Confidence Through Evidence

MagicTouch

Sirolimus Coated Balloon

Going the extra mile; to ensure your smile.

#HelloFuture

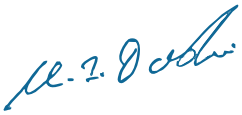
Acknowledgement

We, Concept Medical would like to extend our gratification to all individuals who have helped and inspired us throughout the conduct of all our registries. It is our privilege to express our heartfelt thanks to Dr. Sameer Dani, Chief Investigator of Nanolute Registry for his continued support. We are also honoured to take this opportunity to forward our gratitude and appreciate Dr. Bernardo Cortese, Principal Investigator of FASICO and EASTBOURNE registry, Dr. Alexandre Abizaid, Principal Investigator of BRAZIL-FIM. We are also glad to acknowledge Dr. Sandeep Basavarajaiah, Principal investigator of UK-SEB Registry for his constant source of encouragement and succour, which provided impetus and paved the way for the successful commencement of this clinical study. The current work would not have been possible without the expertise and guidance from all the scholarly investigators during these studies. In addition, they were always accessible and willing to help us with our research. We gratefully recognize and appreciate all the investigators for their zeal and constant encouragement throughout the course of these studies.

Finally, we must express our very profound gratitude to the whole team for providing the unfailing support and continuous invigoration throughout the process of research and writing this booklet.

The credit goes to all of our team and the keen investigators who have been a part of this journey.
This accomplishment would not have been possible without them.

For Concept Medical

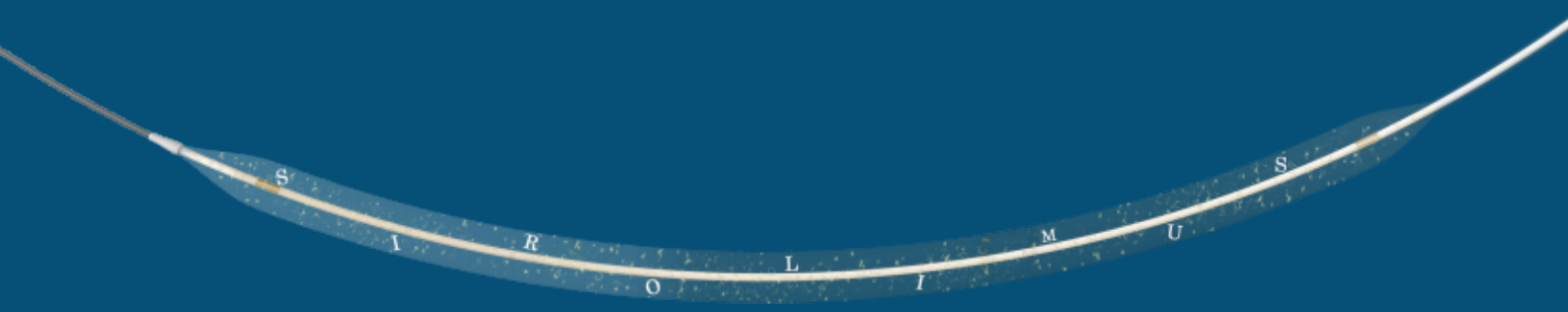


MANISH DOSHI
Managing Director

Overview of MagicTouch SCB

MagicTouch SCB is a Sirolimus Coated Balloon Catheter for Percutaneous Transluminal Coronary Angioplasty.
A CE approved product with approved indications like:

- In-Stent Restenosis (ISR);
- Small Vessels;
- Bifurcation Lesions.



TECHNOLOGY
An innovative proprietary Nanolute technology providing better bioavailability of the drug.

DRUG
A proven drug with a safe profile.

COATING
A uniform coating in the inflated position of the balloon catheter.

CARRIER
A phospholipid carrier which is biocompatible in nature.

CHALLENGES OF DELIVERING SIROLIMUS

1. LIPOPHILICITY OF SIROLIMUS

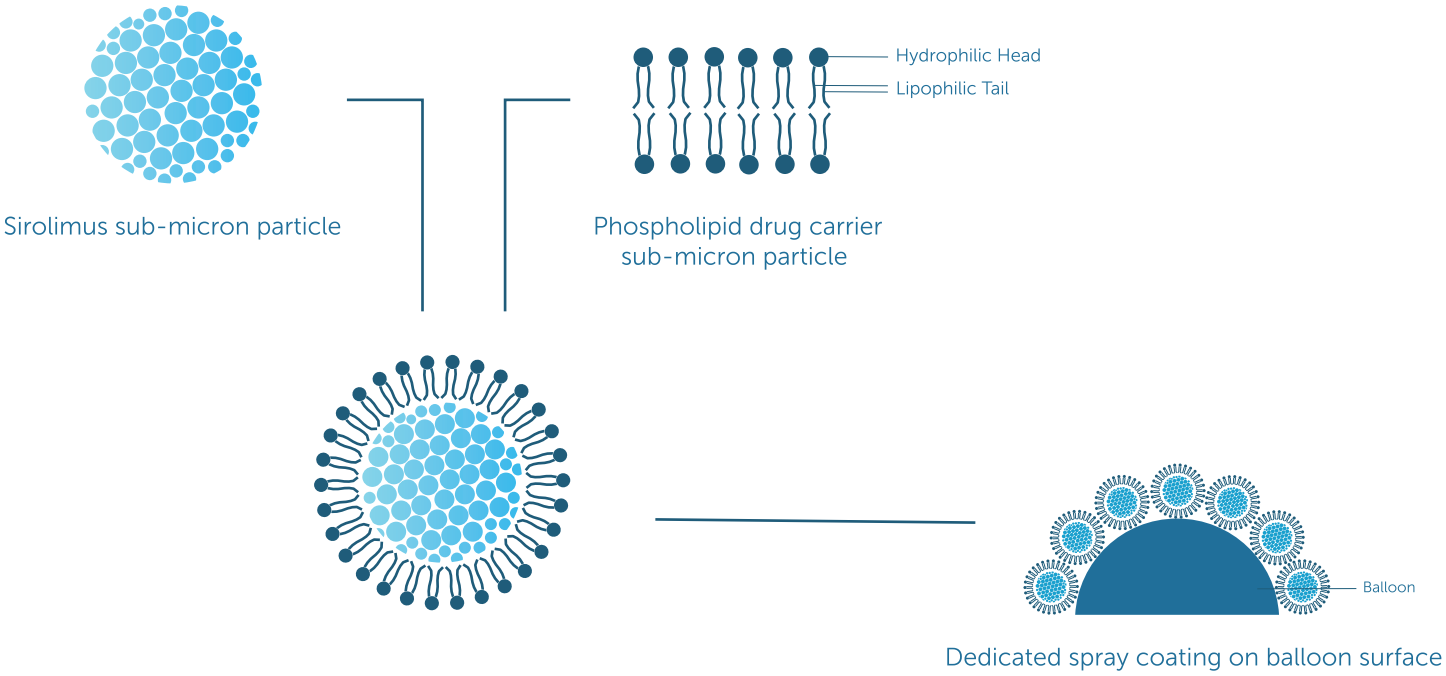
- Poor Lipophilicity
- Directly correlates to the adhesion property
- Difficult to coat on the balloon surface

2. BIOAVAILABILITY OF SIROLIMUS

- Poor Bioavailability
- Difficult to deliver in adequate concentration in-tissue
- Difficult longer tissue drug retention

Nanolute Technology

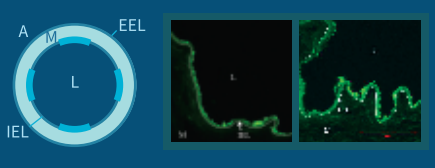
- Conversion of Sirolimus drug into sub-micron sized particles.
- Encapsulation of sub-micron sized Sirolimus drug into highly biocompatible drug carrier – Phospholipid.
- Phospholipid comprises of one hydrophilic head and two lipophilic tails, which improves adhesion property of encapsulated Sirolimus.
- Drug carrier along with drug is coated on the unfolded balloon to achieve 100% coating on balloon surface.
- Unique and proprietary refolding mechanism facilitates better crossing profile.
- Upon inflation of MagicTouch SCB at target site, drug carrier with Sirolimus drug inside gets transferred to the vessel wall following the principle of co-efficient diffusion.
- Upon body PH variation, drug carrier mimics the body lipids and liberates Sirolimus.
- The sub-micron sized Sirolimus drug particles penetrate the deepest layer of the vessel over a period.



SIROLIMUS DISTRIBUTION STUDY

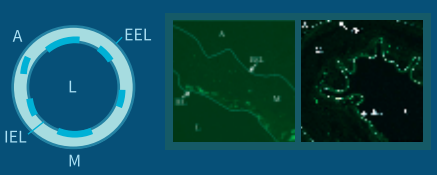
DTF labelled Sirolimus was used to study the drug distribution following DCB treatment*

1 HR



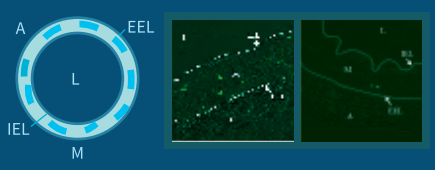
Presence of drug in tissue layer
Intima

DAY 3



Presence of drug in tissue layer
Media

DAY 7



Presence of drug in tissue layer
Adventitia

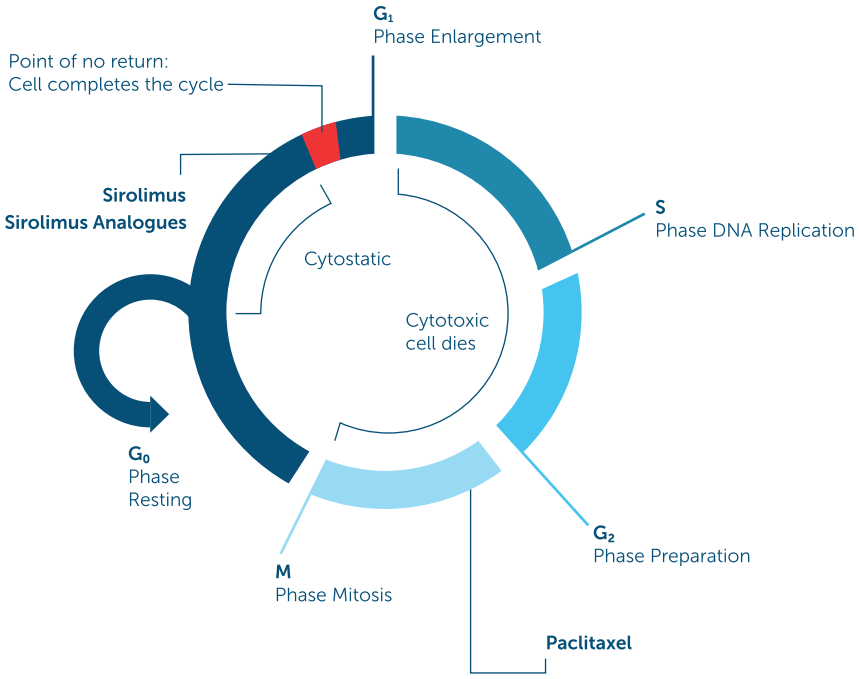
A: Adventitia; EEL: External Elastic Lamina; IEL: Internal Elastic Lamina; L:Lumen; M: Media
**EuroIntervention. 2013 May 20;9(1): 148-56*

Why Sirolimus?

Sirolimus and Paclitaxel Drugs are the players in the cardiovascular Devices. The compound and its pharmacologic properties hold a major key for the safety and efficacy of DCB.

- Sirolimus drug is cytostatic drug with immunosuppression action whereas Paclitaxel drug is cytotoxic drug (also considered as antineoplastic/anticancer).
- Both compounds show inhibition of the cell cycle but have different modes of action.
- Sirolimus restrains the degradation of cyclin-dependent kinase inhibitor (CKI) that plays crucial role for VSMC cycle regulation, which represents the initial phase of the cell cycle.
- In contrast to Sirolimus, Paclitaxel impacts predominantly during the mitosis (M) phase of cell cycle through centrosomal impairment, induction of abnormal spindles, and suppression of spindle microtubule dynamics.

Paclitaxel arrests cells at a stage at which they are supposed to divide, pro-apoptotic mechanisms are likely to occur, thus eventually leading to apoptotic cell death.



Attribute	Limus	Paclitaxel
Mode of action	Cytostatic	Cytotoxic
Margin of safety	10,000 fold	100 fold
Anti-restenosis	Optimal	Good
Tissue absorption & elution	More difficult	Easier
Level of competition	Low	Very high
Cardiologist perception	Positive	Controversial

Extensive Clinical Programs

Study Name	Type of Study	Target Patients	Country	Status
NANOLUTE	Prospective Multicenter, Real world	450 Patients	INDIA	Enrolment completed Interim data available
FASICO	Prospective Single arm, Single center	32 Patients	ITALY	Study completed with 6 months data available
BRAZIL FIH	Brazil first in man, Non-randomized study	30 Patients	BRAZIL	Enrolment completed Interim data available
EASTBOURNE	Prospective, Multicenter, Spontaneous, Clinical registry	2000 Patients	GLOBAL	Enroling
RETROSPECTIVE UK	Retrospective, Single center, Single arm study	153 Patients	UK	8 months data available
UK SEB REGISTRY	Prospective, Multicenter, Spontaneous, Clinical registry	500 Patients	UK	Enroling

UPCOMING CLINICAL TRIALS

Study Name	Type of Study	Target Patients	Country
TRANSFORM I	Prospective, randomized multicenter study	114 Patients	ITALY and UK
TRANSFORM II	Prospective, multicentric, spontaneous, International, open label randomized clinical registry	190 Patients	ITALY, UK, POLAND and BRAZIL

NANOLUTE STUDY

Nanolute Study

Principal Investigator:
Dr. Sameer Dani,
Life Care Institute of Medical Sciences and Research and Apollo hospitals, Ahmedabad, India

Co-Investigators:
Dr.Keyur Parikh[1], Dr.Hemang Baxi[1], Dr.Urmil Shah[1], Dr.Ranjan Shetty[2], Dr.Prathap Kumar[3], Dr.Jagdish Hiremath[4], Dr. V Surya Prakash Rao[5], Dr. P. L. N. Kapardhi[5], Dr. Apurva Vasavada[6], Dr. Prabhakar Shetty[7], Dr.Karthik Vasudevan[7]

1. Care Institute of Medical Sciences, Ahmedabad, India. 2. Kasturba Medical College, Manipal, Mangalore, India. 3. Meditrina Hospitals, Pattom, Trivandrum, India. 4. Ruby Hall Clinic, Pune, India. 5. Apollo Hospitals, Hyderabad, India 6. Care Hospitals & Tristar Hospital, Surat, India. 7. Columbia Asia Hospital, Bengaluru, India

STUDY DETAILS

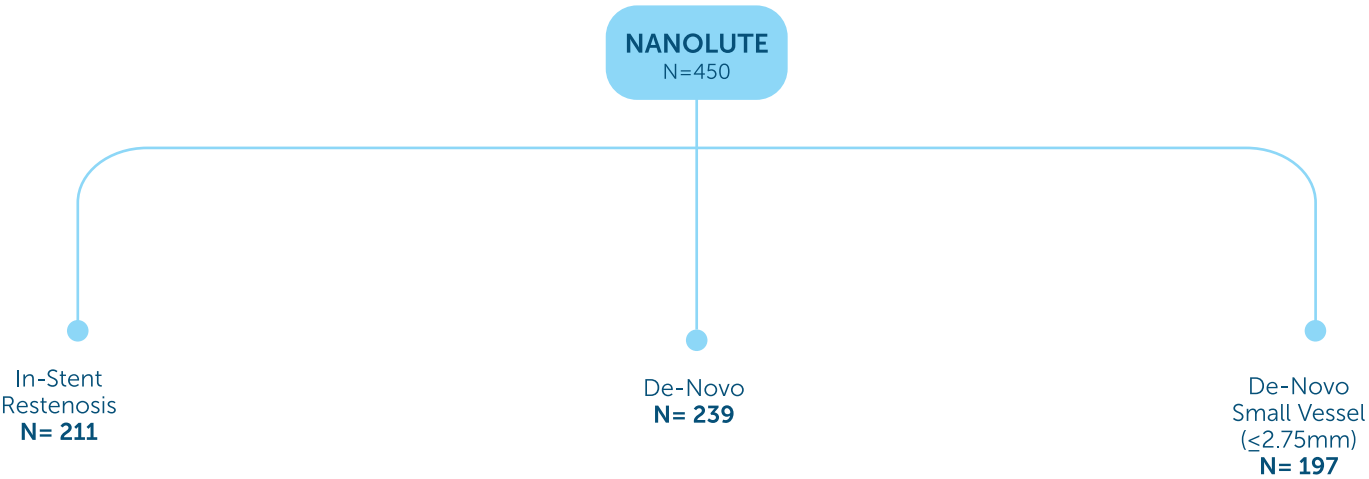
Objective
To evaluate the safety and efficacy of MagicTouch Sirolimus Coated Balloon in the patients with coronary artery disease.

Study Design
Prospective, multicenter clinical registry enroling real world, all-comers patient from the routine clinical practice at various interventional cardiology sites in India. All patients have clinical follow-up at 1 month, 6 months, 1 year and 2 years.

ENDPOINTS

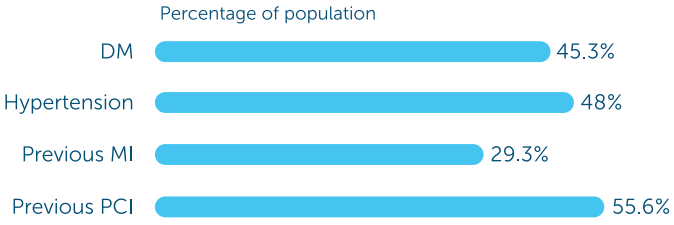
Primary Endpoint
Major Adverse Cardiac Event (MACE); a composite of Cardiac Death, Target Vessel Myocardial Infarction (TV-MI) and Target Lesion/Vessel Revascularization (TLR/TVR) at 6 months.

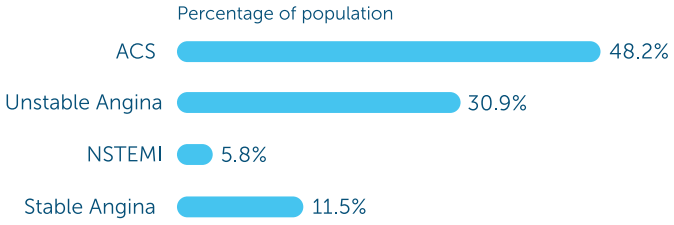
Secondary Endpoint
MACE at 1 year.



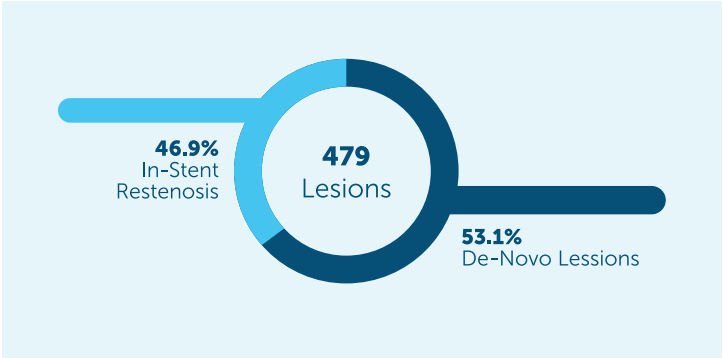
RESULTS

Complex real-world patients
No. of patients, N=450





Types of lesions
No. of lesions=479

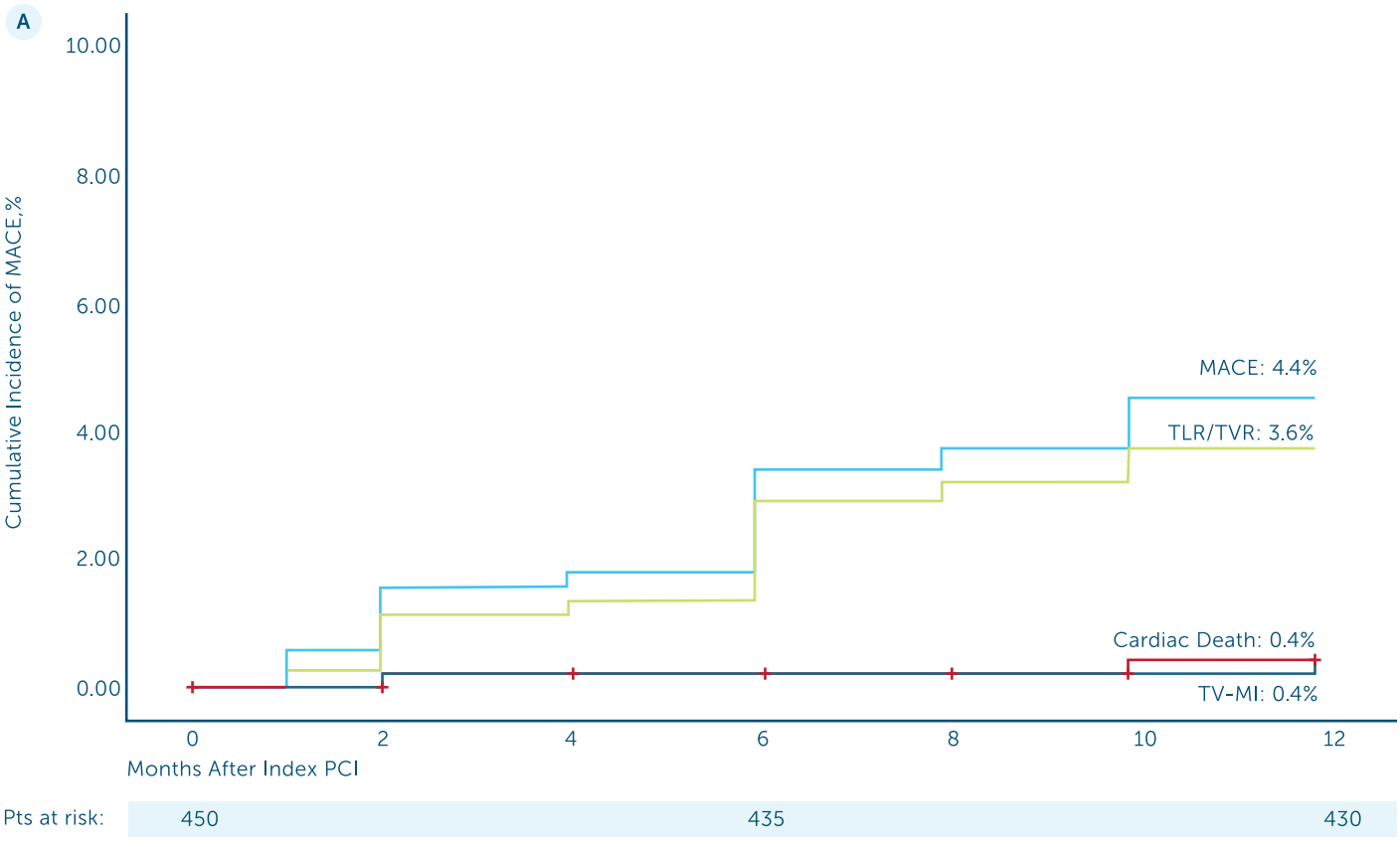


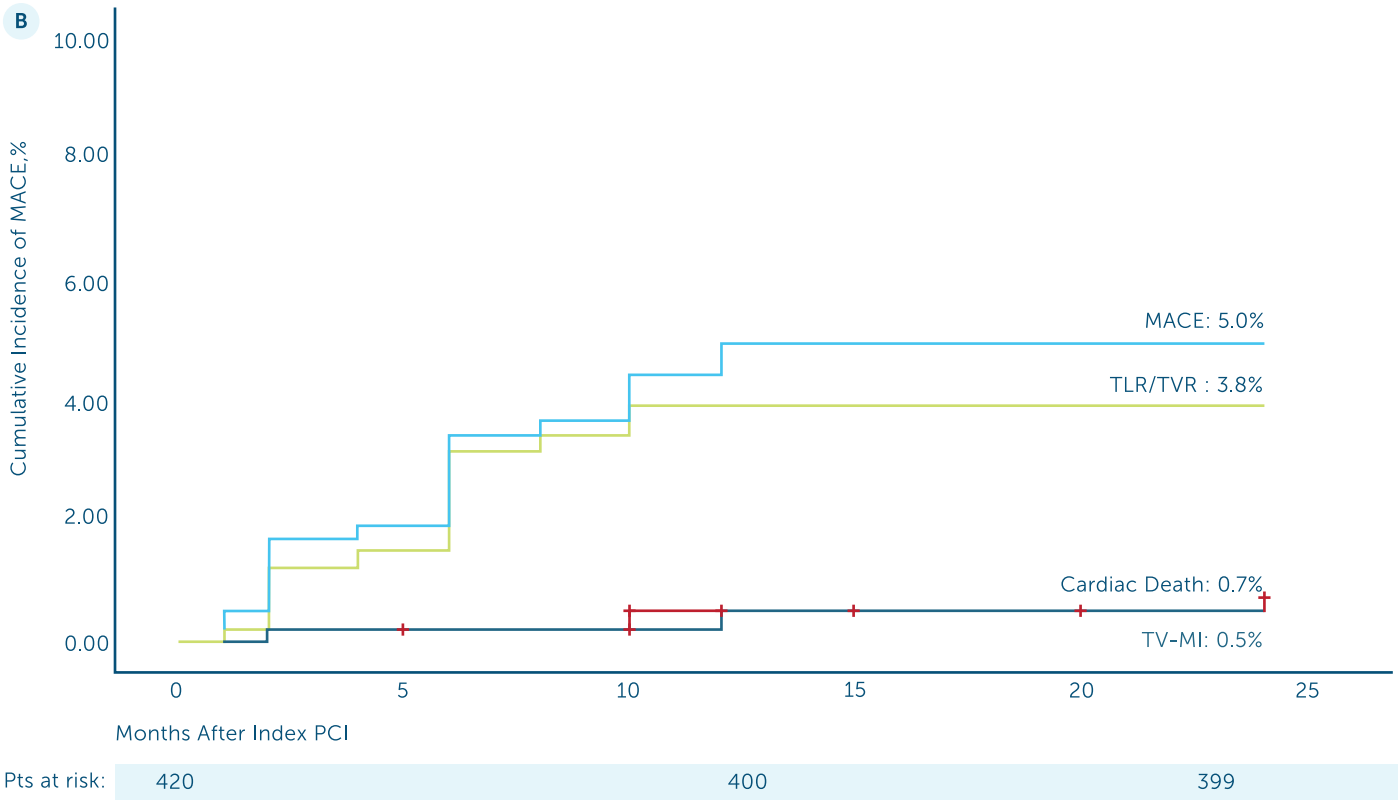
Procedure details
No. of devices: 534

Procedural Characteristics	
Device per patient	1.2
SCB Alone therapy, %	92.2
SCB+ Additional Treatment, %	7.8
Procedural Success, %	99.6
Vessel dissection, %	0.4

SCB Characteristics (mm ± SD)	
Mean length	22.6 ± 7.5
Mean diameter	2.7 ± 0.5

Time-to-event curve for MACE through 2 years





The event rates presented here were calculated by Kaplan–Meier methodology. Kaplan-Meier cumulative incidence curve (A). At 1-year for the MACE and (B). At 2-years for the MACE.

Parameters, N (%)		Hazard Ratio	95.0% CI for Exp(B)		p-Value
			Lower	Upper	
DM	204(45.3)	1.075	0.415	2.786	0.882
--NO-DM	246(54.7)				
HT	216(48.0)	0.962	0.371	2.492	0.936
--NON-HT	234(52.0)				
ACS	217(48.2)	1.548	0.589	4.067	0.375
--NO-ACS	233(51.8)				
SA	205(45.6)	0.832	0.317	2.186	0.709
--NON-SA	245(54.4)				
SMALL VESSEL	172(38.2)	0.669	0.236	1.900	0.451
--LARGE VESSEL	278(61.8)				
ISR	211(46.9)	1.629	0.620	4.280	0.322
--NON-ISR	239(53.1)				

Conclusion

In the present study, MagicTouch Sirolimus Coated Balloon demonstrated promising rates of MACE at 1 year. A similar trend was shown throughout 2 years.

Logistic Regression performed for confounding factors reveal that hypertension, DM, ACS, stable angina, small vessel and ISR are not strongly associated with increased incidence of MACE.

IN-STENT RESTENOSIS

PROMISING CLINICAL OUTCOMES IN CHALLENGING SUB-GROUP

Magictouch SCB in In-Stent Restenosis

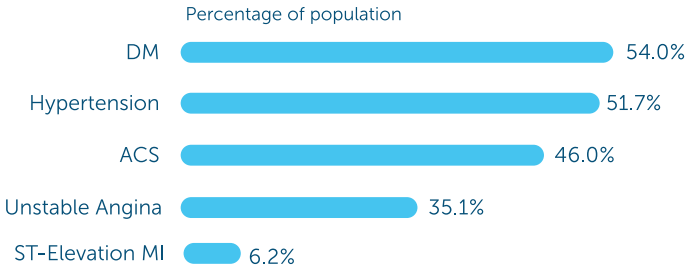
In-Stent Restenosis (ISR) has been a major drawback with Percutaneous Coronary Intervention (PCI). Although the use of coronary stents brought a dramatic improvement in patients' clinical and procedural outcomes, the long-term outcome of stent implantation remains significantly constrained by the risk of developing ISR. The Drug Coated Balloons (DCB) may be an attractive option in the management of ISR lesions.

In NANOLUTE, 211 patients presented with in-stent restenotic lesions. Total 225 ISR lesions were treated with 258 MagicTouch SCB. The baseline characteristics, lesion and procedural details and clinical outcomes are presented as under:

RESULTS

Complex real-world patients

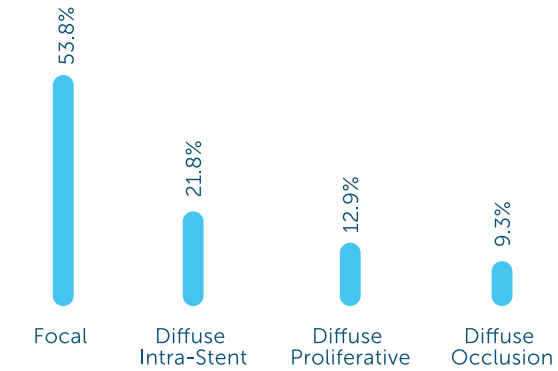
No. of patients=211



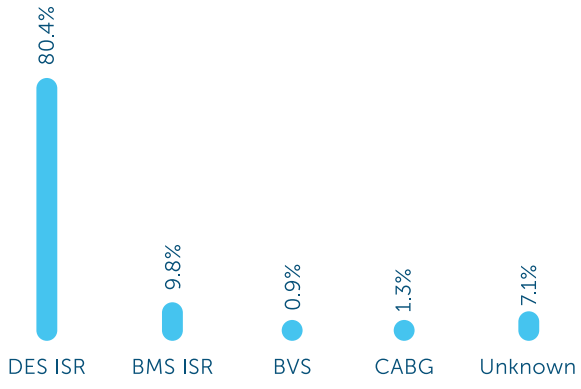
Types of ISR

No. of lesions: 225

According to Mehran's classification



Type of stent associated with ISR



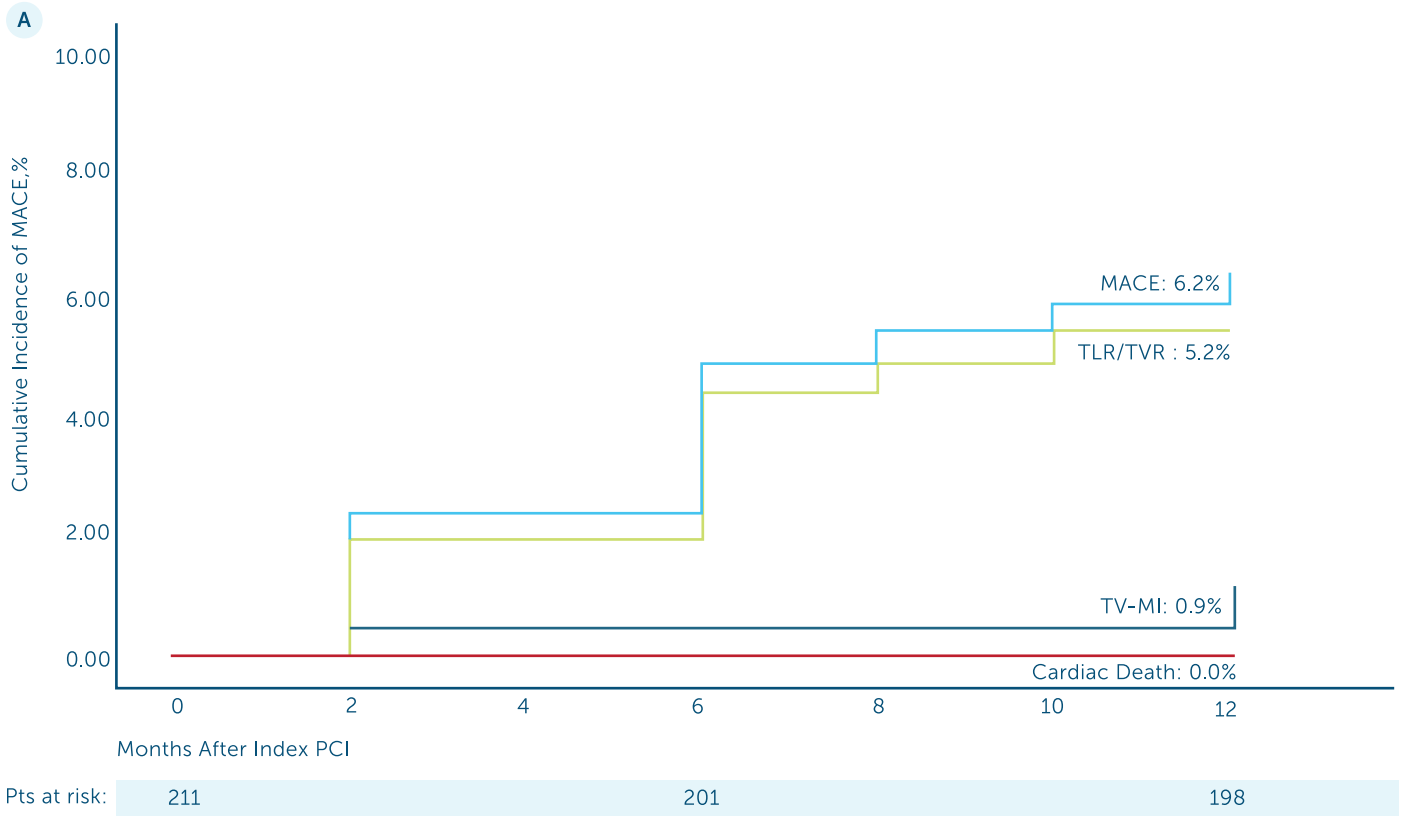
Procedure details

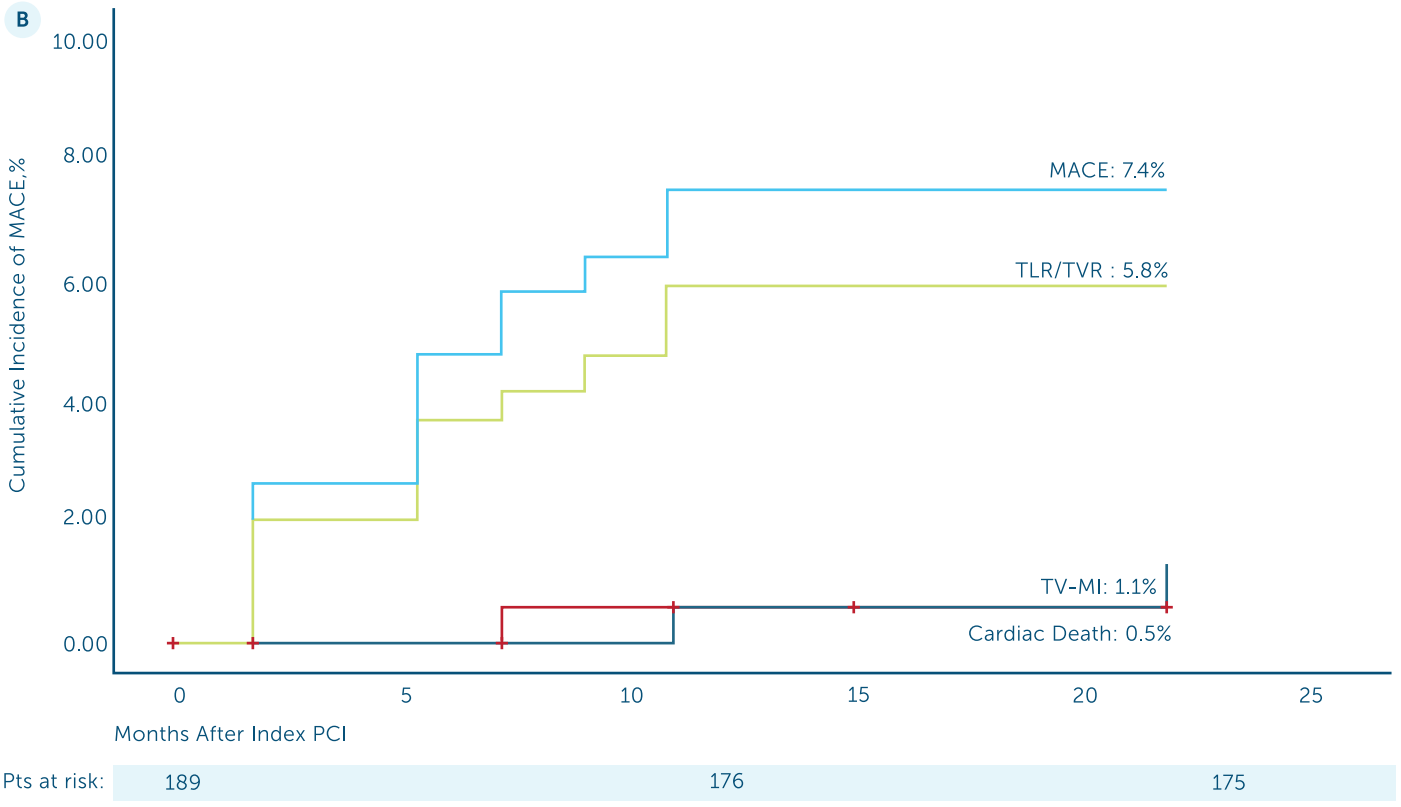
No. of devices: 258

Procedural Characteristics	
Device per patient	1.2
SCB Alone therapy, %	91.9
SCB+ Additional Treatment, %	8.1
Procedural Success, %	99.5
Vessel dissection, %	0.5

SCB Characteristics (mm ± SD)	
Mean length	23.0 ± 7.6
Mean diameter	2.9 ± 0.4

Time-to-event curve for MACE through 2 years

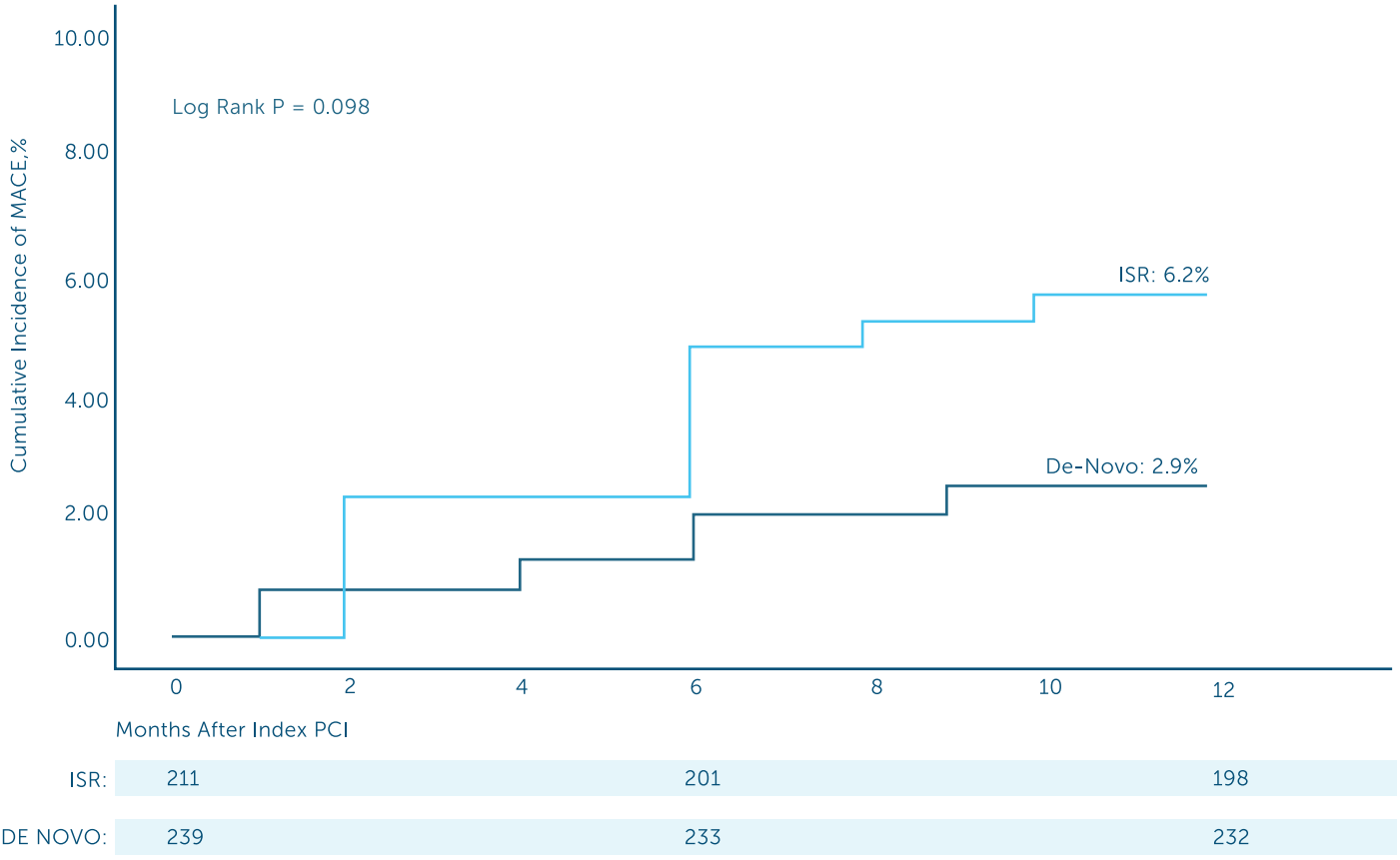




The event rates presented here were calculated by Kaplan–Meier methodology. Kaplan-Meier cumulative incidence curve (A). At 1-Year for the MACE and (B). At 2-Years for the MACE.

Time-to-event curve for MACE for the patients with ISR vs. De-Novo lesion through 1 year

Patients were stratified as per the types of lesions they presented. 211 patients had ISR lesions while rest of 239 patients had De-Novo lesions. The comparison between both cohorts are presented in terms of MACE in the curve below:



ISR:	211	201	198
DE NOVO:	239	233	232

Time-to-event curves for the components of MACE through 1-year. The event rates presented here were calculated by Kaplan–Meier methodology and compared with the log-rank test.

Conclusion

The analysis suggests that MagicTouch SCB is safe and effective in treating patients with ISR and results in reduced revascularization rates up to 2 years.

No significant difference between ISR and De-Novo cohort suggests that MagicTouch SCB is effective and safe in treating ISR as well as De-Novo coronary lesions.

DE-NOVO SMALL VESSEL (≤2.75mm)

PROMISING CLINICAL OUTCOMES
IN CHALLENGING SUB-GROUP

Magictouch SCB in De-Novo Small Vessel

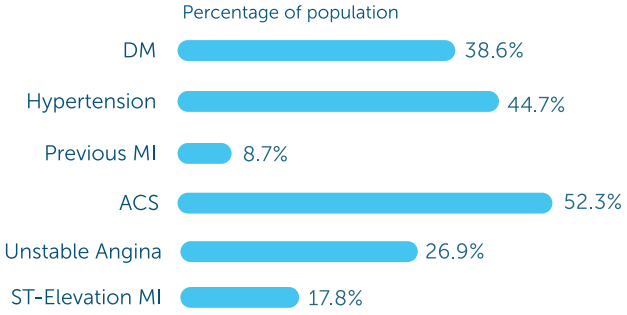
PCI of small coronary vessels (≤2.75mm) represents a challenge for myocardial revascularization, because of the high-risk of stent restenosis and the increased risk of adverse clinical events. This is because of the limited ability of the vessel to adapt to neointima formation that might develop after stent implantation. Vessel size is inversely correlated with the risk of restenosis and adverse outcome after Percutaneous Coronary Interventions. DCBs may be advantageous in this (small vessel) setting.

In NANOLUTE study, 197 patients had 205 lesions located in small coronary arteries (≤2.75mm) The baseline characteristics, lesion and procedural details and clinical outcomes are presented as under:

RESULTS

Complex real-world patients

No. of patients=197 (≤2.75mm)



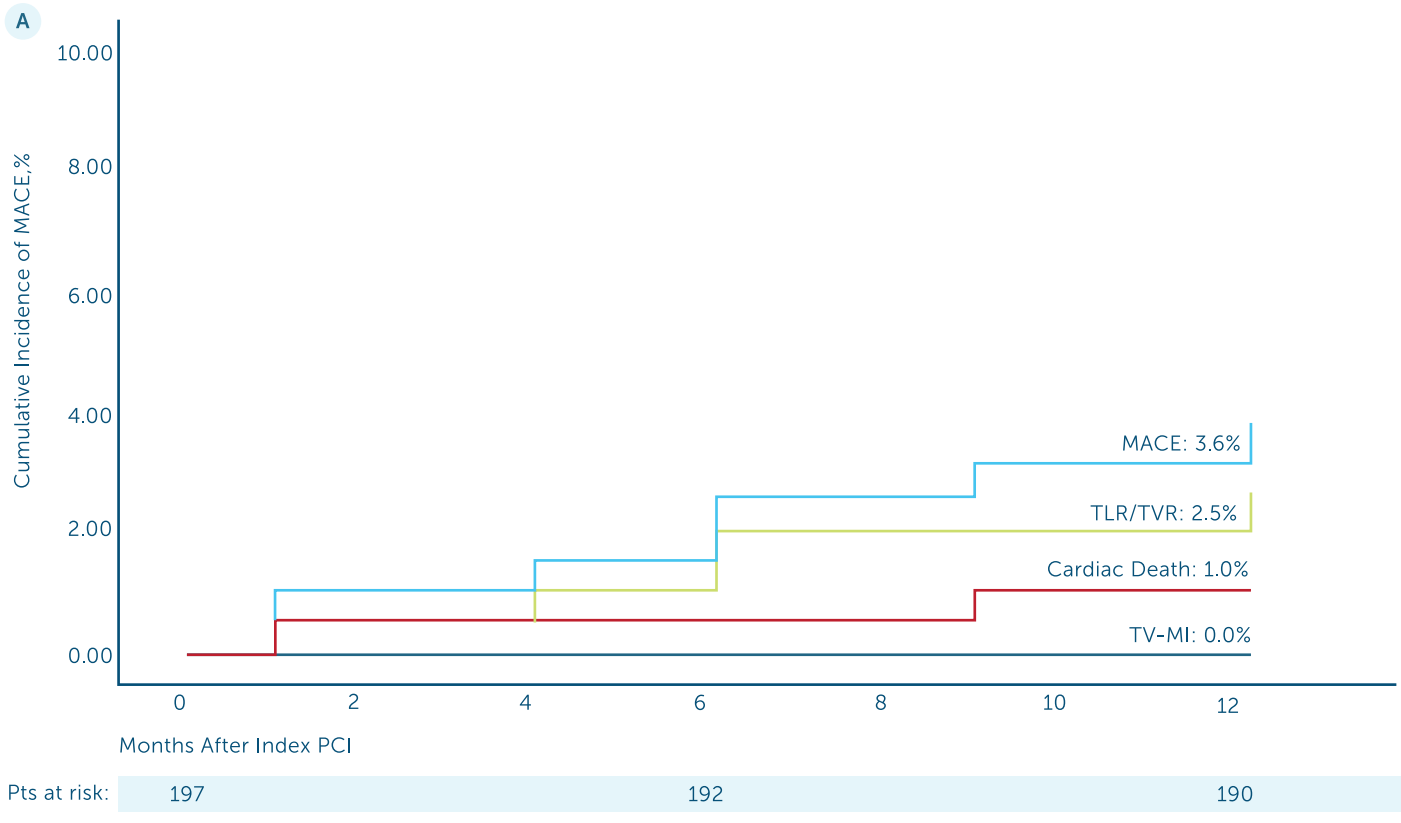
Procedure details

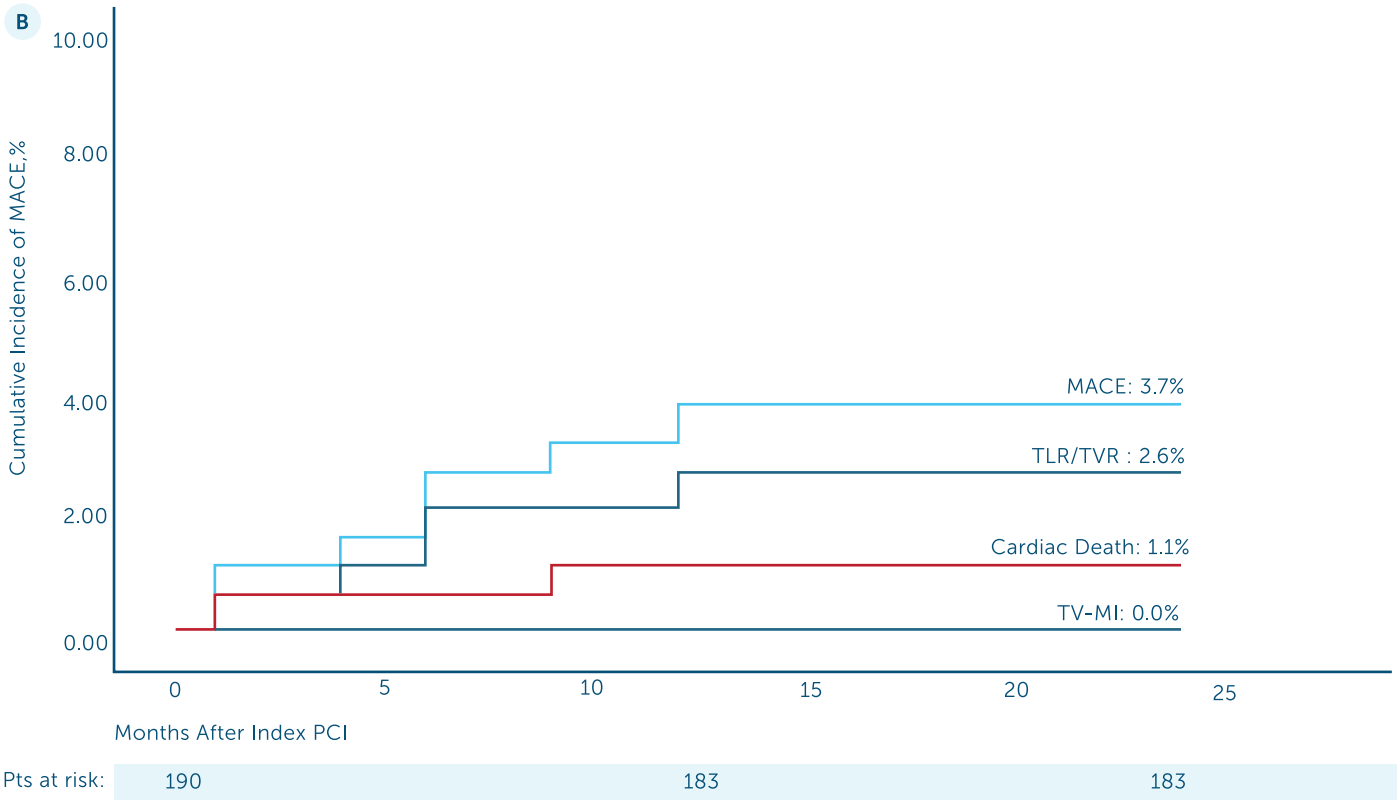
No. of devices: 217

Procedural Characteristics	
Device per patient	1.1
SCB Alone therapy, %	92.4
SCB + Additional treatment, %	7.6
Procedural success, %	99.4
Vessel dissection, %	0.6

SCB Characteristics (mm ± SD)	
Mean Length	22.0± 7.6
Mean Diameter	2.3 ± 0.2

Time-to-event curve for MACE through 2 years





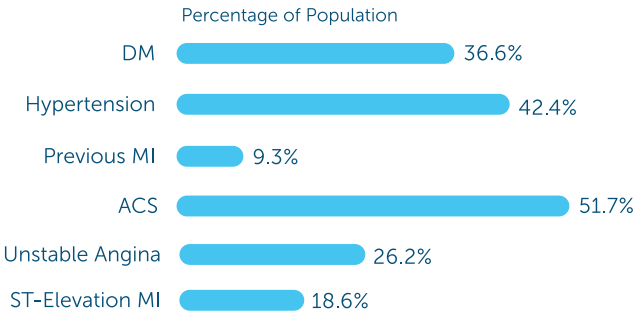
The event rates presented here were calculated by Kaplan–Meier methodology. Kaplan-Meier cumulative incidence curve (A). At 1 year for the MACE and (B). At 2 years for the MACE

Among 197 patients, 172 patients had 183 lesions located in small coronary arteries (≤2.5mm).
The baseline characteristics, lesion and procedural details and clinical outcomes are presented as under:

RESULTS

Complex real-world patients

No. of patients=172 (≤2.5mm)



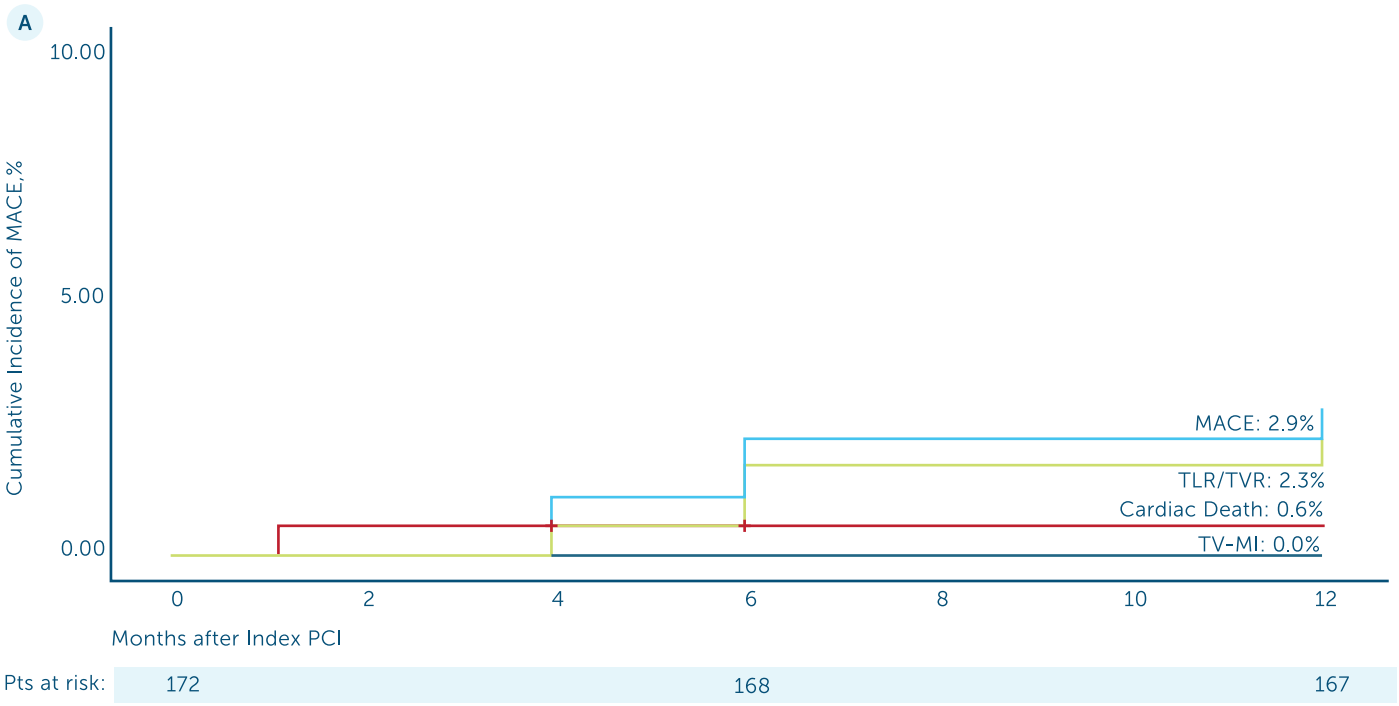
Procedure details

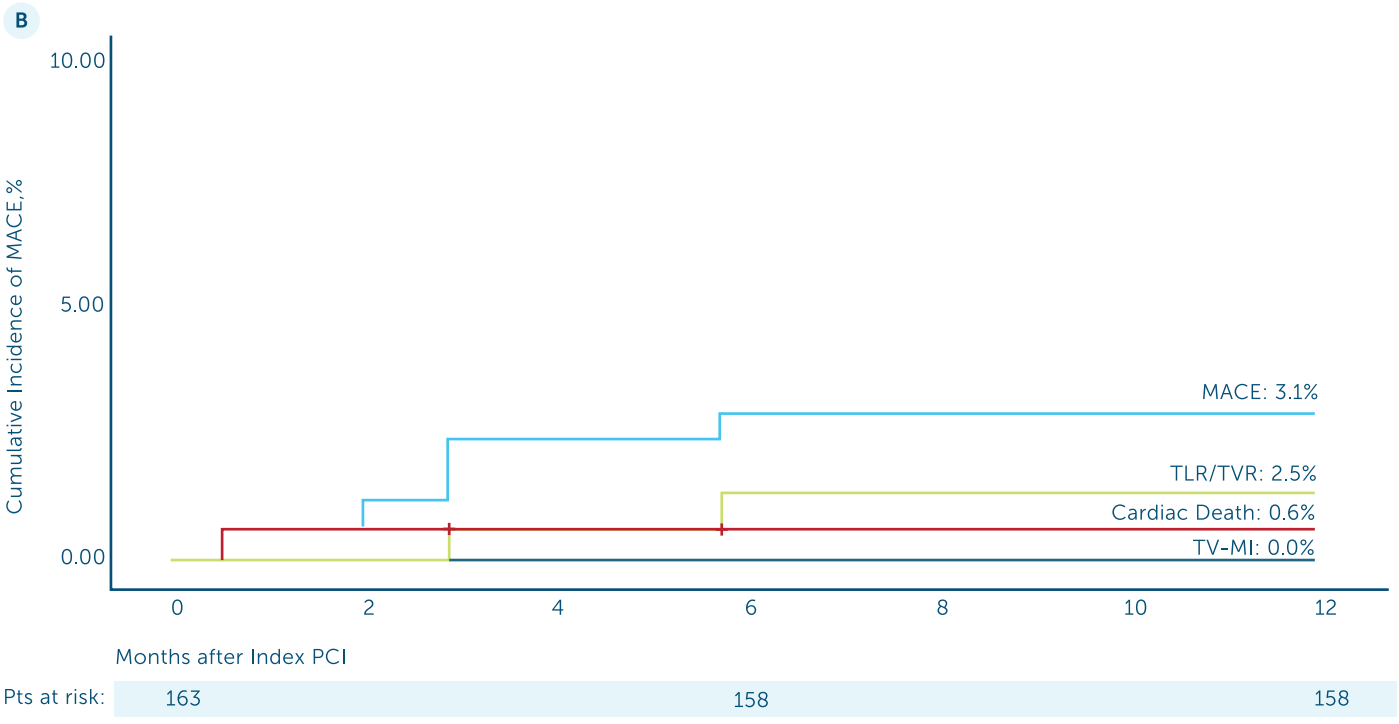
No. of devices: 189

Procedural Characteristics	
Device per patient	1.1
SCB Alone therapy, %	92.4
SCB+ Additional treatment, %	7.6
Procedural success, %	99.4
Vessel dissection, %	0.6

SCB Characteristics (mm ± SD)	
Mean length	22.0 ± 7.6
Mean diameter	2.3 ± 0.2

Time-to-event curve for MACE through 2 years





The event rates presented here were calculated by Kaplan–Meier methodology. Kaplan-Meier cumulative incidence curve (A). At 1 year for the MACE and (B). At 2 years for the MACE

Conclusion

MagicTouch SCB is found to be safe and efficacious in treating the lesions located in small coronary vessels up to 2 years of clinical follow-up.

FASICO

THE FATEBENEFRATELLI SIROLIMUS COATED-BALLOON

FASICO

IMMEDIATE AND SHORT-TERM PERFORMANCE OF A NOVEL SIROLIMUS-COATED BALLOON DURING COMPLEX PERCUTANEOUS CORONARY INTERVENTIONS

Principal Investigator:
Dr. Bernardo Cortese,
Unità Operativa di Cardiologia,
ASST Fatebenefratelli-Sacco, Milano, Italy

STUDY DETAILS

Objective
The aim of the study was to demonstrate the acute performance and the 6-month.Efficacy and safety of this device in a real-world, complete population

Study Design
The FAtebenefratelli SIrolimus COated-balloon (FASICO) is an all-comer prospective registry of the first consecutive patients, who had at least one lesion treated with SCB between April and July 2016 at the first European centre. The aim of the study was to demonstrat the acute performance and the 6-month efficacy and safety of this device in a real world, complex population.

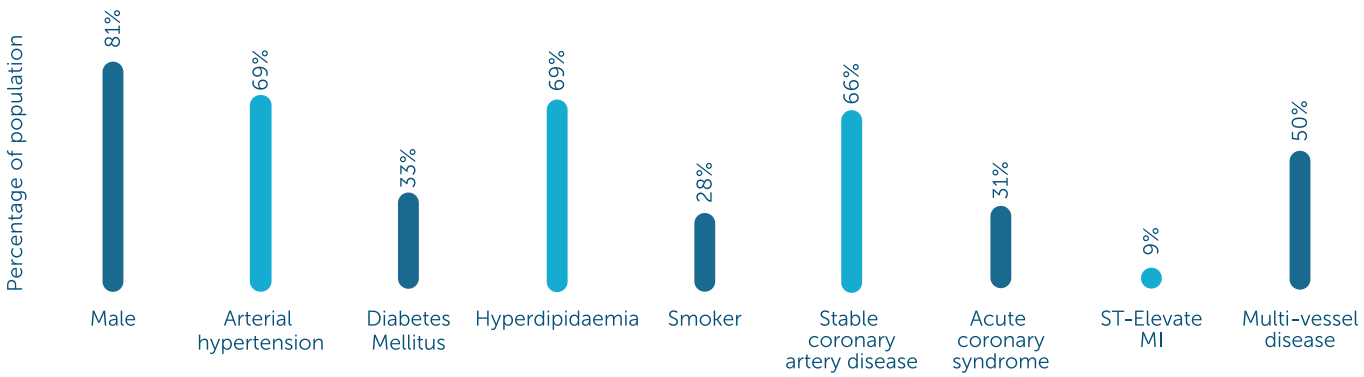
ENDPOINTS

2 Primary endpoints were individuated for the current analysis.

- Immediate technical and clinical performance of this device in terms of procedural success, defined as final % diameter stenosis<50% with 3 TIMI flow and the absence of in-hospital adverse events.
- The co-primary endpoint was the rate of major adverse cardiac events (MACE), a total of cardiac death, myocardial infarction(MI), TLR at the longest available follow-up

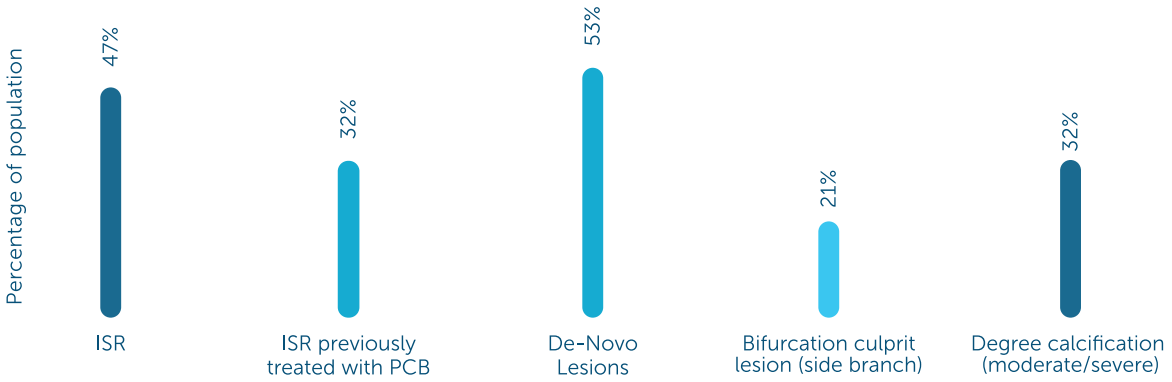
RESULTS

Baseline Characteristics:
No. of patients, N=32

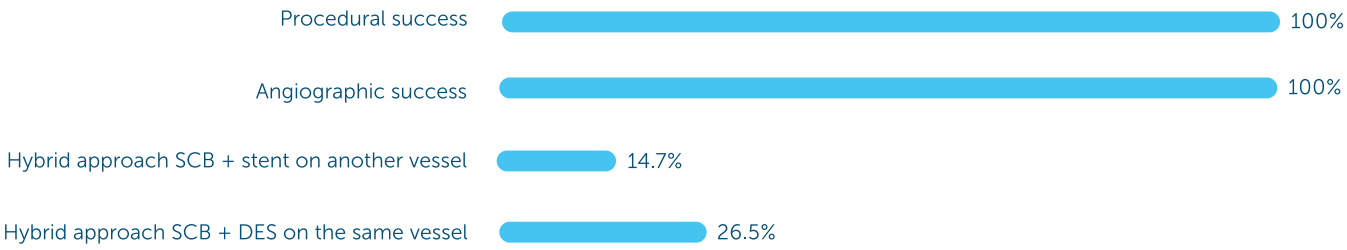


Lesion Characteristics

No. of lesions:34



Procedure Details



Clinical Follow-Up (Average: 6.9 ± 1.7 months)

N=32	
DAPT on going, %	31.6
All-cause death, %	0
Cardiac death, %	0
Target lesion revascularization, %	9.4
MI, %	0
MACE, %	9.4

Conclusion

The DCB investigated in this registry is the first one eluting Sirolimus and approved for human use in Europe. This device was shown to be a safe and effective alternative to currently used DCB at short-term follow-up, in a real world, complex population.

Cortese B, Di Palma G, Latini RA, Elwany M, Orrego PS, Seregni RG. Immediate and short-term performance of a novel sirolimus-coated balloon during complex percutaneous coronary interventions. The FAtebenefratelli SIrolimus COated-balloon (FASICO) registry. Cardiovascular Revascularization Medicine. 2017 Oct 1;18(7):487-91. http://dx.doi.org/10.1016/j.carrev.2017.03.025].

BRAZIL-FIH

FIRST IN HUMAN ASSESSMENT OF MAGICTOUCH SCB IN CORONARY ISR

Principal Investigator:
Alexandre Abizaid,
Dante Pazzanese Hospital of Cardiology,
São Paulo, SP Brazil

STUDY DESIGN

Objective
To demonstrate the safety and efficacy of Drug Coated Balloon Magic Touch in reducing late luminal loss / suppression of neointimal tissue formation, assessed by intravascular ultrasound, in the treatment of intra-stent restenosis. Lesions with a diameter of > 3.0mm to <3.5mm and a length of <20mm.

Study Design
A prospective, multicenter, single arm study designed to include 30 patients. Angiographic follow-up will be performed in all patients at 6 months. All patients will be submitted to clinical follow-up at 30 days, 6 months and 12 months. Evaluation by IVUS will be performed at 6 months.

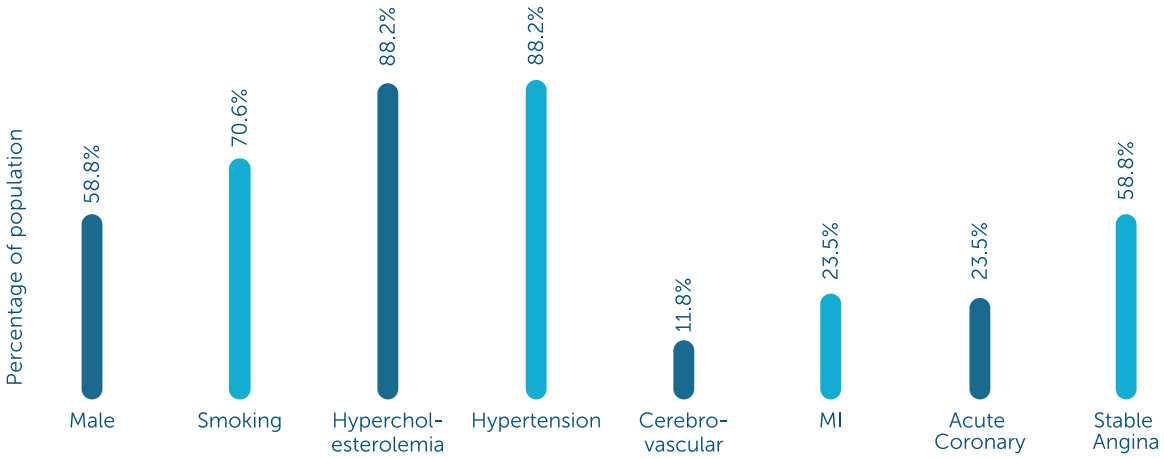
ENDPOINTS

Primary Endpoint
The percentage (%) of intra-stent formation of neointimal tissue will be assessed by IVUS at 6 months.

Secondary Endpoint
- Binary restenosis during angiographic follow-up of performed at 6 months;
- Vascular complications from index procedure to hospital discharge;
- Target lesion failure (TLF), defined as death, MI and ischemic revascularization of the target lesion at 30 days, 6 months and 12 months.

RESULTS

Baseline Characteristics:
No. of patients, N=17



Type of stent associated with ISR

BMS-ISR:
52.9%

DES-ISR:
47.1%

Clinical Outcomes at 30 days and 6 months

Complication	30 days (N=15)	6 months (N=15)
Death, %	0	6.7†
MI, %	0	0
TLR, %	0	0
TLF, %	0	6.7‡
Vascular Complication, %	0	0

† Subject had bare metal stent (BMS)-ISR at baseline.
Death was vascular (non-cardiac) related.

QCA RESULTS

Angiographic Characteristics & Outcomes

No. of patients, N = 16

QCA Pre-procedure	mm±SD
Reference diameter, mm	2.8 ± 0.4
MLD, mm	0.1 ± 0.4
% DS	65.4 ± 13.9
QCA Post Procedure	**mm±SD**
Reference diameter	2.9 ± 0.3
MLD	2.4 ± 0.34
% DS	16.7 ± 8.7
Acute gain	1.4 ± 0.5
QCA Follow-up 6 months	**mm±SD**
Reference vessel diameter	2.9 ± 0.3
MLD	2.0 ± 0.4
% DS	28.6 ± 13.3
Late Lumen loss	0.3 ± 0.4

**Qualitative and quantitative angiographic analyses were performed offline by experienced operators blinded to procedural results. Quantitative analysis was performed with validated 2D software for QCA analysis (QAngio XA version 7.3, Medis, Leiden, Netherlands).*

IVUS RESULTS:

Variable, N=13	mm ± SD
Average Lumen Area (mm^2)	6.2 ± 2.1
Average Lumen Diameter (mm)	2.8 ± 0.5
Average Vessel Area (mm^2)	14.7 ± 4.8
Average Vessel Diameter (mm)	4.3 ± 0.7
Average Balloon Area (mm^2)	7.6 ± 2.5
Average Balloon Diameter (mm)	3.0 ± 0.5
Plaque Area (mm^2)	8.6 ± 2.9
Intimal Area (mm^2)	1.5 ± 0.7
Plaque Burden (mm^2)	0.57 ± 0.05
Vessel Volume (mm^3)	532.3 ± 462.5
Balloon Volume (mm^3)	276.5 ± 252.5
Lumen Volume (mm^3)	219.3 ± 202.0
Plaque Volume (mm^3)	313.0 ± 262.2
NIH Volume (mm^3)	57.4 ± 53.3
% of NIH obstruction	20.6 ± 8.0
Malapposed Volume (mm^3)	0.2 ± 0.3

RETROSPECTIVE-UK STUDY



Investigators:
Sandeep Basavarajaiah,
Handi Salim,
Ishaq Mohammed
Heart of England NHS Trust,
Birmingham, UK

STUDY DESIGN

It is retrospective study which analysed patients treated with MagicTouch SCB between duration April 2018 to October 2018.

RESULTS

Baseline Characteristics:

No. of Patients=153

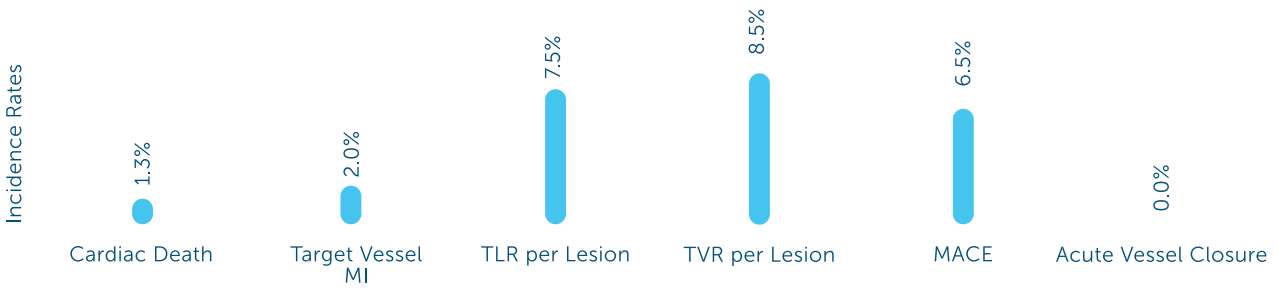
Age, Years ± SD	64.6 ± 11.4 (range; 37-90)
Male	73%
Hypertension	72%
CKD	14%
Smoking (current)	18%
Diabetes	40.5%
ACS	61%
STEMI	10%

Lesion and Procedural Characteristics:

No. of Lesions N_L =199

Target Vessels, %	
LAD / D1	41%
LCx / OM / IM	28%
RCA/ PDA / PL	27%
SVG /LMS	2.5% / 1%
Type of Lesions, %	
ISR	42%
De-Novo	58%
Procedural Details, %	
Pre-dilatation	94%
Non-compliant balloons	59%
Scoring	6%
Cutting	2%
Rotational atherectomy	2%
Bailout stenting	6.5%
Dissection	3.0%
Recoil	3.5%
Device Details	
Mean diameter	2.8 mm
Mean length	27 mm

Clinical Outcomes [Median Follow-up: 253 days (8.4 months)]:



Small Vessel De-Novo Subsets (< 3.0 mm)

No. of patients=86

Age, Years ± SD	64.6 ± 11.4 (Range; 37-90)
Male	70%
Hypertension	80%
CKD	20%
Current Smoker	13%
Diabetes	41%
ACS	67%

Lesion and Procedural Characteristics:

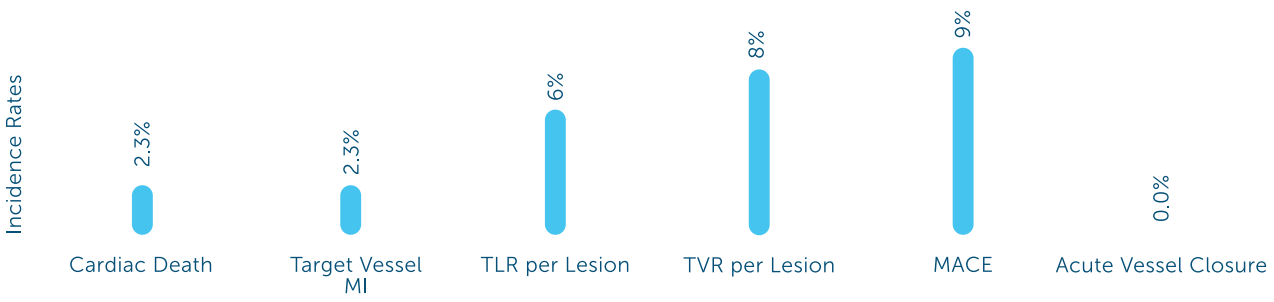
No. of lesions N_L=99

Target Vessels, %	
LAD / D1	48%
LCx / OM / IM	28%
RCA/ PDA / PL	23%

Procedural Details, %	
Pre-dilatation	92%
Non-compliant balloons	40%
Scoring	1%
Cutting	0
Rotational atherectomy	2%
Bailout stenting	9%
Dissection	5%
Recoil	4%

Device Details, %	
Mean diameter	2.3 mm
Mean length	26 mm

Clinical Outcomes [Median Follow-up: 253 days (8.4 months)]:



Conclusion

The results from this relatively new technology DCB is encouraging with low-rates of hard endpoints and MACE rates. Relatively high rates of TLR and TVR can be related to complex patient group and lesions. Clinical outcomes in patients with small vessel (<3mm) were equally encouraging with acceptable rates of repeat revascularization.

EASTBOURNE REGISTRY

THE ALL-COMERS SIROLIMUS-COATED BALLOON EUROPEAN REGISTRY

EASTBOURNE

Principal Investigator:
Dr. Bernardo Cortese,
Clinica San Carlo, Milano, Italy

STUDY DETAILS

Objective
The purpose of this study is 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.

Study Design
This is a prospective, multi-centre, spontaneous clinical registry that will enrol real world, all comer patients at various interventional cardiology sites in Europe and Asia. All Patients will have a clinical follow-up at 1, 6, 12, 24 and 36 months.

ENDPOINTS

Primary Endpoints

Target Lesion Revascularization (TLR at 12 months)

Secondary Endpoints

MACE (Major Adverse Cardiac Events) as a composite of cardiac death, myocardial infarction (MI) and TLR at 1, 6, 12, 24 and 36 months; any individual element of MACE; procedural success (defined as technical and angiographic success in the absence of MACE during hospitalization).

1234 PATIENTS ENROLLED

EASTBOURNE Participating Countries.

UK PROSPECTIVE REGISTRY ON SIROLIMUS DRUG-COATED BALLOON

Principal Investigator:
Sandeep Basavarajaiah,
Heart of England NHS Trust, Birmingham

STUDY DETAILS

Objective
The purpose of this study is to observe and evaluate the performance of a Sirolimus-eluting Drug-Coated Balloon (SCB) for the treatment of any coronary lesions, including de-novo lesions and in- stent restenosis.

Study Design
This is a prospective, multicenter, clinical registry that will enroll real world, all-comers patients at various interventional cardiology sites in England. All patients will have a clinical follow-up at 1, 6, 12 and 24 months.

ENDPOINTS

Primary Endpoints

Target vessel failure at 12-months, which will be a combination of cardiac death, target vessel MI and ischaemia target vessel revascularization.

Secondary Endpoints

Individual components of primary endpoints including target vessel revascularization during follow-up, procedural success and need for bailout stenting post DCB.

Target enrolment: 500 patients
STATUS : ENROLMENTON-GOING

UPCOMING CLINICAL TRIALS

TRANSFORM-I
Randomized controlled trial of SCB vs. PCB

TRANSFORM-II
Randomized controlled trial of SCB vs. DES

TRANSFORM I

TREATMENT OF SMALL CORONARY VESSELS: RANDOMIZED CONTROLLED TRIAL FOR MAGICTOUCH SIROLIMUS COATED BALLOON

Study Chair
Patrick W. Serruys,
Netherlands

Principal Investigator:
Dr. Bernardo Cortese,
Clinica San Carlo,
Milano, Italy

STUDY DETAILS

Objective
The objective of the study is to compare angiographic outcomes of MagicTouch sirolimus coated balloon (Concept Medical) versus SeQuent Please Neo paclitaxel coated balloon (Bbraun) for the treatment of de novo coronary artery lesions in small vessels (≤2.5 mm) with respect to Net Gain (mm) at 6 months follow-up.

Study Design
A prospective, randomized, multicenter study in subjects with small vessels, i.e. at least one de-novo lesion in a small vessel (≤2.5mm).

ENDPOINTS

Primary Endpoints
The primary endpoint is in-segment (balloon treated area) Net Gain (mm) at 6 months post-procedure.

Secondary Endpoints
Device success (Lesion based); Procedure success; Angiographic outcomes (Late Lumen Loss, Minimal Limen Diamere, percent diameter stenosis, restenosis rate); Device oriented composite. Endpoint (DoCE /TLF) defined as the composite of cardiac death, TV-MI and clinically indicated target lesion revascularization (TLR); Acute/subacute/early/late vessel closure/thrombosis.

TARGET ENROLMENT: 114 PATIENTS

TRANSFORM II

TREATMENT OF SMALL CORONARY VESSELS: RANDOMIZED CONTROLLED TRIAL FOR MAGICTOUCH SIROLIMUS COATED BALLOON

Principal Investigator:
Dr. Bernardo Cortese,
Clinica San Carlo,
Milano, Italy

Study Chair
Alexandre Abizaid,
Dante Pazzanese
Hospital of Cardiology,
São Paulo, Brazil

STUDY DETAILS

Objective
The purpose of this study is to observe and evaluate the efficacy of the SCB compared to the gold standard treatment for native vessel disease, namely new generation everolimus-eluting stents (EES). Given the inherent limitations of stents in small coronary arteries, in this study only patients with small coronary vessels (≤2.75 mm diameter by visual estimation) will be enrolled.

Study Design
This is a prospective, multi-centric, spontaneous, international, randomized clinical study, in an open-label randomized fashion, where patients with native coronary artery disease in vessels with diameter ≤2.75 mm (visual estimation) and with a clinical indication to PCI, suitable to the use of either a DES or a SCB, will be enrolled.

ENDPOINTS

Primary Endpoints
The primary objective of the study is to verify the non- inferiority of SCB compared to DES in terms of in-lesion-treated late lumen loss (LLL) (namely, within 5 mm proximally or distally of the treated segment) at a 6 months angiographic follow up.

Secondary Endpoints
- Percent diameter stenosis and binary restenosis at angiographic follow-up
- Occurrence of major adverse cardiovascular events at clinical follow-up (6, 12, 24 and 36 months)
- Performance of the SCB in terms of late lumen vessel gain by angiography and Optical-coherence tomography

TARGET ENROLMENT: 190 PATIENTS

ABBREVIATIONS:

- ACS: Acute Coronary Syndrome
- BMS: Bare Metal Stent
- CI: Confidence Interval
- DES: Drug Eluting Stent
- DES ISR: Drug Eluting Stent In-Stent Restenosis
- DM: Diabetes Mellitus
- DS: Diameter Stenosis
- ISR: In-stent restenosis
- IVUS: Intravascular Ultrasonography
- LLL: Late Lumen Loss
- LV: Large Vessel
- MACE: Major Adverse Cardiac Event
- MLD: Minimal Luminal Diameter
- NSTEMI: Non-ST elevated Myocardial Infarction
- NIH: Neo-intimal Hyperplasia
- OCT: Optical Coherence Tomography
- PCB: Paclitaxel Coated Balloon
- PCI: Percutaneous Coronary Intervention
- PTCA: Percutaneous Transluminal Coronary Angioplasty
- QCA: Quantitative Coronary Angiography
- RVD: Reference Vessel Diameter
- SA: Stable Angina
- SCB: Sirolimus Coated Balloon
- STEMI: ST-elevated Myocardial Infarction
- SV: Small Vessel
- TLR: Target Lesion Revascularization
- TLF: Target Lesion Failure
- TVF: Target Vessel Failure
- TV-MI: Target Vessel Myocardial Infarction
- TVR: Target Vessel Revascularization
- UA: Unstable Angina


They said put your
heart into it,
and we did.
#HelloFuture

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