ƏDƏBİYYAT İCMALI AÇIQ GİRİŞ (OPEN ACCESS)

ÜRƏYİN İŞEMİK XƏSTƏLİYİNDƏ DƏRMAN ÖRTÜKLÜ BALONLAR EUROPCR 2026 FONUNDA MÜASİR SÜBUTLAR VƏ PRAKTİK YANAŞMA

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ABSTRACT

Drug-coated balloons (DCBs) enable the delivery of an antiproliferative agent to the vessel wall without leaving a permanent metallic implant. Although this technology was initially used mainly for in-stent restenosis and small-vessel disease, recent randomized evidence and data presented at EuroPCR 2026 have expanded its potential role to de novo lesions, large coronary vessels, bifurcations, chronic total occlusions, and complex percutaneous coronary interventions. Nevertheless, the success of a DCB strategy depends less on balloon delivery itself than on adequate lesion preparation, accurate vessel sizing, and achievement of a stable post-angioplasty result. This review discusses contemporary evidence for coronary DCB intervention in the context of EuroPCR 2026, with particular emphasis on patient and lesion selection, procedural technique, intracoronary imaging, antithrombotic therapy, and the remaining limitations of this evolving strategy.

Keywords: drug-coated balloon, drug-eluting stent, de novo coronary lesion, in-stent restenosis, bifurcation, complex PCI, EuroPCR 2026

Introduction

Although contemporary percutaneous coronary intervention is largely based on drug-eluting stents (DES), the permanent presence of a metallic implant within the vessel wall may be associated with late neoatherosclerosis, stent thrombosis, restenosis, loss of vasomotor function, and limitations on future revascularization options. Drug-coated balloon angioplasty delivers an antiproliferative agent to the vessel wall during a brief balloon inflation, allowing revascularization without an additional metallic scaffold or permanent polymer. This “leave nothing behind” approach is particularly attractive when repeat stenting is undesirable [1–3].

For many years, the use of DCBs was largely confined to in-stent restenosis and small-vessel disease. However, the development of newer devices, the emergence of sirolimus-based platforms, broader use of intracoronary imaging, and greater standardization of lesion preparation have accelerated the expansion of this strategy into de novo and more complex coronary anatomy. Data presented at EuroPCR 2026 have shifted the discussion from a simple comparison of DCB versus DES towards a clinically more relevant comparison between systematic metal implantation and a DCB-first strategy with provisional DES when required [4–7].

Evolution of DCB Technology and Drug Selection

The principal antiproliferative agents used in coronary DCBs are paclitaxel and sirolimus. Because of its high lipophilicity, rapid cellular uptake, and prolonged tissue retention after brief contact, paclitaxel became the drug of choice for first-generation DCBs. These platforms have the longest clinical track record, particularly for

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the treatment of restenosis. Sirolimus is attractive because of its cytostatic mechanism and extensive use in DES technology; however, its lower lipophilicity requires microlayer, microreservoir, or nanocarrier systems to retain the drug within the vessel wall [2,3].

Newer sirolimus-coated balloons aim to provide controlled and more sustained drug delivery. Nevertheless, a class effect should not be assumed across DCB platforms. Drug dose, coating matrix, excipient, particulate loss, transfer efficiency, and balloon deliverability vary substantially among devices. Accordingly, results obtained with one platform should not automatically be extrapolated to another, and device selection should be guided by platform-specific clinical evidence [1–3].

New Evidence in De Novo Coronary Lesions

The SELUTION DeNovo Trial

SELUTION DeNovo is the largest randomized coronary DCB trial conducted to date. Across 62 centres, 3,323 patients were randomized to a strategy of sirolimus-eluting balloon angioplasty with provisional DES implantation when necessary or to systematic DES implantation. At one year, target vessel failure occurred in 5.3% of patients in the sirolimus-eluting balloon group and 4.4% in the DES group, meeting the prespecified non-inferiority criterion in the intention-to-treat analysis. Bailout stenting was required in 20.7% of patients assigned to the DCB strategy. Clinically driven target vessel revascularization was more frequent with the DCB strategy, occurring in 3.3% versus 2.1%. In the per-protocol analysis, however, non-inferiority was not formally confirmed [4].

These findings do not indicate that DCBs have replaced DES in all de novo lesions. Rather, they suggest that, in appropriately selected lesions with a stable and satisfactory result after optimal angioplasty, a sirolimus-eluting balloon strategy with provisional DES may represent an alternative to systematic DES implantation. The study also reinforces that bailout stenting should not be viewed as failure of the DCB strategy, but as a prespecified safety component of the procedure.

Complex PCI Subgroup

At EuroPCR 2026, the complex PCI subgroup of SELUTION DeNovo was presented separately. Complex PCI was defined by the presence of at least one of the following: treatment of all three coronary vessels, treatment of three or more lesions, use of three or more drug-eluting balloons or stents, treatment of both branches of a bifurcation, chronic total occlusion, or a total device length exceeding 60 mm. At one year, target vessel failure occurred in 7.2% of patients treated with the DCB strategy and 10.2% of those treated with DES, corresponding to an absolute risk difference of −3.0 percentage points. The early separation of the event curves was mainly related to lower rates of target vessel myocardial infarction and cardiac death [5]. These findings are clinically encouraging and hypothesis-generating, but the subgroup analysis was not independently powered to demonstrate superiority.

Large Vessel Lesions

Restricting DCB use solely on the basis of vessel diameter no longer reflects contemporary practice. Emerging data suggest that vessels measuring 3.0 mm or more may also be treated with a DCB when the lesion morphology is suitable and preparation is optimal. The principal determinant of suitability is the post-preparation result rather than vessel size alone: residual stenosis should ideally be no greater than 30%, TIMI 3 flow should be maintained, and there should be no flow-limiting dissection, substantial elastic recoil, or progressive intramural haematoma [1,8]. Nevertheless, additional randomized studies are needed to establish the long-term safety and repeat revascularization risk of a DCB-only strategy in large coronary vessels.

In Stent Restenosis

In-stent restenosis remains the best-established coronary indication for DCB angioplasty. Its principal advantage is avoidance of an additional metallic layer within an existing stent. Restenosis, however, is not a single pathological entity, and treatment should be directed at its mechanism. Intravascular ultrasound or optical coherence tomography can distinguish stent

underexpansion, neoatherosclerosis, neointimal hyperplasia, stent fracture, and edge-related abnormalities. DCB treatment alone is inadequate if stent underexpansion has not been corrected. In such cases, high-pressure balloon dilatation, intravascular lithotripsy, or, in selected circumstances, atherectomy may be required. A new DES may be more appropriate when there is stent fracture, a persistent mechanical problem, or an edge dissection [1,2,9].

Bifurcation Lesions

The most immediately applicable role for DCBs in bifurcation PCI is the treatment of the side branch. A strategy combining provisional DES implantation in the main vessel with DCB treatment of the side branch after optimal preparation aims to avoid a metallic layer at the side-branch ostium, reduce the need for two-stent techniques, and limit late restenosis. Available studies indicate that DCB treatment of the side branch may reduce late lumen loss and restenosis compared with plain balloon angioplasty [10,11]. Nevertheless, a low threshold for bailout stenting should be maintained in lesions involving a large side branch, long ostial disease, or flow-limiting dissection. A DCB-only strategy in both the main vessel and side branch is promising but cannot yet be considered routine practice.

Chronic Total Occlusion and Hybrid Treatment

The presentation of PICCOLETO-X at EuroPCR 2026 increased interest in DCB-based treatment of chronic total occlusions. This international real-world cohort of approximately 1,000 patients suggested that DCB-only and hybrid strategies may be feasible in selected CTO anatomy [6]. Lesions crossed within the plaque, with a suitable distal vessel, adequate lumen gain, and no major recoil appear most amenable to DCB treatment. By contrast, extensive subintimal passage, large dissections, impaired distal flow, or persistent recoil favour DES implantation. Thus, in CTO intervention, DCB should not be viewed as a universal substitute for DES but as a component of a hybrid strategy that can reduce the length of permanently implanted metal.

Acute Coronary Syndromes

DCB treatment may be considered in selected patients with acute coronary syndromes. In the ACS subgroup of the SELUTION DeNovo programme, one-year outcomes with a sirolimus-eluting balloon and minimal-stenting strategy were comparable to those observed in the chronic coronary syndrome cohort [7]. However, evidence for a DCB-only approach remains limited in the presence of a large thrombus burden, ongoing no-reflow, unstable dissection, severe residual stenosis, or significant recoil. Restoration of flow, reduction of thrombotic material, adequate lesion preparation, and a stable final result are essential prerequisites. More robust randomized data are required before routine DCB-only treatment can be recommended in ST-segment elevation myocardial infarction.

Optimal Procedural Technique

The outcome of DCB angioplasty is determined largely by lesion preparation. The objective is to establish a stable lumen before drug delivery and to identify promptly whether bailout stenting is required. Vessel size may be estimated angiographically, but intracoronary imaging is particularly valuable in complex, calcified, large-vessel, and restenotic lesions. For initial preparation, a semicompliant or non-compliant balloon is generally selected at a balloon-to-artery ratio of approximately 0.8–1.0. Scoring or cutting balloons may be useful in fibrotic or resistant lesions, whereas intravascular lithotripsy or atherectomy should be considered for severe calcification according to calcium morphology [1,2].

The DCB diameter should approximately match the reference vessel diameter at a 1:1 ratio, and the treated segment should extend about 2–3 mm beyond each edge of the prepared lesion. Unnecessary manipulation and delay during delivery should be minimized because they may cause loss of the balloon coating. Inflation duration should follow the instructions for use of the specific device and is commonly 30–60 seconds. After DCB treatment, provisional DES implantation should not be delayed when there is a flow-limiting

dissection, persistent recoil, or an unsatisfactory residual lumen.

Procedural stage	Acceptable result	Practical decision
Vessel assessment	Reference diameter and lesion length accurately defined	IVUS or OCT preferred in complex lesions
Lesion preparation	Residual stenosis ≤30% with TIMI 3 flow	Additional plaque modification if the result is inadequate
Dissection assessment	Non-flow-limiting dissection	DES for flow limitation or progressive dissection
DCB delivery	Approximately 1:1 sizing with 2–3 mm overlap at each edge	Inflation according to the device instructions for use
Final assessment	Stable lumen without major recoil or haematoma	Bailout DES when the final result is unstable

Antithrombotic Therapy

Because DCB-only PCI leaves no additional metal or permanent polymer, it may permit a shorter course of dual antiplatelet therapy. In chronic coronary syndrome, one month of DAPT is commonly used when there is no competing indication or high ischaemic risk. The duration of antithrombotic therapy, however, should be determined not only by the device but also by the clinical presentation, bleeding risk, and whether bailout stenting was required. In acute coronary syndromes, current ACS antithrombotic recommendations and the patient's individual bleeding risk should be considered even when no stent has been implanted. When a bailout DES is used, antiplatelet treatment should follow the requirements of the implanted stent and the clinical setting [12].

Limitations and Future Directions

Although current evidence supports expansion of DCB use, important uncertainties remain. Pharmacokinetic and clinical performance differ among platforms, and direct randomized comparisons between sirolimus- and paclitaxel-coated balloons remain limited. Long-term randomized evidence is insufficient for large-vessel disease, STEMI, left main disease, long diffuse lesions, and CTO. Studies also vary in lesion-preparation protocols, bailout criteria, and endpoint definitions. The five-year results of SELUTION DeNovo should clarify whether a DCB-first strategy confers late clinical advantages or increases the need for repeat revascularization.

Future trials should compare systematic metal implantation with minimal-metal strategies rather than limiting the comparison to individual DCB and DES devices. Combining intracoronary imaging, physiological assessment, and standardized angiographic endpoints may improve patient selection. Further work is also required to determine which patients derive a clinically meaningful benefit from positive vessel remodelling and late lumen enlargement after DCB angioplasty.

Conclusion

Following EuroPCR 2026, drug-coated balloons can no longer be regarded as a niche technology confined to in-stent restenosis and small-vessel disease. With optimal lesion preparation and prespecified bailout criteria, a DCB-first strategy is emerging as a credible alternative to systematic DES implantation in selected de novo lesions, large vessels, bifurcations, and complex PCI. Nevertheless, the fundamental requirement for successful DCB intervention is not drug delivery alone but the creation of an adequate and stable lumen. DCB use should therefore remain an individualized decision based on platform-specific evidence, intracoronary imaging, and the clinical and anatomical characteristics of the patient and lesion.

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