

Safety 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 safety 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 for RCTs comparing DCB with DES in de novo coronary lesions. 12 RCTs were included. Outcomes were major bleeding and all-cause mortality. Pooled risk ratios (RR) with 95% confidence intervals (CI) were estimated using random-effects models, and heterogeneity was assessed using the I^2 statistic.

Results: DCB was associated with lower risk of major bleeding (RR 0.67; 95% CI 0.46-0.98; $P=0.04$; $I^2=0\%$; Figure 1) compared to DES. There was no significant difference in all-cause mortality between the two groups (RR 1.08; 95% CI 0.80-1.46; $P=0.61$; $I^2=5\%$; Figure 2).

Conclusions: Compared with DES, DCBs are associated with a significant reduction in major bleeding, potentially making them a preferable option for patients with a high bleeding risk.