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

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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



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: dru balloon	ig-eluting stent; ISR: in-stent re	estenosis; LL	L: late luminal loss; MACE: major adve	rse cardiac events; TLR: target lesion revasculari	sation; UCB: un	coated

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.	1	С	
DES are recommended for the treatment of in-stent re-stenosis (within BMS or DES).	1	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	1	Α	507-511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	lla	С	

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

21^{el} CardioVascular Summit TCTAP 2016



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)



ISAR-DESIRE 4 Trial

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





ISAR-DESIRE 4 Trial

Primary Endpoint :Diameter Stenosis at Follow-up Angiography

Secondary endpoints : TLR and Restenosis







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



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) A		F Co	Proportion o-morbid	n of lities	Pre-ML	.D (mm)	Pre-D	S (%)	Lesion Le	ngth (mm)	Post-MI	_D (mm)	Post-l	DS (%)
mai (rear)	Age	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	67.0	72 604	A1 E0/	77.004	DEB	DES	POBA	DEB	DES	POBA	DEB	DES	POBA	DEB	DES	POBA	DEB	DES	POBA
(2012)	07.9	13.0%	41.370	11.970	0.97	0.93	0.88	64.4	66.7	67.7	N/R	N/R	N/R	2.29	2.53	2.10	18.5	12.8	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)	<u>65.5</u>	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

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



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 (m	onths)
					Angiographic	Clinical
DCB						
PACCOCATH-ISR P= and IP4=	2006 (I)- 2008 (II)	BMS and DES	BA vs DCB	108 (54/54)	6	60
PEPCAD IP*	2009	BMS	PES vs DCB	131 (65/66)	6	12
Habara et al ^y	2011	DES	BA vs DCB	50 (25/25)	6	6
PEPCAD-DES#	2012	DES	BA vs DCB	110 (38/72)	6	6
Habara et a ^{ja}	2013	BMS and DES	BA vs DCB	210(72/138)	6	6
ISAR DESIRE 3 th	2013	DES	BAIN PESINDOB	402 (134/131/137)	6-8	12
PEPCAD China ISR [®]	2014	DES	PES vs DCB	215 (106/109)	9	12

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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

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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 infarct	ion					
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: dr	ug-coated balloon; LLL: late luminal loss; MACE: ma	ajor adverse	cardiac events; MB: main branch; SB: si	de branch; TLR: target lesio	n revascularisa	tion

21st CardioVascular Summit TCTAP 2016

RESEARCH ARTICLE

Open Access

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

Georg M Fröhlich¹, Alexandra J Lansky², Dennis T Ko³, Olga Archangelidi⁴, Rodney De Palma¹, Adam Timmis⁵ and Pascal Meier^{1,2*}

Study	Paclitaxel eluting balloon	Controls stent type(s)	Setting	Clopidogrel (mts)	Follow-up (mts)	Primary endpoint	MACE	TLR	Bare metal stenting
DEB-AMI	DIOR 2 nd generation	TAXUS DES, Genius Magic Euroscore BMS	STEMI	12	6	LLL	death, MI, TVR	restenosis >50% ischemia	100%
Stella et al	DIOR 1 st 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	б	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 1 st 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%)

Table 2 Baseline characteristics of included trials

Fröhlich et al. BMC Medicine 2013, 11:123

Death

AMI

	D	EB	Compara	tor	Risk Ratio		Risk Ratio	Accession of the second s	0	EB	Comp	arator	Risk Ratio		
Study	Total	Deaths	Total De	aths	Ξ.	RR	95%-CI	Study	Total	ST	Total	ST	É es	RR	95%-CI
Comparator = BMS DEB AMI (DEB vs BMS) 2012 Stella (DEB vs BMS) 2012 PERFECT (DEB vs BMS) 2011 Verder (DEB vs BMS) 2011	50 40 62	0 0 0	51 37 58	201		0.20	(0.01; 4.14) 0.02; 45.50] (0.01; 7.51)	Comparator = BMS DEB AMI (DEB vs BMS) 2012 Stella (DEB vs BMS) 2012 PERFECT (DEB vs BMS) 2011	50 40 62	2 0 0	51 37 58	0 0 0		5.10 0.93 0.94	(0.25; 103.6 (0.02; 45.5 (0.02; 46.4
Random effects model Heterogeneity: Faquared = 0%, tau-aqu	219 ared=(0 , P=0.929	214	-		0.29	[0.06; 1.48]	Herdeg (DEB+BMS vs BMS) 200 Random effects model Heterogenetly: Faquared = 0%, tau-squ	09 67 219 ared=0, F	0 = 0.855	68 214	0	-	1.01	[0.02; 50.4 [0.29; 10.60
Comparator = DES DEB AMI (DEB vs DES) 2012 Stella (DEB vs DES) 2012 PEPCAD III (DEB vs DES) 2009 PICCOLETO (DEB vs DES) 201 BELLO (DEB vs DES) 2012 Herdeg (DEB +BMS vs DES) 200 Random effects model Heterogenesty: Faguared = 0%, tau-squ	50 40 312 10 28 90 90 90 67 587	0 0 3 1 1 0 <i>P=0.984</i>	49 40 325 29 92 67 602	0 0 1 1 1 0		0.98 (1.00 (3.12 (1.04 (1.02 (1.00 (1.42)	0.02; 48 44] 0.02; 49 19] 0.33; 29 88] 0.07; 15 77] 0.06; 16 10] 0.02; 49 67] [0.41; 4.85]	Comparator = DES DEB (AMI DEB vs DES) 2012 Stella (DEB vs DES) 2012 PICCOLETO (DEB vs DES) 2011 Herdeg (DEB+BMS vs DES) 200 Random effects model Heterogeneilly: Faquared = 0%, 1au-aqui	50 40 0 28 9 67 185 aved = 0,	2 0 0 0 P=0.685	49 40 29 67 185	0 1 0		+ 4.90 0.33 1.04 1.00 1.22	[0.24; 99.5 [0.01; 7.9 [0.02; 50.4 [0.02; 49.6 [0.22; 6.7 (
Random effects model Heterogeneity: i-squared=0%, lau-squ	806 ared=0), P=0.944	816	Fav	0.2 0.5 1 2 5 vors DEB Favors	0.79	[0.30: 2.11]	Random effects model Heterogeneilly: Faquared=0%, lau-aqu	404 aved = 0,	P=0.937	399	Favo	0.2 0.5 1 2 orsDEB Favors	- 1.45	[0.42: 5.0

Stent Thrombosis

Μ	Α	CE

1990-1997		DEB	Compa	rator	Risk F	₹atio				(S. M.)	D	EB	Com	parator	Risk Ratio		
Study	Total	M	Total	MI		1 E	RR	9	5%-CI	Study T	otal	MACE	Total	MACE	4	RR	95%-CI
Comparator = BMS						1				Comparator = BMS							
DEB AMI (DEB vs BMS) 2012	50	1.12	51	8		1	5.10	[0.25; 10	03.60]	DEBAMI (DEB vs BMS) 2012	50	10	51	12		0.85	ID 40 1 79
Stella (DEB vs BMS) 2012	40	1	37	2	_	-	1.39	[0.25;	7.85]	Stella (DEB vs BMS) 2012	40	8	37	11		0.67	m 30 1 49
PERFECT (DEB vs BMS) 2011	62	1	58	1		-	0.94	[0.06, 1	14.61]	Herden (DEB+BMS vs BMS) 2000	67	9	69	18		0.51	(0.25 1.05
Herdeg (DEB+BMSvsBMS) 20	09 67	0	88 (3	+ 8	1-	0.14	[0.01;	2.75]	Random effects model	157	5	156	10	0	0.66	10 43: 1.02
Random effects model	219		214		-	-	1.09	[0.33;	3.62]	Hatermone@r LisrelaterTer0% Techemia	od=0	P=0624			222		laura, mar
Heterogeneity: I-squared = 0%, tau-squ	ared=0	2, P=0.40	2			1			000000	neter og en englinn ag være or som af sære og sæ	00-0	5-F. H 10546.1					
Comparator= DES						ŧ				Comparator = DES							
DED ANU (DED DEC) 2012	50		40	0		1		10.04	00.000	DEB AMI (DEB vs DES) 2012	50	10	49	2		- 4.90	[1.13; 21.23
DEBAMI (DEB VS DES) 2012	50		48	0	-		4.90	10.24, 8	38.52]	Stella (DEB vs DES) 2012	40	8	40	7		1.14	[0.46; 2.85
Stella (UEB vs UES) 2012	-40		40	4		1	0.75	10.18	3.14]	PICCOLETO (DEB vs DES) 2010	28	10	29	4		2.59	[0.92; 7.30
PEPCAD III (DEB vs DES) 2009	312	14	325	1		1	14.58	[1.93, 11	10.24]	BELLO (DEB vs DES) 2012	90	9	92	15		0.61	(D.28; 1.33
PICCOLETO (DEB vs DES) 201	0 28		29	0		1		10.13, 1	73.12]	Herdeo (DEB+BMS vs DES) 2009	67	9	67	9		1.00	10.42 2.36
BELLO (DEB vs DES) 2012	90	- R	92	5		1	0.20	[0.02,	1.72]	Ali(DEB vs DES) 2011	45	6	39	6		0.97	ID 30 2 47
Herdeg (DEB+BMS vs DES) 200	09 67	0	67	1			0.33	[0.01;	8.04]	Random effects model	320	0	316		-	1.23	10 72: 2.11
Random effects model	587		602			1	- 1.45	[0.35;	6.06]	Heterogeneity: Fsguared = 45%, tau-sgu	aned'=	0.2007, P = 0.106					Letter and
Helerogeneity: Fsquared = 55.5%, tau-	aquarec	1.688, P	= 0.047			ŧ						80708080808080080					
Random effects model	806		816		<	-	1.26	[0.49;	3.21]	Random effects model	477		472		\$	0.95	[0.64; 1.39
Heterogeneity: I-squared = 35.7%, tau-	aquared	= 0.7749,	P = 0.122			Į.		÷.	25	Heterogeneity: Esquared = 40.4%, tau-sq	uared	= 0.136, P = 0.098	l.			7	
					00.05 1	1									02 05 1 2	5	
					0.2 0.5 1	4	0							E		e Control	
				Fa	vors DEB	Favor	rs Control							r a	VOIS DEB Favor	s control	

Fröhlich et al. BMC Medicine 2013, 11:123

TLR

	D	EB	Com	parator	Risk Ratio		100 100 10			0	EB	Com	parator	Risk Ratio	ā.		
Study	Total	TLR	Total	TLR	1	RR	95	%-CI	Study	Total	Restenosis	Total F	estenosis	Constantine UNC	RF	95%	6-CI
Comparator = BMS																	
DEB AMI(DEB vs BMS) 2012	50	10	51	9		1.13	[0.50]	2.55]	Comparator = BMS								-
Stella (DEB vs BMS) 2012	40	8	37	10		0.74	0.33;	1.67]	DEB AMI (DEB vs BMS) 2012	42	13	42	10		1.30	[0.64;	2.63]
PERFECT (DEBvs BMS) 2011	62	3	58	9		0.31	10.09	1.10	PERFECT (DEBvs BMS) 2011	59	3	56	13 -	-8	0.27	[0.07;	0.731
Herdeg (DEB+BMS vs BMS) 201	09 67	9	68	15		0.61	0.29	1.29]	Herden (DEB+BMS vs BMS) 20	19 54	8	56	22		0.36	10 18	0 771
Random effects model	219		214		0	0.71	0.46;	1.10]	Random affects model	155		154		-	0.51	ID 18-	1 441
Heterogeneity: Asquared = 3.7%, tau-so	quared = i	0.0076, P	= 0.374					201202	Heterogeneity: I-squared = 78.1%, tau-i	squared =	0.6485, P = 0.0	10			0.01	10.10.	1.444
Comparator = DES									N 55486								
DEB AMI (DEB vs DES) 2012	50	10	49	1		9.80 [1.30;	73.69]	Comparator = DES								
Stella (DEB vs DES) 2012	40	8	40	6		1.33	[0.51;	3.49]	DEB AMI (DEB vs DES) 2012	42	13	43	3	_	4.44	[1.36:	14.461
PEPCAD III (DEB vs DES) 2009	312	31	325	15		2.15	[1.19;	3.91]	PICCOLETO (DEBysDES) 20	10 28	9	29	3	-	- 3.11	m 94	10.311
PICCOLETO (DEB vs DES) 201	10 28	9	29	3		3.11 [0.94;	10.31]	PELLO/DERus DES) 2012	01	0	00	12		0.61	10.00	1 501
BELLO (DEB vs DES) 2012	90	4	92	7		0.58	(0.18;	1.93]	BELLO (DEB VS DES) 2012	01	0	04	2	-1	0.07	10.28,	1.30
Herdeg (DEB+BMS vs DES) 200	09 67	9	67	8		1.12	[0.46;	2.74]	Herdeg (DEB+BM 5 vs DE5) 200	19 54	8	04	8	I_	1.00	[0.40;	2.47]
Ali (DEB vs DES) 2011	45	3	39	4		0.65	(0.15;	2.73]	Random effects model	205		208			- 1.61	[0.67;	3.85]
Random effects model	632		641		0	1.53	0.90;	2.59]	Heterogeneity: Fsquared=66.2%, tau-s	quared=(15198, P= 0.031	£					
Heterogeneity: I-squared = 42%, tau-sq	waved = 0	200, P=	0.111														
Random effects model	851		855		4	1.09 /	0.71:	1.681	Random effects model	360	2000 - 7524	362		\$	0,96	[0.48;	1.93]
Heterogeneity: I-squared = 53%, tau-sq	wared = 0	265, P=	0.019					,	Heterogeneity: I-squared = 74.6%, tau-	sdnaveq :	0.634, p < 0.00	М		+-			
					0.2 0.5 1 2 5									0.2 0.5 1 2	5		
				Em		Control							Esvin	PER Favo	control		

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.

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 Mínguez¹*, MD, PhD; Juan Manuel Nogales Asensio¹, MD, PhD; Luis Javier Doncel Vecino¹, MD; Jorge Sandoval², MD; Sebastián Romany³, MD; Pedro Martínez Romero⁴, MD, José Antonio Fernández Díaz⁵, MD; Javier Fernández Portales³, MD, PhD; Reyes González Fernández¹, MD, PhD; Ginés Martínez Cáceres¹, MD; Antonio Merchán Herrera¹, MD, PhD; Fernando Alfonso Manterola², 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	<i>p</i> -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 resteriosis	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

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

Franz X. Kleber¹ · Harald Rittger² · Josef Ludwig² · Antonia Schulz¹ · Detlef G. Mathey³ · Michael Boxberger⁴ · Ralf Degenhardt⁵ · Bruno Scheller⁶ · Ruth H. Strasser⁷

	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 %)	9ª (25.7 %)	0.045

* Two of them had been stented

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

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 Lefèvre², MD, FESC, FSCAI; Philippe Brenot³, MD; Jean Fajadet⁴, MD; Pascal Motreff⁵, MD, PhD; Patrice Guerin⁶, MD, PhD; Patrick Dupouy⁷, MD; Christian Schandrin⁸, MD; DEBSIDE trial investigators

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Table 3. Side branch late lumen loss at six months in DEBSIDEand 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

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								

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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)

Fredictors of Adverse Event's at 12- Month's							
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			×.				

Dradictors of Advarsa Evants at 12 Manths

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.

Native vessels with diffuse disease

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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 ^{*}†

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	$\textbf{2.52} \pm \textbf{0.29}$	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

IVUS = intravascular ultrasound; NA = not applicable; other abbreviations as in Table 1.

DEB Update 2016 - De Novo lesions and ISR

JACC: CARDIOVASCULARINTERVENTIONS 2013; 6: 1 1 5 3 - 9

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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	- 49)
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)
СТО	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	- 1 2
OCT	5 (11.9)
IVUS	18 (42.9)

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	ble 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: myo infarction; TLR: target lesion revascularisation	cardial

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 ?

21^{el} CardioVascular Summit TCTAP 2016

DEB Update 2016 - De Novo lesions and ISR

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 TransPax^{te} Coating Platrum-Indian Marketbands PTFE-coated Higotube Utra-Low Tip Profile

Magic Touch

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

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