LUCCA – LUcerne Complex and CAlcified PCI Meeting 3.0

Morning session II – "Drug coated balloons in complex coronary lesions"

State of the art lecture: Less stents = better outcomes

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Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention

Mahesh V. Madhavan, MD,[1,2] Ajay J. Kirtane, MD, SM,[1,2] Björn Redfors, MD, PhD,[1,2] Philippe Généreux, MD,[3,4,5] Ori Ben-Yehuda, MD,[1,2] Tullio Palmerini, MD,[6] Umberto Benedetto, MD, PhD,[7] Giuseppe Biondi-Zoccai, MD, MSc,[8,9] Peter C. Smits, MD,[1] Clemens von Birgelen, MD, PhD,[1] Roxana Mehran, MD,[1,2] Thomas McAndrew, PhD,[1] Patrick W. Serruys, MD,[10] Martin B. Leon, MD,[1,2] Stuart J. Pocock, PhD,[1] Gregg W. Stone, MD[1,2]

TABLE 1 Baseline Clinical Characteristics by Stent Type

	All Patients (N = 25,032)	BMS (n = 3,758)	DES1 (n = 7,934)	DES2 (n = 13,380)
Age, yrs	62.7 ± 10.9	61.6 ± 10.8	62.4 ± 11.2	63.3 ± 10.7
Male	71.9 (17,984/25,027)	73.2 (2,759/3,715)	72.2 (5,728/7,933)	71.3 (9,537/13,379)
White	92.9 (13,603/14,644)	93.7 (2,376/2,537)	93.9 (5,647/5,822)	91.6 (5,760/6,285)
BMI, kg/m²	28.9 ± 5.3	28.6 ± 5.2	29.1 ± 5.5	28.9 ± 5.3
Diabetes mellitus	23.6 (5,907/25,013)	22.7 (844/3,712)	23.4 (1,857/7,927)	24.0 (3,206/13,374)
Insulin-treated	6.8 (1,699/25,013)	6.8 (253/3,712)	6.4 (509/7,927)	7.0 (937/13,374)
Recent smoker	27.6 (6,822/24,753)	30.0 (1,105/3,681)	30.6 (2,398/7,835)	25.1 (3,319/13,241)
Hypertension	64.2 (16,035/24,993)	64.4 (2,382/3,701)	64.4 (5,102/7,921)	64.0 (8,551/13,371)
Hyperlipidemia	64.6 (16,041/24,846)	65.9 (2,432/3,692)	62.6 (4,934/7,885)	65.4 (8,875/13,269)
Prior MI	23.0 (5,701/24,824)	29.6 (1,093/3,706)	20.3 (1,598/7,868)	22.7 (3,006/13,250)
Prior PCI	19.4 (4,835/24,932)	20.9 (775/3,706)	18.1 (1,433/7,903)	19.7 (2,627/13,323)
Prior CABG	6.9 (1,720/25,022)	6.7 (250/3,775)	6.1 (480/7,932)	7.4 (990/13,375)
LVEF, %	57.6 ± 11.0	57.1 ± 11.2	57.1 ± 11.3	58.8 ± 10.3
<40%	5.6 (561/10,100)	6.1 (168/2,755)	6.7 (289/4,355)	3.5 (104/3,010)
Clinical presentation				
ACS	52.6 (12,128/23,054)	54.9 (1,847/3,367)	62.2 (4,510/7,255)	46.4 (5,771/12,432)
STEMI	17.6 (4,391/25,029)	20.1 (749/3,718)	31.1 (2,469/7,931)	8.8 (1,179/13,380)
NSTEMI	8.0 (2,003/25,029)	0.0 (0/3,718)	3.0 (235/7,931)	13.2 (1,768/13,380)
Unstable angina	24.8 (5,728/23,054)	32.6 (1,098/3,367)	24.9 (1,806/7,255)	22.7 (2,824/12,432)
SIHD	47.4 (10,926/23,054)	45.1 (1,520/3,367)	37.8 (2,745/7,255)	53.6 (6,661/12,432)

J Am Coll Cardiol 2020;75:590–604

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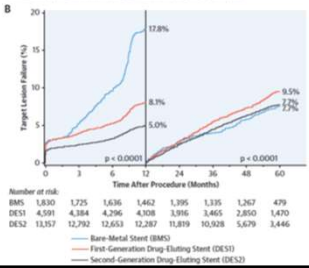
Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention



J Am Coll Cardiol 2020;75:590–604

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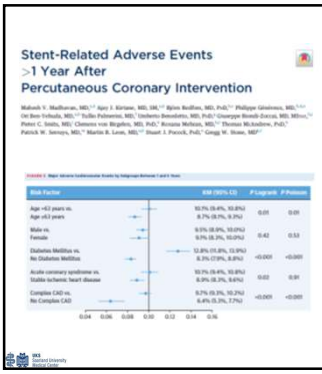
Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention

Mahesh V. Madhavan, MD,[1,2] Ajay J. Kirtane, MD, SM,[1,2] Björn Redfors, MD, PhD,[1,2] Philippe Généreux, MD,[3,4,5] Ori Ben-Yehuda, MD,[1,2] Tullio Palmerini, MD,[6] Umberto Benedetto, MD, PhD,[7] Giuseppe Biondi-Zoccai, MD, MSc,[8,9] Peter C. Smits, MD,[1] Clemens von Birgelen, MD, PhD,[1] Roxana Mehran, MD,[1,2] Thomas McAndrew, PhD,[1] Patrick W. Serruys, MD,[10] Martin B. Leon, MD,[1,2] Stuart J. Pocock, PhD,[1] Gregg W. Stone, MD[1,2]



J Am Coll Cardiol 2020;75:590–604

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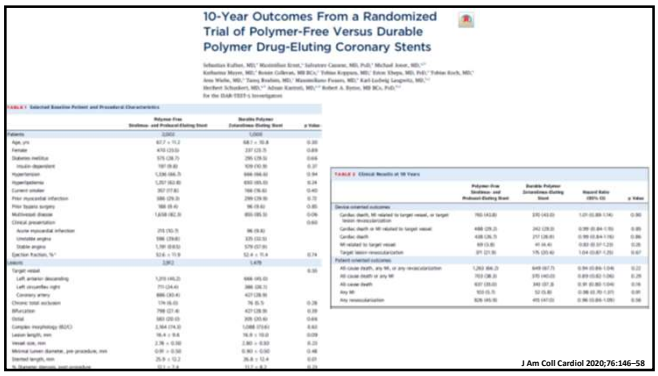
10-Year Outcomes From a Randomized Trial of Polymer-Free Versus Durable Polymer Drug-Eluting Coronary Stents

J Am Coll Cardiol 2020;76:146–58

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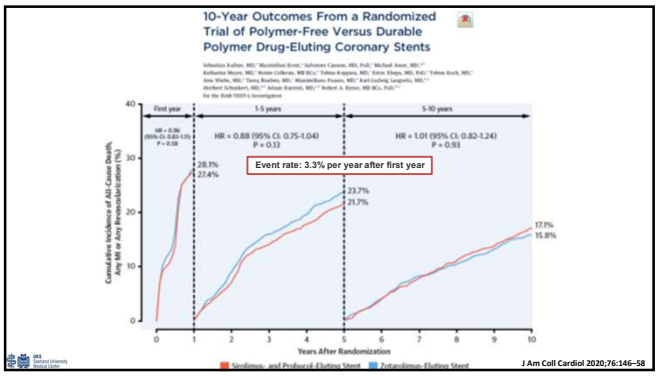

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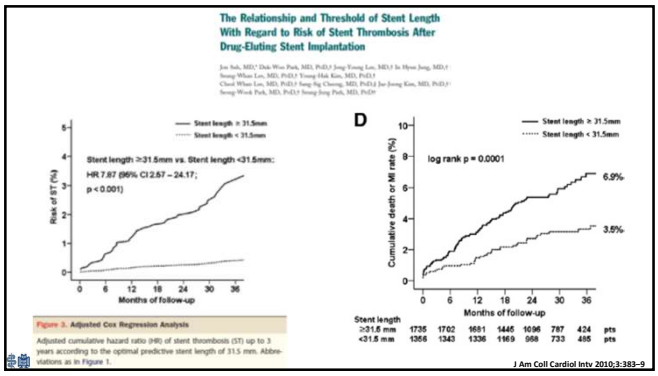
The Relationship and Threshold of Stent Length With Regard to Risk of Stent Thrombosis After Drug-Eluting Stent Implantation

J Am Coll Cardiol Intv 2010;3:383–9

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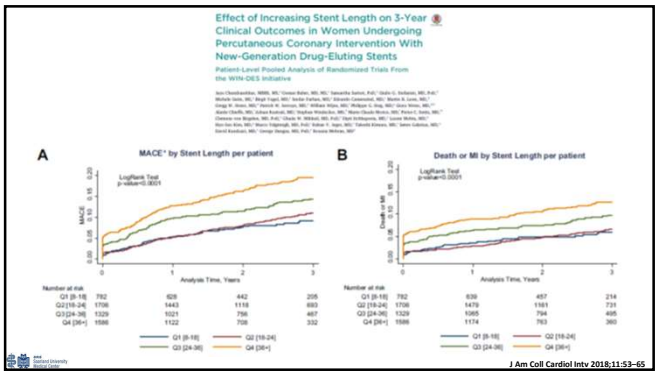

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Percutaneous coronary intervention 1

Coronary balloon angioplasty, stents, and scaffolds

Robert A Byrne, Gregg W Stone, John Ormiston, Adnan Kastrati

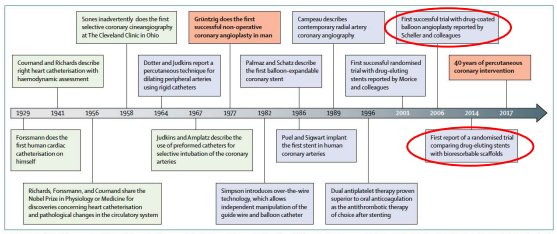

Figure 1: Timeline of diagnostic cardiac catheterisation, coronary balloon angioplasty, stent, and scaffold implantation as contributors to improvements in freedom from cardiovascular death
Developments in diagnostic catheterisation are shown in green, coronary angioplasty in red, and catheter therapeutics in blue. References to support milestones are provided in the appendix.

Lancet 2017; 390: 781–92

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EuroIntervention — a SPECIAL TRIBUTE TO THE 40 YEARS OF ANGIOPLASTY

State of the art: balloon catheter technologies – drug-coated balloon

Figure 4. *Prototype drug-coated balloon catheters (ca. 2001) and clinical samples for the first-in-man trial (2003).*

Alfonso F., Scheller B. EuroIntervention 2017;13:680-695

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2018 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS)

Restenosis		
DES are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	IIa	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	IIa	C

restenosis (see section 13.4). In terms of the use of DCB angioplasty for *de novo* disease, a number of small randomized trials have been reported with somewhat conflicting results.[599–601] At present, there are no convincing data to support the use of DCB angioplasty for this indication.

Neumann, European Heart Journal 2018

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FEATURED EDITORIAL

Prevention of restenosis: is angioplasty the answer?

Bruno Scheller, Ulrich Speck, Michael Böhm

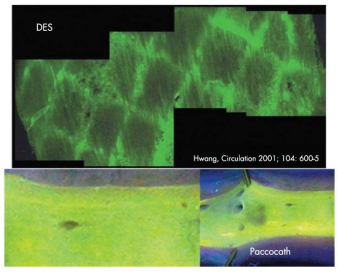

Figure 1 Inhomogeneous drug distribution from luminal surface after implantation of a drug-eluting stent (DES) (reprinted with permission from Hwang CW, Wu D, Edelman ER. Physiological transport forces govern drug distribution for stent-based delivery. *Circulation* 2001;104:600–5).[1] Homogeneous drug distribution from luminal surface after an inflation of 60 s with a drug-coated balloon (porcine coronary artery, experiments done by Nicola Kaufels, Berlin, Germany).

Heart 2007; 93: 539-41

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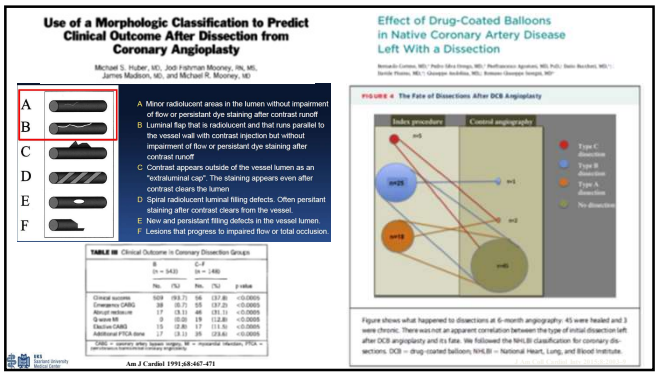
Use of a Morphologic Classification to Predict Clinical Outcome After Dissection from Coronary Angioplasty
A Minor radiolucent areas in the lumen without impairment of flow or persistant dye staining after contrast runoff
B Luminal flap that is radiolucent and that runs parallel to the vessel wall with contrast injection but without impairment of flow or persistant dye staining after contrast runoff
C Contrast appears outside of the vessel lumen as an "extraluminal cap". The staining appears even after contrast clears the lumen
D Spiral radiolucent luminal filling defects. Often persitant staining after contrast clears from the vessel.
E New and persistant filling defects in the vessel lumen.
F Lesions that progress to impaired flow or total occlusion.
Am J Cardiol 1991;68:467-471
Effect of Drug-Coated Balloons in Native Coronary Artery Disease Left With a Dissection
FIGURE 4 The Fate of Dissections After DCB Angioplasty
Index procedure
Control angiography
Type C dissection
Type B dissection
Type A dissection
No dissection
Figure shows what happened to dissections at 6-month angiography: 45 were healed and 3 were chronic. There was not an apparent correlation between the type of initial dissection left after DCB angioplasty and its fate. We followed the NHLBI classification for coronary dissections. DCB = drug-coated balloon; NHLBI = National Heart, Lung, and Blood Institute.

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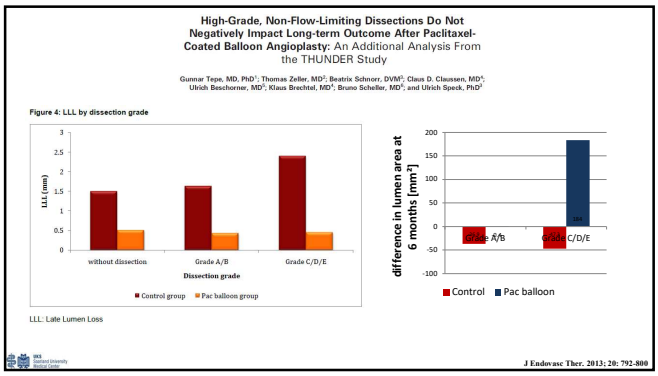
High-Grade, Non-Flow-Limiting Dissections Do Not Negatively Impact Long-term Outcome After Paclitaxel-Coated Balloon Angioplasty: An Additional Analysis From the THUNDER Study
Figure 4: LLL by dissection grade
LLL (mm)
without dissection
Grade A/B
Grade C/D/E
Dissection grade
Control group
Pac balloon group
difference in lumen area at 6 months [mm²]
Control
Pac balloon
LLL: Late Lumen Loss
J Endovasc Ther. 2013; 20: 792-800

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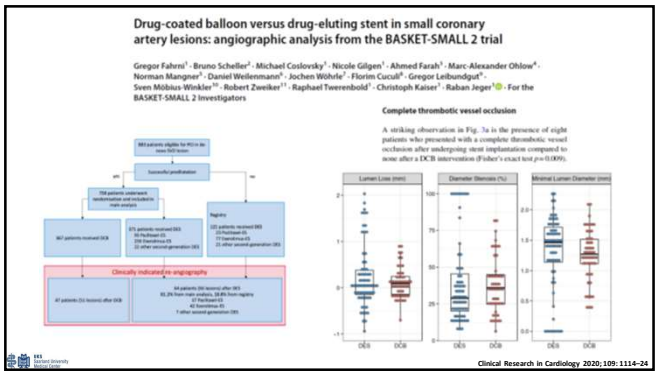
Drug-coated balloon versus drug-eluting stent in small coronary artery lesions: angiographic analysis from the BASKET-SMALL 2 trial
Complete thrombotic vessel occlusion
Clinical Research in Cardiology 2020;109:1114–24

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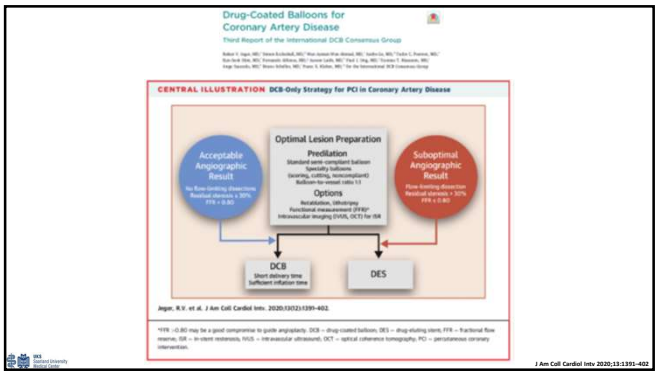
Drug-Coated Balloons for Coronary Artery Disease
Third Report of the International DCB Consensus Group
CENTRAL ILLUSTRATION DCB-Only Strategy for PCI in Coronary Artery Disease
Acceptable Angiographic Result
Optimal Lesion Preparation
Predilation
Options
Suboptimal Angiographic Result
DCB
DES
Jeger, R.V. et al. J Am Coll Cardiol Intv. 2020;13(12):1391-402.
J Am Coll Cardiol Intv 2020;13:1391-402

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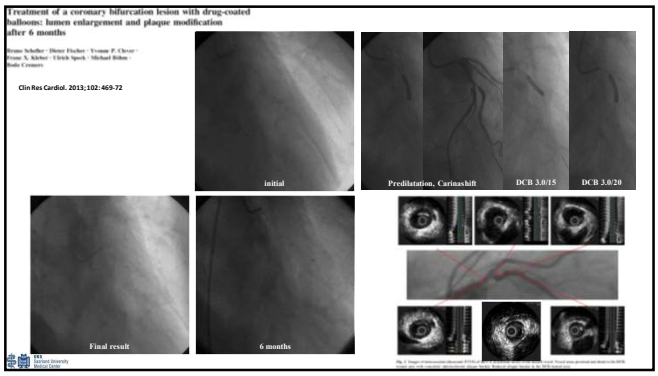
Treatment of a coronary bifurcation lesion with drug-coated balloons: lumen enlargement and plaque modification after 6 months
Clin Res Cardiol. 2013;102:469-72
initial
Predilatation, Carinashift
DCB 3.0/15
DCB 3.0/20
Final result
6 months

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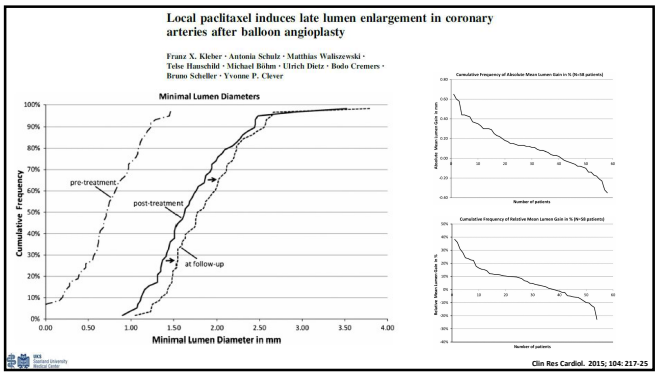
Local paclitaxel induces late lumen enlargement in coronary arteries after balloon angioplasty
Minimal Lumen Diameters
pre-treatment
post-treatment
at follow-up
Cumulative Frequency
Minimal Lumen Diameter in mm
Clin Res Cardiol. 2015; 104: 217-25

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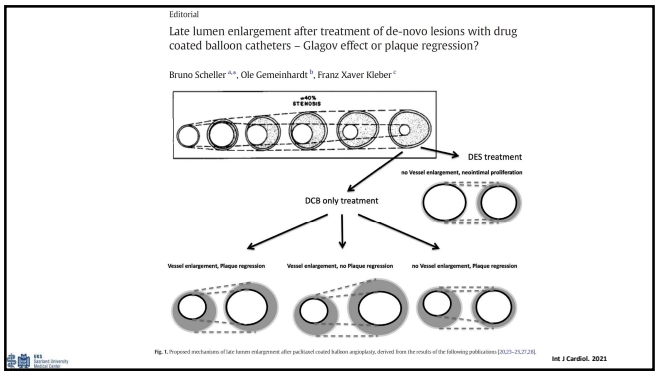
Editorial
Late lumen enlargement after treatment of de-novo lesions with drug coated balloon catheters – Glagov effect or plaque regression?
Bruno Scheller
≥40% STENOSIS
DES treatment
no Vessel enlargement, neointimal proliferation
DCB only treatment
Vessel enlargement, Plaque regression
Vessel enlargement, no Plaque regression
no Vessel enlargement, Plaque regression
Int J Cardiol. 2021

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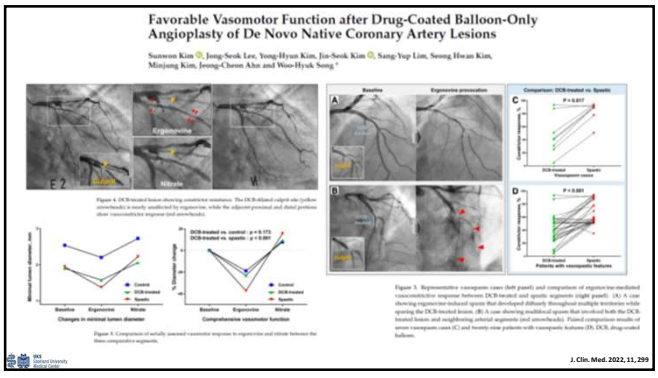
Favorable Vasomotor Function after Drug-Coated Balloon-Only Angioplasty of De Novo Native Coronary Artery Lesions
Sunwon Kim, Jong-Seok Lee, Yong-Hyun Kim, Jin-Seok Kim, Sang-Yup Lim, Seung Hwan Kim, Minjung Kim, Jeong-Cheon Ahn and Woo-Hyuk Song
Baseline
Ergonovine provocation
Nitrate
J. Clin. Med. 2022, 11, 299

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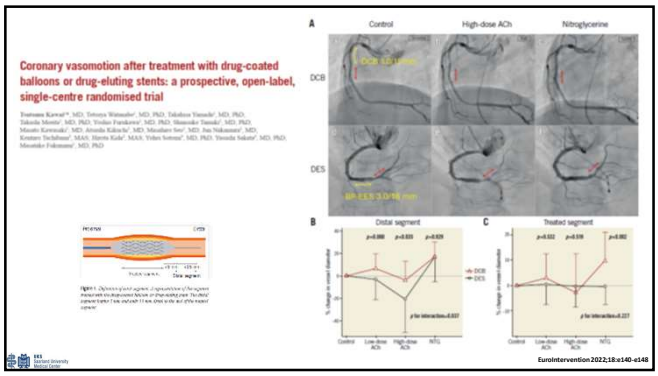
Coronary vasomotion after treatment with drug-coated balloons or drug-eluting stents: a prospective, open-label, single-centre randomised trial
A
Control
High-dose ACh
Nitroglycerine
DCB
DES
B
Distal segment
C
Treated segment
EuroIntervention 2022;18:e140-e148

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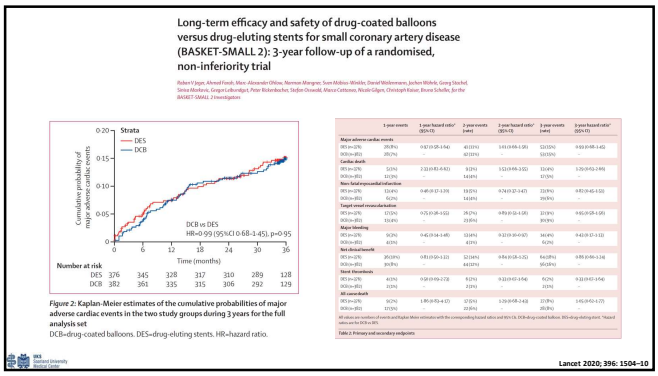
Long-term efficacy and safety of drug-coated balloons versus drug-eluting stents for small coronary artery disease (BASKET-SMALL 2): 3-year follow-up of a randomised, non-inferiority trial
Strata
DES
DCB
Cumulative probability of major adverse cardiac events
DCB vs DES
HR=0·99 (95%CI 0·68-1·45), p=0·95
Time (months)
Number at risk
DES 376 345 328 317 310 289 128
DCB 382 361 335 315 306 292 129
Lancet 2020; 396: 1504–10

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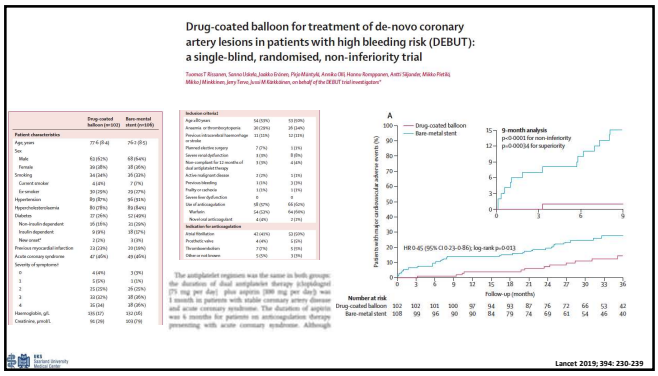
Drug-coated balloon for treatment of de-novo coronary artery lesions in patients with high bleeding risk (DEBUT): a single-blind, randomised, non-inferiority trial
Drug-coated balloon
Bare-metal stent
9 month analysis
p<0·0001 for non-inferiority
p=0·0003 for superiority
HR 0·45 (95% CI 0·23–0·86); log-rank p=0·013
Follow-up (months)
Number at risk
Drug-coated balloon 102 102 101 100 97 94 93 87 76 72 66 53 42
Bare-metal stent 108 99 96 90 90 84 79 74 69 61 54 46 40
Lancet 2019; 394: 230-239

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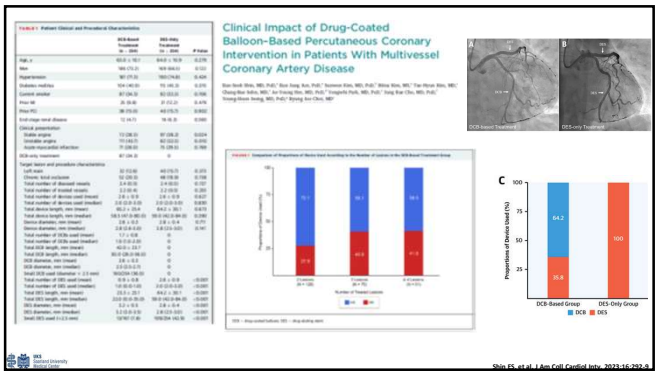
Clinical Impact of Drug-Coated Balloon-Based Percutaneous Coronary Intervention in Patients With Multivessel Coronary Artery Disease
DCB-based Treatment
DES-only Treatment
DCB-Based Group
DES-Only Group
Shin ES, et al. J Am Coll Cardiol Intv. 2023;16:292-9.

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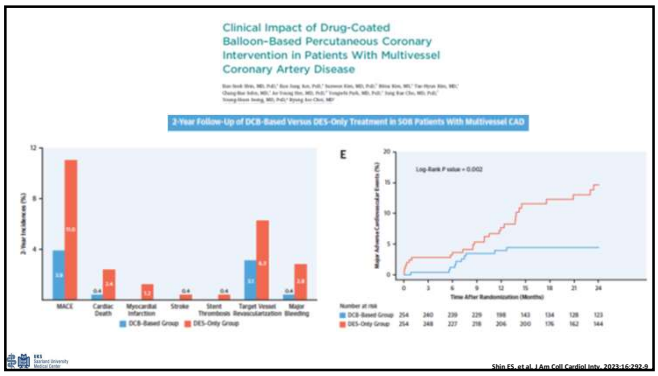

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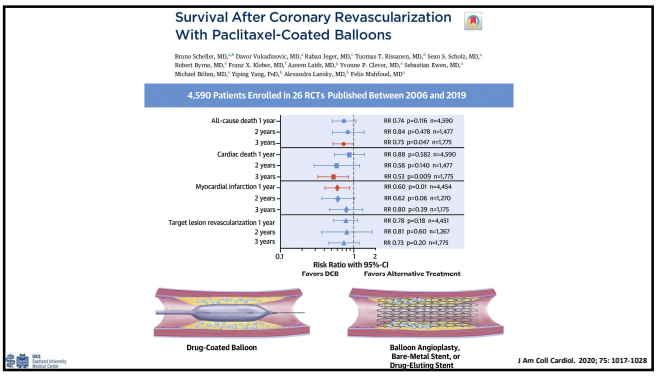

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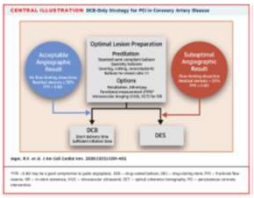
Use of Drug Coated Balloons in the Coronary Arteries

- Stent-related events 2-3% per year
- DCB-only strategy to reduce number and length of stents
- Lesion preparation is the first and most important step of the procedure
- Careful lesion preparation improves outcomes of DCB and DES
- Decision between DCB and DES per lesion after preparation
- DCBonly if diameter stenosis < 30% and absence of flow-limiting dissection, otherwise DES
- Benefits: late lumen enlargement, vasomotion, no stent-related complications



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