



Drug-Coated Balloons Versus Drug-Eluting Stents Following Coronary Atherectomy in Severely Calcified Lesions: A Systematic Review and Meta-analysis



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Severely calcified coronary lesions are associated with increased risk of procedural complications, stent underexpansion, and restenosis. While atherectomy prepares vessels for treatment, drug-eluting stents (DES) are traditionally preferred over drug-coated balloons (DCB). DCBs offer a stent-free alternative that may improve vessel remodeling and may require shorter antiplatelet therapy. However, for severely calcified lesions, it remains unclear whether DCB or DES is more effective. Following PRISMA guidelines, a systematic search of PubMed, Embase, Web of Science, Scopus, and Cochrane Central identified randomized controlled trials and adjusted observational studies comparing DCB versus DES following atherectomy. The study endpoints included major adverse cardiovascular events (MACE), all-cause death, myocardial infarction (MI), target lesion revascularization (TLR), and major bleeding. Random-effects models were used to estimate pooled risk ratios (RRs) and 95% confidence intervals (CIs). Eight observational studies comprising a pooled total of 1,968 patients (698 DCB and 1,270 DES) met the inclusion criteria. There was no statistically significant difference between the DCB and DES strategies regarding MACE (RR 1.12; 95% CI 0.85 to 1.47; $I^2 = 0\%$), MI (RR 1.11; 95% CI 0.40 to 3.04; $I^2 = 0\%$), major bleeding (RR 1.11; 95% CI 0.36 to 3.37; $I^2 = 0\%$), all-cause mortality (RR 1.18; 95% CI 0.78 to 1.79; $I^2 = 0\%$), or cardiac death (RR 0.67; 95% CI 0.34 to 1.32; $I^2 = 0\%$). However, DES was associated with a significantly lower risk of TLR in the pooled analysis (RR 1.82; 95% CI 1.14 to 2.91; $I^2 = 37.4\%$) and in the Kaplan–Meier curve (HR = 1.64, 95% CI 1.11 to 2.42, $p = 0.014$). In conclusion, following mechanical atherectomy for calcified lesions, both DCB and DES demonstrate favorable MACE, mortality, and safety profiles. However, DES exhibits a consistent association with lower TLR. Given the observational nature and inherent selection biases of the data, these findings cannot establish definitive causal relationships and require caution.

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Percutaneous coronary intervention (PCI) of severely calcified coronary artery lesions has been associated with high procedural complexity, challenging device delivery, and suboptimal stent expansion. These factors contribute to higher rates of restenosis, stent thrombosis, and adverse cardiovascular outcomes, even in the era of contemporary drug-eluting stents (DES).^{1,2}

To overcome these limitations, calcium modification strategies such as rotational atherectomy (RA), orbital atherectomy (OA) and intravascular lithotripsy are often used to improve lesion compliance and facilitate device delivery and expansion.^{2,3} Despite these advances, DES implantation in heavily calcified lesions is associated with a higher risk of adverse clinical outcomes.^{1,4} Drug-coated balloons (DCBs) have emerged as an alternative strategy, delivering antiproliferative drugs without leaving a permanent implant, potentially reducing the need for prolonged dual antiplatelet therapy.^{3,5,6} The concept of combining atherectomy with DCB, thereby enabling a “leave nothing behind” approach, has gained increasing interest. By reducing calcium burden through atherectomy, this strategy may enhance drug penetration into the vessel wall and improve vascular healing.³

However, clinical evidence supporting this approach remains limited, and concerns persist regarding the risk of restenosis and the adequacy of lumen gain compared with DES-based strategies.⁶ Several observational studies have evaluated outcomes of DCB versus DES following atherectomy in severely calcified lesions, reporting generally comparable rates of major adverse cardiovascular events (MACE) and target lesion revascularization (TLR), albeit with heterogeneous results and limited statistical power.^{1,4,5,6} Given the absence of large randomized trials and the variability of available evidence, the optimal revascularization strategy following atherectomy of severely calcified coronary lesions remains uncertain. We conducted a systematic review and meta-analysis of the available observational evidence to evaluate the comparative effectiveness and safety of DCBs versus DESs following coronary atherectomy in patients with severely calcified coronary lesions.

Methods

This systematic review and meta-analysis were conducted following the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.^{7,8} The review protocol was registered in the International Prospective Register of Systematic Reviews.

Search strategy

A comprehensive literature search was performed in PubMed and Embase, Cochrane Library of Randomized Trials, Web of Science, and Scopus, up to February 2026. The PubMed search strategy integrated Medical Subject Headings (MeSH) and free-text keywords as follows: (“Atherectomy”[MeSH] OR “Atherectomy, Coronary”[MeSH] OR atherectomy OR “rotational atherectomy” OR “orbital atherectomy” OR rotablation) AND (“Drug-Eluting Balloons”[MeSH] OR “drug-coated balloon” OR “drug-eluting balloon” OR DCB OR DEB) AND (“Drug-Eluting Stents”[MeSH] OR “drug-eluting stent” OR DES). Similar search strategies were adapted using equivalent keywords and syntax for the other databases.

Inclusion criteria and study selection

Studies were included if they met the following criteria: (1) enrolled patients with severely calcified coronary artery lesions undergoing PCI with atherectomy; (2) compared DCBs versus DES following atherectomy; (3) were randomized controlled trials (RCTs) or observational studies with adjusted analyses. Although RCTs were actively sought during the systematic screening, none fulfilled the eligibility criteria. Consequently, the final analysis was exclusively composed of nonrandomized observational trials; (4) reported at least one clinical outcome of interest, including major adverse cardiovascular events (MACE), all-cause mortality, cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), or major

bleeding. Studies without a direct comparison group, case reports, reviews, and those lacking extractable data were excluded.

Across the included source studies, ‘severe calcification’ was defined based on standardized criteria: angiographically, as readily apparent radiopacities noted without cardiac motion before contrast injection involving both sides of the vessel wall; or via intravascular imaging (IVUS/OCT), as a maximum calcium arc exceeding 180°, accompanied by high plaque burden or cross-sectional resistance requiring mechanical modification.

The study selection process was conducted using the Rayyan platform (<https://www.rayyan.ai/>),⁹ with 2 independent reviewers screening titles and abstracts (C.R. & L.S.). Disagreements were resolved by the first author (R.S.-M.).

Data extraction and endpoints

Data were extracted using a standardized sheet and included study characteristics such as author, year, country, design, sample size, and follow-up duration; baseline patient characteristics including sex, age, diabetes mellitus, hypertension, previous ACS, previous CABG, previous stroke, history of heart failure, chronic kidney disease, and history of bleeding; and clinical outcomes including in-hospital mortality, long-term mortality, recurrent MI, bleeding events, stroke, cardiogenic shock, and acute kidney injury. The primary endpoints were TLR and MACE. The secondary endpoints were all-cause mortality, cardiac death, recurrent MI, and bleeding events.

Statistical analysis

For dichotomous outcomes, pooled risk ratios (RRs) with 95% confidence intervals (CIs) were calculated using a random-effects model in R version 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria) with the meta package. Between-study heterogeneity was assessed using the I^2 statistic. Small-study effects and potential publication bias were evaluated by visual inspection of funnel plots and formally tested with Egger’s regression test. Sensitivity analyses were performed using a leave-one-out approach, in which the pooled estimate was recalculated after excluding each study one at a time.¹⁰

Traditional meta-analytic approaches for time-to-event outcomes often struggle with censoring and inconsistent reporting, typically relying on limited pooled medians or fixed event rates. To overcome these limitations, this study employed a curve-based, two-stage reconstruction process to generate individual patient data (IPD) from published Kaplan–Meier curves. Using the “IPDfromKM” R package, raw coordinate data were extracted and integrated with reported numbers at risk to reconstruct patient-level event times. The fidelity of this reconstruction was rigorously validated by comparing original and reconstructed distributions using Kolmogorov–Smirnov statistics and assessing reproducibility through independent dual reconstructions.^{11,12} The primary utility of this approach is its capacity to preserve individual censoring patterns and varying follow-up durations across different cohorts, enabling a granular, time-dependent assessment of outcomes over the entire follow-up.

Quality assessment

The included studies were submitted to evaluate their methodological quality through the ROBINS I tool.¹³ The purpose was to determine the overall quality of the literature through the analysis of individual studies.

Results

Study selection and baseline characteristics

The study selection process is summarized in Figure 1. A total of 2,594 records were identified through the systematic database search, and after removal of 1,427 duplicates, the remaining records underwent title and abstract screening, followed by full-text assessment of potentially eligible studies. Ultimately, 8 observational studies met the inclusion criteria and were incorporated into the final analysis.^{14–20,21} These studies included patients with severely calcified coronary artery disease undergoing PCI with atherectomy-based lesion preparation, followed by treatment with DCB or DES. Across the studies, atherectomy was performed using rotational, orbital, directional, or intravascular imaging-guided rotational techniques. In

aggregate, the included studies enrolled 1,968 patients, of whom 698 (35.4%) were treated with DCB and 1,270 (64.6%) with DES. Baseline characteristics of the included populations from each study are detailed in Table 1. Follow-up duration ranged from 1 to 5 years across the included studies.

Patient and procedure characteristics

The clinical and angiographic characteristics of the included studies are summarized in Table 2. RA was the primary modality for lesion preparation in the majority of the studies, although OA^{17,19} and directional coronary atherectomy¹⁸ were also utilized. Regarding pharmacological profiles, the DCB groups almost exclusively utilized paclitaxel-coated devices (notably the SeQuent Please and AGENT systems), whereas the DES groups received newer-generation

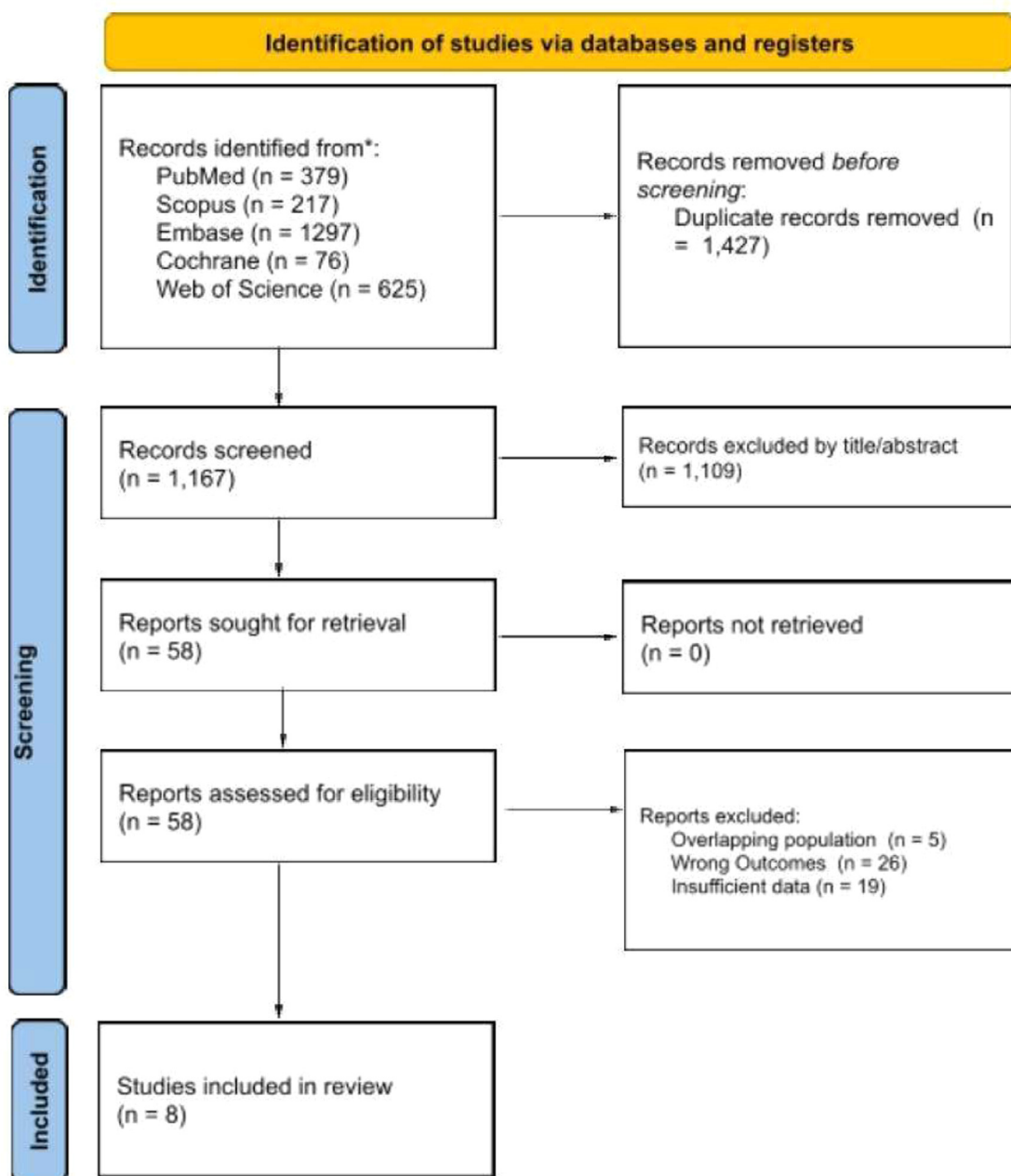


Figure 1. PRISMA flow diagram of study selection for the systematic review and meta-analysis.

Table 1
Baseline characteristics of the patients in the included studies

Study	Group	Number of patients	Age (years)	Male Sex no. (%)	CKD no. (%)	Diabetes Mellitus no. (%)	LVEF, (%)	Multivessel Disease no. (%)	Bifurcation Lesion no. (%)	Lesion length (mm)	Preprocedural MLD (mm)
Dong et al. ¹⁴	DCB	57	66.68 ± 9.13	30 (52.6%)	4 (7%)	24 (42.1%)	63 (60 to 65)	20 (34.5%)*	2 (3.5%)	NA [†]	NA
	DES	261	65.64 ± 7.99	154 (59%)	29 (11.1%)	96 (36.8%)	62 (60 to 64)	119 (43.4%)*	51 (18.6%)	NA [†]	NA
Iwasaki et al. ¹⁵	DCB	69	76 ± 7.2	44 (64%)	6 (9%)	37 (54%)	61 ± 10	26 (38%)	NA	19 ± 11	1.35 ± 0.49
	DES	88	74 ± 8.4	58 (67%)	17 (19%)	41 (47%)	62 ± 10	44 (50%)	NA	19 ± 10	1.29 ± 0.49
Li et al. ¹⁶	DCB	124	64.9 ± 7.4	65 (52.4%)	NA	32 (25.8%)	NA	NA	18 (14.5%)	45.6 ± 8.7	0.55 ± 0.14
	DES	124	66.3 ± 7.8	69 (55.6%)	NA	36 (29%)	NA	NA	13 (10.5%)	46.7 ± 9.8	0.53 ± 0.16
Mitsui et al. ¹⁷	DCB	43	75 (70 to 79)	37 (86%)	12 (27.9%) [‡]	12 (48.8%)	NA	NA	NA	NA	NA
	DES	92	74.5 (68 to 80)	74 (80.4%)	16 (17.4%) [‡]	48 (52.2%)	NA	NA	NA	NA	NA
Murai et al. ¹⁸	DCB	58	67 ± 12.5	50 (86.2%)	21 (36.2%)	22 (37.9%)	NA	28 (48.3%)	11 (19%)	13.9 ± 9.9	1.34 ± 0.45
	DES	51	69.4 ± 9.7	44 (86.3%)	20 (39.2%)	25 (49%)	NA	20 (39.2%)	4 (7.8%)	16.5 ± 7.6	1.14 ± 0.52
Takamura et al. ¹⁹	DCB	94	69.5 ± 11.4	63 (73.8%)	35 (37.7%)	58 (61.3%)	54.1 ± 14.3	NA	26 (27.7%)	10.6 ± 10.9	0.95 ± 0.47
	DES	159	73.2 ± 8.6	115 (72.2%)	50 (31.5%)	93 (58.3%)	53.7 ± 12.4	NA	51 (31.9%)	10.8 ± 13.4	1 ± 0.53
Ueno et al. ²⁰	DCB	54	71 ± 9	38 (70.4%)	19 (35.2%)	33 (61.1%)	NA	NA	46 (67.6%) [‡]	11.89 ± 6.41	0.87 ± 0.35
	DES	69	71 ± 9	45 (65.2%)	28 (40.6%)	39 (56.5%)	NA	NA	46 (47.9%) [‡]	18.78 ± 7.91	0.90 ± 0.41
Yui et al. ²¹	DCB	102	NR	NR	NR	NR	NR	NR	NR	NR	NR
	DES	369	NR	NR	NR	NR	NR	NR	NR	NR	NR

* Considered as triple vessel disease.

† Total device length reported: 42.60 ± 17.42 mm (DCB) vs 52.16 ± 20.76 mm (DES), but not the length of the lesion in isolation.

‡ CKD not directly reported; hemodialysis used as a proxy.

§ Data per lesion (n = 68 DCB; n = 98 DES), not per patient.

platforms eluting everolimus, zotarolimus, sirolimus, or biolimus. The use of intravascular imaging (IVUS or OCT) was highly prevalent, reaching 100% in several cohorts,^{17,18,20,21} reflecting its critical role in confirming adequate lesion preparation before a DCB-only strategy. The left anterior descending (LAD) artery was the most frequent target vessel across all studies, ranging from 51% to 81% of cases. Complex lesion subsets were well-represented, with bifurcation lesions present in up to 58.5% of the population²⁰ and chronic total occlusions (CTO) identified in a smaller subset of patients, reaching 14.5% in the DCB arm of the Li et al.¹⁶ study. The DES group often exhibited a higher prevalence of complex features, such as higher rates of bifurcation involvement in the Dong et al.¹⁴ study, highlighting the inherent selection bias where stenting was preferred for more anatomically challenging scenarios.

Primary outcomes

Target lesion revascularization

Seven studies with 1,650 patients contributed data on TLR (Figure 2). Of these, 641 patients (38.8%) underwent DCB treatment. In the pooled analysis, there was a difference between groups for DCB versus DES (RR 1.82; 95% CI 1.14 to 2.91; $I^2 = 37.4\%$). Additionally, in the Kaplan–Meier curve comparing both interventions, a progressive separation of events occurred during follow-up for DCB versus DES (HR = 1.64, 95% CI 1.11 to 2.42, $p = 0.014$, Figure 3).

Major adverse cardiac events

Six studies with 1,388 patients contributed data on MACE (Figure 4). Among these, 538 patients (38.8%) were treated with DCB. There was no significant difference between the 2 strategies in the pooled analysis for DCB versus DES (RR 1.12; 95% CI 0.85 to 1.47; $I^2 = 0\%$). In the Kaplan–Meier analysis, event curves for MACE remained closely aligned throughout follow-up, with no significant separation between the DCB and DES groups (HR = 1.11, 95% CI 0.82 to 1.51, $p = 0.764$, Figure 5).

All-cause mortality

Five studies with 1,140 patients reported all-cause mortality (Figure 6). Among these, 414 patients (38.4%) were treated with DCB. In the pooled analysis, there was no significant difference between treatment strategies for DCB versus DES (RR 1.18; 95% CI 0.78 to 1.79; $I^2 = 0\%$).

Cardiac death

Seven studies with 1,650 patients contributed data on cardiac death (Figure 7). Of these, 641 patients (45.7%) underwent DCB. The pooled analysis demonstrated no significant difference between groups for DCB versus DES (RR 0.67; 95% CI 0.34 to 1.32; $I^2 = 0\%$).

Myocardial infarction

Seven studies with 1,561 patients reported MI during follow-up (Figure 8). Among these, 507 patients (32.4%) were treated with DCB. The pooled analysis demonstrated no significant difference between the 2 strategies for DCB versus DES (RR 1.11; 95% CI 0.40 to 3.04; $I^2 = 0.0\%$).

Major bleeding

Three studies with 673 patients contributed data on major bleeding (Figure 9). Of these, 318 patients (47.3%) underwent DCB. The pooled analysis showed no significant difference between treatment groups for DCB versus DES (RR 1.11; 95% CI 0.36 to 3.37; $I^2 = 0\%$).

Sensitivity analyses

Detailed leave-one-out plots for each outcome are provided in the Supplementary Appendix Figures S1–S6. The overall results were

Table 2
Patient and procedure characteristics

Study	Group	Atherectomy type	Drug type	Intravascular imaging	Bifurcation lesions	CTO	Main target vessel
Dong et al. ¹⁴	DCB	Rotational	Paclitaxel	58.6%	3.45%	10.3%	LAD (72%)
	DES	Rotational	Everolimus/Zotarolimus	38.6%	18.61%	9.1%	LAD (55%)
Iwasaki et al. ¹⁵	DCB	Rotational	Paclitaxel	100%	NR	NR	LAD (59%)
	DES	Rotational	Everolimus/Zotarolimus/Sirolimus/Biolimus	100%	NR	NR	LAD (60%)
Li et al. ¹⁶	DCB	Rotational	NR	63%	14.5%	NR	LAD (75.8%)
	DES	Rotational	NR	63%	10.5%	NR	LAD (70.5%)
Mitsui et al. ¹⁷	DCB	Orbital	Paclitaxel	100%	NR	NR	LAD (51%)
	DES	Orbital	Everolimus/Sirolimus	100%	NR	NR	LAD (68%)
Murai et al. ¹⁸	DCB	Directional	Paclitaxel	100%	19%	NR	LAD (81%)
	DES	Directional	Everolimus	100%	7.8%	NR	LAD (80%)
Takamura et al. ¹⁹	DCB	Rotational/Orbital	Paclitaxel	82.8%	27.7%	3.1%	LAD (52.9%)
	DES	Rotational/Orbital	NR	88%	31.9%	4.7%	LAD (51.9%)
Ueno et al. ²⁰	DCB	Rotational	Paclitaxel	100%	58.5%	7.3%	LAD (56.1%)
	DES	Rotational	Everolimus/Zotarolimus/Sirolimus/Biolimus	100%	56.1%	12.2%	LAD (51.2%)
Yui et al. ²¹	DCB	Rotational	NR	NR	NR	NR	NR
	DES	Rotational	Second-Generation	NR	NR	NR	NR

Abbreviations: CTO = chronic total occlusion; DCB = drug-coated balloon; DES = drug-eluting stent; LAD = left anterior descending artery; NR = non-reported.

generally robust in leave-one-out sensitivity analyses, with no single study exerting a disproportionate influence on the pooled estimates. Funnel plots for the assessed outcomes are also provided in the [Supplementary Appendix Figures S7–S12](#). No clear visual asymmetry was observed.

Risk of bias

The summary of the quality assessment for the included cohorts is presented in [Supplementary Figure 13](#). Overall, 4 studies^{14,15,17,19} were judged to have a serious risk of bias, primarily driven by baseline confounding and selection bias inherent to their observational designs. The remaining 3 studies by Lee et al., Murai et al., and Ueno et al. exhibited an overall moderate risk of bias. While all 8 studies demonstrated a low risk of bias regarding the classification of interventions, they consistently revealed a moderate risk of performance bias due to a lack of operator blinding and procedural discretion in cointerventions. Additionally, a moderate risk of attrition bias was noted across most cohorts due to incomplete angiographic or imaging follow-up without explicit handling of missing data. Lastly, due to the absence of preregistered protocols, a moderate risk of bias in the selection of reported results was assigned. In aggregate, the predominance of these nonrandomized designs necessitates a cautious interpretation of the pooled clinical estimates.

Discussion

In this systematic review and meta-analysis of studies comparing DCB versus DES following atherectomy for severely calcified coronary lesions, both strategies demonstrated overall comparable clinical

performance across the evaluated outcomes. With primary endpoints defined as TLR and MACE, and secondary endpoints including all-cause mortality, cardiac death, MI, and major bleeding, the pooled analyses showed no statistically significant differences between treatment strategies for MACE, mortality, MI, or major bleeding. However, DES was associated with lower TLR, indicating that the main difference between strategies was related to repeat lesion revascularization rather than to hard cardiovascular or safety outcomes.

In our meta-analysis, both the pooled analysis and the Kaplan–Meier time-to-event analysis showed less TLR with DES. This consistent finding across both statistical methods suggests a reproducible signal in favor of DES for repeat lesion revascularization, although it should be interpreted in the context of heterogeneity in follow-up duration and the inherent differences in study designs across the included cohorts. The application of this curve-based IPD reconstruction, following the validated Guyot algorithm, provides major clinical utility. Unlike traditional meta-analyses limited to fixed summary-level data, this approach accounts for individual censoring and varying follow-up periods. It allows us to track the exact timing of event divergence, capturing long-term observational trends that would otherwise remain hidden in aggregate summaries. For MACE, both the pooled analysis and the Kaplan–Meier assessment showed no significant difference between groups, with event curves remaining closely aligned throughout follow-up. Similarly, all secondary endpoints remained largely neutral between strategies.^{22–24, 25}

These findings are broadly consistent with previous meta-analytic evidence in small-vessel and calcified coronary lesions showing comparable outcomes between balloon-based drug delivery strategies

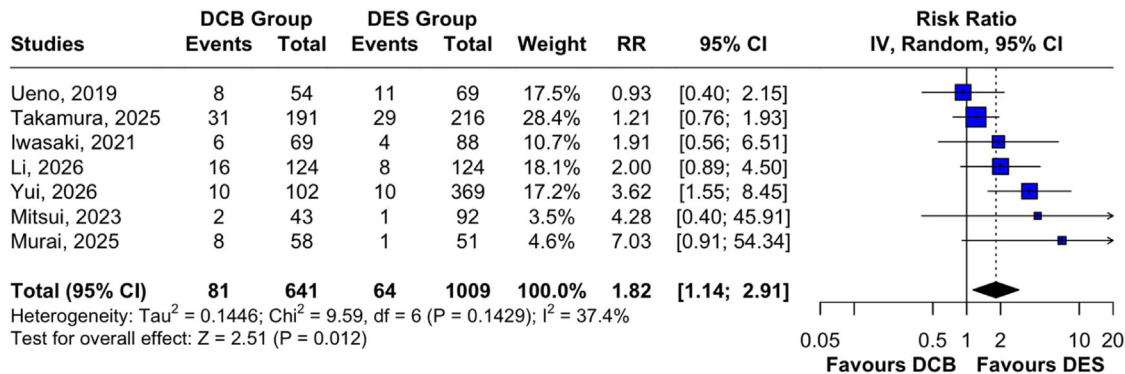


Figure 2. Forest plot for target lesion revascularization comparing drug-coated balloon and drug-eluting stent following atherectomy.

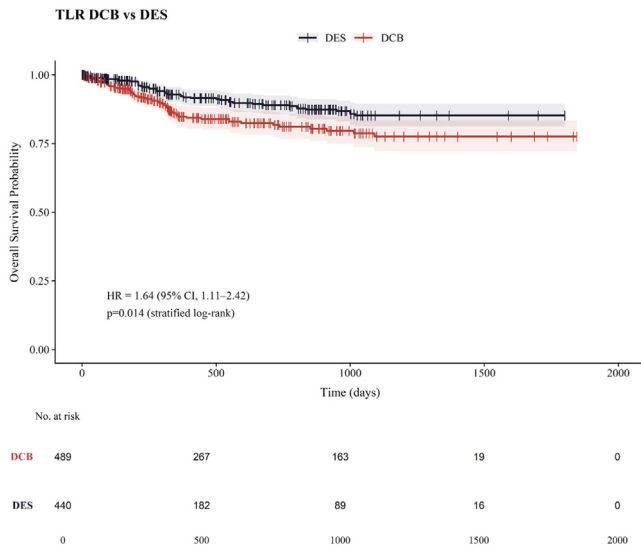


Figure 3. Kaplan–Meier curve for target lesion revascularization comparing drug-coated balloon and drug-eluting stent following atherectomy.

and DES.^{26,27,28} However, the present analysis extends this evidence to the more specific setting of severely calcified coronary lesions treated with atherectomy before DCB or DES. In this scenario, the neutral findings for MACE, mortality, MI, and major bleeding are consistent with previous literature, whereas the TLR signal suggests that repeat revascularization may remain the main endpoint differentiating both strategies.

A critical consideration in interpreting these findings is the systematic selection bias inherent to all included observational studies, which precludes the establishment of definitive causal relationships regarding therapeutic efficacy and safety. Across all cohorts, allocation to DCB or DES relied on operator discretion, instead of a randomized criterion. In practice, DCB was preferentially reserved for lesions achieving satisfactory postatherectomy preparation in several cohorts, while DES was deployed in more complex or suboptimally prepared scenarios. This pattern was observed in studies in which DES was used after suboptimal preparation or in anatomically more complex lesions, including higher rates of bifurcation, left main, or LAD involvement.^{14,17,21} However, the direction and magnitude of selection bias varied considerably across cohorts, since other studies showed adverse lesion features concentrated in the DCB arm, including ostial or bifurcation involvement, smaller reference vessel diameter, severe calcification, or calcified nodules.^{19,20} Finally, some cohorts either attempted to reduce baseline imbalance through propensity score matching or did not report a clear directional imbalance in lesion complexity between strategies.^{15,16,18}

Consequently, while the DCB-treated population represents a relatively procedurally favorable subset in most studies, the direction and magnitude of selection bias varied considerably across cohorts. Coupled with these selection dynamics, the commercial heterogeneity of devices, including different generations of DES, various paclitaxel-coated balloon delivery systems, and diverse mechanical atherectomy mechanisms (rotational, orbital, or directional), adds layers of clinical variance that naturally compound the uncertainty of unadjusted observational comparison.^{14–20, 21}

These selection dynamics have direct implications for the interpretation of the TLR signal observed in the Kaplan–Meier analysis. Since the selection bias operated in favor of DCB in the majority of cohorts by enriching that group with better-prepared lesions, the observed late separation in revascularization rates is noteworthy. Nevertheless, residual confounding from unmeasured variables, including differences in lesion complexity indices, intravascular imaging protocols, atherectomy aggressiveness, and operator ability, cannot be excluded.

From a guideline perspective, the overall balanced pattern observed across most endpoints is consistent with the current view that treatment decisions in severely calcified coronary lesions remain individualized, and no single strategy can be considered uniformly superior across all anatomical scenarios.^{29,30} The available evidence supports a framework in which DCB following atherectomy remains a reasonable alternative to DES in selected patients with favorable postpreparation results, while acknowledging that a residual risk of late TLR may exist.^{29,30} Adequately powered randomized studies are required to determine whether the observed TLR difference reflects a true device-related effect or residual selection bias.

Limitations

Several limitations should be acknowledged when interpreting our findings. First, the overall sample size and number of included studies were small, with low statistical power for relatively infrequent outcomes and for subgroup analyses. Second, residual heterogeneity across studies should be considered, particularly with respect to lesion anatomy, atherectomy technique, follow-up duration, and operator-driven treatment selection. Third, because our sample is composed entirely of nonrandomized cohorts, our findings are inherently limited by selection and operator biases. While our study utilized advanced curve-based IPD reconstruction to evaluate time-to-event distributions, these statistical techniques are descriptive and cannot adjust for unmeasured confounding or the initial clinical judgment that guided device selection. Consequently, these data must be interpreted strictly as hypothesis-generating, emphasizing the definitive need for RCTs to establish causal clinical comparisons. Finally, because DCB use after atherectomy is a new strategy, the possibility

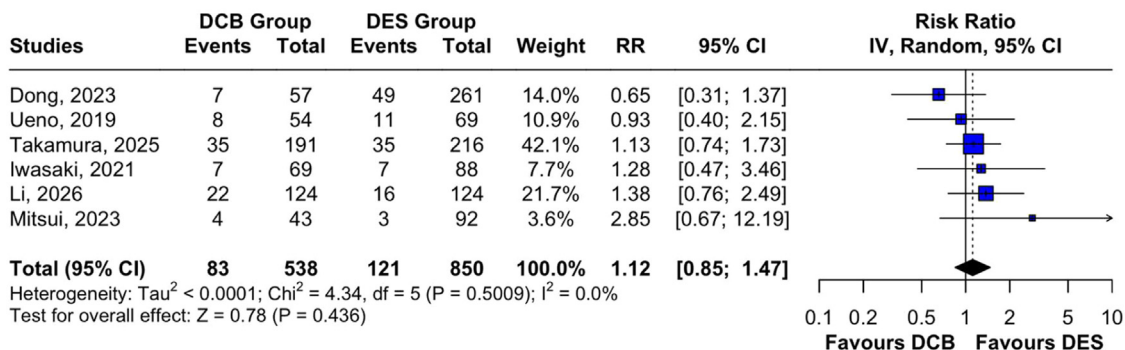


Figure 4. Forest plot of major adverse cardiac events comparing drug-coated balloon and drug-eluting stent following atherectomy.

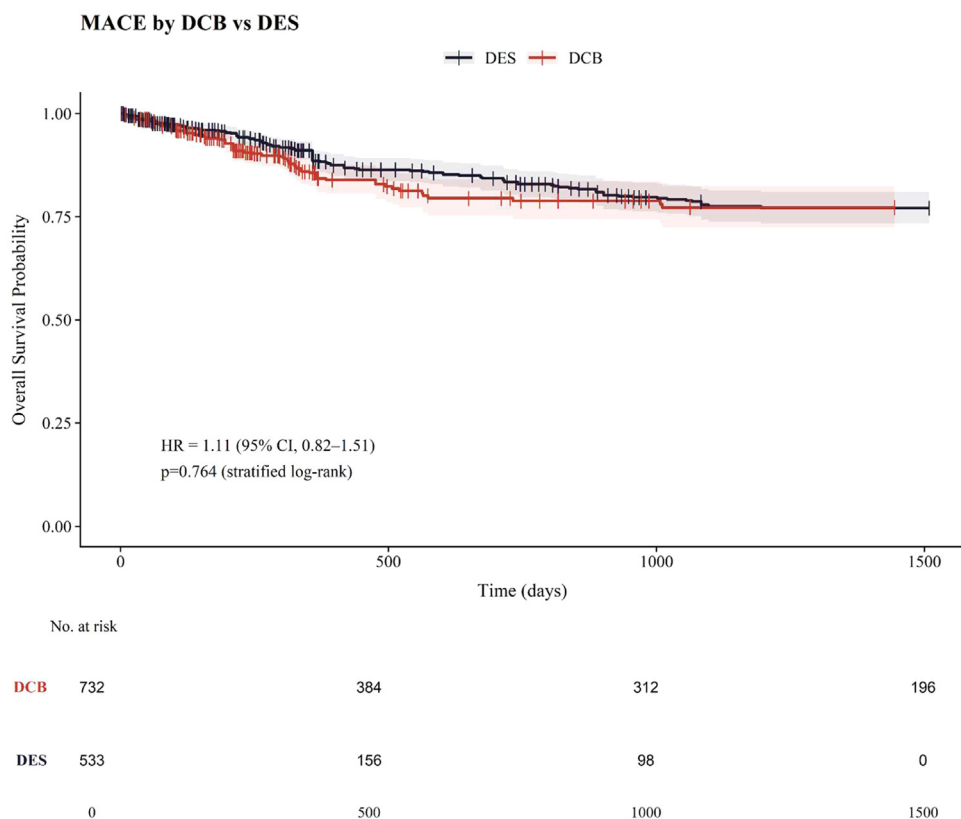


Figure 5. Kaplan–Meier curve for major adverse cardiac events comparing drug-coated balloon and drug-eluting stent following atherectomy.

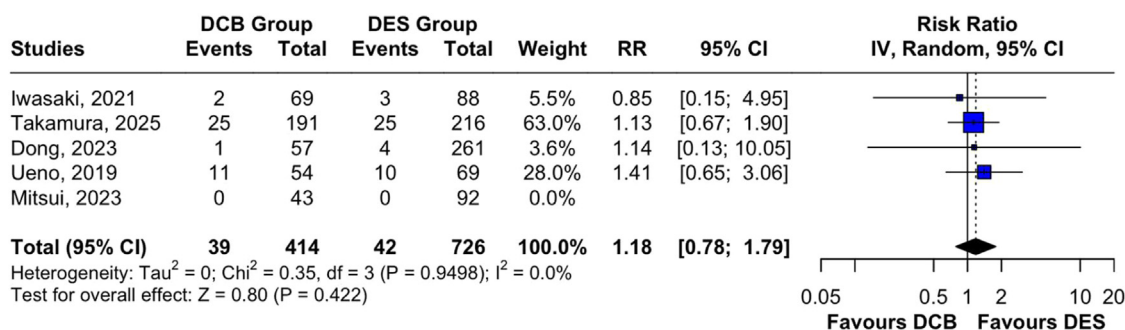


Figure 6. Forest plot of all-cause mortality comparing drug-coated balloon and drug-eluting stent following atherectomy.

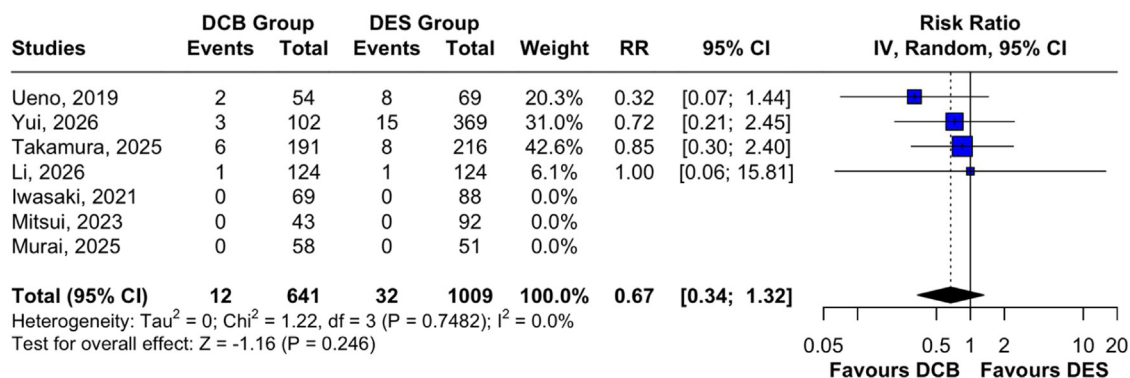


Figure 7. Forest plot of cardiac death comparing drug-coated balloon and drug-eluting stent following atherectomy.

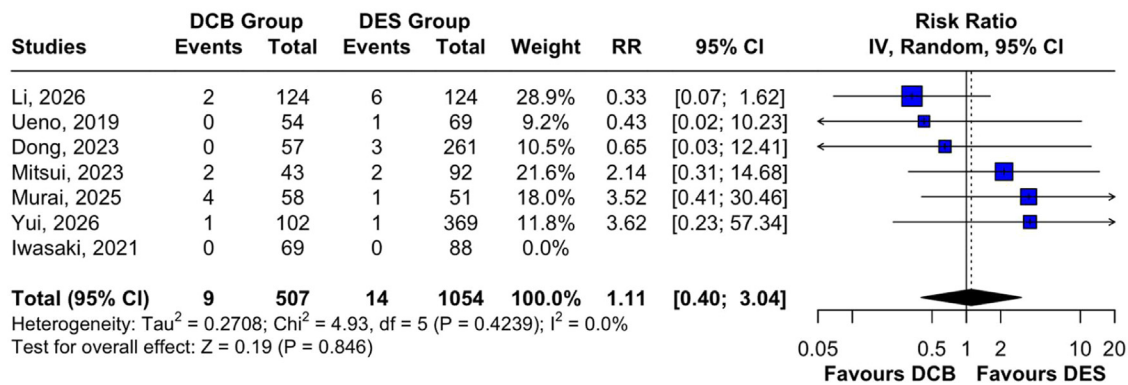


Figure 8. Forest plot of myocardial infarction comparing drug-coated balloon and drug-eluting stent following atherectomy.

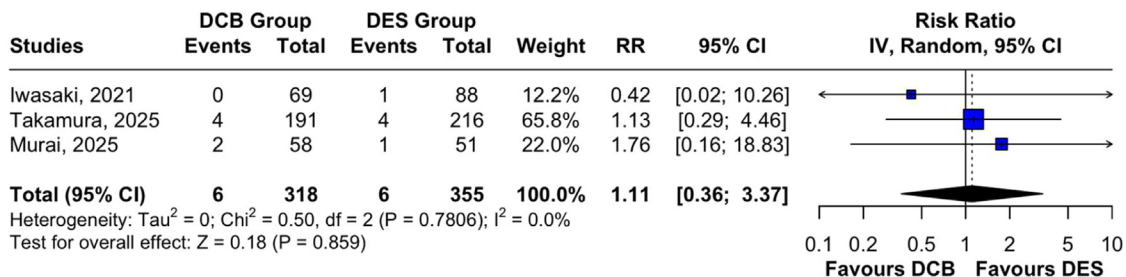


Figure 9. Forest plot of major bleeding comparing drug-coated balloon and drug-eluting stent following atherectomy.

of differential familiarity between devices and operator-dependent bias cannot be excluded.

Conclusions

In summary, both DCB and DES demonstrate high clinical utility following mechanical atherectomy for calcified lesions, resulting in favorable rates of MACE, mortality, MI, and major bleeding. Conversely, both pooled estimates and time-to-event curves reveal a consistent association with lower TLR in favor of DES. Because these findings derive from observational cohorts with inherent selection biases, they cannot establish definitive causal relationships and require strict caution.

Declaration of competing interest

Dr. Brilakis: consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), Cordis, Elsevier, GE Healthcare, Heartflow, IMDS, Medtronic, Recor Medical, SHockwave, SIS Medical, Teleflex, and Terumo; research support: AngioWave, Boston Scientific, GE Healthcare; owner, Hippocrates LLC, Systole LLC; shareholder: Cleerly Health, LifeLens Technologies, Inc, MHI Ventures, Stallion Medical, TrueVue Inc. All authors report no relationships that could be construed as a conflict of interest. All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.amjcard.2026.06.024>.

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