

Tratamiento “DEB Only” pequeño vaso

A menor diámetro de vaso, mayor impacto de proliferación endotelial

Vaso de 3 mm de diámetro

Vaso de 2 mm de diámetro

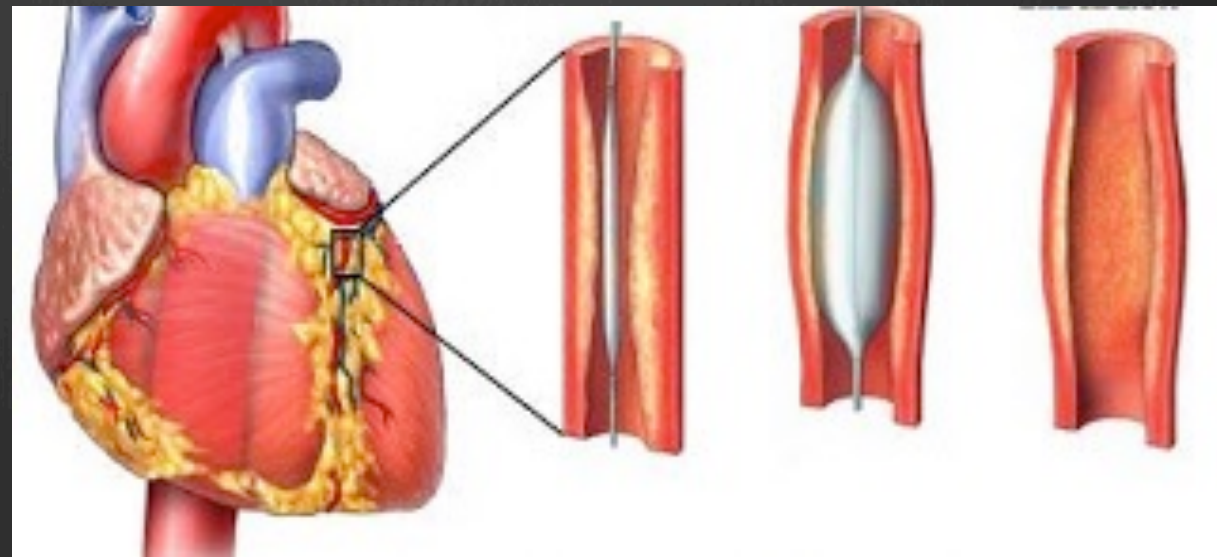
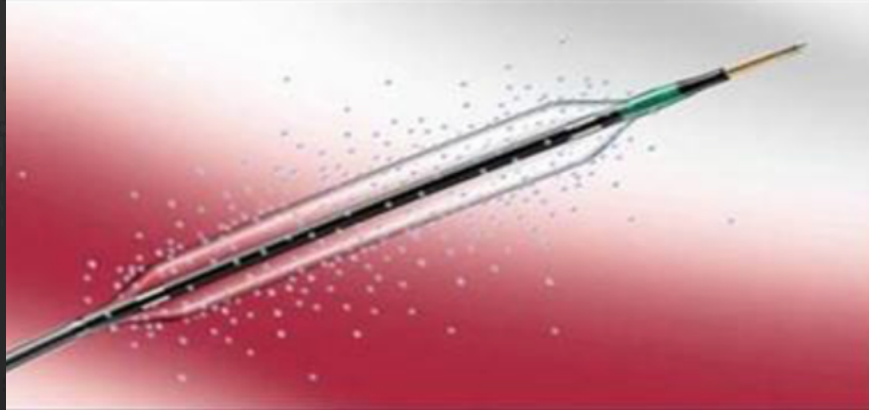


Si tenemos 1 mm de hiperplasia endotelial

33% disminución de diámetro

50% disminución de diámetro

DEB en lesiones de pequeño vaso



PEPCAD I (The Paclitaxel-Eluting PTCA Balloon in Coronary Artery Disease)

Clin Res Cardiol (2010) 99:165–174
DOI 10.1007/s00392-009-0101-6

ORIGINAL PAPER

Treatment of small coronary arteries with a paclitaxel-coated balloon catheter

Martin Unverdorben · Franz X. Kleber · Hubertus Heuer · Hans-Reiner Figulla ·
Christian Vallbracht · Matthias Leschke · Bodo Cremers · Stefan Hardt ·
Michael Buerke · Hanns Ackermann · Michael Boxberger · Ralf Degenhardt ·
Bruno Scheller

118 pacientes

Lesiones $\geq 70\%$ y ≤ 22 mm

Diámetro vaso 2,25 a 2,8 mm (media fue de 2,36 mm)

Objetivo primario:

LLL en segmento tratado a 6 meses

* 32 pacientes necesitaron el implante de un stent (BMS) adicional tras el tratamiento con balón farmacoactivo (27,1%)

PEPCAD I (The Paclitaxel-Eluting PTCA Balloon in Coronary Artery Disease)

12 (QCA: 6)-Month Follow-Up:

	DCB	DCB + BMS
Ø In-segment LLL (6 Month)	0.16 ± 0.38 mm	0.62 ± 0.73 mm
Binary restenosis rate in-segment (6 Month)	4/82 (5.5 %)	13/32 (44.8 %)
MI (12 Month)	1/82 (1.3 %)	1/32 (3.1 %)
TLR (12 Month)	4/82 (4.9 %)	9/32 (28.1 %)
MACE (12 Month)	6.1 %	37.5 %

PEPCAD I (The Paclitaxel-Eluting PTCA Balloon in Coronary Artery Disease)

CLINICAL RESEARCH

Eurointervention 2013;9:620-8

Treatment of small coronary arteries with a paclitaxel-coated balloon catheter in the PEPCAD I study: are lesions clinically stable from 12 to 36 months?

Martin Unverdorben¹, MD; Franz X. Kleber², MD; Hubertus Heuer³, MD; Hans-Reiner Figulla⁴, MD; Christian Vallbracht⁵, MD; Matthias Leschke⁶, MD; Bodo Cremers⁷, MD; Stefan Hardt⁸, MD; Michael Buerke⁹, MD; Hanns Ackermann¹⁰, PhD; Michael Boxberger¹¹, PhD; Ralf Degenhardt¹, PhD; Bruno Scheller^{7*}, MD

36-Month Follow-Up:

	DCB	DCB + BMS
MI	2/82 (2.4 %)	2/32 (6.3 %)
TLR	4/82 (4.9 %)	11/32 (34.4 %)
Stent thrombosis	0	2/32 (6.3 %)
MACE	7.3 %	40.6 %

Unverdorben M et al. Treatment of small coronary arteries with a paclitaxel-coated balloon catheter in the PEPCAD I study: are lesions clinically stable from 12 to 36 months? Eurointervention. 2013;9 (5):620-8

Interventional cardiology

Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomised clinical trial. The PICCOLETO Study

Bernardo Cortese,¹ Andrea Micheli,¹ Andrea Picchi,¹ Amelia Coppolaro,¹
Loria Bandinelli,¹ Silva Severi,² Ugo Limbruno¹

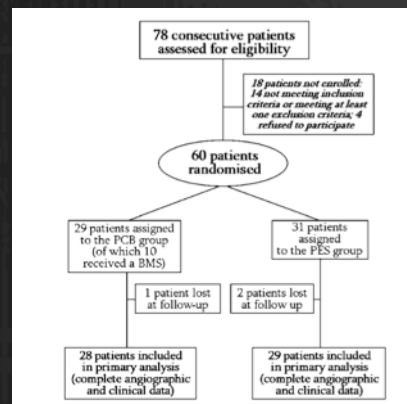
Estudio randomizado, prospectivo, unicéntrico
Vasos $\leq 2,75$ mm

Objetivos:

1°. LLL a 6 meses

2° Reestenosis binaria

MACE : muerte cardiaca, IAM, TLR a 9 meses



	PCB (n=28)	Taxus stent (n=29)	p
Multivessel PCI	17 (60.7%)	19 (65.5%)	0.70
Target vessel, LAD	15 (53.6%)	15 (51.7%)	0.89
Target vessel, LCX	5 (17.9%)	3 (10.4%)	0.41
Target vessel, RCA	8 (28.5%)	11 (37.9%)	0.45
Need to change PCB due to difficult positioning	5 (17.9%)	NA	NA
Stents implanted per lesion	0.36	1.17	0.024
Stent or balloon diameter \pm SD (mm)	2.48 \pm 0.30	2.54 \pm 0.10	NA
Stent or balloon length \pm SD (mm)	18.6 \pm 5.24	18.9 \pm 7.63	NA
Lesion predilatation (uncoated balloon)	7 (25.0%)	25 (86.2%)	0.001
Maximal inflation pressure \pm SD (atmospheres)	7.71 \pm 2.2	13.41 \pm 1.38	0.02
Final MLD \pm SD (mm)	2.47 \pm 0.22	2.63 \pm 0.23	0.009
Final lesion stenosis \pm SD (% LD)	19.0 \pm 17.3	9.9 \pm 9.2	0.016
Angiographic success	96.4%	100%	0.30
Procedural success	96.4%	100%	0.30

* Bailout 35,6%

Cortese B., Micheli A., Picchi A., Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomised clinical trial. *Heart*. 2010;96:1291-1296

Resultados angiográficos a 6 meses

	PCB (n = 28)	Taxus stent (n = 29)	p
Reference vessel diameter \pm SD (mm)	2.54 \pm 0.47	2.58 \pm 0.24	0.73
MLD \pm SD (mm)	1.11 \pm 0.65	1.94 \pm 0.72	0.0002
Per cent diameter stenosis \pm SD	43.6 \pm 27.4	24.3 \pm 25.1	0.029
Angiographic binary restenosis	9 (32.1%)	3 (10.3%)	0.043

Resultados clínicos a 9 meses

	PCB (n = 28)	Taxus stent (n = 29)	p
Death	1 (3.6%)	1 (3.5%)	0.98
Cardiac death	0	0	0.97
Myocardial infarction	1 (3.6%)	0	0.30
Target lesion revascularisation	9 (32.1%)	3 (10.3%)	0.15
Target vessel revascularisation	9 (32.1%)	4 (13.8%)	0.10
Stent thrombosis*/abrupt vessel closure	0	0	0.97
MACE	10 (35.7%)	4 (13.8%)	0.054

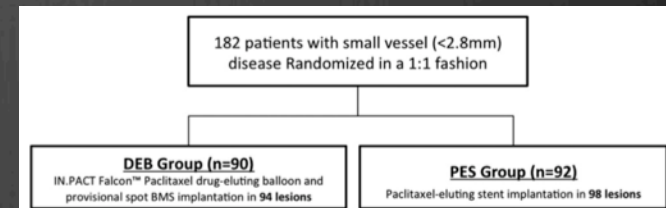
Cortese B., Micheli A., Picchi A., Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomised clinical trial. *Heart*. 2010;96:1291-1296

CLINICAL RESEARCH

Interventional Cardiology

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



	DEB (n = 94)	PES (n = 98)	p Value
Balloon pre-dilation	91 (96.8)	81 (82.7)	0.002
DEB			
Diameter, mm	2.49 ± 0.2		
Length, mm	25.6 ± 6.3		
Pressure, atm	9.6 ± 2.5		
Duration of inflation, s	56.6 ± 2.5		
Bailout BMS stenting	19 (20.2)		
Stent implanted within DEB segment	19 (100)		
PES			
Diameter, mm		2.49 ± 0.2	
Length, mm		18.5 ± 5.6	
Pressure, atm		17.2 ± 3.5	
Post-dilation		47 (50.0)	
Device success	92 (97.9)	95 (96.9)	0.69

Objetivos:

- 1° LLL a 6 meses
- 2° MACE: Muerte cardiaca, IAM, TVR
- Reestenosis binaria
- TLR

DEB en lesiones de pequeño vaso

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CLINICAL RESEARCH **Interventional Cardiology**

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

	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 ± 7.45	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	29.84 ± 10.24	15.42 ± 6.92	<0.001
In-segment	33.21 ± 10.56	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

	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	0.06
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

	DEB (n = 90)	PES (n = 92)	p Value
In-hospital MACE			
Periprocedural MI	1 (1.1)	3 (3.3)	0.33
Recurrent PCI	0	0	
Death	0	0	
30-day MACE (days 0-30)			
MACE	2 (2.2)	4 (4.3)	0.42
MI	1 (1.1)	4 (4.4)	0.18
TLR	1 (1.1)	0	0.31
TVR (including TLR)	2 (2.2)	0	0.15
Death	0	0	
Cumulative MACE (days 0-180)			
MACE	9 (10)	15 (16.3)	0.21
MI	1 (1.1)	5 (5.5)	0.10
TLR	4 (4.4)	7 (7.6)	0.37
TVR (including TLR)	7 (7.8)	10 (11.0)	0.46
Death	1 (1.1)	1 (1.1)	0.99

Latib A, Colombo A, Castriota F, et al. 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. *J Am Coll Cardiol.* 2012;60:2473-80

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A 2-year follow-up of a randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels the BELLO study 

Cumulative incidence of MACE.

	DEB (n = 90)	PES (n = 92)	P value
MACE up to 6 months	9 (10.0)	15 (16.3)	0.21
Death	1 (1.1)	1 (1.1)	0.99
Cardiac death	0	0	
MI	1 (1.1)	5 (5.5)	0.10
TLR	4 (4.4)	7 (7.6)	0.37
TVR	7 (7.8)	10 (11.0)	0.46
MACE up to 1 year	11 (12.4)	21 (23.1)	0.06
Death	1 (1.1)	1 (1.1)	0.99
Cardiac death	0	0	
MI	1 (1.1)	6 (6.6)	0.06
TLR	6 (6.7)	11 (12.1)	0.22
TVR	9 (10.1)	15 (16.5)	0.21
MACE up to 2 years	13 (14.8)	23 (25.3)	0.08
Death	1 (1.1)	2 (2.2)	0.58
Cardiac death	0	0	
MI	3 (3.4)	8 (8.8)	0.13
TLR	6 (6.8)	11 (12.1)	0.23
TVR	9 (10.2)	16 (17.6)	0.16

Naganuma T, Latib A, Sgueglia GA, et al. A 2-year follow-up of a randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels the BELLO study. *Int J Cardiol* 2015;184:17–21.

ORIGINAL ARTICLE

Prospective 'real world' registry for the use of the 'PCB only' strategy in small vessel de novo lesions

U Zeymer,¹ M Waliszewski,² M Spiecker,³ O Gastmann,⁴ B Faurie,⁵ M Ferrari,⁶ M Alidoosti,⁷ C Palmieri,⁸ T N Heang,⁹ P JL Ong,¹⁰ U Dietz¹¹

Registro multicéntrico (Europa y Asia) prospectivo Vasos 2 a 2,75 mm

Obj. Primario: TLR a 9 meses

Obj. Secundario: Trombosis aguda/subaguda

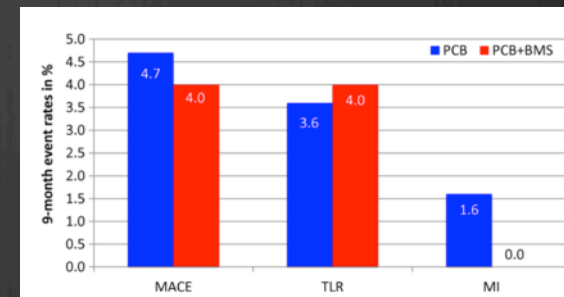
MACE: TLR

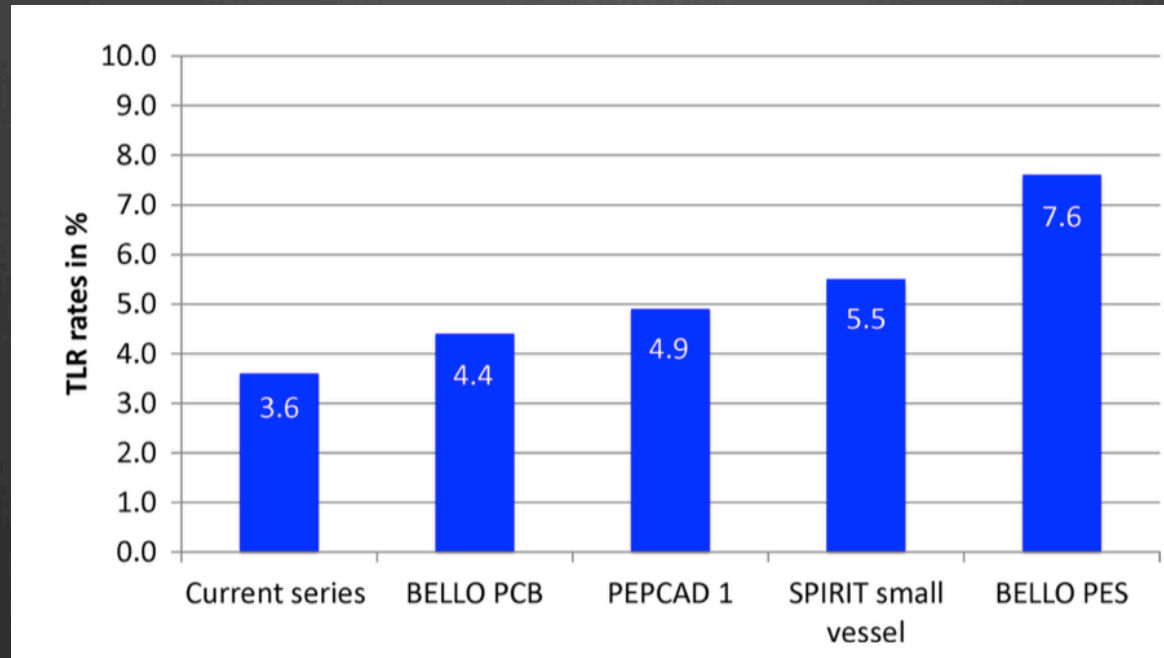
IAM

Muerte cardiaca

6% pacientes necesitan un BMS adicional

	All Patients	DCB-only	DCB/BMS	p value
Patients	447	420	27	-
Lesions	471	438	33	-
TLR	14 (3.6%)	13 (3.6%)	1 (4.0%)	0.922
MACE	18 (4.7%)	17 (4.7%)	1 (4.0%)	0.866
Thrombosis rate in the target lesion	0 (0.0%)	0 (0.0%)	0 (0.0%)	-





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CORONARY ARTERY DISEASE

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

BEATRIZ VAQUERIZO, M.D., Ph.D.,¹ FAUSTINO MIRANDA-GUARDIOLA, M.D.,²
EDUARDO FERNÁNDEZ, M.D.,³ JOSÉ RAMÓN RUMOROSO, M.D.,⁴
JOSEP ANTONI GÓMEZ-HOSPITAL, M.D.,⁵ FRANCISCO BOSSA, M.D.,⁶
ANDRÉS IÑIGUEZ, M.D.,⁷ IMANOL OATEGUI, M.D.,⁸ and ANTONIO SERRA, M.D.¹

Registro multicéntrico prospectivo
104 pacientes
Vaso ≤ 2,5 mm

2 centros a los 6-8 meses: seguimiento angiográfico

Follow-Up	1 Month	12 Months
Overall death	(0) 0	(3) 2.9
Cardiac	(0) 0	(2) 1.9
Non-cardiac	(0) 0	(0) 0
Q and nonQ wave MI	(0) 0	(1) 1.0
Target lesion revascularization	(0) 0	(3) 2.9
MACE	(0) 0	(5) 4.8
Stent Thrombosis (ARC)	(0) 0	(1) 1.0

N = 51 (39.3% 1st G of DIOR)	Preangioplasty	Postangioplasty	Angio FU
Reference diameter, mm	1.95 ± 0.32		
Lesion length, mm	12.8 ± 7.1		
MLD, mm	0.49 ± 0.28	1.54 ± 0.34	1.23 ± 0.53
Diameter stenosis, %	76.8 ± 13.4	23.2 ± 10.2	39.7 ± 26.1
Acute gain, mm		1.05 ± 0.3	
Late luminal loss, mm			0.31 ± 0.2
Binary restenosis, n (%)			(10) 19.6

* Bailout 7%

Vaquerizo B, et al. Treatment of small vessel with the paclitaxel drug-eluting balloon: 6-month angiographic and 1-year clinical outcomes of the spanish multicenter registry. J Interven Cardiol 2015;28:430-38.

Análisis multivariado

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

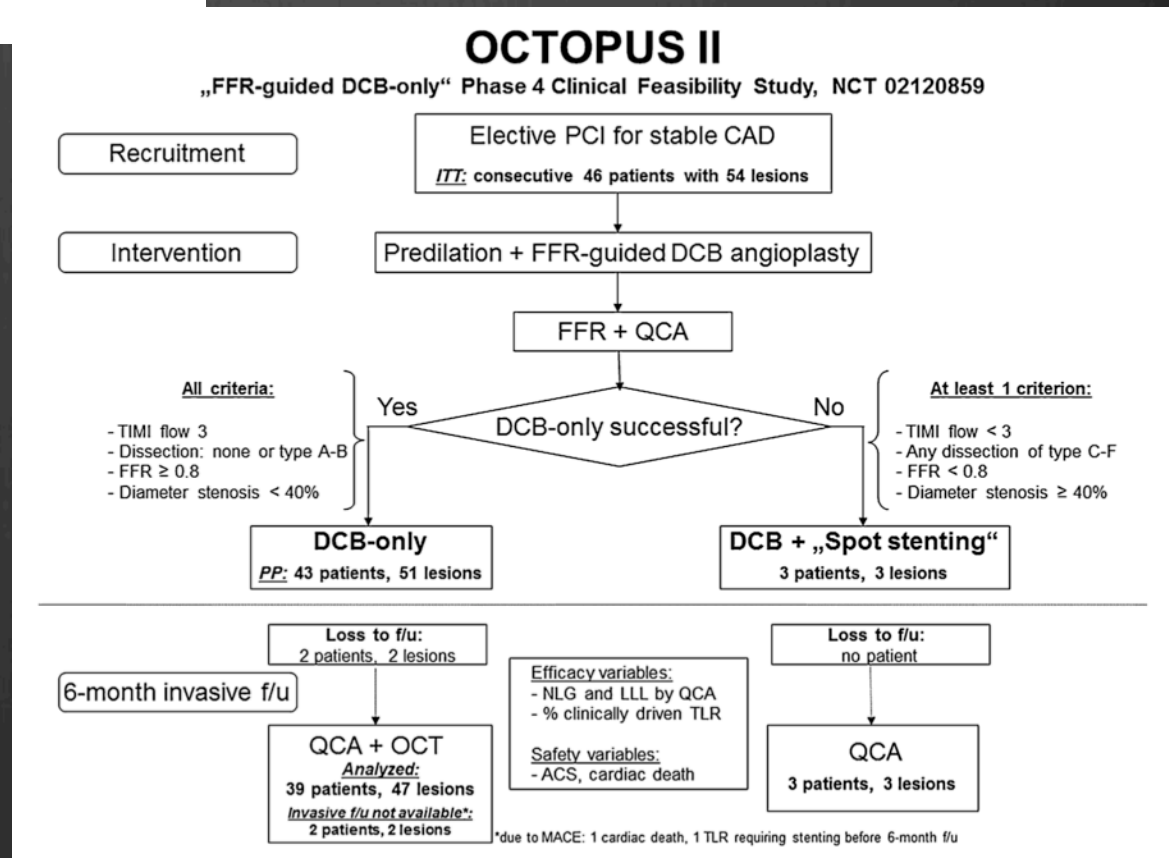
Vaquerizo B, et al. Treatment of small vessel with the paclitaxel drug-eluting balloon: 6-month angiographic and 1-year clinical outcomes of the spanish multicenter registry. J Interven Cardiol 2015;28:430-38.



Fractional flow reserve-guided coronary angioplasty using paclitaxel-coated balloons without stent implantation: feasibility, safety and 6-month results by angiography and optical coherence tomography

Tudor C. Poerner¹ · Corinna Duderstadt¹ · Björn Goebel¹ · Daniel Kretschmar¹ · Hans R. Figulla¹ · Sylvia Otto¹

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**Fractional flow reserve-guided coronary angioplasty using paclitaxel-coated balloons without stent implantation: feasibility, safety and 6-month results by angiography and optical coherence tomography**Tudor C. Poerner¹ · Corinna Duderstadt¹ · Björn Goebel¹ · Daniel Kretzschmar¹ · Hans R. Figulla¹ · Sylvia Otto¹Received: 3 May 2016 / Accepted: 30 June 2016 / Published online: 5 July 2016
© The Author(s) 2016. This article is published with open access at Springerlink.com**Table 2** Procedural and lesion characteristics and 6-month invasive follow-up, per-protocol analysis

Characteristics		Baseline N = 51 lesions Mean ± SD or N (%)	PCI results N = 51 lesions Mean ± SD or N (%)	6-month F/U N = 47 lesions Mean ± SD or N (%)
Target lesion	LAD/LCX/RCA	19/21/11		
	Bifurcation lesion	9 (17.6 %)		
	AHA/ACC lesion type A/B/C	6/31/14		
QCA	Reference lumen diameter (mm)	2.32 ± 0.48	2.52 ± 0.44*	2.27 ± 0.0.87°
	Minimal lumen diameter (mm)	0.82 ± 0.26	1.80 ± 0.42*	1.85 ± 0.73*
	Diameter stenosis (%)	63.9 ± 10.9	28.1 ± 10.8*	19.5 ± 20.4*°
	Lesion length (mm)	15.9 ± 5.5		
Intervention	FFR	0.64 ± 0.19	0.91 ± 0.06*	
	DCB diameter (mm)	2.84 ± 0.34		
	DCB length (mm)	24.22 ± 5.86		
	DCB dilation time (s)	53 ± 10		
	DCB pressure (bar)	10.8 ± 2.3		
	DCB/artery ratio	1.27 ± 0.19		
	Fluoroscopy time (min)	9.9 ± 7.4		
	Dissections in angiography	0 (0 %)	27 (52.9 %)*	4 (7.8 %)*°
	Troponin elevations	0 (0 %)	3 (6 %)	0

p < 0.001: * vs. baseline, *p* < 0.05: ° vs. PCI result

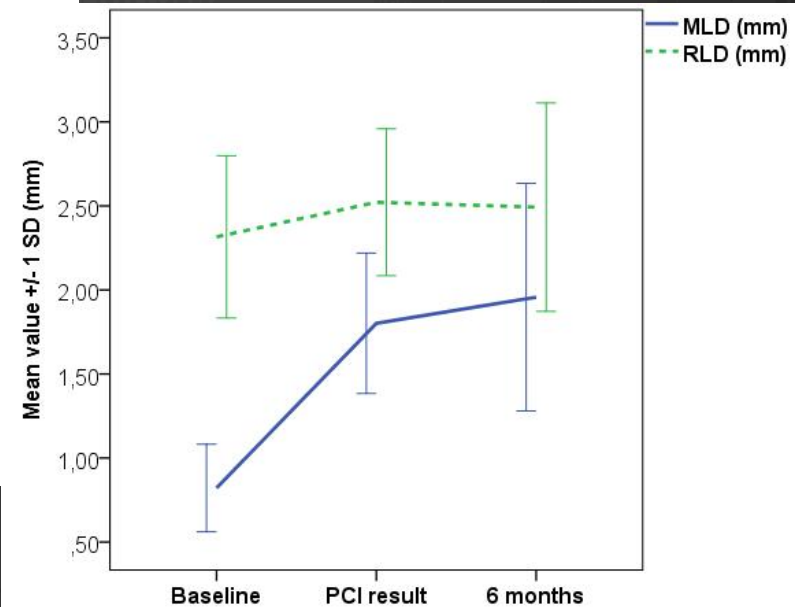
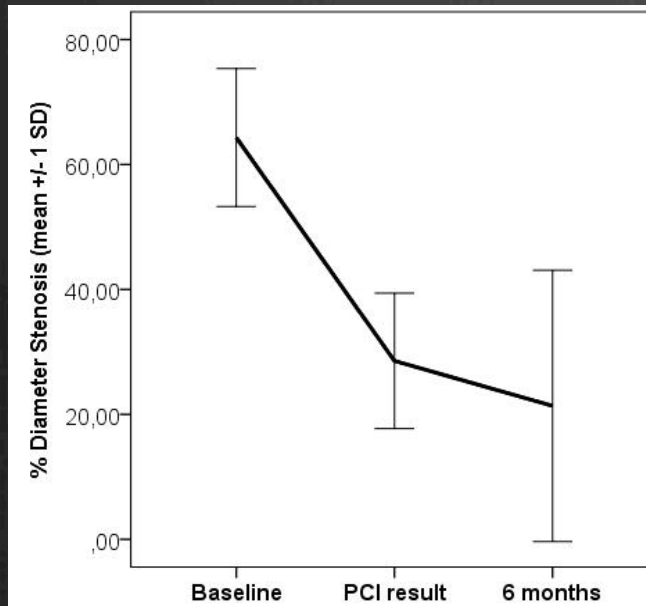
LAD left anterior descending artery, LCX left circumflex, RCA right coronary artery, SD standard deviation, N number, FFR fractional flow reserve, DCB drug-coated balloon, DCB/artery ratio nominal balloon diameter/RLD-1, QCA quantitative coronary angiography



Fractional flow reserve-guided coronary angioplasty using paclitaxel-coated balloons without stent implantation: feasibility, safety and 6-month results by angiography and optical coherence tomography

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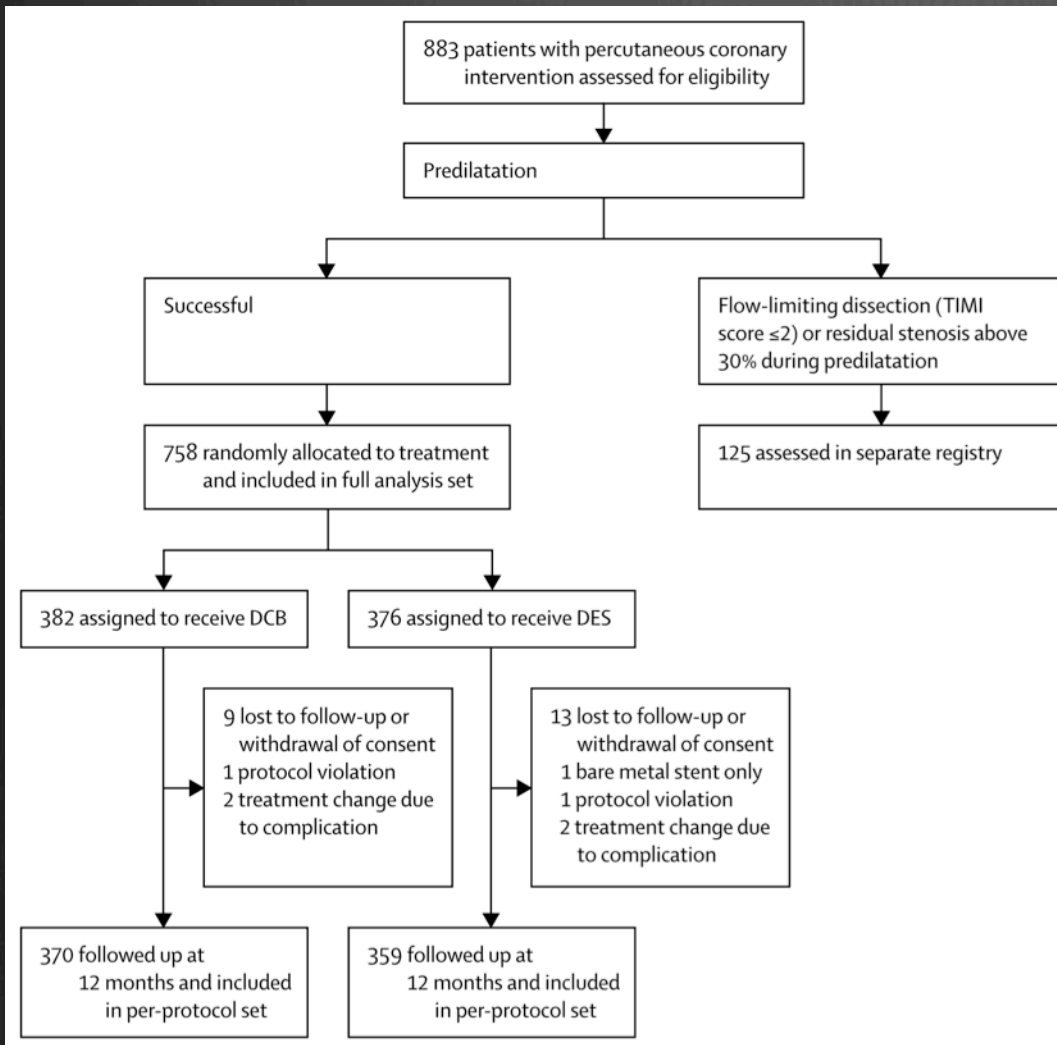
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Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial



Raban V Jeger, Ahmed Farah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Gregor Leibundgut, Daniel Weilenmann, Jochen Wöhrle, Stefan Richter, Matthias Schreiber, Felix Mahfoud, Axel Linke, Frank-Peter Stephan, Christian Mueller, Peter Rickenbacher, Michael Coslovsky, Nicole Gilgen, Stefan Osswald, Christoph Kaiser, Bruno Scheller, for the BASKET-SMALL 2 Investigators



comparación DEB vs. 2nd Gen DES (246 Xience, 94 Taxus Element

pacientes fueron tratados con SQPLS NEO más stent.

•4 semanas con DAPT para SQPLS NEO-only y 6 meses para DES

•Objetivo primario: MACE a 12 meses

- Muerte cardiaca
- Infarto no fatal
- TVR

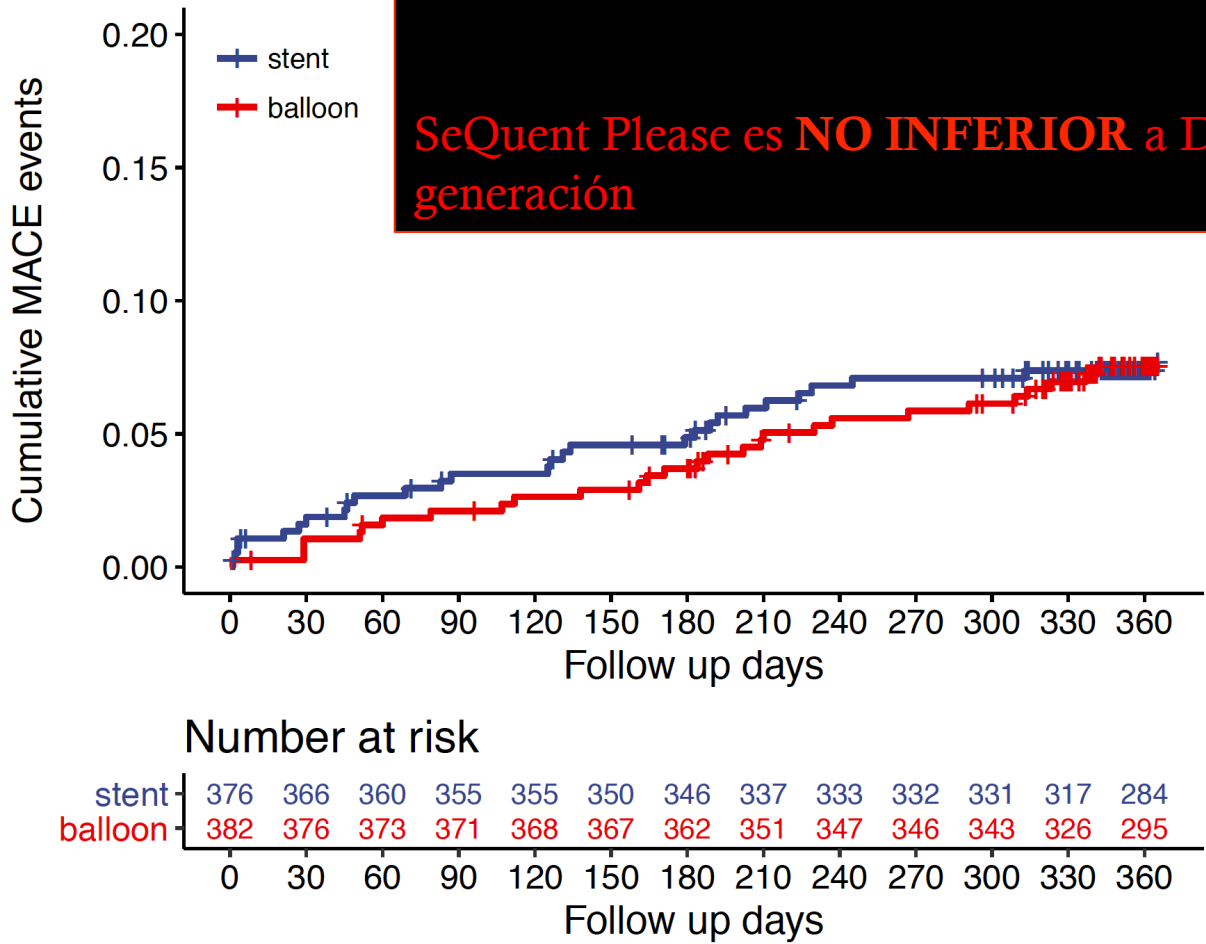
RESULTADOS BASKET-SMALL 2 (1/2)

Evento	Variable	Grupo	Resultados	N	Valor-p
TVR	Brazo tratamiento	DES	4.5 %		
		SQPLS NEO	3.4 %	758	0.438
MI (no fatal)	Brazo tratamiento	DES	3.5 %		
		SQPLS NEO	1.6 %	758	0.112
Muerte Cardíaca	Brazo tratamiento	DES	1.3 %		
		SQPLS NEO	3.1 %	758	0.113
MACE	Brazo tratamiento	DES	7.5 %		
		SQPLS NEO	7.3 %	758	0,918

RESULTADOS BASKET-SMALL 2 (2/2)

MACE después de 12 meses fue 7.57 % para SQPLS NEO y 7.54 % para DES

SeQuent Please es **NO INFERIOR** a DES de segunda generación



CONCLUSIONES:

El tratamiento de lesiones de novo con DEB en vaso pequeño es seguro, y con una baja tasa de TLR.

El tener que implantar un BMS asociado al DEB empeora el resultado a medio plazo por el “geographic mismatch”.