International Journal of Multiphysics
Volume 18, No. 3, 2024
ISSN: 1750-9548

An Overview on Drug Coated Balloon

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Abstract:

Drug-eluting stents (DES) have revolutionized percutaneous coronary intervention (PCI) by reducing restenosis and target vessel revascularization. However, permanent metallic scaffolds are associated with vascular inflammation, hypersensitivity, and late complications such as neo-atherosclerosis and stent thrombosis. Drug-coated balloons (DCB) represent an attractive alternative by delivering antiproliferative drugs directly to the vessel wall without leaving an implant behind. This strategy provides potential advantages including reduced metal burden, restoration of vasomotor function, and avoidance of long-term polymer-related complications.

Keywords: Drug-coated balloon, coronary artery disease, bifurcation lesion, in-stent restenosis, percutaneous coronary intervention, small vessel disease.

Introduction:

Drug-eluting stent (DES) technologies have significantly reduced the risk of restenosis and stent thrombosis, establishing the safety and efficacy of percutaneous coronary interventions (PCI) for the treatment of obstructive coronary artery diseases (CAD) **(1)**.

An inherent limitation of the metallic stent is the presence of a foreign material within the native coronary artery, which can cause vascular inflammation, hypersensitivity, neo-atherosclerosis and subsequent stent thrombosis **(2)**. It should be emphasized that the late luminal enlargement and restoration of vasomotor function are both compromised by the permanent metallic cage **(3)**.

A drug-coated balloon (DCB) is an attractive alternative to DES in that it delivers antiproliferative drugs (e.g., paclitaxel or sirolimus) directly to the vessel wall via a lipophilic matrix, eliminating the need for a permanent carrier such as a metallic prosthesis and/or a durable polymer. Safety and efficacy of this technology have been studied primarily in patients with in-stent restenosis (ISR) or de novo small vessel lesions, but wider clinical indications are being considered. In this scenario, we need to recognize the importance of lesion assessment and technical issues, as well as the limitations of this technology in order to provide the best clinical practice for patients. Herein, the task force of the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) was convened to describe the expert consensus on DCBs. This document aims to summarize its concept, current clinical evidence, possible indications, technical considerations, and future perspectives **(3)**.

Drug-coated balloon technologies

A balloon catheter, a highly lipophilic drug, and a coating matrix that regulates local drug delivery to the vessel wall comprise the DCB. In contrast to the stent-based technologies, the DCB is able to deliver the drug uniformly to the vessel wall. Paclitaxel is primarily used as an antiproliferative drug, and a specific balloon coating containing a contrast medium as an excipient reduced neointimal hyperplasia in a porcine coronary overstretch model **(3)**.

A rapamycin analogue (i.e., sirolimus) was recently tested in human coronary arteries. These two predominant antiproliferative drugs act differentially with tissue. Paclitaxel absorbs quickly, localizes in

subintimal space, and partitions significantly in adventitia, whereas sirolimus absorbs slowly and spreads throughout entire artery where it dilutes down to subtherapeutic levels **(4)**.

A major drawback of sirolimus and its derivatives is generally the poorer transfer rate compared to paclitaxel **(5)**. Due to reversible binding to the mammalian target of rapamycin receptor (mTOR), this poses a technical challenge in maintaining drug permeation in tissue **(6)**.

Crystalline coating sustains higher and longer drug concentrations in tissue compared to amorphous coating **(7)**. Other novel ideas have been proposed, such as micro-reservoir or nanotechnology for balloon-based local drug administration. Given such significant differences in antiproliferative drugs and their doses, release kinetics, and tissue concentrations, it would be premature to expect a "class effect" among various DCB technologies **(8)**. Nevertheless, the recent randomized AGENT trial demonstrated comparable clinical safety and efficacy within 6 months between the two DCBs with different paclitaxel doses and excipients **(9)**.

Clinical Indications for DCB use:

Treatment of coronary in-stent restenosis (ISR):

ISR has been considered as one of the "best" target for the DCB because it can avoid multiple layers of metallic stents. Clinical safety and efficacy of the DCB for ISR lesions have been thoroughly studied, and current Japanese and Western guidelines offer consistent recommendations (class I, level of evidence A) **(10, 11)**.

It is important to understand the substantial difference of ISR between bare-metal stents (BMS) and DES. The BMS-ISR is generally characterized by excessive neointimal proliferation (i.e., hyperplasia), whereas the DES-ISR is more complicated because it can be perceived as a result of antiproliferative drugs' insufficient effect or failure to function (i.e., late neo-atherosclerosis). Indeed, the DES-ISR was only independent predictor of target lesion revascularization (TLR) in Japanese pre- and post-marketing study for the SeQuent Please® DCB **(12)**. Intracoronary imaging techniques, preferably OCT, would be recommended to identify the underlying causes of ISR (class IIa, level of evidence C) **(11)**.

Small vessels

Small vessel disease is usually defined as < 3.0 mm in reference vessel diameter. Stent or scaffold implantation in such a small vessel may be disadvantageous when compared to the implantation in a large vessel because late lumen loss occupies a greater percentage of the respective vessel diameter, resulting in higher rates of ISR and adverse events **(13)**.

In the randomized BASKET-SMALL 2 trial, a paclitaxel-iopromide-coated DCB was found to be non-inferior to the second-generation DES in terms of a composite of cardiac death, non-fatal myocardial infarction, or target vessel revascularization (TVR) at 12 months **(14)**.

Furthermore, the RESTORE SVD China trial found that the DCB was non-inferior to the Resolute Integrity® DES in terms of percentage diameter stenosis at 9 months and had comparable target lesion failure (TLF) rates at 1 year. These findings may support the use of DCB as an alternative to DES in small vessel diseases, but only when lesion preparation is sufficiently accomplished **(15)**.

Possible de novo large vessel lesions

Despite growing and encouraging scientific evidences of DCB in de novo lesions with large reference vessel diameters (≥ 3.0 mm), randomized comparison with DES for this indication remains limited. In the DEBUT trial, individuals with a high bleeding risk (HBR) were compared between the DCB and the BMS. Within 9 months, there was no acute vessel closure and only 1% of major adverse cardiac events in the DCB group, demonstrating its superiority to the BMS **(16)**.

In the PEPCAD NSTEMI trial, non-inferiority of a paclitaxel-iopromide-coated DCB regarding TLF at 9 months was evident compared to the metallic stents (i.e., BMS or DES). However, in the DCB group, 85% of patients received only DCB, while 15% received additional stent implantation. This result highlights a

possibility of "bail-out" stenting being unavoidable even in a certain amount of cases who would prefer DCB-only strategy **(17)**.

Briefly, the use of DCB for de novo large vessel lesions will be possible subject to registration in a real-world all-comers ALLIANCE registry. The statement also offered the following conditions; (1) patients having HBR or those for whom long-term antiplatelet therapy is considered undesirable; or (2) lesions for which clinical effectiveness of DES is not well established (e.g., ostial circumflex or jailed side branch). Clinical implications of DCB for specific patient or lesion subset are discussed in the following sub-headings **(3)**.

1. Bifurcation lesions

Bifurcation is still a challenging lesion subset and it is responsible for approximately 20% of cases undergoing PCI **(18)**. The most widely accepted approach to date is single cross-over stenting in the main vessel, with side branch balloon dilatation or provisional stenting as needed **(10)**. Following ostial side branch balloon dilatation, subsequent DCB significantly reduced angiographic late lumen loss (0.13 mm vs. 0.51 mm) and binary restenosis at 9 months (6% vs. 26%) compared to no additional treatment **(19)**.

A similar finding was confirmed in a meta-analysis of 349 cases comparing conventional balloon and DCB for side branch outcomes **(20)**. Based on these results, DCB would be a preferable approach to the side branch when the DES was deployed in the main vessel. The DCB-only approach to bifurcation is appealing because it avoids carina shift, but it is more technically challenging. In this scenario, sequential DCB dilatation following optimal lesion preparation is recommended because kissing DCB dilatation may develop coronary dissection or perforation. DCB clearly provides an advantage by reducing the number of stent layers in patients with bifurcation restenosis, particularly when the index PCI used two-stent techniques **(21)**.

The recent European Bifurcation Club (EBC) consensus document, however, does not support systematic DCB use in de novo bifurcation lesions due to a lack of conclusive evidence **(22)**.

Recently, the DCB in conjunction with the directional coronary atherectomy (DCA) demonstrated excellent clinical outcomes for bifurcation lesions (81% at left main bifurcation) **(23)**. The percentage plaque area after DCA was 56.3% in this Japanese multicenter registry, and the primary endpoint (TVF at 12 months) and binary restenosis were observed in 10.9% and 2.3%, respectively. This could imply that DCA followed by DCB could be an attractive option for preventing carina shift in large vessel bifurcation lesions (Fig. 1) **(3)**.

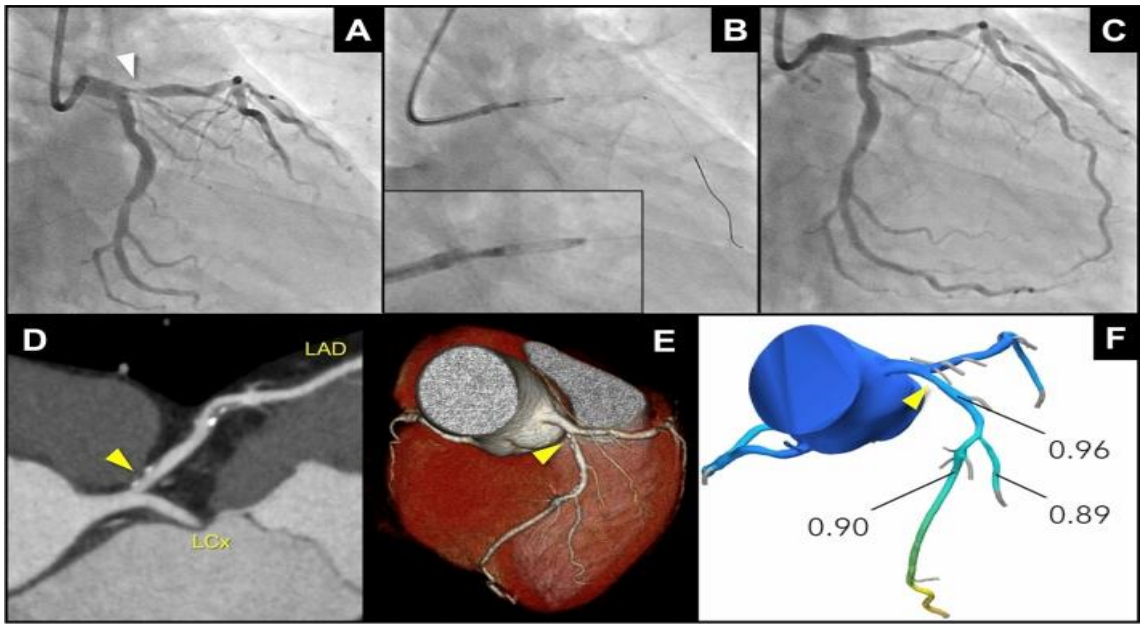

Figure (1): A case treated with DCB-only strategy using directional coronary atherectomy for ostial left anterior descending lesion. A 65-year-old man presenting with chronic coronary syndrome. **a** Pre-procedural angiogram

revealed a focal lesion at ostial left anterior descending (white arrow head). **b** Plaque was removed by the directional coronary atherectomy (Atherocut®, NIPRO Corp, Tokyo, Japan) followed by a paclitaxel-coated balloon (SeQuent Please Neo®, B. Braun, Melsungen, Germany). **c** Post-procedural angiographic result was fine. The patient was asymptomatic and scheduled follow-up was planned by the coronary computed tomography (CT) angiography at 12 months after the procedure. The maximum intensity projection (**d**), volume rendering (**e**), and CT-derived fractional flow reserve (FFRCT) (**f**) showed excellent results without any evidence of restenosis (yellow arrow heads). This case highlights an advantage of the "stentless" or "leave nothing behind" strategy in non-invasive anatomical and functional assessment by CT scan at the clinical follow-up **(3)**.

2. Diffuse long lesions

Diffuse long lesions may frequently require stenting with long (≥ 60 mm) overlapping DESs which is known as a predictor of adverse events such as restenosis or stent thrombosis **(24)**.

Given the natural step-down of vessel diameter and recent data supporting the safety and efficacy of DCB-only strategy in small vessel lesions, a hybrid approach combining DES (proximal) and DCB (distal) has been proposed for treating de novo diffuse long lesions. For example, the "full metal jacket" with metallic DESs would be undesirable specifically for young patients having diffuse long lesions because it would preclude the possibility of future surgical options. A previous study demonstrated that a DCB-only strategy and a hybrid approach had comparable rates of major adverse cardiovascular events (20.8% vs. 22.7%; $p = 0.74$) and TLR (9.6% vs. 9.3%, $p = 0.84$), respectively **(25)**.

Another recent study also demonstrated that in diffuse lesions (mean lesion length: 44 mm), patients treated with DCB alone or in combination with DES had comparable 3-year clinical outcomes **(26)**. The HYPER pilot study will evaluate the 12-month clinical outcomes of a hybrid (DES/DCB) approach in 100 patients with diffuse CADs **(27)**.

3. Calcified lesions

Calcified lesion remains as an "Achilles' heel" of PCI even in the DES era. The following factors contribute to its poor response to DES technologies; (1) stent under expansion; (2) vessel wall overstretch resulting in medial injury or disruption; (3) damaged polymer coatings; (4) stent fractures; and (5) delayed arterial healing responses. Although the efficacy of the DCB in such lesions has not yet been proven, the DCB-only strategy may be considered as a reasonable therapeutic option if the metallic DES is not expected to be expandable or effective. Calcified nodules or nodular calcifications have been identified as one of the most malignant phenotype of lesion morphologies associated with poor clinical outcomes **(28)**.

Sometimes eruptive calcified tissue is protruding into the lumen beyond the stent struts even after DES implantation. Such a type of lesion is considered to be an extremely high risk for restenosis and is typically resistant to currently available therapeutic approaches. Although the DCB-only strategy for calcified nodules is still being researched, by eliminating the implantation of metallic prostheses, it may leave additional therapeutic choices **(3)**.

4. Acute coronary syndrome (ACS)

Only limited data regarding the DCB are available in patients presenting with ACS. The REVELATION trial found that the DCB-only strategy was not inferior to DES in terms of fractional flow reserve at 9 months in 120 patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI **(29)**.

Interestingly, only one case with abrupt closure and one case requiring TLR were observed in the DCB group. In 210 cases of non-ST-segment elevation myocardial infarction (NSTEMI), the recent PEPCAD NSTEMI trial found no difference in TLF between paclitaxel DCB and metallic stents (i.e., BMS or DES). These findings might support the use of DCB in ACS patients, although a caution is necessary given that these were very carefully selected populations **(17)**.

In contrast to chronic coronary syndrome (CCS), ACS is caused by the presence of thrombus. The possibility that thrombus could obstruct the distribution of antiproliferative drugs to the vessel wall and underlying tissue is a potential concern. Another concern is acute abrupt vessel closure which occurred in 8.3% of cases when plain old balloon angioplasty (POBA) was used as the default strategy **(3)**.

Dissections, elastic recoil, vasospasm, and thrombus formation are common causes, and these complications must be avoided in order for DCB procedures to be successful. On the other hand, metallic DES was reported to be more frequently associated with incomplete stent apposition and uncovered struts in STEMI than in CCS **(30)**. Thus, the concept of DCB-only strategy in thrombotic lesions—eliminating metallic prosthesis without compromising the risk of acute abrupt vessel closure and TLR—is potentially appealing, but proof-of-concept studies are obviously required **(3)**.

5. High-bleeding risk (HBR)

High-bleeding risk (HBR) has recently gained a lot of clinical and academic interest in interventional cardiology, because as many as 64% of Japanese patients undergoing PCI met the Japanese HBR (J-HBR) criteria **(31)**.

In theory, the aforementioned "stentless" or "leave nothing behind" approach with the DCB may offer an advantage in reducing bleeding risk through shorter duration of DAPT over metallic stent implantation. The current Japanese guideline recommend 1–3 months DAPT for CCS patients treated with DCB-only strategy (class IIa, level of evidence B) **(32)**.

The possibility of a shorter DAPT cannot be ruled out given the absence of foreign materials in the coronary artery and the extremely low incidence of acute thrombotic occlusion reported in the previous literatures, even though recent DES trials consistently showed that a very short (1 month) DAPT strategy significantly reduced the risk of major bleeding without compromising the risk of thrombotic events **(33)**.

The current instructions for use (IFU) proposed at least 3-month DAPT after the treatment with DCB, whereas the safety of 1-month of DAPT has been shown for CCS patients with small vessel diseases. Appropriate antiplatelet therapy after DCB is an issue to be explored in the future **(16)**.

Technical considerations

Lesion preparation

The proposed procedural strategy for the DCB is shown in the Fig. (2). Optimal lesion preparation is of paramount importance to maximize the effect of DCB. Adequate angiographic findings defined as thrombolysis in myocardial infarction (TIMI) grade 3 flow, residual stenosis $\leq 30\%$, and absence of major dissections (i.e., NHLBI classification type C–E) after pre-dilatation were associated with a lower risk of repeat TLR in ISR lesions **(34)**. The HOST-ISR-DEB cohort study found that fully optimized procedures with a balloon-to-stent ratio > 0.91, total inflation time > 60 s, and residual stenosis $< 20\%$ has a significantly lower incidence of TLF within 2 years than partially or non-optimized procedures **(35)**.

Pre-dilatation with a scoring balloon prior to DCB significantly reduced the incidence of binary angiographic restenosis in a previous randomized trial in patients with DES restenosis (18.5% vs. 32.0%) **(36)**.

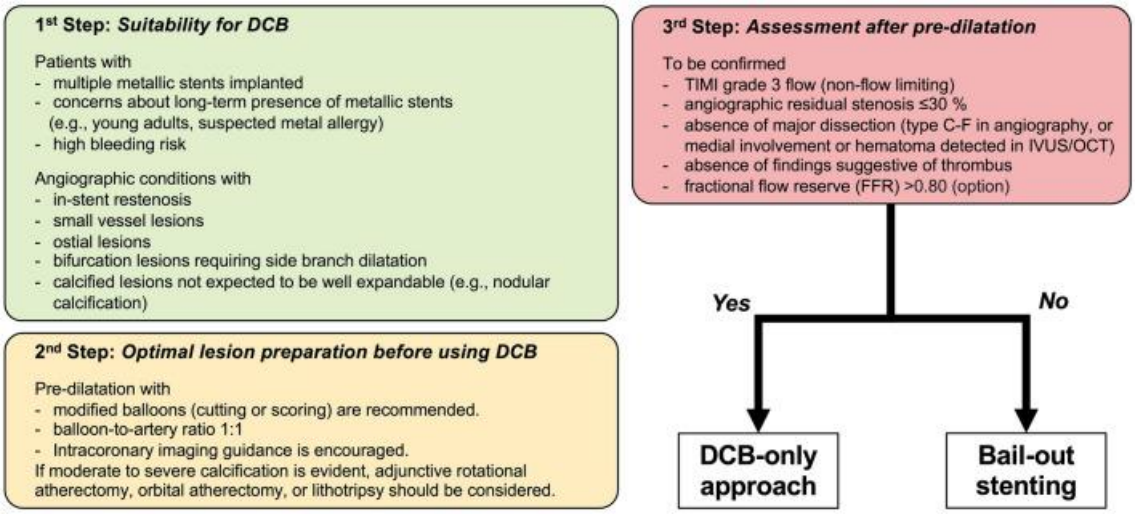

Figure (2): A proposed step-by-step approach for the DCB-only strategy. For possible indication of large vessel (≥ 3.0 mm) lesions **(3)**.

More aggressive pre-dilatation or debulking devices, such as rotational atherectomy or excimer laser, should be considered for calcified lesions. Notably, orbital atherectomy and intracoronary lithotripsy are not recommended for stent-related lesions in the IFU reviewed by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). When major dissections are suspected in angiogram, intravascular ultrasound (IVUS) rather than OCT may better provide the severity of dissections in a safer manner **(37)**. A non-flow limiting intimal dissection can be left untreated, whereas medial dissection, intramural hematoma, or extra-medial injury should be fixed with "bail-out" stenting **(3)**.

Functional assessment after the lesion preparation may be an option to aid our decision-making for the DCB-only strategy. Aside from angiographic residual stenosis, fractional flow reserve (FFR) of > 0.90 or coronary flow reserve (CFR) of > 2.5 has been identified as a cutoff predicting better clinical outcomes following conventional balloon angioplasty. The advent of the DCB lowered the threshold for FFR to 0.85 or even 0.75. Although the limited data must be acknowledged in this regard, the expert consensus would propose FFR of > 0.80 after lesion preparation as a reasonable cutoff to proceed to the DCB-only strategy **(38)**.

Despite the fact that the DES is the most common and established therapeutic strategy in modern PCI, the use of the DCB is steadily increasing in various clinical settings. The DCB technology, like the BRS, is expected to be a therapeutic approach that facilitates the "leave nothing behind" strategy. However, clinical indications of the DCB other than classical ISR or small vessel disease need be further evaluated. Furthermore, additional scientific evidences for the DCB-only strategy should be discussed alongside the "gold standard" DES for the treatment of de novo CADs **(3)**.

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