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

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Declaration of interest

- Research contracts (B. Braun Melsungen AG, Germany)

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Conclusions

- First large randomized controlled trial testing the efficacy and safety of a paclitaxel-iopromide-coated balloon vs. second-generation drug-eluting stent (DES) in a large all-comer population regarding clinical endpoints
- Drug coated balloons (DCB) are non-inferior to DES in lesions of small native coronary arteries regarding major adverse cardiac events (MACE) up to 12 months, with similar event rates for both treatment groups

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Background

- 1977: First coronary angioplasty
- Limitations: acute vessel closure (elastic recoil, flow-limiting dissections), however without dual antiplatelet therapy ⇨ development of stents
- Currently, 2nd-generation DES are the preferred treatment strategy for de-novo coronary lesions
- Efficacy of DES is limited in small vessels due to elevated rates of in-stent-restenoses
- DCB are an established treatment strategy for in-stent restenoses of both bare metal and drug-eluting stents
- The efficacy and safety of DCB in de-novo stenoses is unknown

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Purpose and key points about methods

- Multicenter, randomized controlled non-inferiority trial (14 centers in Germany, Switzerland, and Austria)
- Patients undergoing PCI in native coronary arteries <3 mm
- Randomization after successful predilatation only (no flow-limiting dissections, no residual stenosis >30%)
- Initial comparison Sequent Please® DCB (B.Braun Melsungen) vs. Taxus Element® DES (Boston Scientific), then changed to Xience® DES (Abbott Vascular) after 25% of patients
- Primary Endpoint: Non-inferiority for 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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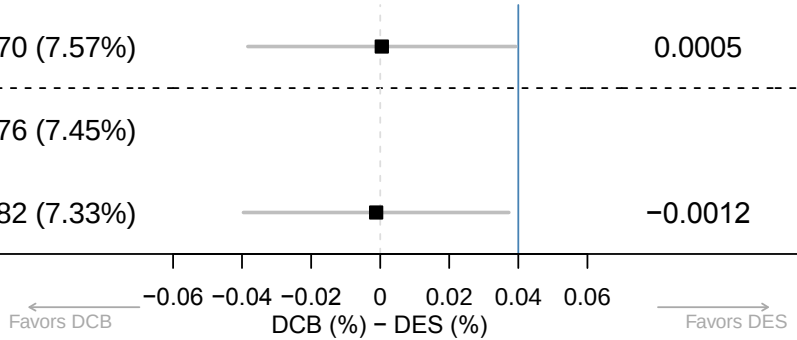
Results

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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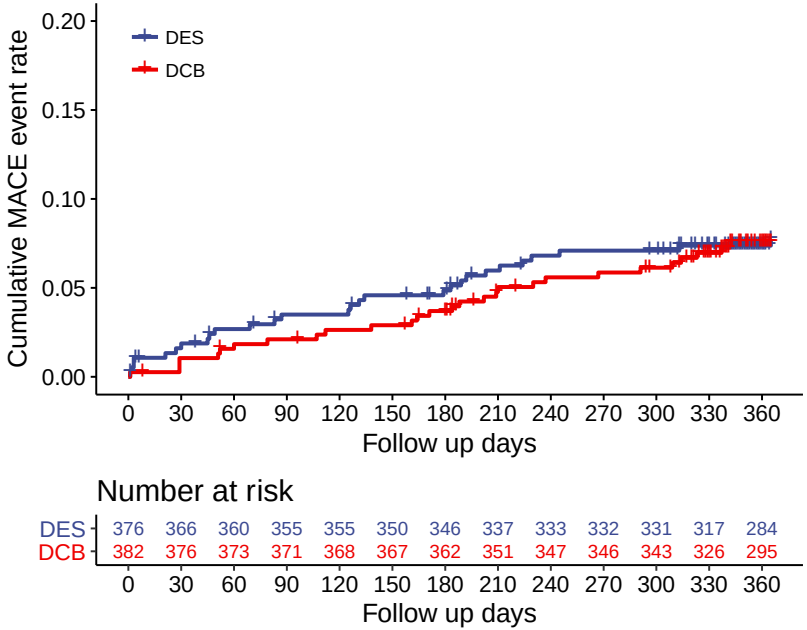
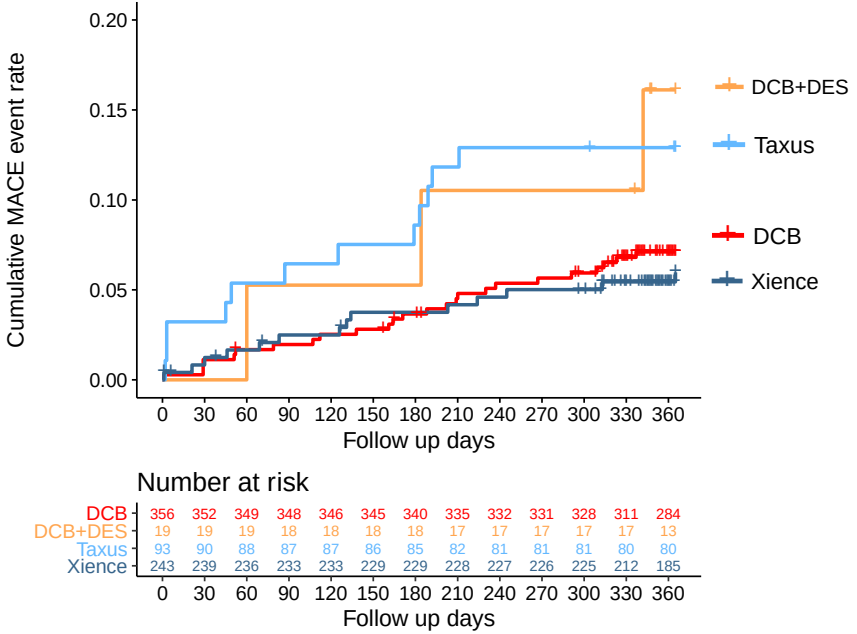
Results





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Key messages

- Small native coronary artery disease may safely be treated with DCB after successful predilatation
- Potential benefit of leaving behind an intact vessel
  - ⇨ No thrombotic events, no prolonged dual antiplatelet therapy if bail-out stenting is not necessary
- Reduced number of very late adverse events expected
  - ⇨ Long-term follow-up needed
- Learning curve for stent-free interventions
  - ⇨ The courage not to treat angiographic images but the actual vessel accepting some degree of recoil and minor dissections after DCB treatment without so called stent-like results is key