

Clinical Impact of Drug-Coated Balloon-Based Percutaneous Coronary Intervention in Patients with DM

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Background/Aims: Drug-coated balloon (DCB) treatment leaves nothing of lesions behind, and it reduces the risk of stent-associated maladaptive biologic responses causative of restenosis and thrombosis, and allows for favorable natural vascular healing. Data on DCB treatment in the context of diabetes mellitus (DM) is limited. We aimed to investigate the clinical impact of DCB-based revascularization on percutaneous coronary intervention (PCI) in patients with DM.

Methods: A total of 330 patients with DM successfully treated with DCB alone or combined with drug-eluting stent (DES) were retrospectively enrolled (DCB-based group) and compared with 330 propensity-matched patients treated with second-generation DES from the PTRG-DES registry (n = 13,160 patients, study identifier: NCT04734028) (DES-only group). The DCB-based treatment group received interventions performed according to international and Asia-Pacific consensus recommendations for DCB treatment. Major adverse cardiovascular events (MACE) comprised cardiac death, myocardial infarction, stroke, stent or target lesion thrombosis, target vessel revascularization, and major bleeding at 1 year.

Results: Baseline clinical characteristics were comparable between the groups. In the DCB-based group, 57.0% of patients were treated with DCBs only and 43.0% were treated with the DES hybrid approach. The number of stents and total stent length were significantly reduced by 70.0% and 68.1%, respectively, in the DCB-based group compared with the DES-only group. Moreover, the DCB-based group had a lower rate of MACE than the DES-only group (4.2% vs 8.5%; p = 0.024) at 1-year follow-up.

Conclusions: The DCB-based treatment approach showed a significantly reduced stent burden for DM patients and led to a lower rate of MACE than the DES-only treatment. This study shows that DCB-based treatment approach safely reduces stent burden in DM, and improved clinical outcomes may be expected by reducing stent-related events. (Impact of Drug-Coated Balloon Treatment in De Novo Coronary Lesion; NCT04619277)

Figure 1. Kaplan-Meier curves with cumulative hazards of major adverse cardiovascular events.

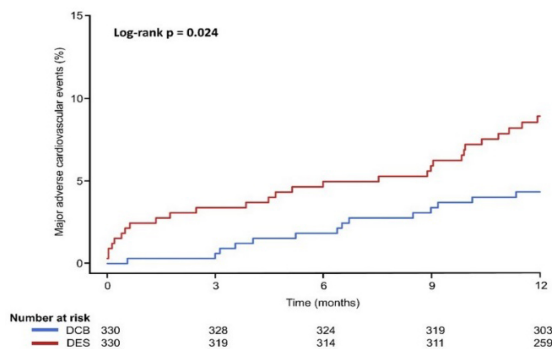


Figure 2. Comparison of proportions of devices used between the 2 groups.

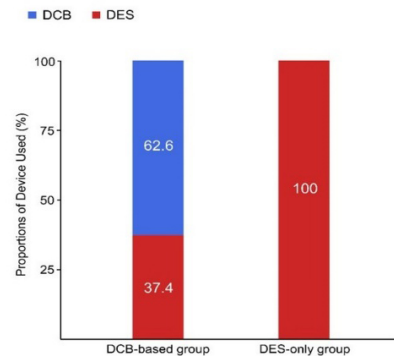


Table 1. Patient clinical and procedural characteristics

	DCB-based treatment (n = 330)	DES-only treatment (n = 330)	P Value
Age, years	63.8 (10.0)	63.7 (9.6)	0.952
Men	239 (72.4)	244 (73.9)	0.725
Hypertension	245 (74.2)	242 (73.3)	0.859
Current smoker	53 (16.1)	47 (14.2)	0.587
Prior MI	36 (10.9)	33 (10.0)	0.799
Prior PCI	74 (22.4)	61 (18.5)	0.247
End-stage renal disease	46 (13.9)	44 (13.3)	0.910
Clinical presentation			
Stable angina	121 (36.7)	152 (46.1)	0.018
Unstable angina	148 (44.8)	105 (31.8)	0.001
Acute myocardial infarction	61 (18.5)	73 (22.1)	0.287
DCB-only treatment	188 (57.0)	-	
Target lesion and procedure characteristics			
Left main	32 (9.7)	29 (8.8)	0.788
Total number of treated vessel	2.0 (0.8)	2.0 (0.7)	0.917
Total number of device used	1.9 (1.0)	2.0 (0.9)	0.058
Total device length, mm	49.1 (29.8)	52.4 (28.4)	0.141
Mean device diameter, mm	2.7 (0.3)	2.7 (0.3)	0.666

Values are mean ± SD or n (%).

Abbreviations: DCB = drug-coated balloon; DES = drug-eluting stent; MI = myocardial infarction;

PCI = percutaneous coronary intervention

Table 2. Comparison of clinical outcomes according to group at 1 year

	DCB-based treatment (n = 330)	DES-only treatment (n = 330)	P Value*
Major adverse cardiovascular events	14 (4.2)	28 (8.5)	0.024
Cardiac death	2 (0.6)	1 (0.3)	0.566
Myocardial infarction	1 (0.3)	2 (0.6)	0.564
Stroke	1 (0.3)	5 (1.5)	0.100
Stent thrombosis (definite/probable)	0	3 (0.9)	0.083
Target vessel revascularization	8 (2.4)	13 (3.9)	0.265
Major bleeding	2 (0.6)	7 (2.1)	0.093

Values are n (%). * P Value is from the log-rank test.

Major adverse cardiovascular events were composed of cardiac death, myocardial infarction, stroke, stent thrombosis, target vessel revascularization, and major bleeding (Bleeding Academic Research Consortium bleeding type 3 or greater).

Abbreviations: DCB = drug-coated balloon; DES = drug-eluting stent