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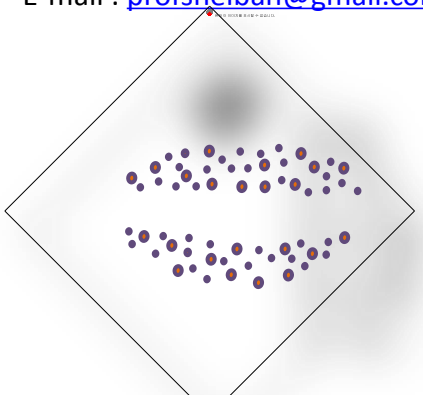
Updated Data for DEB 2016: De Novo Lesions and ISR Lesions

I Sheiban
University of Turin

Director Interventional Cardiology
Pederzoli Hospital
Pechiera del Garda (Verona) / Italy

E-mail : profsheiban@gmail.com



Role of DEBs in PCI

DEBs area a new and effective PCI treatment option
Advantages of DEB over direct stent approach
•Reduction in DAPT
•No foreign object left behind (vascular restoration possible)

Current and potential indications include

•ISR
•small vessels
•patients on oral anticoagulation or at high risk for initiation of oral anticoagulation
•True Bifurcations with long (>5mm) SB lesions or complex SB ISR difficult to treat with DES

1. Kleber et al. Drug-coated balloons for treatment of coronary artery disease: updated recommendations from a Consensus group. Clin Res Cardiol (2013) 102:758---797

Clinical Data

- **ISR**
- **Native coronary vessels :**
  - **Bifurcation**
  - **Small Vessels**
  - **De novo lesions**
  - **AMI**
  - **….**

DEB Clinical Trials : DES for ISR

Study	Devices	Number of patients	Primary outcome/follow-up	TLR, %/follow-up	Bail-out stent rate, %	Reference
PACCOCATH-ISR I	Paccocath vs. UCB	54	LLL 0.03 mm vs. 0.74 mm/6 mos	0 vs. 23/12 mos	8	8
PACCOCATH-ISR I/II	Paccocath vs. UCB	108	LLL 0.14 mm vs. 0.81 mm/6 mos MACE 15% vs. 32%/5 yrs	3 vs. 20/24 mos 5 vs. 21/5 yrs	6	9, 10
PEPCAD II	SeQuent Please vs. TAXUS	131	LLL 0.17 mm vs. 0.38 mm/6 mos	6 vs. 15/12 mos	3	11
PEPCAD-DES	SeQuent Please vs. UCB	110	LLL 0.43 mm vs. 1.03 mm/6 mos	15 vs. 37/6 mos	1	12
Habara et al	SeQuent Please vs. UCB	50	LLL 0.18 mm vs. 0.72 mm/6 mos	4.3 vs. 42/6 mos	–	13
ISAR-DESIRE 3	SeQuent Please vs. TAXUS Liberté vs. POBA	472	Diameter stenosis 38% vs. 37.4% vs. 54.1%/6-8 mos	22.1 vs. 13.5 vs. 43.5/6-8 mos	–	14
SeQuent Please worldwide registry	SeQuent Please	1,207	MACE 5.3% for BMS ISR, 11.6% for DES ISR/9 mos	3.8 for BMS ISR, 9.6 for DES ISR/9 mos	–	15
Spanish multicentre registry	DIOR I/II	126	MACE 16.7%/12 mos	12 (9 for BMS ISR, 15 for DES ISR)/12 mos	4	16
Valentines I	DIOR II	250	MACE 11.1%/8 mos	7.4/8 mos	5	17
PEPPER	Pantera Lux	81	LLL 0.07 mm (BMS ISR -0.005 mm, DES ISR 0.19 mm)/6 mos	3.9/6 mos 9.2/12 mos	–	18
DELUX registry	Pantera Lux	1,064	MACE 8.7%/6 mos	3.9/6 mos	–	19
Cremers et al	IN.PACT Falcon	23	LLL 0.07 mm/6 mos	4/6 mos	–	20

BMS: bare metal stent; DES: drug-eluting stent; ISR: in-stent restenosis; LLL: late luminal loss; MACE: major adverse cardiac events; TLR: target lesion revascularisation; UCB: uncoated balloon

JP Loh, IM, Barbash ; R Waksman; EuroIntervention 2013;9:979-988

2014 ESC/EACTS Guidelines on myocardial revascularization

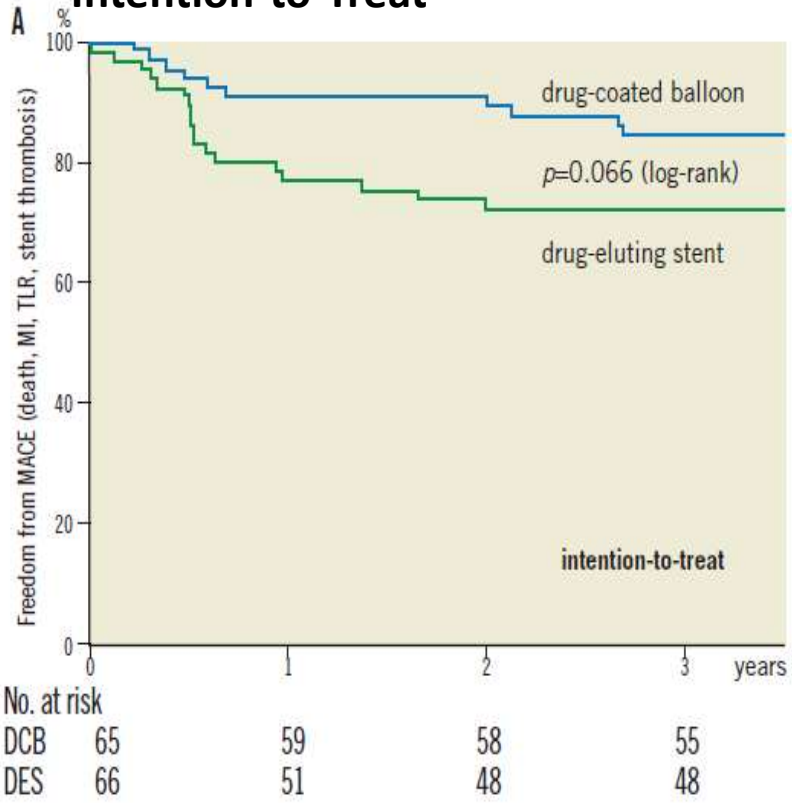
The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	

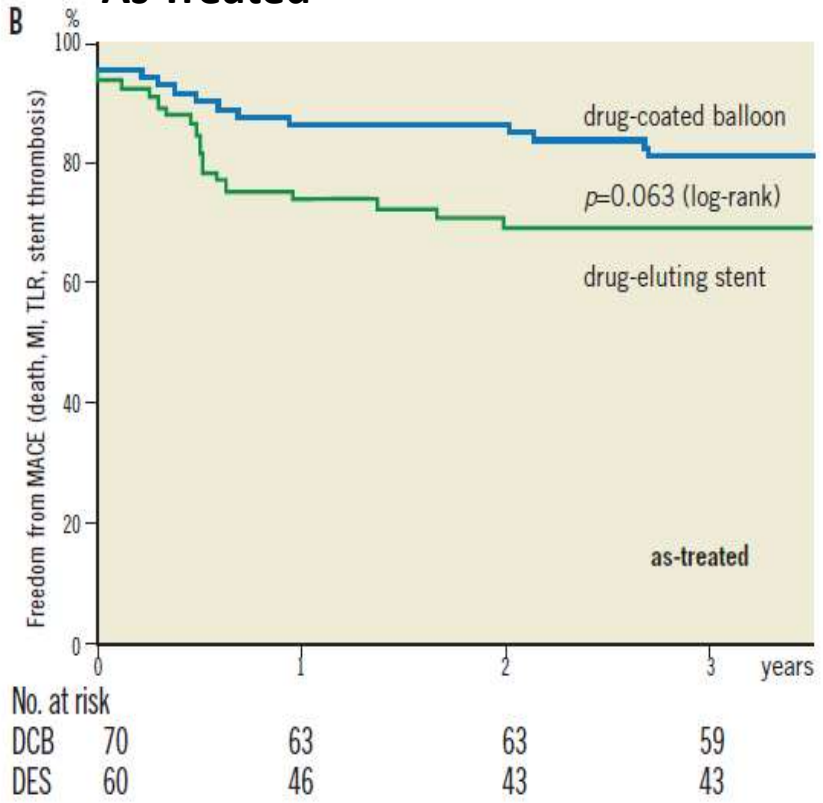
Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis: the three-year results of the PEPCAD II ISR study

MACE at 3 years

Intention-to-Treat



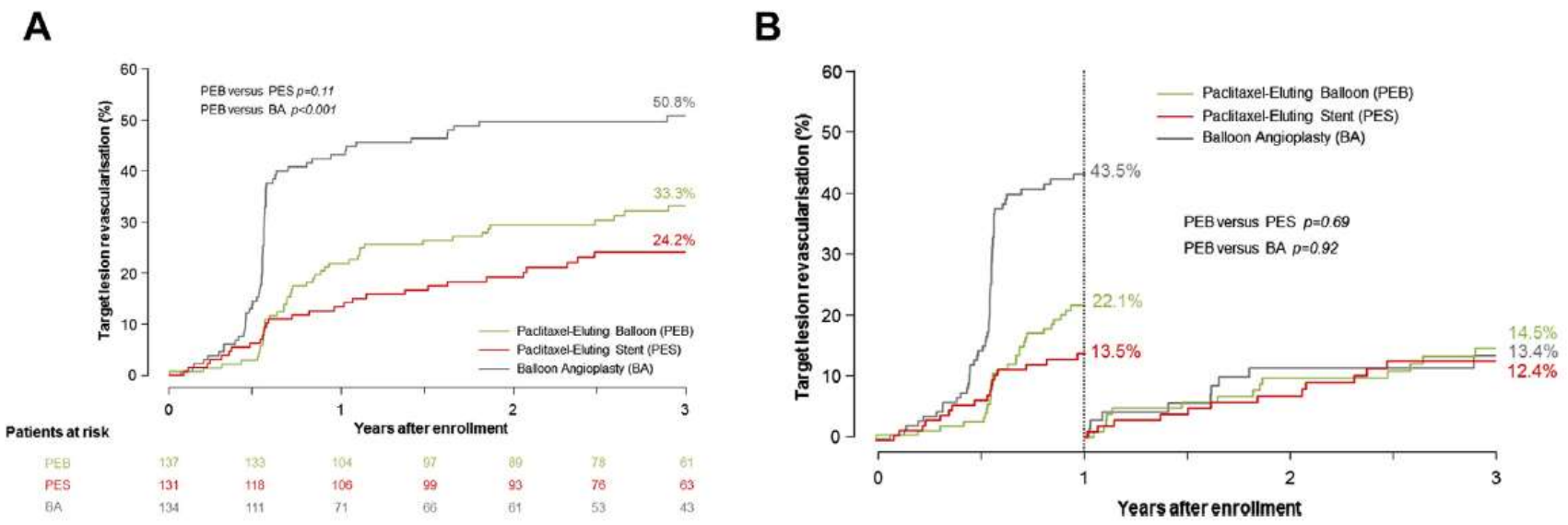
As Treated



M. Unverdorbenet al EuroIntervention 2015;11:926-934

Long Term Efficacy and Safety of Paclitaxel-Eluting Balloon for the treatment of Drug_Eluting Stent Restenosis. 3-year Results of a Randomized Controlled Trail (ISAR-DESIRE 3 Trial)

FIGURE 1 Cumulative Survival Analysis Curves and Landmark Analysis for TLR



Cumulative survival analysis curves at 3 years **(A)** and landmark analysis from 1 to 3 years **(B)** for target lesion revascularization (TLR) by treatment group. BA = balloon angioplasty; PEB = paclitaxel-eluting balloon; PES = paclitaxel-eluting stent(s).

S. Kufner at al ; JACC: Cardiovasc Int 2015; epub ahead of print

ISAR-DESIRE 4 Trial

Intarcoronary Stenting and Angiographic Results : Optimizing Treatments of Drug Eluting Stent In-Stent Resstenosis

Design

PRIMARY ENDPOINT:
Percent diameter stenosis at follow-up angiography

TEST HYPOTHESES:
neointimal modification with scoring balloon pre-dilation before DCB would be superior to standard balloon pre-dilation before DCB

%DS= 26.25% vs. 35%
2-sided α-level = 0.05
power = 80%
101 patients per group

252 patients with DES-restenosis enrolled between June 2012 and December 2014 in 4 centers in Germany

- Scoring balloon plus paclitaxel-coated balloon (N=125)
- Standard balloon plus paclitaxel-coated balloon (N=127)

Angiographic follow-up at 6-8 months in 80.4% (N=203)*

Clinical follow-up at 12 months

**no significant differences across groups*

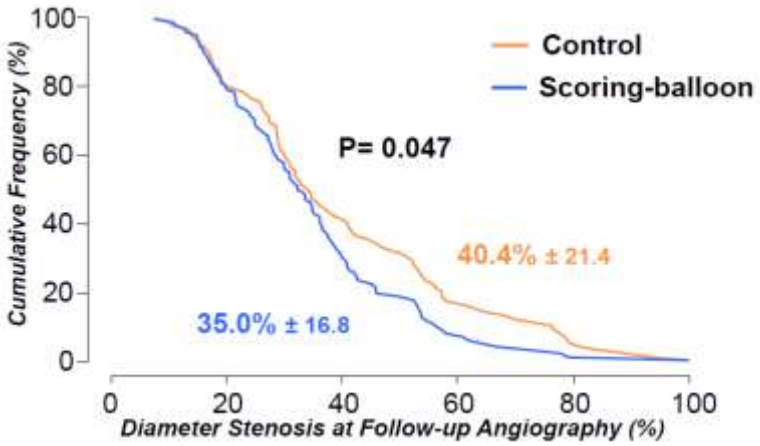
Angiosculpt scoring balloon

Pantera Lux paclitaxel-coated balloon

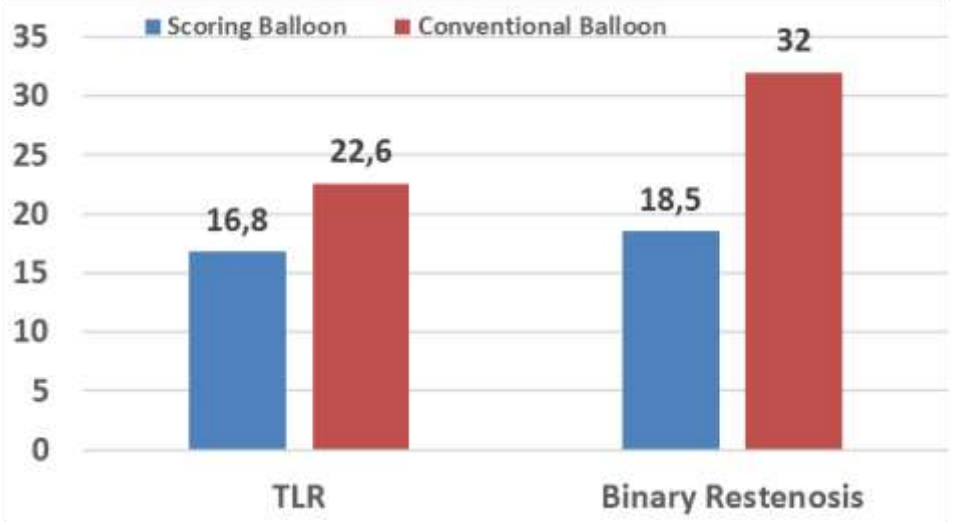
Presented at TCT 2015

ISAR-DESIRE 4 Trial

Primary Endpoint :Diameter Stenosis at Follow-up Angiography



Secondary endpoints : TLR and Restenosis



Presented at TCT 2015

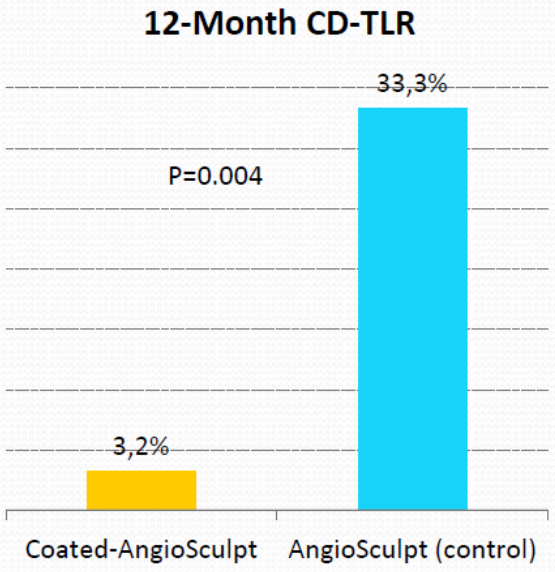
Original Studies

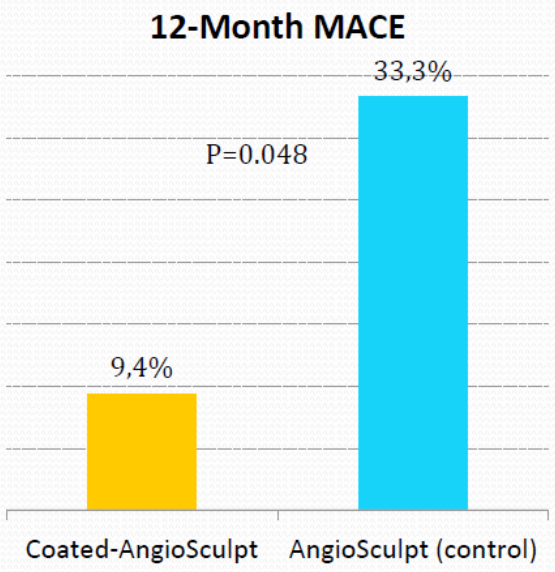
A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: Results From the Multi-Center Randomized Controlled PATENT-C First in Human Trial

61patients:
28 uncoated and 33 coated
Clinical follow-up at 30 days, 6 months, 1 and 2 years
6 –month repeat angiogram

1-Year Results

➢ **Significant reduction in clinically-driven TLR and MACE rates at 1-year with DCAS**





Scheller et all. Cath and Cardiovasc Interv ; epub Sep 2015

Comparison Among Drug-eluting Balloon, Drug-eluting Stent, and Plain Balloon Angioplasty for Treatment of In-Stent Restenosis: A Network Meta-analysis of 11 Randomized Controlled Trials

Total Pts = 2059 , Treatment : POBA = 557; DES = 808; DEB= 694

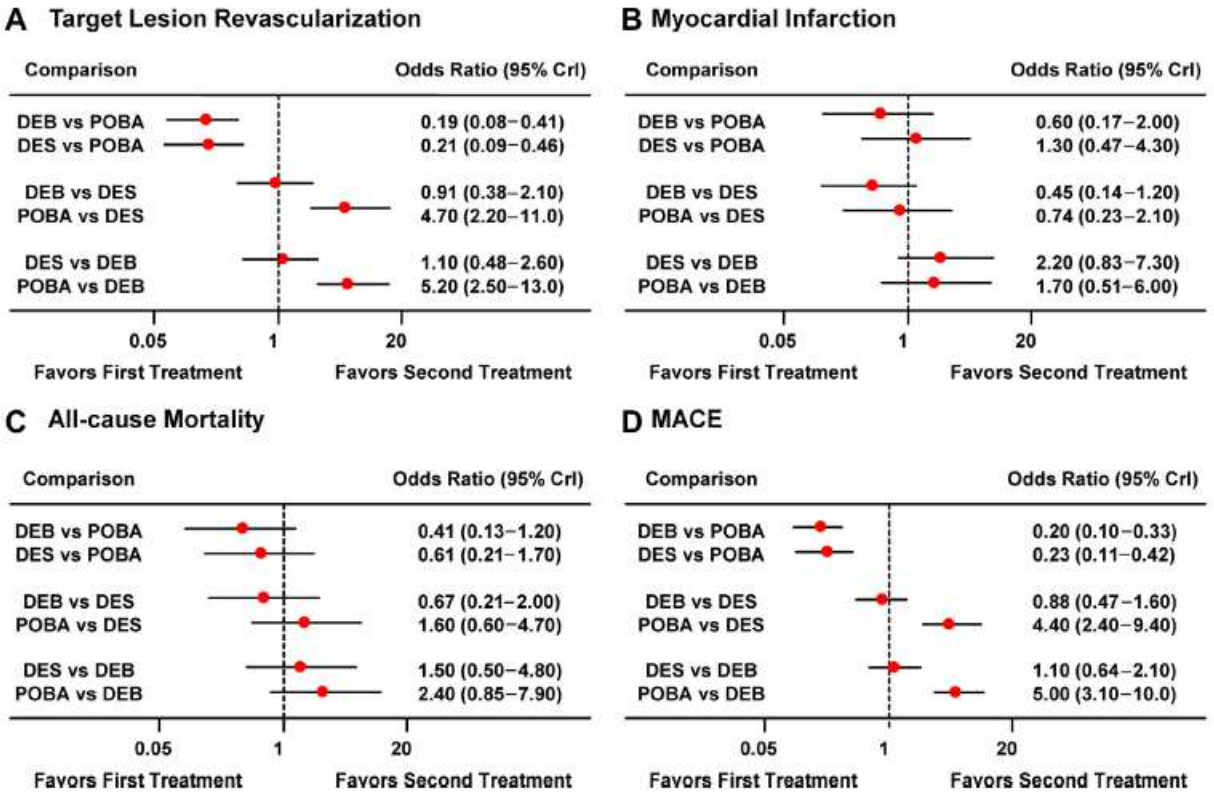
Trial (Year)	Age	Proportion of Co-morbidities			Pre-MLD (mm)		Pre-DS (%)		Lesion Length (mm)		Post-MLD (mm)		Post-DS (%)	
		HTN	DM	Dyslipid	Group1	Group2	Group1	Group2	Group1	Group2	Group1	Group2	Group1	Group2
ISAR-DESIRE (2005)	64.3	54.3%	27.7%	56.7%	DES 0.94	POBA 0.95	DES 62.4	POBA 61.8	DES 11.95	POBA 12.3	**DES 2.54**	POBA 2.07	**DES 9.35**	POBA 19.9
RIBS-II (2008)	64.0	54.7%	34.7%	61.3%	DES 0.74	POBA 0.70	DES 72.0	POBA 74.0	DES 16.9	POBA 15.7	**DES 2.69**	POBA 2.29	**DES 8.0**	POBA 40
PEPCAD-II (2009)	64.8	81.7%	29.8%	74.8%	DEB 0.74	DES 0.77	DEB 73.9	DES 72.8	DEB 15.7	DES 15.4	DEB 2.30	**DES 2.56**	DEB 19.5	**DES 11.2**
Habara et al. (2011)	69.4	64.0%	62.0%	62.0%	DEB 0.99	POBA 0.92	DEB 64.1	POBA 68.4	DEB 12.7	POBA 13.2	DEB 1.99	POBA 2.00	**DEB 25.7**	POBA 31.0
ISAR-DESIRE 3 (2012)	67.9	73.6%	41.5%	77.9%	DEB 0.97	DES 0.93	POBA 0.88	DEB 64.4	DES 66.7	POBA 67.7	DEB N/R	DES N/R	POBA N/R	**DEB 2.29**	**DES 2.53**	POBA 2.10	**DEB 18.5**	**DES 12.8**	POBA 23.3
PEPCAD-DES (2012)	67.8	94.5%	35.4%	78.2%	DEB 0.66	POBA 0.62	DEB 72.1	POBA 74.0	DEB 11.2	POBA 12.2	DEB 2.15	POBA 2.14	DEB 12.6	POBA 13.7
PACCOCATH-ISR I&II Pooled Analysis (2012)	65.9	81.5%	26.9%	75.0%	DEB 0.70	POBA 0.63	DEB N/R	POBA N/R	DEB 18.6	POBA 18.3	DEB 2.34	POBA 2.43	DEB N/R	POBA N/R
CRISTAL (2012)	67.7	75.1%	39.1%	79.2%	DES 1.09	POBA 1.18	DES 58.8	POBA 53.7	DES 14.6	POBA 13.4	**DES 2.51**	POBA 2.12	**DES 9.5**	POBA 18
Habara et al. (2013)	69.0	84.6%	44.7%	82.7%	DEB 0.86	POBA 0.84	DEB 65.6	POBA 66.1	DEB 12.8	POBA 13.7	DEB 1.97	POBA 1.90	DEB 21.9	POBA 23.1
PEPCAD China ISR (2014)	61.9	68.4%	36.7%	34.0%	DEB 0.85	DES 0.86	DEB 68.3	DES 68.4	DEB 12.5	DES 13.1	DEB 2.39	**DES 2.56**	DEB 10.5	**DES 7.1**
RIBS V (2014)	65.5	72.0%	25.9%	69.3%	DEB 1.02	DES 0.93	DEB 61.0	DES 65.0	DEB 13.7	DES 13.8	DEB 2.16	**DES 2.38**	DEB 19.0	**DES 11.0**

Lee et al., JACC Cardiovasc Interv. 2015; 8: 382-94

Comparison Among Drug-eluting Balloon, Drug-eluting Stent, and Plain Balloon Angioplasty for Treatment of In-Stent Restenosis: A Network Meta-analysis of 11 Randomized Controlled Trials

Total Pts = 2059 , Treatment : POBA = 557; DES = 808; DEB= 694

FIGURE 3 Results of Bayesian Network Meta-analysis for 1-Year Rates of Clinical Outcomes in Random-Effects Model



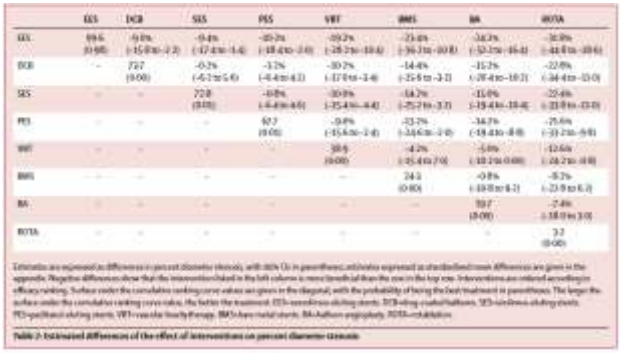
Results of a Bayesian network meta-analysis with a random-effects model for the risk of target lesion revascularization **(A)**, myocardial infarction **(B)**, all-cause mortality **(C)**, major adverse cardiovascular events within 1-year follow-up period **(D)**. Abbreviations as Figures 1 and 2.

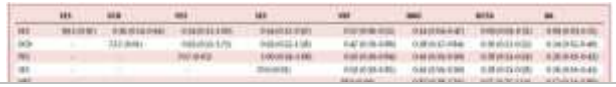
Lee et al., JACC Cardiovasc Interv. 2015; 8: 382-94

Percutaneous coronary interventional strategies for treatment of in-stent restenosis: a network meta-analysis

George C M Siontis, Giulio G Stefanini, Dimitris Mavridis, Konstantinos C Siontis, Fernando Alfonso, María J Pérez-Vizcayno, Robert A Byrne, Adnan Kastrati, Bernhard Meier, Georgia Salanti, Peter Jüni, Stephan Windecker

	Year	Type of ISR	Interventions	Sample size (control/ intervention)	Follow-up (months)	
					Angiographic	Clinical
DCB						
PACCOCATH-ISR I[15] and II[16]	2006 (I)–2008 (II)	BMS and DES	BA vs DCB	108 (54/54)	6	60
PEPCAD II[9]	2009	BMS	PES vs DCB	131 (65/66)	6	12
Habara et al[17]	2011	DES	BA vs DCB	50 (25/25)	6	6
PEPCAD-DES[18]	2012	DES	BA vs DCB	110 (38/72)	6	6
Habara et al[19]	2013	BMS and DES	BA vs DCB	210 (72/138)	6	6
ISAR-DESIRE 3[20]	2013	DES	BA vs PES vs DCB	402 (134/131/137)	6-8	12
PEPCAD China ISR[21]	2014	DES	PES vs DCB	215 (106/109)	9	12





The authors concluded that the risk of TLR was similar with both DES and DCB, and both were better than BA. However, the RIBS-IV trial was not included in that analysis and no distinction was made between different DES types

Lancet, 2015; 386: 655-64

Clin Res Cardiol
DOI 10.1007/s00392-015-0934-0

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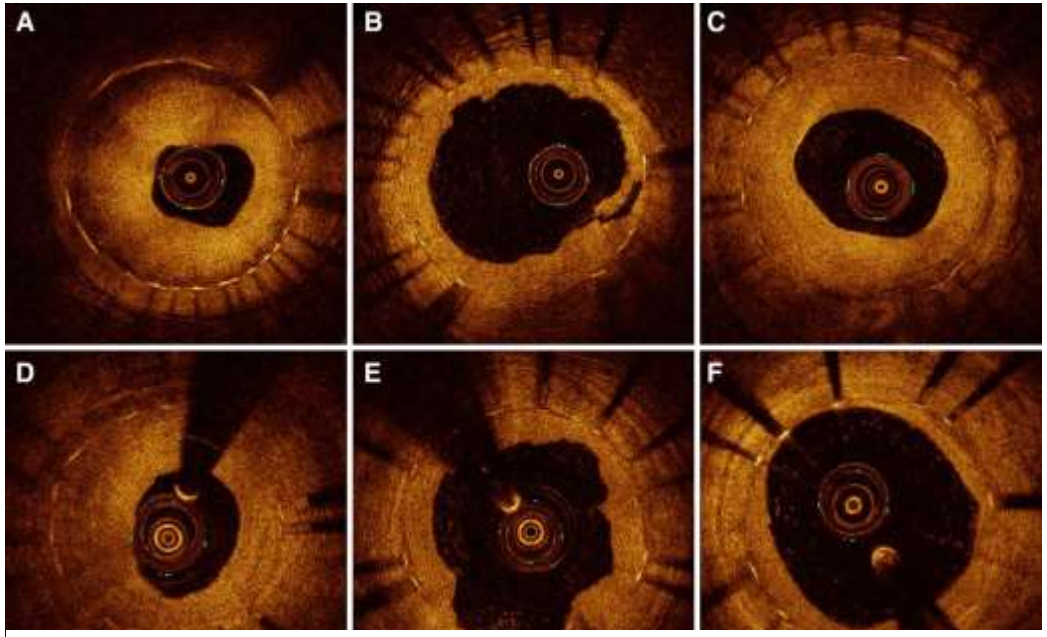
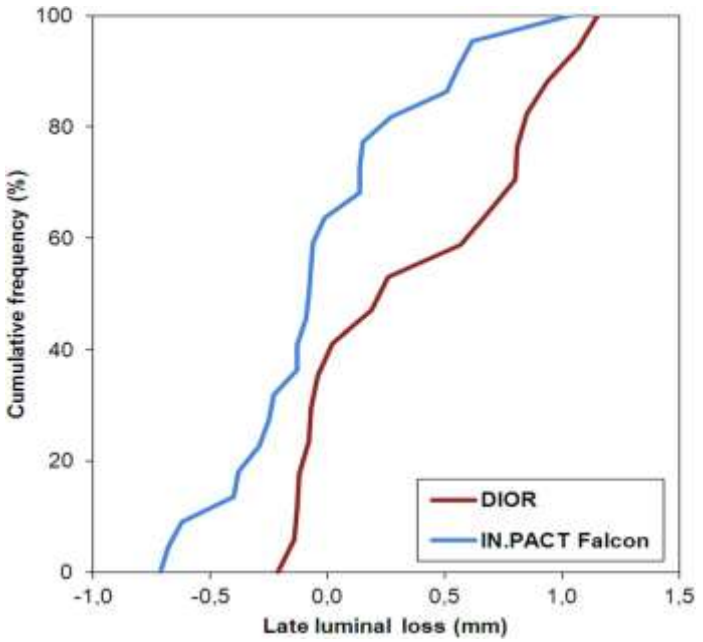
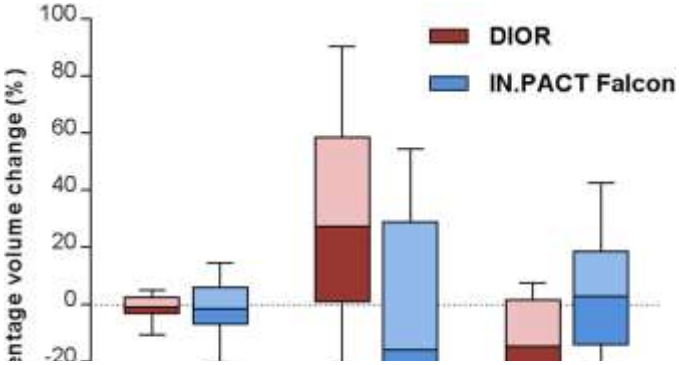
ORIGINAL PAPER

Comparative assessment of the antirestenotic efficacy of two paclitaxel drug-eluting balloons with different coatings in the treatment of in-stent restenosis

Freek Nijhoff[1] · Pieter R. Stella[1] · Maartje S. Troost[1] · Anouar Belkacemi[2] · Hendrik M. Nathoe[1] · Michiel Voskuil[1] · Mariam Samim[1] · Pieter A. Doevendans[1] · Pierfrancesco Agostoni[1,3]







Conclusions **The IN.PACT Falcon DEB showed higher antirestenotic efficacy than the DIOR in the treatment of ISR, demonstrating that DEB with an excipient-based coating is not equally effective.**

Clin Res Cardiol 2016; epub ahead of print

Clinical Data on DEB for De Novo lesons in different subsets :

Table 4. Complex coronary lesions.

Study	Devices	Number of patients	Primary outcome/follow-up	TLR, %/follow-up	Bail-out stent rate, %	Reference
Diffuse lesion						
Pilot long lesion study	DCB+BMS	12	LLL 0.48 mm/6 mos	16/6 mos	–	34
Diabetes mellitus						
PEPCAD IV	SeQuent Please+BMS vs. TAXUS	84	LLL 0.51 mm vs. 0.53 mm/6 mos	7.7 vs. 8.3/9 mos	–	35
DEAR	DIOR II+BMS (vs. DES vs. BMS)		MACE 13.2% (vs. 18.6% vs. 32.3%) /12 mos	6.6/12 mos	–	36
Chronic total occlusion						
PEPCAD CTO	BMS+SeQuent Please (vs. TAXUS)	48	LLL 0.64 mm (vs. 0.43 mm)/6 mos	14.6 (vs. 14.6)/12 mos	–	37
Acute myocardial infarction						
DEB-AMI	SeQuent Please+BMS	30	TLR 17%/12 mos	17/12 mos	–	38
DEB-AMI	DIOR II+BMS vs. BMS vs. TAXUS	149	LLL 0.64 mm vs. 0.74 mm vs. 0.21 mm/6 mos	20 vs. 17.6 vs. 2%/6 mos	–	39
Bifurcation						
DEBIUT registry	DIOR I (MB+SB) followed by BMS MB	20	No MACE/4 mos	0/4 mos		41
DEBIUT trial	DIOR I (MB+SB) followed by BMS MB vs. BMS MB vs. DES MB	117	MB: LLL 0.41 mm vs. 0.49 mm vs. 0.19 mm SB: LLL 0.19 mm vs. 0.21 mm vs. –0.11 mm/6 mos	20 vs. 27 vs. 15/18 mos	7.5 (SB)	42
PEPCAD V	SeQuent Please (MB+SB) followed by BMS MB	28	MB: LLL 0.38 mm SB: LLL 0.21 mm/9 mos	3.8/9 mos	14	43
Sgueglia et al	BMS MB followed by kissing DCB (SeQuent Please, IN.PACT Falcon, DIOR II, Pantera Lux)	12	Procedural success 100% No MACE/8 mos			44

BMS: bare metal stent; DCB: drug-coated balloon; LLL: late luminal loss; MACE: major adverse cardiac events; MB: main branch; SB: side branch; TLR: target lesion revascularisation

JP Loh, IM, Barbash ; R Waksman; EuroIntervention 2013;9:979-988

RESEARCH ARTICLE Open Access

Drug eluting balloons for *de novo* coronary lesions – a systematic review and meta-analysis

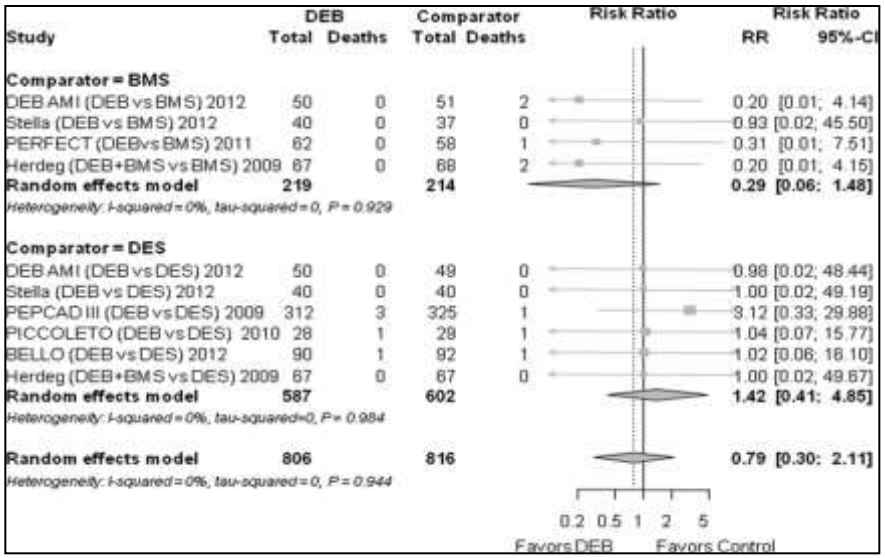
Georg M Fröhlich[1], Alexandra J Lansky[2], Dennis T Ko[3], Olga Archangelidi[4], Rodney De Palma[1], Adam Timmis[5] and Pascal Meier[1,2*]

Table 2 Baseline characteristics of included trials

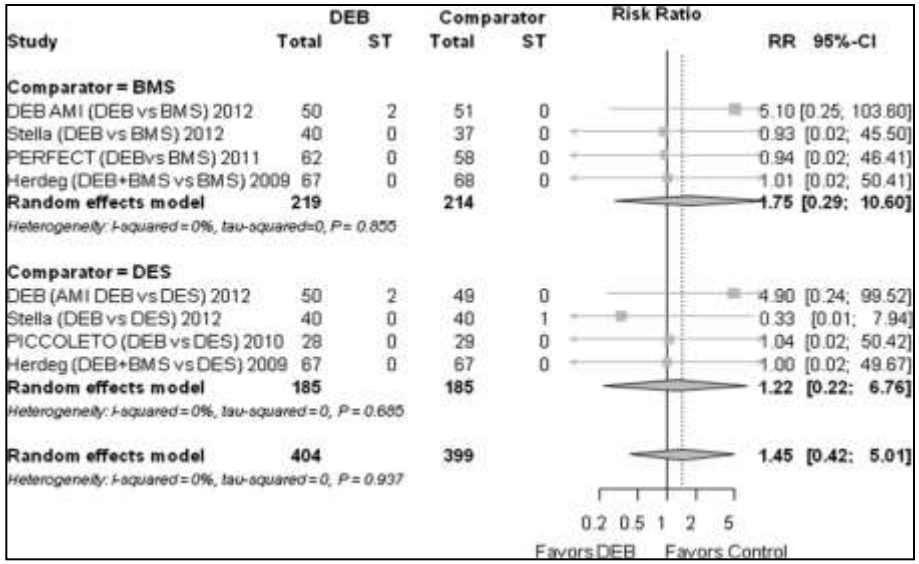
Study	Paclitaxel eluting balloon	Controls stent type(s)	Setting	Clopidogrel (mts)	Follow-up (mts)	Primary endpoint	MACE	TLR	Bare metal stenting
DEB-AMI	DIOR 2nd generation	TAXUS DES, Genius Magic Euroscore BMS	STEMI	12	6	LLL	death, MI, TVR	restenosis >50% ischemia	100%
Stella *et al.*	DIOR 1st generation	TAXUS DES, Liberté BMS	stable/unstable CAD, bifurcation	3 after BMS, 12 after DES	12 (angio 6)	LLL	death, MI, TVR	restenosis >50% ischemia	100%
PEPCAD III	Coroflex DEBlue	Cypher DES	stable/unstable CAD	1 after DEB	9	LLL	NA	NA	100%
PERFECT	SeQuent Please+ PERFECT Stent	PERFECT Stent (EPC capturing Stent)	Stable CAD	3	6	LLL	death, MI, TLR	NA	100%
BELLO	INPACT Falcon	TAXUS DES	stable/unstable CAD small vessels	3 after DEB, 12 after DES	6	LLL	death, MI, TVR	any repeat revascularization	20.2%
Herdeg *et al.*	GENIE Acrostak	TAXUS DES, Multi-Link BMS	stable CAD	6	6	LLL	death, MI, TVR, stent thrombosis	any repeat revascularization	100%
Ali *et al.*	SeQuent Please	TAXUS DES	stable CAD in diabetics	NA	9	LLL	NA	NA	100%
PICCOLETTO	DIOR 1st generation	TAXUS DES	stable/unstable CAD small vessels	1 after DEB, 3 after BMS, 12 after DES/unstable	9 (angio 6)	diameter stenosis	death, STEMI, TLR	>50% restenosis	NA (>100%)

Fröhlich et al. BMC Medicine 2013, 11:123

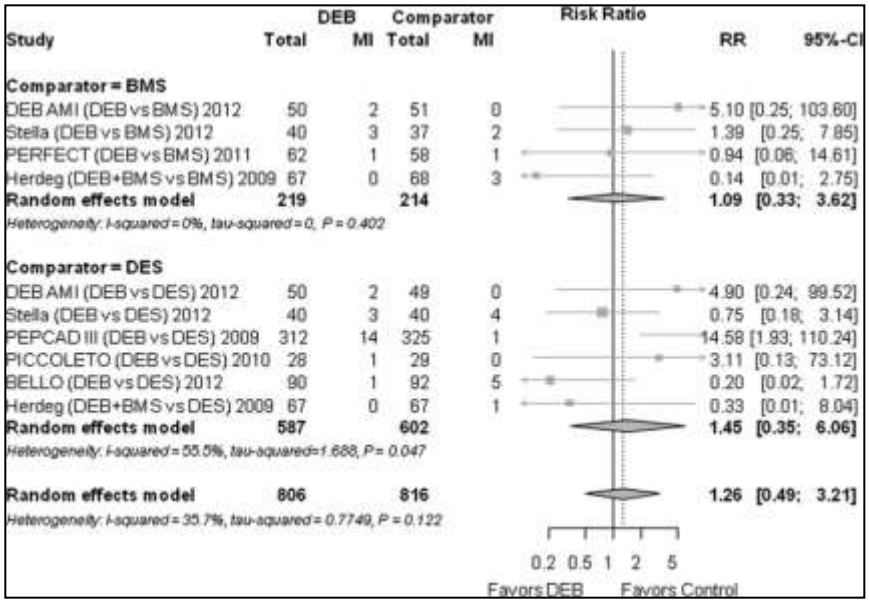
Death



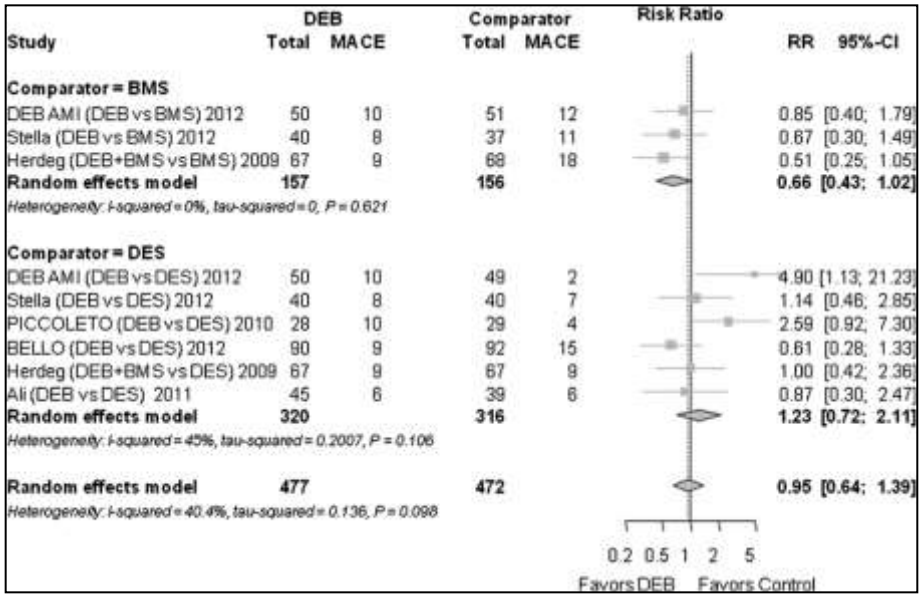
AMI



Stent Thrombosis

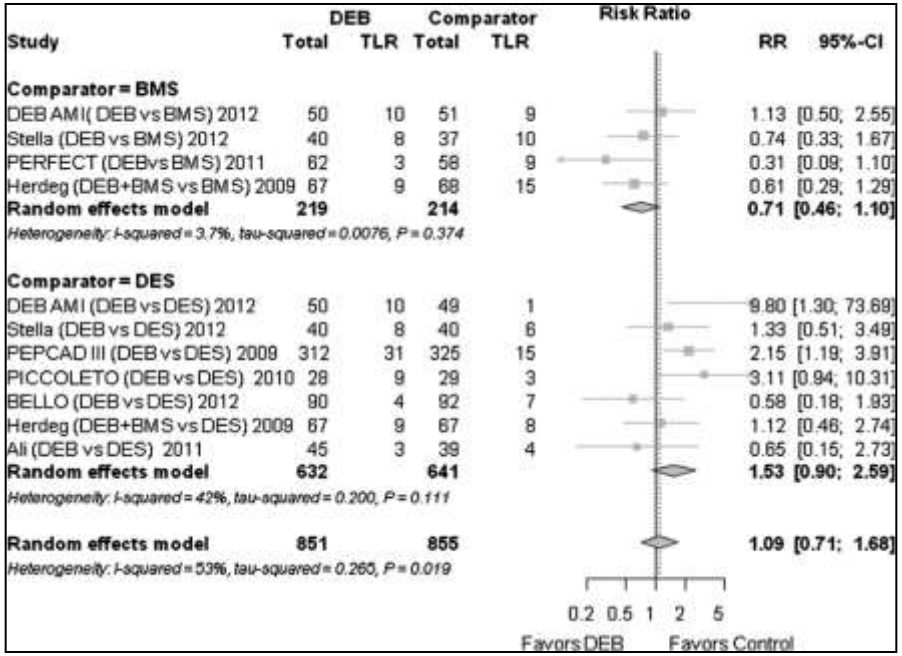


MACE

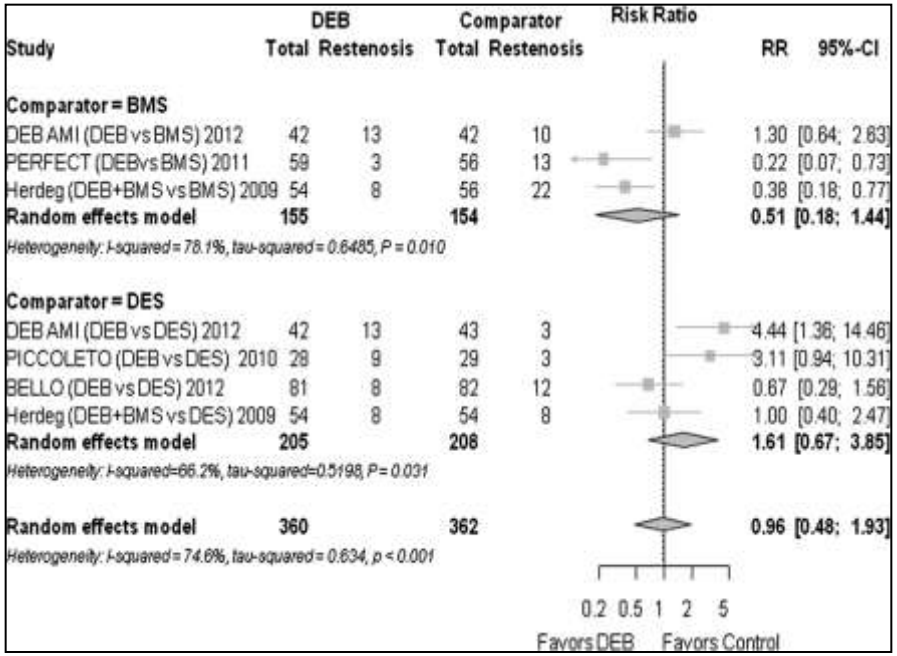


Fröhlich et al. BMC Medicine 2013, 11:123

TLR



Restenosis



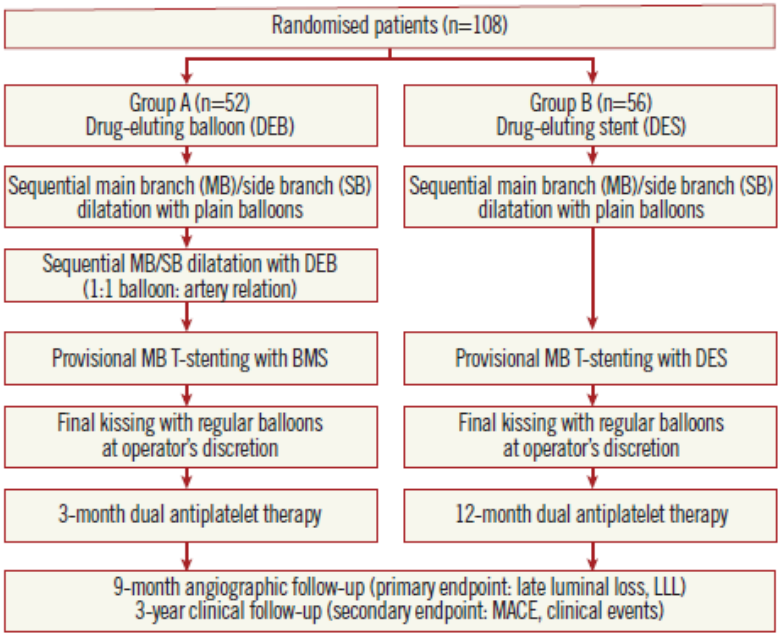
Conclusion:

- **DEB are not superior to current standard therapies (BMS or drug eluting stent (DES)) in treating de novo coronary lesions.**
- **DEB efficacy seems to lie in between DES and BMS with a trend towards superiority over BMS alone.**
- **DEB may be considered in patients with contraindications for DES.**

Fröhlich et al. BMC Medicine 2013, 11:123

A prospective randomised study of the paclitaxel-coated balloon catheter in bifurcated coronary lesions (BABILON trial): 24-month clinical and angiographic results

José Ramón López Mínguez[1]*, MD, PhD; Juan Manuel Nogales Asensio[1], MD, PhD; Luis Javier Doncel Vecino[1], MD; Jorge Sandoval[2], MD; Sebastián Romany[3], MD; Pedro Martínez Romero[4], MD, José Antonio Fernández Díaz[5], MD; Javier Fernández Portales[3], MD, PhD; Reyes González Fernández[1], MD, PhD; Ginés Martínez Cáceres[1], MD; Antonio Merchán Herrera[1], MD, PhD; Fernando Alfonso Manterola[2], MD, PhD; on behalf of the BABILON Investigators



24-month follow-up clinical events.

	All patients n=108	pDEB group n=52	DES group n=56	*p*-value
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	1
Non-fatal MI	4 (3.7%)	2 (3.8%)	2 (3.6%)	1
Stroke	1 (0.9%)	1 (1.9%)	0 (0.0%)	0.477
CABG	2 (1.9%)	1 (1.9%)	1 (1.8%)	1
New PCI	17 (15.7%)	11 (21.2%)	6 (10.7%)	0.125
TVR	11 (10.2%)	9 (17.3%)	2 (3.6%)	0.018
TLR	10 (9.3%)	8 (15.4%)	2 (3.6%)	0.045
Other vessel PCI	9 (8.3%)	5 (9.6%)	4 (7.1%)	0.734
Follow-up MACE	13 (12%)	9 (17.3%)	4 (7.1%)	0.105
In-hospital or follow-up MACE	16 (14.8%)	9 (17.3%)	7 (12.5%)	0.456
Restenosis (global)	12 (11.1%)	9 (17.3%)	3 (5.4%)	0.048
MB restenosis	8 (7.4%)	7 (13.5%)	1 (1.8%)	0.027
SB restenosis	5 (4.6%)	3 (5.8%)	2 (3.6%)	0.670
MB stent occlusion	2 (1.9%)	1 (1.9%)	1 (1.8%)	0.958

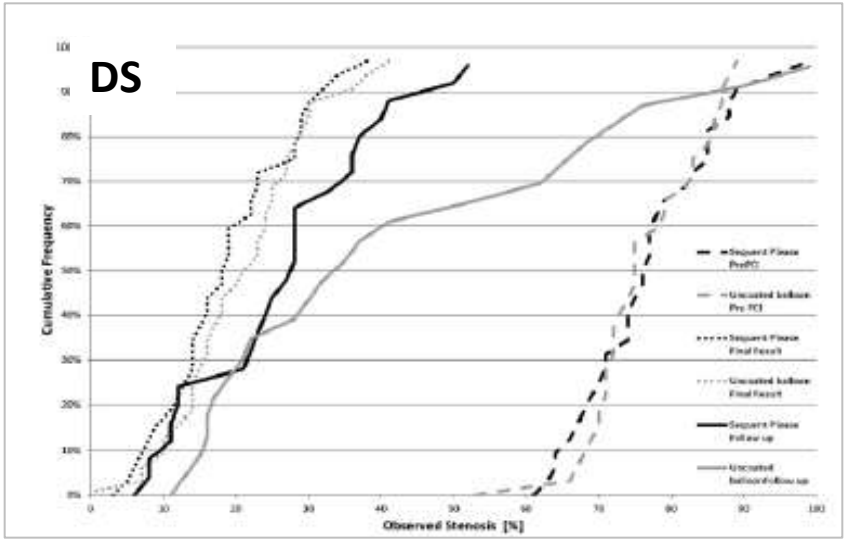
EuroIntervention 2014;10:50-57

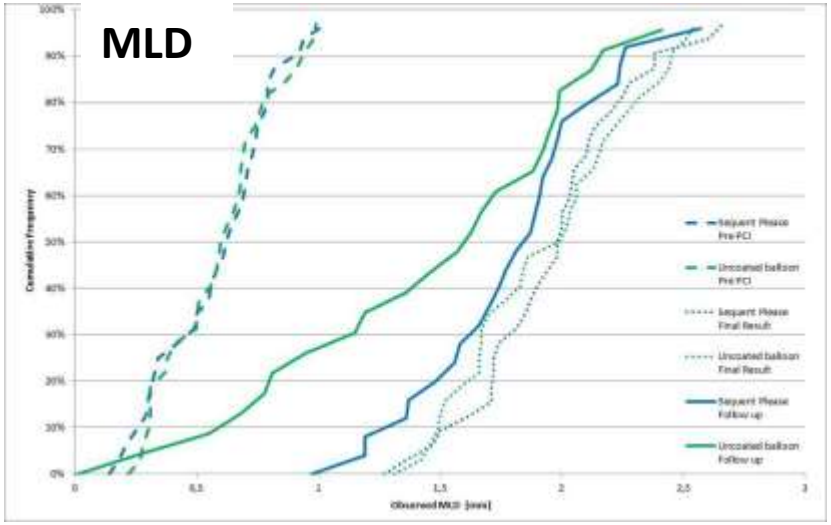
Drug eluting balloons as stand alone procedure for coronary bifurcational lesions: results of the randomized multicenter PEPCAD-BIF trial

Franz X. Kleber[1] · Harald Rittger[2] · Josef Ludwig[2] · Antonia Schulz[1] · Detlef G. Mathey[3] · Michael Boxberger[4] · Ralf Degenhardt[5] · Bruno Scheller[6] · Ruth H. Strasser[7]

	DCB, $N = 25$	POBA, $N = 23$	p
Reference diameter (mm)	2.40 ± 0.37	2.37 ± 0.33	n.s.
MLD (mm)	1.78 ± 0.37	1.39 ± 0.70	0.015
Stenosis grade in lesion (%)	25.7 ± 12.8	40.7 ± 26.7	0.010
MLD in segment (mm)	1.76 ± 0.36	1.37 ± 0.69	0.016
Stenosis grade in segment (%)	26.6 ± 12.9	42.4 ± 27.5	0.012
LLL in lesion (mm)	0.13 ± 0.31	0.51 ± 0.66	0.013
LLL in segment (mm)	0.08 ± 0.31	0.47 ± 0.61	0.006
LLL Index in lesion	0.08 ± 0.25	0.36 ± 0.48	0.012
LLL Index in segment	0.04 ± 0.28	0.36 ± 0.47	0.005
Binary restenosis grade (≥50 %) (n)	2 (5.9 %)	9[a] (25.7 %)	0.045

[a] Two of them had been stented





Conclusion

In bifurcation lesions that show only class A or B dissection and recoil not beyond 30 % the use of DCBs is a sound strategy.

Kleber et al Clin Res Cardiol 2016 DOI 10.1007/s00392-015-0957-6

DANUBIO - a new drug-eluting balloon for the treatment of side branches in bifurcation lesions: six-month angiographic follow-up results of the DEBSIDE trial

Jacques Berland[1]*, MD; Thierry Lefèvre[2], MD, FESC, FSCAI; Philippe Brenot[3], MD; Jean Fajadet[4], MD; Pascal Motreff[5], MD, PhD; Patrice Guerin[6], MD, PhD; Patrick Dupouy[7], MD; Christian Schandrin[8], MD; DEBSIDE trial investigators

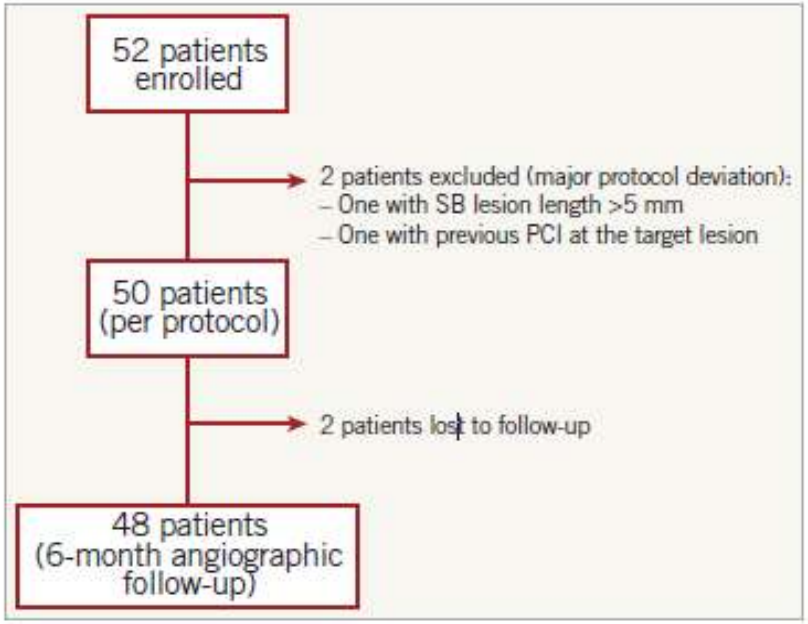


Table 3. Side branch late lumen loss at six months in DEBSIDE and previous trials.

Trial	Study device	Technique	Months	SB LLL (mm)
DEBSIDE (2014)	DANUBIO	Predilatation: conventional balloon in MB+SB MB: DES SB: DEB	6	–0.04±0.34
PEPCAD V (2011)[8]	SeQuent Please	MB+SB: DEB MB: BMS	9	0.21±0.47
DEBIUT (2011)[7]	DIOR I	Predilatation: DEB in MB+SB MB: BMS	6	0.19±0.66
Herrador et al (2013)[10]	SeQuent Please	Predilatation: conventional balloon in MB or SB SB: DEB MB: DES	12	0.09±0.40
BABILON (2014)[9]	SeQuent Please	Predilatation: conventional balloon in MB+SB MB+SB: DEB MB: BMS	9	–0.04±0.64

EuroIntervention 2015;11:868-876

Small Vessels

Table 2. Coronary small vessel disease.

Study	Devices	Number of patients	Primary outcome/follow-up	TLR, %/follow-up	Bail-out stent rate, %	Reference
PEPCAD I	SeQuent Please	118	LLL 0.18 mm in DCB-only, 0.73 in DCB+BMS/6 mos	4.9 in DCB-only, 27.1 in DCB+BMS/12 mos	28	23
PICCOLETTO	DIOR I vs. TAXUS	57	Diameter stenosis 43.6% vs. 24.3%/6 mos	32.1 vs. 10.3/9 mos	36	24
Spanish DIOR registry	DIOR I/II	103	LLL 0.34 mm/6 mos	3/12 mos	7	25
BELLO	IN.PACT Falcon vs. TAXUS	182	LLL 0.08 mm vs. 0.29 mm/6 mos	4.4 vs. 7.6/6 mos	20	26

BMS: bare metal stent; DCB: drug-coated balloon; LLL: late luminal loss; TLR: target lesion revascularisation

Treatment of Small Vessel Disease With the Paclitaxel Drug-Eluting Balloon: 6-Month Angiographic and 1-Year Clinical Outcomes of the Spanish Multicenter Registry

Multicenter Registry

- **104 patients with native coronary lesions in small vessels (≤ 2.25mm)**
- **PEB**
- **Regular balloon dilatation followed by a larger PEB for a minimum 45–60 sec**
- **Angiographic success was 93%** (7% bailout BMS implantation due to coronary dissection)

Predictors of Adverse Event s at 12- Months

MACE	HR	IC 95%	P-Value
DEB + Bailout BMS	18.74	2.58–135.84	0.004
STEMI	9.99	1.40–71.18	0.022
Complete Revascularization	0.10	0.01–0.87	0.038
TLR			
DEB + Bailout BMS	30.99	2.79–344.07	0.005
Restenosis			

Conclusion: The use of this PEB for the treatment of SMD provides excellent 1-year outcomes with only 4.8% MACE. The need for a bailout BMS was a strong predictor of MACE and TLR.

B. VAQUERIZO et al **J Interven Cardiol 2015;9999:1–9- Ahead of publ**

Native vessels with diffuse disease

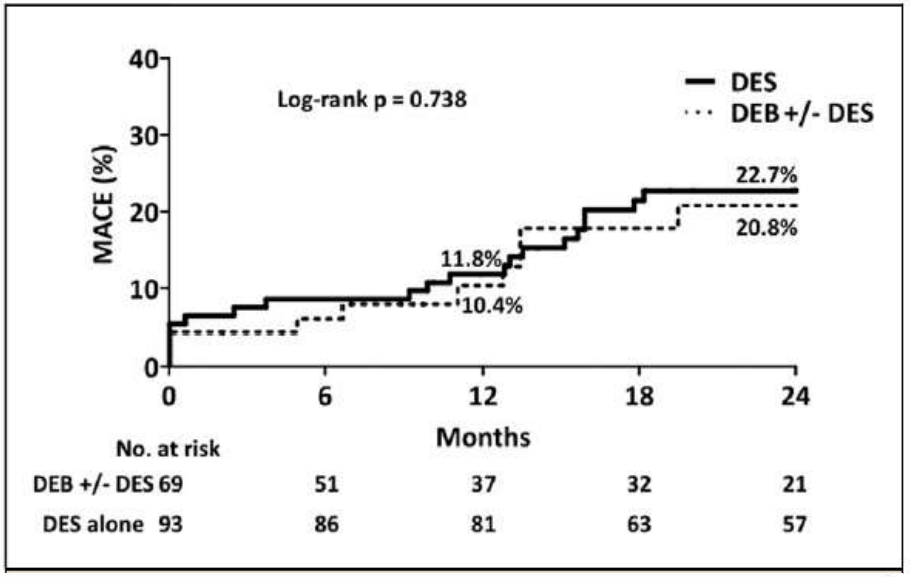
The Role of Drug-Eluting Balloons Alone or in Combination With Drug-Eluting Stents in the Treatment of De Novo Diffuse Coronary Disease

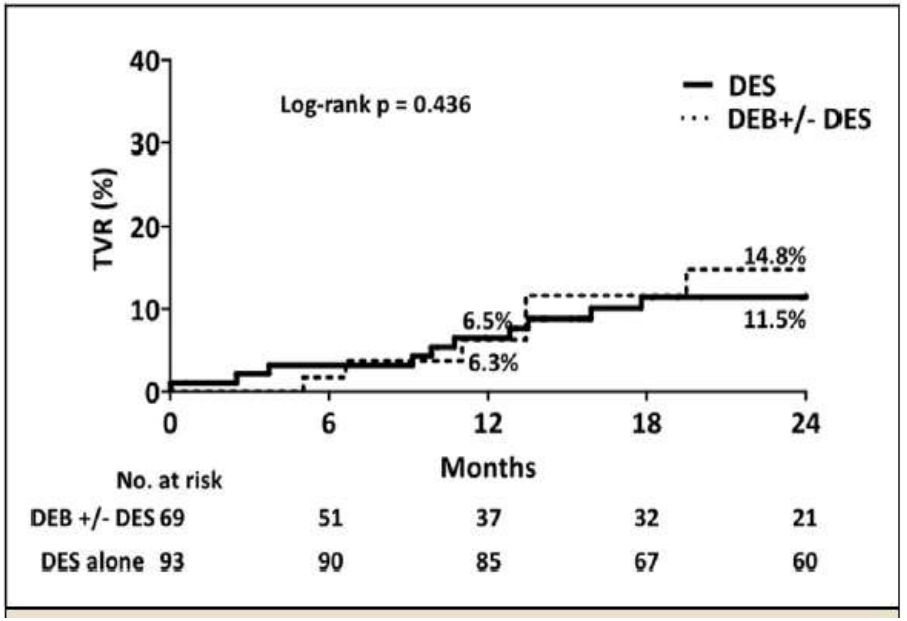
Charis Costopoulos, MD,*†‡ Azeem Latib, MD,*† Toru Naganuma, MD,*†
Alessandro Sticchi, MD,* Filippo Figini, MD,* Sandeep Basavarajaiah, MD,*†‡
Mauro Carlino, MD,* Alaide Chieffo, MD,* Matteo Montorfano, MD,* Charbel Naim
Masanori Kawaguchi, MD,*† Francesco Giannini, MD,* Antonio Colombo, MD*†

Table 2. Lesion and Procedural Characteristics

Characteristic	DEB ± DES Strategy (n = 93)	DES-Alone Strategy (n = 93)	p Value
Vessel treated			0.48
Left anterior descending artery	37 (39.8)	43 (46.2)	
Circumflex artery	16 (17.2)	18 (19.4)	
Right coronary artery	40 (43.0)	32 (34.4)	
Location of lesion in treated vessel			0.10
Proximal	4 (4.3)	10 (10.8)	
Mid/distal	89 (95.7)	83 (89.2)	
Balloon pre-dilation	80 (86.0)	84 (90.3)	0.36
Procedural adjuncts			
IVUS	37 (39.8)	30 (32.3)	0.28
Rotablation	3 (3.2)	4 (4.3)	0.70
Device characteristics			
DEB diameter, mm	2.52 ± 0.29	NA	
DES diameter, mm	2.95 ± 0.42	2.79 ± 0.25	<0.01
Total stent length,* mm	29.0 ± 9.1	50.2 ± 18.2	<0.01

Values are n (%) or mean ± SD. *DEB ± DES (n = 41), DES alone (n = 93).
IVUS = intravascular ultrasound; NA = not applicable; other abbreviations as in Table 1.





JACC: CARDIOVASCULAR INTERVENTIONS 2013; 6: 1153–9

Hybrid strategy with a bioresorbable scaffold and a drug-coated balloon for diffuse coronary artery disease: the "no more metallic cages" multicentre pilot experience

Hybrid Stretegy : patients with diffuse *de novo* or in-stent restenosis treated with
- **BRS implantation (larger proximal segment)**
- **DCB inflation (smaller distal segment or bifurcation side branch)**

Lesion and procedural characteristics

	Patients, n=42
Target vessel	
Left anterior descending	29 (69.0)
Left circumflex	8 (19.0)
Right coronary artery	5 (12.0)
Radial approach	17 (40.5)
Hybrid (BRS plus DCB) indication	
De novo diffuse or tandem coronary disease	37 (88.1)
CTO	2 (5.4)
Bifurcation (side branch >2.0 ≤2.75 mm)	9 (24.3)
Diffuse BMS ISR	5 (11.9)
Rotational atherectomy	1 (2.4)
Scoring balloons	5 (11.9)
Intracoronary imaging	
OCT	5 (11.9)
IVUS	18 (42.9)

BMS: bare metal stent; BRS: bioresorbable scaffold; CTO: chronic total occlusion; DCB: drug-coated balloon; ISR: in-stent restenosis; IVUS: intravascular ultrasound; OCT: optical coherence tomography; PCI: percutaneous coronary intervention

Clinical outcomes following BRS plus DCB hybrid strategy (median FU = 12 months)

	Patients, n=42
Procedural success, n (%)	42 (100)
Periprocedural MI (CK MB >5 times the upper limit of normal), n (%)	2 (4.7)
Median follow-up period, months	12 (IQR 6-18)
Angiographic follow-up, n (%)	22 (52.4)
Events from hospital discharge to the longest available follow-up	
All-cause death, n (%)	0
TLR per patient, n (%)	5 (11.9)
ID-TLR per patient, n (%)	2 (4.7)
BRS segment TLR, n (%)	4 (9.5)
BRS segment ID-TLR, n (%)	2 (4.7)
DCB segment TLR, n (%)	1 (2.3)
Definite/probable BRS/DCB segment thrombosis, n (%)	0

BRS: bioresorbable scaffold; CK MB: creatine kinase MB; DCB: drug-coated balloon; ID: ischaemia-driven; MI: myocardial infarction; TLR: target lesion revascularisation

A. Ielasi et al , EuroIntervention 2016;11:e1-e1595

AMI

First Results of the DEB-AMI (Drug Eluting Balloon in Acute ST-Segment Elevation Myocardial Infarction) Trial

A Multicenter Randomized Comparison of Drug-Eluting Balloon Plus Bare-Metal Stent Versus Bare-Metal Stent Versus Drug-Eluting Stent in Primary Percutaneous Coronary Intervention With 6-Month Angiographic, Intravascular, Functional, and Clinical Outcomes

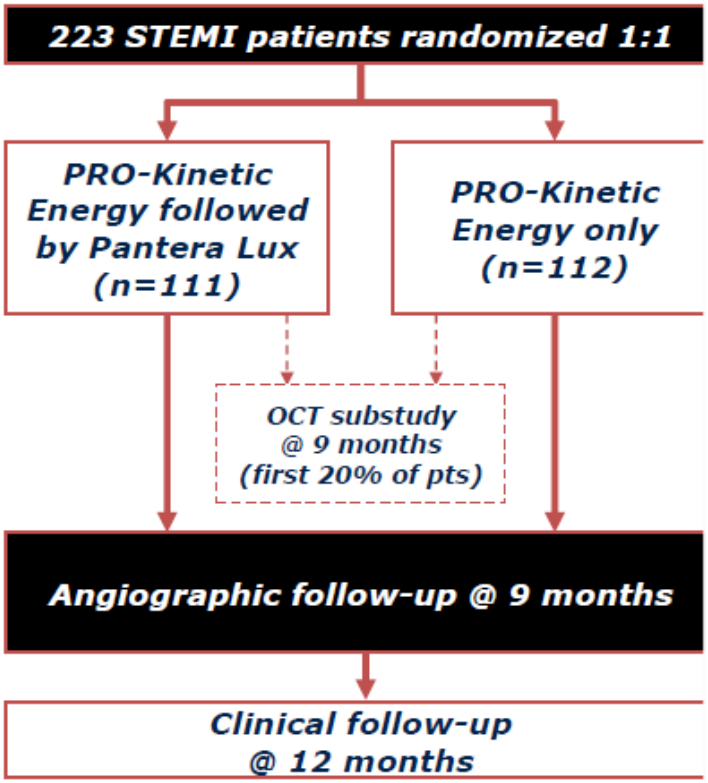
	BMS (n = 51)	DEB (n = 50)	DES (n = 49)	p Value DEB vs. BMS
Events at 1-month follow-up				
Cardiac death	1*(2.0)	0	0	0.32
Myocardial infarction	0	2†(4.0)	0	0.24
Target lesion revascularization	0	2†(4.0)	0	0.24
Target vessel non-lesion revascularization	0	0	0	—
Stent thrombosis	0	2†(4.0)	0	0.24
Cumulative events at 6-month follow-up				
Cardiac death	2 (3.9)	0	0	0.16
Myocardial infarction	0	2 (4.0)	0	0.24
Target lesion revascularization	9 (17.6)	10 (20.0)	1 (2.0)	0.76
Target vessel non-lesion revascularization	1 (2.0)	1 (2.0)	1 (2.0)	0.99
Stent thrombosis	0	2 (4.0)	0	0.24
Major adverse cardiac events	12 (23.5)	10 (20.0)	2 (4.1)	0.67

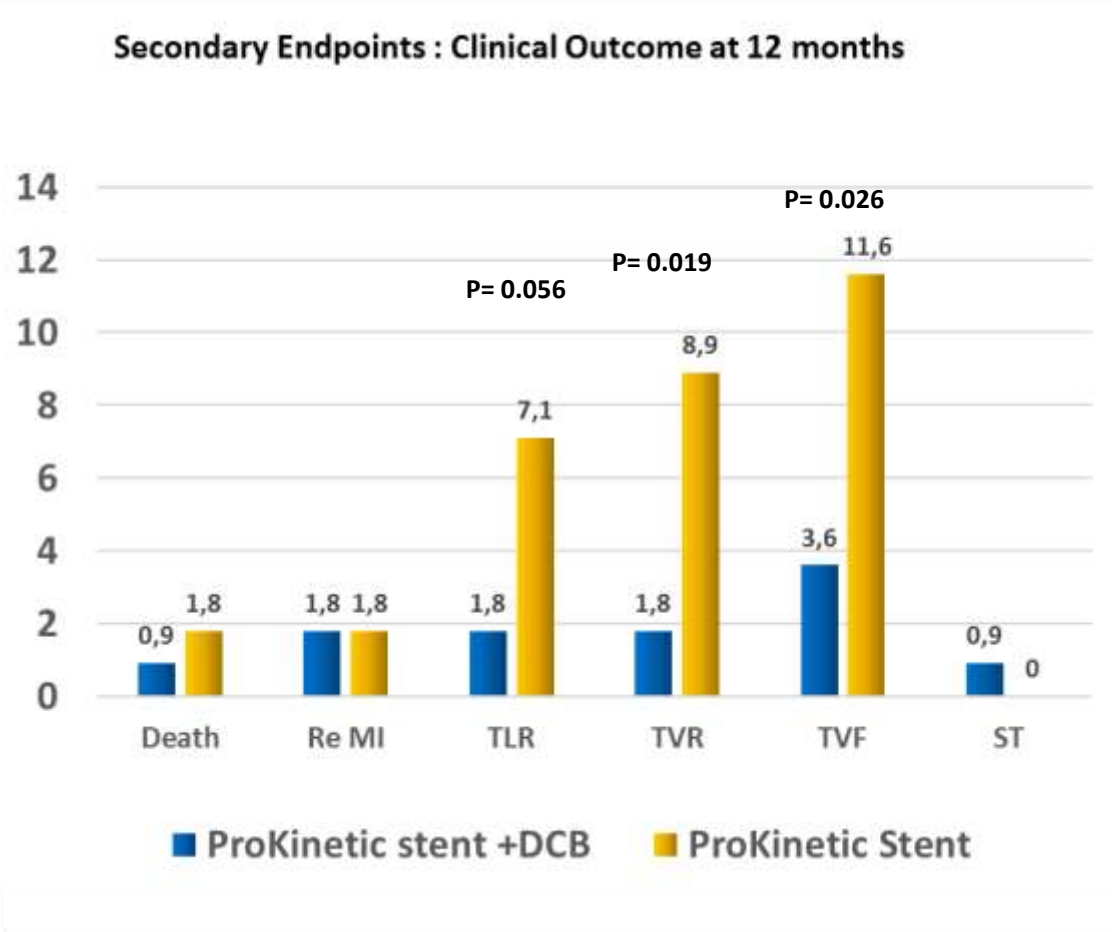
Values are n (%). *Event occurred in-hospital. †Of these 2 patients, 1 patient had a stent thrombosis, myocardial infarction, and target lesion revascularization in-hospital.

Abbreviations as in Table 1.

Belkacemi et al. JACC 2012, 59 (25):2327–37

PEBSI: A Randomized Trial of Paclitaxel-Eluting Balloon After Bare Metal Stent Implantation vs Bare Metal Stent in ST Elevation Myocardial Infarction





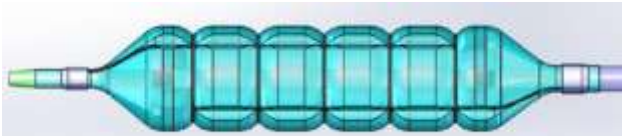
Presented at ACC 2015

What is Next ?

Drug-coated AngioSculpt

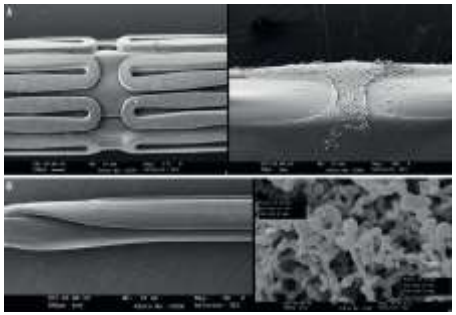
- AngioSculpt Platform
- Paclitaxel (3 µg/mm²) + proprietery excipient
- Diameters 2.0, 2.5, 3.0, 3.5 mm
- Lengths 10 – 15 - 20 mm
- 6F GC compatible

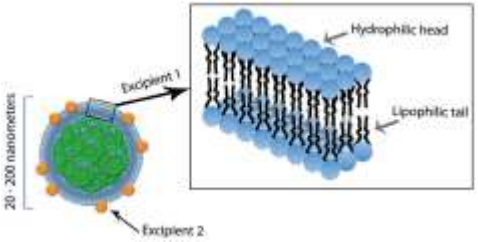
The Chocolate Touch™ Balloon



Advantages of Chocolate Platform

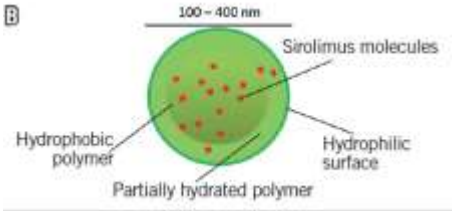
- The CS is designed to cover the coated balloon during insertion, delivery through tortuosity, and balloon unfolding
- The inflated Chocolate has a larger surface area vs. POBA
- The inflated balloon opens the vessel by angioplasty, while passively transferring the vessel wall to paclitaxel
- Upon deflation, the CS and balloon are removed from the vessel; no part of the device remains





Magic Touch

Virtue™ nanoparticle



Take Home Message:

- Drug-eluting balloons represent an innovative technology in interventional cardiology with established efficacy and safety in treating coronary ISR (both BMS and DES ISR). So far DEBs are reccomended in recent ESC Guidelines for the treatment of both BMS and DES ISR (Class I - Evidence A)
- Promising data for additional indications have been reported in the treatment of de-novo lesions , side branches in bifurcation lesions, in small vessels . However Data for these indications are limited to few small randomised trials and registries . Larger randomised trials (vs newer generation DES) using clinical rather than surrogate angiographic outcomes are warranted .
- New limus-eluting balloons with innovative coating approaches (Nanotechnology) are on arrival for clinical use and might add a further improvement in clinical outcome
- DEBs are not equal : different manufaturing and drug release kinetics. Need for head to head comparison for a more appropriate use