BENHA MEDICAL JOURNAL bmj

Print ISSN 1110-208X.

Online ISSN 2357-0016

Drug Coated Balloons vs Drug Eluting Stents in De Novo Coronary Stenotic Lesions

Amr A. El-Sayed, Khaled E. El-Rabat, Sara H. Gad, Al-Shimaa M. Sabry

Abstract:

Background: While drug-eluting stents (DES) remain the cornerstone of coronary revascularization, their use is associated with notable drawbacks, including restenosis and the requirement for prolonged dual antiplatelet therapy. Drug-coated balloons (DCBs) have emerged as a promising stentless alternative with potential clinical advantages. This investigation aimed to compare the safety and efficacy of DCBs versus DES in treating de novo coronary stenotic lesions in cases with non-ST elevation acute coronary syndromes (NSTACS). **Methods:** A prospective, randomized controlled trial was conducted on 102 NSTACS cases (51 per group) across two centers. Group I received DCBs, while Group II received DES. Cases were monitored over a 12-month period to evaluate both clinical and angiographic outcomes. **Results:** The two groups exhibited comparability regarding baseline demographic, clinical, laboratory, or angiographic characteristics (P>0.05). Procedural complications were rare and similar across groups (P=0.556). Restenosis was observed in 3.9% of cases in DCB in contrast with 2% in the DES (P=1). Major adverse cardiovascular events noticed in 3.9% of DCB-treated cases and 2% of those treated with DES (P=1), with no mortality reported. **Conclusion:** DCBs represent a safe and effective alternative to DES in managing de novo coronary lesions, particularly in small vessels, with comparable short-term outcomes. Larger-scale studies are recommended to validate long-term benefits and explore broader indications.

Keywords: Drug-Coated Balloon, Drug-Eluting Stent, De Novo Coronary Lesions, Percutaneous Coronary Intervention, Acute Coronary Syndrome.

Cardiovascular Medicine Department, Faculty of Medicine Benha University, Egypt.

Corresponding to:
Dr. Sara H. Gad.
Cardiovascular Medicine Department, Faculty of Medicine Benha University, Egypt.
Email: Sansona71@gmail.com

Received:
Accepted:

Introduction

Recent advancements in percutaneous coronary intervention (PCI) have markedly improved clinical outcomes in both chronic and acute coronary syndromes. Drug-eluting stents (DES) remain the cornerstone of coronary revascularization due to their ability to suppress neointimal hyperplasia and reduce restenosis rates [(1)].

Nonetheless, DES use is accompanied by persistent challenges such as in-stent restenosis (ISR), thrombosis, and delayed endothelial repair, issues particularly prevalent in diffuse or anatomically complex lesions. Established predictors of stent failure include excessive stent length, overlapping segments, and heavy calcification, all increasingly encountered in routine practice [(2)].

Furthermore, the permanent metallic scaffold of DES can impair vasomotion and provoke endothelial dysfunction, often necessitating extended dual antiplatelet therapy (DAPT), a concern in frail populations due to elevated bleeding risks [(3)].

To bypass these limitations, drug-coated balloons (DCBs) have emerged as a viable, scaffold-free alternative. DCBs enable local delivery of antiproliferative agents, typically paclitaxel, directly to the arterial wall, facilitating vascular healing without implanting a permanent device[(4)]. This approach preserves native vessel physiology, negates the need for precise stent sizing, and is particularly advantageous in small-caliber vessels, bifurcations, and tortuous anatomies. Moreover, the reduced requirement for prolonged DAPT makes DCBs especially attractive for high-bleeding-risk cases [(5)].

While initially validated for ISR, DCBs are now supported by extensive evidence, including randomized trials and meta-analyses, for their safety and efficacy. The PICCOLETO II trial, for instance, demonstrated that DCBs are non-inferior to DES in treating de novo lesions in small vessels, with comparable rates of major adverse cardiac events (MACE) and indications of superior safety [(6)]. Emerging evidence, such as that from Shin and co-authors suggests this benefit may extend to larger vessels and complex lesions [(7)]. Additionally, hybrid strategies combining DCBs and DES for long or diffuse disease have proven feasible and effective, without increasing thrombotic risk [(8)].

Accordingly, the present investigation aims to further explore and compare the clinical outcomes of DCB versus DES in de novo coronary stenotic lesions, aiming to contribute to the evolving paradigm of PCI.

Patients and methods:

Patients:

This prospective, randomized, controlled clinical trial (RCT) was conducted across two major cardiology centers, Benha University Hospital and Zagazig Military Hospital, over the course of 12 consecutive months, from January 2023 through January 2024. The trial adhered to rigorous scientific and ethical standards to ensure both reliability and reproducibility. Prior to inclusion, all eligible cases received a comprehensive verbal and written explanation outlining the investigation's objectives, methodology, and anticipated benefits or risks. Only after obtaining fully informed, written consent were individuals officially enrolled. To maintain confidentiality and secure sensitive patient data, each participant was assigned a unique, anonymized identification code.

Ethical Considerations

Ethical approval for the investigation protocol was obtained from the Research Ethics Committee of the Faculty of Medicine at Benha University. This approval confirmed that the investigation complied with national and international ethical guidelines governing human research, including respect for autonomy, beneficence, and confidentiality.

Sample Size Calculation

The required sample size was determined via OpenEpi version 3, an open-access, statistically validated tool commonly

employed in the design of clinical trials. Based on an alpha error (Type I error) of 0.05, a power of 80% (1 - β), and an estimated event incidence of 25% within the exposed population, the minimum calculated sample size detecting a statistically significant difference between groups was 102 cases. Consequently, a total of 102 participants were randomized in a 1:1 ratio into two equal groups, ensuring balanced allocation with 51 cases per arm.

Inclusion and Exclusion Criteria

The **inclusion criteria** focused on adult cases presenting with acute chest pain suggestive of non-ST-segment elevation acute coronary syndrome (NSTACS), as evidenced by electrocardiographic (ECG) changes, regardless of the presence or absence of elevated cardiac biomarkers.

Exclusion Criteria: Cases were excluded from the investigation if they had a history of prior percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), as these interventions could confound the evaluation of treatment efficacy in a first-time NSTACS population. Additional exclusion criteria included presentation with ST-segment elevation myocardial infarction (STEMI), the presence of multivessel or multilesion coronary artery disease, and impaired renal function defined by a serum creatinine level greater than 1.5 mg/dL. Cases in cardiogenic shock or those with severely reduced left ventricular systolic function were also excluded, as their clinical instability could significantly influence procedural outcomes and safety profiles. Furthermore, individuals with akinetic myocardial segments within the intended target vessels were deemed ineligible due to concerns about stent or balloon efficacy in non-viable tissue. Lastly, any patient who declined to provide informed consent was excluded from participation, in accordance with ethical standards for human research.

These criteria ensured the selection of a homogeneous investigation population with first-time NSTACS suitable for the interventions being tested.

Patient Allocation and Interventions

A total of 102 cases that met the inclusion criteria were enrolled and randomized into two treatment groups. Both non-ST-elevation myocardial infarction and unstable angina cases were included.

- **Group I** underwent **PCI via DCBs**
- **Group II** underwent **PCI with DES**

Randomization ensured unbiased assignment and comparability between groups. Both groups were monitored closely over a full 12-month follow-up period to assess clinical outcomes, including procedural success, recurrence of ischemic events, and major adverse cardiovascular events (MACE).

Methods:

Preprocedural Evaluation

All participants underwent a thorough clinical assessment, which included medical history, physical examination, and baseline investigations. Laboratory tests encompassed complete blood count (CBC), cardiac biomarkers, renal and hepatic panels, lipid profile, and coagulation parameters. Additionally, all cases received resting electrocardiography (ECG) and transthoracic echocardiography. Hypertension and diabetes mellitus were defined according to contemporary clinical guidelines [9, 10].

Angiography and Interventional Protocol

Coronary angiography was performed via either femoral or radial arterial access, with anatomical lesion assessment guided by the SYNTAX scoring system [11]. Cases in Group I were treated with DCBs preloaded with paclitaxel, ensuring optimal drug transfer via balloon inflation sustained for 60 seconds. A successful intervention was defined by the restoration of Thrombolysis in Myocardial Infarction (TIMI) grade III flow and residual stenosis <50%. Bailout DES deployment was limited to cases with significant, flow-limiting dissection [12, 13]. In Group II, PCI was performed with DES implantation

aiming for <20% residual luminal narrowing, adhering to contemporary revascularization standards.

In-Hospital Management

All participants were preloaded with DAPT, receiving 300 mg aspirin and 600 mg before intervention, followed by maintenance dosing per protocol. Unfractionated heparin was administered intra-procedurally to achieve an activated clotting time (ACT) between 300–350 seconds, ensuring anticoagulation during device manipulation. Upon completion, guideline-directed medical therapy for coronary artery disease (CAD) was continued, including beta-blockers, statins, and ACE inhibitors or ARBs as indicated.

Follow-Up and Outcomes

Cases were clinically monitored over a 12-month period to capture the occurrence of MACE, which included all-cause death, MI, cerebrovascular accidents, hospitalization due to heart failure, and repeat coronary revascularization [14]. Surveillance coronary angiography was scheduled at one year or earlier if prompted by recurrent symptoms or clinical suspicion of restenosis.

Approval code: MD 4-2-2023

Statistical Considerations

The collected data underwent comprehensive statistical analysis using IBM SPSS Statistics, Version 26 (SPSS Inc., 2018). Descriptive statistics were employed to illustrate the investigation variables: categorical data were summarized through frequencies and percentages, providing a structured overview of distribution patterns, while continuous variables were represented either by means with standard deviations or medians with interquartile ranges, contingent upon the results of normality assessments. For inferential analysis, appropriate statistical tests were chosen based on variable type and distribution characteristics. The independent samples Student's *t*-test was utilized to evaluate intergroup differences in continuous variables, assuming approximately normal distributions. Categorical variables were compared using the Chi-square test; however, in cases where expected frequencies were light, Fisher's exact test was implemented to maintain statistical rigor. All tests were two-sided, with statistical significance set at $P < 0.05$. This significance threshold was used to distinguish findings that are unlikely to have occurred by chance, thereby reinforcing the reliability of the observed associations and group differences.

Results

The two investigation arms exhibited comparability in baseline demographics, clinical presentation, and medical history (**Table 1**).

Laboratory investigations likewise exhibited comparability between groups. Troponin elevation was noted in 47.1% of Group I cases, as opposed to 56.9% in Group II (P=0.322). Mean serum creatinine titter was 0.7 ± 0.1 mg/dL in Group I versus 0.7 ± 0 mg/dL in Group II (P=0.106). Hemoglobin concentration was slightly diminished in Group I (12.6 ± 1.3 g/dL) as opposed to 13.2 ± 1.6 g/dL in Group II (P=0.077). Triglyceride titers exhibited comparability (185.4 ± 41 vs. 184.6 ± 40.8 mg/dL; P=0.917), as did total cholesterol titers (242.7 ± 46.8 vs. 244 ± 46.2 mg/dL; P=0.884), HDL (43.9 ± 9.3 vs. 43.8 ± 9.4 mg/dL; P=0.941), and LDL (113.6 ± 126 vs. 112 ± 8.6 mg/dL; P=0.486) (**Table 2**).

Angiographic parameters exhibited comparability across the two groups. Single-vessel disease was observed in 70.6% of Group I cases, as opposed to 62.7% in Group II, while two-vessel involvement was noted in 29.4% and 37.3%, respectively (P=0.401). Target vessels affected included LAD, LCX, RCA, and their combinations, with similar distributions between groups (Group I: 25.5%, 21.6%, 23.5%, 13.7%, 5.9%, 9.8%; Group II: 25.5%, 17.6%, 17.6%, 19.6%, 7.8%, 11.8%; P=0.925). Although distal

lesions were more frequent in Group I (23.5% vs. 7.8%), and proximal lesions more prevalent in Group II (54.9% vs. 37.3%), the overall lesion distribution exhibited comparability (P=0.056). Device parameters including mean stent/balloon length (24.1 ± 4.8 mm vs. 25.3 ± 4.3 mm; P=0.213), diameter (2.8 ± 0.3 mm vs. 2.8 ± 0.2 mm; P=0.344), and SYNTAX score (59.9 ± 4.9 vs. 60.3 ± 5.5; P=0.685) showed no meaningful deviation (**Table 3**).

Procedural complications exhibited comparability as well (P=0.556). Most cases had uneventful courses: 94.1% in Group I and 96.1% in Group II. Allergic reactions noticed in one patient per group, while isolated events of chest pain (Group II), hypotension (Group I), and arrhythmia (unspecified) were recorded (**Table 4**).

Regarding postprocedural outcomes, restenosis was documented in two cases in Group I as opposed to one in Group II (P=1). MACE incidence exhibited comparability (P=1), with unstable angina in two cases in Group I and one in Group II. No deaths were reported in either group during the 12-month follow-up (**Table 5**).

Table 1: Demographic and clinical characteristics of studied participants.

Variable		Group I (n=51)	Group II (n=51)	Test of Significance	P value
Age (years)		62.1 ± 7.5	59.9 ± 7.5	t=1.419	0.159
Sex	Male	29 (56.9%)	32 (62.7%)		
	Female	22 (43.1%)	19 (37.3%)	χ^2=0.367	0.545
BMI		26 ± 2.9	25.7 ± 2.9	t=0.392	0.696
Diabetes Mellitus (DM)		21 (41.2%)	24 (47.1%)	χ^2=0.358	0.550
Hypertension (HTN)		42 (82.4%)	40 (78.4%)	χ^2=0.249	0.618
Hypercholesterolemia		18 (35.3%)	19 (37.3%)	χ^2=0.042	0.837
Smoking		5 (9.8%)	12 (23.5%)	χ^2=3.459	0.063
Family History of CHD		3 (5.9%)	7 (13.7%)	χ^2=1.774	0.183
Heart Rate (bpm)		83.5 ± 10.9	84.6 ± 11.0	t=0.506	0.614
SBP (mmHg)		128.7 ± 14.1	127.9 ± 13.2	t=0.319	0.751
DBP (mmHg)		76.7 ± 6.9	76.8 ± 6.9	t=0.144	0.886
Clinical Presentation	NSTEMI	24 (47.1%)	29 (56.9%)	χ^2=0.982	0.322
	Unstable Angina	27 (52.9%)	22 (43.1%)		
LVEF Baseline		59.9 ± 4.9	60.3 ± 5.5	t=0.407	0.685

Data were presented as Mean ± SD or n (%).

Table 2: Laboratory data of studied participants.

Variable		Group I (n=51)	Group II (n=51)	Test of Significance	P value
Troponin	Positive	24 (47.1%)	29 (56.9%)	χ^2=0.982	0.322
	Negative	27 (52.9%)	22 (43.1%)		
Serum Creatinine (mg/dL)		0.7 ± 0.1	0.7 ± 0.1	t=1.629	0.106
Hemoglobin (g/dL)		12.6 ± 1.3	13.2 ± 1.6	t=1.786	0.077
Triglycerides (mg/dL)		185.4 ± 41.0	184.6 ± 40.8	t=0.104	0.917
Cholesterol (mg/dL)		242.7 ± 46.8	244.0 ± 46.2	t=0.147	0.884
HDL (mg/dL)		43.9 ± 9.3	43.8 ± 9.4	t=0.074	0.941
LDL (mg/dL)		113.6 ± 12.0	112.0 ± 8.6	t=0.699	0.486

Data were presented as Mean ± SD or n (%).

Table 3: Angiographic data among studied participants

Variable		Group I (n=51)	Group II (n=51)	Test of Significance	P value
Number of Vessels Involved	Single Vessel	36 (70.6%)	32 (62.7%)	χ^2=0.706	0.401
	Two Vessels	15 (29.4%)	19 (37.3%)		
Target Vessels	LAD	13 (25.5%)	13 (25.5%)	χ^2=1.932	0.925
	LCX	11 (21.6%)	9 (17.6%)		
	RCA	12 (23.5%)	9 (17.6%)		
	LAD & LCX	7 (13.7%)	10 (19.6%)		
	LAD & RCA	3 (5.9%)	4 (7.8%)		
	LCX & RCA	5 (9.8%)	6 (11.8%)		
Stenotic Segment	Distal	12 (23.5%)	4 (7.8%)	t=5.749	0.056
	Middle	20 (39.2%)	19 (37.3%)		
	Proximal	19 (37.3%)	28 (54.9%)		
Stent/Balloon Length (mm)		24.1 ± 4.8	25.3 ± 4.3	t=1.255	0.213
Stent/Balloon Diameter (mm)		2.8 ± 0.3	2.8 ± 0.2	t=0.952	0.344
SYNTAX Score		59.9 ± 4.9	60.3 ± 5.5	t=0.407	0.685

Data were presented as Mean ± SD or n (%).

Table 4: Complications during the procedure of studied participants

Variable	Group I (n=51)	Group II (n=51)	Test of Significance	P value
None	48 (94.1%)	49 (96.1%)	χ^2=3.010	0.556
Allergy	1 (2.0%)	1 (2.0%)		
Chest Pain	0 (0.0%)	1 (2.0%)		
Hypotension	1 (2.0%)	0 (0.0%)		
Arrhythmia	1 (2.0%)	0 (0.0%)		

Data were presented as n (%).

Table 5: One year outcome percentage.

Variable		Group I (n=51)	Group II (n=51)	Test of Significance	P value
Restenosis		2 (3.9%)	1 (2.0%)	FE=0.343	1.000
Success Rate		49 (96.1%)	50 (98.0%)	FE=0.343	1.000
MACE	Unstable Angina	2 (3.9%)	1 (2.0%)	FE=0.343	1.000
	Mortality	0 (0.0%)	0 (0.0%)	--	--

Data were presented as n (%).

Discussion

DES remains a cornerstone in coronary revascularization; however, their use is not without drawbacks, notably the potential for ISR and the requirement for extended DAPT. In contrast, DCBs have gained attention as an innovative, stent-free alternative, particularly advantageous in small vessels [15]. This RCT involved 102 cases presenting with first-time NSTACS, who were assigned to undergo PCI with either DCB (Group I) or DES (Group II), aiming to evaluate and contrast the safety

and therapeutic efficacy of both modalities in managing de novo coronary stenoses.

Findings from this trial indicate that the DCB-based approach yielded clinical and angiographic outcomes on par with DES, particularly in non-ST elevation acute coronary syndrome settings. Notably, DCB use in small vessels proved effective while circumventing the implantation of permanent metallic scaffolds.

Our observations are verified by Colombo and co-authors [16], who investigated DCB as a frontline option for de novo lesions. Their work affirmed the efficacy of DCBs relative to DES in vessels under 2.75 mm in diameter. Nevertheless, they advised caution in extrapolating these benefits to larger vessels (>2.75 mm), given the paucity of robust randomized data in such contexts, especially among older or more complex patient populations.

Additional corroboration is provided by the PICCOLETO II trial, a multicenter, randomized investigation, which demonstrated that a new-generation paclitaxel-coated DCB yielded superior outcomes regarding late lumen loss (LLL) when as opposed to DES in cases with small coronary arteries [17]. Importantly, clinical endpoints were comparable between the groups. Notably, at the 3-year follow-up, the incidence of MACE was elevated in the DES arm, further supporting the long-term clinical advantage of DCB therapy in this subset [3].

Further evidence stems from the BELLO trial, which randomized cases with small vessel disease (mean reference diameter: 2.15 mm) to receive either a DCB or a Taxus DES. Results favored the DCB strategy, revealing significantly reduced LLL at 6 months (0.09 mm vs. 0.30 mm, *P*=0.001). While bailout BMS implantation was necessary in 21.1% of the DCB, their angiographic outcomes (LLL=0.33 mm) remained comparable to those in the DES cohort. Moreover, MACE rates did not differ significantly (10% DCB vs. 16.3% DES, *P*=0.18) [18].

Similarly, the Valentines II registry, which assessed DCBs used adjunctively in de novo coronary lesions, reported encouraging short-term outcomes at 8 months: MACE incidence was 8.7%, with target vessel revascularization at 6.9%, and combined rates of MI and cardiac mortality at 2%. These findings reinforce both the safety and effectiveness of DCBs in routine clinical practice [19].

Interestingly, clinical outcomes were more favorable among non-diabetic cases, who exhibited a lower MACE incidence (6.8% vs. 13.8% in diabetic counterparts), while the necessity for bailout stenting remained relatively low at 11.3%. These observations align with findings from both the Spanish DIOR registry and the SeQuent Please Worldwide registry, which reported consistently low rates of TLR and MACE, even within real-world practice environments. Notably, the latter registry documented a comparatively elevated frequency of bailout stenting.

Conversely, the PICCOLETO I trial [20], the first randomized head-to-head evaluation of the first-generation Dior-I DCB versus DES in vessels smaller than 2.75 mm, was prematurely halted due to significantly superior outcomes in the DES, including reduced rates of restenosis and TLR. The subpar performance of DCBs in that trial was largely attributed to factors such as subtherapeutic drug dosage, insufficient lesion preparation, and inadequate balloon deployment technique.

Overall, our findings align with recent evidence signifying that DCBs represent a practical and safe alternative to DES in select cases of de novo coronary disease, mainly small vessel lesions. However, further robust studies are warranted to define their role in larger or more complex lesions. Device selection should continue to be guided by comprehensive clinical and angiographic evaluation.

This investigation was limited by its relatively small sample size and limited follow-up duration, which may not fully capture long-term outcomes such as late

restenosis or stent thrombosis. Additionally, the investigation focused on single-vessel disease in NSTACS cases, limiting generalizability to multivessel or more complex lesions. Larger multicenter investigations with extended follow-up are warranted to confirm these observations and assess the broader applicability of DCB therapy.

Conclusion:

DCBs are a non-inferior alternative to DES in selected de novo lesions, though DES remains necessary in cases of dissection or residual stenosis. While DCBs show potential, current evidence does not yet establish their equivalence to top-tier DES, highlighting the need for larger trials and newer-generation DCBs.

Sources of Funding

This investigation was conducted independently and did not benefit from any targeted financial support. No grants were obtained from governmental bodies, academic institutions, commercial enterprises, or charitable foundations. All resources required for the execution of the research, including data collection, analysis, and manuscript preparation, were provided by the authors themselves, underscoring their dedication to advancing scientific knowledge in the field of interventional cardiology.

Author Contributions

All members participated equally and substantially in the conception, design, execution, and interpretation of the investigation. Each author was actively involved in patient enrollment, clinical decision-making, data analysis, and critical revision of the manuscript. The collaborative nature of this work reflects shared intellectual ownership and mutual commitment to the integrity of the research.

Conflicts of Interest

The authors affirm that there are no actual or perceived conflicts of interest, financial, personal, or professional, that could compromise the integrity or impartiality of this research. No affiliations exist that might influence the interpretation or presentation of the results.

References

1. Abubakar M, Javed I, Rasool HF, Raza S, Basavaraju D, Abdullah RM, et al. Advancements in Percutaneous Coronary Intervention Techniques: A Comprehensive Literature Review of Mixed Studies and Practice Guidelines. Cureus. 2023;15:e41311.
2. Condello F, Spaccarotella C, Sorrentino S, Indolfi C, Stefanini GG, Polimeni A. Stent Thrombosis and Restenosis with Contemporary Drug-Eluting Stents: Predictors and Current Evidence. J Clin Med. 2023;12.
3. Cortese B, Testa G, Rivero F, Erriquez A, Alfonso F. Long-Term Outcome of Drug-Coated Balloon vs Drug-Eluting Stent for Small Coronary Vessels: PICCOLETO-II 3-Year Follow-Up. JACC Cardiovasc Interv. 2023;16:1054-61.
4. Marchetta M, Sasso S, Paragliola V, Maffi V, Chiricolo G, Massaro G, et al. Leaving Nothing Behind: Expanding the Clinical Frontiers of Drug-Coated Balloon Angioplasty in Coronary Artery Disease. J Cardiovasc Dev Dis. 2025;12.
5. Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD, et al. Third universal definition of myocardial infarction. Eur Heart J. 2012;33:2551-67.
6. Abdelaziz A, Elsayed H, Atta K, Desouky M, Gomaa M, Kadhim H, et al. Drug-coated balloons versus drug-eluting stents in patients with small coronary artery disease: an updated meta-analysis. BMC Cardiovasc Disord. 2025;25:339.
7. Shin ES, Jun EJ, Kim S, Kim B, Kim TH, Sohn CB, et al. Clinical Impact of Drug-Coated Balloon-Based Percutaneous Coronary Intervention in Patients With Multivessel Coronary Artery Disease. JACC Cardiovasc Interv. 2023;16:292-9.
8. Kufner S, Joner M, Thannheimer A, Hoppmann P, Ibrahim T, Mayer K, et al. Ten-Year Clinical Outcomes From a Trial of Three Limus-Eluting Stents With Different Polymer Coatings in Patients With Coronary Artery Disease. Circulation. 2019;139:325-33.
9. Williams B, Mancia G, Spiering W, Agabiti Rosei E, Azizi M, Burnier M, et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension. Eur Heart J. 2018;39:3021-104.
10. Genuth S, Alberti KG, Bennett P, Buse J, Defronzo R, Kahn R, et al. Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care. 2003;26:3160-7.

11. Sianos G, Morel MA, Kappetein AP, Morice MC, Colombo A, Dawkins K, et al. The SYNTAX Score: an angiographic tool grading the complexity of coronary artery disease. EuroIntervention. 2005;1:219-27.
12. Cortese B, Silva Orrego P, Agostoni P, Buccheri D, Piraino D, Andolina G, et al. Effect of Drug-Coated Balloons in Native Coronary Artery Disease Left With a Dissection. JACC Cardiovasc Interv. 2015;8:2003-9.
13. Cox DA, Stone GW, Grines CL, Stuckey T, Cohen DJ, Tcheng JE, et al. Outcomes of optimal or "stent-like" balloon angioplasty in acutemyocardial infarction: the CADILLAC trial. Journal of the American College of Cardiology. 2003;42:971-7.
14. Bosco E, Hsueh L, McConeghy KW, Gravenstein S, Saade E. Major adverse cardiovascular event definitions used in observational analysis of administrative databases: a systematic review. BMC Med Res Methodol. 2021;21:241.
15. Shahrori ZMF, Frazzetto M, Mahmud SH, Alghwyeen W, Cortese B. Drug-Coated Balloons: Recent Evidence and Upcoming Novelties. J Cardiovasc Dev Dis. 2025;12.
16. Colombo A, Leone PP, Ploumen EH, von Birgelen C. Drug-coated balloons as a first choice for patients with de novo lesions: pros and cons. EuroIntervention. 2024;20:e120-e2.
17. Cortese B, Di Palma G, Guimaraes MG, Piraino D, Orrego PS, Buccheri D, et al. Drug-Coated Balloon Versus Drug-Eluting Stent for Small Coronary Vessel Disease: PICCOLETO II Randomized Clinical Trial. JACC Cardiovasc Interv. 2020;13:2840-9.
18. Latib A, Colombo A, Castriota F, Micari A, Cremonesi A, De Felice F, et al. A randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels: the BELLO (Balloon Elution and Late Loss Optimization) study. J Am Coll Cardiol. 2012;60:2473-80.
19. Waksman R, Serra A, Loh JP, Malik F, Torguson R, Stahnke S, et al. Drug-coated balloons for de novo coronary lesions: results from the Valentines II trial. EuroIntervention. 2013;9:613-9.
20. Cortese B, Micheli A, Picchi A, Coppolaro A, Bandinelli L, Severi S, et al. Paclitaxel-coated balloon versus drug-eluting stent during PCI of small coronary vessels, a prospective randomised clinical trial. The PICCOLETO study. Heart. 2010;96:1291-6.

To cite this article: Amr A. El-Sayed , Khaled E. El-Rabat, Sara H. Gad, Al-Shimaa M. Sabry. Drug Coated Balloons vs Drug Eluting Stents in De Novo Coronary Stenotic Lesions. BMFJ XXX, DOI: 10.21608/bmfj.2025.410653.2597.