

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	Feasibility 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



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

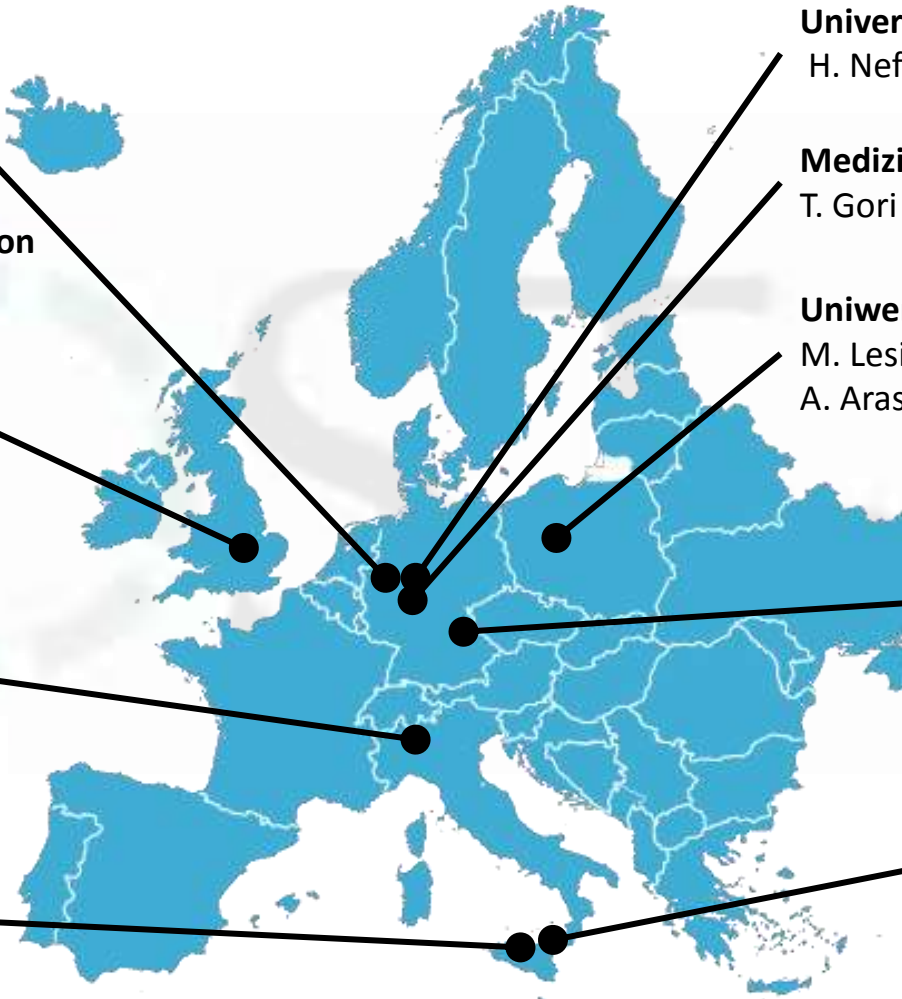
M. Lesiak
A. Araszkiwicz

Klinikum Großhadern, Munich

J. Mehilli

Ferrarotto Hospital, Catania

C. Tamburino (PI)
D. Capodanno (co-PI)
P. Capranzano



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%)

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

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

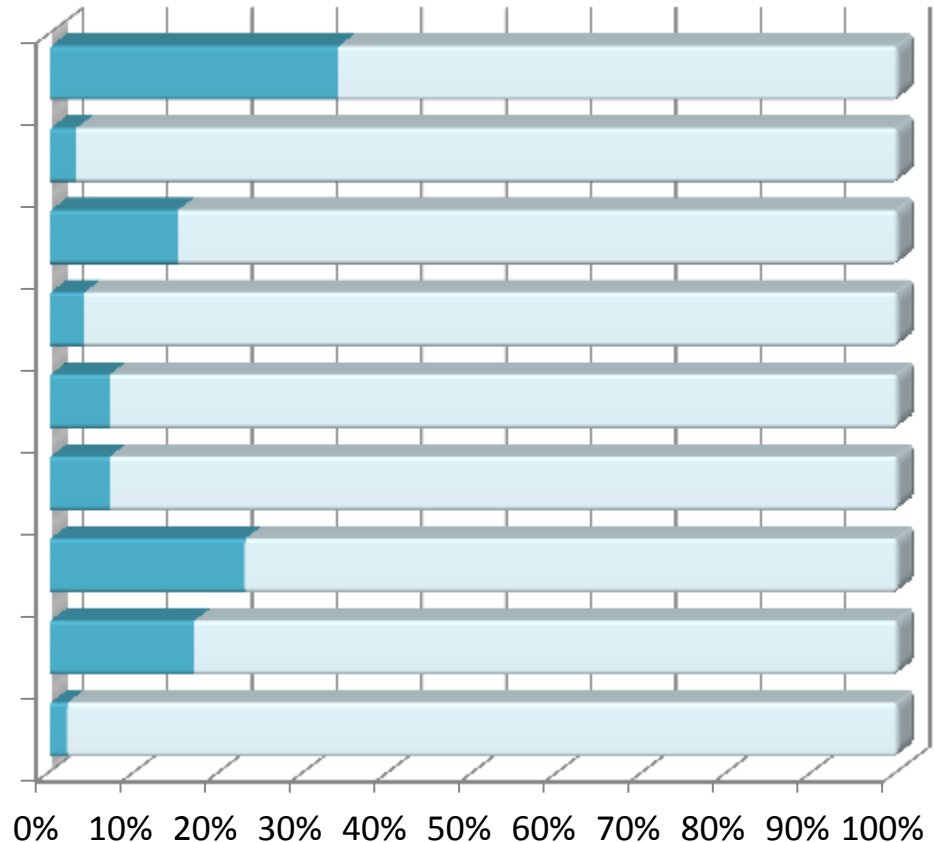
CTO, N=96/1,440(6.7%)

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

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

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

Angiographic

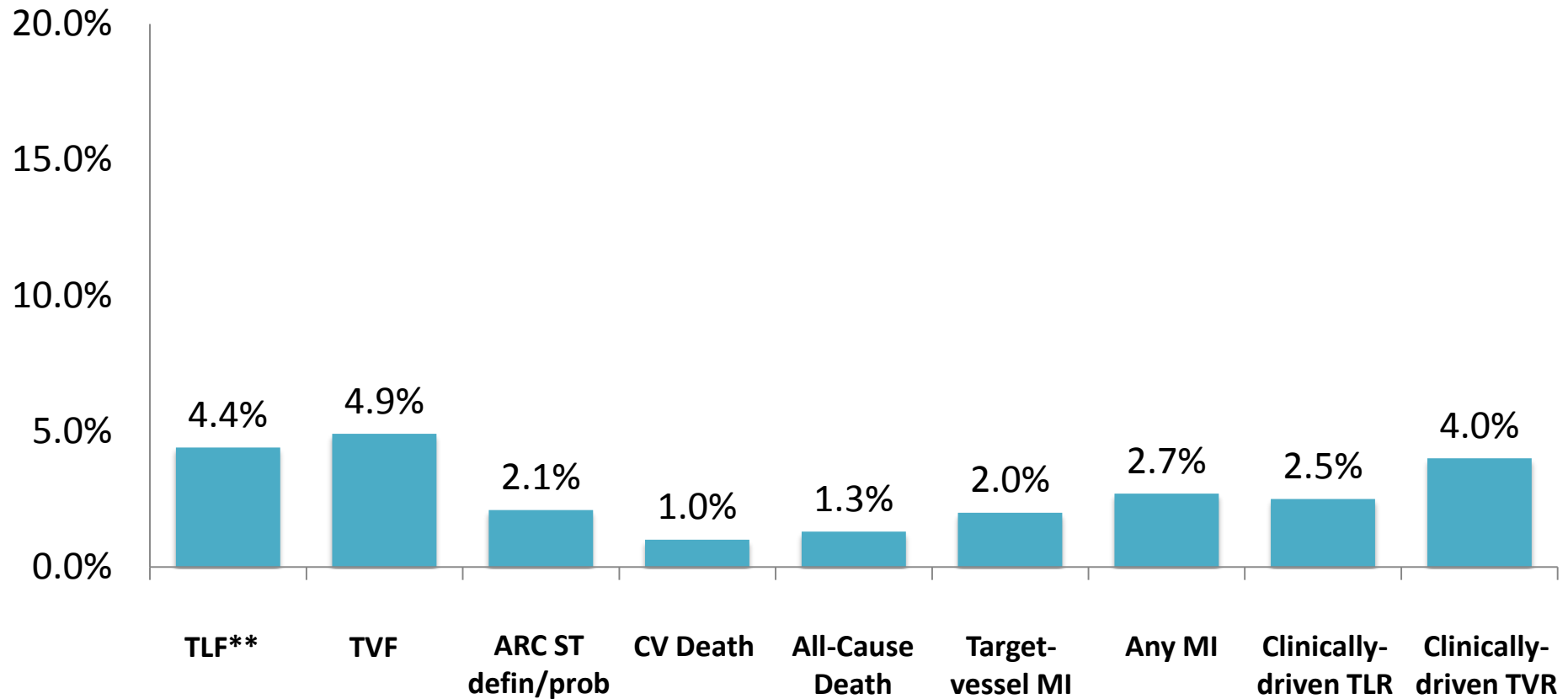


*Compared to ABSORB II eligibility (Diletti et al. Am Heart J. 2012;164:654-63)



6-Month Outcomes* 1189 patients

6-month follow-up available in 76%



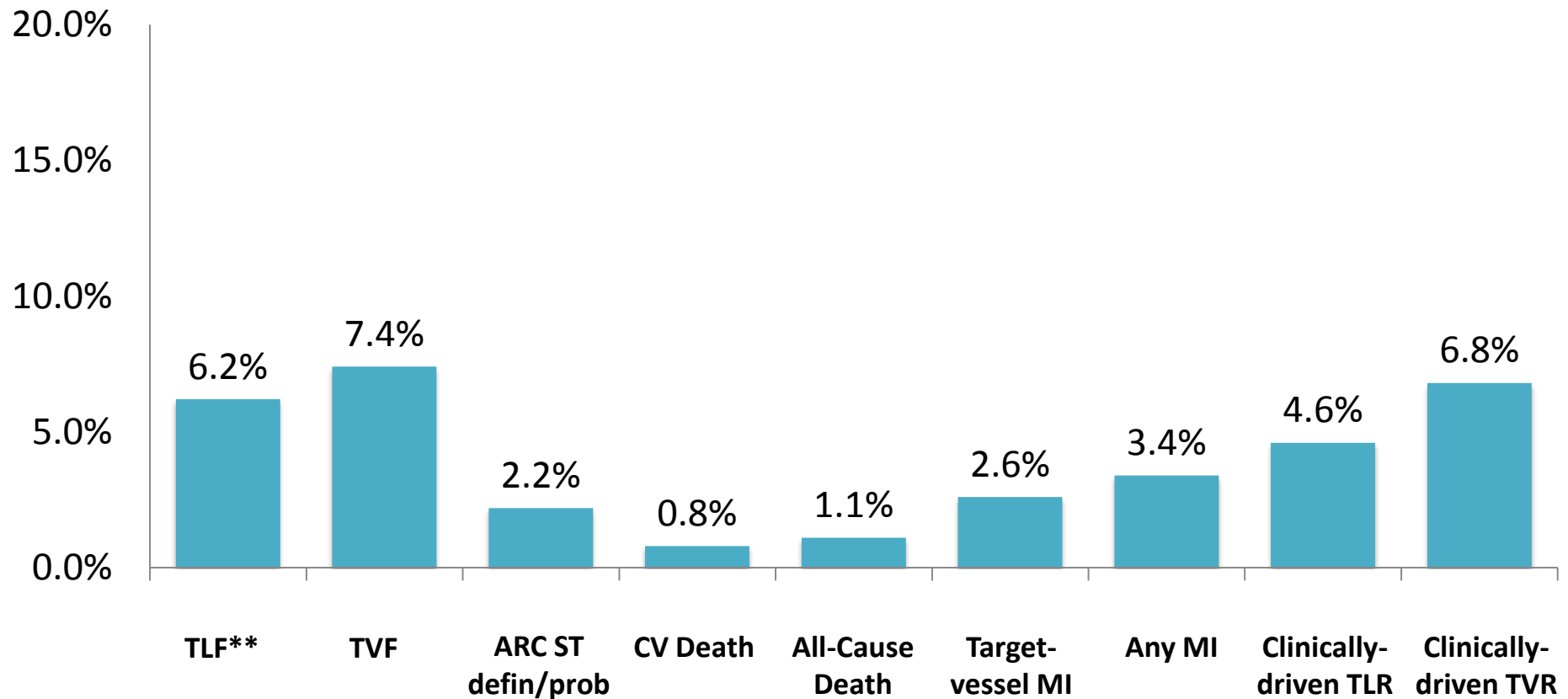
*Event rates are expressed as Kaplan Meier estimates

** Device-Oriented composite primary endpoint



1-Year Outcomes* 1189 patients

1-year follow-up available in 86%

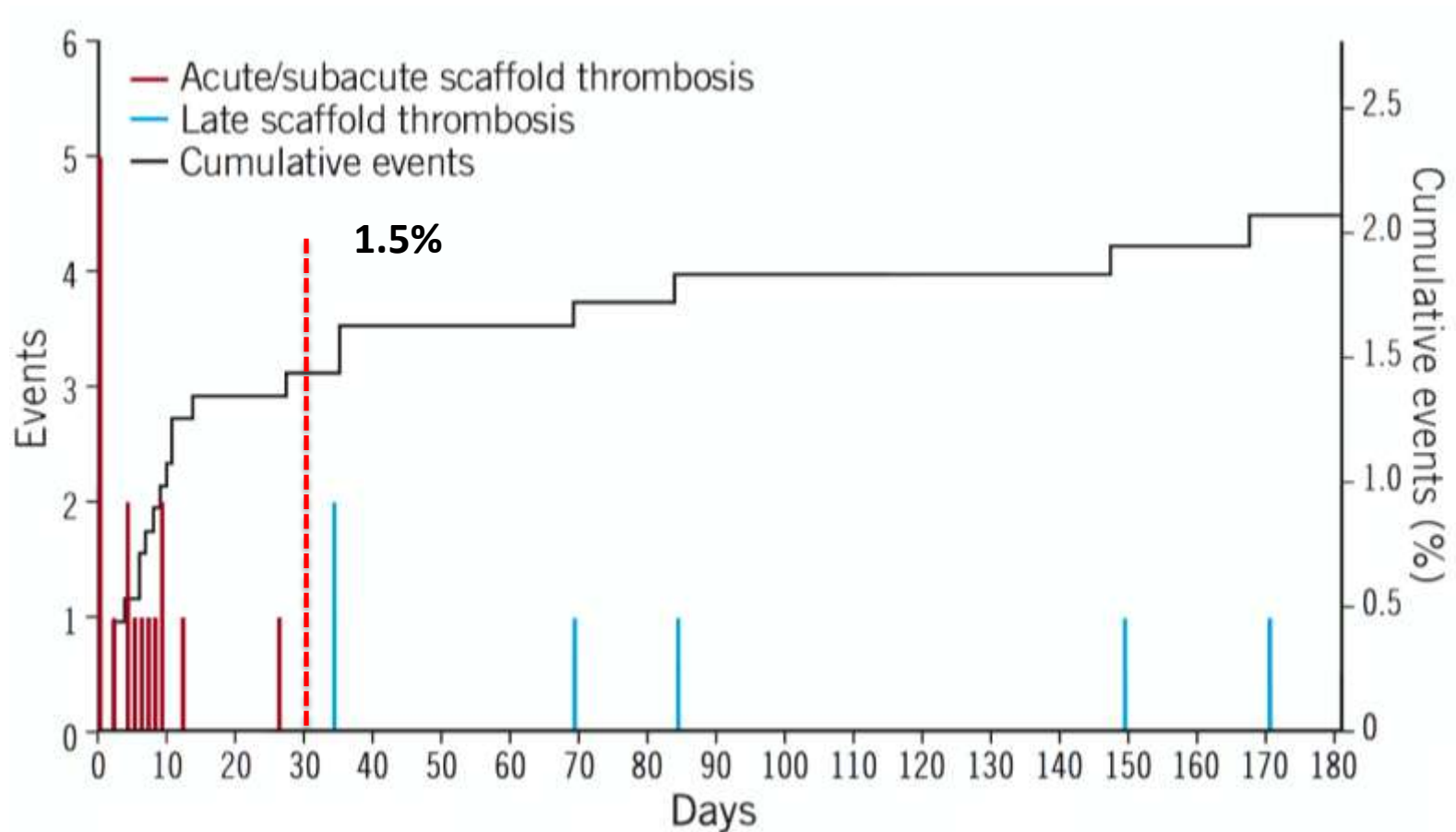


*Event rates are expressed as Kaplan Meier estimates

** Device-Oriented composite primary endpoint



GHOST-EU Scaffold Thrombosis : 1189 patients

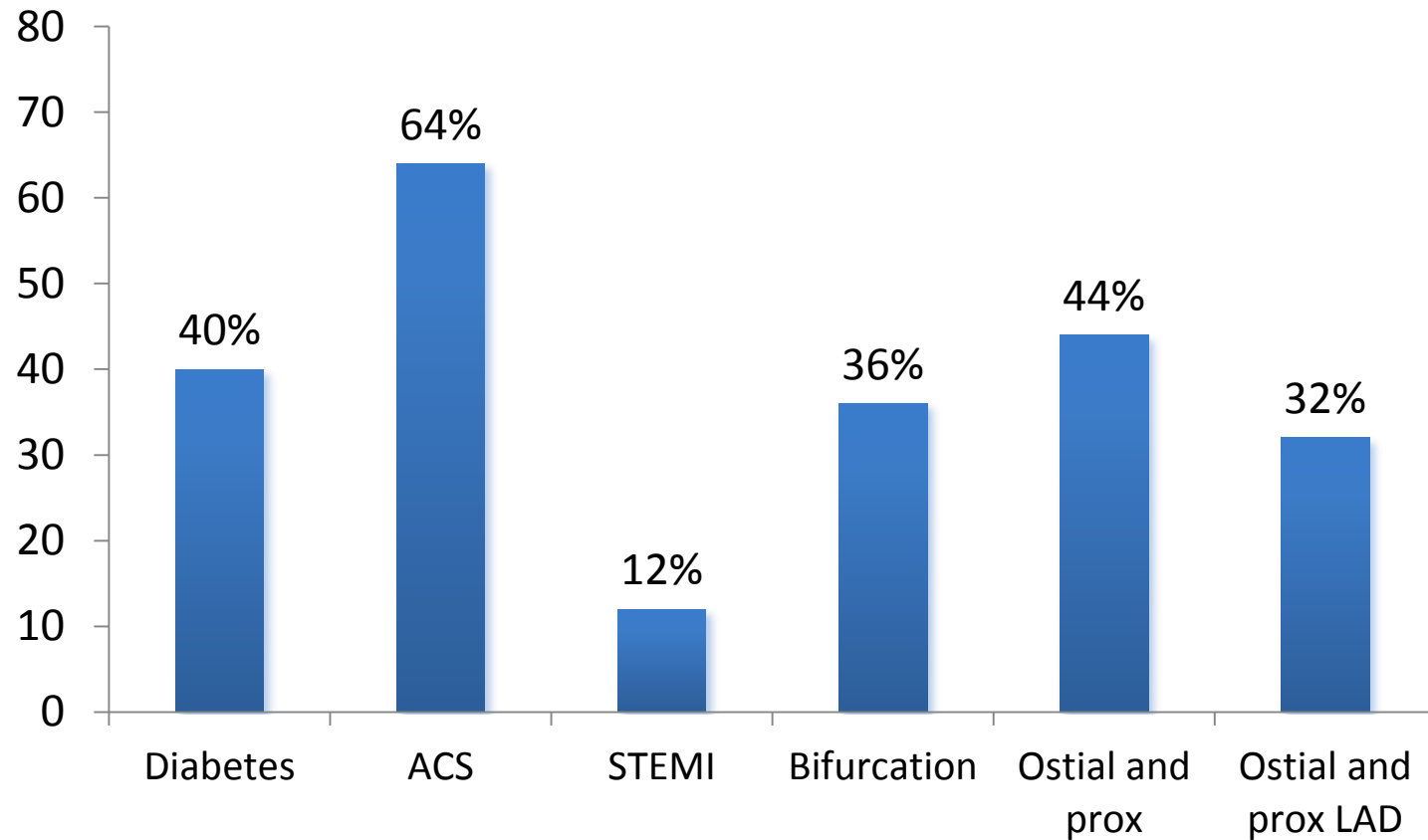


Scaffold Thrombosis GHOST-EU: 1189 patients

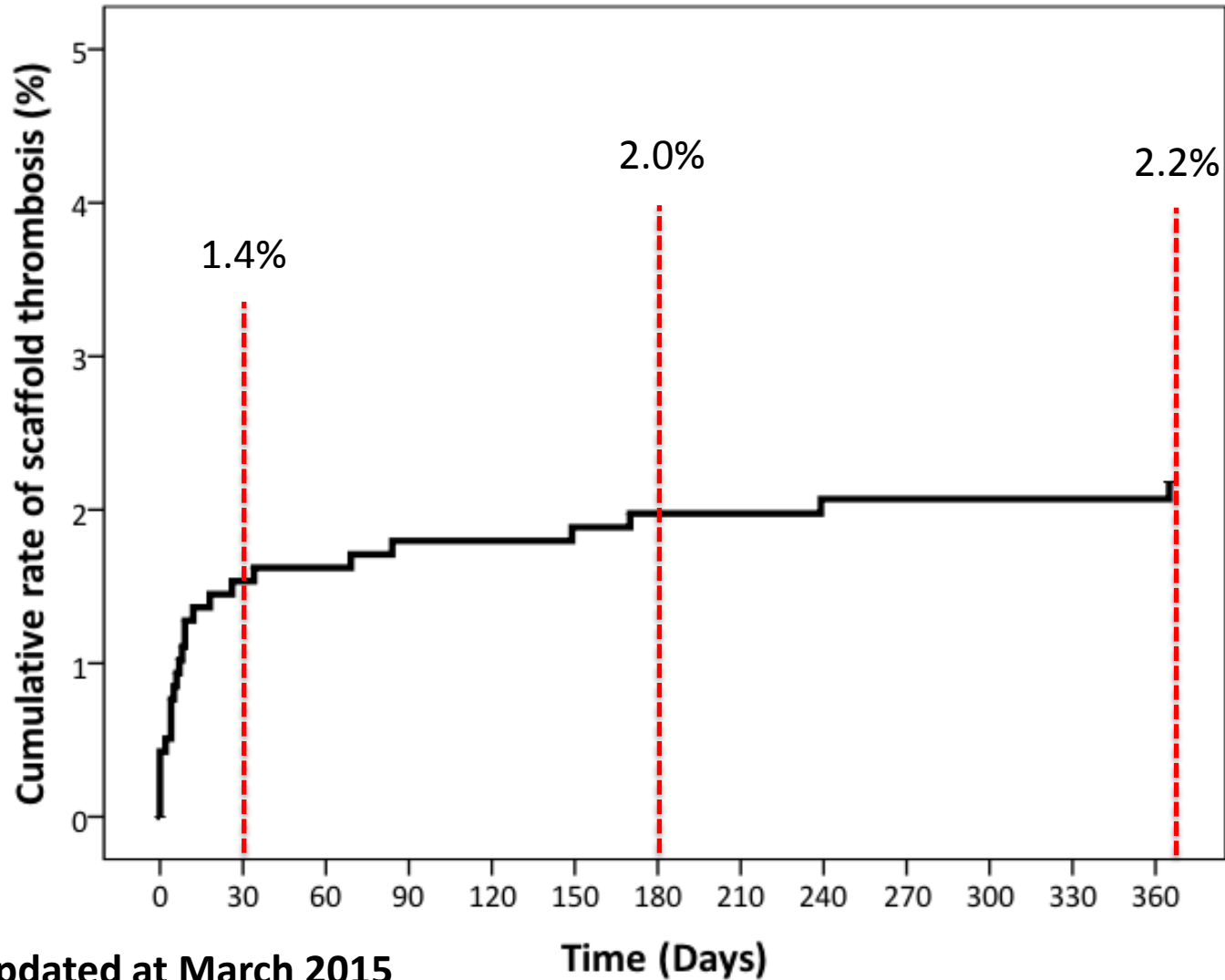
- 23 cases: 20 angiographically confirmed ST and 3 probable ST.
- 70% occurred in the first month after PCI, **at a median of 5 days**, suggesting the need for scrupulous lesion selection and PCI techniques when using BVS.
- **Intravascular imaging** was performed in only 4 of 23 patients who experienced 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



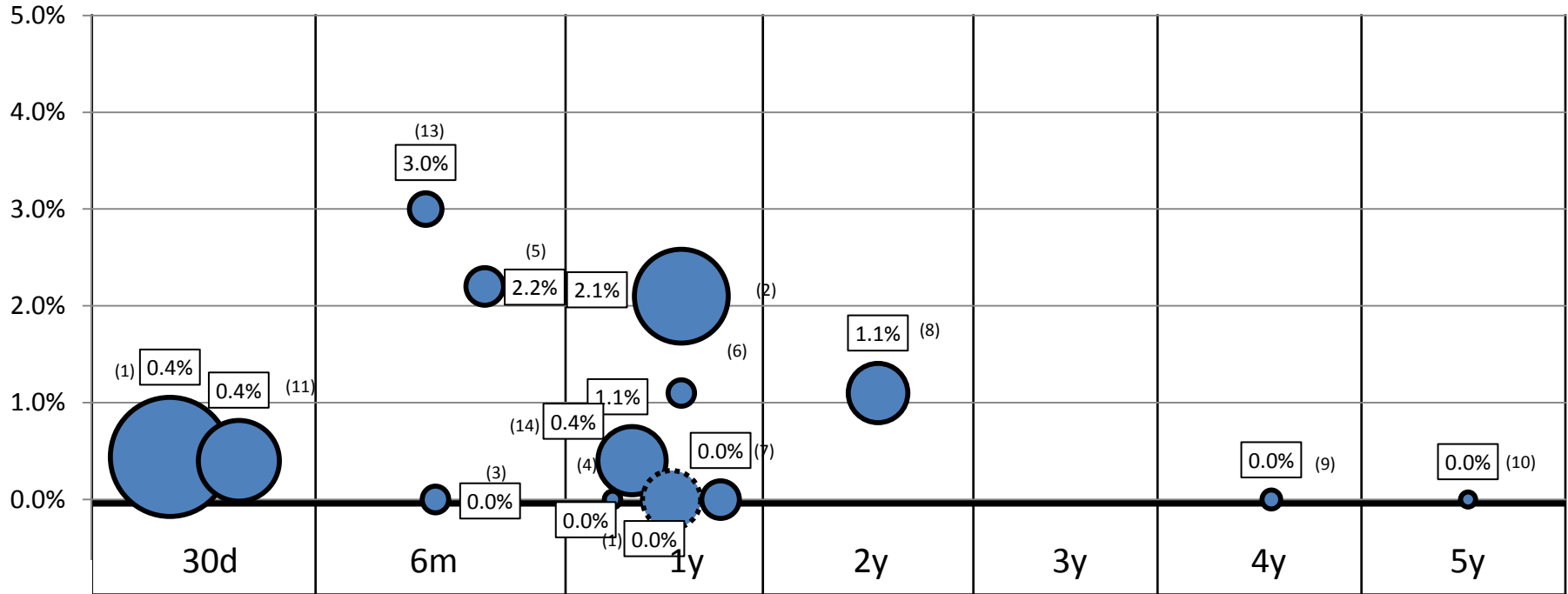
Follow-up updated at March 2015

Time (Days)



ABSORB Data

Scaffold Thrombosis (Longest Available FU)



(1) ABSORB FIRST: All Comers (@AsiaPCR2015)

(2) GHOST-EU: All Comers (@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

Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study 'Prague 19'

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Aims Bioresorbable vascular scaffolds (BVS) have been studied in chronic coronary artery disease, but not in acute ST-segment elevation myocardial infarction (STEMI). This prospective multicentre study assessed the feasibility and safety of BVS implantation in acute ST-segment elevation myocardial infarction (STEMI) in patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results Bioresorbable vascular scaffold implantation became the default strategy for all coronary STEMI patients between 11 December 2011 and 30 August 2013. A total of 41 patients underwent BVS PCI in their STEMI (41/41) (100%) in the intervention arm for BVS implantation. The BVS device success was 99% (40/41) in patients with ST-segment elevation myocardial infarction (STEMI) and 100% (41/41) in patients with ST-segment elevation myocardial infarction (STEMI). The primary endpoint (TIMI 3) was achieved in 38/41 patients (93%). The secondary endpoint (TIMI 3) was achieved in 38/41 patients (93%). The primary endpoint (TIMI 3) was achieved in 38/41 patients (93%). The secondary endpoint (TIMI 3) was achieved in 38/41 patients (93%).

Conclusion Bioresorbable vascular scaffold implantation in acute STEMI is feasible and safe. The procedure needs evaluation by angiography and OCT area analysis. The early clinical results are promising.

Keywords Bioresorbable vascular scaffold • Biodegradable stent • Acute myocardial infarction • Primary PCI • Optical coherence tomography

Introduction Bioresorbable vascular scaffolds (BVS) have been shown to have favourable long-term outcome in the first generation of drug-eluting stents (DES) [1]. In the second generation of drug-eluting stents (DES) [2], the use of bioresorbable scaffolds (BVS) and the use of bioresorbable scaffolds (BVS) have been shown to have favourable long-term outcome in the first generation of drug-eluting stents (DES) [1]. In the second generation of drug-eluting stents (DES) [2], the use of bioresorbable scaffolds (BVS) and the use of bioresorbable scaffolds (BVS) have been shown to have favourable long-term outcome in the first generation of drug-eluting stents (DES) [1].

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Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study

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Aims We evaluated the feasibility and safety of performance of bioresorbable everolimus-eluting vascular scaffolds (BVS) for the treatment of patients presenting with ST-segment elevation myocardial infarction (STEMI).

Methods and results The present investigation is a prospective, single-arm, single-centre study. Following 24 h after the BVS implantation in STEMI patients. Quantitative coronary angiography and optical coherence tomography (OCT) data were evaluated. Clinical outcomes were assessed at the 30-day follow-up. The intent-to-treat population comprised a total of 49 patients. The procedure success was 97.9%. The primary endpoint (TIMI 3) was achieved in 47/49 patients (96%). The secondary endpoint (TIMI 3) was achieved in 47/49 patients (96%). The primary endpoint (TIMI 3) was achieved in 47/49 patients (96%). The secondary endpoint (TIMI 3) was achieved in 47/49 patients (96%).

Conclusion In the present study, the BVS implantation in patients presenting with acute ST-segment elevation myocardial infarction (STEMI) was safe and feasible. Larger studies are currently needed to confirm these preliminary data.

Keywords Bioresorbable vascular scaffold • ST-segment elevation myocardial infarction • Optical coherence tomography

Introduction Primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (STEMI) is currently the treatment of first choice for patients presenting with ST-segment elevation myocardial infarction (STEMI) in comparison of catheter-based treatment. The first generation of drug-eluting stents (DES) have been shown to reduce the need for repeat revascularization compared with bare-metal stents (BMS) [1] and the newer-generation DES with improved biocompatibility of polymers may lower the need for repeat revascularization [2]. However, the implantation of metal stents is not devoid of important drawbacks, such as permanent occlusion of the vessel and permanent treatment of coronary stenosis, late stent thrombosis, impossibility of late lesion

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Early outcome after implantation of Absorb bioresorbable drug-eluting scaffolds in patients with acute coronary syndromes

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¹Department of Medicine II, University Medical Center Jülich; ²Stamberg University; ³Stamberg; ⁴Stamberg; ⁵Stamberg; ⁶Stamberg; ⁷Stamberg

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This paper is freely available online at <http://dx.doi.org/10.1093/eurheartj/ehu101>

Aims The safety of BVS implantation in patients with a high risk for early thrombotic complications has not been studied. We report on the outcome of patients with acute coronary syndromes (ACS) treated with bioresorbable, everolimus-eluting, vascular scaffolds (BVS).

Methods and results In 19 consecutive patients with ACS (19 patients) treated with BVS between May 2011 and May 2013 were compared with a control group composed of 281 consecutive patients (281 patients) who underwent conventional drug-eluting stent (DES) implantation in the same time period. The incidence of major adverse cardiac events (MACE) (death, nonfatal myocardial infarction, or revascularization) before discharge or one month and six months was evaluated. Clinical characteristics and presentation were similar between groups. Procedural characteristics were also similar between groups, except for the use of glycoprotein IIb/IIIa inhibitors (p=0.02). Procedural success was obtained in all but two patients in the BVS group. In-hospital, 30-day and six-month MACE rates were similar between both groups (all p>0.1), with most complications occurring during the first six days. Deaths or percutaneous coronary intervention occurred in two BVS patients and one DES patient during the index admission and it occurred in another patient in each group in the first month after BVS/DES implantation. In multivariate analysis, BVS utilization did not influence the likelihood of MACE (p=0.9).

Conclusion BVS implantation for patients with ACS is safe, with outcomes comparable with those of drug-eluting stent stents.

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41 STEMI
Kočka V et al.

Eur Heart J. 2014;35:787-94

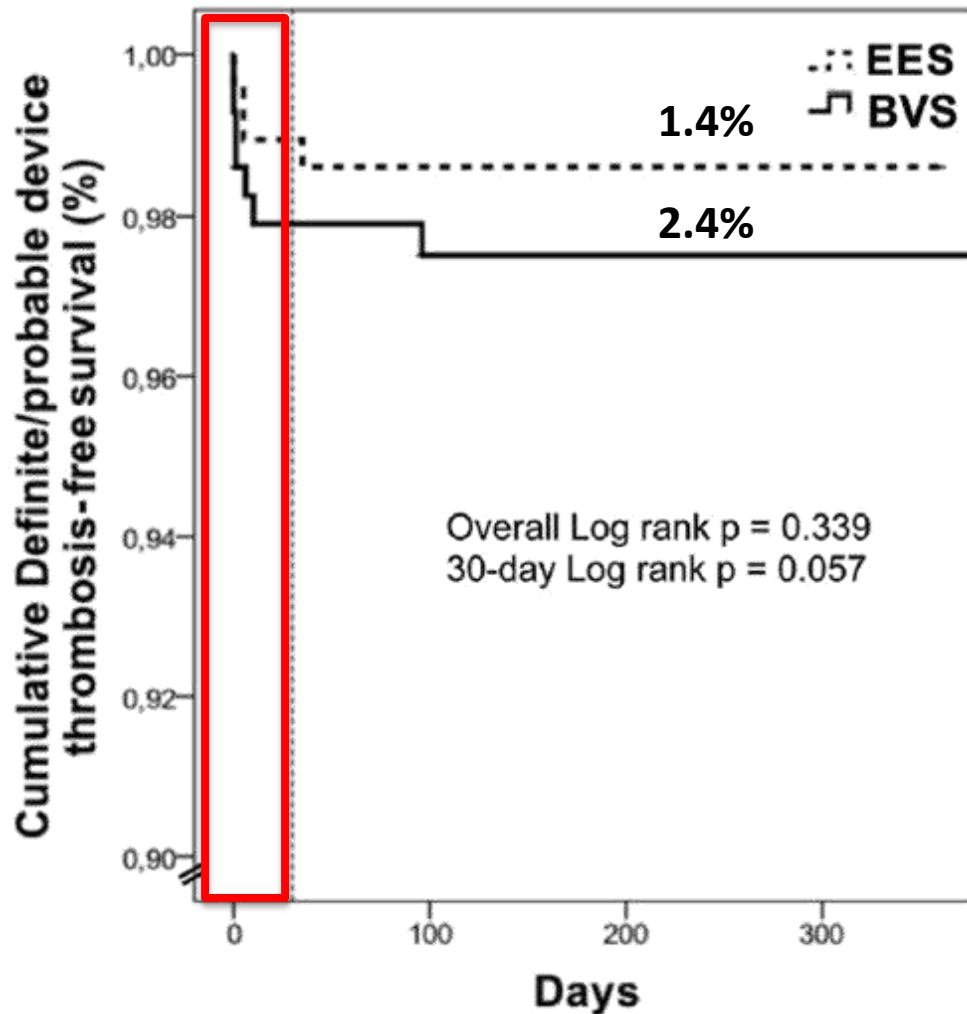
49 STEMI
Diletti R et al.

Eur Heart J. 2014;35:777-86

150 ACS
Gori T et al

EuroIntervention 2014;9:1036-41

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%.

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

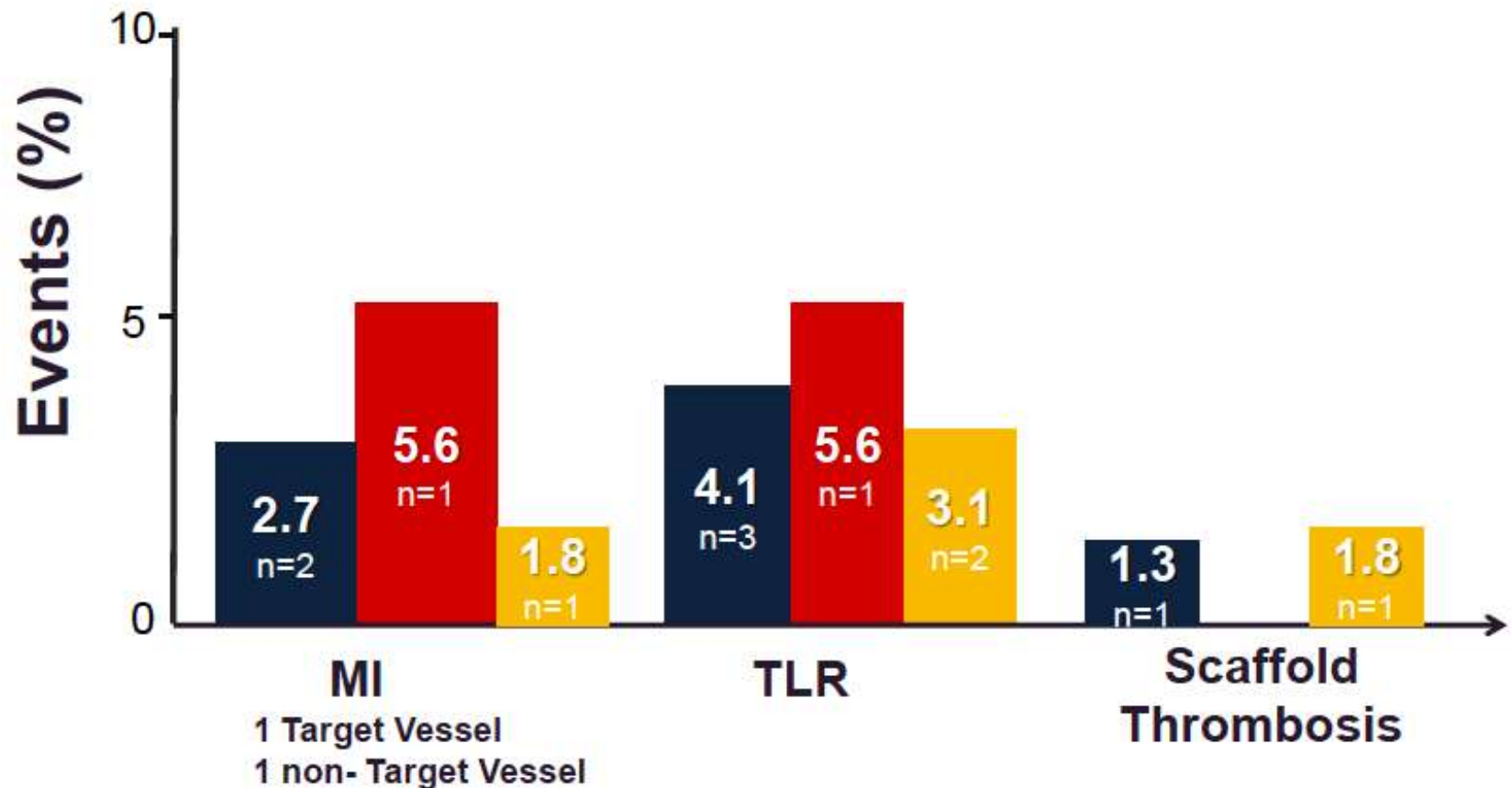
Procedural Characteristics (2)

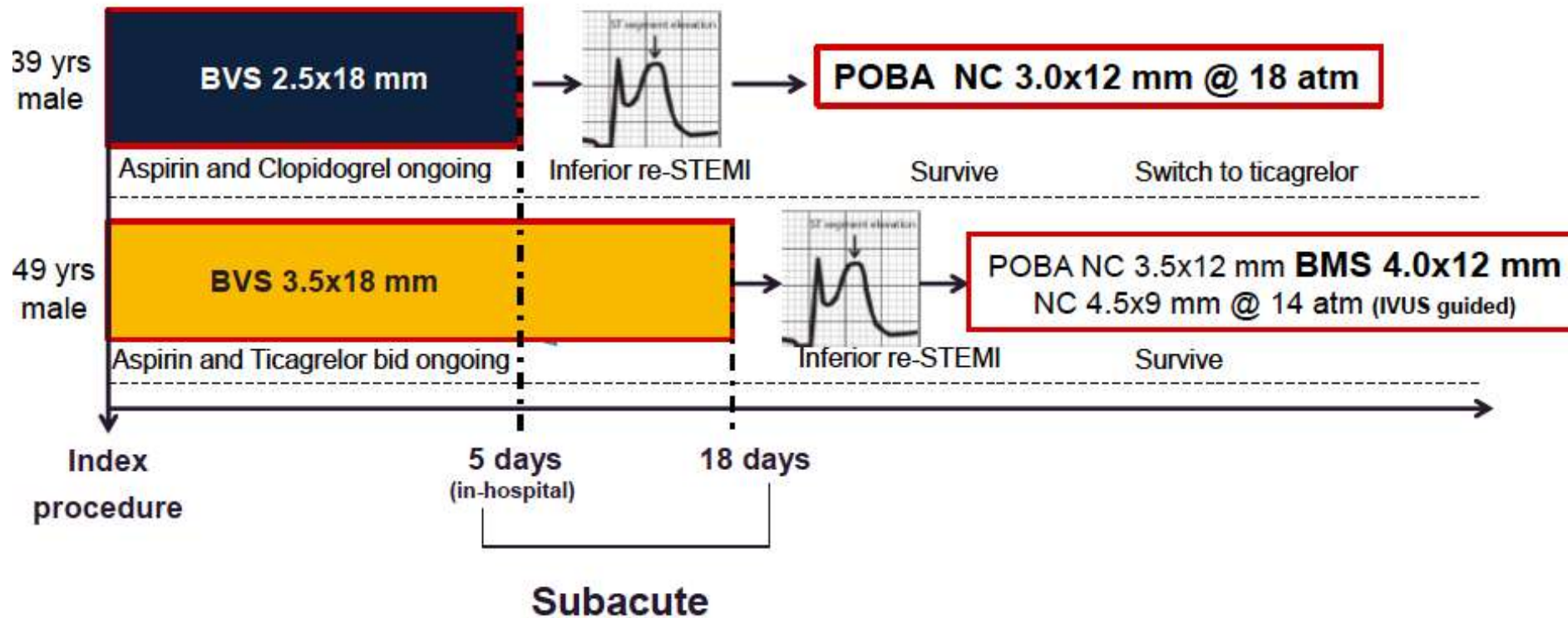
Patients, n (%)	Overlapping BVS			p Value
	Overall n=74	Yes n=18	No n=56	
Thrombectomy	32 (43.2)	3 (16.7)	29 (51.8)	0.008
Pre-dilatation	67 (90.5)	18 (100)	49 (87.5)	0.1
Drug-eluting stent same vessel	2 (2.7)	1 (5.6)	1 (1.8)	0.4
IVUS/OCT	2 (2.7)	1 (5.6)	1 (1.8)	0.4
N° BVS implanted per patient, median ± 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

Follow-up events

Median Follow-up time: 4 (IQR 1-12) months

- Overall, n=74
- Single BVS, n=56
- Overlapping BVS, n=18



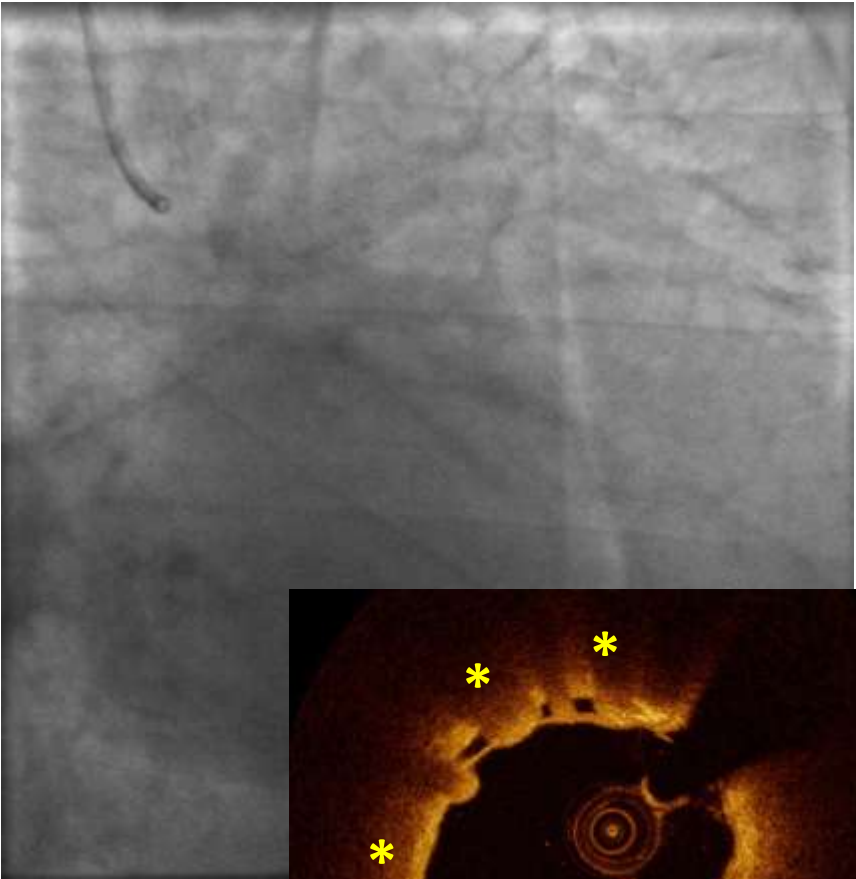
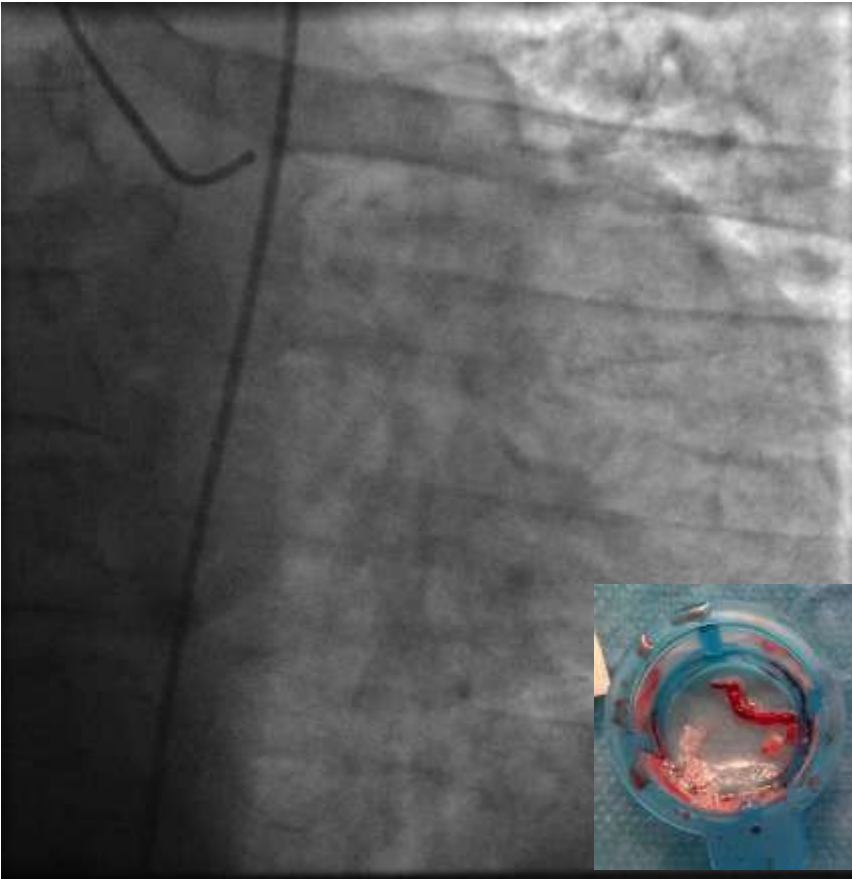


Patients enrolled N=319; lesions N = 406
From 1/3/2013 to 30/06/2014

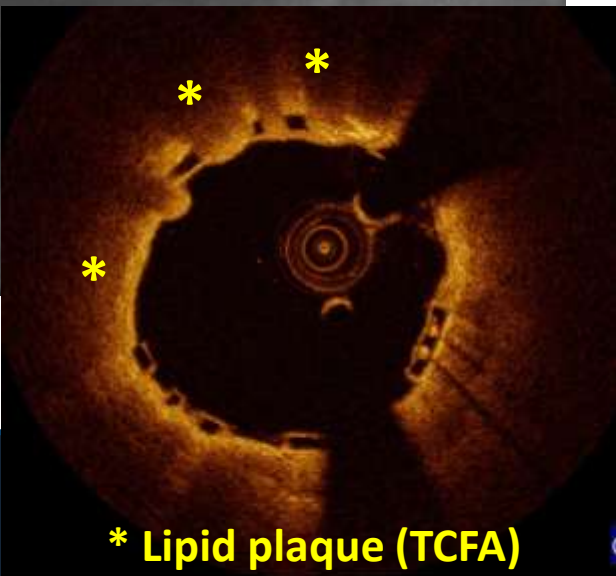
- 6-months FU in 305 patients **95.6%**
- 1-year FU in 281 patients: **88.1%** of overall population and **95%** of those eligible (n=296)

Variable	Patient-based (N = 319)
Age, years \pm SD	60.7 \pm 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



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.

