

Impact of diabetes on outcome with drug-coated balloons versus drug-eluting stents: the BASKET-SMALL 2 trial

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Objectives: To evaluate the impact of diabetes mellitus on 3 year clinical outcome in patients undergoing drug-coated balloon (DCB) or drug-eluting stent (DES) treatment for de-novo lesions.

Background: For the treatment of de-novo coronary small vessel disease DCB are non-inferior to DES regarding clinical outcome up to 3 years.

Methods: In this prespecified analysis of a multicenter, randomized, non-inferiority trial, including 758 patients with de-novo lesions in coronary vessels <3mm who were randomized 1:1 to DCB (n=382) or DES (n=376) and followed over 3 years for major adverse cardiac events (MACE: cardiac death, non-fatal myocardial infarction [MI], and target-vessel revascularization [TVR]), outcome was analyzed regarding the presence or absence of diabetes mellitus.

Results: In non-diabetic patients (n=506) rates of MACE (13.0% vs. 11.5%, hazard ratio [HR] 1.24, 95% confidence interval [CI] 0.73–2.09,

p=0.43), cardiac death (2.8% vs. 2.9%, HR 0.97, 95% CI 0.32–2.92, p=0.96), non-fatal MI (5.1% vs. 4.8%, HR 1.00, 95% CI 0.44–2.28, p=0.99), and TVR (8.8% vs. 6.1%, HR 1.64, 95% CI 0.83–3.25, p=0.16) were similar in DCB and DES. In diabetic patients (n=252) rates of MACE (19.3% vs. 22.2%, HR 0.82, 95% CI 0.45–1.48, p=0.51), cardiac death (8.8% vs. 5.9%, HR 2.01, 95% CI 0.76–5.31, p=0.16), non-fatal MI (7.1% vs. 9.8%, HR 0.55, 95% CI 0.21–1.49, p=0.24) were similar in DCB and DES, whereas TVR was significantly lower with DCB compared to DES (9.1% vs. 15.0%, HR 0.40, 95% CI 0.17–0.94, p=0.036). In addition, need for TVR was highest in diabetic patients treated with DES (Picture 1).

Conclusions: The rates of MACE are similar in DCB and DES in de-novo coronary lesions of diabetic and non-diabetic patients. In diabetic patients the need for TVR was significantly lower with DCB compared to DES.

