GHOST update: BRS in bifurcations, techniques, acute and long-term outcome

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(on behalf of the GHOST-EU Investigators)

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Potential conflicts of interest

Speaker's name: Azeem Latib

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

Consultant: 4-Tech, DIRECT FLOW MEDICAL, MEDTRONIC, MILLIPEDE

Honorarium: BOSTON SCIENTIFIC, ACIST MEDICAL, ABBOTT, SPECTRANETICS

Introduction

➢ Bioresorbable vascular scaffolds (BVS) have emerged as an alternative to conventional metallic DES for the treatment of coronary artery disease.

➢ Currently, BVS use is expanding from simple to more complex lesions such as bifurcations, calcific lesions, diffuse disease, thrombus-containing lesions, ISR and CTO, despite technical challenges associated with their implantation.

➢ Of note, clinical outcomes after treatment with BVS for complex coronary lesions have yet to be fully clarified.

Potential advantages of BVS

➢ BVS undergo complete resorption within 2-3 years following implantation,

➢ and thus result in there being no residual permanent metallic cage within the treated coronary artery.

➢ This may have long-term benefits for the vessel including restoration of endothelial function, vascular healing and positive remodeling.

eep
editorial expedited publication

Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry

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Extended Use*

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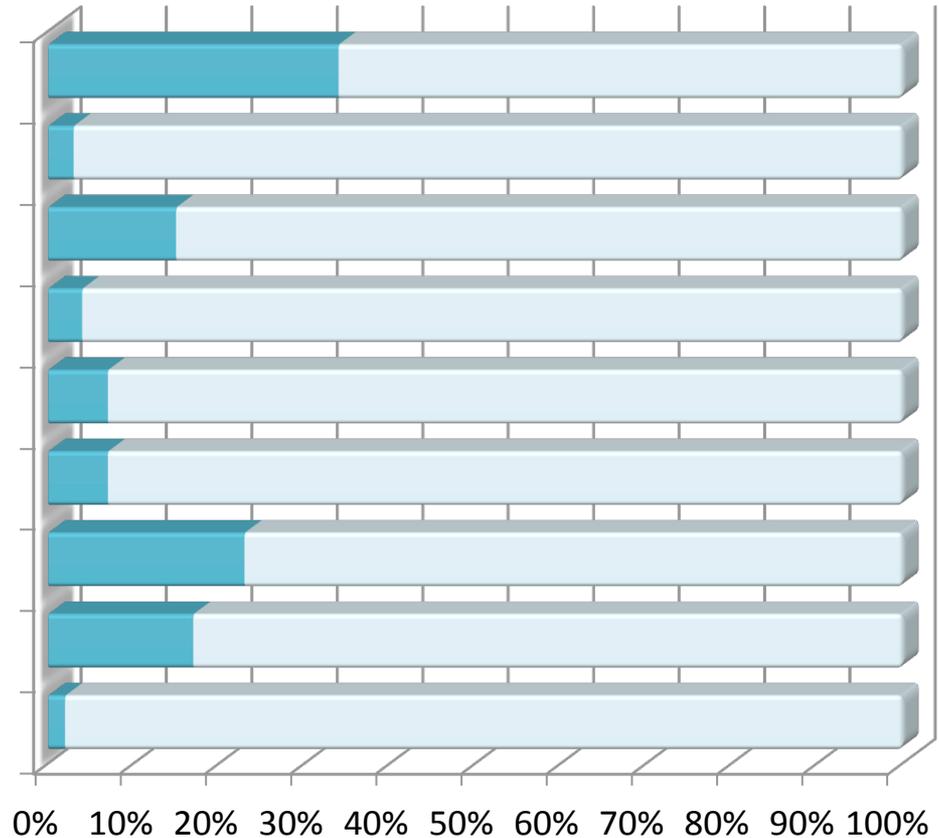
ISR, N=49/1,440 (3.4%)

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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Baseline Characteristics

	n=289
Age, years	61.6 ± 11.6
Male gender	234 (81.0)
Diabetes mellitus	73 (25.3)
Insulin	24 (8.3)
Dyslipidemia	164 (56.7)
Hypertension	213 (73.7)
Current smokers	65 (22.5)
Previous PCI	106 (36.7)
Previous CABG	10 (3.5)
History of CVA	7 (2.4)
History of renal disease	**31** (10.7)

Baseline Characteristics

	n=289
Clinical presentation	
Stable angina or silent ischemia	190 (65.7)
Unstable angina	37 (12.8)
NSTEMI	32 (11.1)
STEMI	30 (10.4)
ACS at presentation	99 (34.3)
LVEF, %	53.6 ± 8.6
Multivessel disease	110 (38.1)

Angiographic Characteristics

	302 bifurcations (%)
Medina classification	
1.1.1	83 (27.5)
1.0.1	17 (5.6)
0.1.1	35 (11.6)
1.1.0	66 (21.9)
1.0.0	33 (10.9)
0.1.0	61 (20.2)
0.0.1	7 (2.3)
True bifurcation (1.1.1/1.0.1/0.1.1)	135 (44.7)

Angiographic Characteristics

	302 bifurcations (%)
Bifurcation site	
LAD/diagonal	210 (69.5)
LCx/marginal	60 (19.9)
Distal RCA	17 (5.6)
Distal LM	15 (5.0)
Bifurcation angle	55.0 ± 21.6
CTO	25 (8.3)
In-stent restenosis	14 (4.6)
SYNTAX score	14.7 ± 8.1

Bifurcation strategy

302 bifurcations (SB ≥2.25mm on visual assessment)
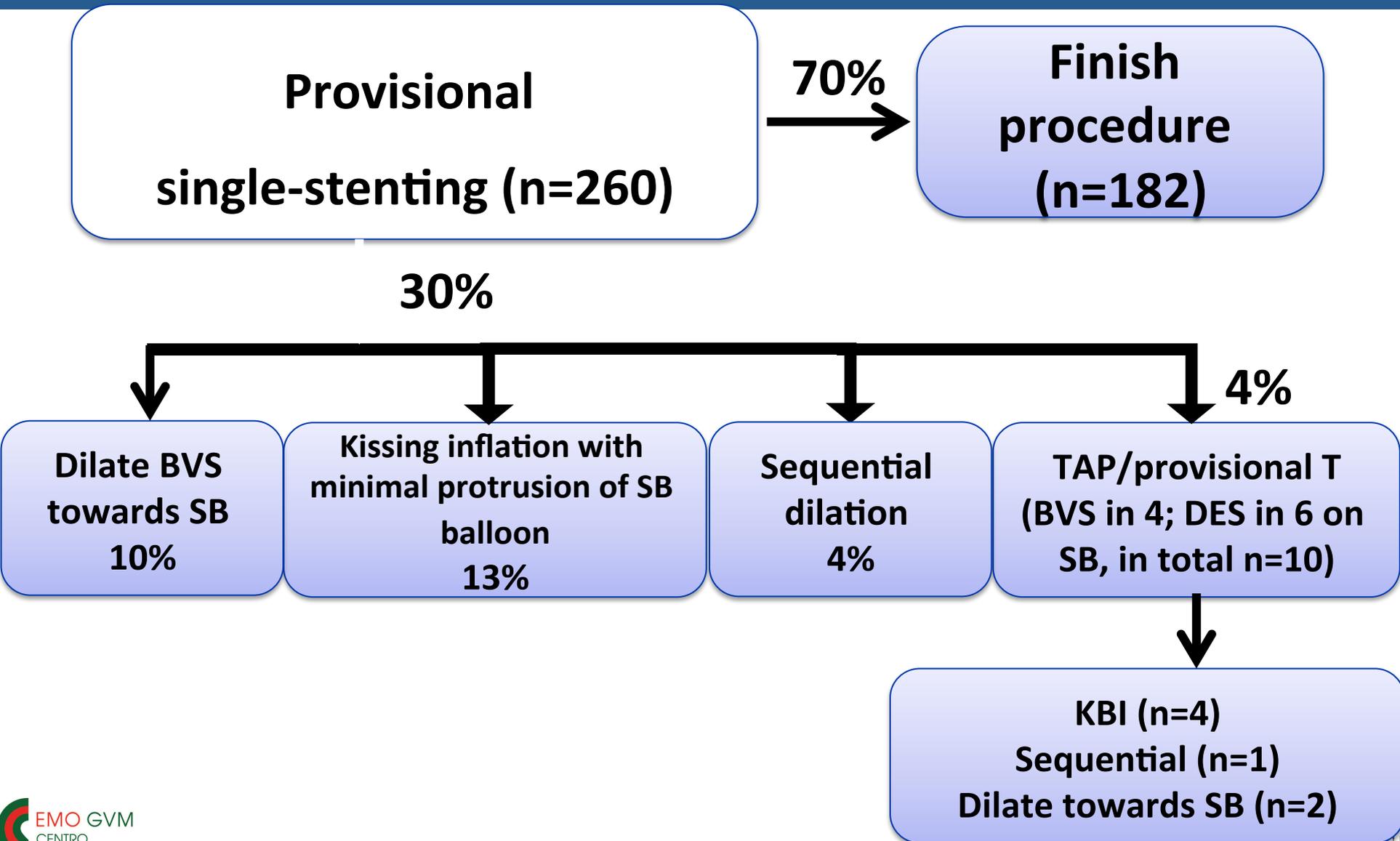
Provisional single-stenting in 86% (n=260)
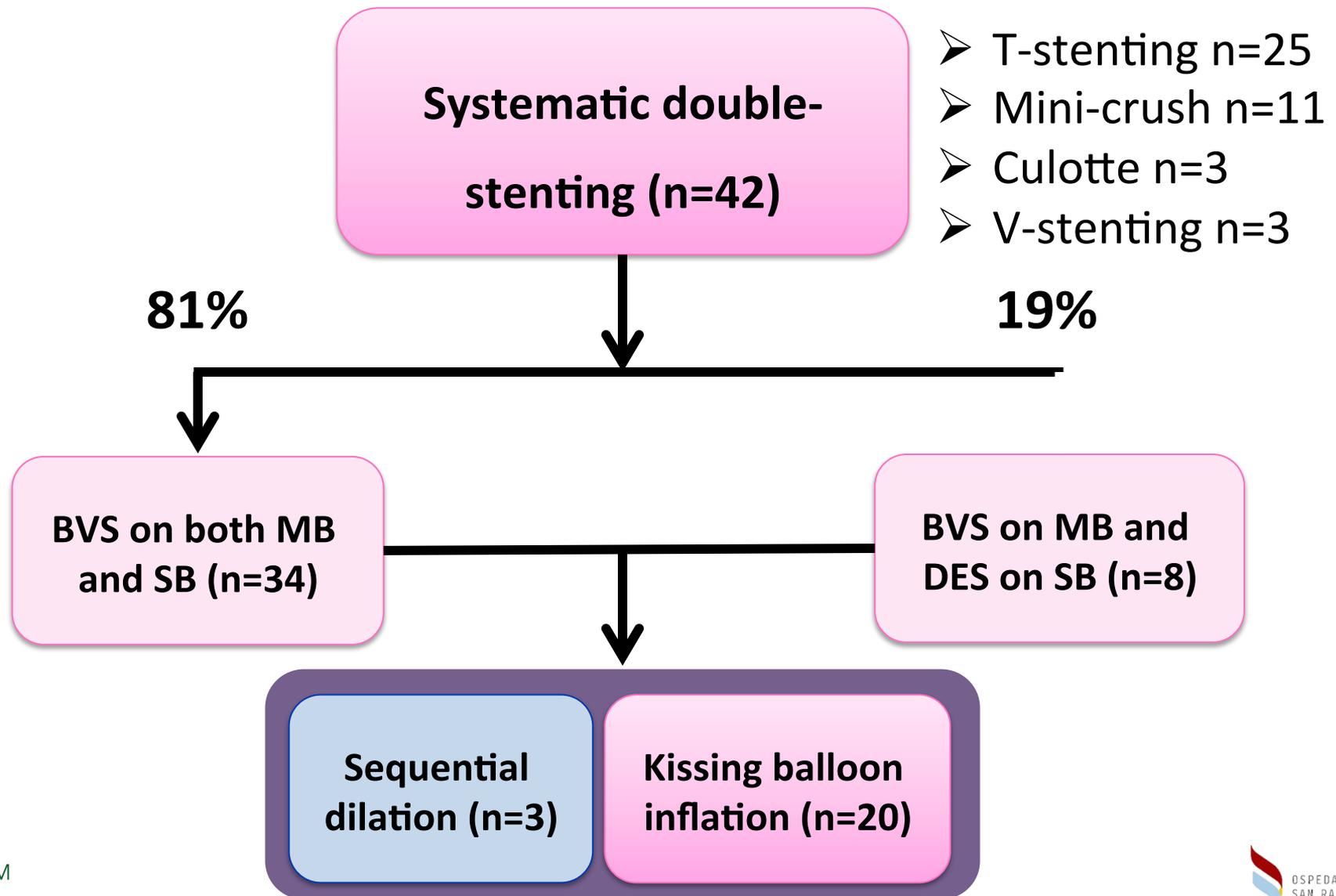
Systematic double-stenting in 14% (n=42)

Provisional-single stenting

Provisional single-stenting (n=260) — **70%** → **Finish procedure (n=182)**

30%

4%

| Dilate BVS towards SB 10% | Kissing inflation with minimal protrusion of SB balloon 13% | Sequential dilation 4% | TAP/provisional T (BVS in 4; DES in 6 on SB, in total n=10) |

↓

KBI (n=4)
Sequential (n=1)
Dilate towards SB (n=2)

Double-stenting strategy in 14%

Systematic double-stenting (n=42)

- T-stenting n=25
- Mini-crush n=11
- Culotte n=3
- V-stenting n=3

81%

19%

BVS on both MB and SB (n=34)

BVS on MB and DES on SB (n=8)

Sequential dilation (n=3)

Kissing balloon inflation (n=20)

Procedural Characteristics

	302 bifurcations (%)
7 or 8 French sheath	36/289 (12.5)
Radial access	114/289 (39.4)
Pre-dilatation in MB	288/302 (95.4)
Post-dilatation in MB	185/302 (61.3)
Pre-dilatation in SB	50/52* (96.2)
Post-dilatation in SB	39/52 (75.0)
Rotational atherectomy	8 (2.6)
Cutting balloon	6 (2.0)
Scoring balloon	12 (4.0)
IVUS	67 (22.2)
OCT	64 (21.2)

Procedural characteristics

		302 bifurcations
	Number of BVS	1.36 ± 0.68
	BVS diameter, mm	3.11 ± 0.36
Main-branch	Total BVS length, mm	30.8 ± 18.7
	Post-dilatation balloon size, mm	3.33 ± 0.94
	Maximum dilatation pressure, atm.	18.8 ± 5.2
	Number of BVS	1.05 ± 0.23
Side-branch	BVS diameter, mm	2.68 ± 0.34
(BVS on SB in	Total BVS length, mm	22.1 ± 8.5
38 cases)	Post-dilatation balloon size, mm	2.69 ± 0.35
	Maximum dilatation pressure, atm.	17.0 ± 5.4

Clinical Outcomes
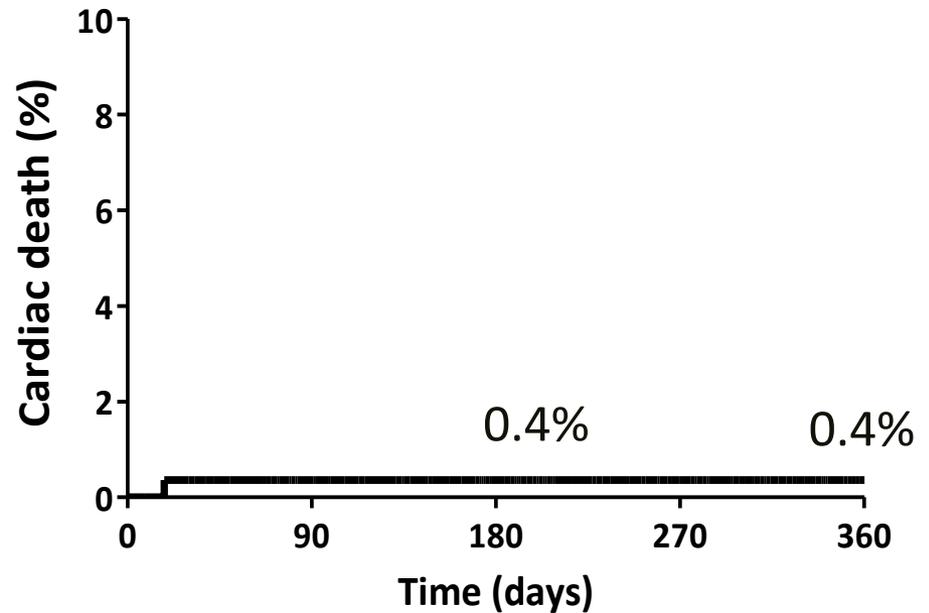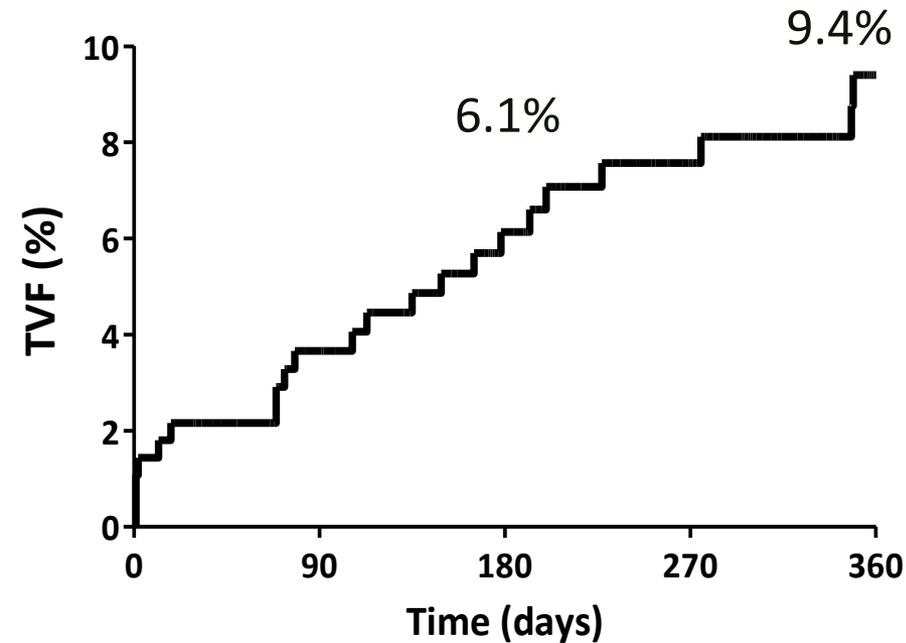
Time (days)	0	30	90	180	270	360
Number at risk	289	271	250	215	173	131
Event rate (%)		2.2	3.7	6.1	7.6	9.4

Time (days)	0	30	90	180	270	360
Number at risk	289	276	259	229	186	143
Event rate (%)		0.4	0.4	0.4	0.4	0.4

TVF includes cardiac death, target-vessel MI and clinically-driven TLR

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Clinical Outcomes
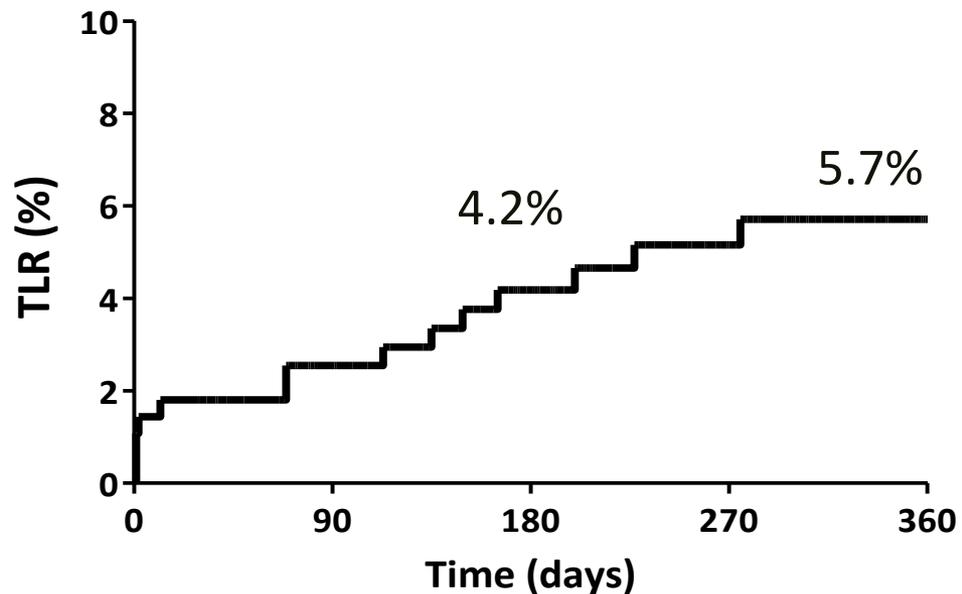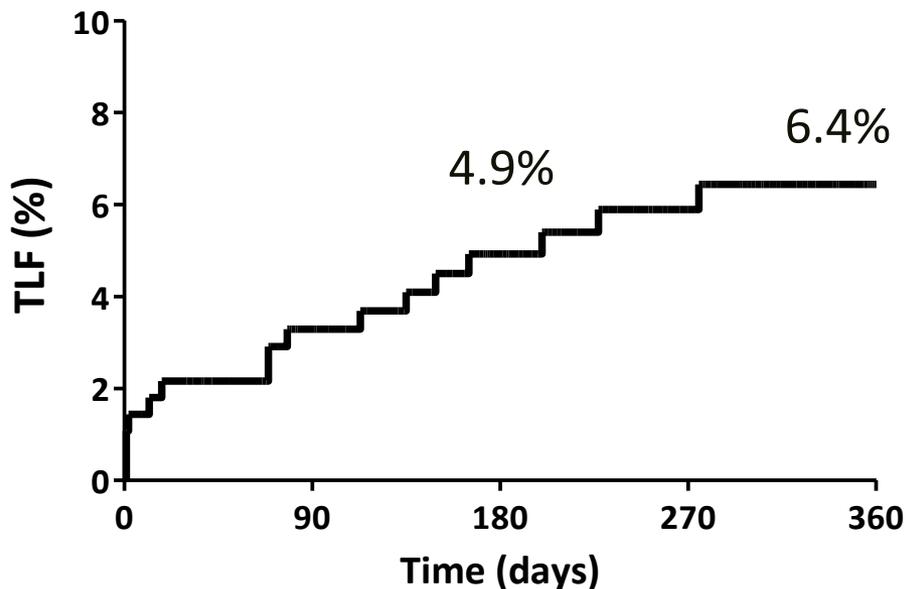
Time (days)	0	30	90	180	270	360
Number at risk	289	271	251	217	175	135
Event rate (%)		2.2	3.3	4.9	5.9	6.4

Time (days)	0	30	90	180	270	360
Number at risk	289	272	253	219	174	134
Event rate (%)		1.8	2.5	4.2	5.2	5.7

TLF includes cardiac death, target vessel MI
and clinically driven TLR
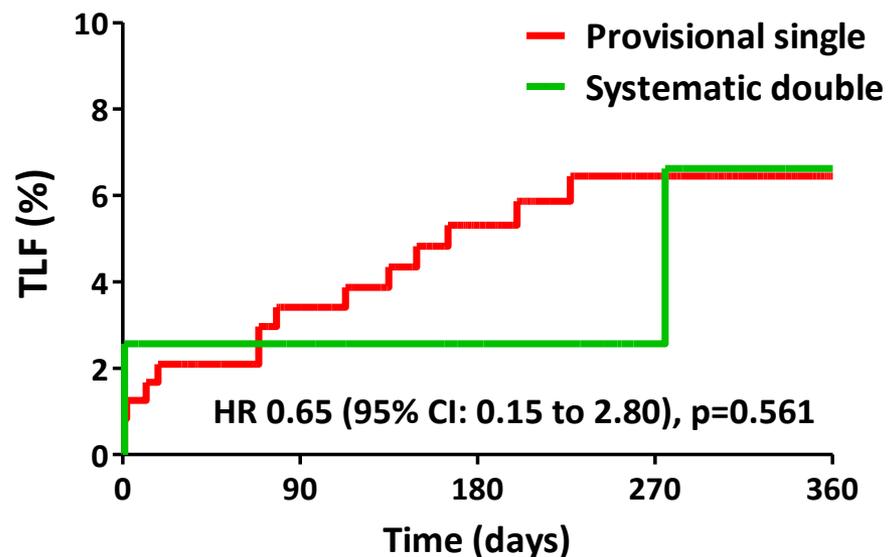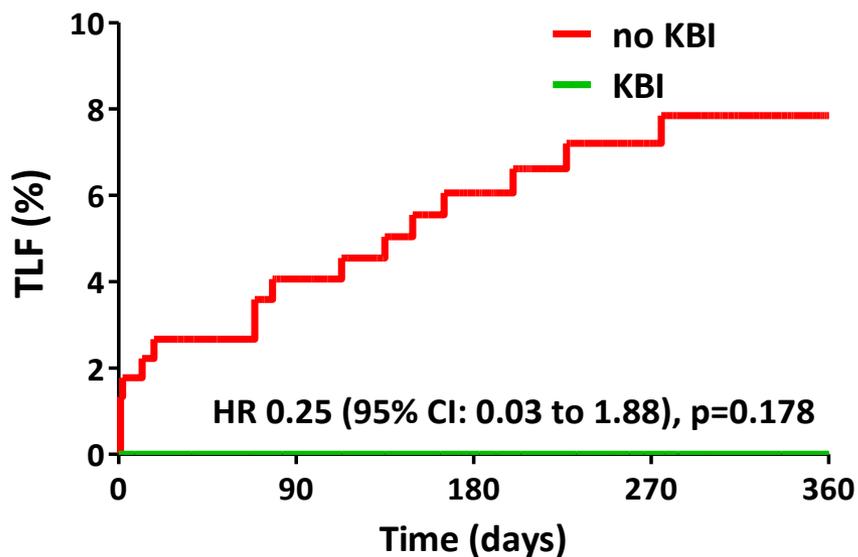
Predictors of TLF

- Variables evaluated on univariate analysis:
  - Clinical: Age, Gender, Current smoker, Diabetes, Previous PCI. CKD, LVEF, ACS, Prasugrel or Ticagrelor use
  - Lesion: ISR, CTO, True bifurcation,
  - Procedural: IVUS, OCT, Postdilatation on MB, Double-stenting, KBI, Sequential dilation/dilate MB-BVS towards SB

Independent predictors of TLF

ACS: HR 3.91 (95% CI: 1.55 to 9.86), p=0.004

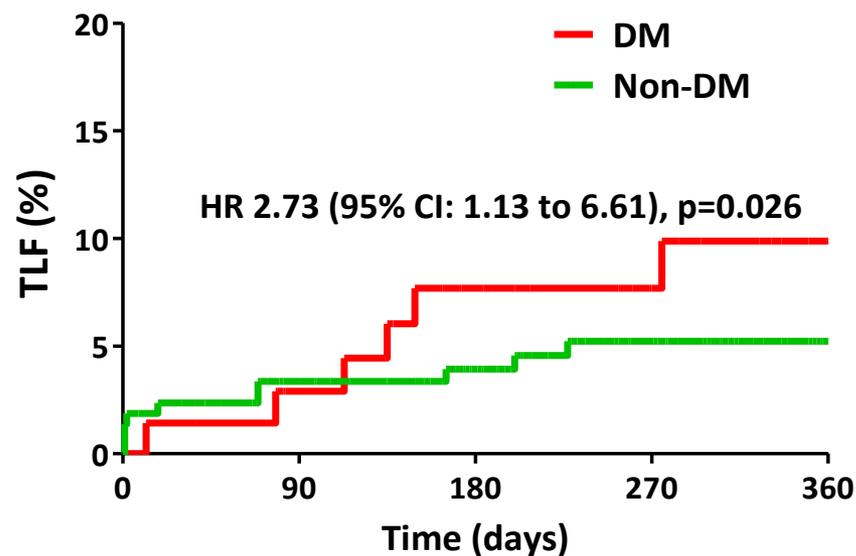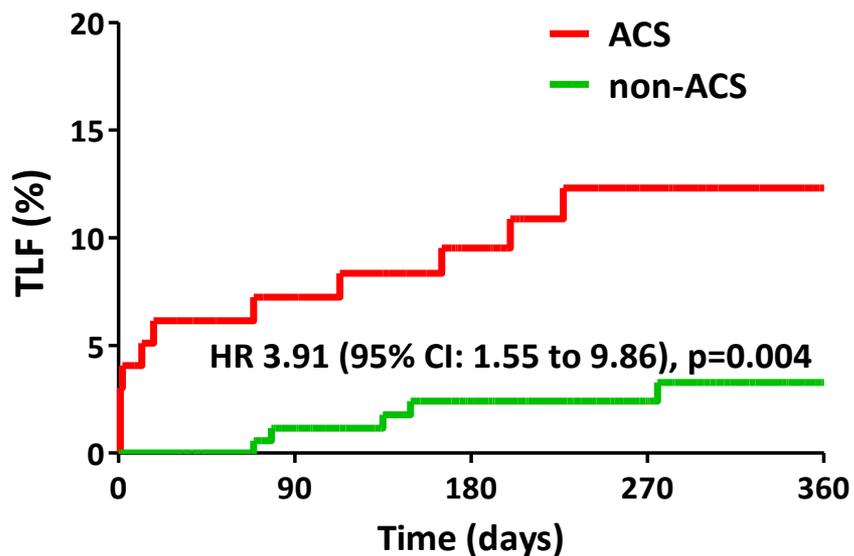DM: HR 2.73 (95% CI: 1.13 to 6.61), p=0.026

Predictors of TLF

Left panel: TLF (%) vs Time (days), curves for "no KBI" (red) and "KBI" (green). HR 0.25 (95% CI: 0.03 to 1.88), p=0.178

Right panel: TLF (%) vs Time (days), curves for "Provisional single" (red) and "Systematic double" (green). HR 0.65 (95% CI: 0.15 to 2.80), p=0.561

Time (days)	0	30	90	180	270	360
Number at risk						
KBI	54	53	50	37	29	24
No KBI	235	219	203	182	147	112
Event rate (%)						
KBI		0	0	0	0	0
No KBI		2.7	4.1	6.1	7.2	7.8

Time (days)	0	30	90	180	270	360
Number at risk						
Single	249	234	216	185	151	114
Double	40	38	37	33	25	22
Event rate (%)						
Single		2.1	3.4	5.3	6.4	6.4
Double		2.6	2.6	2.6	2.6	6.6

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Predictors of TLF

Left chart:
- ACS (red)
- non-ACS (green)
- TLF (%) vs Time (days)
- HR 3.91 (95% CI: 1.55 to 9.86), p=0.004

Right chart:
- DM (red)
- Non-DM (green)
- TLF (%) vs Time (days)
- HR 2.73 (95% CI: 1.13 to 6.61), p=0.026

Time (days)	0	30	90	180	270	360
Number at risk						
ACS	99	90	85	73	59	49
Non-ACS	190	190	167	145	117	87
Event rate (%)						
ACS		6.1	7.2	9.5	12.3	12.3
Non-ACS		0	1.1	2.4	2.4	3.3

Time (days)	0	30	90	180	270	360
Number at risk						
DM	73	70	64	54	43	35
Non-DM	216	202	188	164	134	101
Event rate (%)						
DM		1.4	2.9	7.7	7.7	9.9
Non-DM		1.9	3.4	3.9	5.2	5.2

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Clinical Outcomes
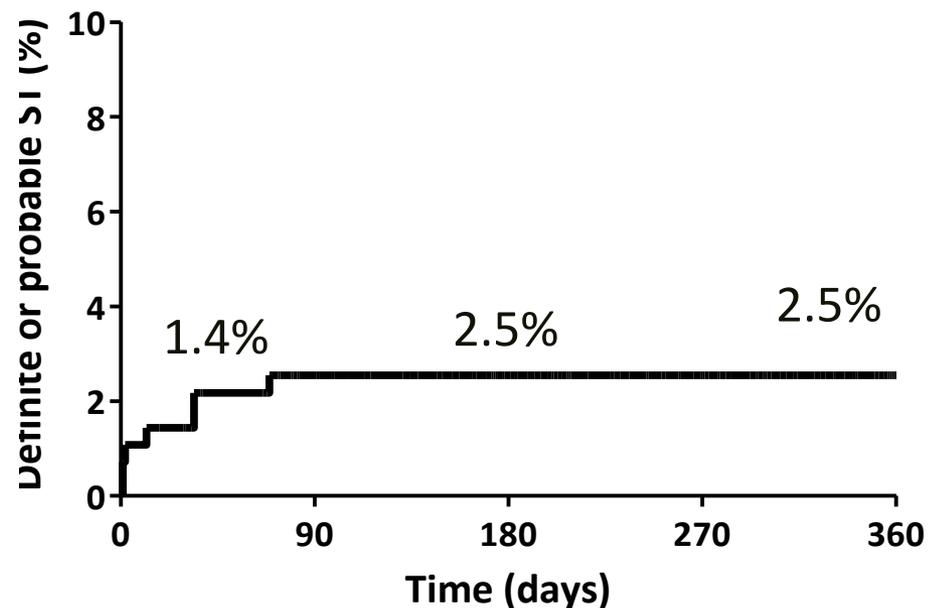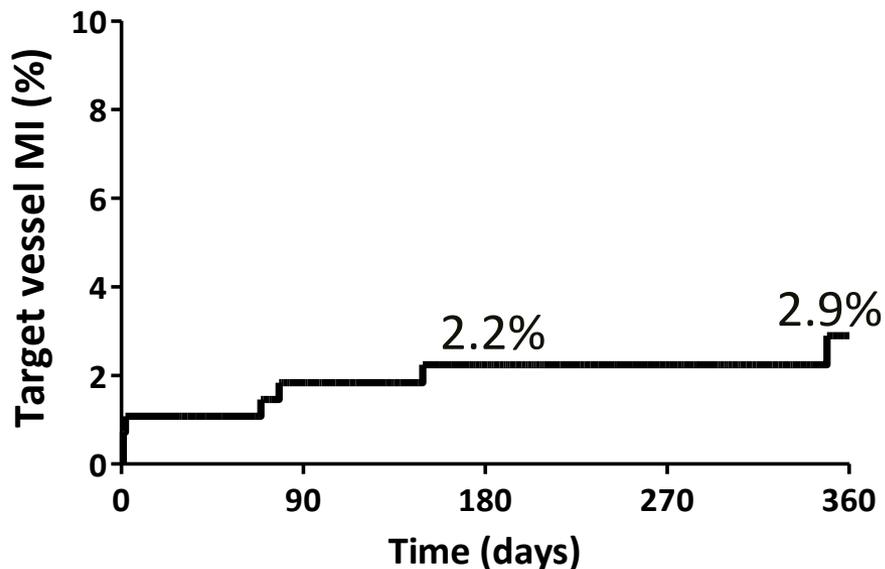
Time (days)	0	30	90	180	270	360
Number at risk	289	274	255	224	180	139
Event rate (%)		1.1	1.8	2.2	2.2	2.9

Time (days)	0	30	90	180	270	360
Number at risk	289	272	252	221	181	137
Event rate (%)		1.4	2.5	2.5	2.5	2.5

Prasugrel or ticagrelor was used in 55 (19.0%) patients.

GHOST-EU 8/23 ST were in bifurcations

Kaplan-Meier 30-day and 6-mo ST in bifurcations: 1.4% and 2.5%, respectively
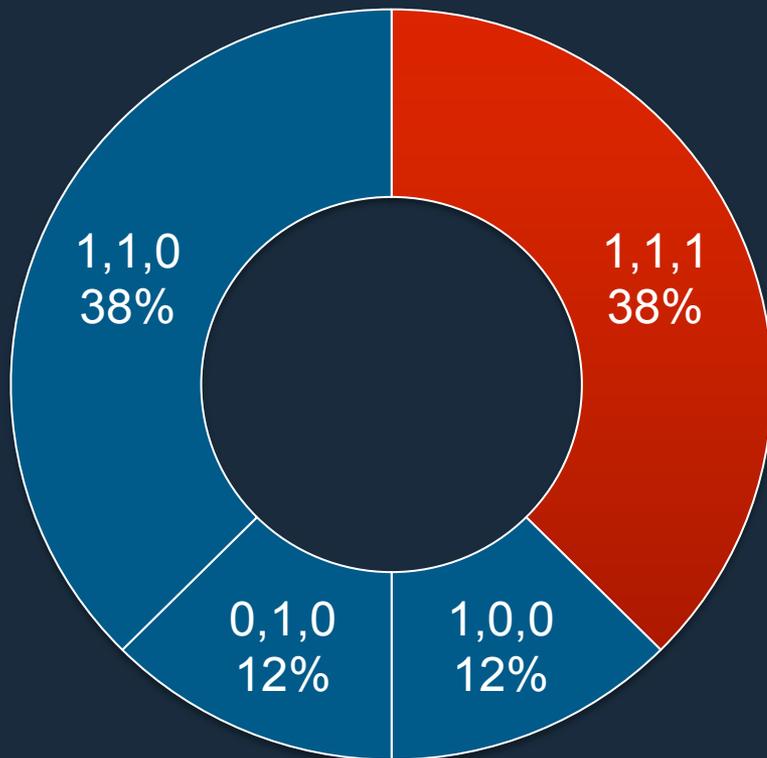
Case	Days
#1	69
#2	2
#3	0
#4	34
#5	34
#6	0
#7	12
#8	373

1,1,0 38%

1,1,1 38%

0,1,0 12%

1,0,0 12%

Medina classes in 8 bifurcations ST

ACS = acute coronary syndromes; PD = main branch post-dilatation;
IG = intravascular guidance; DAPT = on dual antiplatelet therapy

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Naganuma T, Latib A, et al. GHOST-EU Investigators

UNIVERSITÀ
degli STUDI
di CATANIA

Predictors of Definite or Probable ST

- Variables evaluated on univariate analysis:
  - Clinical: Age, Gender, Current smoker, Diabetes, Hypertension, Previous PCI, CKD, LVEF, ACS, Prasugrel or Ticagrelor use
  - Lesion: ISR, CTO, True bifurcation,
  - Procedural: IVUS, OCT, Postdilatation on MB, Double-stenting, KBI, Sequential dilation/dilate MB-BVS towards SB

Univariate predictors of Stent Thrombosis
ACS: HR 13.58; 95% CI: 1.67 to 110.39; p=0.015
Postdilatation of MB: 0.11; 95% CI: 0.01 to 0.90; p=0.040

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Conclusions

- GHOST-EU represents one of the largest real-world cohorts of bifurcations treated with BVS

- Provisional approach was default strategy (86%)

- Cross-over from provisional to double-stenting in 4%

- Elective double stenting only in 14%

- BVS in bifurcations is associated with acceptable rates of MACE, TVF & TLR

- Stent thrombosis rate of 2.5% at 12-months is concerning and is most probably related to learning curve and suboptimal technique

Discussion: potential explanations for high ST

1. ACS presentation in the majority (BVS implantation in a thrombus-containing lesion)

2. Low usage of intravascular imaging guidance

3. Low postdilation rates that may have resulted in BVS underexpansion or malapposition

4. Inadequate antiplatelet therapy especially in the patients presenting with ACS (only 2 of the 7 were prescribed newer and more potent P2Y12 inhibitors).