P2BiTo Registry update and future

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XIII European Bifurcation Club Meeting – Porto, Portugal – 13 & 14th October 2017

Potential conflict of interest to report:

Honoraria, Institutional grant/research support, Consultant, Employment in industry, Owner of a healthcare company, Stockholder of a healthcare company, Other(s)

	Yes	No
Marco Zimarino (Speaker)	☑	☐
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Ignacio J Amat-Santos	☐	☐
Francesco Radico	☐	☐
Emanuele Barbato	☑	☐
Alaide Chieffo	☐	☑
Plinio Cirillo	☐	☐
Ricardo A Costa	☐	☐
Erglis Andreis	☑	☐
Habib Gamra		
Nicola Maddestra	☐	☐

	Yes	No
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Vojko Kanic	☐	☐
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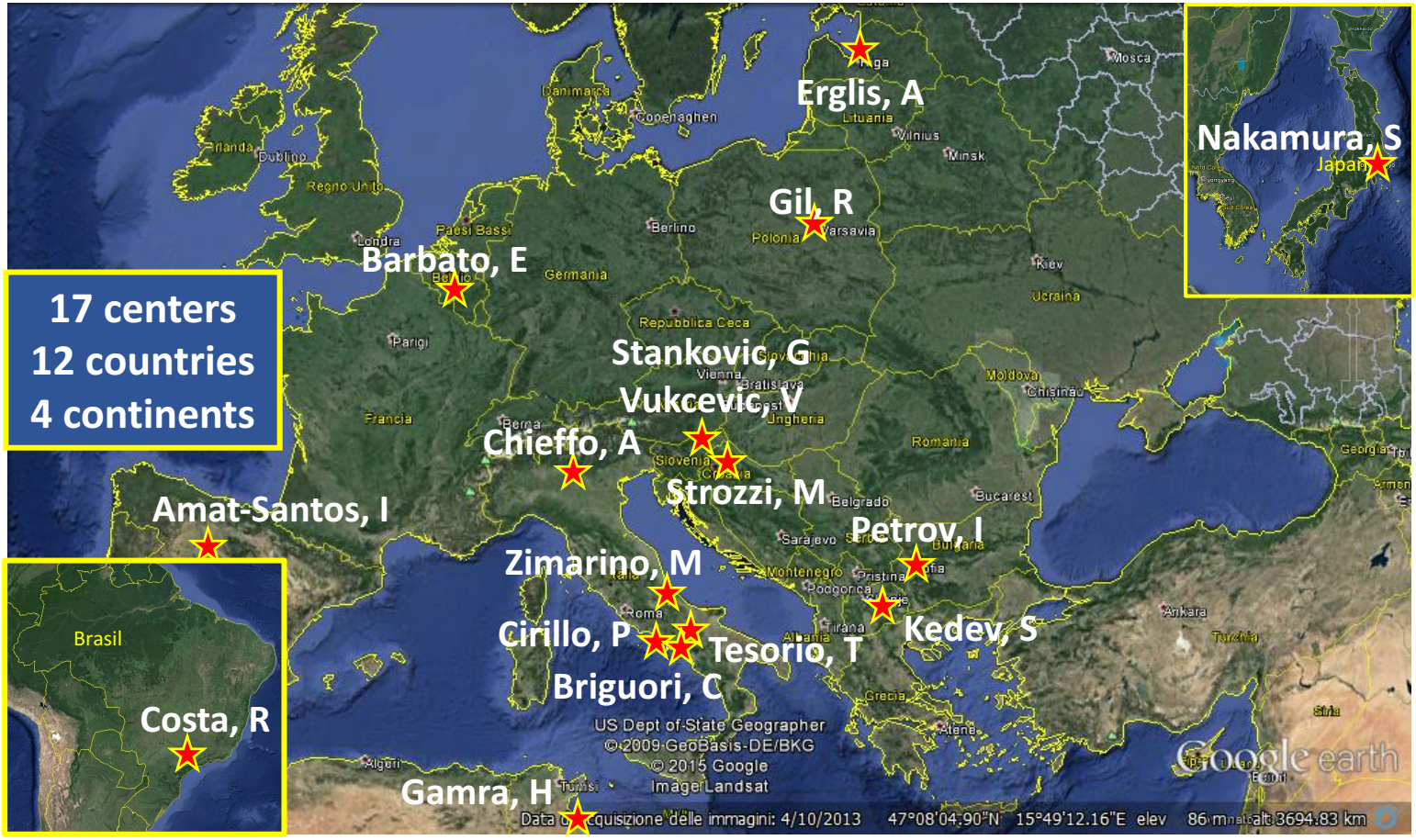
Sunao Nakamura	☐	☐
Mariano Pellicano	☑	☐
Ivo Petrov	☑	☐
Maja Strozzi		
Tullio Tesorio	☐	☐
Vladan Vukcevic		
Raffaele De Caterina	☑	☐
Goran Stankovic	☐	☐

Study population

5,036 pts undergoing PCI who received "biologically active" stents (DES and BVS) in coronary bifurcations during 2012-14; follow-up available in 4,506 patients (89%) at 18 months (IQR 11-28)

Primary endpoint –Major Adverse Cardiac Cerebrovascular Events (MACCE):

All-cause death, MI (excluding periprocedural), Stroke, Stent thrombosis (definite/probable)



Methods

- PCI access site, as well as the choice of DES or BVS and the treatment strategy were left to the individual operator's discretion.
- Stent Strategy:
  - Single-stenting: MB or SB
  - Double-stenting: both MB and SB.
  - Bail-out stenting: any stent deployed beyond the planned strategy, with either one or double stenting.
- True bifurcation = Medina 1.1.1/1.0.1/0.1.1
- After PCI, aspirin was continued indefinitely, and the duration of P2Y12 inhibitors was recommended at physician's judgement.

In-hospital outcomes

	n = 5,036	%
Death	53	1.1
Periprocedural MI	584	11.6
Stent Thrombosis	50	1.0
Stroke	28	0.6

Follow-up Outcomes

	N= 4,506 (89%)	%
MACCE – Primary Endopoint	434	11.0
- Death (Cardiovascular)	453	5.2
- MI (excluding periprocedural)	235	3.5
- Stroke	75	1.7
- Stent thrombosis	110	2.4

Clinical risk characteristics

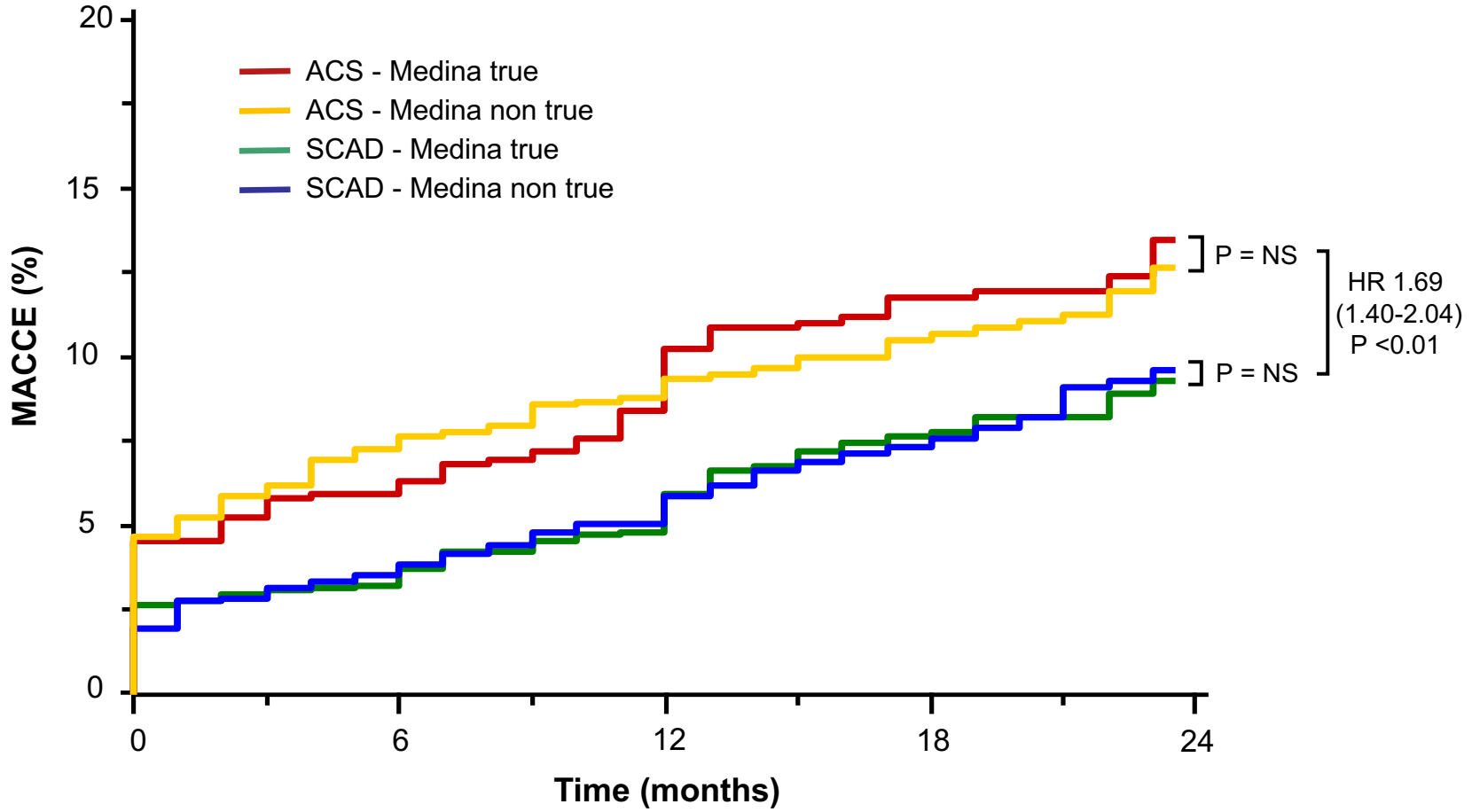
	MACCE HR (95% CI)	Death HR (95% CI)	MI HR (95% CI)	Stent Thrombosis HR (95% CI)	Stroke HR (95% CI)
Age >65 ys	**1.87 (1.56-2.26)**	**2.42 (1.87-3.13)**	**1.47 (1.07-2.02)**	1.05 (0.72-1.54)	**3.25 (2.06-5.14)**
Sex (M)	0.87 (0.71-1.07)	0.82 (0.63-1.08)	1.09 (0.78-1.53)	1.20 (0.80-1.80)	0.85 (0.52-1.39)
Diabetes	**1.42 (1.16-1.73)**	**1.53 (1.17-2.01)**	1.18 (0.84-1.65)	1.09 (0.73-1.62)	1.56 (0.96-2.54)
Hypertension	**1.38 (1.10-1.73)**	1.31 (0.96-1.79)	1.17 (0.80-1.71)	2.00 (1.28-3.14)	**3.17 (1.82-5.53)**
Dyslipidemia	0.97 (0.79-1.19)	0.79 (0.60-1.04)	0.98 (0.69-1.39)	0.76 (0.53-1.11)	1.11 (0.68-1.84)
Smoker	1.13 (0.95-1.36)	0.99 (0.77-1.28)	1.20 (0.87-1.64)	1.38 (0.95-2.01)	0.89 (0.57-1.41)
Prior MI	1.20 (0.97-1.49)	**1.33 (1.00-1.80)**	**2.51 (1.26-4.99)**	0.64 (0.42-1.00)	0.83 (0.44-1.58)
Prior CABG	**1.77 (1.19-2.64)**	**2.09 (1.20-3.65)**	1.26 (0.88-1.81)	1.36 (0.60-3.09)	1.22 (0.45-3.31)
Prior PCI	0.95 (0.78-1.16)	0.85 (0.65-1.12)	0.92 (0.66-1.28)	0.79 (0.53-1.17)	1.01 (0.63-1.63)
Prior Stroke	**1.51 (1.02-2.23)**	**1.72 (1.00-3.00)**	1.00 (0.52-1.91)	0.99 (0.43-2.29)	**1.98 (0.79-5.04)**
LVEF ≤ 30%	**5.66 (3.11-10.30)**	**8.89 (3.89-20.30)**	**6.75 (2.40-18.94)**	**2.93 (0.83-10.29)**	4.09 (0.94-17.7)
ACS at admission	**1.69 (1.40-2.04)**	**1.69 (1.44-2.55)**	**2.12 (1.53-2.94)**	**2.50 (1.66-3.59)**	1.01 (0.63-1.57)

Procedural risk variables and treatment strategies

	MACCE HR (95% CI)	Death HR (95% CI)	MI HR (95% CI)	Stent Thrombosis HR (95% CI)	Stroke HR (95% CI)
Left Main	1.28 (0.94-1.75)	**1.63 (1.05-2.54)**	1.23 (0.73-2.10)	1.28 (0.63-2.56)	0.50 (0.23-1.02)
ISR	1.42 (0.93-2.18)	1.07 (0.60-1.90)	1.51 (0.74-3.07)	1.43 (0.65-3.18)	1.84 (0.67-5.84)
Calcifications	**1.52 (1.23-1.86)**	**1.95 (1.45-2.63)**	1.38 (0.96-2.00)	1.41 (0.91-2.20)	0.95 (0.56-1.61)
SB lesion length ≥ 9 mm	**2.26 (1.35-3.35)**	**2.36 (1.34-4.13)**	1.08 (0.52-2.24)	**3.51 (1.27-9.69)**	**9.49 (4.30-20.86)**
MB lesion length ≥17 mm	**1.92 (1.39-2.64)**	**1.70 (1.09-2.63)**	**1.88 (1.01-3.48)**	1.35 (0.65-2.81)	**4.71 (2.23-9.94)**
Medina "true"	1.18 (0.97-1.45)	1.15 (0.86-1.53)	1.17 (0.83-1.63)	1.14 (0.75-1.75)	1.40 (0.86-2.27)
MVD (vs. SVD)	**1.59 (1.29-1.96)**	**1.67 (1.25-2.22)**	**1.79 (1.28-2.52)**	**2.02 (1.33-3.06)**	0.89 (0.54-1.46)
SYNTAX score (vs. <22):					
22-32	0.80 (0.60-1.04)	0.82 (0.56-1.20)	0.65 (0.40-1.08)	0.72 (0.45-1.15)	1.04 (0.54-1.99)
>32	**2.04 (0.94-4.46)**	**2.45 (0.83-7.24)**	1.78 (0.48-6.62)	1.05 (0.25-4.42)	1.90 (0.28-12.86)
FFR	0.68 (0.39-1.18)	0.74 (0.34-1.62)	0.91 (0.35-2.36)	0.94 (0.24-3.72)	0.90 (0.23-3.49)
IVUS and/or OCT	1.21 (0.88-1.67)	0.93 (0.59-1.45)	0.87 (0.50- 1.49)	0.73 (0.39-1.36)	3.02 (0.86-6.67)
Stent type : BVS (vs. DES)	**1.55 (1.08-3.81)**	0.73 (0.20-1.94)	2.51 (0.62-10.06)	2.28 (0.41-12.59)	1.00 (0.14-7.28)
Planned double stent	1.27 (0.95-1.69)	**1.67 (1.12-2.50)**	1.03 (0.62-1.70)	1.53 (0.80-2.92)	0.53 (0.26-1.07)
Bail-out stent	**2.28 (1.39-3.54)**	**2.44 (1.27-4.67)**	**3.45 (1.56-7.63)**	**2.07 (0.87-4.86)**	**3.44 (1.12-11.10)**
Total stent length ≥23 mm	**1.22 (1.03-1.35)**	1.21 (0.93-1.57)	1.16 (0.84-1.60)	1.33 (0.97-1.96)	0.73 (0.46-1.13)
Final kissing balloon	0.94 (0.77-1.15)	1.02 (0.77-1.35)	0.76 (0.54-1.07)	1.00 (0.67-1.49)	0.91 (0.57-1.46)
GPIs use	1.04 (0.78-1.39)	1.29 (0.86-1.95)	0.86 (0.53-1.41)	1.40 (0.70-2.81)	0.92 (0.45-1.89)

Clinical presentation and Medina classification

Fig. 2A

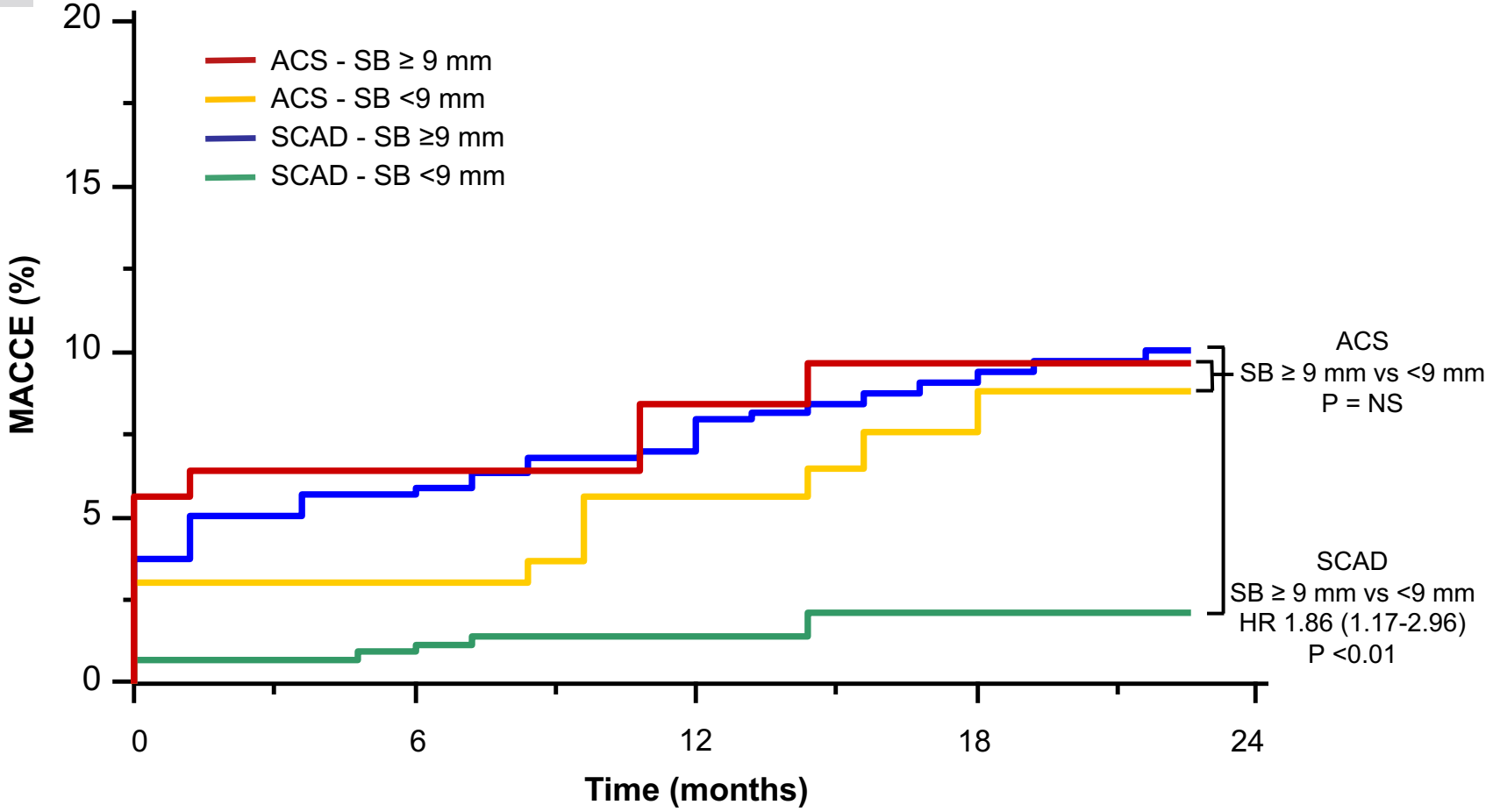


n. at risk

ACS - Medina true	1291	1047	759	607	421
ACS - Medina non-true	1054	1127	787	593	428
SCAD - Medina true	1383	754	582	442	291
SCAD - Medina non-true	1308	919	641	479	324

Clinical presentation and SB lesion length

Fig. 2B

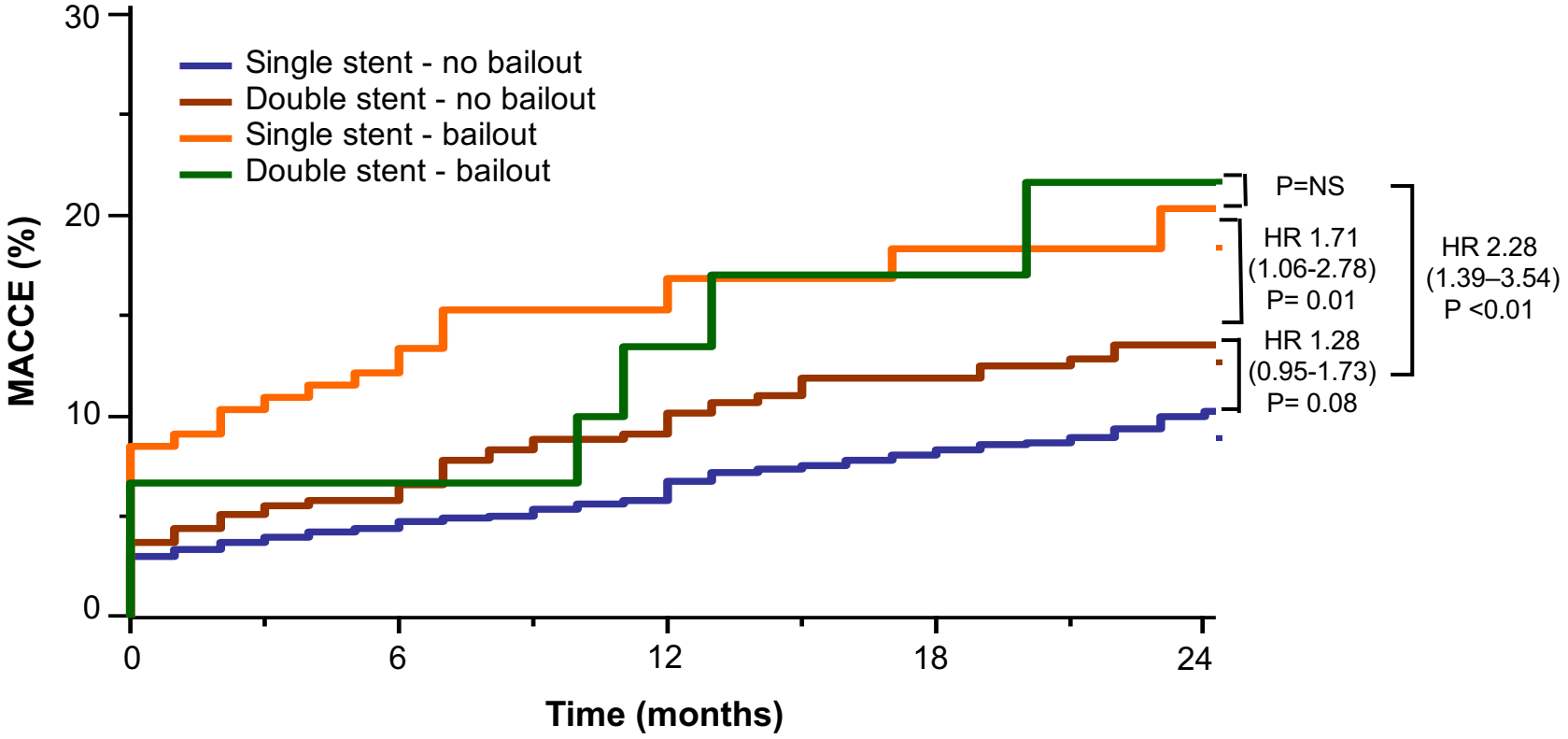


n. at risk

ACS - SB ≥9 mm	116	98	68	60	48
ACS - SB <9 mm	157	151	88	66	51
SCAD - SB ≥9 mm	452	424	307	255	205
SCAD - SB <9 mm	417	407	136	84	52

Stent Strategy

Fig.3



n. at risk

Double stent – bailout	33	28	24	19	12
Single stent - bailout	194	139	67	52	32
Double stent – no bailout	525	375	315	275	212
Single stent - no bailout	4284	3278	2339	1750	1188

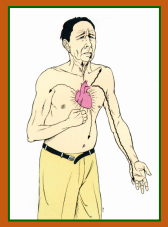
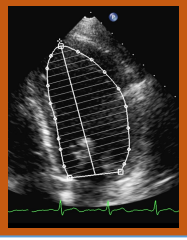
Independent risk factors for MACCE

	HR (95% CI)	P
LVEF <30%	4.37 (3.25-5.89)	<0.01
SB lesion length ≥ 9 mm	2.21 (0.91-5.37)	0.07
Bail-out stenting	1.95 (1.38-2.75)	<0.01
BVS	1.89 (1.05-3.81)	0.05
Age>65	1.76 (1.42-2.17)	<0.01
ACS at admission	1.53 (1.26-1.88)	<0.01
Diabetes	1.47 (1.20-1.79)	<0.01

Conclusions

Clinical variables

Age>65 ys
Diabetes
ACS at admission
LVEF ≤ 30%

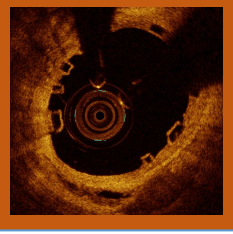



Angiographic characteristics

SB lesion ≥ 9 mm

Treatment strategy

Bail-out stenting
BVS

MACCE

death, nonfatal MI, stroke and definite/probable ST

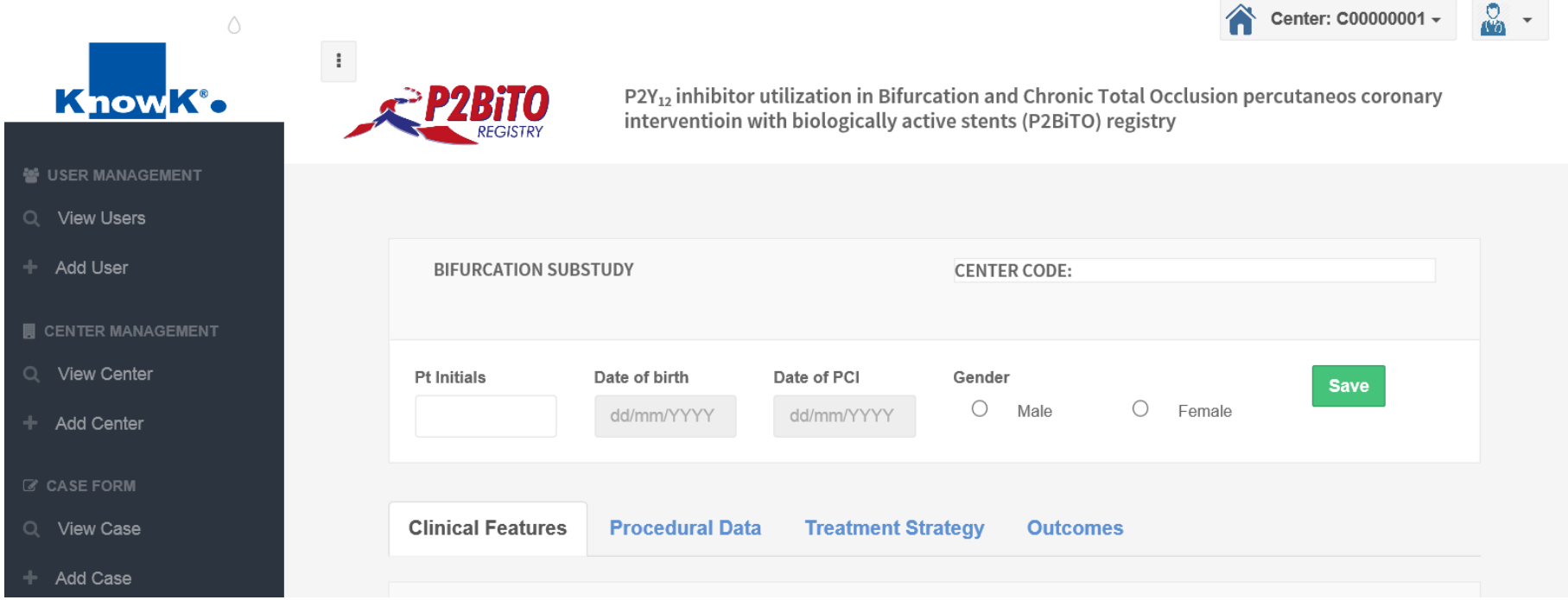
Substudies

Ignacio Amat-Santos	Left Main
Alaide Chieffo	Diabetes
Mariano Pellicano	DAPT duration
Plinio Cirillo	Access site
Ivo Petrov	Dedicated stents

www.p2bito.org

available from January 1st, 2018…

Prospective enrolment



Internet-based registry, serving as an infrastructure

for multicenter, prospective, open-label RCT

KnowK®

USER MANAGEMENT
- View Users
- Add User

CENTER MANAGEMENT
- View Center
- Add Center

CASE FORM
- View Case
- Add Case

Clinical Features | Procedural Data | Treatment Strategy | Outcomes

ACCESS:

○ Femoral ○ Radial

CAD EXTENT

1 LM vessel disea

DISEASED VESSELS:

☐ LM ☐ LAD ☐ LCx ☐ RCA

Syntax Score

○ Complete Revascularization ○ Functional Revascularization ○ Incomplete Revascularization

Total lesions(n°)

Lesion treated (n°)

Implanted BMS (n°)

Implanted DES (n°)

Implanted BVS (n°)

QUALITATIVE BIFURCATION ASSESSMENT

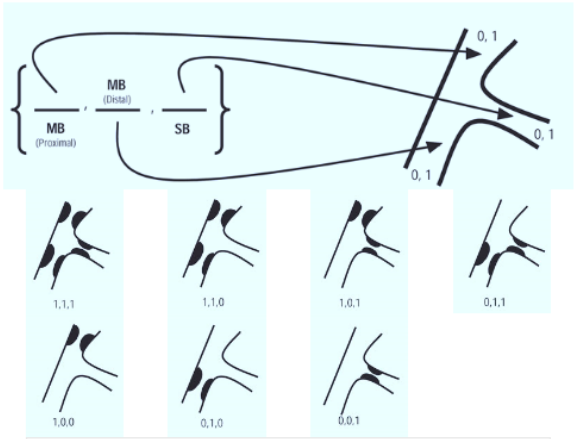
BIFURCATION LOCATION:

○ LAD ○ LCx
○ RCA ○ LM

○ De Novo ○ ISR ☐ CTO

SEGMENT:

○ Proximal ○ Mid ○ Distal



MEDINA ___/___/___