CARDIOVASCULAR SUMMIT
TCTAP 2015

April 28-May1 , 2015 Seoul. Korea

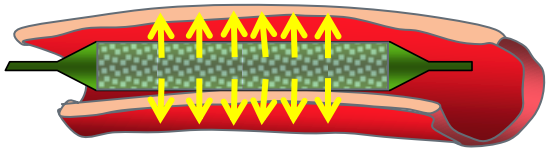
Drug –Eluting Balloons 2015

for ISR, Small Vessel , AMI etc..

I Sheiban
University of Turin

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

E-mail : profsheiban@gmail.com



Potential Advantages of DEB

- Local drug delivery over very short period of time : not weeks /months
- Avoid chronic inflammation due to absence polymers
- Better re-endothelialization: reduced dual antiplatelet therapy
- No distortion of original vessel anatomy (BIF)
- No double / triple metal layers in case of ISR or BIF
- Easy lesion crossing / deliverabilityby balloon only

What Are The Clinical Scenarios Where DEB Strategy Can Have a Clear Advantage ?

- In-stent Restenosis
- Bifurcation Lesions (SB)
- Small Vessel Disease
- Vulnerable Plaque-AMI
- Native vessels ?

Clinical Data on the use of DEB for :

- ISR
- Bifurcation
- Small Vessels
- Native " De Novo " lesions

Some Clinical Data o n the use of DEB for :

- ISR
- Bifurcation
- Small Vessels
- Native « De Novo « lesions

Drug-eluting Balloons (DEB) Used in Clinical Trials

Drug-Coated Balloon	Manufacturer	Drug-Delivery Technology	Excipient	Dose Density, $\mu g/m^2$
Dior I	Eurocor (Bonn, Germany)	Nanoporous balloon	Dimethyl sulfate	3
Dior II	Eurocor (Bonn, Germany)	Nanoporous balloon	Shellac	3
Elutax	Aachen Resonance (Aachen, Germany)	Coated	None	2
Genie	Acrostak Corp. (Geneva, Switzerland)	Nanoporous double balloon	None Uses a liquid drug delivery catheter	10 μmol/l
In.Pact Falcon	Medtronic-Invatec (Frauenfeld, Switzerland)	Coated	FreePac urea	3
Moxy	Lutonix Inc. (Maple Grove, Minnesota)	Coated	Nonpolymeric	2
Pantera Lux	Biotronik (Bulach, Switzerland)	Coated	Butyryl-tri-hexyl citrate	3
SeQuent Please	B. Braun Melsungen AG (Berlin, Germany)	Coated	Iopromide	3
Coroflex DEBlue (Hybrid system of Coroflex blue cobalt chromium BMS premounted onto SeQuent Please DCB)	B. Braun Melsungen AG (Berlin, Germany)	Coated	Iopromide	3

DES vs. POBA : RIBS II: 150 patients with BMS-restenosis: SES vs. POBA

Table 3. In-Hospital and One-Year Clinical Events

Event	SES Group (n = 76)	BA Group (n = 74)	p Value	HR (95% CI)
Hospital events, n (%)				
Death	1 (1.3)	0 (0)	0.49	—
Myocardial infarction	0 (0)	0 (0)	1	1
Target vessel revascularization	0 (0)	0 (0)	1	1
Coronary angioplasty	0 (0)	0 (0)	1	1
Coronary surgery	0 (0)	0 (0)	1	1
Any major hospital event	1 (1.3)	0 (0)	0.49	—
Events at 9 months, n (%)				
Death	3 (3.9)	1 (1.4)	0.32	0.34 (0.03–3.27)
Myocardial infarction	2 (2.6)	1 (1.4)	0.57	0.51 (0.05–5.61)
Target vessel revascularization	3 (3.9)	10 (13.5)	0.03	3.56 (0.98–12.9)
Coronary angioplasty	2 (2.6)	7 (9.5)	0.08	3.65 (0.76–17.5)
Coronary surgery	1 (1.3)	3 (4.1)	0.54	2.06 (0.19–22.7)
Any major event at 9 months	4 (5.3)	11 (14.9)	0.05	2.93 (0.93–9.20)
Events at 1 year, n (%)				
Death	3 (3.9)	3 (4.1)	0.98	1.02 (0.21–5.05)
Myocardial infarction	2 (2.6)	2 (2.7)	0.99	1.01 (0.14–7.17)
Target vessel revascularization	8 (10.5)	22 (29.7)	0.003	3.16 (1.40–7.09)
Coronary angioplasty	7 (9.2)	18 (24.3)	0.01	2.83 (1.18–6.76)
Coronary surgery	1 (1.3)	4 (5.4)	0.16	4.12 (0.46–36.9)
Any major event at 1 year	9 (11.8)	23 (31.1)	0.004	2.90 (1.34–6.28)

Patients with more than one event are counted only once for the composite clinical end points, although each event is listed separately in the corresponding category. p values from Cox analysis.
CI = confidence intervals; HR = hazard ratio; — = undefined; other abbreviations as in Table 1.

Alfonso F. et al, JACC 2006;56:2152-60

Drug Rleuting Balloons 2015

DEB vs. POBA PEPCAD-DES :110 patients with DES-restenosis: Paclitaxel-eluting balloon vs POBA (SES & PES)

Clinical Outcome at 6 Months

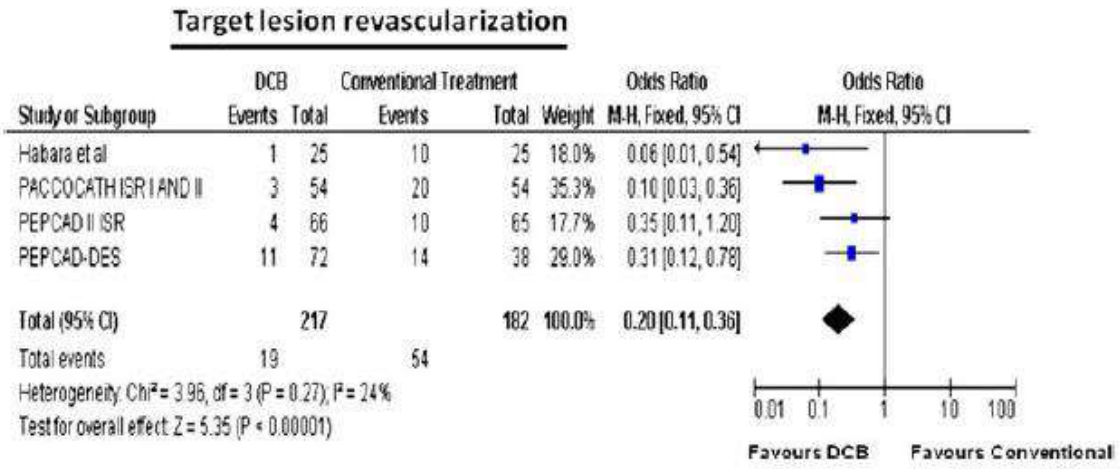
	Drug-Coated Balloon (n = 72)	Uncoated Balloon (n = 38)	p Value
Target lesion revascularization	11 (15.3%)	14 (36.8%)	0.005
Myocardial infarction	0 (0.0%)	1 (2.6%)	0.35
Cardiac death	1 (1.4%)	4 (10.5%)	0.048
MACE	12 (16.7%)	19 (50.0%)	<0.001
Stent thrombosis			
Definite	0	0	
Possible	1 (1.4%)	4 (10.5%)	0.048

Angiographic Outcome at 6 Months according to type of restenotic stent

	Drug-Coated Balloon	Uncoated Balloon	p Value
Non-PES	56	31	
Late lumen loss, mm	0.41 ± 0.65	0.90 ± 0.65	0.004
PES	16	7	
Late lumen loss, mm	0.46 ± 0.50	1.58 ± 1.03	0.021

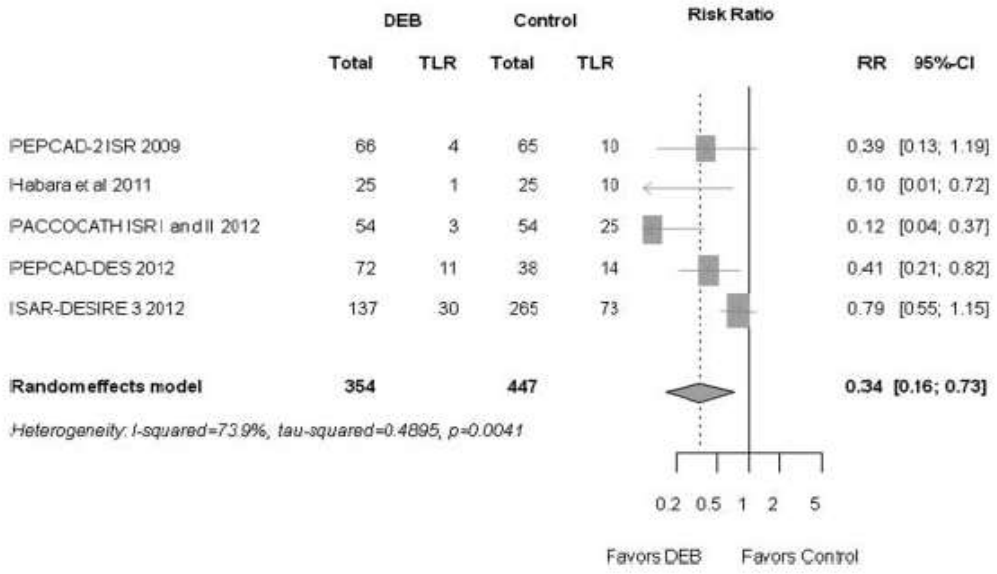
Rittger H. et al, JACC 2012;

Drug Rleuting Balloons 2015



DEB vs POBA

Navarese et al. *Clin Res Cardiol* 2013



DEB vs DES

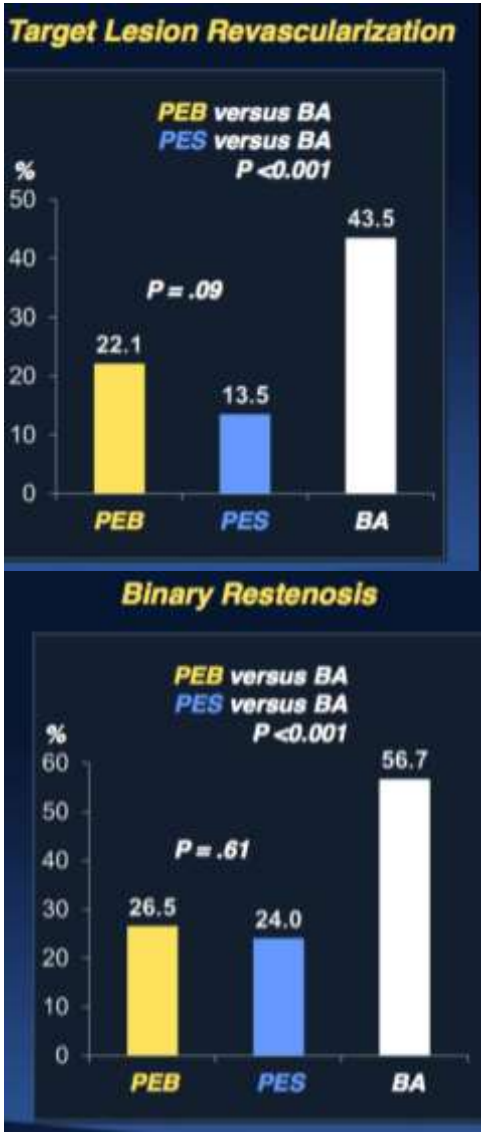
Indermuehle et al. *Heart*2013

DES restenosis: ISAR DESIRE 3

	PEB	PES	Balloon angioplasty	p values		
				PEB vs PES	PEB vs balloon angioplasty	PES vs balloon angioplasty
Death	3 (2·2%)	6 (4·6%)	7 (5·3%)	0·27	0·17	0·80
Myocardial infarction	3 (2·1%)	3 (2·4%)	2 (1·5%)	0·92	0·70	0·63
Q wave myocardial infarction	1 (0·7%)	1 (0·8%)	0	0·95	0·34	0·32
Target lesion thrombosis	1 (0·7%)	1 (0·8%)	0	0·97	0·33	0·31
Target lesion revascularisation	30 (22·1%)	17 (13·5%)	56 (43·5%)	0·09	<0·0001	<0·0001
Target vessel revascularisation	33 (24·2%)	21 (16·6%)	58 (45·1%)	0·18	0·0001	<0·0001
Death or myocardial infarction	6 (4·4%)	9 (6·9%)	9 (6·8%)	0·35	0·36	0·97
Death, myocardial infarction, or target lesion revascularisation	32 (23·5%)	25 (19·3%)	61 (46·2%)	0·50	<0·0001	<0·0001

Data are n (%). Percentages are Kaplan-Meier estimates. PEB=paclitaxel-eluting balloon. PES=paclitaxel-eluting stent.

Table 4: **Clinical results at 1 year by treatment group**



RCT

402 patients

137 (34%) were assigned to PEB

131 (33%) to PES

134 (33%) to balloon angioplasty

Byrne AB et al. Lancet 2013

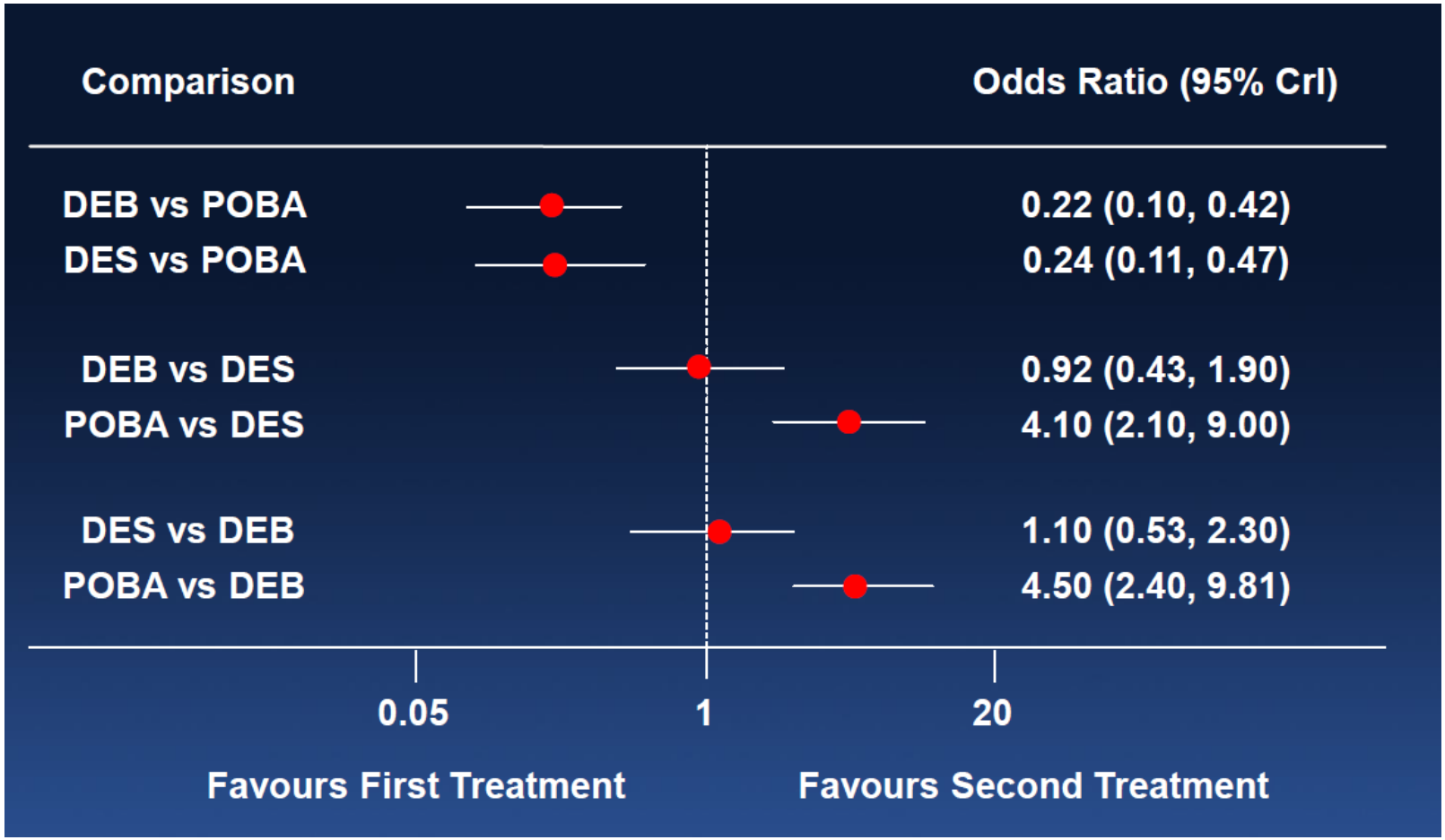
Comparison Among Drug-eluting Balloon, Drug-eluting Stent, and Plain Balloon Angioplasty for Treatment of In-Stent Restenosis: A Network Meta-analysis of 11 Randomized Controlled Trials

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

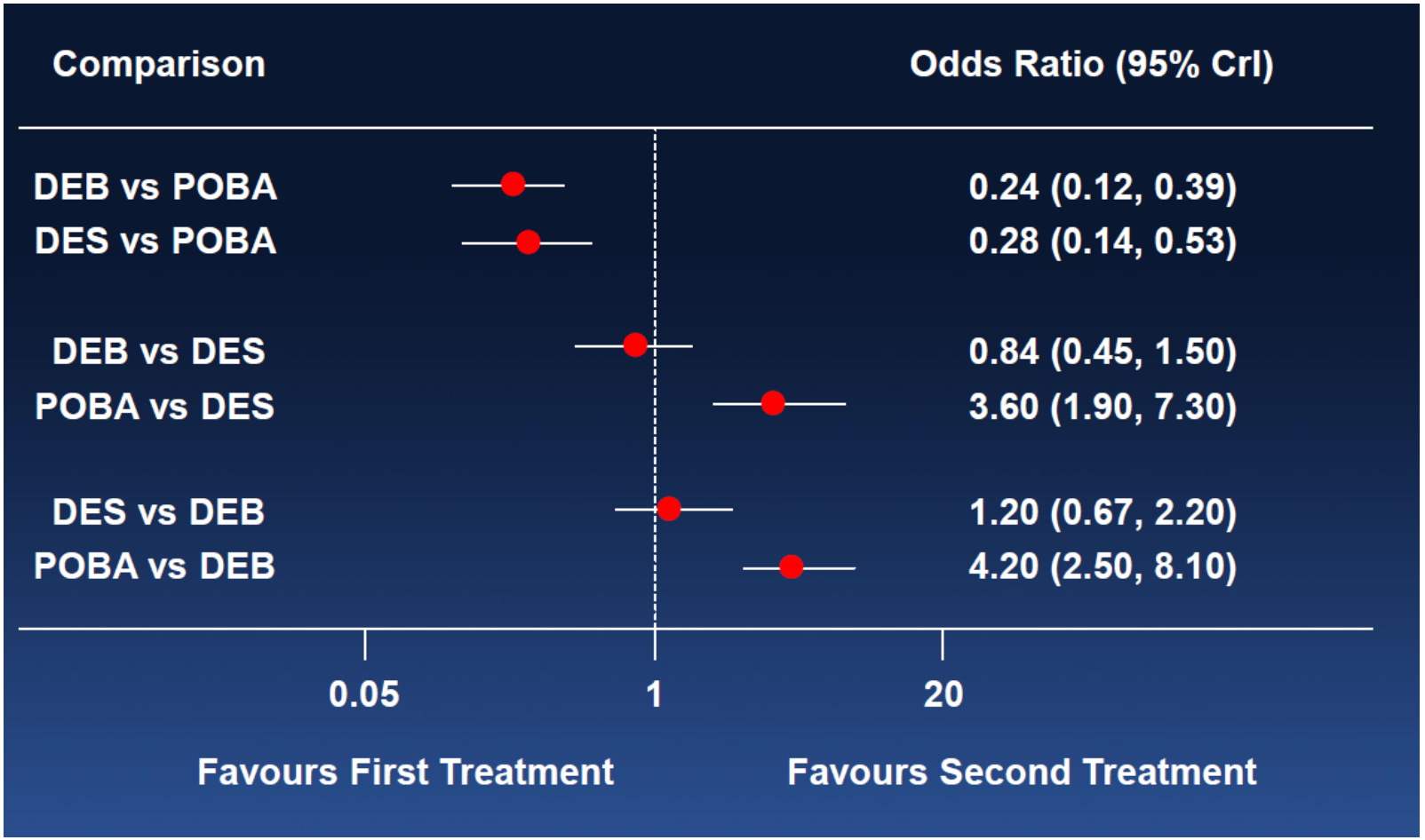
JM Lee, TCT 2014

Target Lesions Revascularization



JM Lee, TCT 2014

MACE



JM Lee, TCT 2014

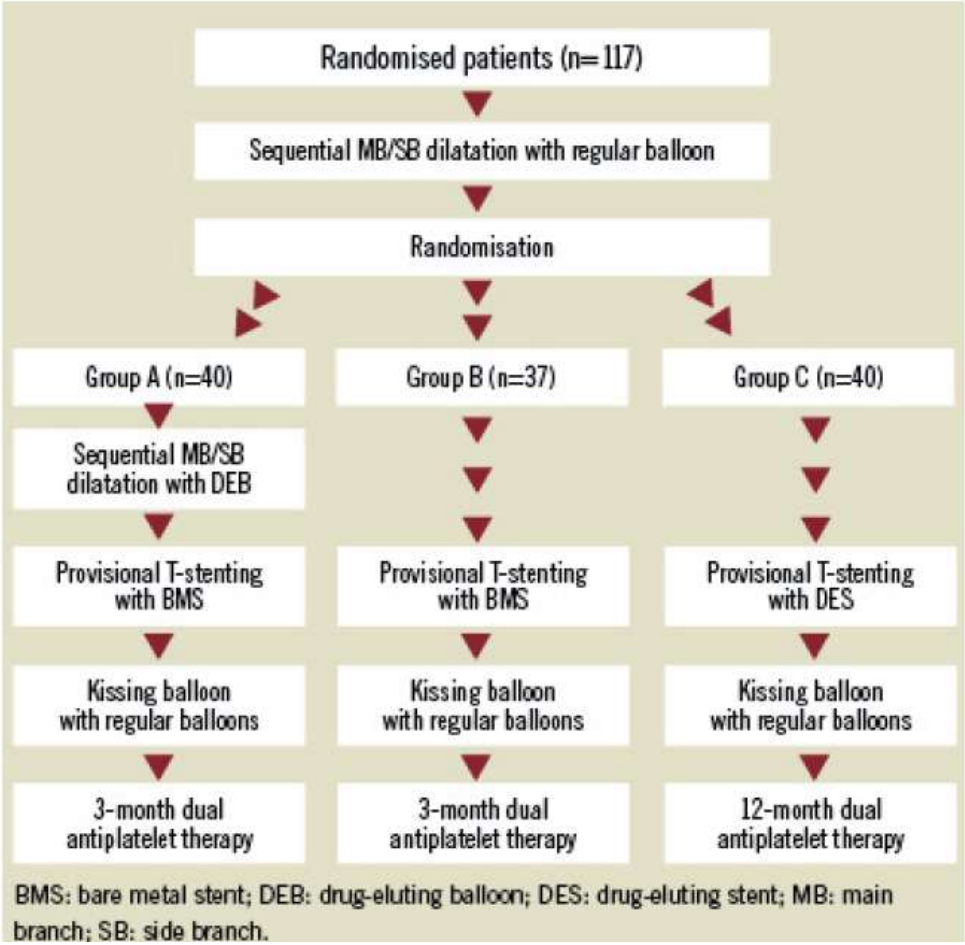
Some Clinical Data o n the use of DEB for :

- ISR
- **Bifurcation**
- Small Vessels
- Native « De Novo « lesions

Drug Rleuting Balloons 2015

Coronary bifurcation lesions treated with the drug-eluting balloon: a preliminary insight from the DEBIUT study

Belkacemi A et al , *EuroIntervention* 2011;7: K66-K69.



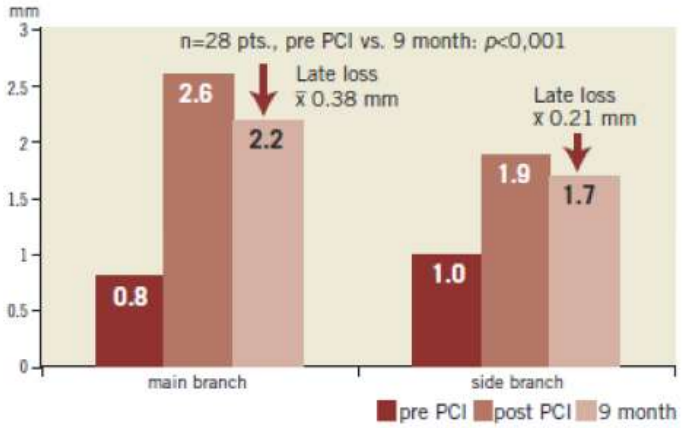
BMS: bare metal stent; DEB: drug-eluting balloon; DES: drug-eluting stent; MB: main branch; SB: side branch.

Drug Rleuting Balloons 2015

Treatment of bifurcation lesions with a drug-eluting balloon: the PEPCAD V (Paclitaxel Eluting PTCA Balloon in Coronary Artery Disease) trial

Detlef G. Mathey[1]*, MD; Imke Wendig[1], MD; Michael Boxberger[2], PhD; Klaus Bonaventura[3], MD; Franz X. Kleber[3], MD

Minimal Lumenal Diameter of MB and SB pre-intervention , post intervention and at 9 month FU



Clinical Outcome

30 day follow up	
MACE	0/28 (0%)
9 month follow up	
Death	0/28 (0%)
Late Stent Thrombosis (1x definite, 1x probable)	2/28 (7,1%)
Restenosis with TLR	1/28 (3,6%)
Restenosis without TLR	2/28 (7,1%)

EuroIntervention 2011;7:K61-K65

Pubblished Studies of Bifurcation PCI with DEB

Reference	Number of patients	DEB	Follow-up	DAPT	Stent thrombosis
Fanggiday et al[2]	20	DIOR	4 months	3 months	0
Mathey et al[3]	28	SeQuent Please	9 months	3 months	2 (6 and 8 months)
Belkacemi et al[4]	40	DIOR	12 months	3 months	0
Sgueglia et al[5]	14	SeQuent Please, In.Pact Falcon, DIOR II, Pantera Lux	234±81 days	3 months	0

DAPT: dual antiplatelet therapy; DEB: drug-eluting balloon

Some Clinical Data o n the use of DEB for :

- ISR
- Bifurcation
- **Small Vessels**
- Native « De Novo « lesions

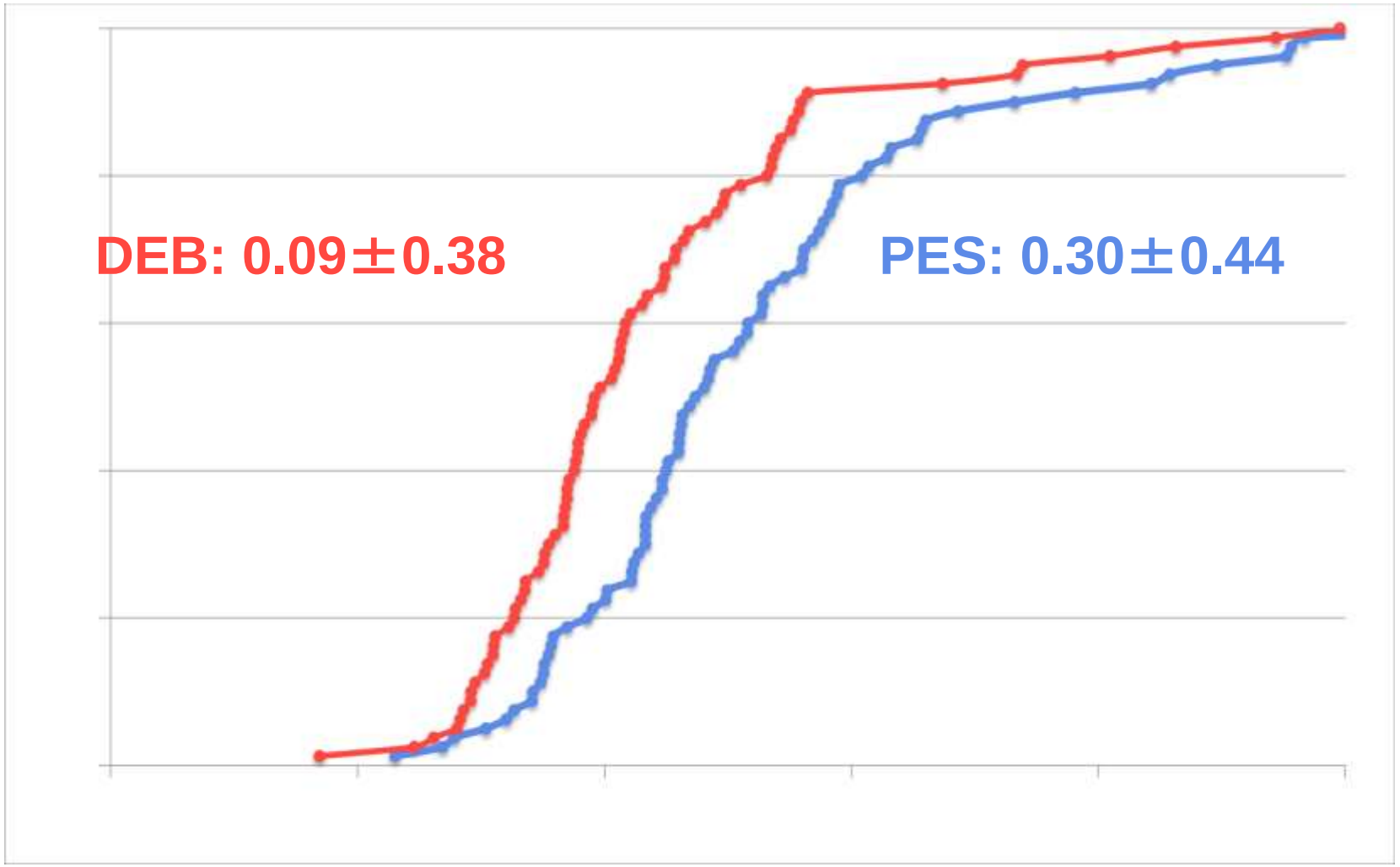
DEB : InPact Falcon

Bello Trial : 182 patients with **small vessel (<2.8mm)** disease Randomized in a 1:1 fashion

DEB Group (n=90)	PES Group (n=92)
94 lesions	97 lesions
	1: Lost at follow-up
90 (100%) patients with clinical follow-up at 6-months	91 (98.9%) patients with clinical follow-up at 6-months
12: Refused Angio **1: Died**	**15: Refused Angio** **1: Died**
77 (85.6%) patients with angiographic follow-up of 80 (85.1%) lesions included in the primary analysis	75 (81.5%) patients with angiographic follow-up of 81 (83.5%) lesions included in the primary analysis

Angio Corelab and CEC Adjudication

Primary Endpoint In-stent (in-balloon) Late Loss in de-novo lesions of small vessels



Some Clinical Data o n the use of DEB for :

- ISR
- Bifurcation
- Small Vessels
- **AMI**
- Native « De Novo « lesions

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

Some Clinical Data o n the use of DEB for :

- ISR
- Bifurcation
- Small Vessels
- AMI
- **Native vessels**

The Valentines II Trial

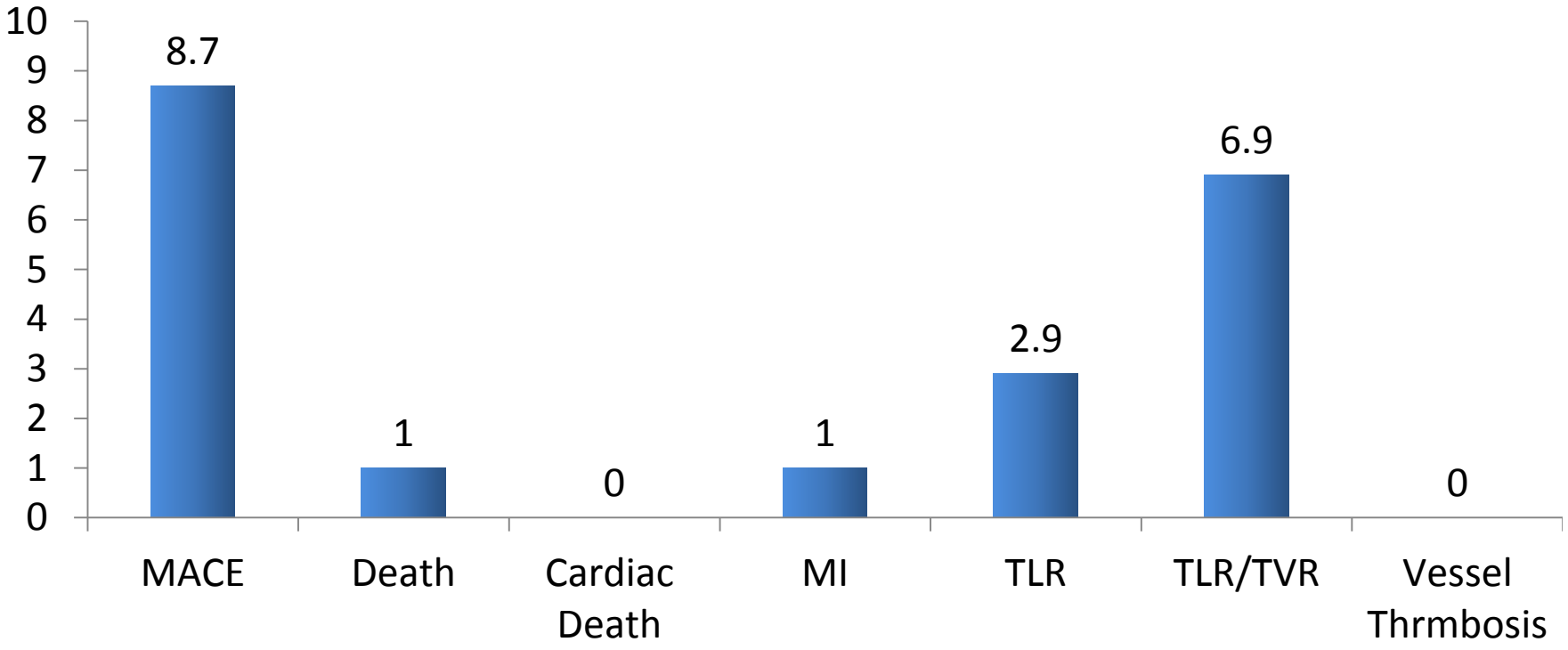
A Multicenter Trial
103 pts in 39 Centers in 16 Countries

99% Completed Follow Up

DEB in Native vessels (DIOR II)
Only bail-out stenting occured in 13 pts (12,6%)

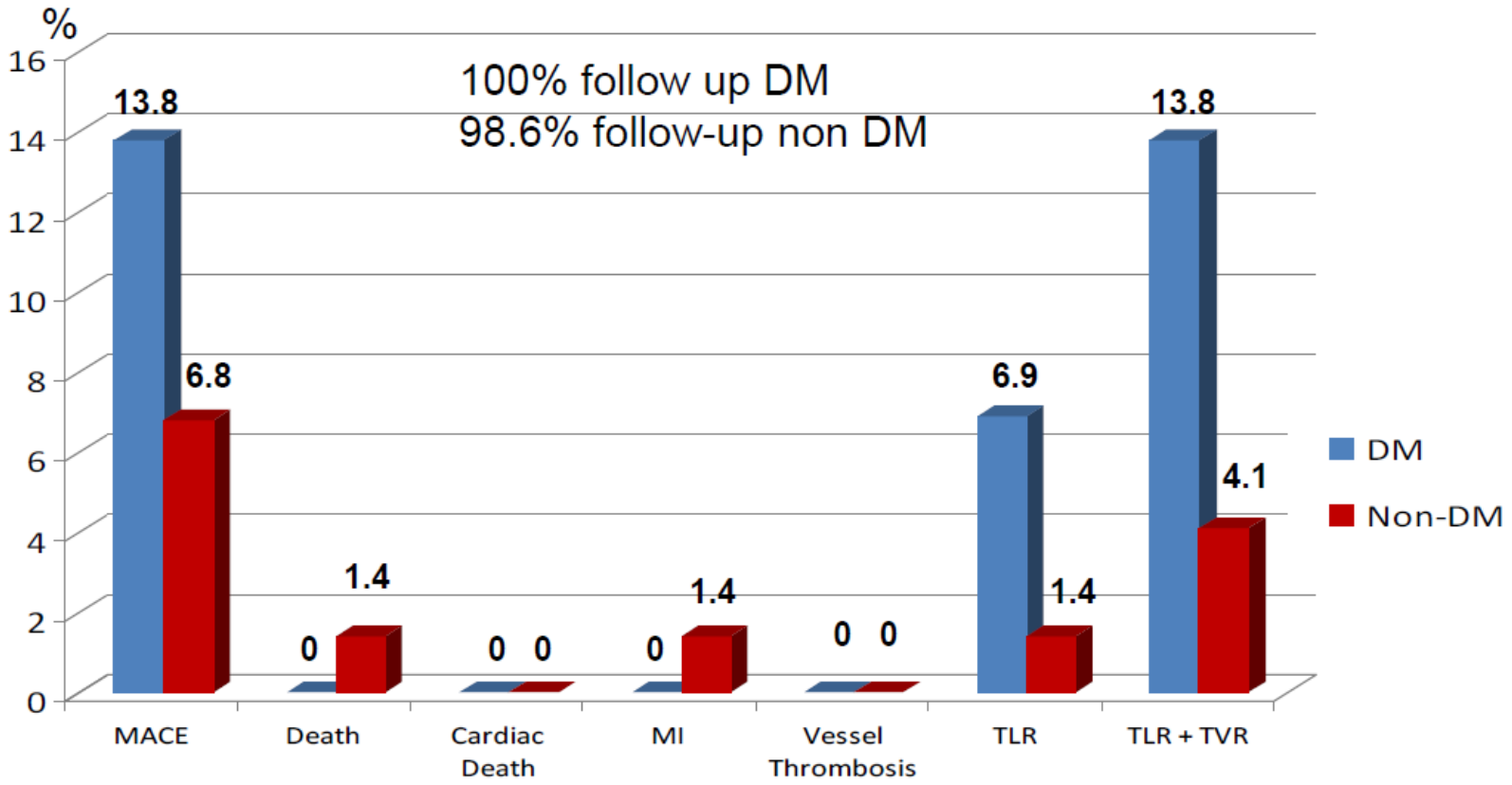
Mean Follow up = 227 ± 40 days

Valentine II Trial : Clinical Follow-up Outcomes (n=102)



EuroIntervention 2013

Valentine II Trial : Clinical Follow-up Outcomes (n=102) in Diabetic Patients



EuroIntervention 2013

Drug eluting balloon versus drug eluting stent in percutaneous coronary interventions: Insights from a meta-analysis of 1462 patients

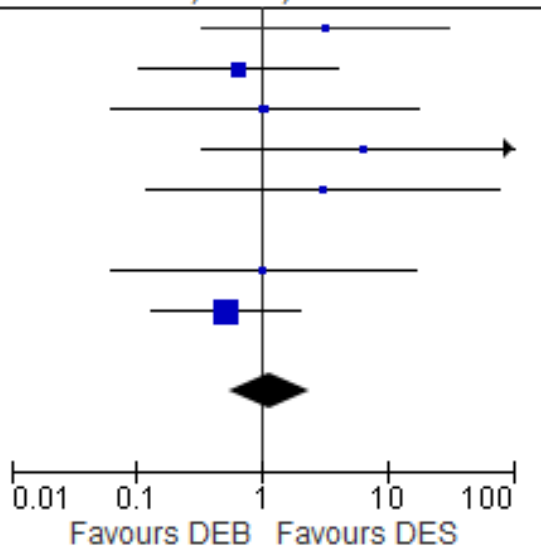
A. Lupi et al , Int J Cardiol 2013)

Author	Year	Journal	RCT	Eponim	Patients	Inclusion criteria	Exclusion	Comparison	DEB	DES	Diabetes	ACS	Follow up	Angiographic follow up
Hamm	2009	AHA 2009	yes	PEPCAD III	637	De novo stenoses; CSA, UA, silent ischemia	STEMI, NSTEMI, CTO, ISR, bifurcation	DEB (plus 100% BMS vs DES	SEQuent Please	Sirolimus	175 (27.5%)	na	9 months	85.1%
Unverdorben	2009	Circulation	yes	PEPCAD II	131	ISR	STEMI, NSTEMI, bifurcation	DEB (plus 7,5% BMS) VS DES	SEQuent Please	Paclitaxel	39 (29.8%)	33	12 months	88.6%
Cortese	2010	Heart	yes	PICCOLETO	60	Small vessels; de novo stenoses; CSA, UA, silent ischemia	STEMI, CTO, ISR, bifurcation	DEB (plus NA% BMS) VS DES	DIOR	Paclitaxel	24 (40.0%)	na	9 months	95%
Ali	2011	Eurointervention	yes	PEPCAD IV	84	Diabetes; CSA, UA, silent ischemia	STEMI, CTO, ISR, bifurcation	DEB (plus 100% BMS vs DES	SEQuent Please	Paclitaxel	84 (100.0%)	10	6 months	89.3%
Stella	2012	Catheter Cardiovasc Interv	yes	DEBIUT	120	Bifurcations; de novo stenoses; CSA, UA, silent ischemia	STEMI, CTO	DEB (plus 100%BMS) vs DES	DIOR	Paclitaxel	13 (10.8%)	na	12 months	100%
Belkacemi	2012	J Am Coll Cardiol	yes	DEBAMI	150	All comers STEMI	diabetes plus type C lesion, LM, 3 vessel disease	DEB (plus 100%BMS) vs DES	DIOR	Paclitaxel	11 (7,3%)	150	6 months	84.7%
Latib	2012	J Am Coll Cardiol	yes	BELLO	182	Small vessels; de novo stenoses; CSA, UA, silent ischemia	STEMI, CTO, ISR, bifurcation	DEB (plus 21% BMS) VS DES	IMPACT	Paclitaxel	74 (40,7%)	42	6 months	89.6%
Mieres	2012	Cardiovasc Rev Med	no	DEAR	316	Diabetes; CSA, UA, silent ischemia	STEMI	DEB (plus 95,6% BMS) VS DES	DIOR	miscellanea	316 (100.0%)	214	12 months	na

Overall death

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1- Hamm 2009	3	296	1	313	7.3%	3.19 [0.33, 30.88]
2- Unverdorben 2009	2	66	3	65	22.2%	0.65 [0.10, 4.00]
3- Cortese 2010	1	28	1	29	7.2%	1.04 [0.06, 17.43]
4- Ali 2011	3	45	0	39	3.7%	6.51 [0.33, 129.98]
5 -Stella 2012	1	40	0	40	3.7%	3.08 [0.12, 77.80]
6- Belkacemi 2012	0	50	0	49		Not estimable
7 - Latib 2012	1	90	1	92	7.4%	1.02 [0.06, 16.60]
8- Mieres 2012	3	91	8	129	48.5%	0.52 [0.13, 2.00]
Total (95% CI)		**706**		**756**	**100.0%**	**1.13 [0.54, 2.37]**
Total events	14		14			

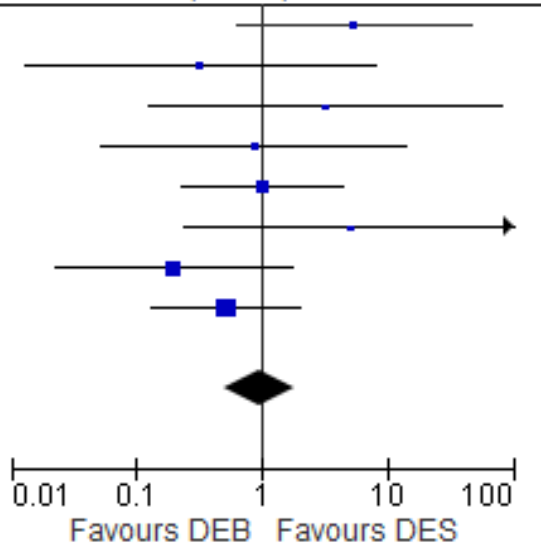
Heterogeneity: Chi² = 4.15, df = 6 (P = 0.66); I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)



Myocardial Infarction

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1- Hamm 2009	5	296	1	313	4.9%	5.36 [0.62, 46.16]
2- Unverdorben 2009	0	66	1	65	7.8%	0.32 [0.01, 8.08]
3- Cortese 2010	1	28	0	29	2.4%	3.22 [0.13, 82.38]
4- Ali 2011	1	45	1	39	5.4%	0.86 [0.05, 14.28]
5 -Stella 2012	4	40	4	40	18.6%	1.00 [0.23, 4.31]
6- Belkacemi 2012	2	50	0	49	2.5%	5.10 [0.24, 109.06]
7 - Latib 2012	1	90	5	92	25.3%	0.20 [0.02, 1.71]
8- Mieres 2012	3	91	8	129	33.1%	0.52 [0.13, 2.00]
Total (95% CI)		**706**		**756**	**100.0%**	**0.95 [0.50, 1.80]**
Total events	17		20			

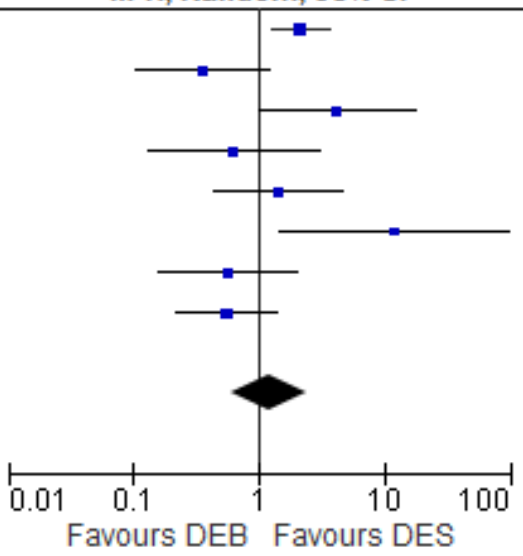
Heterogeneity: Chi² = 7.45, df = 7 (P = 0.38); I² = 6%
Test for overall effect: Z = 0.17 (P = 0.87)



Target lesion revascularization

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Odds Ratio M-H, Random, 95% CI
1- Hamm 2009	41	296	22	313	18.5%	2.13 [1.23, 3.67]
2- Unverdorben 2009	4	66	10	65	12.7%	0.35 [0.11, 1.20]
3- Cortese 2010	9	28	3	29	11.0%	4.11 [0.98, 17.23]
4- Ali 2011	3	45	4	39	10.1%	0.63 [0.13, 2.98]
5 -Stella 2012	8	40	6	40	13.1%	1.42 [0.44, 4.53]
6- Belkacemi 2012	10	50	1	49	7.1%	12.00 [1.47, 97.80]
7 - Latib 2012	4	90	7	92	12.3%	0.56 [0.16, 2.00]
8- Mieres 2012	7	91	17	129	15.2%	0.55 [0.22, 1.38]
Total (95% CI)		**706**		**756**	**100.0%**	**1.19 [0.60, 2.38]**
Total events	86		70			

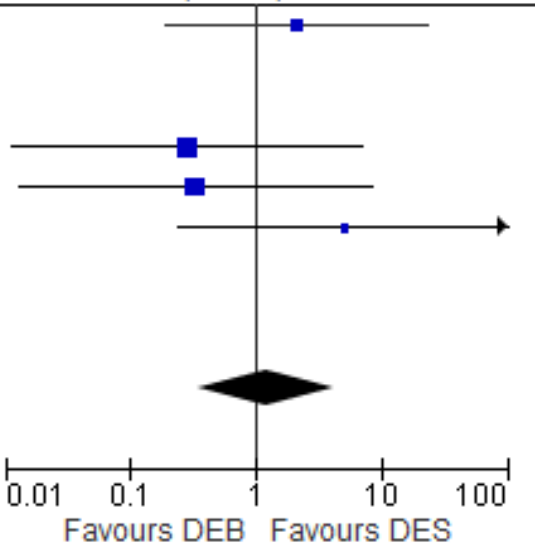
Heterogeneity: Tau² = 0.59; Chi² = 20.22, df = 7 (P = 0.005); I² = 65%
Test for overall effect: Z = 0.50 (P = 0.61)



PCI vessel thrombosis

Study or Subgroup	DEB Events	DEB Total	DES Events	DES Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1- Hamm 2009	2	296	1	313	21.4%	2.12 [0.19, 23.53]
2- Unverdorben 2009	0	66	0	65		Not estimable
3- Cortese 2010	0	28	0	29		Not estimable
4- Ali 2011	0	45	1	39	35.2%	0.28 [0.01, 7.12]
5 -Stella 2012	0	40	1	40	32.8%	0.33 [0.01, 8.22]
6- Belkacemi 2012	2	50	0	49	10.6%	5.10 [0.24, 109.06]
7 - Latib 2012	0	90	0	92		Not estimable
8- Mieres 2012	0	91	0	129		Not estimable
Total (95% CI)		**706**		**756**	**100.0%**	**1.20 [0.34, 4.19]**
Total events	4		3			

Heterogeneity: Chi² = 2.47, df = 3 (P = 0.48); I² = 0%
Test for overall effect: Z = 0.29 (P = 0.77)



RESEARCH ARTICLE Open Access

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

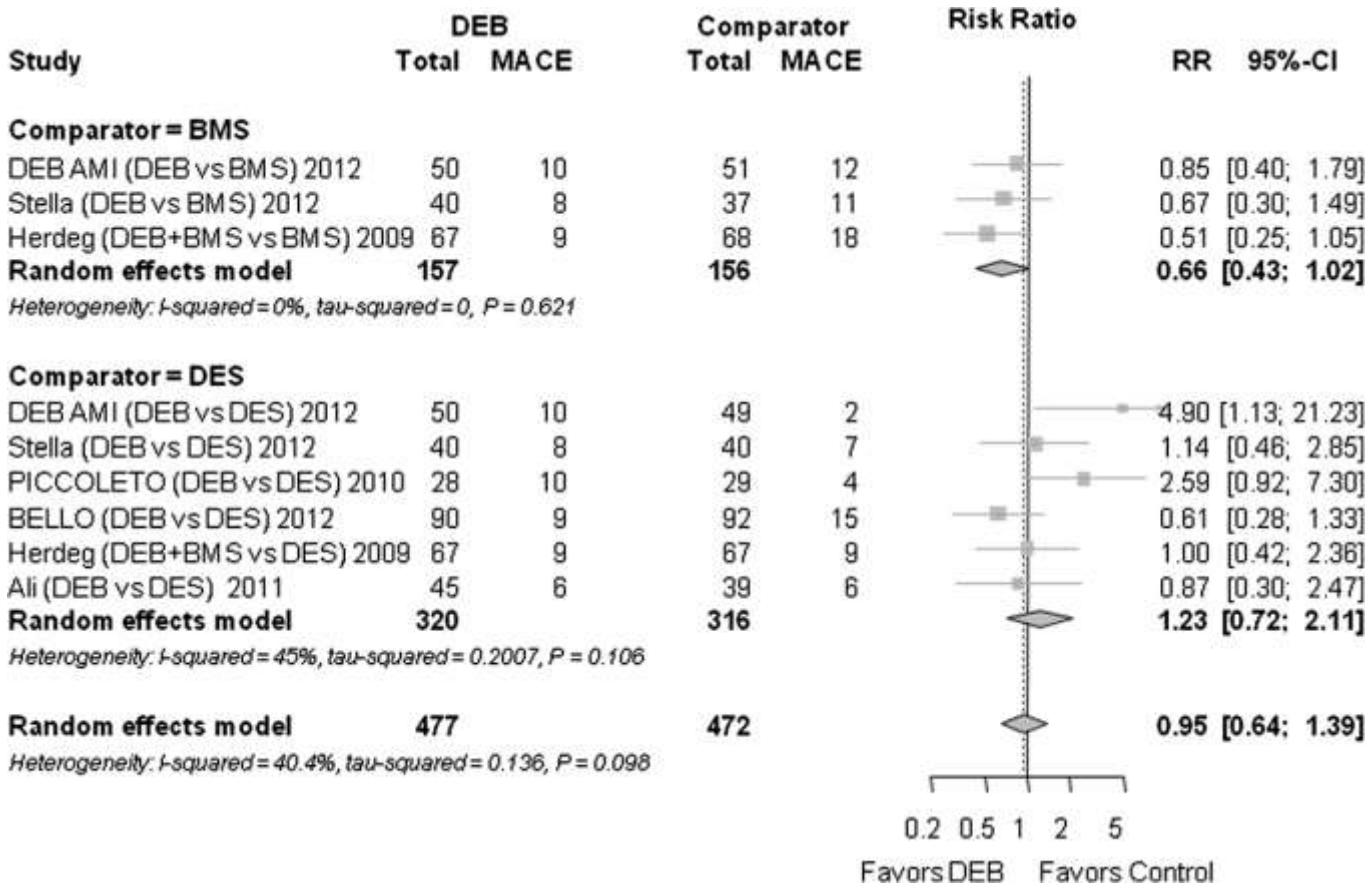
Georg M Fröhlich[1], Alexandra J Lansky[2], Dennis T Ko[3], Olga Archangelidi[4], Rodney De Palma[1], Adam Timmis[5] and Pascal Meier[1,2*]

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

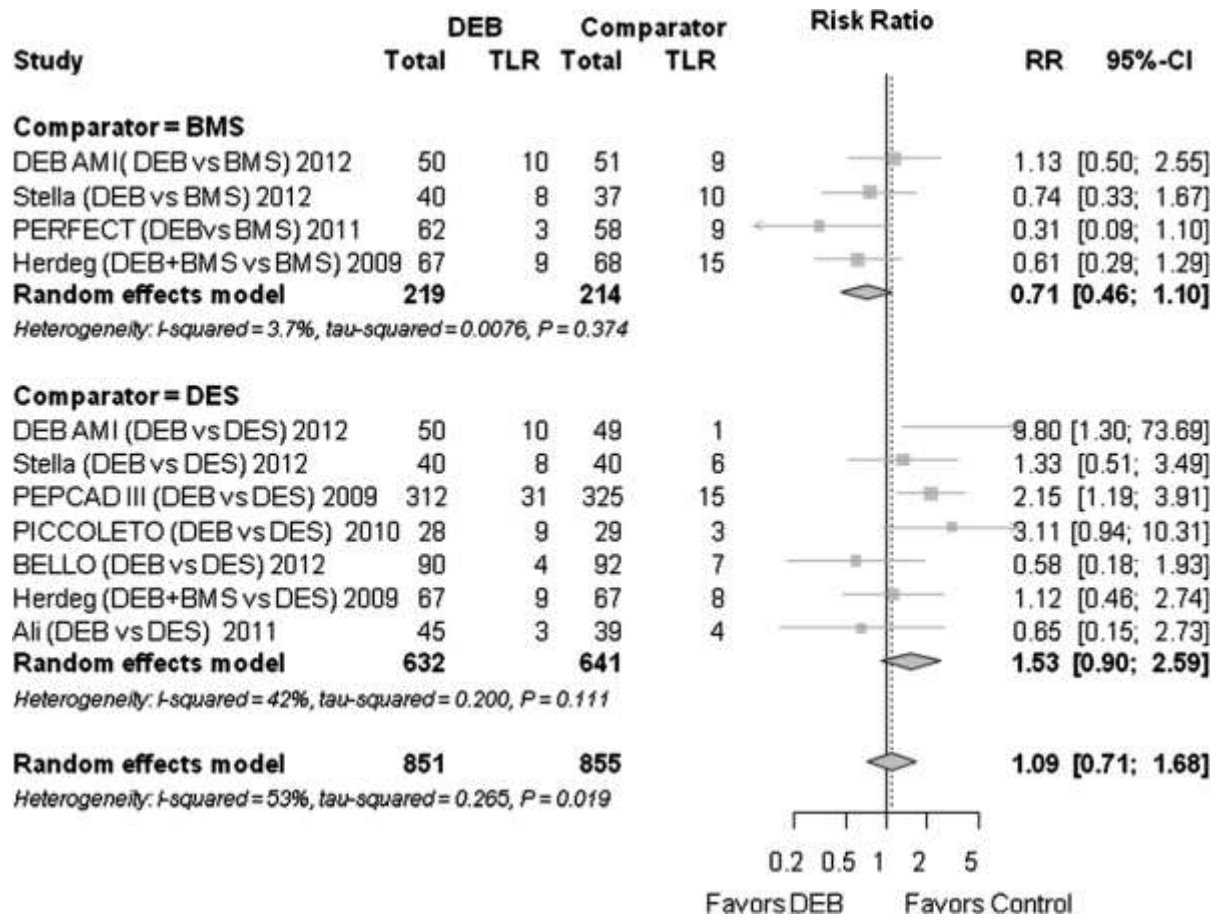
MACE



Fröhlich et al. BMC Medicine 2013, 11:123

Drug Rleuting Balloons 2015

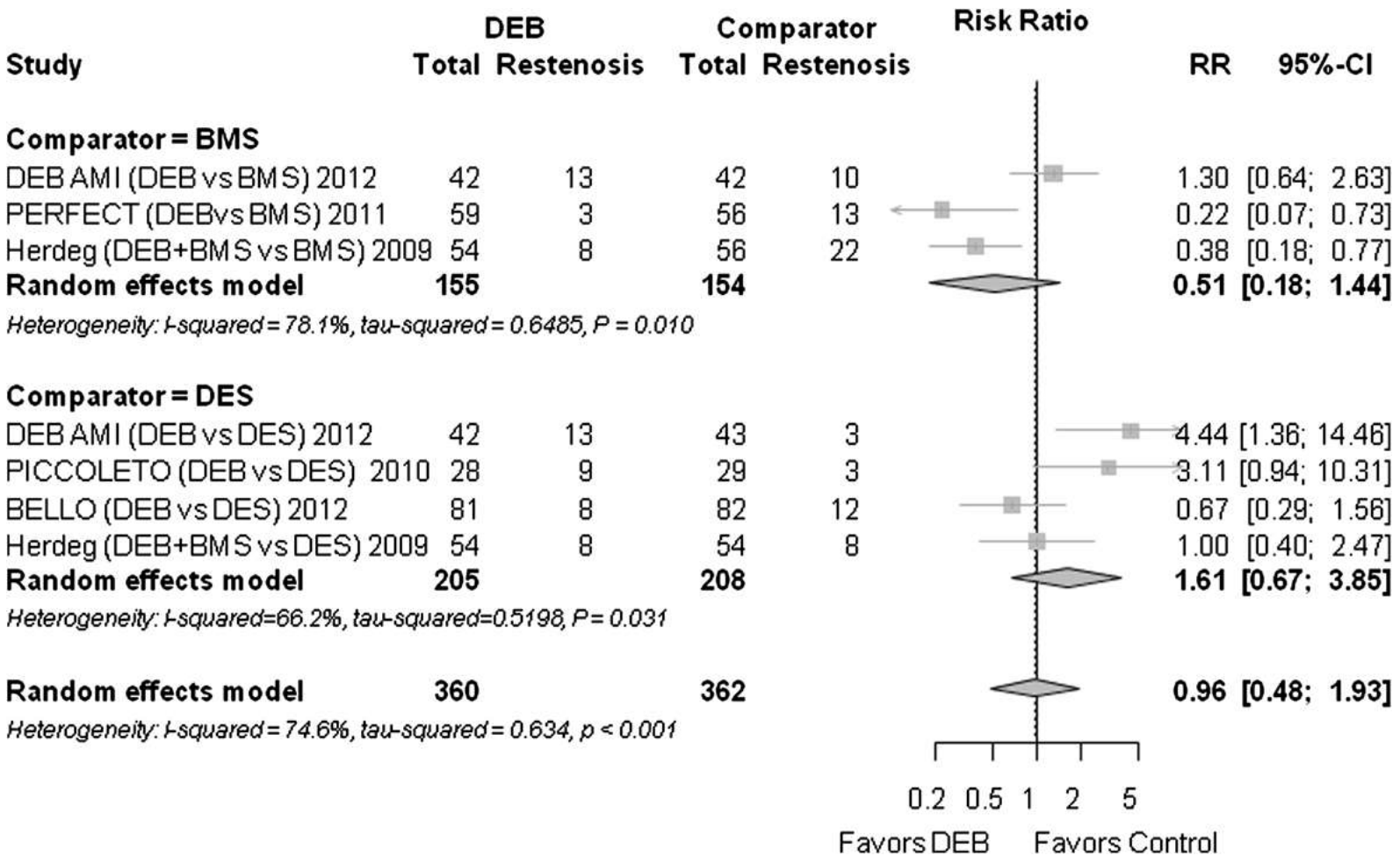
TLR



Fröhlich et al. BMC Medicine 2013, 11:123

Drug Rleuting Balloons 2015

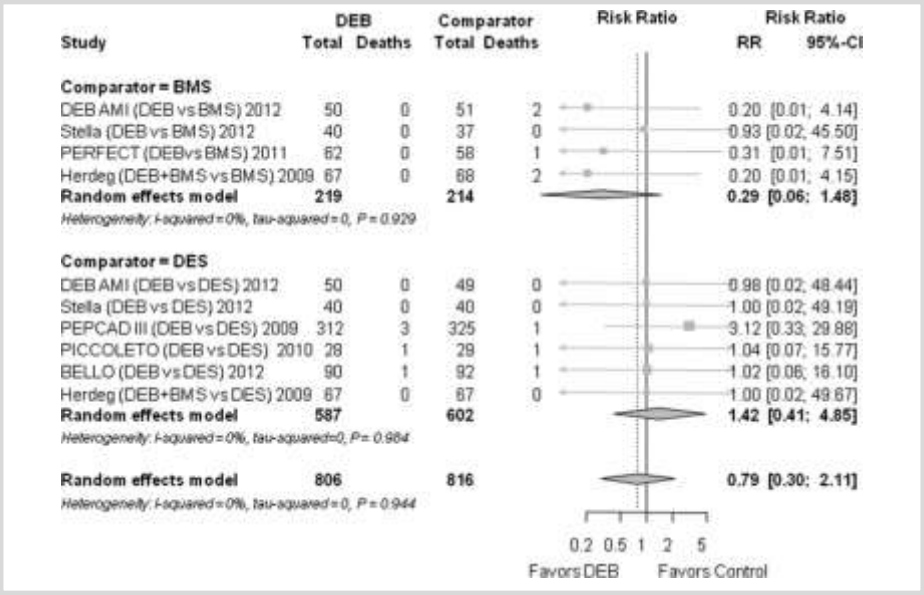
Restenosis



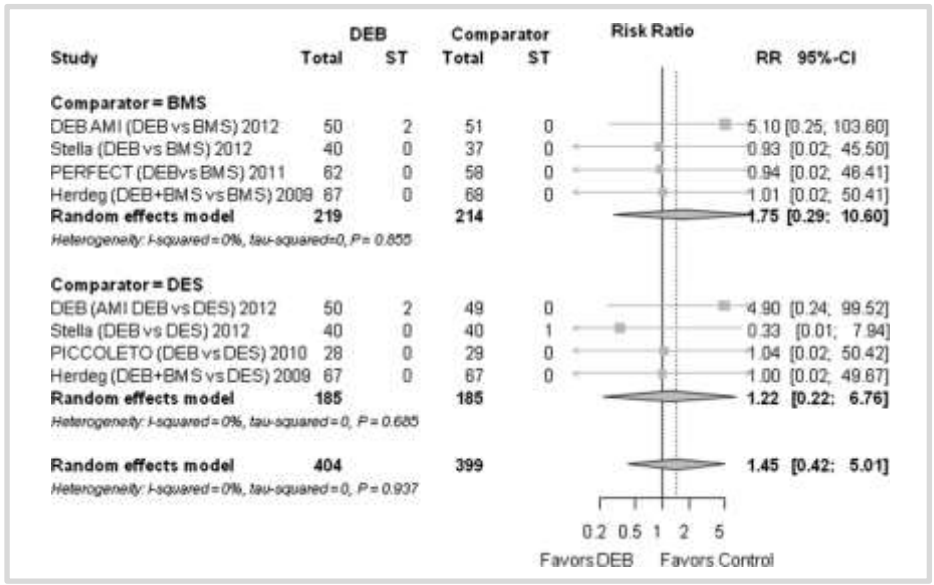
Fröhlich et al. BMC Medicine 2013, 11:123

Drug Rleuting Balloons 2015

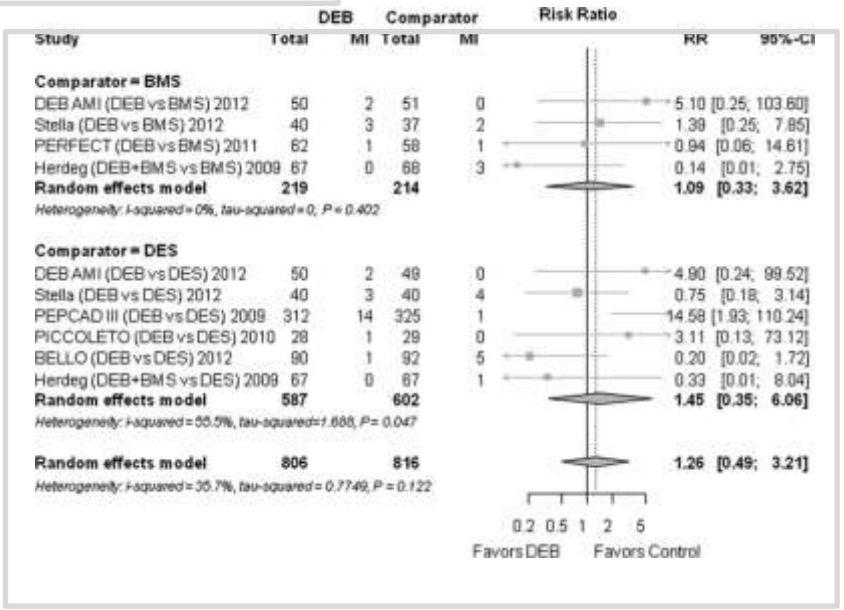
Death



AMI



Stent Thrombosis



Fröhlich et al. BMC Medicine 2013, 11:123

Take Home Message:

- Drug-eluting balloons represent an innovative device in interventional cardiology
- Four DEB have provided clinical data for BMS and DES ISR with a significant decrease in TLR rates within the first 9 to 12 months after PCI of ISR.
- Promising data for additional indications have been reported in the treatment of side branches in bifurcation lesions, de-novo lesions in small vessels
- New DEB Sirolimus-coated with innovative coating approaches (Nanotechnology) are on arrival for clinical use and might add a further improvement in clinical outcome
- So far DEB is reccomended in recent ESC Guidelines for the treatment of BMS and DES ISR
- Available data for the other lesion subsets are still limited . Need for further targeted clinical trials