

BASKET-SMALL 2: DCB vs. DES for Small CAD

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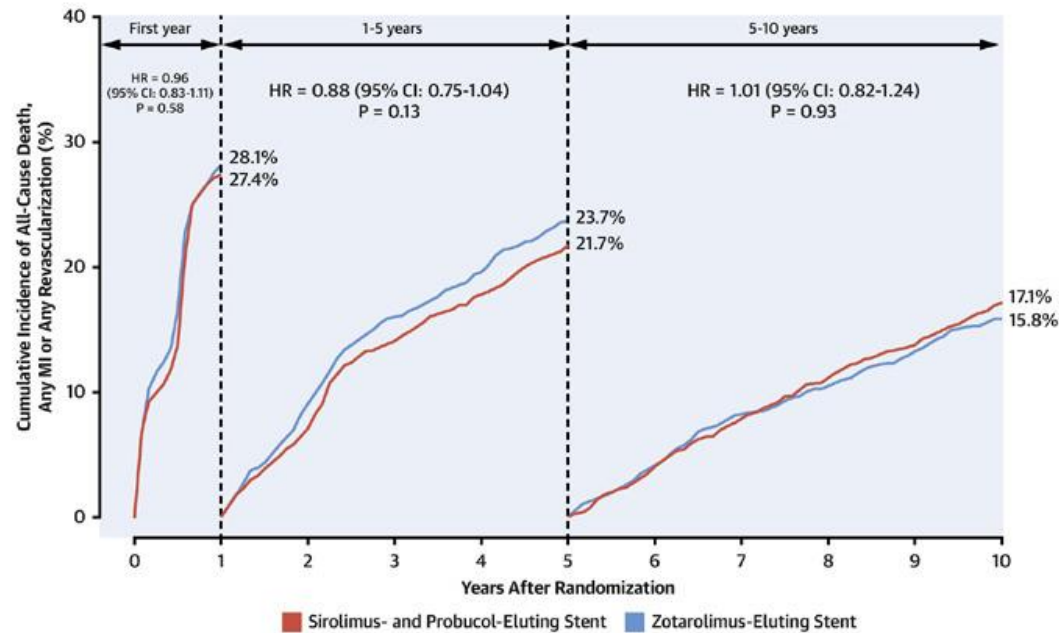
Disclosure

- **Bruno Scheller, MD**
- Shareholder: InnoRa GmbH, Berlin, Germany
- Lecture fees and consulting honoraria: B.Braun, Medtronic

Unmet Clinical Needs in the Era of Drug Eluting Stents

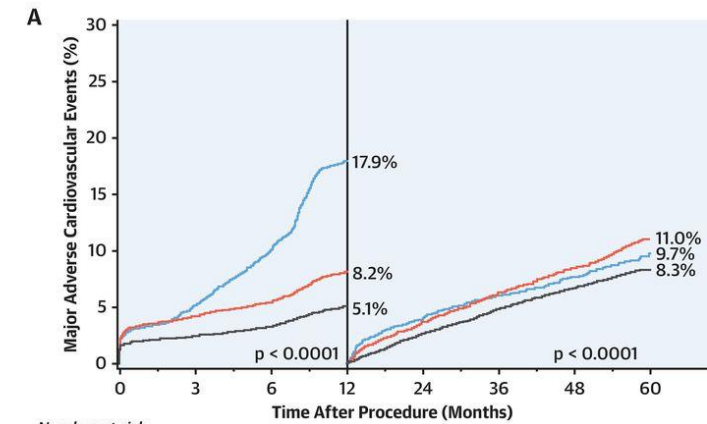
Event rate: 3.3% per year after first year

CENTRAL ILLUSTRATION: Landmark Analysis, Patient-Oriented Outcomes According to Treatment Groups



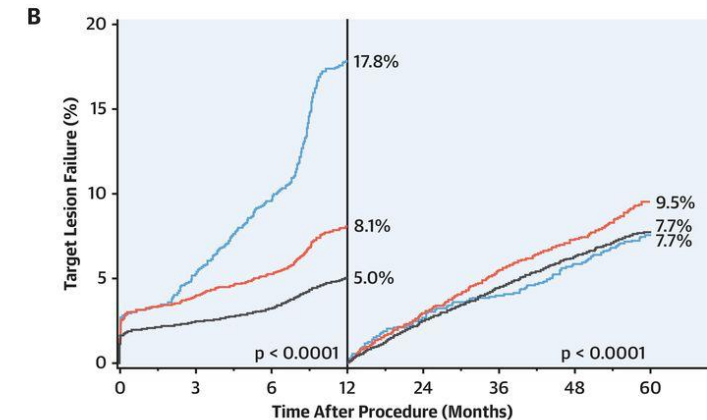
Kufner, S. et al. J Am Coll Cardiol. 2020;76(2):146-58.

CENTRAL ILLUSTRATION: Very-Late Stent-Related Cardiovascular Events



Number at risk:

	0	3	6	12	24	36	48	60
BMS	3,718	3,506	3,309	2,984	2,811	2,497	2,029	746
DES1	7,934	7,543	7,403	7,112	6,707	5,595	3,688	1,757
DES2	13,380	13,003	12,853	12,502	11,998	11,080	5,848	3,523



Number at risk:

	0	3	6	12	24	36	48	60
BMS	1,830	1,725	1,636	1,462	1,395	1,335	1,267	479
DES1	4,591	4,384	4,296	4,108	3,916	3,465	2,850	1,470
DES2	13,157	12,792	12,653	12,287	11,819	10,928	5,679	3,446

— Bare-Metal Stent (BMS)
— First-Generation Drug-Eluting Stent (DES1)
— Second-Generation Drug-Eluting Stent (DES2)

Madhavan, M.V. et al. J Am Coll Cardiol. 2020;75(6):590-604.

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



Mahesh V. Madhavan, MD,^{a,b} Ajay J. Kirtane, MD, SM,^{a,b} Björn Redfors, MD, PhD,^{b,c} Philippe Généreux, MD,^{b,d,e} Ori Ben-Yehuda, MD,^{a,b} Tullio Palmerini, MD,^f Umberto Benedetto, MD, PhD,^g Giuseppe Biondi-Zoccai, MD, MSTAT,^{h,i} Pieter C. Smits, MD,^j Clemens von Birgelen, MD, PhD,^k Roxana Mehran, MD,^{b,l} Thomas McAndrew, PhD,^b Patrick W. Serruys, MD,^m Martin B. Leon, MD,^{a,b} Stuart J. Pocock, PhD,ⁿ Gregg W. Stone, MD^{b,l}

FIGURE 3 Major Adverse Cardiovascular Events by Subgroups Between 1 and 5 Years

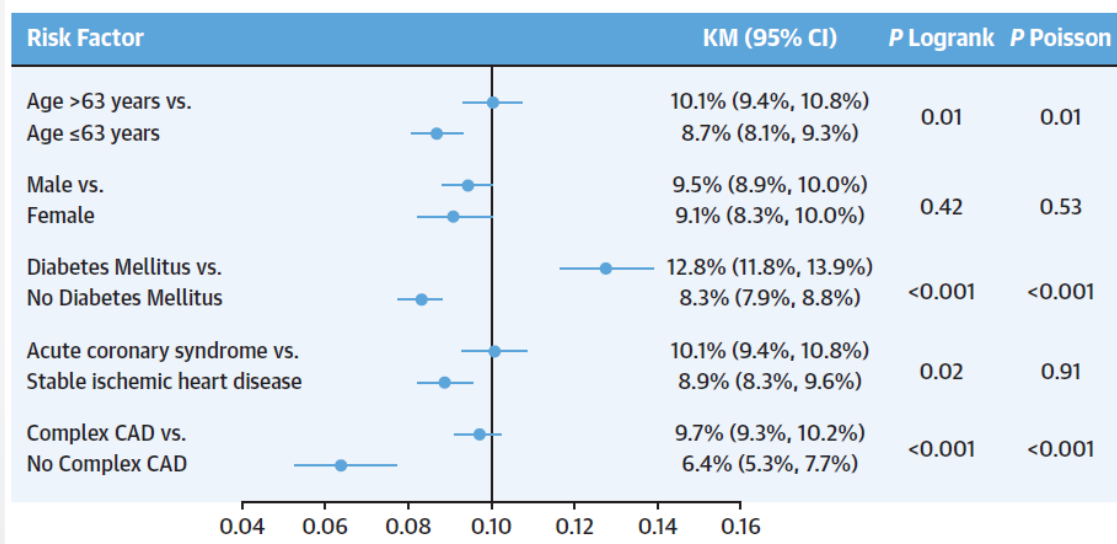


TABLE 6 Multivariable Predictors of Adverse Outcomes by Poisson Regression Analysis

	Major Adverse Cardiovascular Events		Target Lesion Failure		Stent Thrombosis	
	RR (95% CI)	p Value	RR (95% CI)	p Value	RR (95% CI)	p Value
Through 1 yr						
DES1 (vs. BMS)	0.50 (0.43-0.59)	<0.0001	0.56 (0.45-0.67)	<0.0001	0.83 (0.56-1.26)	0.43
DES1 (vs. DES2)	1.35 (1.09-1.67)	0.006	1.32 (1.05-1.64)	0.02	1.37 (0.71-2.50)	0.32
Age (per 5 yrs)	1.00 (0.99-1.10)	0.16	1.00 (0.97-1.00)	0.76	0.94 (0.87-1.00)	0.12
Male	0.85 (0.76-0.96)	0.007	0.84 (0.73-0.97)	0.02	0.81 (0.58-1.10)	0.23
Diabetes mellitus	1.40 (1.30-1.60)	<0.0001	1.40 (1.20-1.60)	<0.0001	1.80 (1.30-2.50)	0.0006
Recent smoker	1.10 (0.95-1.20)	0.21	1.00 (0.86-1.20)	0.82	1.70 (1.20-2.40)	0.003
ACS (vs. stable presentation)	1.10 (0.94-1.20)	0.38	0.95 (0.82-1.10)	0.44	0.93 (0.62-1.40)	0.72
Hypertension	1.20 (1.10-1.40)	0.002	1.30 (1.10-1.50)	0.003	1.10 (0.81-1.60)	0.49
Hyperlipidemia	0.95 (0.85-1.10)	0.43	0.93 (0.81-1.10)	0.37	0.90 (0.65-1.30)	0.53
Prior CABG	1.40 (1.20-1.70)	0.0002	1.50 (1.20-1.80)	0.0003	1.00 (0.54-1.90)	0.95
Prior myocardial infarction	1.00 (0.91-1.20)	0.65	0.99 (0.85-1.20)	0.94	1.60 (1.10-2.40)	0.009
Prior PCI	1.00 (0.90-1.20)	0.68	1.00 (0.86-1.20)	0.91	1.40 (0.91-2.00)	0.14
Moderate-severe calcium LM or LAD disease	1.20 (1.00-1.30)	0.01	1.10 (0.98-1.30)	0.09	1.50 (1.10-2.10)	0.008
>1 treated lesion	1.70 (1.40-2.00)	<0.0001	1.60 (1.30-1.90)	<0.0001	2.30 (1.60-3.40)	<0.0001
Baseline RVD (per 1 mm)	0.75 (0.67-0.83)	<0.0001	0.76 (0.67-0.87)	<0.0001	0.92 (0.69-1.20)	0.57
Pre-procedure DS (per 5%)	1.00 (0.98-1.00)	0.77	1.00 (0.97-1.00)	0.99	1.00 (0.96-1.10)	0.54
Lesion length (per 10 mm)	1.20 (1.10-1.30)	<0.0001	1.20 (1.10-1.30)	<0.0001	1.20 (1.10-1.40)	0.003
Between 1 and 5 yrs						
DES1 (vs. BMS)	1.00 (0.83-1.19)	0.95	1.16 (0.91-1.54)	0.30	2.38 (1.30-4.35)	0.005
DES1 (vs. DES2)	1.30 (1.09-1.56)	0.004	1.25 (1.04-1.51)	0.02	1.96 (1.20-3.22)	0.007
Age (per 5 yrs)	1.00 (1.00-1.10)	0.01	1.10 (1.00-1.10)	0.005	0.92 (0.85-1.00)	0.04
Male	1.10 (0.97-1.20)	0.14	1.10 (0.92-1.20)	0.42	1.40 (0.94-2.10)	0.10
Diabetes mellitus	1.50 (1.30-1.60)	<0.0001	1.50 (1.30-1.70)	<0.0001	1.20 (0.85-1.80)	0.29
Recent smoker	1.40 (1.30-1.60)	<0.0001	1.40 (1.20-1.70)	<0.0001	1.50 (1.10-2.10)	0.02
ACS (vs. stable presentation)	0.99 (0.88-1.10)	0.84	1.10 (0.92-1.20)	0.42	1.10 (0.77-1.60)	0.59
Hypertension	1.10 (0.97-1.20)	0.17	1.00 (0.89-1.20)	0.69	1.10 (0.75-1.50)	0.78
Hyperlipidemia	0.92 (0.82-1.00)	0.18	0.92 (0.80-1.10)	0.27	1.00 (0.72-1.40)	0.98
Previous CABG	1.90 (1.60-2.30)	<0.0001	2.00 (1.70-2.40)	<0.001	1.30 (0.75-2.40)	0.33
Previous myocardial infarction	1.20 (1.00-1.30)	0.04	1.00 (0.89-1.20)	0.62	1.30 (0.92-2.00)	0.13
Previous PCI	1.30 (1.10-1.50)	<0.0001	1.30 (1.10-1.50)	0.004	1.50 (1.00-2.20)	0.04
Moderate-severe calcium LM or LAD disease	1.10 (0.99-1.30)	0.06	1.20 (1.00-1.30)	0.03	1.10 (0.79-1.60)	0.55
>1 treated lesion	1.30 (1.10-1.50)	0.0008	1.30 (1.10-1.60)	0.001	1.20 (0.80-1.80)	0.38
Baseline RVD (per 1 mm)	0.79 (0.71-0.88)	<0.0001	0.70 (0.62-0.80)	<0.0001	0.81 (0.60-1.10)	0.16
Pre-procedure DS (per 5%)	0.98 (0.96-1.00)	0.07	0.98 (0.96-1.00)	0.21	1.00 (0.95-1.0)	0.88
Lesion length (per 10 mm)	1.10 (1.00-1.10)	0.005	1.10 (0.99-1.10)	0.11	1.20 (1.10-1.30)	0.006

PCI in small vessels: the case for a drug-coated balloon based intervention

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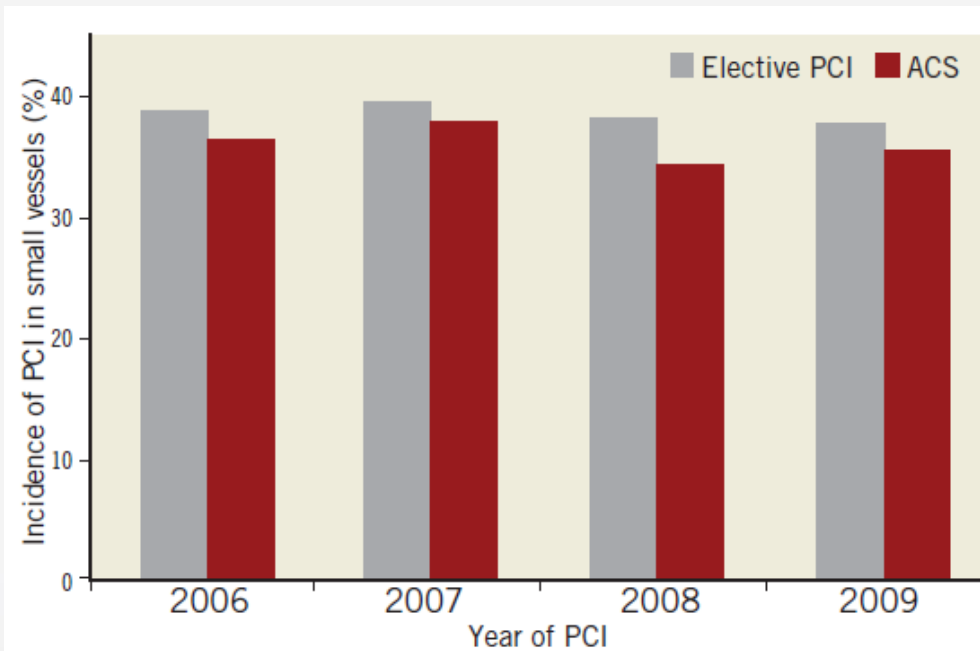


Figure 1. Incidence of PCI in vessels of <2.8 mm in patients with stable coronary artery disease and patients with acute coronary syndromes in the German ALKK-PCI registry.

Drug-coated balloons for de novo lesions in small coronary arteries: rationale and design of BASKET-SMALL 2


Nicole Gilgen¹ | Ahmed Farah² | Bruno Scheller³ | Marc-Alexander Ohlow⁴ | Norman Mangner⁵ | Daniel Weilenmann⁶ | Jochen Wöhrle⁷ | Peiman Jamshidi⁸ | Gregor Leibundgut⁹ | Sven Möbius-Winkler¹⁰ | Robert Zweiker¹¹ | Florian Krackhardt¹² | Christian Butter¹³ | Leonhard Bruch¹⁴ | Christoph Kaiser¹ | Andreas Hoffmann¹ | Peter Rickenbacher¹ | Christian Mueller¹ | Frank-Peter Stephan¹ | Michael Coslovsky¹ | Raban Jeger¹  | for the BASKET-SMALL 2 Investigators

TABLE 1 Key features of devices used

Comparator	Drug-Coated Balloon	Drug-Eluting Stent	
Device	Paclitaxel-coated balloon	Paclitaxel-eluting stent	Everolimus-eluting stent
Trade name	SeQuent Please (B. Braun Melsungen AG, Berlin, Germany)	TAXUS Element (Boston Scientific Corporation, Natick, MA)	Xience (Abbott Vascular, Santa Clara, CA), Promus (Xience distributed by Boston Scientific)
Platform	Polymer-free balloon	Platinum-chromium alloy	Cobalt-chromium alloy
Drug	Paclitaxel (3 µg/mm ²)	Paclitaxel (1 µg/mm ²)	Everolimus
Mode of action	Inhibition of M-phase	Inhibition of M-phase	Inhibition of G ₁ -phase
Matrix/polymer	Iopromide	Permanent polymer (poly[styrene-b- isobutylene-b-styrene])	Permanent polymer (poly[vinylidene fluoride-co-hexafluoropropylene])
Drug application	Single shot	Slow release	Slow release
Drug distribution	Homogenous	Strut-based inhomogenous	Strut-based inhomogenous

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

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

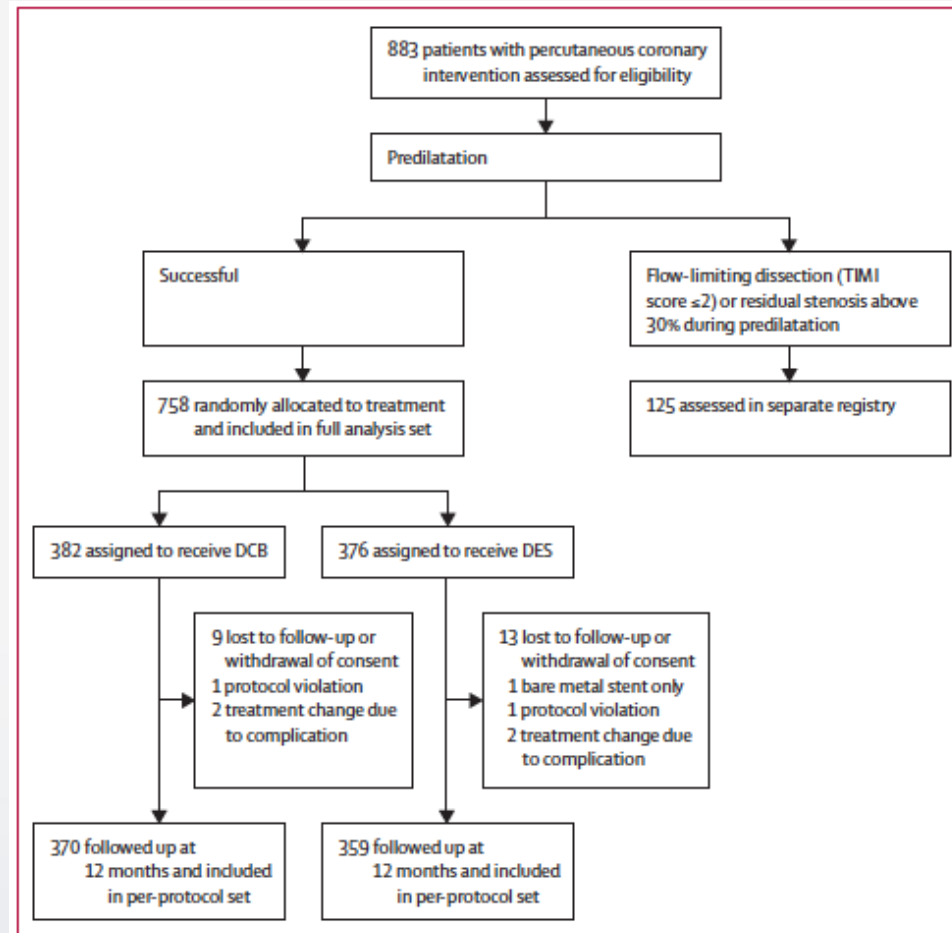


Figure 1: Trial profile
TIMI=thrombolysis in myocardial infarction. DCB=drug-coated balloons. DES=drug-eluting stents.

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

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

	Drug-coated balloon (n=382)	Drug-eluting stent (n=376)
Mean age, years	67.2 (10.3)	68.4 (10.3)
Sex		
Male	295 (77%)	262 (70%)
Female	87 (23%)	114 (30%)
Mean body-mass index	28.4 (4.5)	28.2 (4.6)
Smoking status*		
Current smoker	82 (22%)	72 (20%)
Former smoker	144 (39%)	123 (34%)
No smoker	148 (40%)	172 (47%)
Hypercholesterolaemia†	262 (69%)	259 (70%)
Arterial hypertension‡	324 (85%)	332 (89%)
Family history of CAD	150 (43%)	128 (38%)
Diabetes§		
Insulin dependent	48 (13%)	47 (13%)
Non-insulin dependent	74 (19%)	83 (22%)
No diabetes	259 (68%)	243 (65%)
Previous myocardial infarction	160 (42%)	133 (35%)
Previous PCI	235 (62%)	241 (64%)
Previous CABG	37 (10%)	34 (9%)

	Drug-coated balloon (n=382)	Drug-eluting stent (n=376)
Cerebrovascular insult¶		
No	352 (92%)	339 (90%)
Stroke	16 (4%)	23 (6%)
Transient ischaemic attack	13 (3%)	14 (4%)
PAOD	27 (7%)	26 (7%)
COPD	28 (7%)	36 (9%)
Renal failure	54 (14%)	59 (16%)
Presentation		
STEMI	11 (3%)	4 (1%)
NSTEMI	53 (14%)	56 (15%)
Unstable angina	48 (13%)	42 (11%)
Stable angina	270 (70%)	274 (73%)
Oral anticoagulation	33 (9%)	31 (8%)
LVEF, median (IQR)	60% (50–60)	60% (55–65)

Data are n (%) or mean (SD) unless otherwise stated. CAD=coronary artery disease. PCI=percutaneous coronary intervention. CABG=coronary artery bypass graft. PAOD=peripheral arterial occlusive disease. COPD=chronic obstructive pulmonary disease. STEMI=ST-elevation myocardial infarction. NSTEMI=non-ST-elevation myocardial infarction. LVEF=left ventricular ejection fraction. *Data were only available for 374 participants in the drug-coated balloon group and 367 in the drug-eluting stent group. †Data were only available for 381 in the drug-coated balloon group and 370 in the drug-eluting stent group. ‡Data were only available for 374 in the drug-eluting stent group. §Data were only available for 381 in the drug-coated balloon group and 373 in the drug-eluting stent group. ¶Data were only available for 381 in the drug-coated balloon group.

Table 1: Baseline characteristics

	Drug-coated balloon	Drug-eluting stent
Target vessel		
Left anterior descending artery	128 (34%)	116 (31%)
Left circumflex artery	179 (47%)	183 (49%)
Right coronary artery	75 (20%)	77 (20%)
Multivessel disease	313 (82%)	285 (76%)
Bifurcation lesion	22 (6%)	29 (8%)
Mean procedural success, n (SD)	96% (19)	98 (13)
Mean number of DCB or DES, n (SD)	1.68 (0.82)	1.26 (0.55)
Mean length of DCB or DES, mm (SD)	23.93 (11.74)	23.18 (12.85)
Mean effective size of DCB or DES, mm (SD)	2.75 (2.14)	2.57 (0.25)
Mean inflation pressure, atm (SD)	11.06 (3.54)	13.58 (3.90)
Mean duration of inflation, sec (SD)	48.45 (28.24)	23.36 (18.92)
Compliant balloon for predilatation	282 (73%)	276 (74%)

Data are n (%) or mean (SD). DCB=drug-coated balloons. DES=drug-eluting stents.

Table 2: Angiographic data

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

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

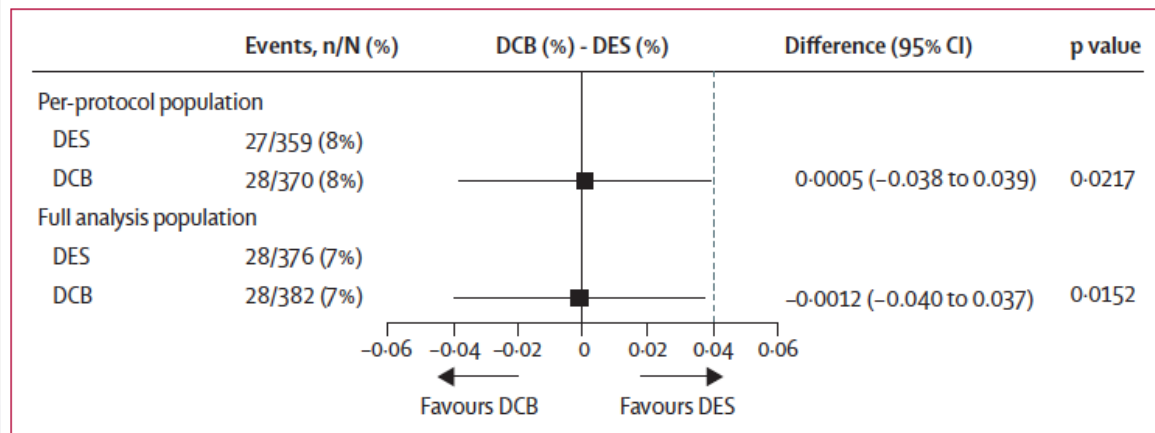


Figure 2: Major adverse cardiac events by study group

Data are absolute difference in event rates between the DCB and DES groups. The p-value tests whether the absolute difference in rates is equal to the pre-defined non-inferiority margin (0.04). DCB=drug-coated balloons. DES=drug-eluting stents.

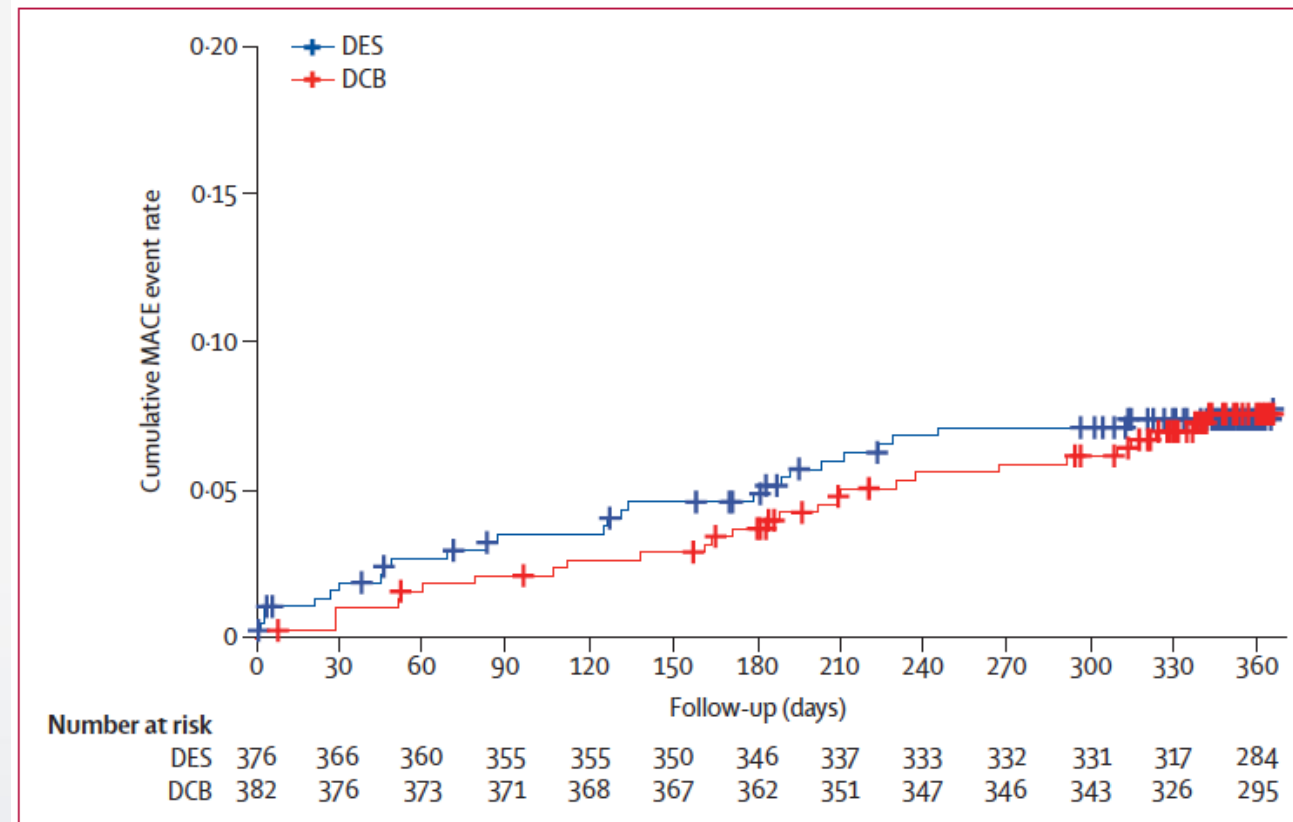


Figure 3: Cumulative incidence rates for MACE

Full analysis population. MACE=major adverse cardiac events. DCB=drug-coated balloons. DES=drug-eluting stents.

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

Raban V Jeger, Ahmed Farah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Daniel Weilenmann, Jochen Wöhrle, Georg Stachel, Sinisa Markovic, Gregor Leibundgut, Peter Rickenbacher, Stefan Osswald, Marco Cattaneo, Nicole Gilgen, Christoph Kaiser, Bruno Scheller, for the BASKET-SMALL 2 Investigators

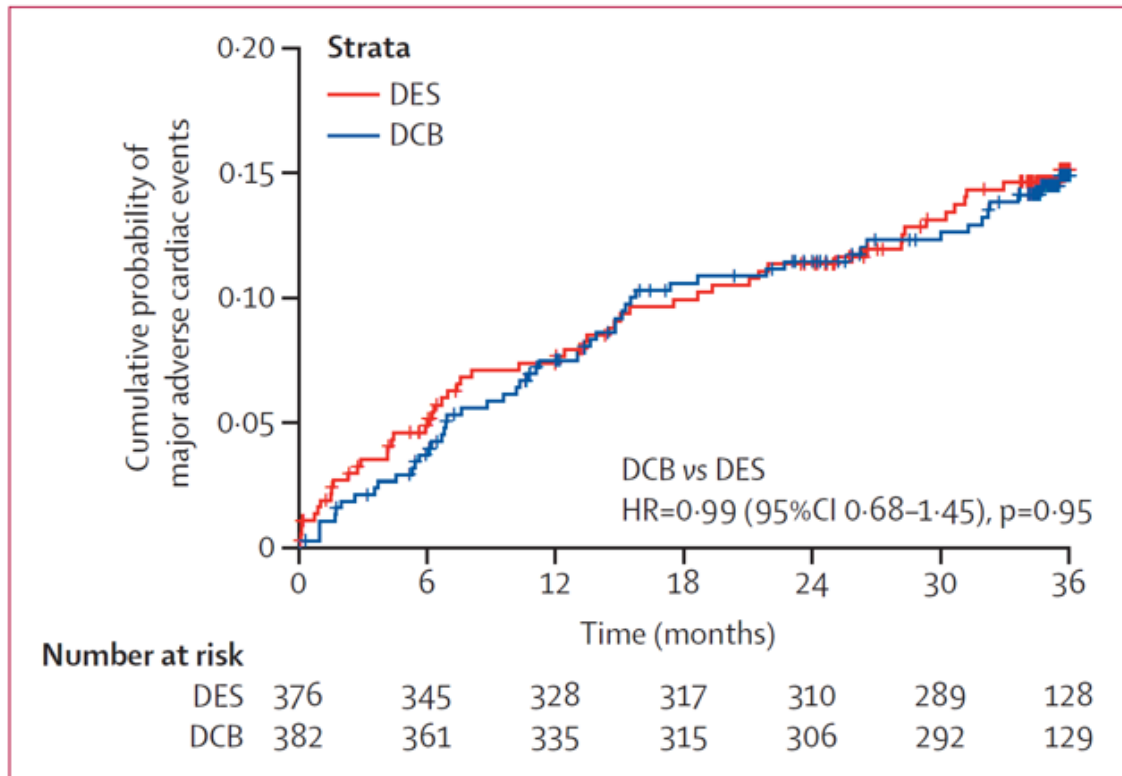


Figure 2: Kaplan-Meier estimates of the cumulative probabilities of major adverse cardiac events in the two study groups during 3 years for the full analysis set

DCB=drug-coated balloons. DES=drug-eluting stents. HR=hazard ratio.

	1-year events	1-year hazard ratio* (95% CI)	2-year events (rate)	2-year hazard ratio* (95% CI)	3-year events (rate)	3-year hazard ratio* (95% CI)
Major adverse cardiac events						
DES (n=376)	28 (8%)	0.97 (0.58-1.64)	41 (11%)	1.01 (0.66-1.56)	53 (15%)	0.99 (0.68-1.45)
DCB (n=382)	28 (7%)	..	42 (11%)	..	53 (15%)	..
Cardiac death						
DES (n=376)	5 (1%)	2.33 (0.82-6.62)	9 (3%)	1.53 (0.66-3.55)	13 (4%)	1.29 (0.63-2.66)
DCB (n=382)	12 (3%)	..	14 (4%)	..	17 (5%)	..
Non-fatal myocardial infarction						
DES (n=376)	13 (4%)	0.46 (0.17-1.20)	19 (5%)	0.74 (0.37-1.47)	23 (6%)	0.82 (0.45-1.51)
DCB (n=382)	6 (2%)	..	14 (4%)	..	19 (6%)	..
Target vessel revascularisation						
DES (n=376)	17 (5%)	0.75 (0.36-1.55)	26 (7%)	0.89 (0.51-1.56)	32 (9%)	0.95 (0.58-1.56)
DCB (n=382)	13 (4%)	..	23 (6%)	..	30 (9%)	..
Major bleeding						
DES (n=376)	9 (3%)	0.45 (0.14-1.46)	13 (4%)	0.32 (0.10-0.97)	14 (4%)	0.43 (0.17-1.13)
DCB (n=382)	4 (1%)	..	4 (1%)	..	6 (2%)	..
Net clinical benefit						
DES (n=376)	36 (10%)	0.81 (0.50-1.32)	52 (14%)	0.84 (0.56-1.25)	64 (18%)	0.86 (0.60-1.24)
DCB (n=382)	30 (8%)	..	44 (12%)	..	56 (16%)	..
Stent thrombosis						
DES (n=376)	4 (1%)	0.50 (0.09-2.73)	6 (2%)	0.33 (0.07-1.64)	6 (2%)	0.33 (0.07-1.64)
DCB (n=382)	2 (1%)	..	2 (1%)	..	2 (1%)	..
All-cause death						
DES (n=376)	9 (2%)	1.86 (0.83-4.17)	17 (5%)	1.29 (0.68-2.43)	27 (8%)	1.05 (0.62-1.77)
DCB (n=382)	17 (5%)	..	22 (6%)	..	28 (8%)	..

All values are numbers of events and Kaplan Meier estimates with the corresponding hazard ratios and 95% CIs. DCB=drug-coated balloon. DES=drug-eluting stent. *Hazard ratios are for DCB vs DES.

Table 2: Primary and secondary endpoints

Causes of death after treatment of small coronary artery disease with paclitaxel-coated balloons

Raban V. Jeger^{1,5} · Christoph Kaiser¹ · Norman Mangner² · Franz X. Kleber³ · Bruno Scheller⁴ · for the BASKET-SMALL 2 Investigators

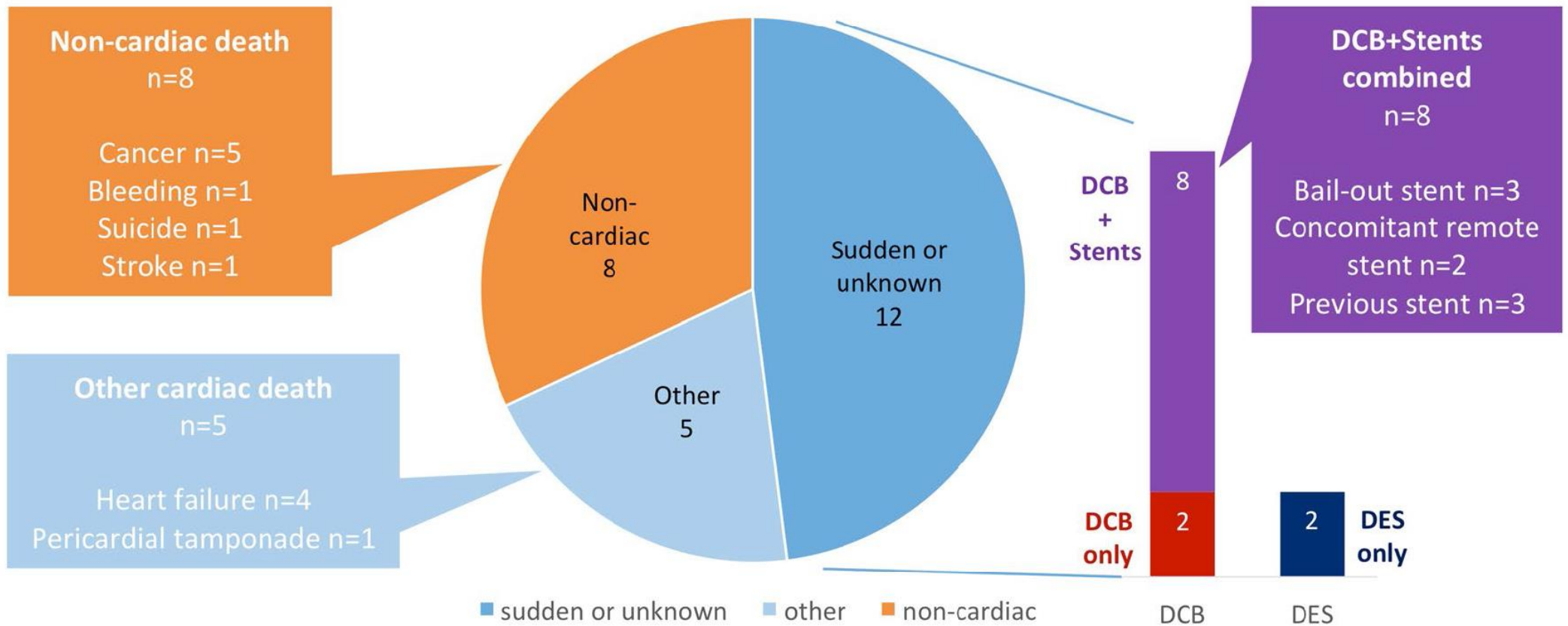



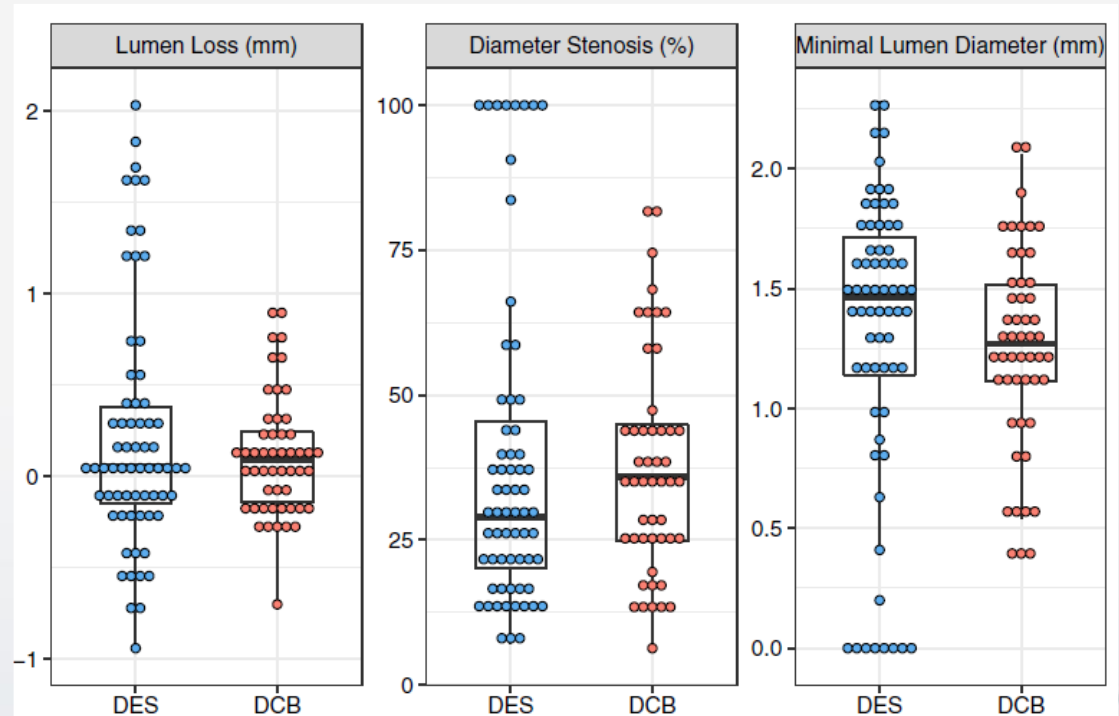
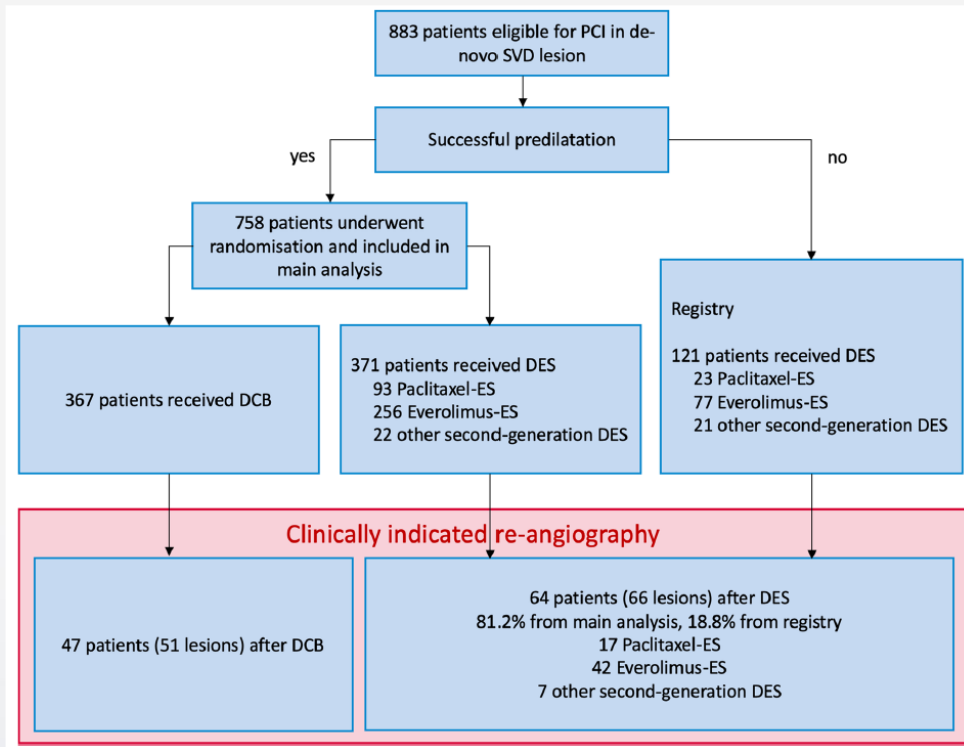
Fig. 1 Causes of death in BASKET-SMALL 2. *DCB* drug-coated balloon, *DES* drug-eluting stent

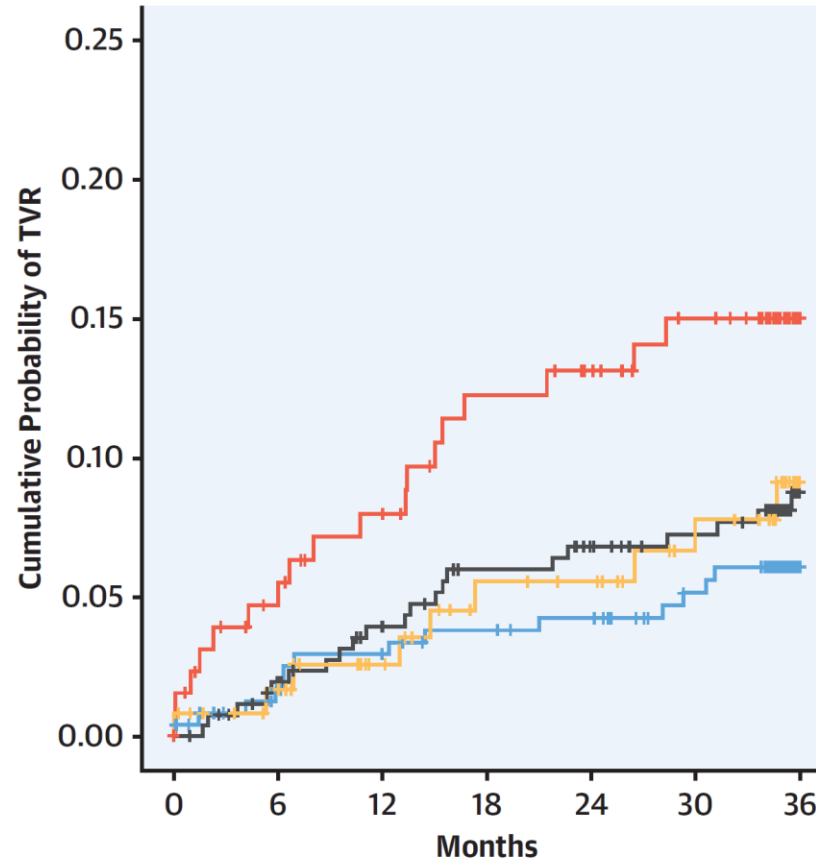
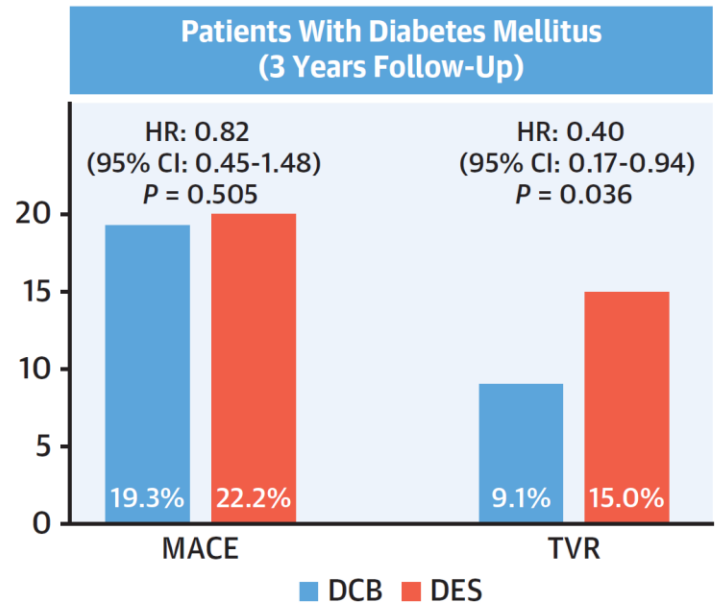
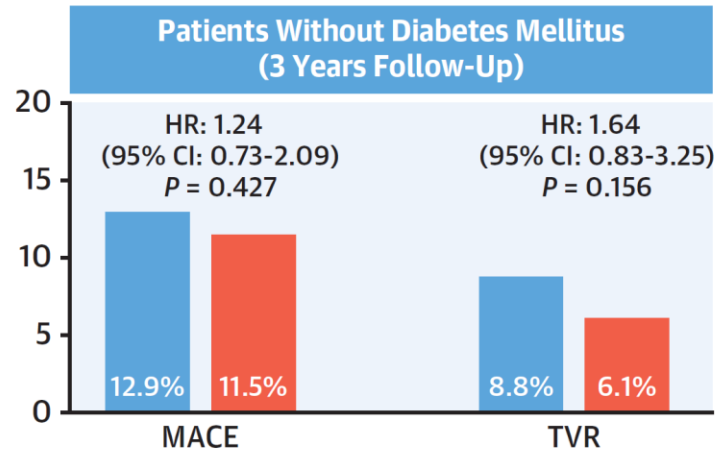
Drug-coated balloon versus drug-eluting stent in small coronary artery lesions: angiographic analysis from the BASKET-SMALL 2 trial

Gregor Fahrni¹ · Bruno Scheller² · Michael Coslovsky¹ · Nicole Gilgen¹ · Ahmed Farah³ · Marc-Alexander Ohlow⁴ · Norman Mangner⁵ · Daniel Weilenmann⁶ · Jochen Wöhrle⁷ · Florim Cuculi⁸ · Gregor Leibundgut⁹ · Sven Möbius-Winkler¹⁰ · Robert Zweiker¹¹ · Raphael Twerenbold¹ · Christoph Kaiser¹ · Raban Jeger¹  · For the BASKET-SMALL 2 Investigators

Complete thrombotic vessel occlusion

A striking observation in Fig. 3a is the presence of eight patients who presented with a complete thrombotic vessel occlusion after undergoing stent implantation compared to none after a DCB intervention (Fisher's exact test $p=0.009$).





No. at risk:

Months	0	6	12	18	24	30	36
Nondiabetic & DES (blue)	246	232	225	221	218	207	85
Diabetic & DES (red)	130	118	109	102	98	89	45
Nondiabetic & DCB (black)	260	249	237	227	221	214	90
Diabetic & DCB (yellow)	122	114	102	92	90	82	41

+ Nondiabetic & DES + Diabetic & DES
+ Nondiabetic & DCB + Diabetic & DCB

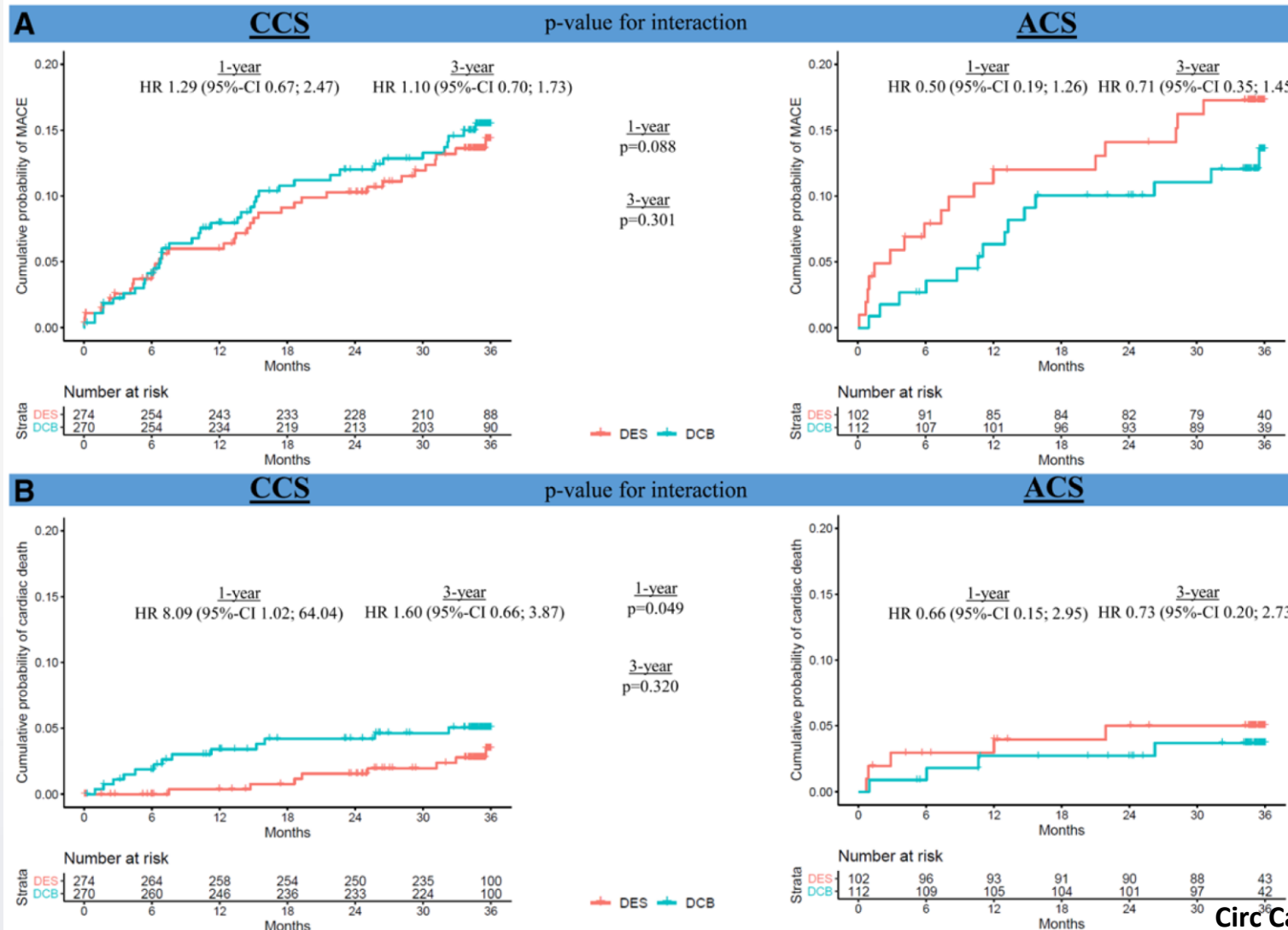
Impact of Diabetes on Outcome With Drug-Coated Balloons Versus Drug-Eluting Stents

The BASKET-SMALL 2 Trial

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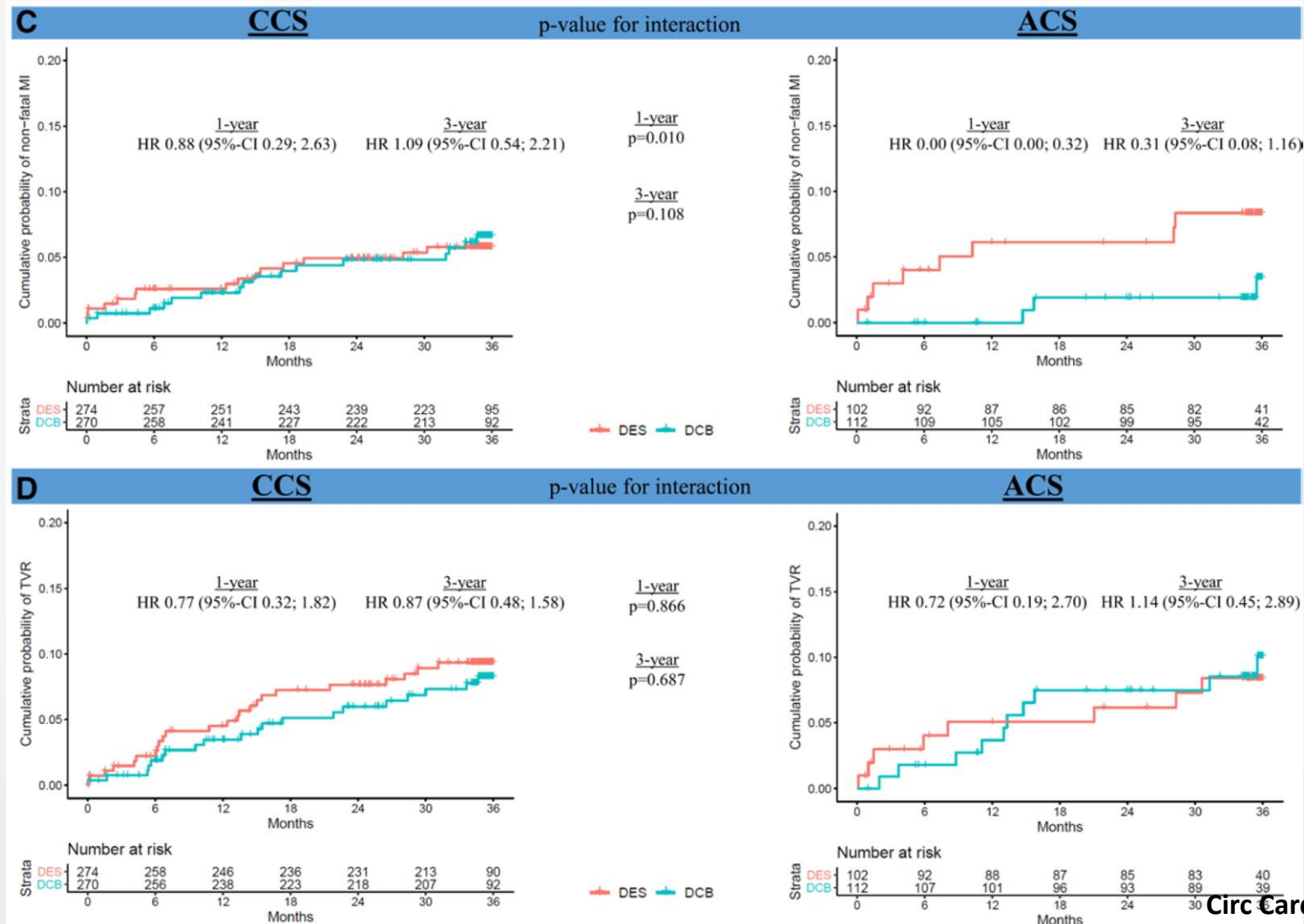
Safety and Efficacy of Drug-Coated Balloons Versus Drug-Eluting Stents in Acute Coronary Syndromes: A Prespecified Analysis of BASKET-SMALL 2

Norman Mangner MD; Ahmed Farah, MD; Marc-Alexander Ohlow, MD; Sven Möbius-Winkler MD; Daniel Weilenmann, MD; Jochen Wöhrle MD; Axel Linke, MD; Georg Stachel MD; Sinisa Markovic, MD; Gregor Leibundgut, MD; Peter Rickenbacher, MD; Marco Cattaneo PhD; Nicole Gilgen, MD; Christoph Kaiser, MD; Bruno Scheller MD; Raban V. Jeger MD; for the BASKET-SMALL 2 Investigators



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Drug-coated balloons for small coronary artery disease in patients with chronic kidney disease: a pre-specified analysis of the BASKET-SMALL 2 trial

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Drug-coated balloon versus drug-eluting stents in small coronary artery disease with and without chronic kidney disease

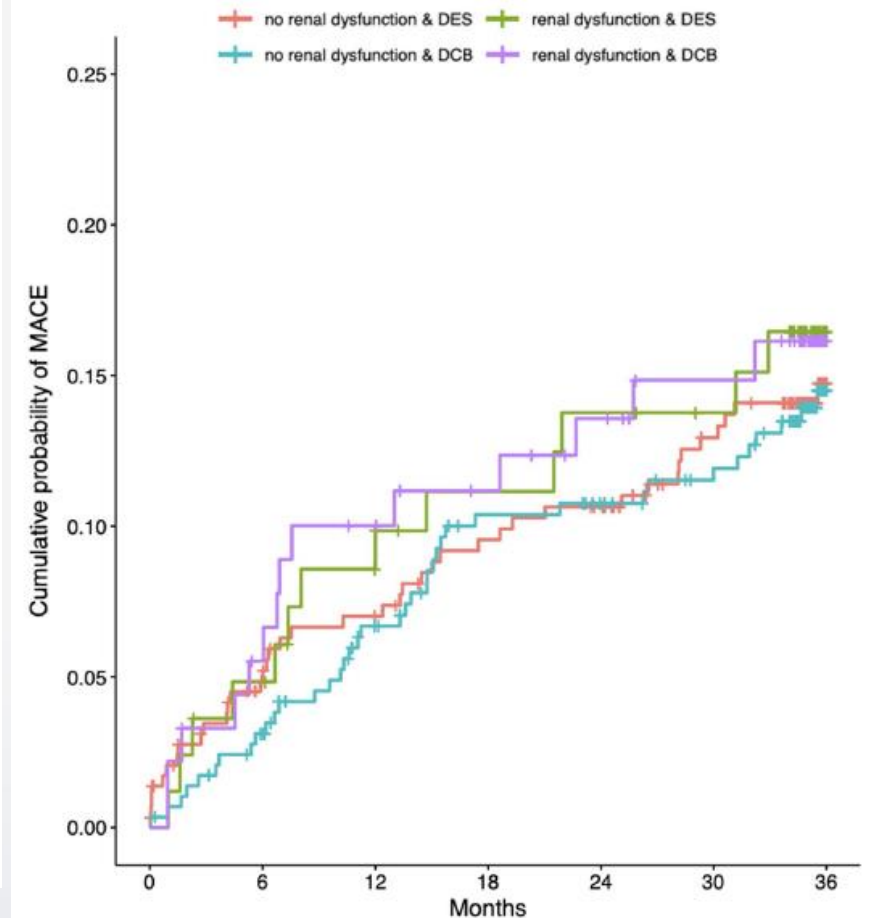
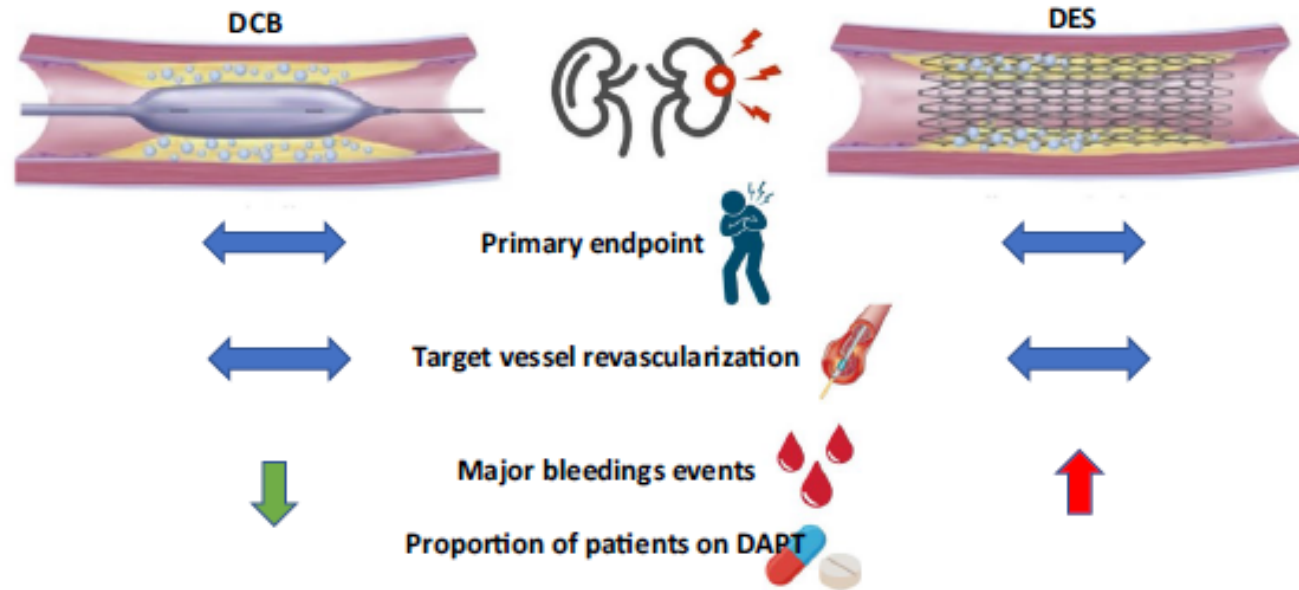
Large multi-center, randomized, controlled, non-inferiority trial (BASKET-SMALL 2) (n=758)

Efficacy and safety of DCBs versus second-generation DESs in small vessel coronary artery disease (<3 mm)

Primary endpoint: composite of cardiac death, non-fatal myocardial infarction, and target vessel revascularization during 3 years

Prespecified subgroup analysis in patients with chronic kidney disease (eGFR <60 ml/min/1.73 m²)

174 (23%) patients with CKD, 91 randomized to DCB and 83 to DES implantation.



Drug-Coated Balloon for Small Coronary Artery Disease in Patients With and Without High-Bleeding Risk in the BASKET-SMALL 2 Trial

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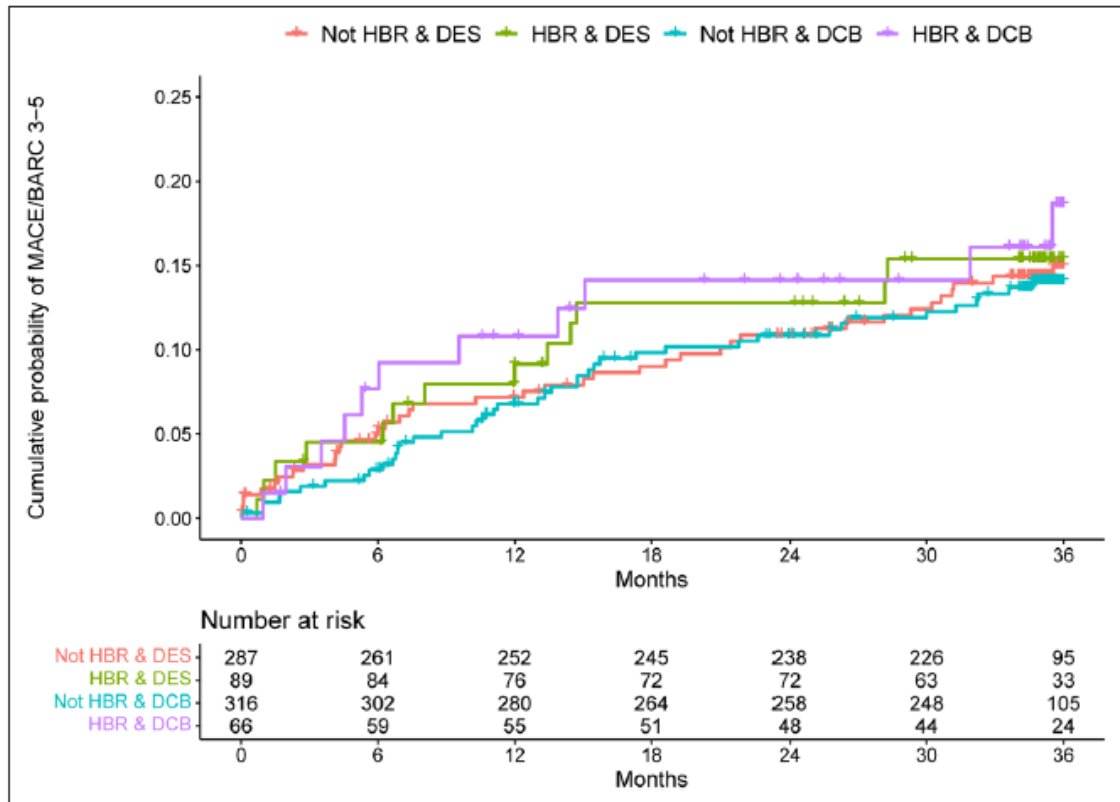


Figure 2. Cumulative event rates of net clinical events including major adverse cardiac events (MACE) and Bleeding Academic Research Consortium (BARC) 3–5 bleeding by treatment arm and high-bleeding risk (HBR). Kaplan-Meier estimates of the cumulative probabilities of net clinical events including MACE and BARC 3–5 bleeding in the 2 study arms during 3 y. DCB indicates drug-coated balloon; and DES, drug-eluting stent.

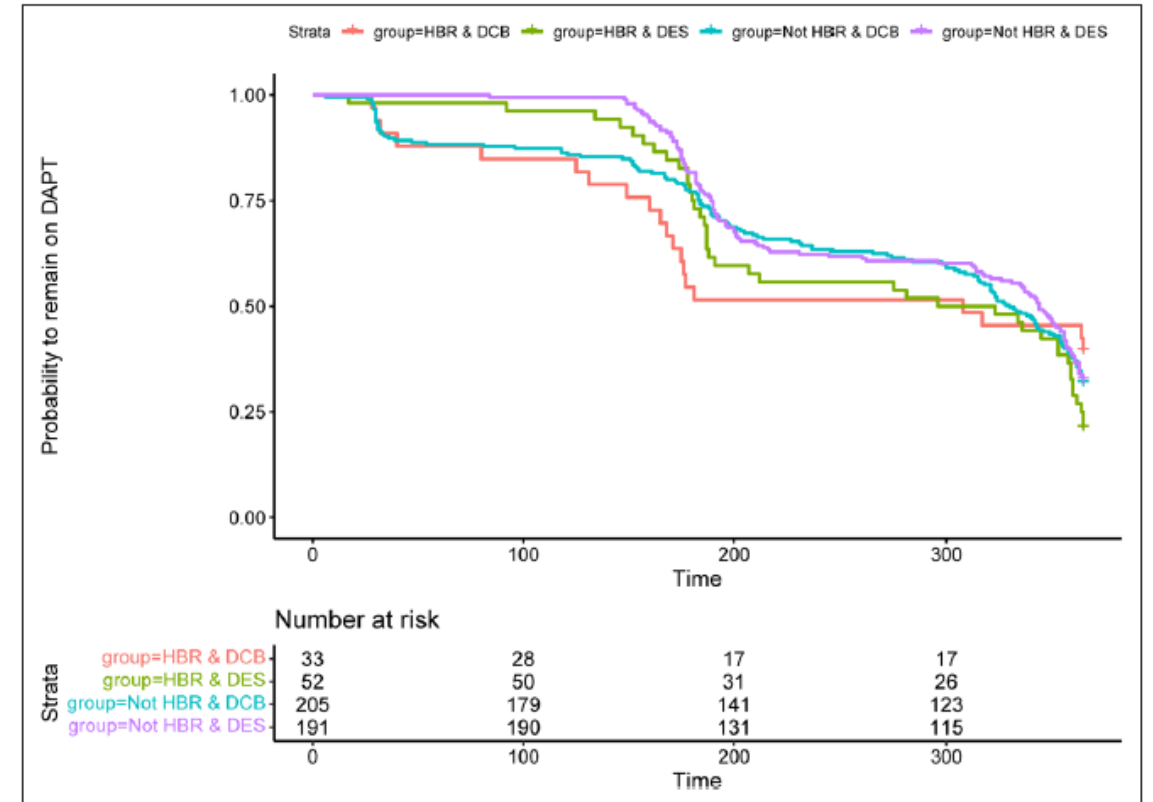


Figure 3. Kaplan-Meier estimates of the probability to remain on dual antiplatelet therapy (DAPT) during 12 mo by treatment arm and high-bleeding risk (HBR), for patients who started on DAPT after the percutaneous coronary intervention (PCI). DCB indicates drug-coated balloon; and DES, drug-eluting stent.

Drug-Coated Balloon for Small Coronary Artery Disease in Patients With and Without High-Bleeding Risk in the BASKET-SMALL 2 Trial

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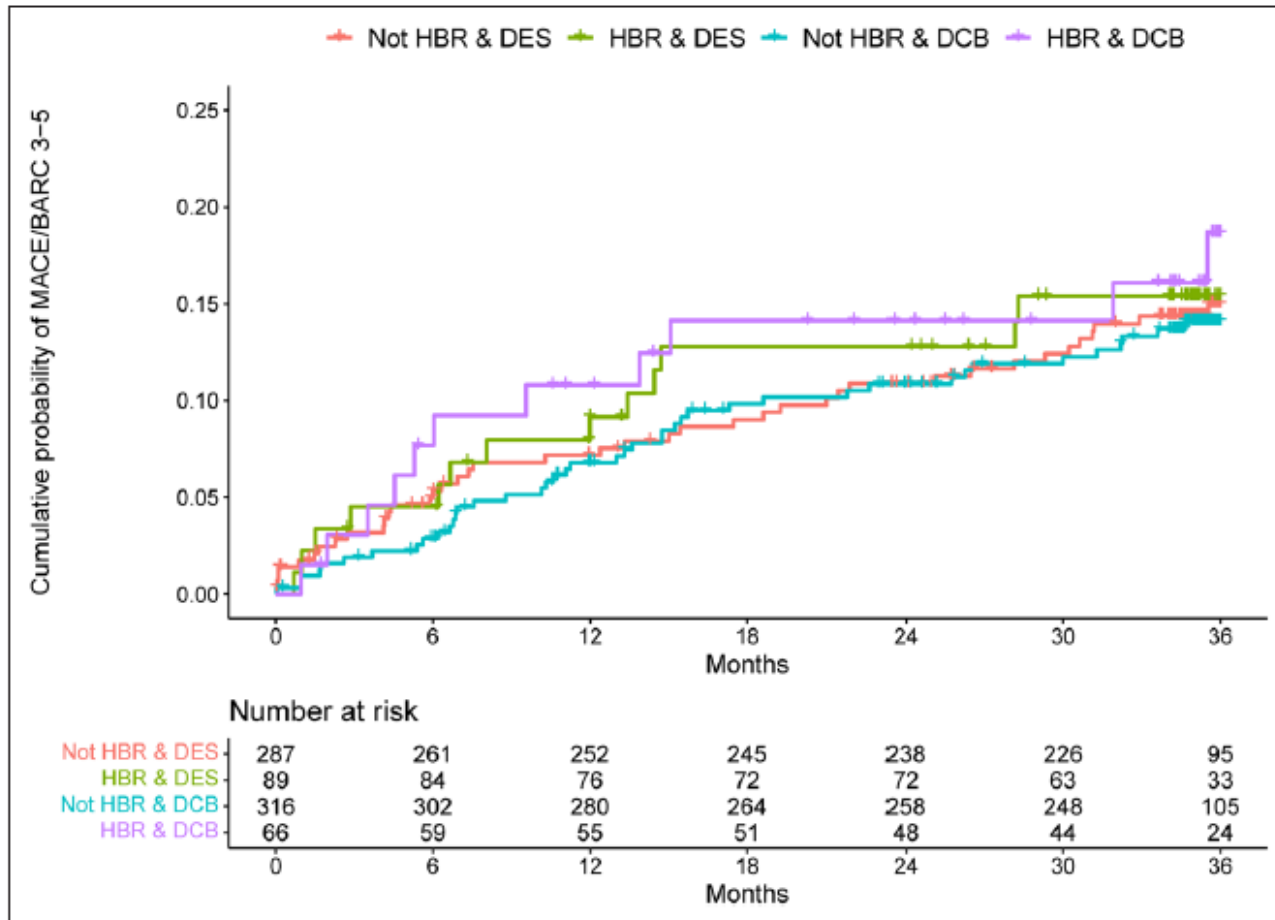


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Kaplan-Meier estimates of the cumulative probabilities of net clinical events including MACE and BARC 3–5 bleeding in the 2 study arms during 3 y. DCB indicates drug-coated balloon; and DES, drug-eluting stent.

WHAT THE STUDY ADDS

- The present analysis investigated the effect of drug-coated balloon versus drug-eluting stent in patients with and without high-bleeding risk in small coronary arteries.
- Rates of major bleeding events were overall low but tended to be lower after drug-coated balloon versus drug-eluting stent. 1.6% versus 3.7%; $P=0.064$
- There was no difference in major adverse cardiac events between drug-coated balloon and drug-eluting stent regardless of bleeding risk.

BASKET-SMALL 2

- Largest published RCT comparing DCBonly and DES
- ‚Small vessel‘ RCT (< 3 mm in diameter)
- DCBonly noninferior to DES @ 1 and 3 years in terms of MACE
- No vessel closure in DCBonly vs. (clinically silent) stent closures
- Possible advantage of DCBonly masked by relevant number of large vessels treated with DES in both groups
- Potential advantages of DCBonly in predefined subgroups:
 - reduction of MACE in Diabetic and ACS patients
 - reduction of bleeding in CKD and HBR
- Small vessels are the best accepted indication after ISR. However, the real benefit of DCBonly will only become apparent in the treatment of large vessels with a more significant impact on hard clinical endpoints.