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REVIEW

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How to perform a successful drug-coated balloon angioplasty? Tips and tricks

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Abstract

Drug-coated balloons (DCB) offer an excellent alternative to stents as the antiproliferative drugs are delivered via balloons and hence there is no permanent implant of metal or polymer. This rationale applies perfectly in in-stent restenosis (ISR) as we want to avoid another layer of metal in a previously failed stent. However, their use has also been extended to de novo lesions especially in patients and lesion subsets where stents are not ideal. There is an increased desire toward expanding this further and studies are now being done which are testing DCB in large-caliber vessels. As the use of DCB is escalating, we felt the importance of writing this article whereby we aim to provide important tips and tricks when using DCB especially for the operators who are in the early phase or have the desire of embarking this technology. From our experience, the DCB-angioplasty substantially differs on several aspects from DES-angioplasty. We have provided several case bases examples including algorithm when using DCB in ISR and de novo lesions.

KEYWORDS

BALA—balloon angioplasty, BALD—balloon, drug coated/eluting, SRES—stent restenosis

1 | INTRODUCTION

Drug-coated balloons (DCB) are designed to deliver antiproliferative drugs to the vessel wall without the need for a permanent metal platform or polymer.[1] They were initially designed for the treatment of in-stent restenosis (ISR) with an aim to avoid another layer of metal in a previously failed stent.[2,3] However, their use has also been extended to de novo lesions, especially in patients and lesion subsets where stents are not ideal such as small vessels, diffuse disease, side-branches, and patients with high-bleeding risk (HBR) who may not be able to take dual antiplatelet therapy for an extended period.[4–7] The Use of DCBs in coronary intervention is escalating due to a consistent trickle of positive data. Current data supports the use of DCBs in small vessels as they are found to be non-inferior to stents and some studies even show superiority.[5,7–9] There are ongoing trials that are even comparing DCB with DES in larger vessels.[10] The idea of leaving nothing behind is exciting as the metal tends to permanently cage the vessel impairing vasomotion and prone to restenosis, which are often difficult to treat with high rates of recurrence. Bioresorbable scaffolds (BRS) were designed with the idea of leaving nothing behind, but the resorption took more than 3 years and more importantly, the long-term outcomes were disappointing with an increased risk of scaffold thrombosis.[11,12] DCB offer such an option of leaving nothing behind. The future for DCBs is exciting as we now enter a new era of stentless angioplasty. While

Abbreviations: BRS, bioresorbable scaffold; DCB, drug coated balloons; DES, drug eluting stent; ISR, in-stent restenosis; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LCx, left circumflex artery; PCB, paclitaxel coated balloons; PDA, posterior descending artery; RCA, right coronary artery; SCB, sirolimus-coated balloons.

Europe and Asia have been the early adopters of DCBs and provided most of the data in the literature, cardiologists in the United States have not been given such an opportunity as this technology is not yet available for coronary intervention. However, the FDA has now approved them for clinical trials in the United States and we can expect more data from the other side of the Atlantic. Since the use of DCB is escalating globally, in this article we aim to provide important tips and tricks when using them in coronary intervention, following the concept that DCB-angioplasty substantially differs in several aspects from DES-angioplasty.

2 | LESIONS AND PATIENT SELECTION FOR DCBs

It is important to select appropriate cases for DCB based on the current evidence and guidelines in literature. We recommend considering DCB in following lesion and patient subsets and we have provided case examples for each section.

2.1 | ISR

ISR is one of the classic indications for DCBs as the rationale of avoiding another layer of metal is more pragmatic. There is a plethora of evidence in the literature that supports the use of DCBs over plain old baloon angioplasty (POBA) or DES in restenotic lesions. In fact, DCB is endorsed by the ESC guidelines, which gives class IA recommendation for the use of DCB in ISR.[13]

3 | CASE 1

A 72-year-old man presented with crescendo angina in the background of previous PCI to codominant left circumflex system with a DES (3.5 × 30 mm) 2 years previously. The index procedure was done with no intracoronary imaging. The angiogram showed focal ISR in the mid-segment of the stent (Figure 1A, Supporting Information: Video S1). Intravascular imaging revealed grossly undersized and under-expanded stent with some intimal hyperplasia (Figure 1B,C, Supporting Information: Video S2). Interestingly, vessel distal to stent had a diameter of 4.5 mm and proximal to the stent was 5.0 mm (Figure 2). The IVUS findings gave us the confidence to expand the stent with 4.5 and 5.0 mm noncomplaint balloons (Figure 3A). Repeat imaging demonstrated well expanded stent with no strut fracture (Figure 3B, Supporting Information: Video S3). Subsequently, we used a long DCB to achieve excellent results (Figure 3C,D, Supporting Information: Video S4). This case demonstrates the value of intravascular imaging in ISR.

3.1 | De novo lesions

The use of DCBs in de novo lesions is escalating especially in small vessels and this is due to the emergence of evidence in the last few years that have shown that DCBs are non-inferior to current-generation DES. The Basket Small 2 randomized trial showed that DCBs are clinically non-inferior to DES in small vessels (<3.0 mm) at 12 months and at 3 years.[9] The PICCOLETO II trial demonstrated that angiographic late lumen loss was significantly superior in the DCB group as compared to DES and this was translated into better clinical endpoints at 3 years where freedom from MACE was significantly

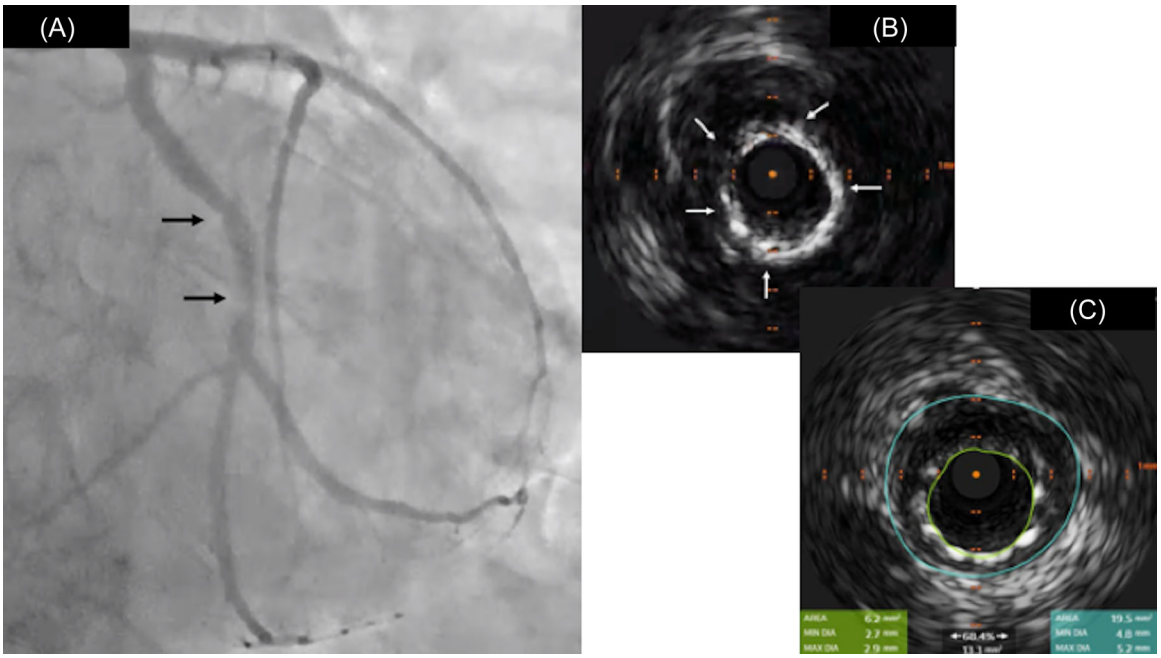

FIGURE 1 (A) Coronary angiogram demonstrating in-stent restenosis in the body of left circumflex artery stent. (B, C) Intravascular ultrasound demonstrating under-expanded and under-sized stent. [Color figure can be viewed at wileyonlinelibrary.com]

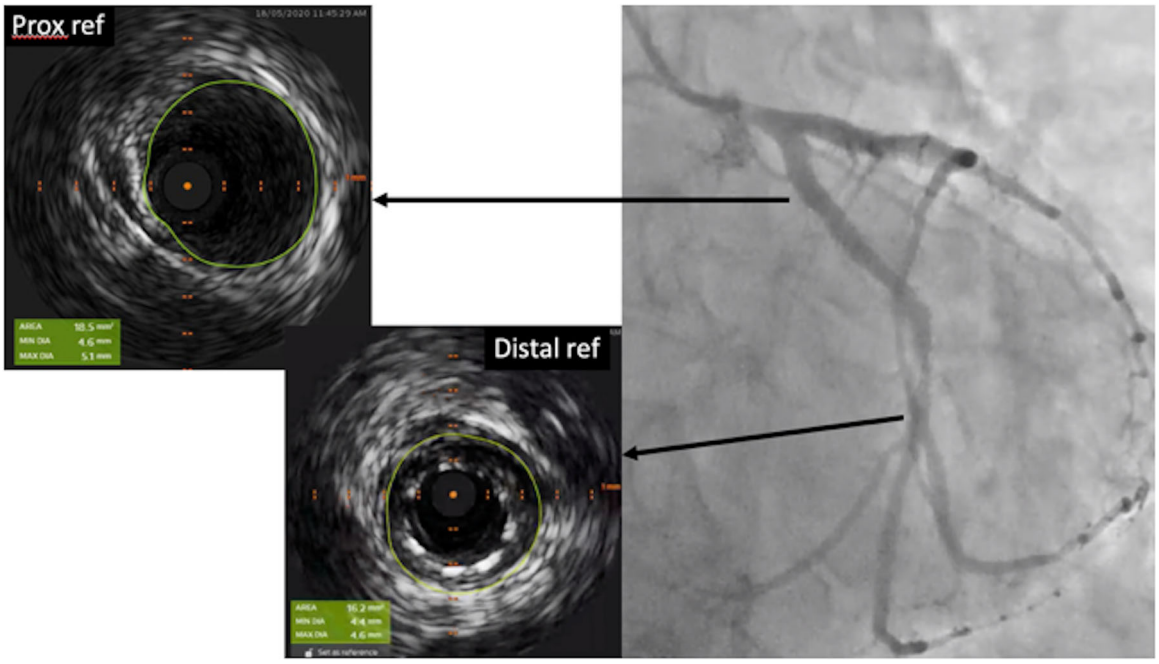

FIGURE 2 Intravascular ultrasound demonstrating a distal reference diameter of 4.5 mm and a proximal reference area of 5.0 mm. [Color figure can be viewed at wileyonlinelibrary.com]

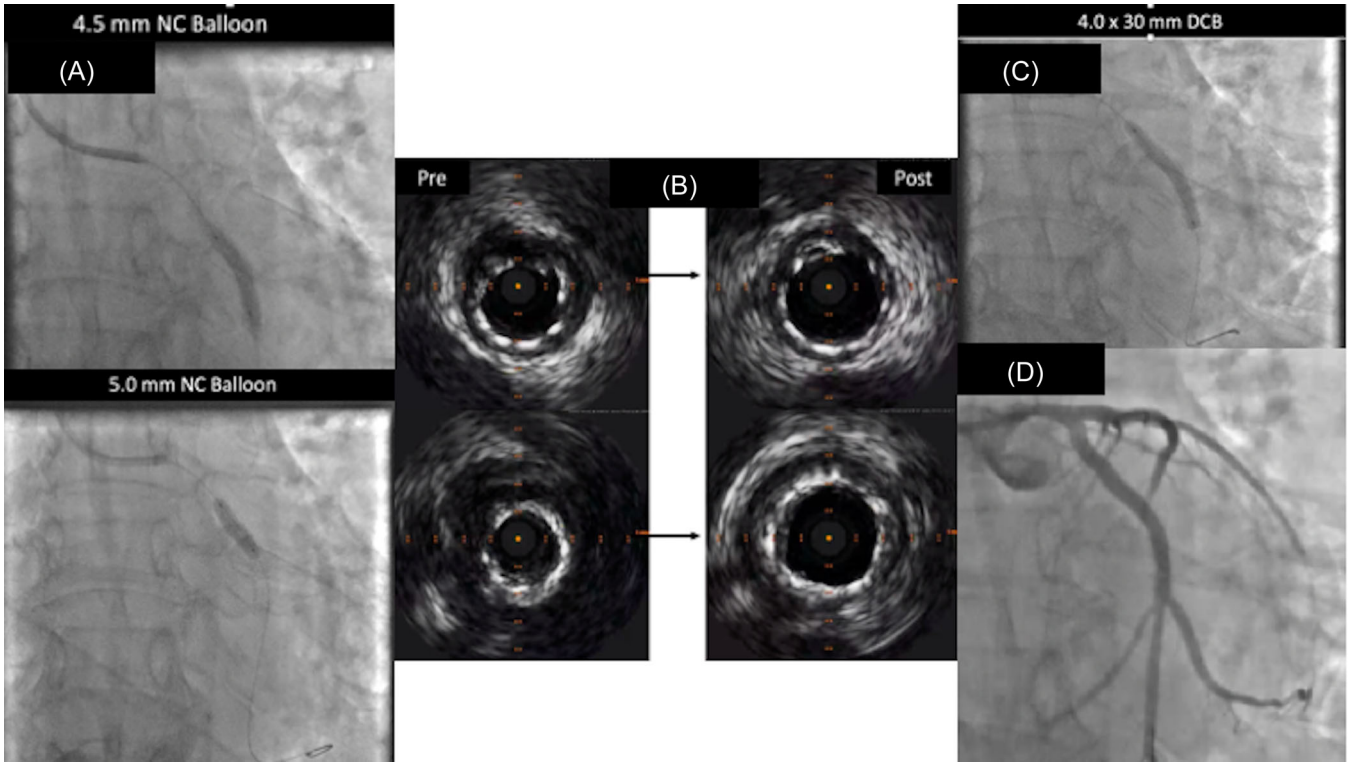

FIGURE 3 (A) Balloon dilatation with 4.5 and 5.0 mm noncompliant balloons. (B) Intravascular ultrasound demonstrating well-expanded stent. (C, D) Treatment with long drug-coated balloons to achieve good results. [Color figure can be viewed at wileyonlinelibrary.com]

better in the DCB group over DES.[14] As of now, there is no formal recommendation from the ESC on the use of DCBs in de novo lesions, but these trials have been published since the last guidelines were released in 2018 and future guidelines may recommend DCBs in de novo lesions. There is no strong data to support the use of DCB in larger vessels (>3.0 mm) and hence we do not recommend the use of DCB in such vessels unless there are compelling indications such as patients with HBR group or those awaiting urgent surgery.

4 | CASE 2

A 48-year-old lady with a background of diabetes mellitus and crescendo angina was found to have a subtotal occluded LAD with diffuse disease and significant stenosis in the proximal segment of a large first-diagonal (Figure 4, Supporting Information: Video S5). The left circumflex artery also had a long segment of significant disease (Figure 4, Supporting Information: Video S6). She was turned down for surgical revascularization at the heart-team meeting due to the diffuse nature of the LAD disease and hence was considered for angioplasty. With conventional angioplasty, she would have received a long layer of small DES resulting in a full-metal jacket. Given her young age and diabetes mellitus, we felt that she would be a high risk for future restenosis and hence we opted for a hybrid strategy. Following aggressive pre-dilatation with non-compliant and scoring balloons, we had good POBA results except in the proximal segment of the diagonal and LAD which had persistent recoil (Figure 5, Supporting Information: Videos S7 and S8). The proximal segment of LAD and diagonal received 1 DES respectively. The rest of the LAD and LCx were treated with long DCBs (Figure 6) to achieve good

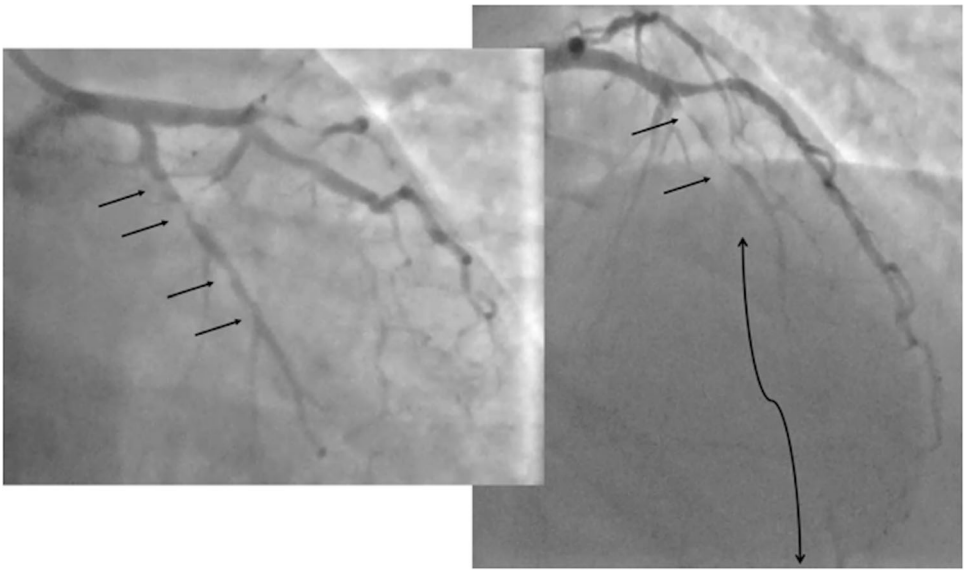

FIGURE 4 Coronary angiogram demonstrating sub-totally occluded left anterior descending artery with diffuse disease involving a large first diagonal which had a significant proximal disease. Diffuse disease in the left circumflex artery (shown by the arrows).

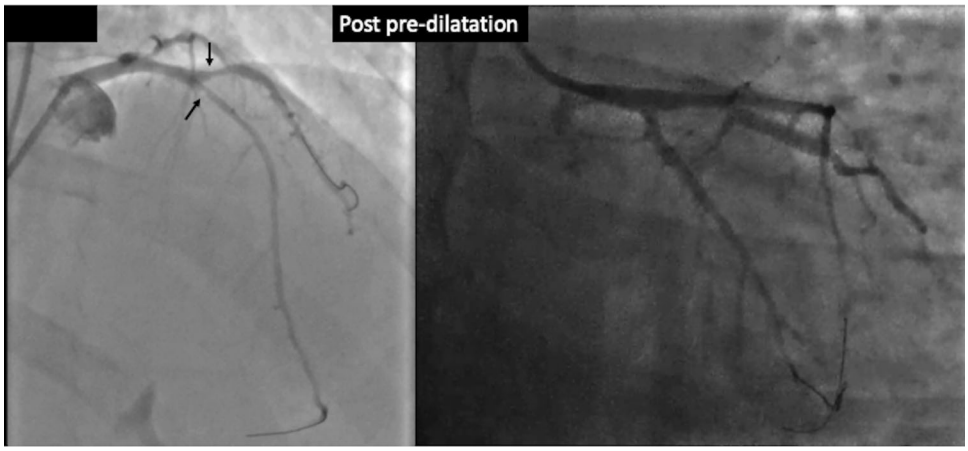

FIGURE 5 Postpredilatation angiogram showing good POBA result except focal segment in left anterior descending artery and diagonal (shown by the arrows).

FIGURE 6 Left anterior descending artery (LAD) and diagonal treated with a combination of drug-eluting stent (proximally) and drug-coated balloons (DCBs) (mid-distal segment of LAD). The entire left circumflex artery was treated with DCB only.

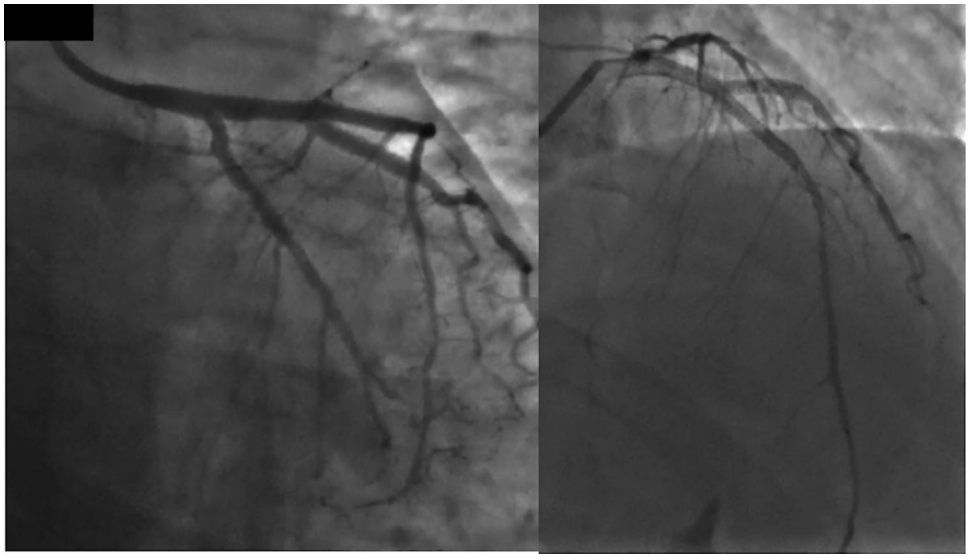

FIGURE 7 Final angiographic result and follow-up angiogram seen in PA-caudal and PA-cranial views.

results (Figure 7, Supporting Information: Videos S9 and S10). At 6-month follow-up she was asymptomatic and the angiogram demonstrated positive remodeling in the segments treated with DCBs (Figure 8, Supporting Information: Videos S11 and S12). This case demonstrates that diffuse disease especially in small vessels (<3.0 mm) can be treated with DCB and a long-layer of stenting can be avoided, which has long-term consequences, especially in the background of diabetes mellitus.

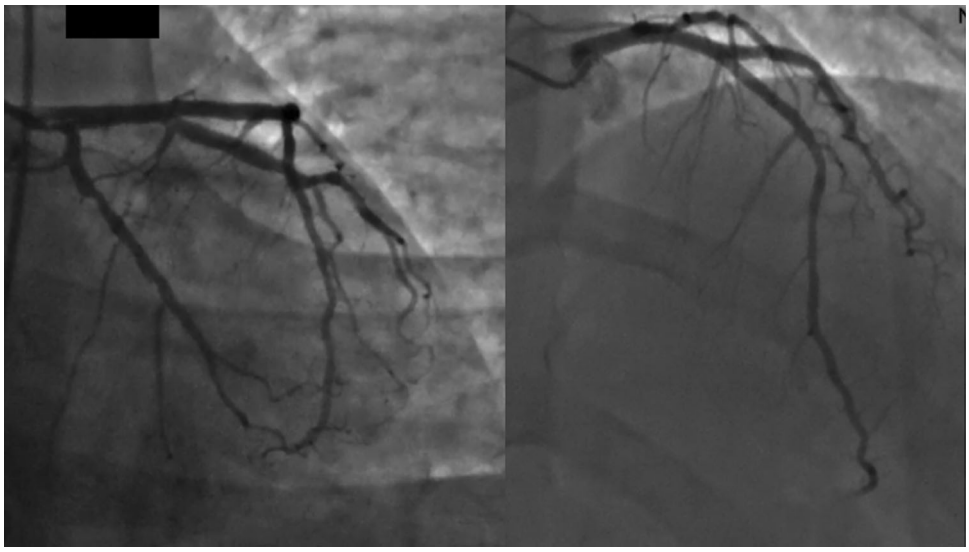

FIGURE 8 Follow-up angiogram showing excellent results with positive remodeling in the drug-coated balloons treated segments.

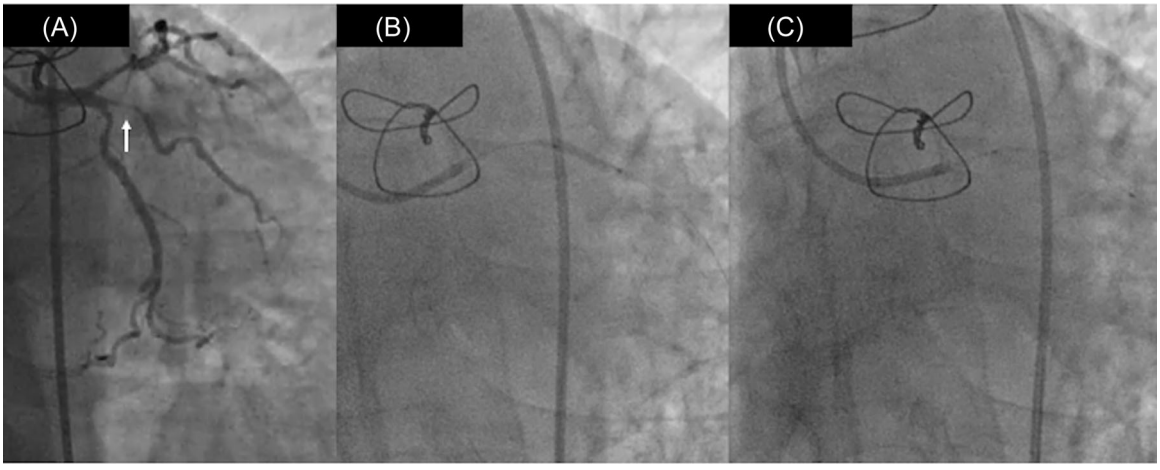

FIGURE 9 (A–C) Tight stenosis in the ostium and proximal segment of first obtuse marginal treated with POBA and drug-coated balloons.

4.1 | Bifurcation lesions

Bifurcation lesions are considered one of the complex subsets in coronary intervention. The current strategy in most bifurcation (including true bifurcation) is provisional stenting and to consider placing stents in the side branch if there is flow or lumen compromise. One rationale is to consider DCB in the side branch with a stent in the main branch to minimize metal-work and hence reduce the risk of ISR and stent thrombosis. There is some evidence in the literature that support this idea.[15,16] The DCB-only approach is also an option in 0,0,1 Medina classification where the main-branch is free of any significant disease, and placing a stent in the main-branch would not be the best option. Landing the stent accurately at the ostium can be tricky as the ostium may be missed or the stent may over-shoot into the main branch, especially in non-90-degree bifurcation. We present a case example of such bifurcation lesions treated with DCB.

5 | CASE 3

A 64-year-old man with crescendo angina and previous CABG (mammary graft to LAD, vein grafts to obtuse marginal and RCA) had both vein grafts occluded with a tight stenosis in the ostium of obtuse marginal (OM) (Figure 9A, Supporting Information: Video S13). There were retrograde collaterals to the occluded RCA from the left system (circumflex artery). The plan was to treat OM and do a staged PCI to RCA occlusion. Since the lesion was right at the ostium, placing a stent accurately would have been difficult and if the stent were to protrude into the main branch, it could have affected retrograde channels to occluded RCA. So, we treated the lesion with a DCB (2.5 × 30 mm) after successful pre-dilatation to achieve good results (Figure 9B,C, 10A, Supporting Information: Video S14). The patient returned for staged PCI to RCA in 3 months and the check angiogram showed positive remodeling of the treated segment with DCB (Figure 10B, Supporting Information: Video S15).

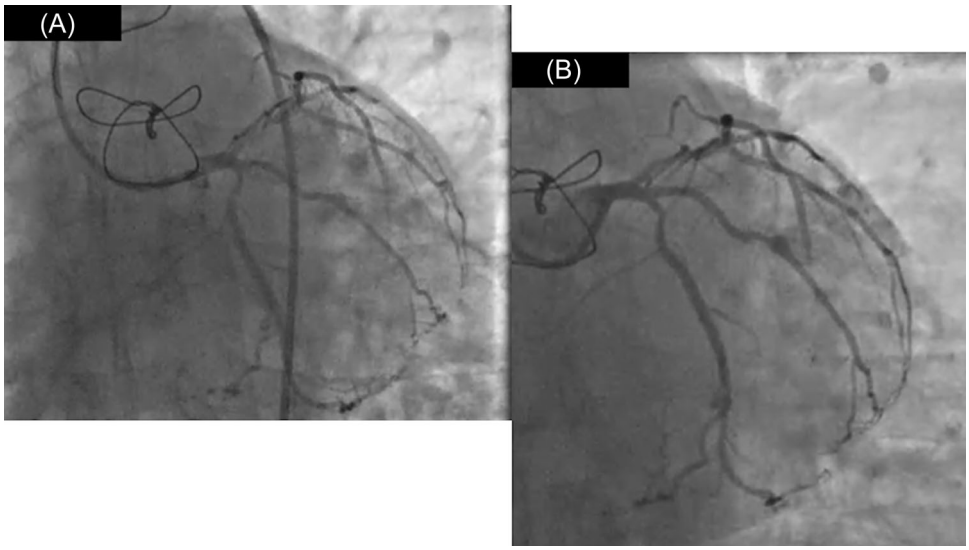

FIGURE 10 (A, B) Postdrug-coated balloons and 6-month follow-up angiogram results showing positive remodeling.

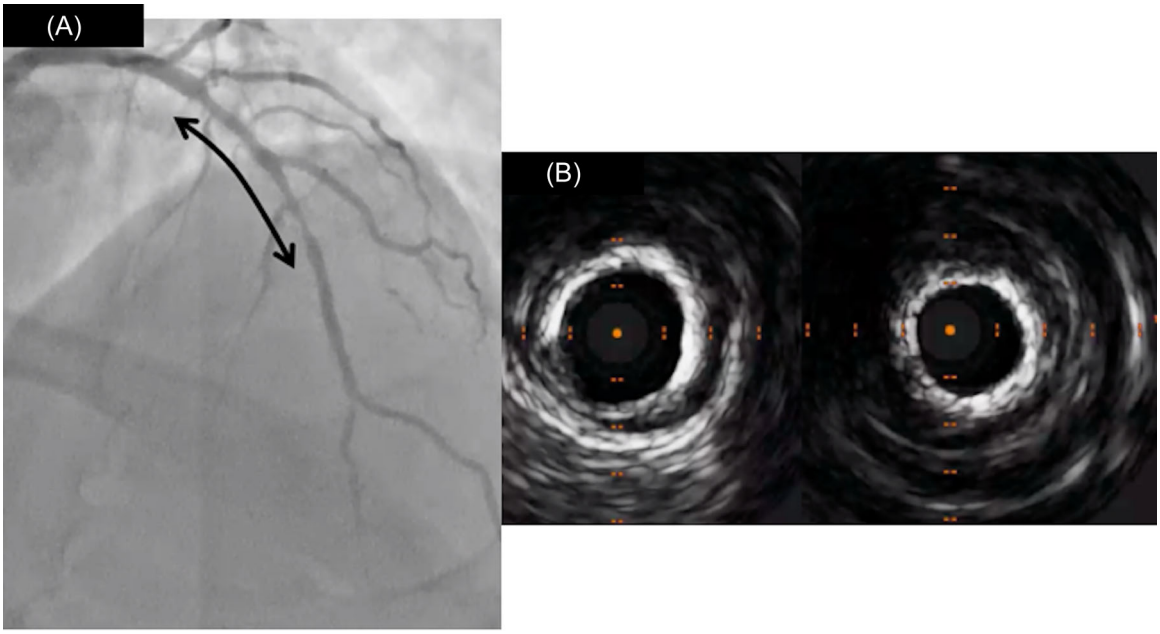

FIGURE 11 (A, B) Tight calcified stenosis in the midsegment of left anterior descending artery with intravascular ultrasound confirming a napkin ring of calcium. [Color figure can be viewed at wileyonlinelibrary.com]

5.1 | HBR patients

The HBR patients are challenging as most of them have risk factors (such as old age, low hemoglobin, renal impairment, and low body weight) that make them prone to restenosis and stent thrombosis, but also increase the bleeding risk, especially in patients with dual antiplatelet therapy on board. So, it is not unreasonable to consider DCB in such patients or in those awaiting urgent surgery. In Basket Small 2 study, of the 758 patients randomized, 155 (20%) had HBR; these patients had higher mortality at 3 years (hazard ratio [95% confidence interval], 3.09 [1.78–5.36]; $p < 0.001$). The rates of major bleeding events were overall low but tended to be lower after DCB versus DES (1.6% vs. 3.7%; $p = 0.064$).[17]

6 | CASE 4

We report a case of calcified lesion in an HBR patient who had significant angina in the background previous PCI to LAD with a bare-metal stent inserted in 2004. He was diagnosed with colorectal cancer and was awaiting hemicolectomy. The angiogram showed calcified restenosis in the mid-segment of the left anterior descending artery (LAD) (Figure 11A). The upfront imaging revealed a concentric rim of calcium (Figure 11B), which failed to yield with conventional non-compliant balloons (Figure 12A). We then used a 3.5 mm shockwave balloon to successfully crack the calcium (Figure 12B) which was confirmed on IVUS (Figure 13A). Since he was waiting for urgent cancer surgery, we used 3.5 × 35 mm DCB to achieve good

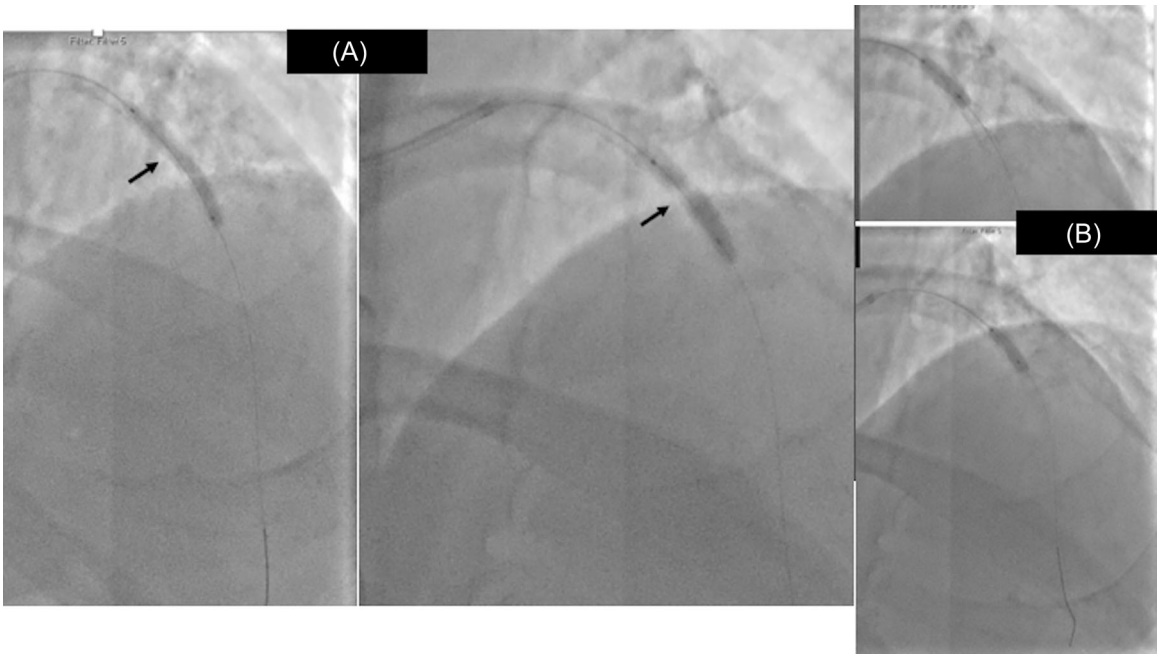

FIGURE 12 (A, B) Conventional noncompliant balloons failed to crack the lesion, but were successful with a 3.5 mm shockwave balloon.

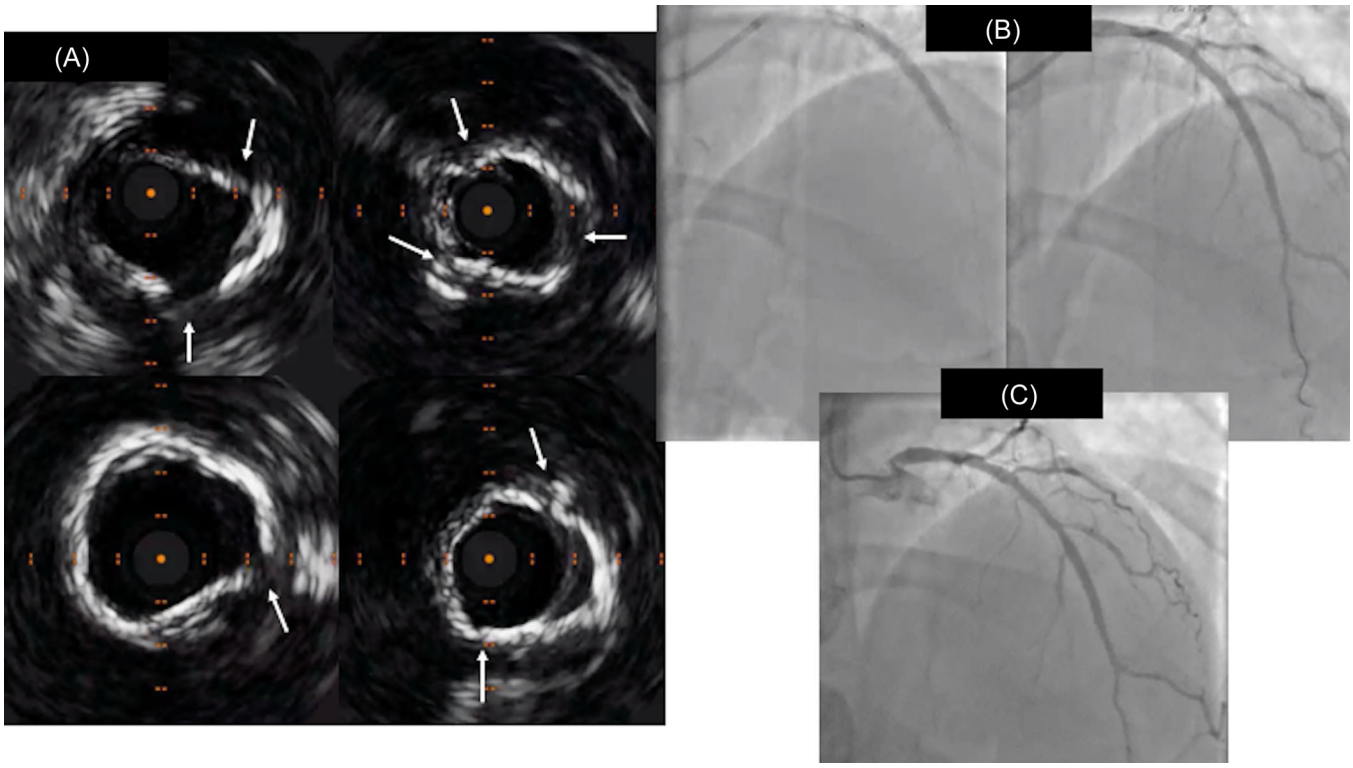

FIGURE 13 (A–C) Intravascular ultrasound showing significant cracks in the calcium post-IVL (A) and lesion treated with drug-coated balloons to achieve good results (B) and continued good results on follow-up angiogram (C). [Color figure can be viewed at wileyonlinelibrary.com]

results (Figure 13B). He only received dual antiplatelet therapy (DAPT) for 2 weeks and in the third week had a successful bowel operation. The good result continued on the check angiogram at 4 months (Figure 13C).

6.1 | Lesion preparation before DCB-angioplasty

Lesion preparation is vital before DCB. Although, suboptimal preparation may be forgiving before stent due to metallic scaffolding, but suboptimal preparation before DCB may not be forgiving. DCB is just a drug delivery device, and their use should be decided only after adequate lesion preparation. We recommend 1:1 ratio between DCB and vessel size.

6.1.1 | Semicompliant and noncompliant balloons

These are the commonly used pre-dilatation balloons before stent placement and hence remain the mainstay for lesion preparation even before the use of DCB. Since most de novo lesions treated with DCB are generally long, we recommend using long pre-dilatation balloons (>20 mm) unless the lesion treated is shorter. Although there is no data on the duration of inflation, from our large experience, prolonged inflation (20–30 s) generally results in less recoil and also lower risk of dissections. In addition, it generates ischemic preconditioning which will be useful when using DCB as the inflation time can be up to 60 seconds and patients generally tolerate it better.

6.1.2 | Scoring balloons, cutting balloons, or additional therapies

Scoring and cutting balloons are used in complex lesions when conventional balloons fail to prepare the lesion. These balloons should be considered in fibrocalcific or ostial lesions when noncompliant balloons do not result in optimal lesion preparation. There is theoretical benefit in considering scoring or cutting balloons routinely before DCB to induce cracks and dissection to aid better drug transfer. There is randomized data to support this strategy in restenotic lesions, but no such data exists for de novo lesions. We performed a multicenter study on the role of predilating tools before DCB use. Our study did not show any benefit with the use of a scoring balloon before DCB in de novo lesions, but this was a retrospective study with several limitations including a selection bias and hence we need randomized data.[18] As of now, we cannot recommend the routine use of scoring balloons or cutting balloons in de novo lesions, but these tools can be considered in some specific settings: ISR, ostial, and calcified lesions. In highly calcific lesions, the operator may consider the use of atherectomy or intravascular lithotripsy before DCB. In fact, drug uptake is impaired by severe calcification, and additional tools aid in cracking the calcium and helps in drug uptake.

6.2 | Intravascular imaging

Intravascular imaging aids in every aspect of coronary intervention ranging from understanding the lesions characteristics, lesion preparation, choosing balloon and stent size, and finally optimization of the procedure. However, the use of intravascular imaging remains low across the globe due to several factors such as: inertia, finance, lack of reimbursement, and lack of expertise in image interpretation. In the case of DCB, we believe that intravascular imaging should be used for lesion assessment in all cases of ISR and complex (calcific) lesions as shown in Case 1 and Case 4 respectively. Routine imaging in noncomplex lesions is not required and the balloon size can be selected based on the angiographic assessment. We also cannot recommend its use for final lesion assessment after drug delivery as it adds no value unlike following stent where further optimization can be considered.

6.2.1 | Physiology

The use of physiology to determine the hemodynamic significance of a lesion should be considered in moderate stenosis on coronary angiography, but there is no data to support to use of coronary physiology to evaluate the success following treatment with DCBs. The acute gain post-DCB is usually not as good as post-stent placement and hence trying to achieve values similar to those obtained with DES can be misleading. Positive remodeling seen with DCB is usually seen over time and not acutely, and hence relying on coronary physiology may lead to aggressive lesion preparation which may cause flow-limiting dissection requiring stents. As per the current recommendations, angiographic assessments alone are made postDCB to evaluate the success.

6.3 | Algorithms for the use of DCB in ISR and de novo lesions

We have designed a simple step-by-step algorithm that operators can consider when undertaking PCI in ISR and de novo lesions.

6.3.1 | ISR (Figure 14)

We strongly recommend upfront intra-vascular imaging in ISR to understand the mechanism of stent failure. Mechanical issues should be corrected with aggressive balloon dilatation and in some cases, we may need use of specialized balloons (scoring, cutting, or shockwave balloons) or even excimer laser. Once mechanical issue correction is confirmed on imaging, we recommend use of scoring or cutting balloons before DCB provided there is no persistent recoil or flow-limiting dissection in which case DES has to be considered.

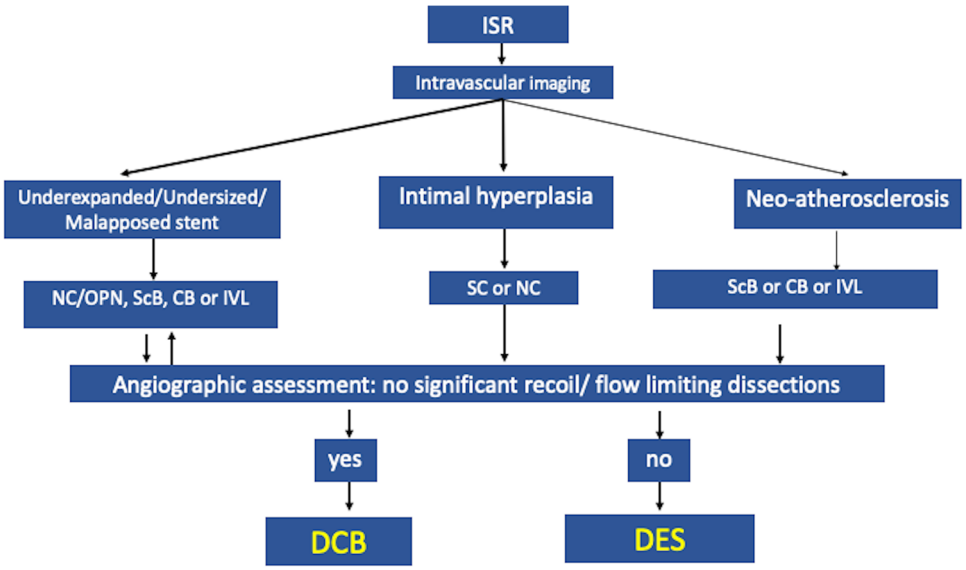

FIGURE 14 Step-by-step algorithm when dealing with in-stent restenosis. [Color figure can be viewed at wileyonlinelibrary.com]

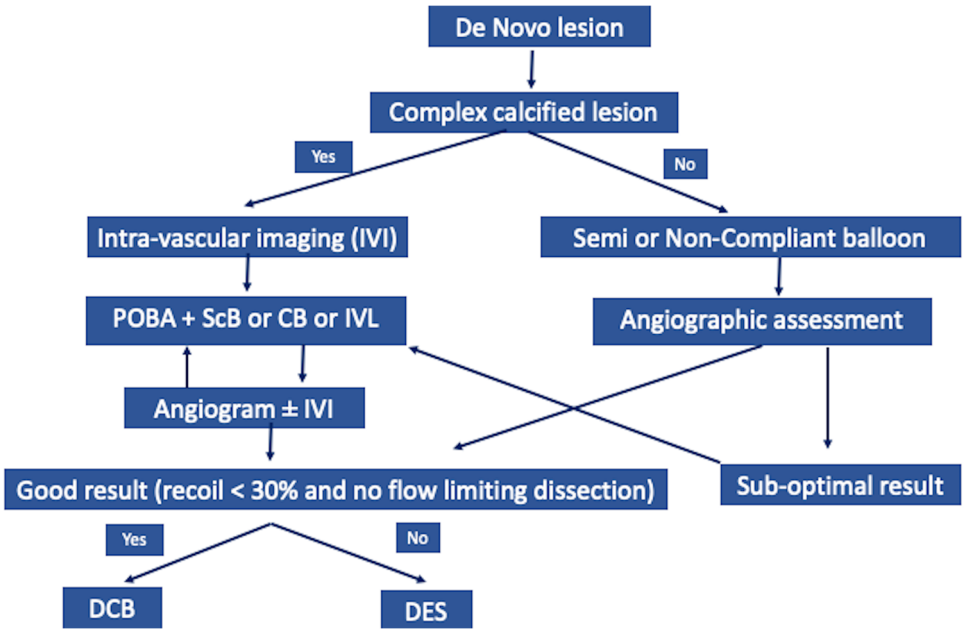

FIGURE 15 Step-by-step algorithm when considering drug-coated balloons in de novo lesions. [Color figure can be viewed at wileyonlinelibrary.com]

6.3.2 | De novo lesions (Figure 15)

If lesions are noncomplex, pre-dilatation with semi-compliant or noncompliant balloons should be sufficient. If optimal result is obtained post POBA (recoil of <30% or no flow limiting dissection), DCB can be considered. If results are suboptimal, intravascular imaging is recommended following which either bigger balloons or specialized balloons can be considered before DCB. If the result is still suboptimal, the stent should be considered over DCBs. In complex lesions, we strongly recommend imaging-guided lesion preparation.

6.4 | Assessing postlesion preparation

Although recoil post lesion preparation before stent is acceptable as the metal scaffolding generally takes care of it, no such mechanism exists for DCB and hence lesion preparation is of paramount importance before DCB use. If there is significant recoil (>30%) despite all the efforts to achieve adequate good lesion preparation, we recommend DES implantation. Similarly, dissection is an important aspect of lesion assessment before DCB. The current practice is to consider DES over DCB if there are flow limiting or Type C or higher dissections.

6.5 | DCB selection

DCBs aim to deliver high concentration of antiproliferative drug to a target lesion with the aim of preventing neo-intimal hyperplasia. The two antiproliferative drugs currently used in DCBs are Paclitaxel and Sirolimus. The first antiproliferative agent to be used in DCB technology was Paclitaxel, which has rapid absorption across the intima and prolonged tissue retention with a pharmacological advantage over Sirolimus which is has poor lipophilicity and poor tissue retention. However, thanks to technological improvements this goal has now been achieved by several companies and Sirolimus coated balloons have been in clinical use since 2015. Since then, there has been consistent trickle of positive data on these devices proving its safety and efficacy.[4,19] Operators have wide selection of DCBs to choose, and currently Paclitaxel has relatively more clinical data over Sirolimus.

6.6 | DCB application: Technical tips

Operators should not meddle with the DCBs especially the coated segment and they should ideally be delivered within 60 s of contact with bloodstream to minimize drug loss. If it takes more than 2-min, it should be abandoned as most drug would have lost in transit. In complex lesions and those requiring long lengths of DCBs, operators have to ensure to optimize support with appropriate guiding catheter and/or supportive wire before delivering DCBs. In some cases, it might be advisable to even consider guide extension catheters. Once at the lesion site, they have to be inflated at a nominal pressure for a period of 45–60 s. If there is any issue about the tolerance (such as ischemia or hemodynamic compromise), two-step inflation can be performed, with a minimum of 20 s of inflation time for each one, without moving the balloon between inflations.

6.7 | Bailout stenting

PostDCB assessment is a crucial step. We recommend taking an initial angiogram just after drug delivery and performing one or two final assessments after 3–5 min in orthogonal views. Bailout stenting with DES should be performed if there is acute vessel recoil of >30% and/or flow-limiting dissections (>type B). In terms of choosing a DES as a bailout device, one of the initial concerns was the potential toxicity from double doses of antiproliferative drugs (from DCBs and DES), but none of the trials on de novo lesions where bailout stenting has been performed has not shown any adverse events with such a strategy. Also, we recommend only treating the recoiled segment with a *short DES* especially if DCBs are used in long lesions. This strategy minimizes the stent length as the recoil may be focal. Trying to cover the whole area with DES defeats the purpose of using DCB in long lesions, especially in small vessels. Therefore, bailout stenting has to be kept minimal, especially in small vessels and long lesions. After the widespread use of DES in the last two decades, interventional cardiologists' eyes are trained to expect stent-like results, and anything less is considered as suboptimal. However, one has to refrain from unnecessary stenting as lesions become quiescent with time after DCB, with some trials having shown improved angiographic outcomes from Paclitaxel balloons. In the PICCOLETO II trial, late loss in the DCB arm was 0.04 versus 0.17 in the DES arm.[14] In case of dissection, we advise against taking repeated injections as they propagate dissections and may convert nonflow-limiting dissections into higher ones. There is no need to routinely admit patients treated with DCB overnight for observation especially if same-day discharge is a norm for elective patients. However, if there are any technical concerns (dissections), operators may admit patients for observation. The rates of bailout stenting will be higher in the initial phase of DCB embracement, but as the operators gain more experience, the rate will drop.

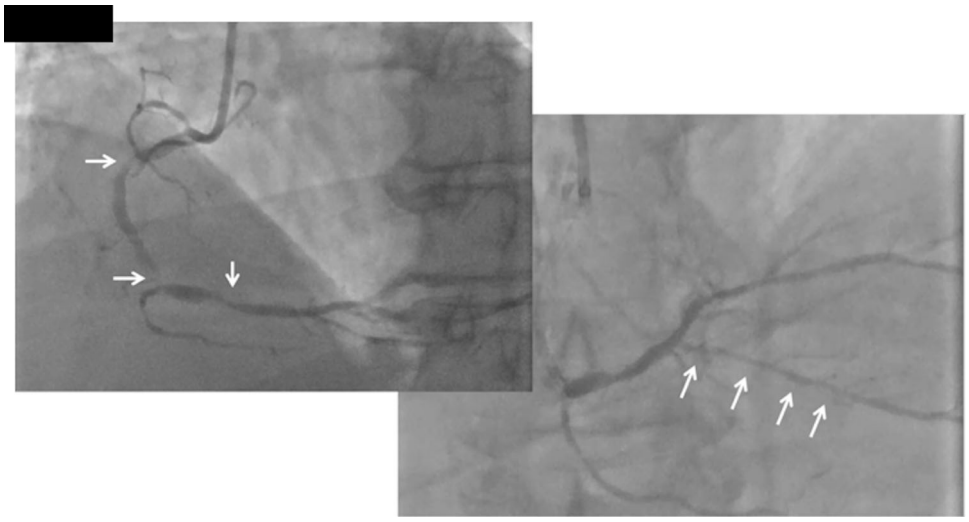

FIGURE 16 Angiogram of right coronary artery showing diffuse disease involving posterior descending artery.

6.8 | Follow-up after DCB angioplasty

There is limited data on the duration of DAPT post-DCB, but the current consensus is 1–3 months unless in ACS where it is extended to 12 months as per the current guidelines. In elective patients standard Aspirin and Clopidogrel can be sufficient but in complex lesions, newer P2Y12 inhibitors can be considered. In the high bleeding risk patient, DAPT can be shortened for even 2–3 weeks (*as shown in Case 4*). There is also a study that has shown that a single antiplatelet regimen post DCB in HBR without increasing the risk of acute vessel occlusion.[20] There is no data to support routine angiographic follow-up in patients treated with DCBs unless they are part of a clinical trial that mandates angiographic follow-up. However, in the initial phase of practice, the operators can consider angiographic follow-up after the patient's consent, to instill confidence especially to check for positive remodeling and healing of any nonflow limiting dissection. In patients needing multivessel PCI, the operator may consider staging the procedure to evaluate the outcome of the segment(s) treated with DCB. We also encourage clinical follow-up of all patients treated with DCB either as a part of the registry or own interest to evaluate clinical results, especially in the initial phase of DCB practice. We show some case examples above which have demonstrated positive remodeling of the vessel during follow-up angiography. The case below demonstrates the fate of nonflow-limiting dissection.

7 | CASE 5

A 72-year-old man with diffuse disease in the RCA and PDA (Figure 16) underwent angioplasty with a hybrid strategy. Main RCA received 3 overlapping DES and PDA was treated with two overlapping DCB

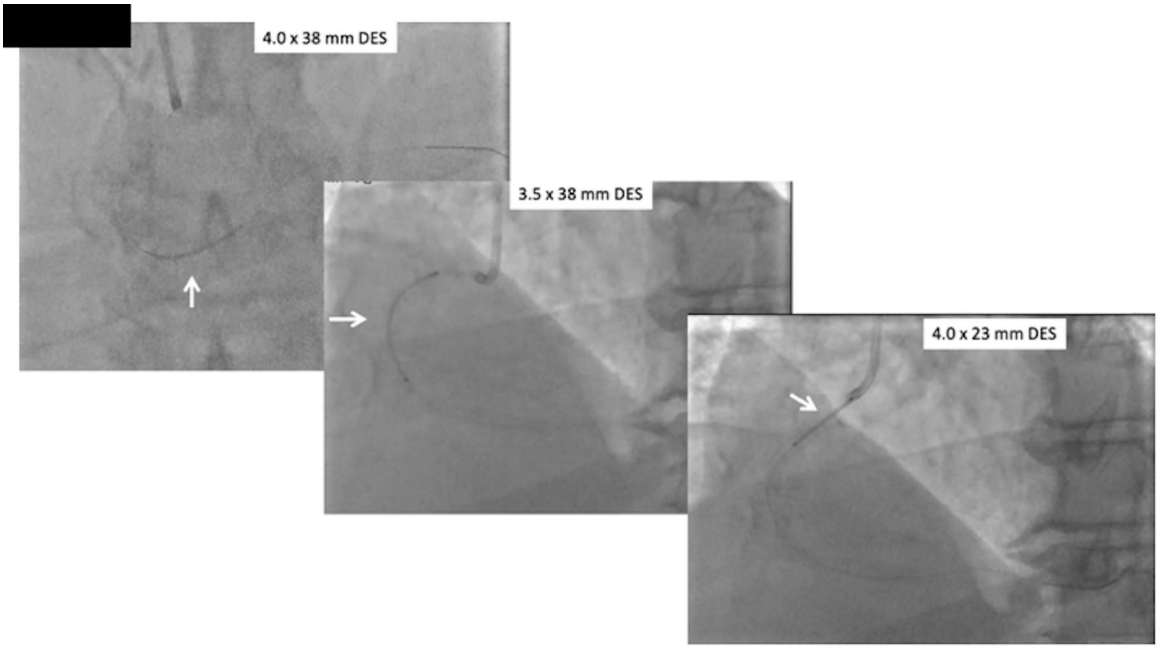

FIGURE 17 Right coronary artery treated with three overlapping drug-eluting stents.

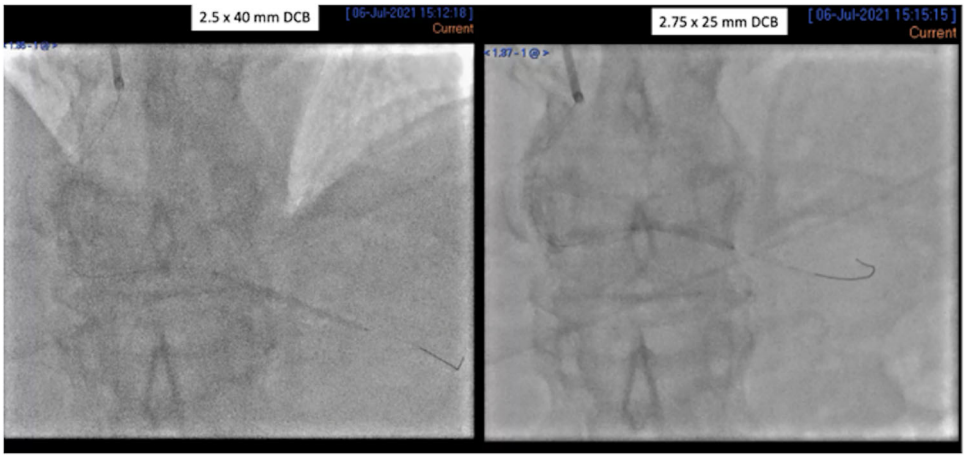

FIGURE 18 Posterior descending artery treated with two overlapping long drug-coated balloons. [Color figure can be viewed at wileyonlinelibrary.com]

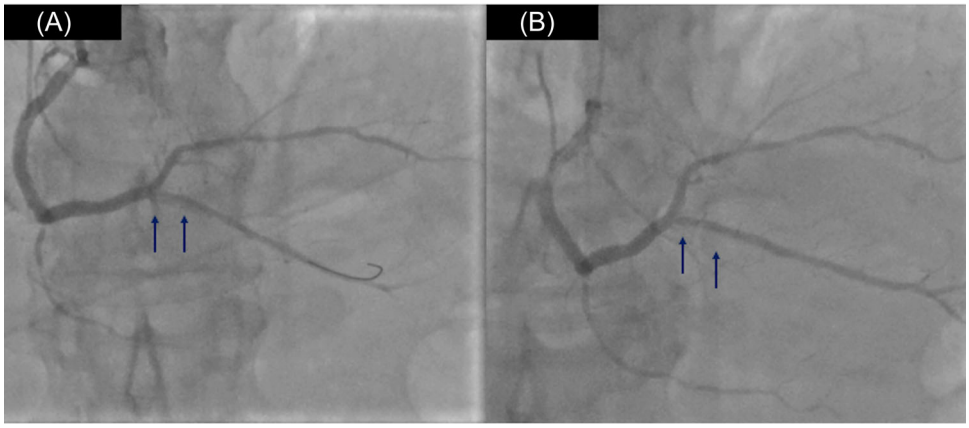

FIGURE 19 (A, B) Linear nonflow limiting dissection in the proximal segment of posterior descending artery postdrug-coated balloons (A) and completing healing of dissection with positive remodeling during follow-up angiogram (B). [Color figure can be viewed at wileyonlinelibrary.com]

(Figures 17 and 18) There was a linear not-flow limiting dissection in the PDA post-DCB, but this was not treated with a bailout stenting (Figure 19A, Supporting Information: Video S16). During the follow-up angiogram, not only the dissection had completely healed, but vessel had also positively remodeled (Figure 19B, Supporting Information: Video S17). This case demonstrated that nonflow limiting dissection can be left alone post-DCB.

8 | CONCLUSIONS

The use of DCBs is consistently escalating globally as there is increasing desire to leave nothing behind after angioplasty. Some brands of this class of devices have now been approved in the United States for clinical trials. There are several ongoing trials on DCBs specifically aimed at de novo lesions and hence the future appears bright. Although there are several experienced operators in the field of DCB, due to growing interest in the field there will be more operators embarking DCBs for the first time. For this purpose, we have provided a comprehensive article on special tips and tricks needed during DCB PCI focusing on the literature, personal experience, and case-based examples.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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