

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

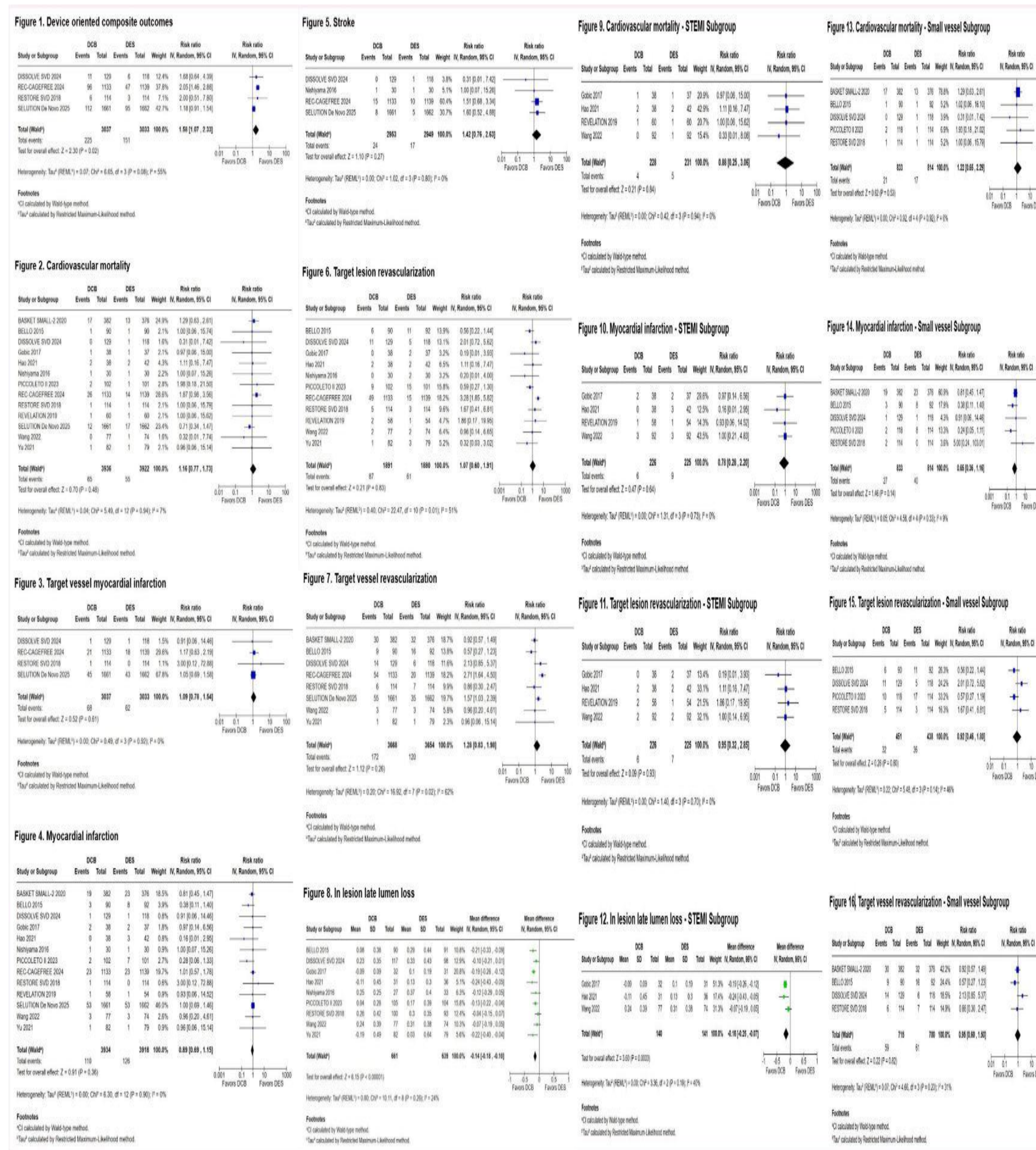
We searched PubMed, Cochrane, and Embase through December 2025. 13 RCTs were included. Device-Oriented Composite Outcomes (DOCO) were defined as a composite of cardiovascular death, target-vessel MI (TV-MI), and target lesion revascularization (TLR). Prespecified subgroups included small vessel disease (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 target vessel revascularization (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.

CONCLUSION

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.



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