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Drug-coated Balloons vs. Drug-eluting Stents for the Treatment of Small Coronary Artery Lesions: Angiographic Analysis from the Randomised BASKET-SMALL 2 Trial

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Potential conflicts of interest

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☑ I have the following potential conflicts of interest to declare:

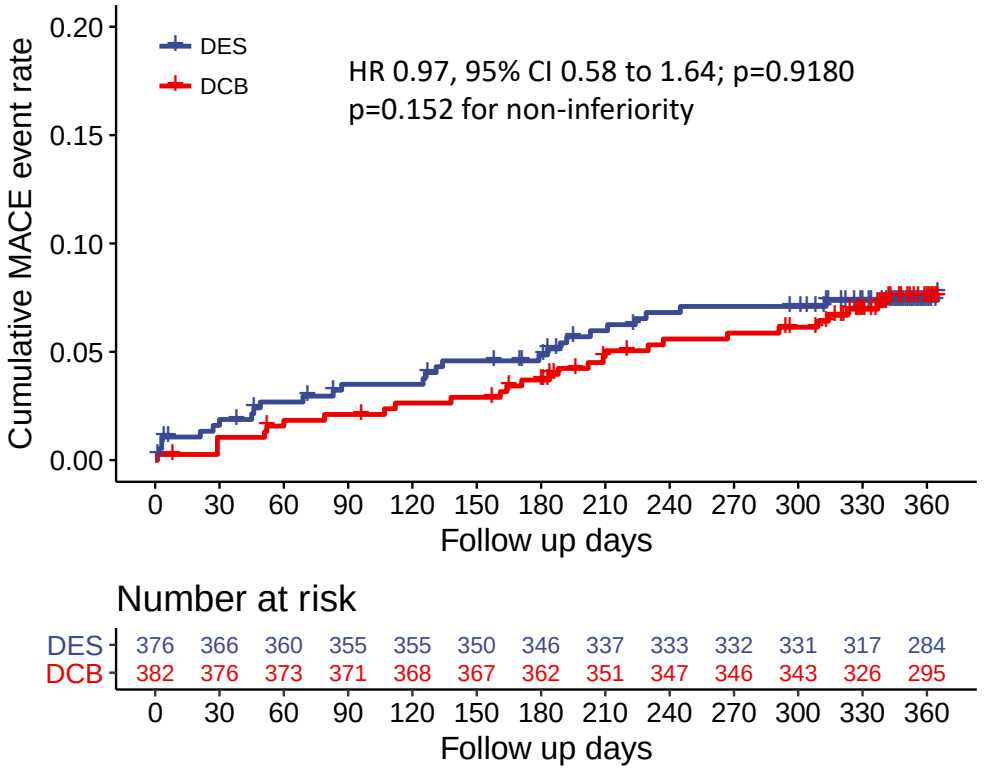
Receipt of grants / research supports: B. Braun Melsungen AG

Receipt of honoraria or consultation fees: B. Braun Melsungen AG

BASKET-SMALL 2 Angiographic Analysis

Background and Aims

- Drug-eluting stents (DES) are the default strategy for the treatment of coronary artery disease but have limitations in small vessels with elevated rates of clinical endpoints
- In BASKET-SMALL 2, drug coated balloons (DCB) were non-inferior to DES in small vessel disease regarding clinical events up to 12 months, with similar event rates for both treatment groups
- Angiographic data following treatment with DCB and DES in small vessel disease are sparse



Jeger RV et al. Lancet 2018 Sep 8;392(10150):849-856

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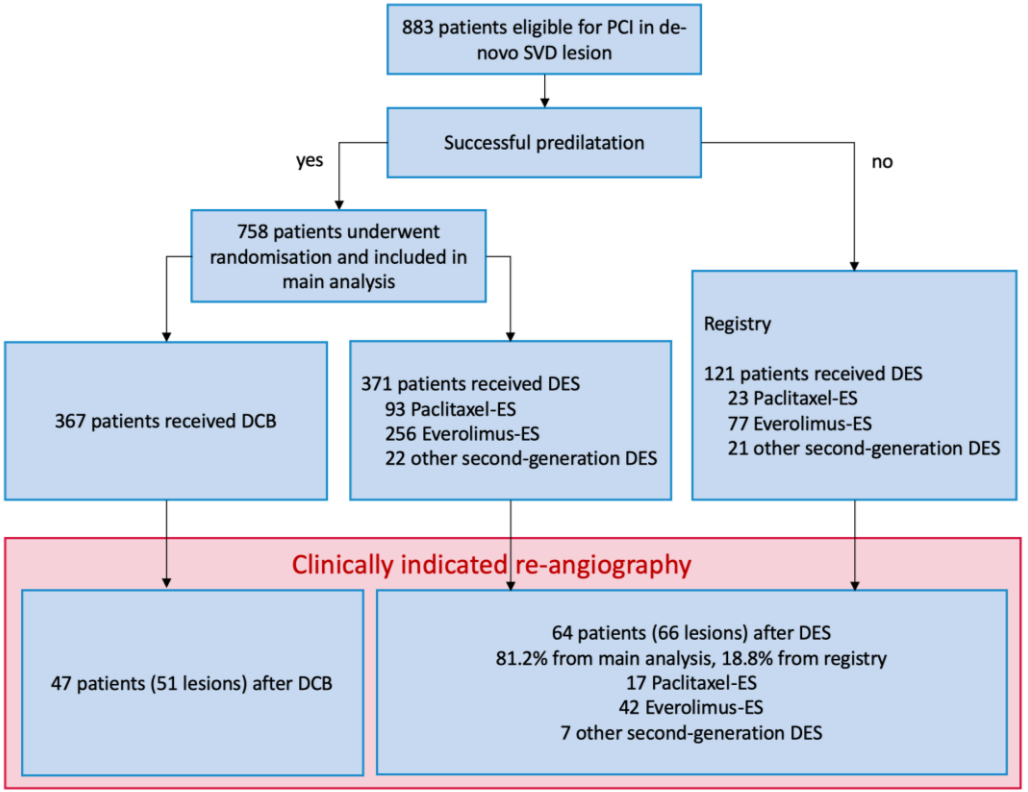
Study Design and Patient-Flow Chart

- Prespecified analysis of a multicenter, randomized controlled non-inferiority trial
- Percutaneous coronary intervention in native coronary arteries <3 mm
- Randomization after successful predilatation only; registry of patients without successful predilatation
- Comparison of Sequent Please® DCB (B.Braun Melsungen) vs. Taxus Element® DES (Boston Scientific) and Xience® DES (Abbott Vascular)
- Analysis of clinically indicated follow-up angiographies within the first year after the index procedure, comparison with baseline



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Baseline Clinical and Lesion Characteristics

	DES	DCB	p-Value
Patients	64	47	
Age, years	66.6 (11.3)	68.1 (9.4)	0.45
Male sex	45 (70.3)	38 (80.9)	0.27
Diabetes mellitus	23 (36.0)	16 (34.0)	0.96
Insulin-dependent	12 (18.8)	9 (19.1)	
Hypertension	57 (89.1)	39 (83.0)	0.41
Dyslipidaemia	53 (84.1)	38 (80.9)	0.80
Smoking	30 (46.8)	33 (70.2)	0.02
Current smoker	7 (10.9)	14 (29.8)	
Former smoker	23 (35.9)	19 (40.4)	
Family history of CAD	33 (52.4)	14 (33.3)	0.07
Previous myocardial infarction	16 (25.0)	21 (44.7)	0.04
Previous PCI	38 (59.4)	25 (53.2)	0.56
Acute coronary syndrome	22 (34.4)	14 (29.8)	0.64
STEMI	0	1 (2.1)	
NSTEMI	10 (15.6)	7 (14.9)	
Unstable angina	12 (18.8)	6 (12.8)	
Renal failure	13 (20.3)	11 (23.4)	0.82

	DES	DCB	p-Value
Patients	64	47	
Multivessel disease	51 (79.7)	36 (76.6)	0.88
2-vessel disease	18 (28.1)	14 (29.8)	
3-vessel disease	33 (51.6)	22 (46.8)	
Lesions	66	51	
Target vessel			0.90
Left anterior descending	9 (13.6)	8 (15.7)	
Diagonal	11 (16.7)	8 (15.7)	
Left circumflex	32 (48.5)	26 (51.0)	
Right coronary artery	4 (6.1)	1 (2.0)	
PDA or PLA	10 (15.2)	8 (15.7)	
Lesion type			0.51
B1	30 (45.5)	28 (54.9)	
B2	13 (19.7)	6 (11.8)	
C	5 (7.6)	2 (3.9)	
Lesion calcification			0.49
Moderate	21 (32.3)	12 (23.5)	
Severe	3 (4.6)	4 (7.8)	

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Quantitative Coronary Angiography Measurements at Baseline and after the Procedure

	DES (n = 66)	DCB (n = 51)	p-Value
Baseline			
Reference vessel diameter, mm	2.02 (0.23)	2.08 (0.31)	0.28
Minimal lumen diameter, mm	0.51 (0.27)	0.61 (0.35)	0.08
Diameter stenosis, %	75.0 (12.3)	70.0 (13.5)	0.04
Length, mm	11.4 (8.8)	11.2 (6.0)	0.90
Post procedure			
Minimal lumen diameter, mm			
In-segment	1.53 (0.34)	1.36 (0.23)	0.004
In-stent/In-balloon	1.83 (0.29)	1.48 (0.25)	<0.001
Diameter stenosis, %			
In-segment	23.7 (17.8)	33.8 (11.7)	0.001
In-stent/In-balloon	8.8 (15.7)	27.7 (15.0)	<0.001
Acute gain, mm			
In-segment	1.02 (0.42)	0.75 (0.34)	<0.001
In-stent/In-balloon	1.32 (0.35)	0.87 (0.38)	<0.001

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Angiographic Outcome at Follow-up

	DES (n = 66)	DCB (n = 51)	Estimate (95%CI)	p-Value
Time until follow-up, days	175 (77-224)	170 (82-229)		0.70
Minimal diameter, mm				
In-segment	1.49 (1.26-1.76)	1.27 (1.12-1.52)	-0.19 (-0.38-0.00)	0.048
In-stent/in-balloon	1.76 (1.47-2.02)	1.35 (1.13-1.70)	-0.35 (-0.54--0.17)	<0.001
Diameter stenosis, %				
In-segment	29.0 (20.3-45.5)	35.8 (24.8-44.9)	7.18 (0.08-14.28)	0.047
In-stent/in-balloon	18.8 (9.6-35.8)	34.5 (19.1-42.8)	14.7 (7.7-21.6)	<0.001
Late lumen loss, mm				
In-segment	0.06 (-0.15-0.40)	0.10 (-0.14-0.26)	0.09 (-0.05-0.23)	0.20
In-stent/in-balloon	0.13 (-0.14-0.57)	0.10 (-0.16-0.34)	0.03 (-0.13-0.19)	0.72
Net gain, mm				
In-segment	1.40 (0.75-1.89)	1.18 (0.89-1.59)	-0.29 (-0.56--0.01)	0.045
In-stent/in-balloon	1.46 (0.93-2.08)	1.24 (0.84-1.86)	-0.39 (-0.70--0.09)	0.011
Binary restenosis, %			OR	
In-segment	21.5 (14)	20.4 (10)	0.91 (0.35-2.25)	0.83
In-stent/in-balloon	18.5 (12)	16.3 (8)	1.01 (1.00-1-03)	0.66

Difference between post-procedure and follow-up angiography

Diameter stenosis (In-stent/In-balloon)

DES +10.0%
DCB +6.8%

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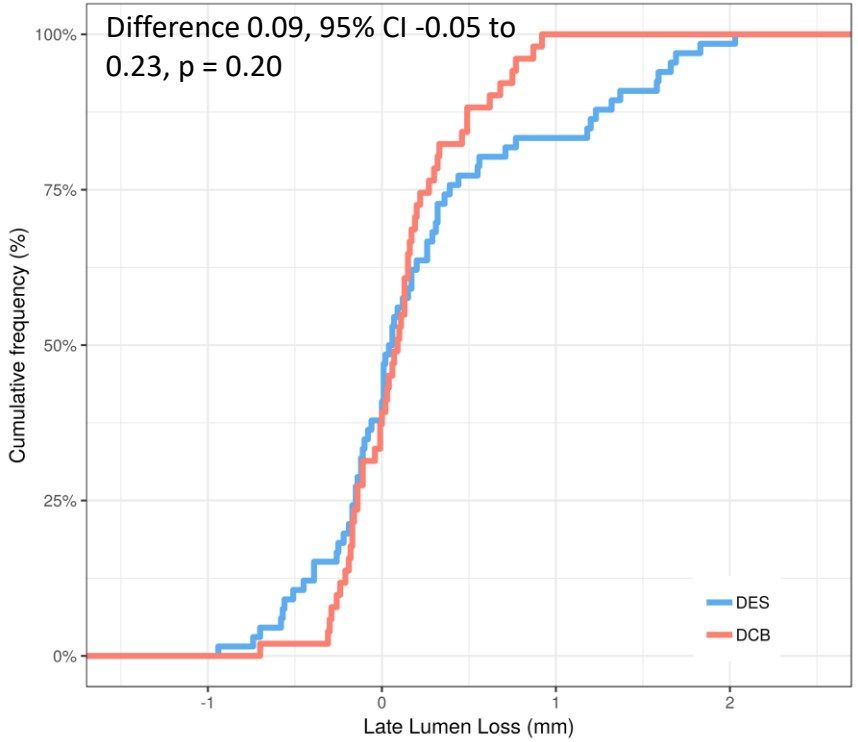
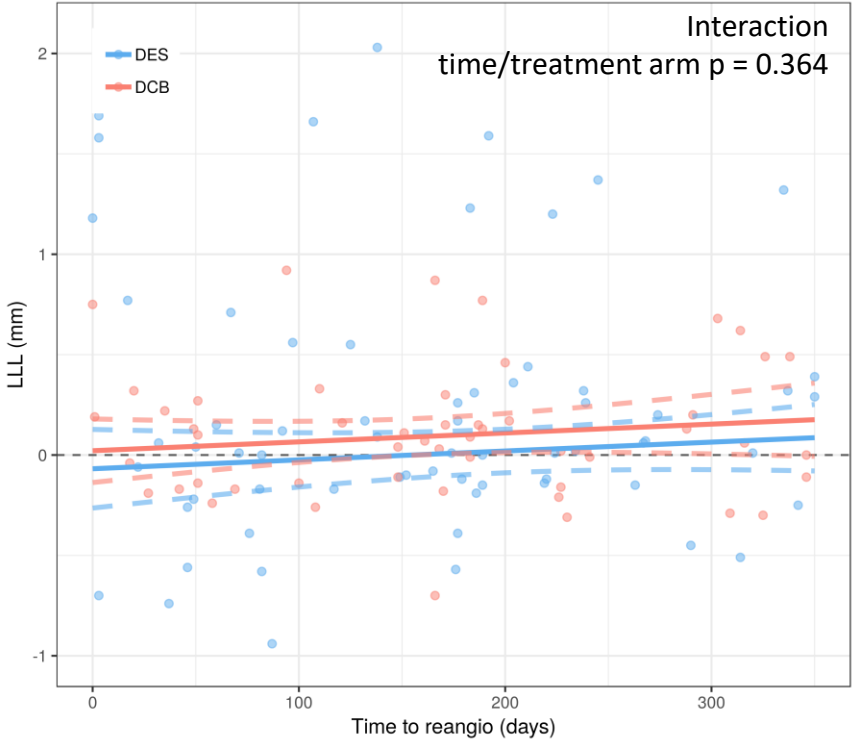
In-segment Late Lumen Loss Distribution



In-segment Late Lumen Loss by Time



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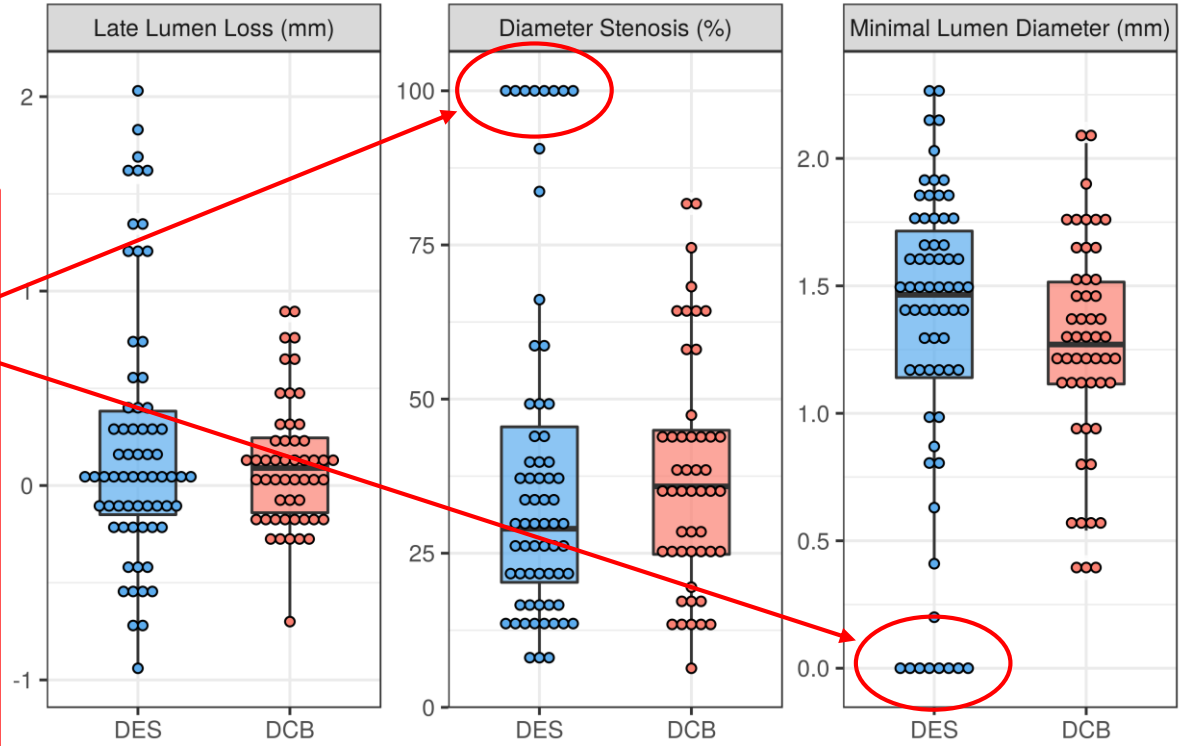
Complete thrombotic vessel occlusion in 8 patients with DES (Xience n=5, Taxus n=3) vs. none with DCB (p = 0.009)

Clinical presentation:
- 3 STEMI
- 1 NSTEMI
- 3 unstable angina
- 1 heart failure

All but one on DAPT



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Conclusions

- All-comer clinical trial with event-driven angiographies, no planned angiographic follow-up
  - No influence of planned angiographies on clinical event rates
- After the procedure, larger acute lumen gain and less residual stenosis in DES as compared with DCB
  - Despite absence of stent-like results in DCB similar clinical event rates as in DES
- During follow-up similar late lumen loss in both treatment arms up to one year, with a reduction of the difference in diameter stenosis between DES and DCB as compared with baseline angiography
  - Stable angiographic result in both treatment arms
- Complete thrombotic occlusion of the target lesion in 8 patients after DES implantation as compared with none in DCB
  - Safety of DCB strategy in small coronary vessel disease

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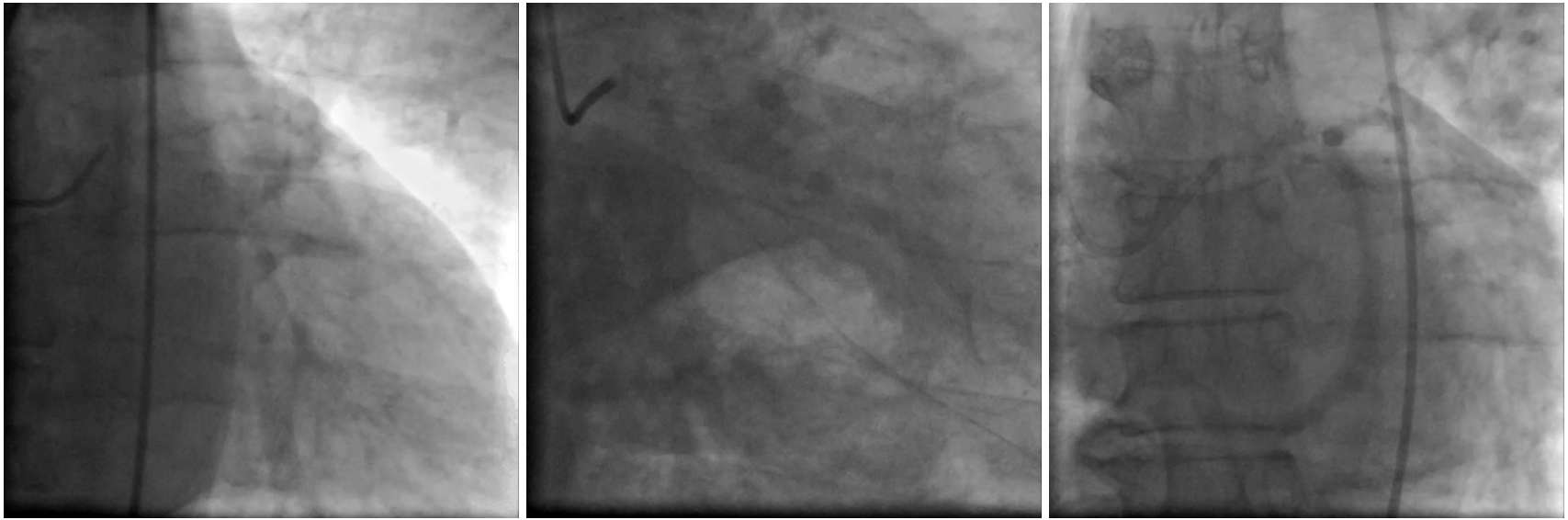
Acute Stent Thrombosis after DES Implantation



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3-Year Follow-Up After DCB Treatment