When would you elect to use a DCB versus a DES for SFA interventions, and what guides your decision making?

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Although the drug-coated balloon (DCB) was initially thought to be an alternative to stenting in superficial femoral artery (SFA) interventions, it is our opinion that the DCB will never walk alone, as the limitations of this technology (in particular, the lack of mechanical scaffolding and uncertainties regarding adequate drug delivery to complex, calcified lesions) prevent its solo use in several cases.

Anatomic and procedural considerations play a significant role in the treatment choice. Lesion length, type of recanalization (subintimal vs intraluminal), degree of calcification, and lesion site (ostial, popliteal) are all to be considered when choosing the primary strategy. As a general rule, we try to avoid stenting when unnecessary due to the possibility of a malignant behavior of stent restenosis, which is often more difficult to treat and prone to recurrence than restenosis after percutaneous transluminal angioplasty. Stenting is also best avoided when the popliteal artery is involved due to the well-known risk of stent fracture which, although reduced in the most recent stent designs, remains a significant concern.

In our practice, we believe that in many cases, the choice between a DCB and drug-eluting stent (DES) can be done after predilatation. We perform an optimal predilatation with a balloon matched 1:1 to the vessel size, often taking advantage of the noncompliant characteristics of the last-generation devices. While aggressive predilatation may more frequently result in flow-limiting dissections, we strongly believe that the very compliant DCBs should mainly be thought as drug-delivery devices that require optimal lesion preparation in order for the drug to be optimally released. While this strategy might result in a relatively higher number of flow-limiting dissections, we are confident that in many cases, the use of a bailout bare metal stent (BMS), taking care to stent only within the DCB-treated area, leads to an excellent long-term result.

While not tested, we sometimes use the combination of DCB and bailout DES for the most difficult cases, in which we aim for both scaffolding and neointimal suppression.

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For decades, there has been enthusiastic development in the peripheral field for the best endovascular treatment for femoropopliteal artery occlusive disease. Various players have already appeared on the green; however, long-term outcomes are not satisfactory with every device, due to the occurrence of restenosis and limited patency rates.

To control the issue of restenosis, which is an inflammatory-triggered process, it has been proposed to apply antiproliferative drugs via a paclitaxel-coated balloon or DES. According to the current literature, DCBs have resulted in promising midterm outcomes in rather short and not-too-complex (TASC II A/B) femoropopliteal artery lesions in terms of primary patency (67%–91%) and freedom from target lesion revascularization

(TLR) (76%–92%).[1-4] Recent data from the randomized Zilver PTX trial compared well, with a primary patency rate of 83% and a freedom from TLR of 90% after paclitaxel-eluting stent angioplasty, also in TASC II A/B lesions.[5] Interestingly, similar outcomes after DCB and DES in long femoropopliteal lesions (lesion length, 194 ± 86 mm and 195–64 mm, respectively) were found in a just-published analysis.[6] The primary patency rate was promising (76% and 70%, respectively), and freedom from clinically driven TLR (84% and 81%, respectively) was high after DCB and DES at 12-month follow-up. Overall, both modalities work well in short and longer lesions.

It should, however, be taken into consideration that drug-coated angioplasty has the same technical limitations as plain balloon angioplasty, and unfortunately, it is impossible to anticipate which lesion will show relevant severe dissection or acute recoil after balloon angioplasty. Every interventionist has to take into consideration that the overall rate of provisional stenting after DCB varies considerably varied (between 20%–30%) and even seems to be higher in longer target lesions.[4,5] As the natural course of our patients with peripheral occlusive artery disease is progressive in most cases, it might be wise to maintain more future options by first applying prolonged balloon angioplasty in the transition of the distal SFA to the popliteal artery. Furthermore, the long-term outcome after stent angioplasty could be limited by the extreme mechanical forces in this area.

The decision whether to choose a DCB or DES is even more complex in lesions with challenging characteristics, such as severe calcification, multisegment involvement, or thrombus. The data in these settings are very limited, and decision making on an individual case by case basis is warranted. There are good arguments to use DCBs first in segments that are more exposed to mechanical forces, such as the popliteal artery or bifurcation. In conditions where positioning of the balloon and further drug transfers from the balloon surface to the vessel wall and transmission might be lower due to considerable calcified or thrombotic lesions (with consecutive lower effectiveness), it might be better to choose a DES platform to improve the effect of the drug.

In these scenarios, a third player might have a more important role in the future. Lesion preparation can potentially be used with mechanical or laser-assisted debulking or a scoring balloon in order to reconstitute the vessel lumen and reduce elastic vessel recoil and dissection, and thus prepare for homogenous drug application in the target lesions and facilitate drug uptake.

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Without a doubt, if we avoid leaving a prosthetic behind, that's a better approach. At the end of the day, as long as the results are near equivalent, physicians want to avoid leaving a foreign object in a patient's body.

I do think we need more randomized trial data, because the trials and data to date have primarily been designed for device approval or retrospective reviews, and the bias in those trials make it difficult to evaluate how these devices will be utilized most effectively in the typically treated population. Certainly, the data have been strong for DCBs for short-to medium-length lesions in nonseverely calcified vessels that can be dilated. In both trials, there is a selection bias typical of controlled studies. The protocols required a successful stenosis predilatation before using the DCB. Knowing this, when physicians choose lesions, whether realized or not, there is investigator bias; they are looking for lesions that they predict are dilatable, and those are usually not severely calcified. The calcification issue is especially difficult to get your arms around.

DES now have reported 4-year results with very reasonable outcomes. There will be a publication soon on the Japanese postmarket experience that I think is going to be very supportive of DES, and there did not seem to be a negative effect of calcification on the results.

Up front, we'll start with simple, medium-length lesions that respond to predilatation for DCBs. More complex lesions that do not respond to PTA well or calcified lesions will side toward DES. As we get more data, we'll figure out how to adjust to optimize results.

The one area I do think will be cut and dry a lot sooner than anyone thinks is in-stent restenosis (ISR). Early data are very positive for DCBs—the data are striking. You almost don't need *P* values for the kind of patency improvements that are being seen. On the surface, it seems to make basic science sense because restenosis is a much more homogenous tissue. It's not like when you treat a typical de novo lesion in the SFA and there is plaque, thrombus, calcium—it's a very heterogeneous

environment that you are placing your device into in the first place. With ISR, it is a homogeneous intimal hyperplasia, and you would almost expect to have a repetition of the animal studies because you should be able to get a uniform uptake of the drug circumferentially. If the early data show that the drug is being taken up and working, that's a more cut and dry procedure because it's a more uniform blockage. I would not predict that there is going to be a lot of variation of ISR.

For native vessels, we still need a lot more data, and we have to consider some of the other nonpatient-related drivers. Reimbursement is already available for DES. We probably won't have that at first for DCBs, but the sooner we get that, the better, because if we're only going to be paid the amount that is paid for regular balloon angioplasty, the cost is going to be tough for the hospitals to absorb. It's a complex issue, without a doubt. The good news is, we have technologies that are, in the long run, going to cut down on the number of repeat procedures. For the insurer, that will decrease the amount paid per patient over the years. That's really an upside.

As experience grows, I think we'll get a lot more data on where DCBs will be optimized versus DES. As we receive approval for DCBs in the United States, everyone will be using them in areas where they don't want to stent for sure, and then usage will broaden as the experience grows. DCB data will need to also mature with longer-term follow-up. From a stent standpoint, they've had low fracture rates, very dependable 4-year restenosis and TLR rates, and the 5-year data will be presented at the VIVA meeting this year. The data will ultimately drive decision-making.

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She has disclosed that she has received speaker's fees from Medtronic, Bard, and Biotronik and has been a consultant for Bard and Covidien.

The answer to this question is very simple: I'm a believer in "nothing left behind." I'm not so much interested in metal that remains in the vessels, and therefore, my first choice is always a DCB. As we have reimbursement for the device in most countries, I use a DCB for a TASC B, C, or D lesion upon first presentation and also on restenotic lesions, as well as for ISR in the femoropopliteal area. If a really nasty flow-limiting dissection remains, I use a DES as a kind of bailout stent. My decision making is guided by the results we now have available on DCB usage in the femoropopliteal area. I refer specifically to the fantastic results of INPACT SFA and the good results of LEVANT 2.

Below the knee (BTK), it takes much more time to find the proper solution. We have two DCBs available in Europe for BTK usage (Passeo-18 Lux, Biotronik, and Lutonix, Bard Peripheral Vascular), and I also use them if a patient presents with restenotic disease and critical limb ischemia that is not improving. In cases when stents are needed for BTK treatment, I would treat such a lesion with a DES bailout stent. ■

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