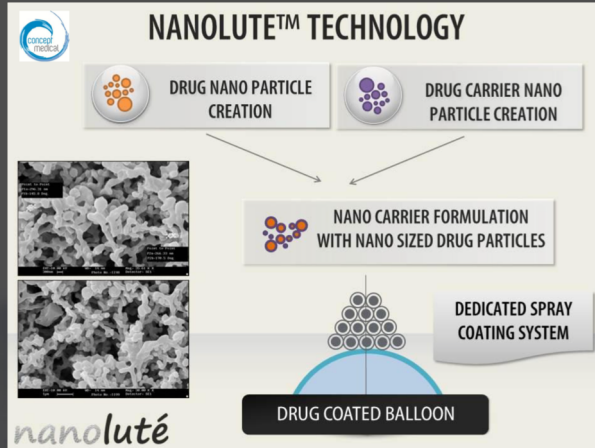




Magic Touch® Sirolimus-coated balloon

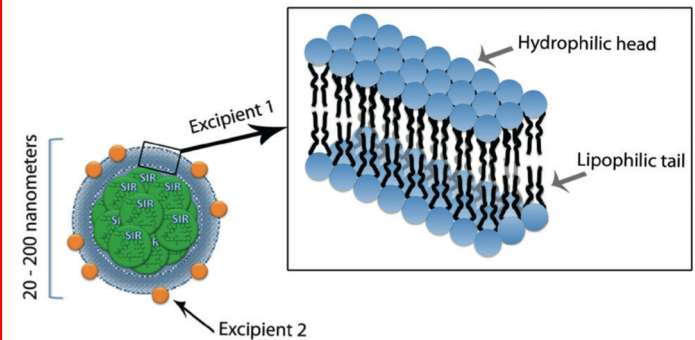


Encapsulation of
sirolimus

Protective pack

Increase
impermeability

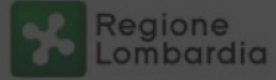
Phospholipid bilayer



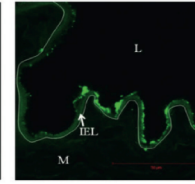
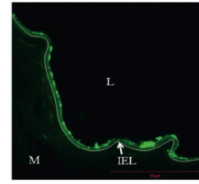
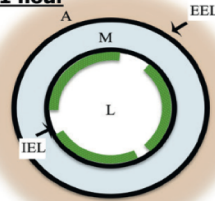
nanolute

sirolimus 'journey'

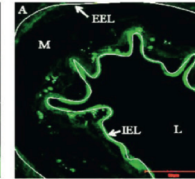
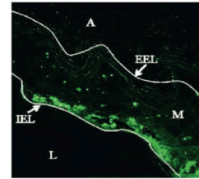
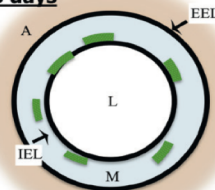
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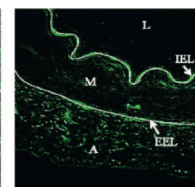
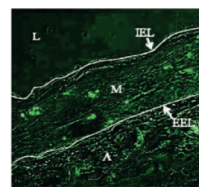
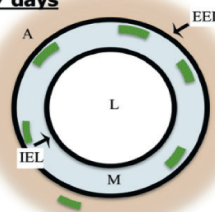
1 hour



3 days



7 days





A novel nanocarrier sirolimus-coated balloon for coronary interventions:
12-Month data from the Nanoluté Registry[☆]

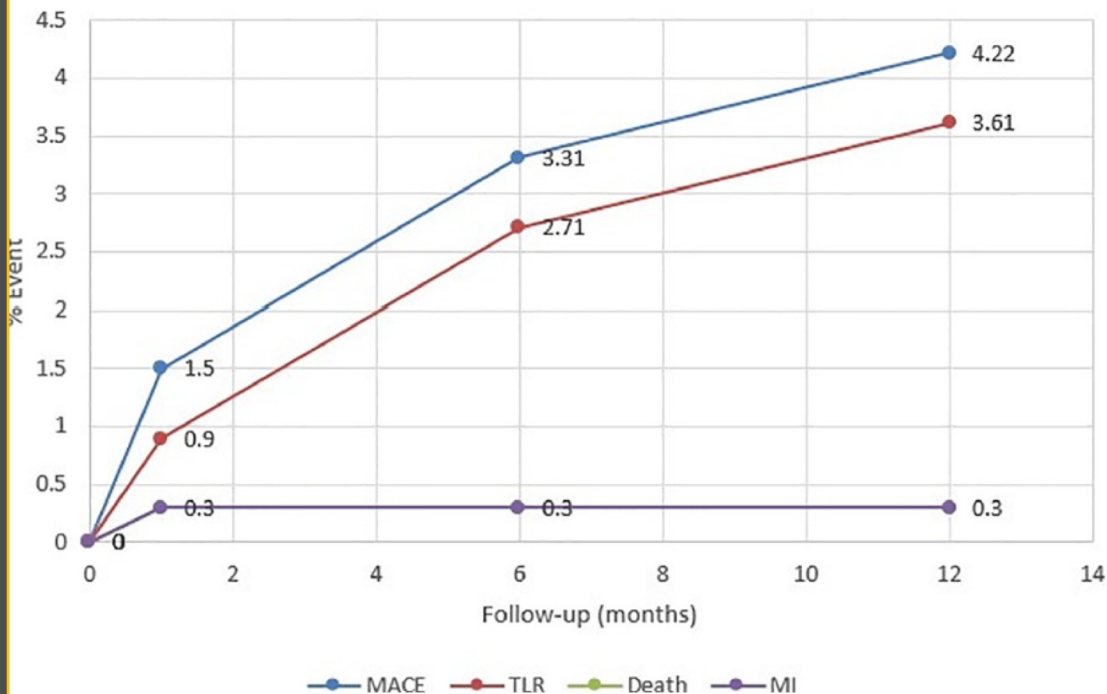
Sameer Dani^a, Dinesh Shah^b, Prakash Sojitra^c, Keyur Parikh^d, Ranjan Shetty^e,
Gaetano di Palma^f, Bernardo Cortese^{g,h,*}

Accreditata con il Servizio Sanitario Nazionale

Sistema Sanitario



Time-to-Event Chart for Major Adverse Cardiac Events (Cardiac Death, Myocardial Infarction, Target Lesion / Target Vessel Revascularization)



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

- all-comer prospective 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 6 months of follow up;
- we investigated the immediate technical and clinical performance of this device;
- PE: the occurrence of MACE at short term.

FASICO registry

n=32, lesions=34

Age, mean [SD] 68.56 [$\pm 9,45$]

Male gender, % 11

Diabete mellitus, % 38

ACS, % 32

ISR, % 47

ISR and failure of PCB 31

Moderate/severe calcifications 32

Multivessel disease 50

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, $\mu\text{g/l}$ (SD)	40 (21.6)
Angiographic success, %	100
Procedural success, %	100

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]

Follow up median, days

194 (38-335)

Mean diameter, mm

2.20 ± 0.68

MLD, mean SD

2.14 ± 0.7

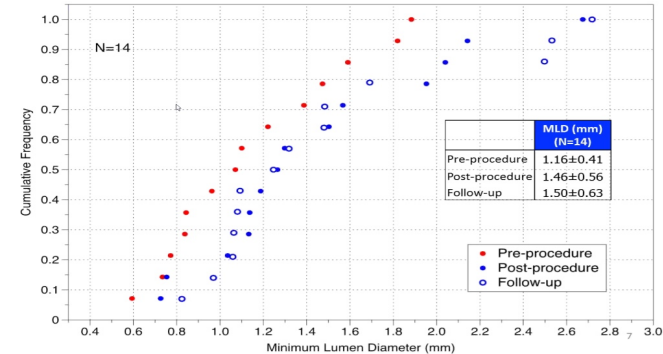
LLL, mean SD

0.09 ± 0.34

Binary restenosis, n (%)

2 (7.4)

Cumulative frequency distribution curves of Minimum Lumen Diameter





The EASTBOURNE Registry

the All-comers Sirolimus-coated Balloon eUROpean rEgistry



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
- External validation of quality of data input
- Centralised clinical event assessment
- Real world, all comers patients, consecutive enrollment
- 1500 patients at 30 european/asiatic sites
- Clinical follow up to 24 months.
- Primary Investigator B. Cortese,
- Chairman A. Colombo

Study endpoints



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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

Main Exclusion criteria



Sister

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EUROPEAN REGISTRY

- 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.

Enrollment - current status

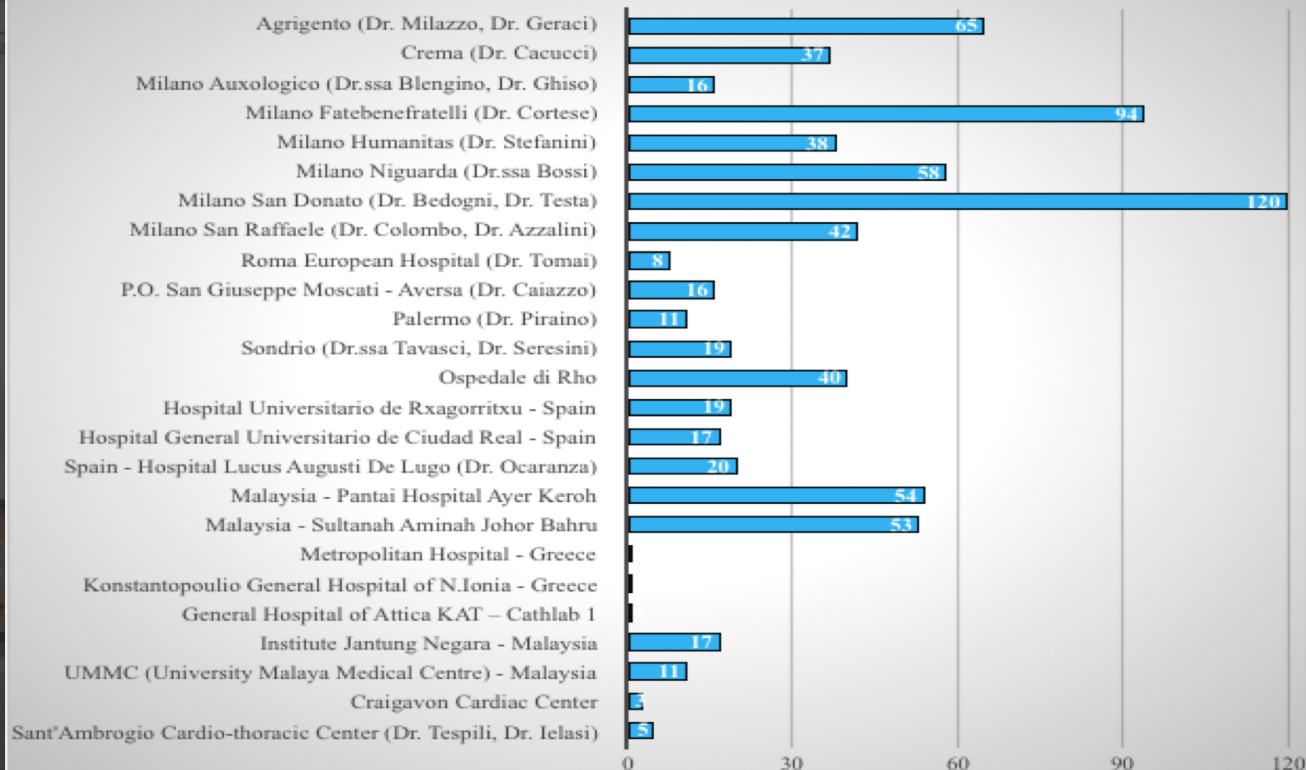
920 patients enrolled



Sister

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Enrolment per Site



August 2018: EASTBOURNE interim analysis



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EUROPEAN REGISTRY

Study population, n=710	N (%)
Age years, mean \pm SD	65.58 \pm 15.77
Female	141(19.85)
Arterial hypertension	504(70.98)
Diabetes mellitus	294(41.40)
Insulin-dependent diabetes mellitus	93(13.09)
Dyslipidaemia	478(67.32)
Congestive Heart Failure	47(6.61)
Multi-vessel disease	455(64.08)
LV Ejection Fraction, %, mean \pm SD	51.77 \pm 11.15
Previous MI	293(41.26)
Previous PCI	451(63.52)
Previous CABG	77(10.84)

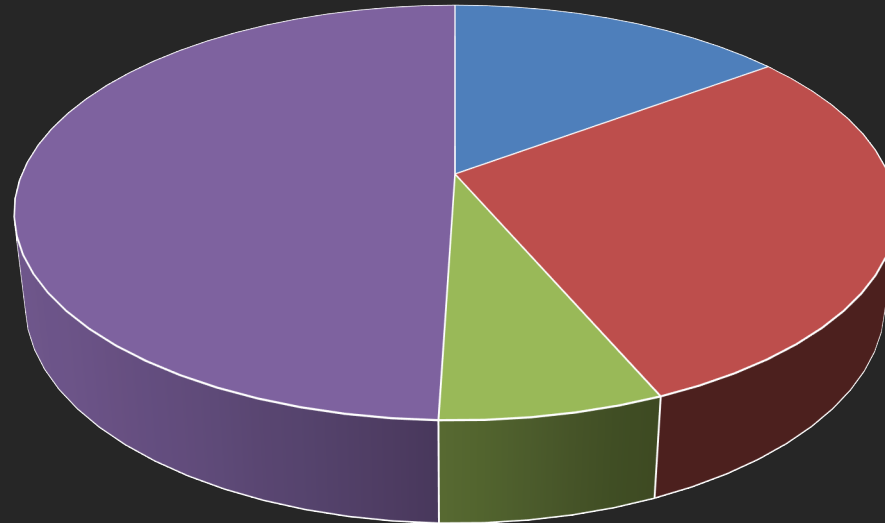
August 2018: EASTBOURNE interim analysis



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EUROPEAN REGISTRY

Clinical presentation



■ UA ■ NSTEMI ■ STEMI ■ Stable CAD

B. Cortese, TCT 2018

August 2018: EASTBOURNE interim analysis



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THE EASTBOURNE REGISTRY

MUS-COATED BALLOON
REGISTRY

Lesion and procedural Characteristics	N (%)
A	148(20.84)
B1	225(31.69)
B2	159(22.39)
C	116(16.33)
de-novo lesions, %	377(53.27)
ISR, %	275(46.73)
<i>Type of ISR according to Mehran's classification</i>	
Focal	127(46.18)
Diffuse	102(37.09)
Proliferative	32(11.63)
Occlusive	14(5.09)
BMS	43(15.63)
DES	225(81.81)
BVS	7(2.54)

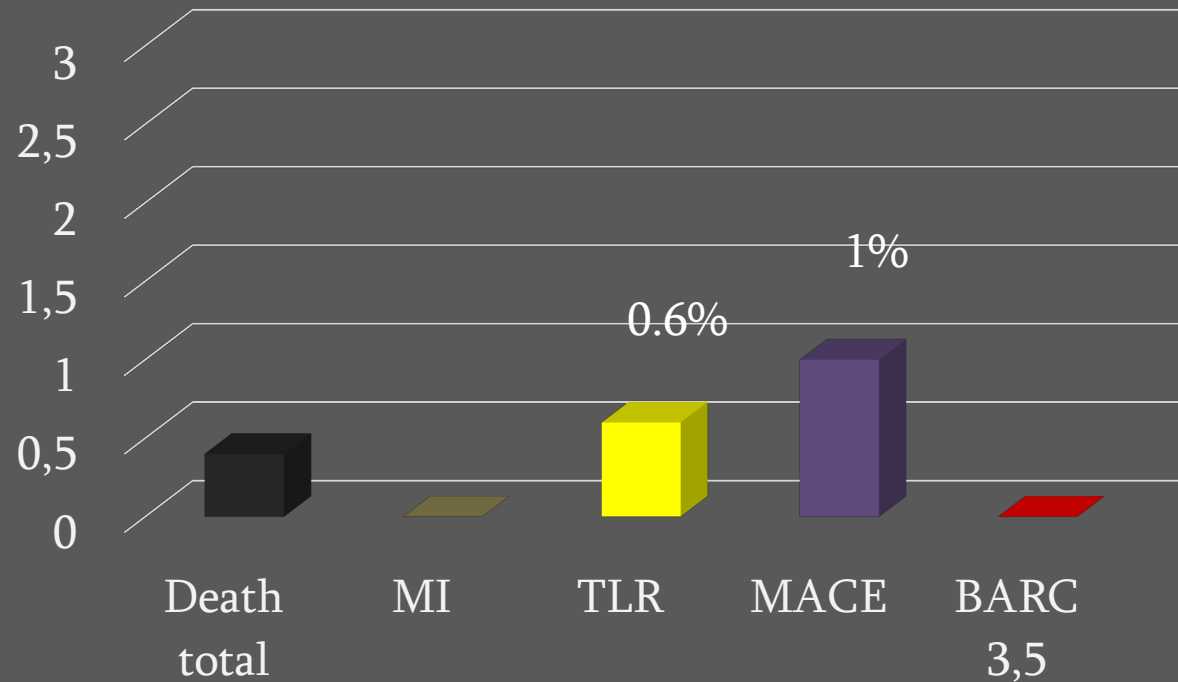
August 2018: EASTBOURNE interim analysis

Lesion and procedural Characteristics

Diameter stenosis pre, % \pm SD	92.18 \pm 11.82
RVD, mm \pm SD	2.83 \pm 2.73
Lesion length, mm \pm SD	18.41 \pm 8.84
MLD, mm \pm SD	0.68 \pm 0.73
Multi-vessel PCI	302(47.18)
Pre-dilatation	590(92.18)
Procedural complications	18(2.81)
Stenting after DCB use	54(8.43)
Angiographic success	628(98.125)
Device malfunction	0(0)
Diameter, mm	2.63 \pm 0.57
Length, mm	22.01 \pm 7.08
Inflation Time, sec	60.08 \pm 26.24
Inflation Pressure, atm	10.24 \pm 4.16

August 2018: EASTBOURNE interim analysis

1-month follow up, n=514



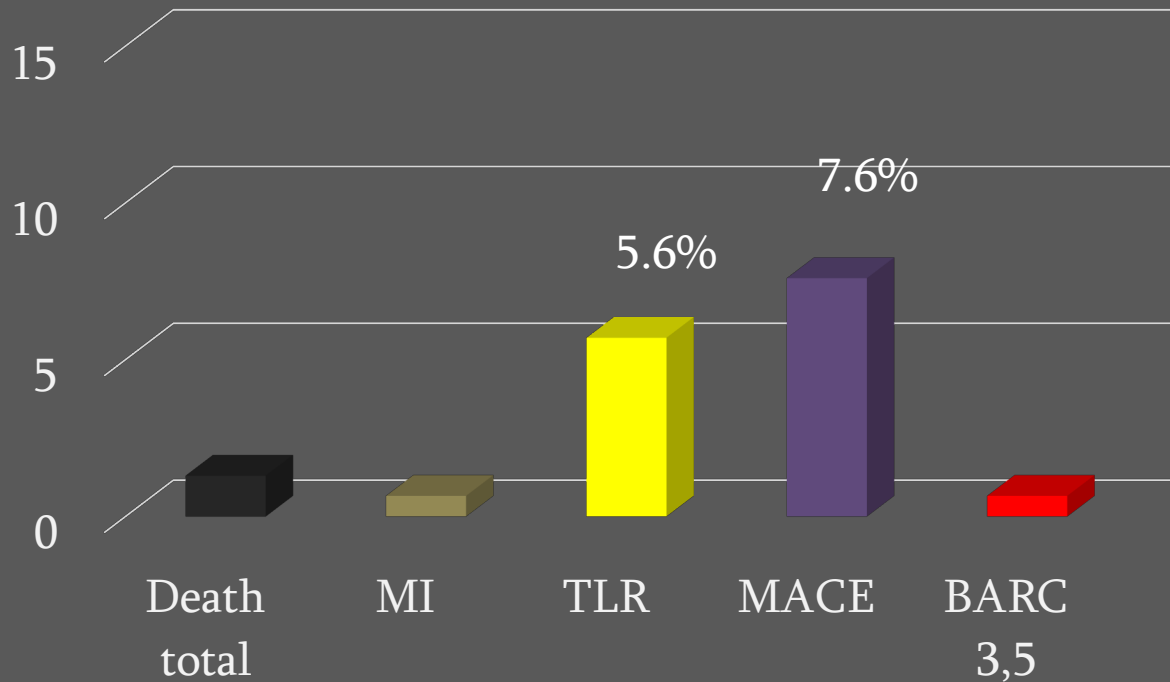
B. Cortese, TCT 2018

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August 2018: EASTBOURNE interim analysis

6-month follow up, n=300



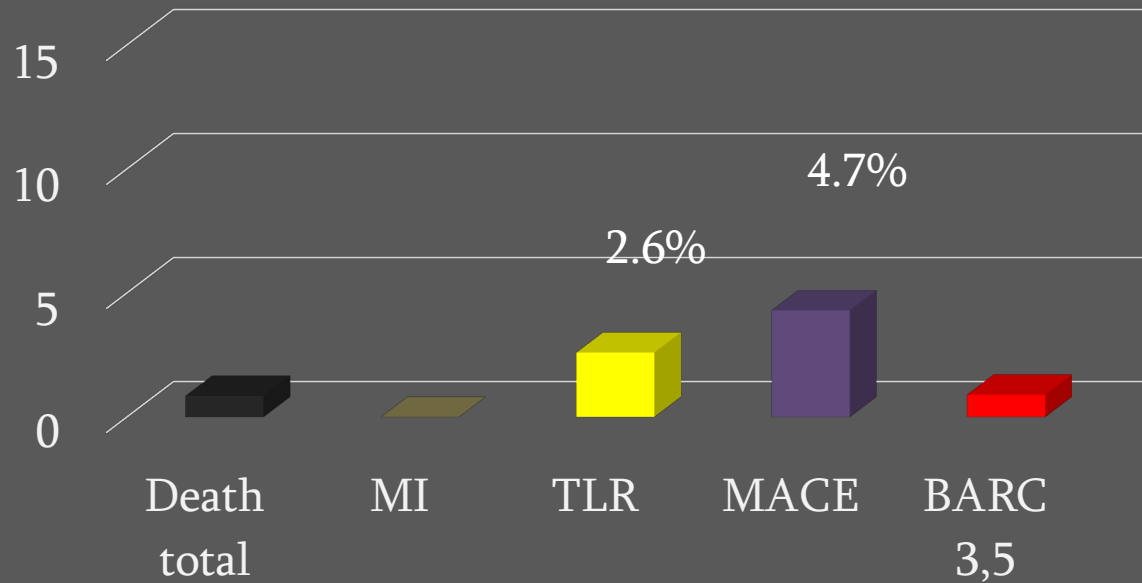
B. Cortese, TCT 2018

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EUROPEAN REGISTRY

August 2018: EASTBOURNE interim analysis

12-month follow up, n=117



Denver, TCT 2017



San Diego, TCT 2018



conclusions

- SCB might constitute a new therapeutic option in the setting of coronary lesions, also considering its improved deliverability.
- Preliminary retrospective and interim data seem to show the safety and efficacy of this therapeutic model.
- For this reason we decided to increase the population of EASTBOURNE from 1000 to 1500 patients, in order to better assess the primary efficacy endpoint of TLR.
- RCTs will be crucial to test the real efficacy of this device.