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Drug-Eluting Balloons

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Potential conflicts of interest

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Speaker's name: Klaus Bonaventura

☒ **I have the following** potential conflicts of interest to report:

- ☐ Grant/Research Support
- ☒ Consulting Fees/Honoraria: B. Braun, Boehringer, B. Braun, Bristol-Myers Squibb, Lilly, Medtronic, Pfizer, Sanofi Aventis
- ☐ Major Stock Shareholder/Equity
- ☐ Royalty Income
- ☒ Ownership/Founder: Personal MedSystems
- ☐ Intellectual Property Rights
- ☐ Other Financial Benefit

Interventional Cardiology - The 2nd revolution

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1977

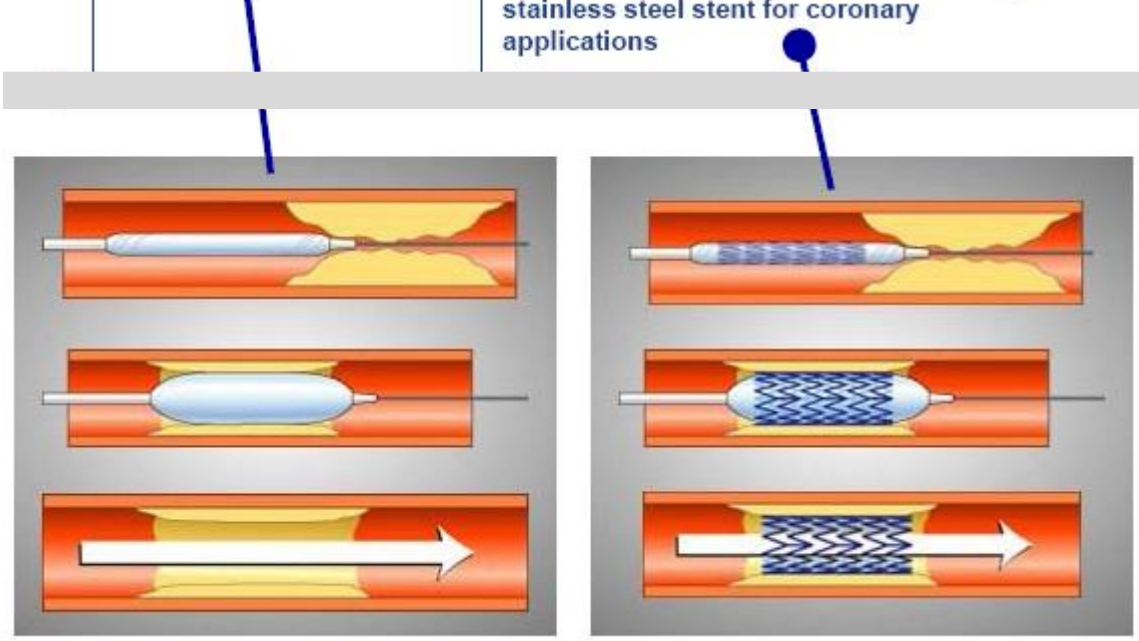
1. Balloon (PTCA):

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



Intimal dissection following balloon angioplasty

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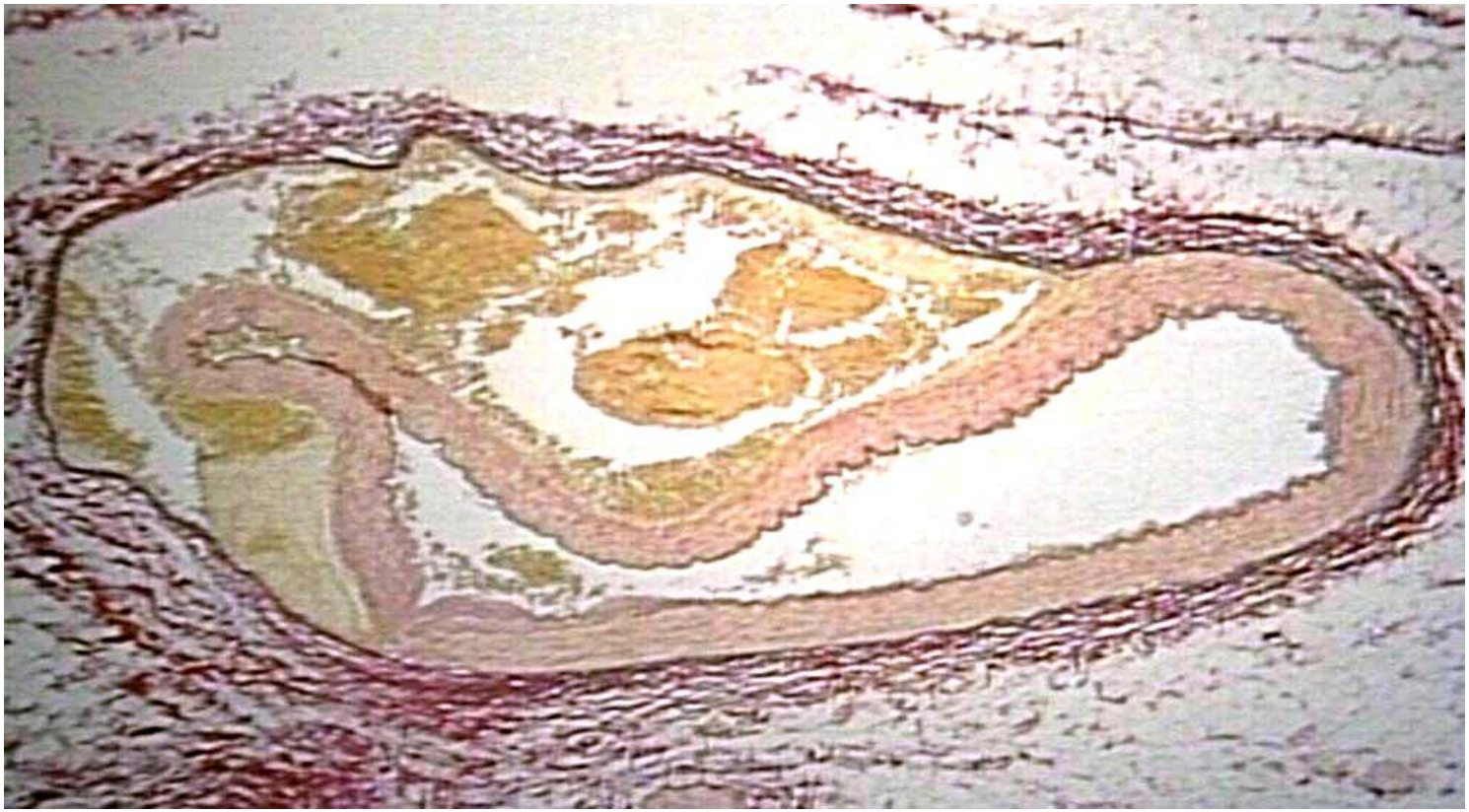

Bare Metal Stent

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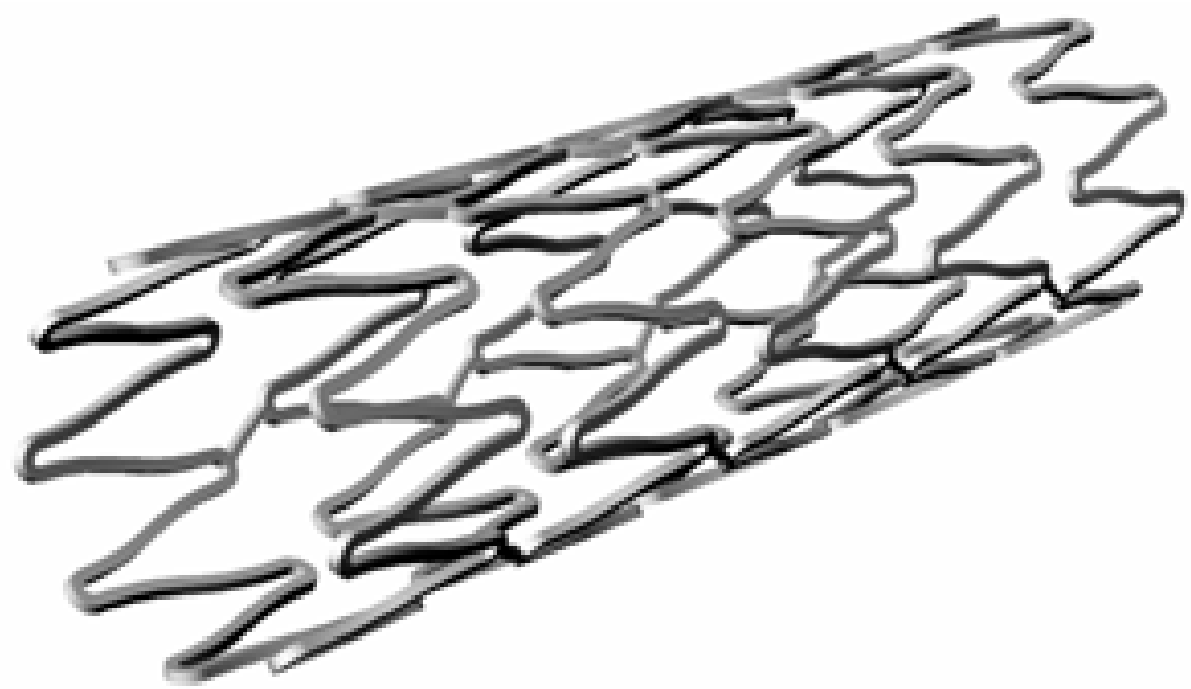

Dual Antiplatelet Therapy (DAPT) after Bare Metal Stent

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⇨ **4 weeks**

Restenosis after Bare Metal Stenting

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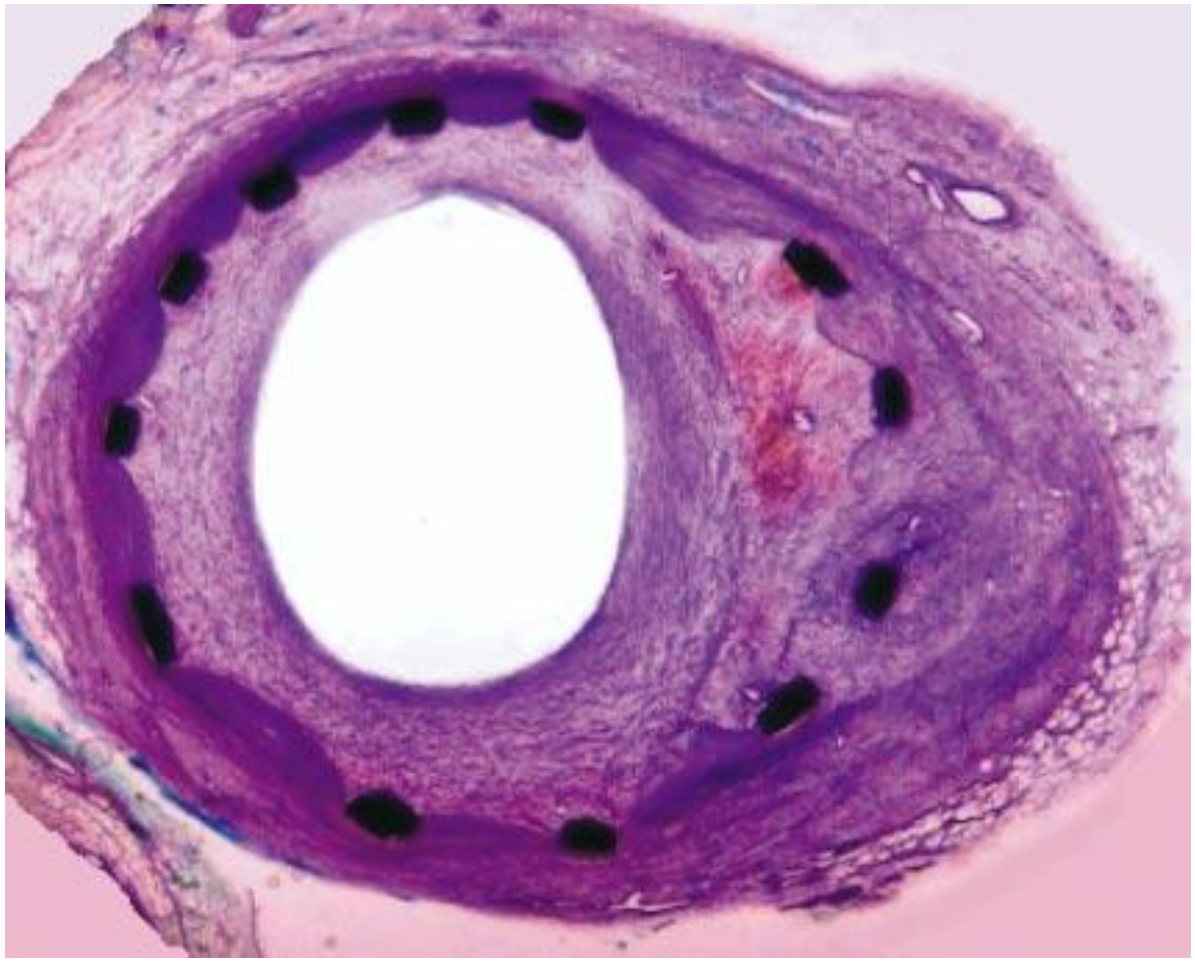


Interventional Cardiology - The 3rd Revolution

ERNST VON BERGMANN KLINIKUM

1977

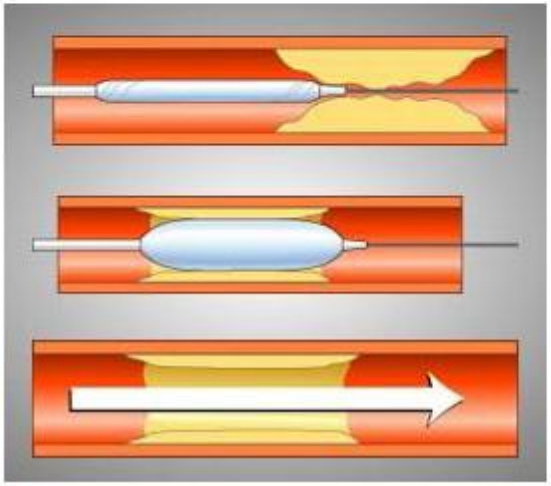
1. Balloon (PTCA):
Andreas Gruntzig performs the first PTCA in Zurich, Switzerland

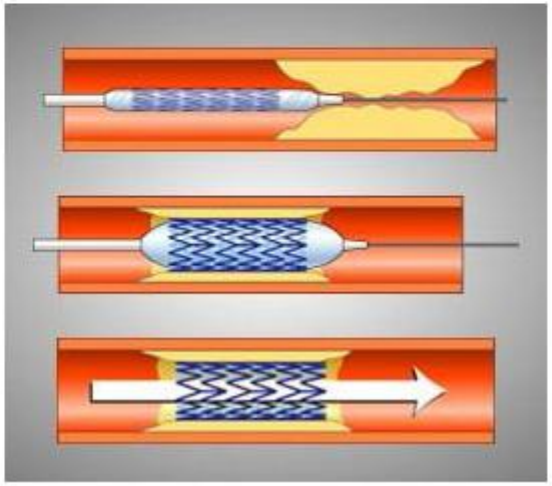
1988

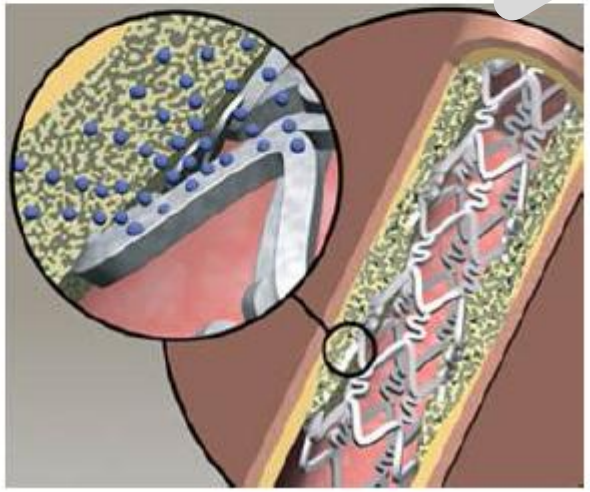
2. Bare Metal Stent (BMS):
Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications

2002 - 2003

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







Drug-Eluting Stent

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Without Drug Coating

With Drug Coating

Dual Antiplatelet Therapy after Drug-Eluting Stent

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⇨ **(6-) 12 months**

Drug-Eluting Stent

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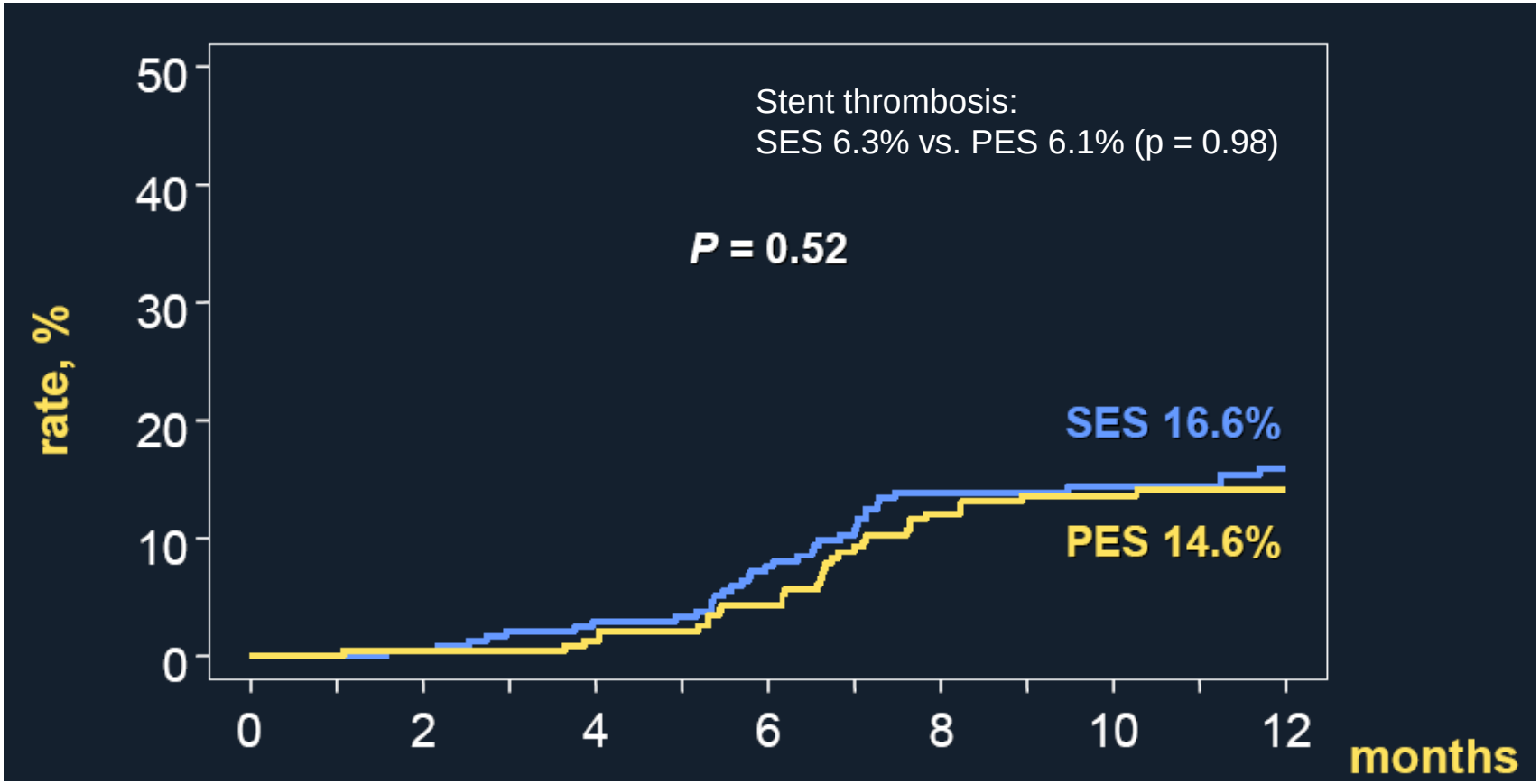
⇨ ISAR-DESIRE 2: TLR



Byrne, R, TCT 2009

Heterogeneity of neointimal Healing after DES Placement

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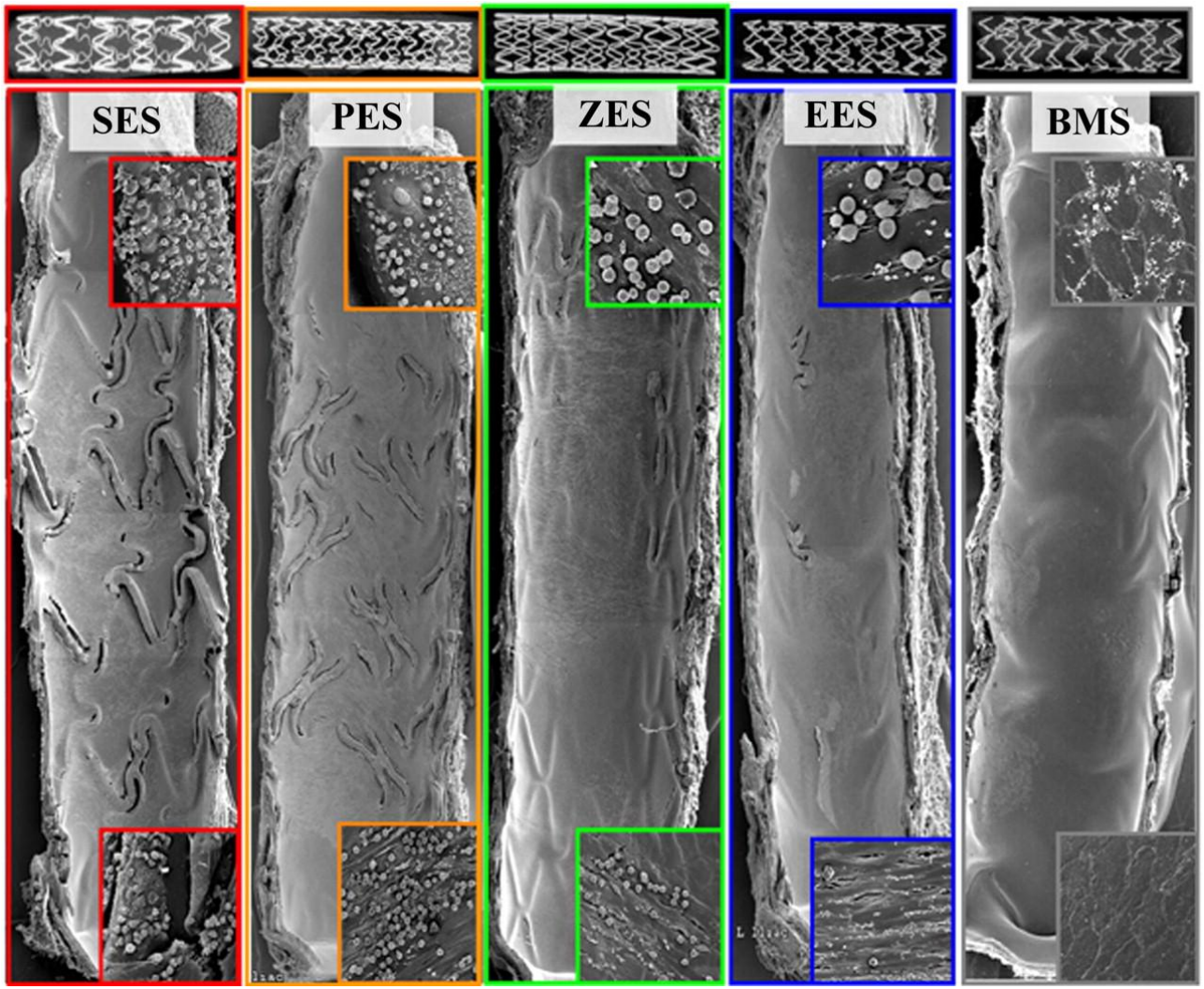

Joner M et al. J Am Coll Cardiol, 2008; 52:333-342

ESC-Guidelines Atrial Fibrillation

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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

Interventional Cardiology - The 4th Revolution

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- ⇨ **Drug-Coated Balloon (DCB) = Drug-Eluting Balloon (DEB)**
- ⇨ ***Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent***

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„Leaving Nothing Behind“

DCB & BVS

Drug-Coated Balloon (DCB)

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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., Dariush 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; 355:2113-2124

Drug-Coated Balloon (DCB)

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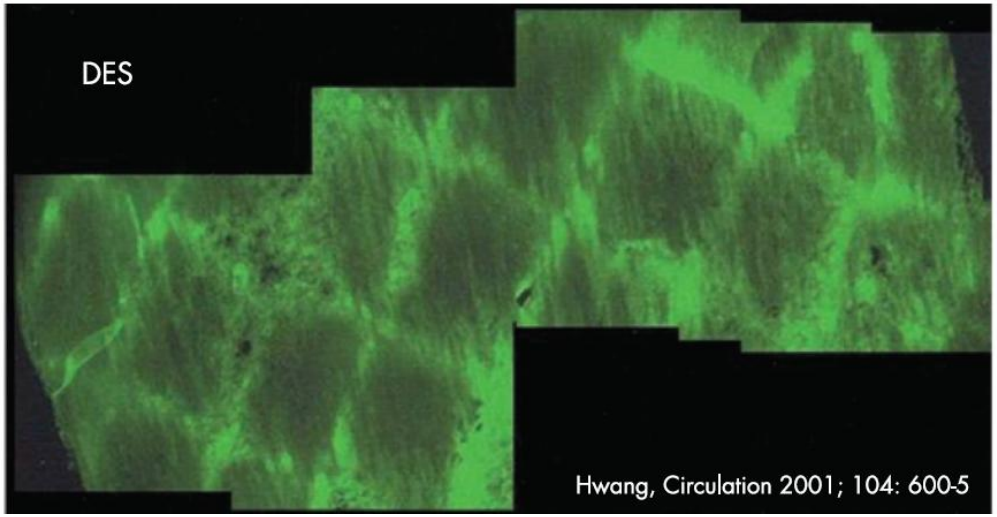
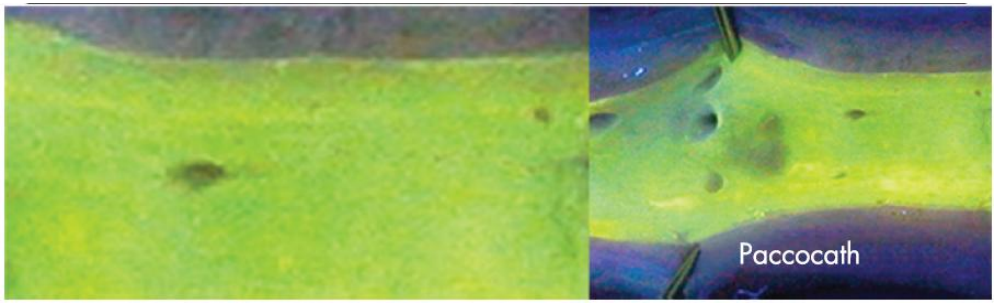
Drug-Coated Balloon (DCB)



⇨ **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

Drug-Coated Balloon

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In-Stent Restenosis

Small Vessel Disease

Bifurcation Lesions

De-Novo Coronary Lesions

Recommendations by the German Consensus Group

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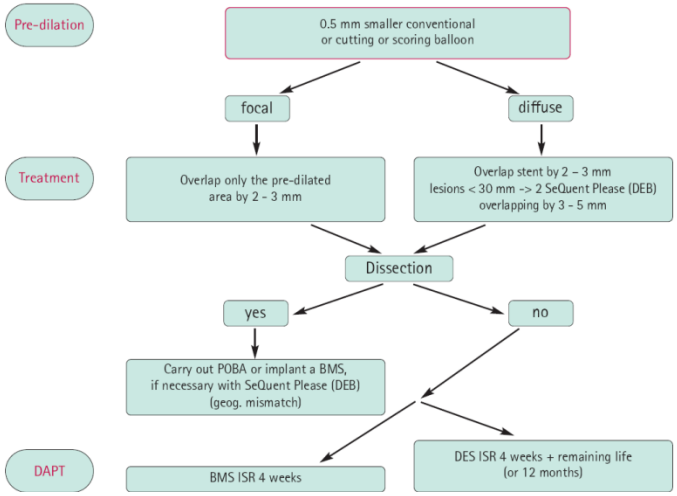
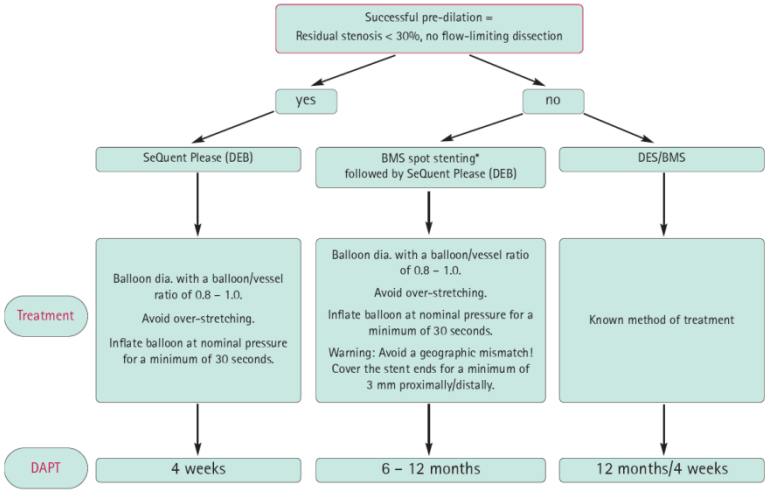
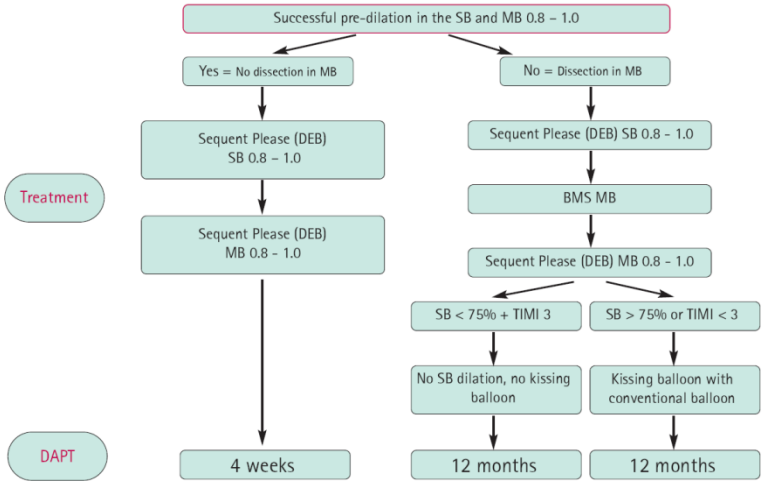
Treatment of In-stent Restenosis (ISR)



Treatment of Small Vessel Disease (SVD)



Treatment of Bifurcation Stenoses



Eurointervention 2011;7:K125-128

Drug-Coated Balloon

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In-Stent Restenosis

Small Vessel Disease

Bifurcation Lesions

De-Novo Coronary Lesions

PACCOCATH ISR I + II

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

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- ⇨ 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

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

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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	23	22		
Minimal luminal diameter — mm				
In-stent	1.60±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 1.09)	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 (43)	1 (5)	0.39 (0.15 to 0.63)	0.002
In-segment	10 (43)	1 (5)	0.39 (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

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	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

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	Drug-Coated Balloon	Drug-Eluting Stent	Difference (95% CI)	*P*
Angiographic follow-up at 6 months				
Angiographic follow-up, n (%)	57 (86.4)	59 (90.8)	−0.04 (−0.15 to 0.05)	0.43
Minimal lumen diameter				
In-stent, mm	2.08±0.56	2.11±0.78	−0.04 (−0.29 to 0.21)	0.77
In-segment, mm	2.03±0.56	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±0.29	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.)

HABARA

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

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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

Cost Effectiveness

of Paclitaxel-Eluting Balloon Catheter in Patients with Bare-Metal Stent Restenosis

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Clin Res Cardiol
DOI 10.1007/s00392-012-0428-2

ORIGINAL PAPER

Cost-effectiveness of paclitaxel-coated balloon angioplasty and paclitaxel-eluting stent implantation for treatment of coronary in-stent restenosis in patients with stable coronary artery disease

Klaus Bonaventura · Alexander W. Leber · Christian Sohns · Mattias Roser · Leif-Hendrik Boldt · Franz X. Kleber · Wilhelm Haverkamp · Marc Dorenkamp

Received: 12 December 2011 / Accepted: 8 February 2012

Bonaventura K et al. Clin Res Cardiol. 2012 Feb 21. [Epub ahead of print]

Cost Effectiveness

of Paclitaxel-Eluting Balloon Catheter in Patients with Bare-Metal Stent Restenosis

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⇨ **Initial procedure costs:**

- DCB: € 3,604.14
- DES implantation: € 3,309.66

Δ € 294.48

⇨ **Over a 12-month time horizon:**

- DCB strategy: € 4,130.38
- DES implantation: € 5,305.30

Δ € 1,174.92

⇨ **DCB slightly more effective in terms of life expectancy** than the DES strategy (0.983 versus 0.976 years).

Bonaventura K et al. Clin Res Cardiol. 2012 Feb 21. [Epub ahead of print]

ESC Guidelines 2010 for In-Stent Restenosis (ISR)

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	Class[a]	Level[b]	Ref.[c]
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A	15, 28
DES[d] are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.	I	A	45, 46, 55, 215
Distal embolic protection is recommended during PCI of SVG disease to avoid distal embolization of debris and prevent MI.	I	B	171, 213
Rotablation is recommended for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	I	C	—
Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI.	IIa	A	204–208
For PCI of unstable lesions, i.v. abciximab should be considered for pharmacological treatment of no-reflow.	IIa	B	55, 209, 212
Drug-eluting balloons[d] should be considered for the treatment of in-stent restenosis after prior BMS.	IIa	B	174, 175
Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	IIb	C	—
Cutting or scoring balloons may be considered for dilatation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments.	IIb	C	—
IVUS-guided stent implantation may be considered for unprotected left main PCI.	IIb	C	—
Mesh-based protection may be considered for PCI of highly thrombotic or SVG lesions.	IIb	C	—
For PCI of unstable lesions, intracoronary nitroprusside or other vasodilators may be considered for pharmacological treatment of no-reflow.	IIb	C	—

Drug-eluting balloons[d] should be considered for the treatment of in-stent restenosis after prior BMS. IIa B

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DEB only

- ⇨ Male, 55 years
- ⇨ PCI of In-stent Restenosis of RCA

In-stent Restenosis of RCA

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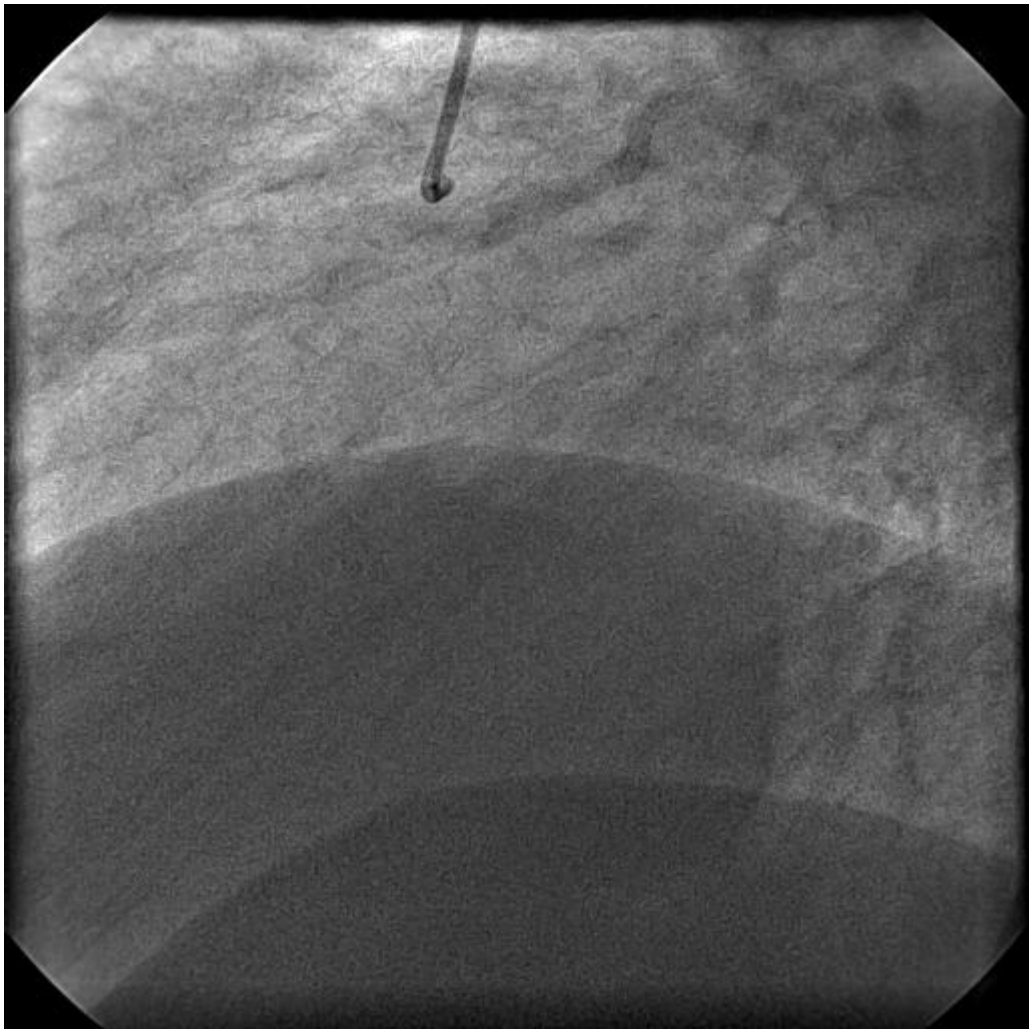
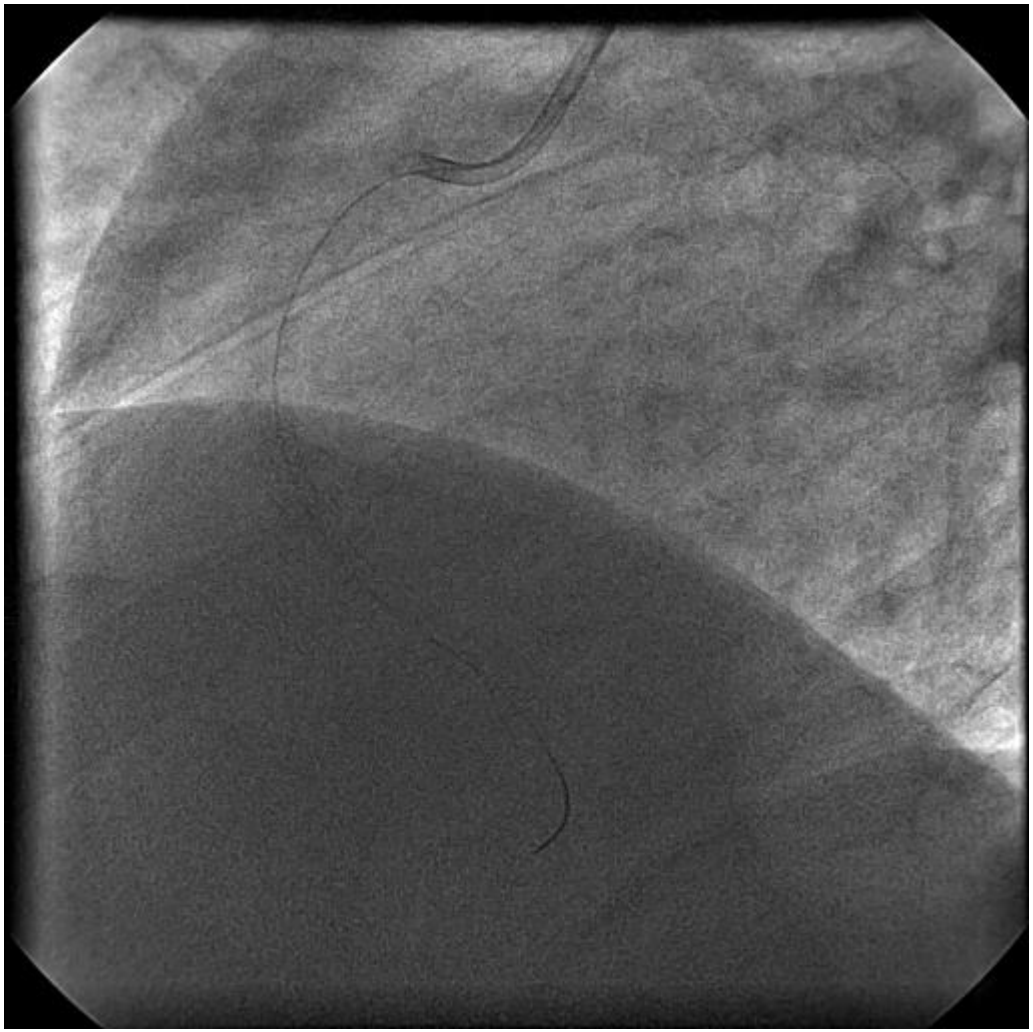


RCA with guidewire



Predilatation with 3.5/15 mm balloon

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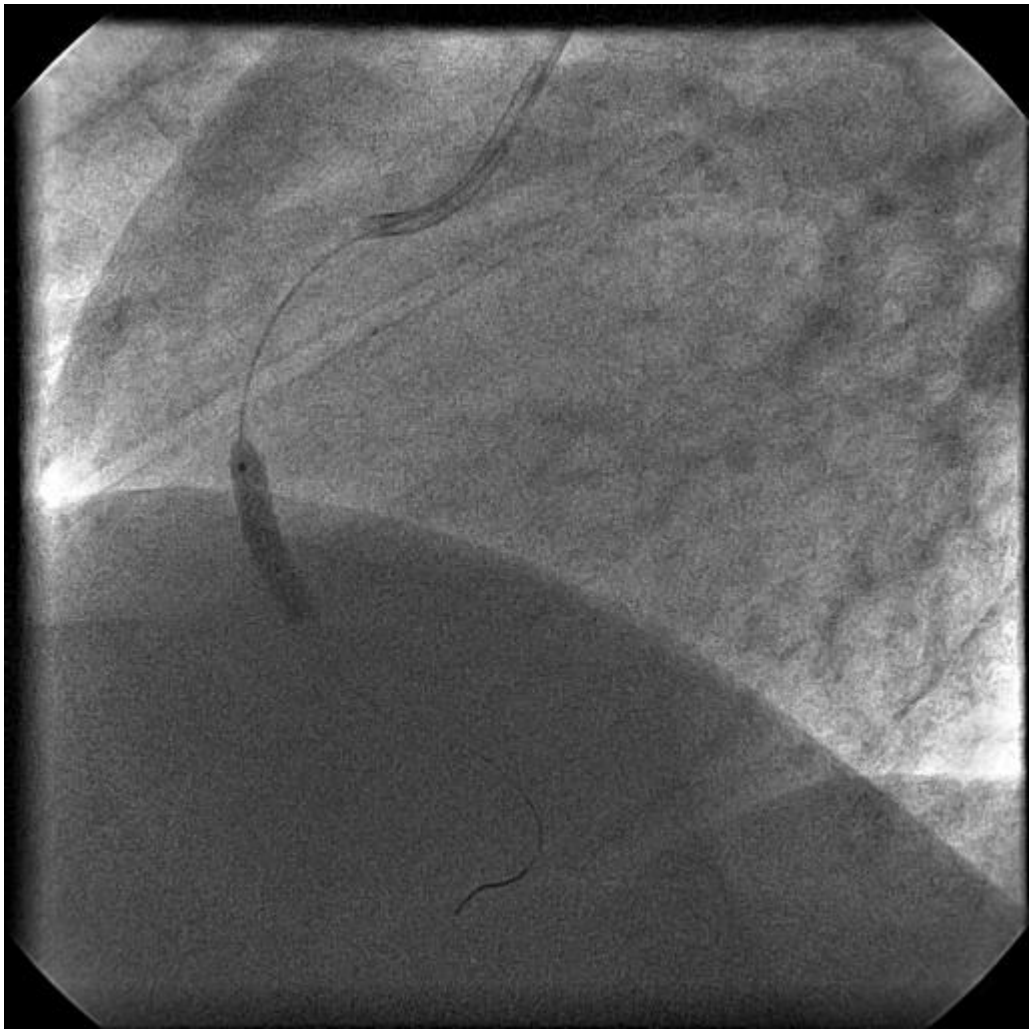

RCA after predilatation

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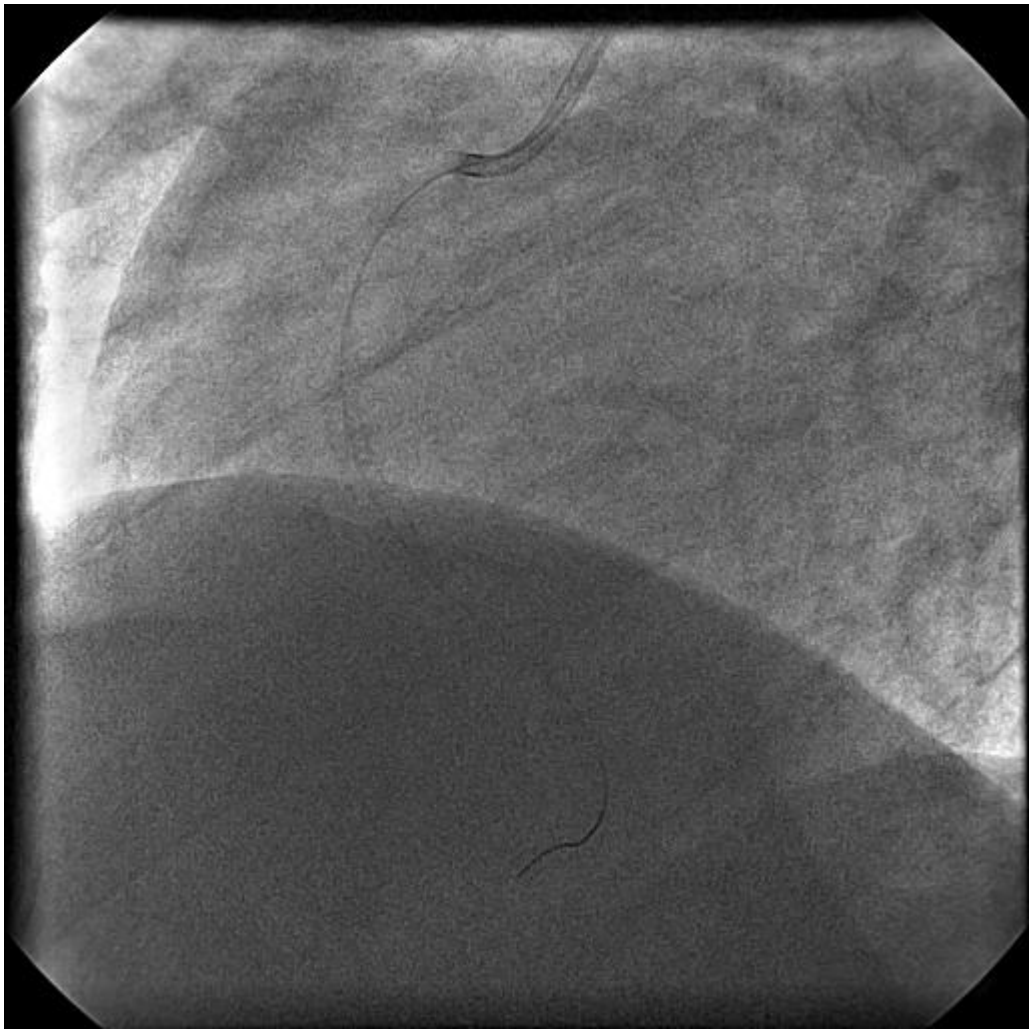

RCA with DCB 3.5/20 mm *(Sequent Please)*

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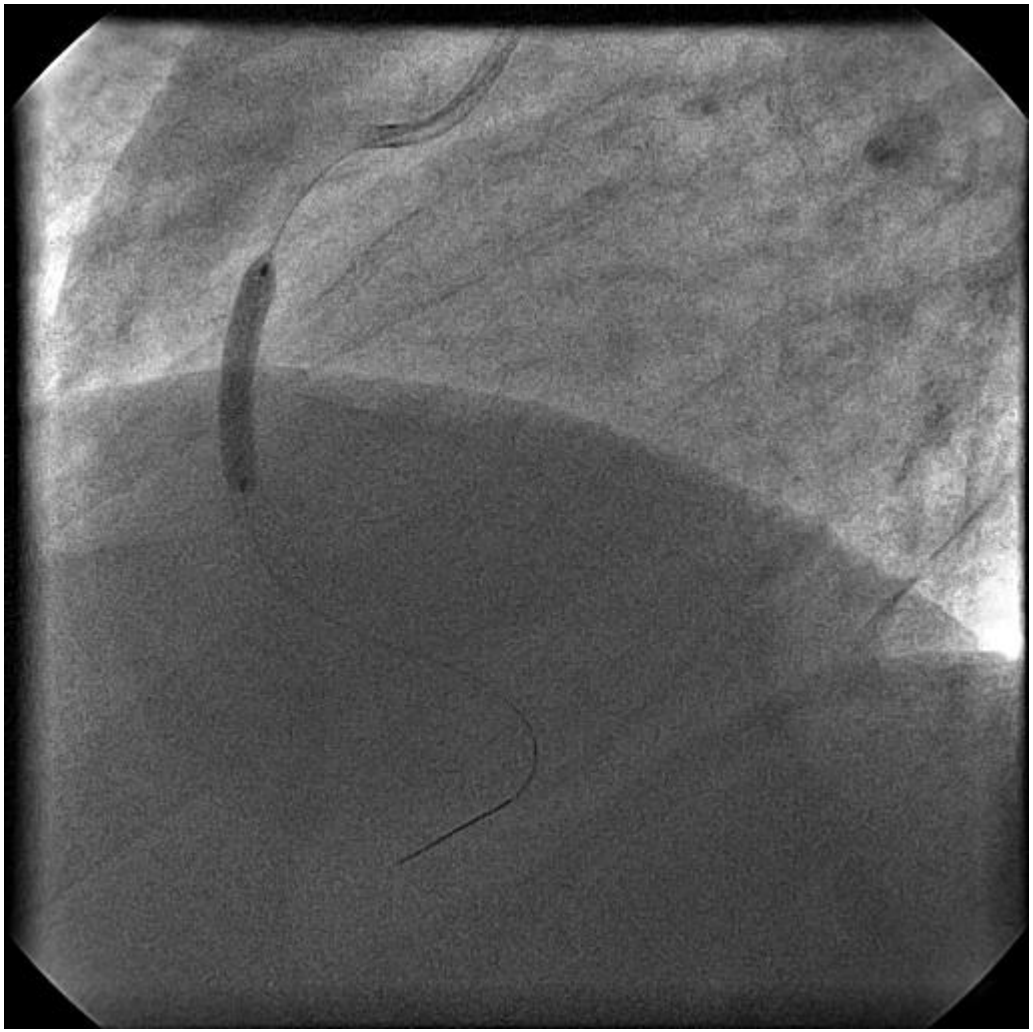

RCA with DCB 3.5/17 mm *(Sequent Please)*

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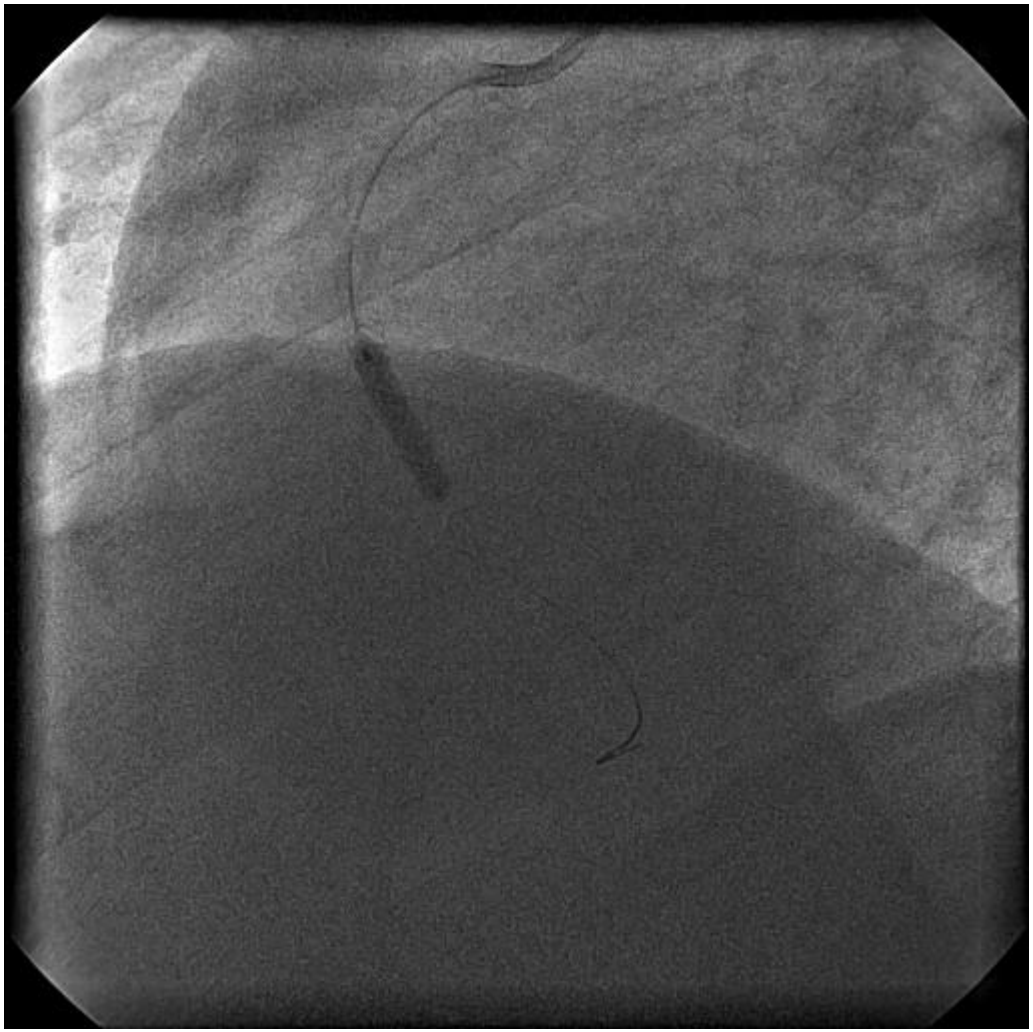

RCA, final result after DCB only

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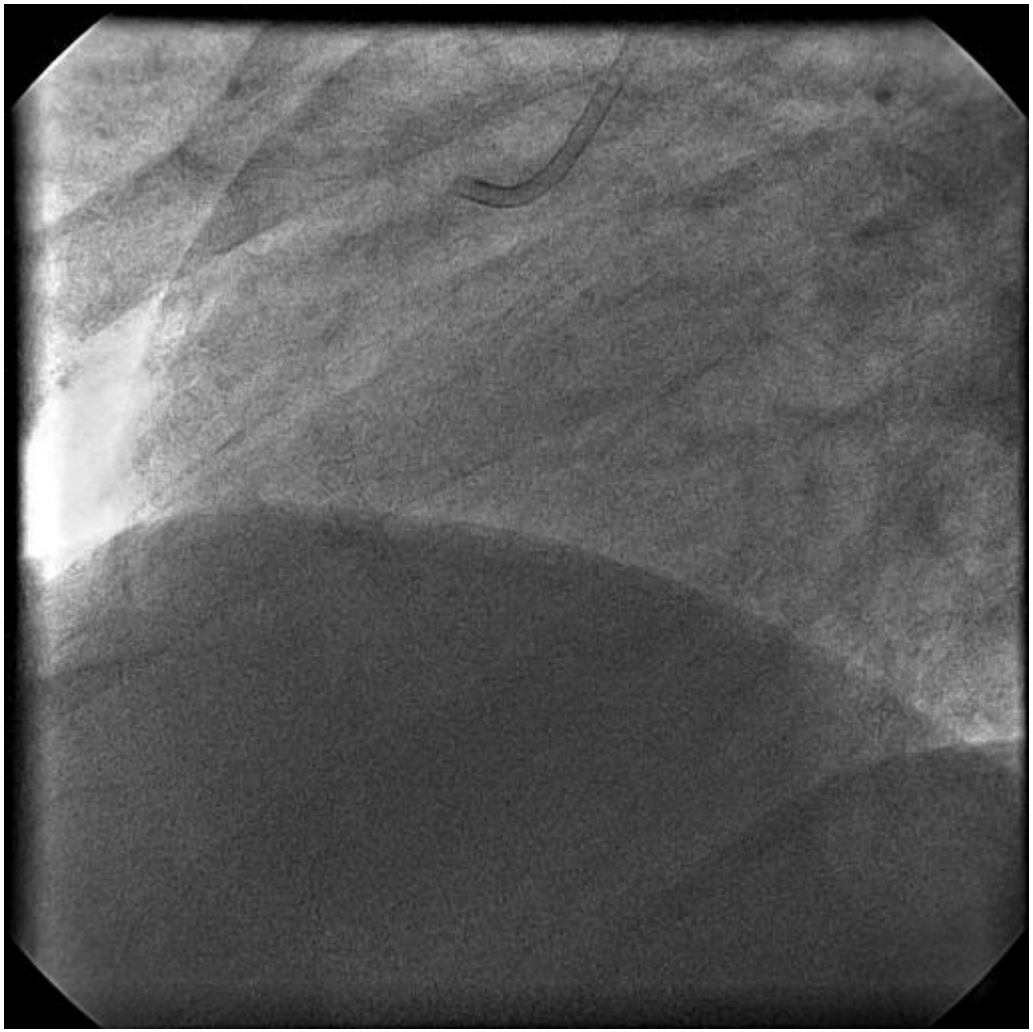

RCA, 4 months after DCB only

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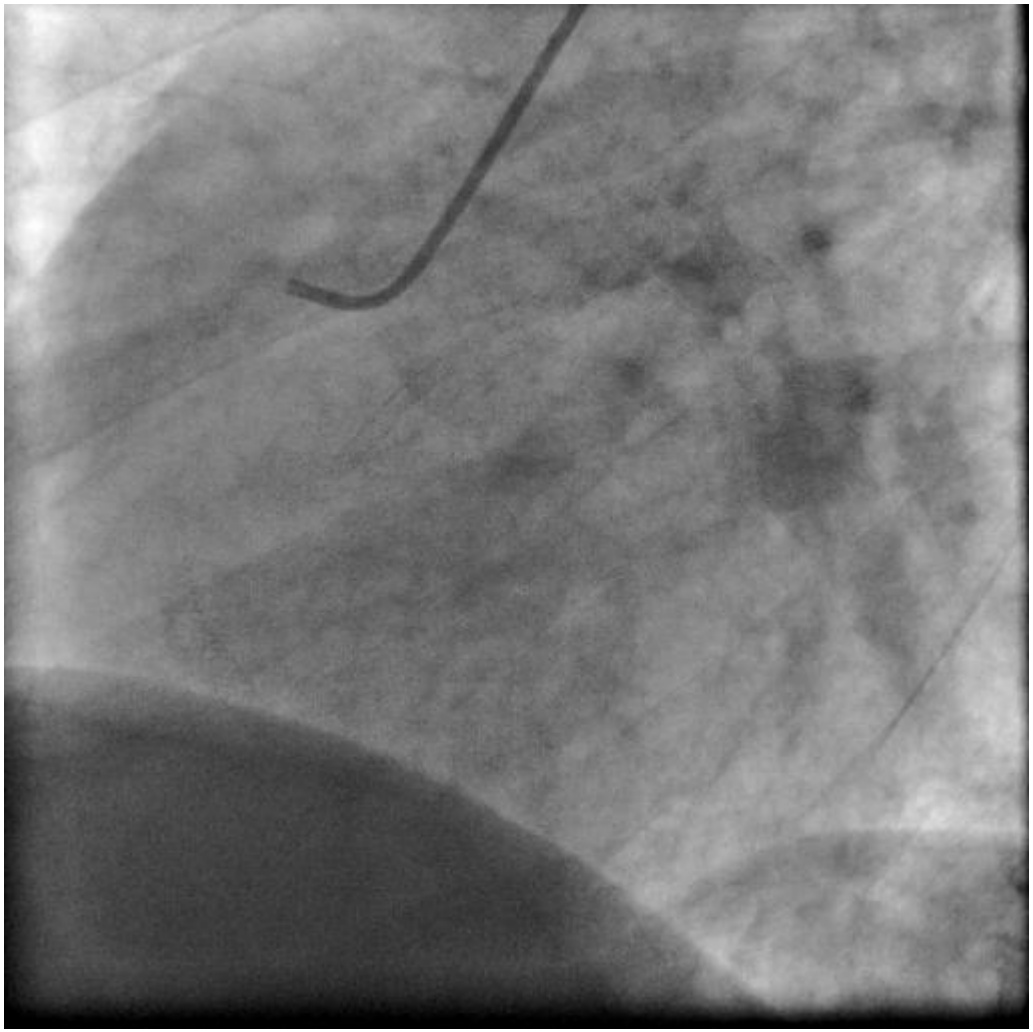

Drug-Coated Balloon

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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

ERNST VON BERGMANN KLINIKUM

- ⇨ 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

ERNST VON BERGMANN KLINIKUM

⇨ 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

ERNST VON BERGMANN KLINIKUM

⇨ DEB only: 1-Year MACE Results

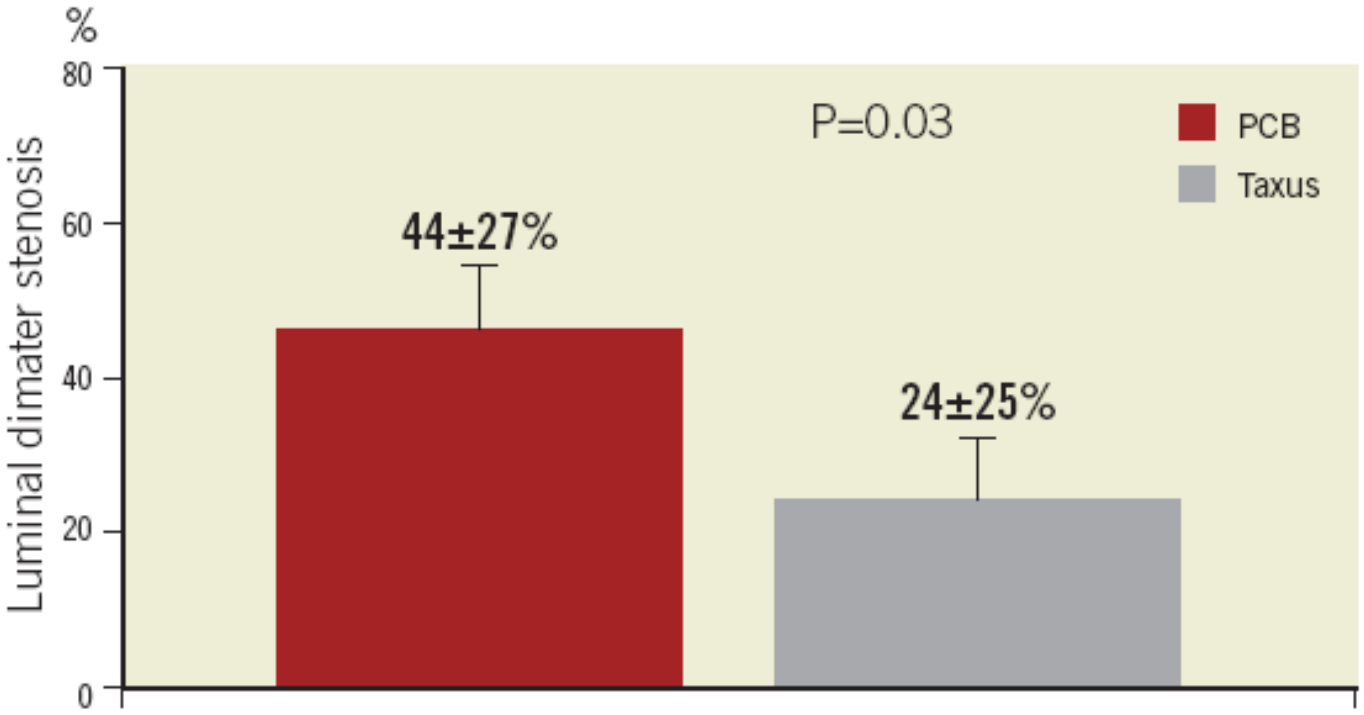
	DEB ITT	DEB Only
n	114	82
Stent thrombosis	1.7%	0%
TLR	11.9%	4.9%
Death	2.9%	0%
MI	1.7%	1.3%
MACE	15.3%	6.1%

PICCOLETO

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

ERNST VON BERGMANN KLINIKUM

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



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

Roughened Balloon Surface vs. Matrix Coating

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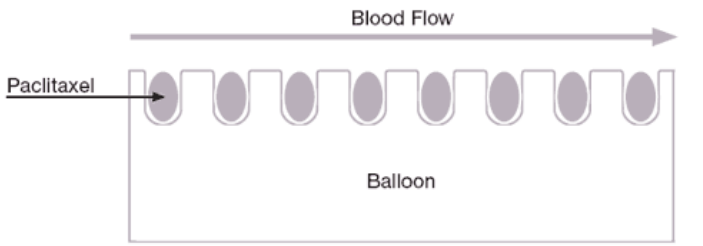
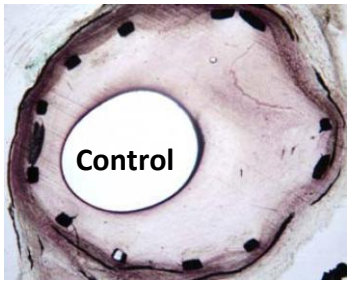
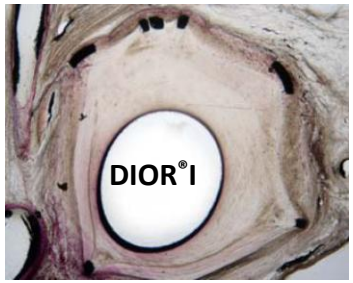
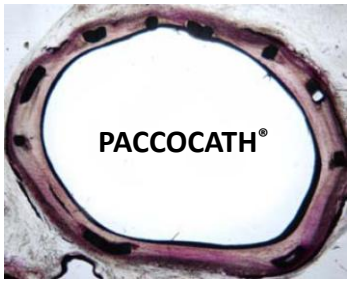
DIOR microporous balloon surface structure

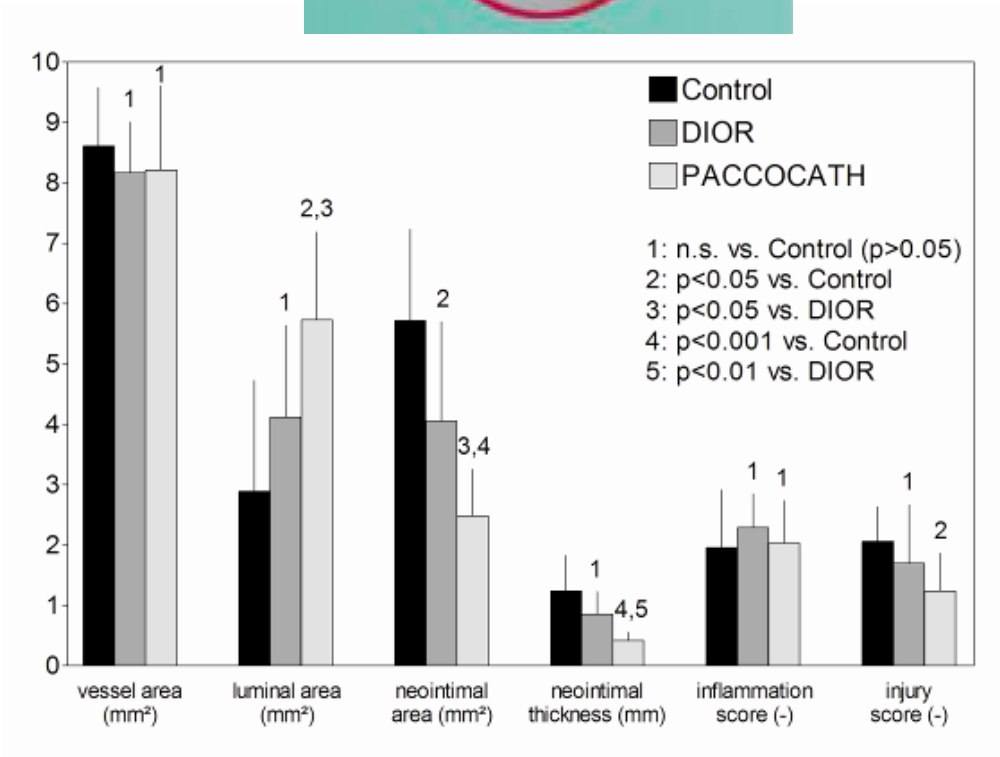








Matrix Coating - Paclitaxel Iopromide
Sequent Please



Cremers B et al., Clin Res Cardiol 2009; 98: 325–330

Drug-Coated Balloon

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In-Stent Restenosis

Small Vessel Disease

Bifurcation Lesions

De-Novo Coronary Lesions

Consensus Statement of the German consensus group: SeQuent® Please - DEB only:

Treatment of Bifurcation Stenoses

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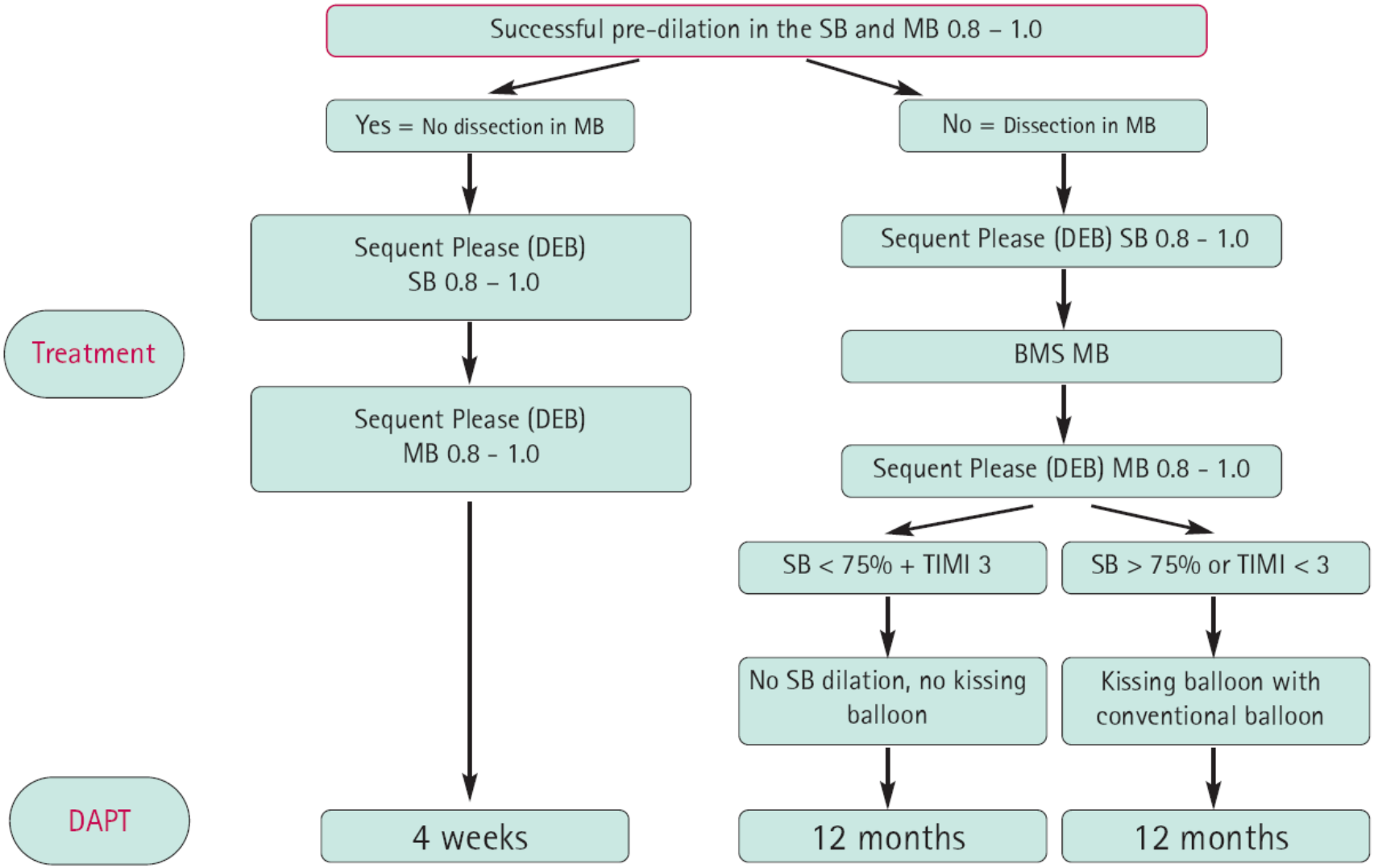
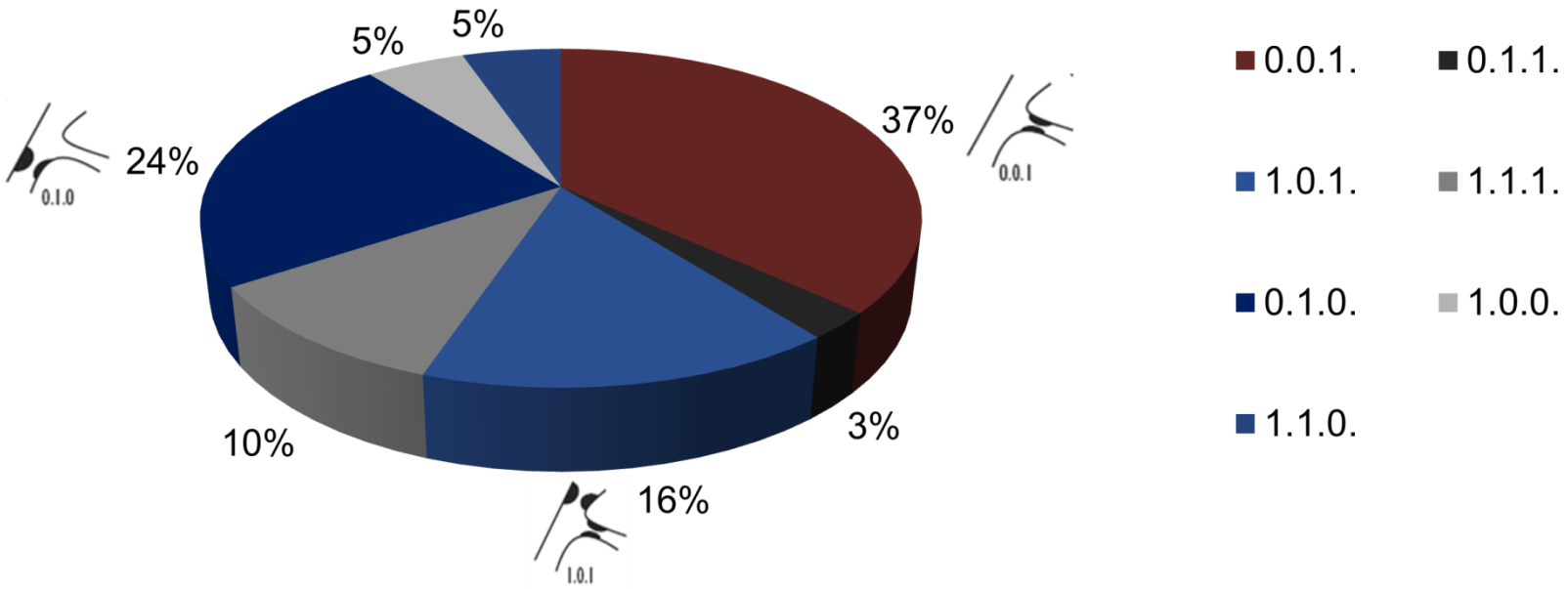


Eurointervention 2011;7:K125-128

DCB in Bifurcation Lesions: Potsdam Registry



- ⇨ 38 interventions
- ⇨ The procedure was successful in all patients.
- ⇨ Additional stenting of the main branch was needed in 3 (7.9%) interventions.

Bonaventura K, Asia PCR 2013

DCB in Bifurcation Lesions: Potsdam Registry

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- ⇨ No MACE (cardiac death, myocardial infarction, target lesion revascularization) occurred up to 30 days.
- ⇨ **Target lesion revascularization at 12 months: 0%**
- ⇨ Duration of DAPT was 4.2 ± 3.8 months.

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Drug-Coated Balloon

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In-Stent Restenosis

Small Vessel Disease

Bifurcation Lesions

De-Novo Coronary Lesions

Two Different Causes for Restenosis

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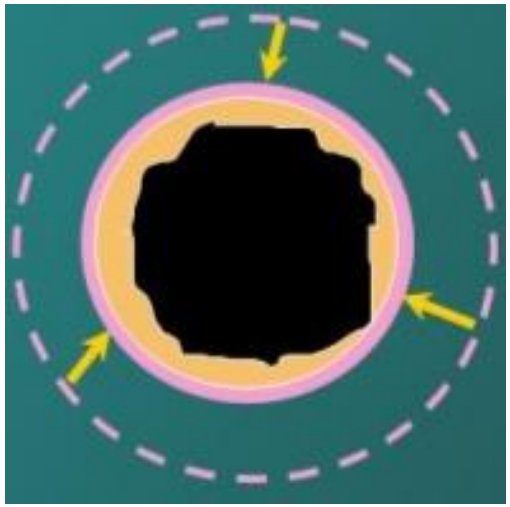
Recoil & Negative Remodeling



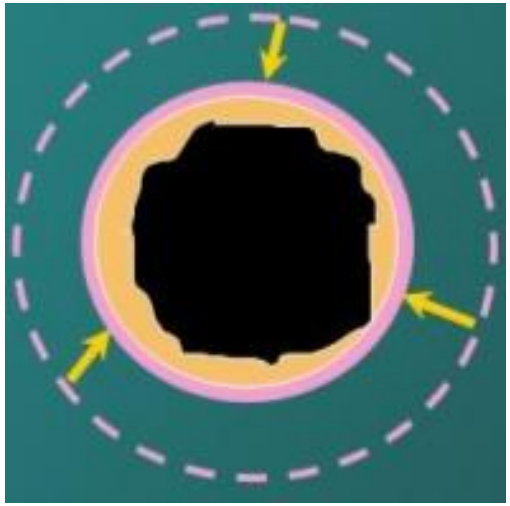
Stenting (BMS, DES)

Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent

Two Different Causes for Restenosis

ERNST VON BERGMANN KLINIKUM

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

ERNST VON BERGMANN KLINIKUM

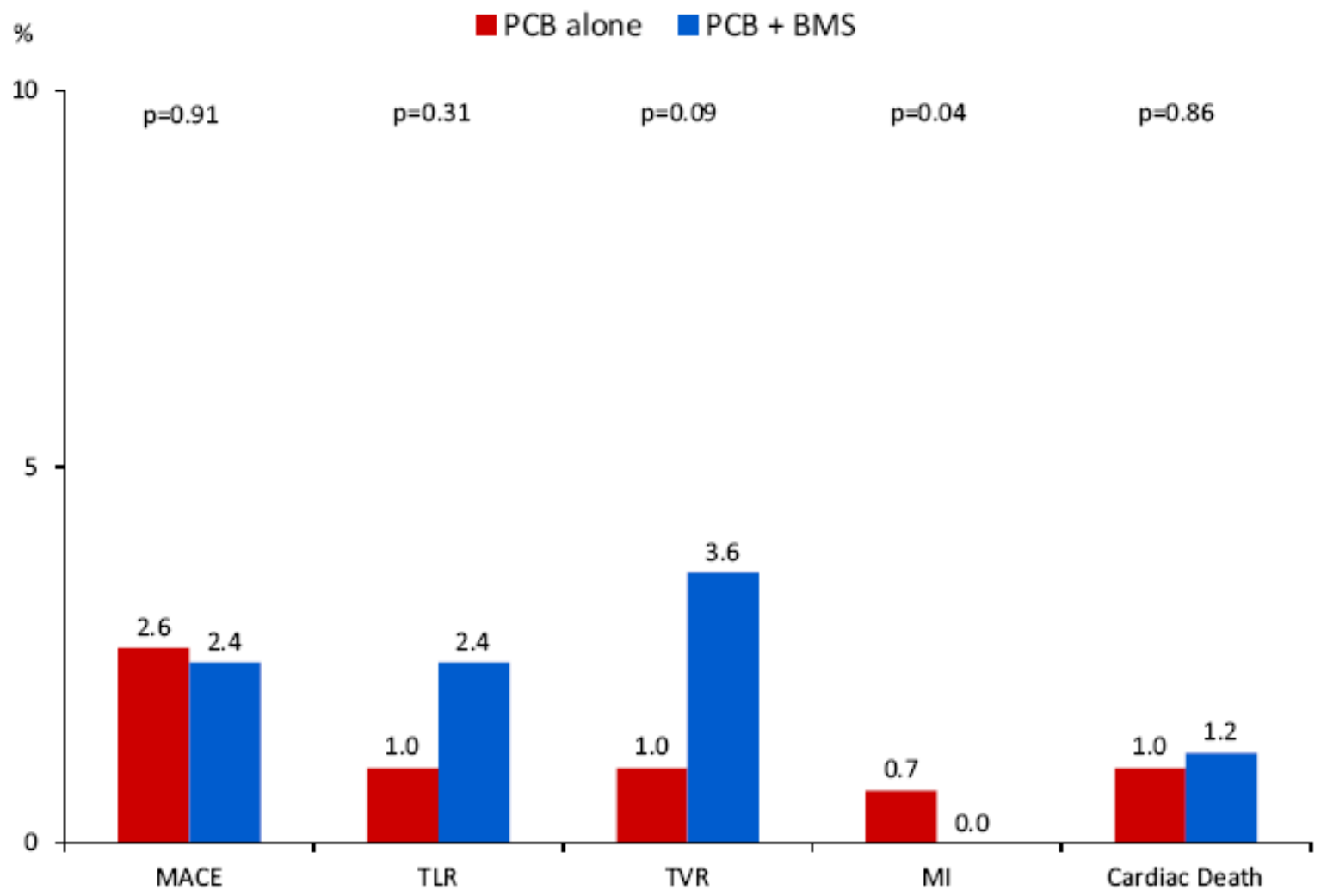
Trial Number of patients	Intervention	Indication	Late lumen loss	Follow-up
PEPCAD I SVD[1] (n=118)	SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS	De novo, small vessels	0.16 mm	6 months
PEPCAD V[2] (n=28)	SeQuent™ Please	De novo, bifurcation (side branch)	0.21 mm	6 months
PICCOLETO[3] (n=60)	Dior™ 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.

SeQuent Please World Wide Registry

PCB Treatment for De Novo Lesions: Clinical Events

ERNST VON BERGMANN KLINIKUM



Woehrle J et al. J Am Coll Cardiol. 2012 Oct 30;60(18):1733-8

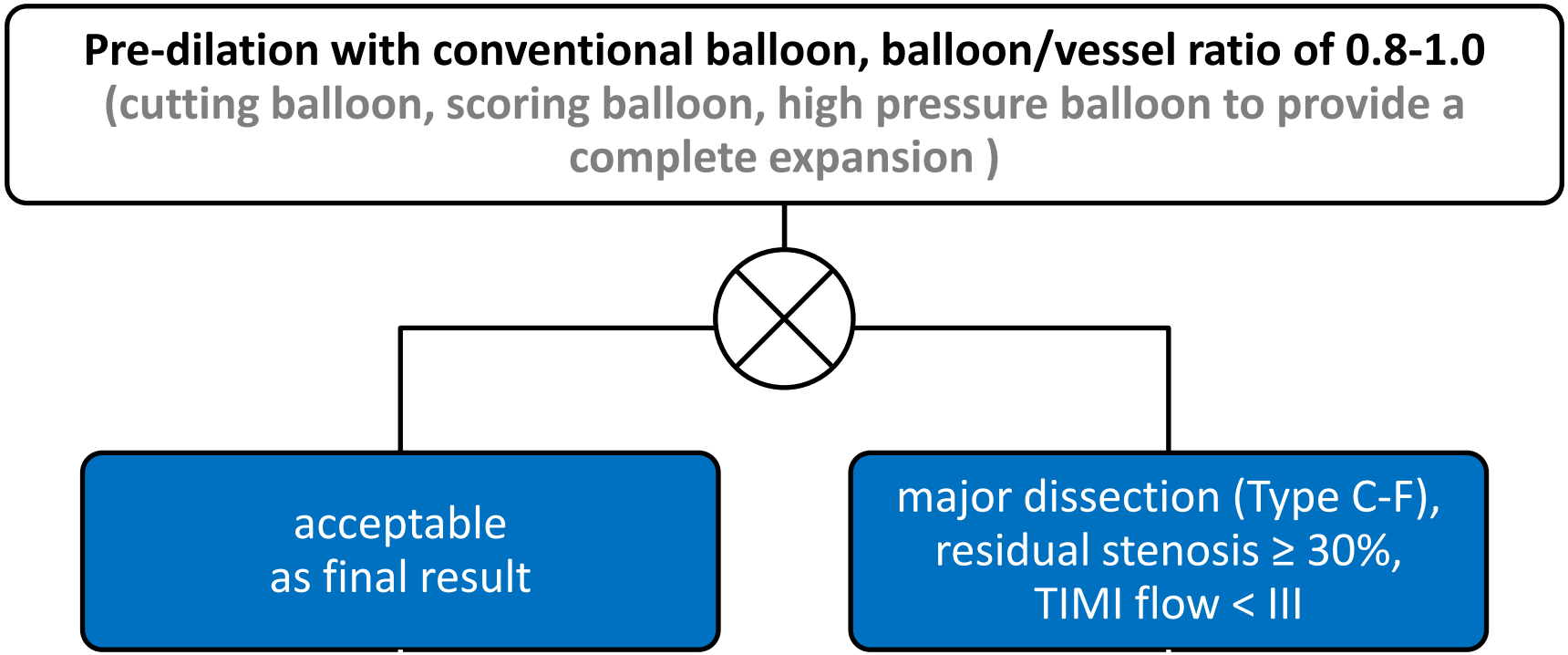
Acute and late thrombosis after DCB in De-novo Lesions

ERNST VON BERGMANN KLINIKUM

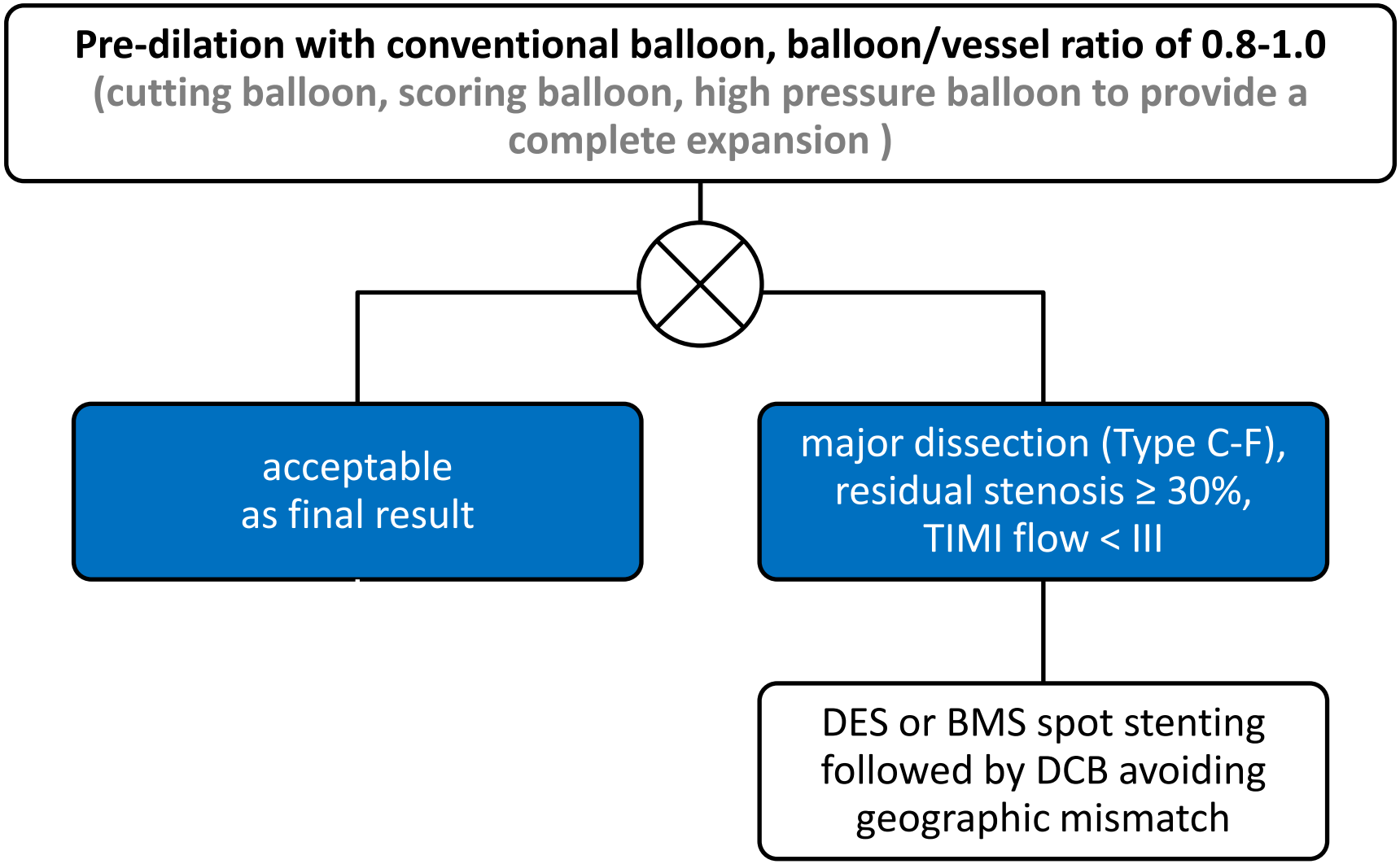
Trial Number of patients	Intervention	Indication	Duration of DAPT	Acute and late thrombosis at follow-up
PEPCAD I SVD[1] (n=118)	SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS	De novo, small vessels	1 month	DCB: 0%, DCB + BMS: 6.3%
PEPCAD V[2] (n=28)	SeQuent™ Please	De novo, bifurcation (side branch)	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

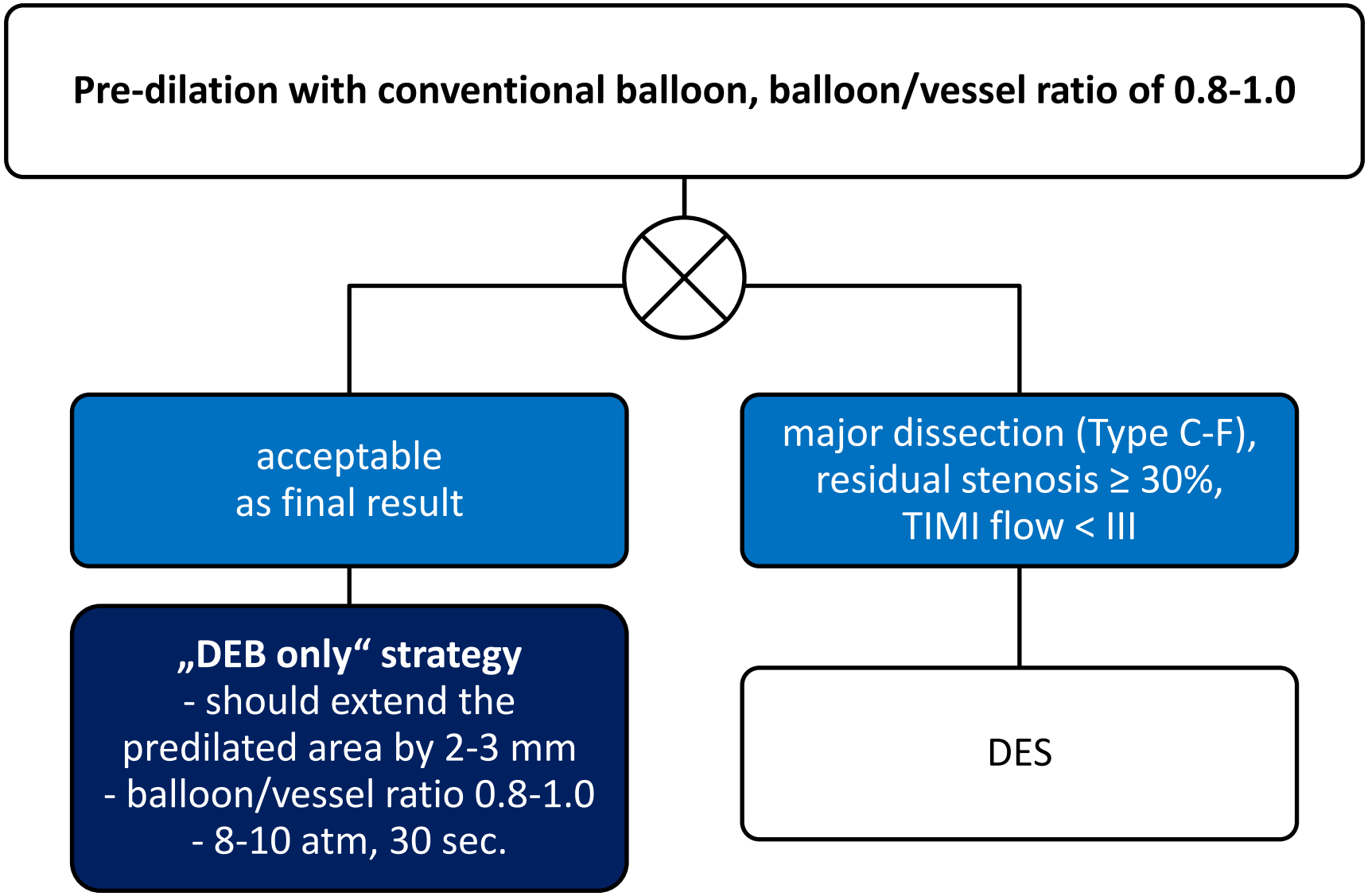
„DEB-only“ Strategy



„DEB-only“ Strategy



„DEB-only“ Strategy



Angiographic localized haziness after drug-coated balloon angioplasty in de-novo lesions

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⇨ The acute results after DCB only intervention might show haziness, however there is a tendency on improvement with time.

Bonaventura K, Asia PCR 2013

Dual Antiplatelet Therapy after Drug-Coated Balloon

ERNST VON BERGMANN KLINIKUM

⇨ **4 weeks**

Bonaventura K. Eurointervention 2011;7:K125-128

DAPT and Triple Therapy as short as possible

ERNST VON BERGMANN KLINIKUM

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

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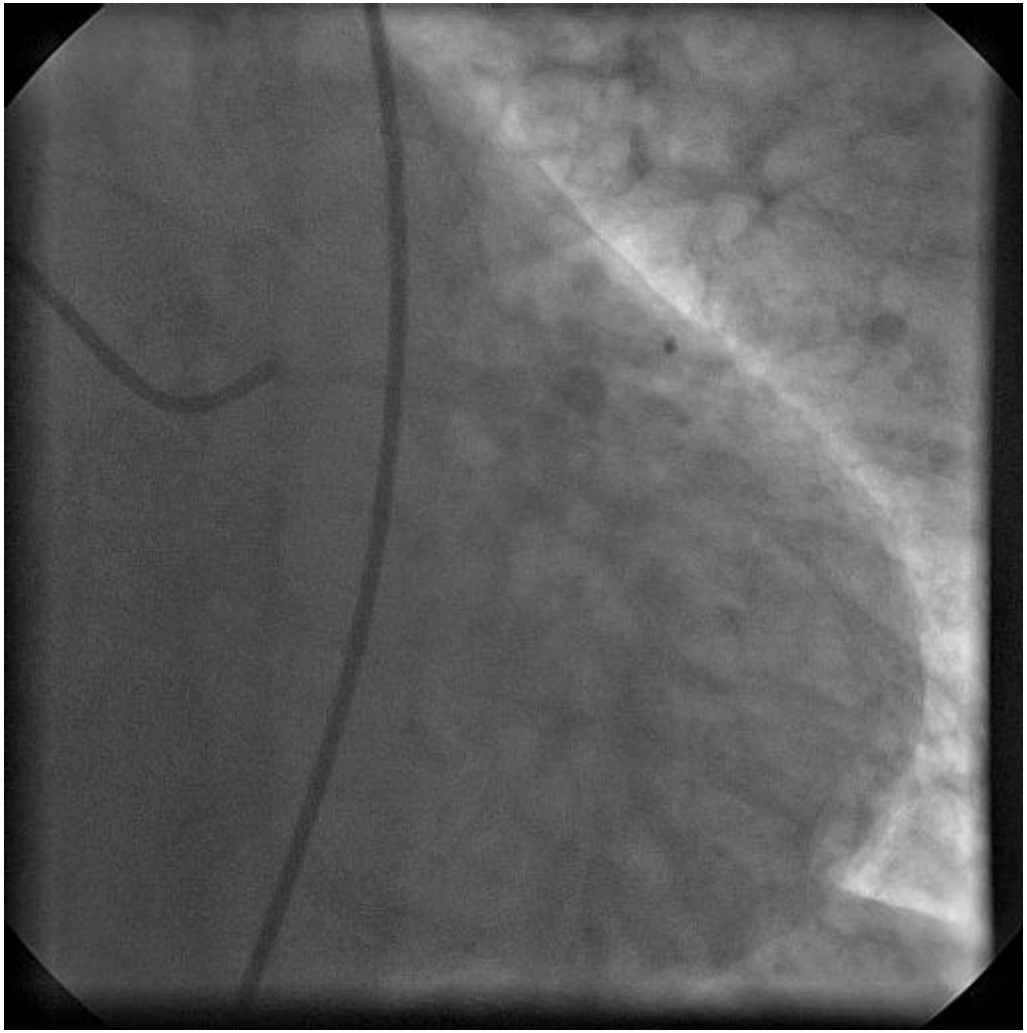
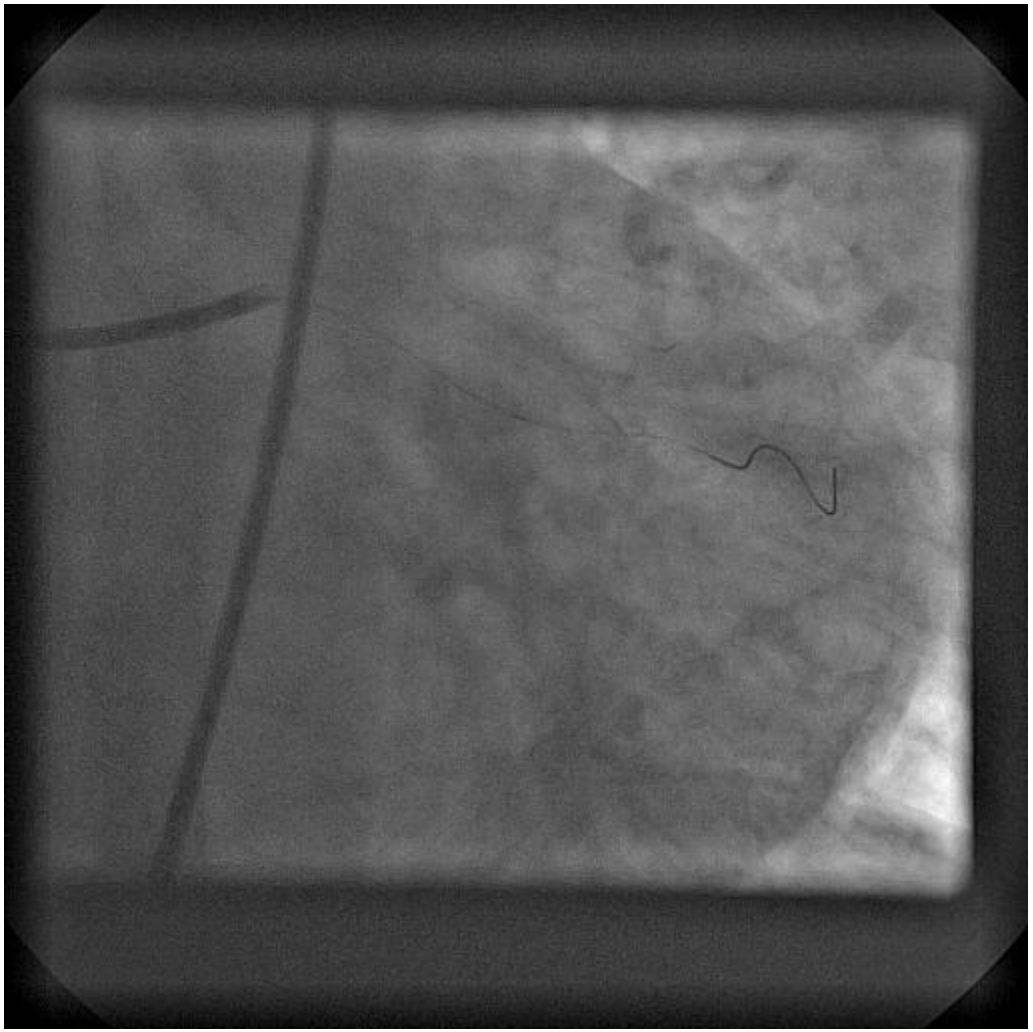
DCB only

- ⇨ Female, 67 years
- ⇨ Elective intervention of M1CX, positive stress test

RH, M1CX before 2.5/15 mm balloon



RH, M1CX after 2.5/15 mm balloon



RH, M1CX with DCB 2.5/20 mm *(Sequent Please)*

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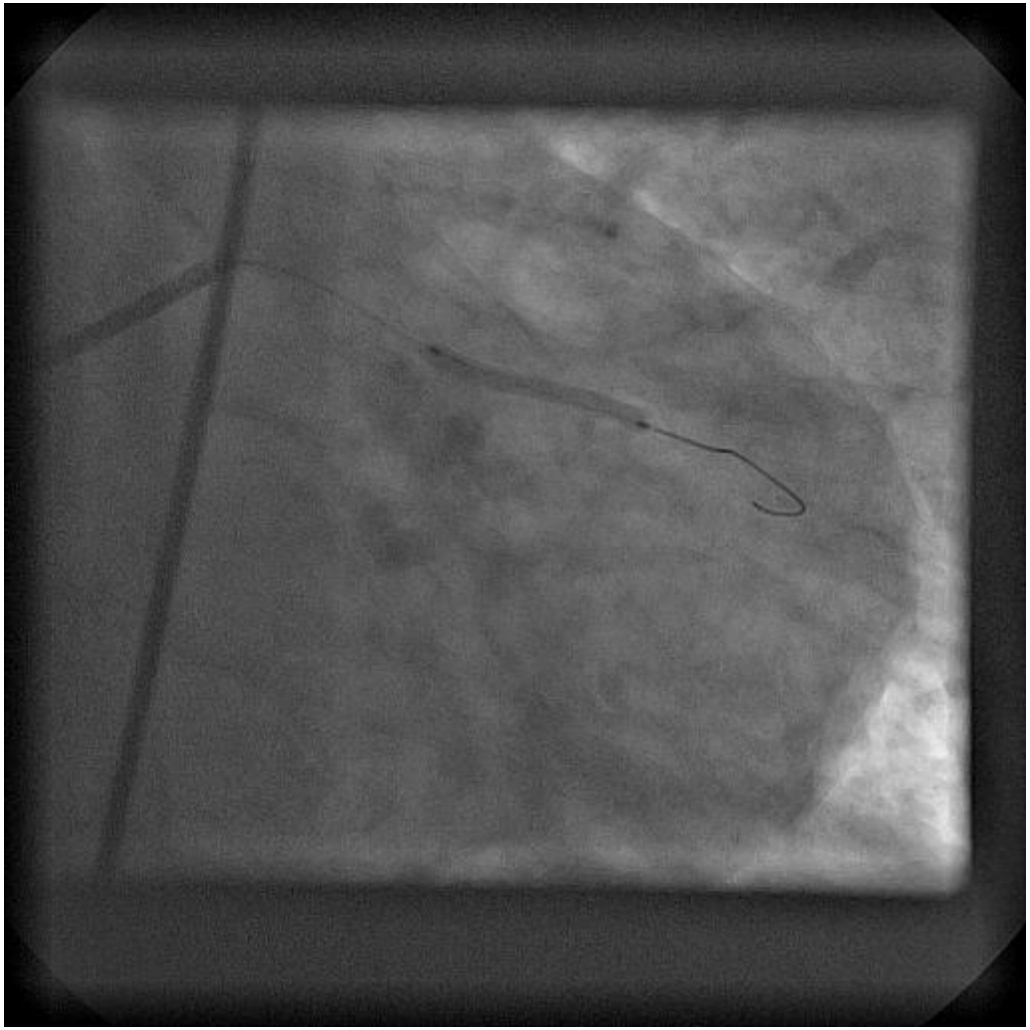

RH, M1CX, “final result” after DCB only

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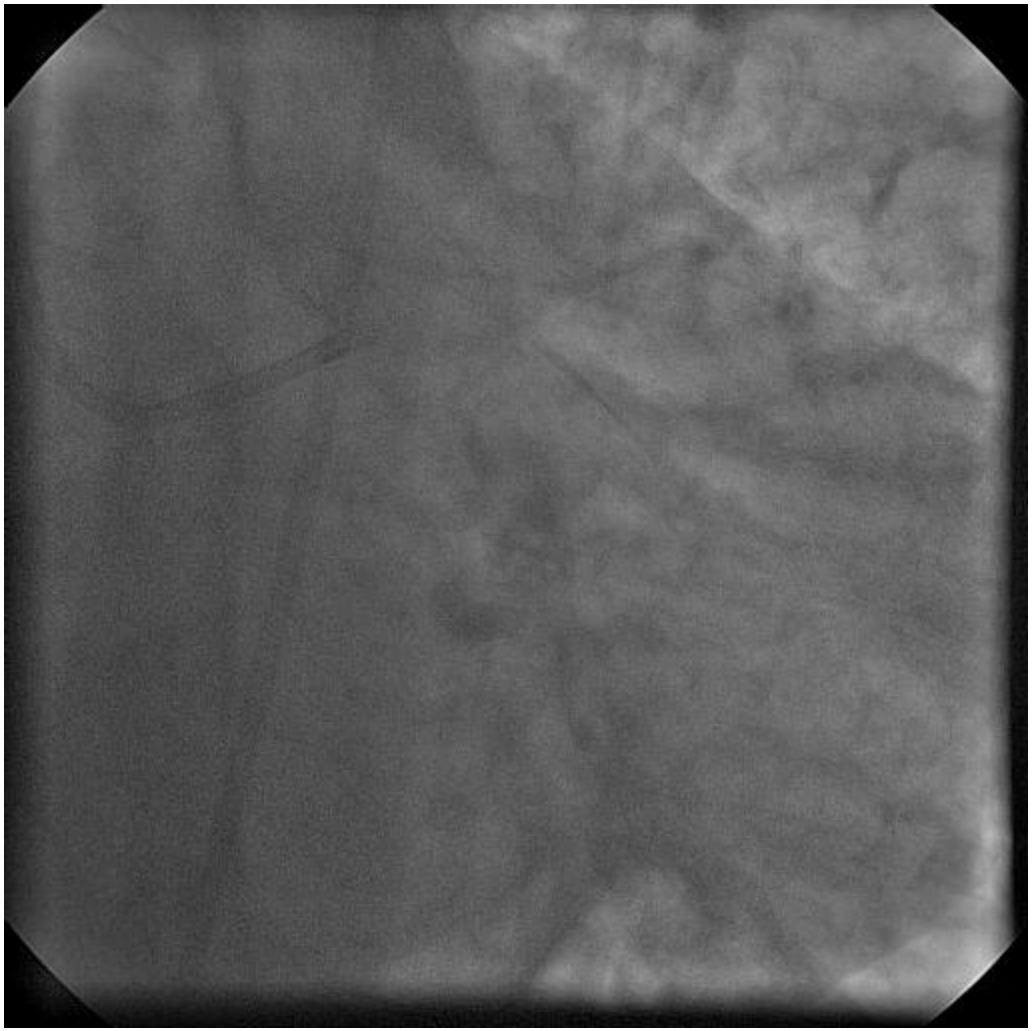
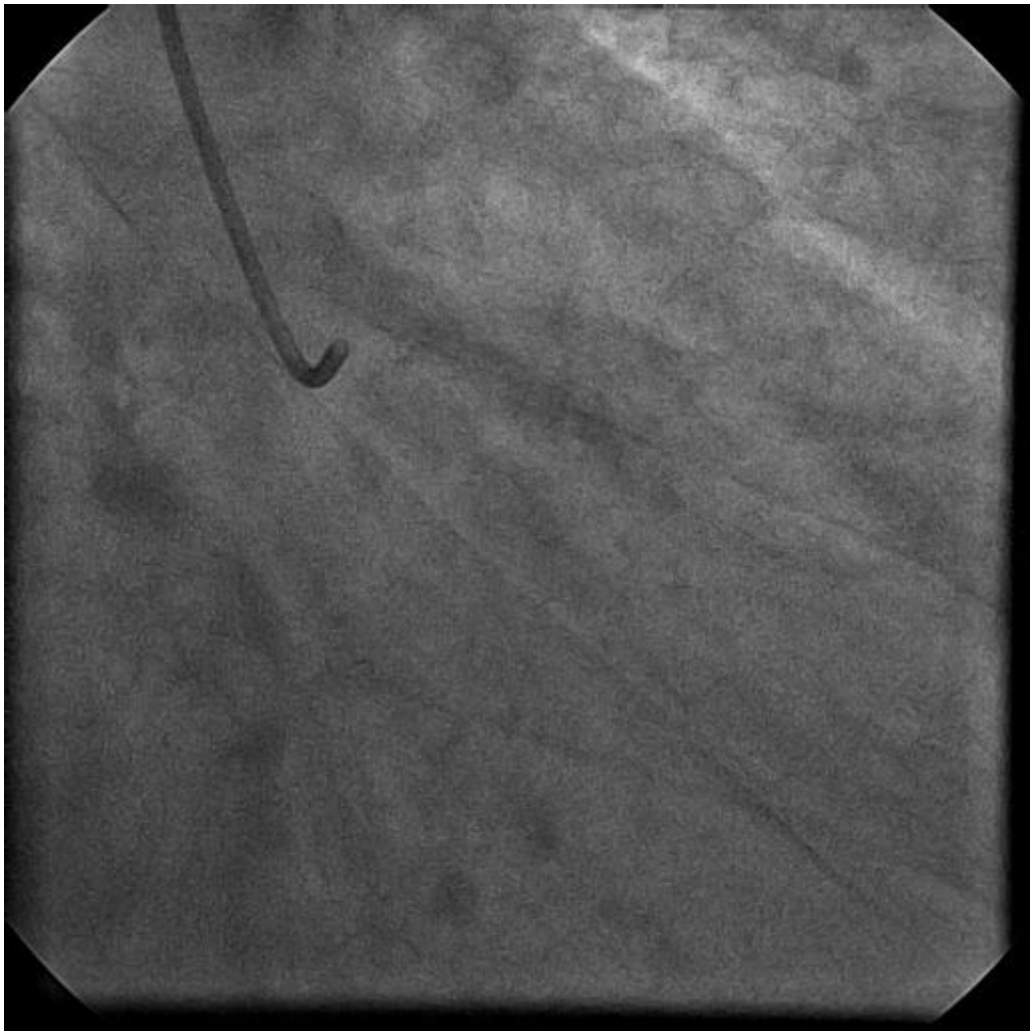


RH, M1CX, 4 months after DCB only

ERNST VON BERGMANN KLINIKUM



Conclusions

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- ⇨ The use of DCB in **in-stent restenosis**, **bifurcation lesions** and **small vessel disease** is **established.**
- ⇨ **Favorable results in de-novo coronary artery disease**
- ⇨ **No class-effect** of DCB
- ⇨ DEB only is **not** associated with a higher rate of acute or late **thrombosis**.
- ⇨ Localized **haziness** after DCB angioplasty in de-novo lesions does **not** increase the risk of acute coronary thrombosis.

Conclusions

ERNST VON BERGMANN KLINIKUM

- ⇨ The possible **reduction in the duration of DAPT** to one month may represent additional advantages regarding safety, patient compliance and costs for the “DCB only” strategy.
- ⇨ **Short period of triple therapy - especially in patients with atrial fibrillation and in patients with increased bleeding risk**