Reappraising Drug-Coated Balloons in Modern Percutaneous Coronary Intervention: A Review of Evidence, Techniques, and Practice Implications

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Abstract

Purpose: Drug-coated balloons (DCBs) have emerged as an important alternative or adjunct to drug-eluting stents (DES) in percutaneous coronary intervention (PCI), particularly in clinical scenarios where minimizing permanent implants or shortening dual antiplatelet therapy (DAPT) is desirable. This review summarizes recent technological advances, clinical evidence, and guideline recommendations for the use of DCBs in modern PCI practice.

Methods: We performed a comprehensive review of current international guidelines, expert consensus statements, and key clinical trials focusing on DCB use in various coronary lesion subsets and patient populations.

Results: DCBs have demonstrated comparable efficacy to DES in treating in-stent restenosis and small vessel disease, supported by randomized controlled trials and meta-analyses. Growing evidence also supports their use in de-novo large vessel disease, bifurcation lesions, and selected STEMI cases, particularly when optimal lesion preparation is achieved. DCB-only strategies are associated with favorable long-term outcomes and allow for shorter DAPT duration, making them particularly advantageous in patients at high bleeding risk.

Conclusions: Drug-coated balloons (DCBs) have become an essential tool in contemporary coronary intervention. Their use reflects a shift from routine stenting toward a more patient- and lesion-specific revascularization strategy. Optimal outcomes depend on evidence-based case selection, meticulous lesion preparation, and technical precision, underscoring the value of this “leave-nothing-behind” approach in modern PCI.

Keywords: drug-coated balloon; percutaneous coronary intervention; coronary artery disease; review

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Introduction

Over the past three decades, percutaneous coronary intervention (PCI) has undergone continuous innovation, with drug-eluting stents (DES) representing the cornerstone of coronary revascularization. By combining mechanical scaffolding with local antiproliferative drug delivery, DES have dramatically reduced restenosis compared with bare-metal stents (BMS). Ongoing advancements in stent platforms, polymer technologies, and pharmacologic agents have further enhanced their long-term safety and efficacy[1].

Despite these achievements, the DES era faces persistent challenges. The presence of a permanent metallic scaffold can impair natural vasomotion, limit future revascularization options, and predispose to neo-atherosclerosis or late stent thrombosis. In complex scenarios — such as small vessel disease, bifurcation lesions, diffuse disease requiring extensive stenting, or in-stent restenosis (ISR) — these limitations become clinically relevant. Moreover, prolonged dual antiplatelet therapy (DAPT), necessary to prevent stent thrombosis, poses significant bleeding concerns in patients at high bleeding risk.

These considerations have driven a paradigm shift toward the "leave-nothing-behind" strategy in contemporary interventional cardiology. Drug-coated balloon (DCB) angioplasty embodies this concept by delivering an antiproliferative drug directly to the vessel wall during a brief balloon inflation, leaving no permanent implant. This approach preserves vascular physiology, facilitates future interventions, and allows for more flexible DAPT duration, tailored to patient risk profiles.

Initially developed for the treatment of ISR, DCB therapy has expanded to de-novo lesions, including small vessels, bifurcations, and even selected acute coronary syndromes. With over a decade of accumulated evidence from randomized trials and real-world registries — and the recent advent of new-generation sirolimus-coated balloons — it is timely to re-evaluate the evolving role of DCBs in modern PCI. This review summarizes current guidelines, expert consensus statements, and key clinical trials to provide an evidence-based framework for optimal DCB use across diverse patient populations and lesion subsets.

The Evolution of DCB Technology: Mechanisms and Pharmacokinetics

DES and DCB share the common therapeutic objective of delivering antiproliferative agents locally to reduce neointimal hyperplasia and prevent restenosis. However, they differ fundamentally in their mechanisms of action, pharmacokinetics, and vascular effects. DES provide mechanical scaffolding while gradually releasing drugs through a durable or bioresorbable polymer coating. Modern DES have evolved to feature ultrathin struts (< 80 μm), which promote faster re-endothelialization, reduce the risk of stent thrombosis, minimize late lumen loss, and improve device deliverability[2].

Nonetheless, the presence of a permanent metallic implant may still impair vasomotion and is associated with a long-term risk of neo-atherosclerosis or stent thrombosis. By contrast, DCBs are angioplasty balloons coated with antiproliferative drugs — most commonly paclitaxel, and more recently, sirolimus — embedded in a carrier matrix to facilitate rapid drug transfer during balloon inflation, typically lasting 30 to 60 seconds.

Paclitaxel and sirolimus represent two distinct drug classes used in DCBs, each with different pharmacological properties and mechanisms of action. Paclitaxel is a cytotoxic agent that stabilizes microtubules, thereby disrupting mitosis and inducing cell death. By contrast, sirolimus is a cytostatic compound that binds to the cytosolic protein FKBP12, forming a complex that inhibits the mammalian target of rapamycin (mTOR), effectively halting cell cycle progression[3]. The key pharmacological and mechanical differences between these two

agents, which dictate their respective carrier platforms, are summarized in Table 1. Compared to sirolimus, paclitaxel is highly lipophilic and features prolonged tissue retention. One unique aspect of paclitaxel is its ability to penetrate deeper into the arterial wall, reaching the tunica adventitia and promoting positive vascular remodeling, which has been associated with late lumen enlargement[4,5]. This phenomenon has not been observed with sirolimus. Due to its lower lipophilicity and shorter tissue retention time, sirolimus requires more advanced delivery platforms, such as phospholipid-encapsulated nanocarriers, to achieve sustained drug delivery. However, sirolimus offers a broader therapeutic window and additional anti-inflammatory benefits. For example, preclinical studies have shown that sirolimus suppresses neutrophil activation and transmigration, whereas paclitaxel may have pro-inflammatory effects[6].

Although head-to-head clinical comparisons remain limited, existing randomized trials and meta-analyses suggest that paclitaxel- and sirolimus-coated balloons have similar safety and efficacy profiles, particularly with respect to target lesion revascularization (TLR) and major adverse cardiovascular events (MACE)[7].

Overall, by avoiding the need for a permanent scaffold or polymer, DCBs help preserve native vessel anatomy and endothelial function. This "leave-nothing-behind" approach is particularly advantageous in patients requiring shorter DAPT strategies or in lesions where metallic stents are suboptimal — such as small vessels, bifurcations, or ISR.

Guideline and Consensus Frameworks for DCB Use

The expanding evidence base for DCBs has led to their inclusion in major international guidelines and expert consensus documents, establishing a framework for their clinical application. Concurrently, recommendations on DAPT duration following DCB-only PCI have evolved in parallel, reflecting a shift from a device-centered approach toward a more patient- and lesion-focused approach to revascularization.

Table 1. Pharmacological and Mechanical Properties of Antiproliferative Agents Used in Drug-Coated Balloons.

Feature	Paclitaxel	Sirolimus
Mechanism	Cytotoxic	Cytostatic
Molecular Target	Microtubule stabilization	mTOR pathway inhibition
Lipophilicity	High	Moderate to low
Tissue Retention	Prolonged	Shorter, requiring advanced carriers to achieve sustained effect
Vascular Remodeling	Associated with late lumen enlargement	Neutral effect
Delivery Platform	Simpler excipients are sufficient	Requires advanced nanocarriers or excipients
Biological Property	Strong antiproliferative activity	Antiproliferative and anti-inflammatory properties

mTOR, mammalian target of rapamycin

International and Asian Perspectives (Taiwan and Japan) and Recommendations

The 2018 European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS) Guidelines on Myocardial Revascularization provide the most authoritative recommendations for DCB use. For ISR, DCBs receive a Class I, Level of Evidence A recommendation for bare-metal stent (BMS) restenosis and a Class IIa, Level of Evidence A recommendation for drug-eluting stent (DES) restenosis. DCBs may also be considered for de-novo lesions in small coronary vessels, although this indication was not formally assigned a recommendation class at the time. The guidelines emphasize that a class effect cannot be assumed across all DCBs, given variations in antiproliferative agents, doses and coating technologies among manufacturers[8]. This highlights the importance of selecting devices supported by robust clinical evidence.

In Taiwan, the National health insurance reimburses DCB use for the treatment of both BMS-ISR and DES-ISR, reflecting their established role in this setting.

Expert consensus from Japan supports broader clinical applications, including use in patients at high bleeding risk, younger individuals seeking to avoid permanent metallic implants, and complex anatomical subsets such as ostial or diffuse long lesions — often employing a hybrid strategy with DES proximally and DCB distally. The Japanese statement also underscores the need for meticulous lesion preparation and readiness for bailout stenting when necessary[9].

Guidance on DAPT Duration

One of the key advantages of the "leave-nothing-behind" strategy is the ability to individualize DAPT duration according to patient risk rather than device requirements. With DES, DAPT duration is determined by the time required for endothelialization to mitigate stent thrombosis. By contrast, the absence of a permanent scaffold with DCBs decouples DAPT decisions from device considerations, allowing treatment to be guided primarily by bleeding risk and clinical presentation (e.g. stable coronary artery disease vs. acute coronary syndrome).

Pathophysiologic Rationale for Shortened DAPT

The biological rationale for shortening DAPT after DCB-only PCI rests on the concept of device-independent thrombogenicity. Unlike DES, which leave a permanent metallic scaffold and polymer coating that may cause chronic inflammation and delayed healing, DCB angioplasty facilitates positive vascular remodeling and spontaneous vessel healing. Recent optical coherence tomography (OCT) evidence has demonstrated that DCB treatment effectively promotes the healing of iatrogenic dissections, with studies showing that the majority of dissection flaps spontaneously reattach to the tunica media within a few months[10]. This rapid biological recovery, characterized by dissection healing and late lumen enlargement without a permanent implant, contrasts sharply with the polymer-induced delayed healing seen with DES. Consequently, once this acute healing phase is complete, the requirement for prolonged antiplatelet therapy is substantially reduced.

This principle is reflected in current recommendations from different societies:

- **ESC (2018):** Recommends 6 months of DAPT for stable coronary artery disease treated with DCB-only PCI, with a reduction to 3 months acceptable in high bleeding risk patients[8].
- **Asia-Pacific Consensus Group:** Suggests lifelong aspirin with clopidogrel for at least 1-3 months in ISR, and at least 1 month of DAPT followed by lifelong aspirin for de-novo stable coronary lesions[11].

- **Taiwan Society of Cardiology (TSOC):** Advises 1 month of DAPT for BMS-ISR and 2 months for DES-ISR. No formal recommendation has been issued for de-novo lesions treated with DCB-only PCI.

The corresponding recommendations are summarized in Table 2. Notably, the 2023 TSOC guideline for chronic coronary syndrome recommends DAPT durations as short as 1-3 months even for new-generation DES, illustrating the broader trend toward shorter DAPT regimens across all device types[12].

Evidence-Based Clinical Applications

1. In-Stent Restenosis (ISR)

Clinical Challenge: ISR presents a therapeutic dilemma. While implanting another DES is effective, it creates a "stent-in-stent" scenario with multiple layers of metal, which can impair vessel healing and is associated with worse long-term outcomes. The underlying pathophysiology also differs; bare metal stent ISR (BMS-ISR) is primarily driven by aggressive neointimal hyperplasia, whereas drug eluting stent ISR (DES-ISR), in stark contrast, often involves more complex mechanisms, including the formation of neo-atherosclerosis[13].

Pivotal Evidence: DCB therapy was specifically developed to address ISR by delivering an antiproliferative drug without adding a new metallic layer.

The **RIBS V** trial randomized patients with BMS-ISR to either a paclitaxel-coated balloon (PCB) or an everolimus-eluting stent (EES). At long-term follow-up, the PCB was non-inferior to the EES for clinical endpoints such as MACE and TLR, although the EES group demonstrated superior angiographic results with a larger minimal lumen diameter and lower late lumen loss (LLL)[14,15].

The **RESTORE** trial evaluated patients with the more challenging scenario of DES-ISR. It found that PCBs and EES achieved comparable clinical outcomes, with only modest, non-clinically significant differences in angiographic parameters favoring the EES[16,17].

Practice Implications: Based on this strong evidence, DCB is the preferred and

Table 2. Current Recommendations on DAPT Duration After DCB-Only PCI.

Guideline / Consensus	Clinical Context	Recommended DAPT Duration
ESC / EACTS (2018)	Stable CAD treated with DCB-only PCI	6 months; may be shortened to 3 months in high bleeding risk patients
Asia-Pacific Consensus Group	Both BMS-ISR and DES-ISR	Lifelong aspirin with clopidogrel for 1–3 months
	De-novo coronary lesions treated with DCB-only PCI (non-ACS)	At least 1 month DAPT followed by lifelong aspirin
Taiwan Society of Cardiology (TSOC)	BMS-ISR	1 month of DAPT
	DES-ISR	2 months of DAPT
	De-novo coronary lesions treated with DCB-only PCI	No formal recommendation

CAD: coronary artery disease, DCB: drug-coated balloon, PCI: percutaneous coronary intervention, DAPT: dual antiplatelet therapy, HBR: high bleeding risk, BMS: bare-metal stent, DES: drug-eluting stent, ISR: in-stent restenosis, ACS: acute coronary syndrome.

guideline-endorsed strategy for a first-time ISR episode. This approach effectively treats the restenosis while avoiding the creation of a thick, multi-layered metallic scaffold. Implantation of an additional DES is generally reserved for cases of recurrent restenosis following an initial DCB treatment failure.

2. De-Novo Lesions in Small Vessel Disease (SVD)

Clinical Challenge: SVD, typically defined as lesions in vessels with a reference diameter of < 2.75 mm or < 3.0 mm, is associated with a higher risk of restenosis after any intervention[18]. In small vessels, even a minimal amount of LLL represents a proportionally greater compromise of the vessel lumen, leading to higher rates of clinically significant ISR.

Pivotal Evidence: The landmark BASKET-SMALL 2 trial directly compared a paclitaxel-iopromide-coated DCB with second-generation DES in over 750 patients with de-novo lesions in small coronary arteries (< 3.0 mm). The trial demonstrated that DCBs were non-inferior to DES with respect to MACE at both 1-year and 3-year follow-up[19].

Practice Implications: The results of the **BASKET-SMALL 2 trial** establish DCBs as a clinically valid and durable alternative to DES for the treatment of SVD. This is particularly relevant for patients in whom minimizing permanent implants is a priority, such as younger patients or those with diffuse disease where preserving future revascularization options is important.

3. De-Novo Lesions in Large Vessels

Clinical Challenge: While DES are highly effective in large coronary arteries (reference diameter ≥ 2.75 or ≥ 3.0 mm), the necessity of a permanent implant in this setting is being questioned. In large vessels, the risk of acute recoil after balloon angioplasty is lower, and the long-term disadvantages of a stent (impaired vasomotion, risk of late thrombosis) may outweigh its benefits in selected cases.

Pivotal Evidence: Growing evidence supports a DCB-only strategy in this context. A large, prospective multicenter registry of DCB use for de-novo lesions in large vessels demonstrated excellent outcomes, with a 2-year target lesion failure rate of only 2.6%, and a very low bailout stenting rate of 1.8%[20]. These findings are corroborated by a comprehensive meta-analysis of 15 studies including nearly 4,000 patients, which found no significant differences between DCBs and DES in rates of TLR, cardiac death, or myocardial infarction. Notably, the analysis suggested a potential long-term safety advantage for DCBs, with significantly lower rates of target lesion failure[21].

Practice Implications: In appropriately selected patients with de-novo large vessel disease, DCB-only PCI is a safe and effective alternative to DES, provided that meticulous lesion preparation is performed. This strategy is especially appealing for long, diffuse lesions where minimizing the total metal burden is a clinical priority.

4. Bifurcation Lesions: A Strategy for the Side Branch

Clinical Challenge: The management of the side branch (SB) in a provisional stenting strategy is a common challenge. While stenting the main vessel is standard, compromising the SB ostium often requires further intervention. Plain old balloon angioplasty (POBA) of the SB is associated with a high rate of restenosis, while committing to a two-stent technique significantly increases procedural complexity and risk.

Pivotal Evidence: DCBs offer an elegant solution by treating the SB ostium with an antiproliferative drug without requiring a second stent.

The **PEPCAD-BIF** trial showed that using a DCB on the SB after main vessel stenting resulted in a significantly lower restenosis rate (6% vs. 26%) and less LLL compared to POBA[22].

The larger, multicenter randomized **DCB-BIF** trial confirmed these findings, demonstrating

that a DCB strategy for the compromised SB led to a significant reduction in the primary composite MACE endpoint at one year, compared to a non-compliant balloon (7.2% vs. 12.5%; HR: 0.56)[23].

Practice Implications: DCB treatment of a compromised SB is superior to POBA and is an effective strategy to preserve SB patency while avoiding the complexities and risks of a two-stent approach. It has become a preferred technique for managing the SB in a provisional stenting algorithm.

5. Acute Coronary Syndromes: A Niche Role in STEMI

Clinical Challenge: The highly thrombotic and inflammatory environment of ST-elevation myocardial infarction (STEMI) presents unique challenges for PCI. The goal is to rapidly restore flow while promoting optimal long-term vascular healing, which can be complicated by stent implantation in a thrombus-laden vessel.

Pivotal Evidence: The **REVELATION** trial explored a DCB-only strategy in selected STEMI patients. The study found that DCB angioplasty was non-inferior to DES, based on the physiological primary endpoint of fractional flow reserve (FFR) at 9 months[24]. However, this promising result must be tempered by the high rate of bailout stenting (18%) in the DCB arm, which was primarily driven by flow-limiting dissections.

Practice Implications: The use of DCBs in STEMI remains a niche application, suitable only for a highly selected group of patients with favorable anatomy (e.g., non-severely calcified lesions), low thrombus burden (often after thrombus aspiration), and an excellent angiographic result after pre-dilatation. It is not a mainstream strategy but can be considered a viable, non-stent option in ideal circumstances.

6. Special Populations: The High-Bleeding-Risk Patient

Clinical Challenge: In patients at high bleeding risk (HBR), the primary goal is to minimize the duration of DAPT to prevent major or life-threatening hemorrhagic complications. While short-DAPT regimens with modern DES are feasible, a "leave-nothing-behind" strategy is theoretically even safer.

Pivotal Evidence: The **DEBUT** trial randomized HBR patients with de-novo coronary lesions to either a PCB or a BMS, with all patients receiving only 1 month of DAPT. The results were striking: the PCB group had a significantly lower rate of MACE at 9 months, compared to the BMS group (1% vs. 14%), with no increase in acute vessel closure[25].

Practice Implications: For HBR patients, DCB angioplasty offers a powerful combination of anti-restenotic efficacy comparable to a DES and the flexibility for a very short DAPT regimen, a benefit not offered by BMS. This makes DCB a compelling first-line option in this challenging patient population.

Procedural Best Practices for DCB-Only Angioplasty: The Key to Success

The clinical success of DCB angioplasty is not merely a function of selecting the right patient or lesion; it is critically dependent on meticulous procedural technique. Unlike DES, which can provide mechanical scaffolding to correct a suboptimal angioplasty result, a DCB-only strategy offers no such "forgiveness." The final outcome is almost entirely determined by the quality of the vessel preparation before the DCB is deployed. This reality necessitates a cultural shift in interventional practice, moving away from a reliance on the implant to fix imperfections and toward a focus on achieving technical perfection from the outset.

The successful adoption of DCBs requires operators to master a higher-level skillset. It is not enough to know when to use a DCB; one must know how to create the ideal vessel environment for it to work. This implies a need for dedicated training, and, in many cases, the routine use of intravascular imaging to confirm an optimal result before proceeding with drug delivery.

A Step-by-Step Approach to a DCB-Only Strategy

(1) Thorough Lesion Preparation: This is the absolute, non-negotiable first step. The goal is to achieve maximal luminal gain and resolve underlying plaque morphology. This requires aggressive pre-dilatation, typically with a non-compliant or scoring balloon that is sized 1:1 to the reference vessel diameter. The inflation should be slow and sustained to ensure full balloon expansion and lesion modification[26].

(2) Defining an Acceptable Post-Preparation Result: While angiographic assessment is the first line of evaluation, reliance on angiography alone may underestimate the severity of dissections or residual burden. To standardize the "leave-nothing-behind" strategy, we recommend adhering to precise intravascular imaging thresholds before drug delivery. An optimal result suitable for DCB-only treatment should meet the following objective criteria:

Angiographic Success: Residual diameter stenosis ≤30% with TIMI 3 flow maintained. Regarding dissection management, there must be no flow-limiting dissection. According to the NHLBI classification, this means an absence of Type C, D, E, or F dissections[27]. Minor, non-flow-limiting dissections (Type A or B) are generally acceptable and may even be associated with late lumen gain due to positive remodeling[28].

Imaging Criteria (If Available): For operators using intravascular imaging, objective thresholds for a "leave-nothing-behind" strategy include a residual plaque burden < 50% on IVUS and the absence of intramural hematoma or a major intimal flap (dissection arc < 60° and length < 2 mm) on OCT, and a post-dilatation Minimal Lumen Area (MLA) meeting optimal stent expansion criteria (IVUS > 5.5 mm² or OCT > 4.5 mm²)[29].

Physiological Goal (Optional but Recommended): In stable patients, measuring the post-preparation FFR can provide additional confidence. A value > 0.80 suggests that the luminal gain is hemodynamically sufficient and that a stent is likely unnecessary[30,31].

(3) DCB Sizing and Deployment: The DCB should be sized 1:1 to the reference vessel diameter to ensure adequate apposition and uniform drug transfer. The balloon should be inflated to its nominal pressure for a single, prolonged period — a minimum of 30 to 60 seconds is recommended — to allow sufficient time for the drug and its carrier to transfer into the vessel wall.

(4) Final Assessment and Bailout Strategy: After the DCB is removed, a final angiogram is performed to assess the result. The operator must remain prepared for bailout stenting. The threshold for placing a stent should be low if there is any evidence of a new flow-limiting dissection or significant elastic recoil resulting in a residual stenosis of > 50%. A stent should always be readily available on the table.

Conflict of interest

The authors declare no conflicts of interest.

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