Long-term outcomes of drug coated balloons versus drug eluting stents in patients with small vessel coronary artery disease

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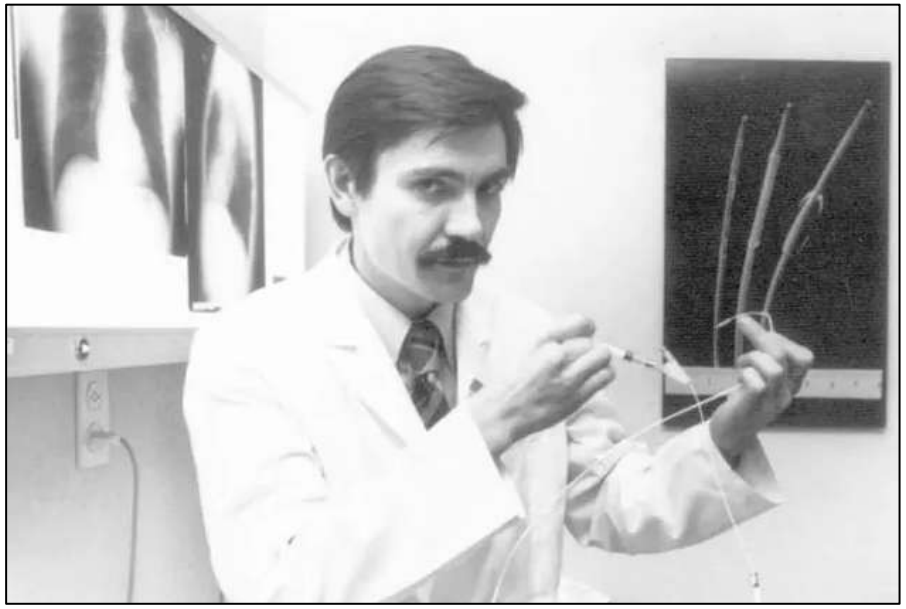
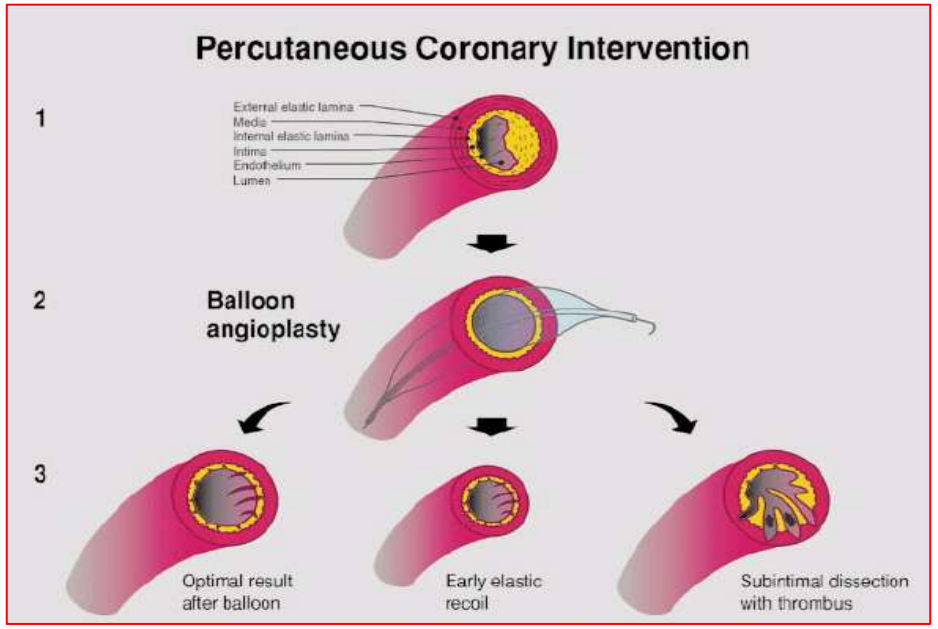
Azerbaijan Society of Cardiology
7TH AZERBAIJAN INTERVENTIONAL CARDIOLOGY MEETING


FIRST
DO NO HARM.
HIPPOCRATES

First Balloon Angioplasty

1977





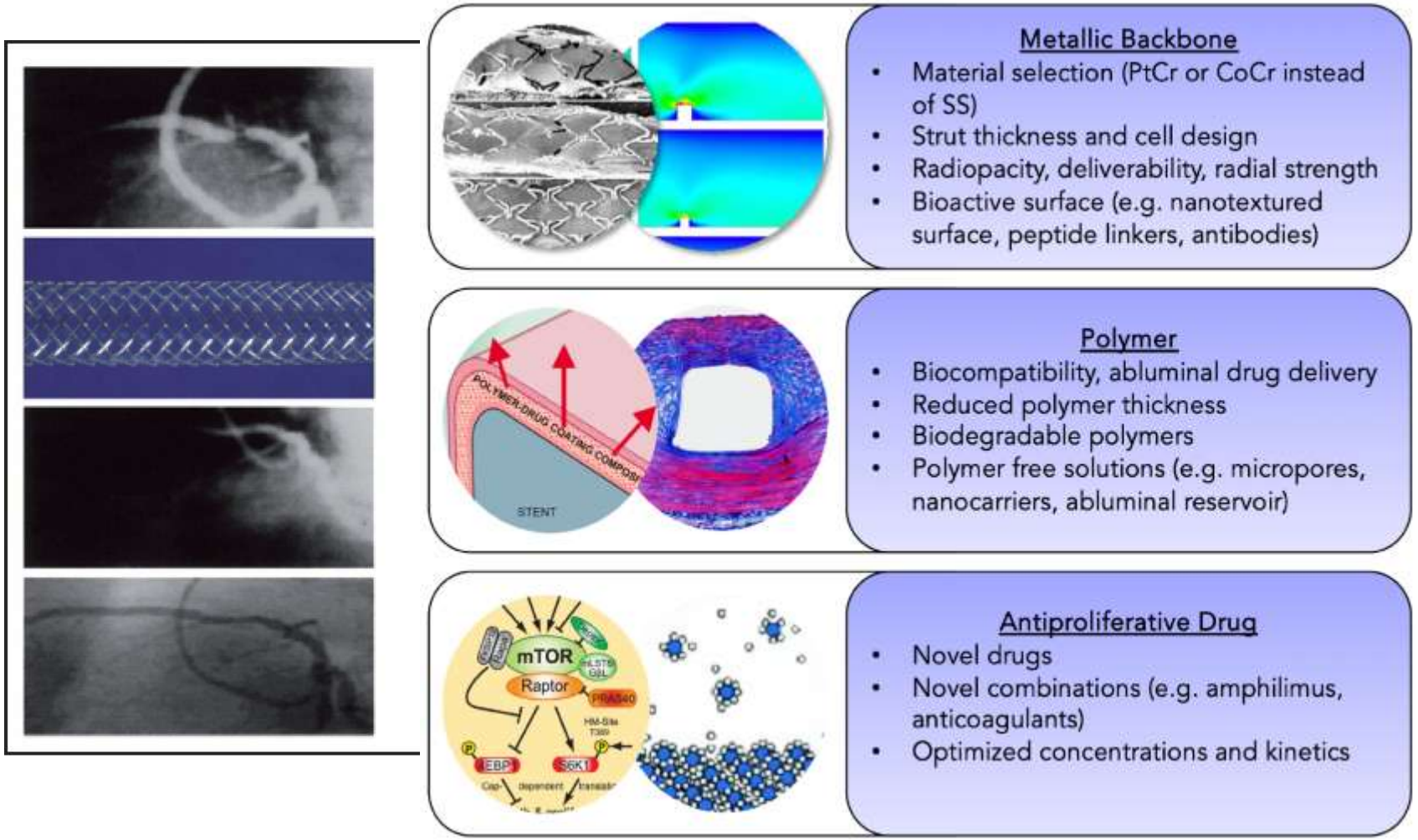
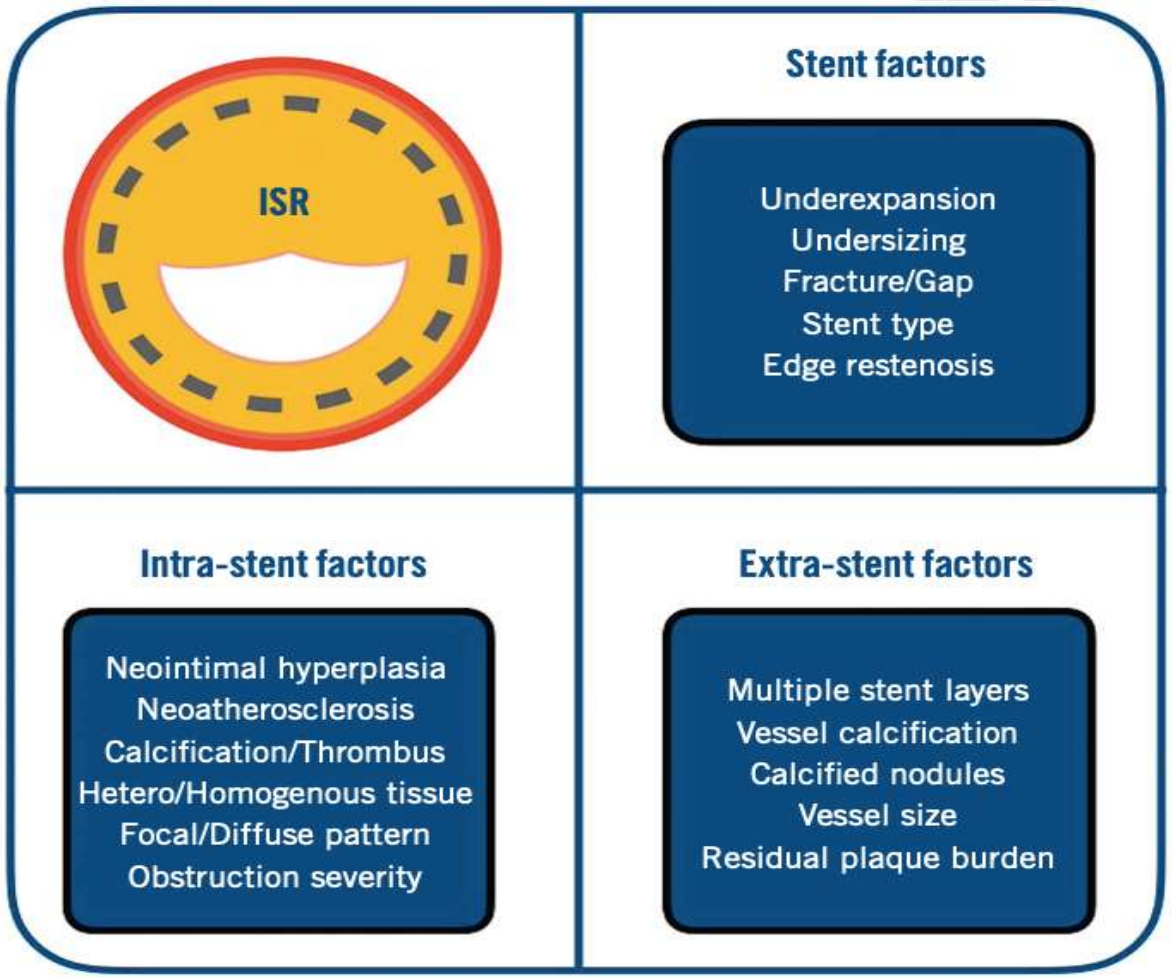


Figure 1

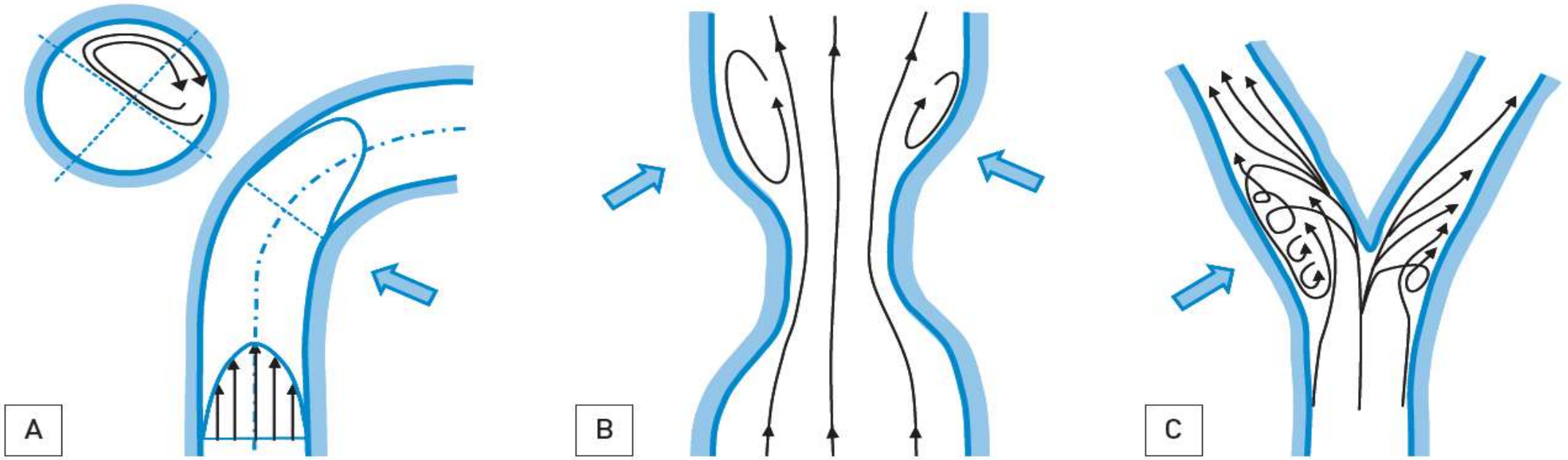
First human coronary stent implantation in March 1986. (a) Restenosis post balloon angioplasty (b) Self-expanding WALLSTENT (c) Immediate results post stent (d) Angiographic results at 11-year follow-up.

In-stent restenosis



Even with the latest generation of DES, device-associated annual event rates of 2 to 3 % are seen beyond the first year

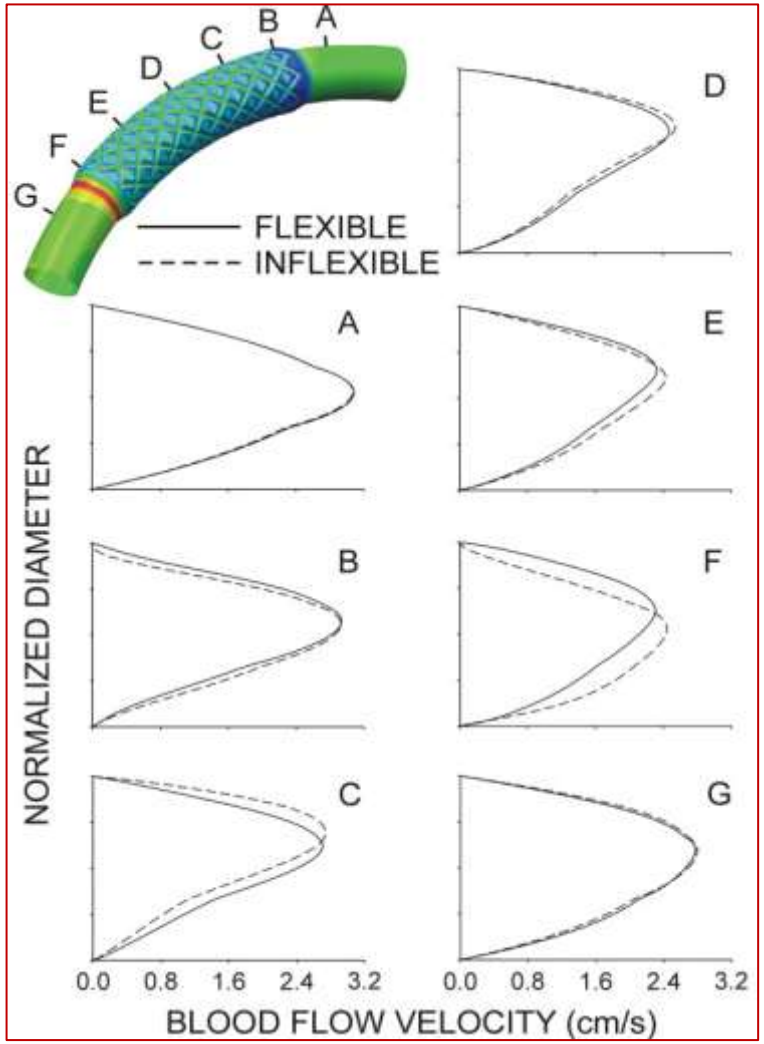
Biomechanical Fundamentals

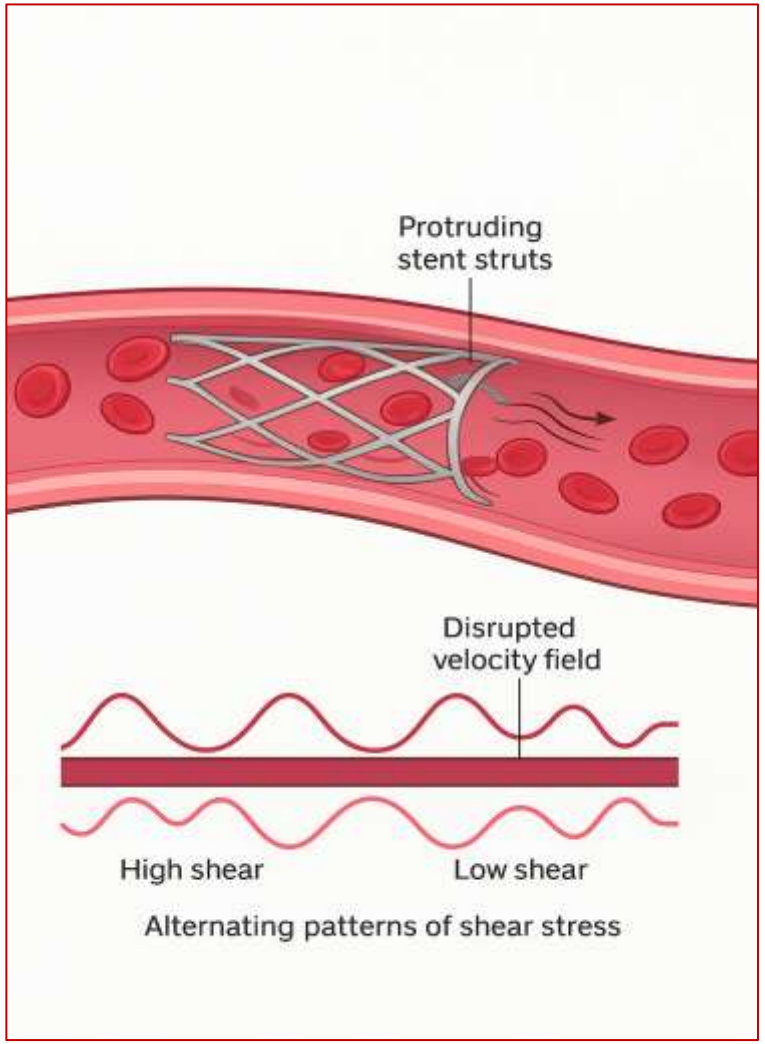


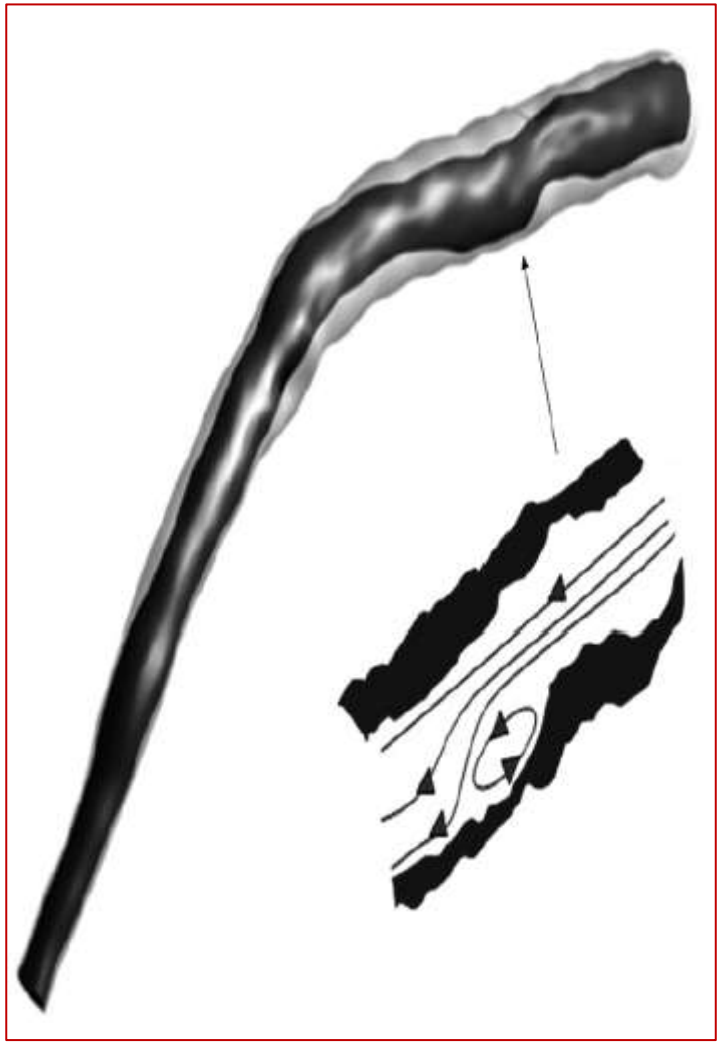
Biomechanical stresses acting on the arterial wall.The normal stress component is the blood pressure (red arrow), and the tangential stress component is the shear stress (green arrow).

Blood flow induced shear stresses at the vessel wall.The shear stress is defined by the product of blood viscosity and shear rate and for Poiseuille flow it can be directly computed from viscosity (η), flow rate (Q) and diameter (D).

SHEAR STRESS IN STENTED SEGMENTS





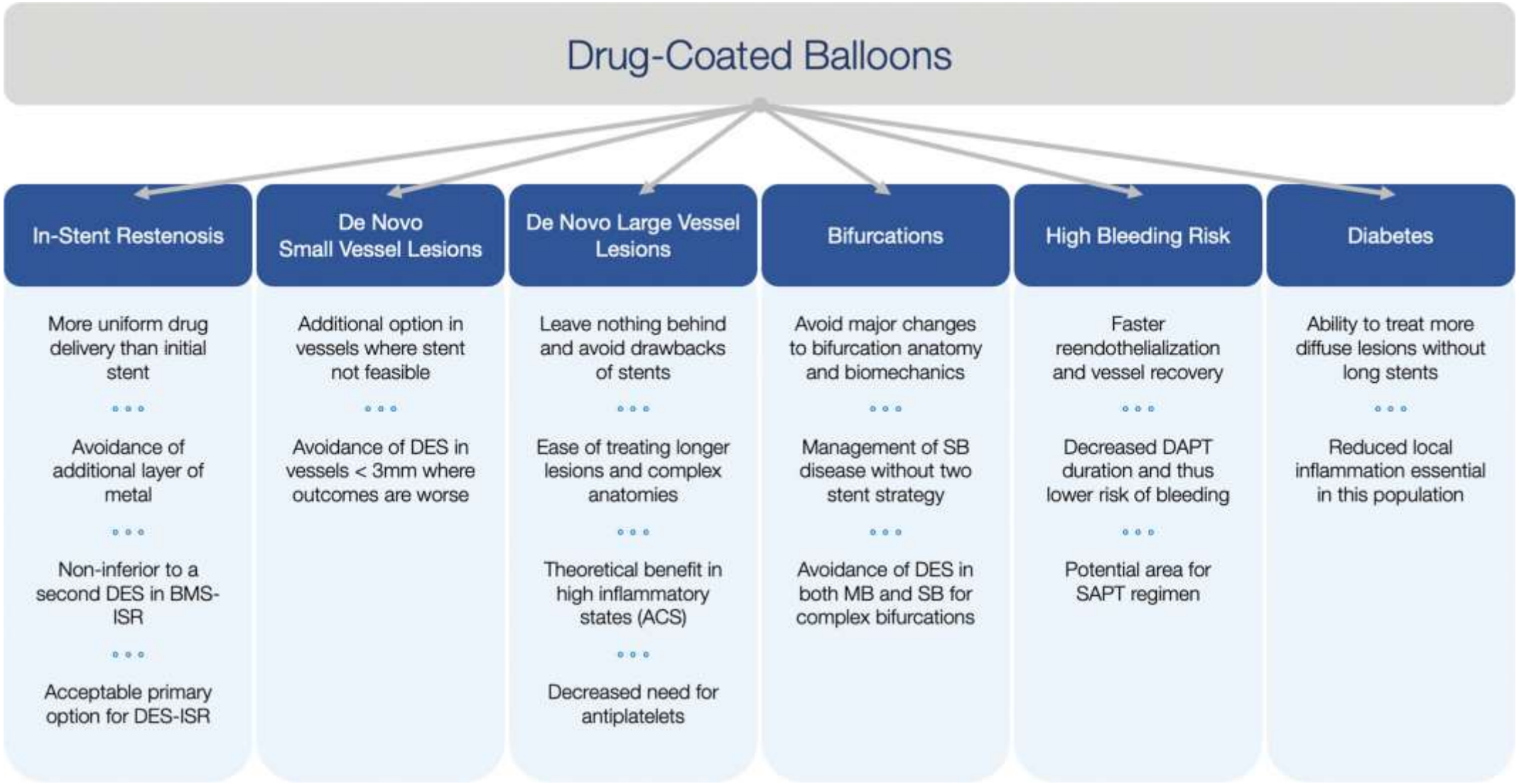


De novo lesions in small vessels

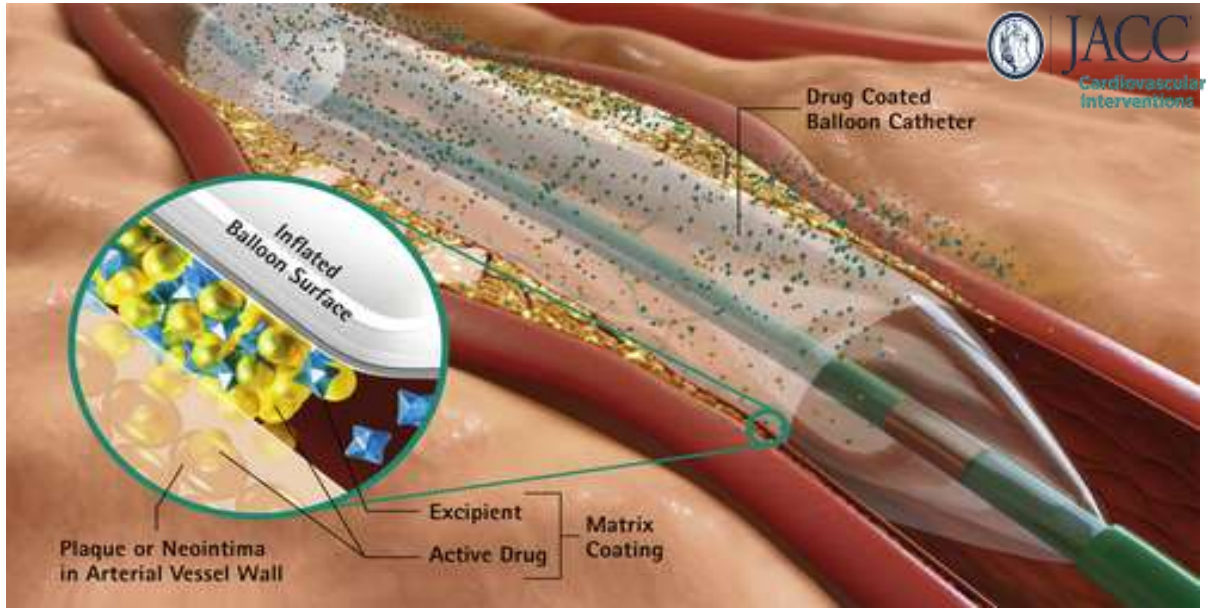
- The interventional treatment of coronary small-vessel disease, usually defined as lesions in vessels ≤2.75 or <3.0 mm, remains challenging

- Although DES are as effective in small as in large vessels, the resulting late lumen loss occupies a higher percentage of the respective vessel diameter - leading to higher rates of ISR and clinical events.

- DCB angioplasty for small-vessel disease (SVD) represents a compelling treatment option that may potentially reduce both restenosis and target lesion thrombosis by circumventing the implantation of a permanent metallic layer.

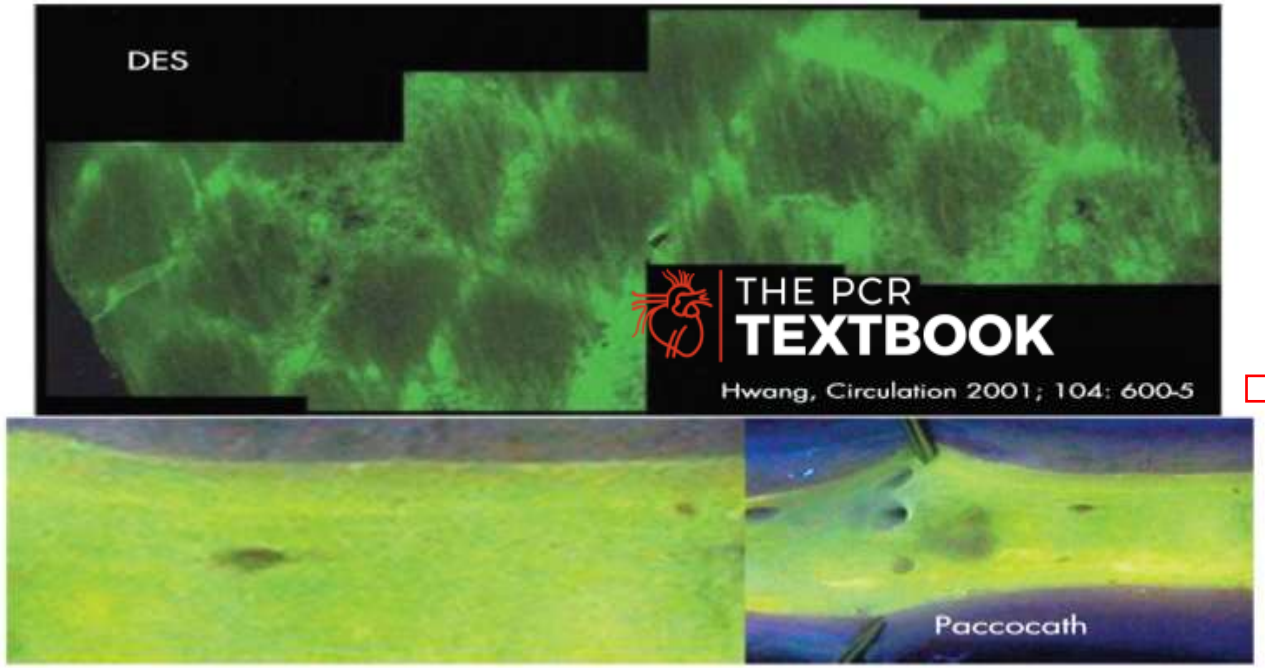


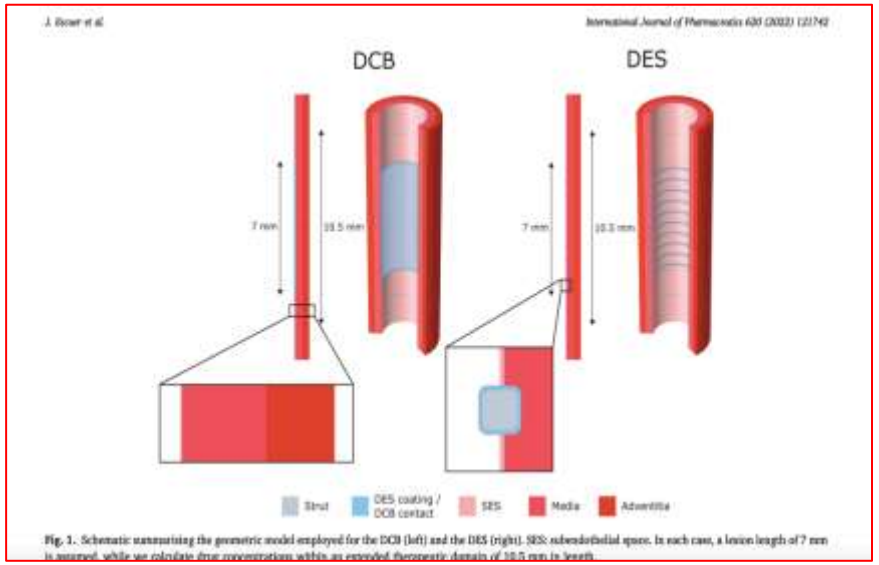
Serge Korjian. Circulation: Cardiovascular Interventions. Drug-Coated Balloons in the Management of Coronary Artery Disease, Volume: 17, Issue: 5, Pages: e013302, DOI: (10.1161/CIRCINTERVENTIONS.123.013302)



They are composed of :

- Semicompliant polyurethane and nylon balloons
- poated with antiproliferative drugs often encapsulated within a biocompatible, lipophilic polymer matrix.
- Balloons are coated using micropipetting, dipping, spraying, or imprinting techniques
- Commonly coated with paclitaxel, due to its hydrophobic and lipophilic properties which enable delivery and drug retention in tissue after short balloon inflation.





Raban V. Jeger et al. *J Am Coll Cardiol Intv* 2020; 13:1391-1402.

PEPCAD I

paclitaxel-coated balloon

Baseline data		
Number of patients		120
Age		68.0±8.1 years
Male gender		87 (72.5%)
Hypertension		105 (87.5%)
Hyperlipidaemia		97 (80.8%)
Diabetes mellitus/insulin-dependent		41 (34.2%)/ 12 (10.0%)
Coronary artery disease	Single-vessel disease Two-vessel disease Three-vessel disease	46 (38.3%) 45 (37.5%) 29 (24.2%)
Lesion location	LAD LCX RCA	46 (38.3%) 53 (44.2%) 21 (17.5%)
Lesion type	Type A Type B1 Type B2 Type C Other	17 (14.2%) 71 (59.2%) 29 (24.2%) 1 (0.8%) 2 (1.7%)
Reference diameter		2.36±0.19 mm
Lesion length		11.46±4.72 mm
Minimal lumen diameter before intervention		0.71±0.25 mm
Minimal lumen diameter post intervention		1.89±0.30 mm
Acute lumen gain		1.18±0.37 mm
Deployment pressure		11.9±3.0 mmHg
Balloon inflation time		57.3±17.3 sec
Balloon length		16.6±5.2 mm
GP IIb/IIIa antagonists		2 (1.7%)

Inclusion criteria:
stable or unstable angina, or an abnormal functional study and a single *de novo* lesion in a native coronary artery with a reference diameter between 2.25 mm and 2.8 mm.

Exclusion criteria :

- acute myocardial infarction within 48 hours preceding the procedure
- severe renal insufficiency (GFR <30 ml/min),
- known hypersensitivity or contraindication to the required medication,
- malignancies with a life expectancy of less than three years.
- Angiographic exclusion criteria encompassed lesions more than 22 mm long, stenoses below 70% of the luminal diameter, unprotected left main stenosis, lesions with a major side branch (>2 mm),
- restenoses.

		0 to 12 months		12 to 36 months	
		DCB only	DCB+BMS	DCB only	DCB+BMS
Count [N]		82 (68.3%)	32 (26.7%)	82 (68.3%)	32 (26.7%)
Missing [N]		0 (0%)	0 (0%)	6/82 (7.3%)	3/32 (9.4%)
Deaths	Total	0 (0%)	0 (0%)	0/32 (0%)	1/82 (1.2%)
	Cardiac	0/82 (0.0%)	0/32 (0%)	0/82 (0.0%)	0/32 (0%)
	- Lesion-related	0/82 (0.0%)	0/32 (0%)	0/82 (0.0%)	0/32 (0%)
	- Non-lesion-related	0/82 (0.0%)	0/32 (0%)	0/82 (0.0%)	0/32 (0%)
	- Unknown	0/82 (0.0%)	0/32 (0%)	0/82 (0.0%)	0/32 (0%)
	Non-cardiac (no MACE)	0/82 (0%)	0/32 (0%)	1/82 (1.2%)	0/32 (0%)
Myocardial infarction	Total	**1/82 (1.22%)	**1/32 (3.1%)	0/82 (0%)	0/32 (0%)
	CK-elevation >3 times upper normal limit	**1/82 (1.3 %)	**1/32 (3.1 %)	0/82 (0.0%)	0/32 (0 %)
	Stent thromboses	0/82 (0.0%)	*2/32 (6.3%)	0/82 (0.0%)	0/32 (0 %)
	Premature discontinuation of clopidogrel	0/82 (0.0%)	0/32 (0.0%)	0/82 (0.0%)	0/32 (0 %)
	Per protocol anti-aggregation	0/82 (0.0%)	*2/32 (6.3%)	0/82 (0.0%)	0/32 (0 %)
PCI or CABG for in-segment stenosis >50%		4/82 (4.9%)	9/32 (28.1%)	0/32 (0%)	0/32 (0%)
PCI or CABG for in-lesion stenosis >50%		4/82 (4.9%)	9/32 (28.1%)	0/82 (0%)	0/32 (0%)
PCI/CABG for target vessel stenosis >50%***		1/82 (1.2%)	3/32 (9.4%)	2/82 (2.4%)	1/32 (3.1%)
PCI or CABG for other vessel stenosis >50%		8/82 (9.8%)	6/32 (18.8%)	1/82 (1.2%)	0/32 (0%)
Total events		14/82 (17.1%)	21/32 (68.8%)	4/82 (4.9%)	1/32 (3.1%)
Three-year MACE: TLR, lesion-related myocardial infarction, and cardiac death		5/82 (6.1%)	12/32 (37.5%)	0/82 (0%)	0/32 (0%)

Primary endpoint :after six months in-segment late lumen loss
Secondary endpoints :stent thrombosis,
target lesion revascularisation, myocardial infarction
death up to three years

Target lesion was dilated once for at least 30 seconds with the paclitaxel-coated balloon catheter
The compliance of the balloon allowed for a diameter range from 2.3 mm (5 atm) to 2.8 mm (15 atm).
In the case of severe elastic recoil or dissection, bare metal stents were deployed.

Randomized Controlled trials on DCB Only in De Novo Lesions of Small Coronary Vessels

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 13, NO. 12, 2020
JUNE 22, 2020:1391–402

TABLE 3 Randomized Controlled Trials of DCB Only in De Novo Lesions of Small Coronary Vessels

Study Name (Ref. #)	Comparators	n	Follow-Up Duration	Angiographic Follow-Up	p Value	MACE (%)	p Value	TLR (%)	p Value
PICCOLETO (58)	Dior PCB vs. TAXUS Liberté PES	57	6 months (angio) 9 months (clinical)	MLD 1.11 ± 0.65 mm vs. 1.94 ± 0.72 mm	0.0002	35.7 vs. 13.8	0.054	32.1 vs. 10.3	0.15
BELLO (59,66)	IN.PACT Falcon PCB vs. TAXUS Liberté PES	182	6 months (angio) 12 months (clinical) 3 yrs (clinical)	LLL 0.08 ± 0.38 mm vs. 0.29 ± 0.44 mm	0.001	10 vs. 16.3 14.4 vs. 30.4	0.21 0.015	4.4 vs. 7.6	0.37
RESTORE SVD (61)	Restore PCB vs. Resolute Integrity ZES	230	9-12 months (angio) 12 months (clinical)	LLL 0.26 ± 0.42 mm vs. 0.30 ± 0.35 mm, diameter stenosis 29.6 ± 2.0% vs. 24.1 ± 2.0%	0.41, <0.001	9.6 vs. 9.6	1.0	4.4 vs. 2.6	0.72
BASKET-SMALL 2 (60)	Sequent Please PCB vs. TAXUS Element PES and Xience EES	758	6 months (angio)* 12 months (clinical)	LLL 0.13 mm (−0.14 to 0.57 mm) vs. 0.10 mm (−0.16 to 0.34 mm)	0.72	8 vs. 8	0.918, 0.0152†	3.4 vs. 4.5	0.438

Only randomized controlled trials in patients with lesions in native coronary vessels ≤2.75 or 3.0 mm are included. *Only clinically indicated angiography. †Noninferiority.
ZES = zotarolimus-eluting stent; other abbreviations as in Tables 1 and 2.

Dior PCB (Eurocor, Bonn, Germany) VS Taxus Libertè DES

PICCOLETO

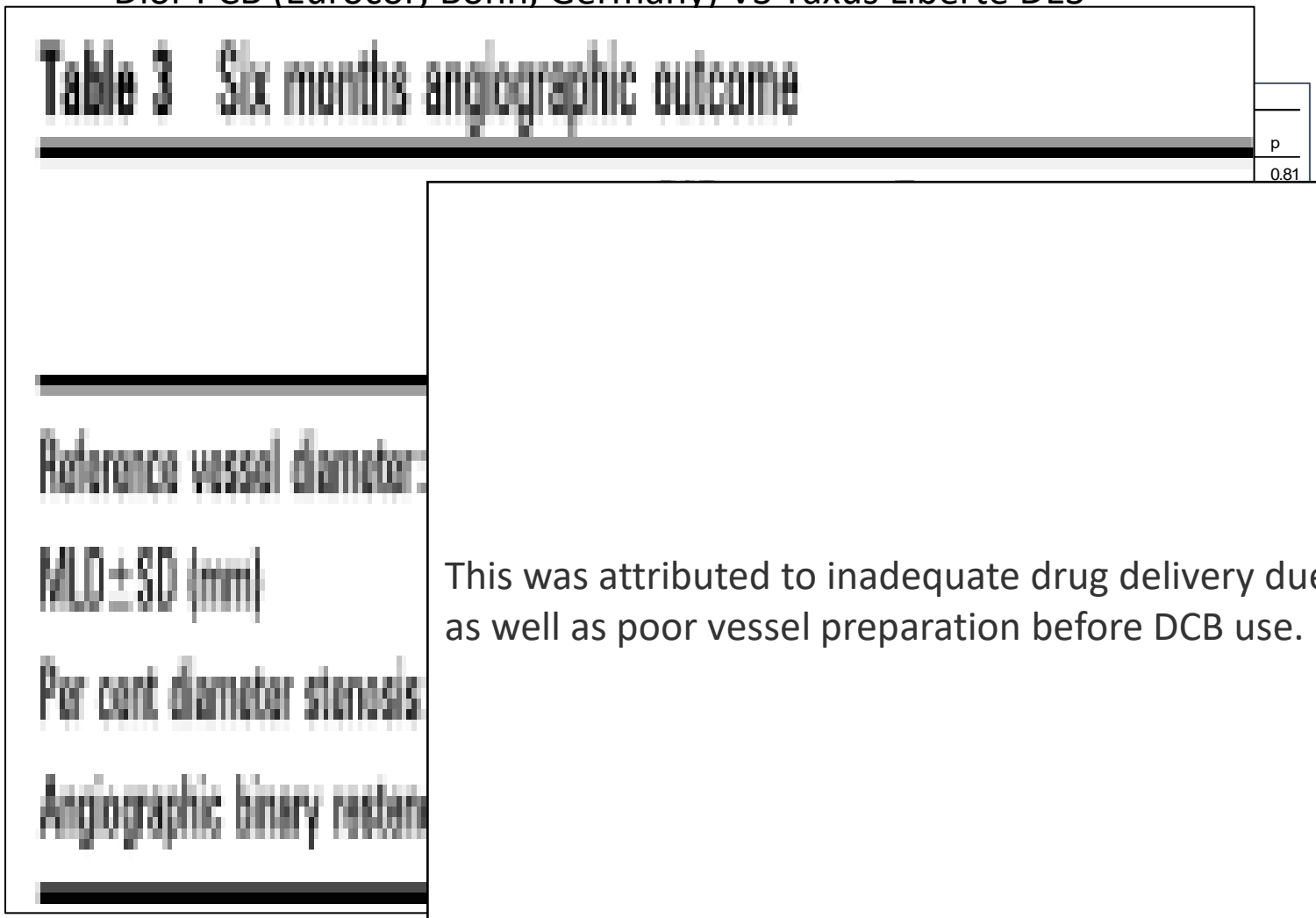


Table 3 Six months angiographic outcome

		p
Reference vessel diameter		0.81
MLD±SD (mm)		
Per cent diameter stenosis		
Angiographic binary restenosis		

This was attributed to inadequate drug delivery due to the DCB design, as well as poor vessel preparation before DCB use.

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

se,[1] Andrea Micheli,[1] Andrea Picchi,[1] Amelia Coppolaro,[1]
,[1] Silva Severi,[2] Ugo Limbruno[1]

aneous coronary intervention (PCI) of
ed by an increased risk of restenosis
e, even when drug-eluting stents
In recent years, the paclitaxel-
has been shown to reduce
on and the need for target lesion
R) in an in-stent restenosis setting.
during PCI of small coronary vessels
ompared to one of the most widely

COLETO randomised clinical trial,
or unstable angina undergoing PCI of
ls (≤2.75 mm) were randomised to
s) or Taxus DES (29 patients). The
oint was per cent diameter stenosis
phic follow-up (non-inferiority).
s were angiographic binary
rrence of major adverse cardiac
h, Q-wave myocardial infarction,
ow-up.
oups were not dissimilar regarding
phic characteristics. Study was
olment of two-thirds of patients due
of one study group. The primary end
because the PCB group showed
heter stenosis (43.6% vs 24.3%,
phic restenosis was higher as well
.043), whereas MACE were 35.7%
13.8% in the DES group (p=0.054).
CB failed to show equivalence to
angiographic end points during PCI
teries.
tration Number (EudraCT code):

nary intervention (PCI) of small
vessels is a true challenge for
tional cardiology, due to the
estenosis and adverse outcome.[1]
ting stent (DES) use, thanks to
therapeutic agents to reduce
lasia, has changed this scenario.[2]
increased risk of stent throm-
at any time after stent implan-
matter of concern in all vessel
ecific scientific data are lacking.
a standard, uncoated balloon,
balloon (PCB) has been shown
al proliferation and the need for
cularisation (TLR) in an in-stent
and recently DES.[7] Investigators

of these two trials concluded that this new method of local drug delivery would not require stent implantation to fight restenosis.

The purpose of this study was to evaluate the impact of a PCB during PCI of small native coronary vessels compared to standard treatment with DES.

METHODS

The PICCOLETO study was a prospective, single centre, randomised trial comparing the efficacy of the Dior PCB (Eurocor, Bonn, Germany) with Taxus Libertè DES (Boston Scientific Corporation, Natick, MA, USA) in small coronary arteries (diameter ≤2.75 mm). The study was entirely conducted at the interventional cardiology unit of Ospedale della Misericordia in Grosseto, Italy.

Between August 2007 and August 2008, after obtaining informed written consent, all consecutive patients of at least 18 years of age with stable or unstable angina and a clinical indication for PCI of at least one small coronary artery were randomised to treatment with PCB or Taxus stent.

Patients were excluded from the study if they met at least one of the following criteria: acute myocardial infarction within the previous 48 h, unstable haemodynamics, chronic renal insufficiency with a serum creatinine level of more than 2.0 mg/dl, known hypersensitivity or contraindication to aspirin, heparin, clopidogrel or paclitaxel, sensitivity to contrast media that could not be controlled with premedication and life expectancy of less than 2 years.

Randomisation was performed in a 1:1 ratio by computerised, open-label assignment in consecutive blinded envelopes. A randomly permuted blocks method was used to generate the randomisation plan. Although operators were not blinded to the device used, the clinical end points were adjudicated by two investigators blinded with regard to patients' treatment allocation. A local ethics committee approved the study. This clinical trial obtained an EudraCT code (2009-012268-15).

The Dior PCB is a coronary dilatation catheter with a nanoporous balloon surface coated with paclitaxel microcrystals. Paclitaxel coating concentration is 3 μg/mm^2 of balloon surface area, homogeneously distributed. During inflation, the drug is released onto the vessel wall.

Patients randomised to the control group were treated with the Taxus Libertè DES described elsewhere.[8] PCB were available in diameters of 2.25, 2.5 and 2.75 mm, and in lengths of 15–25 mm. Taxus

Secondary end points o
-angiographic binary re
-occurrence of major adverse cardiac events (MACE: death, new ST elevation myocardial infarction[12] and TLR) at 9 months clinical follow-up (non-inferiority).

DCB (paclitaxel with dextran) VS everolimus-eluting stent (EES)

noninferiority between the 2 arms hypothesized

CONCLUSIONS

The PICCOLETO II trial for the first time shows the angiographic superiority in terms of LLL, and the equivalence in terms of MLD and percent diameter stenosis, of a novel DCB over 1 of the best-in-class DES for the treatment of de novo coronary lesions in small vessels. This trial also shows the clinical noninferiority of the DCB strategy after 12 months.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 13, NO. 24, 2020
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Drug-Coated Balloon Versus Drug-Eluting Stent for Small Coronary Vessel Disease

PICCOLETO II Randomized Clinical Trial

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ABSTRACT

OBJECTIVES This study sought to compare the performance of a novel drug-coated balloon (DCB) (Elutax SV, Aachen Resonance, Germany), with an everolimus-eluting stent (EES) (Abbott Vascular, Santa Clara, California) in patients with de novo lesions.

BACKGROUND Small vessel coronary artery disease (SVD) represents one of the most attractive fields of application for DCB. To date, several devices have been compared with drug-eluting stents in this setting, with different outcomes.

METHODS The PICCOLETO II (Drug Eluting Balloon Efficacy for Small Coronary Vessel Disease Treatment) trial was an international, investigator-driven, multicenter, open-label, prospective randomized controlled trial where patients with de novo SVD lesions were randomized to DCB or EES. Primary study endpoint was in-lesion late lumen loss (LLL) at 6 months (independent core laboratory), with the noninferiority between the 2 arms hypothesized. Secondary endpoints were minimal lumen diameter, percent diameter stenosis at angiographic follow-up, and the occurrence of major adverse cardiac events at 12 months.

RESULTS Between May 2015 and May 2018, a total of 232 patients were enrolled at 5 centers. After a median of 189 (interquartile range: 160 to 202) days, in-lesion LLL was significantly lower in the DCB group (0.04 vs. 0.17 mm; $p = 0.001$ for noninferiority; $p = 0.03$ for superiority). Percent diameter stenosis and minimal lumen diameter were not significantly different. At 12-month clinical follow-up, major adverse cardiac events occurred in 7.5% of the DES group and in 5.6% of the DCB group ($p = 0.55$). There was a numerically higher incidence of spontaneous myocardial infarction (4.7% vs. 1.9%; $p = 0.23$) and vessel thrombosis (1.8% vs. 0%; $p = 0.15$) in the DES arm.

CONCLUSIONS In this multicenter randomized clinical trial in patients with de novo SVD lesions, a new-generation DCB was found superior to EES in terms of LLL as the angiographic pattern and comparable in terms of clinical outcome. (Drug Eluting Balloon Efficacy for Small Coronary Vessel Disease Treatment [PICCOLETO II]; NCT03899818) (J Am Coll Cardiol Intv 2020;13:2840-9) © 2020 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received May 20, 2020; revised manuscript received July 28, 2020, accepted August 19, 2020.

ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2020.08.035

DEB VS DES

BELLO

Table 6 Subgroup Analysis of In-Stent (In-Balloon) Late Loss

	No. of Lesions		Late Loss, mm			
	DEB	PES	DEB	PES	p Value	p Value for Interaction
Diabetes						
Yes	32	31	0.05 ± 0.41	0.32 ± 0.52	0.001	0.52
No	49	51	0.10 ± 0.38	0.28 ± 0.39	0.06	
Reference vessel diameter						
<2.25 mm	54	41	0.07 ± 0.35	0.29 ± 0.41	0.006	0.12
2.25–2.5 mm	19	31	0.06 ± 0.41	0.37 ± 0.49	0.02	
Lesion length						
≤13.9 mm (median)	40	41	0.05 ± 0.33	0.29 ± 0.45	0.008	0.71
>13.9 mm (median)	41	41	0.11 ± 0.42	0.30 ± 0.43	0.03	
DEB only	67	82	0.02 ± 0.32	0.29 ± 0.44	<0.001	—
DEB + BMS	14	82	0.37 ± 0.51	0.29 ± 0.44	0.59	

Vol. 60, No. 24, 2012
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.09.020

Interventional Cardiology

enter Study Comparing luting Balloon With a ent in Small Coronary Vessels

tion and Late Loss Optimization) Study

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sco De Felice, MD,|| Alfredo Marchese, MD,¶ Maurizio Tespili, MD,#
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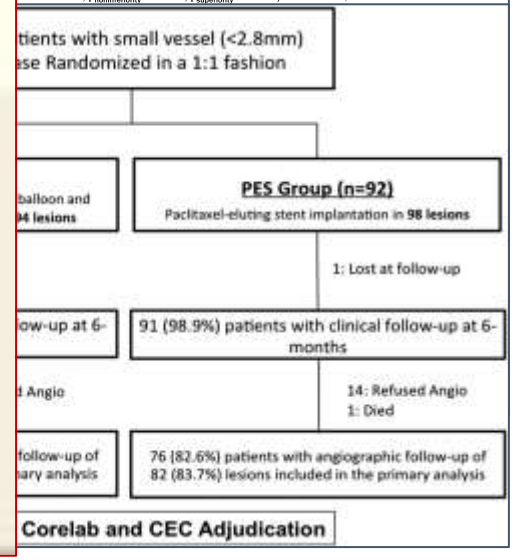
me, Bari, Bergamo, Latina, Mantova, Catania, Torino, and Parma, Italy

dy was to evaluate the efficacy of drug-eluting balloons (DEB) compared with paclitaxel-) for the reduction of restenosis in small vessels.

own to be effective in the treatment of coronary in-stent restenosis, but data are limited re-cy in de novo disease.

tion and Late Loss Optimization) is a prospective, multicenter trial that randomized 182 pa-located in small vessels (reference diameter <2.8 mm) to treatment with paclitaxel DEB and etal stenting (n = 90) or PES implantation (n = 92). The primary endpoint was noninferiority stent (in-balloon) late loss with a delta of 0.25 mm. Secondary endpoints were angiographic esion revascularization, and major adverse cardiac events (MACE; death, myocardial infarc-revascularization) at 6 months.

istics were well matched, except for a smaller vessel size in the DEB group (2.15 ± 0.27 mm m; p = 0.003). The majority (89%) of lesions involved vessels with a diameter <2.5 mm. Bail-equired in 20% of lesions in the DEB group. The primary endpoint of in-stent (in-balloon) late dy less with DEB compared with PES (0.08 ± 0.38 mm vs. 0.29 ± 0.44 mm; difference 0.34 to −0.09; $p_{noninferiority} < 0.001$; $p_{superiority} = 0.001$). At 6 months, DEB and PES were as-



Restore DCB VS the RESOLUTE Integrity DES

TABLE 3 Quantitative Coronary Angiographic Results (Intention-to-Treat Population)

	Small Vessel Group				Very Small Vessel Group
	Restore DCB Group	Resolute DES Group	Difference (95% CI)	p Value	
Pre-procedure					n = 32
Reference ve				01	1.86 ± 0.28
Minimal lumi				92	0.48 ± 0.22
Diameter ste				30	74.3 ± 10.7
Lesion length				63	12.2 ± 5.6
Post-procedure					n = 32
Minimal lumi					
In-device				001	1.40 ± 0.24
In-segmen				001	1.38 ± 0.22
Diameter ste					
In-device				001	23.4 ± 10.2
In-segmen				001	23.7 ± 10.1
9-month follow-up QCA	n = 100	n = 93			n = 29
Minimal luminal diameter, mm					
In-device	1.40 ± 0.43	1.75 ± 0.39	−0.4 (−0.5 to −0.2)	<0.001	1.14 ± 0.46
In-segment	1.40 ± 0.42	1.71 ± 0.39	−0.3 (−0.4 to −0.2)	<0.001	1.12 ± 0.44
Diameter stenosis, %					
In-device	29.3 ± 20.2	22.8 ± 15.3	6.5 (1.5 to 11.6)	0.01	37.3 ± 22.5
In-segment	29.3 ± 20.2	23.9 ± 15.9	5.5 (0.3 to 10.6)	0.04	38.4 ± 21.5
Late lumen loss, mm					
In-device	0.26 ± 0.42	0.30 ± 0.35	−0.1 (−0.2 to 0.1)	0.41	0.28 ± 0.40
In-segment	0.25 ± 0.42	0.27 ± 0.36	−0.02 (−0.1 to 0.1)	0.73	0.27 ± 0.38
Net luminal gain,* mm					
In-device	0.78 ± 0.45	1.11 ± 0.43	−0.3 (−0.5 to −0.2)	<0.001	0.66 ± 0.47
In-segment	0.77 ± 0.45	1.08 ± 0.42	−0.3 (−0.4 to −0.2)	<0.001	0.65 ± 0.46
Binary restenosis, %					
In-device	11.0 (11)	7.5 (7)	3.5 (−4.7 to 11.6)	0.40	17.2 (5)
In-segment	11.0 (11)	8.6 (8)	2.4 (−6.0 to 10.8)	0.58	17.2 (5)

The Restore DCB was noninferior to the second-generation RESOLUTE Integrity DES for the secondary endpoint of in-segment (MLD; LLL)

RESTORE

JACC: CARDIOVASCULAR INTERVENTIONS
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PUBLISHED BY ELSEVIER
VOL. 11, NO. 23, 2018

Drug-Coated Balloon Versus Drug-Eluting Stent for Small-Vessel Disease

The RESTORE SVD China Randomized Trial

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate the angiographic efficacy and clinical outcomes of the Restore paclitaxel-coated balloon in a randomized trial designed to enable its approval with an indication for small-vessel disease (SVD).

BACKGROUND Higher rates of restenosis and stent thrombosis limit the effectiveness of drug-eluting stent (DES) treatment of SVD. Whether a drug-coated balloon (DCB)–only strategy is effective in de novo SVD is not yet established.

METHODS In the noninferiority RESTORE SVD China trial, eligible patients with reference vessel diameter ≥2.25 and ≤2.75 mm were randomized to the Restore DCB or the RESOLUTE Integrity DES in a 1:1 ratio stratified by diabetes and number of lesions treated. Patients with RVD ≥2.00 and <2.25 mm were enrolled in a nested very small vessel registry. Angiographic and clinical follow-up were planned at 9 months and 1 year, respectively, in all patients. The study was powered for the primary endpoint of 9-month in-segment percentage diameter stenosis.

RESULTS Between August 2016 and June 2017, a total of 230 subjects at 12 sites were randomized to the DCB group (n = 116) or DES group (n = 114); 32 patients were treated with the DCB in the very small vessel cohort. Nine-month in-segment percentage diameter stenosis was 29.6 ± 2.0% with the DCB versus 24.1 ± 2.0% with the DES; the 1-sided 97.5% upper confidence limit of the difference was 10.9%, achieving noninferiority of the DCB compared with the DES (p for noninferiority < 0.001). The DCB and DES had comparable 1-year rates of target lesion failure (4.4% vs. 2.6%, p = 0.72).

CONCLUSIONS In this multicenter randomized trial, the Restore DCB was noninferior to the RESOLUTE DES for 9-month in-segment percentage diameter stenosis. (Assess the Efficacy and Safety of RESTORE Paclitaxel Eluting Balloon Versus RESOLUTE Zotarolimus Eluting Stent for the Treatment of Small Coronary Vessel Disease; NCT02946307) (J Am Coll Cardiol Intv 2018;11:2381–92) © 2018 by the American College of Cardiology Foundation.

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ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.09.009

eligible for enrolment

- acute coronary syndrome,
- chronic angina pectoris,
- or silent ischemia, angiographic lesions in native coronary arteries with a diameter of 2 mm to less than 3 mm.

randomisation was possible

predilatation of the lesion with an angioplasty balloon was successful—ie, if an acceptable angiographic result was obtained (no higher-grade dissections National Heart, Lung, and Blood Institute grade C to F, no decreased blood flow (thrombolysis in myocardial infarction score ≤2), or no residual stenosis >30%)

In summary, BASKET-SMALL 2 - first large randomised controlled trial testined the efficacy of a paclitaxel-iopromide-coated DCB versus second-generation DES in a large all-comer population regarding clinical endpoints. Study showed that DCB are non-inferior to DES in lesions of small native coronary arteries regarding MACE up to 12 months, with similar event rates for both groups.

BASKET-SMALL 2

ced balloons for small coronary artery disease
SMALL 2): an open-label randomised
iority trial

arah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Gregor Leibundgut, Daniel Weilenmann, ichter, Matthias Schreiber, Felix Mahfoud, Axel Linke, Frank-Peter Stephan, Christian Mueller, Peter Rickenbacher, ie Gilgen, Stefan Osswald, Christoph Kaiser, Bruno Scheller, for the BASKET-SMALL 2 Investigators

coated balloons (DCB) are a novel therapeutic strategy for small native coronary artery disease. ety and efficacy is poorly defined in comparison with drug-eluting stents (DES).

SMALL 2 was a multicentre, open-label, randomised non-inferiority trial. 758 patients with de- m in diameter) in coronary vessels and an indication for percutaneous coronary intervention were (1:1) to receive angioplasty with DCB versus implantation of a second-generation DES after tation via an interactive internet-based response system. Dual antiplatelet therapy was given nt guidelines. The primary objective was to show non-inferiority of DCB versus DES regarding rdiac events (MACE; ie, cardiac death, non-fatal myocardial infarction, and target-vessel fter 12 months. The non-inferiority margin was an absolute difference of 4% in MACE. This trial is nicalTrials.gov, number NCT01574534.

April 10, 2012, and February 1, 2017, 382 patients were randomly assigned to the DCB group and Non-inferiority of DCB versus DES was shown because the 95% CI of the absolute difference in rotocol population was below the predefined margin (−3·83 to 3·93%, p=0·0217). After 12 months, MACE were similar in both groups of the full-analysis population (MACE was 7·5% for the DCB the DES group; hazard ratio [HR] 0·97 [95% CI 0·58–1·64], p=0·9180). There were five (1·3%) hs in the DES group and 12 (3·1%) in the DCB group (full analysis population). Probable or definite three [0·8%] in the DCB group vs four [1·1%] in the DES group; HR 0·73 [0·16–3·26]) and major 1%] in the DCB group vs nine [2·4%] in the DES group; HR 0·45 [0·14–1·46]) were the most vents.

nall native coronary artery disease, DCB was non-inferior to DES regarding MACE up to 12 months, rates for both treatment groups.

rischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung, Basel Cardiovascular on, and B Braun Medical AG.

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drug-eluting stents (DES) are the nt for percutaneous coronary inter- coronary artery disease.[1] However, the restricted in small coronary arteries.[2] plies to bare metal stents (BMS)[3] and d second-generation DES.[4] ons (DCB) are a novel concept for the ary artery disease and an established for restenosis of BMS[5,6] and DES.[7,8] based on the fast delivery of highly the vessel wall after single balloon specific matrix.[9] To overcome the ic recoil and flow-limiting dissections oplasty, optimal lesion preparation is essential, as outlined in recommendations.[10] The feasibility of the technique in small-vessel coronary artery disease has been suggested in several pilot studies.[11,12]

However, to our knowledge, a large randomised trial comparing DCB with second-generation DES with clinical endpoints has not been done.

The Basel Kosten Effektivitäts Trial–Drug-Coated Balloons versus Drug-eluting Stents in Small Vessel Interventions (BASKET-SMALL) 2 trial aimed to test the non-inferiority of DCB versus second-generation DES in small vessel coronary artery disease using a 12-month composite clinical endpoint of major adverse cardiac events (MACE), consisting of cardiac death, non-fatal myocardial infarction, and target vessel revascularisation in a large all-comer population.

Published Online August 28, 2018 http://dx.doi.org/10.1016/S0140-6736(18)31719-7

See Online/Comment http://dx.doi.org/10.1016/S0140-6736(18)31826-3

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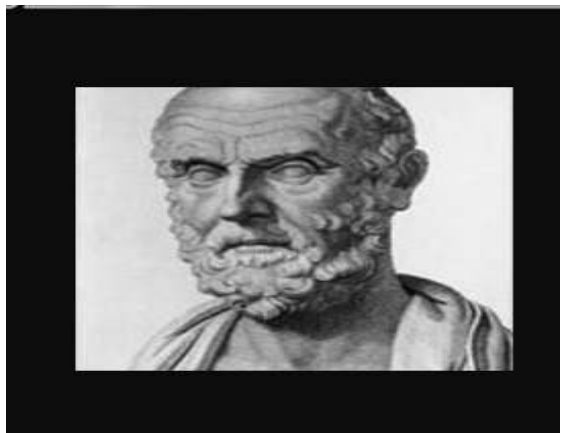
ished online August 28, 2018 http://dx.doi.org/10.1016/S0140-6736(18)31719-7

Conclusion

The Nature of The Problem

Life is short,art is long,opportunity fleeting,experience treacherous,judgment difficult..

- Hippocrates (460-400 B.C)



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