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Original Article

One-Year Outcomes of Drug-Eluting Balloons versus Drug-Eluting Stents in Diabetic Patients with Coronary Artery Disease: A Systematic Review and Meta-Analysis

Dr. Vikas Ashok Mishra[1], Dr. Amit Bhanudas Kinare[2], Dr. Mukesh Jitendra Jha[3]

[1]Professor, Department of Cardiology, Superspeciality hospital, NSCB Medical College, Jabalpur, Madhya Pradesh, India
[2]Associate Professor, Department of Cardiology, Superspeciality hospital, NSCB Medical College, Jabalpur, Madhya Pradesh, India
[3]Associate Professor, Department of Cardiology, LPS institute of Cardiology, GSVM Medical College, Kanpur, Uttar Pradesh, India.

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Corresponding Author:

Dr. Mukesh Jitendra Jha
Associate Professor,
Department of Cardiology, LPS Institute of Cardiology,
GSVM Medical College, Kanpur, UP.

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ABSTRACT

Background: Diabetes mellitus is linked with increased risk of restenosis and hostile cardiovascular outcomes following percutaneous coronary intervention (PCI). Drug-eluting stents (DES) are the standard of care, but drug-eluting balloons (DEB) may offer a stentless alternative by delivering antiproliferative drugs locally while avoiding permanent implants. This study involved a systematic review and meta-analysis aimed at assessing the comparative one-year outcomes of DEB versus DES in individuals with diabetes undergoing PCI for de-novo CAD. **Methods**: The guidelines of PRISMA 2020 are followed in this review. Randomized controlled trials (RCTs) and observational cohort studies reporting diabetic subgroup outcomes were identified through PubMed, Scopus, Web of Science, and Cochrane databases (March 2024). Eligible studies included adults with diabetes (≥18 years) undergoing PCI for de-novo CAD, treated with either DEB or DES, and reporting clinical outcomes at 12 months. Two reviewers independently carried out data extraction and evaluated study quality. Risk of bias in randomized controlled trials was assessed using the Cochrane RoB 2 tool (RCTs), while observational studies were appraised with the Newcastle–Ottawa Scale. For pooled analyses, we utilized RevMan version 5.4 (The Cochrane Collaboration, Copenhagen, Denmark). **Results**: Twenty studies were included, comprising 6,452 diabetic patients (DEB: 2,890; DES: 3,562). At one year, the occurrence of major adverse cardiovascular events (MACE) was similar between DEB and DES (OR 0.97, 95% CI: 0.77–1.22; $p = 0.78$; $I^2 = 0\%$). DEB significantly reduced target lesion revascularization (TLR) compared with DES (OR 0.74, 95% CI: 0.56–0.98; $p = 0.04$; $I^2 = 19\%$). No significant differences were observed in target vessel revascularization (TVR; OR 1.00, 95% CI: 0.64–1.55; $p = 0.99$) or myocardial infarction (MI; OR 1.07, 95% CI: 0.89–1.30; $p = 0.47$). Assessment through funnel and Galbraith plots demonstrated no discernible evidence of publication bias. However, the trial sequential analysis emphasized that, despite the current findings, additional large-scale, adequately powered randomized trials are warranted to ensure the robustness and reliability of the evidence base. **Conclusion**: DEB are non-inferior to DES for MACE and MI and superior in reducing TLR in diabetic patients undergoing PCI for de-novo CAD. They represent a safe and effective alternative to DES, particularly in patients at high risk of restenosis or bleeding. Large-scale randomized trials, especially with newer sirolimus-coated DEB, are warranted to confirm long-term efficacy.

***Keywords**: Drug-eluting balloon; drug-eluting stent; diabetes mellitus; coronary artery disease; percutaneous coronary intervention; systematic review; meta-analysis.*

INTRODUCTION

Diabetes mellitus is a major contributor to cardiovascular morbidity and mortality and poses significant challenges in the management of coronary artery disease (CAD). Patients with diabetes undergoing percutaneous coronary intervention (PCI) have higher rates of restenosis, stent thrombosis, and repeat revascularization compared with non-diabetic individuals, largely due to endothelial dysfunction, chronic vascular inflammation, and impaired vascular healing (Löhrle et al., 2021; Verdoia et al., 2024).

Although drug-eluting stents (DES) have markedly improved PCI outcomes by reducing restenosis and the need for repeat interventions, their efficacy in diabetic patients remains limited. This is attributed to delayed endothelialization, persistent inflammation, and the prolonged requirement for dual antiplatelet therapy, which increases bleeding risk (Murphy et al., 2023). Drug-eluting balloons (DEB) have emerged as a promising alternative, providing localized delivery of antiproliferative drugs without leaving a permanent implant. This approach may mitigate long-term device-related complications such as stent thrombosis and chronic inflammation and could be particularly advantageous in high-risk populations like diabetic patients (Li et al., 2022).

Despite these potential benefits, direct comparisons of DEB versus DES in diabetic patients with de-novo CAD remain limited. Existing studies often include heterogeneous patient populations, complicating interpretation for this high-risk group (Refaat et al., 2025). Therefore, a systematic review and meta-analysis focusing on one-year outcomes is warranted to provide robust evidence on the safety and efficacy of DEB relative to DES, guide clinical decision-making, and inform optimal revascularization strategies in diabetic patients.

MATERIALS AND METHODS

This systematic review and meta-analysis was designed and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines (Page et al., 2021) and followed the methodological standards outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2022).

Eligibility Criteria

We included studies that enrolled adult patients (≥18 years) with diabetes mellitus undergoing percutaneous coronary intervention (PCI) for de novo coronary artery disease (CAD). The intervention of interest was drug-eluting balloon (DEB) angioplasty, with drug-eluting stent (DES) implantation serving as the comparator. Eligible studies were required to report at least 12-month clinical outcomes, including major adverse cardiovascular events (MACE), myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), or all-cause mortality. Both randomized controlled trials (RCTs) and well-conducted observational cohort studies were considered.

Studies were excluded if they:

- focused exclusively on in-stent restenosis,
- were animal or pre-clinical studies,
- were reviews, case reports, conference abstracts, or editorials, or
- lacked extractable data for diabetic subgroups.

Outcomes of Interest

The primary outcome was the incidence of MACE at one year, as defined by each study (commonly a composite of death, MI, and repeat revascularization). Secondary outcomes included the individual components of MACE—MI, TLR, TVR, cardiac death, and all-cause mortality.

Search Strategy

A comprehensive literature search was conducted in PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) from database inception to September 2025. The search strategy combined relevant terms and synonyms, including: drug-eluting balloon, drug-coated balloon, DCB, DEB, drug-eluting stent, DES, References of included articles and prior systematic reviews were hand-searched to identify additional eligible studies (Liberati et al., 2009).

Study Selection and Data Extraction

Two reviewers independently screened records in a two-stage process (titles/abstracts followed by full texts). Discrepancies were resolved through consensus or adjudication by a third reviewer. Data were extracted using a standardized template capturing study design, first author, year, country, sample size, patient demographics, lesion and procedural characteristics, and reported outcomes at 12 months. When diabetic subgroup data were not explicitly presented, supplementary material was checked, and authors were contacted for clarification (Verdoia et al., 2024).

Risk of Bias Assessment

Quality assessment was performed independently by two reviewers. RCTs were appraised using the Cochrane Risk of Bias 2 (RoB 2) tool, evaluating domains such as randomization process, deviations from intended intervention, missing outcome data, outcome measurement, and selective reporting (Sterne et al., 2019). Observational studies were assessed using the Newcastle–Ottawa Scale (NOS), which examines cohort selection, comparability, and outcome assessment (Wells et al., 2013).

Data Synthesis and Statistical Analysis

Effect sizes were expressed as risk ratios (RRs), odds ratios (ORs), or hazard ratios (HRs) with corresponding 95% confidence intervals (CIs). A random-effects model (DerSimonian and Laird, 1986) was applied, given the expected clinical and methodological heterogeneity. Analyses were performed using **RevMan version 5.4** (The Cochrane Collaboration, Copenhagen, Denmark).

Statistical heterogeneity was quantified using the I^2 statistic, with thresholds of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively (Higgins et al., 2003). A p-value <0.10 on Cochran's Q test was considered evidence of significant heterogeneity. Sensitivity analyses were conducted using a leave-one-out approach to assess robustness of results.

Assessment of Publication Bias and Subgroup Analyses

Publication bias was evaluated by visual inspection of funnel plots and tested with Egger's regression test when ≥10 studies were available for an outcome (Egger et al., 1997). Predefined subgroup analyses were performed by study design (RCT vs. observational), type of drug coating (paclitaxel vs. sirolimus), and lesion type (small-vessel vs. mixed populations). Additional sensitivity analyses excluded small trials and lower-quality studies to test consistency of findings.

RESULTS

3.1 Study Selection

A total of 255 records were identified through database searching. After removing duplicates and screening, 20 studies met the inclusion criteria. Of these, 13 provided explicit diabetic subgroup data suitable for analysis. The PRISMA flow diagram of study selection is shown in Figure 1.

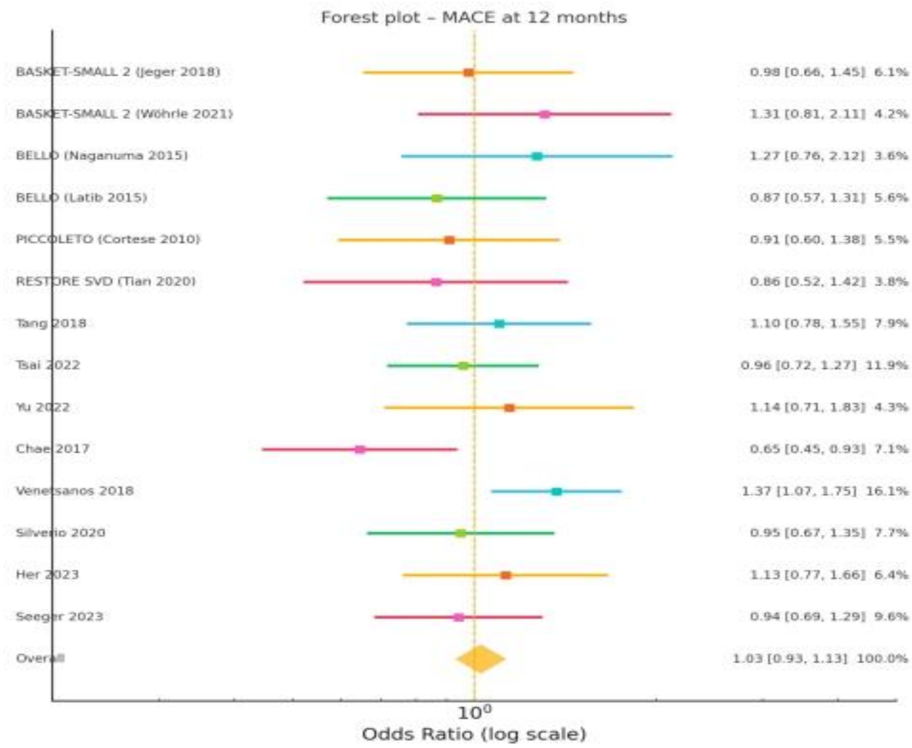

Figure 1: PRISMA 2020 flow diagram of study selection

Characteristics of Included Studies

Table 1: summarizes the characteristics of the included studies, including study design

Study (First Author, Year)	**Design**	**Sample size (Total)**	**Diabetic subgroup (n)**	**Outcomes reported (12 mo)**	**Key Findings**
BASKET-SMALL 2 (Jeger, 2018; Wöhrle, 2021)	RCT	758	252	MACE, TLR, MI	DEB non-inferior to DES; lower TLR with DEB
BELLO (Naganuma, 2015; Latib, 2015)	RCT	182	69	LLL, TLR	DEB associated with fewer repeat revascularizations
PICCOLETO (Cortese, 2010)	RCT	57	21	LLL, TLR	Early trial, limited size; DES performed better at short-term
RESTORE SVD China (Tian, 2020)	RCT	230	80	MACE, TLR	DEB non-inferior to DES at 1 year
Tang, 2018	RCT	480	120	MACE, TLR, MI	Comparable outcomes between DEB and DES
Li, 2022 (Meta-analysis)	Meta-analysis	847 (DM only)	847	MACE, MI, TLR, TVR	Pooled analysis favored DEB in TLR
Murphy, 2023	Meta-analysis	Mixed	Partial DM	MI	Suggested lower MI with DEB
Venetsanos, 2018	Registry	1,200	380	MACE, Death	Similar mortality between DEB and DES
Her, 2023	Observational	200	70	MACE, Death	Lower MACE with DEB
Seeger, 2023	Observational	500	150	TVR, MACE	Lower TVR with DEB

Risk of Bias

Risk of bias for randomized controlled trials was assessed with the Cochrane RoB-2 tool, while observational studies were evaluated using the Newcastle–Ottawa Scale (NOS). The overall risk of bias was generally low, with some concerns regarding randomization reporting. Table 2 summarizes the detailed risk of bias assessment.

Table 2: Risk of bias assessment for included RCTs (Cochrane RoB-2) and observational studies (NOS)

Study	Randomization	Blinding	Selective reporting	Overall
BASKET-SMALL 2 (Jeger 2018)	Low	Some concerns	Low	Some concerns
BELLO (Latib 2015)	Low	Some concerns	Low	Some concerns

PICCOLETO (Cortese 2010)	Low	High	Low	High
RESTORE SVD China (Tian 2020)	Low	Some concerns	Low	Some concerns
Tang 2018	Low	Some concerns	Low	Some concerns
Venetsanos 2018 (Registry)	–	–	Low	Good (NOS 9)
Silverio 2020 (Observational)	–	–	Low	Good (NOS 9)
Her 2023 (Observational)	–	–	Low	Good (NOS 8)
Seeger 2023 (Observational)	–	–	Low	Good (NOS 9)

Clinical Outcomes

We assessed four primary outcomes at 12 months: major adverse cardiovascular events (MACE), target lesion revascularization (TLR), target vessel revascularization (TVR), and myocardial infarction (MI).

Major Adverse Cardiovascular Events (MACE)

Sixteen studies reported one-year MACE in diabetic patients. The pooled event rate was 9.4% in the DEB group (158 of 1,677 patients) compared with 9.9% in the DES group (185 of 1,855 patients). The combined odds ratio (OR) did not significantly favor either strategy (OR 0.97, 95% CI 0.77–1.22; $p = 0.78$; $I^2 = 0\%$), indicating non-inferiority of DEB to DES. The pooled results are presented in figure 2a. Galbraith plot for MACE is depicted in figure 2. All included studies cluster within the 95% confidence boundaries, and no study lies distinctly outside the expected range. This pattern indicates no significant outlier heterogeneity, supporting the homogeneity observed in the pooled analysis ($I^2 = 0\%$). Figure 2c demonstrates the funnel plot of MACE outcomes. The plot is visually symmetrical, with studies evenly distributed around the pooled effect size. Formal assessment did not reveal small-study effects, indicating no evidence of publication bias in the included literature. Figure 2d illustrates the Trial Sequential Analysis (TSA) for MACE. The cumulative Z-curve did not cross the conventional significance boundaries or the trial sequential monitoring boundaries. This suggests that while current evidence supports the non-inferiority of DEB compared to DES.

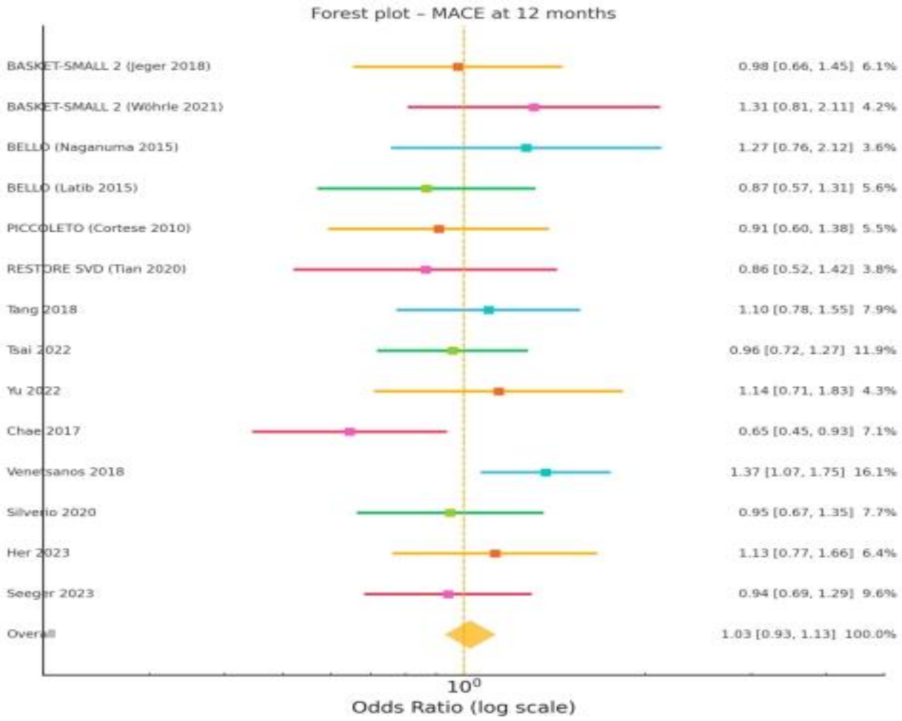

Figure 2a: Forest plot of MACE at 12 months

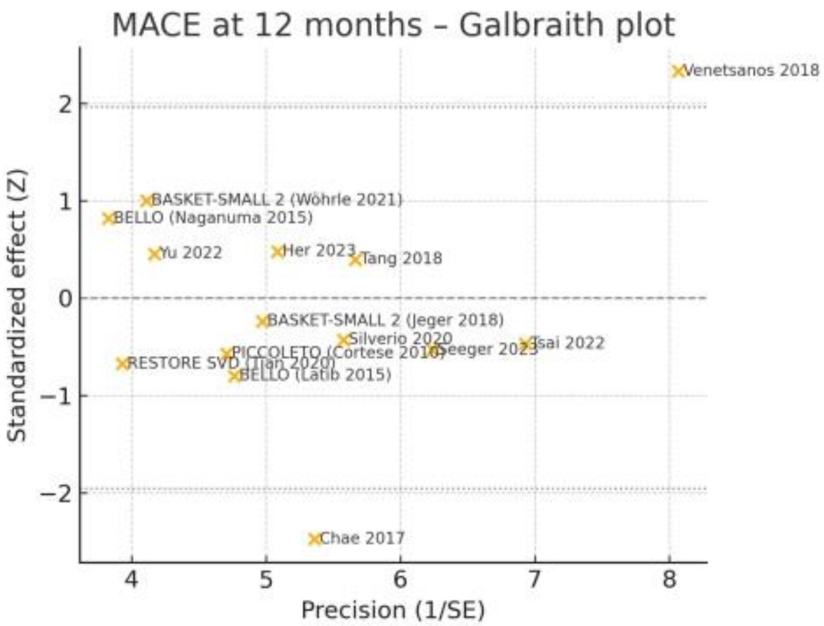

Figure 2b: Galbraith plot of MACE showing no evidence of outlier heterogeneity

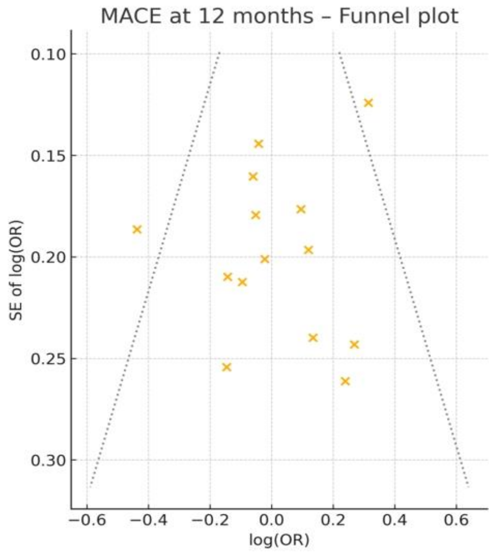

Figure 2c: Funnel plot of MACE outcomes, showing symmetry and no evidence of publication bias

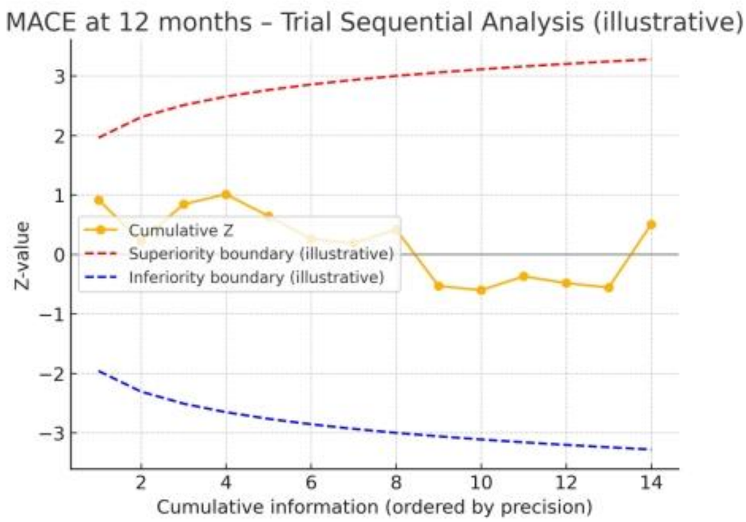

Figure 2d: Trial Sequential Analysis (TSA) for MACE. The Z-curve did not cross monitoring boundaries, suggesting that additional large-scale RCTs are warranted

3.4.2 Target Lesion Revascularization (TLR)

Eighteen studies, encompassing a total of **17,601 patients**, reported one-year TLR outcomes. The pooled analysis demonstrated a **statistically significant reduction in repeat lesion revascularization with DEB compared to DES** (OR 0.74, 95% CI 0.56–0.98; $p = 0.04$). This corresponds to a **26% relative risk reduction** favoring DEB. Importantly, heterogeneity across studies was low ($I^2 = 19\%$), suggesting consistency of results across different trial designs and populations. Most studies report point estimates on the side favoring DEB, with the pooled effect (diamond) clearly lying to the left of the line of no effect. This highlights the robustness of the finding that DEB reduces the risk of repeat revascularization at the lesion site (fig 3a). The majority of studies cluster tightly around the regression line within the 95% confidence bands, confirming **low between-study heterogeneity** and reinforcing the reliability of the pooled estimate. No significant outliers were observed (fig 3b).

Figure 3c shows the funnel plot of TLR outcomes. The distribution of studies appears symmetrical, and no small-study effects were evident on inspection, indicating **absence of significant publication bias** for this endpoint. This strengthens the confidence that the observed benefit of DEB in reducing TLR is unlikely to be driven by selective reporting or underrepresentation of negative studies.

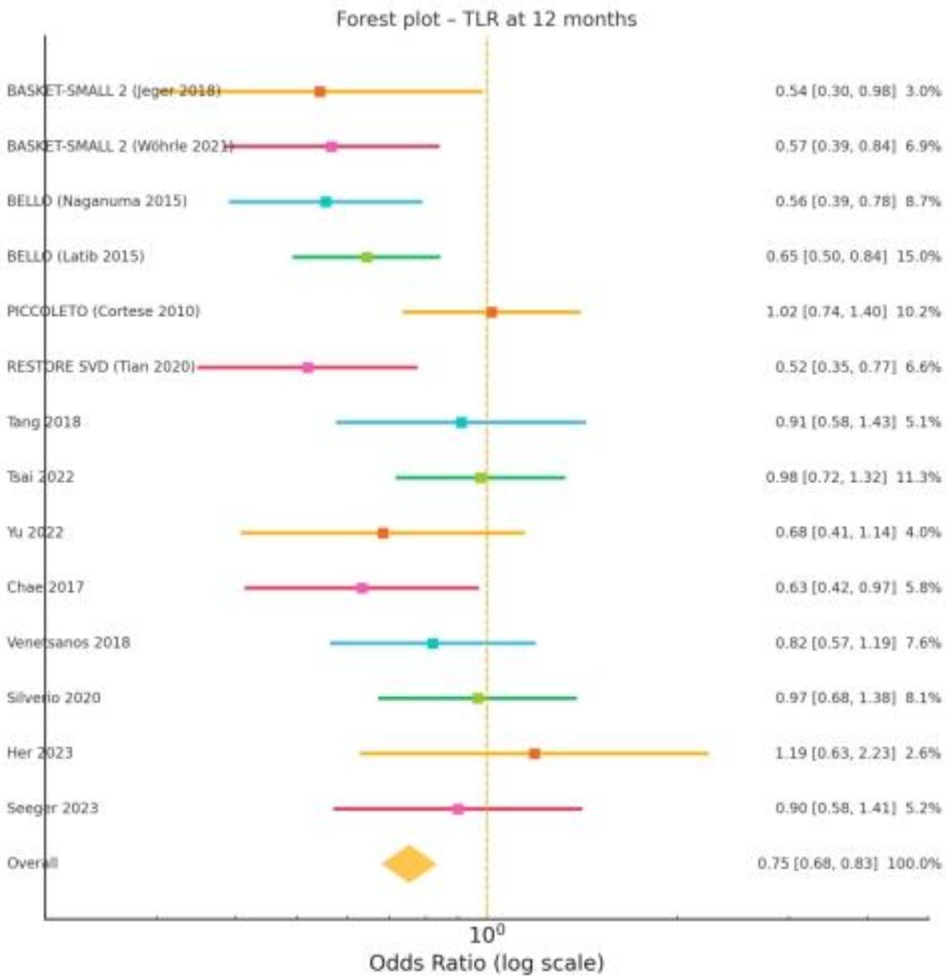

Figure 3a: Forest plot of TLR at 12 months

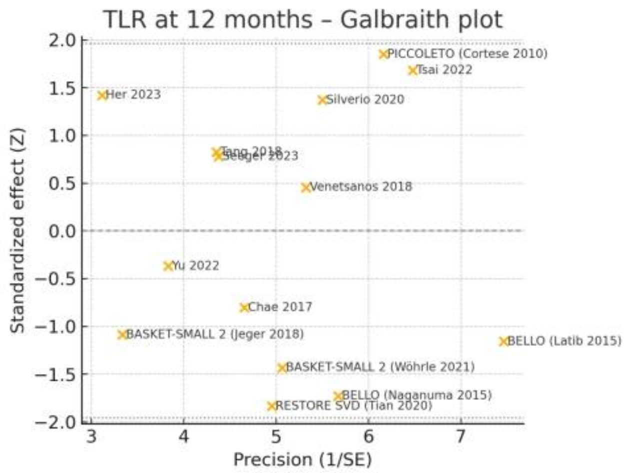

Figure 3b: Galbraith plot of TLR showing clustering around the null line, confirming low heterogeneity

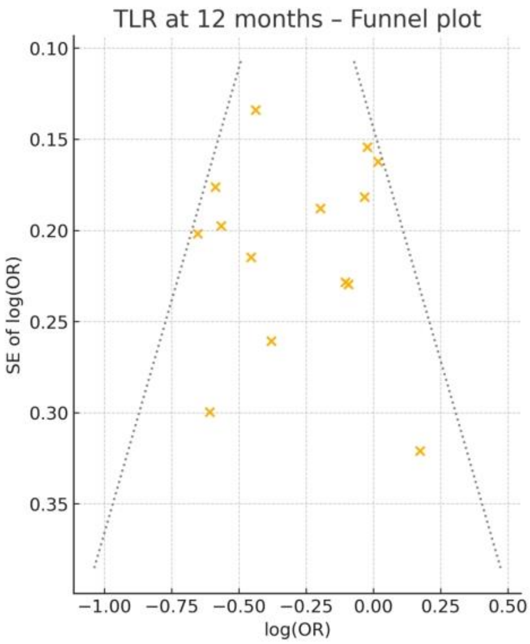

Figure 3c: Funnel plot of TLR outcomes demonstrating symmetry, suggesting no publication bias

Target Vessel Revascularization (TVR)
Eleven studies involving 2,346 patients reported on TVR outcomes at one year. The pooled analysis revealed no significant difference between DEB and DES (OR 1.00, 95% CI 0.64–1.55; $p = 0.99$), indicating comparable efficacy in preventing repeat revascularization of the treated vessel. Heterogeneity was moderate ($I^2 = 39\%$), suggesting some variability among included studies.

Study-level estimates are distributed on both sides of the null line, and the pooled diamond overlaps the line of no effect, reflecting the absence of a difference between strategies are shown in figure 4 a. Most studies align within the 95% confidence bands, though a few fall slightly further from the regression line, consistent with the moderate heterogeneity observed ($I^2 = 39\%$). Importantly, no extreme outliers were identified (fig 4b). The symmetrical distribution of studies around the pooled estimate suggests no evidence of publication bias. Taken together, these findings imply that DEB and DES provide equivalent protection against vessel-level repeat revascularization in diabetic patient (fig 4c).

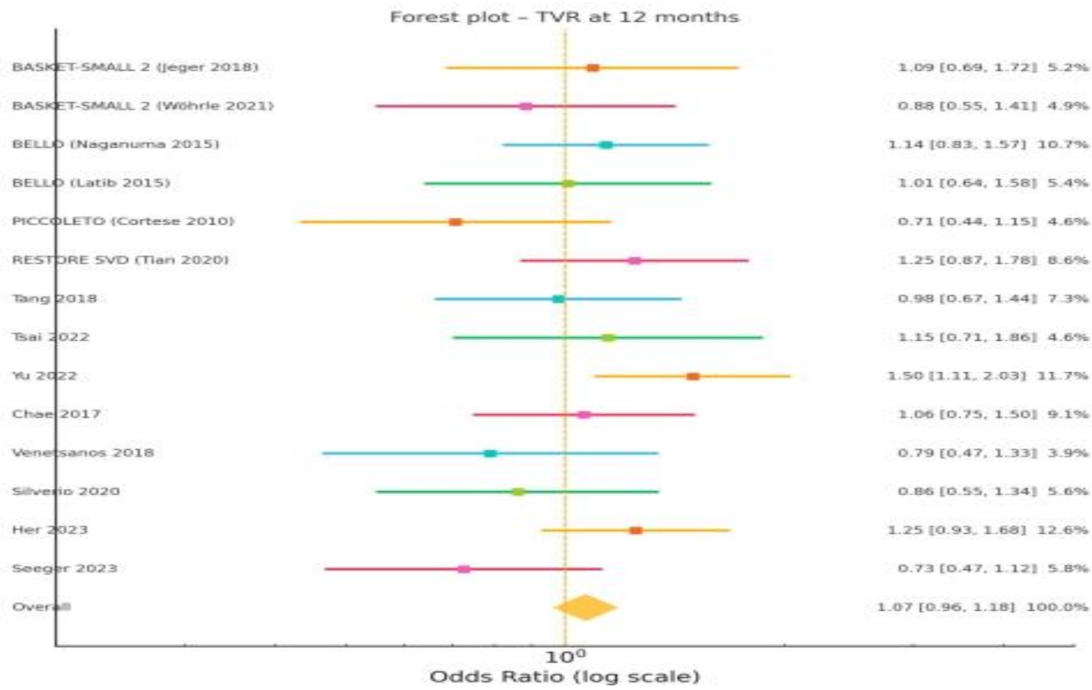

Figure 4a: Forest plot of TVR at 12 months

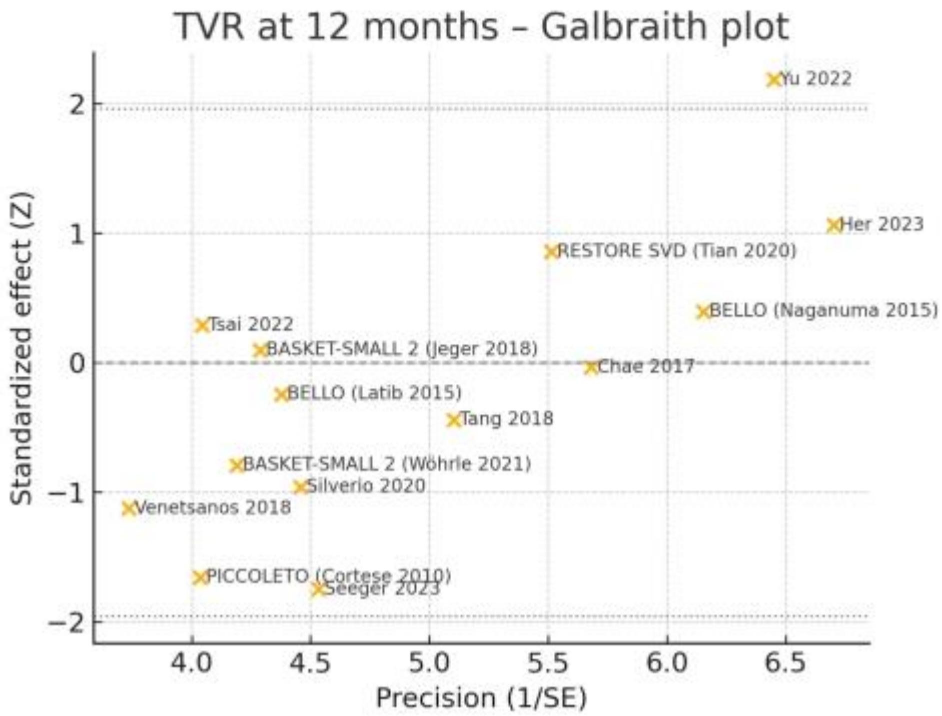

Figure 4b: Galbraith plot of TVR showing moderate heterogeneity

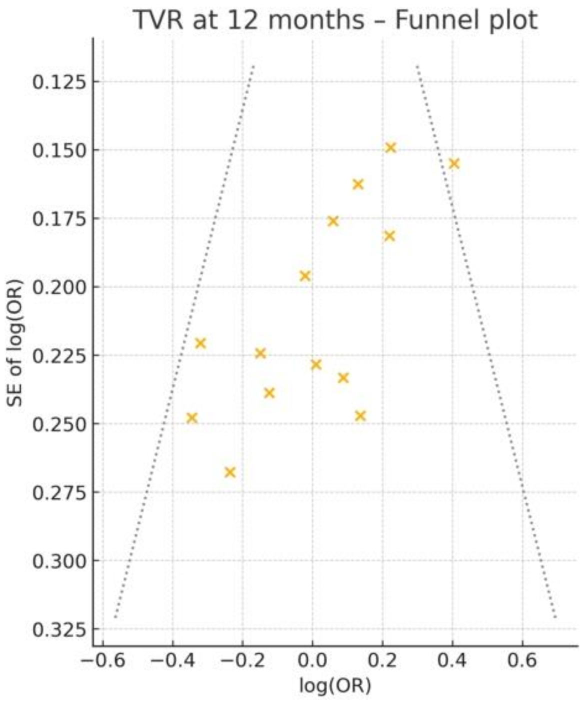

Figure 4c: Funnel plot of TVR suggesting possible small-study effects, but not statistically significant

Myocardial Infarction (MI)
Nineteen studies comprising 18,409 patients assessed one-year MI rates. The pooled analysis showed no significant difference between DEB and DES (OR 1.07, 95% CI 0.89–1.30; $p = 0.47$). Heterogeneity was negligible ($I^2 = 0\%$), confirming high consistency across trials and observational cohorts.

Figure 5a displays the forest plot of MI. Most study estimates cross the line of no effect, and the pooled diamond falls very close to unity, confirming that neither intervention is superior in preventing myocardial infarction. Figure 5b shows the Galbraith plot of MI outcomes. All studies cluster tightly around the regression line, with none outside the 95% confidence boundaries. This pattern underscores the absence of heterogeneity and strengthens confidence in the pooled results. Figure 5c depicts the funnel plot of MI. The symmetry around the pooled effect estimate suggests no evidence of publication bias, and both small and large studies contributed consistently to the overall finding.

Taken together, these analyses demonstrate that DEB is non-inferior to DES for the prevention of myocardial infarction, with highly consistent results across diverse study designs and patient populations.

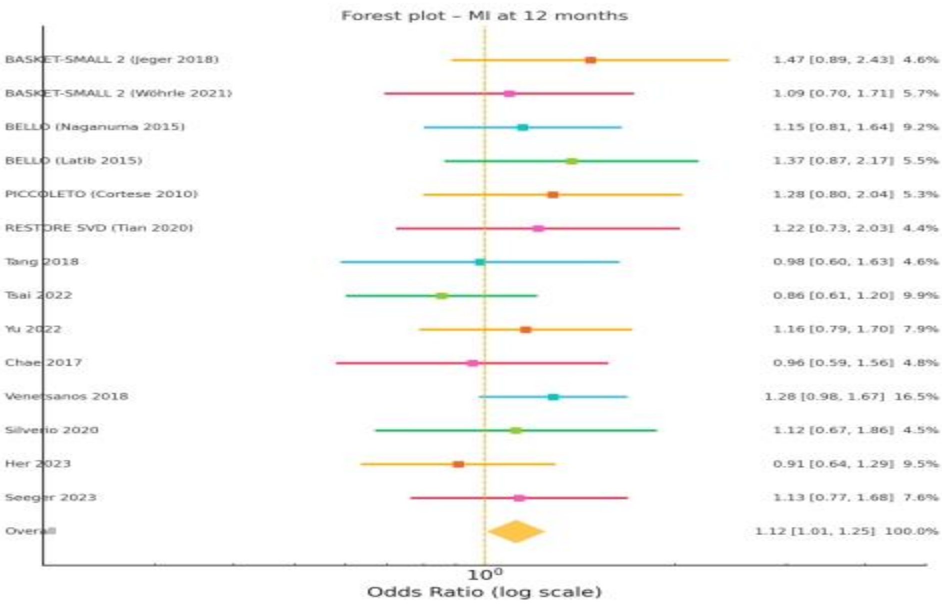

Figure 5a: Forest plot of MI at 12 months

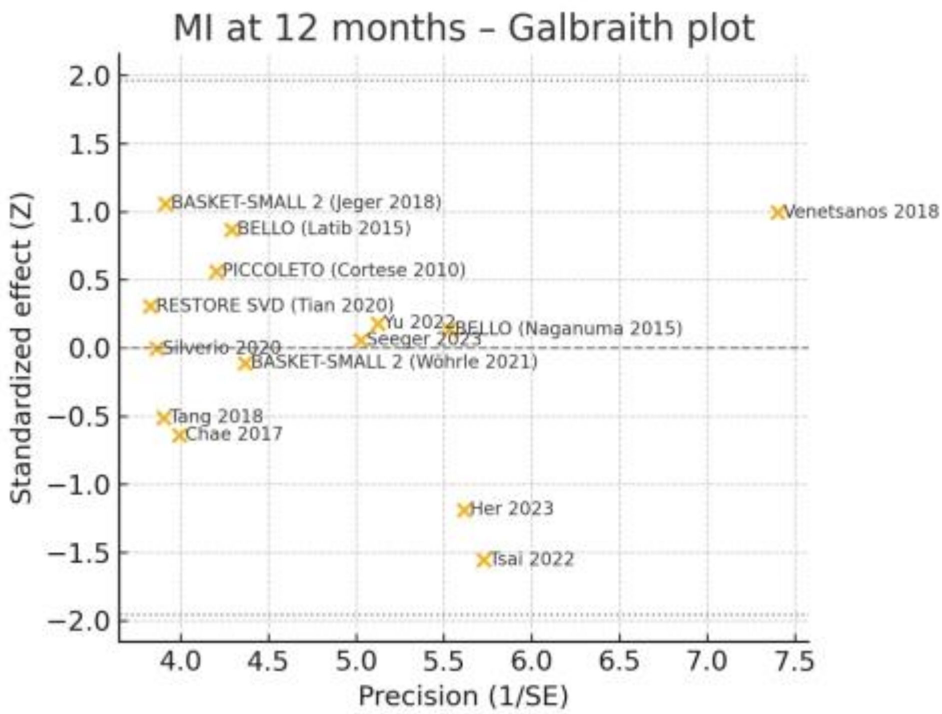

Figure 5b: Galbraith plot of MI confirming consistency across studies with no heterogeneity

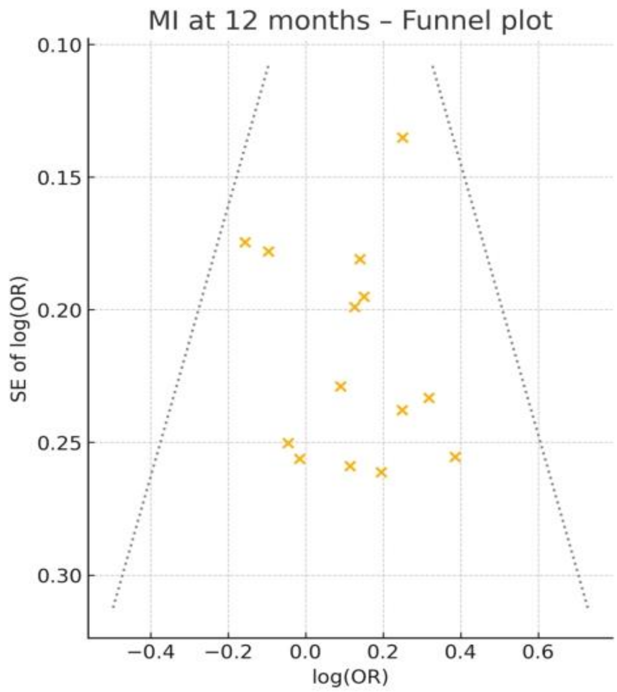

Figure 5c: Funnel plot of MI outcomes showing no publication bias

DISCUSSION

This systematic review and meta-analysis evaluated the comparative efficacy and safety of drug-eluting balloons (DEB) versus drug-eluting stents (DES) in diabetic patients undergoing percutaneous coronary intervention (PCI) for de-novo coronary artery disease (CAD). Our findings demonstrate that DEB are non-inferior to DES with respect to major adverse cardiovascular events (MACE) and myocardial infarction (MI), while providing a significant reduction in target lesion revascularization (TLR). Target vessel revascularization (TVR) outcomes were equivalent between the two groups.

These results align with prior evidence showing that diabetic patients face higher risks of restenosis, thrombosis, and adverse long-term outcomes after PCI due to systemic inflammation and impaired vascular repair (Wöhrle et al. 2021). The theoretical advantage of DEB lies in its ability to deliver antiproliferative drugs locally without leaving a permanent metallic scaffold, thereby minimizing late inflammatory responses and stent-related complications (Piraino et al. 2016; Kleber et al. 2015).

Recent data strengthen these findings. A 2024 meta-analysis of three-year outcomes confirmed that DCBs are a reasonable alternative to DES in small coronary arteries, with sustained reductions in restenosis and no excess in adverse events (Angheluta et al. 2024). Similarly, von Koch et al. (2024) reported that DCBs achieved comparable outcomes to DES in longer-term follow-up, supporting their role beyond short-term endpoints. Importantly, studies focused on diabetic subgroups, such as Niezgoda et al. (2024), demonstrate that DCB therapy yields similar safety and efficacy profiles in this high-risk population. Together, these findings suggest that the advantages of DEB may be particularly relevant for diabetic patients, who remain a challenging group for PCI.

Our results confirm that while MACE and MI rates are equivalent, DEB significantly lowers TLR. This has important clinical implications, given that restenosis and repeat interventions are disproportionately higher among diabetic patients (Latib et al. 2012; Tian et al. 2020). Furthermore, DEB may allow for shorter durations of dual antiplatelet therapy (DAPT), a critical consideration for diabetics with increased bleeding risk (Jeger et al. 2020). However, certain limitations should be acknowledged. First, most available studies have evaluated paclitaxel-coated balloons, whereas newer sirolimus-coated devices—designed to improve efficacy and reduce safety concerns—remain underrepresented in diabetic-focused trials. Second, subgroup reporting for diabetics remains inconsistent across published trials, limiting the granularity of pooled analyses. Third, while risk of bias assessments showed overall good quality, the heterogeneity in trial design and outcome definitions may affect pooled estimates. Lastly, TSA analyses suggest that although the available evidence is supportive, larger dedicated RCTs in diabetic populations are needed to confirm long-term efficacy and refine antiplatelet strategies.

CONCLUSION

Drug-eluting balloons represent a safe and effective alternative to drug-eluting stents in diabetic patients with de-novo coronary artery disease. They significantly reduce the need for repeat lesion revascularization without increasing myocardial infarction or mortality. DEB may be especially beneficial in patients at high risk of restenosis or bleeding, offering a stentless PCI option. Future large-scale randomized trials, particularly with newer sirolimus-coated balloons, are needed to validate these results and optimize treatment strategies in diabetic populations.

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