

Beyond the one-year horizon: Long Term Outcome of patients undergoing *Sirolimus Coated Balloon* Angioplasty for Coronary Atherosclerosis

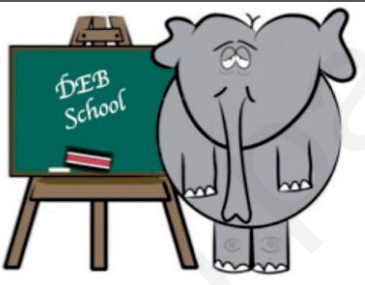
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Potential conflicts of interest

Speaker's name: Bernardo Cortese

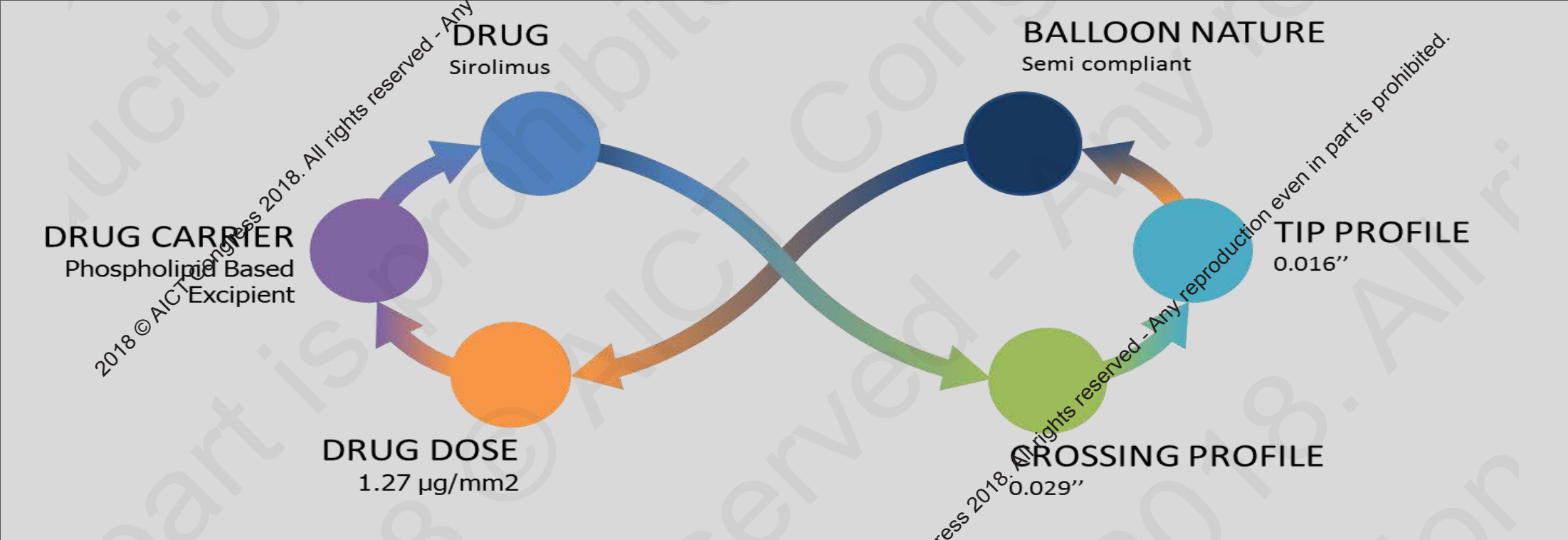
I have the following potential conflicts of interest to report (last 2 years):

Consultant: Aachen Resonance, Abbott Vascular, Astra Zeneca, Kardia, Innova, Stentys, Daiiki-Sankyo.

Honorarium: Hexacath, Amgen, Stentys, Sanofi, B.Braun.

Institutional grant/research support: AB Medica, St Jude, Abbott Vascular.

DEVICE DESCRIPTION



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DCBs: players

-LIMUS

PACLITAXEL

Cytostatic

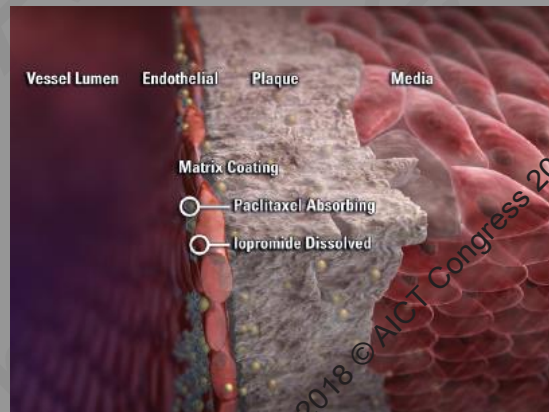
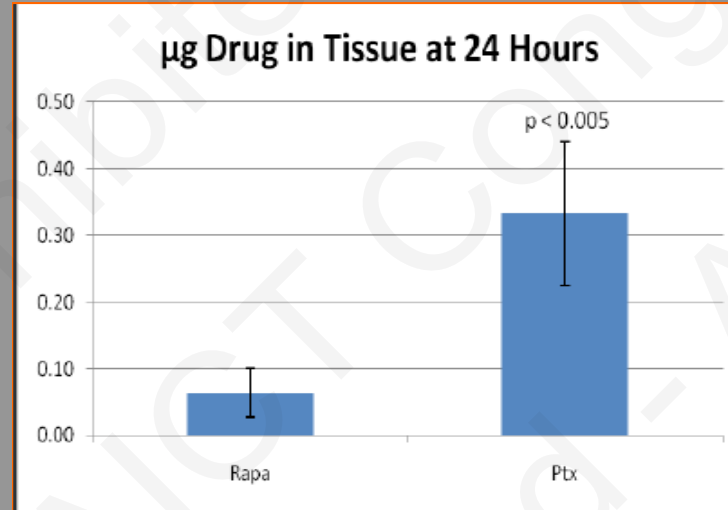
Cytostatic (toxic for very high doses)

Lower lipophilia

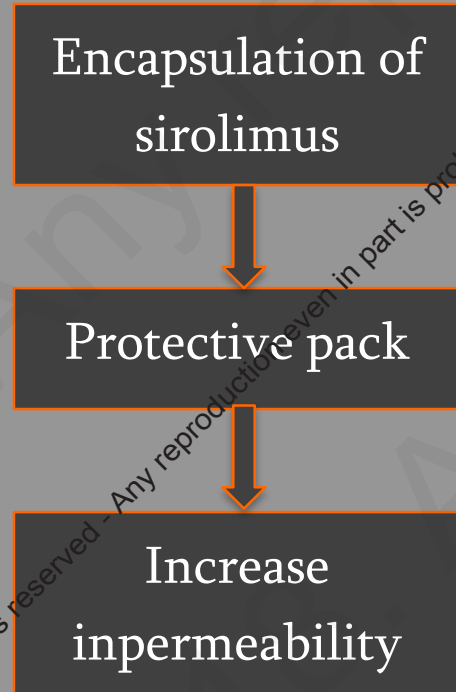
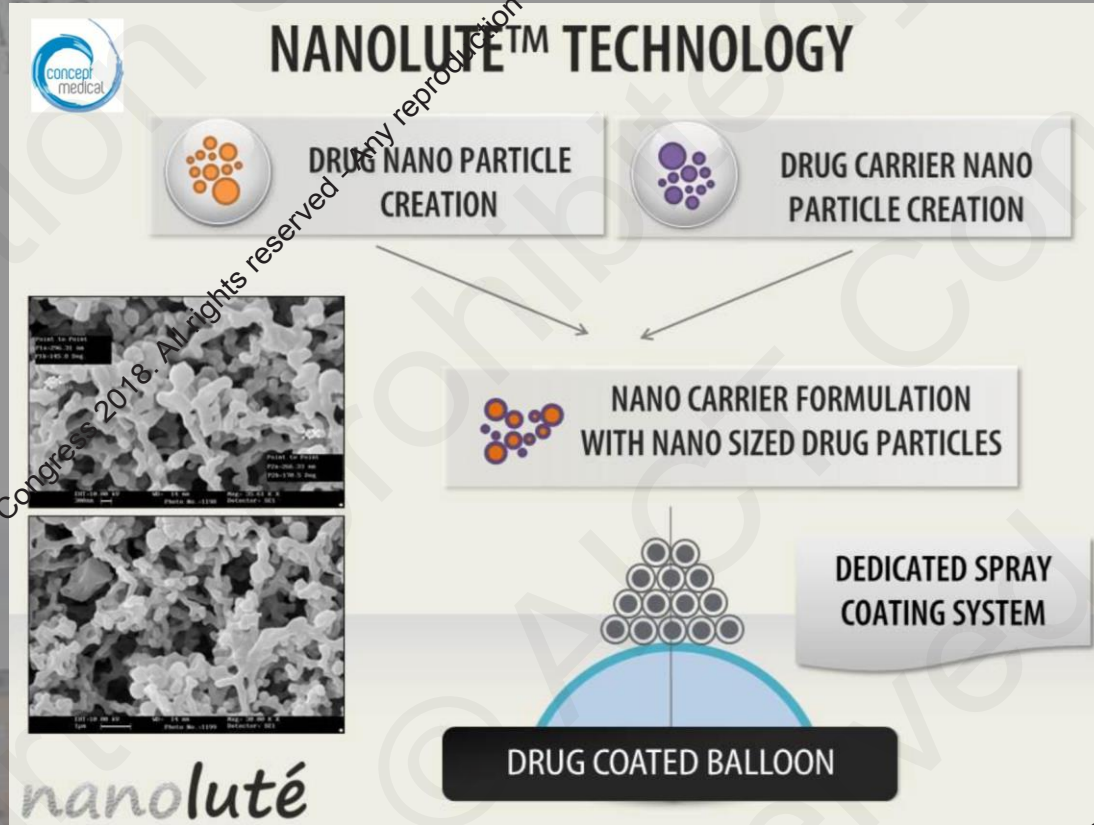
High lipophilia

More potent SMC inhibition

High tissue penetration

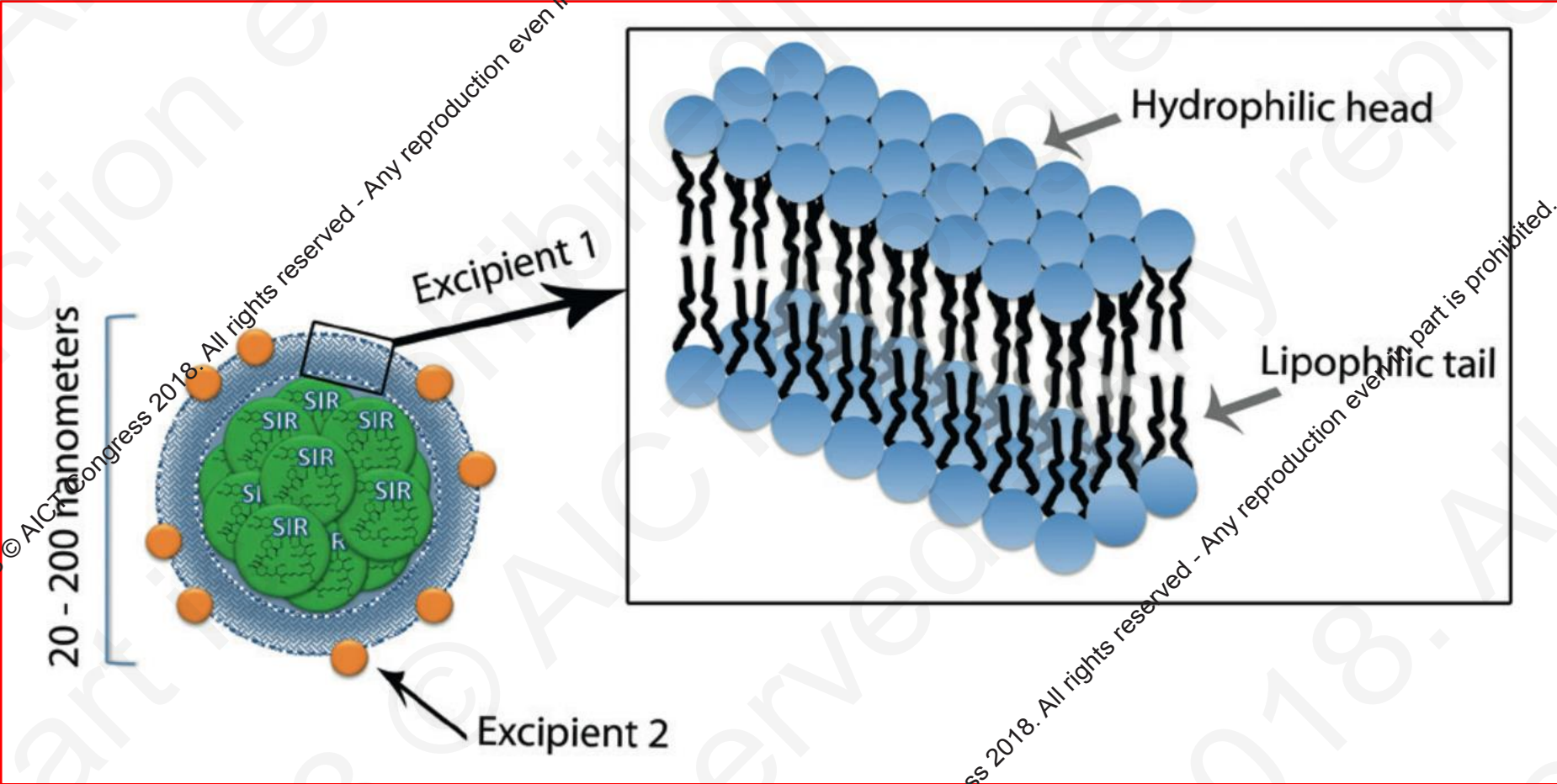


Magic Touch® Sirolimus-coated balloon



nanoluté

Phospholipid bilayer



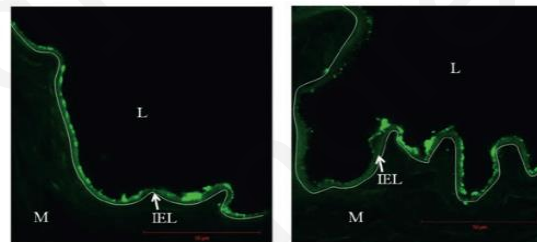
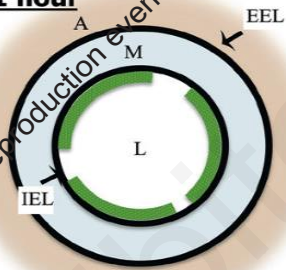
Calcium-Phosphorous component

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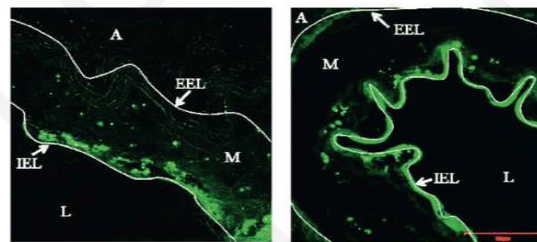
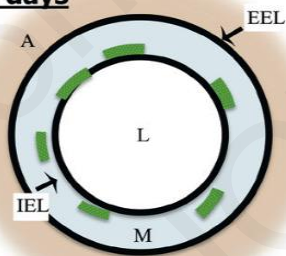
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sirolimus 'journey'

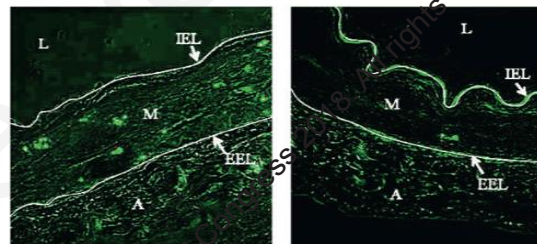
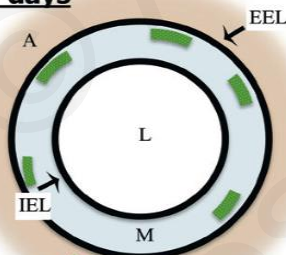
1 hour



3 days



7 days



NANOLUTE STUDY DESIGN AND ENDPOINTS


Study Design

Study Design

Prospective, Multi-center clinical registry, all comers patients at Indian centers.
Clinical Follow-up up to 2 years.


Primary Endpoint

MACE (Major Adverse Cardiac Event) is a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR) at 6 months



Cardiovascular Revascularization
Medicine

Available online 28 June 2018
In Press, Accepted Manuscript



A novel nanocarrier sirolimus-coated balloon for coronary interventions: 12-month data from the Nanoluté registry ☆

Sameer Dani ^a, Dinesh Shah ^b, Prakash Sojitra ^c, Keyur Parikh ^d, Ranjan Shetty ^e, Gaetano di Palma ^f, Bernardo Cortese ^{f, g} ✉

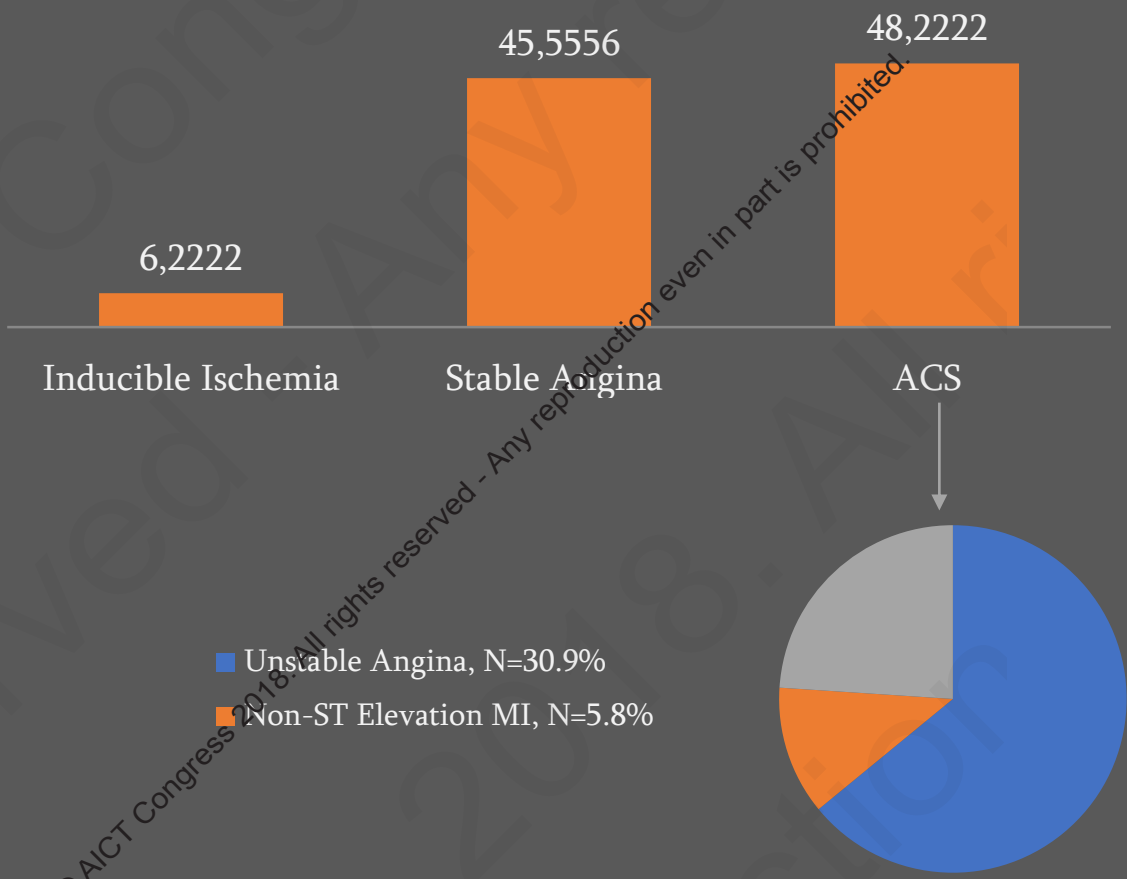
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BASELINE CHARACTERISTICS

OVERALL POPULATION=450

Baseline characteristics, N=450	
Age, years ± SD	60.1 ± 10.1
Male, %	82.0
Female, %	18.0
Cardiovascular risk factors, %	
Diabetes Mellitus	45.3
Hypertension	48.0
Family history of CAD	3.1
Previous CV history, %	
MI	29.3
PCI	55.6
CABG	6.9
Additional risk factors, %	
Peripheral vascular disease	0.4
Renal Insufficiency	3.6
Left ventricular dysfunction	8.2

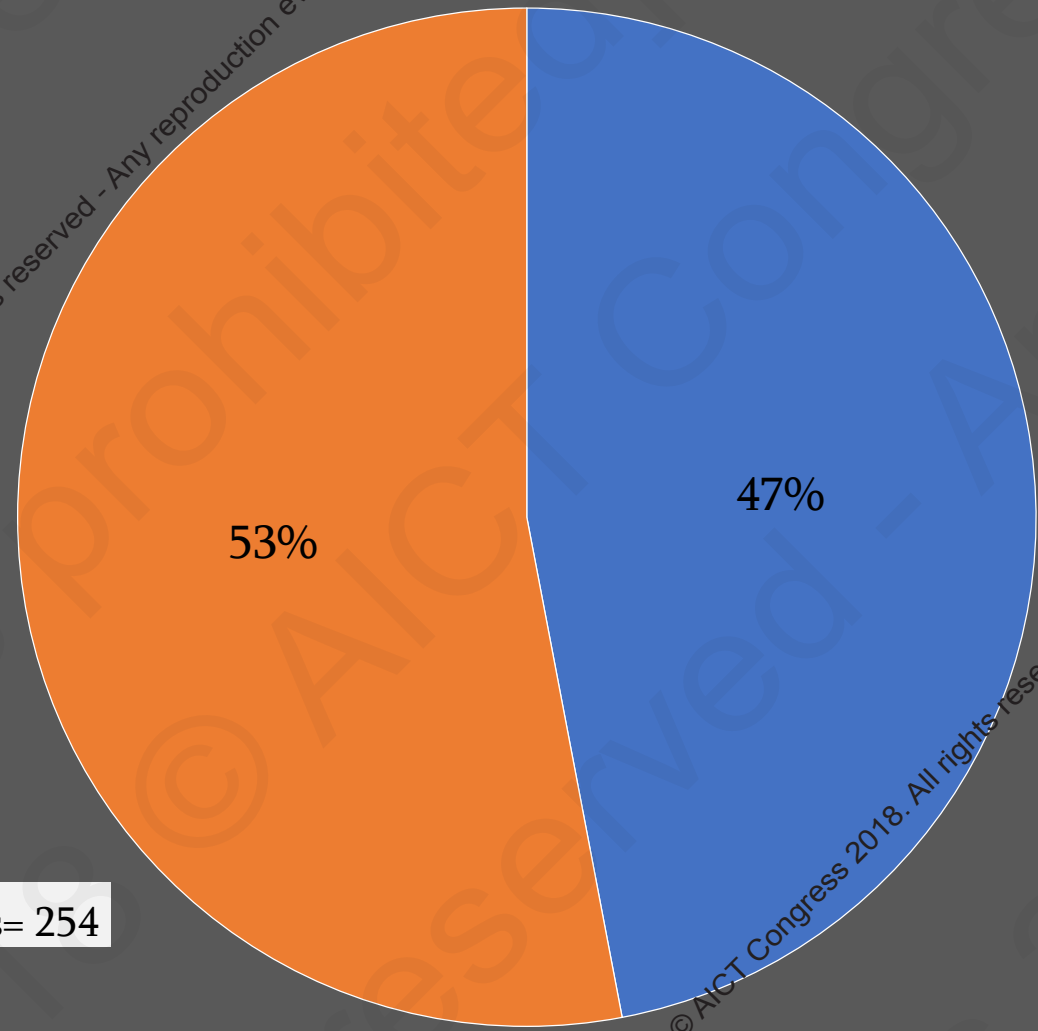
CLINICAL PRESENTATION, %



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LESION CHARACTERISTICS

No. of Lesions= 479



No. of de-novo lesions= 254

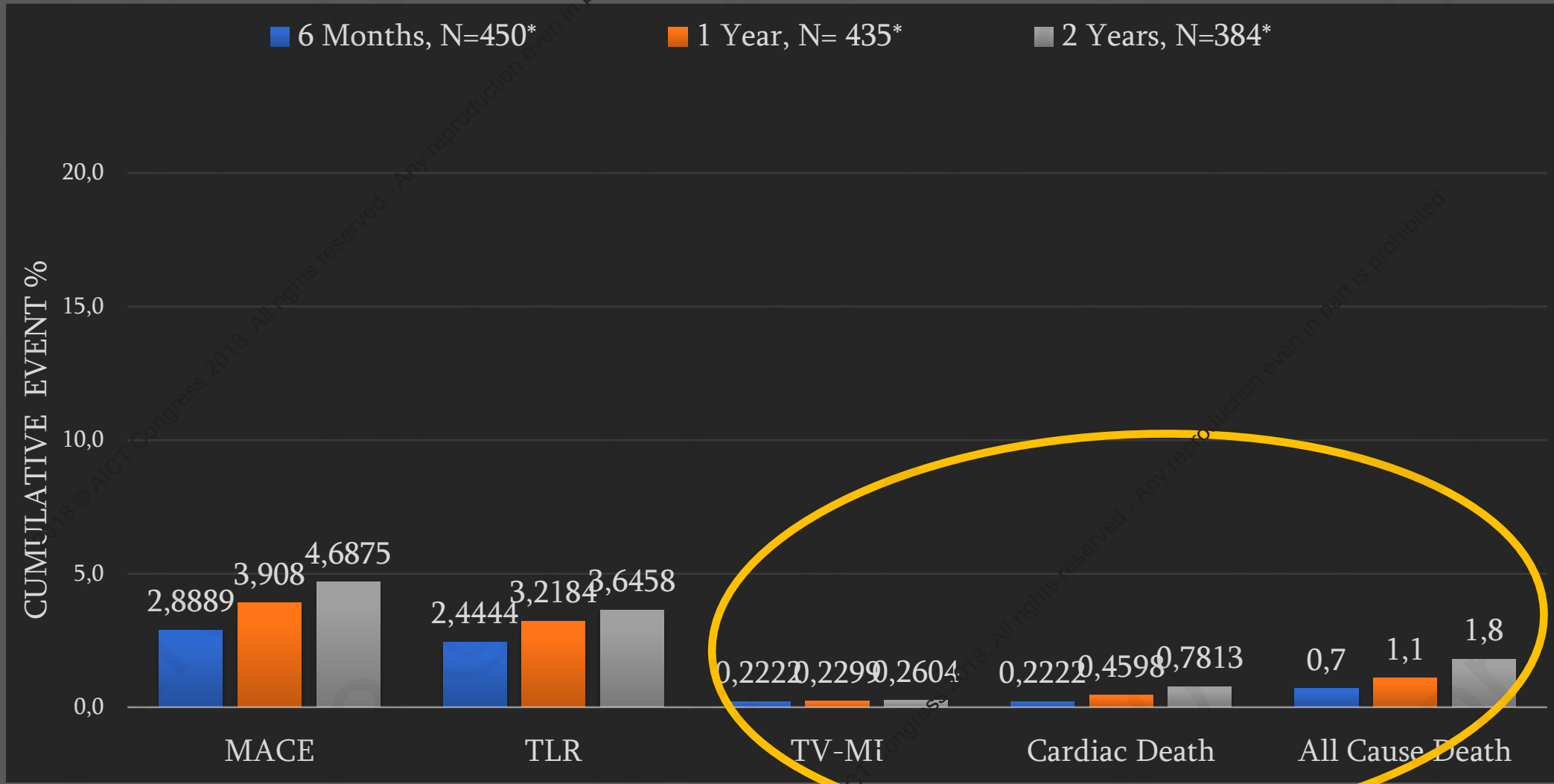
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TARGET VESSEL LESION & PROCEDURAL CHARACTERISTICS

No. of Lesions= 479, No. of devices= 534

Procedure Details, %	
Devices per patient	1.2
SCB Alone therapy	92.0
SCB+ Additional stenting	8.0
Vessel Dissection	0.4
Procedural Success	99.6
Device details, mm ± SD	
Mean SCB Length	22.6 ± 7.5
Mean SCB Diameter	2.7 ± 0.5

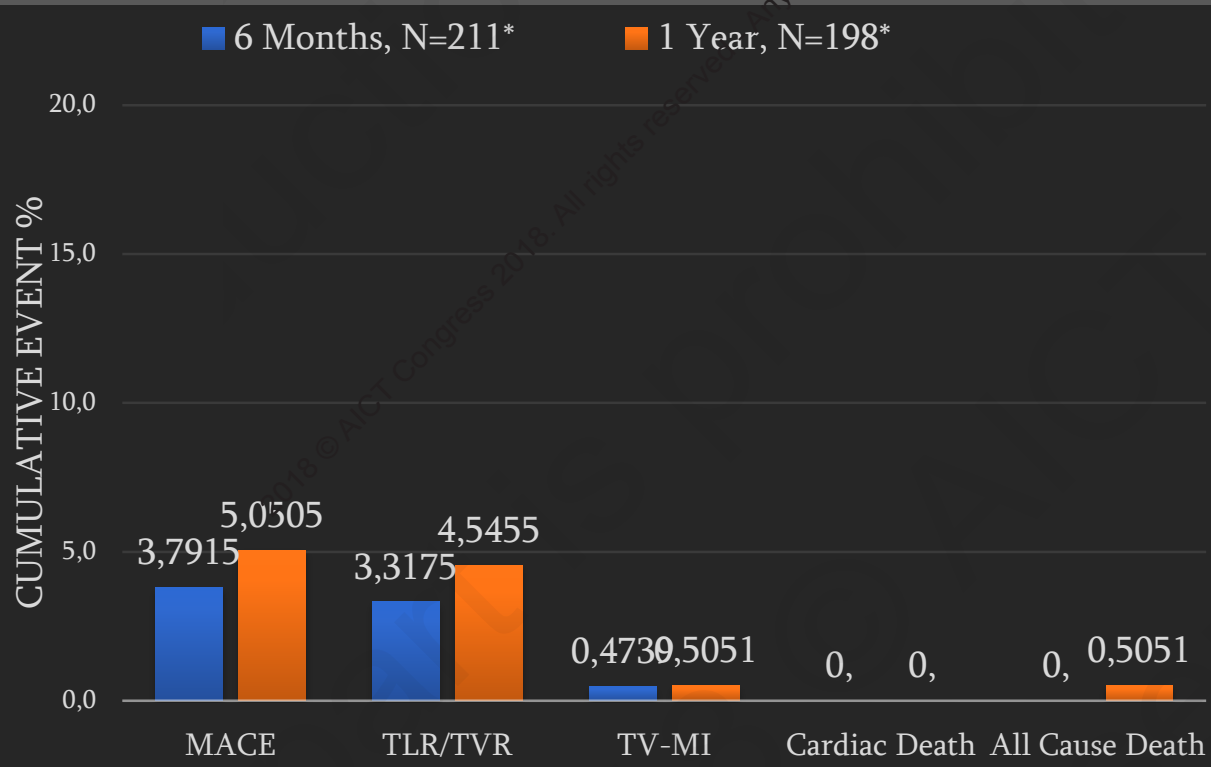
CUMULATIVE CLINICAL OUTCOMES UP TO 2 YEARS



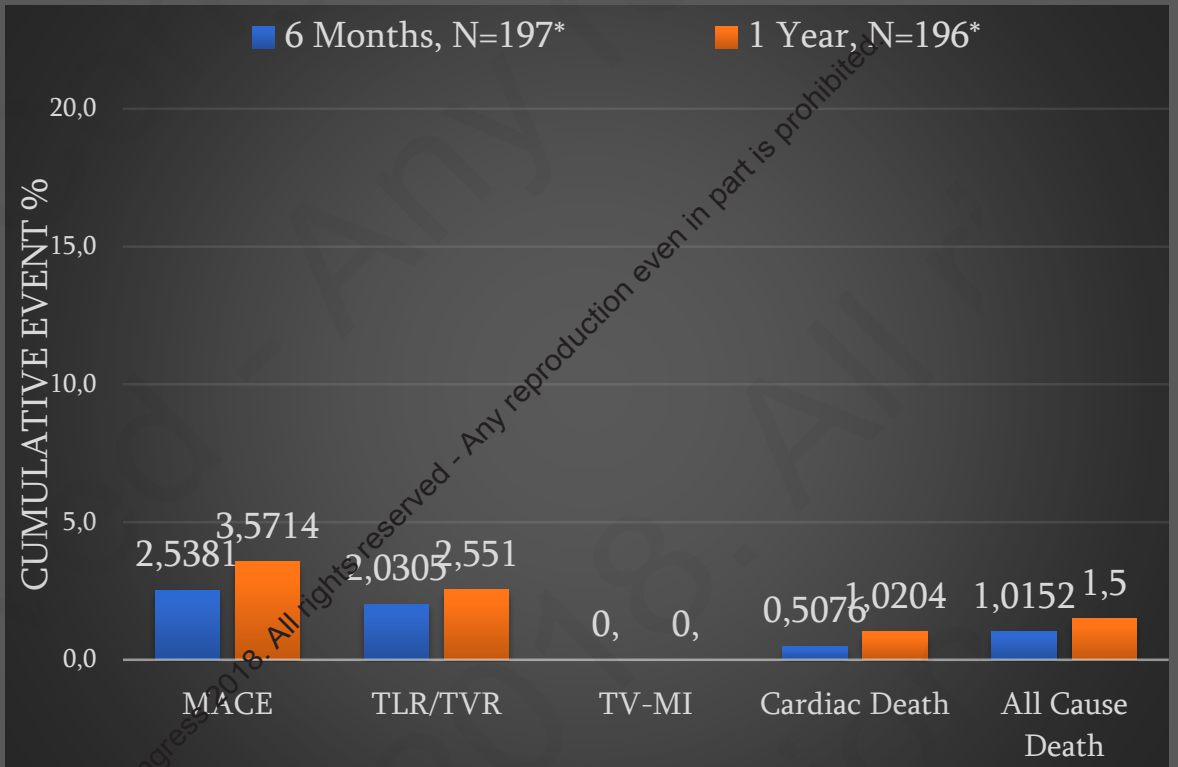
*No of Patients completed clinical follow-up till August 2018.

CUMULATIVE OUTCOMES IN ISR AND SMALL VESSEL UP TO 1 YEAR

In-Stent Restenosis, N= 211



De-Novo Small Vessel, N= 197



*No of Patients completed clinical follow-up till August 2018.

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Nanoluté Registry-LIMITATIONS

- **Single arm registry**
- **Performed in India with only one type of population**
- **Not external adjudication of events**
- **Absence of quality assessment of data source**



The EASTBOURNE Registry

the All-comers Sirolimus-coated Balloon eURopean rEgistry



THE EASTBOURNE REGISTRY
THE ALL-COMERS SIROLIMUS-COATED BALLOON
EUROPEAN REGISTRY

- prospective, multicenter, spontaneous clinical registry
- consecutive enrollment
- real world, all comers patients
- 1500 patients at ca. 30 european/asian sites
- clinical follow up: 2 years (CEC)
- chairmen: B. Cortese, A. Colombo

Inclusion criteria: any type of coronary lesions, including native vessel disease and in-stent restenosis.



Study endpoints



THE EASTBOURNE REGISTRY
THE ALL-COMERS SIROLIMUS-COATED BALLOON
EUROPEAN REGISTRY

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

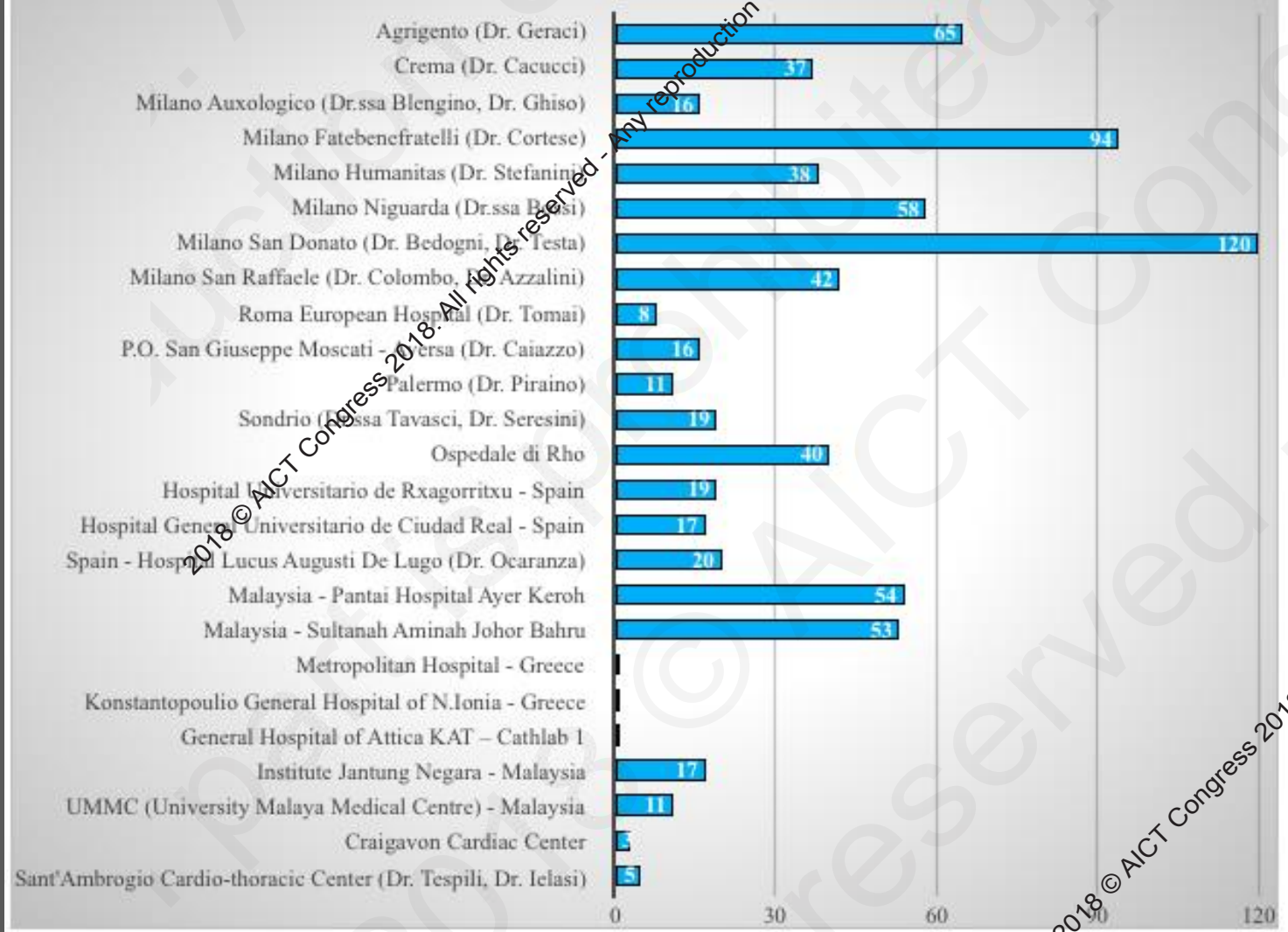


Total = 766



THE EASTBOURNE REGISTRY
THE ALL-COMERS SIROLIMUS-COATED BALLOON
EUROPEAN REGISTRY

Enrolment per Site



Interim analysis presentation @ TCT during Innovation session – Sept. 21st

enrollment 31.08.18

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CONCLUSIONS

Technological improvements are key factors to warrant an adequate transfer of anti-proliferative drugs in diseased coronary arteries without prostheses.

SCB might constitute a new therapeutic option in the setting of complex coronary lesions, also considering the good deliverability and tractability of Magic Touch.

Newer studies which are enrolling patients in Europe will provide further insights.

14th

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