BVS: Experience and Clinical Data

Experience in Complex Lesions & Acute MI

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Potential conflicts of interest

Speaker's name: Corrado Tamburino

✓ **I have the following** potential conflicts of interest to report:

Research contracts
☑ Consulting Medtronic, Abbott v, Edwards, Boston Sc.
Employment in industry
Stockholder of a healthcare company
Owner of a healthcare company
Other(s)

I do not have any potential conflict of interest

Overview of all-comers or complex lesion registries

Registries				
Study Title	**Design**	**Number of Patients**	**Primary Endpoint**	**Patient FU (Years)**
BVS EXPAND	All – comers Registry (excl STEMI)	300	1 – Year MACE	5
ASSURE	All – comers Registry	180*	Safety and Efficacy	3
ABSORB CTO	Feasibility in CTO	35*	Safety and Performance	2
PABLOS	Feasibililty in Bifurcations	30	Device, Procedural, Main and Side Branch Success	2
IT-DISSAPEARS	MVD and Long Lesion Registry	1000	Safety and Efficacy	5
GABI-R	All – comers Registry	5000	Safety and Efficacy	5
REPARA	All – comers Registry	1500	1- Year MACE	1
POLAR ACS	ACS Registry	100*	Safety, clinical device, procedure success and in-hospital MACE	1
France ABSORB	Feasibility in de novo lesions	2000	1 – Year MACE	1
GHOST	All – comers Registry	consecutive and continuous enrolment	Target Vessel Failure (TVF)	1
Prague 19	STEMI (STEMI Killip I/II)	100	Clinical Outcomes	1

* Enrollment Complete
Update from Sep 2014

Sources: Dr. G. Stone, Bioresorbable Vascular Scaffold: Acute Performance and Safety Symposia, EuroPCR 2014 and www.clinicaltrials.gov

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GHOST-EU: Participating centers

ElisabethKrankenhaus, Essen
C. Naber
S. Pyxaras

Royal Brompton Hospital, London
C. Di Mario
A. Mattesini

San Raffaele Hospital and Emocolumbus Clinic, Milan
A. Colombo
A. Lateeb

S. G. Di Dio Hospital, Agrigento
G. Caramanno
S. Geraci

University of Giessen, Giessen
H. Nef

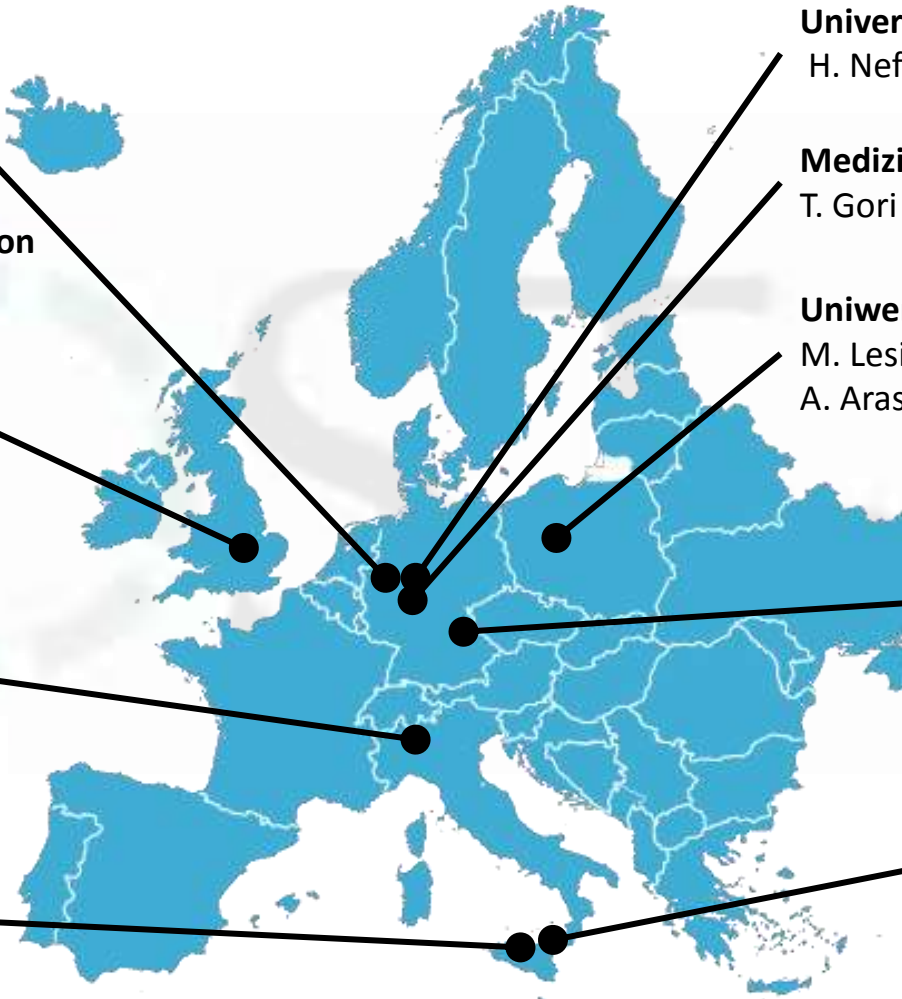**Medizinische Klinik, Mainz**
T. Gori

Uniwersytet Medyczny, Poznan
M. Lesiak
A. Araszkiewicz

Klinikum Großhadern, Munich
J. Mehilli

Ferrarotto Hospital, Catania
C. Tamburino (PI)
D. Capodanno (co-PI)
P. Capranzano

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GHOST-EU Extended Use* 1.189 patients

Clinical

NSTEMI/STEMI, N=406/1,189(34.1%)

LVEF<30%, N=32/980 (3.3%)

CKD (eGFR<60), N=111/743 (14.9%)

Angiographic

ISR, N=49/1,440 (3.4%)

Ostial, N=90/1,282 (7.0%)

CTO, N=96/1,440(6.7%)

Bifucations, N=333/1,440(23.1%)

Thrombus, N=242/1,440(16.8%)

Left main, N=17/1,427(1.2%)

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
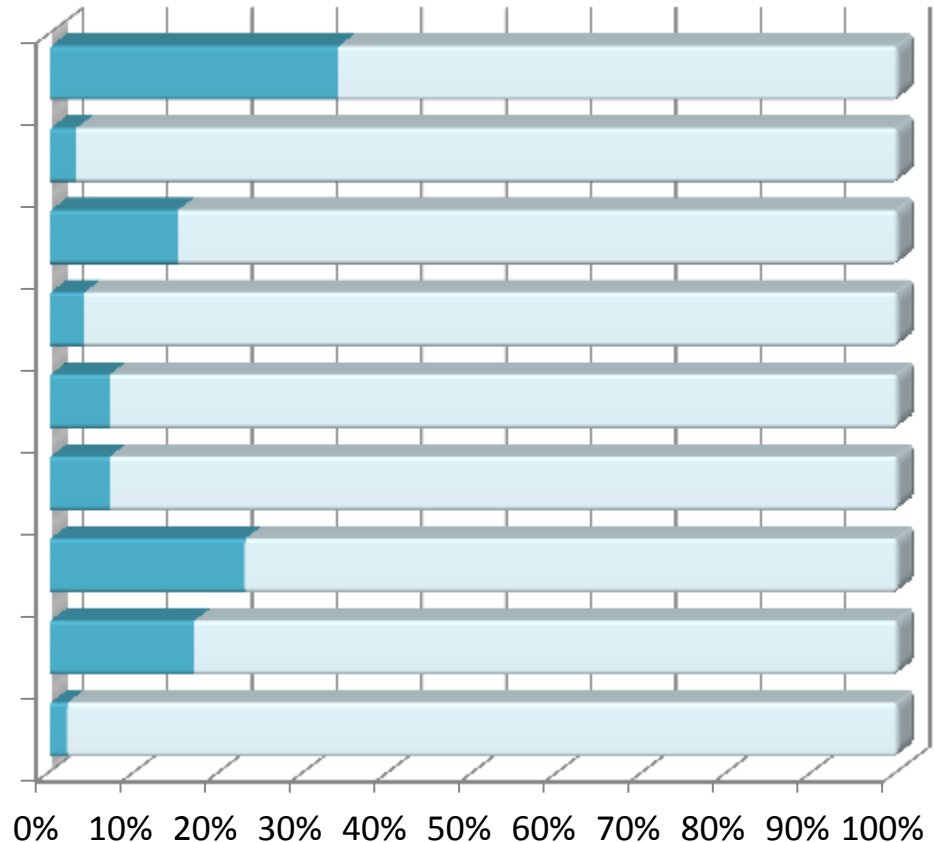
*Compared to ABSORB II eligibility (Diletti et al. Am Heart J. 2012;164:654-63)

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Capodanno D et at. EuroIntervention 2015;10:1144-53.

6-Month Outcomes* 1189 patients
6-month follow-up available in 76%

*Event rates are expressed as Kaplan Meier estimates
** Device-Oriented composite primiry endpoint

1-Year Outcomes* 1189 patients
1-year follow-up available in 86%
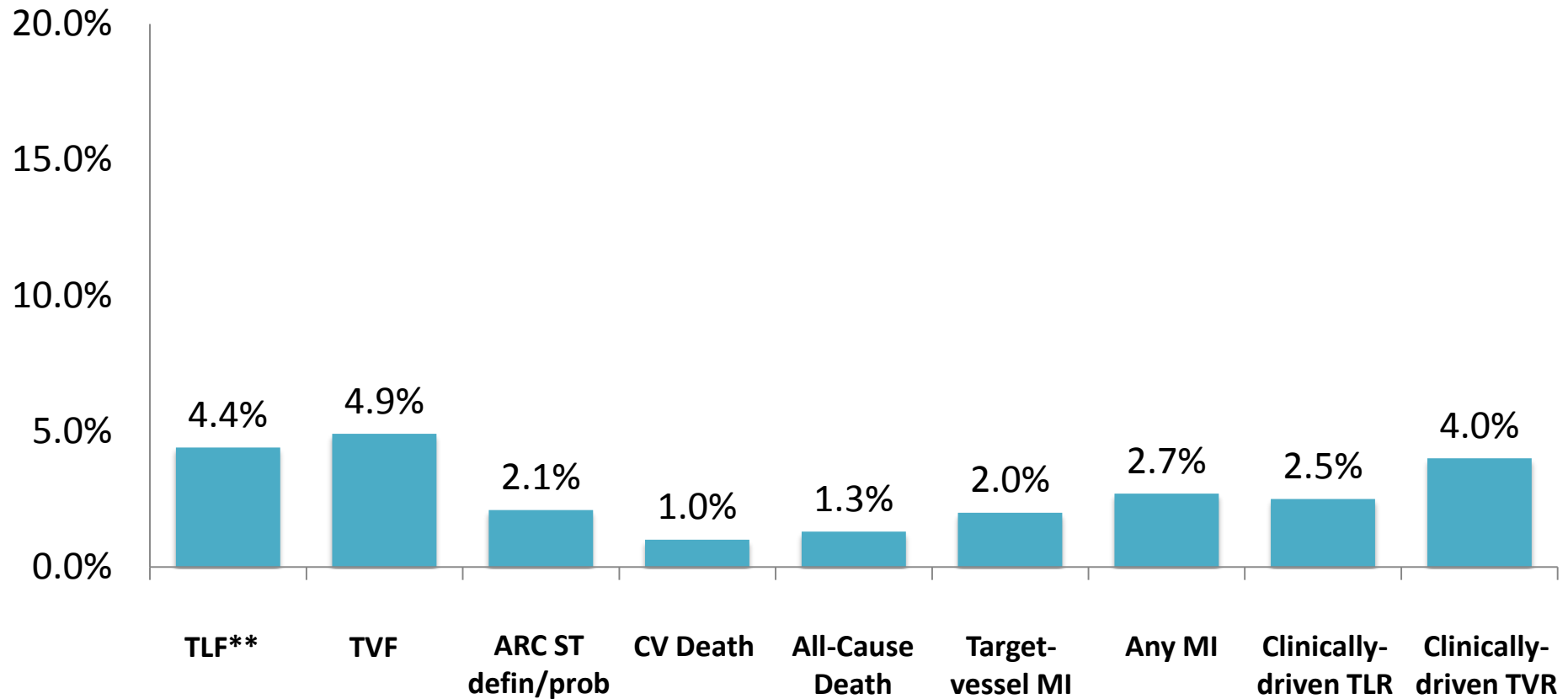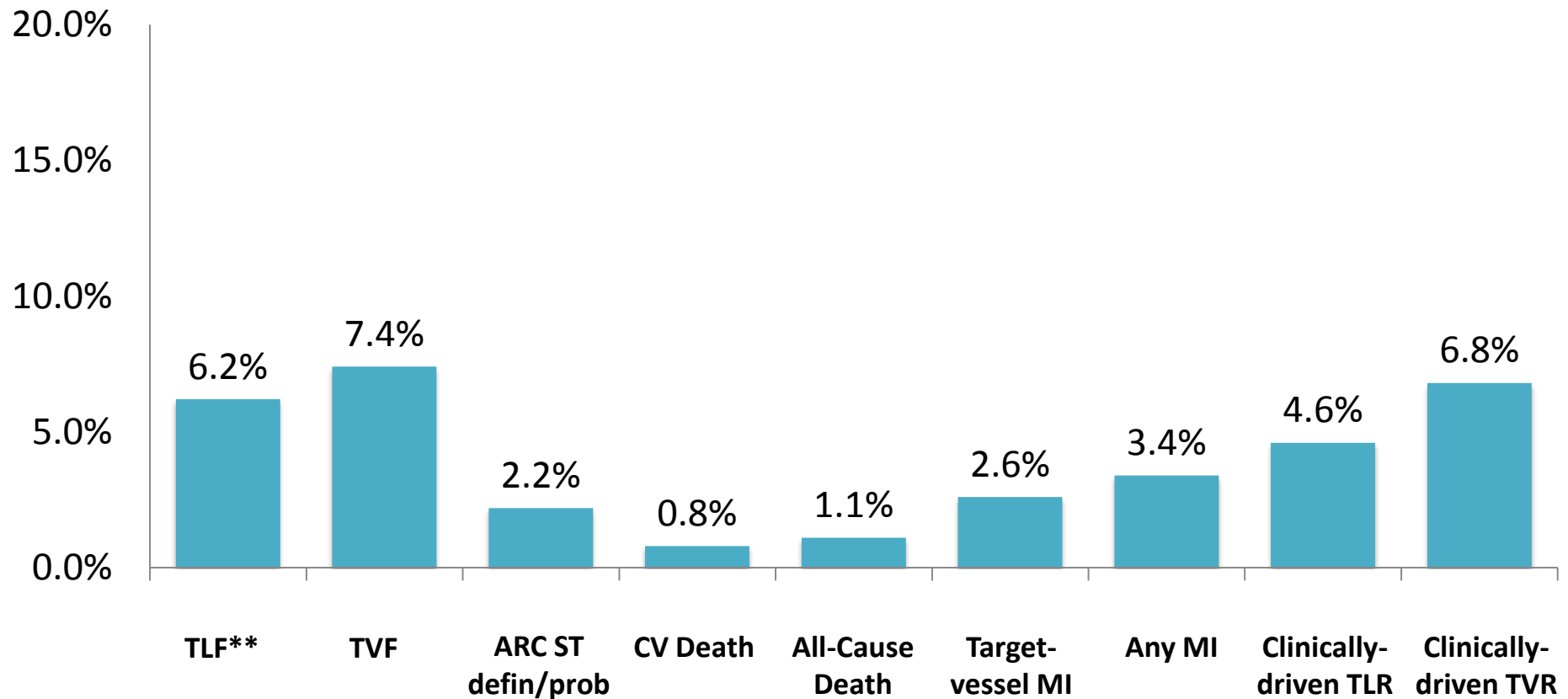
*Event rates are expressed as Kaplan Meier estimates
** Device-Oriented composite primary endpoint

GHOST-EU Scaffold Thrombosis : 1189 patients

Capodanno D et at. EuroIntervention 2015;10:1144-53.
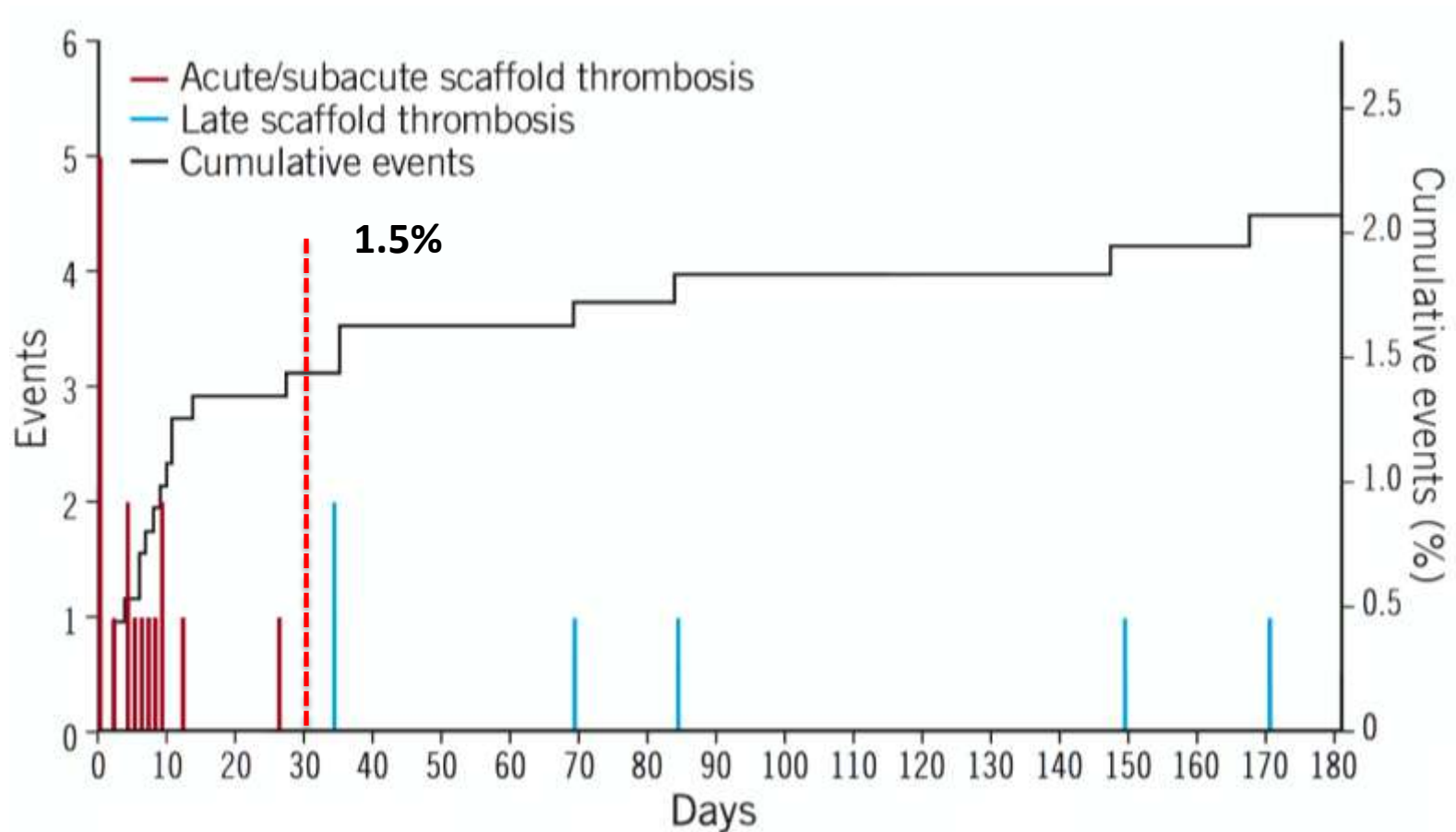
Scaffold Thrombosis GHOST-EU: 1189 patients

- 23 cases: 20 angiographically confirmed ST and 3 probable ST.

- 70% occurred in the first month after PCI, **at a median of 5 days, suggesting the need for scrupulous lesion selection and PCI techniques when using BVS.**

- Intravascular imaging was performed in only 4 of 23 patients who experienced ST, of whom 2 discontinued DAPT.

- 18 of 23 were on clopidogrel.

- 20 of 23 patients were on DAPT at the time of ST.

Prevalence of clinical and angiographic factors among 25 patients with scaffold thrombosis
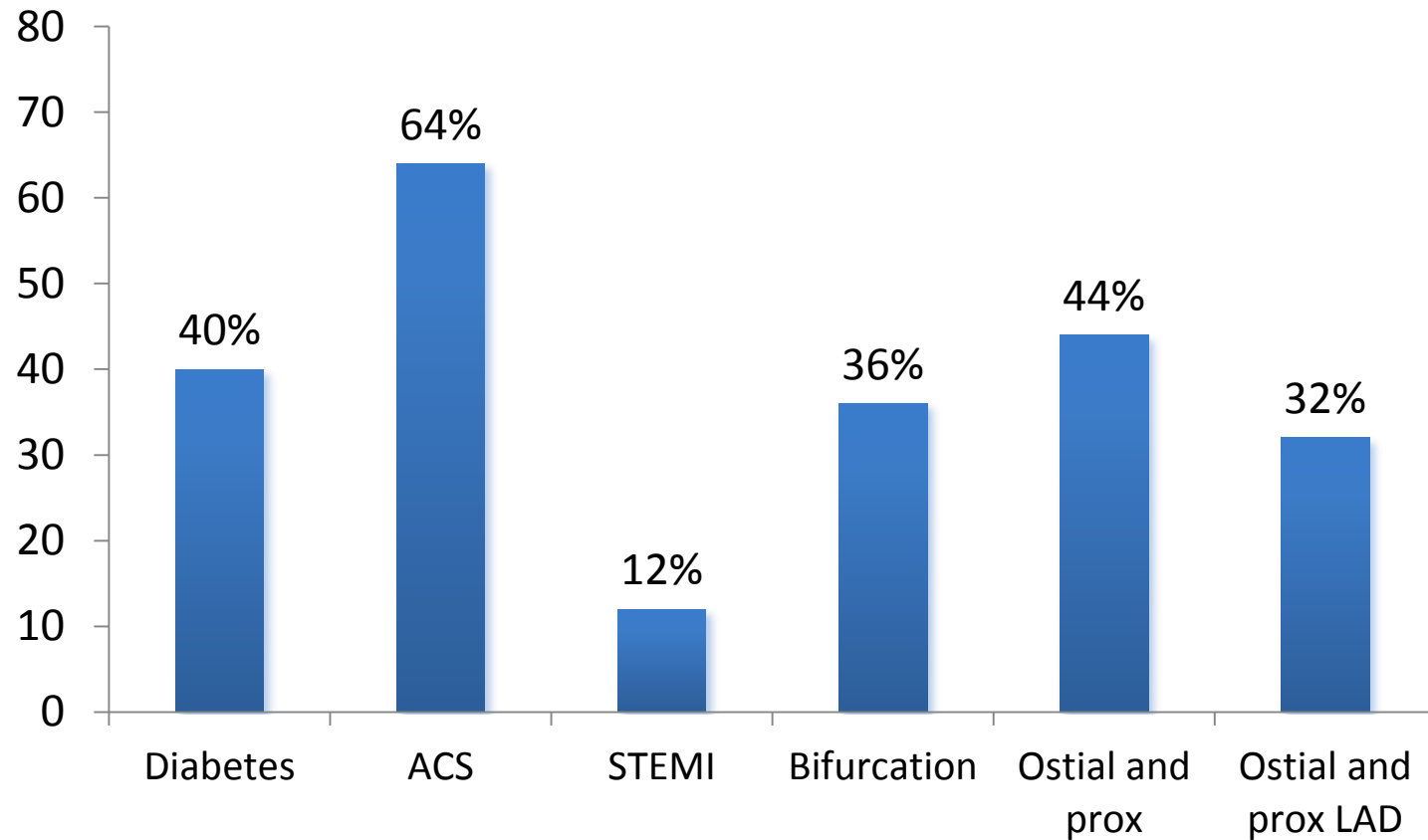
Scaffold Thrombosis GHOST-EU (n=1189):
25 patients
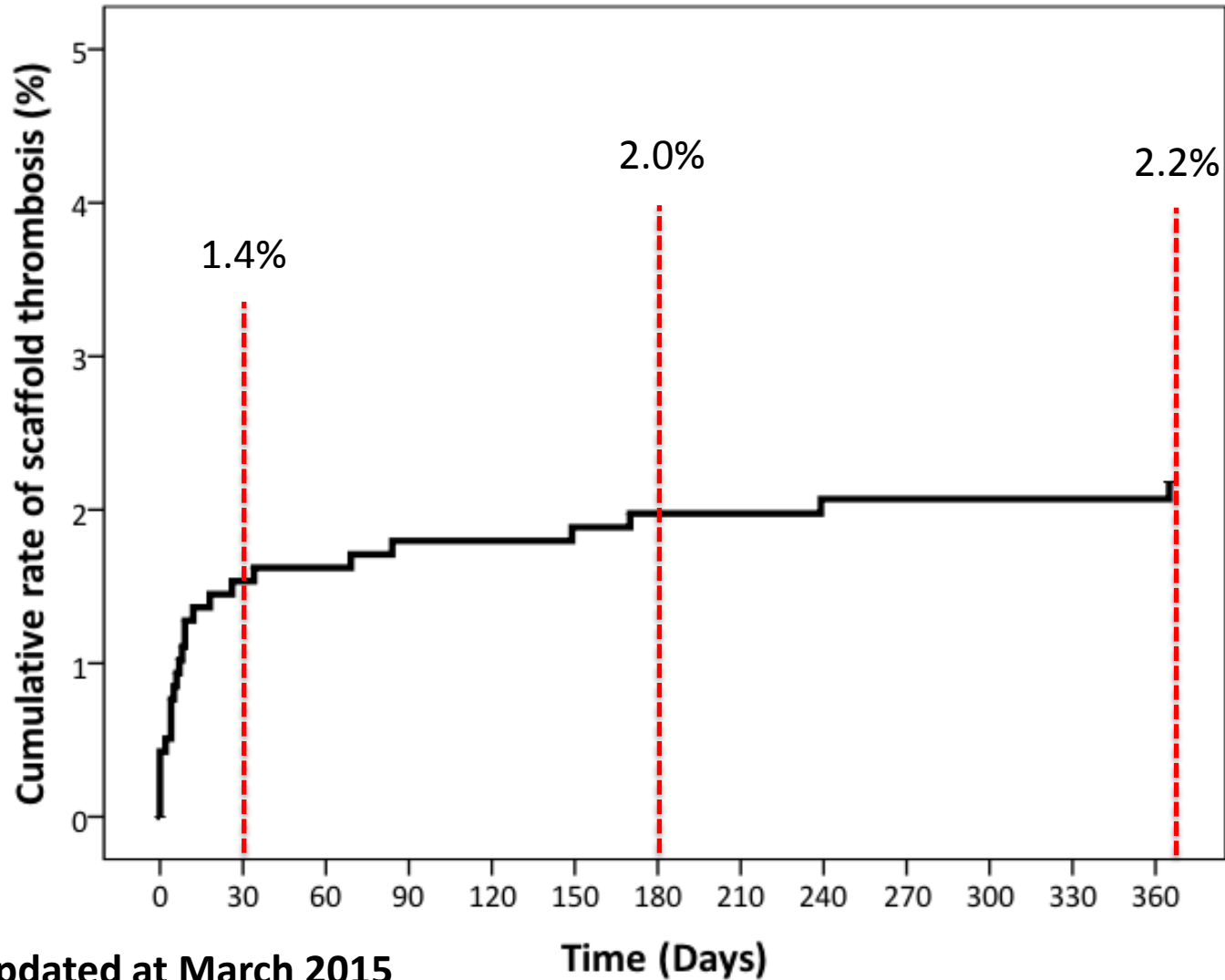
Follow-up updated at March 2015

ABSORB Data
Scaffold Thrombosis (Longest Available FU)
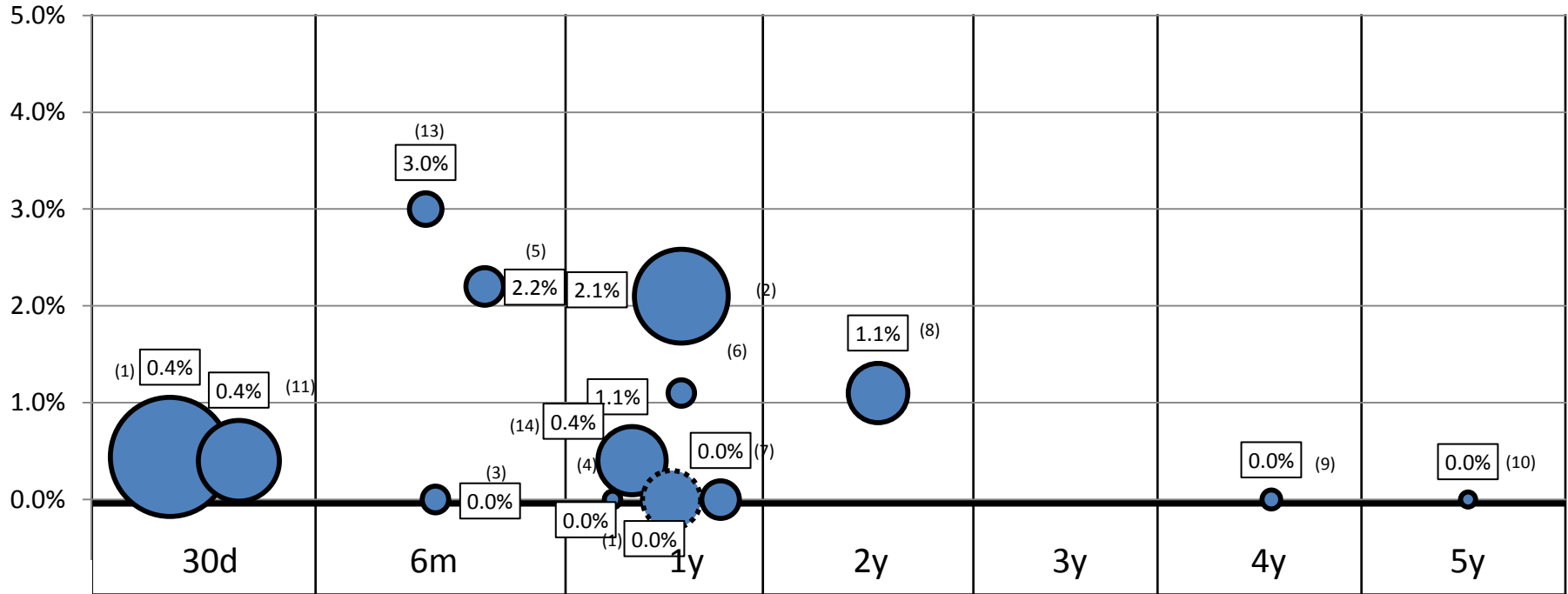
(1) ABSORB FIRST: **All Comers (@AsiaPCR2015)**

(2) GHOST-EU: **All Comer**s (@JIM2015)

(3) Dr. Costopoulos on CCI: **All Comers (in CCI2014)**

(4) CTO (Dr. Serra): **CTO (on Eurointervention2014)**

(5) ABSORB EXPAND: **All Comers (@EuroPCR2014)**

(6) POLAR ACS: **ACS (@ EuroPC2014)**

(7) ASSURE: **All Comers (on Eurointervention2014)**

(8) ABSORB EXTEND: **selected (@ EuroPCR2014)**

(9) ABSORB Cohort B: **simple (@ EuroPCR2014)**

(10) ABSORB Cohort A: **simple @ EuroPCR2011)**

(11) GABI-R: **All Comers (@Germand congress2014)**

(12) ABSORB II**: selected (in Lancet 2014)**

(13) AMC Registry**: AC (in Eurointervention 2014)**

(14) Polish BVS registry: **all comers (@NFIC2014)**

Scaffold thrombosis incidence in ACS

Study (Journal / int congress)	Population	FU	Total ST	SAP,N	ST in SAP	ACS, N	ST in ACS	STEMI, N	ST in STEMI
Kraak et al., AMC Single Centre (EIJ)	All-comers	6M	4 (3.0%)	82	1 (1.2%)	53	3 (5.7%)	17	0 (0%)
ABSORB FIRST (euroPCR2014)	All-comers	1M	2 (0.3%)	295	N/A	505	N/A	N/A	N/A
Azzalini et al. (euroPCR2014)	All-comers	N/A	4 (1.2%)	N/A	3 (N/A)	N/A	0 (N/A)	N/A	1 (N/A)

When excluding the Ghost EU,
In 3120 patients with a mean follow-up of 10.6 Months,
· SAP 0.68%, ACS 1.71%, STEMI 0.67%

When including the Ghost EU,
In 4309 patients with a mean follow-up of 10.3 Months,
· SAP 0.94%, ACS 2.16%, STEMI 1.22%

Kajiya et al. (EIJ)	STEMI	3M	0 (0%)	-	-	-	-	11	0 (0%)
Diletti et al. , BVS STEMI (EHJ)	STEMI	1M	0 (0%)	-	-	-	-	49	0 (0%)
Kocka et al., PRAGUE-19 (EHJ)	STEMI	4M	1 (2.4%)	-	-	-	-	41	1 (2.4%)
Wiebe et al. (Clin Res Cardiol)	STEMI	6M	0 (0%)	-	-	-	-	25	0(0%)
Ielasi et al., RAI registry (EIJ)	STEMI	6M	1(1.4%)	-	-	-	-	74	1(1.4%)
Capodanno et al., GHOST (EIJ)	All-comer	6M	23 (2.1%)	626	9 (1.4%)	563	14 (2.5%)	192	4 (2.1%)

Outcomes of BVS in acute MI

Absorb BVS for ACS patients

Growing evidence of feasibility

41 STEMI
Kočka V et al.
Eur Heart J. 2014;35:787-94

49 STEMI
Diletti R et al.
Eur Heart J. 2014;35:777-86

150 ACS
Gori T et al
EuroIntervention 2014;9:1036-41

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BVS-EXAMINATION Study: 290 STEMI matched patients
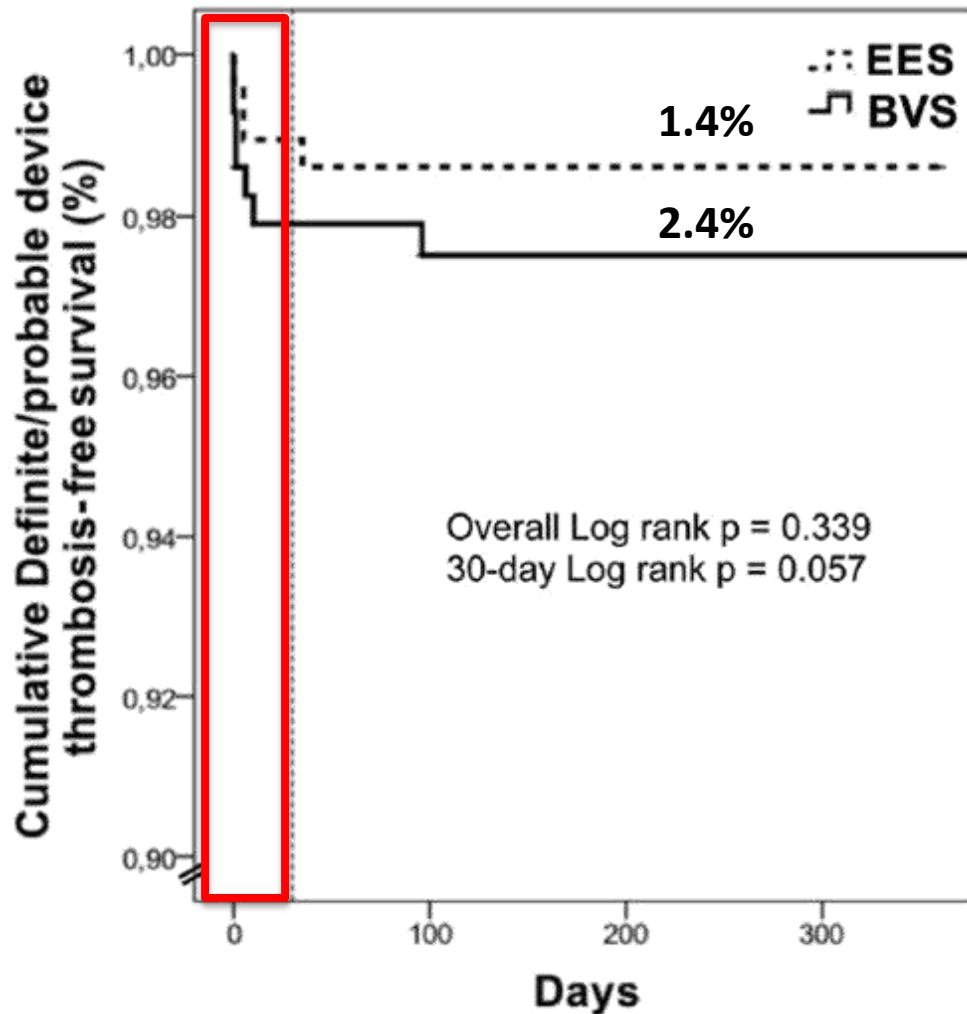
- One BVS thrombosis occurred in a patient with 2 BVS overlapped, who stopped DAPT (aspirin and ticagrelor) 3 days before.
- Among BVS the thrombectomy use was 74.8% and post-dilatation 36.3%.

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Brugaletta S et al. J Am Coll Cardiol Intv 2015;8:189–97

BVS-EXAMINATION Study: 290 STEMI matched patients

	BVS Group (n = 290)	EES Group (n = 290)	BMS Group (n = 290)	HR [95% CI]*	p Value*	HR [95% CI]†	p Value†
Clinical outcome at 1 year‡							
DOCE	12 (4.1)	12 (4.1)	17 (5.9)	0.94 (0.23–4.32)	0.994	0.50 (0.13–1.88)	0.306
Cardiac death	6 (2.1)	6 (2.1)	6 (2.1)	0.87 (0.08–9.90)	0.908	2.46 (0.15–40.43)	0.528
TV MI	6 (2.1)	4 (1.4)	3 (1.0)	1.65 (0.28–9.90)	0.583	2.52 (0.62–10.31)	0.198
TLR	5 (1.7)	4 (1.4)	10 (3.4)	1.93 (0.25–14.91)	0.527	0.95 (0.15–5.85)	0.955
Definite/probable device thrombosis	7 (2.4)	4 (1.4)	5 (1.7)	1.10 (0.69–17.54)	0.948	0.79 (0.07–9.20)	0.852
Definite device thrombosis	5 (1.7)	2 (0.7)	2 (0.7)	1.10 (0.70–17.66)	0.944	1.19 (0.74–19.03)	0.902

*Comparison between BVS and EES. †Comparison between BVS and BMS. ‡HRs have been estimated in the timeframe after 30 days up to 1 year.

CI = confidence interval; DOCE = device-oriented endpoint; HR = hazard ratio; TLR = target lesion revascularization; TV = target vessel; other abbreviations as in Table 1.

Primary PCI and Stent Type During the Study Period

December 2012

STEMI patients undergoing PPCI
n= 1,232

Patient receiving **DES**
n= 795 (64.5%)

Patient receiving **BMS**
n= 363 (29.5%)

Patient receiving **BVS**
n=74 (111 BVS; 6.0%)

Single BVS n=56 (75.7%)

Multiple Overlapping BVS n=18 (24.3%)

March 2014

Ielasi A. Eurointervention 2014 ahead of print

Procedural Characteristics (2)

Patients, n (%)	Overall n=74	Overlapping BVS		p Value
		Yes n=18	No n=56	
Thrombectomy	32 (43.2)	3 (16.7)	29 (51.8)	0.008
Pre-dilatation	67 (90.5)	18 (100)	49 (87.5)	0.1
Drug-eluting stent same vessel	2 (2.7)	1 (5.6)	1 (1.8)	0.4
IVUS/OCT	2 (2.7)	1 (5.6)	1 (1.8)	0.4
N° BVS implanted per patient, median ± ST	1.3±0.6	2.3±0.5	1.0±0.2	0.0001
BVS diameter per patient, median ± ST	3.1±0.4	3.1±0.4	3.1±0.4	0.1
BVS length per patient, median ± ST	29.8±17.0	55.3±13.7	21.6±6.5	0.0001
Post-dilatation	69 (93.2)	18 (100)	51 (91.1)	0.2
Bivalirudin	2 (2.7)	1 (5.6)	1 (1.8)	0.4
Glycoprotein IIb/IIIa administration	23 (31.1)	4 (22.2)	19 (33.9)	0.2

Ielasi A. Eurointervention 2014 ahead of print

Ielasi A. Eurointervention 2014 ahead of print

GHOST | Ferrarotto Population
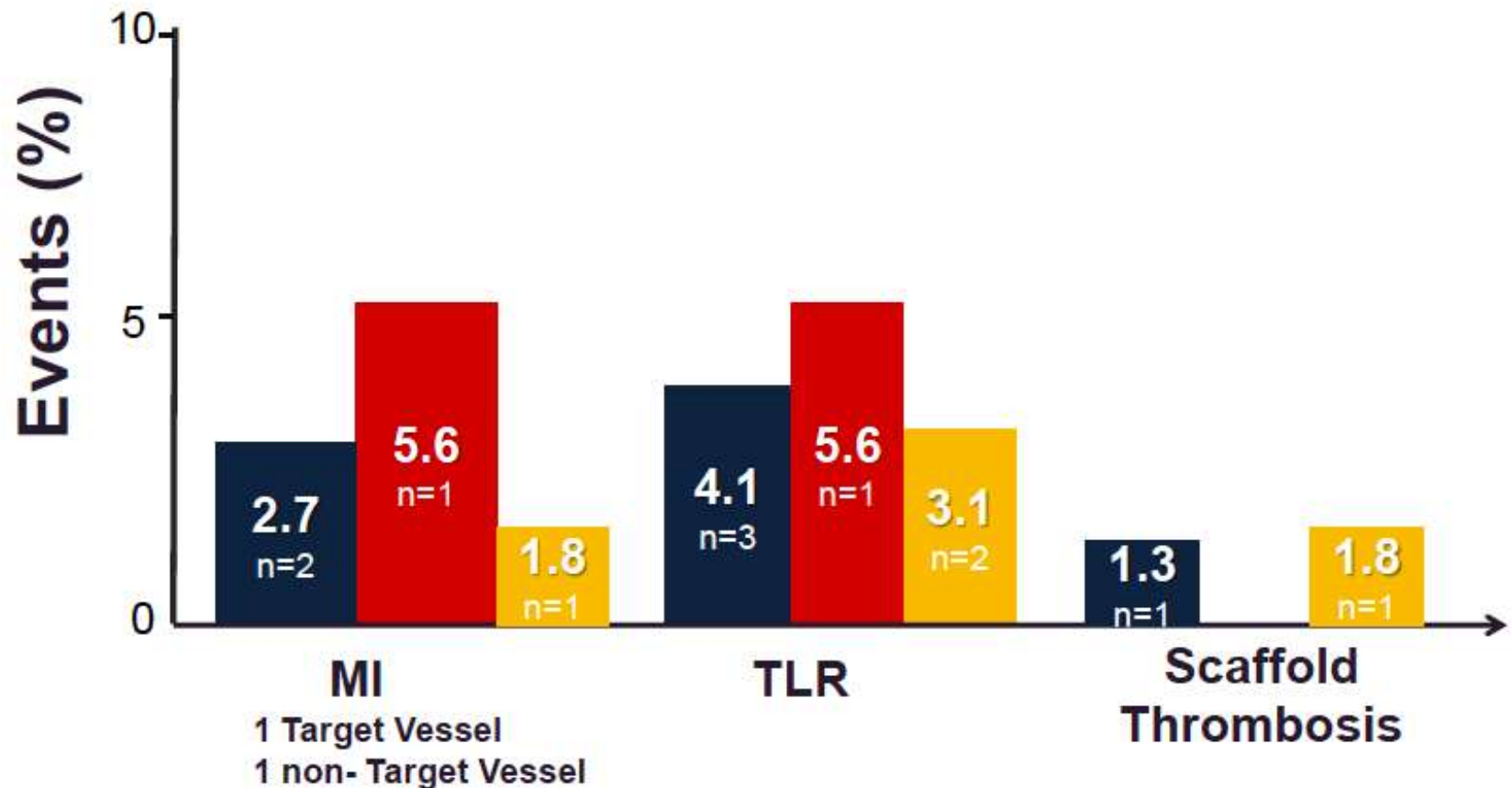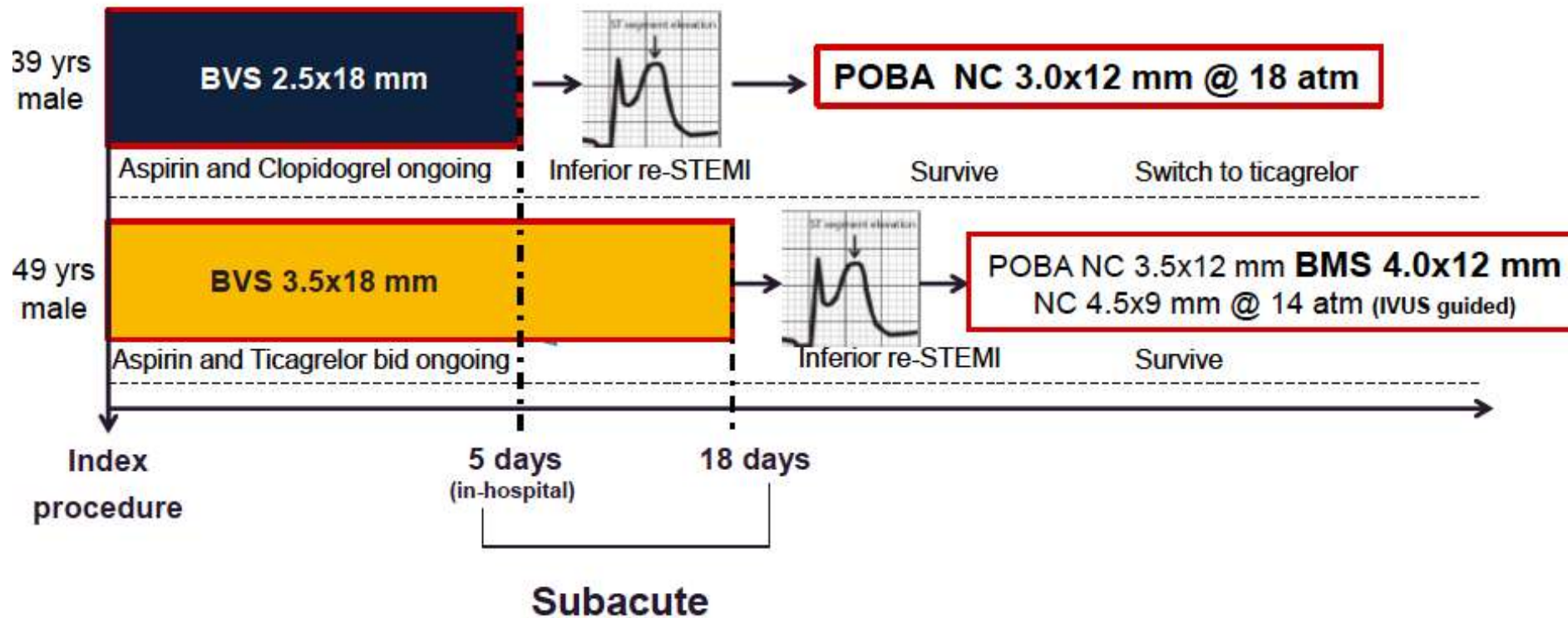
Patients enrolled N=319; lesions N = 406
From 1/3/2013 to 30/06/2014

- **6-months FU in 305 patients 95.6%**
- **1-year FU in 281 patients: 88.1% of overall population and 95% of those eligible (n=296)**

Ferrarotto Population Clinical characteristics

Variable	Patient-based (N = 319)
Age, years±SD	60.7 ± 9.6
Male	272 (85.3%)
Diabetes mellitus	**79 (24.8%)**
On insulin	32 (10.0%)
Dyslipidemia	187 (58.6%)
Hypertension	221 (69.3%)
Smoker	117 (36.7%)
Previous PCI	102 (32.0%)
Prior CABG	10 (3.1%)
ACS	**158 (49.5%)**
NSTEMI	**46 (14.4%)**
STEMI	**58 (18.2%)**

Case from GHOST Ferrarotto –
Male, 69 yrs old with hypertension, diabetes, smoking, family history, hyperlipidemia.
Presenting with lateral STEMI
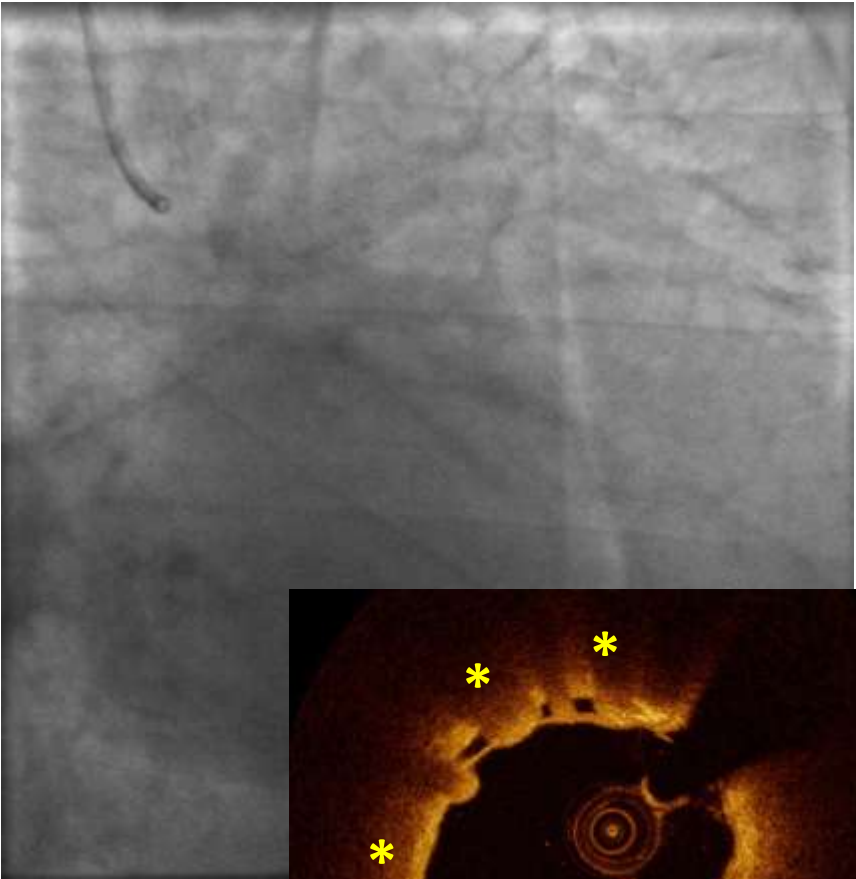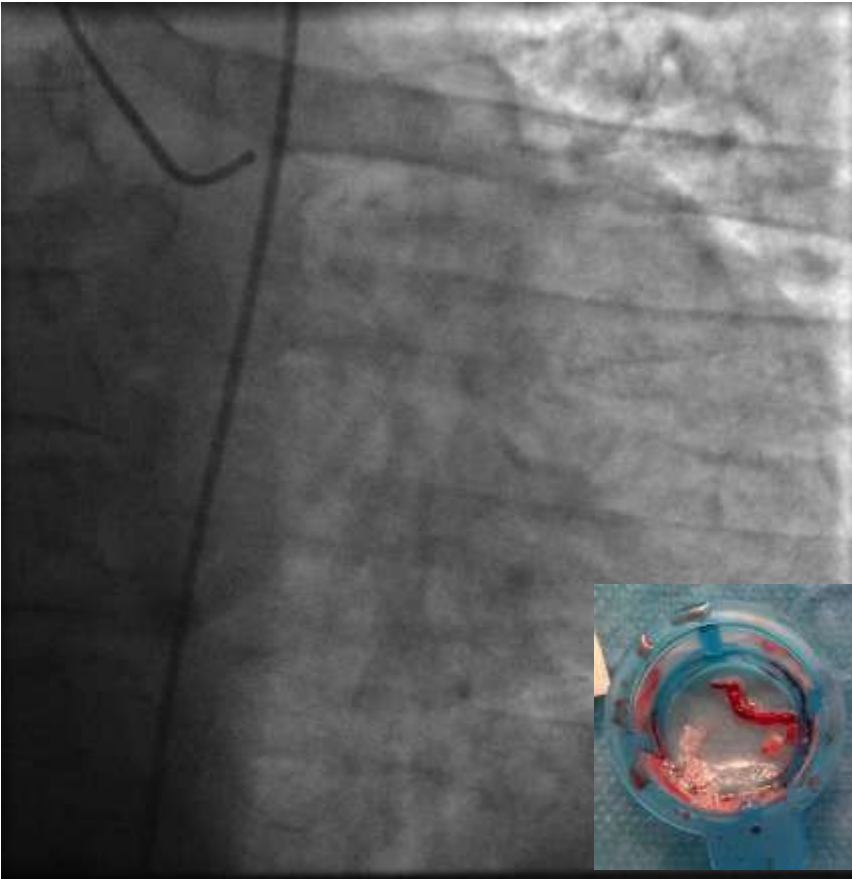
After thrombus aspiration **direct** implantation of one BVS
(3.0/18 mm) on LCX-marginal

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* **Lipid plaque (TCFA)**
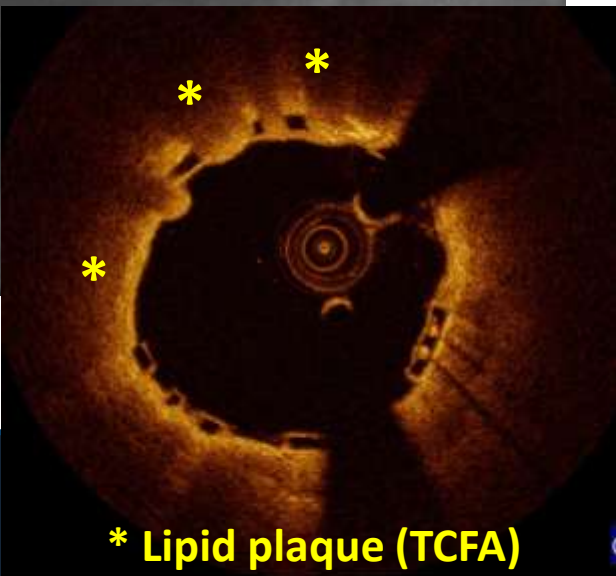
Variable	Patients (n=58)
Reference vessel diameter (mm)	3.1 ± 0.5
Average scaffold diameter (mm)	3.3 ± 0.3
Total scaffold length (mm)	22.7 ± 5.7
Pre-dilatation	56 (96.6%)
Post-dilatation	**39 (67.2%)**
Overlapping	9 (15.5%)
Optical coherence tomography use	11 (19%)
Intravascular ultrasound use	2 (3.4%)

Over a mean follow-up of 352.8 ± 89.6 days:

- No death, MI and scaffold thrombosis occurred.
- Only 1 case of TLR at 604 days was observed

Conclusions

- One-year efficacy outcomes with BRS in complex lesions are very promising.

- In complex lesions an increase in early ST has been reported.

- BVS outcomes in STEMI have been evaluated in relatively small studies, of which one has found an increase in early ST.

- The increase in early ST reported in some registries suggests the need for optimal implantation technique, especially in complex settings.

- More data are needed to better evaluate the safety and efficacy of BVS in complex lesions.

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