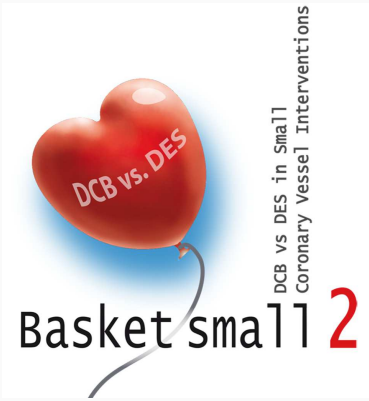


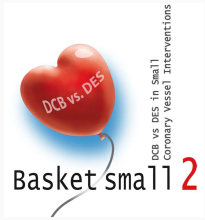
Drug-Coated Balloons for Small Coronary Artery Disease: BASKET-SMALL 2

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, and Bruno Scheller, for the BASKET-SMALL 2 Investigators

ESC Congress
Munich 2018

BASKET-SMALL 2

Funding



- Swiss National Science Foundation
- Basel Cardiovascular Research Foundation
- B. Braun Medical AG, Switzerland

No influence of the funding sources on design, conduct, or analysis of the trial

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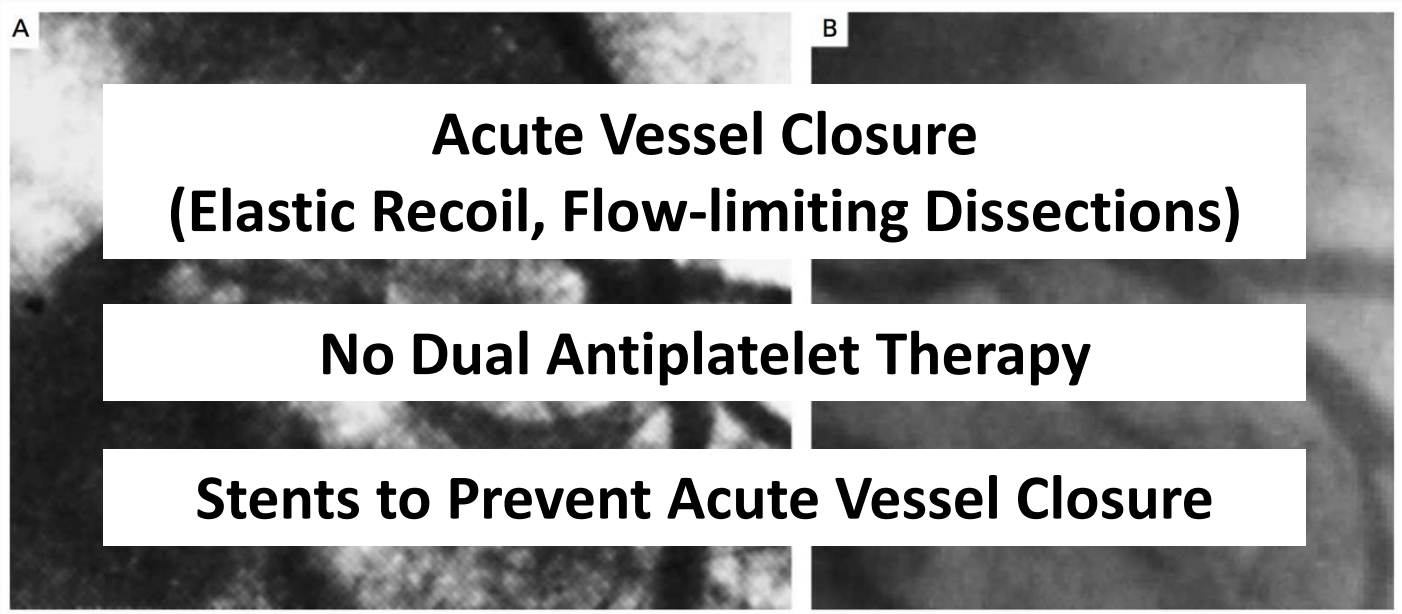
Background: Coronary Angioplasty



1977 2000

Meier B, N Engl J Med 2001;344:144-5

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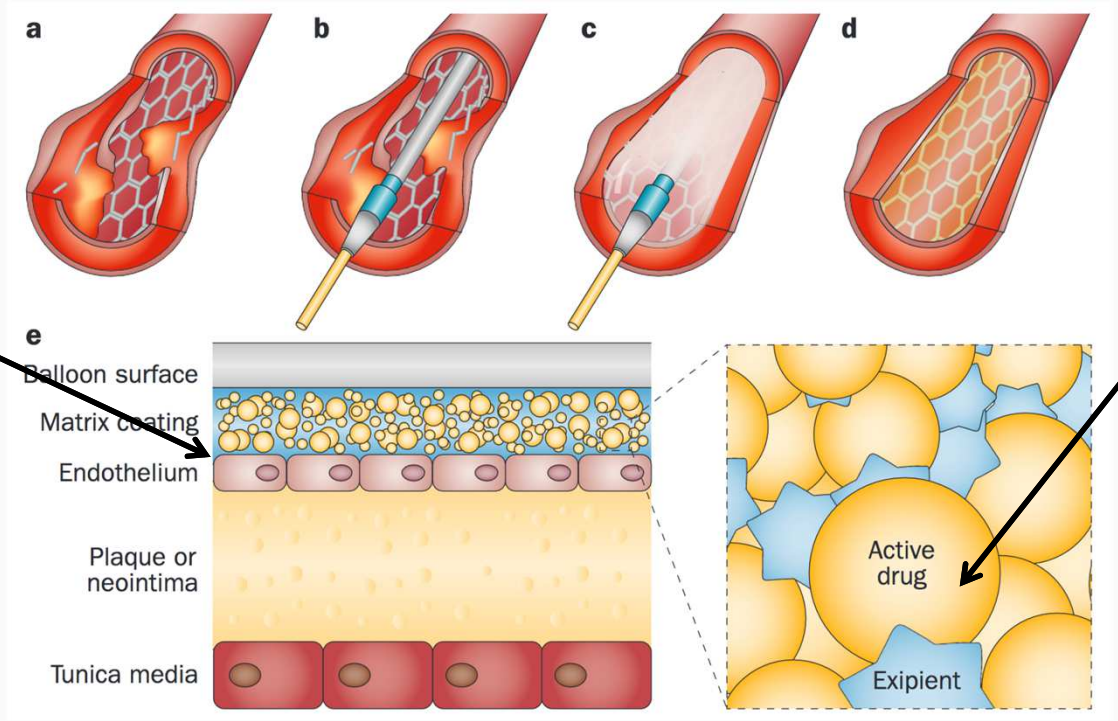
Background: Drug-Coated Balloons

Fast and Homogenous Drug Delivery into the Vessel Wall



Highly Lipophilic Drug & Coating Matrix

Byrne RA et al, Nat Rev Cardiol 2014;11:13-23

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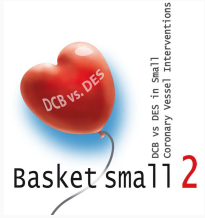
Rationale



- 2nd-generation drug-eluting stents (DES) are the preferred treatment for de-novo coronary lesions
- Efficacy of DES is limited in small vessels due to high rates of instent-restenosis
- Drug-coated balloons (DCB) are an established treatment strategy for in-stent restenoses of bare metal stents and DES
- The efficacy and safety of DCB in de-novo stenoses is unknown

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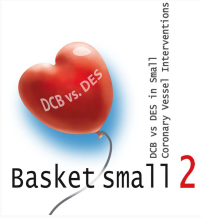
Design



- Multicenter, randomized controlled non-inferiority trial (14 centers in Germany, Switzerland, and Austria)
- Patients undergoing PCI in native coronary arteries <3 mm
- Initial comparison Sequent Please® DCB (B.Braun Melsungen) vs. Taxus Element® DES (Boston Scientific), then changed to Xience® DES (Abbott Vascular) after appr. 25% of patients
- Primary endpoint: Non-inferiority for major adverse cardiac events (MACE; cardiac death, non-fatal myocardial infarction, and target vessel revascularization) @ 12 months
- Expected MACE rates of 7% for DCB and 10% for DES with non-inferiority margin <4% (upper limit of the two-sided 95% confidence interval of the absolute risk difference)
- Sample size calculation (based on Xience®): 758 patients

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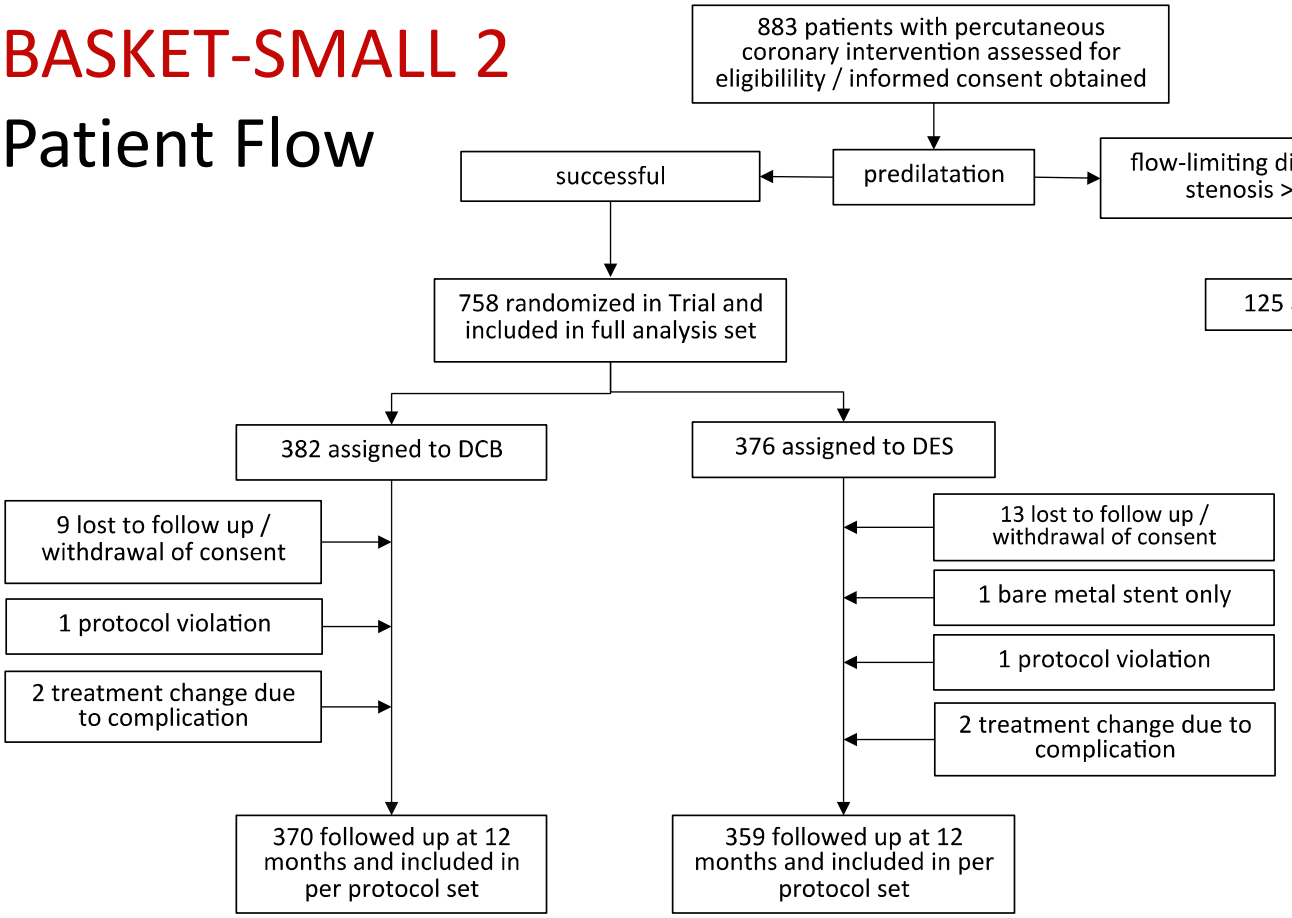
Patient Flow



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Clinical Baseline Characteristics

	DCB (n=382)		DES (n=376)		
Age (mean, SD)	67.2	(10.3)	68.4	(10.3)	
Sex Male (%)	295	(77.2)	262	(69.7)	p=0.0232
Current/former smoker (%)	226	(60.4)	195	(53.1)	
Hypercholesterolemia (%)	262	(68.8)	259	(70.0)	
Arterial hypertension (%)	324	(84.8)	332	(88.8)	
Family history of CAD (%)	150	(42.6)	128	(38.0)	
Diabetes mellitus (%)	122	(32.0)	130	(34.9)	
Previous MI (%)	160	(41.9)	133	(35.4)	
Cerebrovascular insult (%)	29	(7.6)	37	(9.8)	
PAOD (%)	27	(7.1)	26	(6.9)	
COPD (%)	28	(7.3)	36	(9.6)	
Renal failure (%)	54	(14.1)	59	(15.7)	

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Angiographic Baseline Characteristics

	DCB (n=382)		DES (n=376)	
Target vessel				
Left anterior descending artery (%)	128	(33.5)	116	(30.9)
Left circumflex artery (%)	179	(46.9)	183	(48.7)
Right coronary artery (%)	75	(19.6)	77	(20.5)
Bifurcation lesion (%)	22	(5.8)	29	(8.0)
Procedural success (%, mean, SD)	96	(19)	98	(13)
Number of DCB or DES (mean, SD)	1.68	(0.82)	1.26	(0.55)
Length of DCB or DES (mm; mean, SD)	23.93	(11.74)	23.18	(12.85)
Effective size of DCB or DES (mm; mean, SD)	2.75	(2.14)	2.57	(0.25)
Inflation pressure (atm; mean, SD)	11.06	(3.54)	13.58	(3.90)
Duration of inflation (sec; mean, SD)	48.45	(28.24)	23.36	(18.92)

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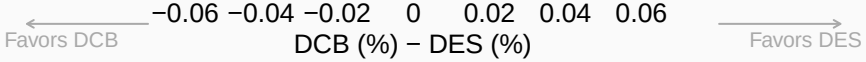
Primary Endpoint (Non-Inferiority)

Set	Level	Events	Difference	CI	p
PPS	DES	27 / 359 (7.52%)			
	DCB	28 / 370 (7.57%)	0.0005	[−0.038, 0.039]	0.0217
FAS	DES	28 / 376 (7.45%)			
	DCB	28 / 382 (7.33%)	−0.0012	[−0.040, 0.037]	0.0152



PPS, per protocol set; FAS, full analysis set.

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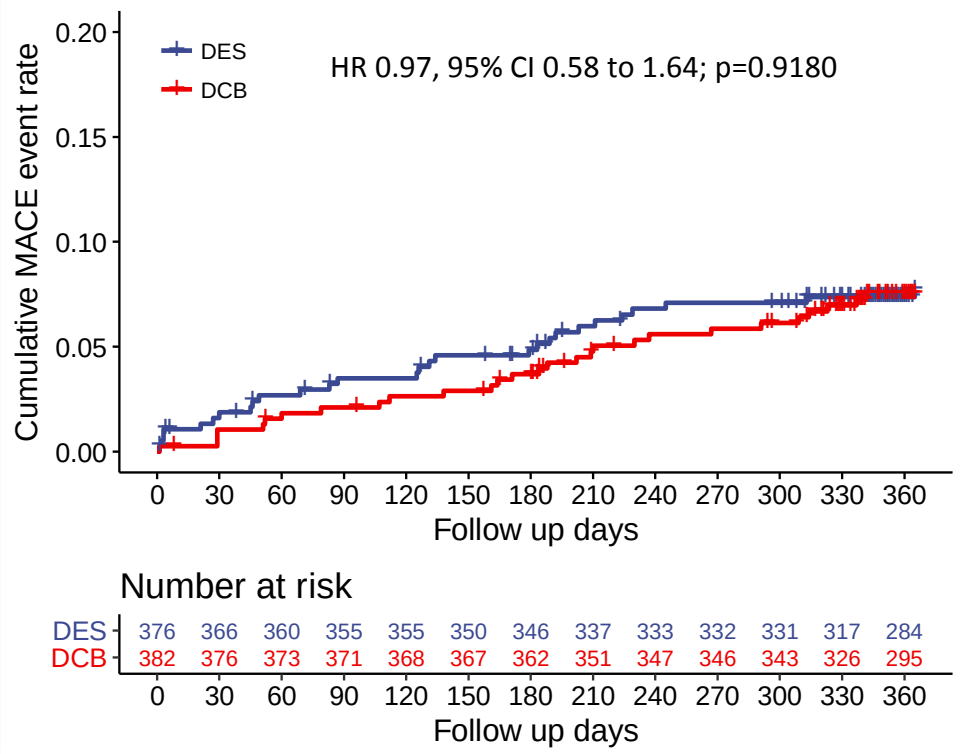
MACE (12 Months)



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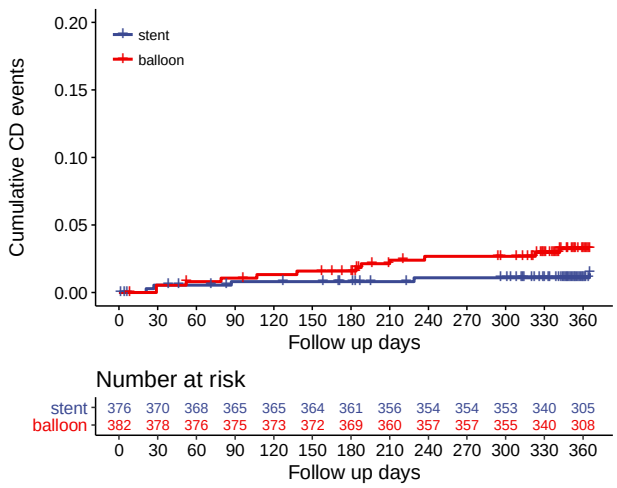
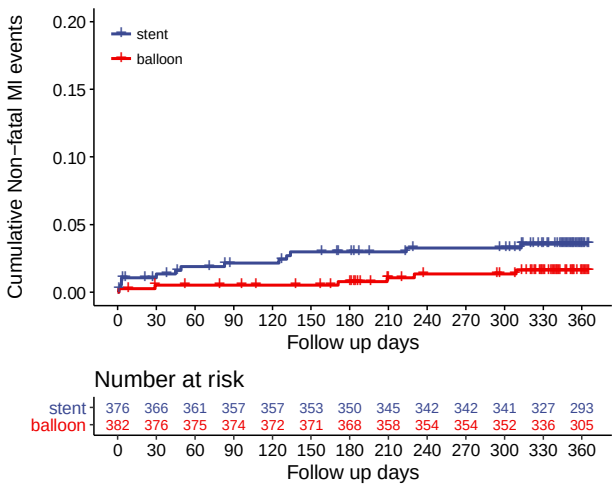
Single Components of MACE (12 Months)

Cardiac Death



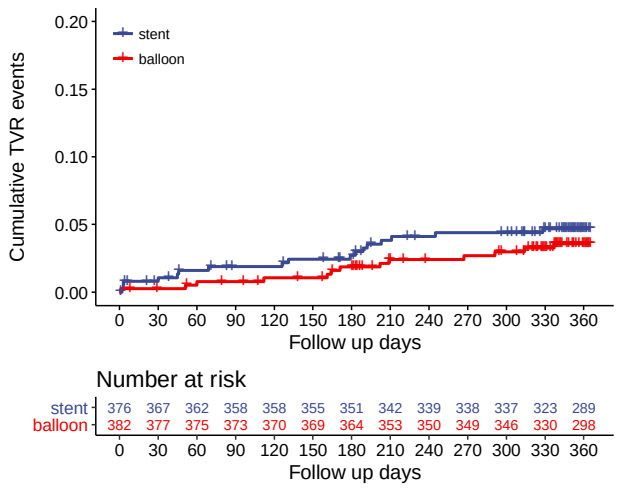
3.1 vs. 1.3%; HR 2.33, 95% CI 0.82 to 6.61; p=0.1131

Non-fatal Myocardial Infarction



1.6 vs. 3.5%; HR 0.46, 95% CI 0.17 to 1.20; p=0.1123

Target-vessel Revascularization



3.4 vs. 4.5%; HR 0.75, 95% CI 0.36 to 1.55; p=0.4375

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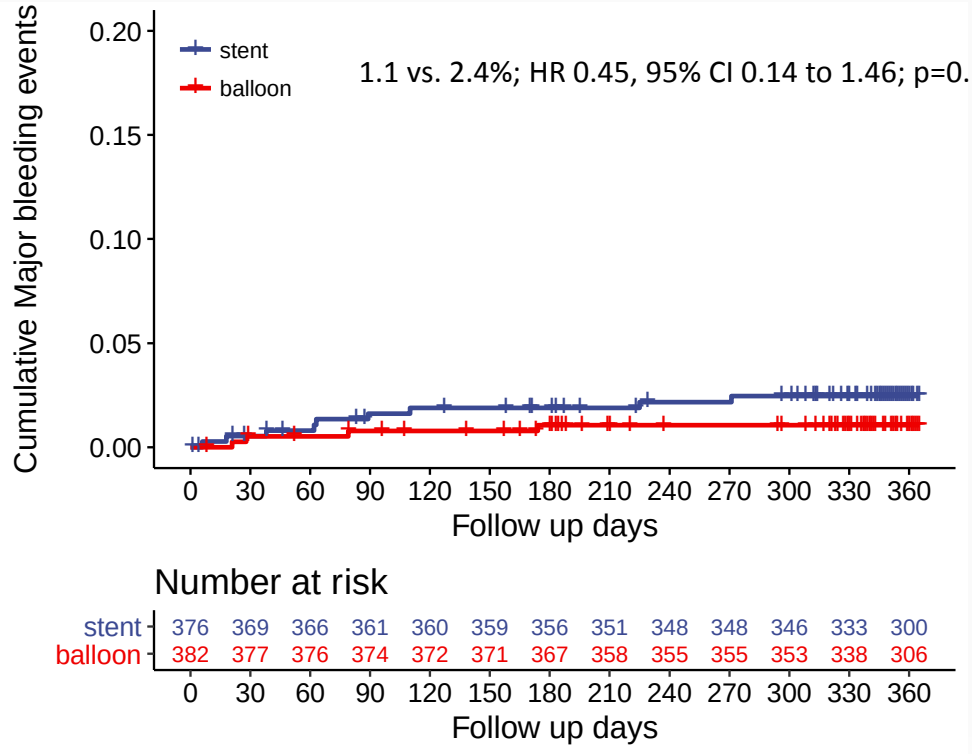
Major Bleeding (BARC ≥3, 12 Months)



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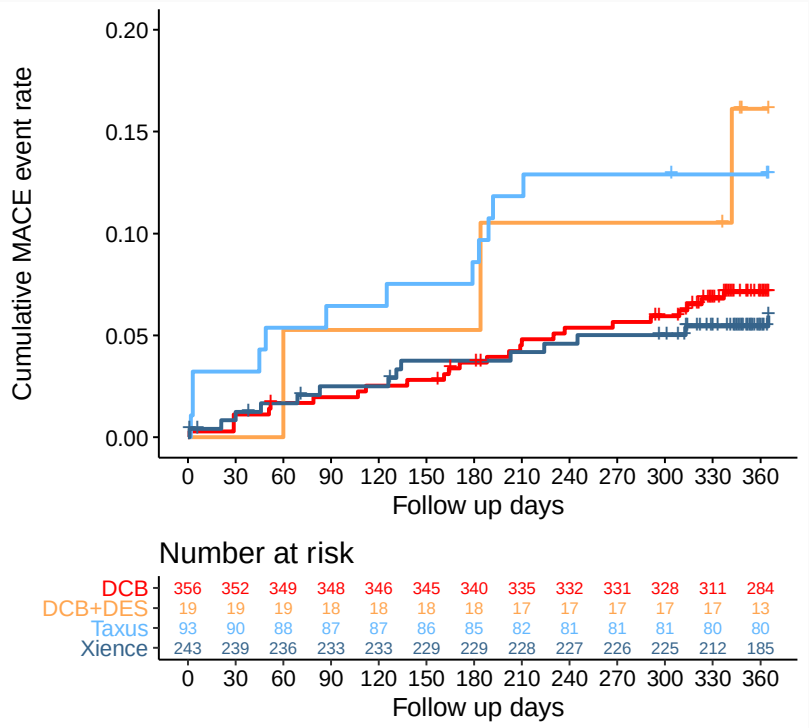
MACE (12 Months) for Device Subgroups



DCB+DES

Taxus

DCB

Xience

15.8 vs. 7.0%; HR 2.11, 95% CI 0.62 to 7.19; p=0.2306

12.8 vs. 5.7%, HR 2.04, 95% CI 0.88 to 4.76; p=0.0987

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Conclusions

- First large randomized controlled trial testing the efficacy of a paclitaxel-iopromide-coated DCB vs. second-generation DES in a large all-comer population regarding clinical endpoints
- 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 treatment groups

Small native coronary artery disease may safely be treated with DCB after successful predilatation

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Thank you!

Center	Country	PI
Central Clinik Bad Berka	Germany	M.-A. Ohlow
University Hospital Basel	Switzerland	C. Kaiser
University Hospital Saarland, Homburg	Germany	B. Scheller
Knappschaftskrankenhaus Klinikum Westfalen Dortmund	Germany	A. Farah
Heart Center Leipzig	Germany	N. Mangner
University Hospital Jena	Germany	S. Möbius-Winkler
Cantonal Hospital Baselland Liestal	Switzerland	G. Leibundgut
Cantonal Hospital St. Gallen	Switzerland	D. Weilenmann
University Hospital Ulm	Germany	J. Wöhrle
Medical University Graz	Austria	R. Zweiker
Cantonal Hospital Luzern	Switzerland	P. Jamshidi
Charité University Hospital Berlin	Germany	F. Krackhardt
Heart Center Brandenburg Bernau	Germany	C. Butter
Unfallkrankenhaus Berlin	Germany	L. Bruch