

Efficacy of Drug Coated Balloon Versus Drug Eluting Stent for De Novo Coronary Lesion: A Meta analysis of Randomized Trials

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Background: Data on the efficacy of drug coated balloons (DCB) compared to drug eluting stents (DES) in de novo coronary lesions is evolving.

Methods: We searched PubMed, Cochrane, and Embase through December 2025. 13 RCTs were included. Device-Oriented Composite Outcomes (DOCO) were defined as a composite of cardiovascular death, target-vessel MI, and TLR. Prespecified subgroups included small vessel disease (diameter <3 mm) and STEMI. Pooled risk ratios (RR) with 95% confidence intervals (CI) were estimated using random-effects models.

Results: DCB was associated with a significantly higher risk of DOCO (RR 1.58; 95% CI 1.07-2.33; P=0.02; I²=55%). No significant differences were found in cardiovascular mortality (RR 1.16; P=0.48), TV-MI (RR 1.09; P=0.61), MI (RR 0.89; P=0.36), stroke (RR 1.42; P=0.27), TLR (RR 1.07; P=0.83), and TVR (RR 1.28; P=0.26). Paradoxically, DCB demonstrated superior angiographic efficacy, significantly reducing in-lesion late lumen loss compared to DES (MD -0.14; 95% CI -0.18 to -0.10; P<0.00001; I²=24%). Results were consistent across STEMI and small-vessel subgroups.

Conclusions: Despite improved angiographic efficacy with reduced late lumen loss, DCB were associated with a higher risk of DOCO, supporting DES as the current standard of care while highlighting the need for further randomized trials to define the role of DCB in selected patient populations.