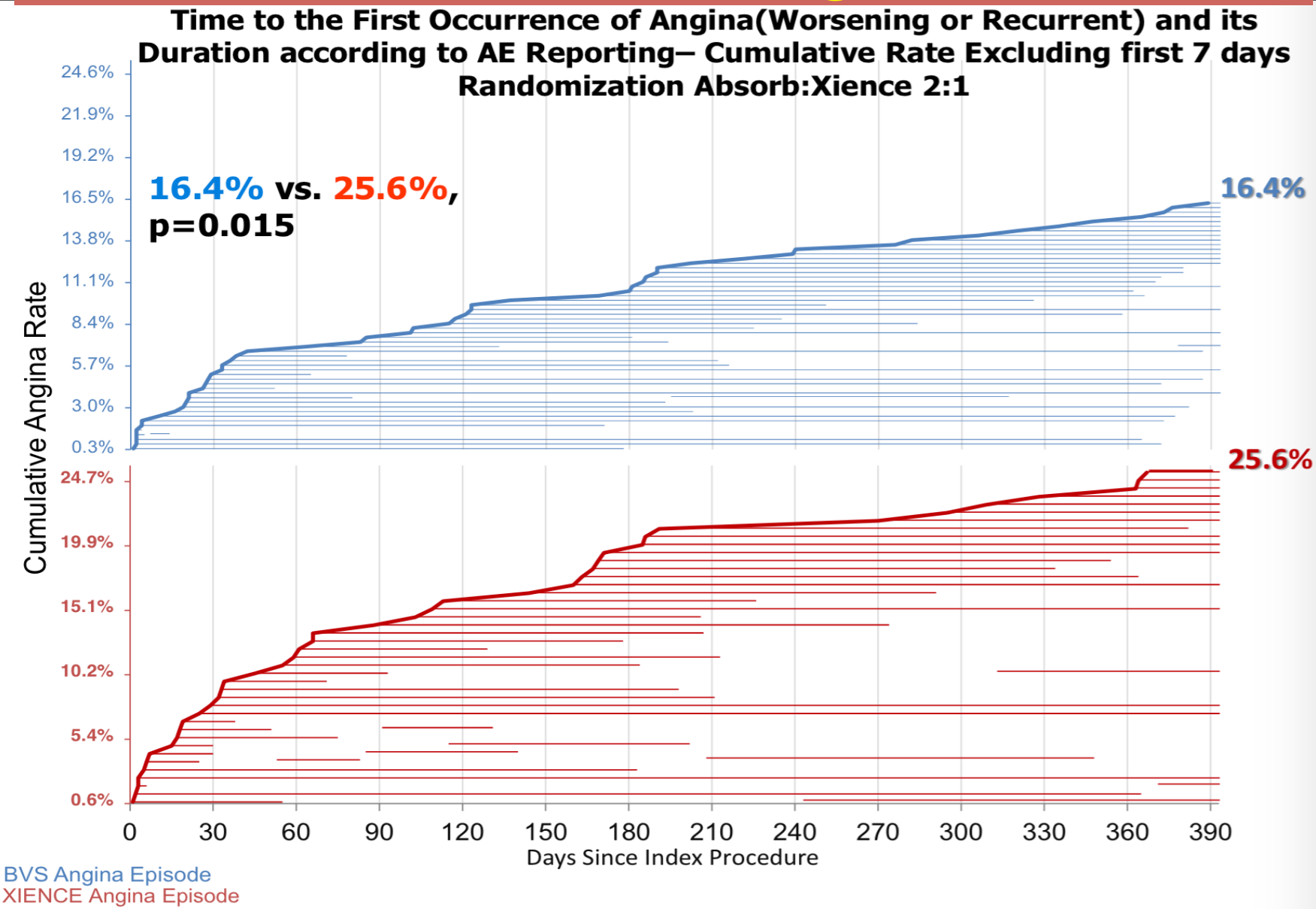
ABSORB II – Trial Design

	Absorb (N=335 patients)	XIENCE (N=166 patients)	P-value
All Diabetes, %	23.9	24.1	N.S.
Stable Angina, %	63.9	64.5	N.S.
Unstable Angina, %	20.3	22.3	N.S.
Two or more lesions treated, %	8.7	9.6	N.S.
Calcified lesions, %	12.7	15.5	N.S.
B1 lesions, %	53.2	50.0	N.S.
B2 lesions, %	43.8	48.3	N.S.
Lesion Length (mm)	13.8	13.8	

Absorb II- clinical results

	Absorb N=335	XIENCE N=166	p value
DoCE (Device-Oriented Composite Endpoint)	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
Definite Scaffold/Stent Thrombosis (%)	0.6	0.0	1.00
PoCE (Patient-Oriented Composite Endpoint)	7.3	9.1	0.47
All death (%)	0	0.6	0.33
All MI (%)	4.5	1.2	0.06
All NQMI (%)	3.9	1.2	0.16
All QMI (%)	0.6	0	1.00
All revascularization (%)	3.6	7.3	0.08

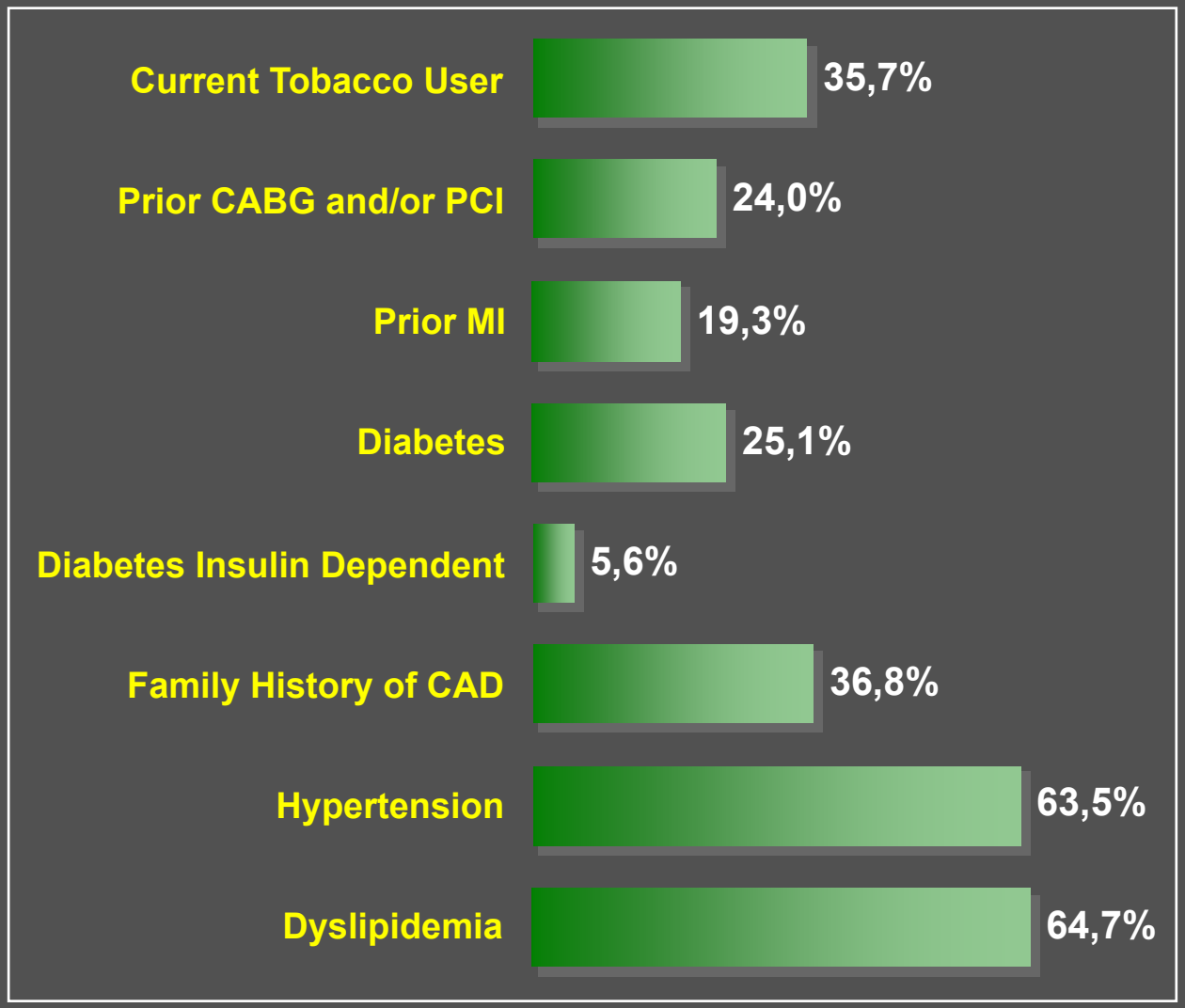
Absorb II- angina



ABSORB FIRST: An interim report on 30-day clinical outcomes from 1800 patients in a large, prospective, global registry

Eric Eeckhout[1], Christoph Kurt Naber[2], Vivian W. Mao[3], Karine Miquel-Hebert[3], Yuan Gao[3], Wai-Fung Cheong[3], Peter Staehr[3] and Ashok Seth[4]

[1] Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland; [2]Contilia Heart and Vascular Center, Elisabeth Krankenhaus Essen, Germany; [3]Abbott Vascular, Santa Clara, California, USA; [4]Fortis Escorts Heart Institute, New Delhi, India

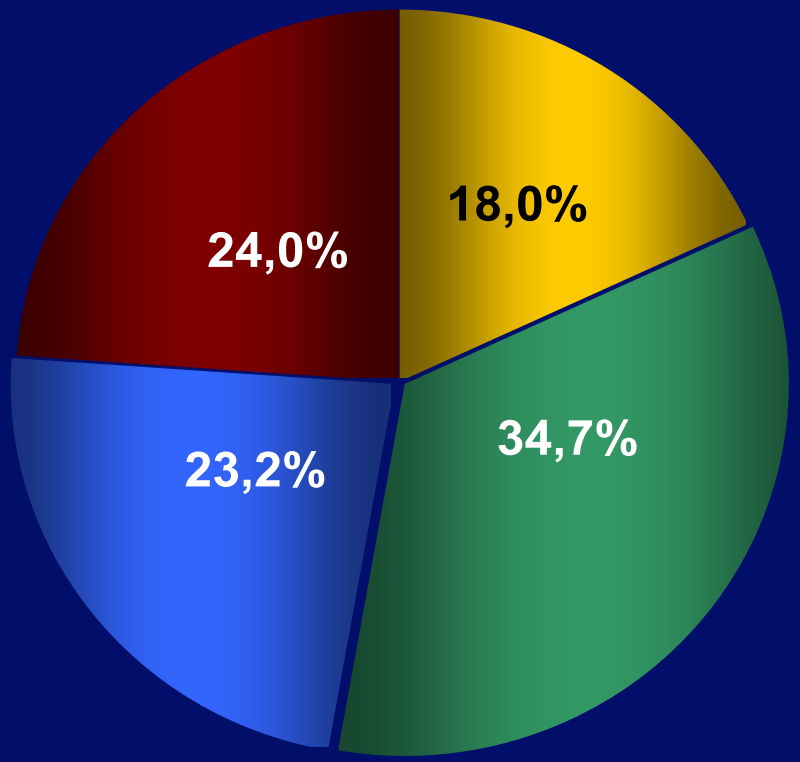

Current Tobacco User
35,7%
Prior CABG and/or PCI
24,0%
Prior MI
19,3%
Diabetes
25,1%
Diabetes Insulin Dependent
5,6%
Family History of CAD
36,8%
Hypertension
63,5%
Dyslipidemia
64,7%

Target Lesion Characteristics

Characteristics	L = 2215
Calcification (Moderate/Severe)	16.7%
Bifurcation	12.4%
Tortuosity	10.1%
Total Occlusion	9.3%
Ostial lesion	5.5%

L: Lesions

Lesion type (AHA/ACC)



B2/C Lesions: 47.2%

Total occlusion, ostial lesions: exclusion from prior ABSORB trials

Clinical Outcomes up to 30 days

Clinical Events	In hospital (N=1801)	30 days (N=1801)
All Death	0.0%	0.0%
Cardiac Death	0.0%	0.0%
MI	0.6%	0.8%
QMI	0.1%	0.2%
Non-QMI	0.4%	0.6%
ID-TLR	0.3%	0.4%
MACE	0.6%	0.9%
TLF	0.5%	0.7%

Note: 30-day events for the subset of patients who did not reach 1 year follow-up, were self-reported

Definite/Probable Scaffold Thrombosis

Scaffold Thrombosis	Rate
All patients (N=1801)	
Early (0-30 days)*	0.44%
Acute (< 1 day)	0.00%
Sub-acute (1-30 days)*	0.44%

*Note: 30-day event data for those patients who did not complete 1 year follow up were based on the patient self-reporting only

Interim Clinical Outcomes up to 1 Year (N=430)

Clinical Events	In hospital	30 days	1 year
All Death	0.0%	0.0%	0.0%
Cardiac Death	0.0%	0.0%	0.0%
MI	0.7%	0.9%	1.2%
QMI	0.0%	0.0%	0.0%
Non-QMI	0.7%	0.9%	1.2%
ID-TLR	0.2%	0.2%	0.2%
MACE	0.9%	1.2%	1.4%
TLF	0.9%	0.9%	0.9%
Def/Prob ST	0.0%	0.0%	0.0%

Note: Interim clinical outcome data from those 430 patients who complete 1 year follow-up

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Comparison of Everolimus- and Biolimus-Eluting Coronary Stents With Everolimus-Eluting Bioresorbable Vascular Scaffolds

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

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

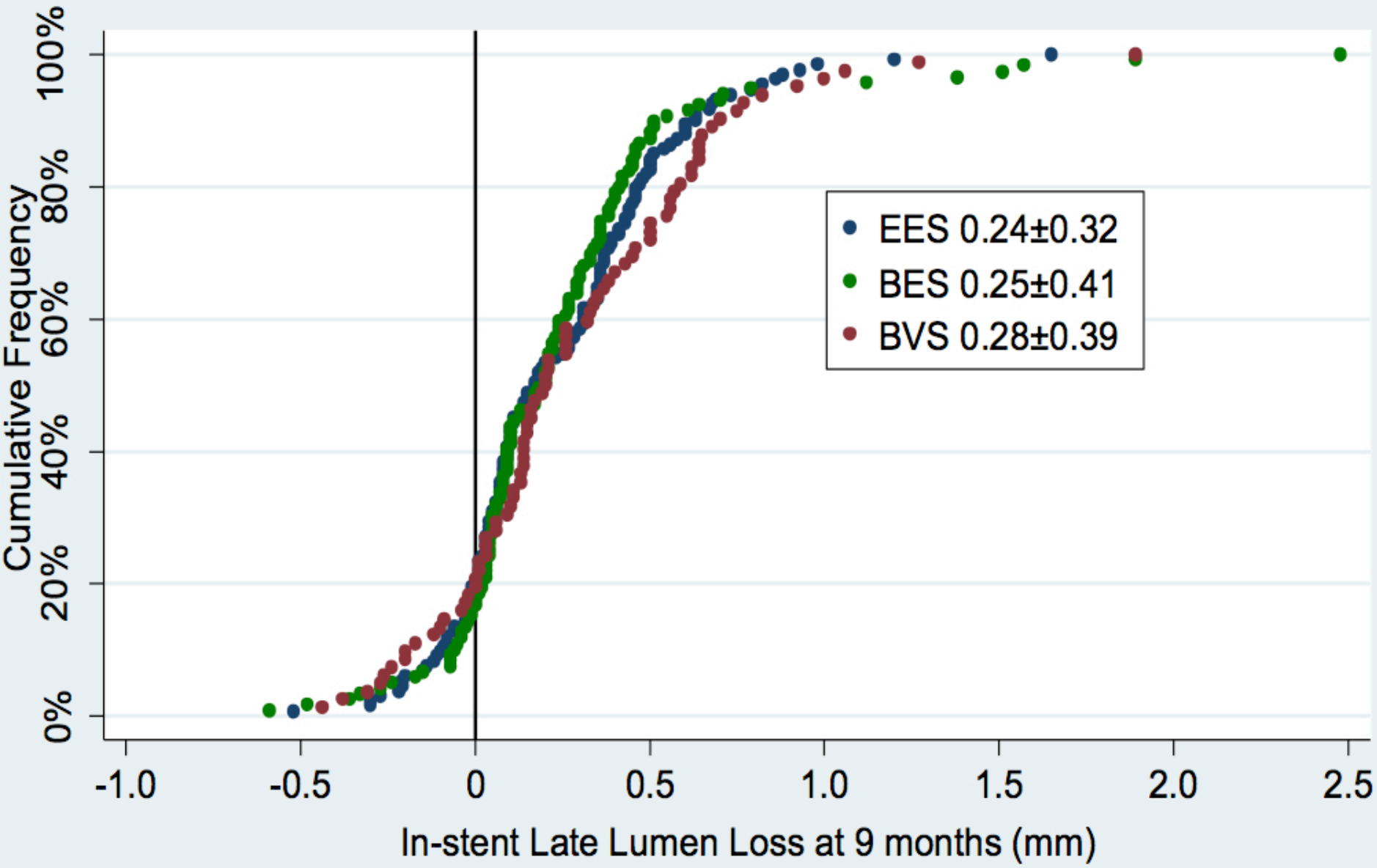


TABLE 4 Clinical Outcomes at 9 Months

	EES (n = 80)	BES (n = 80)	EES/BES (n = 160)	BVS (n = 78)	p Value EES vs. BVS	p Value BES vs. BVS	p Value EES/BES vs. BVS
Device-oriented composite	11 (14)	4 (5)	15 (9)	9 (12)	0.68	0.14	0.60
Cardiac death	0 (0)	0 (0)	0 (0)	1 (1)	0.49	0.49	0.33
MI of the target vessel	0 (0)	0 (0)	0 (0)	0 (0)	–	–	–
TLR	11 (14)	4 (5)	15 (9)	8 (10)	0.50	0.21	0.83
Clinically indicated	7 (9)	2 (3)	9 (6)	6 (8)	0.81	0.16	0.54
Patient-oriented composite	26 (33)	15 (19)	41 (26)	21 (27)	0.44	0.22	0.83
All-cause mortality	3 (4)	0 (0)	3 (2)	1 (1)	0.62	0.49	1.00
Any MI	1 (1)	0 (0)	1 (1)	1 (1)	1.00	0.49	0.55
Repeat revascularization	24 (30)	15 (19)	39 (24)	19 (24)	0.43	0.39	0.99
TVR	14 (18)	8 (10)	22 (14)	11 (14)	0.56	0.43	0.94
Clinically indicated	8 (10)	5 (6)	13 (8)	8 (10)	0.96	0.36	0.59
Stent thrombosis (possible)	0 (0)	0 (0)	0 (0)	1 (1)	0.49	0.49	0.33

Investigator –Randomized Controlled Trials – Overview and Status Update
(Not Sponsored by Abbott Vascular)

Study Title	Design	Number of Patients Enrolled	Primary Endpoint	Patient FU (Years)
AIDA	All – comers RCT vs Xience	418/2690	2-Yr TVF	5
TROFI II	STEMI RCT vs XIENCE	57/190	6-Mo neo-intimal healing score	3
PROSPECT II ABSORB	RCT vs OMT in unstable asymptomatic pts	300*	2-Yr IVUS MLA	3
PROACTIVE	RCT vs XIENCE	11/20	Peri-Proc Platelet Reactivity	1
VANISH	RCT vs XIENCE	30/60	Evolution of myocardial blood flow values over time	3
EVERBIO II**	Non-inferiority RCT EES, vs BES, vs BVS	240	Late lumen loss at 9 mo	5
ISAR ABSORB MI**	Randomized, non-inferiority vs EES	260	Percentage diameter stenosis at 6-8 months	1

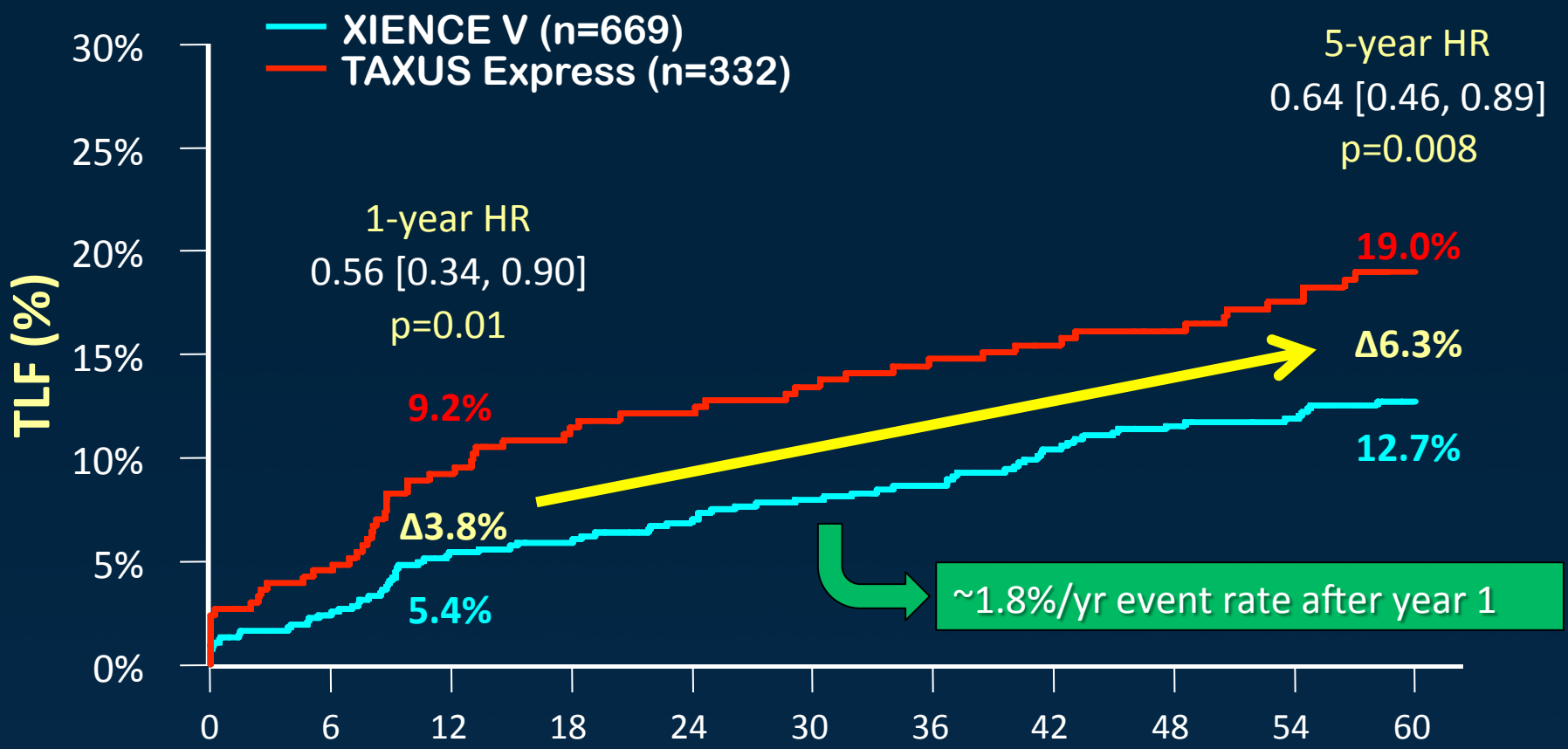
Unrestricted Investigator Trials
* Enrolment has not started yet
** ISS w/o Abbott Funding – not all information is available

Investigator-driven Registries - Overview and Status Update
(Not Sponsored by Abbott Vascular)

Study Title	Design	Number of Patients Enrolled	Primary Endpoint	Patient FU (Years)
BVS EXPAND	All – comers Registry (excl STEMI)	260/300	1 – Yr MACE	5
ASSURE	All – comers Registry	180/180	Safety and Efficacy	3
ABSORB CTO	Feasibility in CTO	20/20	Safety and Performance	2
PABLOS	Feasibililty in Bifurcations	4/30	Device, Procedural, Main and Side Branch Success	2
IT-DISAPPEARS	MVD and Long Lesion Registry	6/1000	Safety and Efficacy	5
GABI-R	All – comers Registry	448/5000	Safety and Efficacy	5
REPARA	All – comers Registry	41/1500	1- Yr MACE	1
POLAR ACS	ACS Registry	100/100	Safety, clinical device, procedure success and in-hospital MACE	1
France ABSORB	Feasibility in de novo lesions	2000*	1 – Yr MACE	1
GHOST**	All – comers Registry	consecutive and continuous enrolment	Target Vessel Failure (TVF)	1
RAI	All-comers, effective implantation	consecutive and continuous enrolment	TLF & scaffold thrombosis 1 year	5
Prague 19**	STEMI (STEMI Killip I/II)	79/300	Clinical Outcomes	1

is the rate of BVS thrombosis higher than the one of currently used DES?

SPIRIT III: Target Lesion Failure @5 years



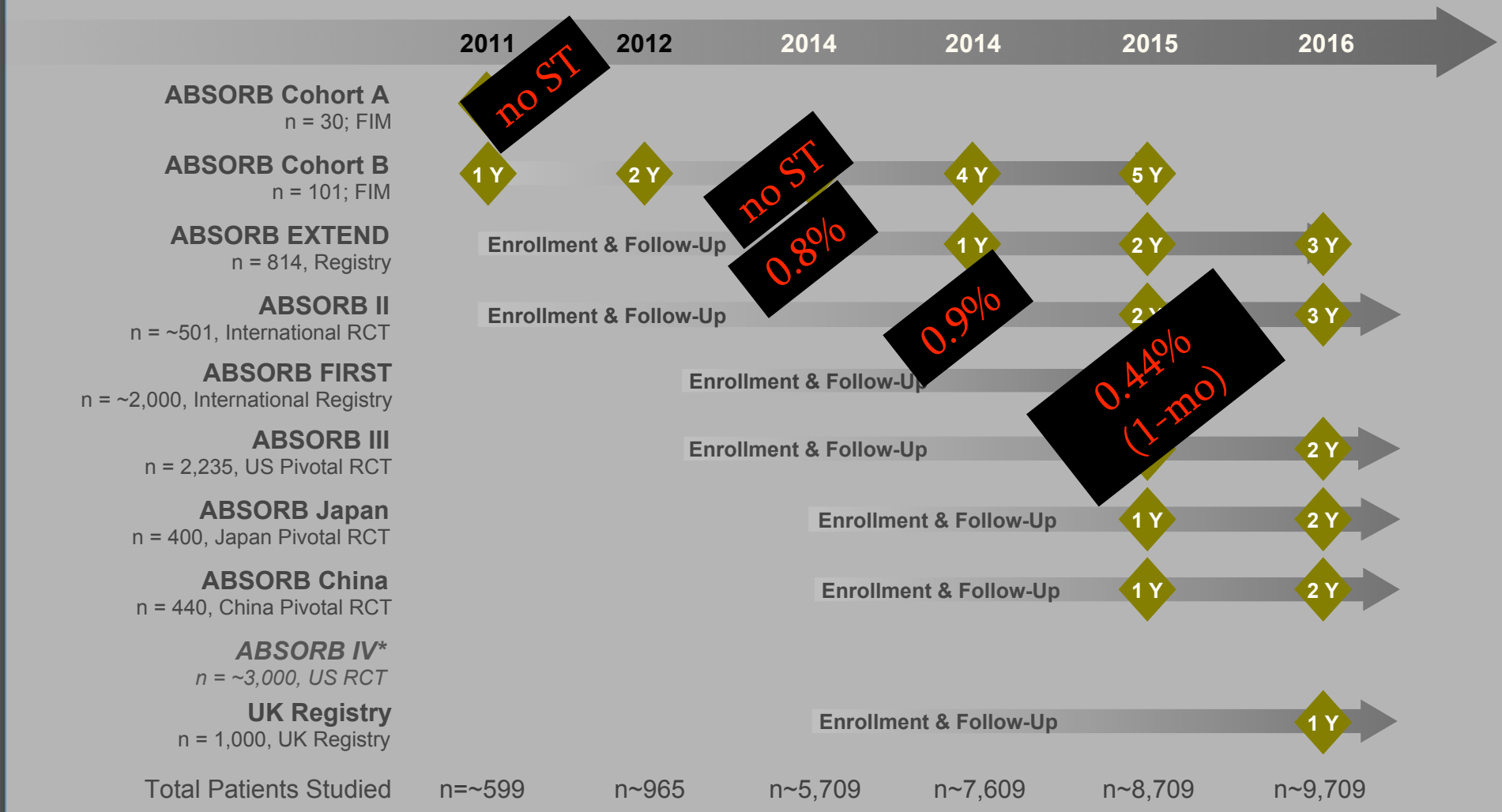
Number at risk

XIENCE V	669	646	616	601	582	571	565	548	537	529	521
TAXUS	332	310	288	274	269	262	255	248	243	231	223

TLF = cardiac death, target vessel MI, or ischemic-driven TLR

Gada H et al. J Am Coll Cardiol Intv 2013;6:1263–6.

The ABSORB Clinical Trial Program



Each trial *n* reflects total patients. Data as of January 2014
*ABSORB IV trial is in the planning stage and subject to change

European multicenter GHOST-EU registry

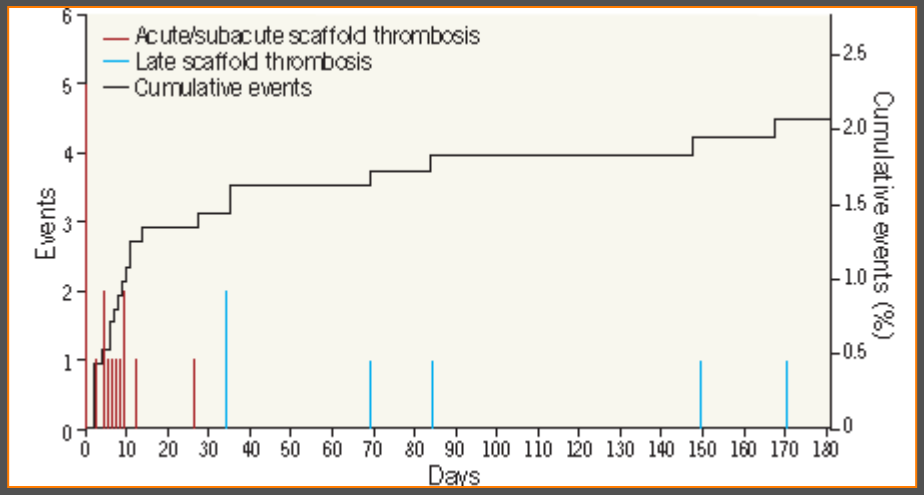
1.189 pts

Clinical presentation	
Stable angina or silent ischaemia	52.6% (626/1,189)
Unstable angina	13.2% (157/1,189)
Non-ST-segment elevation MI	18.0% (214/1,189)
ST-segment elevation MI	16.1% (192/1,189)
ACS at presentation	47.4% (563/1,189)

6 months

Table 3. Kaplan-Meier estimates of cardiac events at follow-up.

Efficacy and safety measures	30-day	6-month
TLF	2.2%	4.4%
TVF	2.3%	4.9%
All death	0.8%	1.3%
Non-cardiac death	0.2%	0.3%
Cardiac death	0.6%	1.0%
Any MI	1.4%	2.7%
Target vessel MI	1.1%	2.0%
TVR	1.6%	4.0%
TLR	1.1%	2.5%
ARC ST definite/probable	1.5%	2.1%



15/23 in first 30 days
11/15 are ACS
14/23 no postdilation

Capodanno et al Eurointervention ‘14

AMC Single Centre Real World Registry

Table 4. Clinical outcomes.

	Total cohort

Table 5. Scaffold thromboses.

Case	Initial PCI indication	Treated vessel	Lesion type	Calcification	Thrombus present	Pre-dilatation	Pre-dilatation balloon type and size (mm)	Absorb size (mm) and inflation pressure (atm)	Post-dilatation	Post-dilatation balloon type, size (mm) and inflation pressure (atm)	Antiplatelet therapy	Treatment scaffold thrombosis	Type thrombosis	Possible reason
1	OHCA	Mid LAD	A	No	No	Yes	2.5×15	3.0×18 (12)	Yes	2.5×15 NC balloon (8)	Ascal, ticagrelor	T…	Definite subacute	Distal edge dissection
		Distal LAD	B2	No	No	Yes	2.5×15	3.0×28 (14)	Yes	2.5×15 NC balloon (10)		XIENCE 3.0×38 mm XIENCE 3.0×18 mm		
2	NSTEMI	Proximal LAD	B2	No	Yes	No	–	2.5×18 (16)	No	–	Ascal, plavix	T…	Definite subacute	Incomplete expansion distal part of the scaffold
3	UAP	Distal LAD	B1	No	No	Yes	2.5×15	2.5×28 (24)	Yes	2.5×15 NC balloon (24)	Ascal, ticagrelor		Definite subacute	DAPT cessation
4	NSTEMI	Proximal RCx	B1	No	No	Yes	2.5×15	3.5×28 (10)	Yes	3.5×16 NC balloon (16)	Ascal, plavix		Definite late	DAPT cessation

7 days

3 days

23 days

90 days

Kraak et al Eurointervention '14

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	
	MI	
	TVR	
	TLR	3 (4.1)
	CABG	0
	Definite/probable ST	1 (1.3)

5 days

BVS underexpansion

Ielasi & Cortese, Eurointervention '14

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

POCE (%)

DOCE (%)

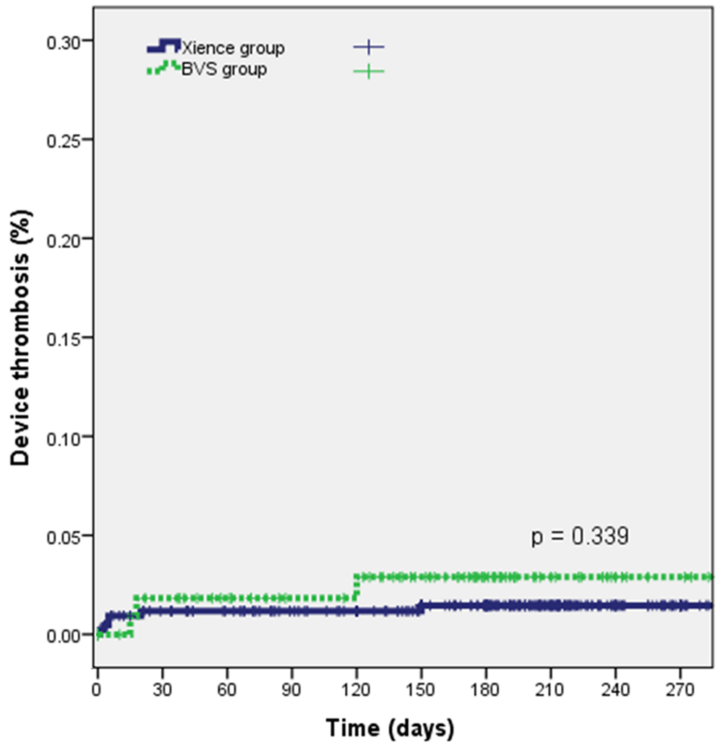
Death (%)

Myocardial inf

TLR (%)

TVR (%)

Stent thrombos



Xience	441	403	391	377	366	345	321	255	205	178
BVS	122	107	101	95	93	84	69	52	45	41

ST 6-mo: 2.5 vs 1.4% (OR 1.83, 0.5-7.4)

Cortese & Ielasi, submitted

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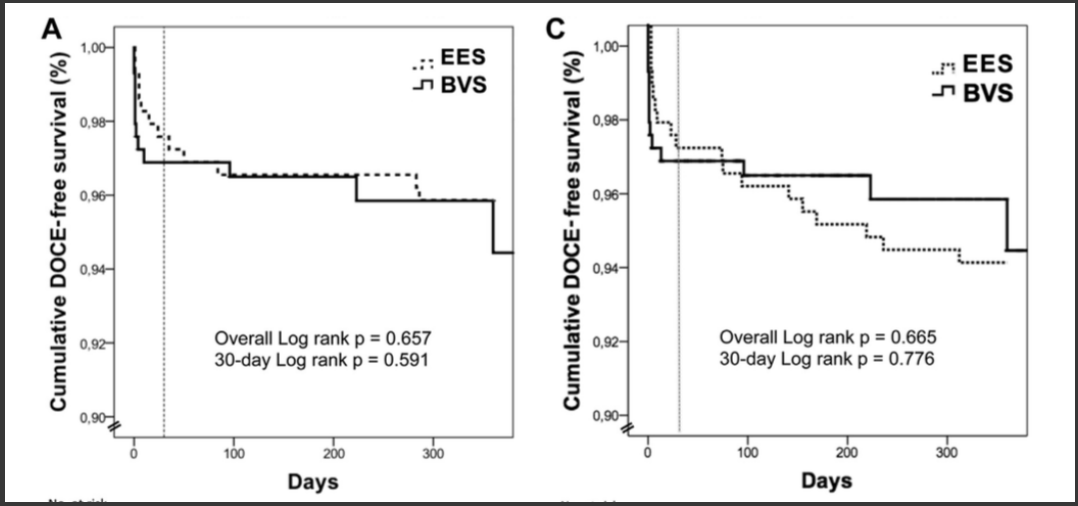
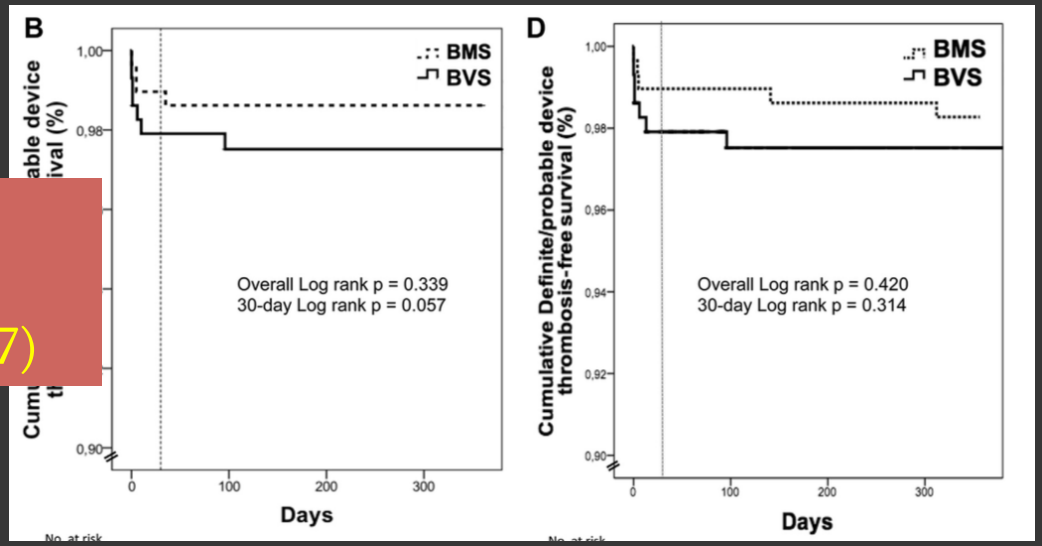
Absorb Bioresorbable Vascular Scaffold Versus Everolimus-Eluting Metallic Stent in ST-Segment Elevation Myocardial Infarction: 1-Year Results of a Propensity Score Matching Comparison



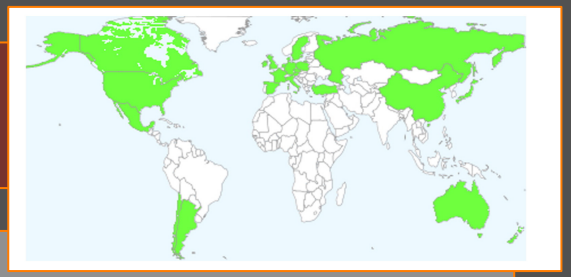


ST 30-d: 2.1 vs 0.3% (OR 6, 0.7-49)

ST 360-d: 2.4 vs 1.4% (OR 1.1, 0.7-17)

Brugaletta et al, JACC Int 15

aims



to “interview” the most qualified experts on this technology aiming at understanding at which stage we are, and where we are going.

Experts:

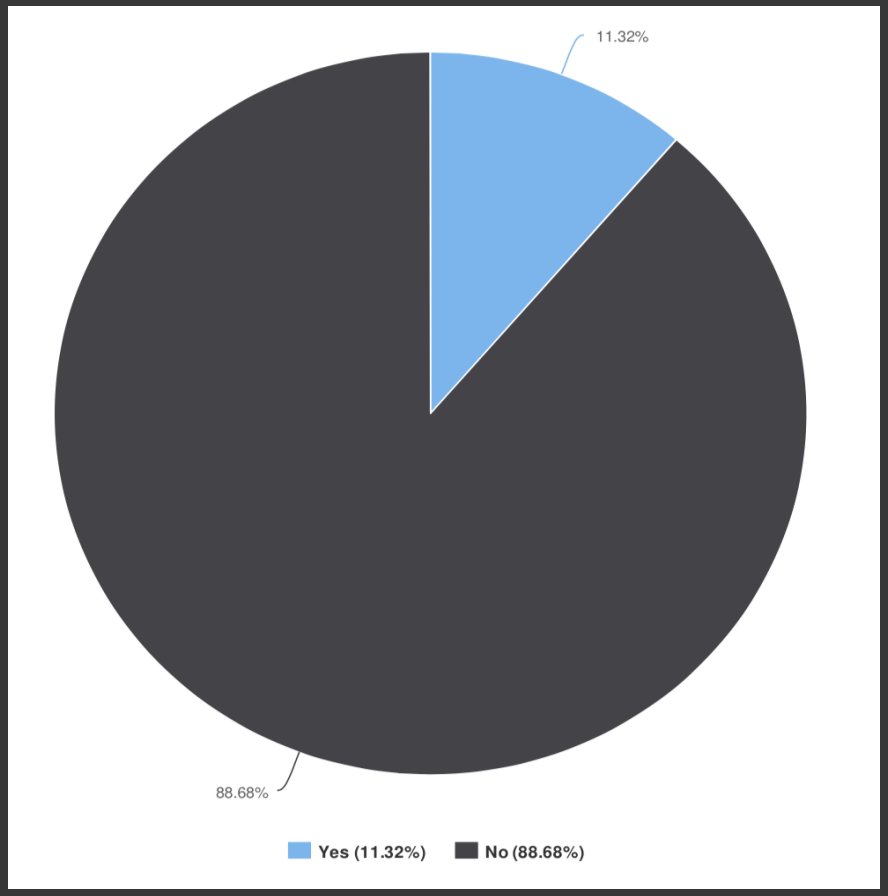
-first name/corresponding author of at least one publication, *or*

-documented experience with 20 implantations.

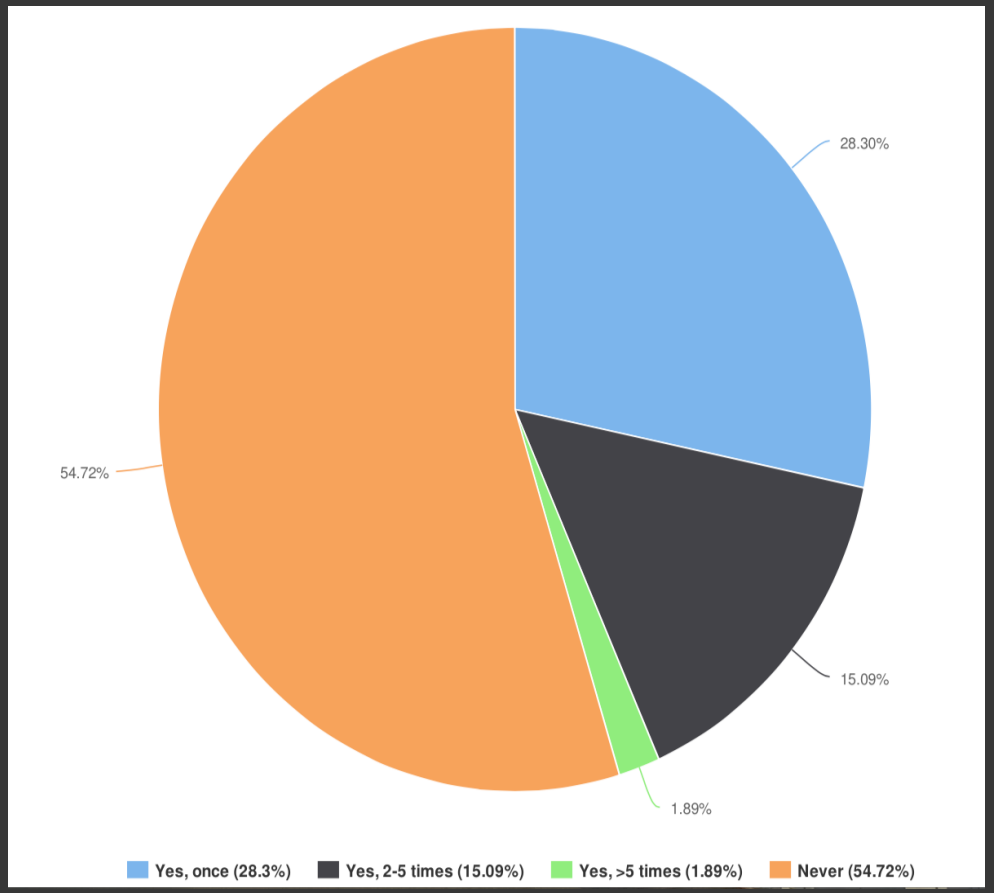
Cortese, Valgimigli, Int J Cardiol 2014

Q 13, 14: have you ever had a patient with scaffold thrombosis?

intraprocedural



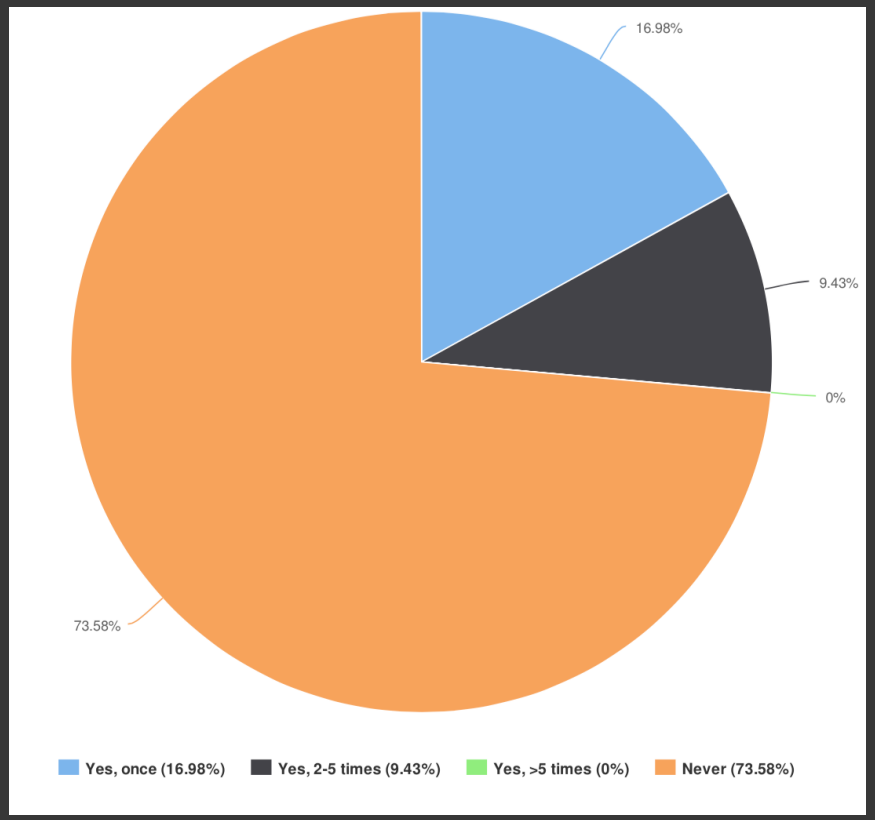
early



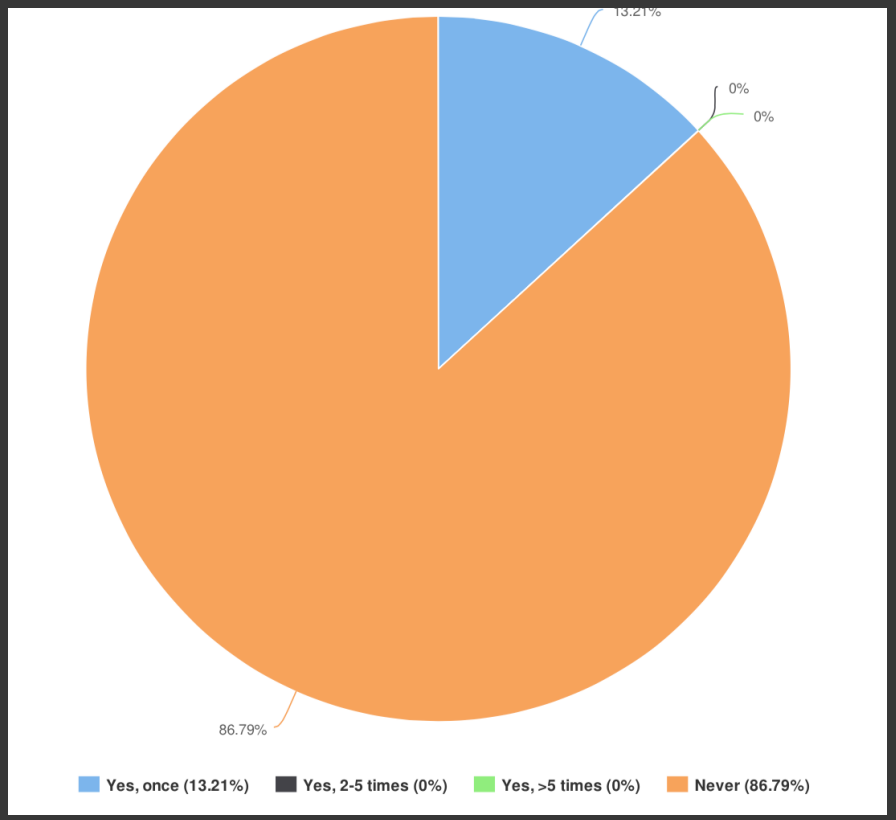
Cortese, Valgimigli, Int J Cardiol 2014

Q 15, 16: have you ever had a patient with scaffold thrombosis?

late



very late



Cortese, Valgimigli, Int J Cardiol 2014

14) 14) Do you think that scaffold thrombosis is an issue (more than with currently available DES) if the implantation correct and DAPT never interrupted?

	Response (%)
Yes	39.62
No	60.38
Answered Question	
Skipped Question	

18) 18) Based on available scientific data, in the next 12 months do you think that Absorb BVS use in your cath lab w

	Response (%)
increase	48.15
remain the same	44.44
decrease	7.41
Answered Question	

Cortese, Stefanini, 2015, unpublished

Scaffold thrombosis

<30 days	30-360d	1-2y	>2y
major problems, esp. ACS	no specific issues	no issues/ lack of data	no issues

correct implantation?

Everbio II, Absorb II

reabsorption complete

CONCLUSIONS

BVS represent, along with DCB, a needful armamentarium that you deserve to have in your shelf

available sci. data seem to show that they are equivalent to DES – but we need longer follow up

BVS implantation is a delicate intervention that deserves more time than normal DES-PCI

ST: Experts' perception is that it seems an issue during the first month and
may be related to the implantation.

BVS- a clinical update by mid-2015

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