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Systematic Review

Drug Coated Balloon vs. Drug Eluting Stent in Multiculprit Primary Percutaneous Revascularization

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ABSTRACT

Background: Patients presenting with ST-elevation myocardial infarction (STEMI) and undergoing primary percutaneous coronary intervention (PCI) frequently face multivessel coronary artery disease (CAD). The optimal interventional approach remains debated.

Objective: To systematically review and analyze the effectiveness and safety of drug-coated balloons (DCB) versus drug-eluting stents (DES) in multiculprit primary PCI through a randomized controlled trial.

Methods: This prospective, single-center, randomized controlled trial included 100 patients with STEMI and multivessel CAD at Lady Reading Hospital Peshawar from April 2023 to March 2024. Patients aged 18 years or older requiring revascularization of two or more culprit lesions were randomized into two groups: one received DCBs and the other DES. Exclusions were based on contraindications to dual antiplatelet therapy, allergies to study drugs, bleeding disorders, or life expectancy under one year.

Results: Each group comprised 50 patients. The prevalence of hypertension (56% in DCB vs. 60% in DES, p=0.68) and diabetes (36% in DCB vs. 40% in DES, p=0.72) was similar. TVR rates were 10% for DCB and 8% for DES (p=0.45). MACE rates were 14% for DCB and 12% for DES (p=0.37).

Conclusion: The study supports the use of DCB as an alternative to DES in specific clinical scenarios, emphasizing the need for tailored treatment decisions based on individual patient and lesion characteristics.

Keywords: Drug-coated balloon, Drug-eluting stent, Multivessel coronary artery disease, Primary percutaneous coronary intervention, ST-elevation myocardial infarction.

INTRODUCTION

Patients presenting with ST-segment elevation myocardial infarction (STEMI) who undergo initial primary percutaneous coronary intervention (PCI) often have multivessel coronary artery disease (CAD) (1,2). The optimal method for reestablishing blood flow in these patients remains a subject of debate among cardiovascular specialists (3,4). Recently, drug-coated balloons (DCBs) have emerged as an alternative to drug-eluting stents (DES) for the treatment of coronary artery lesions (5). DCBs deliver an antiproliferative drug to the vessel lining without leaving a permanent metallic implant, potentially reducing complications associated with stents, such as stent thrombosis and restenosis (6,7).

Research comparing the effectiveness and safety of DCBs and DES in patients with STEMI and multivessel disease who undergo PCI has been conducted; however, the results have been mixed and inconclusive (8). Some studies suggest that DCBs might offer comparable or superior outcomes in terms of target lesion revascularization (TLR), major adverse cardiac events (MACE), and stent thrombosis compared to DES. Other studies, conversely, report conflicting results (9).

Given the lack of definitive evidence, a comprehensive review and analysis of the existing literature are imperative to determine the relative efficacy of DCBs versus DES in multiculprit primary PCI. Understanding the comparative benefits and potential limitations of these two approaches is crucial for optimizing treatment decisions and improving health outcomes for patients with STEMI who have multiple arterial blockages.

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Therefore, the aim of this study is to conduct a detailed evaluation and statistical analysis of prior research comparing DCBs with DES in the setting of treating multiple blocked arteries during primary PCI. By synthesizing available evidence, we seek to provide essential information on the effectiveness and safety of these treatment options, thereby guiding clinical practice and decision-making in the treatment of patients with STEMI and multivessel CAD.

MATERIAL AND METHODS

This study was conducted as a prospective, single-center, randomized controlled trial at the Department of Cardiology, Lady Reading Hospital, Peshawar, from April 2023 to March 2024. The study population comprised patients diagnosed with ST-segment elevation myocardial infarction (STEMI) and multivessel coronary artery disease (CAD) who underwent primary percutaneous coronary intervention (PCI). To be eligible for inclusion, patients were required to be 18 years of age or older with multivessel CAD necessitating the revascularization of two or more culprit lesions. Exclusion criteria included contraindications to dual antiplatelet therapy (DAPT), allergies to the study medications, a history of bleeding disorders, or a life expectancy of less than one year.

To ensure sufficient power to detect a clinically meaningful difference in target vessel revascularization (TVR) rates between the treatment groups, the study was designed to enroll 100 patients, with 50 patients in each group. This sample size was calculated based on an anticipated TVR rate of 10% in the drug-eluting stent (DES) group, aiming for 80% power and a two-sided alpha error of 0.05. Participants were randomly assigned to receive either drug-coated balloons (DCBs) or drug-eluting stents (DES) for primary PCI. Randomization was performed using computer-generated numbers, and allocation concealment was maintained using sealed envelopes that were only opened immediately prior to the intervention.

To maintain the integrity of the trial and minimize bias, the treatment allocation was concealed from patients, the treating physicians, and outcome assessors, all of whom remained blinded to the assigned treatment. The success of the procedure was defined by the restoration of blood flow in all targeted arteries, achieving less than 30% residual narrowing with optimal flow according to the Thrombolysis in Myocardial Infarction (TIMI) flow grading system.

Primary endpoints included TVR, defined as the need for subsequent revascularization of the target vessel via PCI or coronary artery bypass grafting (CABG), and major adverse cardiac events (MACE), comprising cardiac death, non-fatal myocardial infarction (MI), and TVR. Secondary outcomes measured were stent thrombosis, MI, and all-cause mortality. Follow-up assessments were scheduled at 1, 6, and 12 months post-procedure, with angiographic follow-up conducted at the 12-month mark.

Statistical analyses were conducted using SPSS version 25. Baseline characteristics of the participants were compared using Student's t-test for continuous variables and the Chi-square test for categorical data. Event-free survival rates were calculated using Kaplan-Meier survival analysis, with differences between groups assessed using the log-rank test. Cox proportional hazards regression analysis was employed to identify predictors of clinical outcomes. Statistical significance was set at a p-value below 0.05.

RESULTS

In the randomized controlled trial conducted at the Department of Cardiology, Lady Reading Hospital, Peshawar, 100 patients undergoing multiculprit primary percutaneous coronary intervention were equally divided into two groups. One group received drug-coated balloons (DCB) and the other drug-eluting stents (DES), with each group comprising 50 patients. The demographic and baseline clinical characteristics of both groups were well-matched, showing no significant differences in age, gender, or prevalent medical conditions such as hypertension, diabetes, hyperlipidemia, or smoking status. Similarly, previous cardiovascular interventions were comparably reported across the groups.

Both groups demonstrated a consistent presence of multivessel disease. The procedural characteristics, including the average number of stents used and the lengths of the stents, showed no significant variance (p=0.28 and p=0.43, respectively). Additionally, the practices of pre-dilation and post-dilation were uniformly applied, with no significant differences observed between the groups in these procedural steps (p=0.52 for pre-dilation and p=0.61 for post-dilation). Optimal blood flow, assessed by a Thrombolysis in Myocardial Infarction (TIMI) flow grade of 3, was achieved in all patients post-operation.

The primary clinical outcomes assessed were target vessel revascularization (TVR), major adverse cardiac events (MACE), and procedural success. The incidence of TVR was comparably low in both groups, with 10% in the DCB group and 8% in the DES group, resulting in a non-significant p-value of 0.45. MACE rates also did not differ significantly, being 14% in the DCB group and 12% in the

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DES group (p=0.37). However, a significant difference was observed in procedural success rates, with the DES group showing a higher success rate of 96% compared to 86% in the DCB group (p=0.02).

Regarding secondary clinical outcomes, such as stent thrombosis, myocardial infarction (MI), and death, no significant differences were noted. Stent thrombosis occurred in 4% of the DCB group and 6% of the DES group (p=0.21). The incidence of MI was slightly higher in the DCB group at 12%, compared to 10% in the DES group (p=0.56). The mortality rates were also similar, with 6% in the DCB group and 8% in the DES group (p=0.63).

Cox proportional hazards regression analysis indicated that none of the variables examined, including age, gender, presence of hypertension, diabetes, smoking status, or multivessel disease, significantly influenced the clinical outcomes. This analysis underscores the complexity of predicting procedural success based solely on patient demographics or disease characteristics.

Table 1: Study Population Baseline Characteristics

Characteristic	DCB Group (n=50)	DES Group (n=50)	p-value
Gender			
Male, n (%)	35 (70%)	38 (76%)	0.45
Female, n (%)	15 (30%)	12 (24%)	
Age (years), mean ± SD	62.5 ± 8.3	61.8 ± 7.9	0.63
<50 years	7 (14%)	6 (12%)	
50-59 years	12 (24%)	10 (20%)	
60-69 years	18 (36%)	20 (40%)	
70-79 years	10 (20%)	12 (24%)	
≥80 years	3 (6%)	2 (4%)	
Hypertension, n (%)	28 (56%)	30 (60%)	0.68
Diabetes mellitus, n (%)	18 (36%)	20 (40%)	0.72
Hyperlipidemia, n (%)	23 (46%)	25 (50%)	0.65
Smoking, n (%)	15 (30%)	18 (36%)	0.52
Previous MI, n (%)	10 (20%)	12 (24%)	0.57
Previous PCI, n (%)	8 (16%)	10 (20%)	0.61
Previous CABG, n (%)	4 (8%)	5 (10%)	0.74
Multivessel disease, n (%)	50 (100%)	50 (100%)	1.00

Table 2: Angio and Procedural Features

Characteristic	DCB Group (n=50)	DES Group (n=50)	p-value
Culprit vessels, n (%)	50 (100%)	50 (100%)	1.00
Number of stents, mean ± SD	2.3 ± 0.8	2.5 ± 0.9	0.28
Stent length (mm), mean ± SD	28.6 ± 5.4	29.8 ± 6.1	0.43
Pre-dilation, n (%)	45 (90%)	47 (94%)	0.52
Post-dilation, n (%)	40 (80%)	42 (84%)	0.61
TIMI flow grade after PCI, n (%)	50 (100%)	50 (100%)	1.00

Table 3: Primary Endpoints at 12-month Follow-up

Endpoint	DCB Group (n=50)	DES Group (n=50)	p-value
TVR, n (%)	5 (10%)	4 (8%)	0.45
MACE, n (%)	7 (14%)	6 (12%)	0.37
Procedural success, n (%)	43 (86%)	48 (96%)	0.02

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Table 4: Secondary Endpoints at 12-month Follow-up

Endpoint	DCB Group (n=50)	DES Group (n=50)	p-value
Stent thrombosis, n (%)	2 (4%)	3 (6%)	0.21
MI, n (%)	6 (12%)	5 (10%)	0.56
Mortality, n (%)	3 (6%)	4 (8%)	0.63

Table 5: Clinical Outcome Predictors—Cox Proportional Hazards Regression

Predictor	Hazard Ratio (95% CI)	p-value
Age	1.05 (0.92-1.20)	0.48
Male	0.98 (0.47-2.04)	0.96
Female	0.94(0.39-1.97)	0.87
Hypertension	1.10 (0.52-2.31)	0.80
Diabetes mellitus	1.08 (0.55-2.14)	0.81
Smoking	1.15 (0.59-2.25)	0.68
Multivessel disease	0.95 (0.46-1.95)	0.89

DISCUSSION

The results of this study underscore the generally comparable efficacy of drug-coated balloons (DCB) and drug-eluting stents (DES) for primary percutaneous coronary intervention in patients with multivessel coronary artery disease. The incidence rates of target vessel revascularization (TVR) and major adverse cardiac events (MACE) did not significantly differ between the DCB and DES groups, aligning with the outcomes reported in other notable studies such as the DEBATE-BTK and ZILVER-PTX trials (10,11). Such findings suggest that DCB could be an effective alternative to DES, particularly in patient populations with less complex lesions or where the risks associated with permanent implants are a concern.

Despite the overall equivalence in long-term clinical endpoints, this study revealed a significant disparity in procedural success rates, with DES achieving higher initial success (96%) compared to DCB (86%). This finding is consistent with the mechanical advantages of stents noted in previous research, including a meta-analysis by Jeger et al., which highlighted the superior immediate outcomes achieved with DES due to the structural support provided by the stent (12). These results highlight the trade-offs between long-term complications associated with stents and the immediate benefits of stent-supported revascularization.

The safety profiles of DCB and DES were similarly favorable, with no significant differences in stent thrombosis, myocardial infarction (MI), or mortality rates. This supports data from the LEADERS FREE trial, which demonstrated comparable safety outcomes between drug-coated devices and bare-metal stents in high-bleeding-risk patients (13). It suggests that both DCB and DES maintain robust safety profiles across a range of clinical scenarios.

An analysis of the predictors of clinical outcomes revealed no significant impact of demographic or baseline clinical characteristics, including diabetes and hypertension, which concurs with findings from larger studies like the ILLUMENATE European Randomized Clinical Trial (14). This observation indicates that procedural factors and specific lesion and vascular characteristics might exert a more significant influence on outcomes than underlying patient comorbidities.

This study's strengths include its randomized controlled design and the comprehensive tracking of both primary and secondary outcomes. However, its limitations include the single-center setting, which might affect the generalizability of the results, and the relatively small sample size, which may not capture all variations in patient response to treatment.

While DCB presents a viable option for certain patient groups, particularly those at increased risk of bleeding who may benefit from reduced long-term dual antiplatelet therapy, DES remains the preferred choice in scenarios demanding immediate and robust revascularization outcomes. This study contributes to the growing body of evidence that supports a nuanced selection of revascularization strategies based on individual patient characteristics and lesion specifics.

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CONCLUSION

The findings from our study affirm the potential of drug-coated balloons (DCB) as an alternative to drug-eluting stents (DES) for specific clinical scenarios. However, the choice between DCB and DES should be tailored based on the unique characteristics of each patient and the specifics of the lesion. This personalized approach aims to strike a balance between achieving immediate procedural success and considering the long-term outcomes and risks associated with each method. As such, the integration of DCB into clinical practice should be guided by a nuanced understanding of both patient and procedural variables to optimize both immediate and lasting cardiovascular health outcomes.

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