euro PCR

The EASTBOURNE Registry

thE All-comers Sirolimus-coaTed BallOon eURopeaN rEgistry

Second Investigators meeting

EuroPCR 2017

Magic Touch®
Sirolimus-coated balloon

SCB
SIROLIMUS COATED BALLOON

delivery system

Low Profile Balloon -higher Trackability
Short a-traumatic tip
Thin kink resistant shaft
High Pressure resistant balloon
Hydrophilic coated thin SS shaft

Based on the nanoluté technology

$$\frac{dM}{dt} = P \cdot A \cdot C_1$$

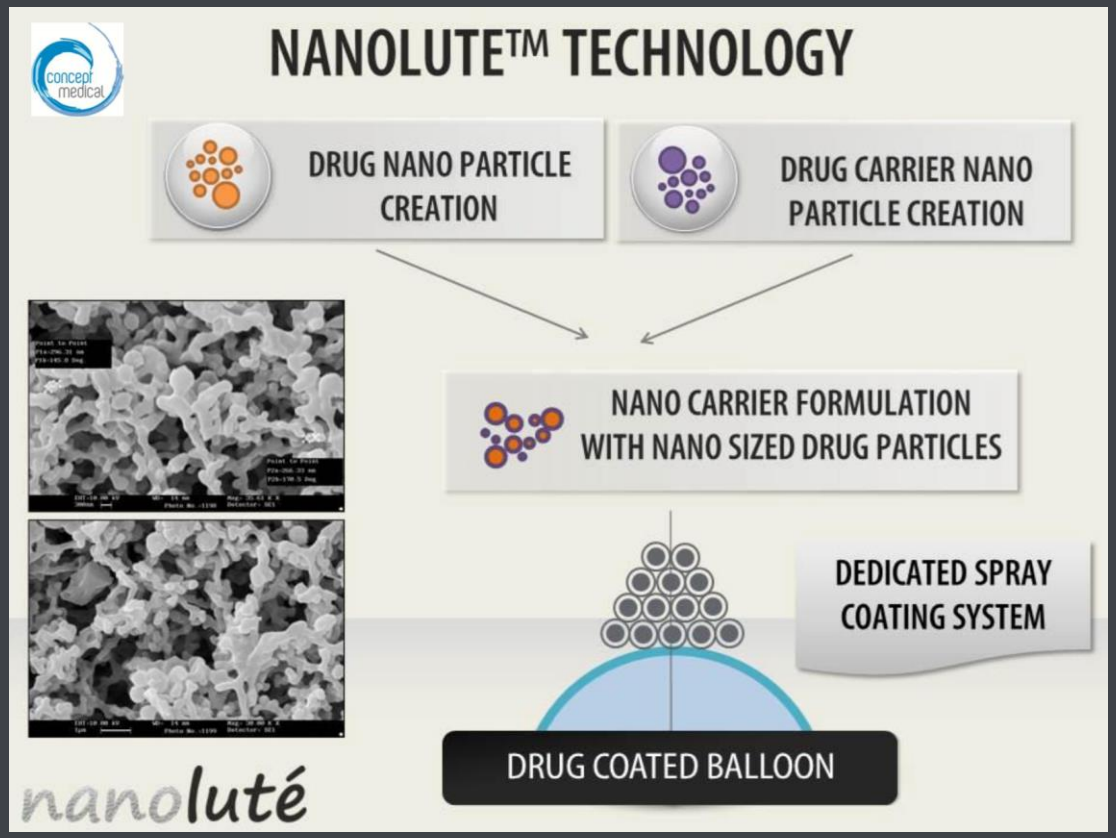
absorption rate

drug permeability

vessel surface

drug concentration

iMPAC PRACTICE



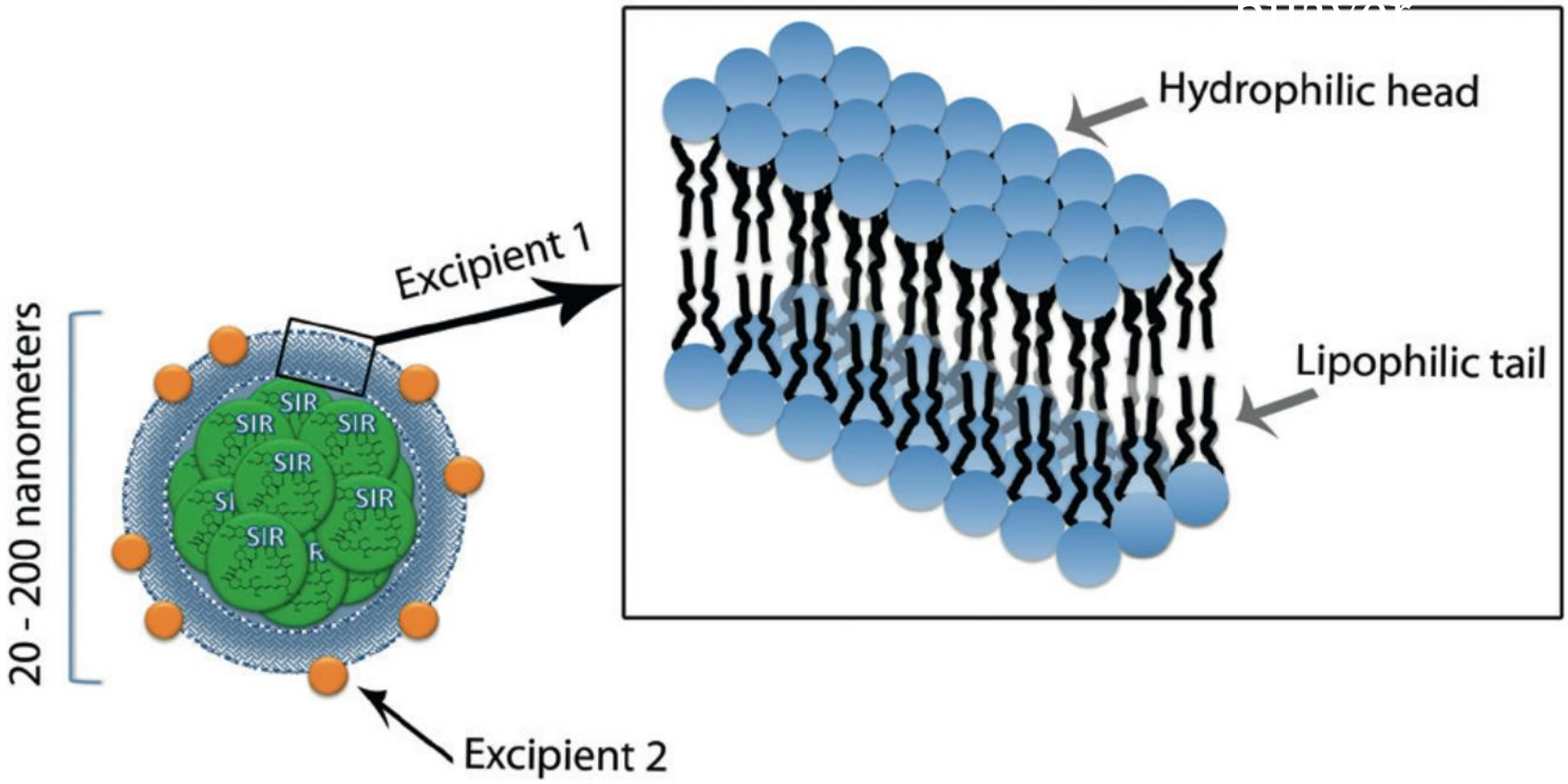
Encapsulation of sirolimus

↓

Protective pack

↓

Increase inpermeability


Hydrophilic head
Lipophilic tail
Excipient 1
Excipient 2
20 - 200 nanometers
SIR
SIR
SIR
SIR
SIR
SIR
SIR

Immediate and short term performance of a novel, sirolimus-coated balloon for coronary applications. The FAtebenefratelli SIrolimus COated balloon (FASICO) registry

-all-comer retrospective registry of the first consecutive SCB patients (April -September 2016) at the first european centre that had the device available for human use;

-at least 3 months of follow up;

-we investigated the immediate technical and clinical performance of this device;

-the occurence of MACE at short term.

B Cortese et al, Cardiovasc Revasc Med '17

Immediate and short term performance of a novel, sirolimus-coated balloon for coronary applications. The FAtebenefratelli SIrolimus COated balloon (FASICO) registry

Patients	32
Lesions	34
Age, mean [SD]	68.56 [±9,45]
Male gender, %	11
Diabetes mellitus, %	38
ACS, %	32
ISR, %	47
ISR and failure of PCB	*31*

B Cortese et al, Cardiovasc Revasc Med '17

Immediate and short term performance of a novel, sirolimus-coated balloon for coronary applications. The FAtebenefratelli SIrolimus COated balloon (FASICO) registry

Lesion length, mean, mm [SD]	18,16 [±9,24]
RVD, mean, mm [SD]	2,68 [±0,5]
Diameter stenosis, % [SD]	86,76 [±10,83]
SCB length, mean, mm (SD)	21.02 (4.7)
SCB diameter, mean, mm (SD)	2.6 (0.52)
Inflation time, mean, sec (SD)	50 (16.7)
Inflation pressure, mean, atm. (SD)	11.6 (4.73)
Minimal lumen diameter pre, mean, mm (SD)	0.39 (0.08)
Minimal lumen diameter post, mean, mm (SD)	2.20 (0.44)
DES use after DCB, n [%]	2 [6]
Hybrid appr SCB+DES on the same vessel, n (%)	9 (26.5)
Hybrid appr SCB+stent on another vessel (same PCI), n (%)	5 (14.7)

B Cortese et al, Cardiovasc Revasc Med '17

Immediate and short term performance of a novel, sirolimus-coated balloon for coronary applications. The FAtebenefratelli SIrolimus COated balloon (FASICO) registry

Procedural success, n	32
In-hospital events, n	0
MACE (6 mo.), n	3
MI, n	0
TLR, n	3

The EASTBOURNE Registry

thE All-comers Sirolimus-coaTed BallOon eURopeaN rEgistry

To observe and evaluate the performance of a Sirolimus-eluting Drug-Coated Balloon (SCB) for the treatment of *any type of coronary lesions*, including native vessel disease and in-stent restenosis.

- Prospective, multicenter, spontaneous clinical registry
- Consecutive enrollment
- real world, all comers patients
- 1000 patients at 20-30 european sites.

Study details

Chairmen

Antonio Colombo (Ospedale San Raffaele, Milano)

Bernardo Cortese (A.O. Fatebenefratelli, Milano)

Steering Committee

Bernardo Cortese (A.O. Fatebenefratelli, Milano, Italy)

Simon Eccleshall (Norfolk, UK)

Alfonso Ielasi (A.O. Bolognini, Seriate, Italy)

Azeem Latib (San Raffele e Columbus, Milano, Italy)

Giulio Stefanini (Humanitas, Milano, Italy)

Luca Testa (San Donato, Milano, Italy)

Data manager

Barbara Cappi (A.O. Fatebenefratelli, Milano)

bcappi72@gmail.com

Study flow-chart

Index procedure

↓

30 days clinical follow-up

↓

6 months clinical follow-up

↓

12 months clinical follow-up

↓

24 months clinical follow-up

Study endpoints

Primary endpoint:

- Target lesion revascularization (TLR) at 12 months

Secondary endpoints:

- angiographic success (<50% final stenosis)
- procedural success (angio success + no in-hospital events)
- MACE (cardiac death, MI, TLR at 6,12 and 24 months)
- Every single element determining the MACE endpoint

Inclusion criteria

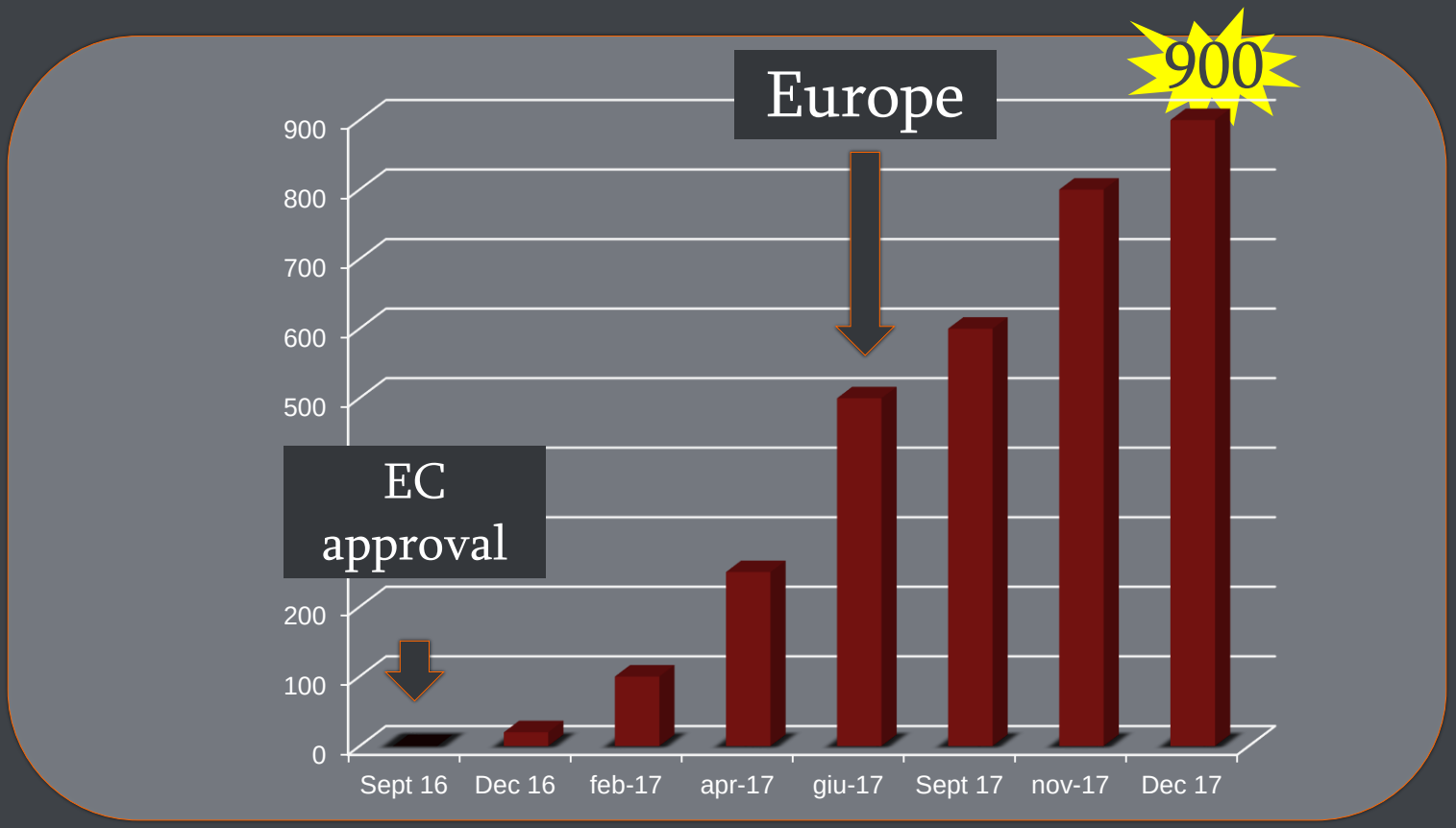
- Patients with coronary artery disease (including patients with chronic stable angina, silent ischemia, any acute coronary syndromes) with clinical indication to PCI
- Age ≥ 18 years

Written informed consent

Main Exclusion criteria

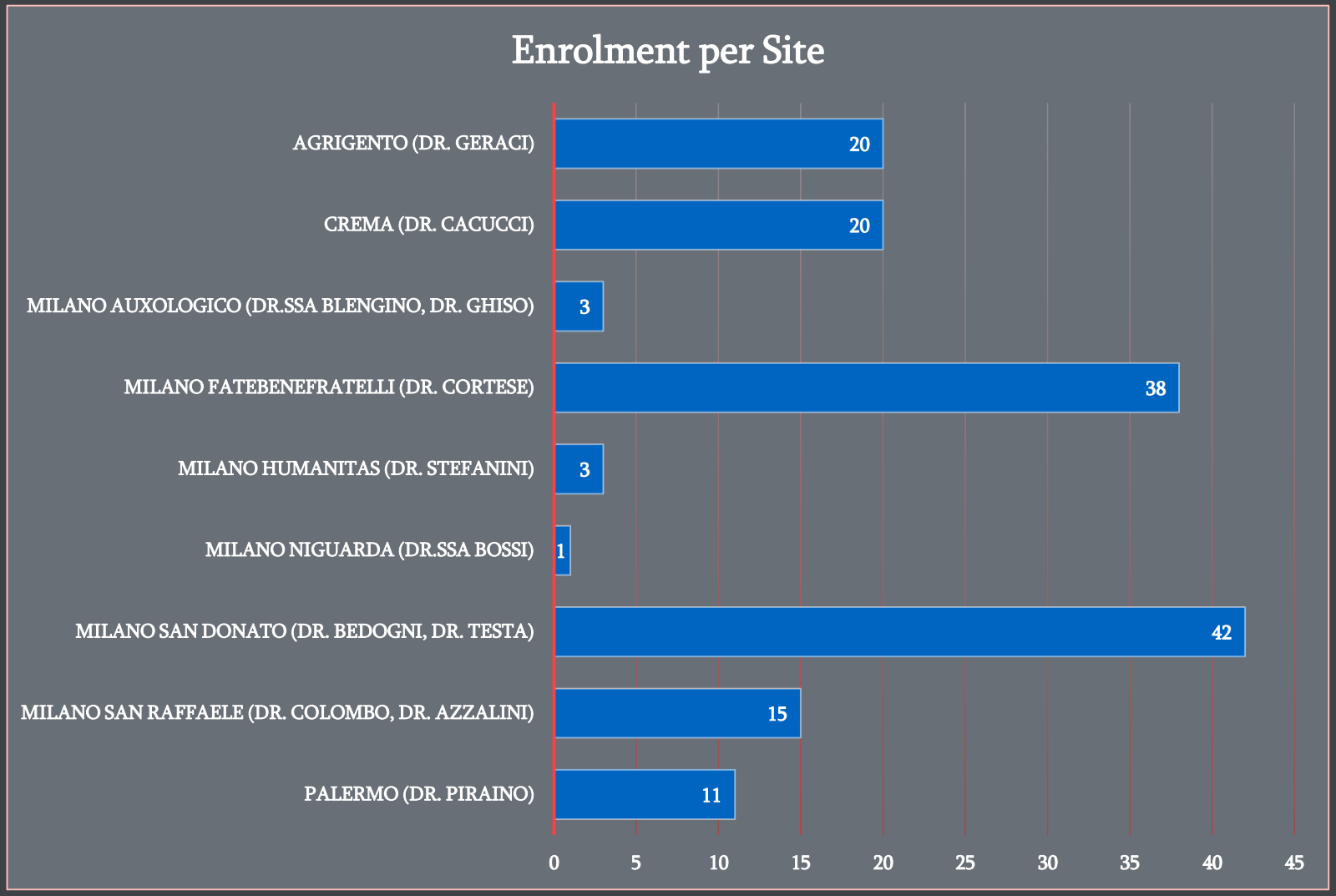
- Target lesion/vessel with any of the following characteristics:
  - successful pre-dilatation not performed in the target lesion, or not efficacious (residual stenosis >50%);
  - severe calcification of the target vessel, also proximal to the lesion;
  - highly tortuous vessel which can impair access of device to treatment site.
- Visible thrombus at lesion which is not treatable with aspiration.

Recruitment Goals



Current Status

153 patients enrolled



Participating Sites

ACTIVE

Ospedale San Raffaele (Milano)
IRCCS Policlinico San Donato (Milano)
Ospedale Fatebenefratelli e Oftalmico (Milano)
Istituto Scientifico Ospedale San Luca (Milano)
Istituto Clinico Humanitas (Milano)
Ospedale Niguarda Ca' Granda (Milano)
Azienda Ospedaliera Ospedale Maggiore (Crema)
ASP S. Giovanni di Dio (Agrigento)
A.O. Universitaria Policlinico P. Giaccone (Palermo)
Ente Ospedaliero Ospedali Galliera (Genova)
ASST Alto Lario (Sondrio)

PENDING EC APPROVAL

Azienda Ospedaliera Carlo Poma (Mantova)
Istituto Clinico Sant'Anna (Brescia)
Clinica San Gaudenzio (Novara)
Ospedale di Circolo e Fondazione Macchi (Varese)
Ospedale General Madre Giuseppina Vannini (Roma)
Ospedale San Giovanni Evangelista (Tivoli)
European/Aurelia Hospital (Roma)
Villa San Pietro Fatebenefratelli (Roma)
Policlinico Universitario Agostino Gemelli (Roma)
Presidio Ospedaliero Villa Sofia (Palermo)
Ospedale Civile Sant'Andrea (La Spezia)
A.O. Universitaria Consorziale Policlinico di Bari (Bari)
Fondazione di Ricerca e Cura G. Paolo II (Campobasso)
Ospedale Sacro Cuore di Gesù Fatebenefratelli (Benevento)
Ospedale San Giuseppe Moscati (Aversa)
ASST Bergamo Est (Seriate-BG)
Ospedale Maggiore SS. Annunziata (Savigliano-CN)
Fondazione Toscana Gabriele Monasterio (Pisa, Massa)
Norfolk and Norwich University Hospital (UK)
Hospital Universitario Virgen de la Salud de Toledo (Spain)
Hospital Lucus Augusti de Lugo (Spain)
Hospital Universitario de Cartagena (Spain)

Some technical hints

- Lesion pre-dilatation with an SC or NC balloon is mandatory!
- DCB inflation time should be at least 30 sec (preferably 60 if tolerated); 60+20 sec is allowed.
- *if lesion pre-dilatation is not successful*, or if recoil or major dissection is observed after pre-dilatation, the operator may change the angioplasty strategy.

Some technical hints

The decision to implant a stent after DCB is left to the operator, but strongly recommended only in case of:

- residual major dissection;
- flow-limiting dissection;
- final TIMI flow <3.

When a stent has to be implanted, a II generation DES or a BVS are recommended, over a BMS.

try leave stent implantation rate <10%

Anti-thromboyic therapy

All patients will be prescribed Aspirin (100 mg per day) life-long, and either

-Clopidogrel (75 mg daily), or

-Prasugrel (10 mg daily), or

-Ticagrelor (90 mg twice a day)

for 1 month,

6 months in case of further stenting

Cardiologist may vary the duration of DAPT according to the clinical presentation and device(s) used.

Catheterization and Cardiovascular Interventions 00:00–00 (2013)

Original Studies

Drug-Coated Balloon Treatment of Coronary Artery Disease: A Position Paper of the Italian Society of Interventional Cardiology

Bernardo Cortese,[1] MD, Sergio Berti,[2] MD, Giuseppe Biondi-Zoccai,[3] MD, Antonio Colombo,[4] MD, Ugo Limbruno,[5] MD, PhD, Francesco Bedogni,[6] MD, Alberto Cremonesi,[7] MD, Pedro Leon Silva,[1] MD, and Gregory A. Sgueglia,[8] MD, PhD

Drug-coated balloons are a new tool for the treatment of patients with coronary artery disease. The main feature of this technology is a rapid and homogenous transfer of an antiproliferative drug (paclitaxel) to the vessel wall just at the time of balloon inflation, when neointimal proliferation, in response to angioplasty, is the highest. Moreover, drug-coated balloons share adjuntive advantages over stents: the absence of permanent scaffold and polymer, the respect of the original coronary anatomy, and limited inflammatory stimuli, thereby allowing for short-term dual antiplatelet therapy. To this day, a lot of devices are available in the market, with limited scientific data for the vast majority of them. Thus, the Italian scientific society of interventional cardiologists GISE decided to coordinate the efforts of a group of reknown experts on the field, in order to obtain a Position Paper on the correct use of drug-coated balloons in all the settings of coronary artery disease, giving a class of indication to each one, based on the clinical evidence. This Position Paper represents a quick reference for operators, investigators, and manufactures to promote the understanding and the correct use of the drug-coated balloon technology in everyday clinical practice.

Key words: coronary artery disease; drug delivery; percutaneous coronary intervention

e-CRFs

http://eregistry.espl.net.in

e-CRFs - follow up reminder

EASTBOURNE Registry

eastbourne.espl.net.in/_PL/INVESTIGATOR/Home.aspx

Aggiungi elementi alla barra Preferiti selezionando ☆ o importandoli da un altro browser. Importa Preferiti

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Follow up Remainder

Following patient has followup in May-2017

Patient Code	Name	Discharge Date	1 Month Follow Up	6 Month Follow Up	12 Month Follow Up	24 Month Follow Up
01-001	APC	22/09/2016	22/10/2016	21/03/2017	22/09/2017	22/09/2018
01-002	DFL	23/09/2016	23/10/2016	22/03/2017	23/09/2017	23/09/2018
01-003	CI	28/09/2016	28/10/2016	27/03/2017	28/09/2017	28/09/2018
01-004	MAF	02/10/2016	01/11/2016	31/03/2017	02/10/2017	02/10/2018
01-005	CT	11/10/2016	10/11/2016	09/04/2017	11/10/2017	11/10/2018
01-006	VA	20/10/2016	19/11/2016	18/04/2017	20/10/2017	20/10/2018
01-007	GR	20/10/2016	19/11/2016	18/04/2017	20/10/2017	20/10/2018
01-008	DLM	24/10/2016	23/11/2016	22/04/2017	24/10/2017	24/10/2018
01-009	PF	30/10/2016	29/11/2016	28/04/2017	30/10/2017	30/10/2018
01-010	OI	26/10/2016	25/11/2016	24/04/2017	26/10/2017	26/10/2018

First | Previous | 1 | Next | Last

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e-CRFs - screening

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eastbourne.espl.net.in/_PL/SPONSOR/1_ENROLLMENT.aspx?PID=252&PCD=01-013

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Inclusion Criteria:

Patient must satisfy all of the following criteria:

SR NO	DESCRIPTION	STATUS	
1	Age >= 18 years.	◉ Yes	○ No
2	Patients with symptomatic coronary artery disease (including patients with chronic stable angina, silent ischemia, and acute coronary syndromes) with clinical indication to PCI.	◉ Yes	○ No

Exclusion Criteria:

Patient should not have any of the following criteria:

SR NO	DESCRIPTION	STATUS	
1	Patients with known (and untreatable) hypersensitivity or contraindication to Aspirin, Heparin, Clopidogrel, Prasugrel, Ticagrelor, Sirolimus or a sensitivity to contrast media which cannot be adequately pre-medicated	○ Yes	◉ No
2	Patients participating in another clinical evaluation.	○ Yes	◉ No
3	Target lesion/vessel with any of the following characteristics: •successful pre-dilatation not performed in the target lesion, or not efficacious (residual stenosis >50%); •severe calcification of the target vessel, also proximal to the lesion; •highly tortuous lesions which can impair access of device to treatment site.	○ Yes	◉ No
4	Visible thrombus at lesion which is not treatable with aspiration.	○ Yes	◉ No

Patient is an acceptable candidate for the study ◉ Yes ○ No

Enrollment Date 04/11/2016

Screen Failure Reported ? ○ Yes ◉ No

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e-CRFs - baseline

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5. History of Renal Insufficiency (Creatinine < 30 mg/dL)	○ Yes	◉ No
6. Family History of Coronary Artery Disease	○ Yes	◉ No
7. Previous Stroke	○ Yes	◉ No
8. Previous Congestive Heart Failure	○ Yes	◉ No
9. Previous Myocardial Infarction	○ Yes	◉ No
10. Previous CABG	○ Yes	◉ No
11. Previous PCI	◉ Yes	○ No
12. Peripheral Vascular Disease	◉ Yes	○ No
13. Multi Vessel Disease (MVD)	◉ Yes	○ No
14. Left Ventricular Ejection Fraction	50 %	
15. Cardiac Markers	○ Yes	◉ No
16. Creatinine	1.1 mg/dL	
17. Haemoglobin	12.5 g/dL	
18. Cardiac related medications prior to admission (tick all that apply)	◉ Yes	○ No

☑ Aspirin ☐ Clopidogrel ☐ Prasugrel
☐ Ticagrelor ☑ Statin

Add Update

2.0 PRE - PROCEDURE

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e-CRFs - pre procedure

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Bernardo Cortese, MD, Milano, Italy
Antonio Colombo, MD, Milano, Italy
Dr Gaetano Di Palma crcmilano@gmail.com

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BASELINE CHARACTERISTICS AND PROCEDURE DATA

Patient ID: 01-011

1.0 BASELINE CHARACTERISTICS

2.0 PRE - PROCEDURE

2.1 Clinical Indication For PCI

Angina Status: ◉ Stable Angina ○ Silent Ischemia ○ Non STEMI ○ Unstable Angina ○ STEMI<12 hours ○ STEMI>12 hours

Class ◉ Class I ○ Class II ○ Class III ○ Class IV

2.2 Cardiac Medication Prior To Procedure

1. ASA Pre-procedure Loading Dose 0 mg

2. Antiplatelet drug (loading dose) taken pre-procedure ○ Yes ◉ No

Add | Update

3.0 PROCEDURE

4.0 DISCHARGE DATA

LOGOUT << INVESTIGATOR << Patient Info << BASELINE CHARACTERISTICS

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e-CRFs - procedure

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Any complications during procedure ○ Yes ◉ No

3.10 Rotational Atherectomy ○ Yes ◉ No

3.11 Cutting Balloon ○ Yes ◉ No

3.12 Thrombus Extraction ○ Yes ◉ No

3.13 IVUS Evaluation ○ Yes ◉ No

3.14 OCT Evaluation ○ Yes ◉ No

3.15 Additional Treatment

Stent Implanted ◉ None ○ PRE DEB ○ POST DEB ○ PRE & POST DEB

3.16 Angiographic Success (< 50% Stenosis) ◉ Yes ○ No

3.17 Device Malfunction ○ Yes ◉ No

3.18 Any Adverse Event (AE) ○ Yes ◉ No

3.19 Any Serious Adverse Event (SAE) ○ Yes ◉ No

Add Update

4.0 DISCHARGE DATA

LOGOUT << INVESTIGATOR << Patient Info << BASELINE CHARACTERISTICS

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e-CRFs - discharge

EASTBOURNE Registry

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BASELINE CHARACTERISTICS AND PROCEDURE DATA

Patient ID: 01-011

1.0 BASELINE CHARACTERISTICS

2.0 PRE - PROCEDURE

3.0 PROCEDURE

4.0 DISCHARGE DATA

Date. 21/10/2016

4.1 Discharge Details

4.1.1 Any Major Adverse Cardiac Event (MACE) during hospitalization?	○ Yes	◉ No
4.1.2 Any Adverse Event (AE)	○ Yes	◉ No
4.1.3 Any Serious Adverse Event (SAE)	○ Yes	◉ No

4.2 Drugs Prescribed At Discharge

1. Aspirin	◉ Yes	○ No
Second Antiplatelet agent	◉ Yes	○ No
Type of antiplatelet agent: clopidogrel		
Dose: 75 mg		
2. Duration of DAPT prescribed: 1		

Add Update

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e-CRFs - follow up

EASTBOURNE Registry

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FOLLOW UP

Patient ID: 01-011

1.0 1 MONTH FOLLOW UP

Follow Up Date 25/11/2016

5.1 Follow-Up Details

5.1.1 Any Major Adverse Cardiac Event (MACE)	○ Yes	◉ No
5.1.2 Any Adverse Event (AE)	○ Yes	◉ No
5.1.3 Any Serious Adverse Event (SAE)	○ Yes	◉ No

5.2 Current Medications

1.	Aspirin	◉ Yes	○ No
2.	P_2Y_{12} Inhibitor	○ Yes	◉ No
3.	Statin	◉ Yes	○ No

Date of Discontinuation of DAPT DD/MM/YYYY

Add Update

2.0 6 MONTHS FOLLOW UP

3.0 12 MONTHS FOLLOW UP

4.0 24 MONTHS FOLLOW UP

5.0 ANGIOGRAPHY FOLLOW UP

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Substudies

Please send an email to:

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CENTRE/S	
DATE OF PROPOSAL	
TITLE	
DURATION OF FOLLOW-UP	
CHARACTERISTICS OF THE POPULATION OF SUBSTUDY	
VARIABLES TO BE CONSIDERED	
PROJECT DESCRIPTION	TEXT
PROJECT P.I.(s)	
BIBLIO REFERENCES	
TEMPT. JOURNAL WHERE TO PUBLISH THE SUBSTUDY	