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Impact of coronary artery calcification on long-term outcomes after implantation of first and second-generation drug-eluting stents: a patient-level analysis of 18 randomized trials

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Background: Available data on the long-term impact of coronary artery calcification (CAC) after percutaneous coronary intervention (PCI) with drug-eluting stents (DES) are limited.

Purpose: We evaluated the long-term impact of CAC on outcomes after PCI and the respective performance of first- and second-generation DES.

Methods: We pooled patient-level data from 18 randomized trials evaluating DES categorized according to the presence of angiographic core lab-confirmed moderate or severe CAC in any target lesion. Outcome measures of interest were the patient-oriented composite endpoint (POCE; death, myocardial infarction [MI], or any revascularization), the device-oriented composite endpoint of target lesion failure (TLF; cardiac death, target vessel MI or ischemia-driven target lesion revascularization), and definite or probable stent thrombosis (ST). Multivariable Cox proportional

regression with study as a random effect was used to assess 5-year outcomes.

Results: A total of 19,833 patients were included. Moderate or severe CAC was present in 6211 (31.3%) patients and associated with increased 5-year risk of the POCE (adjHR 1.12, 95% CI 1.05–1.20, $p < 0.001$), TLF (adjHR 1.21, 95% CI 1.09–1.35, $p < 0.001$), and a trend for greater ST (adjHR 1.24, 95% CI 0.99–1.54, $p = 0.06$). In patients with CAC, second-generation DES were associated with a reduction in the 5-year risk of TLF and ST, and a trend for reduced POCE compared with first-generation DES (Table).

Conclusion: In this large-scale study, target lesion moderate or severe CAC was associated with adverse patient- and device-related outcomes at 5 years, risks that were reduced but not eliminated with second-generation DES.

	No or Mild CAC			Moderate or Severe CAC			p Value for Interaction
	Second-Generation DES (n=8157)	First-Generation DES (n=5465)	Adjusted Hazard Ratio (95% Confidence Interval)	Second-Generation DES (n=3803)	First-Generation DES (n=2408)	Adjusted Hazard Ratio (95% Confidence Interval)	
Patients-oriented composite endpoints	1527 (22.3%)	1431 (29.6%)	0.87 (0.79-0.97)	869 (27.3%)	724 (35.3%)	0.88 (0.78-1.00)	0.85
Target lesion failure	704 (10.4%)	462 (15.6%)	0.69 (0.60-0.80)	470 (14.8%)	247 (19.8%)	0.73 (0.61-0.87)	0.61
All-cause death	402 (6.8%)	383 (8.9%)	0.81 (0.69-0.94)	287 (10.2%)	224 (12.4%)	0.86 (0.71-1.04)	0.77
Myocardial infarction	282 (4.0%)	367 (7.6%)	0.53 (0.43-0.64)	195 (6.0%)	186 (8.8%)	0.61 (0.48-0.77)	0.29
Target vessel	221 (3.2%)	172 (5.7%)	0.57 (0.43-0.76)	157 (4.7%)	101 (8.0%)	0.57 (0.43-0.76)	0.95
Any revascularization	1062 (18.7%)	993 (20.5%)	0.96 (0.85-1.08)	538 (20.5%)	499 (24.3%)	0.91 (0.78-1.05)	0.50
Ischemia-driven TLR	426 (6.1%)	482 (9.9%)	0.65 (0.54-0.77)	258 (8.0%)	237 (11.6%)	0.69 (0.56-0.86)	0.59
Probable or definite stent thrombosis	79 (1.2%)	157 (3.2%)	0.47 (0.34-0.67)	63 (2.1%)	89 (4.1%)	0.60 (0.41-0.89)	0.27

Data are expressed as n (Kaplan-Meier estimated rate). Covariates for the multivariable models: age; sex; current smoker; insulin-treated diabetes mellitus; non-insulin treated diabetes mellitus; hypertension; hyperlipidemia; prior percutaneous coronary intervention; prior coronary artery bypass graft surgery; prior myocardial infarction; percutaneous coronary intervention indication: number of treated lesions (>1 lesion treated versus one treated lesion) and total stent length. CAC = coronary artery calcification; DES = drug-eluting stents; TLR = target lesion revascularization.