

# One year clinical outcome of percutaneous treatment with Sirolimus eluting balloons: Results from Nanolute prospective registry

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# Potential conflicts of interest

Speaker's name: Bernardo Cortese

☐ I have the following potential conflicts of interest to report:

Participation in a company sponsored speaker's bur: Abbott

Receipt of grants / research supports: AB Medica, Abbott, St. Jude Medical, Stentys

Receipt of honoraria or consultation fees: Abbott, AstraZeneca, DAIICHI SANKYO and ELI-LILLY, Stentys

# Magic Touch® Sirolimus-coated balloon

world's first drug coated balloon to successfully deliver  
sirolimus drug

Based on the *nanoluté* technology

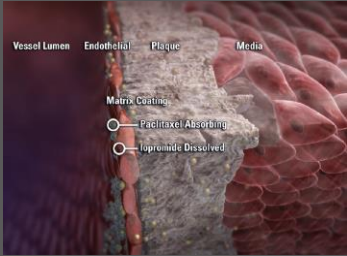


PTCA  
BALLOON

## PTCA BALLOON

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

# Fick's law of diffusion



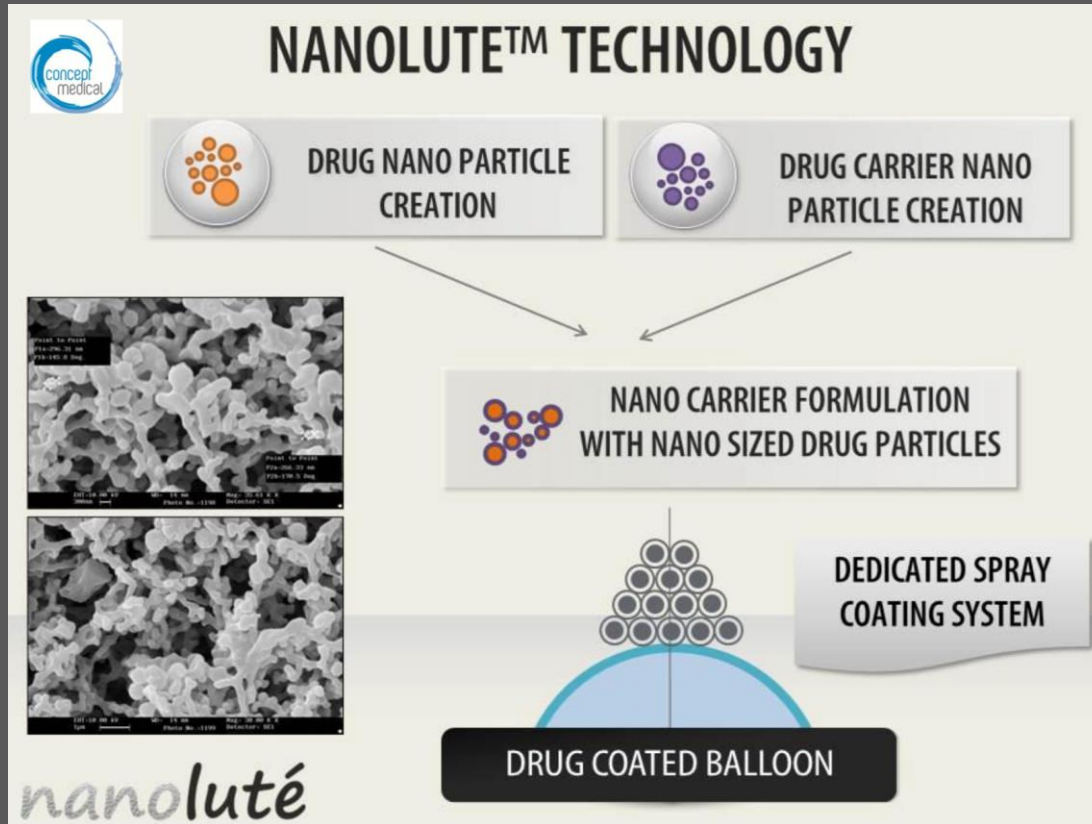
$$\frac{dM}{dt} = P \cdot A \cdot C_1$$

absorption  
rate

drug  
permeability

drug  
concentration

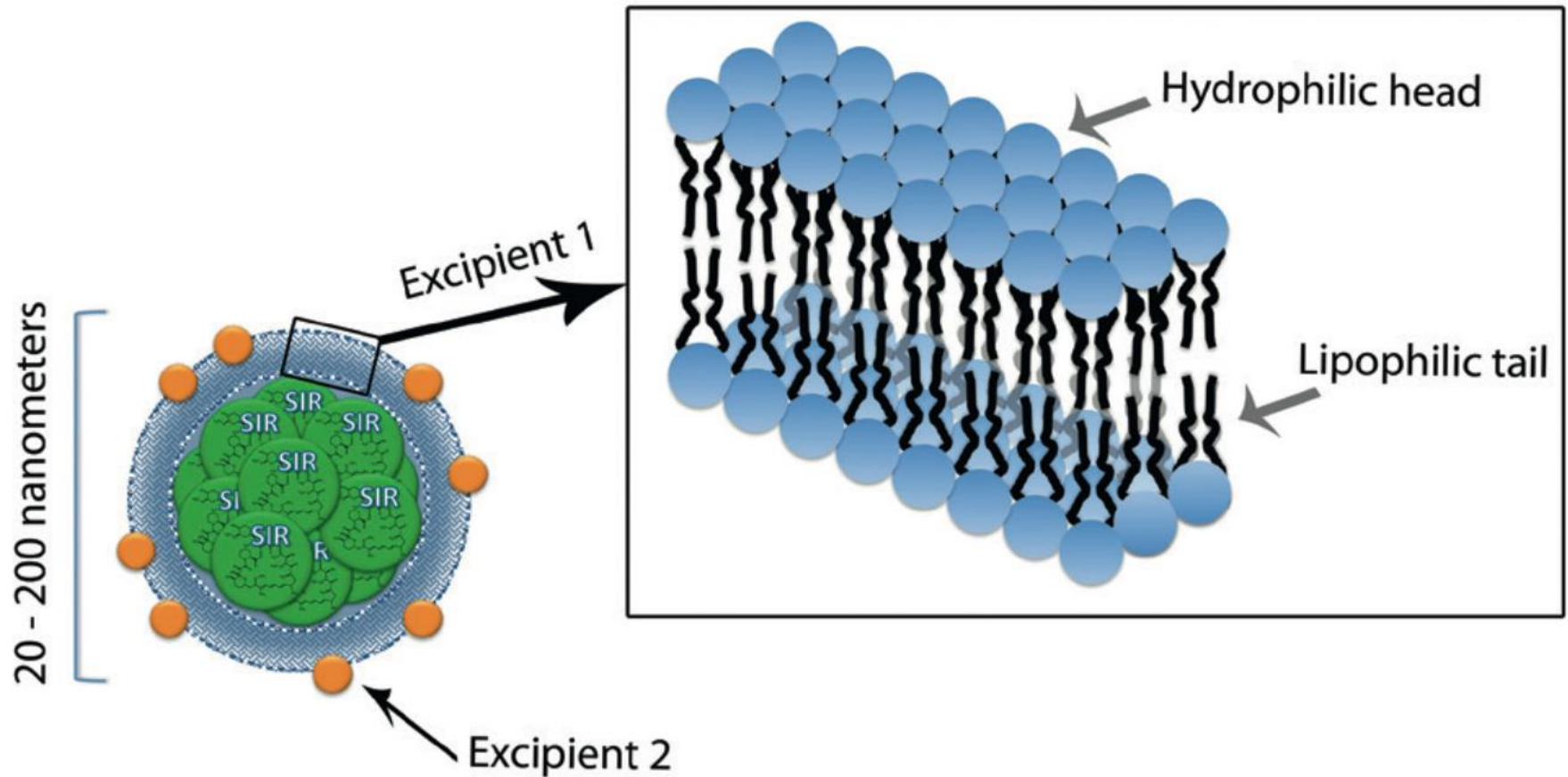
vessel  
surface



Encapsulation of  
sirolimus

Protective pack

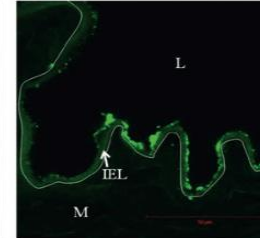
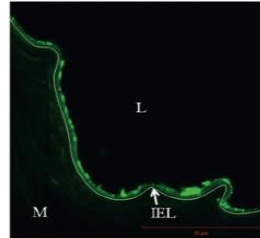
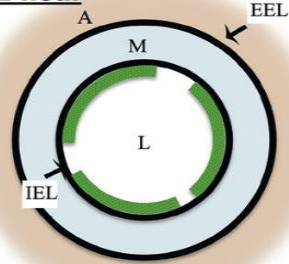
Increase  
impermeability



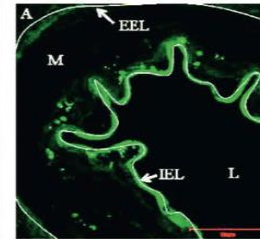
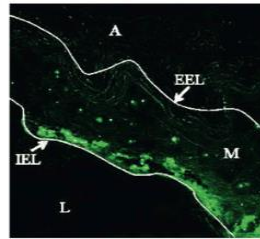
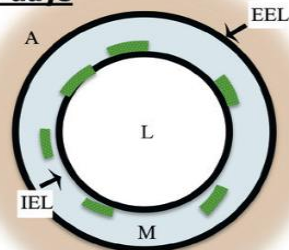
Calcium-Phosphorous  
component

# sirolimus journey

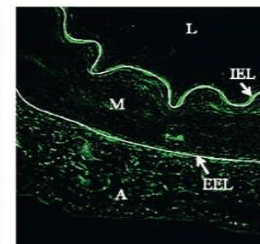
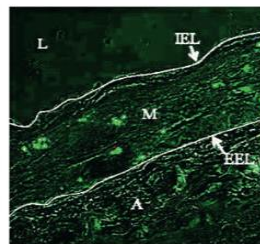
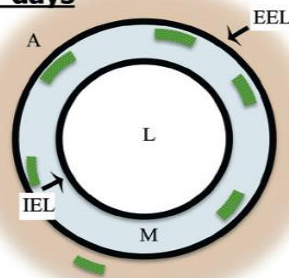
**1 hour**



**3 days**



**7 days**







Immediate and short-term performance of a novel sirolimus-coated balloon during complex percutaneous coronary interventions. The FAtebenefratelli Sirolimus COated-balloon (FASICO) registry<sup>☆</sup>

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## Lesion characteristics (n = 34)

### Target lesion:

|        |       |
|--------|-------|
| LAD, % | 64.93 |
| CX, %  | 13.86 |
| RCA, % | 21.21 |

ISR, n (%)

ISR previously treated

De-novo lesions, n (%)

Lesion length, mean (SD)

Reference vessel diameter

Bifurcation culprit lesion

Percent lesion stenosis

Degree calcification

Multi-vessel diseases

Clinical follow up (average: 6.9 ± 1.7 months).

|  |           |
|--|-----------|
| DAPT ongoing, n [%]                    | 10 [31.6] |
| All-cause death, n [%]                 | 0         |
| Cardiac death, n [%]                   | 0         |
| Target lesion revascularization, n [%] | 3 [9.4]   |
| MI, n [%]                              | 0         |
| MACE, n [%]                            | 3 [9.4]   |

|   |             |
|---|-------------|
| 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) |
| Hybrid approach SCB + DES on the same vessel, n (%)                   | 9 (26.5)    |
| Hybrid approach SCB + stent on another vessel (same procedure), n (%) | 5 (14.7)    |
| TnI peak after PCI, average value, µg/l (SD)                          | 40 (21.6)   |
| Angiographic success, %   | 100         |
| Procedural success, %   | 100         |



# NANOLUTÈ REGISTRY

## Study Design

Prospective, Multi-center clinical registry real world, all comers patients at various indian Interventional Cardiology Sites.

Clinical Follow-up at 1,6 and 12 Months.

Purpose of this registry is to evaluate the safety and efficacy of MT SCB in the patients with CAD.

- No. of patients enrolled = 408

No. of patients completed 6 months follow-up: 386

No. of patients completed 12 months follow-up: 347

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# STUDY ENDPOINTS

## Primary Endpoint:

MACE (cardiac death, TV-MI and TLR) at 6 months.

Procedural success (technical and angiographic success in the absence MACE at hospital discharge).

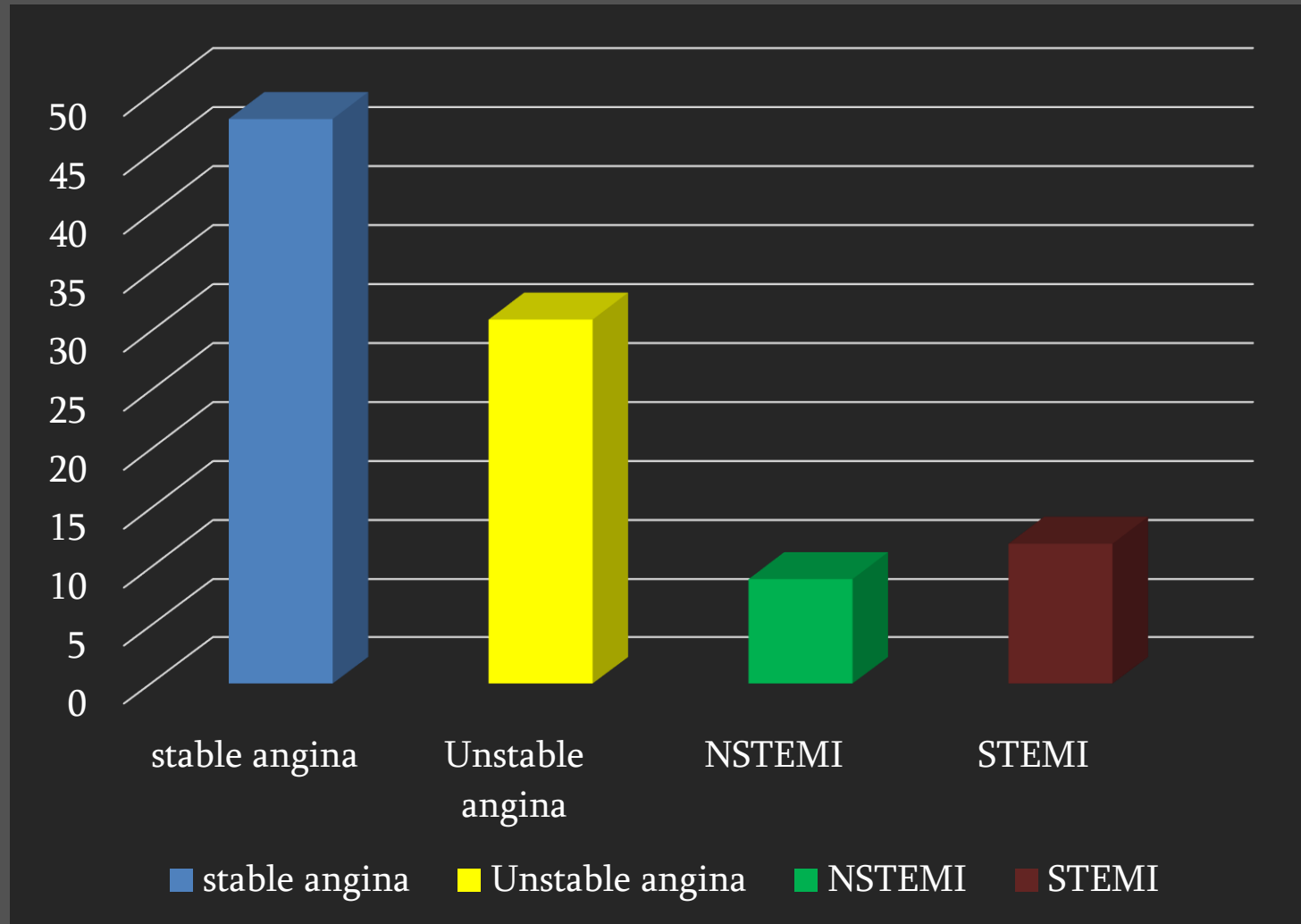
## Secondary Endpoints

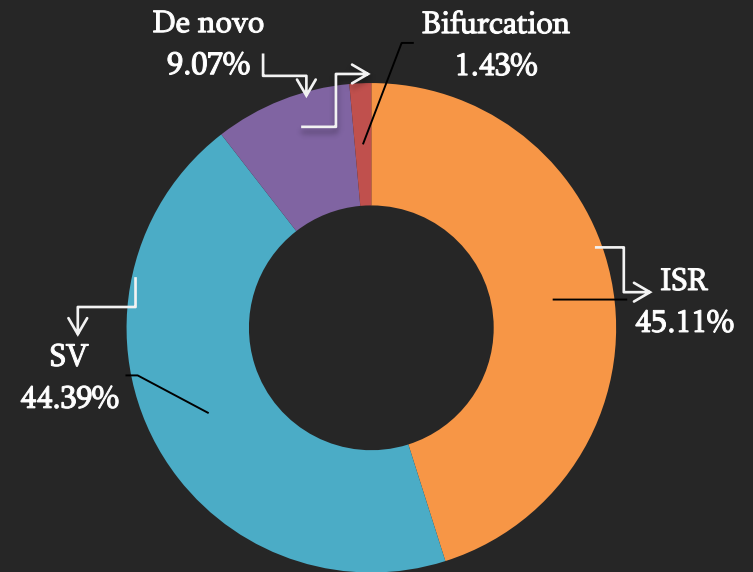
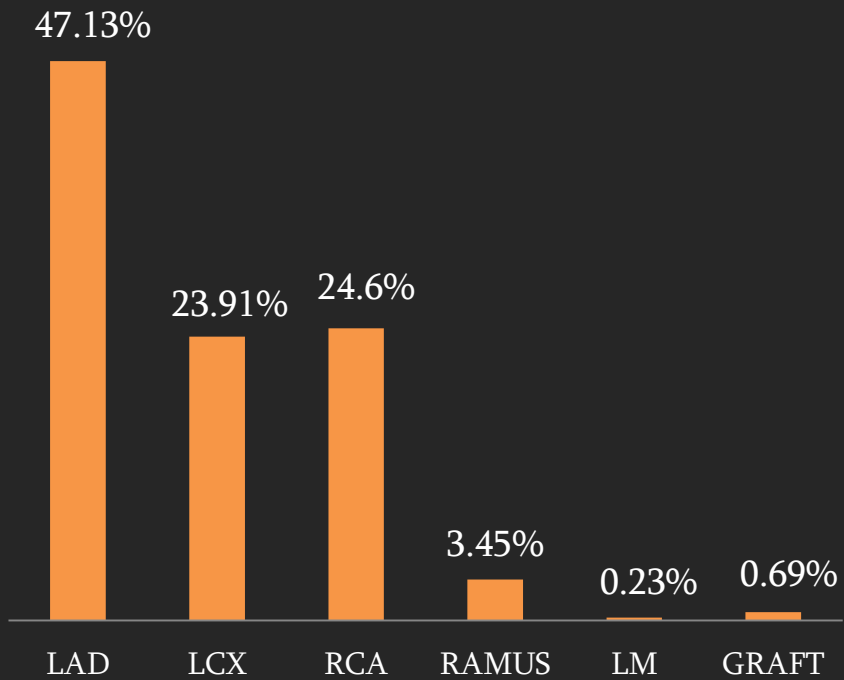
MACE at 12 months.

# BASELINE CHARACTERISTICS

|                       |                   |
|-----------------------|-------------------|
| Population            | 408               |
| Lesions               | 435               |
| Age, years $\pm$ SD   | 59.81 $\pm$ 10.38 |
| Male, N(%)            | 334(81.86)        |
| Female, N(%)          | 74(18.14)         |
| Diabetes Mellitus     | 181(44.36)        |
| Hypertension          | 189(46.32)        |
| Family history of CAD | 13(3.19)          |
| MI                    | 123(30.15)        |
| PCI                   | 214(52.45)        |
| CABG                  | 25(6.13)          |

# INDICATIONS TO PCI

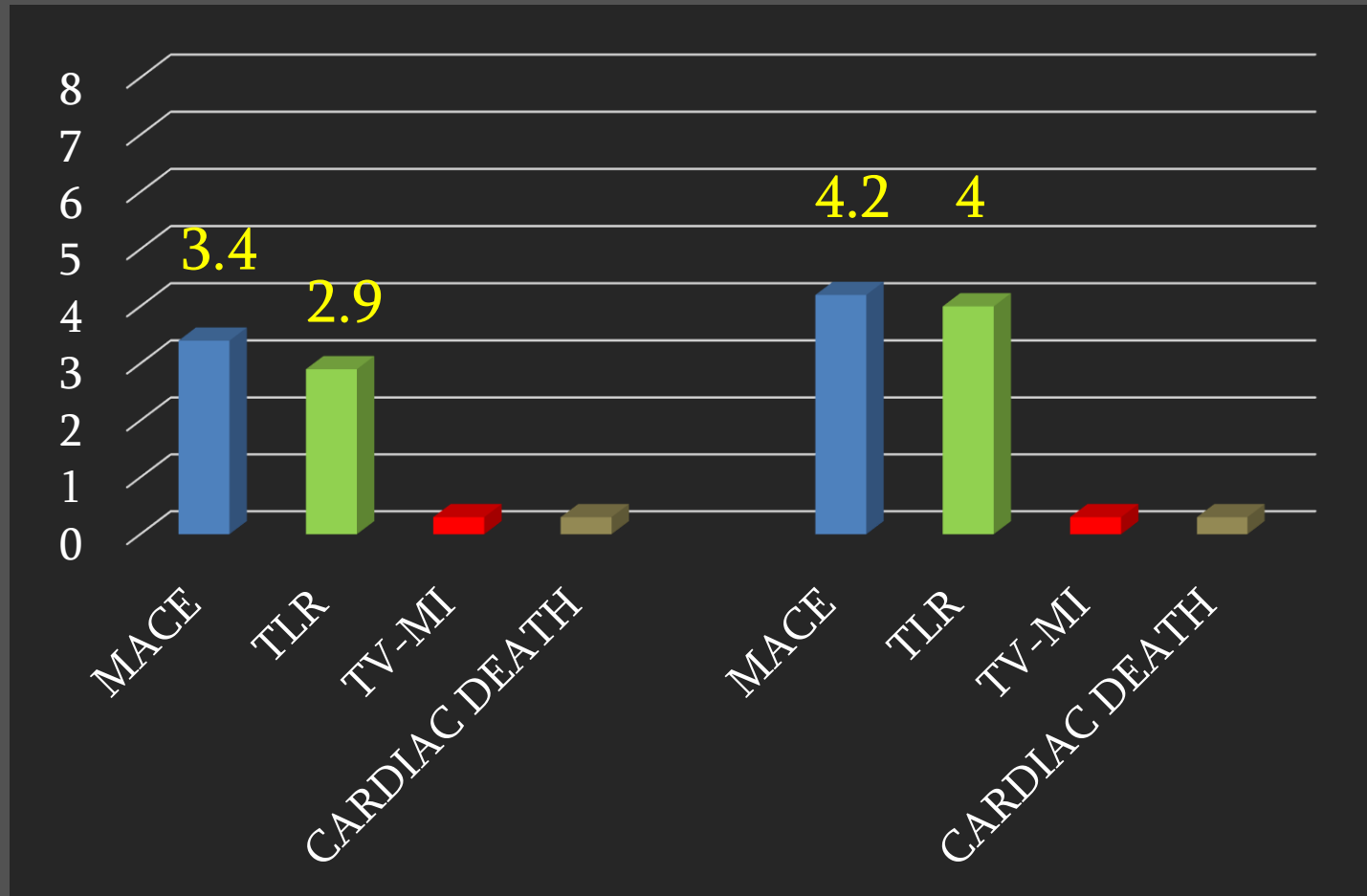




# PROCEDURE AND DEVICE DETAILS

|                         |               |
|-------------------------|---------------|
| Procedural success      | 406 (99.5)    |
| Device per patient      | 1.19          |
| SCB + BMS               | 28(6.86)      |
| SCB Length              | 22.26 ± 7.19  |
| SCB Diameter            | 2.69 ± 0.45   |
| Inflation pressure, ATM | 11.26 ± 5.27  |
| Inflation time, SEC     | 49.71 ± 24.50 |

## CLINICAL OUTCOME



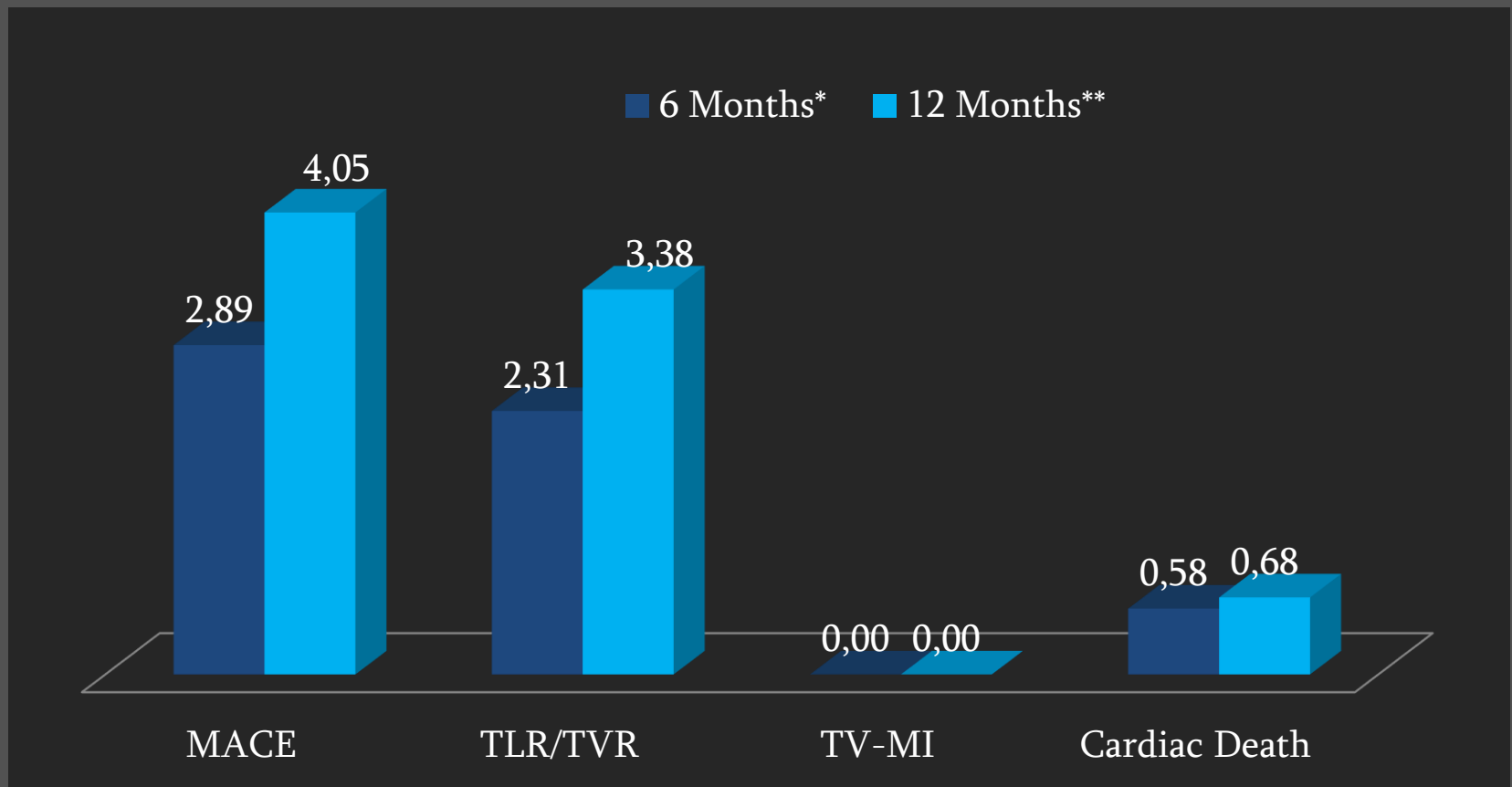
*\*386(94.6%) patients completed 6 months follow-up till March 2017.*

*\*\*347 (85%) patients completed 12 months follow-up till March 2017.*



# SCB IN DE-NOVO SMALL VESSEL (n=187)

## SAFETY AND EFFICACY AT 6 & 12 MONTHS

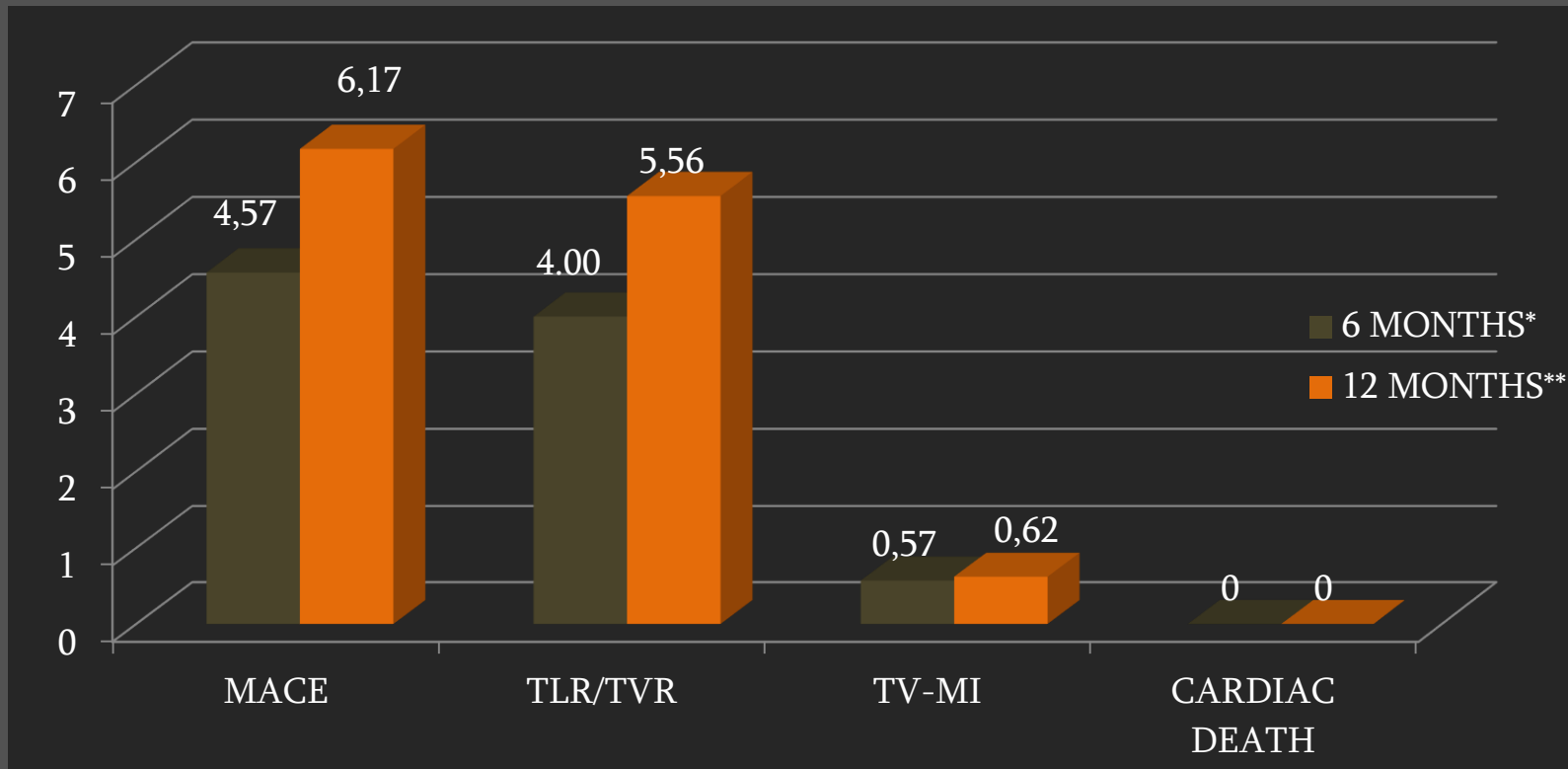


*\*173(92.51%) patients completed 6 months follow-up till March 2017.*

*\*\*148(79.14%) patients completed 12 months follow-up till March 2017.*

# SCB IN IN-STENT RESTENOSIS

## SAFETY AND EFFICACY AT 6 & 12 MONTHS



*\*175(96.15%) patients completed 6 months follow-up till March 2017.*

*\*\*162(89.01%) patients completed 12 months follow-up till March 2017.*

# limitations

- done in one type of (indian) population
- absence of independent source data analysis
- absence of independent event monitoring
- absence of an event adjudication committee



# 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.
- PI: B. Cortese



## CONCLUSION

SCB might constitute a new therapeutic option, considering the overall complexity of modern-era interventional cardiology.

The results of this registry, performed in indian patients, are encouraging, but deserve more complete clinical assessment in broader patients populations.

A synergistic DCB use with new-generation DES is intriguing.