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

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Declaration of interest

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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%)  0.0005        [−0.038, 0.039]     0.0217
DCB     28 / 370 (7.57%)     
FAS     DES       28 / 376 (7.45%)  −0.0012       [−0.040, 0.037]     0.0152
DCB     28 / 382 (7.33%)     

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

Cumulative MACE event rate

Follow up days
Number at risk

DES 376 366 360 355 350 346 337 333 332 331 317 284
DCB 382 376 373 371 368 367 362 351 347 346 343 326 295

Follow up days
Number at risk

DCB+DES 356 352 349 348 346 345 340 335 332 331 328 311 284
Taxus 19 19 19 18 18 18 16 17 17 17 17 13
Xience 93 90 88 87 86 85 82 81 81 80 80

DCB 243 239 236 233 229 228 227 226 225 212 185
DCB+DES
Taxus
Xience
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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