

Superior safety profile of Drug Coated Balloon compared to Drug Eluting Stent for De Novo Coronary Lesion:

A Meta-analysis of Randomized Trials

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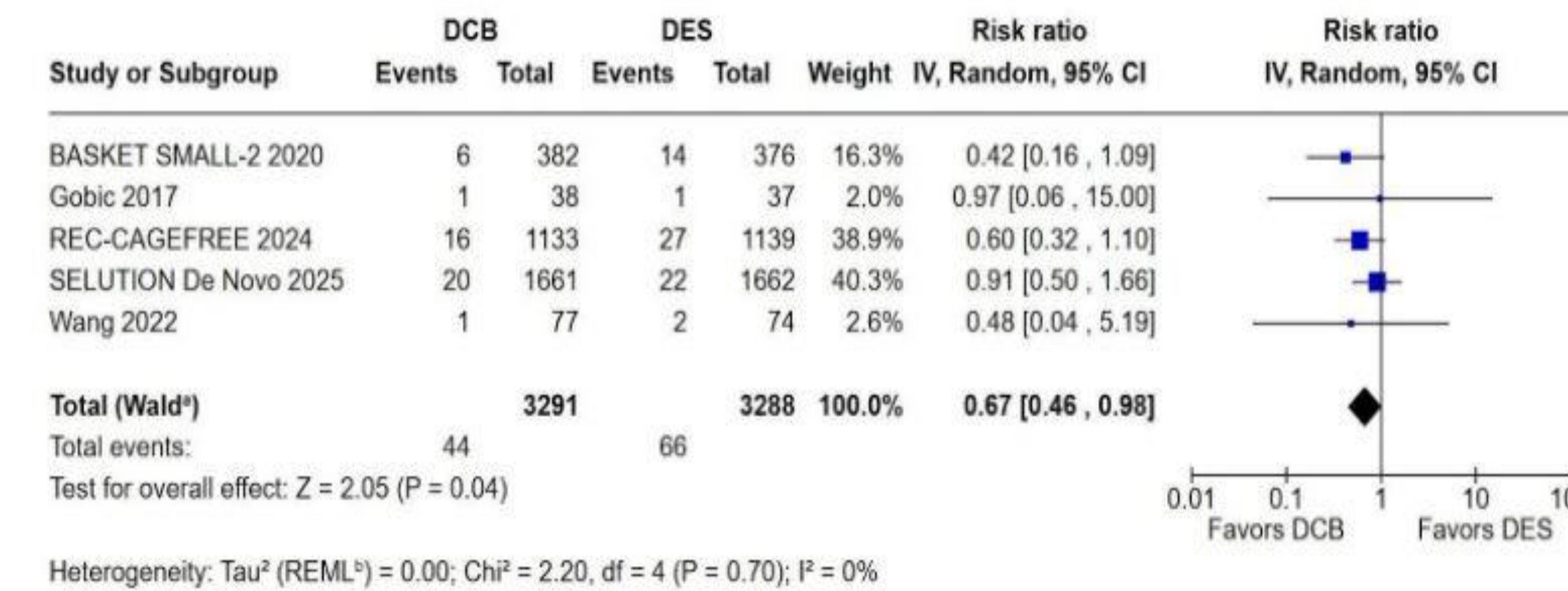
BACKGROUND

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 I² statistic.

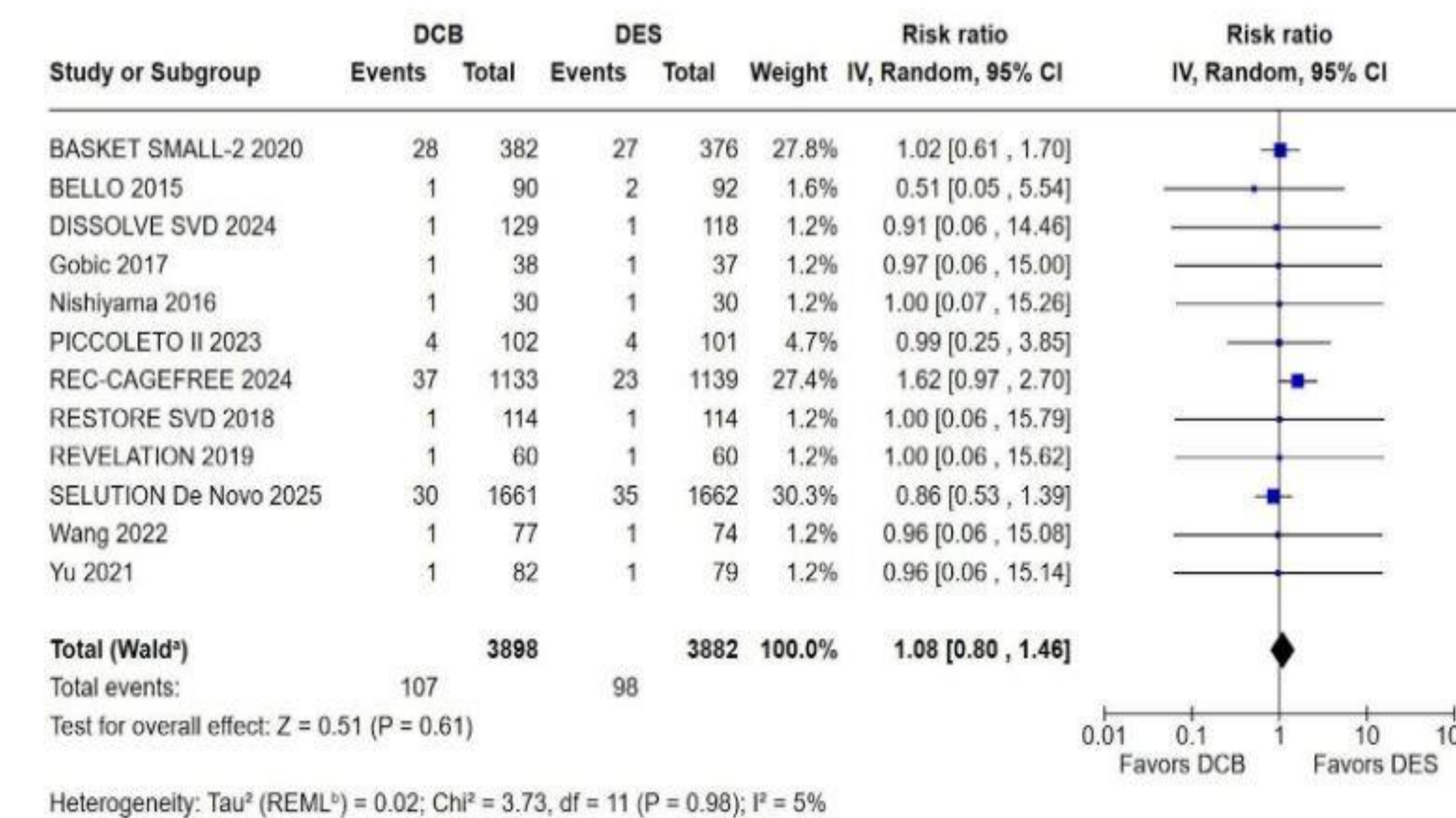
Figure 1. Major bleeding



Footnotes

*CI calculated by Wald-type method.
³Tau² calculated by Restricted Maximum-Likelihood method.

Figure 2. All-cause mortality



Footnotes

*CI calculated by Wald-type method.
³Tau² calculated by Restricted Maximum-Likelihood method.

RESULTS

DCB was associated with lower risk of major bleeding (RR 0.67; 95% CI 0.46-0.98; P=0.04; I²=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; I²=5%; Figure 2).

CONCLUSION

Compared with DES, DCB significantly reduce major bleeding, potentially making them a preferable option for high bleeding risk patients with de novo coronary lesions.



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