APPAC
ACTUALISATIONS
ET PERSPECTIVES
EN PATHOLOGIE
CARDIOVASCULAIRE

Drug Eluting Balloon :

toujours le DEBut de l'histoire ?

10h00-11h00 //Ateliers Salles de sous-commissions

BIOTRONIK
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Perpsectives du Drug Eluting Ballon

N. AMABILE (Paris) - D. BROUCQSAULT (Lens) - G. GIBAULT-GENTY (Le Chesnay) - M. GODIN (ROUEN)

1977

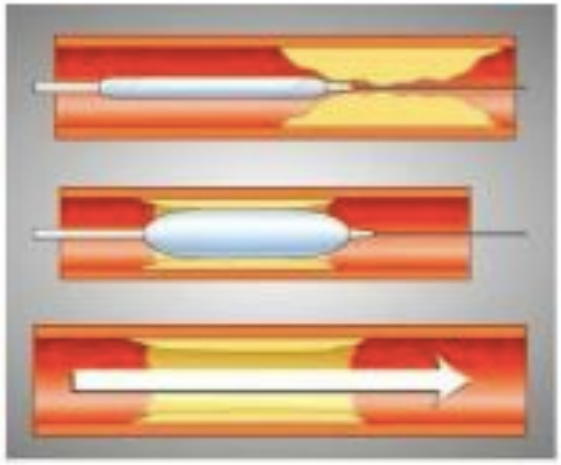
1. Balloon (PTCA):
Andreas Gruntzig performs the first PTCA in Zurich, Switzerland

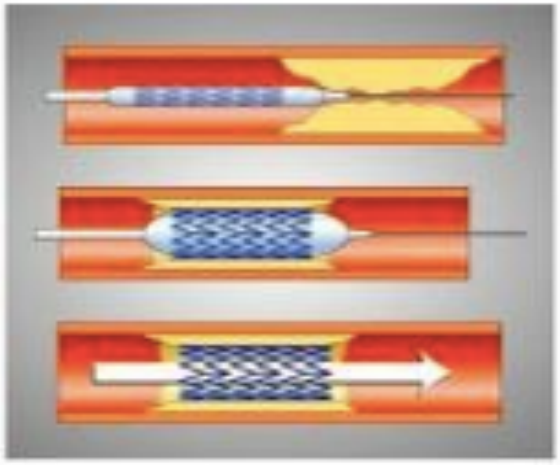
1988

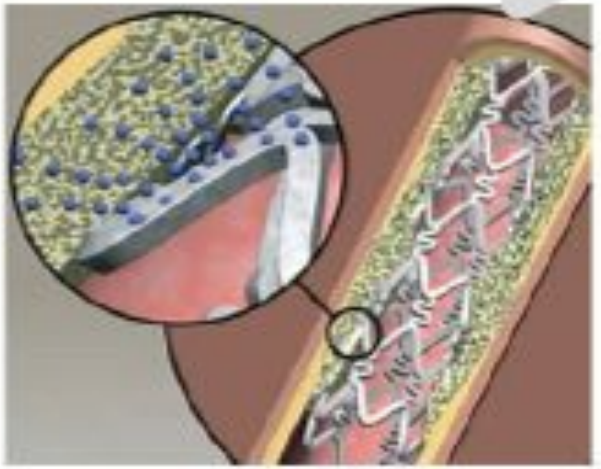
2. Bare Metal Stent (BMS):
Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications

2002 - 2003

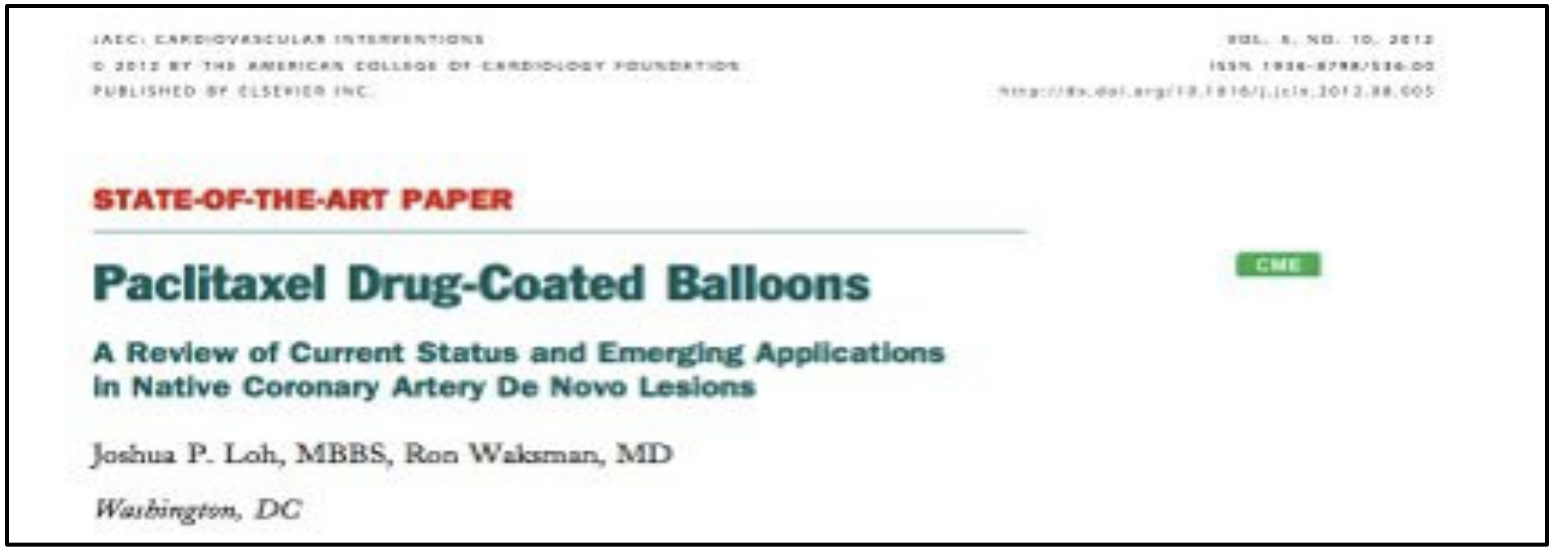
3. Drug-eluting stents (DES):
introduced to the European and U.S. markets







Où en sommes nous?



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STATE-OF-THE-ART PAPER

CME

Paclitaxel Drug-Coated Balloons

A Review of Current Status and Emerging Applications in Native Coronary Artery De Novo Lesions

Joshua P. Loh, MBBS, Ron Waksman, MD

Washington, DC

- Lésion de novo
- Resténose intrastent
- Le futur : bifurcations
  patients à risque hémorragique
  pré-opératoire
  autres…

Où en sommes nous?

- Lésion de novo

Table 1. Overview of DCB Used in Clinical Trials of De Novo Coronary Lesions

Drug-Coated Balloon	Manufacturer	Drug-Delivery Technology	Excipient	Dose Density, $\mu g/mm^2$
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
InPact 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

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A Randomized Multicenter Study Comparing a Paclitaxel Drug-Eluting Balloon With a Paclitaxel-Eluting Stent in Small Coronary Vessels

The BELLO (Balloon Elution and Late Loss Optimization) Study

Azeem Latib, MD,* Antonio Colombo, MD,* Fausto Castriota, MD,† Antonio Micari, MD,‡ Alberto Cremonesi, MD,§ Francesco De Felice, MD,‖ Alfredo Marchese, MD,¶ Maurizio Tespili, MD,# Patrizia Presbitero, MD,** Gregory A. Sgueglia, MD,†† Francesca Buffoli, MD,‡‡ Corrado Tamburino, MD,§§ Ferdinando Varbella, MD,‖‖ Alberto Menozzi, MD¶¶

Milan, Lecce, Palermo, Cotignola, Rome, Bari, Bergamo, Latina, Mantova, Catania, Torino, and Parma, Italy

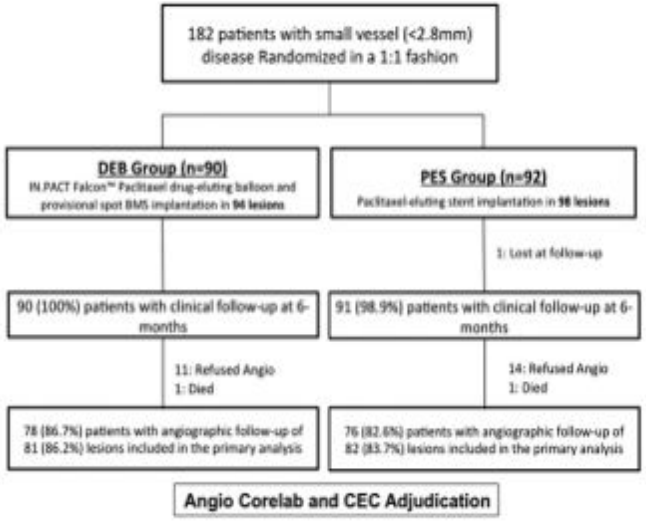
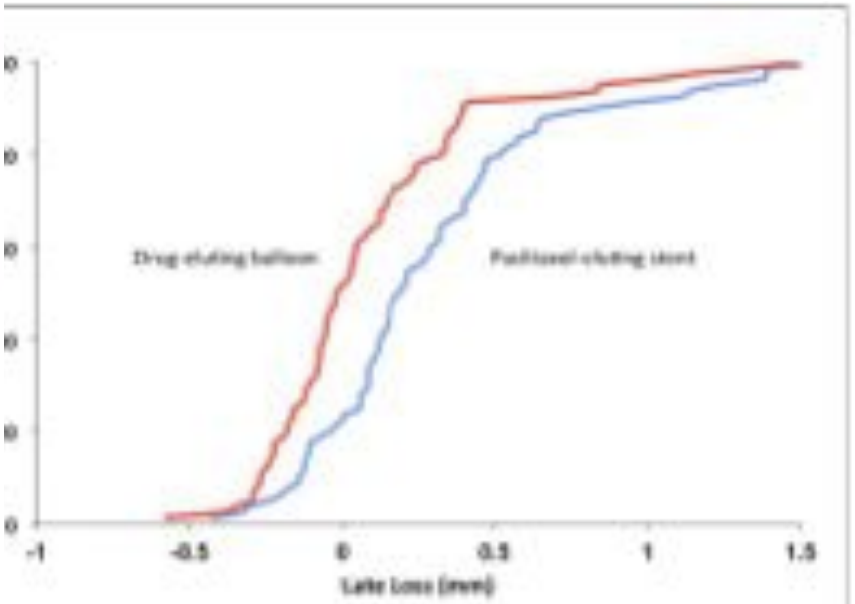


Table 4 Angiographic Outcomes at Follow-up

	DEB	PES	p Value
No. with angiographic follow-up	81	82	
Minimal lumen diameter, mm			
In-stent/In-balloon	1.48 ± 0.41	1.68 ± 0.51	0.006
In-segment	1.42 ± 0.40	1.52 ± 0.50	0.16
Diameter stenosis, %			
In-stent/In-balloon	32.31 ± 16.66	26.69 ± 20.38	0.06
In-segment	34.99 ± 15.97	33.33 ± 19.99	0.56
Late lumen loss, mm			
In-stent/In-balloon	0.08 ± 0.38	0.29 ± 0.44	0.001
In-segment	0.05 ± 0.37	0.17 ± 0.45	0.09
Net gain, mm			
In-stent/In-balloon	0.87 ± 0.41	1.06 ± 0.52	0.009
In-segment	0.81 ± 0.39	0.90 ± 0.49	0.20
Binary restenosis, %			
In-stent/In-balloon	8 (10)	10 (12.4)	0.64
In-segment	8 (10)	12 (14.6)	0.35



re 2 Late Loss Distribution

lative frequency distribution curves of in-stent (in-balloon) late loss
low-up angiography.

Late lumen loss after DEB dans lésions de novo

Trial Number of patients	Intervention	Indication	Late lumen loss	Follow-up
PEPCAD I SVD[1] (n=118)	SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS	De novo, small vessels	0.16 mm	6 months
PEPCAD V[2] (n=28)	SeQuent™ Please	De novo, bifurcation (side branch)	0.21 mm	6 months
PICCOLETO[3] (n=60)	Dior™ II (n=29) vs. DES	De novo, small vessels	Not published	6 months
DEBUIT[4] (n=117)	Dior™ (n=40) vs. Dior™ + BMS vs. DES	De novo, bifurcation	0.11 mm	9 months
Valentines II[5]	Dior™ II	De novo	0.30 (overall)	6-9 months

[1]Unverdorben M et al. Clin Res Cardiol. 2010 Mar;99(3):165-74. [2]Mathey DG; Eurointervention 2011;7:K61-65.
[3]Cortese B et al. Heart 2010;96:1291-1296. [4]Stella R, TCT 2010, [5]Serra CRT 2012.

Où en sommes nous?

- Lésion de novo
- Resténose intrastent

Heart

Drug-eluting Balloon Angioplasty for In-stent Restenosis

A Systematic Review and Meta-Analysis of Randomised Controlled Trials

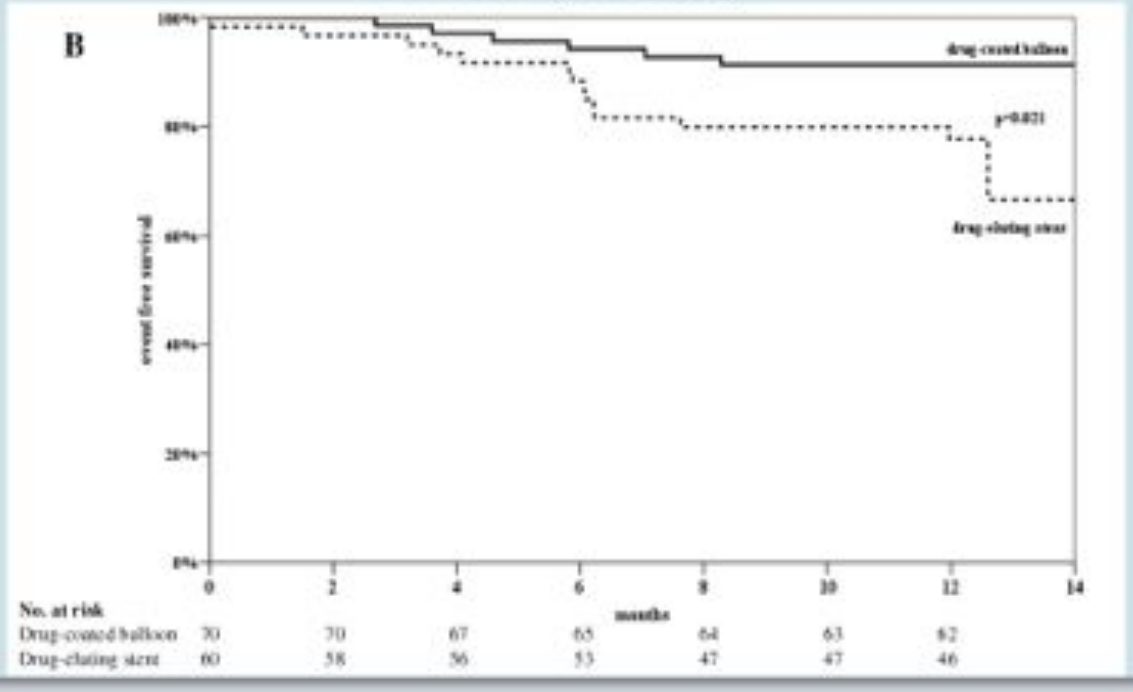
Andreas Indermuehle, Rahul Bahl, Alexandra J Lansky, Georg M Froehlich, Guido Knapp, Adam Timmis, Pascal Meier | Disclosures

Heart. 2013;99(5):327-333.

PEPCAD II ISR – Angiographic follow-up

DEB (SeQuent® Please) versus DES (Taxus®) for the Treatment of Coronary In-stent Restenosis

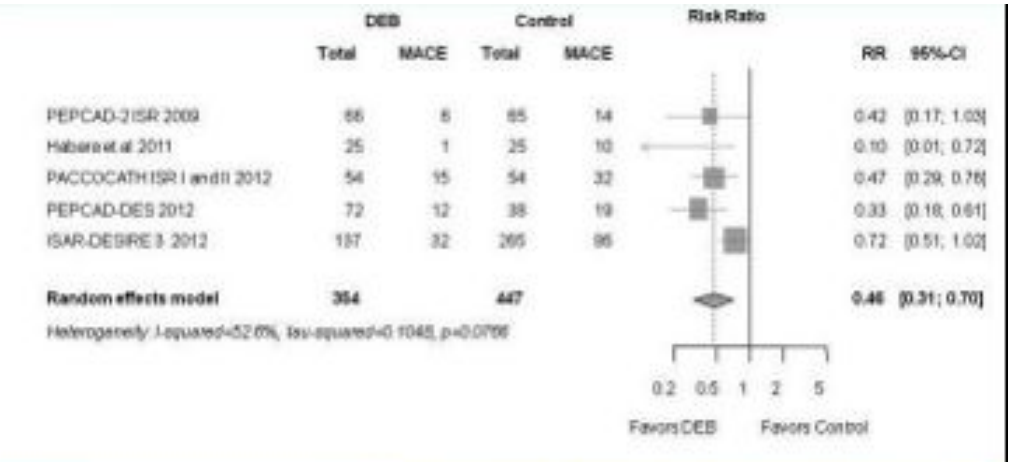
Freedom from stent thrombosis, target lesion revascularization, myocardial infarction, and death (as treated)

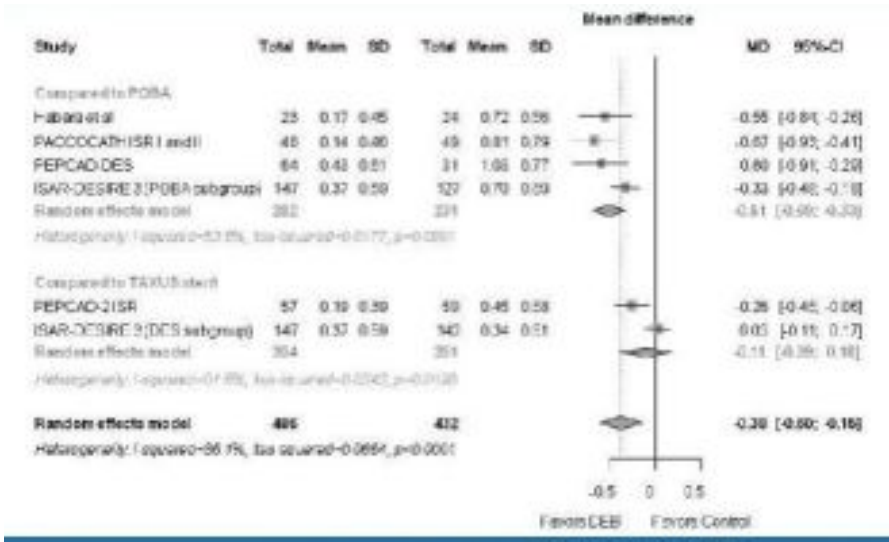


Unverdorben, M. et al. Circulation 2009;119:2986-2994

Où en sommes nous?

- Lésion de novo
- Resténose intrastent



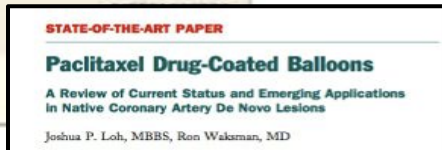


Où en sommes nous?

- Lésion de novo
- Resténose intrastent
- Le futur : bifurcations

Table 6. Clinical Trials of DCB Use in Bifurcation Lesions

Study	Design	Patients, N	Primary Endpoint (Follow-Up, Months)	TLR, % (Follow-Up, Months)	Bailout Stent Rate, %	Ref. #
DEBIUT registry	Dior I (MB + SB) followed by BMS MB	20	MACE none (4)	0 (4)		(41)
DEBIUT trial	Dior I (MB + SB) followed by BMS MB vs. BMS MB vs. DES MB	117	LLL distal MB 0.41 vs. 0.49 vs. 0.19 mm LLL SB 0.19 vs. 0.21 vs. −0.11 mm (6) Superiority of DCB over BMS not met	20 vs. 27 vs. 15 (18)	7.5 (SB stenting)	(42)
PEPCAD V	SeQuent Please (MB + SB) followed by BMS MB	28	LLL MB 0.38 mm LLL SB 0.21 mm (9)	3.8 (9)	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)	0 (8)		(44)
KISSING DEBBIE	BMS MB followed by kissing DCB	Ongoing				
BABILON	SeQuent Please SB + Taxus MB vs. Taxus MB	Ongoing				


STATE-OF-THE-ART PAPER

Paclitaxel Drug-Coated Balloons

A Review of Current Status and Emerging Applications in Native Coronary Artery De Novo Lesions

Joshua P. Loh, MBBS, Ron Waksman, MD

Où en sommes nous?

- Lésion de novo
- Resténose intrastent
- Le futur : bifurcations
  patients à risque

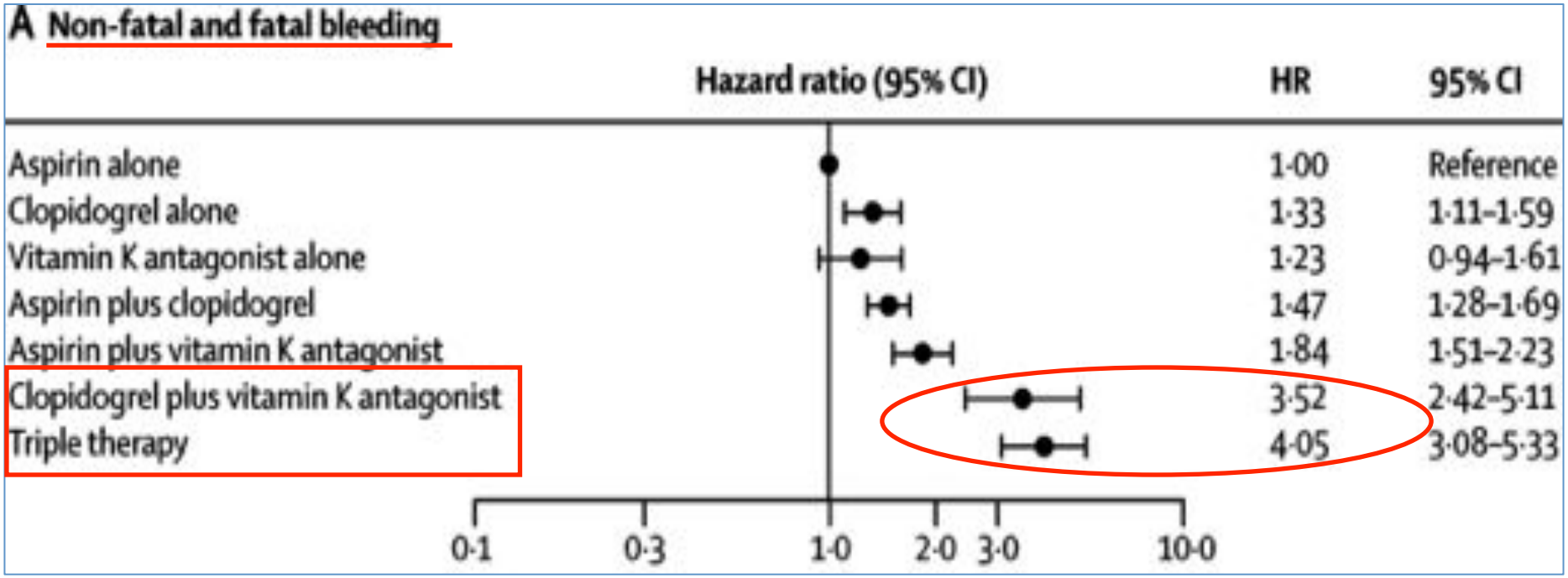
PANELUX : étude innovante

- Patients à risque

Haemorrhagic risk	Clinical setting	Stent implanted	Anticoagulation regimen
Low or intermediate (e.g. HAS-BLED score 0–2)	Elective	Bare-metal	1 month: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day Lifelong: VKA (INR 2.0–3.0) alone
	Elective	Drug-eluting	3 (-olimus[a] group) to 6 (paclitaxel) months: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day Up to 12th month: combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day[b] (or aspirin 100 mg/day) Lifelong: VKA (INR 2.0–3.0) alone
	ACS	Bare-metal/ drug-eluting	6 months: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day Up to 12th month: combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day[b] (or aspirin 100 mg/day) Lifelong: VKA (INR 2.0–3.0) alone
High (e.g. HAS-BLED score ≥3)	Elective	Bare-metal[c]	2–4 weeks: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day Lifelong: VKA (INR 2.0–3.0) alone
	ACS	Bare-metal[c]	4 weeks: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day Up to 12th month: combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day[b] (or aspirin 100 mg/day) Lifelong: VKA (INR 2.0–3.0) alone

ESC-Guidelines for the management of atrial fibrillation 2010, http://www.escardio.org

Risque d'une triple association



Sørensen et al; Lancet 2009

REVIEW

Stent thrombosis in 2008: Definition, predictors, prognosis and treatment

La thrombose de stent en 2008 : définition, facteurs prédictifs, pronostic et traitement

Gilles Lemesle[a,b], Cédric Delhaye[a], Laurent Bonello[b], Axel de Labriolle[b], Ron Waksman[b,*], Augusto Pichard[b]

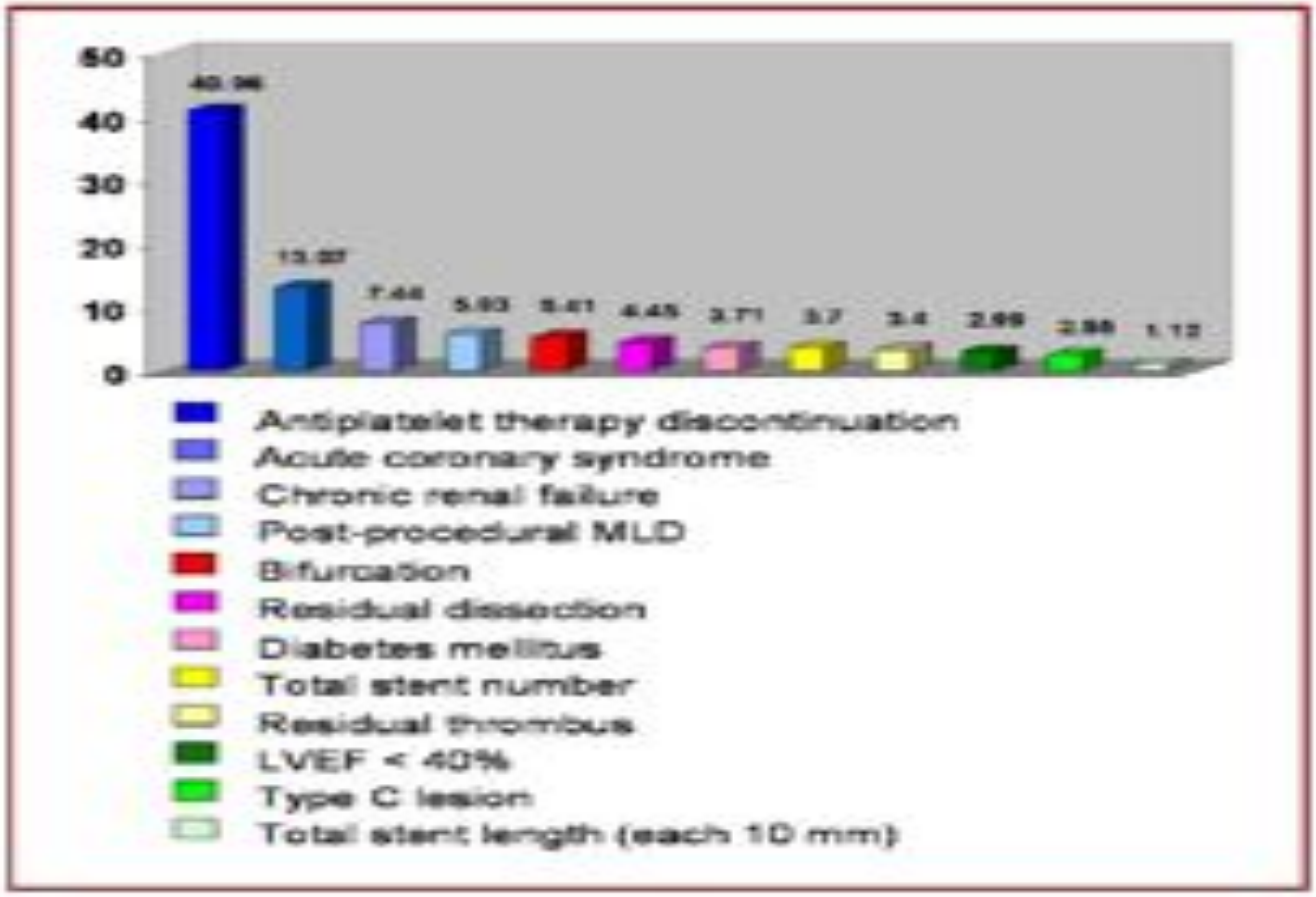


Figure 4. Hazard ratios (HR) of predictors for stent thrombosis.

PaneLux PTCA

PANELUX

50 years

BIOTRONIK

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PANELUX : étude innovante

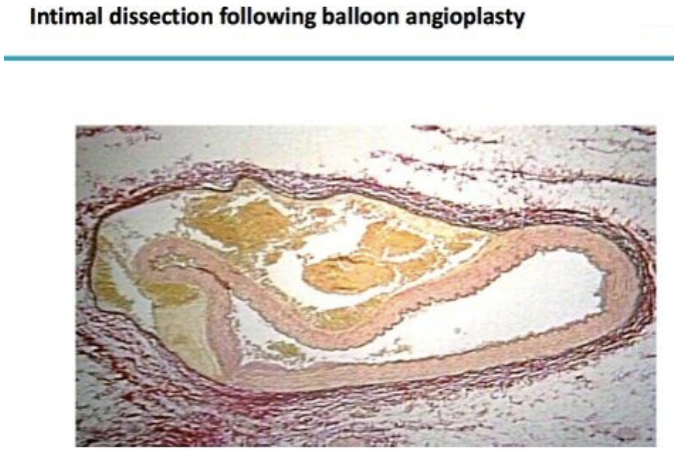
- Patients à risque hémorragique
- Durée double AAP et ballon actif (pré-op)

Table 7. Vessel Thrombosis Rate in DCB Use and Duration of DAPT

Study	Device	Vessel Thrombosis Rate, % (n/N)	Duration of DAPT, Month(s)	Clinical Follow Up, Months
PEPCAD I	SeQuent Please	0 (0/82) in DCB only 6.3 (2/32) in DCB + BMS	1 3	6
PICCOLETTO	Dior I	0 (0/18) in DCB only 0 (0/10) in DCB + BMS	1 3	9
Spanish DIOR registry	Dior I/II	1 (1/103)	Not available	12
BELLO	In.Pact Falcon	0 (0/94)	Not available	6
LOCAL TAX	Genie + BMS	0 (0/87)	6	6
PEPCAD III	Coroflex DEBlue	2 (6/310)	6	9
PERFECT	SeQuent Please + EPC-capturing stent	0 (0/62)	3	6
INDICOR	SeQuent Please + BMS	6.1 (3/49) in DCB 1st 3.1 (1/48) in BMS 1st	3	12
De Novo Pilot study	Magic + BMS	0 (0/28)	3	6
PEPCAD IV	SeQuent Please + BMS	0 (0/45)	3	6
PEPCAD CTO	SeQuent Please + BMS	0 (0/48)	3	6
DEBAMI	SeQuent Please + BMS	6.7 (2/30) (1 patient at 2 months, 1 patient at 6 months)	3	12
DEB-AMI	Dior II + BMS	4 (2/50) (1 patient at day 4, 1 patient at day 5)	Not available	6
Valentines II	Dior II	0 (0/103)	3	7.5
Pilot Long Lesion study	DCB (+ provisional BMS)	0 (0/12)	Not available	6
DEBIUT registry	Dior I + BMS	0 (0/20)	3	4
DEBIUT trial	Dior I + BMS	0 (0/40)	3	12
PEPCAD V	SeQuent Please + BMS	7 (2/28) (1 patient at 6 months, 1 patient at 8 months)	3	9
Sgueglia et al.	4 different DCB + BMS	0 (0/12)	3	8

PANELUX : étude innovante

- Patients à risque hémorragique
- Durée double AAP
- Angioplastie BMS +DEB car bailout+++



Bailout stenting

Table 2. Clinical Trials of DCB Use in Small Vessel Disease

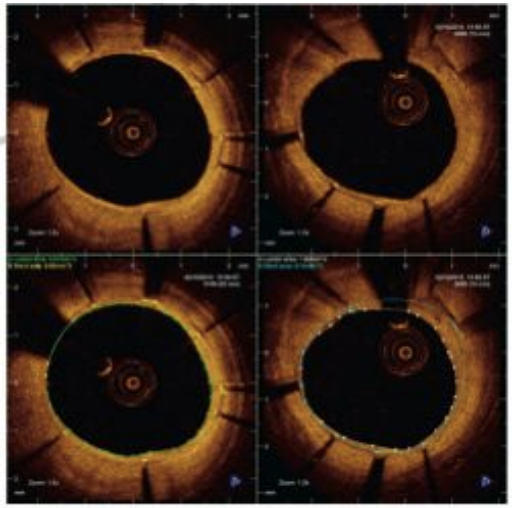
Study	Design	Patients, N	Primary Endpoint (Follow-Up, Months)	TLR, % (Follow-Up, Months)	Bailout Stent Rate, %	Ref. #
PEPCAD I	SeQuent Please	116	LLL 0.18 mm in DCB-only, 0.73 in DCB + BMS (6)	4.9 in DCB-only, 27.1 in DCB + BMS (12)	28	(12)
PICCOLETTO	Dior I vs. Taxus	57	Diameter stenosis 43.6% vs. 24.3% (6) Noninferiority not met	32.1 vs. 10.3 (9)	36	(13)
Spanish DIOR registry	Dior I/II	103	LLL 0.34 mm (6)	3 (12)	7	(14)
BELLO	In.Pact Falcon vs. Taxus	182	LLL 0.09 vs. 0.30 mm (6) Superiority of DCB	4.4 vs. 7.7 (6)	21	(15)
DCB-Only Small Vessel Disease: Worldwide registry	SeQuent Please	Ongoing				

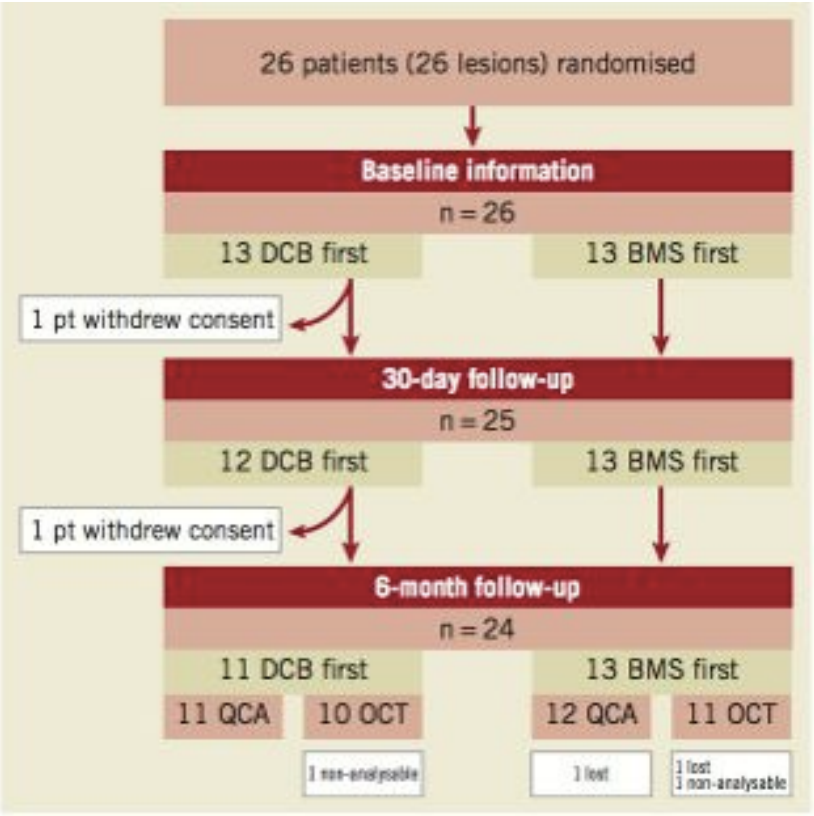
PANELUX : étude innovante

- Patients à risque
- Durée double AAP
- Angioplastie BMS +DEB car bailout+++
- BMS puis DEB ou DEB puis BMS

Paclitaxel-coated balloon in combination with bare metal stent for treatment of *de novo* coronary lesions: an optical coherence tomography first-in-human randomised trial, balloon first vs. stent first

EuroIntervention 2011;7:711-722





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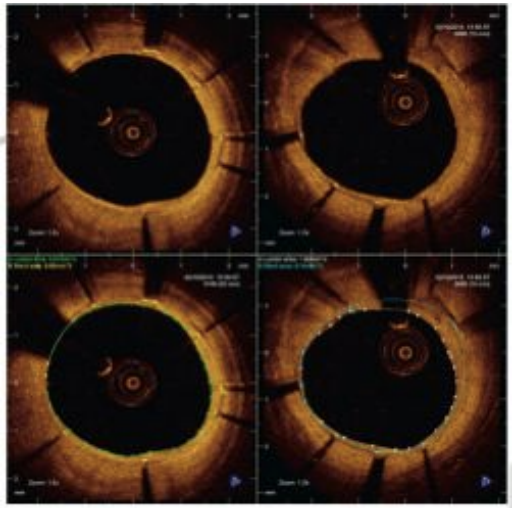

Post-implant	DCB first 10 pt, 11 stents	BMS first 12 pt, 12 stents	*p*-value	All 22 pt, 23 stents
Stent length (mm)	14.91±6.47	17.48±3.77	0.151	16.25±5.28
Min stent area (mm²)	7.77±2.36	5.30±1.46	0.013	6.49±2.28
Mean stent area (mm²)	9.11±2.38	6.50±1.79	0.013	7.75±2.44
Stent volume (mm³)	134.99±75.77	114.71±41.86	0.928	124.41±59.94
% frames with ISA	18.7±17.7	7.2±9.5	0.091	12.7±14.9
Max ISA area (mm²)	1.21±1.41	0.47±0.65	0.190	0.82±1.12
ISA volume (mm³)	2.14±1.89	0.70±1.08	0.051	1.39±1.66
ISA volume (% of stent vol)	2.24±2.53	0.52±0.77	0.118	1.34±2.00
6 months follow-up				
MLA (mm²)	4.94±2.88	3.48±2.41	0.270	4.21±2.69
Mean lumen area (mm²)	6.86±2.91	5.14±2.17	0.193	6.00±2.65
Lumen volume (mm³)	95.75±57.32	90.68±38.56	0.748	93.22±47.74
% frames with ISA	4.06±7.05	0.57±1.88	0.270	2.31±5.34
Max ISA area (mm²)	0.43±0.68	0.03±0.09	0.243	0.23±0.52
ISA volume (mm³)	0.56±0.88	0.02±0.08	0.243	0.29±0.67
ISA volume (% of stent vol)	0.37±0.75	0.02±0.08	0.243	0.20±0.55
Max NIH area (mm²)	4.02±1.77	2.93±1.74	0.151	3.48±1.80
NIH volume (mm³)	30.14±23.71	27.35±14.41	0.974	28.74±19.20
% NIH vol obstruction	25.3±15.9	24.9±13.6	0.922	25.1±20.6

Paclitaxel-coated balloon in combination with bare metal stent for treatment of *de novo* coronary lesions: an optical coherence tomography first-in-human randomised trial, balloon first vs. stent first

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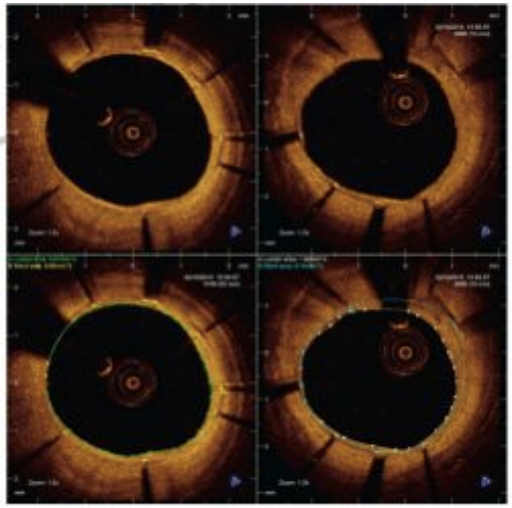

	DCB first	BMS first	OR (95% CI)	*p*-value	All
Post-implant	**10 patients 10 lesions 11 stents 1849 struts**	**12 patients 12 lesions 12 stents 2025 struts**			**22 patients 22 lesions 23 stents 3874 struts**
Apposition					
Well-apposed	1644 (88.9%)	1902 (93.9%)	0.53 (0.24, 1.15) 0.54 (0.21, 1.42)*	0.106 0.213*	3546 (91.5%)
ISA	187 (10.1%)	110 (5.4%)	1.91 (0.81, 4.51) 1.82 (0.66, 5.04)*	0.139 0.247*	297 (7.7%)
NASB	18 (1.0%)	13 (0.6%)	1.51 (0.45, 5.07) 1.81 (0.51, 6.39)*	0.507 0.357*	31 (0.8%)
6-months follow-up	**10 patients 10 lesions 11 stents 1580 struts**	**11 patients 11 lesions 11 stents 1785 struts**			**21 patients 21 lesions 22 stents 3365 struts**
Apposition					
Well-apposed	1536 (97.2%)	1779 (99.7%)	0.10 (0.02, 0.55) 0.21 (0.03, 1.68)*	0.008 0.143*	3315 (95.8%)
ISA	37 (2.3%)	2 (0.1%)	25.57 (5.58, 117.47) 12.56 (1.70, 93.10)*	<0.0001 0.013*	39 (1.2%)
NASB	7 (0.4%)	4 (0.2%)	1.79 (0.21, 14.92) 0.63 (0.09, 4.26)*	0.592 0.638*	11 (0.3%)
Coverage					
Covered struts	1437 (90.9%)	1690 (94.7%)	0.47 (0.14, 1.63) 0.89 (0.25, 3.11)*	0.237 0.857*	3127 (92.9%)
Thickness of coverage (µm)	261 (238)*	225 (195)*			242 (217)
Corrected mean (µm)†	104	132	0.78 (0.32, 1.90) 1.15 (0.43, 3.08)*	0.575 0.763*	

Data reported as # (%), except for the thickness of coverage, reported as mean (SD). *Estimation of the effect after correction by vessel size (mean stent area). †Ln transformed. Estimate or the effect and confidence intervals represent group A/group B ratio.

Merci votre aide et à Biotronik de poursuivre l'innovation en cardiologie interventionelle

- Etude innovante car :
- Evaluation d'une population à risque
- Validation d'une double AAP courte pour ballon actif
- Nouvelle stratégie : BMS puis DEB

- **Abstract 17319: Biological Determinants of Neointimal Proliferation After Intracoronary Therapy With Drug-Eluting Devices: Role of Endothelial Progenitor Cells and Interleukin 1 FamilyTudor C Poerner; Sylvia Otto; Kristina Nitsche; Johannes Gassdorf; Florian Janiak; Christian Jung; Hans R FigullaDiv of Cardiology, Univ Hosp of Jena, Jena, GermanyObjectives: A prospective randomized trial (Fig. 1) compared the Xience V everolimus-eluting stent (DES) with the Coroflex Blue bare metal stent postdilated with the Sequent Please paclitaxel-eluting balloon (BMS+DEB) in patients (pt) with stable angina using optical coherence tomography (OCT) at 6-month follow-up (f/u).Methods: Noncovered struts (in %) and the volume of neointimal proliferation indexed per cm stent length (in mm^3/cm) were determined by OCT. EPC were counted as cells simultaneously expressing CD34, CD133 and KDR epitopes and apoptosis was assessed by annexin V test. EPC and interleukins were measured at baseline and f/u and given as mean values.Results: OCT and blood samples were available in 76 pt (38 pt with 47 DES and 38 pt with 39 BMS+DEB). More neointimal proliferation was seen after BMS+DEB (15.69 ± 7.6 mm^3/cm vs. 11.21 ± 5.3 mm^3/cm after DES, p=0.002). The proportion of uncovered struts did not differ between DES (4.1 ± 8.9 %) and BMS+DEB (3.8 ± 7.3 %, n.s.). For DES, indexed neointimal volume correlated inversely with age (r=-0.33, p=0.019) and with the noncovered struts (r=-0.48, p=0.001) and interleukins correlated with age (IL1ra: r=0.46, p=0.011; IL18: r=0.4, p=0.021), too. For BMS+DEB, indexed neointimal volume correlated inversely with EPC (r=-0.33, p=0.02) and with the noncovered struts (r=-0.59, p<0.001), while noncoverage showed a positive association with EPC (r=0.37, p=0.012) and an inverse relationship with apoptotic EPC (r=-0.33, p=0.023). In the entire population, indexed neointimal volume was inversely associated with EPC (r=-0.27, p=0.009) and noncoverage (r=-0.48, p<0.001), the latter was also inversely correlated with apoptotic EPC (r=-0.29, p=0.006) and IL1ra was associated with age (r=0.33, p=0.007).Conclusions: DES was associated with less neointimal proliferation at 6 months than BMS+DEB, while the strut coverage was similar. EPC might help to refine patient selection for certain drug-eluting device therapies.**

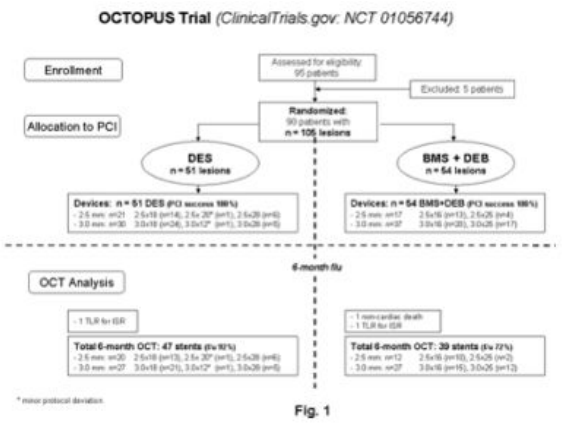

Fig. 1

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A Randomized Multicenter Study Comparing a Paclitaxel Drug-Eluting Balloon With a Paclitaxel-Eluting Stent in Small Coronary Vessels

The BELLO (Balloon Elution and Late Loss Optimization) Study

Azeem Latib, MD,* Antonio Colombo, MD,* Fausto Castriota, MD,† Antonio Micari, MD,‡ Alberto Cremonesi, MD,§ Francesco De Felice, MD,‖ Alfredo Marchese, MD,¶ Maurizio Tespili, MD,# Patrizia Presbitero, MD,** Gregory A. Sgueglia, MD,†† Francesca Buffoli, MD,‡‡ Corrado Tamburino, MD,§§ Ferdinando Varbella, MD,‖‖ Alberto Menozzi, MD¶¶

Milan, Lecce, Palermo, Cotignola, Rome, Bari, Bergamo, Latina, Mantova, Catania, Torino, and Parma, Italy

Table 4 Angiographic Outcomes at Follow-up

	DEB	PES	p Value
No. with angiographic follow-up	81	82	
Minimal lumen diameter, mm			
In-stent/In-balloon	1.48 ± 0.41	1.68 ± 0.51	0.005
In-segment	1.42 ± 0.40	1.52 ± 0.50	0.16
Diameter stenosis, %			
In-stent/In-balloon	32.31 ± 16.66	26.69 ± 20.38	0.06
In-segment	34.99 ± 15.97	33.33 ± 19.99	0.56
Late lumen loss, mm			
In-stent/In-balloon	0.08 ± 0.38	0.29 ± 0.44	0.001
In-segment	0.05 ± 0.37	0.17 ± 0.45	0.09
Net gain, mm			
In-stent/In-balloon	0.87 ± 0.41	1.06 ± 0.52	0.009
In-segment	0.81 ± 0.39	0.90 ± 0.49	0.20
Binary restenosis, %			
In-stent/In-balloon	8 (10)	10 (12.4)	0.64
In-segment	8 (10)	12 (14.6)	0.35

Table 3 Quantitative Coronary Angiography Measurements at Baseline and After the Procedure

	DEB (n = 94)	PES (n = 97)	p Value
Baseline			
Reference vessel diameter, mm	2.15 ± 0.27	2.26 ± 0.24	0.004
Minimal lumen diameter, mm	0.60 ± 0.24	0.62 ± 0.22	0.64
Diameter stenosis, %	72.14 ± 10.05	72.78 ± 9.27	0.65
Length, mm	15.32 ± 7.46	14.94 ± 7.96	0.73
Final			
Minimal lumen diameter, mm			
In-stent/In-balloon	1.56 ± 0.32	1.99 ± 0.28	<0.001
In-segment	1.47 ± 0.30	1.69 ± 0.36	<0.001
Diameter stenosis, %			
In-stent/In-balloon	29.64 ± 10.24	15.42 ± 6.92	<0.001
In-segment	33.21 ± 12.56	26.84 ± 12.54	<0.001
Acute gain, mm			
In-stent/In-balloon	0.96 ± 0.30	1.37 ± 0.31	<0.001
In-segment	0.87 ± 0.29	1.08 ± 0.37	<0.001

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In-segment	1.42 ± 0.40	1.52 ± 0.50	0.16
Diameter stenosis, %			
In-stent/In-balloon	32.31 ± 16.66	26.69 ± 20.38	0.06
In-segment	34.99 ± 15.97	33.33 ± 19.99	0.56
Late lumen loss, mm			
In-stent/In-balloon	0.08 ± 0.38	0.29 ± 0.44	0.001
In-segment	0.05 ± 0.37	0.17 ± 0.45	0.09
Net gain, mm			
In-stent/In-balloon	0.87 ± 0.41	1.06 ± 0.52	0.009
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Baseline			
Reference vessel diameter, mm	2.15 ± 0.27	2.26 ± 0.24	0.004
Minimal lumen diameter, mm	0.60 ± 0.24	0.62 ± 0.22	0.64
Diameter stenosis, %	72.14 ± 10.05	72.78 ± 9.27	0.65
Length, mm	15.32 ± 7.46	14.94 ± 7.96	0.73
Final			
Minimal lumen diameter, mm			
In-stent/In-balloon	1.56 ± 0.32	1.99 ± 0.28	<0.001
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Length, mm	15.32 ± 7.45	14.94 ± 7.99	0.73
Final			
Minimal lumen diameter, mm			
In-stent/In-balloon	1.56 ± 0.32	1.99 ± 0.28	<0.001
In-segment	1.47 ± 0.30	1.69 ± 0.36	<0.001
Diameter stenosis, %			
In-stent/In-balloon	28.64 ± 10.24	15.42 ± 6.90	<0.001
In-segment	33.21 ± 10.56	26.84 ± 12.54	<0.001
Acute gain, mm			
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In-segment	0.87 ± 0.29	1.08 ± 0.37	<0.001