45TH

45th Annual International Congress of the
EGYPTIAN SOCIETY OF CARDIOLOGY
CardioEgypt 2018

Is There a Role For Drug Coated Balloon?

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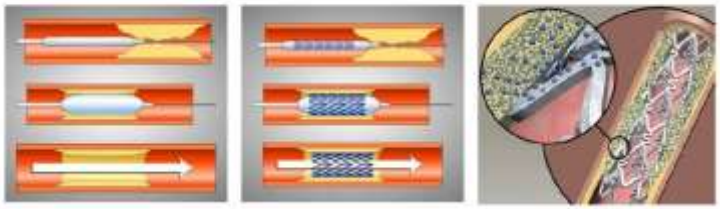
Interventional Cardiology - The Revolution

1977
1. Balloon (PTCA):
Andreas Gruentzig performs the first PTCA in Zurich, Switzerland

1988
2. Bare Metal Stent (BMS):
João 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



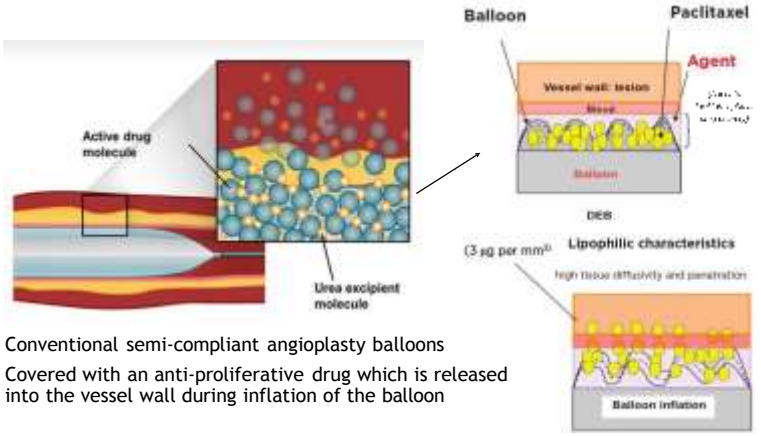
Interventional Cardiology - The 4th Revolution

‘Leaving Nothing Behind’

DCB

- The drug coated balloon (DCB) platform offers several theoretical benefits over stent-based technologies.
- DCB allows the homogenous transfer of an anti-proliferative drug to reduce neo-intimal hyperplasia whilst maintaining normal vessel anatomy , function, and avoiding permanent vascular implants.

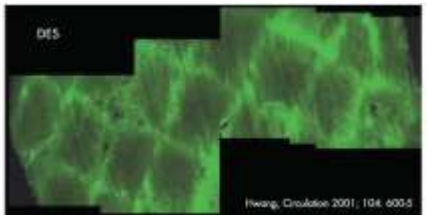
Components of DEB



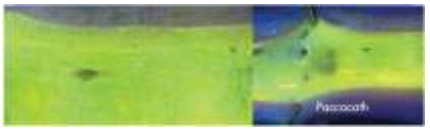
Conventional semi-compliant angioplasty balloons

Covered with an anti-proliferative drug which is released into the vessel wall during inflation of the balloon

Drug distribution



- **Drug-Eluting Stent**
  - Slow release
  - Persistent drug exposure
  - ~ 100 - 200 µg dose
  - Polymer
  - Stent mandatory



- **Drug-Coated Balloon**
  - Immediate release
  - Short-lasting exposure
  - ~ 300 - 600 µg dose
  - No polymers

Active substance on DEB is lipophilic with high absorption rate through vessel wall

Ideal drug : rapid uptake and prolonged retention

Why Paclitaxel?

- Highly lipophilic – Rapid intracellular uptake and retention in vessel wall for nearly a week
- Acts by irreversible binding to microtubules, inhibiting cell division and migration - structural intracellular changes cause long-lasting effects
- Short incubation time (3 minutes) with paclitaxel almost completely inhibits vascular smooth muscle cell proliferation for up to 12-14 days

- Zotarolimus – Also lipophilic, potential candidate for DCB applications

CE approved - DCBs

CE-approved drug-coated balloons (in alphabetical order)

Device	Carrier	Drug
Danubio	BTHC	Paclitaxel
Dior II	Shellac	Paclitaxel
Elutax	–	Paclitaxel
IN.PACT Falcon	Urea	Paclitaxel
Moxy	Polysorbate	Paclitaxel
Pantera Lux	BTHC	Paclitaxel
Protégé NC	BTHC	Paclitaxel
SeQuent Please	Iopromide	Paclitaxel

BTHC = butyryl-tri-hexyl citrate; CE = Conformité Européenne.

Practical points before DCB use

- Proper vessel preparation with predilation balloon 0.5-1.0 mm smaller than intended DEB
- Ensure adequate 1:1 sizing between vessel and DCB
- Shorten transfer time from access sheath to DEB inflation
- Single prolonged inflation for complete drug release till manufacturer's recommended time (60 or 30 sec) – if not tolerated, fractional release in quick intermittent inflations till recommended time is complete

Randomised controlled trials with DCB

	Year	Sample size (control/intervention)	Type of ISR	Interventions	Revascularization RATE		MACE rate	Follow-up (months)	
					DCB	control		Angiographic	Clinical
PACCOCATH-ISR I and II	2006-08	108 (54/54)	BMS, DES	BA vs DCB	9.3%	38.9%	27.8%	6	64
PEPCAD II	2009	131 (65/66)	BMS	PES vs DCB	6.3%	15.4%	9.1%	6	36
Habara et al	2013	50 (25/25)	DES	BA vsDCB	4.3%	41.7%	4%	6	6
PEPCAD-DES	2012	110 (38/72)	DES	BA vsDCB	15.3%	36.8%	16.7%	6	6
Habara et al	2013	210 (72/138)	BMS and DES	BA vsDCB	4.5%	31.9%	-	6	6
ISAR-DESIRE 3	2013	402 (134/131/137)	DES	BA vs PES vs DCB	22.1%	13.5%	23.5%	6–8	12
PEPCAD China ISR	2014	215 (106/109)	DES	PES vs DCB	14.5%	13.6%	-	9	12

Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions

Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
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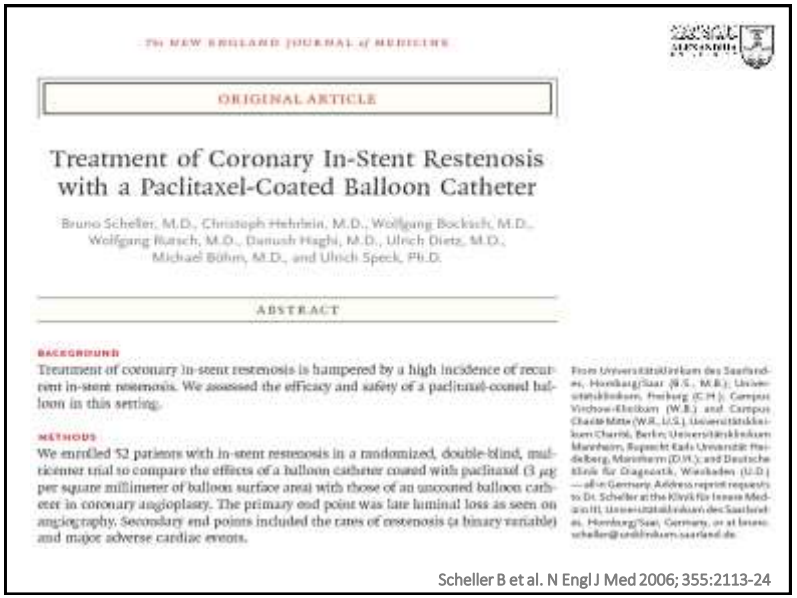
- De-Novo Coronary Lesions



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D., Wolfgang Rutsch, M.D., Danush Haghi, M.D., Ulrich Dietz, M.D., Michael Böhm, M.D., and Ulrich Speck, Ph.D.

ABSTRACT

BACKGROUND

Treatment of coronary in-stent restenosis is hampered by a high incidence of recurrent in-stent restenosis. We assessed the efficacy and safety of a paclitaxel-coated balloon in this setting.

METHODS

We enrolled 52 patients with in-stent restenosis in a randomized, double-blind, multicenter trial to compare the effects of a balloon catheter coated with paclitaxel (3 μg per square millimeter of balloon surface area) with those of an uncoated balloon catheter in coronary angioplasty. The primary end point was late luminal loss as seen on angiography. Secondary end points included the rates of restenosis (a binary variable) and major adverse cardiac events.

From Universitätsklinikum des Saarlandes, Homburg/Saar (B.S., M.B.); Universitätsklinikum, Freiburg (C.H.); Campus Virchow-Klinikum (W.B.) and Campus Charité Mitte (W.R., U.S.), Universitätsklinikum Charité, Berlin; Universitätsklinikum Mannheim, Ruprecht Karls Universität Heidelberg, Mannheim (D.H.); and Deutsche Klinik für Diagnostik, Wiesbaden (U.D.) — all in Germany. Address reprint requests to Dr. Scheller at the Klinik für Innere Medizin III, Universitätsklinikum des Saarlandes, Homburg/Saar, Germany, or at bruno.scheller@uniklinikum-saarland.de.

Scheller B et al. N Engl J Med 2006; 355:2113-24

PACCOCATH ISR I + II

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

- Efficacy and Safety of Paclitaxel-Coated Balloons in Coronary In-Stent Restenosis
- Two trials
  - separately randomized
  - double-blind, multicenter
  - identical protocol
  - 108 patients in total
- Paccocath ISR I: 52 patients
- Paccocath ISR II: 56 patients

Scheller B et al. N Engl J Med 2006;355:2113-24.

PACCOCATH ISR I + II

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Table 2. (Continued.)

Variable	Uncoated Balloon (N = 26)	Paclitaxel-Coated Balloon (N = 26)	Absolute Difference (95% CI)	P Value
Angiographic findings at 6 mo				
No. of patients	25	22		
Minimal luminal diameter — mm				
In-stent	1.40±0.89	2.31±0.66	−0.71 (−1.18 to 0.24)	0.004
In-segment	1.57±0.86	2.22±0.57	−0.65 (−1.09 to 0.21)	0.005
Late luminal loss — mm				
In-stent	0.76±0.86	0.09±0.49	0.67 (0.24 to 1.08)	0.003
In-segment	0.74±0.86	0.03±0.48	0.70 (0.28 to 1.12)	0.002
Restenosis — no. (%)				
In-stent	10 (45)	1 (5)	0.38 (0.15 to 0.63)	0.002
In-segment	10 (45)	1 (5)	0.38 (0.15 to 0.63)	0.002

Scheller B et al. N Engl J Med 2006;355:2113-24.

PACCOCATH ISR I + II: Long-term

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

	Uncoated Balloon	Drug Coated Balloon	p
n	54	54	
Follow-up	5.2 ± 1.5 yrs	5.6 ± 0.9 yrs	0.108
Death	8 (14.8 %)	5 (9.3 %)	0.556
MI	8 (14.8 %)	5 (9.3 %)	0.556
TLR	21 (38.9 %)	5 (9.3 %)	0.001
Stent thrombosis	0	0	1.000
Stroke	5 (9.3 %)	5 (9.3 %)	1.000
MACE	32 (59.3 %)	15 (27.8 %)	0.002

Scheller, PCR 2011

PEPCAD II

Paclitaxel-Coated Balloon Catheter Versus Paclitaxel-Coated Stent for the Treatment of Coronary In-Stent Restenosis

	Drug-Coated Balloon	Drug-Eluting Stent	Difference (95% CI)	P
Angiographic follow-up at 6 months				
Angiographic follow-up, n (%)	57 (86.4)	59 (88.8)	−0.04 (−0.15 to 0.05)	0.43
Minimal lumen diameter				
In-stent, mm	2.08±0.58	2.11±0.78	−0.04 (−0.29 to 0.21)	0.77
In-segment, mm	2.03±0.54	1.96±0.82	0.07 (−0.19 to 0.33)	0.60
Diameter stenosis, %	29.4±17.5	34.2±24.3	−4.7 (−12.5 to 3.1)	0.23
Late lumen loss, mm				
In-stent	0.19±0.39	0.45±0.68	−0.26 (−0.47 to −0.06)	0.01
In-segment	0.17±0.42	0.38±0.61	−0.21 (−0.40 to −0.02)	0.03
Late lumen loss index, mm				
In-stent	0.12±0.26	0.28±0.48	−0.16 (−0.30 to −0.02)	0.03
In-segment	0.11±0.28	0.30±0.53	−0.19 (−0.35 to −0.03)	0.02
Binary restenosis rate, n (%)				
In-stent	4 (7)	10 (16.9)	−0.10 (−0.23 to 0.03)	0.17
In-segment	4 (7)	12 (20.3)	−0.13 (−0.27 to 0.01)	0.06

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

Effectiveness of DCB in Pts with in-DES restenosis

Intervention Type	Trial Name	Type of comparison	Sample size (n)	Type of DEB	Angiographic and Clinical Outcomes		
					6 mo late loss	TLR	MACE
DES-ISR		RCT					
Sirolimus/ Everolimus/ Paclitaxel ISR	PEPCAD DES	DEB vs POBA	n=110	SeQuent™ Please	0.43±0.61 vs 1.03±0.77 mm*	6 mo: 15.3 vs 36.8%*	6 mo: 16.7% vs 36.8%*
Sirolimus-ISR	Habara S et al.	DEB vs POBA	n=50	SeQuent™ Please	0.18±0.45 vs 0.72±0.55 mm*	6 mo: 4.3% vs 41.7%*	
Limus-ISR	ISAR-DESIRE 3	DEB vs PES vs POBA	n=137/131 /134	SeQuent™ Please	DEB 0.37±0.59 vs PES 0.34±0.61 mm, p=NA DEB/PES vs POBA 0.70 ± 0.60 mm*.	DEB 22.1 vs PES13.5%* DEB/PES vs POBA 43.5%*	DEB 23.5 vs PES 19.2%* DEB/PES vs POBA 46.3%*
Sirolimus/ Everolimus/ Paclitaxel ISR	RIBS IV	DEB vs EES (XV)	n= 308	SeQuent™ Please		12 mo: 16% vs 8% (p0.03)	12 mo: 18% vs 10% (p 0.04)

HABARA

Effectiveness of Paclitaxel-Eluting Balloon Catheter in Patients With Sirolimus-Eluting ISR

Follow-up rate: 94% (47/50 Lesions, PEB group: 23, BA group: 24)

	Paclitaxel-Eluting Balloon	Conventional Balloon Angioplasty	
Late luminal loss (in-lesion)	0.17 ± 0.45	0.72 ± 0.56	0.001
Late luminal loss (in-segment)	0.18 ± 0.45	0.72 ± 0.55	0.001
Binary restenosis	2 (8.7)	15 (62.5)	0.0001
Target lesion revascularization)	1 (4.3)	10 (41.7)	0.003

JACC: Cardiovascular Interventions , 2011; 4: 149-54

AHJ

Comparison of drug-eluting stents and drug-coated balloon for the treatment of drug-eluting coronary stent restenosis: A randomized RESTORE trial.

Author information

Abstract

BACKGROUND: This study sought to evaluate the optimal treatment for in-stent restenosis (ISR) of drug-eluting stents (DES-ISR).

METHODS: This is a prospective, multicenter, open-label, randomized study comparing the use of drug-eluting balloon (DEB) versus second-generation everolimus-eluting stent for the treatment of DES ISR. The primary end point was in-segment late loss at 9-month routine angiographic follow-up.

RESULTS: A total of 172 patients were enrolled, and 74 (43.0%) patients underwent the angiographic follow-up. The primary end point was not different between the 2 treatment groups (DEB group 0.15±0.49 mm vs DES group 0.19±0.41 mm; P= .54). The secondary end points of in-segment minimal luminal diameter (MLD) (1.59±0.69 mm vs 2.09±0.46 mm; P= .02), in-stent MLD (1.90±0.71 mm vs 2.29±0.46 mm; P= .005), in-segment percent diameter stenosis (34%±21% vs 26%±15%; P= .05), and in-stent percent diameter stenosis (33%±21% vs 21% ±15%; P= .002) were more favorable in the DES group. The composite of death, myocardial infarction, or target lesion revascularization at 1 year was comparable between the 2 groups (DEB group 7.0% vs DES group 4.7%; P= .51).

CONCLUSIONS: Treatment of DES-ISR using DEB or second-generation DES did not differ in terms of late loss at 9-month angiographic follow-up, whereas DES showed better angiographic results regarding minimal MLD and percent diameter stenosis. Both treatment strategies were safe and effective up to 1 year after the procedure.

JACC
Cardiovascular Interventions

JACC Cardiovasc Interv. 2018 Feb 12;11(3):275-283. doi: 10.1016/j.jcin.2017.10.024. Epub 2017 Nov 7

A Randomized Comparison of Paclitaxel-Eluting Balloon Versus Everolimus-Eluting Stent for the Treatment of Any In-Stent Restenosis: The DARE Trial.

Baan J Jr[1], Claessen BE[2], Dijk KB[3], Vendrik J[4], van der Schaaf RJ[5], Vlaar PJ[6], van Boven N[7], Gosselink ATM[8], van Dalen BM[7], Driessen A[9], Amoroso G[9], de Winter RJ[2], Koch KT[10], Suttorp MJ[11], Bax WH[12], Vis MM[13], Wykrzykowska JJ[14], Piek JJ[15], Tijssen JGP[16], Henriques JPS[17]

Author information

Abstract

OBJECTIVES: The authors sought to evaluate the relative performance of a drug-eluting balloon (DEB) and a drug-eluting stent (DES) in patients with any (bare-metal or drug-eluting stent) in-stent restenosis (ISR).

BACKGROUND: The treatment of ISR remains challenging in contemporary clinical practice.

METHODS: In a multicenter randomized noninferiority trial, patients with any ISR were randomly allocated in a 1:1 fashion to treatment with a DEB (SeQuent Please paclitaxel-eluting balloon, B. Braun Melsungen, Melsungen, Germany), or a DES (XIENCE everolimus-eluting stent, Abbott Vascular, Santa Clara, California). The primary endpoint was noninferiority in terms of in-segment minimal lumen diameter (MLD) at 6-month angiographic follow-up. Secondary endpoints included angiographic parameters at 6 months and clinical follow-up up to 12 months.

RESULTS: A total of 279 patients, of whom 56% had DES-ISR, were randomized at 8 sites to treatment with DEB (n = 147) or DES (n = 137). As compared with DES, DES was associated with larger MLD and lower % stenosis immediately post-procedure (1.84 ± 0.46 vs. 1.72 ± 0.36; p = 0.016; and 26 ± 10% vs. 30 ± 10%; p = 0.03). Angiographic follow up was completed at 196 ± 53 days in 79% of patients. With respect to the primary endpoint of in-segment MLD at 6 months, DES was noninferior to DES (DES 1.71 ± 0.51 mm vs. DES 1.74 ± 0.61 mm; p for noninferiority <0.0001). Target vessel revascularization at 12-month follow-up was similar in both groups (DES 7.1% vs. DES 5.8%; p = 0.60).

CONCLUSIONS: In patients with ISR, treatment with DEB was noninferior compared with DES in terms of 6-month MLD. There were no differences in clinical endpoints, including target vessel revascularization up to 12 months. Therefore, use of a DEB is an attractive treatment option for in-stent restenosis, withholding the need for additional stent implantation.

DCB: INDICATIONS and EVIDENCE
In-stent restenosis

ESC guidelines on myocardial revascularization 2014

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

Drug-Coated Balloon

In-Stent Restenosis	**Small Vessel Disease**
Bifurcation Lesions	De-Novo Coronary Lesions

PEPCAD I

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

- Prospective, single-arm, observational, multi-center
- 118 patients, angiographic follow-up 89 %
- Paclitaxel eluting balloon Sequent Please in patients with lesions in coronary arteries of 2.25 –2.8 mm in diameter.
- Endpoint: late lumen loss at 6 months.

Unverdorben M et al. Clin Res Cardiol. 2010 Mar;99(3):165-74.

PEPCAD I

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

- DEB only: 6 Months Results

Follow-up angiography (82 Patients)	
Late lumen loss In-segment	0.16 ± 0.38 mm
Binary restenosis rate In-segment	4 (5.5 %)
Target lesion revascularization	4 (4.9 %)
Death	0

Unverdorben M et al. Clin Res Cardiol. 2010 Mar;99(3):165-74.

PEPCAD I

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

- DEB only: 1-Year MACE Results

	DEB ITT	DEB Only
n	114	82
Stent thrombosis	1.7%	0%
TLR	11.9%	4.9%
Death	2.9%	0%
MI	1.7%	1.3%
MACE	15.3%	6.1%

PCR 2011

PICOLETO

Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomized clinical trial

Paclitaxel-coated balloon DIOR® vs. Taxus DES in small coronary vessels (≤ 2.75 mm), n=28 + 29 patients

Intervention Type	Trial Name	Type of comparison	Sample size (n)	Type of DEB	Angiographic and Clinical Outcomes		
					6 mo late loss	TLR	MACE
Small Vessel				RCT			
MRD= 2.54±0.47 mm	PICOLETO trial	DEB vs PES	n=60	Dior I	Ballout BMS DEB group: 35.7%. ISR: 32.2% vs 10.3%*		35.7 vs 13.8%*

Cortese B et al. Heart 2010;96:1291-1296

Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- **Bifurcation Lesions**
- De-Novo Coronary Lesions

DCB

De Novo lesions: Bifurcation

Two strategies

Sequential DEB treatment of the bifurcation branches followed by BMS implantation in the MB – RCT available

Simple MV stenting followed by kissing DEB – Recent with sparse evidence

DCB

De Novo lesions: Bifurcation

Intervention Type	Trial Name	Type of comparison	Sample size (n)	Type of DEB	Angiographic and Clinical Outcomes		
					6 mo late loss	TLR	MACE
Bifurcated lesion		RCT					
Provisional T stent strategy	Stella et al. [illegible]	(A) DEB MB & SB & BMS MB vs (B) BMS MB & POBA SB (C) DES MB & POBA SB	n=117	Dior II	(A) MB proximal 0.58±0.65 MB distal 0.41±0.60 / SB 0.19±0.66 (B) MB proximal 0.60±0.65 MB distal 0.49±0.89 / SB 0.21±0.57 (C) MB proximal 0.13±0.45 MB distal 0.16±0.64 /SB 0.11±0.43* ISR: (A) 24.2% (B) 28.6%. (C) 17.5% p=0.45 MACE : (A) 20%. (B) 29.7%. (C) 17.5% p=0.40		

Drug-Coated Balloon

In-Stent Restenosis

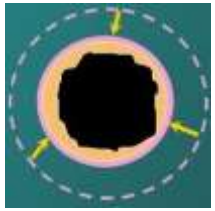
Small Vessel Disease

Bifurcation Lesions

De-Novo Coronary Lesions

Two Different Causes for Restenosis

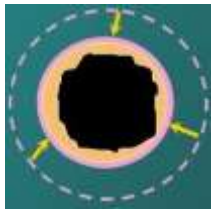
Recoil & Negative Remodeling



Stenting (BMS, DES) *Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent*

Two Different Causes for Restenosis

Recoil & Negative Remodeling



Stenting (BMS, DES) *Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent*

Neointimal Hyperplasia

Drug-Coated Balloon

(Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent)

Late lumen loss after DCB in De-novo Lesions

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

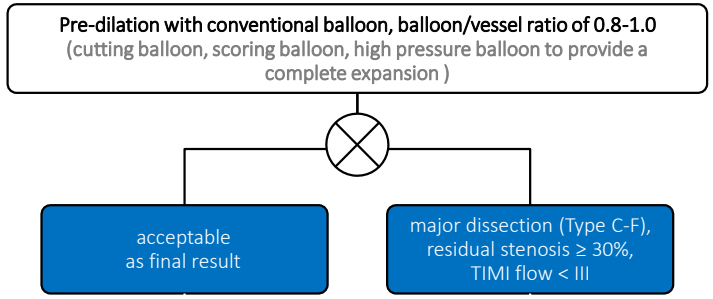
[1]Unverdorben M et al. Clin Res Cardiol. 2010 Mar;99(3):165-74. [2]Mathey DG; Eurointervention 2011;7:K61-65. [3]Cortese B et al. Heart 2010;96:1291-1296. [4]Stella R, TCT 2010, [5]Serra CRT 2012.

Acute and late thrombosis after DCB in De-novo Lesions

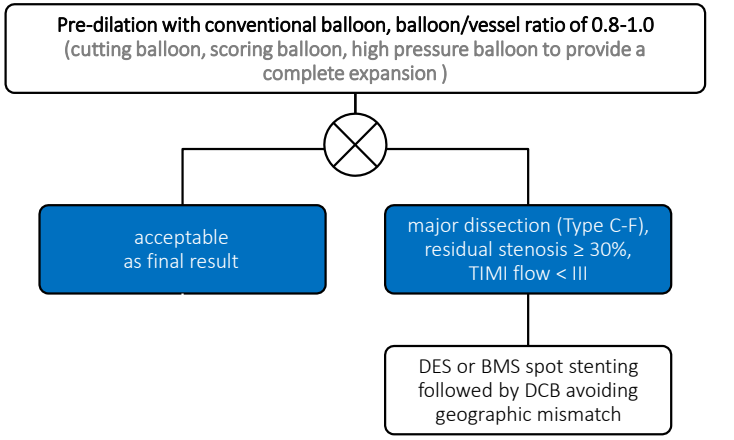
Trial Number of patients	Intervention	Indication	Duration of DAPT	Acute and late thrombosis at follow-up
PEPCAD I SVD[1] (n=118)	SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS	De novo, small vessels	1 month	DCB: 0%, DCB + BMS: 6.3%
PEPCAD V[2] (n=28)	SeQuent™ Please	De novo, bifurcation (side branch)	3 months	DCB: 0%
PICCOLETO[3] (n=60)	Dior™ II (n=29) vs. DES	De novo, small vessels	1 month in cases of stable angina and lone DEB use, 3 months in cases of DEB and provisional stent implantation	DCB: 0%, DES: 0%
DEBUIT[4] (n=117)	Dior™ (n=40) vs. Dior™ + BMS vs. DES	De novo, bifurcation	DEB: 3 months, DEB + BMS: 3 months, DES: 12 months	DCB: 0% DCB + BMS: 0%, DES: 2.5%
Potsdam Heart Center (n=85)[5]	**SeQuent™ Please**	**De novo**	**5.4 months**	**DCB: 0%**

[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]Bonaventura K, TCT 2012

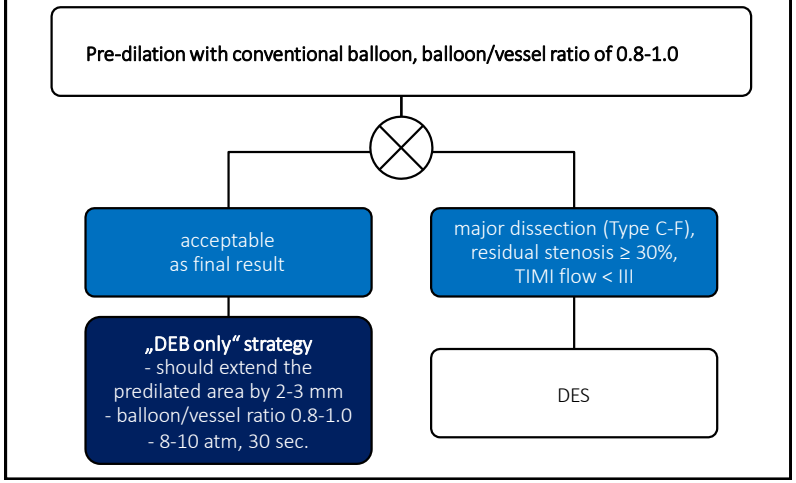
„DEB-only“ Strategy



„DEB-only“ Strategy



„DEB-only“ Strategy



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

Background Concerns remain regarding the long-term safety of DES in STEMI. DEB could provide an attractive alternative in order to achieve potentially similar effectiveness but limiting the long-term hazards related to late-acquired stent malapposition and thus stent thrombosis.

Methods In this randomized, international, 2-center, single-blinded, 3-arm study, STEMI patients were randomly assigned to group A: BMS; group B: DEB plus BMS; or group C: DES after successful thrombus aspiration. The primary endpoint was 6-month angiographic in-stent late-luminal loss. Secondary endpoints were in-stent binary restenosis, major adverse cardiac events (MACE: cardiac death, myocardial infarction, target vessel revascularization). In a subgroup of patients, stent (mal)apposition (by optical coherence tomography) and endothelial function (by acetylcholine infusion) was assessed.

Results Overall, 150 patients were randomized. Procedural success was achieved in 96.7%. In groups A, B, and C, respectively, late-luminal loss was 0.74 ± 0.57 mm, 0.64 ± 0.56 mm, and 0.21 ± 0.32 mm ($p < 0.01$); binary restenosis was 26.2%, 28.6%, and 4.7% ($p = 0.01$); and MACE rates were 23.5%, 20.0%, and 4.1% ($p = 0.02$), respectively. The median percentage [25th to 75th interquartile range] of uncovered and malapposed stent struts per lesion was 0 [0 to 0.35], 2.84 [0 to 6.63], and 5.21 [3.25 to 14.5] ($p < 0.01$). Significant paradoxical vasoconstriction was seen in groups B and C.

Conclusions In STEMI patients, DEB followed by BMS implantation failed to show angiographic superiority to BMS only. Angiographic results of DES were superior to both BMS and DEB. Moreover, DEB before implantation induced more uncovered and malapposed stent struts than BMS, but less than after DES. (Drug-Eluting Balloon in Acute Myocardial Infarction [DEB-AMI], NCT00856765) (J Am Coll Cardiol 2012;59:2327-37) © 2012 by the American College of Cardiology Foundation

DAPT and Triple Therapy as short as possible

4 weeks

- Planned surgery
- Bleeding event
- Increased bleeding risk
- Need for oral anticoagulation / triple therapy
  - **Atrial fibrillation**
    - Mechanical heart valve
    - Embolism
    - Thrombophilie
  - …
- Stent thrombosis

Conclusions

- The use of DCB for the treatment of ISR is well established and appears to yield similar results to DES without the introduction of an additional stent layer.
- DCB may have a role in the context of challenging coronary anatomy and small vessel disease where results with stent insertion are unfavourable.
- The data regarding the use of DCB for the treatment of de-novo coronary disease still favors the new generation of DES.
- The possible reduction in the duration of DAPT to 1 m may represent additional advantages, especially in pts with AF and in patients with increased bleeding risk.

Conclusions

- Further trials are required to clarify the ideal duration of dual anti-platelet treatment following DCB use and to further elucidate the ideal clinical context for their use.


Thank You!