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Drug-Coated Balloons Versus Drug-Eluting Stents in ST Elevation Myocardial Infarction: A Meta-analysis

The current drug-coated balloons (DCBs) are semicompliant and use an excipient to retain the drug. Upon inflation, there is rapid and homogenous delivery of the drug into the vessel wall.[1] DCBs can allow for a "leave nothing behind" strategy. Drug-eluting stents (DESs) leave behind a metallic implant and may contribute to late stent thrombosis, restenosis, and impaired vasomotor function.[2] An immediate, reliable, safe, and stable result is important in ST elevation myocardial infarction (STEMI). It needs to be determined if DCBs can provide such a result.[3] The goal of this meta-analysis is to compare the efficacy of DCBs versus the benchmark therapy of DES in STEMI.

We searched multiple databases for studies comparing the efficacy and safety of DCBs versus DES in STEMI. We used the odds ratio (OR) and corresponding 95% confidence interval (CI) for measuring outcomes.

Three studies were included (2 randomized controlled trials [RCTs], 1 post hoc analysis of an RCT).[2–4] Follow-up varied between 6 and 12 months. A total of 284 patients (138 DCB, 146 DES), with 21% women (24% DCB, 18% DES) were included. Hypertension was seen in 32% (32% DCB, 32% DES), diabetes 9% (11% DCB, 7% DES), hyperlipidemia 18% (15% DCB, 21% DES), and smoking in

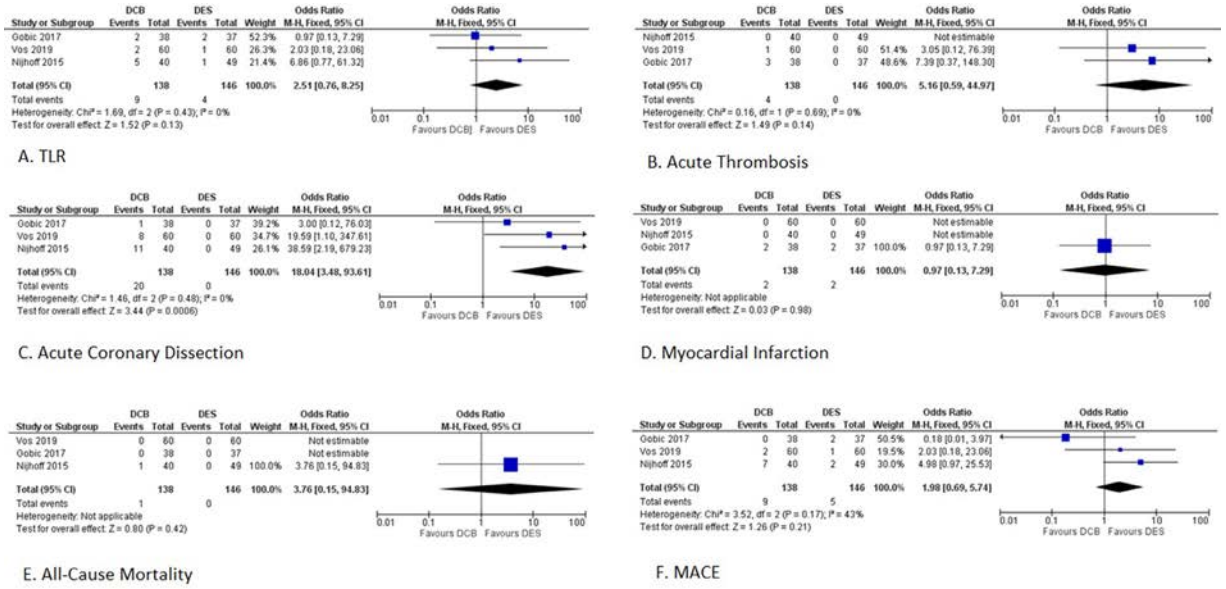

Figure 1. Forrest plots for comparison of different clinical outcomes between drug coated balloon and drug eluting stent in STEMI. Horizontal lines represent 95% confidence intervals (CI). The rectangles represent the point estimate, and the size of the rectangle is proportional to the weight given to each study in the meta-analysis. The diamond represents the summary estimate (size of the diamond = 95% CI). The vertical line represents the reference of no increased risk. Acute coronary dissection here includes type D-F only. MACE was defined as cardiac death, recurrent myocardial infarction, target lesion revascularization in Vos et al, cardiac death, recurrent MI, TLR, stent thrombosis in Gobic et al; death, MI and TLR by Nijhoff et al. MACE = major adverse cardiac events, MI-myocardial infarction; TLR = target lesion revascularization.

49% (47% DCB, 50% DES). Paclitaxel DCBs and predominantly second-generation DES were used. Although DCBs showed a numerically higher number of target lesion revascularization (6.5% vs 2.7%, OR 2.51, 95% CI 0.76 to 8.25, p = 0.13), acute thromboses (2.9% vs 0%, OR 5.16, 95% CI 0.59 to 44.97, p = 0.14), and major adverse cardiac events) (6.5% vs 3.4%, OR 1.98, 95% CI 0.69 to 5.74, p = 0.21) (Figure 1), these results were not statistically significant. No significant difference was seen between DCB and DES for myocardial infarction (1.4% vs 1.3%, OR 0.97, 95% CI 0.13 to 7.29, p = 0.98), and all-cause mortality (0.7% vs 0%, OR 3.76, 95% CI 0.15 to 94.83, p = 0.42) (Figure 1). More type D or worse coronary dissections were seen with DCBs (14.5% vs 0%, OR 18.4, 95% CI 3.48 to 93.61, p = 0.0006). In the DCB group, bailout stenting with a bare-metal stent was required in 18 patients (13.0%) for type D or worse coronary dissection (13,9.4%), and residual coronary artery stenosis (4, 2.9%). One case (0.7%) was transitioned over to DES for unknown reasons.

Thus, all outcomes were statistically similar between DCBs and DES, except a significantly higher number of type D (or worse) acute coronary dissections with DCBs. This contributed to bail-out stenting procedures. Coronary artery dissections A-C are considered benign, while D-F are intervened upon urgently. A total of 14.5% DCB resulted in dissections D-F. Whether this number is reproduced in larger RCTs or is an acceptable number for bailout stenting remains to be determined. The use of DCB in STEMI may be considered in carefully selected patients, for example, to avoid jailing of a major side-branch, when the culprit vessel is too small, or in the presence of previous stents. The current evidence for the use of DCB in STEMI is not sufficient to recommend this modality routinely.

Disclosures

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Meta-Analysis Comparing Direct Oral Anticoagulants to Low Molecular Weight Heparin for Treatment of Venous Thromboembolism in Patients With Cancer

Low molecular weight heparin (LMWH) is considered the standard anticoagulant therapy for patients with cancer-associated Venous Thromboembolism (VTE).[1−3] Although the efficacy and safety of direct oral anticoagulants (DOACs) in the treatment of VTE in patients without cancer has been validated,[4] their role in cancer-associated VTE is still evolving. We conducted a meta-analysis of the published randomized controlled trial (RCTs) comparing DOACs with LMWH for the treatment of VTE in cancer patients.

We performed a comprehensive literature search of electronic databases (Embase, MEDLINE, and Cochrane Central) from inception to May 30, 2020 using a predefined search strategy. Two reviewers independently screened all results in successive stages: title/abstract followed by full-text review. Studies were selected if they were RCTs, included cancer patients with VTE, and compared clinical outcomes between DOACs and LMWH.

The principal efficacy outcome was recurrence of VTE, either symptomatic or incidentally discovered. None of the trials utilized serial surveillance imaging to assess for asymptomatic recurrent VTE. The principal safety outcome was incidence of major bleeding (defined as overt bleeding leading to a decrease in the hemoglobin level of ≥ 2 g/dl, transfusion of 2 or more units of blood, occurring at a critical site, or fatal bleeding). Secondary outcomes included clinically relevant nonmajor bleeding (CRNMB) and all-cause mortality. CRNMB was defined as clinically overt bleeding not meeting criteria for major bleeds, associated with impairment of daily living or requiring medical attention. All outcomes were assessed at 6 months.

For statistical analysis, we calculated pooled risk ratios (RRs) with 95% confidence intervals (CI) using a random-effects model.[5,6] Stata version-15 was used for statistical analysis (StataCorp LLC). All p values were two-tailed with statistical significance specified at 0.05. Heterogeneity among studies was assessed using the Higgins I^2 value.[7]

The initial literature search yielded 1,662 citations. Four RCTs with a total of 2,894 patients were included in this study level meta-analysis.[8−11] Details of the study designs and baseline characteristics of patients are shown in Table 1. Of the 2,894 patients, 1,446 received a DOAC and 1,448 received LMWH. Almost all patients had active cancer (98% to 100%) and were receiving concurrent cancer treatment (57% to 73%). Patients with a poor functional status- Eastern Cooperative Oncology Group performance score >2, and those with basal cell or squamous cell skin cancer were excluded.

Recurrent VTE at 6 months was decreased in patients treated with DOACs compared to LWMH (5.2% vs 8.2%; RR 0.62, 95% CI 0.43 to 0.91; p = 0.01; I^2 = 30%; Figure 1A). CRNMB was higher with DOACs as compared to LMWH (10.3% vs 6.3%; RR 1.65, 95% CI 1.19 to 2.28; p = 0.002; I^2 = 29%;